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Cancer and work

Understanding occupational cancers and taking action to eliminate them

Edited by
Tony Musu and Laurent Vogel

etui.

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We would like to thank all authors who contributed to this edited volume for the care they took in presenting complex issues in a clear and understandable manner and for their patience (the publication of the book was delayed several times by urgent work concerning the revision of the relevant EU legislation).

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General introduction

Tony Musu and Laurent Vogel

The number of new cases of cancer diagnosed each year in the European Union is somewhere in the region of 2.6 million (excluding non-melanomatous skin cancers), while annual cancer-related mortality stands at around 1.3 million. The most fatal forms of cancer are lung cancers for men and breast cancer for women, and cancer has overtaken cardiovascular disease to become the leading cause of death in many European countries. This worrying development highlights the shortcomings of current prevention policies and suggests that the war on cancer will face fierce political opposition as a result of the fundamental questions it raises about our mode of production.

The link between cancer and working conditions has been acknowledged and extensively documented in the scientific literature for more than two centuries, and several hundred carcinogens have been found to be present in workplaces. Levels of exposure to these carcinogens are a major source of social inequalities in health, however, since an individual's risk of being diagnosed with a work-related cancer varies considerably depending on the position he or she occupies in the social hierarchy; it is much higher for cleaners or construction workers than for managerial staff, for example.

An examination of the situation on the ground reveals that cancer prevention remains an extremely neglected aspect of occupational health activities, in part reflecting the gulf between policies in this field and those in the field of public health. Although cancer is recognised as a public health priority, it is all too often pushed to the back burner by occupational health policymakers and practitioners. It is as if workplaces are not acknowledged as places where people spend a major part of their lives. Double standards govern many aspects of risk regulation, leading to a paradoxical situation where we are afforded better protection in terms of what we eat and the environment around us than in terms of the work we do. Eliminating workplace exposure to carcinogens is probably the most effective way of reducing both the overall number of cancers and their unequal, class-based distribution. There is an urgent need for primary prevention measures not dependent on individual behaviour but which eradicate risk by zeroing in on high-risk groups.

As companies incur very few costs in connection with work-related cancers, prevention-related efforts of this kind continue to face major obstacles. The latency period between exposure and disease onset can sometimes be very long, and a significant proportion of patients diagnosed with cancer no longer work for the company where exposure took place. With most of the costs (both direct and indirect) defrayed by public health and social security systems or by the sufferers and their families, any preventive action is perceived as a burden on businesses. What is more, the link between cancer and work

remains largely invisible. Occupational disease compensation systems kick in for only a very limited number of cancers as the number of cancers recognised as occupational diseases account for only a very small fraction of the total number of work-related cancers. Similarly, the relevant statistics underestimate and distort the true scale of the problem, with multiple sources of bias hampering the recognition of cancers as occupational diseases. The likelihood of real-life case of work-related cancer appearing in these statistics is therefore low, with the situation looking particularly bleak for women and those subject to multiple workplace exposures. Gaining recognition that a cancer is of occupational origin can also be particularly challenging for groups of workers in precarious employment, such as temporary staff and migrant and seasonal workers.

Since waging an effective war on occupational cancers involves challenging the right of employers to exercise their own discretion in respect of labour organisation and production methods, the balance of political and social power represents the main hurdle. The vast majority of occupational cancers result from normal production processes and the deliberate prioritisation of profit over human health. Prevention therefore necessitates a certain level of public and social control over production activities. This is abundantly clear from the asbestos saga: although industry claimed for decades that it would be impossible to do without the substance and predicted that banning it would result in job losses on a catastrophic scale, alternative technologies were ultimately found to replace all of its former uses. We cannot therefore merely sit and wait for these technologies to come along – binding measures must be imposed and societal pressure leveraged to push forward their development.

This book is being published at a particularly important moment in time, since the process of revising the EU's *acquis* on the prevention of work-related cancers was relaunched in May 2016 after a protracted period of paralysis. This process is likely to last several years, for a variety of reasons. Firstly, the delay has led to a backlog of revisions, with many of the proposed amendments overdue since the start of the century. Secondly, the minimalist nature of the European Commission's initial proposals means that it will be necessary to revise them on a regular basis. Thirdly, recent research findings provide a basis for much more ambitious legislation, encompassing multiple exposures, endocrine disrupters, nanomaterials and more. Looking beyond the current revision process, consideration must also be given to the possibility of adopting an umbrella strategy for the elimination of work-related cancers; this topic is examined in the responses submitted by the European Trade Union Confederation (ETUC) within the context of the EU consultation on work-related cancers during the second half of 2017 (reproduced in the annex at the end of this book).

Most of the contributions in this book focus on chemical carcinogens, but this should not be interpreted as an attempt to downplay the importance of other factors (whether physical or biological in nature or relating to work organisation). For example, workers' exposure to solar radiation is a significant cause of work-related skin cancers. These issues are examined in other publications by the European Trade Union Institute (ETUI), and we will continue to revisit them on a regular basis over the years to come.

This book is a collaborative effort and the result of over 20 years of cooperation between the ETUI, researchers in a variety of disciplines and trade union networks. It does not purport to be an exhaustive analysis of all of the factors discussed, but instead examines the current state of the art, practical examples of preventive action, legislative developments and the visibility of work-related cancers, particularly in the context of occupational disease compensation systems. Its aim is to further feed the ongoing debate and promote discussion of an ambitious strategy for eliminating work-related cancers.

We would like to thank all of the authors who have allowed this project to come to fruition, and in particular two of our late colleagues whose contributions to the ETUI's involvement in the war on occupational cancers are hard to overstate: Henri Pezerat (1928-2009) and Simon Pickvance (1949-2012). Their critical and insightful comments and unwavering willingness to help played a vital role in the establishment of a common approach to occupational cancers among Europe's trade unions. This book is dedicated to them.

Part 1

Knowledge production and awareness-raising tools

Introduction

The interrelationship between knowledge production, awareness-raising measures and the drafting of prevention policies in the field of occupational health is as complex as it is important. New knowledge boosts research into preventive solutions, but this knowledge will be produced only if it is called for by society – for example by workers struggling to protect their health.

In an ideal world, the process might look something like this: initial alerts regarding the incidence of cancers linked to occupational exposure result in the systematic gathering of knowledge, which serves as a basis for prevention-related measures that are ultimately generalised and transformed into legislation backed up by effective checks and sanctions. In practice, however, the process is far less linear and far more conflict-ridden. The production and systematisation of knowledge and the application of this knowledge at a regulatory decision-making level all entail a re-examination of the unequal distribution of wealth and power within society, meaning that the entire process – and not merely specific aspects of it, such as occupational health campaigning or policy choices relating to risk regulation – is politically fraught.

The first contribution summarises recent scientific findings in the field of carcinogenesis, making the point that current efforts to prevent occupational cancers take too little account of these discoveries. Epidemiological research has traditionally focused on people performing a particular job who are exposed to high levels of a specific carcinogen, but effective prevention is now understood to involve legislating on multiple carcinogens at levels lower than was previously the case. Other harm factors may also play a key role in carcinogenesis; for example, studies examining the role played by oxidative stress make it clear that prevention means more than simply avoiding exposure to classified carcinogens.

The second contribution looks at interactions between chemical and non-chemical exposures. Although this book mainly concentrates on chemical agents, other carcinogenic factors are also present in workplaces, with synergies often arising between the two; to take just one example, nurses are exposed to a range of different chemical carcinogens and also work night shifts, in part explaining the high incidence of breast cancer among members of this profession.

The third contribution builds on its author's personal experiences to discuss a key issue affecting preventive action: for over a century, industry has invested heavily in scientific research with the sole aim of 'manufacturing doubt', and a good chunk of the research available – on lead, asbestos, endocrine disrupters, pesticides and many other topics – has been funded by industry sources for the express purpose of challenging the findings of independent researchers. This is a necessary side effect of the way in which scientific knowledge is produced (by permanently refining and re-examining previous findings and potentially replacing them with new ones), but it leads to a dangerous confusion between the unavoidable element of uncertainty inherent to any scientific activity and the need to respond effectively and without delay to reduce or eliminate risks. Significantly, one of the industrial groups referred to in this contribution – Monsanto – remains mired in controversy over one of the largest scandals in the history of risk regulation within the EU: expert regulatory agencies acted in contravention of the conclusions published by the International Agency for Research on Cancer by continuing to allow the production of glyphosate in Europe, meaning that the multinational's ceaseless and well-planned campaigning efforts were not in vain.

The next contributions all describe cases in which a link has been established between the fields of public health and occupational health. Teams of researchers with modest resources at their disposal have developed original tools which help to challenge the invisibility of 'work' as a factor in carcinogenesis by compensating for the inexcusable failure to include workplace exposure to carcinogens in cancer registries.

The fourth contribution describes the outcomes achieved by the GISCOP93 team in the Seine-Saint-Denis region of France. This research and action project involves systematically reconstructing the CVs of patients diagnosed with cancer (mainly of the respiratory tract) and then examining the carcinogens to which they may have been exposed. For these patients, cancers are now more readily recognised as occupational diseases.

The fifth contribution describes the NOCCA project, which uses the cancer registries of five Nordic countries (Iceland, Norway, Sweden, Finland and Denmark) as a basis for identifying the jobs associated with the highest incidences of cancer for men and women (broken down by tumour location). This makes it the world's most comprehensive source of statistics on the link between work and cancer.

The sixth contribution discusses OCCAM, a project recording cases of cancer diagnosed within the national healthcare system in a number of regions in Italy, and then using this data as a basis for identifying jobs (and potentially companies) with a particularly high incidence of specific types of cancer.

Chapter 1

Current concepts in carcinogenesis

G rard Lasfargues

1. Introduction

It is now well established that human diseases, particularly cancers, are the result of complex interactions between genetic and environmental factors, with the latter being definable in the broad sense of the term as general environmental and occupational exposure factors or even behavioural factors and social determinants.

The development of molecular biology and tumour genome research techniques and all the ‘-omics’ technologies has led to a better understanding of the complexity of carcinogenesis, in particular by revealing numerous genetic and epigenetic changes and by highlighting the importance of new concepts in terms of the characteristics of dangers and exposures to carcinogens. Prompting us to revisit risk assessment methods, these concepts also concern the low doses and mixtures of carcinogens particularly present in work environments, the critical periods of exposure essential for understanding effects such as those of endocrine disruptors, and more generally the need for an adapted inclusive approach to exposures via the exposome concept¹.

2. Reminder of traditional concepts in carcinogenesis

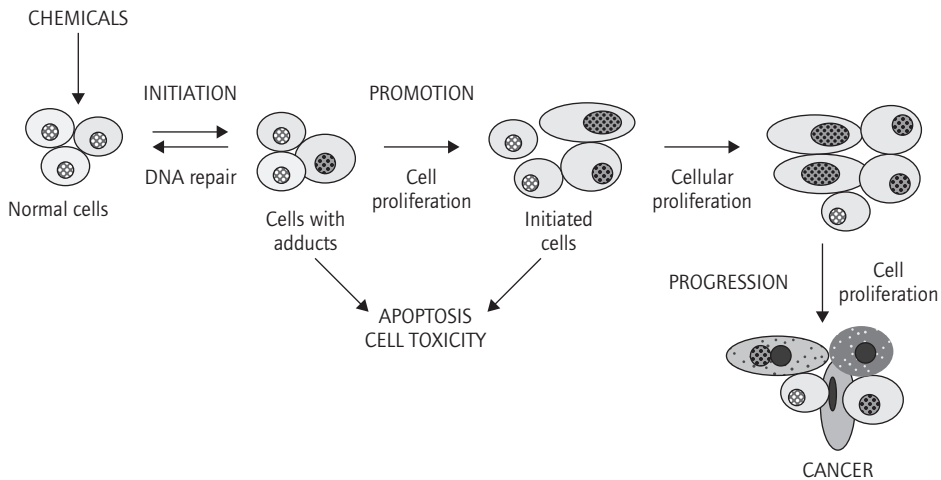
Carcinogenesis refers to the phenomena transforming a normal cell into a cancer cell, with the development of a cancer the culmination of a series of events stemming from the uncontrolled proliferation of malignant cells under the cumulative effect of multiple genetic changes. It is common to distinguish between several key stages in carcinogenesis (cf. Figure 1): initiation of the tumour, during which irreversible changes in the DNA (deoxyribonucleic acid) of the cell nucleus allow a normal cell to acquire properties that will gradually transform it into a tumour cell (initiated cell); tumour promotion phase, which involves the proliferation (abnormal multiplication) of the clone of the initiated cells; tumour progression phase, which marks the passage from precancerous lesions to malignant lesions, involving independent cell proliferation, invasive spread of the tumour and its capacity to metastasise.

-
1. The exposome encompasses the *totality* of human environmental (i.e. non-genetic) exposures from conception onwards, complementing the genome. It was first proposed in 2005 by a cancer epidemiologist Christopher Paul Wild, in an article entitled “Complementing the genome with an ‘exposome’: the outstanding challenge of environmental exposure measurement in molecular epidemiology” (Publisher’s note).

In the end, the cancer cells gradually acquire a number of properties differentiating them from normal cells: capacity to proliferate; independence from environmental signals, particularly anti-proliferative signals; resistance to apoptosis (programmed cell death); and capacity for angiogenesis (formation of their own vascular system) and metastatic invasion and spread (dissemination through the blood or lymphatic system to distant organs).

This multi-stage carcinogenesis process usually takes a long time, namely several years or even decades.

Figure 1 **Chemical carcinogenesis stages and the occurrences involved in each one**



Source: adapted from Oliveira *et al.* (2007)

Toxic substances act on the chromosomes and genetic makeup (DNA). Environmental carcinogens can be cancer initiators, directly genotoxic substances or promoters, which is particularly the case with numerous chemicals to which workers may be repeatedly exposed.

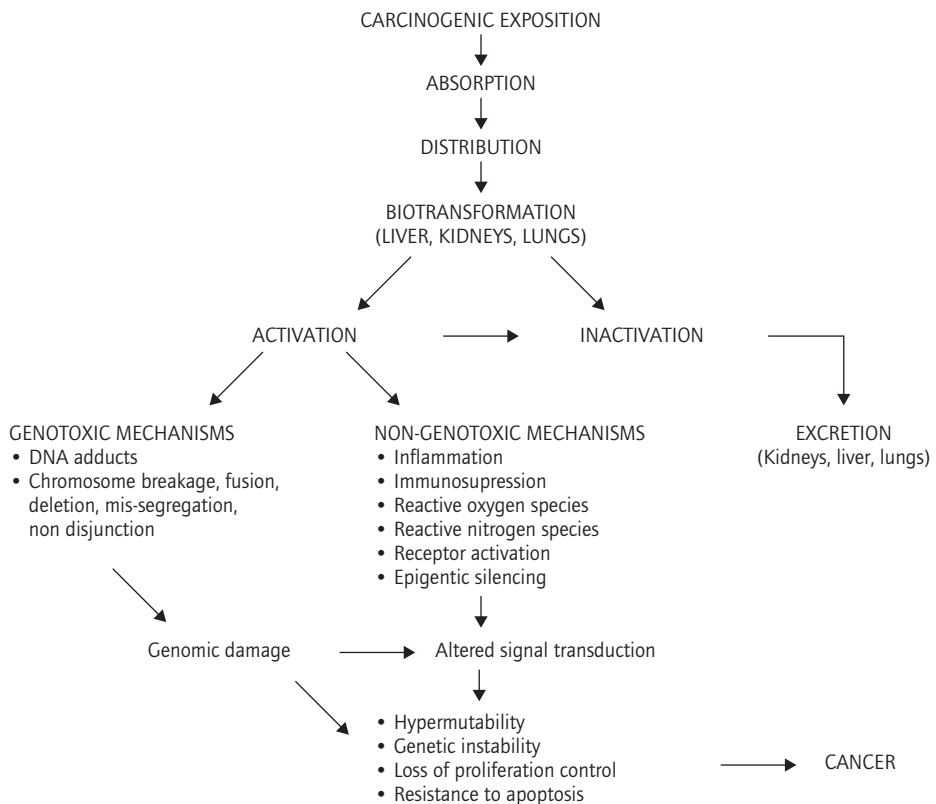
DNA is subject to constant attacks throughout the life of the cell, with DNA lesions usually being efficiently repaired by the repair mechanisms. However, the failure or suppression of the essential gene repair systems, particularly under the influence of environmental factors, can trigger or aggravate a cell transformation process and therefore a carcinogenesis mechanism. DNA replication allows the genetic material from a mother cell to be transmitted to daughter cells during cell division. If the DNA contains unrepaired lesions, this can cause gene mutations, i.e. sequence changes in the DNA molecules transmitted to the daughter cells or rearrangements in the DNA that manifest themselves as chromosome aberrations. Certain genes, such as oncogenes and tumour suppressor genes, are involved in the operation or control of crucial cell functions, such as growth, division, cell differentiation or apoptosis, which allows cell division to be balanced. Mutations occurring in these genes encourage cell transformation and the appearance of a clone of abnormal cells.

Genotoxic carcinogens are therefore capable of altering DNA and causing specific mutations in a gene or gene sequence (chromosome mutations). Some have a clastogenic effect (chromosome breakage) or aneugenic effect (anomalies in the distribution and number of chromosomes).

Tumour promoters do not interact directly with the DNA. They encourage genetic instability and carcinogenesis through various actions: stimulation of oxidative stress processes; proinflammatory effect; action on the immune defence system; involvement of epigenetic mechanisms or endocrine disruption effect, etc.

Numerous chemical substances are in fact pro-carcinogens needing metabolic activation in order to have a carcinogenic effect. The biotransformation that occurs via the body's metabolic pathways is intended to transform such substances into inert compounds so that they can be eliminated. During this process, however, these molecules can be metabolically activated, which means that they become capable of interacting with the DNA or triggering effects encouraging carcinogenesis (cf. Figure 2).

Figure 2 **Metabolic activation of chemical compounds and genotoxic and non-genotoxic actions**



Source: adapted from Oliveira *et al.* (2007)

Among these effects, oxidative stress plays a significant role, essentially by producing reactive oxygen species (ROS) such as free radicals, oxygenated ions and peroxides. These highly unstable oxygenated chemical species attack the cellular components such as the lipid membranes or DNA.

The production of ROS is normal in aerobic living organisms and cells possess an antioxidant system based on enzymes (catalase, glutathione peroxidase, superoxide dismutase, etc.) and small molecules (vitamins C and E). However, the imbalance between these two production and defence phenomena is a mechanism involved in carcinogenesis. It is also involved in the occurrence of chronic cardiovascular, inflammatory and neurodegenerative diseases and in ageing. Among the external agents that particularly cause oxidative stress, we can cite, for example, ionising radiation, ultraviolet radiation, air pollution and chemical agents such as certain pesticides or metals.

3. Concepts in epigenetics

There is now clear evidence that environmental exposures (chemical, physical, psychosocial, etc.) can influence the expression of genes involved in signalling pathways that are key to the cell by changing the genome environment. Epigenetics covers these changes in gene activity in the absence of a change in the DNA sequence. Epigenetic changes alter the chromatin structure² and its conformity, allowing gene expression to be altered. The best characterised epigenetic change is DNA methylation.

Epigenetic changes are transmissible during cell divisions, but differ from gene mutations affecting the DNA sequence, due to their potentially reversible character. The critical changes appearing in the cancer cells, such as the activation of oncogenes, the deactivation of tumour suppressor genes and failures to repair the DNA, can be caused not only by genotoxic mechanisms, but also by epigenetic mechanisms. The study of these mechanisms, which may be involved at all stages of carcinogenesis, is therefore essential not only to better diagnose and treat cancers, but also to prevent them. By extracting the DNA and chromatin from the cell nucleus, we can effectively characterise the epigenetic changes associated with environmental exposures and better understand how genes and environment interact to encourage the occurrence of diseases such as cancers.

The epigenome therefore seems to be a real biosensor for cumulative exposures to multiple ‘stressors’ of chemical and other origins. The ubiquity of these mechanisms, their potential involvement in all types of cancer in humans and their reversibility open the door to interesting prospects for identifying new and relevant biomarkers that could be used particularly in epidemiological research and for cancer prevention strategies.

2. Chromatin is the form that DNA takes in the cell nucleus. It is the basic substance of chromosomes and consists of DNA, RNA and proteins. There are two types of protein: histones and non-histone proteins.

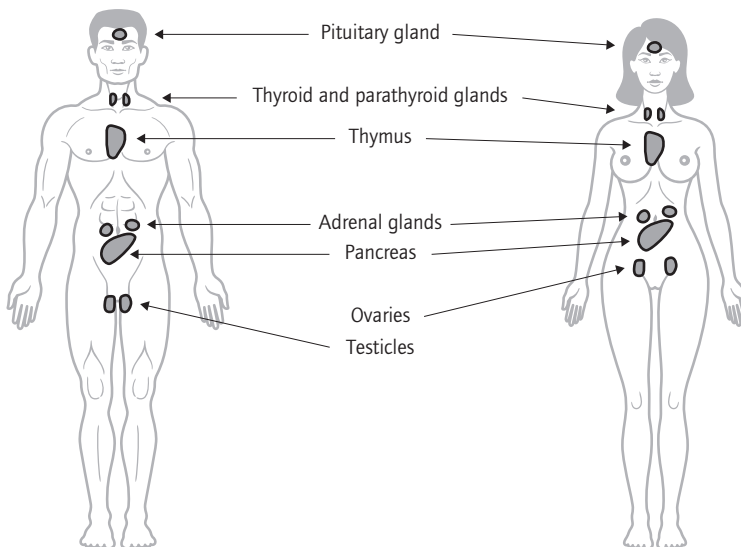
4. Endocrine disruptors and cancers

The reported increase in the frequency of certain cancers such as breast, prostate and testicular cancers, as also in fertility and metabolic problems and urogenital defects in children, is all that is needed to point to the contribution of endocrine disruptor exposures to the increased risks of these pathologies that we are now seeing.

Exposure to endocrine disruptors is in fact suspected of having many adverse health effects in humans: male fertility problems, with a trend towards a reduction in the concentration and quality of sperm; defects in the male reproductive system, such as cryptorchidism (testicular malposition) and hypospadias (urethral malposition); female reproductive problems, such as abnormalities in sexual differentiation, ovarian function, fertility, embryo implantation and gestation; sexual maturation problems (for example: early puberty); disruptions in thyroid function; metabolic disorders, diabetes and obesity; immune system alterations; increased frequency of hormone-dependent cancers such as testicular, prostate, breast and other cancers.

Endocrine disruptors are exogenic substances or mixtures (i.e. foreign to the living organism) that can alter the normal function of the body's hormonal system. This system consists of numerous endocrine glands such as the pituitary gland, thyroid gland, adrenal glands, pancreas, ovaries in women and testicles in men (cf. Figure 3). These organs secrete hormones that are carried by the blood and that are essential to the efficient functioning of the human body, controlling essential functions such as growth and development, body temperature regulation, metabolisms and the reproductive system.

Figure 3 Endocrine system



Endocrine disruptors can interfere with a natural hormone at all stages, from hormone synthesis and production, through transport, to binding to a receptor, action or elimination. At cell level, there are multiple potential action mechanisms. An endocrine disruptor can therefore bind to a natural hormone cell receptor (such as oestrogen receptors) and have an agonist effect (imitating the hormone) or, on the other hand, an antagonist effect (blocking the action of the hormone). It can bind to other types of receptor that are not hormone-specific, disrupt cell signals, interfere with the genome or epigenome pathways, and so on. The most common disruption effects involve the disruption of oestrogen, androgen, thyroid hormone and cortisol activity and the disruption of the metabolic functions of carbohydrates and lipids.

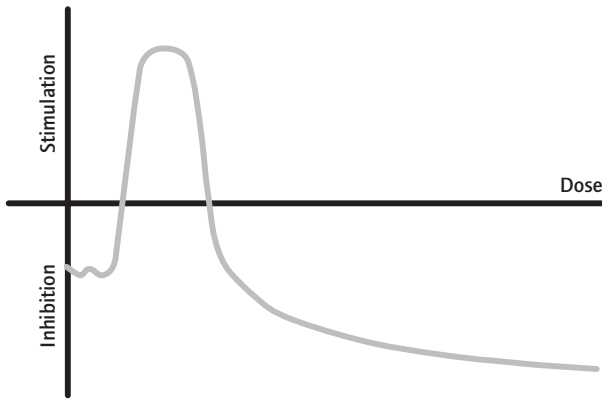
Numerous substances with an endocrine disruption effect are used in or produced by industry: plasticisers such as bisphenol A (BPA) are used in the manufacture of rigid and transparent polycarbonates (baby bottles, recyclable bottles, etc.) or are found in the epoxy resins of beverage can coatings; phthalates, which make plastics more flexible and facilitate their shaping, are present in many PVC articles; polybrominated flame retardants are used in the composition of furniture foams, carpets and electronic equipment; perfluorinated compounds are used in many industrial applications (non-stick coatings of kitchen utensils, treatment of textiles, packaging, etc.); reprotoxic glycol ethers have commonly been used for their solvent properties, particularly in paints, inks or adhesives; parabens are particularly used in the cosmetics industry; persistent organic pollutants such as polychlorobiphenyls (PCBs) were previously used in electric transformers or certain pesticides (DDT, chlordecone, etc.).

In terms of work environments, several major industries are affected with regard to both production and use: pharmaceutical and chemical industries, agriculture, etc. Dermal exposures may predominate, such as for BPA and the exposure of cashiers or printers when handling thermal tickets, glycol ethers for painters, or pesticides among applicators. Inhalation is sometimes the main route, involving exposures to certain metals like lead. Dietary intake, a predominant route for certain endocrine disruptors such as BPA, can be added to the other routes of entry into the body.

Currently, the risks of occupational exposure to endocrine disruptors are still largely invisible. The health effects vary significantly depending on the substance – with these effects potentially appearing in the offspring of men and women who have been exposed – and on the specific conditions of exposure. Three important concepts need to be taken into account in this respect when assessing and preventing risks: the possibility of low-dose effects with specific dose-effect relationships; not uncommon co-exposures to several endocrine disruptors; and the critical periods of exposure, particularly the perinatal period when the mother becomes pregnant.

For certain endocrine disruptors such as BPA, experimental studies report specific non-monotonic dose-response or dose-effect relationships (cf. Figure 4).

Figure 4 Inverted U curve (non-monotonic effect)



The low-dose effects observed therefore seem to be greater, even in comparison to those observed at an average or high dose.

The diethylstilbestrol (Distilbene®) case, in which it was observed that cancers could originate in the foetus, has promoted the concept of an 'exposure window'. Much work currently indicates that, at certain critical periods (prenatal and perinatal periods and puberty), the body is particularly sensitive to endocrine disruptors, with the effect becoming apparent at a much later stage. Research, particularly experimental research conducted on several animal or human lines, also shows that effects can be transmitted to offspring or subsequent generations, particularly carcinogenic effects. Mother-child cohorts are currently being monitored to confirm these effects caused by a range of endocrine disruptors.

Lastly, the issue of low-dose cocktail effects is also the focus of current thinking on endocrine disruptors, given exposure to complex mixtures in food or the environment. Substances can interact, resulting in additive, synergistic or sometimes antagonistic effects.

One substance can also sometimes have multiple effects, for example both carcinogenic or mutagenic and endocrine-disrupting. This is the case with Distilbene®, a medication which has caused vaginal, breast and uterine cancers in the daughters of treated women, the insecticide Chlordecone (Kepone) for prostate cancer in the Antilles, or dioxins such as 2,3,7,8-TCDD, which is classified in Category 1 (known carcinogen) by the International Agency for Research on Cancer (IARC). Associations between exposure to other endocrine disruptors such as pesticides and plasticisers (BPA, phthalates) and the occurrence of various hormone-dependent cancers (breast, thyroid, uterine, prostate, ovarian, testicular) have been observed in certain experimental or epidemiological studies.

Given the very large number of substances on the European market for which the level of toxicological information is insufficient, we must improve our knowledge of these

mechanisms so that the toxicity pathways activated by endocrine disruptors can be better understood and described. This approach involving the toxicity pathways, which may allow action to be taken without waiting for sufficient information on the thousands of substances, is the subject of major research programmes initiated at international level (see the exposome concept further on).

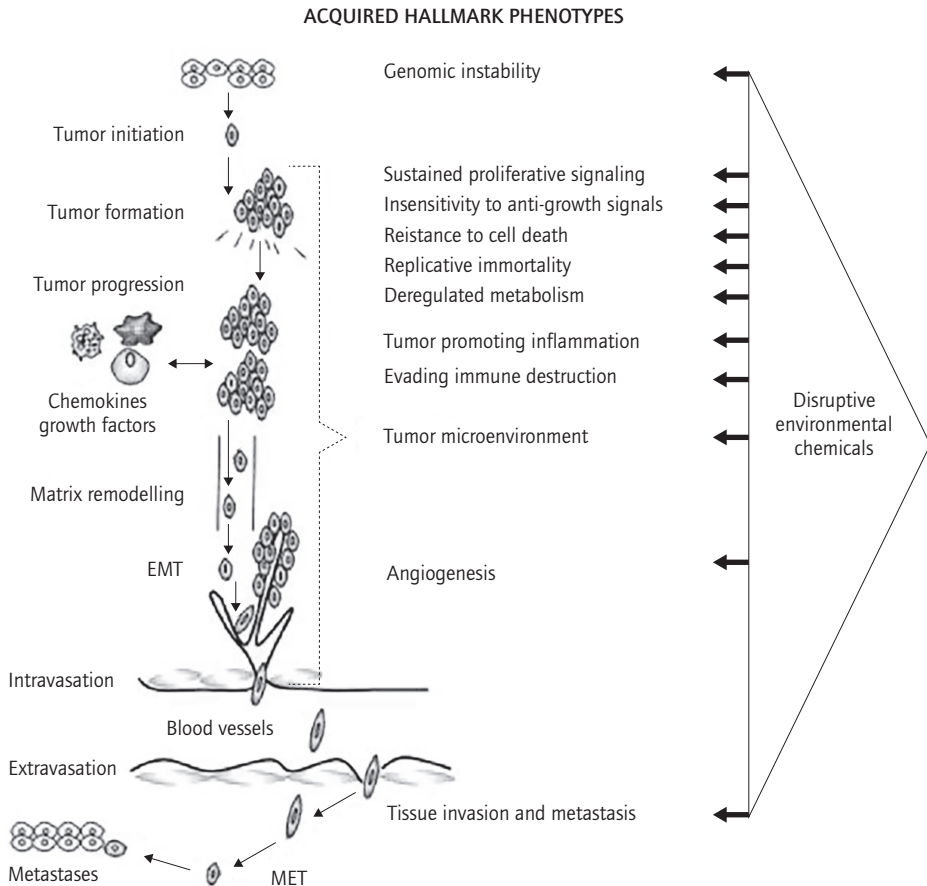
5. The issue of low doses and mixtures of chemical agents

Advances made in understanding the complexity of carcinogenesis, and more generally the mechanisms of interaction between toxic substances and the genome and epigenome, justify the extent of the research currently being carried out to better assess the potential effects of mixtures of chemical agents at low doses in combination with lifelong exposures, from the perinatal period to the end of the working life and beyond. Significant gaps still exist in the understanding of toxicity data for numerous substances that are, however, widely used. For example, only 50 % of the chemical agents classified by the EPA (the US Environmental Protection Agency) as high production volume chemicals have undergone minimum carcinogenicity testing, while the possibility of low-dose effects, often not anticipated and studied, further complicates the issue.

In a recent scientific review, a group of researchers identified several examples of non-monotonic dose-effect relationships for substances for which the low-dose effects could not be predicted in advance through those observed at a high dose. These environmental disruptors may, depending on the situation, affect the various stages of carcinogenesis by influencing the acquisition of the phenotypic characteristics of cancer cells (cf. Figure 5), in particular: genomic instability and mutations, which allow DNA changes to be transmitted from one cell to daughter cells via not only mutations but also epigenetic changes; inflammation which, in addition to disrupting immune defence adaptation phenomena, encourages the growth of tumour cells and contributes to their survival, to angiogenesis and to the metastatic process; and deregulation of the cell metabolism. Said scientific review cites several dozen examples of disrupting substances capable of acting on the key mechanisms of carcinogenesis (numerous metals, pesticides, various organic compounds, endocrine disruptors, nanomaterials, etc.), with over half potentially having these low-dose effects, some with a non-monotonic dose-effect relationship profile.

Growing knowledge of the biology of cancer therefore suggests that the cumulative effects of these chemical substances involve various pathways that are relevant for assessing the carcinogenic risk, with the possibility of synergistic mechanistic effects not necessarily taken into account in the current methods of regulatory assessment of the risks posed by chemical substances, based on common toxicity mechanisms or modes of action.

Figure 5 Disruptive potential of environmental exposures to mixtures of chemicals



Source: adapted from Goodson III W.H. *et al.* (2015)

6. The exposome concept

All the current concepts described here concerning epigenetics, endocrine disruptors, low doses, cumulative and integrated exposures, and the possibility of cocktail effects ultimately lead to the more general exposome concept. This term was proposed by C. Wild to describe all the environmental exposures of an individual throughout his/her life, i.e. from the period of conception. The “environmental exposures” concept is very broad as it not only covers all the chemical, physical and biological exposures, but also the behavioural, psychological, social and other factors. In particular, the relationship between the external environment and the internal environment of the organs and cells, themselves subject to multiple influences from the external exposures combined with the influences of various internal regulation systems (hormone metabolism, intestinal microflora, inflammation, oxidative stress, ageing, etc.), is a crucial element of this concept, ultimately leading to exposomes for these various targets being taken into account.

Lastly, as seen above with endocrine disruptors, the timing of the exposure, encompassing critical periods in life such as the perinatal period, is an important dimension. C. Wild in fact highlights that, ‘unlike the genome, the exposome is a highly variable and dynamic entity that evolves throughout the individual’s life’: hence the difficulty in terms of measurement, needing to incorporate both the qualitative and the quantitative dimension. Given the rise in chronic diseases, he rightly insists on the need for public health to be capable of developing exposure measurement methods that can be as precise as those developed for describing the human genome. The contribution of the ‘-omics’ technologies, used to better understand the mechanisms of pathologies such as cancer, could therefore help in assessing exposures by establishing the signature or fingerprint of specific external environmental exposures combined with internal factors. This involves examining, for example, whether these exposures result in measurable changes to the epigenome, transcriptome (the set of all RNA messengers), metabolome (the set of all metabolites and small molecules) or proteome (the set of all proteins). The challenge is also to validate, from that point, relevant effect and exposure biomarkers that can be used to monitor the population, in particular through large cohorts formed from the general or working population.

The importance of these methodological developments is entirely clear as they have the potential to allow the effects of combined exposures, cocktails of chemical agents or combinations of chemical, physical and other exposures to be predicted. Being able to study the potential toxic or carcinogenic effects of the mixtures of chemical agents most commonly found, for example, in food or water is clearly relevant, but it is impossible to do this for the infinite number of combinations of the thousands of chemical compounds to which humans are potentially exposed. Thanks to current methods, it is, however, now possible to quickly identify, for a contaminant or for categories of contaminants, the activated receptors or signalling pathways at cell level, as well as the main toxicity pathways. This in turn allows us to study the interactions between toxicity pathways and establish predictive toxicity modelling tools for numerous families of substances (databases, mapping, etc.), as is currently happening in some major international programmes.

Ultimately, all these current concepts clearly illustrate the huge complexity of today’s environmental exposures and risks. Being able to tackle the challenge of understanding this complexity within risk assessment, by integrating new concepts and appropriate methods (biology, modelling, etc.), is a major concern for occupational, environmental and public health and prevention.

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Chapter 2

Interactions between chemical exposures and non-chemical exposures in work-related cancers

Andrew Watterson

1. Introduction: mechanisms of action of cancer-causing substances

1.1 Non-chemical carcinogens

Physical agents such as ionizing and non-ionizing radiation and 'heat' and light, biological agents such as viruses, and even 'management systems' (such as shift/night work) can all affect human biology. Some of these agents on their own may be capable of causing work-related cancers.

Ionizing radiation has sufficient energy to remove tightly bound electrons from atoms and so create ions that include gamma rays and some ultra-violet rays. This is the type of radiation people usually think of as 'radiation' and it includes nuclear power and several medical uses of radiation such as X-rays. Non-ionizing radiation has sufficient energy to move atoms in a molecule around or cause them to vibrate, but not enough to remove electrons (EPA 2013). It includes extremely low frequency electrical and magnetic fields, wireless communications, power lines, microwave ovens and mobile phones. There is much controversy with regard to the possible potential carcinogenic effects of such phones. Ionizing radiation, however, has been identified as a human carcinogen for many decades and its precise effects are not always clear at different doses and over different lengths of time.

Several studies of radio frequency radiation mobile phone base stations, antennae for transmitters, smart meters and medical applications as well as various types of radar, mobile and cordless phones, Bluetooth devices and amateur radios have been carried out (IARC 2013:34). There was some limited evidence of human carcinogenicity due to mobile phone radiofrequency radiation but positive associations between mobile phones and two types of cancer: gliomas and acoustic neuromas and so radiofrequency electromagnetic fields are listed as possibly carcinogenic (IARC 2013:419).

Biological agents can occur in workplace settings and several may increase the risk of certain types of cancer in humans. The agents include a range of blood-borne viruses such as hepatitis B and C virus and human immunodeficiency virus which would present threats to health, emergency and lab workers, custodial services, cleaners, plumbers, public sector workers dealing with waste treatment, hairdressers and beauticians and even vehicle recovery and repair workers (HSE 2011). Various zoonotic diseases have also been linked to occupational cancers including lung cancer and to a lesser extent lymphomas and myelomas especially with regard to animal

husbandry and the meat and poultry industries through animal viruses (Johnson *et al.* 2012).

Management systems such as those requiring employees to work a significant number of night shifts are now known to be a cause of work-related breast cancer in women in such sectors as health, emergency services, the military and transport (especially airline cabin crews). The exact mechanisms for the effect have not been established but they appear to relate to long-term exposures to artificial light at night and the effect on organs involved with the endocrine system and its disruption. There may therefore be risks for men as well as women. Denmark compensates women with breast cancer who have worked in the above occupations for more than twenty years and meet other criteria (Watterson 2013).

Very high temperatures can contribute to occupational cancers, with evidence in the mainstream scientific literature that burns from workplace injuries could cause cancer available for well over a quarter of a century (Er-fan *et al.* 1992) and now widely accepted.

1.2 Mechanisms of action of cancer-causing substances and how non-chemical exposure may be relevant

Scientists have researched and identified a number of specific industrial and public sectors, occupations, substances and processes that cause cancer (carcinogens) and mutations (mutagens) in humans and/or lab tests. These often initially involved analysing exposures to one substance and one process rather than the interaction of multiple exposures.

The multi-step stages of cancer causation were unrecognised at the beginning of much research and questions of cancer multi-causality from many different exposures were rarely considered. Methods to investigate them were also often lacking. The complexity of cancer causation was not understood. Debates and sometimes regulatory interest then moved on to identifying substances and processes that might ‘inter-act’, perhaps as promoters (substances that promote but do not cause cancers), or co-cancer-causing substances (co-carcinogens may cause additive or synergistic or combined effects and examples are given below). Then mixtures of chemicals (dealt with elsewhere in this book) and their possible cancer-causing effects were identified as an under-researched and possibly significant factor.

The carcinogens now identified may be used in workplaces but many could be present in the wider environment (our air, food, water and soil) – either naturally or due to human activity – thus creating double jeopardy. Many people have multiple exposures to numerous carcinogenic substances and processes at work and over a working lifetime via different routes, at different levels and in different ways. Trying to establish if there are interactions between chemical and non-chemical carcinogens in the workplace is very complicated and very under-researched at present. Recognition of susceptibility to cancers through a range of factors – including genetics, age, gender and ethnicity –

have emerged as additional factors to consider. Genetics and gender for example have sometimes been wrongly used to exclude or try to exclude workers from endangered workplaces rather than removing or reducing exposure to the carcinogens.

However, the most vulnerable workers may also be those most likely to work with a large range of chemical, biological and physical agents that cause cancer, possibly in the worst-regulated employment sectors where long hours, shifts including night work, poor health and safety management and little or no inspection are the norm. Poverty, poor diet and living conditions as well as other illnesses may also expose such workers to a host of other factors interacting with occupational carcinogens and further increasing their risks of contracting work-related cancers. In 2012, an EU Occupational Health and Safety workshop looked at occupationally-caused and related cancers, identifying 'hidden' groups whose occupational exposure to cancer risks and carcinogenic processes was under-represented in exposure data and intervention strategies (EASHW 2012). Noting an unrecognised work-related cancer burden in lower socio-economic classes, they floated the concept of 'socially discriminating cancers'. Typical exposed groups included migrants, part-time workers, those employed as sub-contracted staff and women and young workers, often working in the service sector. These are some of the groups most likely to be exposed to the interactions briefly discussed in this chapter.

The report of the US President's Panel on environmental cancer published in 2010 specifically noted the poor understanding and definition that existed with regard to the actions and potential interactions of some known carcinogens, especially in the light of emerging technologies, new processes and new substances (Reuben 2010). IARC research also originally dealt only with chemicals but now covers agents that include: "specific chemicals, groups of related chemicals, complex mixtures, occupational or environmental exposures, cultural or behavioural practices, biological organisms and physical agents" (IARC 2012a:8).

2. Biological factors including shift /night work and chemicals

The body itself may produce important chemicals able to keep us healthy or damage our health. Sometimes synthetic chemicals may interfere with the beneficial elements of the process. For example, endocrine disruptors in the workplace or environment may interfere with these biological processes and hence increase, decrease, block - or alter in other ways - our production of hormones. This could potentially lead to breast cancer in women and a small number of men, or prostate cancer in men. These synthetic endocrine disruptors could include various pesticides, agents in plastic or solvents. Other chemicals may interfere with human biology by affecting the immune system – immunotoxic substances. Benzene, formaldehyde and diesel fumes have all been identified as strongly immunotoxic (Veraldi *et al.* 2006). They are also human carcinogens in their own right and widely present in one form or another in many workplaces.

Recent studies on the links between night shift work and breast cancer in women have raised further questions about possible interactions between chemical and non-

chemical workplace exposures. Shift work and artificial light at night appear to affect the human biochemistry of females and males. Management systems requiring such work may thus lead to occupational cancers through impacting a worker's biology. But the risks are potentially even greater in terms of interactions. Some studies have tried to unravel exposures of women cabin crew who may work nights, be exposed to radiation through flying and sometimes spray cabins with suspect cancer-causing pesticides or endocrine disruptors. There are therefore four potential carcinogens here (Colditz *et al.* 2006) and they could theoretically increase the worker's cancer risks. Other recent studies have noted that increased breast cancer risks in anaesthetists could be linked to chemical exposures or night shift work and that interactions between the two could be relevant in breast cancer progression. However, because of the nature of the study, the results were limited (Rabstein *et al.* 2014). Further complications arise when factors such as obesity are considered. Night shift work itself may be an 'obesogen' and access to healthy food at night and physical exercise may be limited and contribute to and be part of the occupational cancer risk (Watterson 2013).

Viral and zoonotic diseases can act as cancer initiators but may also work together with chemical carcinogens. Schistosomiasis (or bilharzia) is a well-known zoonotic disease caused by parasites and linked to bladder cancer. Interactions between tars and viruses in lab tests were revealed as early as 1911. Some kidney cancers, it is suggested, may occur following chemical and viral exposures and Kaposi's sarcoma could result from exposures to viruses, adverse immune effects and exposure to chemicals such as nitrites and alumina-silicates (Haverkos 2004). More recent studies and reviews have also suggested that meat and poultry workers have elevated risks of lung cancer, adjusting for smoking, and that these are linked potentially to exposure to viruses. Such workers can also be exposed to chemical carcinogens like nitrosamines, frying and cooking aerosols and plastic wrapping fumes. The possible impact of these multiple exposures has not been fully studied (Johnson and Choi 2012).

The IARC recently reviewed biological agents, recognising that cancers could result from "the interaction of multiple risk factors including those related to the infectious agent itself, host-related factors including immune status and environmental cofactors such as chemicals, ionizing radiation, immunosuppressive drugs, or another infection". These might reactivate latent oncogenic viruses. They further noted that "the contribution of several of these additional factors to the development of infection-associated cancers is likely to be substantial, but has not yet been elucidated in detail" (IARC 2012: 44).

Finally, there may be indirect factors that could influence exposures to carcinogens. Climate change will lead to the spread in Europe of more zoonotic disease vectors (carriers of disease) that may cause cancer in humans. Biological and physical factors will come together in a different set of interactions that could additionally include the use of cancer-causing agro-chemicals and endocrine disruptors to control the new disease vectors. Working in hot and humid conditions may increase risks of heat stress, dehydration and fatigue including the difficulty of using personal protective equipment in such conditions. This may increase exposures to carcinogens and their uptake. Threats of interactions are thus set to increase.

3. Physical factors and chemicals

Interactions of chemicals, such as those in tars, with physical factors such as sunlight have been recognised in occupations such as roofers in construction work and those working on road surfacing.

Interactions between ionising radiation and chemicals have been studied more closely than other interactions since the 1990s but they still remain relatively under-researched and very difficult to study (see for example Chen and McKone 2001). Most studies have focussed more on chemical exposures and occupational cancer and not interactions between non-ionising radiation and chemicals in nuclear production and uranium-processing plants. IARC's latest monograph on radiation looked at interactions between radon and tobacco smoke but did not look at interactions with other chemicals (IARC 2013:244).

Arc welders and their assistants may be exposed to high levels of ultraviolet radiation when using gas metal and gas tungsten techniques and to medium levels when using shielded metal arc welding equipment. This exposure on its own could lead to work-related skin cancers (Dixon 2007). There could also be other interactions, though proper protective equipment and appropriate types of sun blockers would greatly reduce some of these risks.

4. Psycho-social stress, chemicals and occupational cancer

This field is perhaps the least researched of all. One commentator noted in 2009 that 'there are undoubtedly other interacting factors, such as prenatal and early childhood exposures, nutrition, physical activity, genetics, and psychosocial factors such as stress, which together may ultimately be responsible for the development of cancer in ways we do not yet fully appreciate' (Clapp *et al.* 2009:20). Stress may also be a proxy for other factors that will increase exposures to carcinogens through long hours of work in poor conditions and with poor pay and potential exposure to many and the most hazardous known human carcinogens compounded perhaps by greater exposure in the non-work environment in terms of neighbourhoods and homes. If and how stress may affect the immune system and hence susceptibility to interactions of chemical and non-chemical carcinogens in the workplace has not been fully researched.

5. Conclusions

Major challenges remain with regard to testing methods for chemical/non-chemical interactions and limits, how limits are to be set for these multiple exposures and what the full implications of interactions may be. Asbestos/tobacco interactions have been widely recognised in occupational cancer studies. However, this research has sometimes been used by employers to try and deny worker compensation claims by arguing that tobacco alone explained asbestos worker lung cancers and then that contributory factors such as smoking justified cutting worker compensation. It looks like similar approaches

are or could be adopted by some employers with regard to obesity and lack of physical exercise, citing these as causes of cancers to try to evade responsibility for exposing their employees to known or suspected carcinogens in the course of their work. Trade unions will need to be wary of this ploy.

Much is still either uncertain or unknown about interactions between chemicals and physical and biological factors. Trade unions trying to establish or improve workplace precautionary and prevention occupational cancer policies and practices should thus take into account data gaps and lack of certainty about the multiple causes of cancer.

Until toxicology and epidemiology catch up with this field, the best action employees and their trade unions can take is to focus on the individual workplace chemical, physical and biological carcinogens and related co-carcinogens and promoters that may be used with them. Removing the individual carcinogens or reducing exposure to levels as low as possible through policies such as sunsetting or toxics use reduction will also ensure reductions in known and suspected interactions between all types of substances and processes known or suspected as being carcinogenic. This is an effective use of time and resources for trade unions because it is a win-win approach.

Simple steps to ensure existing regulations are in operation and fully enforced will have a part to play too. In Denmark, following the findings on night shift work and breast cancer in women, labour inspectors began re-checking workplaces where night shift work was done, enforced the Working Time Directive and pressed for the best shift systems and facilities available. Elsewhere in Europe, governments ignored the findings, did not inspect workplaces regularly at night and argued for their own national research on the interactions.

As more research becomes available about interactions between chemical and other carcinogens, specific and more targeted workplace reduction and removal strategies could be developed to take account of the findings, as for instance already done with regard to tars and exposure to sunlight.

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Chapter 3

Pollution of the literature on occupational cancer

Richard Clapp

1. Introduction

In this chapter, we address the pollution of science and the creation of flawed literature on occupational causes of cancer. We present several examples, including international and national epidemiological studies, review articles and scientific presentations used in regulatory proceedings in the U.S. These are primarily from the author's personal experience, and many other examples may be found in books such as *Doubt is Their Product: How Industry's Assault on Science Threatens Your Health* (Michaels 2008) and *Deceit and Denial: The Deadly Politics of Industrial Pollution* (Markowitz and Rosner 2002). We conclude that these examples from the occupational cancer literature illustrate a contested territory that scientists and advocates must be aware of when evaluating new information about carcinogens.

2. The dioxin story

The forty-year history of occupational literature on dioxins and their ability to cause cancer is a dramatic example of the pollution of science by industry and its paid consultants. It illustrates the lengths to which the polluters will go in order to sow doubt about the causes of cancer in workers and thereby delay or undermine regulation of harmful exposures. The earliest publications that suggested that dioxin caused cancer in humans were published in Sweden in the 1970s (Hardell 1977; Hardell and Sandstrom 1979). These studies are widely cited as the first epidemiologic evidence that phenoxyacetic acid herbicides and their contaminants were associated with soft tissue sarcoma. Additional studies were published by Swedish authors (Eriksson *et al.* 1981; Hardell *et al.* 1981) that linked phenoxy herbicides to both lymphomas and sarcomas. At about the same time, workers at a BASF plant in Germany who had been exposed to dioxins in an accident in 1953 were found to have a higher mortality rate due to cancer twenty-seven years later (Thiess *et al.* 1982).

By the late 1970s, military veterans of the United States war in Vietnam also began to notice increased cancer rates associated with Agent Orange sprayed during the 1960s. The herbicide, a mixture of 2,4-D and 2,4,5-T, was contaminated with dioxin during production and contained substantial amounts of tetrachlorodibenzo-p-dioxin (TCDD). Agent Orange had been produced by Dow Chemical, Monsanto Corporation, Diamond Shamrock and Syntex Agribusiness, among others, and attorneys representing U.S. veterans filed a class action lawsuit against several of these companies in 1980. The outcome of the lawsuit was a settlement, in 1984, in which seven chemical companies

agreed to pay \$180 million to affected veterans and the veterans agreed not to pursue any future claims against the companies. The Federal Court Judge, Jack Weinstein, maintained that the settlement was fair, given the limited evidence at that time that Agent Orange caused cancer and other serious health effects.

In parallel with the veterans' lawsuit, government agencies in New Jersey and Massachusetts began research projects to determine the health impacts of Agent Orange on veterans who resided in their states. In Massachusetts, we had a state bonus system that gave cash bonuses to veterans who were in the military during the period of the Vietnam conflict and that distinguished between those who had served "in-country" in Vietnam and those who served elsewhere. Using this information, we produced a report that showed a nearly nine-fold increase in deaths due to soft tissue sarcoma in the "in-country" veterans. The analysis was done and the report written by two of us in the Massachusetts Department of Public Health, with financial support from another state agency, the Office of the Commissioner of Veterans Services. As we began to discuss the report within our agency, the Deputy Commissioner of Public Health initially argued that our analysis was "preliminary" and should not be released. He was eventually overruled and we proceeded to write a formal report summarizing our methods and results. On preparing to release the report publicly, we were told that we should not speak to the media and that all press communications should be handled by the Commissioner of Public Health. Employees of the other state agency that had provided funds were able to distribute the report, and a Vietnam veteran elected to the State House of Representatives also made sure the report was widely available.

The release of the Massachusetts report, which occurred after the Agent Orange lawsuit settlement, received wide media attention and spurred other states to conduct similar analyses of causes of death in veterans in their states. Two states which had bonus systems similar to the one in Massachusetts, West Virginia and Wisconsin, performed similar analyses and came up with similar results with regard to soft tissue sarcoma deaths in Vietnam veterans. The Massachusetts mortality study was eventually published in a scientific journal (Kogan and Clapp 1988) and added to the literature documenting adverse health impacts of military service in Vietnam.

By the late 1980s, considerable attention was being paid to dioxin and related chemicals and their potential mechanism of action in humans and experimental animals. A scientific conference was convened in Cold Spring Harbor, New York, with the major conclusion of the report of the proceedings being that a cellular receptor seemed to mediate all or most of the adverse effects of dioxin and dioxin-like compounds (Gallo *et al.* 1991). Since this means that a certain internal dose must occur before the effects begin to become manifest, the implication was that there is a safe "threshold" below which dioxin exposure would not pose a health risk. The U.S. regulatory agency most focused on dioxin was the Environmental Protection Agency (EPA), and the Administrator in the period 1989-1993, William Reilly, announced that the Agency would reassess its policies regarding dioxin with this new mechanistic information in mind. The compilation of the scientific basis for the reassessment began in 1991 and was supposed to be completed in eighteen months.

In the meantime, the U.S. Congress was considering a bill filed by two Vietnam veterans, Tom Daschle from South Dakota and John Kerry from Massachusetts. The hearings before the Senate Committee on Veterans Affairs included testimony by veterans, scientists and others concerned with the ongoing health effects of Agent Orange exposure. The legislation that eventually passed both houses of Congress was called “The Agent Orange Act of 1991.” It mandated the Veterans Administration (VA) to compensate Vietnam veterans who had been diagnosed with soft tissue sarcoma, non-Hodgkin’s lymphoma and chloracne because these were presumed to have been caused by exposure to Agent Orange and its contaminants in Vietnam. The bill also required the VA to support an ongoing review of the scientific literature by the National Academy of Sciences to determine whether other diseases were associated with Agent Orange exposure, leading to a need to compensate Vietnam veterans.

Shortly after the passage of the Agent Orange Act, researchers from the National Institute for Occupational Safety and Health (NIOSH) published an analysis of the causes of death in their dioxin workers registry (Fingerhut 1991). By this time, there were approximately fifteen studies in the scientific literature evaluating whether herbicides or dioxin were associated with particular cancers in humans. The NIOSH registry cohort was comprised of 5,172 male workers assembled from employees of twelve U.S. plants where they had been exposed to dioxin. Although the authors were very cautious in their conclusions, they reported significant excess cancer deaths from all cancers combined, and a nine-fold excess of soft tissue sarcoma in the sub-group of employees with more than one year of exposure and more than twenty years between first exposure and death. These authors also examined other cancers, such as non-Hodgkin’s lymphoma, stomach cancer and multiple myeloma, finding excesses below the conventional levels of statistical significance. Nevertheless, this study was a watershed event in the assessment of the occupational cancer risks of dioxin exposure. An editorial accompanying the publication indicated that this article changed the balance of evidence, suggesting that when patients were diagnosed with soft tissue sarcoma, their physician should inquire about potential dioxin exposure (Bailar 1991).

Soon after the NIOSH dioxin workers registry study was published, Monsanto Company employees submitted an analysis of deaths in workers of one of its plants in Nitro, West Virginia (Collins *et al.* 1993). This plant had been included in the NIOSH study, and it was the location of a chemical manufacturing process accident in 1949 that exposed 754 workers to high levels of TCDD. The Monsanto Company authors noted that four of the confirmed cases of soft tissue sarcoma in the NIOSH study were from the Nitro, West Virginia plant. They went on to describe other exposures in the plant, especially 4-aminobiphenyl. This chemical had been associated with bladder cancer in previous studies, but not with soft tissue sarcoma. Nevertheless, Collins and co-authors produced a series of sub-group analyses which they claimed showed an increased risk of soft tissue sarcoma with exposure to 4-aminobiphenyl in the Nitro plant workers, but not with TCDD exposure. They stated: “these results suggest that STSs observed in the Fingerhut, et al study were not attributable to TCDD exposure alone ...” and furthermore that results from a recent follow-up of German BASF workers (Zober *et al.* 1990) should also take into account exposure to another bladder carcinogen. The

Monsanto authors therefore used their results to cast doubt on two other published studies showing increased cancer risks from TCDD exposure.

I had the opportunity to be on a panel with Dr. Collins at the International Society for Environmental Epidemiology meeting in Edmonton, Alberta in 1996. My presentation focused on the literature regarding Vietnam veterans and the diseases linked to Agent Orange exposure in the scientific literature at that point. Dr. Collins, who was by then working for Dow Chemical Company, said that his job was to raise doubt about epidemiological findings regarding occupational exposures. It appears that his 1993 publication of the West Virginia Monsanto workers was an example of him doing his job as he saw it.

3. 1994 EPA dioxin reassessment

The first draft of the multiple-volume EPA dioxin reassessment was released for peer review in 1994. The first volume described what was then known about the mechanisms of dioxin toxicity, including immunotoxicity, developmental and reproductive toxicity, and carcinogenicity in experimental animals. The evidence assembled in this draft volume included studies published after 1989 and indicated that there was not likely to be a threshold. The second volume included an extensive review of human epidemiology and a draft dose-response model. The EPA authors relied on the NIOSH dioxin workers registry study, as well as animal studies, to characterize the dose-response relationship. The third volume was a risk characterization, which relied on the health assessment and exposure assessment in the other two volumes. All three volumes were then reviewed by a committee of the EPA Science Advisory Board, which then made recommendations back to the Agency for incorporation into the next draft of the reassessment.

I was a consultant member of the Science Advisory Board (SAB) Dioxin Reassessment Review Committee, and specifically the health panel that reviewed the human epidemiology and dose-response volume in early 1995. We met in a conference hotel over a two-day period and had both public and closed-door sessions. The public sessions included presentations by various Federal agency representatives, stakeholders and affected parties. One presentation was by Thomas Starr, PhD, chairing a panel for a consulting company called ENVIRON and commissioned by the American Forest & Paper Association. Dr. Starr, among other points critical of the EPA draft dioxin reassessment, asserted that Air Force Ranch Hand Vietnam veterans, who did aerial spraying of Agent Orange from in Vietnam, had exhibited no excess cancer. In particular, he asserted that none of the Air Force Ranch Hand veterans had been diagnosed with soft tissue sarcoma. I objected to this because I knew from conversations with Air Force researchers that this was not the case. At that time, there was already one case of STS in a Ranch Hand veteran, and more were found in later follow-up summaries.

The SAB review committee included members who clearly had conflicts of interest that were not revealed at the time of the meeting in 1995. For example, Dr. John Graham, who founded and directed the Harvard Center for Risk Analysis in Boston, received substantial funding from affected chemical companies such as Dow, Monsanto, BASF,

the Chemical Manufacturers Association, and several others at the time he participated in the SAB review. He organized separate lunch meetings in the hotel where the SAB review committee was meeting, presumably to discuss how to advance the agenda of the industry representatives in attendance. One of the other consultant participants in the 1995 SAB review committee was Dr. Dennis Paustenbach, at the time working for the ChemRisk Division of McLaren/Hart. His industry ties were also well-documented, and we will provide more examples of his pollution of the scientific literature later in this chapter.

The SAB Dioxin Reassessment Review Committee submitted its report and recommendations to the EPA Administrator in September 1995. The report commended the Agency for its comprehensive review of the scientific literature, but urged further refinement of the dose-response modeling. SAB reviewers declined to characterize the carcinogenicity but said that almost all of the members would “concur with the EPA’s judgment that 2,3,7,8-TCDD, under some conditions of exposure, is likely to increase human cancer incidence.” (Science Advisory Board 1995) Despite this, much of the subsequent commentary by John Graham and others emphasized the uncertainties remaining in the EPA reassessment, and the need for further research to fill in various gaps.

4. Veterans and Agent Orange

The first volume of the periodic reviews mandated by the Agent Orange Act of 1991 was published by the National Academy Press in 1994. The report was produced by the Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides, which was comprised of scientists who were generally familiar with the literature, but had not conducted Agent Orange research themselves. This first review concluded that there was sufficient evidence of an association between Agent Orange and other herbicides used in Vietnam and soft tissue sarcoma, non-Hodgkin’s lymphoma, Hodgkin’s Disease, chloracne and a condition called porphyria cutanea tarda (in genetically susceptible individuals). The review also listed respiratory cancers, prostate cancer and multiple myeloma as having limited/suggestive evidence of an association, and then a long list of other diseases or conditions for which the evidence was inadequate or insufficient to make a determination at that point (Institute of Medicine 1994:6).

The Veterans and Agent Orange (VAO) reviews continued to be updated every two years throughout the 1990s and up until 2012. Each update reviewed published studies of Vietnam veterans, including both U.S. and Australian veterans, as well as occupational studies of workers in Europe, North America, Asia and Oceania. The reviews also included environmental studies including the large series of studies of persons exposed to dioxin after a 1976 chemical plant explosion in Seveso, Italy. The first studies in this series were by Bertazzi, *et al.* and were published in the scientific literature beginning in 1989 (Bertazzi *et al.* 1989; Bertazzi *et al.* 1992). There were dozens of occupational studies cited in the 1994 Veterans and Agent Orange review, including the Collins *et al.* Monsanto workers study mentioned previously. The review included both production worker studies and agricultural worker studies.

The VAO authors noted that “Collins and his colleagues (1993) from Monsanto have recently hypothesized that heavy exposure to 4-aminobiphenyl alone or in combination with TCDD may explain the observed STS excess. A substantial body of evidence, however, points toward an association of STS with phenoxy herbicides and related compounds, whereas the possibility of a link to 4-aminobiphenyl has not been previously reported” (Institute of Medicine 1994:479). The authors of the first review put this study by Monsanto authors in the context of the large body of literature available at the time, concluding that there was sufficient evidence that herbicides used in Vietnam, and their contaminant TCDD, were associated with soft tissue sarcoma.

The authors of the 1994 Veterans and Agent Orange review also did a detailed analysis of the studies by Hardell and his Swedish colleagues, especially those reporting excess soft tissue sarcoma in herbicide-exposed workers. The reason for this was because “the strongest evidence for an association between STS and exposure to phenoxy herbicides ... although these studies have been criticized ...” What this is referring to are statements made by British epidemiologist Dr. Richard Doll who submitted a letter in 1985 to the Australian Judge who was holding an enquiry into the effects of Agent Orange on Australian veterans exposed during the Vietnam war. Doll’s letter said, among other things, “relating to 2,4-D and 2,4,5-T (the phenoxy herbicides in question), there is no reason to suppose that even TCDD (dioxin), which has been postulated to be a dangerous contaminant of the herbicides, is at the most, only weakly and inconsistently carcinogenic in animal experiments ... Your review of Hardell’s work, with the additional evidence obtained directly from him at interview, shows that many of his published statements were exaggerated or not supportable and that there were many opportunities for bias to have been introduced in the collection of his data. His conclusions cannot be sustained and, in my opinion, his work should no longer be cited as scientific evidence.”

After reviewing the work by Hardell and colleagues in Sweden, the VAO authors concluded in 1994 that “there is insufficient justification to discount the consistent pattern of elevated risks, and the clearly described and sound methods employed. These findings are supported by a significantly increased risk in the NIOSH study (SMR=9.2, CI 1.9-27.0) for the production workers most highly exposed to TCDD (Fingerhut *et al.* 1991), and a similar risk in the IARC cohort ...” (Institute of Medicine 1994:499). So, contrary to Doll’s claim that Hardell’s work should no longer be cited as scientific evidence, the VAO authors cited and included it as part of the evidence that there was a positive association between herbicides and their TCDD contaminant and soft tissue sarcoma. It was later revealed that Richard Doll was receiving substantial funds from Monsanto at the time that he wrote to the Australian Judge (Hardell *et al.* 2006).

5. 2000 EPA dioxin reassessment

The next draft of the EPA dioxin reassessment was released for external review in 2000 and a large number of comments were incorporated before the Science Advisory Board convened another two-day meeting of the Dioxin Reassessment Review Subcommittee in November of that year. I participated in this Subcommittee, as did Drs. John

Graham, Dennis Paustenbach and several others who had been part of the SAB review five years earlier. At this meeting, more attention was paid to conflicts of interest and Subcommittee members were asked to declare any financial conflicts at the public session on the first day. None of the members indicated any financial conflicts, although Dr. Graham said that his wife was in a stock buyers' club and he was not sure whether any of her investments might be in companies that might be affected by the results of the review. An additional requirement at this meeting was that if any Subcommittee members worked at a company that had other employees that were involved in criticizing the EPA dioxin reassessment, then they should agree not to discuss the SAB review with them. Dr. Paustenbach agreed to this requirement, although he was a Vice President of Exponent, Inc. at the time of the November 2000 meeting.

The public session of the Subcommittee meeting was similar to the one held five years earlier, with comments by a range of groups. One speaker, Dr. Dimitrios Trichopoulos, the former Chair of Epidemiology at the Harvard School of Public Health, was speaking on behalf of an expert group assembled by Exponent, Inc. In his remarks, he was particularly critical of the EPA position on the probable human carcinogenicity of dioxin. He also criticized the International Agency for Research on Cancer (IARC) designation of TCDD as a Group I carcinogen. Dr. Trichopoulos claimed that the only way the IARC could have done this was by revising their classification system to include mechanistic information, something they had never done in previous carcinogen designations. A subsequent commenter, Dr. Ellen Silbergeld, pointed out that this was false and that the IARC had included mechanistic information in classifications of carcinogens prior to the dioxin designation in 1997. We will return to Dr. Trichopoulos and the Exponent, Inc. criticism later in this chapter.

After the November meeting, and as the Subcommittee was preparing its report for submission to the EPA Administrator, I reviewed a draft circulated by the EPA staff member in charge of this process. I noticed that there were references in a version of the draft report that we had never seen before and that were not discussed at the Subcommittee meetings. Furthermore, the references seemed out of place and did not refer to the text where they appeared. On inquiring about this, I was told that they were inserted by Dr. Paustenbach and that I should talk directly to him. I arranged a phone call at his office at Exponent, Inc. and when we began the call I found that he had included another staff member at his company on the phone call. He explained that this staff member, Senior Scientist Sean Hays, had provided the reference that he had then inserted in the Subcommittee draft report. As it turned out, this reference by another Exponent staff member was the wrong reference at the point it was inserted and was withdrawn by Dr. Paustenbach. A reference by Exponent, Inc. authors remained elsewhere in the SAB Subcommittee report, however, in a section critical of the EPA calculation of the cancer slope factor for dioxin.

This telephone exchange with Dr. Paustenbach and his Exponent colleague indicated that he had violated his agreement not to discuss the Subcommittee work with others in his company. I considered this an abuse of process and wrote a letter to the SAB Executive Committee to this effect. In my letter, I wrote, "the process leading to the final draft of the Dioxin Reassessment Review Subcommittee (DRRS) was not

transparent, and, in fact, was subverted by at least one member.” I also quoted another Subcommittee member who said “At times I felt that, instead of working in an open and collegial process, we had to maintain constant vigilance for members who were trying to see what could be slipped into the document without other members noticing.” To their credit, the EPA SAB Chair and staff at the time were very concerned about this problem and began a process of assuring more transparency in future Subcommittee deliberations. As it turned out, the SAB has not reconvened a Subcommittee to review further drafts of its dioxin reassessment and it still has not released a final statement about the carcinogenicity of TCDD.

The criticism of the EPA reassessment offered by Dr. Trichopoulos at the SAB Subcommittee meeting in November 2000 began to appear elsewhere. It was used by defendants in a lawsuit in Maine where the plaintiffs were alleging health effects caused by dioxin released from pulp and paper mill waste. The document critical of the literature linking dioxin to human cancers was co-authored by Drs. Philip Cole, Harris Pastides, Thomas Starr and Jack Mandel, along with Dr. Trichopoulos. This same group published their criticism in an article in the *Regulatory Toxicology and Pharmacology* journal in 2003 (Cole *et al.* 2003). Entitled “Dioxin and cancer: a critical review,” this article included some of the same comments that Dr. Trichopoulos had made about the IARC designation of dioxin as a Group I carcinogen, plus a criticism of several occupational epidemiology studies. Cole and co-authors criticized the NIOSH dioxin workers’ study, for example, saying that smoking information from some of the plants was missing or incomplete. They conclude that, “Hence, there is no basis for inferring that smoking was not a confounder in the Fingerhut study” (Cole *et al.* 2003:382).

In discussing an update of the Fingerhut, *et al.* study, Cole and co-authors emphasize that in six more years of follow-up, no additional deaths from soft tissue sarcoma occurred. What they fail to point out is that less than one death due to this rare cancer would have been expected in six additional years of following this cohort. These authors also criticize the EPA for its “failure to adjust adequately for known and possibly confounding exposures to other carcinogens such as asbestos, 4-aminobiphenyl, and smoking” (Cole *et al.* 2003:385). Here is the Collins, *et al.* argument being raised once again, although Cole and co-authors don’t explicitly refer to the 1993 Monsanto study. In their conclusion, the authors say that “the evidence indicates that TCDD is not carcinogenic to human beings at low levels and that it may not be carcinogenic to them even at high levels” (Cole *et al.* 2003:386). In their acknowledgments, they thank Sean Hays and note that “The project was sponsored by the Chlorine Chemistry Council.”

6. Cancer Epidemiology textbook

The 2002 Textbook of Cancer Epidemiology, co-edited by Dimitrios Trichopoulos, summarizes some of the evidence of occupational causes in chapters on individual types of cancer. This often amounts to dismissing the workplace contribution to the overall burden, even in the chapter on bladder cancer, a cancer known to have many occupational causes. In the chapter on lymphomas, the authors misrepresent the results of a Centers for Disease Control study of Vietnam veterans presumed to be exposed

to Agent Orange by asserting that “the highest incidence of lymphomas was found in ground troops stationed in areas of lowest exposure and among sailors in navy ships off the coast of Vietnam” (Adami *et al.* 2002). This assertion is false, and the publication cited actually identifies the highest risk of non-Hodgkin’s lymphoma in Navy shore veterans and ground troops who served in an area of heavy exposure (I Corps). It is not clear why the authors of this textbook chapter, one of whom is Dr. Trichopoulos, made this error, but I first heard it from a consultant for Monsanto Company a few years earlier and it was subsequently repeated in the textbook chapter as if it were true.

7. The IBM mortality study and the battle to publish results

A more recent example of contested information about workplace exposure and cancer developed over the past decade. The origins were in a lawsuit filed in a California County Court in which IBM employees were seeking compensation for illnesses they claimed were due to exposures at a San Jose manufacturing plant. As part of the background for the legal case, attorney Amanda Hawes discovered that IBM had a computerized file of deceased employees whose next of kin had received death benefits. She requested a copy of this file, and a work history file that would document where the deceased workers had worked and what their IBM job titles had been. Initially denying the request, IBM had to be compelled by the Court to provide the electronic data so that a colleague and I could analyze the pattern of deaths in this workforce. The information was eventually provided and was to be kept confidential with employee names encrypted so that no individual worker could be identified. In order to be in the death benefit database, the employee had to have worked at least five years for IBM and not been fired.

In 2003, we began our analysis of over 30,000 deaths that had occurred between 1969 and 2001. Although there had been a few published studies prior to 2003, this was the largest study of deaths in computer industry workers up to that point. With such a large database, we were able to calculate estimates of the risk of death of IBM workers compared to general populations of the U.S., California, and the four counties that comprised the Silicon Valley area. We used a standard occupational mortality statistical software package and carried out an analysis similar to the Vietnam veteran study I had co-authored fifteen years earlier. The results showed large excesses of deaths at IBM due to brain cancer, kidney cancer, non-Hodgkin’s lymphoma, melanoma of skin, leukemia and several other cancers. In females who had worked at the San Jose plant, there was a striking excess of breast cancer. In preparation for the trial, I was required to bring computer print-outs to a deposition and explain to IBM attorneys what my colleague and I had done and how we interpreted the results.

The IBM attorneys, after hearing my description of the calculations and findings, went to the Court and attempted to prevent the statistical results from being used in the trial. The Judge eventually ruled that the statistical analyses were not relevant to the issues in the lawsuit and might prejudice the jury, so I was not able to testify about the mortality study. I did testify about other studies in the literature that showed increased risk of non-Hodgkin’s lymphoma and breast cancer in workers exposed to some of the same chemicals as were used at the San Jose plant. The two plaintiffs whose case was

being presented to the jury in late 2003 and early 2004 had been diagnosed with these two cancers. Under the California law that allowed these two workers to sue IBM, they had to prove that the company had poisoned them, that the company medical staff knew they were poisoned at work, and that the company sent them back to the same environment without telling them that it had poisoned them. If all of that was proven, then the plaintiffs' attorneys also had to show that the cancers in these two workers were caused by the chemicals they worked with. Ultimately, the jury returned a not-guilty verdict.

At the end of the trial, the attorneys for the plaintiffs and IBM were discussing the outcome in the courtroom with members of the jury. This is standard practice in some Courts, and one of the plaintiffs' attorneys said he was disappointed that I had not been allowed to present the results of the mortality study to the jury, but at least I would be able to submit it to a journal for publication. In the following day or so, attorneys for IBM sent a letter to the plaintiffs' attorney saying that the information my colleague and I had analyzed was confidential and that I could not publish it. The IBM attorneys claimed confidentiality, even though the journal article was based on statistical summaries that had been presented at my deposition the previous year. These were in publicly available Court records and had not been stamped confidential at the time. By the time the trial ended, we had drafted a summary of our statistical results that was to be part of a special issue of *Clinics in Occupational and Environmental Medicine* on the electronics industry. This issue was intended to be edited by Dr. Joe LaDou and would include submissions from thirteen other authors (Bailar *et al.* 2007). After a series of exchanges with their lawyers and the editor of the special issue, the publisher, Elsevier, declined to accept my manuscript. The reason they offered was "it is an original research article and the *Clinics in Occupational and Environmental Medicine* publish only review articles." A review of issues for the previous two years revealed that there were six original research articles, so this could not have been the reason for declining my manuscript. The spokesperson for Elsevier said they had not been threatened or coerced by IBM.

In any event, Dr. LaDou and the thirteen authors who intended to publish in the special issue wrote a letter objecting to the exclusion of my manuscript and urging Elsevier to reconsider its decision. When the publisher declined to reconsider, the authors and guest editor boycotted the *Clinics* issue and this became an academic freedom issue. I had to hire my own attorney to get independent advice on whether to submit my manuscript to another journal. I also had to consult with attorneys for Boston University, where I was on the faculty at the time. My attorney advised me that since the statistical results were in the public domain and were not stamped confidential at my deposition, I could publish these findings. Attorneys for Boston University also said they would defend my right to publish if challenged by IBM.

At about this same time, a *Science* magazine journalist named Dan Ferber contacted me to write about the IBM mortality findings and the dispute over publishing them. He wrote an article that appeared in the May 14, 2004 issue of *Science* under the title "Beset by Lawsuits, IBM Blocks a Study That Uses Its Data" (Ferber 2004). In the article, Ferber summarized the main findings of the draft *Clinics* manuscript, which he had

obtained from some unnamed source, and quoted Dr. LaDou as saying the article was the most definitive cancer study to date on workers in the electronics industry. He also quoted one of the IBM attorneys, Robert Weber: “This is one of the clearest examples of what has been characterized as junk science.” Weber asserted that it was “a litigation-produced study in which lawyers supplied key data and gave direction on how the study was to be done.” Weber also stated in this Science article that IBM had commissioned a separate study, led by Elizabeth Delzell from the University of Alabama, who planned to publish it in a peer-reviewed journal.

Several years later, Dan Ferber told me that this was the most difficult article he ever wrote in his fifteen years as a freelance science journalist. He said that an attorney working on behalf of IBM had called him while he was writing the article, and that she had tried to get his editor to suppress the story. He said that his editor referred the article to the magazine’s lawyers and that every word was reviewed for potential liability. He also said that he was required to put in quotes from IBM spokespeople or from others suggested by IBM, something he had never been asked to do before. Ultimately, Ferber said that the Science editorial staff stood by his final draft and agreed to publish it.

The University of Alabama mortality study commissioned by IBM was published in 2005 (Beall *et al.* 2005). Its authors focused on mortality at three IBM manufacturing plants in San Jose, East Fishkill, New York and Burlington, Vermont. They used a different method of analysis and covered a different time period than my colleague and I had been able to analyze in the mortality file we received. One result of their analysis was lower than expected overall mortality, which is often seen in occupational studies and is called “the healthy worker effect.” They also found lower cancer mortality than expected, especially in male workers in these three plants; this latter finding was driven by very low lung cancer mortality in males. We had also found this in our study, which we attributed to low smoking rates in this group of workers because of the nature of their work. The IBM Medical Director said in a public statement that the University of Alabama study showed IBM workers had fewer cancers than expected, without referring to the healthy worker effect.

One finding that stood out in the University of Alabama study was an excess of central nervous system cancer at one of the facilities. The authors say that this was particularly associated with employment in process equipment maintenance, where there was a greater than two-fold excess that was statistically significant. At the end of the article, the authors say that “there was no conclusive evidence that any form of cancer was associated causally with employment,” and that “these positive results emerged in the context of thousands of comparisons and may be due to chance.” They do note that the association of central nervous system cancer with unknown work factors warrants further investigation.

One of the co-authors of the Beall *et al.* study was Robert Herrick, who directed a group at Harvard School of Public Health under a subcontract where they examined the work histories and potential occupational exposures in the three IBM manufacturing facilities. He told me that, as a stipulation in his subcontract agreement, he expected

to be able to publish the results of his group's work on the study. When they found the excess central nervous system cancer in process equipment maintenance workers, the IBM lawyers did not want it to be discussed in the published article. He said the IBM lawyers had a contentious meeting with the Harvard lawyers, and "the Harvard lawyers were more obnoxious" so they prevailed and were able to discuss the excess central nervous system cancer in the 2005 publication. In fact, a further study is underway and may be published in the next year or two. This is an unusual outcome of industry-sponsored studies, and it speaks to the importance of rights to publish results as part of any contract or subcontract by independent researchers. The more typical approach taken by affected industries is illustrated by the hexavalent chromium example.

8. Hexavalent chromium studies

There is an extensive literature on hexavalent chromium and lung cancer in exposed workers, going back many decades. Much of this is discussed by David Michaels in a chapter called "Chrome-Plated Mischief" in his book *Doubt Is Their Product*. Michaels begins the chapter by relating a story that "veteran employees at chromium-processing plants introduced new workers to the peculiarities of the job by inserting a dime in one nostril and withdrawing it from the other" (Michaels 2008:97). He then describes early studies by Thomas Mancuso (Mancuso and Hueper 1951; Mancuso 1975; Mancuso 1997) of workers exposed to hexavalent chromium in a U.S. chromate production plant in Paineville, Ohio. In response to these studies, which showed workers to be at increased risk of death from lung cancer, OSHA announced plans to update its workplace hexavalent chromium standard in 1976, but this was derailed for twenty years by the Reagan and Bush Administrations. Then, in 1993, the Oil, Chemical, and Atomic Workers International Union teamed up with an advocacy group called Public Citizen to petition OSHA for an emergency temporary standard of 0.5 micrograms of hexavalent chromium per cubic meter of workplace air. This was denied, but OSHA in 1996 began the process of updating its out-of-date chromium standard by the normal rule-making process.

The Chrome Coalition, an industry association, began its efforts to counter OSHA in 1996. According to Michaels, the plan was as follows: "Reanalyze old studies, and commission new ones that would yield better results. Quickly get some studies into peer-reviewed journals, and make points to influence OSHA's deliberations" (Michaels 2008:101). Another part of the strategy included a project to "Develop an anti-Mancuso manuscript." The result of this strategy was that OSHA was forced to review and respond to a series of manipulated and deceitful analyses of occupational studies, and ten years later promulgated a new workplace hexavalent chromium standard of 5 micrograms per cubic meter of workplace air. This was an improvement over the previous standard of 52 micrograms per cubic meter, but arguably would still allow the half million U.S. workers exposed to hexavalent chromium to be at excessive risk of cancer.

My own involvement in the hexavalent chromium issue came when I was asked in 2011 to be an epidemiology expert for the U.S. Environmental Protection Agency in an enforcement action against Elementis Chromium. The basis for the enforcement

action was the Toxic Substances Control Act (TSCA) requirement that “Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information ...” As it happened, Elementis Chromium was one of the companies that had participated in a four-plant study, two in the U.S. and two in Germany, and had information about lung cancer risks in workers with low-level exposure to hexavalent chromium. They were one of the companies that were part of the strategy described by Michaels in his “Chrome-Plated Mischief” chapter; the plan was to introduce new studies that would complicate the OSHA standard-setting process.

Briefly, the question before the Court in the Elementis enforcement case was whether the company knew that a new method of manufacturing chrome-based chemical substances, which was purported to be safer, still resulted in increased risks of lung cancer in the workers. If the company knew this, and failed to notify EPA, they were in violation of the Toxic Substances Control Act and would be fined. The company, through its expert witnesses, claimed that there was nothing in the four-plant study results that EPA did not already know, and therefore they were under no obligation to report their findings. One of the company’s experts, Herman Gibb, had already published a study that showed lung cancer risk at low hexavalent chromium exposure levels in an older plant (Gibb 2000). The point of the four-plant study, however, was to evaluate risk in workers using the newer method of manufacturing and processing chrome.

As Michaels pointed out, the authors of the industry-sponsored four-plant study had previously published some of their results, but only after splitting the study into two sub-groups. The lung cancer risk in the U.S. plants, owned by Elementis, was presented in one article (Luippold *et al.* 2005), with the authors stating: “Mortality among chromium chemical workers generally was lower than expected ... Lung cancer mortality was 16% lower than expected, with only three lung cancer deaths (3.59 expected).” The lung cancer risk in the German workers was presented in another article (Birk *et al.* 2006), with its authors noting that, although “lung cancers appeared to be increased (SMR=1.48, 95% CI=0.93-2.25)” there was no clear dose-response. They concluded that there was “a possible threshold effect of occupational hexavalent chromium exposure” (Birk *et al.* 2006:426). So, the effect of splitting the four plants into two groups was to create an ambiguous picture of the risk of lung cancer in workers in the plants using the new chromium processing method. Moreover, the authors of the second study even suggested a threshold, below which there was no risk of lung cancer from hexavalent chromium exposure. This challenges the long-held assumption that there is no safe level of exposure for most carcinogens, including hexavalent chromium.

EPA scientists were able to analyze the trend in lung cancer risk with increasing exposure using data from the entire four-plant study as part of the evidence presented to the Court in the TSCA enforcement action. Using all the data in the Modern Four Plant Report, a steady increase in risk of death due to lung cancer was found with increasing cumulative exposure to hexavalent chromium. As the data extended and filled in gaps that remained after the Gibb study, the EPA conclusion was that this provided “additional information

about substantial risk due to low exposures to hexavalent chromium.” I agreed with this in my testimony before the Court, as did another epidemiologist who testified on behalf of the EPA on the same day.

The administrative decision of Judge Susan Biro was issued in 2013. She found that Elementis had failed to disclose information about substantial risk of injury to human health as a result of exposure to hexavalent chromium, as required under the TSCA. The fine for this was \$2.5 million, but Elementis appealed against this decision and managed to avoid the fine.

Another well-documented example of pollution of the scientific literature also involves hexavalent chromium exposure, although through ingestion of contaminated water and not occupational exposures. This example concerns a series of analyses and re-analyses of cancer mortality in five Chinese villages with hexavalent chromium-contaminated water (Zhang and Li 1987; Zhang and Li 1997). The source of hexavalent chromium was a ferrochromium factory that included a smelter. The first study showed excess overall cancer mortality in the five villages combined, while the second found no association with cancer mortality and hexavalent chromium in the three villages nearest to the source of contamination. The two articles were published in the *Journal of Occupational and Environmental Medicine*, and it later came to light during litigation proceedings that the Chinese authors had received undisclosed payments and intellectual input from U.S. consulting company McLaren/Hart-ChemRisk and the aforementioned Dennis Paustenbach. When this became known publicly, the editor of the journal took the unusual step of retracting the 1997 Shang and Li article in 2006 (Brandt-Rauf 2006).

Two years later, a group from the California Environmental Protection Agency and the Department of Conservation re-visited the data in the Chinese villages with contaminated water and used actual concentrations of hexavalent chromium instead of distance from the factory as the exposure metric (Beaumont *et al.* 2008). In this article, the authors reported substantial increases in stomach cancer mortality in the exposed population compared to the whole province. They also reported somewhat increased lung cancer mortality in the exposed population, although they found this less impressive than the relationship for stomach cancer. They concluded that: “our reanalysis of the Chinese data shows a substantial association between stomach cancer mortality and exposure to Cr6-contaminated drinking water in the 1970-1978 observation period, compared with nearby uncontaminated regions and with Liaoning Province” (Beaumont *et al.* 2008:21).

9. Conclusion

These examples are by no means exhaustive, and they are primarily from my personal experience in conducting and reviewing occupational cancer studies over the past three decades. Others have documented similar examples of pollution of the literature and deliberate attempts to distort the scientific record by specific industries or their consultants. The examples I have cited are perhaps unusual in that these attempts have sometimes been exposed, and in one case retracted, or have failed to achieve

their intended results. Nevertheless, they illustrate the problem of “manufacture of doubt” that permeates the literature and makes its way into the regulatory process. The occupational causes of cancer have been and will continue to be contested territory. It is clear that advocates for workers’ health must continue to be vigilant and bring conflicts of interest and outright scientific misconduct in occupational cancer studies to the light of day.

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Chapter 4

Tracking the occupational exposure of cancer patients: the Giscop93 survey

Emilie Counil

Although the SUMER survey (Medical Surveillance of Occupational Risks) has since 1994 made it possible to monitor some 20 occupational carcinogenic exposures in France on the basis of a representative sample of the working population, there is no institutional, centralised and accessible record of occupational exposure to the numerous carcinogens present in the working environment since the early 20th century. In the absence of readily understandable information for workers on the risks to which they have been exposed and given the decades which generally separate the time of exposure and the outbreak of cancer, it is often difficult for patients to make the link between work and health. Perceptions associated with the main causes of cancer – smoking, drinking and more recently, ‘bad luck’¹ – are very often brought to patients’ attention, and to that of their doctors, who rarely refer to an occupational origin when diagnosing cancer. Yet though the knowledge accumulated on the carcinogenic risks associated with different sectors of activity and jobs is considerable, the mechanisms for concealing the role of working conditions in changes in the incidence of, and mortality due to, cancer are very effective. Of these, job precariousness and the individualisation of the link with work modify power relationships between employers and employees, aggravating the social inequalities of exposure while at the same time making traceability more and more unlikely in view of the piecemeal and adaptable nature of working careers.

In view of all this, a research project concentrating on action was established in the early 2000s in the French *département* of Seine-Saint-Denis (Réseau Scop93 2005; Thébault-Mony 2008). Led by public health researchers in association with hospital doctors, local authorities and a group of experts in occupational health and sickness insurance, this project used an original survey methodology (see Box 1) in order to update the exposure situations encountered by cancer patients throughout their working life. Based on this revelation of exposures which would otherwise have remained largely unknown to the patients themselves, the objective was then to identify the factors aiding or hampering access to the right to financial compensation with respect to the occupational disease². This contribution attempts to set out a number of strengths, but also limitations, of the procedure implemented for reconstructing exposure.

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1. See the arguments put forward by an article published in the prestigious scientific review *Science* (Tomasetti and Vogelstein 2015).
 2. See the contribution of Anne Marchand in this piece.

Box 1 Giscop93 survey

Since March 2002, three hospital departments have been collaborating closely with the Scientific Interest Group on Cancers of Occupational Origin in Seine-Saint-Denis (Giscop93). These departments are referring patients suffering from tumours of the respiratory, urinary or haematological tracts to Giscop93. With their agreement, these patients are contacted by the Giscop team to be interviewed by a sociologist on their careers. These interviews are intended primarily to reconstruct patient careers, documenting the work performed in each position, including the environment in which it was done. Each interview is then submitted to a multidisciplinary expert committee tasked with examining the description of each position with respect to a list of 54 carcinogens acknowledged as being present in the working environment. The experts also examine the eligibility of patients for an occupational disease claim, following this up by prospectively monitoring patients with regard to claiming and being awarded compensation.

1. Territorial base

Very densely populated, the *département* of Seine-Saint-Denis has a high proportion of migrants and blue-collar workers in its working population. It has a long industrial history characterised by small and medium-sized enterprises in addition to the presence of several emblematic plants³. Since the 70s, the *département* has also been characterised by an excessive number of deaths from lung, pleural and bladder cancers. However, as in the other Île-de-France *départements*, no cancer register has yet been set up. The *département* could therefore assume a pilot role in the monitoring of occupational cancers, testing the implementation of an information system at national level. It was on this basis that the local scheme was established, in an attempt to ensure proximity to health, occupational health and compensation players.

2. Cancer as a sentinel for a lack of prevention

Taking inspiration from the concept of occupational “sentinel health events” (SHE[O]) proposed in 1983 by Rutstein et al., cancer is considered here to be a sentinel event in itself, putting researchers on the track of work-related carcinogenic exposure, aside from the application of any filter associated with the work activity. Patient recruitment took place through partner hospital departments (oncology, pneumology, urology departments) not specialised in occupational pathologies. Any person newly diagnosed with primary cancer of the respiratory, urinary or haematological tracts and residing in Seine-Saint-Denis was eligible for the survey.

3. To cite just a few examples: the Mécano plant and the Babcock and Wilcox foundries in la Courneuve, the Illustration printing works in Bobigny, PSA Peugeot-Citroën in Saint-Ouen and then Aulnay-sous-Bois, Saint-Gobins in Aubervilliers, Christophle in Saint-Denis, Idéal Standard and more recently L'Oréal in Aulnay-sous-Bois.

3. The patient as the expert

The survey was built around an aspect key to the whole research: reconstructing a patient's working career. In an interview, a patient is invited to describe, job by job, position by position, the work performed, quite often far removed from the tasks suggested by the simple job title. Separate importance is attached to the environment in which the work was performed. The experience accumulated by the interviewer during interviews allows him to help patients recall details of possible importance in the carcinogen identification phase, meaning that reconstruction is conducted as closely as possible to the reality of patients' individual work.

4. Multidisciplinary expertise in exposure

The variety of work situations and the diversity of carcinogens produced and used in industrial companies mean that a multidisciplinary group of experts is required – occupational doctors, prevention engineers, industrial hygienists, members of a CHSCT [Safety, Hygiene and Working Conditions Committee], sociologists, etc. – to reconstruct patients' exposure. On the basis of the detailed account of the work performed and the experts' knowledge of prevailing working conditions at the times and in the employment areas concerned, the group identifies the following for each position: the carcinogens, their probability of occurrence and other normal descriptors of exposure (intensity, frequency, duration, peaks). More than 54 proven or suspected carcinogens are taken into account.

5. Necessary cooperation

The acquisition of knowledge on occupational exposure is thus based on a combination of a patient's recorded work experience and an in-depth examination thereof by the multidisciplinary group of experts. With each party contributing knowledge and skills, this combination uncovers situations not usually accessible under the normal approach of retrospectively evaluating exposure (see Box 2). Surveys using questionnaires are generally based on the principle that people have been given comprehensive and readily understandable information on their exposure, a situation found to be the exception. Moreover, the job-exposure matrices offer mean indicators masking the variety of situations. What is more, they are only available for some of the many known carcinogens, primarily asbestos.

Box 2 Indirect exposure, ancillary activities

Ms P. worked from 1959 to 1965 as a security guard for the Seigneurie company in Bobigny. 'The company is a paint factory [...] which employed about 300 people at that time, mainly manual workers and secretaries. It was a huge hangar covering almost two hectares. Machines made the paint, which was then poured into tins before being dispatched all over the place. The workers had to spray the drums of paint night and day with jets of water to prevent them 'exploding'. These drums contained toxic products. Her work involved recording the arrivals and departures of trucks in the warehouse. She had a lodge at the entrance to the hangar, about ten metres away from where the trucks arrived. [...] The patient lived in this lodge until 1975 [...]. A large sliding door allowed trucks to enter the warehouse. The patient sometimes went out onto the loading bay for a 'stroll', passing close to the drums of paint. A ventilation system evacuated fumes via the roof but the patient said that the paint smells were still very strong.' On the basis of this account, the experts identified two indirect exposures: benzene in the mixtures (solvents), and diesel exhaust fumes.

Between 1969 and 1986, Mr E worked as a sealing contractor for about 20 companies in the Paris region. 'The patient's work consisted in sealing the flat roofs of new buildings through applying bitumen. [...] The patient also had to carry out a whole range of ancillary work to finish sealing the roofs. He had to install rainwater drain pipes made of lead. He had to strip the lead with 'stearin', an acid which attacked the surface. The patient also applied tin solders to the lead pipes, as well as making expansion joints with lead. [...] He made trim from zinc or copper. Zinc or copper sheets were bent using a bending machine and then he had to apply hydrochloric acid solders with a soldering iron operating on propane gas. [...] Occasionally, four or five times a year, he repainted terraces. [...] The patient had little protection equipment at any of these sites. He wore leather and fabric gloves to handle the bitumen. He wore overalls, which he washed at home. There was often bitumen stuck to them. He washed his hands with a detergent, a special soap based on solvent or spirit. He often used spirit to remove traces of bitumen on his hands or face.' In addition to his exposure to bitumen (PAH) [polycyclic aromatic hydrocarbons], the experts identified three exposures associated with ancillary activities: benzenes in mixtures (solvents), strong acids and lead.

6. Careers at the heart of the survey

Workplaces were examined one by one and exposure identified with respect to the working situations specific to a patient at a given moment - proximity to other sets of jobs in construction and public works, activities of a client enterprise as part of industrial cleaning, etc. As far as possible, the group of experts looked at the whole record of working life, taking account of changes in the labour market and work organisation in order to assess the conditions under which each job was performed. In doing so, the survey revealed a social division of risks (see Box 3), still seen in current SUMER surveys (Cavet and Leonard 2013).

Box 3 Social inequalities with respect to carcinogenic work

Affected mainly by respiratory cancers, a very large proportion of patients, especially skilled workers, had been exposed to at least one carcinogen (almost 90% of men and 65% of women), with more than half of the workplaces characterized by multi-exposure*. This proportion was 12 times higher than among managers and professionals. The survey also makes it possible to assess the effects of the increasing use of sub-contracting and temporary work on the social division of risks. In fact, the careers of almost one in four patients are 'temp careers': low-skilled work characterised by flexibility, instability and lack of continuity. Male patients with such careers, predominant among those starting work since the 1970s, were more likely to have histories burdened by exposure (an accumulation of five carcinogens or more over the entire career) than those pursuing high-skilled, stable and continuous careers. These results suggest that the precariousness of careers noted since the application of the principle of flexibility (Appay and Thébaud-Mony 1997) is reflected in a deterioration in working conditions and is contributing to the development of social inequalities with respect to cancer.

* Exposure to at least two hazards from a list of about 50 proven or possible carcinogens.

7. Surveying cancer patients

The context of cancer, a fatal diagnosis turning patients' lives upside down, necessarily impacts information gathering, as it is impossible for some patients to be surveyed in view of the priority given to care, or even due to premature death. It is difficult to make sense of detailed reconstructions of working careers in view of the perceptions patients have of their work and the probable causes of their illness. Physical and mental exhaustion are often barriers to this laborious reconstruction exercise. And it can be just as difficult for the interviewers, having to find the right balance between empathy and impartiality, listening to the person and striving for thoroughness, a task which continually requires judgements and adjustments [Lanna 2013].

8. Heterogeneity factors

The evaluation of exposure is based on three overlapping sets of knowledge: that of the patient about his work, that of the interviewer about the conduct of the interview and that of the group of experts about exposure situations. Some accounts of jobs are more substantial than others, depending on the context mentioned above, but also depending on the ease with which the patient can talk about his work and his command of French. Over the 14 years of the survey, interviews have been conducted by a series of interviewers, with varied experience with respect to the requirements of research relating to aspects positioned at the intersection of serious illness and work. The conduct of interviews and the encoding of working careers are subject to an ever-changing protocol. At the same time, some 10 occupational health professionals are needed in the joint expert sessions to examine the exposure. The composition of the group of experts

has fluctuated over time, practices have developed, introducing an inevitable degree of variability in the evaluation process.

9. A 'non-representative' sample but an exemplary scheme

Though the surveyed sample can in no way be claimed to be representative – in the statistical sense of the term – of all cancer patients in France and even less of the general population, the survey nevertheless documents a broad range of exposure situations occurring between the 1940s and now and associated with highly unequal positions in the social division of work. Sub-contractors, temporary employees, unqualified cleaning and maintenance workers and migrants have been largely ignored in typical epidemiological studies, which usually concentrate on populations of stable and permanent workers. The situations identified in the particular context of Seine-Saint-Denis thus have overall relevance, revealing prevention shortcomings, all the more pronounced when they concern people whose careers involve some kind of precarity. They also illustrate the inadequacy and unequal nature of the criteria for awarding compensation with respect in particular to the multi-exposure situations experienced by a number of these patients. Finally, and this is particularly important, the results show that it is possible to reconstruct carcinogenic workplace exposures, even ones way back in the past, despite institutional amnesia and the disappearance of records and despite the fragility of our working group (see Box 4).

Box 4 Impossible to preserve a working group

Despite repeated financial backing from a local authority (the Seine-Saint-Denis General Council), the Ministry of Labour and the Départemental League for the Fight against Cancer, the team behind the day-to-day running of the survey scheme is hit by great fluctuation. A real-life example of the 'precariousness of jobs in the higher education and research sector', Giscop93 has for several years been suffering the effects of project-based research financing, as well as the red tape inherent to this sector.

Team members are caught in a system of individual and collective constraints: replacement of part of the team every year, the challenges of multi-disciplinary working, domineering relationships within the academic sphere, the positioning of socially-engaged researchers, a lack of clarity on possible career progression*, etc. The continuity and quality of the work can only be assured at the cost of significant concessions by all concerned in order to maintain a fragile balance between participation in the survey work, including all its invisible dimensions, and involvement in particular research aspects.

*Due both to the chronic lack of financial resources and, since 2012 the Sauvadet Act which imposes a cumulative 3-year maximum for a fixed-term contract and is applied by most higher education and research institutions to non-permanent staff.

Table 1 Differences in the Giscop93 survey with respect to the usual approaches

Divergences and limitations with respect to the usual approaches	Advantages in terms of knowledge acquisition
Recruitment of cancer patients, with no control group	
Does not provide for studying the aetiology of the disease	Cancer as a sentinel with respect to past exposure and access to workers' rights
Patients treated in public hospitals in Seine-Saint-Denis	
Little social diversity: 60% blue-collars, 18% white-collars	'Magnifying glass' effect on a socially less advantaged population, which is also that affected most by cancer
Exclusive study of working life	
No procedure for estimating attributable risks	Detailed career and access to actual work activity
Exclusive research of known carcinogens	
No procedure for identifying new risk factors	Identification of prevention failure situations
Great majority of patients 'exposed'	
Under-representation of non-exposed people and work situations	Diversity in terms of duration, intensity, multi-exposures, etc.
Longitudinal retrospective approach	
Effects of selection (inclusion only of survivors)	Inclusion of the diachronic dimension of careers
Piecemeal career accounts and evidence	
Incomplete or imprecise career accounts, skewed memory	Reliance on workers' memories of their work, but lack of administrative evidence remains a problem for compensation
Deletion of records relating to exposure	
Little company history, lack of evidence of exposure (attestations)	Cooperation between patients and experts, search for specific data (archives, trade unions, etc.)

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Chapter 5

Links between occupations and cancer: the strengths and limitations of the NOCCA project

Klaus Kuhl and Lothar Lissner

1. The NOCCA project

Occupational or work-related causes of cancer are well known in many cases, (e.g. vinyl chloride, chromium, asbestos etc.), but in other cases identification proves to be difficult due to long latency periods and overlaps with lifestyle and environmental factors. One approach to overcoming these problems is presented by the Nordic Occupational Cancer Studies (NOCCA) project.

Geographically covering the Nordics, the NOCCA project links cancer data from national cancer registries to censuses and occupational categories. The study is based on a monitoring of the whole working populations in these countries (see Table 1).

Table 1 NOCCA structure

Country	Census(es)	Persons	Cancers and occupations	Monitoring period
Denmark	1970	2.0 million	Cancers: 469,000 Occupations: 220	1971-2003
Finland	1970, 1980, 1990	3.5 million	Cancers: 489,000 Occupations: 330	1971-2005
Iceland	1980/81	0.1 million	Cancers: 15,000 Occupations: 290	1982-2004
Norway	1960, 1970, 1980	2.5 million	Cancers: 538,000 Occupations: 570	1961-2003
Sweden	1960, 1970, 1980, 1990	6.8 million	Cancers: 1,248,000 Occupations: 300	1961-2005
Total		15 million	Cancers: 2.8 million	1961-2005

The main NOCCA database covers a total of 15 million workers, while the number of cancer cases diagnosed under the latest available census was 2.8 million.

Census data in the Nordic countries include the occupation of each employed person at the time of the census, as coded according to national classifications. Information on each person's occupation was provided through free text in self-administered questionnaires. The NOCCA team established 54 occupational categories, some examples of which can be seen in the following table.

Table 2 Examples of occupational categories used by NOCCA

Category number	Occupation	Description
13	Clerical workers	Includes secretaries and clerical workers in banks and insurance companies, accounting and bookkeeping clerks, keyboard-operating clerks, and other types of office workers.
31	Electrical workers	Workers in this category fit, assemble, install, maintain and repair electrical and electronic equipment such as electrical motors, generators, instruments, signal transmitters and receivers, domestic appliances, switchgear and control apparatus. They install and service electrical wiring systems in homes, industrial plants, ships, motor vehicles and aircraft, and install and service electrical power transmission cables, telephone and telegraph lines and related equipment.
32	Woodworkers	Workers in this category prepare and treat wood, and make, assemble and repair constructions and products made of wood.
33	Painters and decorators	Painters prepare structural surfaces for painting and apply decorative and protective coatings to buildings, ships, motor vehicles and articles made of wood, metal, textiles and other materials. Decorators cover interior walls and ceilings.
34	Other construction workers	Includes workers in the building and construction industry who do not constitute separate occupational categories in this study. Included here are reinforced concreters, cement finishers, terrazzo workers, insulation specialists, glaziers, underwater workers, and other unspecified building and construction workers.
35	Bricklayers	Workers in this category erect and repair foundations, walls and complete structures of brick, stone and similar materials and cover and decorate walls, ceilings and floors of buildings with tiles and mosaic panels.
36	Printers and related workers	Workers in this category compose type, cast and engrave printing plates and operate printing presses to print texts and illustrations. Includes type setters, printers (not textile printers) and book binders.
37	Chemical process workers	Workers in this category distil, refine, cook, roast and grind chemical substances, prepare pulp for paper production, and make paper.

NOCCA aims to identify occupations associated with cancer risks, tracing exposure response associations between work-related factors and cancers. The method used by the team was to compare the observed number of cancer cases in each occupational group with the expected number of such cancer cases within the respective national population. These so-called standardised incidence ratios (SIRs) were calculated for the mentioned 54 occupational categories with regard to over 70 different cancers or subtypes of cancer.

To obtain more quantitative exposure estimates, the NOCCA team applied national Job-Exposure-Matrices (JEMs). These matrices allow occupation-specific exposure estimates, usually based on expert opinion and exemplary measurements in different studies. The first use of the NOCCA-JEM procedure concerned occupational exposure to tri- and tetrachloroethylene and the risk of NHL (non-Hodgkin's lymphoma) and cancers of the liver and kidney.

The following factors were included in NOCCA-JEMs (as of August 2013):

- chemicals: aliphatic and alicyclic hydrocarbon solvents, aromatic hydrocarbon solvents, asbestos, benzene, benzo[a]pyrene, chlorinated hydrocarbon solvents, chromium, formaldehyde, petrol, lead, methylene chloride, nickel, perchloroethylene, sulphur dioxide, toluene, 1,1,1-trichloroethane, trichloroethylene;
- process-generated chemical substances: animal dust, bitumen fumes, welding fumes, wood dust, crystalline silica, diesel exhaust fumes;
- non-chemical factors: ionising radiation, night work, perceived physical workload, ultraviolet radiation.

The JEM analysis allows possible occupational co-exposures (as confounders in research) to be taken into account, as well as lifestyle confounders (smoking, alcohol, obesity, physical exercise, parity, and so on) derived from other available datasets.

Pukkala and colleagues published detailed results of their analyses in 2009. The authors presented the observed number of cancer cases (Obs), and the relative level of the cancer incidence of 54 occupational categories, described by the standardised incidence ratio (SIR), for 48 cancers. The entire national study populations were used as reference rates (national incidence rates). A SIR above 1 means that workers in the respective occupational category are diagnosed more often with cancer than the related national population. If the observed cases are double the number of expected cases, the SIR equals 2 (Table 3). See example below.

Table 3 Example of NOCCA results

Occupational category	Denmark		Finland		Iceland		Norway		Sweden		Total	
	Obs	SIR	Obs	SIR	Obs	SIR	Obs	SIR	Obs	SIR	Obs	SIR
Domestic assistants	[0.23]	0.00	[0.88]	0.00	[0.02]	0.00	[1.05]	0.00	11	1.45	11	1.13
Waiters	67	1.54	7	0.63	[0.58]	0.00	84	1.51	62	1.17	220	1.34
Building caretakers	292	0.98	169	1.01	9	1.62	164	1.10	554	1.15	1.188	1.08
Chimney sweeps	20	2.71	15	1.25	-	-	23	1.50	46	1.36	104	1.52
Hairdressers	84	0.98	2	0.60	[0.82]	0.00	39	0.88	149	1.19	274	1.06

Extract from "Observed incidence of colon cancer among men in the Nordic countries and standardised incidence ratios 1961-2005, by country and occupational category".

Obs: observed cases

SIR: standardised incidence ratios

The SIRs of 1.34 for waiters and of 1.52 for chimney sweeps clearly indicate that these workers have a higher colon cancer risk.

In general, a number of expected associations were confirmed, for example mesothelioma among plumbers, seamen and mechanics, i.e. occupations with asbestos exposures; lip cancer among fishermen, gardeners and farmers engaged in outdoor work; nasal cancer among woodworkers (wood dust); and lung cancer among miners exposed to radon and

silica. Some of the interesting new findings of NOCCA that deserve further attention include cases of cancer of the tongue and vagina among women chemical process workers; melanoma and non-melanoma skin cancer, breast cancer (in both men and women) and ovarian cancer among printers; fallopian tube cancer among packers and hairdressers; penis cancer among automobile drivers; and thyroid cancer among female farmers.

Another conclusion drawn by the NOCCA team was that occupation-related social factors seem to be more important determinants of some cancer risks than the actual occupational ones. For example, they mentioned factors, such as life style changes related to longer education and decreasing physical activity, as well as the high risks of alcohol-related cancers among workers having easy access to alcoholic beverages in their work. In general, the team concluded that some 5% of all cancers both in males and in females are directly related to work, while about 35% in males and 16% in females are attributable to socio-economic factors.

The NOCCA study also provides information about the existing socioeconomic divide, meaning that workers in blue-collar, low-skilled occupations are more at risk, and about factors for which the link to occupations is difficult to establish, such as static/sedentary work, a risk factor for intestinal cancer.

The people behind NOCCA

The NOCCA project is carried out by a large group of epidemiologists, complemented by an equally large group of industrial hygienists from all Nordic countries. Some of the main scientists include:

- Eero Pukkala (general coordination of the project), Finnish Cancer Registry
- Jan Ivar Martinsen, Norwegian Cancer Registry
- Elsebeth Lynge, Copenhagen University (Denmark)
- Pär Sparèn, Karolinska Institute (Sweden)
- Laufey Tryggvadottir, Icelandic Cancer Registry
- Elisabete Weiderpass, Karolinska Institute (Sweden)
- Kristina Kjærheim, Norwegian Cancer Registry

2. Strengths and limitations

The pooled database from the Nordic countries presents several features making it a unique resource for research on occupational cancer:

- it covers all working-age people in five countries;
- monitoring after occupational exposures covers several decades;
- data on occupation (basis for exposure estimate) and cancer data are almost complete and of high quality;
- the proportion of working women is high;
- data on potential confounders such as smoking, parity and obesity can be obtained.

The large scale of NOCCA allows associations between a wide range of risk factors/occupations and cancer sites/cell types to be studied, including rare types, taking into account the wide range of exposures gained from different data sources as mentioned above. In this way NOCCA links cancer data with occupational categories and provides the opportunity to simultaneously evaluate cancer patterns by occupation and occupational patterns by cancer, an approach not otherwise possible, according to the NOCCA team coordinator Eero Pukkala.

NOCCA has proved to be useful for comparisons with findings from other areas: Japanese researchers identified a cluster of 11 cases of cholangio-carcinomas (cancer of the gall or bile duct) among 62 male offset colour printing workers at a plant in Osaka. NOCCA was used to clarify the question whether their findings could be generalised to the printing industry at large. The NOCCA analysis supported the view that the cancer risk extended beyond the specific company and beyond Japan. The researchers identified exposure to chlorinated solvents as a direct cause.

NOCCA identifies occupations at risk but does not necessarily pinpoint direct causes of occupational or work-related cancers. This can be overcome by adding occupation-specific exposure estimates of risk factors to the NOCCA-JEMs. However, it has to be noted that the JEM approach relies to a large extent on expert opinion and not on measurements and may therefore carry larger uncertainties. NOCCA studies may therefore need to be complemented by surveys such as Giscop93. Very much needed in this respect are also company exposure records, but this requires government action and strict enforcement.

In its monitoring, NOCCA assumes that a person will stay in the same occupation. However, in view of the effects of globalisation it seems unlikely that this will always correspond to the lifelong occupational history of a person. Yet the NOCCA team is convinced, referring to the results of special occupational cancer studies, that the risk-diluting effect of misclassification will be small.

For the purpose of NOCCA, workers who work part-time (less than 20 hours a week in one job) are excluded from the data. An EU-OSHA study highlighted this as a factor possibly contributing to the underassessment of women's exposures, as in Europe many women work part-time. In addition, more and more workers work in multiple jobs, and although the number of hours worked in each job may be low, their overall cumulative exposure should be assessed. Such contracting patterns are frequent in services jobs such as cleaning, and even increasingly in construction.

The combination of cancer registry and census data has produced a large pool of high-quality data for the Nordics. Combined with the long monitoring period this allows even rare cases of work-related cancers to be studied. However, it should be remembered that NOCCA only identifies occupations at risk, without necessarily detecting direct causes of work-related cancers.

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Chapter 6

Occupational Cancer Monitoring in Italy

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1. The need for active occupational cancer monitoring

The monitoring of occupational cancer is indispensable for preventing cancer and protecting the health of the population as a whole. In fact, many human carcinogens have been first identified in occupational settings (e.g. asbestos, benzene, formaldehyde, etc.), with this information then used to limit (and hopefully avoid) the exposure of the general population.

In Italy, as a result of legislation on monitoring occupational cancers, three systems for monitoring the effects of occupational exposure to carcinogens have been implemented: the Italian national Mesothelioma Register (ReNaM), the Sinonasal Cancer Register (ReNaTuns) and the OCCAM monitoring system.

The registries relate to all incidences of cancer, recording cases of relevant occupational exposure: asbestos for mesothelioma and wood, leather, chromium for sinonasal cancers.

Since mesothelioma and sinonasal cancer are rare and caused by one or just a few substances, and as exposure to them is nearly always related to occupational settings, they are often referred to as “High etiologic fraction occupational neoplasms”. In Italy, research into them is entrusted to Regional Operating Centres (COR) which record all cases and try to interview all patients or their representatives. This information is periodically sent to the Italian Workers’ Compensation Authority (INAIL), where it is aggregated. This system is described elsewhere (Nesti *et al.* 2005).

Other cancers (e.g. lung, bladder, larynx, lympho-hematopoietic malignancies) that can also be attributable to occupational exposure are difficult to identify because:

- they may be attributable to multiple causes other than occupational ones (e.g. smoking, air pollution, etc.);
- they are common in the general population, meaning that interviewing all patients is not feasible.

Since the proportion of these neoplasms attributable to occupational causes is lower than mesothelioma and sinonasal cancer, they are often referred as “low occupational etiologic fraction neoplasms”.

In Italy, the active search for these neoplasms is based on a monitoring system called OCCAM (Occupational Cancer Monitoring).

2. The OCCAM project

OCCAM is an information system used for studying occupational cancer risks and developing effective prevention strategies by studying cancer cases of occupational origin. The system is based on population-based case-control studies in which:

- incident cases (“cases”) are identified by the available sources: cancer registries and/or hospital discharge records;
- control cases (“controls”) are taken from health service population files;
- the economic activity of the workplaces where subjects (both cases and controls) worked is obtained via an automatic link to social security (National Institute for Social Security, INPS) records, and is considered as “exposure”. The complete list of companies where subjects worked and their respective economic activity codes are linked to each case/control. Workers in a specific industrial sector are considered as “exposed” to that sector (e.g. “exposed” to the textile sector). For workers who have worked in several different sectors, the longest activity is considered as “exposure” in the analyses. People having worked only in the service and retail sectors, i.e. “unexposed”, are used as the control (reference) category. The study thus covers individuals with a working career, whereby state records on working careers go back to 1974.

This system was developed at the Environmental Epidemiology and Cancer Registry Unit at the National Cancer Institute by the head of the Unit, Paolo Crosignani MD under an agreement with the National Institute for the Health and Safety (ISPESL) (now incorporated into Italian Workers’ Compensation Authority (INAIL)) and with the collaboration of the Occupational Department of Pavia University (Crosignani *et al.* 2006).

Up to now carried out periodically by the OCCAM team, these studies are due to be performed in the future by the Regional Centres (CORs) under the supervision of INAIL which will be in charge of accessing the social security records.

The sources used to provide cases are cancer registries (CRs) and hospital discharge records (HDRs). CRs provide incident cases for all the cancers considered in the analyses. As for the HDRs, algorithms have been developed to identify incident cases, with only cancers known to be caused by occupational exposure being considered: larynx, lung, bladder, and lympho-hematopoietic neoplasms. As HDRs are used by the national health system in Italy as the basis for paying for care delivered, they are almost complete. Controls are taken randomly from the health service population files; sampling is carried out concurrently with case incidence.

Results, methodology and certain tools used to treat occupational carcinogens are available on the OCCAM website www.occam.it, of which much of the content is available in English.

3. Results

3.1 Cancer mapping by region, gender and type of cancer

Since 2002, more than 100,000 cancer cases have been examined. The main results are reported in the “Risultati” (Results) section of the OCCAM website. All these results have been sent to the regional health authorities to establish priorities in occupational cancer prevention. In some regions, measures targeting specific economic sectors have been carried out (e.g. in the Lombardy region for the metal-plating sector, where an increased risk of lung cancer had been found) (Panizza *et al.* 2012).

3.2 Case finding

A database containing the careers of all cases has been delivered to each Italian region involved in the OCCAM project, allowing local occupational health units (LHUs) to examine each case likely to be of occupational origin (e.g. all lung cancer cases among employees in the steelmaking or foundry sector). Knowing each production site and company, the LHUs are able to examine many cancer clusters that would otherwise have been ignored. Following in-depth investigations, about one-third of cases have now been recognised as caused by occupational exposure and reported for compensation.

3.3 Analytical Studies

The OCCAM data set has also been used to perform analytical studies on occupational cancer risks, providing cases, controls and the setting where to carry out the study.

Increased breast cancer risks have been observed in the textiles, rubber, paper and electrical manufacturing sectors in Lombardy (Italy) (Oddone *et al.* 2013), as well as in the Province of Milan (Italy) (Oddone *et al.* 2014a), giving rise to a growing suspicion of a possible link to a single large electrical manufacturing plant located there. To this aim, all cases of breast cancer registered in 2002 - 2009 in women who had worked at least one year in the factory and resided in Lombardy were selected. Controls were randomly sampled from all women in the same plant and residing in Lombardy on 31 December 2005. The odds ratios (ORs) for breast cancer were significantly higher in women exposed to chlorinated solvents (OR 1.65, 95% confidence interval (CI) 1.04-2.62), with a twofold increase (OR 2.10, 95% CI 1.21-3.66) among women exposed for at least 10 years. No other significantly increased ORs by exposure or job title were observed. All these analyses were carried out – pursuant to the OCCAM methodology – using company records and without interviewing the employees (Oddone *et al.* 2014b), thereby saving time and money.

An increased breast cancer risk has also been observed among women employed in the health sector. Only cases and controls having worked as nurses were considered for being interviewed on their exposure to shift work. Restricting cases and controls to the health sector allowed the OCCAM team to carry out a case-control study on shift work solely among employees working shifts. This study is currently under way. Preliminary analyses show an increased breast cancer risk among nurses exposed to shift work (Massari *et al.* 2015).

Moreover, studies based on the OCCAM methodology observed an increased risk of breast cancer among women steel foundry workers in Umbria (Italy) (Oddone *et al.* 2014), lung cancer in electroplating industry in Lombardy (Italy) (Panizza *et al.* 2012) and bladder cancer in leather and printing industries also in Lombardy (Amendola *et al.* 2007).

3.4 Estimating cancer risks by factory

Where the observation period given by a CR or an HDR is long enough (at least 10 years) and a factory has a sufficient number of employees (100 or more), the workforce cancer risk can be estimated without performing a cohort study. Instead an OCCAM case-control study can be performed, where:

- exposed cases are those (of a particular type of cancer and gender, e.g. male lung cancer cases) who worked in that factory (recall that OCCAM provides a history of companies where the subject has worked);
- exposed controls are healthy subjects from the population sample who also worked in the factory concerned;
- unexposed cases and controls are those who worked in the retail sector, i.e. the reference category used in the OCCAM case-control design.

This case-control design is equivalent to a case-control study embedded in the cohort of those who worked in that company. Even though the cohort is not enumerated, the completeness of the case series and the sampling of the source population make this analysis equivalent to a formal cohort study. In this way we evaluated the lung cancer risk in the rubber sector (Aiani *et al.* 2011). Moreover, the use of other (unexposed) workers as reference mitigates the underestimation of the true risk caused by the “healthy worker effect”.

3.5 Mapping factories at risk

Cancer estimation by factory can also be carried out systematically for all factories in a specific geographical area and present in the OCCAM database. A list of factories with increased cancer risk has been produced for the Greater Milan area using HDRs from 2000 to 2010. An increased male lung cancer risk has been found in a number of factories belonging to the automotive and building sectors. A list of the factories still in operation has been compiled. All this information will be processed by the Local Occupational

Units to check whether carcinogens are still present in the work environment and also as a reference for compensating lung cancer cases with a potential occupational origin.

4. Other support systems

Within the OCCAM context, two tools have been developed to deal with the problem of recognising low-incidence occupational cancer cases: the literature matrix and the general practitioner (GP) system.

The OCCAM Matrix systematically collects all positive results (i.e. a statistically significant increased risk of specific cancers among employees of a specific economic sector) and sorts them in a “Matrix” by type of cancer and economic sector. This matrix is intended as a tool for supporting connections between the type of cancer, gender and area found during cancer mapping.

The Italian GP system (named MMG from the Italian “Medici di Medicina Generale”) is designed to allow GPs to recognise which of their patients suffer from a neoplasm of potential occupational origin. Based on information on the type of cancer and a patient’s occupation, the MMG tool might recommend the GP to refer the patient to the Local Occupational Health Unit for a more in-depth case investigation. This system is table-driven, allowing a regular update taking account of the latest findings in the literature or from international bodies (e.g. the IARC Monograph no 100). It is available for field test at the web address: www.occam.it/mmg

5. Outlook

There can be no doubt that, without a systemic and organized effort, most, if not all, occupational cancer cases will be ignored. In Italy all these activities are supported by the Occupational Safety Act (legislative decree 81/2008, art. 244). Following the retirement of the head of project, Paolo Crosignani, it is to be expected that the Milan National Cancer Institute will discontinue the work, with it being taken over by the Italian Workers’ Compensation Authority (INAIL).

As a research tool, OCCAM provides unique opportunities to perform in-depth studies on occupational cancer risks, providing cases, controls and settings enabling such studies to be performed at very low cost.

This innovative monitoring system can potentially be transferred to all EU countries, thereby strengthening European public health and cancer prevention policies. It is not expensive, as the system relies on information available in electronic archives. However, data handling needs to be in the hands of a stable organization and the organization in charge of the system needs to be authorised to manage and process identifiable health records. It is a good idea to establish a specific data flow to preserve confidentiality by storing all identifiable health information at source (e.g. in the Cancer Registry, at the Health Authority responsible for the management of Hospital Discharge Records).

According to our experience, this system is a very effective way of detecting low-incidence tumours of occupational origin without incurring major costs.

Last but not least, the OCCAM approach can also be used for monitoring diseases other than cancer. Encouraging results were obtained for neurodegenerative diseases, in particular for multiple sclerosis (Oddone *et al.* 2013).

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Part 2

Trade union campaigns and prevention tools

Introduction

In the field of occupational health and safety, prevention dynamics depend heavily on social mobilization. It is not enough simply to know that a risk exists – what is needed is a balance of power facilitating the identification and enforcement of preventive solutions. The trade union movement can play a decisive role in this respect, though significant obstacles need to be overcome, with employers all too often resorting to job blackmail to defuse trade union action on occupational health issues. Employer pressure is all the more potent because it leverages the ideology of productivism (the belief in a mechanical correlation between productivity increases and social progress) pervading our societies, generally in tandem with the illusion that science will provide solutions to problems as and when they appear. The ‘principle of innovation’, a concept developed in recent years with a view to supplanting the precautionary principle, is based on this very illusion. It is therefore vitally important to boost the autonomy of trade unions and ensure that they are capable of developing appropriate strategies. Specific examples of measures supporting a shift in this direction can be gleaned from the wide range of experiences described in Part 2.

Few would dispute the claim that the war on asbestos has been the most successful campaign against a work-related cancer since the start of the Industrial Revolution. An EU-wide ban on asbestos was adopted in 1999 and entered into force on 1 January 2005; indispensable as it was, however, this ban has not entirely eliminated the problem, since many buildings, production facilities and equipment containing asbestos can still be found in the European Union. Millions of workers continue to be exposed, either because they work in buildings or with facilities containing asbestos, or because they are directly involved in refurbishing, converting or demolishing asbestos-ridden buildings. The first of the contributions in Part 2 describes the ongoing fight waged by the European Federation of Building and Woodworkers against asbestos-related risks.

The second contribution discusses the mobilization of workers at Copenhagen Airport to reduce workplace air pollution, prompted by a number of cancer diagnoses among trade union members. Scientific research carried out in response to this trade union campaign has served as a basis for an improved understanding of the hazards associated with exposure, as well as triggering compensation claims.

The third contribution relates to Spanish trade union campaigns aimed at finding substitutes for carcinogenic solvents. These campaigns have overcome one of the largest obstacles standing in the way of substitution efforts – the siloing of prevention

activities within individual companies – and the tools deployed by the trade unions have made it possible to specify problems, definitions and solutions at sectoral level, greatly accelerating the pace of prevention-related action.

The fourth contribution centres on Germany's experiences in the field of exposure minimisation plans. The German regulatory framework for occupational exposure limit values distinguishes between two different risk levels of contracting cancer regardless of the carcinogen in question: the upper one which should never be exceeded and the lower one which provides much greater protection against cancers and which must be worked towards on the basis of mandatory exposure minimisation plans monitored by worker representatives.

The fifth contribution highlights the importance of ergotoxicology. A critical analysis of prevention-related efforts reveals that traditional occupational hygiene methods often pay too little attention to the work that people actually do. Ergonomics thus plays a key role in ascertaining whether the preventive measures implemented – whether collectively or in the form of PPE – are in fact effective. This very practical requirement helps shift the balance of power within a company by placing a high value on the experience of workforces and questioning the standard division of labour between planners and doers.

Although the legislation on occupational cancers puts substitution at the top of the hierarchy of preventive action, in practice such efforts are often neglected on the pretext that they are technically impossible. It is therefore vitally important for legislative requirements to be backed up with practical tools facilitating substitution. The sixth contribution discusses one such tool: the SUBSPORT website set up by trade unions and environmental protection organisations and serving as a source of substitution-related information for businesses. Similar 'eco-unionist' alliances hold a great deal of potential in terms of winning society over to the fight against carcinogens.

The seventh contribution describes the toxic substance reduction scheme implemented by the US State of Massachusetts. The relevant legislation was adopted in 1989 in response to occupational health, public health and environmental concerns, and includes provisions on cost-sharing arrangements: contributions paid by businesses using toxic substances go towards funding the provision of detailed information aimed at reducing their use. Since action taken to prevent one risk sometimes creates or exacerbates another, particular care is taken to avoid simply shifting the problem elsewhere.

Chapter 7

Asbestos: the long reach of the deadly fibre

Rolf Gehring

“We beat these sacks. The dust went everywhere. We were white from head to toe, and we breathed in all that stuff!”

“If the wind blew the wrong way, the dust spread throughout the town.”¹

These two quotes from people affected by asbestos shed light on how asbestos used to be processed, and how asbestos-containing products were used for decades. There are myriad examples of ways in which asbestos was used. We know of thousands of products used in a variety of fields and occupations²: in the textile industry where the predominantly female workforce stood in piles of asbestos, in the construction industry where workers cut through asbestos-containing slabs with angle grinders and came into contact with exposure levels sometimes one hundred times current exposure limits, or in shipbuilding where tonnes and tonnes of asbestos were used as insulating material, installed by hand. Though those affected by asbestos worked primarily in the construction industry, asbestos also claimed victims among workers in many other sectors of the economy, including shipbuilding, automotive, textiles, or in the manufacturing and handling of asbestos cement.

Workers who worked directly with asbestos were often not informed of the health hazards posed by this substance and there were usually no protective measures at all, especially for those working in close vicinity. Nearby residents or an asbestos worker's family also went without protection. Emissions from processing plants in the ambient air contaminated whole swathes of land and it was normal at the time to take work clothes covered in asbestos home to be washed. The handling of asbestos in ports also meant that the fibres were spread over large distances when the wind blew in a certain direction. In the North Italian town of Monfalcone, home to one of the country's largest shipyards, people are still dying from asbestos-related diseases at a rate significantly higher than the national average, despite the fact that many of them never worked at the shipyard.

Awareness of this problem dates back to the late 19th century when first hints arose that asbestos could pose a hazard to health. By the 1920s, research conducted in a number of countries had proven that asbestos could lead to the scarring of lung tissue (asbestosis). The risk of lung cancer caused by asbestos was confirmed in the late 1930s, followed

1. Taken from Schön A. and Weitowitz H.J. (2014).

2. In Germany there are believed to be around 5,000 different products on the market.

by proof (in the 1960s) that exposure to asbestos triggers pleural and peritoneal mesothelioma. It took years, if not decades, for many countries to even acknowledge these terrible diseases. In the meantime, science also discovered a link between exposure to asbestos and ovarian cancer. Finland now offers compensation for this.

The harmful impact of asbestos on health is predominantly due to the geometry of the fibres (i.e. the ratio of length to diameter). Once inhaled, the needle-like respirable fibres can become lodged in the lung tissue, as the lungs have no defence mechanisms and are unable to shift the fibres. Mesothelioma reduces a person's lung capacity, ultimately leading to an incredibly painful and gruesome death.

1. Suffering and awareness - the fight and slow success

Despite its health hazards, for decades asbestos was considered the 'mineral of a thousand uses', an ideal material. Heat- and acid-proof, it can be used in many areas such as insulation, heat and fire protection, brake pads, etc. These properties, its ready availability and relatively low cost of use mean that in many areas of the world asbestos is still a popular material and a profitable asset. However, major economic interests were and still are the main reason why the epidemiologically and scientifically proven devastating effects of asbestos dust have been concealed, brushed aside and denied. From the very outset, victims have had to fight against this denial, against scientific studies commissioned by those with a vested interest in the continued use of asbestos, and partly even against resistance from trade unions fearing job losses. The number of publications and books documenting these conflicts could now fill whole bookshelves.³ The lengthy latency period before an asbestos-related disease's symptoms and devastating impact become apparent is a further reason for the slow progress in fighting asbestos.

Asbestos-related diseases are insidious in that they often break out 30, 40 years after exposure, if not later. As a result, experts also estimate that the diseases will only peak in some European countries between 2017 and 2025, depending on when asbestos was banned. This means that, despite the Europe-wide ban in force since 2003, the problem of asbestos remains relevant.⁴ According to Belgium's Occupational Diseases Fund, for instance, the number of cases of lung cancers caused by asbestos and the average number of mesothelioma cases have increased further in recent years, now averaging 180 per year. In 2013, 202 people died from asbestos-related lung cancer, well over the average of 112 in previous years. Nevertheless, it is difficult for the Fund's representatives to determine whether the diseases have already reached their peak.

An asbestos-related disease means never-ending suffering for the victims and their families in two respects. The worst part is that there is no cure for asbestos-related

3. Cremers and Gehring (2013) provides an excellent overview and outlines viewpoints from various perspectives. See also the bibliography at the end of this article.

4. The Europe-wide ban is based on an EU directive adopted in 1999, the implementation of which, however, saw Member States being given a certain period of time to transpose it into their respective national law.

diseases; they are usually fatal. This diagnosis completely changes the lives of the victims and their families. Next comes the unthinkable: in most cases their disease is not recognised as an occupational disease and compensation is even rarer.⁵ The fight for recognition often becomes a second source of suffering alongside the actual disease. It is an uphill battle, fought between those with power and those without, and the victims are rarely given confirmation that their work was the cause of their disease – especially not when many years have passed between the victim working with asbestos and the onset of the disease. Workers do not normally have company documents at hand stating which materials they worked with and for how long. They are often completely unaware of the hazards and dust they were exposed to; there are usually no documents about this at all. Either the data was not even collected or documented, or has since been destroyed⁶, meaning that workers have no structural access to this evidence.

Ultimately, however, the constant struggle of victims and their families, as well as of scientists, trade unions and politicians, increased awareness. Since the 1970s, various European countries limited, and eventually completely banned, the use of asbestos and asbestos-containing products. Scandinavian countries took the lead here, as they became aware of the problem early on. Public institutes worked with social partners to address the problem and the use of asbestos was gradually prohibited. Initially, only certain types of asbestos or uses (spraying) were banned; this ban was then further extended to cover all types of asbestos, products and processing. An EU-wide ban on asbestos came into force in 1999, with all Member States having until 2005 to implement it.⁷

2. So asbestos was banned - and then what?

Nevertheless, the ban in Europe has not solved the problem, either globally or within Europe itself. According to the WHO estimates in 2010, some 125 million people around the world are still exposed to asbestos while at work.⁸ The WHO also puts the number of people dying from asbestos-related diseases every year at around 107,000, not including the number of cases that go unreported. At global level, one in three fatal occupational cancers are caused by asbestos. However, global use of asbestos, which at its peak some two decades ago was being used at a rate of approximately five million tonnes per year, has fallen to around two million tonnes, although this figure has been stable for a number of years and is still incredibly high. As a result, asbestos continues to pose one of the biggest occupational and health issues at international level.

5. The main asbestos-related diseases are recognised as occupational diseases or asbestos-related diseases in EU Member States. The issue of individual recognition is, however, a completely different story. In practice, procedures, recognition, compensation and medical care vary wildly between individual Member States. The following two publications provide a sound overview of the current situation: Eurogip (2006) and Kooperationsstelle Hamburg (2013).
6. The asbestos issue is ideally suited to proving that the documentation obligation under European Framework Directive 89/391 was a milestone in occupational health and safety and is crucial to demonstrating causal links and getting justice for victims. Asbestos' long latency period is a major argument in favour of the documentation obligation's minimum period of 40 years.
7. However, this Directive also incorporates exceptions for specific products that have not yet expired.
8. www.who.int/mediacentre/factsheets/fs343/en/

Looking just at Europe, the problem is by no means solved. Although the mining and processing of asbestos and the use of asbestos-containing products have been banned:

- over the next few decades people will continue to fall ill as a result of earlier exposure;
- various asbestos-containing products manufactured outside Europe are still arriving illegally and undetected on the European market;
- the strong, global asbestos lobby and asbestos industry are still “alive and kicking”.

Above all though, we Europeans remain surrounded by asbestos. Housing blocks, public buildings, schools, sports halls, trains and ships are still contaminated. Workers, residents and users are potentially exposed to and affected by asbestos. The hazardous material remains a ticking timebomb hidden in buildings and construction material. Asbestos is becoming a growing problem in the recycling sector (circular economy = recycling of construction materials) and many fields of work lack sufficient checks or fail to implement basic occupational health and safety regulations to protect workers from asbestos.

Asbestos-related diseases and deaths have by no means peaked in Europe, highlighting the important aspect of dealing with victims. The ban on asbestos does not cover the recognition of occupational and other asbestos-related diseases, the right to regular checks for those exposed to asbestos, national recognition practices, help for those affected, or victim compensation. All of these issues remain unresolved.

All too often, victims remain anonymous, with their cases receiving zero publicity or recognition, though rare eye-catching cases do exist where workers receive compensation. For example, in May 2011 a Dutch worker received €50,000 in compensation after it was proven that he was suffering from asbestosis caused by exposure to asbestos. However, how many thousands of people are dying across Europe without any connection to earlier exposure to asbestos ever being made?

Nonetheless, over the past few years support and aid mechanisms for asbestos victims have been established in a number of European countries. In Belgium, for example, a fund for asbestos victims was set up in 2007; the brochure published on its fifth anniversary provided exact statistics on the number of reported and recognised cases.⁹ The organisation is open to anyone needing information or support.

3. The EFBWW campaign for an asbestos-free Europe

In light of the situation detailed above, the European Federation of Building and Woodworkers (EFBWW) started discussing the need for a Europe-wide asbestos campaign in 2007. On 3 March 2011, it launched its Europe-wide campaign, ‘Europe

9. www.afa.fgov.be – Available in Dutch and French.

2023 - Asbestos Free', in the European Parliament.¹⁰ The campaign's goals and basic concept are clear: to influence legislation at European level and help initiate tangible measures to eliminate the remaining asbestos within Member States. First and foremost, however, the campaign is intended to draw the attention of stakeholders and politicians to the topic of asbestos.

Following the European ban, the topic disappeared from public view, with knowledge about the dangers of the substance generally dwindling. This is a further reason why the current campaign is so important. The following five topics have been identified as priorities:

- necessary improvements to working conditions;
- improved registration of existing sources of asbestos, particularly in private and public buildings and infrastructures;
- training/informing the workforce, especially those whose jobs/work bring them into contact with asbestos unintentionally;
- enhanced recognition of asbestos-related diseases;
- compensation and compensation procedures regarding these diseases.

Since the campaign's launch it has become clear that the topic is widely recognised as being relevant if its significance is properly explained and the various remaining areas of concern outlined.

4. In the meantime - prospects

During a joint seminar on asbestos held by the S&D Group (Socialists and Democrats) and the EFBWW in the European Parliament (EP) in June 2011, the proposal was made to submit an EP own-initiative report on asbestos. The proposal was accepted and Stephen Hughes, the *rapporteur*, sought cooperation with unions and victims' associations, ultimately submitting a draft comprising 36 specific points. Following debates within the EMPL committee, a total of 62 points were adopted.¹¹ The points have now been broken down into the following thematic areas:

- screening and registration of asbestos;
- providing training;
- development of removal programmes;
- recognition of asbestos-related diseases;
- support for asbestos victims' groups;
- strategies for a global ban of asbestos.

10. The campaign's action plan is available at www.efbww.org/default.asp?Issue=Asbestos Documents and Posters&Language=EN

11. Visit the Parliament's website to view the report in all EU languages: www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2013-0093+0+DOC+XML+Vo//EN

The individual demands are mainly addressed to the Commission and the Council, with the former in particular called on to take various tangible initiatives. The report also partly addresses Member States.

The fundamental aim of eradicating asbestos from Europe (from all public institutions and buildings by 2028) is a complex matter and can only be achieved through national asbestos removal plans. Poland has taken the lead in this regard by launching a national asbestos removal programme striving to safely remove all asbestos from all of the country's buildings by 2032. However, there are also discussions in this direction taking place in other countries as well as at EU level.

Various joint activities launched by the European social partners in the construction industry are also encouraging. In a project between the EFBWW and FIEC (the European Construction Industry Federation, an employers' association), information material has been compiled for all groups of construction workers who do not intentionally work with asbestos but may still come into contact with it. These groups include electricians, roofers, heating engineers, energy efficiency technicians, demolition workers, and so on. The material is available in 15 languages.¹²

The European Economic and Social Committee (EESC) has also held intense discussions on the asbestos issue, with the result that an own-initiative opinion is now being prepared, covering asbestos removal, the registration of existing sources of asbestos in buildings, and support for asbestos victims. The EESC intends to publish the report at a joint event with the European Parliament and the Committee of the Regions.

By focusing on improved support for victims and better recognition of and compensation for asbestos-related diseases, the EESC is addressing a very important point. A report compiled jointly by the EFBWW, the ETUC and the victims' association International Ban Asbestos Secretariat (IBAS) provides an overview of the recognition of and compensation for asbestos-related diseases in 15 Central and Eastern European countries, as well as comparing recognition practices and medical procedures for monitoring asbestos workers and victims. A similar report covering 13 Western European countries was produced (for both reports see footnote 5). Although most cases are now officially recognised in almost all countries, compensation practices vary wildly. For example, while France has a high level of recognition of asbestos-related lung tumours, in Germany the rate is very low. There is usually no support or places where victims can find information about the various aspects of the disease, recognition thereof, medical support, compensation claims, and so on. One positive development is in Austria where a programme to help asbestos victims has been launched, including the setting-up of a 'one-stop-shop' where victims can find information about all aspects of the problem.

12. The material is available in 15 languages: www.efbww.org/default.asp?Issue=Asbestos&Language=EN

Yet recognition procedures still require victims to prove the causal link between the disease and exposure to asbestos. The European Parliament has made proposals in this regard that have now to be taken up at national level – exactly what the German Cancer Society did in 2014. Together with victims' associations and several trade unions, it called on legislators to reverse or alleviate the burden of proof in procedures for recognising asbestos-related occupational diseases.

Despite these encouraging developments and clear proposals made by the European Parliament, the European Commission *inter alia* has unfortunately failed to include any tangible action plans regarding asbestos in its Occupational Safety and Health (OSH) Strategic Framework 2014-2020. Constant pressure needs to continue to be exerted on European legislators in this regard. There is still a long way to go at all policymaking levels and in practical implementation, as well as with regard to enhanced victim support, before we move on from a European asbestos ban to a genuine solution to the problem.

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Chapter 8

Prevention of pollution-related cancers at Copenhagen Airport

Lars Brogaard and Janne Hansen

Unions at Copenhagen Airport have been campaigning for nearly ten years to get the pollution caused by aircraft and apron vehicles reduced. The air is cleaner as a result, but not yet clean enough. There is a good ongoing social dialogue between the management and the trade unions who share the view that healthy air is vital to protecting the health and safety of the workforce. However, there was not always such consensus. The issue of ensuring a clean working environment had been neglected for many years. The ubiquitous bad smell on the apron was simply considered an inconvenience – something to put up with.

The airport workers' trade union, 3F-Kastrup, has 2,500 to 3,000 members working on the aprons and exposed to air pollution. Mechanics, guards and other security personnel not belonging to 3F also figure among apron staff.

1. Nervousness among staff

For several years, the trade union took due note of the grievances of workers who were concerned about air pollution and those who, suffering from cancer, wanted to know whether the disease was caused by such pollution. We contacted researchers, but the matter had not been sufficiently investigated yet to consider an in-depth analysis of the area concerned. At that time, there was no indication that it was possible to get cancer through working at an airport.

It was frustrating for our trade union not to be able to help the workers or to initiate a procedure to determine whether the air at the airport was dangerous. The situation changed completely, however, when one of our members was diagnosed with early-stage bladder cancer and his condition was recognised as an occupational disease.

Compensation paid in the event of a work-related accident or occupational disease is fixed by law in Denmark. The legal framework of provisions relating to worker compensation insurance can be applied to determine which accidents and which pathologies can be recognised, and how much compensation is to be paid. Occupational diseases are recognised in two ways:

1. Via an official list of effects and symptoms used to qualify a disorder as an occupational disease;
2. An occupational disease commission adopts opinions on a case-by-case basis.

Particulates in the air at the airport come from aircraft and other vehicles. We know that the particulates emitted by diesel engines can cause lung and bladder cancer. These diseases are therefore recognised in Denmark, being on the list of occupational diseases. The substances and materials that the International Agency for Research on Cancer (IARC) lists under Group 2A (probably carcinogenic to humans) are automatically included in the Danish list. It is necessary to prove that the patient was exposed to carcinogens in each case. This evaluation is carried out by occupational physicians working for occupational medicine clinics.

By 2015, five people had had their bladder cancer recognised as being linked to air pollution at the airport, as had another person suffering from chronic obstructive pulmonary disease (COPD) (see Table 1).

Table 1 **Recognised occupational diseases among Copenhagen Airport staff**

Year	Recognised bladder cancer – non-smoker	Recognised bladder cancer – smoker/former smoker	Recognised COPD – non-smoker	Recognised COPD – smoker/former smoker
2008	1			
2011	1	1		1
2014	1	1		

As shown in the table, the disease is recognised even if the patient is or was formerly a smoker. In fact, the law on worker compensation insurance states that what needs to be worked out first is whether patient exposure was sufficient to cause the disease; only then are any other aggravating factors taken into account. The National Board of Occupational Accidents and Diseases (NBOAD) takes these factors into consideration when determining the amount of compensation, which means in practice that if an airport worker is or used to be a smoker, a lower level of compensation will be due.

The decision of the NBOAD is based on the medical expertise of cancerologists and physicians specialising in occupational medicine. The employer and its insurance company may oppose this decision and lodge a complaint against the NBOAD. However, such a case has not yet arisen.

A listing as an occupational disease is fundamental for prevention. Thanks to the mobilisation of the unions and the airport authorities, society as a whole now realises that airport employees can become ill because of their work. From a trade union perspective, this means the following:

- the workers see that their concerns are taken seriously, and it is becoming clear once and for all that something has to be done about pollution;
- the employers can no longer regard particulate matter pollution as negligible or claim that diseases can be put down to lifestyle alone;
- the press has improved access to evidence showing that people can fall seriously ill simply by doing their work.

The interest shown by the press has contributed to keeping the trade union spotlight on this working environment issue, a top priority for them. All this has been made possible by the workers concerned, who have come out of the shadows, and in doing so have made it possible to exert pressure on the airport's management.

2. The information and training of union representatives

The first recognition of a cancer as an occupational disease coincided with the publication of an Italian study on airport personnel which had a major impact in Denmark. That study showed that the DNA of some of the apron staff in Italian airports had been affected, with them developing cancer or reproductive disorders. Other documents also showed that airports could be hazardous workplaces. It was therefore important to provide correct information to our trade union representatives and occupational safety and health (OSH) officers.

We called on the services of an occupational medicine clinic. In cooperation with other researchers, it drew up a descriptive report on the situation. Using this as a basis, we organised a meeting with our members and other groups at the airport also exposed to harmful particulates. We also created an information website which is constantly updated. Being better informed, employee representatives can put the subject on the agenda of health and safety committees and works councils.

3. First measurements

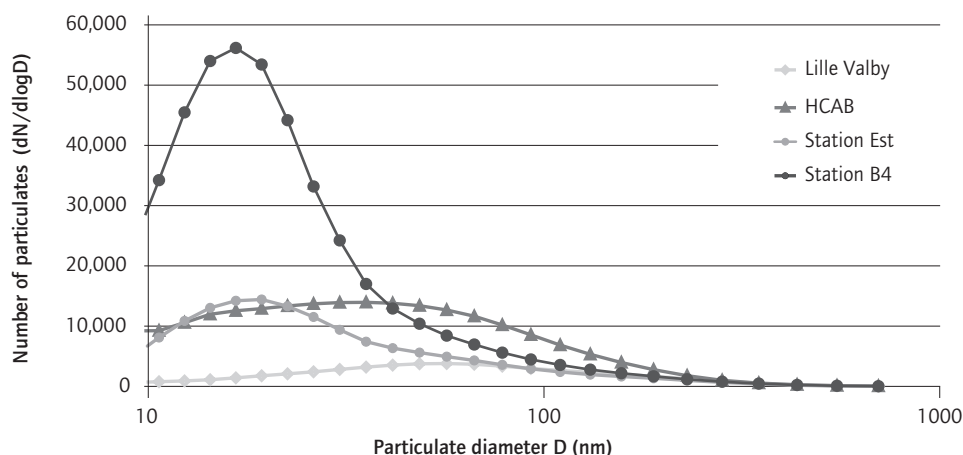
Although the cause-and-effect relationship between bladder cancer and working at the airport was duly recognised in 2008, two unknowns remained: the quantity of particulates workers had been exposed to and the contents thereof. Knowing that this was a complex technical question, we contacted an air pollution expert.

After a long discussion with the employers, we embarked on a measurement campaign. Independent experts were hired to make sure that these measurements were reliable, and a series of measuring stations was set up throughout the airport.

Figure 1 (p. 86) shows the average distribution according to the size of the particulates, checked at the B4 station, the East station, the HCAB station and the regional station of Lille Valby, in Roskilde. The measurements were carried out between 28 July and 30 September 2010.

The results show that ultra-fine particulates (UFPs or nanoparticles) pose a serious problem. UFPs are said to cause cardiovascular disorders, cancer and respiratory and other pathologies. We should point out that measurements were carried out round the clock, so they represent an average. The quantity of particulates was smaller at night, meaning that the daytime exposure of workers is far higher than that shown in this diagram.

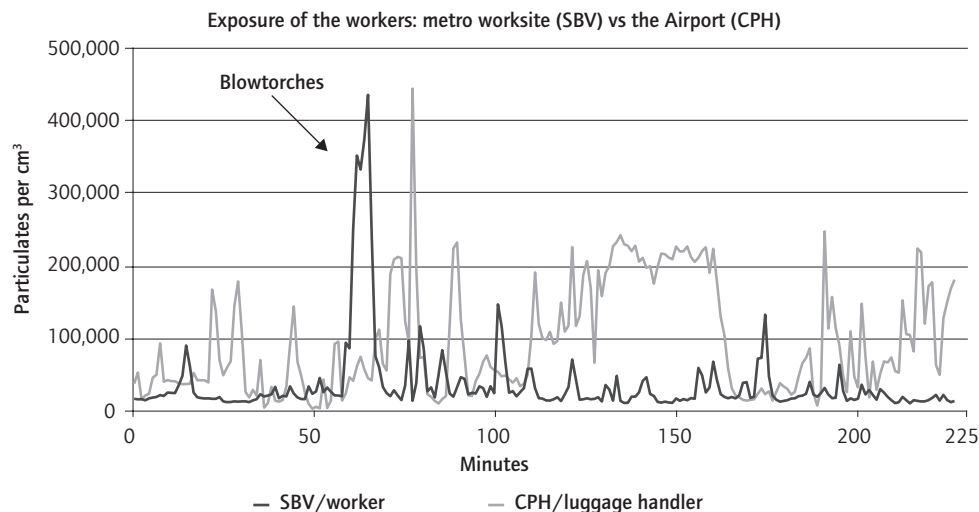
Figure 1 Particulates measured in the airport, in city centre and country side of Copenhagen



Source: Danish Ecocouncil (2012)

The Figure 2 shows that particulate matter pollution at the airport has peaks, and that these peaks correspond to peaks of activity on the aprons. Comparing this data with that from other sectors known for exposure to dust and particulates, we clearly saw that employees at Copenhagen airport were seriously affected.

Figure 2 Comparison between a construction site and the apron area at Copenhagen airport



Source : Press-Kristensen K. (ed.) (2012)

The main problem at Copenhagen Airport is the massive concentration of nanoparticles. This is a complex problem because there are no limit values either at national or EU level. This means that, as a trade union, we do not have a precise quantified objective to demand from the employers. It also means that it is difficult for the Labour

Inspectorate to issue an injunction against the airport authority with precise limit values to be complied with. Instead, it has to make do with keeping a close watch on the airport authority's action plans.

At present, UFP measurements at Copenhagen Airport are carried out by means of fixed measuring stations and individual meters, used to identify areas particularly at risk.

4. International attention

The high level of air pollution and the recognised cases of bladder cancer have attracted international attention. 3F-Kastrup has raised the issue with the EU and with the European Trade Union Confederation (ETUC), in particular by organising a conference at the European Parliament in 2013. A project was devised to raise awareness to the problem in other Member States as well. A document was prepared in four languages, describing the problem in the minutest detail, and we managed to create conditions conducive to local initiatives at East Midlands and Gatwick airports in the UK, where the trade unions are working on the same issue. Copenhagen Airport has every interest in seeing other airports delve into this matter, if only for competition reasons.

It is important that prevention be extended to all airports, starting in Europe where tens of thousands of people work in a polluted environment. Prevention potential is thus enormous.

As a trade union, we have insisted on the importance of prevention, even though precise limits have not been fixed yet. Fewer particulates would mean a healthier work environment and a reduced risk of developing a whole series of diseases. The level of particulates is so high that every initiative that reduces it represents an improvement.

Several workgroups have been set up for prevention purposes, mainly made up of health and safety officers, trade unionists and management representatives.

These groups focus especially on behaviour, technical solutions and changes in work organisation.

The efforts have already produced results in several areas:

- vehicle engines and auxiliary aircraft engines must be switched off, and vehicles must no longer drive empty;
- airport operators (including newcomers) must use environmentally-friendly equipment – and indeed we have been seeing ‘greener’ equipment appear, such as e-vehicles;
- more aeroplanes are now towed to the runways, reducing detours;
- three companies provide masks for their employees. They can wear them in those situations where they are most exposed, for example during take-off and peak activity periods, when many planes take off and land in a short space of time.

That prevention works is demonstrated by the fact that the measurements show that the level of particulates has been reduced by nearly half. It is still very high, and there is still room for improvement. We must not let down our guard but must remain focused on the risks related to working at the airport.

We firmly believe that this type of work can cause diseases other than cancer and COPD. We have therefore decided to take part in a new, large-scale study on other pathologies affecting apron personnel at airports, in particular cardiovascular diseases. One unknown factor remains though: the exact composition of the constituents of aircraft exhaust emissions. This is a subject we would like to study as well.

5. Conclusion

Nobody should become ill because of their work. The trade union must set a clear objective of helping prevent people falling sick because of their work. In addition to the fact that a healthy and fulfilling work environment is a legitimate right, studies have shown that investments in health and safety can pay off. When the workplace is not good, the cost of absences due to illness, treatment and declining productivity goes up. Investments in reducing particulate matter pollution are investments in life and health. They are also financially sound.

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Chapter 9

Trade union initiatives to replace carcinogenic solvents

María José López-Jacob, Cristina Núñez Morán, Miguel Angel Biel-Biel

1. Introduction

The Union Institute of Work, Environment and Health (Instituto Sindical de Trabajo, Ambiente y Salud – ISTAS) is a non-profit foundation run by the Spanish Trade Union Confederation (Comisiones Obreras – CCOO). Among its many tasks, ISTAS is responsible for coordinating a network of trade union technical offices which provide advice on the prevention of occupational risks to the territorial and federal members of the CCOO. 100-plus advisers belong to the network, providing direct support to trade union representatives in occupational health matters (around 190.000 in Spain in 2011, some 80% of whom belong to the two major trade union confederations). ISTAS provides these advisers with training on technical and trade union matters, activity protocols, information, technical backing and tools to improve the quality and consistency of the advice given. By analysing the activity of these advisers, the organisation as a whole is able to obtain information about risk prevention and make detailed studies of risk prevention in Spanish workplaces, exchange experience and work out common intervention criteria with a view to improving working conditions.

The emphasis, in terms of the demands of union representatives and action on the part of advisers, has shifted noticeably in recent years, from being for the most part determined by doubts about representation rights and damages (basically injuries resulting from work-related accidents) towards demands relating to exposure. This shift reflects the priority given to collective risk prevention in union occupational health strategy.

In the case of occupational cancer, this network has focused its activities on identifying the risks and helping to eliminate them. In some cases, elimination is simple: once a readily substitutable carcinogen has been identified, the risk can swiftly be removed, after the trade union has communicated the problem and its proposed solution. In other instances, the process is more drawn out, and a great deal of workplace investigation and awareness-raising are necessary, in addition to negotiations with the labour inspectorate or competent institutions, providing them with information and gaining their support.

Considerable effort goes into managing recognition of the occupational origin of cancer cases, the vast majority of which result from exposure to asbestos.

ISTAS has been working consistently in the field of chemical hazards, encouraging the elimination, substitution and control of dangerous substances and concentrating its efforts essentially on those substances on our 'blacklist'¹ of which the most important are carcinogens. The guides and information material that we have available are geared towards promoting trade union action, by encouraging the intervention of union representatives on the basis of a model which incorporates union mechanisms for actively seeking information, gaining the support of workers, activating trade union resources, and demanding protection rights.

CCOO has spearheaded various trade union campaigns to replace solvents and carcinogens. More specifically, during the 'Cancer o' campaign which we rolled out in 2011 at national trade union level, we produced guides, leaflets and other support materials for all sectors and held numerous meetings and press conferences in addition to various training sessions for advisers². These activities, which are detailed on the website www.cancerceroeneltrabajo.ccoo.es, have definitely helped to increase the knowledge of our delegates and to generate within the organisation the awareness and skills needed to support them.

The case studies described below contain various elements which are commonly encountered in connection with trade union action on exposure to chemical carcinogens.

2. Trichloroethylene. Elimination case study

The public works quality control laboratories in the Community of Castile and León carry out various analyses and tests. One frequent activity is to assess asphalt quality. This is done by using trichloroethylene (a substance classified as H350 – may cause cancer – in European legislation) to dissolve the sample (which is also heated and centrifuged), after which it is weighed and compared with its initial weight, thereby providing the necessary quality indicator. Trichloroethylene was also being used to clean the various containers and sieves employed in the process.

In one of the laboratories, in Burgos, workers found that levels of exposure to the substance exceeded permitted environmental levels, and blood tests also provided indications of high exposure.

The risk prevention representatives at the site collected this information and approached the union for assessment; once the risks were known and the right to demand preventive measures had been established, they drew up an action plan whose first step was to inform workers about the problem and demand that the enterprise tackle the cause. The risk prevention representatives forced through the creation of a Health and Safety Committee (CSS) at the site and also presented it to the inter-enterprise CSS.

1. Blacklist of chemical substances. ISTAS. <http://www.istas.net/web/index.asp?idpagina=3447>

2. These union officials are trained in occupational health and safety. They bring their expertise to the elected representatives of the committees for health and safety in businesses.

The target of the prevention representatives' action plan was to eliminate the carcinogen from workplaces and, meanwhile, to negotiate adequate collective and individual protective measures. While the changes were being discussed and negotiated, the site introduced other measures aimed at providing a better ventilation system and offering more effective and thorough individual protection than that previously provided. However, environmental inspections showed that exposure to the substance had not been eliminated, and workers complained of the cumbersome nature of equipment and the lack of training received.

Management was initially very resistant to change, pointing to the 'inflexibility' of the control standard which prevented the test being carried out in any other way.

Meanwhile, the union advisers sought the backing of ISTAS with a view to finding an alternative to this process. The investigation work threw up the possibility of using an incinerator, which would entirely eliminate the need to use solvents and was also a method already used by the Ministry of Public Works for similar purposes.

Finally, following trials, an incinerator was found to suit the needs of the laboratory and to comply with testing requirements, thus leading to a compromise replacing the former process; later, incinerators were installed in nine provinces in Castile and León, thereby eliminating this risk.

To conclude, a carcinogen which had not raised the concerns of the enterprise or the risk prevention service was eliminated on the initiative of the workers, participation mechanisms were brought into play and the presence and image of the union and its representatives within the enterprise became firmly associated with a proactive stance on health matters, a fact which not only generated the necessary support on the part of the workers, who are now more attuned to occupational health matters, but also led to greater empowerment of union representatives in terms of pursuing other risk prevention initiatives.

3. Printing inks. Elimination case study

The firm, which has 125 employees, manufactures plastic bags for large supermarkets. The process involves printing with organic inks.

After investigating a fatal accident in the firm, with the support of a union adviser, and putting forward plans for improved safety, representatives decided to tackle other aspects of working conditions there. The adviser, who at the time was involved in a trade union campaign to eliminate solvents, began visiting the firm. On his first visit, he noticed the strong smell of solvents which permeated all parts of the site. The workers told him that they had got used to it; however, he was able to get the union representatives to conduct an investigation into the matter.

It turned out that the inks used in the printing process contained toluene and butanol. Although neither substance was regarded as carcinogenic, either under the IARC

classification (group 3) or under Spanish law, the adviser's research (ZDHC; IPCS 1985) produced a finding that several entities regarded toluene, in high concentrations, as being carcinogenic for exposed workers and that other studies recommended taking into account the possible presence of benzene (IARC Group 1a carcinogen) as an impurity in industrial toluene; thus, the assessment of the working environment needed to take that finding into account. The representatives therefore planned to take action on the basis of the possible carcinogenic effect of the substances used, whilst also considering other harmful effects of those substances such as neurological or reproductive toxicity, etc.

They found that the plant consumed enormous quantities of solvents, up to 1 200 litres per day, and that the presence of those substances in the environment resulted to a large extent from the manual process of refilling the inkjet tanks (which were leaky themselves).

A review of existing risk assessment documentation showed that the solvents and their risks had been identified, but that no proposals for preventive measures had been adopted. With the support of the adviser, the representatives began to study the various hygiene reports drawn up by the prevention department and demanded a new study. This came to the conclusion that the prevention department's report (which defined the situation as risk-free) did not correctly reflect the laboratory findings, which indicated that exposure was three times the occupational exposure limit permitted in Spain. The workers' suspicions regarding the prevention department were justified, and even increased when the proposal for alternatives eliminating the risk was rejected.

The adviser found that there were safe alternatives to the printing process and that the union had successful experience with replacing inks containing organic solvents with water-based inks which, instead of containing the organic solvents previously mentioned, included ethyl alcohol and 1-methoxy-2-propanol (CAS Nos 6417-5 and 107-98-2 respectively), which are less harmful to health.

A phone call to the ink supplier confirmed that he could also supply that safe option. Armed with this information, the representatives met with management to set out their proposal for a change in the process, following which initial trials took place.

In parallel with this action, the representatives pursued a policy of communicating with their colleagues in order to inform them of the risks and of the need to change the process; with this in mind, they produced awareness-raising material, used the firm's internal bulletins and organised awareness meetings.

The initial trials did not please customers; there were problems with colour quality, and further trials had to be carried out, compounding the firm's resistance to the change. Following a fire near to the ink storage depot, outside the factory, the representatives urgently demanded an external emergency plan and talked with local neighbours to get them to demand an official risk statement and an environmental assessment. The results of the latter, added to the concerns of the firm's foreign partners, were ultimately decisive in getting the organic inks replaced by water-based inks. Nevertheless, meetings with the workers were also needed to make the change acceptable to everyone, as the

work of cleaning the printing machinery is now more burdensome. But everyone is now happy with the change and unreservedly supports the CCOO representatives in trade union elections.

4. Conclusions

From our experience, one of the greatest obstacles to preventing the risks deriving from the presence of carcinogens (apart from job insecurity, which obviously has a major impact on the ability of workers and their representatives to exert influence) is the failure to identify carcinogens in the occupational environment. A study carried out by CCOO in Madrid (Mancheño Potenciano *et al.* 2003) in 222 enterprises selected at random from all sectors, found at least one carcinogen in 124 of them. In only 22.6% of cases had these substances been identified by the prevention department (despite which, in the majority of those firms, no preventive measures had been taken). In the remainder of the enterprises, the study provided the first indications of such risks. Since then (2003), very little has changed. Information on carcinogens available to workers, their representatives and even company owners remains lacking, limiting the possibility of exercising protection rights in the presence of a risk. The state survey of working conditions (INSHT 2011) shows that there is a lack of information about chemical substances, particularly among non-Spanish nationals (20.7%), women (19.4%) and workers in small enterprises (14.9% in firms employing between 1 and 10 workers).

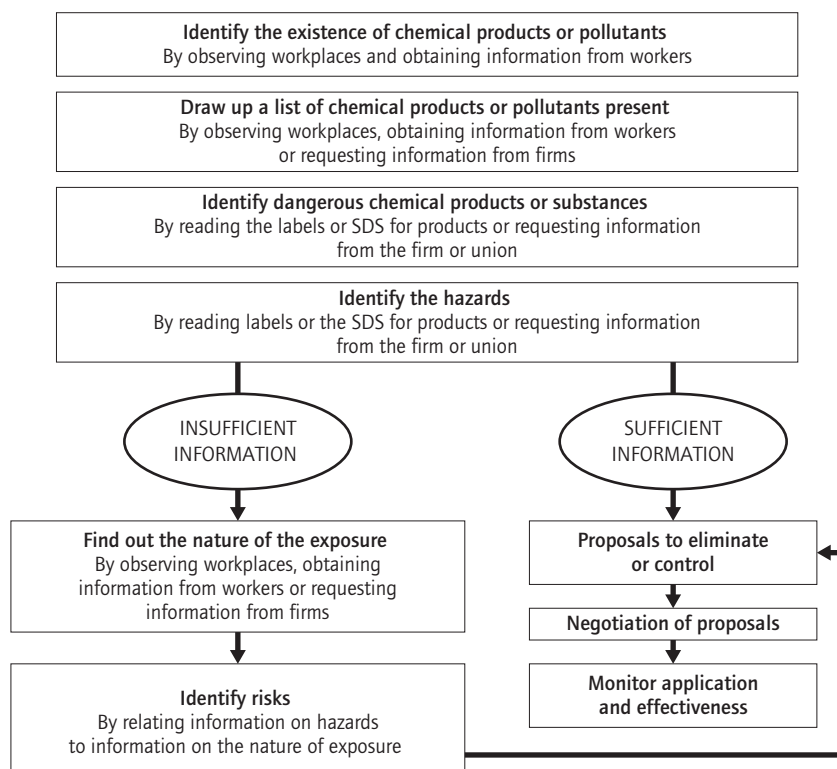
The poor quality of risk prevention work in many prevention departments is another reason. Risk assessments are alarmingly vague about the specific risks associated with exposure to harmful substances, and, apart from training, information and personal protective clothing, there are few proposals to eliminate or control these substances, a matter which is particularly serious in the case of carcinogens. Furthermore, we frequently find that we have to query health and safety reports, which are often incorrect, as well as traditional information sources.

Too often the attitude is one of 'denial' or underestimation of the risk, and this encourages employers to resist change and to levy accusations of trying to alarm the workers and harm the interests of the enterprise and its employees. There is clearly scope for improving the attitude of prevention department officials when negotiating these issues.

We can also draw some positives from our experience in investigating these matters. On the one hand, there is no doubt that, when action achieves the goals set by the parties, the image of representatives among workers and the bodies to which they belong (including public specialist institutions) is visibly enhanced. Issues relating to cancer risks involve an extensive network, which is regarded, in the 'little world' of risk prevention professionals, as involving too many technicalities and complexities. When practical proposals are able to be made, this generates greater confidence to tackle other supposedly problematic issues. Even if not all objectives are achieved, the intervention process has positive effects on relations between representatives and workers and on the dynamics of the bodies to which they belong. The final factor to which we would like

to draw attention is the positive effect of substitution initiatives outside the workplace in terms of reducing environmental hazards and improving the health of local people, and also the potential for establishing links between the trade union and its representatives and the population affected, a strategy which we need to encourage more often in our work.

Figure 1 Trade union intervention against chemical risk at work



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Chapter 10

Reducing carcinogens in the workplace: lessons from Germany on how to complement substitution

Henning Wriedt

1. Introduction

The best way to protect workers from occupational cancer is by substituting carcinogens. This approach is prioritised in the EU Carcinogens and Mutagens Directive (CMD, Dir. 2004/37/EC) ahead of other measures like their use in a closed system and exposure reduction to as low a level as is technically feasible. However, progress with substitution in the workplace is slow. Even if substitution is used with perfect enforcement measures, it would not remove all carcinogens in the workplace. It will take a long time before viable substitution solutions can be developed and implemented for some substances. So a complementary approach to substitution is needed. This contribution outlines the approach developed and implemented for exposure reduction in Germany over the past ten years.

Although carcinogen substitution may at first glance seem like a silver bullet for worker protection, it is slow, does not deal with process-generated carcinogens comprehensively and does not solve the legacy issue of carcinogens used in the past when they come to light again in maintenance and demolition work.

Some carcinogenic metals and their compounds (beryllium, chromium VI, cobalt, nickel) cannot be replaced in the foreseeable future for a number of important uses, including stainless steel welding. Similarly, we do not yet have the technology to completely avoid creating process-generated carcinogens such as crystalline silica, hardwood dust, diesel engine emissions, polycyclic aromatic hydrocarbons (PAHs) and related compounds, or nitrosamines. And even some banned carcinogens like asbestos will remain in the work environment for decades to come, in particular in the maintenance and demolition sectors: millions of tonnes are still present in buildings, tunnels, roads and other infrastructure.

2. The minimisation strategy

For most carcinogens, there is no exposure threshold below which cancer cannot be induced. The only truly safe level is zero exposure. However, the risk of contracting cancer depends heavily on the degree and duration of exposure to the dose. In other words, the risk is subject to the laws of statistics: the higher the dose, the higher the probability of contracting cancer. Limiting exposure reduces the risk of contracting cancer but does not rule it out completely.

The goal of any minimisation approach is therefore to reduce the number of cases of occupational cancer as much as possible. Minimisation is always limited by technical feasibility, which effectively means economic feasibility. Exposure can be reduced to virtually zero using current technologies for the closed systems in the nuclear industry, the pharmaceutical industry and parts of the chemical industry. But they come at a prohibitive cost for other industries such as construction, engineering and metallurgy.

Germany's initial exposure minimisation strategy was based on technical-based occupational exposure limits (OELs) for relevant carcinogens. These OELs defined workplace concentration limits and complemented the general minimisation obligation. Respiratory protective equipment (RPE) had to be worn when it was not possible to comply with the OEL during a work task. First introduced in Germany in 1974, OELs based on the technical state-of-the-art (technical-based OELs) helped establish an exposure ceiling level and thus set the maximum additional risk of contracting cancer. By the end of the 1990s, such technical-based OELs were in use for more than 70 carcinogens.

Yet despite its success in limiting occupational cancer risks, the approach had major shortcomings. These became obvious in the late 1990s:

- No difference was made in many workplaces between technical-based OELs and the parallel, health-based OELs: no further carcinogen exposure reduction was sought once the workplace complied with the technical-based OEL. This hampered progress in minimising exposure.
- The regulatory adaptation of existing technical-based OELs to technological advances was very tedious and time-consuming. By 2002, more than half of the technical-based OELs had not been updated for more than ten years.
- Such OELs were usually based on the processes and tasks with the highest exposure levels (and the lowest levels of technology). This meant there was little incentive to improve exposure situations for processes and tasks with better technical standards: the OELs applied across all processes and tasks, instead of differentiating according to the available technology levels for the different sectors.
- Calculations of the quantitative cancer risks associated with the different OELs showed that about one third of the OELs were associated with additional lifetime cancer risks of more than 1%, another third with additional risks between 0.1% and 1%, and the remaining third with additional risks below 0.1%. The difference between the OEL with the lowest and the highest associated risk was a factor of about 100,000. These huge differences in risk did not have any regulatory consequences, though: additional control measures, such as the use of RPE, had to be applied when the OEL was exceeded, irrespective of the resulting risk.
- In the Netherlands, a system of risk-based OELs had been in place since the mid-1990s, where the maximum risk associated with OELs for carcinogens was limited to 0.4 %. By comparison, for half of the German technical-based OELs the associated risk exceeded the Dutch risk limit.

These problems contributed to Germany's 2004 decision to abandon the approach of technical-based OELs as a tool for minimising exposure of carcinogens, which occurred when the EU's Chemical Agents Directive (CAD, Dir. 98/24/EC) was transposed into German legislation after a long delay. However, the main reason for abandoning the German approach was that it was incompatible with a risk assessment system using health-based OELs.

No alternative approach was pursued at that time. This was mainly due to arguments among stakeholders that emerged during the heated debates over the EU's REACH regulation. Instead, a general risk-related approach was agreed and the tri-partite Committee on Hazardous Substances, set up in 2005, was asked to come up with a detailed concept.

3. The new, risk-related minimisation concept

The new concept addressed the problems of the previous approach. Its main aims were to:

- verify the exposure minimisation requirement at company level;
- prioritise the minimisation of high risks;
- help companies carry out exposure minimisation.

A detailed framework based on the concept was completed by the end of 2007. It is described in the Technical Rule on Hazardous Substances (TRGS 910, Risk-related concept of measures for activities involving hazardous carcinogenic substances)¹.

Since then, 43 carcinogens or groups of carcinogens relevant to workplaces have been or still are being considered for inclusion in that concept. By spring 2015, 20 carcinogens were already covered by the concept and a health-based OEL had been derived for another five. Different solutions were found for a further seven, such as use in closed systems only, or use according to a Technical Rule (comparable to an Approved Code of Practice). Work is still ongoing for 11 carcinogens.

This process ensures that the most important occupational carcinogens in German workplaces will be covered by an action targeting this category of less than 45 carcinogens or groups of carcinogens. There is less concern about certain carcinogens for which a technical-based OEL was in existence until 2004: they are either no longer used in Germany at all or handled in closed systems. It should however be noted that certain workplace carcinogens are not registered under the REACH regulation or are only registered for intermediate use.

1. Available in English at: <http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/TRGS-910.html>

3.1 The conceptual framework

The conceptual framework has three main elements:

1. Three general risk bands (high, medium, and low risk), separated by two risk limits (upper and lower risk limit) to quantify the individual risk of contracting cancer;
2. A general tiered control scheme to reduce exposure, regardless of the risk substance. This has 14 individual control measures, each graded according to the three risk bands;
3. A comprehensive guide to help set exposure-risk relationships (ERR) for individual carcinogens.

The core of the concept concerns the additional quantitative cancer risk for the individual worker through exposure to occupational carcinogens. Additional individual cancer risks are calculated by assuming continuous exposure at the given exposure level during a 40-year working life. On that basis, the upper risk limit was set at 4:1,000 (0.4%) and the lower one at 4:100,000 (0.004%). For the concept's implementation period up until 2018, the lower risk limit is 4:10,000 (0.04%).

These figures, identical to those used in the Netherlands in the mid-1990s, were formally agreed after extensive negotiations among the social partners. The upper limit used figures for the average risk of a fatal work accident across all sectors, which is currently 0.1% in Germany. No workplace-specific figure was set for the final value of the lower limit. Instead, it will apply the same figure for the workplace as environmental regulations do when calculating a target value for environmental cancers in the general population.

The two risk levels serve different functions. The upper one should not be exceeded at all. However, if this upper limit is temporarily exceeded, the use of RPE is mandatory and additional technical measures have to be implemented immediately to reduce exposure. By contrast, the lower risk limit is a target value for the medium term or sometimes even for the long term. To put the upper risk limit into perspective, it is worth noting that an additional cancer risk of 0.4% is about the same as the risk of lung cancer for a non-smoker.

The importance of the two risk limits can also be illustrated by looking at the corresponding concentration values of individual substances. For asbestos, the corresponding upper and lower concentration values are respectively 100,000 fibres/m³ and 10,000 fibres/m³. The same 100,000 fibres/m³ concentration level is defined in the EU directive on exposure to asbestos at work (Dir. 2009/148/EC) as a limit that should not be exceeded. It corresponds to an additional cancer risk of 0.4% and is effectively a common denominator at the level of the upper risk limit. In other words, both the Dutch and the German approaches limit the maximum additional cancer risk for any carcinogen at the same level as that set for asbestos at EU level.

The tiered control scheme at the heart of the concept is based on the hierarchy of preventive and protection measures (i.e. the TOP principle that prioritises technical measures over organisational ones over personal protection). It includes various control measures that should help further reduce exposure. For example, the use of RPE is mandatory in the high-risk band. In the medium-risk band, the employer has to supply RPE to employees but use is left to the discretion of the individual worker. And in the low-risk band, use of RPE is unnecessary. The employer has to tell employees the extent of risk exposure: this is part of the employer's general information duty to help workers decide whether to use RPE in the medium-risk band. A further measure is the action plan, an instrument of strategic importance. Details about this instrument can be found in section 3.4.

The third element, the guide for setting exposure-risk relationships (ERRs), is essential for applying the concept to individual carcinogens. Only an ERR can transform the two substance-independent risk levels into substance-specific concentration levels. The guide ("Guide for the quantification of substance-specific exposure-risk relationships and risk concentrations after exposure to carcinogenic hazardous substances at the workplace") is a technical annex to TRGS 910 and can also be accessed at the website above.

3.2 The substance-specific elements and the initial results

Additional considerations have to be made when setting substance-specific concentration values. Two important ones have so far been identified. The first concerns detrimental non-carcinogenic health effects below the corresponding upper risk concentration value. In such cases where substances show such health effects, the upper concentration value is lowered to a protective value. The second concerns measuring the concentration values: for some substances, in particular certain carcinogenic metals, the calculated lower concentration values are below the limit of measurability under workplace conditions. In such a case the lower concentration value is increased to the current limit of measurability.

Of the 20 ERRs derived so far, values for the upper concentration were set above the former technical-based OELs for just three substances. OSH legislation sets a general mandatory obligation for continuous improvement of working conditions, meaning that the former OEL cannot be exceeded. For two substances, acrylamide and methylenedianiline (MDA), the lower concentration value is above the former OEL. And for both substances, the TRGS 910 explicitly indicates that compliance with the lower concentration value is technically feasible. By contrast, the upper concentration values for 14 substances are below their former OELs. For some substances, in particular the carcinogenic metals (arsenic, cadmium, chromium VI, cobalt, nickel), the difference is considerable: their upper concentration values range from 1 to 10 µg/m³. Compared to the former OELs, they are lower by factors of between 10 and 50. This implies that the former technical-based OELs for the carcinogenic metals correspond to additional cancer risks of between 4 and 20%.

It also means that it will be technically difficult to comply with the upper concentration value for certain tasks that use those metals. The Committee on Hazardous Substances has addressed this situation by compiling some Technical Rules. Section 3.3 has further details.

In addition, health-based OELs have been set for five carcinogens through two separate means: either by modes of action that show the non-genotoxic effects underlying their carcinogenicity or with a threshold for a non-carcinogenic health effect (for concentrations with an extremely low cancer risk). An example from this second group is beryllium, for which a health-based OEL has been set for the alveolar fraction of $0.06 \mu\text{g}/\text{m}^3$.

3.3 The socio-economic dimension: Technical Rules

Like any regulation on occupational health and safety, regulations on occupational carcinogens cannot ignore the socio-economic dimension. The economic feasibility of regulatory measures is directly connected to the issue of job security.

The earlier approach made socio-economic considerations a key aspect of determining technical-based OELs. Regulatory experts were aware of such considerations, but they were not clearly communicated. It meant that workers could easily get the wrong impression that these OELs were at safe levels.

The different aspects are strictly separated in the new concept: health and risk issues are communicated with concentration values, while socio-economic aspects are outlined as a separate instrument using Technical Rules.

At least 12 such Technical Rules already exist or are being prepared for a number of carcinogens, including crystalline silica, diesel engine emissions, carcinogenic metals, PAHs, nitrosamines, asbestos, ceramic fibres, wood dust, ethylene oxide and formaldehyde. The Technical Rules guide employers on how to comply with their legal obligations when working with these carcinogens, especially when conditions create high exposure levels. One example is the long-established Technical Rule on demolition, renovation and maintenance work with exposure to asbestos. Such rules include control measures and the use of personal protective equipment (PPE). The Technical Rules also need to be adapted to technical progress on a regular basis: they are effectively temporary instruments, regularly updated by the Committee on Hazardous Substances.

3.4 The action plan

Copying the Dutch approach, the action plan is an additional element in the documentation of risk assessment, covering tasks with exposure in the medium- and high-risk bands. Employers have to detail their plans for further exposure reduction in the action plan: what control measures they plan to implement; when they plan to implement them; and their exposure reduction targets.

The key strategic role of this instrument should be clear: the action plan aims to make the company's exposure reduction efforts transparent, thus helping to ensure targeted enforcement by the labour inspectorate. At the same time, the plan also allows worker representatives to uphold their rights under German labour law.

3.5 The role of worker representatives

Works councils have wide-reaching control and co-determination rights in occupational health and safety under German labour law. Since details of the future exposure reduction are not prescribed in TRGS 910 (they remain at the discretion of the employer), an employer has to consult the works council, or *Betriebsrat*, on the plans, and has to reach agreement with the council.

The *Betriebsrat* has other powers involving the right to control an employer's risk assessment of tasks involving carcinogens. This right thus allows the works council to check/monitor:

- substitution possibilities and/or the use of a closed system;
- the selection of control measures and their justification vis-à-vis substitution;
- the setting of the degree and duration of workers' exposure;
- specifications on the use of RPE;
- regular information on workers' training;
- regular offers of medical surveillance for workers;
- the existence of an up-to-date list of exposed workers carrying out tasks for which an action plan is obligatory.

The *Betriebsrat* can also negotiate an agreement with the employer on the concrete details of measures to further reduce exposure.

4. Outlook

The risk-related concept was endorsed by the Committee on Hazardous Substances in late 2007 and then tested for a few years before a formal legal basis was established in the Hazardous Substances Ordinance in mid-2013. TRGS 910 was published in early 2014.

A consensus has been reached at expert level on two important issues that will extend the current obligations on carcinogens prescribed by the Ordinance.

The first is the obligation to use carcinogens in a closed system if the upper concentration value cannot be complied with within three years of publication of that value. Exemptions are possible if their use is covered by a Technical Rule.

The second is a notification requirement for tasks involving carcinogens in both the high- and medium-risk bands, i.e. for exposure above the lower concentration value.

Notifications to the factory inspectorate should contain the exposure information. When above the upper concentration value, the action plan must be implemented; when below it only has to be implemented on demand. These requirements are expected to meet with hefty resistance from employer organisations complaining about the additional bureaucratic burden, in particular for SMEs.

ERRs or health-based OELs have been set for most relevant carcinogens. However, there are two controversial exceptions: crystalline silica and diesel engine emissions (DEE). The scientific discussions have mostly been completed for crystalline silica but consensus has yet to be reached². For DEE, the scientific committee in charge is awaiting the results of an assessment of some US epidemiological studies conducted in 2013 before it reaches any conclusions³.

The controversy over those two substances is remarkable in comparison to the scientific discussions on other carcinogens. This is partly explained by the debate in international circles where limit values are heavily contested, especially in the US. Also, German car manufacturers appear to be resisting environmental arguments against lowering limit values in the workplace as it could lead to additional pressure for stricter emission controls to protect the general population.

A possible future controversy concerns the implementation of the final phase of the risk-related concept, agreed in principle as early as 2007: to reduce the lower risk limit by a factor of ten to its final value of 4:100,000 and thus adapt the substance-specific lower concentration values. There is currently tentative agreement that lower concentration values should only be reduced to a level that is still measurable for the respective substance. If this pragmatic suggestion were accepted, it would imply that the current lower concentration values for carcinogenic metals could not be further reduced while there is no progress in measurement and analytics technology.

In conclusion, the new, risk-related concept has done much to stimulate debate on occupational carcinogens in Germany and put a fresh focus on minimising exposure. It has moved certain carcinogens into the limelight, in particular carcinogenic metals, and has showed how their risks were massively underestimated in the past.

The concept is also an opportunity to set much higher levels of transparency on workplace exposure to occupational carcinogens and provides employee representatives with additional tools to prevent occupational cancer.

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2. As of 1st July 2018, Germany had not yet adopted an OEL for crystalline silica. It will have to do it before January 17, 2020 within the framework of the transposition of the European directive 2017/2398 of December 17, 2017.
 3. An OEL for DEEs was adopted in Germany in November 2017. It is 0.05 mg / m³ calculated on elemental carbon.

5. Transferring the approach across Europe

Could such a risk-related approach be implemented in other EU member states or at EU level? The differences between member state legal systems and cultures suggest it might be presumptuous to assume that a Dutch or German approach could be transferred to another system. Nonetheless, it is worth sketching the essentials of a risk-related approach for any national system.

The indispensable elements would include:

- transparency about the level of workplace exposure and the corresponding additional cancer risk, assuming a continuous, life-long exposure at that level;
- the introduction of a broad, substance-independent, upper risk limit above which no worker would be exposed without RPE;
- a clear regulatory separation between scientific and socio-economic considerations, which means abandoning any technical-based OELs;
- a mandatory action plan for the employer to detail his future measures on exposure reduction.

By contrast, the introduction of an overarching, lower risk limit as a target value seems of little relevance for the time being. It is already a major challenge to ensure carcinogens comply with their defined upper risk limit concentration values: the limited resources available should be focused on this urgent issue. The issue of a finite target value can wait until the high risks are sufficiently and successfully dealt with.

There are also concerns about whether these essentials can be agreed across all EU member states. During recent discussions on binding OELs for carcinogens at EU level, the principle of a maximum additional cancer risk for the individual worker was found to conflict with the UK's cost-benefit analysis approach. But a consequence of the British approach is that the risk for individual workers can be much higher if small groups are affected and the significant investment in additional control measures is not vindicated by the comparatively small overall risk to the group.

This approach would be justified within the current framework of utilitarian ethics in the UK. However, two questions remain. First, how can such an approach be reconciled with the basic rights enshrined in the EU Charter of Fundamental Rights, in particular human dignity and the right to the integrity of the person? The second concerns an implicit, yet rarely asked condition of cost-benefit analysis – the level of equality in society: who incurs the costs, and who reaps the benefits of a measure taken or not taken?

But given the rise in inequality over the past 30 years, for workers it seems politically wrong to found socio-economic considerations on cost-benefit analysis. The basic prerequisite of a minimum level of societal equality has completely evaporated.

Reference

BAuA (2014) Technical rule for hazardous substances 910: risk-related concept of measures for activities involving carcinogenic hazardous substances, Dortmund, Federal Institute for Occupational Safety and Health. <https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/TRGS-910.html>

Chapter 11

Ergotoxicological approach to the prevention of carcinogenic risk in the work environment

Brahim Mohammed-Brahim

Interest in understanding the chemical risk in complex work situations was first shown in the 1980s (Silva *et al.* 1980; Delvové 1984; Sznelwar 1992). Known as the ‘ergotoxicological approach’ (Villate 1985: 303), this approach struggled to gain ground among occupational health and safety experts with their prescriptive prevention model that was attractive on a formal level and comfortable in terms of responsibility. But things changed in the 1990s, with the asbestos scandal and the initial epidemiological data on the latent effects of pesticides encouraging us to revisit this approach (Mohammed-Brahim 1999).

1. The asbestos scandal in France: a textbook case

The links between occupational exposure to asbestos and the development of cancers were established quite early on (Doll 1955; Wagner *et al.* 1960). However, it was not until 1977 that the consensual option of ‘controlled use’ was adopted in France, inspired by the social partners, representatives of the State and public institutions, and scientists who came together from 1982 onwards within the Standing Committee on Asbestos. This was felt to be a framework capable of curbing any residual risk of unwanted exposure to asbestos. However, the measures adopted do nothing to prevent, and in fact will allow, an expected total of 68 000 to 100 000 cancers between 2009 and 2050 in France (HCSP 2014). Beyond the legal liability to be determined by the courts and the moral responsibility to be assessed by protagonists, we have started to analyse how the chemical risk could have been viewed in a way enabling such a harmful consensus.

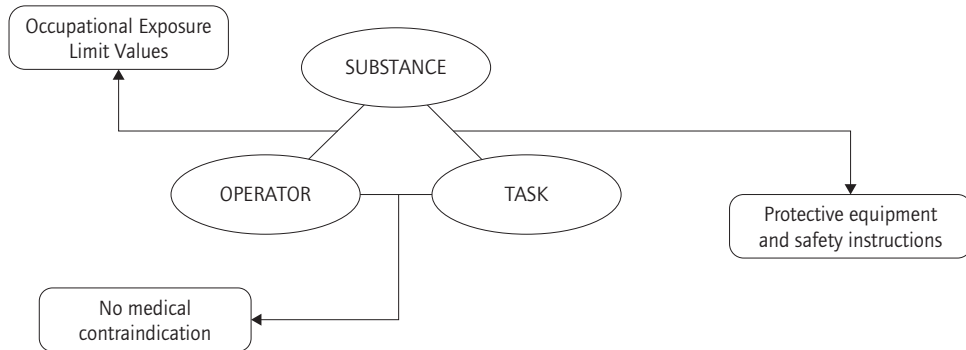
2. The ‘dominant’ chemical risk prevention model or ‘screen model’

The EU OSH Framework Directive of 12 June 1989 sets out the general principles of prevention, three of which directly relate to chemical risk prevention: eliminate or reduce the risk at source; confine, remove or overcome the risk; individually protect from the residual risk. Adapting work to the individual is mentioned only in reference to monotonous work and work at a predetermined work-rate, which should be alleviated (Article 6(2)(d)).

Achieving these aims requires the use of knowledge and practices stemming from industrial toxicology (Occupational Exposure Limit Values – OELs – ‘normative screens’ that must be achieved through a ‘physical screen’ made up of collective and personal protective equipment and safety instructions designed to keep actual exposure

levels below these limits) and occupational medicine (no medical contraindication for exposure in the case of carcinogens, a 'regulatory screen' supposed to prevent the individual residual risk). These three approaches form a prevention model that we have called the 'screen model' (Mohammed-Brahim 2000). The 'dominance' of this model should be noted.

Figure 1 'Screen' model of chemical risk prevention



Source: Mohammed-Brahim (2000)

However, this model is flawed, whether with reference to:

- the OELs, which result more from a social compromise, reached in an unequal relationship between the social partners, than from any 'scientific objectivity';
- the protective equipment and instructions provided upstream of the work situation, where failure to comply is more an expression of the constraints on operators individually and/or collectively than any unfairly assumed negligence on their part;
- no medical contraindication, which replaces preventive medicine with 'predictive' medicine.

In addition, by limiting chemical risk prevention to the use of 'screens' to combat the dangers, the model in fact fails to consider and act on the technical, organisational and even human determinants of these dangers, losing any room for manoeuvre that may have been possible through an integrated approach to chemical risk prevention (Mohammed-Brahim and Garrigou 2009).

3. Ergotoxicology: an effective model of chemical risk prevention, in particular with regard to carcinogens

We hypothesise that the weakness of this model in properly and sustainably preventing chemical risks is linked to the lack of reference to working reality.

Work situations involving exposure to chemical risks are both complex and unique, particularly in terms of carcinogens.

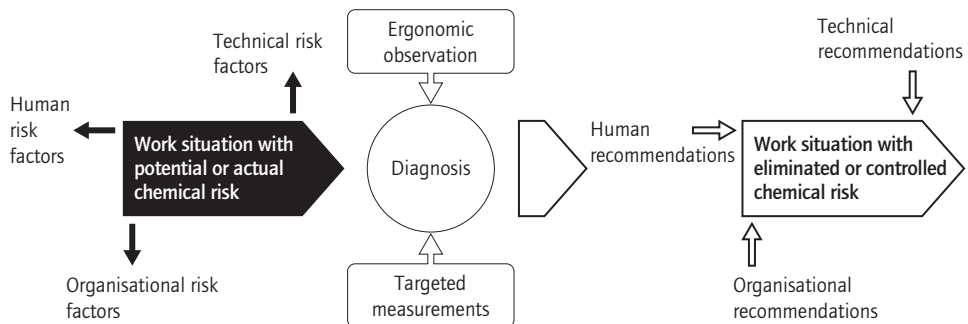
They are complex, in this case, for several reasons:

- scientific uncertainty (the generally multi-causal origin and non-specific nature of cancers, length of latency, absence of an a priori threshold value), which always makes recognition of an exposure-effect relationship controversial and which further delays the introduction of regulations prohibiting and/or limiting use and/or laying down protection measures;
- multiple exposures within the same job and over a career, making it harder to characterise the risk using the reading grid and prevention framework prescribed by the 'dominant' model;
- not always clear perception of the risk by operators in the absence of an effect felt during exposure and/or a definite representation (absence of specific pictogram, no pictogram in the absence of classification of the substance or preparation).

Similarly, they are unique when we take account of their variability (repeated or sustained incidents, work in degraded mode, non-standard hours, added physical workload and/or heat) and the specific careers of each individual (non-evaluated effects of previous exposures, medical history, addictions).

Ergotoxicology offers a prevention model combining technical, organisational and human measures capable of acting on the determinants of the exposure situation identified through an analysis of the work and knowledge stemming from toxicology. This model involves the following process (Mohammed-Brahim 2014):

Figure 2 Breakdown of the ergotoxicological approach



Source: Mohammed-Brahim (2014)

These determinants may therefore be:

- **technical:** specific to the substance(s) (physical, chemical and toxicological properties), linked to the physical environment (heat, noise, architectural configuration), process requirements (alteration of the physical state, intermediate synthetic products, manual interventions) or intrinsically unsuitable protection that may prevent or constrain necessary or useful acts;

- **organisational:** working hours and rates influencing the duration and repetitiveness of exposures, quality requirements incompatible with protection requirements, regulatory constraint, remoteness of decision-making centres, commercial policy;
- **human:** sociodemographic characteristics specific to the business and associated with the typology of the employment pool, training, professional experience, contractual status.

It is clear that these determinants can exist:

- both at ‘micro’ levels, directly linked to the configuration of the situation observed, relatively deterministic, often accessible to observation and offering possibilities for action that are more perceptible, acceptable or achievable in the short term;
- and at ‘macro’ levels, remote from the observables of the work situation, accessible through reports, sometimes involving actors remote from the operators, possibly impacting situations other than the one observed, and offering fewer possibilities for action, at least in the short term, in terms of their construction, implementation and impact.

Access to these determinants is made possible by the ergonomic observation of exposure situations and reports by operators. Videos together with targeted environmental measurements support the self-confrontations among operators and with the expert so that diagnoses can be formulated and validated.

The subsequent combination of actions on these various levels and qualities of determinants, only minimally or not at all in some cases and with much more room for manoeuvre in others, their construction and validation with local operators and their supervisors and the subsequent negotiations with the decision-makers, allows a situation to be constructed in which risk is controlled (or even eliminated), shared, accepted and sustainable.

4. An approach used in the field

This approach, tested over several years, will be illustrated here by two experiments involving the issues mentioned at the start of this paper: asbestos and pesticides.

4.1 Use at asbestos removal sites

Two years after the 1997 Regulation was adopted in France, we were tasked to investigate its implementation in practice. Two sites were therefore monitored and subjected to an end-to-end analysis, from the examination of the calls for tender to final acceptance. The following are some of the significant elements of the diagnosis and recommendations.

Reasoned trade-offs

In order to reduce dust, the Regulation recommends firstly wetting the surfaces to be treated. However, spraying pressurised water vapour or surfactant will also wet the plastic sheeting protecting the floor, causing people to slip. This water also makes the waste much heavier, requiring much more manual handling during its removal. This example, among others, illustrates the trade-off processes of the operators involved, in this case between a real-time risk and a delayed risk against which respiratory protection is deemed to protect them.

Surprising exposures

The work area was sealed off using a double layer of joined plastic sheeting, with only the inner layer being fixed to the walls and floor. Negative pressurisation caused aspiration towards the inside of the second layer. To prevent this problem, operators came up with the idea of gluing the two layers together in places. The glue was sprayed, with the operator being sandwiched between the two layers. However, the glue contained dichloromethane, a substance classified as a group 2B carcinogen by the IARC due to its suspected responsibility for pancreatic cancers. Exposure could be significant due to the confinement and physical workload.

A second finding involved the presence of mineral oils in the air breathed in by the operators, at a rate more than five times the level permitted by standard EN 132. These mineral oils came from the compressors supplying the protection masks with air. Depending on their level of refinement, these oils appear in the list of mixtures classified as group 1 carcinogens by the IARC. Given the number of people likely to be exposed to this source (sandblasting operations in the building, for example), the competent authorities (INRS, Ministry of Employment) were quickly alerted.

Finally, despite the air supply, our measurements revealed the presence of asbestos fibres inside the masks, in some cases exceeding the permitted levels. This was explained by variations in internal pressure due to the differing rates of breathing associated with the physical workload, and by breaks in the seal due to intentional or unintentional disconnections in order to untangle the supply pipes connected to the same supply terminal.

Adverse organisational factors

The Regulation limits the period of work in a confined area to two hours thirty minutes, and even less than that for heavy workloads. However, not only was this period systematically maximised, but recuperation time outside the area was minimised. As a result, the time spent by operators in the work area during a working day could total seven hours thirty minutes. Workload measurements carried out revealed the physical cost of this organisation.

A single chamber was provided for accessing the sealed-off area, both for operators and for removing waste, which led to contamination given that regular cleaning was prevented by time pressure.

Most of the staff were on fixed-term contracts and came from cleaning companies rather than the building sector, particularly the nuclear sector. The staff were therefore inexperienced, with precarious contracts, subject to successive uncontrolled exposures and mostly without any medical monitoring.

Feedback enabling advances in prevention

Leaving aside the failure to comply with the wetting instruction, a formal reading of the work situations would have indicated an almost total observance of the regulatory provisions. However, the ergotoxicological approach revealed deviations leading to exposures that would otherwise not have been suspected, and enabled their understanding and the collective construction of a range of prevention measures.

Feedback allowed urgent decisions to be made, particularly the ban on fixed-term contracts and the monitoring of breathing air supply equipment. This assessment resulted in a document that has been extensively distributed among occupational health and safety experts (Garrigou *et al.* 1998) and a manual for use by occupational doctors (Mohammed Brahim *et al.* 1998). It largely inspired the update of the Regulation, particularly the 2012 decrees.

4.2 Assessment of exposures to pesticides in the seed industry

Stemming from a meeting between a pesticide supplier, the seed industry representatives and the prevention body, this assessment was intended to diagnose exposures to pesticides and their determinants during seed coating operations and to design prevention measures. This occurred in a context of heavy social, media and political pressure (Mohammed-Brahim 2009).

The assessment involved nine companies representative of the variability of the industry (size, type of seed, technology). We will only mention here the most illuminating situations.

Analysis of the activity and targeted measurements

Observing the activity allowed the hypothesis to be made that equipment cleaning was the situation involving the greatest exposure, as confirmed by the respiratory and cutaneous measurements. Depending on the operation, the level was 5 to 20 times higher than that found in other activities. Respiratory exposure seemed to be negligible in all cases. The cutaneous route was the main route of exposure, with 80 % to 100 % occurring through the hands alone.

Personal protective equipment (PPE) – dry suits, full filtering masks and gloves – was required by the occupational health and safety expert.

However, during peak periods, cleaning was repeated up to 10 times, i.e. after each change of seed or preparation. It took around 12 minutes to put on and remove the PPE, i.e. a total of two hours out of the working day. No organisation would be prepared to accept this within working time. In addition, the sheer physical weight of the equipment and the heat in the height of summer were difficult to sustain.

Cleaning or protecting: what is the room for manoeuvre and what are the compromises?

In this case, compromises were built around the evidence that effective protection of the hands alone (gloves, rinsing) reduced exposure to an acceptable level:

- for occupational health and safety experts on the one hand, enabling them to improve their representation in light of our findings;
- for employees on the other hand, as regards managing this personal protective equipment (putting it on, working with it and removing it without damaging it; training seasonal workers, in particular, through practical and taught courses).

At a ‘macro’ level, work was carried out to reduce the number of cleaning operations:

- with professionals, by questioning the actual need for these operations and by reorganising their implementation;
- with the agricultural adviser and sales force, by limiting the range of preparations used.

5. Yes, assessing the work more clearly identifies the chemical risk, at the same time as improving prevention by basing it on the actual work situation

This confirmation is being echoed by an increasing number of occupational health and safety experts and companies in the context of training measures and proposed interventions.

Still relatively unknown, the ergotoxicological approach is also being echoed in regulatory developments, as evidenced in France by the changes made by the 2003 Decree on chemical risk prevention (extension of the definition of dangerous chemicals and of the scope to all exposure situations, reference to real work), and more recently the Decree on asbestos exposure risks (separate assessment for each ‘work process’, individual sampling in situations of significant exposure, reference to the rest time after each shift, etc.).

Occupational health programmes are reinforcing the idea that ergotoxicology represents an alternative approach offering a new dawn in chemical risk prevention in the work environment.

The DRT Circular of 24 May 2006 explaining Decree No 2003-1254 of 23 December 2003 on chemical risk prevention states that 'the analysis of the forms of exposure ... shall be based ... on an analysis of the work situations, workplaces and conditions under which activities involving chemical agents are carried out; this **analysis of actual work** must necessarily be based on the knowledge that employees have of their own activity and workplaces'.

The 2005-2009 Occupational Health Plan sets, as one of its occupational health research objectives, 'renewing the approach methods' for toxicology in particular and 'developing new approaches'. In its annex on the creation of multidisciplinary scientific centres, it talks in particular of 'ergotoxicological approaches'.

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Chapter 12

Substituting hazardous chemicals

Lothar Lissner and Isabella Banduch

1. The SUBSPORT website and the future of substitution information

Substituting hazardous substances at workplaces can be a challenging task. Any alternative chemical or technology should have a similar technical functionality, be readily available, fully tested for toxic properties and technological functionality, and should not create new risks (like new toxins, accidents, carcinogenic chemicals or sensitizing agents). The SUBSPORT website helps people working on substitutions by providing state-of-the-art resources on safer alternatives to hazardous chemicals.

SUBSPORT facts

SUBSPORT (www.subsport.eu) was developed by four organisations:

Kooperationsstelle Hamburg IFE (KOOP) is a German consultancy that studies occupational safety, health and environmental protection. KOOP coordinated the SUBSPORT development, managed the initial three-year phase and is currently responsible for maintenance and development. (www.kooperationsstelle-hh.de)

The Instituto Sindical de Trabajo Ambiente y Salud (ISTAS) is a technical foundation supported by the Spanish Trade Union Confederation (CCOO) to promote improved working conditions, occupational health and safety, and environmental protection in Spain. (www.istas.ccoo.es)

The International Chemical Secretariat (ChemSec) is a Swedish non-profit organisation that promotes dialogue between business, academic institutions, legislators, investors and NGOs on a toxic-free future. (www.chemsec.org)

Grontmij A/S is a Danish consultancy that provides services in the construction, water, occupational health, energy, industry and environment sectors and works towards sustainable development for people's working and private lives. (www.grontmij.dk)

SUBSPORT was made possible through funding between 2010 and 2013 from:

- the European Union's Life+ Programme;
- the Federal Institute for Occupational Safety and Health (BAuA), Germany;
- the Federal Ministry of Agriculture, Forestry, Environment and Water Management (Ministerium für ein Lebenswertes Österreich), Austria.

2. Understanding 'substitution'

Although the term 'substitution' is used in legal documents, it is rarely defined with any precision either practically or politically. Stakeholder perceptions differ widely on whether substitution should be a "fundamental principle", a "duty to both producers and users of chemicals", a "preferred risk reduction strategy" or whether it is "just another tool for managing the same level of risk".

Here are some examples of different interpretations by different stakeholders. CEFIC, the European Chemical Industry Association, sees substitution as "...the replacement of one substance by another with the aim of achieving a lower level of risk." (CEFIC 2011). CEFIC focuses on risk rather than hazard: substitution is not a preferred risk reduction strategy but just one strategy among many technical and organizational options, including the personal protection of people exposed to these substances. Most chemical companies follow this conceptual approach. However, the environmental group Greenpeace has a very different view of substitution to that of the chemical industry: it is much more focused on hazard and the systematic replacement of all hazardous chemicals. Greenpeace says: "The principle of substitution states that hazardous chemicals should be systematically substituted by less hazardous alternatives or preferably alternatives for which no hazards can be identified." This approach shows that NGOs have little trust in risk reduction measures other than replacing hazardous chemicals and that their political goal is risk reduction at source by transition to the safest alternative.

It should be noted that the political and legal definitions combine aspects of both hazard and risk reduction. The European Parliament defines the substitution principle as: "the promotion of safer practices and substances," i.e. both the handling ("practices") and the hazard caused by the substance ("substances") properties shall be reduced.

Scientists emphasise how the process of substitution focuses on hazards or risks and the need to find a functional equivalent for the replaced substance. Lohse/Lissner defined substitution in 2003 as, "the replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures".

The REACH European chemical legislation also uses the term 'concern' and leaves open whether 'the concern' should be reduced by risk- or hazard-related measures. The preamble 12 of REACH says: "An important objective of the new system to be established by this Regulation is to encourage and in certain cases to ensure that substances of high concern are eventually replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available."

These definitions show that the term 'substitution' is used in official industry and NGO statements and in legal texts to promote risk reduction by replacing hazardous chemicals. Although there are various interpretations of substitution and different levels of support for the concept among various stakeholders, there is a common understanding that substitution can and should be used to reduce risk by replacing hazardous chemicals.

3. What does SUBSPORT do?

3.1 Background

SUBSPORT assumes that businesses around the world make many substitutions of hazardous chemicals, if only to avoid problems linked with their use. There might be many reasons for such substitutions: the alternative has a better technological functionality; lower costs for legal compliance and technological risk reduction measures; improving business reputation; reducing the risk of a ‘chemical scandal’; pressure from the public, environmental NGOs and/or trade unions.

However, qualified, easy-to-understand and harmonised descriptions of these substitution activities have been and still are missing. Some businesses might not think it important to promote them, while others might not publish their activities for competitive reasons.

SUBSPORT’s core information portfolio is based on a collection of business reports and similar documents on substitution. Experience shows that employers and workers learn best from good practices in other companies, including those that successfully use substitutes in their processes. SUBSPORT caters for a variety of target groups, and provides specific access points to information, i.e. different levels of detail, adapted language and various navigation options.

3.2 Legal requirements for substitution

This section presents an overview of regulations and international agreements covering substitution issues, whether they refer to substitution directly or closely related issues. Links to the original documents and archived copies are also provided.

3.3 Restricted and Priority Substances database

A typical starting point for website visitors is the SUBSPORT ‘Restricted and Priority Substances Database’. It has 34 lists of hazardous substances that are legally or voluntarily restricted by authorities or companies, or proposed for restrictions by trade unions or NGOs. A specific section provides additional guidance on how to identify substances of concern, by listing the criteria and definitions most commonly used by different stakeholders.

3.4 Substitution Case Stories

A core SUBSPORT offering is the Case Story Database with around 350 substitution ‘case stories’ or practical examples of substitution. Many of these are provided directly by the companies carrying out substitution efforts. The case stories can serve as inspiration and help companies or organisations searching for substitutes to hazardous chemicals.

It can also prove useful, for example, in procurement or in legislative actions like the authorisation process of the EU chemicals regulation REACH. Substances mentioned in the case stories are pre-evaluated for hazards according to the SUBSPORT methodology (Alternative Assessment Methodology, see below). All case stories are available in English. About 100 of the examples are translated into Spanish, German, French or Serbian.

3.5 Extensive substitution assessments

More detailed assessments of alternatives are available for nine substances or groups of substances of very high concern (SVHCs).

1. Chloroalkanes
2. Chromium VI and compounds
3. Bisphenol A
4. Lead and its inorganic compounds
5. Nonylphenol and ethoxylates
6. Tetrachloroethylene
7. Formaldehyde
8. Hexabromocyclododecane (HBCDD): a brominated flame retardant
9. Parabens (methylparaben, ethylparaben, propylparaben, butylparaben)

These assessments were made using the SUBSPORT Specific Substances Alternatives Assessments Methodology.

3.6 Alternative Assessment Methodology

SUBSPORT has developed a harmonised Alternative Assessment Methodology (http://www.subsport.eu/wp-content/uploads/data/SUBSPORT_methodology.pdf) to guarantee the quality of substitution case stories. All the stories in the Case Story Database are assessed with this methodology. Each substitution case story contains the following sections:

- Substance info
- Hazard assessment
- Description of substitution
- Case/substitution evaluation
- Further info
- Further contacts

SUBSPORT has developed its Specific Substances Alternatives Assessments Methodology (www.subsport.eu/wp-content/uploads/data/SUBSPORT_spec_subst_alt_ass_method.pdf) in cooperation with a recognised institute from the US - the Toxics Use Reduction Institute (TURI) in Massachusetts - to design consistent and comparable assessments of substitutes for the selected chemicals. This SUBSPORT methodology

should be applied when conducting an alternatives assessment for the Specific Section of the Case Story Database. It can also be used by businesses for assessing alternatives. The protocol contains the following steps:

- Profiling chemicals
- Identifying functions and uses
- Identifying potential substitutes
- Screening out regrettable substitutions
- Characterizing alternatives
- Comparing alternatives

3.7 The Substance Database according to Screening Criteria (SDSC)

The SDSC (www.subsport.eu/listoflists?listid=31) was set up to prevent situations where one hazardous chemical is replaced with another hazardous chemical. It provides a basic assessment of alternatives.

SUBSPORT developed the SDSC to pre-assess chemical hazards in its substitution Case Story Database as well as to assess alternatives for specific substances. All substances and alternatives are checked for hazards with the following sources:

- The European Chemical Substances Information System database (ESIS-CLP) and, from 2015 onwards, the European Chemicals Agency (ECHA, C&L Inventory database) for substances included in the EU harmonized classification.
- The Substance Database, using SUBSPORT Screening Criteria SDSC to check for hazards of equivalent concern that are not in the EU harmonized classification, as well as IARC carcinogens.

Table 1 SUBSPORT screening criteria

Criteria	Definition
CMR	CLP Regulation cat. 1A, 1B (Dir. 67/548, cat. 1 and 2) IARC cat. 1, 2A, 2B
(v)P(v)BT	REACH Regulation – Annex XIII EC PBT Working Group OSPAR List of substances of possible concern
Endocrine disruptors	OECD Report EU Endocrine disruptors database cat. 1, 2 SIN list database
Neurotoxicants	Vela, Laborda, Garcia Study, 2003, cat. 2-4
Sensitisation agents	CLP Regulation for H334, H317 (Dir. 67/548, for R42, R43)

3.8 Other assessment tools for substitutes and alternatives

The SUBSPORT website also lists common methods and tools for assessing alternatives, as well as guidance on the most useful tools, and the level of knowledge they require.

The following assessment tools are explained on the SUBSPORT website:

1. Column Model for Chemical Substitutes Assessment
2. COSHH Essentials
3. Technical Rules for Hazardous Substances (TRGS) 600
4. Substitution Green Screen for Safer Chemicals
5. Determination and work with code numbered products (MAL Code)
6. Pollution Prevention Options Analysis System (P2OASys)
7. Priority-Setting Guide (PRIO)
8. Quick Scan
9. Stockholm Convention Alternatives Guidance
10. Stoffenmanager

The OECD released a ‘Substitution and Alternatives Assessment’ toolbox in January 2015. This compiles resources linked to chemical substitution and alternatives assessments. It lists a range of resources, including SUBSPORT. KOOP used the experience from SUBSPORT to develop the toolbox.

3.9 Training and seminars

SUBSPORT continues to offer training sessions in different languages on substitution and alternatives assessment. These sessions are discussion-based and focus on participant experiences, with short introductions and practical exercises in working groups.

The Alternatives Identification and Assessment training aims to provide basic concepts and tools to help participants start the substitution processes, understand the different stakeholders, which substances are of most concern, how and where to look for new ideas and alternatives, and introduce existing tools to assess alternatives. The training session targets national and local authorities, industry, trade unions, NGOs and other interested parties dealing with the substitution of hazardous chemicals in products and processes. Training materials are available in Danish, English, French, German and Spanish.

4. Extending SUBSPORT

4.1 Textile sector

KOOP developed a sector specific extension to provide substitution information for the textile sector (funded by the German Environmental Foundation DBU). The following items have been added to the SUBSPORT portfolio:

- textile-specific case stories from enterprises and descriptions of alternative substances and technologies in the textile sector;
- detailed alternatives assessment for chromium VI and compounds;
- incorporation of textile-specific restricted substances lists into the Restricted and Priority Substances Database;
- sector-related alternatives identification and assessment training sessions.

4.2 Extension to Serbia

Serbia is hoping to join the EU and its chemical laws are being harmonized with relevant EU legislation. If the government effectively implements chemical legislation and policies, it should enhance the knowledge and capacities of relevant industry sectors and other stakeholders such as NGOs, associations, authorities and academia. It should raise awareness with both industry and the general public about the possible impact of hazardous chemicals as well as global and EU practices in sound chemicals management.

There are tools at EU level aimed at encouraging and supporting industry as it speeds up the transition to safer alternatives. These tools are not available in Serbia. The ‘Serbia Substitutes’ project, funded by the Norwegian Embassy in Belgrade, made sure the results of the SUBSPORT and SIN List (Chemsec) were available in Serbia, and raised Serbian industry awareness about substituting hazardous chemicals with safer alternatives.

5. The future of SUBSPORT and substitution information

Health and safety consultants Kooperationsstelle Hamburg IFE, an organisation belonging to the Hamburg public sector until 2010, has worked with substitution for over 20 years, starting in 1992 with SUBSPRINT (SUBStitution of organic solvents in the PRINting industry). SUBSPORT is one of the most recent and successful initiatives on support substitution.

One of the biggest challenges is deciding what kind of information stakeholders actually need. This depends on the sector, their basic knowledge, their motivation, the surrounding supply chain, legislation etc. One possible route to developing SUBSPORT is to provide more sector-specific information. Limiting substitution information to certain processes means more specific questions from potential users. That means not just questions about chemistry or toxic properties but also questions about technology, process results, the environmental impact, other OSH concerns and the costs of different cleaning technologies.

The popularity of CLEANTOOL (www.cleantool.org) seems to support this argument: the website, which has been online for ten years, focuses on just one process, metal surface cleaning.

The first European Chemicals Agency (ECHA) public consultation also showed how sector-specific information is important. Rolls-Royce asked ECHA for authorisation to use the phthalate DEHP in the welding process for aircraft turbines. One supplier of aircraft turbines had already replaced DEHP years before, thus offering a safer alternative. However, this supplier was a competitor to Rolls-Royce, so it did not turn up in the public ECHA consultation. That led the ECHA to conclude that no alternative was available, and Rolls-Royce was eventually granted a seven-year exemption to use DEHP. Had the substitute been picked up during the consultation, Rolls-Royce would not have been granted authorisation to use DEHP.

Substitution support works best if it comes with technical expertise. The information should include broad support taking account of the problems often connected to substitution. This would echo the work of Sweden's KEMI and its centre of excellence for substitution. However even a large centre like KEMI cannot cover all the different technological sectors. Rather, a global networking institution is needed to gather such information, collecting available data for the different stakeholders, and offering it in a digestible format.

It should be possible to create an international, non-profit foundation to maintain, update and extend both practical and reference information on substitution and alternative assessments. KOOP and the other active substitution promoters are too small to initiate such a process, which would require investment to create and build such an institution. It would also have to provide neutral expertise, be free from industry or government influence and be driven by scientific principles. KOOP would actively support such an institution and offer it access to its own databases.

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Chapter 13

The Massachusetts Toxics Use Reduction Act: reducing the use of carcinogens

Rachel Massey and Molly Jacobs

1. Introduction

Efforts to regulate workers' exposure to carcinogens at the federal level in the U.S. have encountered many obstacles. The Occupational Safety and Health Act, adopted in 1970, had the potential to significantly improve working conditions in the US. The Occupational Safety and Health Administration (OSHA) made important progress in its first decade of existence, but over time, it has been weakened significantly, both as a result of reductions in funding, and as a result of Supreme Court decisions. For example, an OSHA initiative in 1989 to update Permissible Exposure Limits (PELs) for 212 chemicals and create new PELs for 164 chemicals was vacated by the U.S. Court in 1992. The vast majority of PELs in the U.S. are significantly out of date, as shown by scientific evidence.

In the context of very slow action at federal level to protect workers' health, some states in the US have taken the initiative to move forward independently. The Massachusetts Toxics Use Reduction Act (TURA), adopted in 1989, is one example. This chapter briefly explores what we can learn about preventing workplace exposures to carcinogens from data submitted under TURA over a twenty-year period.

2. The Massachusetts Toxics Use Reduction Act

TURA is designed to protect workers, communities, and the environment by encouraging businesses to reduce their use of toxic chemicals. It is designed to complement, not replace, other regulations governing the use and release of toxic chemicals.

Business sectors covered by TURA include manufacturing; electric, gas and sanitary services; chemical distribution; personal services (such as dry cleaning); and automotive repair, among others. Businesses in these sectors that use or manufacture large quantities of any one of more than 1,000 listed chemicals and have ten or more full-time employee equivalents are required to report their use of these chemicals and their byproducts each year; prepare a Toxics Use Reduction Plan every two years describing how they can reduce their use of toxics; and pay an annual fee. The fee is calculated based on number of employees (a rough proxy for company size) and the number of hazardous chemicals used. Under the current fee structure, the fees paid by individual businesses range from US \$2,950 to US \$31,450, and total revenue collected in fiscal year 2013 was US \$2.9 million.

TURA defines a “large quantity” as 25,000 pounds (11.34 tons) per year if a firm manufactures or processes a substance, 10,000 pounds (4.54 tons) per year if a firm “otherwise uses” a substance, 1,000 pounds (0.454 tons) per year for substances designated as Higher Hazard Substances under TURA, or lower amounts (ranging from 0.1 gram to 100 pounds depending on the substance) for chemicals identified as persistent, bioaccumulative, and toxic (PBT) chemicals by the US Environmental Protection Agency (EPA).

The programme is implemented collaboratively by the Massachusetts Department of Environmental Protection (MassDEP), the Massachusetts Office of Technical Assistance and Technology (OTA) and the Massachusetts Toxics Use Reduction Institute (TURI). Together, the three agencies provide a range of services, including training, grants and technical assistance, to help companies reduce their use of toxic chemicals. Services are provided free of charge to any Massachusetts business (including those not subject to the TURA requirements and fees).

The implementing agencies work together with an Administrative Council, an Advisory Committee and a Science Advisory Board. The Administrative Council, which makes policy decisions on behalf of the programme, is composed of representatives of state agencies in the areas of environment, public health, public safety, economic development and labour. The Advisory Committee includes representation from a range of stakeholders, including representatives of organized labour.

These services, combined with mandatory reporting and planning, have produced important results. Over the first ten years of the programme, from 1990 to 2000, Massachusetts companies subject to TURA reduced toxic chemical use by 40% and on-site releases by 90%. Over the next ten years, from 2000 to 2010, they continued to make improvements, reducing toxic chemical use by 22% and on-site releases by 65%. These figures are production-adjusted, meaning that they represent true improvements in the efficiency with which companies use toxic chemicals per unit of product. Production-adjusted figures are calculated based on year-to-year changes in production volume, as reported by businesses, compared with changes in total chemical use.

3. Core principles of TURA

Toxics use reduction focuses on minimizing the use of toxic substances through process redesign and substitution with safer alternatives, rather than controlling emissions at the “end of the pipe”. It serves as a form of primary prevention by reducing or eliminating carcinogens at their source, thus reducing the opportunity for exposure to industrial carcinogens in the workplace, in the environment, and in consumer products.

Core principles of TURA include the following:

- Focus on use. Many environmental statutes focus strictly on emissions or waste management. TURA, in contrast, focuses upstream on the manufacturing process where chemicals are used and wastes are first generated.

- Focus on hazard. Many environmental statutes rely on qualitative or quantitative risk assessments as a basis for deciding what measures are necessary to protect human health and the environment. By contrast, under TURA, the focus is on hazard. Hazard is an inherent characteristic of a chemical, such as carcinogenicity, neurotoxicity, or mutagenicity. The purpose of TURA is to reduce or eliminate the use of hazardous chemicals. There is no requirement to prove that exposure will occur, or to calculate risk, in order for a chemical to be subject to TURA requirements.
- Protection of workers, consumers and the environment. An industrial facility that has no emissions to the environment may still expose workers to toxic substances used within the facility, and may expose consumers to toxic substances incorporated into the product. The definition of toxics use reduction explicitly creates a mandate to consider the full range of impacts, including those on the environment, workers, and consumers.
- Avoiding risk shifting. The definition of Toxics Use Reduction in the law incorporates the concept of avoiding risk shifting among environmental media or among groups of people.
- Avoiding regrettable substitutions. TURA requires businesses to analyze the environmental health and safety profiles of any alternatives they consider. This requirement helps to guard against regrettable substitutions, in which a business replaces a chemical or material of concern with one of equal or greater hazard. The TURA programme agencies also work to support this goal by conducting alternatives assessments for individual chemical uses, helping to guard against adoption of chemicals whose hazards are poorly understood.

4. Using the TURA data to examine trends in carcinogen use

Because of the annual reporting requirements under TURA, Massachusetts has a valuable data set showing trends in chemical use since 1990. In a recent study, we analyzed this data to learn about trends in the use of carcinogens. (For more detailed information on the trends described below, see Jacobs *et al.* 2014.)

We identified 74 industrial carcinogens that have been reported under TURA at some point between 1990 and 2010. We analyzed trends for this group of 74 chemicals, as well as for subsets of this group. We also divided the group of 74 chemicals into smaller groups of chemicals linked to individual cancer sites or types, and examined each of those groups individually.

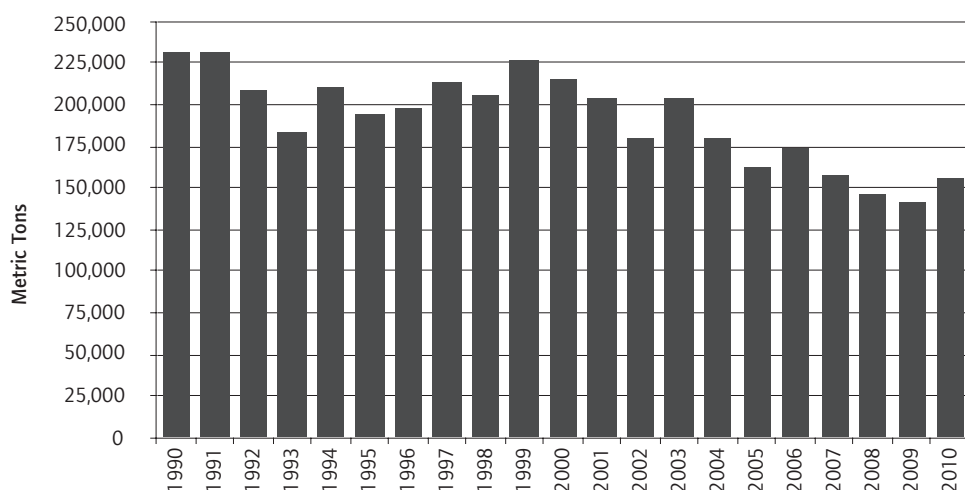
There are some limitations in using the TURA data. Because the law excludes some industry sectors, the TURA programme does not capture chemical use and environmental release data from all businesses that use, manufacture or release chemicals. The TURA data also does not reflect emissions from consumer products. Another limitation is that some facilities subject to TURA requirements have been granted trade-secret

exemptions, rendering their data inaccessible. There are also many important categories of industrial carcinogens that are not captured by the TURA data. These include ionizing radiation, exposures to complex chemical mixtures in workplaces, and exposures in agriculture and via consumer products.

4.1 Overall use and release trends of carcinogens

The data show that from 1990 to 2010, businesses reporting to the TURA programme documented significant reductions in their use and releases of known and suspected carcinogens. While total use fluctuated over the years, overall there was a 32% decline, from 231,078 metric tons in 1990 to 165,802 metric tons in 2010 (Figure 1). The chemical used in the largest quantity was styrene monomer, accounting for 76% of the known and suspected carcinogen total use from 1990 to 2010. Excluding styrene, even greater declines occurred: a 53% reduction, from 51,664 metric tons in 1990, to 24,267 metric tons in 2010.

Figure 1 **Total use of known and suspected carcinogens, Massachusetts TURA Program, 1990-2010**

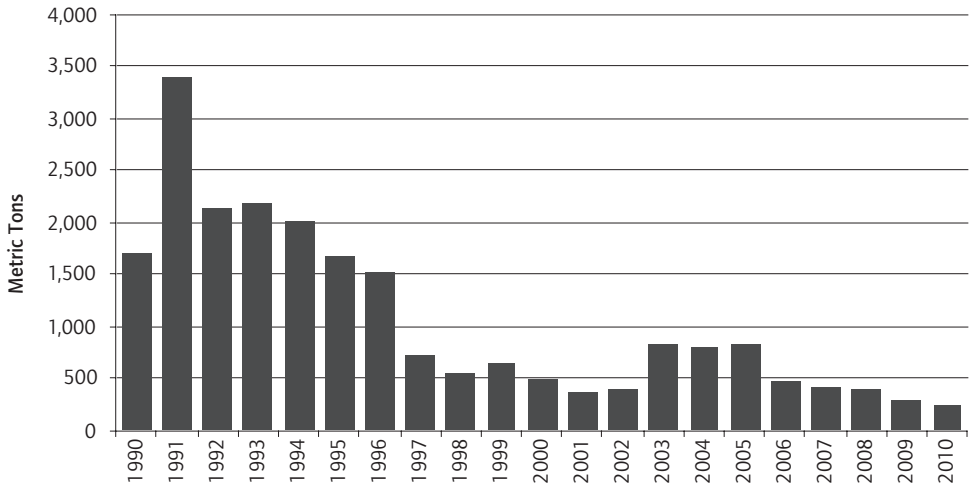


Note: Based on publicly available data. Data claimed trade secret are not included in these figures.

Reporting by electric utilities was phased into the TURA programme in 1991; reductions in emissions are measured beginning that year. Total reported releases have declined substantially since 1991. From 1991 to 2010, releases declined by 93%, from 3,402 metric tons to 249 metric tons, respectively (Figure 2).

While the declines in reported use and release of known and suspected carcinogens by facilities reporting to TURA are promising, large amounts of carcinogens continue to be used and released. In 2010, over 136,000 metric tons of known and suspected carcinogens were used and over 225 metric tons were released to the environment, highlighting the need for on-going efforts to reduce carcinogen use and releases.

Figure 2 **Total environmental releases of known and suspected carcinogens Massachusetts TURA Program, 1990-2010**



Note: Based on publicly available data. Data claimed trade secret are not included in these figures.

4.2 Trends in carcinogens associated with specific cancer sites

We also examined trends for smaller groups of chemicals associated with eleven individual cancer sites, including cancers of the bladder, brain and other central nervous system (CNS), breast, kidney, liver, lung, pancreas, prostate and testis as well as leukemia and non-Hodgkin's lymphoma.

As shown in Table 1 (p. 128), we found that use had decreased for all eleven groups of carcinogens. Releases to the environment have declined for all except the group of chemicals associated with bladder cancer. Because the volume of styrene used far exceeds all other chemicals in Massachusetts, styrene trends can mask those of other chemicals. When we exclude styrene, the declines are greater for a number of categories.

Table 1 Use and environmental releases of carcinogens associated with specific cancer types, percent change, 1990-2010

Type of Carcinogen	Use % Change, 1990-2010	Environmental Releases % Change, 1990-2010
Bladder	-49%*	+18%**
Brain/CNS	-51%	-78%**
Breast/Mammary Gland	-26% (-21%***)	-97%
Kidney	-62%	-86%**
Leukemia	-28% (-59%***)	-86%**
Liver	-58%	-97%
Lung	-31%* (-51%***)	-77%**
Non-Hodgkin's Lymphoma	-28%* (-58%***)	-86%**
Pancreas	-28% (-53%***)	-97%
Prostate	-65%*	-97%
Testis	-88%	-96%

* Overall programme progress is affected by changes in reporting for polycyclic aromatic compounds.

** Trend is influenced by changes in TURA reporting requirements that eliminated the exemption for reporting combustion-related emissions by Waste to Energy (WtE) incinerators.

*** Percent change over the same time period if styrene monomer is excluded from the data.

Note: This table was originally printed in Jacobs *et al.* (2014).

5. Toxics use reduction and cancer prevention: ways forward

Facilities reporting under TURA have achieved significant reductions in their use and releases of carcinogens. These reductions illustrate the benefits of toxics use reduction. When companies are required to examine their use of a toxic chemical, many find ways to use it more efficiently, while many others find options for replacing it with a safer substitute chemical or process.

The Massachusetts Office of Technical Assistance and Technology and the Massachusetts Toxics Use Reduction Institute have documented how these results were achieved in a number of toxics use reduction case studies. Table 2 provides examples of these experiences for 6 known or suspected carcinogens.

While these declines in use and releases of known and suspected carcinogens by facilities reporting to TURA are promising, current quantities being used and released into the environment are still sizable. Key carcinogens that have been used in large quantities over time and still continue to be used in large quantities include styrene monomer, lead and lead compounds, methylene chloride, formaldehyde, and trichloroethylene. The quantities used and released raise continued concern for public and occupational health and indicate a continued need for TUR activities.

Table 2 Carcinogen reduction examples: company case studies

Carcinogen	Toxics use reduction examples
Chloroform	<ul style="list-style-type: none"> ChemGenes Corporation, a biotechnology company with 25 employees, supplies building blocks for DNA and RNA manufacturing. From 2005 to 2012, ChemGenes reduced its use of chloroform by 55% and hexane by 35%, resulting in a net savings of US \$215,000. In 2012, the TURA programme provided a grant to help ChemGenes purchase a new solvent recovery and recycling system, which will allow additional reductions in solvent use. Factoring in the grant, ChemGenes estimates a return on investment in less than two years.
Hexavalent chromium	<ul style="list-style-type: none"> Independent Plating is a metal finishing company. In 2012, Independent Plating installed a trivalent chromium plating line as a substitute for some of its hexavalent chromium processes.
Lead (& cadmium)	<ul style="list-style-type: none"> AlphaGary Corporation (now owned by Mexichem) manufactures plastic compounds for end uses including wire and cable, automotive, consumer goods, packaging and other applications. Beginning in 1998, AlphaGary began work to reduce use of lead in its products. By 2004, the company achieved a 30% reduction in the use of lead and lead compounds, as well as reducing other toxic materials such as cadmium compounds and other heavy metals.
Methylene chloride	<ul style="list-style-type: none"> Crest Foam manufactures flexible polyurethane foam for furniture, cushioning applications for the home, packaging and medical applications. Crest Foam eliminated the use of 86 metric tons/year of methylene chloride by installing an innovative foam manufacturing process that uses CO₂ instead of methylene chloride or CFC-11 as the auxiliary blowing agent. Four Massachusetts facilities were featured in a study of methylene chloride substitution. Three of the facilities (a rubber products company, an electrical equipment manufacturer, and a vessel cleaning company) eliminated methylene chloride, while the fourth (a metal finisher) dramatically reduced its use of methylene chloride.
Perchloroethylene	<ul style="list-style-type: none"> A series of case studies of 8 Massachusetts dry cleaners show how they were able to switch from perchloroethylene to 100% wet cleaning while saving money and reducing their use of energy and water. All the cleaners are small family businesses. Among other examples, KMK Cleaners achieved a 40% reduction in energy costs and more than a 50% reduction in water use, and saved approximately US \$1500 per month in operating costs. Silver Hanger Cleaners reduced electricity use by 20% and natural gas use by 14%, while saving more than US \$2,700 in the first year.
Trichloroethylene	<ul style="list-style-type: none"> V.H. Blackinton is a manufacturer of metal uniform insignia such as badges and metals, as well as jewelry. The facility made substantial investments to modernize its plating and finishing operations, leading to significant reductions in water use and in the use of acids and bases in waste treatment and plating operations. The facility eliminated the use of a number of toxic chemicals, including trichloroethylene. Lightolier is a manufacturer of aluminum reflectors for lighting products with over 400 employees. The facility eliminated the use of approximately 566 metric tons of trichloroethylene. Through process modification and adoption of safer substitutes, the facility eliminated more than 1,814 metric tons of air emissions, with savings of more than US \$2 million.

Note: All the businesses described in this table received assistance from the Massachusetts Office of Technical Assistance and Technology and/or from the Massachusetts Toxics Use Reduction Institute, and the information presented here is drawn from case studies by the two agencies. These case studies are available at: http://www.turi.org/TURI_Publications/Case_Studies

This table was originally printed in Jacobs *et al.* (2014).

5.1 Opportunities for further reductions

The dramatic reductions in carcinogen use and releases over the past twenty years document the feasibility of toxics use reduction as a cancer prevention strategy. There continue to be many opportunities for further reductions in carcinogen use; examples include the following.

Large quantities of formaldehyde continue to be used in the manufacture of adhesives and resins for use in a variety of applications, including the production of chipboard, decorative paper for use in architectural applications, and others. Opportunities for continued reductions in the use of formaldehyde include investment in the development, testing and marketing of safer adhesives and resins based on safer materials.

Hexavalent chromium is another chemical for which important toxics use reduction opportunities exist. Hexavalent chromium is used for corrosion resistance, but can be replaced by safer alternatives in many cases. Some businesses report being reluctant to adopt alternatives primarily due to color consistency. There is an on-going need for collaboration between manufacturers and customers to test and adopt safer alternatives. Research and development is under way to investigate safer alternatives, including trivalent chromium, for a variety of specific applications.

Other notable examples of future TUR/cancer prevention opportunities include reducing the use of methylene chloride and perchloroethylene. Paint strippers containing methylene chloride are banned for consumer use and severely restricted for professional or industrial use in the European Union, but continue to be used in the US.

Perchloroethylene, used widely for garment cleaning, can be replaced entirely with professional wet cleaning, while saving money, energy and water. The TURA programme has provided technical and financial support to many small businesses to help them eliminate this carcinogen from their workplaces. There are minimal technical barriers to shifting to safer alternatives for garment cleaning. There is, however, a significant need for education and financial assistance to enable small businesses to make the transition successfully.

Finally, it should be noted that other regulatory approaches have also been important drivers of changes observed in the TURA data. Examples include OSHA's adoption of regulatory standards for occupational exposure to methylene chloride in 1997, and the US EPA's adoption of Maximum Achievable Control Technology (MACT) standards for halogenated solvents in 1994, as well as subsequent updates (24) (25). More recently, regulations adopted in Europe, such as the Restriction of Hazardous Substances for electronic products, have helped to drive change within Massachusetts (26). There are many opportunities to motivate and facilitate additional TUR in the United States through adoption of complementary regulations at the federal or state level.

Conclusion

Toxics use reduction, which prevents carcinogenic exposures at their source, is a powerful tool for cancer prevention. The large reductions in use and releases of known and suspected carcinogens by facilities reporting to the TURA programme illustrate the impact of toxics use reduction. The experience of this programme has shown that when companies are required to examine their use of a chemical, many find ways to use it more efficiently, others find options to adopt safer substitutes, and others change their manufacturing process altogether to eliminate the need for the chemical. Continued work to minimize the use of carcinogens in manufacturing and services can help to reduce the global burden of cancer.

Acknowledgments

This chapter draws on work previously published, including Jacobs *et al.* (2013) and Jacobs *et al.* (2014). The authors gratefully acknowledge Heather Tenney and Elizabeth Harriman, whose research and guidance were central to the work featured in this chapter.

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Part 3

European legislation and the prevention of occupational cancers

Introduction

When discussing the problem of cancers caused by working conditions, we must always remember that such cancers are perfectly avoidable. To prevent workers dying or suffering from these diseases, all that needs to be done is to eliminate or in some cases just reduce their exposure to carcinogens at work. We now have a sufficient body of scientific research, aetiological and epidemiological data and understanding of workplace reality to identify at least the common elements necessary for effective prevention.

The existence of legislation setting rules for fighting occupational cancers is certainly one of the main pillars. On asking them, companies confirm that legislation is the main factor prompting them to develop prevention policies. The European Union has a range of legislative instruments at its disposal to reduce or even eliminate workplace carcinogens. However, the number of workers exposed to carcinogens in Europe is not going down, as shown by several national surveys of workers. The availability of an appropriate legislative framework is thus of fundamental importance, but not enough to reduce occupational exposure to carcinogens. What is also needed is for this legislation to be known by those whom it targets and that enough resources are available for implementing and enforcing it. The other decisive lever for getting companies to take preventive action is the pressure exerted by workers and their representatives. You will find several concrete examples of union actions in this book. Yet the prevention of occupational diseases is always easier when a legal framework exists. This is the reason why we have devoted a whole section in this book to analysing the legislative situation in Europe, its construction, its strengths and weaknesses, but also its prospects for further development.

In a first contribution, we look back over the history of EU legislation related to preventing occupational cancers. The existing rules can be divided into two main categories: rules governing the marketing and use of chemical substances (including carcinogens) with the REACH and CLP regulations and those specifically targeting the protection of workers exposed to them with the Chemical Agents Directive (CAD) and the Carcinogens and Mutagens Directive (CMD). On tracing the development of these texts, we are immediately struck by the major importance attached to commercial objectives compared to that attached to protecting workers' health. The free movement of goods in Europe was always the primary reason for adopting such laws at EU level, with only secondary importance attached to protecting human health and the environment. It took the scandals associated with vinyl chloride monomer and asbestos

to get the European Commission to start developing specific texts on workplace health. The adoption of the framework directive in 1989 and the CMD in 1990 and finally of the CAD in 1998 constituted milestones in the development of social legislation. These directives were important because they obliged employers to first assess the health risks for workers and then to reduce the risks identified, by for instance substituting hazardous substances by safer alternatives. The directives also established occupational exposure limit values (OELs). The other added value of these texts is that they – once transposed – apply throughout the European Union, imposing minimum standards and requirements which many States would probably not have otherwise introduced.

While no progress was made in OSH legislation during the two terms of office of José Manuel Barroso as head of the European Commission (2004-2014), we must recognize that the rules governing the marketing of chemical substances in Europe have developed in the right direction, providing greater protection for workers. The REACH and CLP regulations were adopted in 2006 and 2008. Despite upholding the ever-present objective of boosting the competitiveness of European industry, they also aim to ensure a high level of health and environmental protection against the risks associated with the use of chemical substances.

In the second contribution in this section, we look at the contributions of these two regulations to preventing carcinogenic, mutagenic or reprotoxic (CMR) risks. Without doubt, these two regulations have helped build up new knowledge on the CMR substances (and the compounds containing them) marketed in Europe. This has led to improved labelling and safety information for those using them in their work. This data is of fundamental importance as it facilitates the assessment and control of risks foreseen in workplace health legislation. The authorisation system imposed by REACH on companies using CMR substances is also proving to be a great incentive for either completely eliminating them or at least substituting them with safer alternatives. This system is allowing the development of synergies with the CMD which requires employers to eliminate or substitute them where technically feasible. However, these two regulations only cover CMR substances marketed in the EU. Yet large numbers of European workers are exposed to carcinogens that have nothing to do with marketed substances, as they are generated during industrial processes. These include diesel engine exhaust emissions, crystalline silica and hardwood dust. The reduction of occupational cancers should thus not rely just on these two regulations and their proper enforcement. Specific health and safety rules for all substances to which workers are exposed are necessary, also governing other such important aspects as training and health surveillance for workers.

The permanent interaction between health and safety rules and market rules gives rise to hundreds of questions in the companies having to apply them. Limit values are a typical example. This instrument is to be found in the Chemical Agents Directive, in the Carcinogens and Mutagens Directive in the form of occupational exposure limits (OELs) and in the REACH regulation in the form of derived no-effect levels (DNELs). In our view, it was important to analyse in detail the way this instrument is used in these three legislative acts.

The third contribution reviews the main current types of OELs for chemical substances (health-based and risk-based limit values) and the different methods used to develop them. It also looks at how the introduction of the REACH regulation has come to influence the notion of limit values in Europe as well as the practical limits of these instruments in general.

The fourth contribution is devoted to an issue debated for more than 15 years in the European institutions: should the scope of the CMD be extended to reprotoxic substances? Six EU Member States have already included them on transposing this directive into their national legislation. The benefits of this extension range from better protection of the reproductive health of about 2 million European workers to a legislative simplification for companies through harmonising OSH legislation and the other EU legislation on chemicals.

The fifth contribution reports on recent progress made in revising the CMD. After a decade of deadlock, this revision was finally relaunched during the Dutch Presidency of the Council in the first half of 2016. This relaunch was the result of the persevering work of the trade unions, alliances forged by the unions with some Member States, but also the need for the Juncker Commission to reinvigorate EU social policy in a context where European citizens are becoming increasingly critical of the construction of the EU.

The final contribution looks at the prospects for further developing the directives protecting workers against chemical risks. The possibility of merging the Chemical Agents Directive and the Carcinogens and Mutagens Directive is already being discussed within the European Commission. The possible contributions of a merged directive towards preventing chemical risks will depend on finding solutions able to overcome the known shortcomings of the two current directives. Possible improvements include the introduction of a detailed action plan requiring employers to minimise exposure to CMR substances, obligations to monitor and report the evolution of exposure to substances of very high concern in the various Member States, and the definition of a method for adopting binding limit values at European level.

Chapter 14

Two-fold legislation: market regulation and workplace prevention

Laurent Vogel

The ESENER survey conducted by the Bilbao Agency emphasises the importance of precise and comprehensive legislation to organise prevention (Rial González *et al.* 2010). According to this survey, which was conducted on the basis of a sample of 36,000 companies, the main factor encouraging companies to develop a prevention policy is the existence of legislation. Ninety percent of companies state that fulfilment of legal obligations is what spurs them to act. In 22 of the 27 countries, this factor heads the responses. In the field of occupational cancer prevention, the importance of a precise and detailed legislative framework is heightened by the dearth of economic incentives within companies, especially as the cost of occupational cancers is almost totally externalised to social security and public health structures.

This contribution briefly analyses the following elements: the development of Community legislation on the marketing of carcinogens and the protection of workers' health. It also addresses the main obstacles encountered in the application of these rules in different Member States. It will be restricted to cancers caused by chemicals, disregarding other carcinogenic factors such as night working, exposure to solar radiation, ionising radiation or biological agents.

In this chapter, we will not be discussing the ongoing process of revising the directive for the protection of workers against carcinogens. Because of the importance of this question, the chapter 18 is devoted to it (page 185).

1. Development of market regulation

For a long time, the European Union ignored the importance of occupational cancers, failing to establish a coherent legislative framework to prevent them. In this field, Community developments were not very different from national developments in its Member States.

The question of harmonising legislation on the marketing of chemicals first arose at the time of creation of the European Economic Community, with the diversity of national legislation considered a potential obstacle to the establishment of the common market. Community rules were adopted with the priority objective of allowing the free circulation of goods. It was only quite slowly that other concerns were taken into account: public health, occupational health and environmental protection. It is therefore not surprising that, on the basis of the Treaty of Rome (1958), the first legislative developments concerned market rules.

2. The 1967 Directive: the illusion of self-regulation by industry

The first Directive adopted goes back to 27 June 1967 (Directive 67/548/EEC). It laid down rules relating to the classification, labelling and packaging of chemicals. It instituted the principle of producer self-regulation, originally without any checks and balances, leaving it up to the chemical industry to determine the intrinsic hazards associated with the substances they were producing. Classification therefore depended mainly on data gathered and selected by the industry, even though the Directive gradually opened up the way to harmonised classification for the most hazardous substances. Such an approach ignored the conflict of interests between a correct assessment of the hazards and the economic profit associated with marketing the substances. Moreover, it took no account of the concrete conditions of use and did not provide for any feedback on the health effects to exposed workers.

In view of the obvious inadequacy of this legislative framework, three strategies were possible with respect to the level of regulation: to strengthen national regulation (this is what France did via its law of 12 July 1977 on the control of chemical products), to count on reform of the Community legislation (the main option for Germany, being mindful of guaranteeing access to the European market for its chemicals) or to wait for hypothetical international agreements (there were lengthy negotiations under the auspices of the OECD, which resulted in 1982 in a purely optional text concerning the data which States *could* require from producers prior to marketing¹).

Reform of Community law took place piecemeal. It multiplied the legislative instruments with respect both to the general market in chemicals and to specific uses (pesticides, cosmetics, etc) or the safety of hazardous installations (the first Seveso Directive 82/501/EEC adopted on 24 June 1982). REACH, the European legislation currently in force for the marketing and use of chemicals, only partially dealt with the drawbacks of a highly fragmented legislative framework, meaning that there are still specific legal systems in different fields.

The 1967 Directive had to be amended many times and has been since supplemented by other legislative instruments intended to mitigate the shortcomings of a self-regulation by the chemical industry limited to the classification and labelling of substances.

In 1976, Directive 76/769/EEC provided for the possibility of restricting the marketing of certain hazardous substances, with fifty-nine measures adopted in 33 years². The asbestos ban, only decided in 1999, shows the slowness of this process.

In 1979, the sixth amendment of the 1967 Directive (Directive 79/831/EEC of 18 September 1979) imposed a distinction between existing substances (about 100,000 substances present on the European market as at 18 September 1981) and new

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1. Decision of 8 December 1982 of the Council of the OECD concerning the minimum pre-marketing set of data in the assessment of chemicals [C(82)196(Final)].
 2. Since the adoption of REACH, the pace of adopting restrictions has slowed down, from the previous average of two new measures a year dropping to just one (Musu 2013).

substances (marketed after 18 September 1981). As regards the latter, manufacturers were required to submit a pre-marketing notification to the competent authorities of one of the Member States. The procedure provided for four elements: a technical dossier supplying the (eco)toxicological data necessary for evaluating the risks which the substance might entail for humans and the environment; a statement concerning the unfavourable effects of the substance in terms of the various uses envisaged; the proposed classification and labelling if the product is hazardous according to the criteria in the Directive; proposals concerning the precautions to be taken for its safe use and disposal. The information required varied depending on the production volume calculated individually (per producer or importer and per year) and independently of an overall estimate of the production volumes for the European market. This shortcoming was mitigated by the fact that the production volume as of which notification was required was 10 kg per year per producer. On this point, the combined rules of REACH and the new CLP Regulation³ represent a regression, illustrating their inability to provide an adequate framework for regulating nanomaterials⁴. Henceforth, the data on substances supplied through the registration dossiers in REACH is only required as of a production volume of 1 tonne per year. The notification of classification required by the CLP regulation can be made after the go-to-market date (within 30 days) and comprises a classification rather than a proposed classification.

The notification obligation introduced for new substances from 1981 onwards was formulated in a particular context. In 1976, the United States had adopted the federal Toxic Substances Control Act (TSCA) after five years of intensive debate in many respects reminiscent of the polemic surrounding the REACH negotiations. At the time, the United States were tending towards a more ambitious policy than the European Union with regard to chemical risks. The reform taking place in Europe in 1979 appeared to be a reaction to this regulatory activity in the United States, provoking the hostility of the European chemical industry (Brickman *et al.* 1985). The debate at that time gave a kind of inverse image of what had occurred at the time of development of REACH, at least with respect to the positions of the state players.

The 7th amendment of the Directive adopted on 30 April 1992 (Directive 92/32/EEC) introduced the obligation for the manufacturer, importer or distributor to provide professional users with a safety data sheet containing the information needed for protecting human health and the environment.

Rules concerning hazardous preparations were instituted with the 1988 adoption of Directive 88/379/EEC⁵. Amended several times, it was completely revised with the adoption of Directive 1999/45/EC.

3. Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures.
4. For numerous nanomaterials, the production volumes are less than one tonne per year per producer. In this case, no registration is obligatory under the terms of REACH. Also, producers tend to under-estimate the fact that the physico-chemical properties of nanomaterials differ appreciably from those of larger particles with the same chemical composition.
5. In this text, a preparation is defined as a mixture or solution comprising two substances or more. In the current terminology, reference is made to mixtures.

In 1993, Regulation (EEC) No 793/93 provided for public authorities to conduct risk assessments of existing substances, but results were disappointing. The inadequate resources allocated to the public toxicological expert bodies combined with the reluctance of the chemical industry to communicate all relevant data made it impossible to overcome the enormous dearth of knowledge on the effects of substances already on the market. Just 141 substances were included in the list of priority substances to be assessed. Thirty-nine assessments were performed before the Regulation was repealed following the entry into force of the REACH reform in 2007.

As time went by, various European regulations were adopted for more specific categories such as medicines, food additives, biocides, waste, cosmetic products, pesticides, detergents, etc. These regulations will not be examined in this article.

The interplay between the provisions of REACH and those of the specific regulations sometimes gives rise to problems. As regards the European regulations on biocides and pesticides, their application has been severely hampered by the European Commission, which has not met its obligations to define criteria concerning endocrine disruptors. These substances play an important role in the increase in hormone-dependent cancers such as breast cancer in women and prostate cancers in men. The Commission's inertia resulted in open conflict with the Member States. In May 2014, Sweden decided to bring a legal action against the European Commission for its failure to meet the obligation to define such criteria by December 2013. The Swedish complaint received the support of several Member States and of the Council of Ministers and the European Parliament. On 16 December 2015, in an unprecedented decision, the General Court of the European Union ruled that the Commission was in breach of EU law by failing to publish the criteria for defining endocrine disruptors.

3. The need for a deep-going reform

By 1995, with the accession of Sweden, Finland and Austria to the EU⁶, the need for radical reform had been acknowledged. The candidates for accession (mainly Sweden) had far more advanced regulation than the Community. Their public opinion would not have allowed just simple alignment with Community rules. During the negotiations over this enlargement of the European Union, the need for a general overhaul of the legislation in force was acknowledged. The act of accession included provisions allowing Austria and Sweden to maintain, for a transitional period of four years, stricter conditions with regard to certain aspects of regulating the chemicals market. Highly symbolically, the first Swedish Commissioner in the European Commission, Ms M. Wallström, was given the environment portfolio between 1999 and 2004. She was to play a very important role in giving impetus to REACH.

Preparations for the reform were undertaken gradually during 1998. The Environment Ministers of the Member States held an informal Council in April 1998 in Chester,

6. The negotiations for enlargement also involved Norway. Norway's accession was rejected by referendum in autumn 1994.

acknowledging the need for reform. On 18 November 1998, the Commission adopted a report on the application of the existing rules⁷, showing that regulation was incoherent, incomplete and poorly applied. It should however be noted that the European Commission was far from adopting a unanimous point of view on this matter. The careful wording of the 1998 report performed the diplomatic function of concealing a certain number of fundamental differences of opinion. Meeting on 20 and 21 December 1998, the Council of Ministers approved the Commission's report, backing a thorough reform.

The differences within the Community institutions came to the fore during 1999. The Commission decided to support a Swedish businessman who was challenging his national legislation. The case involved the general prohibition of the use of trichloroethylene for industrial purposes. The Swedish enterprise Toolex Alpha AB manufactured compact discs and used trichloroethylene to remove grease from production residues. The Swedish chemical product inspectorate refused it authorisation to continue using this substance since the enterprise had not submitted a plan for its substitution.

In July 2000, the European Court of Justice rejected the Commission's point of view and justified its support for the Swedish legislation by means of a general principle of substitution established in Community law (Toolex Alpha AB judgment, 11 July 2000, Case C-473/98). Despite the legal arguments, this trial showed that the Commission remained divided on the imperative need for reform of the Regulation on chemical products and on its content. The support given by the Commission to the Swedish businessman was all the more surprising in that, on 10 May 1999, Parliament and the Council had adopted Directive 1999/33/EC, which extended for a period of two years the derogation allowing Sweden and Austria to apply stricter national rules with regard to certain aspects of the marketing of chemicals. This Directive restated in its recitals the need to undertake a revision of all of the Community rules. Recital 6 stated in particular: 'whereas, during that period [the two years granted for extension of the derogation], coherence of the marketing conditions of hazardous substances and preparations should be sought'. According to the evidence we have gathered from former officials of the European Commission, the Commission's intervention had given rise to deep misgivings in different Directorates-General, which considered that DG Enterprise was aligning itself with the positions of the chemical industry.

For 15 years, we have consistently noted a far more determined political will on the part of DG Environment in favour of policies favourable to human health and the environment⁸. DG Enterprise (renamed DG Growth in 2015) tends to see its own role as a kind of spokesperson for the interests of private companies, wishing to be considered the central decision-making body for chemical products⁹. DG Social Affairs remains

7. Document SEC(1998) 1986 final.

8. With the formation of the new Commission chaired by J.-Cl. Juncker in 2014, the role of DG Environment in European policies concerning chemical risks was greatly reduced. The biocides dossier has been removed from it. This reversal was criticised by environmental protection associations, which detected a sign of strengthening the role of industry lobbies.

9. Mr Geert Dancet, the first director of the European Chemicals Agency (ECHA) based in Helsinki came from the ranks of DG Enterprise and Industry. After the end of a first term of five years, he was reappointed in 2012.

passive. The resources available to it are derisory in comparison with the challenge of chemical risks for workers in Europe. It has fewer than five people working on these matters. The internal tensions came to the surface many times during both the negotiations for REACH and its implementation. Over the two terms of the Barroso Commission, DG Enterprise was able to consolidate its positions thanks to alliances between two successive Commissioners (the German socialist G. Verheugen between 2004 and 2009 and the Italian conservative A. Tajani between 2009 and 2014) and the President of the European Commission. These alliances sometimes damaged the principle of collective responsibility on the basis of which the Commission should adopt positions.

The Commission's White Paper of 27 February 2001 – Strategy for a future chemicals policy (COM(2001) 88 final) – constituted a critical assessment of existing arrangements and proposed significant changes. The different stages of the negotiations were marked by bitter conflicts. Lively debate also took place within the European trade union movement. The European Trade Union Confederation emphasised the need for fundamental reform while the European Mine, Chemical and Energy Workers' Federation (EMCEF) adopted positions close to those of the chemical industry.

Eventually, the most innovative aspects of the White Paper were watered down. It was not just in Europe that REACH came under attack. The Bush administration in the United States racked up the pressure on the European Union not to adopt a regulation increasing the safety obligations of producers of chemical products. In October 2003, the Commission presented its proposal for a regulation. Known by the acronym REACH (Registration, Evaluation, Authorisation of CHemicals), this text was less ambitious than the initial proposals in the White Paper and the draft submitted for public consultation in May 2003. The final compromise, covered by an agreement between Parliament and the Council in December 2006, is a second-rate version in comparison with the initial drafts. It allows industry only to supply highly fragmentary data for two-thirds of the 30 000 substances covered by REACH (for production volumes below 10 t per year per producer). It sets over-lax conditions for the authorisation of substances of very high concern and excludes polymers from the scope of application of the main provisions concerning the registration and evaluation of substances.

REACH was supplemented by Regulation (EC) No 1272/2008 on the classification, labelling and packaging [abbreviated to CLP] of substances and mixtures. Superseding Directives 67/548/EEC and 1999/45/EC, it established a new system based on the globally harmonised system negotiated at international level and is supposed to provide, at worldwide level, for equivalent rules for chemical substances and mixtures with regard to their classification, labelling and packaging. The globally harmonised system does not require the states implementing it to create public control mechanisms which would make notification by producers, examination of the content of the notification and the creation of a stringent harmonised classification determined by the public authorities mandatory. The principles of notification and harmonised classification have clearly been upheld within Europe.

4. A brief initial assessment of REACH

REACH entered into force on 1 June 2007. All CMR substances produced in Europe in quantities exceeding one tonne per year had to be registered before the deadline of 1 December 2010. Furthermore, whatever their production volumes, all substances marketed in Europe and classified as hazardous by their manufacturers had to be notified to ECHA (European Chemicals Agency) before 3 June 2011. Of the 1 300 CMR substances with a harmonised classification in Annex VI to the CLP Regulation, only 67% of them have been registered or notified to the ECHA (ECHA 2015)¹⁰.

According to 2015 ECHA data, 5 675 substances have been notified as CMR (categories 1A, 1B or 2) under the terms of the CLP Regulation, although they are not deemed to be CMR in the harmonised classification (ECHA 2015). Of these substances, 1 169 have been registered under the terms of REACH (which means that they are manufactured or imported at a volume exceeding one tonne per year per manufacturer or importer). These data lead to three conclusions. First, the harmonised classification probably includes significant gaps with respect to the reality of the substances marketed. Second, the fact of limiting the registration of CMRs to substances for which the annual production volume per producer is one tonne constitutes an obstacle to prevention since, according to producers' notifications, there are more than 4 000 different CMRs with production volumes of less than one tonne. Finally, the mechanisms put in place by REACH are too slow and inadequate to rid the market of CMRs.

An additional problem concerns the relative multiplicity of manufacturers (or importers) registering CMRs. The ratio between the number of substances registered and the total number of registration dossiers is of the order of 1 to 10: 419 substances registered as carcinogenic for 3 964 registrations, 223 mutagens registered for 1 642 registrations and 121 reprotoxic substances for 1 451 registrations. The same CMR substance is therefore produced by numerous different manufacturers in the EU and is covered by dossiers that may include significant differences as regards the preventative measures to be adopted¹¹.

The current period corresponds to the gradual implementation of REACH, which is to continue until 2018. This is a decisive stage, during which vital future trends will be decided. The quality of registration dossiers needs in particular to be evaluated. An initial check is undertaken electronically by ECHA, restricted to verifying that all the relevant headings contain information, regardless of their content. The quality of the content of numerous dossiers seems highly problematical. According to ClientEarth, which has reviewed the dossiers for different substances whose effects as endocrine disruptors are known, much of the available and relevant scientific information is not mentioned in the dossiers. The list of candidate substances likely to be subjected to authorisation procedures remains very limited in comparison with all the substances

10. https://echa.europa.eu/documents/10162/13562/cmr_report_2014_en.pdf

11. REACH provided for different methods for exchanging data. As part of a forum for the exchange of information on a single substance, several producers (and/or importers) may decide to establish a consortium to submit a single registration dossier. The formation of a consortium resulting in the submission of a single registration dossier is just an option and not an obligation.

defined as being of great concern under the REACH criteria: 191 substances or groups of substances as of July 2018.

This figure is still far from the 334 substances or groups of substances which are particularly hazardous for workers and which are included in the list of priority substances drawn up by the European Trade Union Confederation (Musu 2011).

The central role played by ECHA also gives rise to legitimate concerns (Schaible and Buonsante 2012). To what extent will it be able to operate without succumbing to the pressure exerted by industry? Does the interpretation it adopts with regard to the content of REACH meet the objectives of the whole REACH text? Two examples illustrate the urgency of these questions.

1. There have already been great controversies with regard to the very restrictive definition which ECHA proposes for the concept what an 'Article' is¹². The number of articles notified due to the presence of a particularly hazardous substance included in the list of candidate substances is very small. Less than 40 substances of extremely great concern had been notified in November 2014. In the great majority of cases, the number of notifications for each substance is limited to less than five different articles. A whole section of the system envisaged by REACH is just not working. To a certain extent, the criteria defined by the Agency have contributed to this paralysis. On 10 September 2015, the European Court of Justice ruled that the ECHA interpretation of 'Article' was too restrictive. For the Court, each of the articles incorporated as a component of a complex product is covered by the duties to notify and to provide information when they contain a substance of very high concern in a concentration above 0.1% of their mass.
2. The introduction of a concept of derived minimal effect level (DMEL) is in no way justified in the text of REACH. The Agency has developed this concept in 'guidance documents'. An examination of DMELs determined by producers with regard to CMRs shows that the levels of health protection they provide are very variable and that the concept of 'tolerable risk' they reflect is clearly less favourable than the OELs [Occupational Exposure Limit Values] defined in Germany for the same substances (Püringer 2011).

The proper functioning of REACH also depends on the active involvement of the public authorities in the different Member States. This involves both the political will and the resources needed to enable public toxicological expertise to be developed. Otherwise, the information available under the terms of REACH depends excessively and dangerously on the data supplied by industry. At present, only a limited number of states are actually cooperating in the proper functioning of REACH. This can be measured quantitatively: of 173 substances proposed for possible inclusion in the list of candidate substances for authorisation, a little fewer than 100 have been proposed by states¹³. The vast majority

¹². This conflict pits ECHA, supported by the European Commission, against six states that interpret the concept of Article more in conformity with the aims of REACH: Belgium, Denmark, France, Germany, Norway and Sweden.

¹³. Data available in December 2014.

of proposals originate from just 7 states: Germany (40 substances), France (17), Sweden (13), the Netherlands (12), Austria (11), Denmark (9) and Norway¹⁴ (7). Other states with a large chemical industry only collaborate marginally: the United Kingdom (2 substances proposed), Belgium (3), Poland (1) and Italy (0).

5. The evolution of European rules for the protection of workers

The European legislation on the protection of workers was introduced later than the market rules. Paradoxically, the question arose over a highly specific situation. In the late 70s, a scandal arose over vinyl chloride monomer (Soffritti *et al.* 2013; Markowitz and Rosner 2013), where it was established that the chemical industry had intentionally concealed vital information concerning the risks of cancer among exposed workers. This explains why, as of 1976, the first Directive adopting measures to limit marketing included vinyl chloride. In 1978, Directive 78/610/EEC was adopted for the protection of workers. Since the legal basis for such a Directive remained uncertain under the terms of the Community Treaty in force at that time, justification for the Directive rested on the assertion that unequal levels of protection for workers had a direct impact on the functioning of the common market.

Framework Directive 80/1107/EEC of 27 November 1980 defined a new approach to health and the safety at work. Centred on industrial hygiene, it provided for the adoption of a set of occupational exposure limit values (OELs) which would be binding in nature for Member States, while allowing them to adopt rules ensuring better protection for workers. These OELs were to be regularly updated to take account of the experience acquired and technical and scientific progress. The Directive provided for the short-term adoption of OELs for nine chemical agents or families of agents: acrylonitrile, asbestos, arsenic and its compounds, benzene, cadmium and its compounds, mercury and its compounds, nickel and its compounds, lead and its compounds, chlorinated hydrocarbons (chloroform, paradichlorobenzene and carbon tetrachloride). Between 1980 and 1988, only two OELs were defined for chemical agents: lead (1982) and asbestos (1983). The inability to reach agreement on a proposed directive concerning benzene brought the whole process to a halt. In 1988, the Framework Directive of 1980 was revised by Directive 88/642/EEC. Henceforth, indicative limit values were adopted, without any binding effect for Member States. The development of indicative OELs has been laborious. On the basis of the 1980 Directive, two lists have been produced (Directives 91/322/EEC and 96/94/EC). Following the adoption of the Directive on chemical risks (Directive 98/24/EC), four lists were adopted on this new legal basis: the first in 2000, the second in 2006, the third in 2009, the fourth in 2017. In all, there are around 120 substances for which an indicative Community OEL has been defined.

On the basis of Directive 80/1107/EEC, Directive 88/364/EEC was adopted, banning four aromatic amines. More general in scope, this Directive banned certain agents or certain activities. The four prohibited carcinogenic substances were included in a list

14. REACH is also applied in the countries of the European Free Trade Association, which includes Norway, Iceland and Liechtenstein.

designed to be supplemented gradually. In reality, this turned out to be the swansong of this period of legislative development.

Fortunately, the political will to improve working conditions was reflected in the adoption of Article 118a of the Treaty under the terms of the provisions of the Single European Act. This made it possible to move on without excessive delay to a new stage in the production of Community legislation. This involved defining, first of all, the essential aspects of prevention in companies, whatever the risk in question and, next, legislating on the different risks by developing more specific texts. This concept formed the basis for Framework Directive 89/391/EEC of June 1989, which extensively updated occupational health law in most Member States.

6. The impetus provided by the Framework Directive of 1989

Since the adoption of Framework Directive 89/391/EEC of 1989, the matter of prevention of cancers has been addressed more systematically. In 1990, a specific Directive was adopted: Council Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work. This text remains the basis for the legislation currently in force. Partially amended in 1997 and 1999¹⁵, an ambitious revision was launched in 2016 (see page 185).

At the time of its adoption, this Directive constituted a positive contribution for the great majority of Member States, which had only highly fragmented and ineffective regulations in the field of protecting workers against carcinogenic chemicals. The Directive went beyond the basic requirements of Framework Directive 89/391 by formulating a general obligation to substitute any carcinogenic agent insofar as technically possible. If this was not possible, the production and use of a carcinogenic agent had to take place in a closed system insofar as technically possible. Otherwise, exposure had to be reduced to the lowest technically possible level. Other preventive measures were envisaged, dependent not on a risk assessment but on the intrinsic hazard characteristics presented by any carcinogenic agent. The Directive clearly sets out the role played by OELs, with its recitals specifying that, even if current scientific knowledge does not make it possible to set a level below which the health risks cease to exist, a reduction in exposure to carcinogenic agents will nonetheless reduce the risks. They emphasise the need to define OELs for all carcinogenic agents: 'limit values and other directly related provisions should be established for all those carcinogens for which the available information, including scientific and technical data, make this possible'.

This important Directive, however, included problematic elements. The experience acquired over more than 25 years shows that these weaknesses have significantly reduced the efficacy of prevention.

¹⁵. The version currently in force is Directive 2004/37 of 29 April 2004, which represents a consolidation of the original Directive with the amendments adopted in 1997 and 1999.

The current scope of application of the Directive concerns workers exposed to carcinogenic and mutagenic substances or preparations¹⁶. When substances have been subject to harmonised classification in categories 1 or 2 (since 2008, the new terminology is 1A and 1B, with the Directive amended correspondingly by Directive 2014/27/EU of 26 February 2014), the scope of application of the Directive is clearly determined. When they meet the criteria for possible classification, the legal uncertainty is major. This is reflected in considerable differences in preventive practices between countries and, in each country, between companies. The Directive does not address the question of substances which have been classified or meet the criteria for classification as suspected carcinogens (former category 3, now category 2). In practice, there is sometimes a difference between the assessments made by the International Agency for Research on Cancer and those used for Community classification. This is the case in particular for formaldehyde, which the IARC considers to be a confirmed carcinogen for humans (group 1), but which was only considered as a suspected carcinogen in the Community classification until 2014 (current class 2) and therefore did not fall within the scope of application of the Directive for the protection of workers¹⁷. But the major difference is to be found elsewhere: the purpose of the Community classification is to facilitate the market while the IARC classification has public health objectives in mind when identifying carcinogenic agents. This means that exposure to carcinogens resulting from the degradation of a substance or, generally, produced by an industrial process are not likely to be incorporated into the Community classification.

The Directive also applies to a list of specific substances, preparations or processes (Annex I to the Directive). This list has just five entries. The discrepancy in scientific knowledge is far more considerable here. As an example, the list mentions hardwood dust, while data exists on the carcinogenic nature of all wood dust. It mentions neither crystalline silica¹⁸ nor diesel particulate emissions, never mind leather dust or rubber dust and fumes, etc. The inadequacies of Annex I also give rise to huge inequalities with regard to prevention. The terminology used is more restrictive than for substances and preparations. Unlike what happens for substances for which a Community classification would be possible, there is no provision for the inclusion of processes meeting the criteria identifying an occupational risk of cancer. Since this is a directive that formulates minimum requirements, the inclusion of other processes depends on national legislation.

The binding OELs (BOELs) determined by the Directive only concerned three substances until 2017: vinyl chloride monomer, benzene and hardwood dust (to which asbestos and lead should be added, for which binding limit values are defined in other directives). This caused two problems. First, these BOELs did not reflect technical progress and need to be revised. Second, the catalogue of binding Community BOELs only covered a very small proportion of workers exposed to carcinogenic or mutagenic

¹⁶. Mutagenic substances were added to the scope of application by Directive 1999/38/EC.

¹⁷. A harmonised classification of formaldehyde as carcinogen 1B came into force in the EU in April 2015.

¹⁸. Crystalline silica was introduced in 2017 when batch 1 of the revised directive was adopted.

substances. Referring to the data from the SUMER 2010 survey¹⁹, it can be seen that, of the 10 carcinogenic chemicals constituting the greatest exposures in France, only two were subject to a binding Community OEL before 2017. These were wood dust (the Community BOEL only concerns hardwoods) and lead (which is not considered carcinogenic in the Community classification and is subject to far too high a limit value from the point of view of health protection). Extending the sample to the 20 agents constituting the most frequent exposures, we see that the contribution of the list of Community OELs to prevention was minimal. A calculation performed on the basis of the SUMER data indicates that the binding Community OELs covered less than 20% of the exposure situations registered for carcinogenic agents²⁰. At national level, there are very great disparities between the number of carcinogenic substances subject to a national OEL and the levels of health protection taken into account. A comparative study by the European Agency for Safety and Health at Work in Bilbao on OELs concerning CMRs shows that the accumulated logjams at Community level have resulted in highly divergent occupational cancer prevention policies in the Member States (Schneider and Kosk-Bienko 2009).

7. Elements for an overall assessment: obstacles in the way of preventing occupational cancers in Member States

The prevention of occupational cancers implies a set of conditions influencing the effectiveness of any prevention policy. These play an enhanced role with respect to risks which are both extremely diffuse and not very socially visible. The experience acquired in the field of prevention makes it possible to identify two core elements in an overall assessment, going beyond the extreme variety of national practices. They relate to the need for collectivisation procedures and to better understanding the great diversity of work involving hazardous exposure.

A coherent legislative framework is a *sine qua non*. Research conducted by the European Agency for Safety and Health at Work shows that, as a driving force for prevention, the existence of legislation is the factor most often cited by employers to explain the implementation of prevention measures (Rial González *et al.* 2010). As a general rule, both at Community level and in the different countries, the legislation enacted essentially concerns the first circle of prevention, putting obligations on employers and providing a framework for prevention activities in companies. Beyond this key dimension, questions should be asked about the weakness of public structures, mainly with respect to collectivisation and control.

19. There is no European data comparable with SUMER. The CAREX programme intended to evaluate the number of workers exposed to carcinogenic substances in Europe supplied data for the '90s (Kauppinen 2000). It was then interrupted. Since 2000, the European Commission has no longer supplied any statistical data on this matter. The European survey on working conditions does not draw any distinction between exposure to carcinogenic agents and exposure to other chemical risks.

20. Of 3,316,000 exposure situations recorded by SUMER 2010, about 600,000 are covered by a binding Community OEL. The actual percentage is lower if it is considered that the Community OEL only concerned hardwood dust, while SUMER lists all of the situations of exposure to wood dust.

The dearth of data originating from different Member States suggests that substitution is only being implemented by a small number of companies and with respect to a limited number of substances. It is more frequent for CMRs used as inputs to the production cycle than for CMRs generated during the production cycle. One of the obstacles to substitution is the weakness of public structures providing access to precise data on alternatives. At Community level, the legislation has never been supplemented by such collectivisation structures. In the Member States, experiences are varied but remain globally inadequate. Public collectivisation bodies are called upon to play a role not just in the field of substitution but in all prevention measures: better knowledge of the risks associated with processes, OEL usefulness and limits, *de facto* performance of personal protection equipment, methods for integrating the prevention of cancers into risk assessments, the role of prevention services and the contribution of a multidisciplinary approach, in particular through ergotoxicology.

The status of prevention services in almost all Community countries also gives rise to problems. Only a few very large companies have in-house prevention specialists with all the skills needed to fight occupational cancers. The majority of services are inter-enterprise services working in a competitive market. They generally design their interventions in a contractual framework with companies which are seen as 'clients'. The control exerted over their independence with respect to employers and over the quality of their work both by workers' organisations and by the labour inspectorate is weak. The services tend to neglect their role in public health (or, worse, they confuse this role with a vague promotion of individual health in a context totally foreign to their mission to transform working conditions). They contribute little to the implementation of collective monitoring systems, whether involving toxicovigilance or mapping actual exposures in relation to work activities. Also, in numerous European countries, there has been a significant weakening of occupational medicine within the prevention services.

The public authorities also have a responsibility in these shortcomings. Though they have access to a set of information defined by the Community Directive, they take few initiatives for information to be effectively gathered, analysed and used to improve prevention. There is no real interaction between workplace prevention services and the public health structures involved in the fight against cancer. Apart from the Nordic countries (Pukkala *et al.* 2009), the national cancer registers are not used systematically to establish links between the work done by patients throughout their working lives and cancer locations. There is generally no monitoring of post-employment health.

The implementation of public information systems is an important issue. Practice shows that numerous companies using chemical products often only have fragmented, and sometimes contradictory information. The data they obtain from suppliers only partially meets their prevention needs. Some data is inaccurate or is formulated in too unspecific terms. An improvement in the information supplied is one of the anticipated consequences of the implementation of REACH but this is not enough. A more effective fight against occupational cancers therefore also involves prevention strategies able to overcome the shortcomings of a fragmented approach, company by company. Though a European strategy in this field would make it possible to achieve greater effectiveness, in the current political context this is considered unlikely. National strategies,

accompanied by cooperation between the public prevention institutions in different countries, are more likely to be put in place.

The development of research is also an important element. The prevention of occupational cancers is still largely guided by knowledge and depictions essentially going back to the '70s and '80s, without consistently incorporating new scientific data on carcinogenesis (Clapp *et al.* 2007). Similarly, findings from epigenetic research and the study of the role played by endocrine disruptors along with the transgenerational effects of certain occupational exposures are ignored. Beyond the incorporation of new scientific data, questions should also be asked about the social construction of prevention practices and their underlying depictions. In particular, the depiction whereby working conditions only play a marginal role in cancers in women merits critical analysis. Although it is true that the share of work where exposure is very high (in particular in construction) is male-dominated, this does not mean that women are sheltered from other types of carcinogenic exposure at work. It is likely that there is a vicious circle between the priority given to male groups in the epidemiology of occupational risks of cancer, the weakness of prevention systems in highly feminised activities and the particularly dramatic levels of under-recognition of occupational cancers in women. Recent studies have highlighted high risks of breast cancer among women in various occupational groups (Engel and Rasanayagam 2015). For some occupations, exposures to chemical substances are the main explanatory factor. For instance, the risk of breast cancer is 5 times higher in the hairdressing and cosmetics sectors, as also among food and beverage production workers. It is 4.5 times higher among dry cleaning and laundry workers, and 4 times higher among workers in the paper and printing industry and among those making rubber and plastic products.

Another important obstacle in the way of improving prevention strategies is the fact that legislation, both at European level and in the different countries, solely imposes minimum obligations on employers. In numerous cases, the reality of risks is more complex. They tend to be concentrated in subcontracting chains and, in any case, to be subject to less systematic prevention throughout such chains. A broadened approach not limited to the employer, but instead assigning prevention obligations to the overall contractor could considerably improve prevention effectiveness. Among the significant data in the results of the SUMER 2010 survey, the two areas of occupational activity where employees are most exposed to carcinogenic agents are maintenance (43%) and building and public works (32%), both of which are greatly associated with subcontracting. Moreover, a sector approach could also make a useful contribution, in particular by developing prevention measures which take account of the frequency of multiple exposures and by identifying 'cocktails' relatively typical for certain activities.

8. Conclusions

In such a complex field, market rules are in constant interaction with occupational health rules. Regulation must be based on public research in numerous different fields and collectivisation tools are essential in order to improve prevention practices. The added value of a Community policy seems obvious. Suffice to note that, before the adoption of

the 1990 Directive on occupational exposure to carcinogenic agents, national legislation was piecemeal and purely reactive, addressing – without any overall coherence – just a few specific risks (asbestos, vinyl chloride, benzene, etc.). In 1990, the majority of Member States of the European Union had not yet ratified ILO Convention 139 (the Occupational Cancer Convention) of 1974, even though its provisions are minimalist²¹.

As shown by more than 40 years' experience, the obstacles in the way of a Community policy are considerable. The challenge is far more antagonistic than for work-related accidents. Effective prevention of occupational cancers would bring to the fore an important factor in social inequalities in health, running contrary to the dominant trend towards an increase in inequalities in most fields. Beyond this challenge for society, it may also be stated that there are few financial incentives pushing employers to upgrade prevention. The morbidity and mortality caused by occupational cancers only involve marginal costs for companies, in particular owing to the often very long latency periods between exposure and the appearance of pathologies. In the great majority of cases, exposure to carcinogens is not associated with a dysfunction in the production process and does not disrupt it. The pressure exerted by the trade union movement is also less strong than in other prevention fields. Different factors contribute to this situation: lower social visibility, great differentiations in the levels of risk depending on the sectors, difficulties in supporting collective intervention at an appropriate level of expertise, the tendency to delegate the most complex questions of prevention to specialists.

Although in some countries, including France, the question of asbestos triggered an acute awareness of the importance of preventing occupational cancers (Henry 2007), the European Union has an institutional culture distancing it from societal expectations. Though the health catastrophe was no less severe in the other countries of Europe, the asbestos scandal did not really leave its mark on the European political scene. Suffice it to note the relative indifference to the European Commission's decision to allow Germany to import several tens of tonnes of asbestos each year until 2017. Discrete lobbying by the companies involved (mainly Dow Chemical) was enough for the European Commission to postpone until 2025 the date of the total ban on asbestos initially planned for 2005²² and to turn a blind eye to the clear illegality of the exemption granted by the German authorities to Dow Chemical²³. The possible health impact of this measure is no doubt minor (except, of course, for asbestos mine workers located in Brazil and in transport activities from the mine to the ports) but its symbolic impact is considerable: it is hampering efforts to ban asbestos worldwide.

Apart from questions of health at work, another factor is increasingly involved. The Community institutions share, to varying degrees, the ideology whereby the ultimate legitimacy of any legislation lies in its economic efficacy. This is a common base for the beliefs of different institutions from the Commission to the European Court of Justice.

21. As of January 2015, 13 EU Member States had not yet ratified this convention: Austria, Bulgaria, Cyprus, Spain, Estonia, Greece, Latvia, Lithuania, Luxembourg, Malta, Poland, Romania and the United Kingdom.

22. ECHA supports the maintenance of this derogation until 31 December 2025. This position reflects the intense lobbying conducted by the multinational Dow Chemical.

23. On the basis of Community law, Germany was able to grant an exemption concerning the import of membranes containing asbestos fibres. The exemption has been extended to the import of fibres.

This instrumental vision of legislation expresses a convergence between the apologists for market laws in the liberal tradition and the political and economic elites of Central and Eastern Europe trained in the Stalinist tradition. While not ruling out debate between different political options, this view considerably impoverishes it and above all shuts the door on social mobilisations and debates on social projects. This tendency can be seen, often like a caricature, in the implementation of a regulatory strategy whose watchwords are impact assessments, the reduction of ‘administrative burdens’ and the simplification of companies’ obligations (Vogel and Van den Abeele 2010). The legitimacy of legislation on occupational cancers lies in the reduction of social inequalities in health and in the coherence of rules intended to reduce an employee’s life, body and health to the status of goods (‘human *resources*’) to be exchanged for a salary. Such legitimacy justifies a significant limitation of the freedom to engage in enterprise and of employers’ prerogatives in technological choices and the organisation of work. This is one of those fields where it seems obvious that the sum of individual egos never results in collective happiness, whatever trust is put in the invisible hand of the market.

The logjam in European policy concerning occupational cancers implies a clear risk of this core element of any prevention strategy being renationalised. This would have two major drawbacks: a loss of effectiveness through the dispersion of efforts among the 28 Member States (a trend already visible in the production of OELs and in the campaigns in favour of substitution) and a negative spiral of competition that would hamper the efforts made in those countries which have made most progress over the last 10 years. Eventually, the question is whether the European Union, which, in the ‘90s, played a stimulating role in prevention policies in the field of occupational health, is at risk of becoming an obstacle to progress in this field.

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Chapter 15

Contributions of the REACH and CLP Regulations to preventing CMR risks

Tony Musu

The vast majority of chemical substances present on the European market have been marketed without sufficient knowledge of their effects on human health or the environment (European Commission 2001). Consumers and professional users are faced with labelling not adequately informing them of the hazards of the substances and mixtures to which they are exposed. Similarly, in the workplace, workers who handle hazardous substances and mixtures use safety data sheets ill-suited to risk prevention.

In order to overcome these problems, the European Union adopted the REACH Regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals) at the end of 2006 and the CLP Regulation (Classification, Labelling and Packaging) in 2008. One of the main aims of these regulations is to ensure a high level of health and environmental protection against risks linked to exposure to chemical substances, including carcinogenic, mutagenic or reprotoxic (CMR) substances.

1. More than 8,000 CMR substances in circulation in Europe ...

Estimated at 323 million tonnes in 2015, the total volume of chemical substances produced each year in the EU28 is impressive. 10% of this (i.e. 32.3 million tonnes) involves CMR substances (Eurostat 2014). One of the benefits of the REACH and CLP Regulations managed by the Helsinki-based European Chemicals Agency (ECHA) is that they ensure more accurate information on the identity and number of these substances. According to data provided by suppliers, over 120,000 different hazardous substances are present on the European market, of which 8,268 are regarded as CMR (category 1A, 1B or 2). These figures are taken from the Classification & Labelling Inventory maintained by the ECHA as a result of the obligation under the CLP Regulation for suppliers to notify the Agency of the classification and labelling of all hazardous substances that they market in the EU, whatever the volume of production.

2. ...but only 1,500 CMR substances with a harmonised classification

The CLP Regulation also stipulates that all category 1A, 1B or 2 CMR substances and category 1 respiratory sensitisers shall normally have a harmonised classification and labelling. The aim is to force the various companies marketing these substances to provide the same information on their intrinsic hazards to all participants in the supply chain.

When the list of around 8,000 CMR substances notified to the ECHA is compared with the list of chemical substances with a harmonised classification (Annex VI to the CLP Regulation), it is clear that only around 1,500 substances (~20%) have a harmonised classification and labelling as CMR substances (see Table 1). The rest are marketed with the classification and labelling determined by their suppliers based on the rules defined in the CLP Regulation. This self-classification system, which also applied under the previous legislation (Directive 67/548/EEC), is therefore used for ~80% of the CMR substances present on the European market. This has a major drawback: the classification and labelling of the same CMR substance may vary from one supplier to another depending on their interpretation of the classification rules. The *raison d'être* of the ECHA public inventory is therefore to highlight the different self-classifications of the same substance in order to encourage companies marketing those substances to agree on a single classification.

Table 1 Number of CMR substances officially listed in the EU in July 2017

Type of CMR substance (category 1A/1B/2)	ECHA Classification and Labelling Inventory	Annex VI to the CLP Regulation	Self-classifications proposed by manufacturers
Carcinogenic	4,427	1,224	3,203
Mutagenic	2,413	620	1,793
Reprotoxic	4,566	389	4,177
Total	8,268	1,517	6,751

Note: category 1A: known for humans; category 1B: presumed for humans; category 2: suspected for humans.

The harmonised classification of CMR substances is important, not only because it allows all European workers and consumers to be informed through the same labelling, but also because it automatically brings these substances within the scope of around 20 other pieces of European legislation controlling their use. These include regulations on pesticides, biocides and cosmetics, as well as various directives on worker protection. For instance, although formaldehyde was classified as carcinogenic for humans in 2004 by the International Agency for Research on Cancer (IARC), it has only been covered by the Carcinogens and Mutagens Directive since May 2015, when it was included in Annex VI to the CLP Regulation under the harmonised classification of a category 1B carcinogen. This now forces employers to eliminate or replace this industrial compound in the workplace with a less hazardous substance or process. This tightening of the regulations should result in reduced exposure for millions of workers in Europe due to changes to production facilities.

An ECHA report on CMR substances confirms that around 6,000 CMR substances are being marketed in Europe without a harmonised classification (ECHA 2015). Unfortunately it is clear that this harmonisation work, undertaken by an ECHA scientific committee following the adoption of the CLP Regulation, is quite slow. The harmonised classifications of almost all the 1,500 CMR substances in the current Annex VI were adopted under the previous European legislation (1967 Directive on the classification of dangerous substances). According to another report of the Agency, between 2009 and 2016 only 35 new CMR substances were added to Annex VI to the CLP Regulation, and

only 10 former CMR substances on this list saw their harmonised classification updated (ECHA 2017).

3. What about the missing data on CMRs in circulation in the EU?

Companies are also required, this time by the REACH Regulation, to provide the ECHA with a registration dossier for each chemical substance manufactured in or imported into the EU above 1 tonne per year. Around 22,000 substances are estimated to be registered out of the 120,000 substances currently listed. This system, based on the ‘no data, no market’ principle, was designed to force registrants to collect and supply ECHA with the missing data on the substances that they market. Throughout the supply chain, companies are also required to provide the information needed for safe use of their substances by means of safety data sheets.

Out of the roughly 8,000 CMR substances present on the European market, at least 1,169 (~15%) have been registered with the Helsinki Agency (ECHA 2015). This relatively modest proportion is explained by the registration rules laid down by the REACH Regulation. In essence, if less than one tonne of the substance is produced per year and per manufacturer, there is no registration obligation. The same applies to all substances falling within the scope of other specific European legislation (pesticides, biocides, cosmetics, medicinal products) or that are used for research and development purposes. This means that the number of CMR substances marketed in Europe for which REACH ensures that some of the missing data is collected (physical properties, (eco)toxicological information, uses, identity of manufacturers, volumes) is limited. However, this still covers a large part of the 32.3 million tonnes of CMR substances that circulate each year on the European market.

The data currently required for REACH registration does not always allow new CMRs to be identified. For example, serious doubts have been raised over the likelihood that potential effects on hormonally mediated carcinogenesis will be detected for registered substances on the basis of current requirements (Kortenkamp *et al.* 2011).

4. The REACH system of authorisation

In addition to the registration system provided for by REACH, companies must obtain authorisation for each of the uses made of CMR substances and other substances of very high concern¹ that are included in Annex XIV to REACH (authorisation list).

These substances cannot be placed on the market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation. This system was designed to encourage manufacturers to progressively replace

1. Substances of very high concern under the REACH Regulation are substances that are carcinogenic, mutagenic and reprotoxic (categories 1A and 1B), PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) as well as substances giving rise to an equivalent level of concern (endocrine disruptors or sensitisers).

substances of very high concern with safer alternatives. The authorisation procedures are in fact long and costly and companies have a vested interest in avoiding them if the use of these substances is not essential to their industrial activities.

To obtain authorisation, the applicant must demonstrate, through an application dossier, that the risk from the use of the substance is 'adequately controlled'. If not, authorisation may still be granted if it is proven that the socio-economic benefits of using the substance outweigh the risks and if there are no suitable alternative substances or technologies available. Authorisations are granted by the European Commission based on an opinion prepared by the ECHA. They are issued for a set period and on a case-by-case basis. The authorisation procedure could in theory be applied to all CMRs (1A and 1B) registered under REACH, whatever their volume of production. However, in practice, a system of selection is provided for by the Regulation because the Helsinki Agency can only deal with a limited number of applications for authorisation per year. Substances are initially included in a candidate list, before being transferred, where applicable, to the list of substances subject to authorisation (Annex XIV). Ten years after the REACH Regulation entered into force, the candidate list contains only 174 substances (including 151 CMRs) and Annex XIV itself contains only 43 substances (including 39 CMRs). The substances included in Annex XIV are selected from among those on the candidate list, in particular by prioritising those produced in large volumes. This means that numerous CMR substances produced in low or average volumes (< 1,000 t/year) will continue to be used pending their possible inclusion in the REACH authorisation system. At the rate that substances are being included in the candidate list and then transferred to the authorisation list, it will be a very long time before all CMR substances (1A or 1B) registered under REACH are assessed. Following criticism of the slowness of the system, in 2013 the European Commission, in collaboration with the Member States and the ECHA, adopted a Roadmap on Substances of Very High Concern (Council of the EU 2013), undertaking to ensure that all relevant and currently known substances of very high concern are included in the REACH candidate list by the end of 2020. Environmental NGOs and trade unions have drawn up their own lists of substances that they consider should be included in the REACH candidate list. In total, the SIN list of the NGOs (Chemsec 2014) and the list of the European Trade Union Confederation (ETUC 2011) identify nearly 900 substances of very high concern. With only 174 substances on the candidate list just three years before the deadline set by the Commission, it is highly likely that the civil society organisations will be sorely disappointed by the results of the roadmap.

5. Initial assessment of the authorisation system

From January 2013 until the end of December 2016, 111 applications for authorisation for a total of 22 substances of very high concern had been received by the ECHA from 195 applicants (see Table 2). The Helsinki Agency and its scientific committees must prepare an opinion on each application to help the Commission decide whether or not to grant the authorisation requested. Out of the 119 opinions already adopted, the ECHA has not yet given a negative opinion to the Commission. In all cases the Agency has recommended granting the authorisation for use requested by the applicants, and

the Commission has already formally granted 34 of these authorisations. It is likely that the Commission will systematically follow the ECHA's opinion.

Table 2 Overview of applications for authorisation received and processed by the ECHA (Jan 2013 - Dec 2016)

Substance	Intrinsic properties	Received applications	Number of applicants	Number of uses	ECHA opinions per use	Commission decisions per use
DEHP and BP	CMR	8	10	17	17	10
Lead chromate pigments (yellow and red)	CMR	1	1	12	12	12
HBCDD	PBT	1	13	2	2	2
Diarsenic trioxide	CMR	4	4	5	5	5
Trichloroethylene	CMR	13	15	19	19	5
Lead chromate	CMR	1	1	1	1	-
Chromium trioxide	CMR	25	61	41	21	-
Sodium dichromate	CMR	17	23	23	15	-
Sodium chromate	CMR	2	4	3	1	-
1,2-Dichloroethane (EDC)	CMR	15	17	19	5	-
Chromium trioxide, Sodium dichromate and Potassium dichromate	CMR	1	6	3	3	-
Potassium dichromate	CMR	4	4	7	4	-
Ammonium dichromate	CMR	3	5	4	2	-
Dichromium tris(chromate)	CMR	1	2	2	2	-
Chromium trioxide ; Dichromium tris(chromate)	CMR	1	2	4	4	-
Strontium chromate	CMR	1	10	2	2	-
Potassium hydroxy octaoxodi zincate dichromate	CMR	1	5	2	2	-
bis (2-methoxyethyl) ether Diglyme	CMR	8	8	9	1	-
Arsenic acid	CMR	1	1	1	-	-
Chromic acid	CMR	1	1	1	1	-
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	CMR	1	1	2	-	-
2,2-dichloro-4,4'-methylenedianiline (MOCA)	CMR	1	1	1	-	-
Total		111	195	180	119	34

Note: an application for authorisation may be submitted by one or more companies. The application may cover one or more uses. Authorisations are granted (or refused) for a specific use and to each applicant.

Source: https://echa.europa.eu/documents/10162/19126370/svhc_roadmap_2017_en.pdf

However, in the view of certain observers, several dossiers do not meet the conditions for authorisation to be granted. This is the case, for example, with the application for authorisation of DEHP, a substance in the phthalate family used as a plasticiser in recycled PVC articles. According to the environmental NGOs, safer alternatives are available on the market and the ECHA should logically have given a negative opinion. The ECHA recognises in its opinions that certain alternatives exist, but as these are more expensive to use than DEHP, the Agency regards them as economically unfeasible for applicants. This practice of the ECHA is debatable because the REACH legislation does not define what constitutes an economically feasible alternative.

6. The ECHA's pro-industrial attitude

It would appear that the ECHA's strategy is to systematically give a favourable opinion to show that the system works and so that future applicants are not deterred from applying for authorisation. The Helsinki Agency also, on its own initiative, organises information sessions prior to the submission of dossiers in order to better prepare those companies using Annex XIV substances. When poor-quality dossiers are submitted, an analysis of the opinions adopted to date shows that the ECHA prefers to grant the authorisation for a short period rather than give a negative opinion. This pro-industrial attitude of the ECHA is not new. The aims of REACH also include the efficient functioning of the internal market and enhanced European competitiveness. The Helsinki Agency has already shown that it is ready to protect the interests of companies, such as, for example, when it had to decide on the balance between protecting commercial data in its possession and transparency vis-à-vis the public (EEB and ClientEarth 2012). In assessing applications for authorisation, two factors have certainly influenced its policy. First, the economic crisis. The ECHA takes the view that, if companies apply for an authorisation that can cost them over EUR 200,000, this is because they really need this authorisation and they should not be penalised by a refusal, particularly against the background of an economic slump. Secondly, there is the Commission's REFIT deregulation programme. All European legislation is being screened to check whether it is truly fit for purpose. As far as the Agency is concerned, it is therefore essential to show that the REACH authorisation system works and is not an obstacle to the efficient functioning of the internal market.

Although we may wonder whether an authorisation system under which no application is ever refused is efficiently functioning, it is worth noting that the aim of encouraging substitution seems to be bearing fruit. For example, no application for authorisation was received by the ECHA before the cut-off date for certain substances of very high concern included in Annex XIV (this was the case, for example, with the fragrance Musk Xylene and the processing agent 4,4'-methylenedianiline). All uses of these substances are therefore automatically prohibited in Europe and only their replacements may be used. Small and medium-sized enterprises in the craft glass production sector have also chosen to find alternatives to the use of arsenic trioxide, rather than trying to obtain authorisation to continue using this carcinogenic substance (Alhaique 2013). It is also generally noted that, when substances are included in the candidate list, many companies stop using them in anticipation of their potential transfer to Annex XIV and the possible break in supply if authorisations were to be refused.

7. Conclusions

The REACH and CLP Regulations have undoubtedly improved European legislation on the use and marketing of chemical substances, including CMR substances. The obligation to register all CMR substances (category 1A and 1B) produced above 1 tonne per year has led to new knowledge being acquired and the quality of labelling and of many safety data sheets being improved for professional users. The obligation to notify classifications and labelling has enabled an inventory to be made of all CMR substances present on the European market (whatever their volume of production). As this inventory is public, it ultimately ensures greater transparency with regard to the CMR substances around us. It is also useful to the authorities in selecting priority CMR substances for harmonised classification.

Although these two regulations now ensure a better understanding of the hazards and risks of numerous CMR substances synthesised by humans, it should be noted that very many European workers are exposed to carcinogens not covered by these regulations. These are CMR substances that result from industrial processes and that are not intended to be marketed, such as diesel emissions, crystalline silica, wood dust, etc. The reduction of occupational cancers, which we should remember are the primary cause of occupational mortality, cannot therefore rest entirely on these two pieces of legislation and their correct application.

However, the fact remains that the authorisation system provided for under REACH genuinely encourages the replacement of carcinogens and therefore prevents occupational cancers. It is regrettable that it is not being fully used by the ECHA, the Commission and the Member States, not only to reduce the huge direct and indirect costs of using substances of very high concern, but also to encourage innovation and the green economy.

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Chapter 16

Occupational exposure limits: uses and limitations in worker protection

Tony Musu

Occupational exposure limits (OELs) are important tools for assessing and monitoring workers' exposure to hazardous substances. They have been used for decades in all industrialised countries to help prevent adverse effects on the health of people exposed to hazardous chemical agents in their workplace. An OEL can be defined as the concentration of a substance, most often in the working atmosphere, to which workers may be exposed repeatedly (throughout their working life) or acutely (for a short time) without any adverse effects on their health or that of their descendants at any time. Comparing the concentration of a hazardous substance measured in the atmosphere to its occupational exposure limit can help to assess the risks for exposed workers and to select appropriate measures to manage such risks. OELs can also be used to check and improve the effectiveness of implemented risk management measures.

We should make it clear from the start that complying with the exposure limits should under no circumstances be considered to be an end goal that will ensure effective prevention. Effective prevention requires a whole range of measures, the priority of which must be to eliminate hazardous chemical substances or replace them with safer processes or alternatives. If elimination or replacement is not possible, then workers' exposure level should be reduced to a minimum by application of a set of preventive and protective measures. Priority should be given to collective measures over individual measures. These principles are established and applied throughout Europe under the EU legislation in force on the protection of workers' health from chemical risks.

The substances for which OELs are set, the methods used to determine the OELs, their legal status and the practices used to revise and implement them in workplaces vary from one industrialised country to another (EU-OSHA 1999; Walters *et al.* 2003; Schenk *et al.* 2008). It is no surprise, then, that different countries apply different OELs for the same substance.

In this chapter, we will review the main types of OEL that exist for chemical substances and the different methods used to develop them. We will also discuss the influence of the REACH regulation on the use of exposure limits in Europe, as well as the general limitations of using OELs.

1. Health-based and risk-based exposure limits

The definition of OELs set out in the introduction to this article implies that it is possible, using the available scientific data, to identify a single exposure threshold below which exposure to a substance causes no adverse effects. In such cases, we talk about ‘health-based OELs’. One substance with this kind of OEL is ethyl acetate, a flammable solvent used mainly in the preparation of paints, plastics, foodstuffs, pharmaceuticals and printing inks. It is an eye irritant with low acute toxicity and can cause drowsiness or dizziness, but none of these effects are expected to be observed in human beings below its OEL of 734 mg/m³ (8-hour time-weighted average).

When the state of knowledge about a substance is not sufficient to determine a single threshold below which no adverse effects on health are observed, we must assume that every level of exposure, however low, brings with it risks of adverse effects. This is the case for ‘non-threshold’ substances such as genotoxic carcinogens, which damage DNA, and respiratory sensitisers. It is possible to develop OELs in such a situation, but they will necessarily be associated with a risk. This risk will have been determined in advance and considered low enough to be ‘acceptable’. In such cases, we talk about ‘risk-based OELs’. This method is currently applied in the Netherlands and Germany (Pronk 2014). While the relationship between levels of exposure to a non-threshold carcinogen and the corresponding risks of developing cancer can be scientifically determined, the definition of what constitutes an ‘acceptable’ risk is a political decision that calls for a societal debate. For example, in the Netherlands, the government decided that no worker could be exposed to a carcinogen at an atmospheric concentration higher than that at which the risk of developing cancer is 4 additional cases per 1000 workers exposed over a 40-year career. This concentration varies from one carcinogen to the next. For arsenic trioxide, which has been proven to be carcinogenic to humans and is used in the glass industry, this risk of 4×10^{-3} corresponds to an OEL of 7 µg/m³. Additional details about the principles for establishing risk-based OELs are available in Henning Wriedt’s contribution in this book (see page 95).

The progress made in recent years in understanding cancer risk and the behaviour of carcinogenic substances suggests that a distinction may be made between genotoxic and non-genotoxic substances (European Commission 2013). For the latter, a no-observed-adverse-effect level may be determined because the cancer risk is dose-dependent and does not involve DNA damage or mutations. In practice, this means that a health-based OEL may be proposed for some carcinogens (such as chloroform or carbon tetrachloride). Similarly, some genotoxic substances could act in a dose-dependent way and a ‘pragmatic’ no-observed-adverse-effect level could be calculated based on mechanistic studies. The following carcinogens could fall within this category: nickel compounds, cadmium compounds, formaldehyde and crystalline silica. It should be noted that this distinction between different types of carcinogens seems to be becoming an established feature of the regulatory landscape both in Europe (REACH Regulation) and elsewhere in the world, though it remains controversial (ETUI 2012).

2. OELs: from scientific concept to social construct

The first stage in establishing an OEL is generally based on scientific knowledge. Experts collect all the relevant data available about the substance (intrinsic properties, studies on humans and/or animals describing the short- and long-term adverse effects, target organs, etc.) and determine whether the substance acts via a non-threshold mechanism or whether a traditional toxicological model (with a threshold) may be used. In the latter case, they establish the no-observed-adverse-effect level (NOAEL) which will be used as a basis for determining the OEL. As the experimental or epidemiological data available is often limited, uncertainty factors (sometimes known as ‘assessment factors’ or ‘safety factors’) are used to take inter- and intra-species variations and other necessary extrapolations into account. The final health-based OEL value for the workplace atmosphere is obtained by dividing the NOAEL value by the uncertainty factors. A public consultation is held during the procedure so that comments and/or information from third parties can be taken into consideration. The OEL is expressed in mg/m³ or parts per million (ppm). The value supplied is generally the time-weighted average (TWA), which is the average concentration of a substance in the air without adverse effects for workers over a normal working period of 8 hours per day or 40 hours per week. It is sometimes accompanied by a short-term exposure limit (STEL) to prevent adverse effects that may arise from brief exposure (typically 15 minutes).

This general methodology is used throughout the world. It is applied, for example, by the American Conference of Governmental Industrial Hygienists (ACGIH) in the United States and by the Scientific Committee on Occupational Exposure Limits (SCOEL) in Europe. Both these bodies set health-based OELs which are published in the form of recommendations.

There can then be a second stage of the process, in which the recommended values may be modified in order to take account of socio-economic factors or technical feasibility before they are applied in workplaces. These changes may be made unilaterally by employers (United States) or negotiated between social partners (Europe). As a consequence, the limits used in practice are much less protective than those recommended by scientists based on the current state of scientific knowledge. The health of exposed workers is therefore sacrificed for the sake of profit (keeping equipment costs down, staying competitive, etc.). When the substance to which workers are exposed is a non-threshold carcinogen and an OEL is applied (regardless of the method used to establish its numerical value), there is risk, albeit a small one, of developing cancer. In this sense, we can say that occupational exposure limits are social constructs, compromises between worker protection and the economic interests of businesses. This is why some trade union organisations in Europe are reluctant to adopt OELs for carcinogens, calling instead, for ethical reasons, for such substances to be banished from workplaces altogether.

3. Different statuses in different jurisdictions

In the United States, the OELs developed regularly by the ACGIH since the 1940s and by the National Institute of Occupational Safety and Health (NIOSH) since 1974 are recommendations and therefore have no legal force. These limits have served, and continue to serve, as the basis for establishing OELs in various industrialised countries. However, the United States also has legally binding OELs. They are adopted by the federal Occupational Safety and Health Administration (US-OSHA). These limits, known as ‘Permissible Exposure Limits’ (PEL), mostly date back to the 1970s and are based on OELs developed by the ACGIH. As they have never been revised since, they are, by US-OSHA’s own admission, outdated and inadequate for protecting workers’ health.

In Japan, OELs are recommendations developed by a scientific institute, which may be converted into binding values by the authorities with responsibility for occupational health (Takahashi and Higashi 2006). In Australia, the limits are known as ‘Workplace Exposure Standards’. They are binding and must be implemented in all workplaces (Safe Work Australia 2013).

In Europe, occupational exposure limits are developed and adopted at both EU and national level. They may be recommendations, or binding values. European legislation on occupational health imposes minimum requirements on all Member States, allowing for states to adopt more stringent measures if they so wish (Vogel 2015).

The recommended OELs are adopted within the framework of the Chemical Agents Directive (98/24/EC), for ‘threshold substances’, and currently concern 150-plus substances. The substances are selected by the European Commission, which then asks the SCOEL to recommend one or more OELs for each of them. These limits are based solely on scientific considerations about health, and take no account of socio-economic feasibility factors. The European Advisory Committee on Safety and Health at Work (ACSH), which comprises workers, employers and Member States, issues an opinion to the European Commission on the values proposed by the SCOEL before they are formally adopted. Once they have been annexed to the Chemical Agents Directive, all Member States must transpose them into their own legislation. However, they can still choose the final value that will be used at national level. It may be the same as, greater than or less than the OEL adopted at EU level. This is why the OELs are said to be ‘indicative’. In some Member States, these OELs will remain recommendations, while in others they will be transposed into binding values.

For a limited number of substances, essentially carcinogens and mutagens, EU legislation also provides for binding OELs. Unlike the indicative OELs, they require socio-economic and technical feasibility factors to be considered. Until 2017, binding OELs have only been adopted for five substances (see Table 1). These are asbestos (a carcinogen), through Directive 2009/148/EC; inorganic lead and its derivatives (reprotoxic substances) through Directive 98/24/EC; and benzene, vinyl chloride monomer and hardwood dust within the framework of the Carcinogens and Mutagens Directive (Directive 2004/37/EC). For these substances, EU countries do not have

a choice; they must, at national level, apply the value defined at European level, or a more stringent value. The Carcinogens and Mutagens Directive has been undergoing revision since 2004 with a view to widening its scope to include reprotoxic substances and adopting binding OELs for an additional twenty-five carcinogenic substances (Musu 2013). The Directive does not set out the method that must be used to develop the binding OELs, and this subject has been debated for many years in Europe, not least among the three interest groups represented within the ACSH. However, the workers' representatives have defined the criteria that should govern the setting of OELs in the Directive (see box below). One solution could be to differentiate between threshold substances and non-threshold substances, and to attach different obligations to each of these categories, including different types of OEL.

Table 1 Carcinogenic substances for which a binding OEL has been adopted in the EU (situation in 2017)

Substance name	CAS number	Mandatory OEL in force (TWA 8h)
Metallic lead and its compounds		150 µg/m ³
Asbestos	77536-66-4, 12172-73-5, 77536-67-5, 12001-29-5, 12001-28-4, 77536-68-6	0.1 fibre/cm ³
Benzene	71-43-2	3.25 mg/m ³
Vinyl chloride monomer	75-01-4	7.77 mg/m ³
Hardwood dust		5.0 mg/m ³

The 10 criteria proposed by European trade unions as a basis for setting OELs in the Carcinogens and Mutagens Directive

1. When adopting binding occupational exposure limits (OELs) in Annex III to the Directive, priority should be given to the carcinogens to which the greatest number of workers in Europe are exposed. The trade unions have drawn up a list of these priority carcinogens (Wriedt 2016). Particular attention should be paid to carcinogens emitted during certain processes (diesel engine emissions, crystalline silica, wood dusts, etc.).
2. The OELs adopted in the Directive must be ambitious and must promote substantial reductions in the highest levels of exposure to carcinogens currently encountered in workplaces.
3. The OELs adopted in the Directive must be based on current best practices, and in particular on the binding OELs enshrined at national level which offer the greatest protection.
4. These OELs must be consistent with the exposure levels which can be achieved by businesses on the basis of their obligations under other European legislation (including the REACH Regulation and its provisions on authorisation).
5. For non-threshold carcinogens, the level of residual risk associated with the OEL must be transparent and should always be communicated together with the numerical value for the OEL.

6. The initial goal for non-threshold carcinogen OELs must be to guarantee a residual risk of no more than four additional cases of cancer per 1,000 workers exposed, regardless of the carcinogen in question. This is the level of residual risk currently used in Germany and the Netherlands as a basis for setting OELs at national level.
7. For threshold carcinogens, the health-based OELs must also offer protection against other potentially harmful effects.
8. Health-related considerations should take precedence over socio-economic considerations when setting OELs. Transitional periods may be agreed with a view to facilitating the implementation of more stringent OELs.
9. The scope of the Carcinogens and Mutagens Directive should be extended to include reprotoxic substances. The indicative OELs which are currently defined in the Chemical Agents Directive for 11 reprotoxic substances (Category 1A or 1B) could then be converted into binding OELs in Annex III to the Carcinogens and Mutagens Directive. Similarly, the binding OEL for lead and its derivatives defined in the Chemical Agents Directive should be updated and transferred into the Carcinogens and Mutagens Directive.
10. The OELs and the Directive should be revised on a regular basis (at least every five years) in the light of the latest scientific findings.

In the absence of a predefined method for developing OELs for carcinogens at European level, the European Commission has, as part of the revision of the Carcinogens and Mutagens Directive, commissioned an analysis of the socio-economic, health and environmental impacts of adopting exposure limits for 25 carcinogens preselected on the basis of the number of workers exposed to them and the existence of OELs for these substances at national level. For each of these carcinogens, the costs and benefits were assessed for different OEL values in order to determine the most cost-effective value. When the value is selected on a socio-economic basis, the risk of contracting cancer at work varies from one carcinogen to another depending on the value selected, meaning that this method has the disadvantage of leading to unequal protection of workers depending on the carcinogen to which they are exposed. The social partners and the Member States have nevertheless agreed, within the ACSH, on the carcinogens for which they recommend the adoption of a binding OEL and on the numerical values of the OELs to be included in the Annex III of the Directive (see Table 2). Additional process-generated substances (crystalline silica, diesel engine exhaust emissions, rubber process dusts and fumes and used engine oils) might also be included in the Annex I to bring them within the scope of the Carcinogens & Mutagens Directive.

Unfortunately, the difficult economic climate in Europe and the REFIT programme being pursued by the Commission have delayed the adoption of these new exposure limits (Vogel and Van den Abeele 2010; Van den Abeele 2014). Irritated by the huge delays incurred in the adoption of new OELs for carcinogens at European level, some Member States called upon the European Commission to make progress in the revision of the Carcinogens Directive and recommended that it urgently adopt exposure limits for the 50 carcinogenic substances responsible for 80 to 90% of occupational exposure in the EU. This initiative was supported by the European Trade Union Confederation in its resolution on occupational health and safety adopted in December 2014 (ETUC 2014). Finally, in May 2016, the European Commission presented a first proposal to revise

the Carcinogens Directive by setting binding OELs for 11 new cancer-causing chemicals and by lowering two of the three binding OELs already in force. A second proposal was published in January 2017 with binding OELs for 5 additional carcinogens. A third wave of limit values for 5 other carcinogens was issued in 2018. These proposals will have to be discussed and agreed on between the European Parliament and the Council of the EU before they are transposed in the EU Member States.

Table 2 Carcinogenic substances for which a binding OEL could soon be adopted in the EU

Substance name	CAS number	Binding OEL proposed (8h TWA)
Acrylamide	79-06-1	0.1 mg/m ³
Aluminium silicate fibres (Refractory ceramic fibres)	142844-00-6	0.3 fibre/ml
Beryllium and inorganic compounds	7440-41-7	0.0002 mg/m ³
Bromoethylene (vinyl bromide)	593-60-2	4.4 mg/m ³
1,3-butadiene	106-99-0	2.2 mg/m ³
Cadmium and inorganic compounds	7440-43-9	0.001 mg/m ³
Chromium VI	7440-47-3, 1333-82-0	0.025 mg/m ³
1,2-dibromoethane (ethylene dibromide)	106-93-4	0.8 mg/m ³
1,2-dichloroethane (ethylene dichloride)	107-06-2	8.2 mg/m ³
Diesel engine exhaust emissions		0.1 mg/m ³
Epichlorohydrin	106-89-8	1.9 mg/m ³
Ethylene oxide	75-21-8	1.8 mg/m ³
Formaldehyde	50-00-0	0.369 mg/m ³
Hardwood dust*		3 mg/m ³
Hydrazine	302-01-2	0.013 mg/m ³
4,4'-methylenebis(2-chloroaniline) – MOCA	101-14-4	5 µmol total MOCA in urine/mol creatinine**
4,4'-Methylenedianiline (MDA)	101-77-9	0.08 mg/m ³
2-Nitropropane	79-46-9	18 mg/m ³
Propylene oxide (1,2-epoxypropane)	75-56-9	2.4 mg/m ³
Respirable crystalline silica	14808-60-7, 14464-46-1, 15468-32-3	0.1 mg/m ³
o-Toluidine	95-53-4	0.5 mg/m ³
Trichloroethylene	79-01-6	54.7 mg/m ³
Vinyl chloride monomer*	75-01-4	2.6 mg/m ³

* Update of an existing binding OEL

** Biological limit value

Note: the numerical values are based on the opinions adopted by the ACHS in 2012, 2013, 2016 and 2017. The final numerical values of the BOELs to be included in the Annex III of the directive might be different.

At national level, in addition to the (indicative or binding) OELs set at European level and transposed into their legislation, several EU Member States also have national OELs for many other substances (including carcinogens), adopted under rules specific to each country. In some countries, the national OELs are binding, while in others they are recommendations. In total, if we add together all the hazardous substances for which an OEL has been developed in one of the industrialised countries, we are now looking at over 2000 substances (IFA 2017).

4. REACH and exposure limits

The debate on OELs was recently revived in Europe by the implementation of the REACH regulation (**R**egistration, **E**valuation and **A**uthorisation of **C**hemicals), which has, since 2007, set the rules for the marketing and use of chemical substances in the European Economic Area. The main objectives of this legislation are to ensure a high level of protection for human health and the environment, as well as to promote innovation and the free movement of chemical substances within the EU. The cornerstone of the Regulation is the shifting of the burden of proof from the regulatory authorities to industry. Manufacturers and importers must now assess the health and environmental risks of their substances before they can market them. They must collect information about their substances and show, by compiling a registration dossier, that they can be used safely. Around 22,000 chemical substances already present on the European market in quantities in excess of 1 tonne per year must be registered with the new European Chemicals Agency (ECHA) at some point before 2018. Non-confidential data about these substances are publicly available on the ECHA website, which currently lists around 16,000 registered chemical substances (ECHA 2017).

The registration system provided under REACH obliges registrants to acquire and then communicate information on the properties and uses of the substances they market. The ‘no data, no market’ principle applies. When the substance is classified as hazardous and is produced in quantities in excess of 10 tonnes per year, a chemical safety report is also demanded in the registration dossier. The system obliges businesses to establish the necessary risk prevention measures for safe use of the substance. This information must be produced for each identified use of the substance and be annexed to its safety data sheet.

4.1 DNELs and DMELs

To be able to determine the appropriate risk management measures when the chemical substance concerned has a no-observed-adverse-effect level, the registrant must develop a health-based reference value called the ‘Derived No-Effect Level’ (DNEL). This is the level of exposure above which humans should not be exposed. If the risk management measures implemented ensure a level of exposure (estimated or measured) lower than the DNEL, then the risk is considered, under REACH, to be adequately controlled. When the route of worker exposure is long-term inhalation, the DNEL is very similar in principle to an occupational exposure limit. It is also expressed using the same units.

When the toxicological data do not allow a no-observed-adverse-effect level to be established (typically for ‘non-threshold’ carcinogens), the registrant is encouraged to develop a value known as the ‘Derived Minimum Effect Level’ (DMEL). This is the level of exposure associated with a residual risk that is considered acceptable. The concept of the DMEL does not appear in the REACH regulation itself, but only in the non-binding guidelines published on the ECHA website to help registrants discharge their obligations. It is very similar in principle to the concept of risk-based OELs used in some European countries.

With the implementation of REACH, some substances for which an OEL already existed at national or European level were assigned DNELs (or DMELs) by their manufacturers when their registration dossiers were compiled.

Many questions have therefore inevitably been asked about the use of DNELs/DMELs and the relationship that should exist between the DNELs/DMELs developed under REACH and the existing (or future) OELs under legislation for the protection of workers' health. These questions, and the answers to them, are not always simple. Already, they have given rise to two seminars, organised by the European Chemicals Agency (ECHA 2012) and the European Commission (European Commission 2014), as well as various publications. A study compared the DNELs developed by businesses with the indicative OELs adopted at European level and the national OELs in Finland (Tynkkynen *et al.* 2015). The results show that the DNELs derived by manufacturers were identical to the indicative OELs adopted in the European legislation for the majority of the substances examined (64 cases out of 87). For some substances, the DNELs were lower than the European indicative OELs (18 cases out of 87) and for others they were higher (five cases out of 87). Examples of substances in each of these categories can be found in Table 3. The comparison of the DNELs with the corresponding national OELs in Finland shows that, while the values were identical or very similar in 49% of the 315 cases examined, they were different for the remaining substances. In 28% of cases, the DNELs were lower than the national OELs, while in 23% of cases the DNELs were higher. Other studies report similar findings (Schenk and Johanson 2011; Schenk *et al.* 2014).

Table 3 Examples of substances for which the DNELs derived by companies are lower than, equal to or greater than the corresponding indicative OELs in the European legislation

Substance	CAS number	IOELV (8h TWA) mg/m ³	DNEL (workers, long-term exposure) mg/m ³
Chloroform	67-66-3	10	2.5
1,2-Dichlorobenzene	95-50-1	122	10
2-Ethoxyethanol	110-80-5	8	0.083
Toluene	108-88-3	192	192
Cyclohexane	110-82-7	700	700
Ethylacrylate	140-88-5	21	21
Chlorobenzene	108-90-7	23	23/42.3*
Heptan-2-one	110-43-0	238	394
Oxalic acid	144-62-7	1	4.03

* Two registration dossiers give two different DNELs.

Source: adapted from Tynkkynen *et al.* (2015)

The cases in which the DNELs and the European indicative OELs are identical can be explained by businesses using the existing European OEL as a DNEL for workers in their registration dossier. This is indeed what the REACH guidelines for businesses recommend in such situations.

The cases in which the DNELs are lower than the European indicative OELs mean that the health-based limit calculated by the manufacturer of the substance is more protective than that recommended by the SCOEL experts. We can imagine two scenarios here. The first possibility is that the data used by the businesses is more recent than that used by the SCOEL. In such an eventuality, the SCOEL should update its OEL in the light of the results of the new epidemiological or animal studies available. The second possibility is that the studies used by the businesses and the SCOEL to develop their respective limits are the same, but that the uncertainty factors used by the businesses are more conservative than those used by the SCOEL. As the details of the DNEL calculation are unfortunately not publicly available, it will be difficult to decide which scenario applies. In any event, we can assume that worker protection is assured in such cases.

The other situation, however, is more worrying. When the health-based limit calculated by the businesses is higher (and therefore less protective) than that calculated by the SCOEL, protection of workers' health is no longer assured. Exposure to the substance at levels lower than the DNEL but higher than the indicative OEL may be problematic. In this case, the ECHA responsible for checking the compliance of the data provided by the companies with the obligations of the REACH regulation should take action to assess the validity of the risk management measures proposed by these businesses.

4.2 Does REACH mean privatisation of exposure limits?

Situations in which a substance has been given a European or national OEL and a DNEL/DMEL under REACH are relatively limited. Eventually, the number of substances for which companies must calculate a DNEL/DMEL will be around ten times the number of substances for which an OEL has so far been developed. We might therefore wonder whether REACH amounts to a privatisation of the exposure limit development process. Some employers do not hesitate to request the abolition of worker protection legislation in Europe in order to avoid duplicating obligations also imposed under REACH. However, such employers are rather quick to forget that the regulation itself explicitly provides that it applies without prejudice to the provisions of worker protection legislation. This means that businesses must comply with the obligations arising from both types of legislation. It should also be remembered that European worker protection legislation provides for many important aspects that are not covered by REACH, such as worker training, the monitoring of worker health, and the development of OELs for by-products of manufacturing processes (e.g. crystalline silica, welding fumes), which fall outside the scope of REACH because they are not marketed.

When a business develops a DMEL for a non-threshold substance, it sets the risk level it deems acceptable itself. For risk-based limits, such as in Germany and the Netherlands, in contrast, the acceptable risk is defined by discussion and consensus between social partners (Püringer 2011).

We should also note that, while the numerical values of the DNELs/DMELs are publicly available on the ECHA website and in the safety data sheet of the substance, the details of the calculation used by the business to determine its DNELs/DMELs, and the reasoning

behind it, are not. This lack of transparency contrasts with the practice of the various scientific committees (national or European), which make documents public when they develop a health- or risk-based OEL. For risk-based OELs, the underlying risk value should be made transparent and always communicated together with the numerical values of the OELs.

4.3 Conflict of jurisdiction

The restriction procedures for which provision is made in the REACH regulation limit marketing or use of a hazardous substance when the risks for human health or the environment are unacceptable. These restrictions, proposed by Member States or the Commission, often prohibit the use of the substance beyond a given concentration in certain items. For example, the presence of certain phthalates in toys is restricted to a very low concentration. Recently, a new type of restriction was proposed in the form of a binding DNEL to limit the risks from occupational exposure to N-methyl-2-pyrrolidone (NMP), a reprotoxic solvent¹. If the proposed restriction is adopted by the European Commission, European businesses using the solvent will have an obligation to apply the DNEL. The mandatory DNEL was proposed by the Netherlands and then developed by an ECHA scientific committee, whereas until now the OELs adopted at European level have always been adopted within the framework of worker protection legislation, with SCOEL involvement. The value proposed by the ECHA scientific committee is four times lower than that recommended by the SCOEL and adopted as an indicative OEL under the Chemical Agents Directive. The tripartite European Advisory Committee on Safety and Health at Work (ACSH), which advises the Commission on OELs, has adopted an opinion expressing its disapproval of REACH interference in the development of European OELs. It will be up to the European Commission to settle this dispute over jurisdiction.

5. Improper use and the limits of OELs

OELs must not be confused with air quality standards, which are designed to protect the general population. Neither must they be used to assess non-occupational exposure. They must not be used to compare the toxicity levels of different substances. It is also worth remembering that an OEL is developed for a specific substance and cannot be used for another substance.

In the workplace, workers are rarely exposed to just one hazardous substance at a time. There are normally several. The risk management measures implemented to keep worker exposure below the OEL for a specific substance are therefore not necessarily effective in controlling the risks from exposure to the other substances present in the working atmosphere.

1. <http://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/1899/term>

For some chemicals, the main route of exposure is not inhalation but rather absorption into and/or through the skin. In those cases, Biological Limit Values are used instead of (or in addition to) inhalation OEL to assess the risks for exposed workers.

Another limitation of an OEL is the fact that its numerical value is, of course, dependent on the state of scientific and metrological knowledge at the time when it is developed and must be revised if new data becomes available. Experience shows that the numerical values of OELs tend to decrease each time they are revised. Unfortunately, too many current OELs are outdated and can no longer be considered adequate for limiting risks of adverse effects on the health of workers and their descendants.

In all countries, it is recognised that small companies generally have limited awareness and understanding of the meaning of OELs and therefore little capacity to apply them adequately in their risk management strategies. There can also be different meanings associated with compliance with OELs in different Member States (Walters *et al.* 2003).

Moreover, the DNELs introduced by REACH are creating some confusion for employers who are used to working with OELs. Despite the similarities mentioned above between a long-term inhalation DNEL for workers and an OEL, it is important to understand the differences between the two concepts. The OEL serves as a point of comparison when the concentration of the hazardous substance in the working atmosphere is measured. If the measured concentration is higher than the limit, measures must be taken to reduce the risks and improve worker protection. The DNEL developed under REACH is not intended to be compared with the concentration of the substance measured in the workplace. The DNEL is a stage in the REACH risk assessment process that serves to develop the exposure scenarios for each particular use of a substance. An exposure scenario establishes the risk management measures and the conditions for safe use of the substance. This information is intended for the various users of the substance and must be included in its safety data sheet. Under worker protection legislation, an inspector may check, for example, that the atmospheric concentration of a hazardous substance in a workplace is lower than its OEL. Under REACH, an inspector will instead check whether the risk management measures indicated in the safety data sheet for the specific use of the substance are implemented in the workplace. The obligations under REACH concern compliance with the established risk management measures and conditions for use, and not compliance with the DNEL.

6. Conclusions

Occupational exposure limits are one possible tool for protecting workers against adverse effects of exposure to hazardous substances. However, effective prevention is based on a hierarchy of measures, the first of which is the elimination of the hazardous substance or its replacement with a safer process or alternative. If elimination or replacement are impossible, workers' exposure should be reduced to a minimum. For carcinogens, the use of a closed system is therefore recommended. The limits, then, are only a secondary tool for assessing risks and deciding on the measures to be implemented to minimise worker exposure when primary prevention measures cannot be taken. Like all tools,

they have their limitations, but they have also been extremely useful in many working situations, including asbestos removal and monitoring and reducing workplace exposure to crystalline silica, wood dust and many man-made chemical compounds that are impossible to replace.

The OEL can differ for the same substance, depending on the country or organisation that sets it. There can be many reasons for these differences. For health-based OELs, variations may be due to the adverse effects considered, the uncertainty factors applied, or the state of scientific knowledge at the time when the OEL is developed. When OELs also take socio-economic or technical feasibility factors into account, the numerical value adopted is a compromise between the protection of workers' health and the economic interests of employers. The same goes for risk-based OELs, which will depend on the definition of 'acceptable risk'. That is why we can describe these occupational exposure limits as 'social constructs'.

In Europe, OELs are also a regulatory tool and efforts have been made over decades to harmonise the methods used to develop them and ensure that an equivalent level of protection is provided for all European workers. Greater harmonisation would also make it possible to avoid the relocation of businesses to countries where protection standards are lower and, thus, competition between businesses at the expense of their workers' health. Though the method applied for 'threshold substances' is widely accepted (health-based OELs), Europe is struggling to agree on a harmonised method for deriving OELs for non-threshold substances. The recent adoption of the REACH regulation is influencing this debate at various levels. There is still some confusion among businesses about the use of DNELs/DMELs developed by manufacturers and indicated on the safety data sheets of their substances. Eventually, through the efforts of the various stakeholders involved and greater transparency about the details of DNEL/DMEL calculations, these uncertainties should be cleared up and worker protection strengthened. Indeed, the new data generated by the REACH system about the substances should make it possible to revise many obsolete OELs, as well as improving risk management measures for the large numbers of workplace chemical substances for which no occupational exposure limits have been set.

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Chapter 17

Why should the scope of the Carcinogens and Mutagens Directive be extended to reprotoxic substances?

Tony Musu

1. Risks for reproduction: largely ignored by EU legislation on protecting workers' health and safety

Reprotoxic (or toxic for reproduction) substances can adversely affect the ability of men and women to reproduce (threat to fertility) and alter child development during gestation and after birth (threat to development). These effects concern libido, the formation of sperm or eggs, fertilisation and implantation of the embryo, but also miscarriage, stillbirth, reduced birth weight, congenital defects and alterations in mental and physical development, up to and including pubertal development.

In France alone, over 234,000 workers were exposed to at least one reprotoxic substance in 2010 (Cavet *et al.* 2015). Some glycol ethers used as solvents or even certain phthalates used as plasticisers can, for example, reduce the quality or number of sperm. These effects can occur either in adulthood or following pre-natal exposure. They may be reversible or irreversible depending on the substance. Other known reprotoxic substances frequently found in the workplace are lead and its compounds, used in the manufacture of alloys, batteries, glass, etc. Lead has effects not only on fertility but also on the neuronal development of children following exposure before or after birth. It is responsible for mental disabilities and losses of IQ. There is no threshold for the neurotoxic effects of lead and all exposures pose a risk. Warfarin used as a biocide and anticoagulant is teratogenic for humans. Following exposure during pregnancy, it causes cardiac defects, facial hypoplasia and mental retardation. In this case, the effects are not reversible.

Although difficult to put a figure on, many of these threats to reproductive health are due to occupational exposures¹, with victims being concentrated in certain sectors such as agriculture, care services, cleaning and maintenance, metallurgy and petrochemicals (Mengeot and Vogel 2008) and hairdressing and cosmetology (Kim *et al.* 2016). These occupational exposures are entirely preventable, with effective prevention therefore essential.

European legislation on the prevention of reproductive risks in the workplace is very patchy. There is no specific text and existing provisions are not only unsatisfactory but also scattered among various pieces of legislation. The 1992 Directive on the protection of pregnant workers and workers who have recently given birth or are breastfeeding

1. In addition to the chemical substances, there are other occupational risk factors for reproductive health: biological agents, ionising radiation, load carrying, prolonged and static work in a standing position, noise, stress, and irregular or night working. These will not be covered here.

(Directive 92/85/EEC) is, for example, inconsistent in terms of prevention. Measures to avoid exposure do not have to be taken until the worker informs her employer that she is pregnant, which occurs around the 10th week of pregnancy. However, exposure to a reprotoxic substance during the early weeks of gestation can result in miscarriage or a higher risk of congenital defects. The options of changing job or possibly taking leave from work, as recommended in the Directive, therefore come too late to prevent these risks.

The 1998 Directive on the protection of workers from chemical risks (Directive 98/24/EC) is also unsatisfactory. It covers all chemical substances produced or used in the workplace without laying down any specific provisions on reprotoxic substances. It requires employers to eliminate or reduce risks to a minimum and provides for binding or indicative occupational exposure limit values (OELs) to be set.

However, just one substance has been attributed binding limit values to date under this Directive: lead and its compounds (Table 1). The inhalation and biological OEL for lead and its compounds, determined in the early 1980s, have never been updated. In its 2002 Recommendation, the Scientific Committee on Occupational Exposure Limits (SCOEL) suggested lowering the biological limit value from 70 µg to 30 µg per 100 ml of blood, while acknowledging that this will not fully protect the offspring of working women (SCOEL 2002). An opinion of the European Chemicals Agency confirms that lead is toxic for child development and that a no-effect level does not exist for pre- or post-natal exposure. The Agency proposes classifying lead in the category of proven reproductive toxicants for humans (category 1A) with harmful effects on fertility, fetuses and breast-fed babies (ECHA 2013).

Table 1 Reprotoxic substance with Binding OEL under Dir 98/24/EC

Name	CAS	Inhalation OEL (8h TWA)		Inhalation OEL (short term)		Notation	Biological OEL	Classification
		mg/ml	ppm	mg/ml	ppm			
Lead and its compounds		0.15				-	70 µg Pb /100 ml blood	R1A

As regards indicative OELs under the Chemical Agents Directive, these currently cover only 150 substances, of which 11 are toxic for reproduction categories R1A or R1B (Table 2). These values are based on health. This means that the available scientific data has identified an exposure threshold below which exposure to the substance does not cause any harmful effect. However, while it is generally accepted that such a threshold can be defined for most reprotoxic effects, this is not always the case, as shown by the example of lead. Moreover, this threshold is unknown for many reprotoxic substances.

This is one of the major failings of the Chemical Agents Directive with regard to preventing risks for reproductive health. If a reprotoxic substance has a threshold, but no OEL has been set, employers do not have any guidance on the exposure level not to be exceeded, and there is no minimisation obligation in the Directive ensuring that the exposure level is reduced, particularly below the threshold of effect.

Table 2 Reprotoxic substances with Indicative OEL under Dir 98/24/EC

Name	CAS	IOEL (8h TWA)		IOEL (short term)		Notation	Specific Directive	Classification
		mg/ml	ppm	mg/ml	ppm			
N,N-Dimethylacetamide	127-19-5	36	10	72	20	skin	2000/39/EC	R1B
Nitrobenzene	98-95-3	1	0.2	-	-	skin	2006/15/EC	R1B, C2
N,N Dimethylformamide	68-12-2	15	5	30	10	skin	2009/161/EU	R1B
2-Methoxyethanol	109-86-4	-	1	-	-	skin	2009/161/EU	R1B
2-Methoxyethyl acetate	110-49-6	-	1	-	-	skin	2009/161/EU	R1B
2-Ethoxy ethanol	110-80-5	8	2	-	-	skin	2009/161/EU	R1B
2-Ethoxyethyl acetate	111-15-9	11	2	-	-	skin	2009/161/EU	R1B
N-Methyl-2-pyrrolidone	872-50-4	40	10	80	20	skin	2009/161/EU	R1B
Mercury and divalent inorganic mercury compounds		0.02	-	-	-	-	2009/161/EU	R1B
Bisphenol A	201-245-8	2	-	-	-	-	2017/164/EU	R1B
Carbon Monoxide	630-08-0	23	20	117	100	-	2017/164/EU	R1A

2. Benefits of the Carcinogens and Mutagens Directive

The nature, severity and potential irreversibility of the health effects resulting from exposure to reprotoxic substances are particularly worrying for exposed workers. Levels of protection at work should therefore be improved by applying the more stringent provisions of the Carcinogens and Mutagens Directive to reprotoxic substances.

This Directive, which was codified in 2004 (Directive 2004/37/EC), specifically covers all substances that are proven or suspected to be carcinogenic and mutagenic for humans (categories 1A and 1B). It requires employers to replace carcinogens and mutagens with safer alternatives where technically possible. If such precautions cannot be taken, employers must ensure that work is carried out in a closed system and they must reduce exposure to a minimum. The OELs adopted under this Directive are always binding and, even if the exposure level for workers is below the OEL, the obligation remains to reduce this level as far as possible. The Carcinogens and Mutagens Directive is therefore more demanding than the Chemical Agents Directive in terms of reducing workplace exposure levels.

The Carcinogens and Mutagens Directive has been under revision since 2004. Under consideration are the extension of its scope to reprotoxic substances and the adoption of binding OELs for new substances. This revision has unfortunately been held up by the European Commission for over 10 years (see chapter 18). However, there are good reasons to include these improvements in a revised directive.

Many reprotoxic substances are currently produced and marketed in the European Union. According to the health, socioeconomic and environmental impact study ordered by the European Commission as part of the revision procedures, in 2012 there were

105 reprotoxic substances in categories 1A and 1B out of the scope of the Carcinogens and Mutagens Directive (Milieu and RPA 2013). In 2017, they were 134 according to an update prepared by ETUI. These are substances with a harmonised classification as reprotoxic agents, but that are not also classified as carcinogens or mutagens under the CLP Regulation. These substances are therefore currently covered by the unsatisfactory provisions of the Chemical Agents Directive. However, in order to have a comprehensive view of the number of reprotoxic substances currently present on the European market and to which workers are potentially exposed, we should also take into account those substances that have been self-classified as R1A or R1B by companies under the CLP Regulation. A search of the Classification & Labelling Inventory available on the ECHA website shows that there are around 1,800 of these substances.

Including reprotoxic substances within the scope of the Carcinogens and Mutagens Directive would be consistent with the REACH Regulation and all other EU legislations on chemicals (Pesticides, Biocides, Cosmetic regulations, etc). Under REACH, those chemicals identified as substances of very high concern include not only category 1A and 1B carcinogens (C) and mutagens (M), but also reprotoxic substances (R) in the same categories. This alignment with REACH and the other EU legislations on chemicals where C, M and R are treated the same could be seen as a regulatory simplification. It would also improve the synergies between these legislations.

Many reprotoxic substances like Bisphenol A or some phthalates have also been identified as endocrine disruptors (see the Ristox database on the ETUI website). As it is impossible to determine a no-effect exposure level for endocrine disruptors (Kortenkamp *et al.* 2011), health-based OELs for threshold reprotoxic substances would be useless for protecting workers from the adverse effects of endocrine disruptors. Including reprotoxic substances within the scope of Directive 2004/37/EC would automatically ensure that the more stringent provisions of the Carcinogens and Mutagens Directive are applied to numerous endocrine disruptors.

Six European countries (Austria, Belgium, the Czech Republic, Finland, France and Germany) have already extended the scope of the Carcinogens and Mutagens Directive to reprotoxic substances when transposing it into their national law. The findings of the impact study ordered by the European Commission are that, in two of these countries (France and Germany – the only ones studied within the group of six), this extension has clearly led to benefits in terms of reducing the exposure of workers to reprotoxic substances (Milieu and RPA 2013).

Finally, it is worth mentioning that according to the revised version of the Carcinogens and Mutagens Directive adopted by the European Parliament and the Council in September 2017, the EU Commission will have to assess the possibility of including reprotoxic substances in the scope of the Directive by the first quarter of 2019 at the latest².

2. Directive (EU) 2017/2398.

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Chapter 18

A tortuous and conflict-laden process: the revision of the directive protecting workers against carcinogens

Laurent Vogel

1. Paralysis for more than ten years¹

The revision of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD) was already foreseen in the EU strategy on workplace health for the period 2002-2006 (European Commission 2002). At that time, four aspects were considered as priority issues by the European Commission: the inclusion of reprotoxic substances in the directive's scope, the adoption of new occupational exposure limits (OELs) with a view to complementing the list of three substances in Annex III, the revision of the existing OELs, and the adoption of criteria for defining OELs.

In accordance with the procedures set forth in the Treaty, unions and employer organisations were consulted twice. The first stage of consultation was launched on 6 April 2004, while the second stage was greatly delayed, not starting until April 2007. At that time, the Commission was still committed to including reprotoxic substances in the directive's scope. The document launching the 2007 consultation stated the following: "the Commission intends to propose an extension of the scope of the Carcinogens and Mutagens Directive to include substances toxic for reproduction".

For its part, the Scientific Committee on Occupational Exposure Limits (SCOEL) had finished a major project, coming up with recommendations for several dozen CMR substances. The slow pace of the social partner consultation (three years between its two stages) did not at first seem alarming. In the context of progressively implementing REACH, it would have been logical to consider this revision as a top priority for the 2007-2012 strategy. The Commission Communication on this strategy (European Commission 2007) constituted a deregulatory turning point linked to the political context of the formation of the first Barroso Commission (which took office in November 2004). At that time, the European Trade Union Institute was to comment: "Future legislative measures are announced in the most diffident terms. The Commission says it will 'continue its work, through the ongoing consultations with the social partners, to find ways of improving prevention with regard to musculoskeletal disorders, carcinogens and needlestick infections'. Movement on the two biggest issues (carcinogens and musculoskeletal disorders) has been stalled for years. The Commission no longer even dares utter the word "directive" despite it featuring in the strategy for 2002-2006. So the Commission will continue its work between 2007 and 2012, but will it ever complete

1. The information contained in this chapter has been updated and is valid as of April 30, 2018.

it? After five years of fudging the issue, it could have given a clearer statement of what ‘ways’ it plans to ‘find’” (Vogel 2007).

In fact, the ambiguous wording of the strategy served to justify a legislative paralysis lasting more than a decade. The main factor was the European Commission’s ‘Better regulation’ policy orientation, under which any tightening of legislation protecting workers against occupational cancers was seen as creating obstacles to company profit-making. Considering that some 100,000 deaths each year in the European Union are the result of occupational cancers, the human cost of the ‘Better regulation’ campaign has been disastrous.

An Impact Assessment Board² was set up in late 2006 to make prior assessments of all legislative proposals, even before they were officially formulated by the Commission. Assessment criteria are vague. As board members obviously do not have the in-depth knowledge of all matters covered by EU policymaking, they tend to only intervene on formal aspects, with a major focus on costs and benefits. The relevance of this approach raises many questions, especially when it comes to making choices about complex regulations whose medium- or long-term consequences are highly hypothetical. In reality, this body is highly dependent on the Commission’s impact assessments. In a way, it has the role of a review committee for such assessments, fine-tuning them at a formal level. Assessments somehow anticipate predictable criticism or are modified as the result of an initial negative opinion or one with reservations. In 2014, the Commission put an end to inter-department consultation – previously indispensable for adopting a legislative proposal – in the case of the board issuing a negative opinion on the quality of an impact assessment. This power to block an initiative in advance thus prevents the sole EU body elected by universal suffrage, the European Parliament, from debating it.

Over the years, the requirements – set by the Commission itself – regarding the content of impact assessments have become increasingly complex. As a result, more resources are being devoted to cost-benefit studies than to the substantive content of legislation. Experience in the United States where strict and very formal cost/benefit rules were introduced in the 1980s illustrates the flaws inherent to a method where most of the data has to be extrapolated due to the high number of uncertainty factors. These flaws are not simple defects, instead leading us to what seems to be their key political purpose: opening up decision-making to the determining influence of lobbies and thereby sidestepping the possible disadvantages of a political system of representative democracy (Heinzerling *et al.* 2005).

With regard to the revision of the CMD, external consultants were commissioned to conduct two impact studies before 2014. The one involved 25 substances for which new or revised OELs were planned. It was completed in 2011 (IOM 2011). The other involved extending the scope of the directive to reprotoxic substances. It was completed in 2013 (Milieu and RPA 2013).

2. The Impact Assessment Board was replaced by the Regulatory Scrutiny Board set up under the 19 May 2015 decision of the Commission President.

By 2013, the Commission was thus in a position to adopt a proposal for revising the directive. The impact study on OELs was largely in favour of such a revision, while that on reprotoxic substances ended on a cautious note, as the available data on reproductive problems caused by occupational exposure was full of gaps. However, the latter study acknowledged that in two countries where these substances were included in regulations governing carcinogens (France and Germany), the impact had been positive from a prevention perspective.

In December 2012, the Barroso Commission launched 'REFIT', the 'Regulatory Fitness and Performance Programme' (European Commission 2012). Its goal was to review all existing European legislation (the *acquis communautaire*) and to submit any new initiative to competitiveness tests. This created a new obstacle in the way of revising the directive, not just requiring the hypothetical impact of any future legislative change to be considered, but also requiring a retrospective analysis of the supposed impact of already existing directives. Since 2 October 2013, REFIT has blocked all proposals aimed at improving workplace health legislation (European Commission 2013a). The initial plan was for this moratorium to finish at the end of the term of office of the Barroso Commission (November 2014), but it was extended for the whole of 2015 by the incoming Juncker Commission.

Justification for this policy came from the wide-ranging public consultation held by the Commission at the initiative of the Commissioner for Industry and Entrepreneurship, Antonio Tajani. Entitled 'Top Ten', this consultation called on SME heads to list any legislation they disliked (European Commission 2013b). Of the more than 20 million SMEs in Europe, just 628 responded. Adding to these a few companies from other corners of the world and a few employer organisations, one just about managed to scrape together 1000 responses. For the majority of countries, the number of responses was lower than 20. For a 3-month consultation, available in 21 different languages, with a large advertising budget, this turned out to be a total fiasco. The questions stank of manipulation as they were concerned only with the negative impact of legislation. The few SMEs that took part in this farce indicated that their 'pet hate' was everything to do with taxes. They also had no liking for having to treat their waste and inform consumers through labelling their products. The obligation to ensure the safety of chemical products was ranked seventh among the 'pet hates', immediately followed by health and safety at work. As regarded specific legislative acts, the 'pet hate' was REACH. In the field of health and safety, the CMD figured as one of the directives considered to be harmful by the employer organisations, but did not figure in the list drawn up by the respondent SMEs. Any serious polling institute would have binned these results. Biased questions, too few responses to constitute a representative sample, etc. The Commission, however, saw the survey as a source of certainties. In numerous official documents published at a later date, it stated having now identified the most onerous legislative fields. 'Top Ten' was to become a gospel truth, echoed from text to text without mention of the doubtful conditions of its birth.

On 6 June 2014, the Commission adopted an EU Strategic Framework on Health and Safety at Work 2014-2020. No legislative measure concerning occupational cancers was foreseen. The general drift of this document was clearly deregulatory, stating

that “In line with the objectives of the REFIT programme, a continuous joint effort by the Commission, other EU institutions and Member States is required to simplify EU legislation and eliminate unnecessary administrative burden. In the coming years, key concerns will be assessing whether existing OSH legislation is fit for purpose, examining how to improve its implementation, and ensuring better, effective and equivalent compliance across Member States and enterprises” (European Commission 2014).

The formation of the new Commission under Jean-Claude Juncker in 2014 brought no change to this approach. At her hearing by the European Parliament on 1 October 2014³, Ms Thyssen – designated for the employment and social affairs portfolio – listed four priorities for her work. Workers’ health and safety were not on her list. The word “cancer” was not mentioned once during the long hearing. The brief statement referring to European legislation on occupational risks was marked by the same fudging as seen over the past decade in the two Barroso Commissions.

The first work programme adopted by the Commission under Mr Juncker’s Presidency in October 2015 maintained this approach, with the revision of the CMD not listed among the legislative initiatives planned for 2016. The justification given for this standstill was that it was necessary to evaluate all existing health and safety legislation and that any changes could only be made after this had been completed.

2. The 2016 U-turn

The spring 2016 announcement that the Commission was finally going to relaunch the revision of the CMD might have come as a surprise as it ran counter to the priorities constantly reaffirmed between 2005 and 2015. There are various factors explaining this U-turn. They show that – even in a very unfavourable political context – the perseverance of union organisations swimming against the tide can end up creating sometimes unexpected alliances.

A growing number of Member States no longer accepted this legislative standstill, as increasingly seen from 2014 onwards. The opinion of these States was that it would be dangerous to have national economies competing against each other, to the detriment of protecting workers’ lives. They were also aware of the amounts spent on public health in association with treating cancer and of the effectiveness of cancer prevention focused on occupational exposure.

In March 2014, the Ministers of Labour from Germany, Austria, Belgium and the Netherlands addressed a hard-hitting letter to the European Commission demanding the revision of the CMD. Its tone was particularly insistent, highlighting the fact that more than 30 million workers in Europe were exposed to carcinogens and mutagens at unacceptable levels. It called for the directive’s urgent revision and recommended

3. The full minutes of this hearing are available at: www.europarl.europa.eu/hearings-2014/resources/library/media/20141022RES75837/20141022RES75837.pdf

the setting of binding OELs for fifty substances, reflecting a very large proportion of exposure situations. It also set forth criteria for setting these OELs.

In December 2014, the Council of ‘Environment’ ministers decided to join Sweden in a lawsuit against the European Commission for blocking the concrete application of a key part of the 2012 biocides pesticides regulation: the Commission was supposed to have defined criteria regarding endocrine disruptors by the end of 2013. While this debate had little to do with workplace health issues, it spotlighted a growing discontent with the Commission regarding the influence of industry lobbies on approaches to chemical risks.

On 9 March 2015, meeting at the initiative of the Latvian Presidency, the Council of ‘Social Affairs’ ministers demanded that the Commission start taking the initiative in revising the CMD. Within less than a year, the battle commenced by four Member States had got most other Member States convinced.

During the first half of 2016, the Dutch EU Presidency helped this objective take on concrete form. Already in the summer of 2015, the Dutch government had made it known to the Commission that it would be making the issue of occupational cancers the main priority of its upcoming presidency in the field of health and safety at work and that it expected a legislative proposal from the Commission. In May 2016, the Dutch Presidency held a major conference in Amsterdam, intensifying dialogue on this issue and giving unprecedented political visibility to the fight against occupational cancers in Europe.

For its part, the European Parliament was not going to be side-lined. On several occasions it expressed its wish for the directive to be revised, in particular extending its scope to cover reprotoxic substances. In a resolution adopted in November 2015, the Parliament “highlights the importance of protecting workers against exposure to carcinogens, mutagens and substances that are toxic to reproduction; stresses, in this context, that women are often exposed to a cocktail of substances, which can increase health risks, including to the viability of their offspring; firmly reiterates its call on the Commission to present a proposal for a revision of Directive 2004/37/EC on the basis of scientific evidence adding more binding occupational exposure limit values where necessary and to develop an assessment system in cooperation with the Advisory Committee on Safety and Health at Work that is based on clear and explicit criteria; believes that possible regulatory overlaps resulting in unintended non-compliance should be addressed in this context”.

Even the employers were divided between supporting the Commission’s deregulatory approach and the finding that the legislative standstill had unforeseen disadvantages. Politics hates a vacuum. The lack of action at the level of EU legislation on occupational health ended up with action being taken elsewhere. Very soon, national legislation attempted to fill the gaps left at EU level, and the business world soon found itself confronted with 28 sets of very different national regulations – one of the disadvantages of having very divergent national OELs. Very soon, other EU legislation had to jump in to fill the gaps. For instance, with regard to the fight against occupational cancers and with

no progress made in upgrading the rules protecting workers, marketing authorisation rules sought – somehow – to respond to the growing concerns. The synergies mentioned everywhere in the declarations of Commission leaders were nothing more than the jumpstart lurchings of a vehicle forced to start while all others remained broken down.

On 25 February 2015, a broad coalition of 21 employer organisations sent a letter to the European Commission. While upholding its ideological support for the principle behind ‘Better regulation’, the letter called on the Commission to clear the way for a revision of the CMD. It was signed by associations from a wide range of sectors: automotive, medical technology, steelmaking, mining, aluminium. etc. It was also backed by the powerful American Chamber of Commerce in Europe, an organisation representing US multinationals. While the letter was obviously not written for the sake of protecting workers’ health, its signatories expressed their concern about the legislative standstill, stating that it could lead to bans or restrictions in the context of REACH. In the view of these employer organisations, the defence of their own interests was leading them to break with the purely deregulatory ideology of their umbrella organisation, BusinessEurope.

Similarly at national level, employer organisations in several countries considered the major disparities between the various national regulations to be a problem. It was this that explained the very firm position of the Dutch employer organisation in favour of revising the directive. On 28 August 2003, the Dutch Minister of Social Affairs and Employment sent a letter to the European Commission calling on it to include the revision of the CMD in the new EU strategy for 2013-2020. The letter reflected a joint position adopted at a tripartite meeting between the Dutch government, employer organisations and unions, highlighting the large differences between Member States’ levels of protection and pointing out that more, and stricter, exposure limits at EU level would help create a ‘level playing field’ and so avoid ‘false competition’⁴.

The evolution of the Commission’s attitude and its internal contradictions are worthy of a detailed examination. However, this would go beyond the bounds of this paper. We will limit ourselves to highlighting a few hypotheses which need to be looked at in greater depth.

Within the EU’s institutional system, the Commission has one key power, that of being the only institution able to take legislative initiative; i.e. neither the Parliament nor the Council can trigger a legislative process. What they can do is to adopt resolutions, exert political pressure and urge the Commission to take action. Official positions of the European Commission are defined collectively by all Commissioners. In practice however, the Commission president and secretary-general play an often-decisive role when it comes to policy choices. In addition, each commissioner at the head of a directorate-general (DG) exerts a varying influence over overall policy. The internal balance of power is complex and fluctuates. Any political initiative (whether legislative or not) is preceded by an inter-DG consultation, allowing all DGs to have their say.

4. Letter from the Dutch Minister of Social Affairs and Employment, L.F. Asscher, to European Commissioner L. Andor, 28 August 2013.

The sometimes surprising evolution of Commission policy on the revision of the CMD is linked to a range of factors exerting contradictory pressure from outside as well as internal conflicts within the Commission. The legislative standstill was given added impetus by an overall ideological approach under which occupational health legislation was considered a burden for companies, and by the effectiveness of industry lobbying which generally targeted specific areas potentially to be covered by the revision (for example crystalline silica, diesel engine exhaust emissions or wood dust)⁵.

Different phases could thus be distinguished in which occupational health policies were overruled by other considerations. Up to 2007, the revision of the CMD seemed to be gaining ground. Though progress was slow, the various preparatory steps (including the two-stage consultation of the social partners) took place.

This momentum was stopped in its tracks by the ‘Better regulation’ campaign, which significantly reduced the say of the ‘Social Affairs’ DG within the Commission. The extreme concentration of decision-making power between the hands of Mr Barroso, the Commission President, Mr Verheugen, the Commissioner for Enterprise (in the first Barroso Commission between 2004 and 2009) and the secretariat-general played an important role in the stalemate over the revision. But this was not just a balance of power issue. It also involved – with a certain share of autonomy – the administrative procedures and the legal framework establishing new bureaucratic mechanisms for assessing the impact of the legislative proposals. Though these mechanisms are supposed to ‘depoliticise’ the legislative process, they in fact make it a lot more arbitrary. Indeed, the criteria for assessing the potential impact of any draft legislation involve studies based mainly on hypothetical projections of costs and benefits on the basis of very fragmentary data. The factors of uncertainty are of such a magnitude that all that is needed was to modify the models on which the projections are based in order to arrive at diametrically opposite conclusions. In addition, throughout the process entrusted to external consultants, the Commission remains in contact with them and may suggest introducing modifications into their studies. This influence is all the more effective as consultants are commercial organizations that want to maintain a favourable position in this lucrative market for impact evaluations. Such a decision-making system is based on a paradox: it is supposed to give priority to expert reports focused on economic impacts. This however minimises the role of expert reports on substantive issues (in this case, toxicological, epidemiological and technological data) and avoids explicitly detailing the policy choices made (for example, the determination of a level of risk considered to be ‘tolerable’ for workers which is linked to the adoption of the limit values).

The U-turn of DG Social Affairs took place towards the end of 2015. In a letter sent on 14 December 2015 to Belgian unions, Commissioner Marianne Thyssen made a series of commitments, stating that she intended to submit two proposals for revising the directive in the course of 2016 and to achieve the goal of 50 OELs by 2020. However, she reaffirmed the position that the legislative proposals could not be drafted before the end of the assessment of existing legislation. The document concerning this assessment

5. These lobbying activities are described in Tansey (2016).

was announced for the beginning of 2016. There was an obvious contradiction here: if the results of the assessment were indispensable for putting forward a legislative initiative, how could one justify the commitment of defining OELs for 50 substances? This shows at what point the formalism and bureaucratisation of EU decision-making caused by ‘Better regulation’ can become a kind of ritual where form take precedence over content.

In reality, the Communication from the Commission concerning the assessment of existing legislation was only adopted on 10 January 2017 (European Commission 2017a). But this 1-year delay has had no consequences for the revision of the CMD. It was launched more than six months before this communication, since 2013 touted as the starting point for any legislative initiative respecting the sacrosanct REFIT principles. The timetable announced in the letter of 14 December 2015 was basically respected, with a first proposal adopted by the Commission on 13 May 2016 and a second on 10 January 2017. Respecting the commitment to adopt 50 OELs by 2020 seems however to be a bit of a problem. Taking into account the first three batches, there should be between 21 and 23 OELs adopted by 2020. Assuming that the fourth batch is adopted by the end of 2020, it is likely to be around 25 OELs, about half of the stated target. For the future, there are many uncertainties since the Commission has not yet published a medium- and long-term plan for the substances to be considered for further legislative developments.

How can this change of heart be explained? Between 2007 and 2015, revision of the CMD was constantly hit by “deadline slippage”, while at the same time other factors developed, the main one of which was the entry into force of REACH (on 1 June 2007). Slowly but surely, the position of DG Enterprise (renamed DG Grow in 2015) was to change. This DG had always maintained close links with industry and was rather hostile to any developments in EU legislation in the field of health and safety, considered to be a burden weighing down on competitiveness and held to be relatively ineffective. The arrival of REACH changed this perception. For many companies, occupational health legislation seemed the ‘lesser evil’ compared to the new authorisation procedures under REACH, leading to a decrease in resistance to the revision of the directive on carcinogens. The revision gained a kind of new legitimacy in the debates on the risk management measures to be adopted for substances of very high concern.

Moreover, through accelerating the production of data on the most dangerous substances, REACH revealed the major gap between the level of protection introduced by the directive and the actual technical possibilities for improving prevention. The bulk of the data gathered during the implementation of REACH indicates that the adoption of OELs ensuring a high level of protection for workers would not come up against any major technological and economic obstacles – contrary to the claims of BusinessEurope. In fact, there was a great distance between the latter’s perception – marked by its deregulatory ideology – and the data provided by the companies concerned. This gap explains to a certain extent the quasi-inversion of roles between DG Enterprise and DG Social Affairs in their approach to regulating the occupational risks associated with chemicals. Traditionally, the former was hostile to such regulation, while the latter was more favourable to it. The current situation is less clear.

Among the substances helping to crystallise the internal discussions in DG Enterprise, we find NMP (N-Methyl-2-pyrrolidone), a substance for which the Netherlands proposed a restriction in 2012, and the main compounds of hexavalent chromium placed on the list of candidates for authorization as from 2010 and subject to the authorization procedure since 2013. In these two cases, it would seem that the measures planned in the specific legislative measures for protecting workers were clearly inadequate compared to those proposed under REACH. The reticence of DG Social Affairs to extend the CMD's scope to reprotoxic substances also seemed unjustified in the light of the fact that both DG Grow and DG Environment considered – quite rightly – that EU legislation was inconsistent. It should also be mentioned here that, in the field of social policies, the near standstill in other areas (mainly regarding the Posted Workers' Directive), in some ways created the need to launch initiatives seen to be less conflict-laden among Member States. Leaving aside automatic UK hostility towards any legislation on workers' rights, it was clear that the revision of the CMD would not face any particularly negative reactions from Member States. Quite the contrary, many of them considered it a priority.

3. The main issues at stake in the revision of the CMD

For practical reasons associated mainly with the bureaucratic impact assessment rituals, the directive is being revised in several phases (batches). This multi-phase approach is not *per se* a problem, especially as it is accepted that a directive effective in fighting occupational cancers needs to be regularly revised to take account of the latest findings. But a series of *ad hoc* revisions targeting specific points risks putting a comprehensive analysis of all prevention needs on the back burner. This is the reason why the European Trade Union Confederation is calling for the adoption of a strategic roadmap defining for the medium term these various needs and setting down an exact timetable for the various legislative measures planned.

The multi-phase approach entails overlapping debates to the extent that the legislative process associated with each batch of proposals can extend over quite a long period and will not be completed when the subsequent batch is submitted to the European Parliament and the Council of Ministers. For instance, the first batch of proposals was presented in May 2016 and ended with the adoption of a directive in December 2017. In the meantime, the second batch was introduced in January 2017, with European Parliament amendments to the proposals being voted on in March 2018 and with the negotiations between the Parliament and the Council to adopt a directive set to end in the second half of 2018. We are seeing the same overlapping with regard to the third batch, presented in April 2018 and set to be adopted in early 2019, while the fourth batch will probably be launched after the European elections in May 2019.

As a strictly chronological narrative would not take account of the vagaries of the revision procedure, we have decided to successively examine the content of each batch of proposals. As a reminder, the revision of the directive on carcinogens is taking place in the context of what is called the ordinary legislative procedure. It is up to the Commission to launch the initiative by adopting a proposal for a directive. This proposal is then submitted to the European Parliament which can adopt it as such,

amend it or reject it. It is then submitted to the Council of Ministers which has the same competences in its function as co-legislator. The directive is not finally adopted until both Parliament and Council agree on the text. This process can take place in several steps if Parliament and Council cannot agree on a joint position at the first step. The Commission continues to play an active role throughout the process. First, it maintains contact with the co-legislators and takes part in any meetings held by the two institutions for negotiating a possible agreement (the so-called ‘trilogue’). Second, it can interrupt the legislative process at any time through withdrawing its proposal. In the case of the CMD revision, this threat has been informally voiced in response to amendments deemed by the Commission to be overambitious, though it is unlikely that it will actually come about, as this would cause a great amount of tension between the Commission and both Parliament and the Council.

An inter-institutional agreement between the European Parliament, the Council and the Commission was reached on 13 April 2016. Its text is quite ambiguous, addressing the contradiction between the democratic necessity to be able to amend legislative proposals put forward by the Commission and the bureaucratic requirement to provide impact assessments of the finally adopted texts. It is highly unlikely that the Commission’s initial impact assessment will have addressed all policy alternatives arising in the course of the legislative process. With regard to both the European Parliament and the Council, an amendment is adopted when it gains a majority of votes, in line with Treaty rules. It is thus a political decision, the legitimacy of which is based on universal suffrage in the case of the European Parliament and on the sovereign representation of each Member State in the case of the Council. The agreement of 13 April 2016 states: “The European Parliament and the Council will, when they consider this to be appropriate and necessary for the legislative process, carry out impact assessments in relation to their substantial amendments to the Commission’s proposal. The European Parliament and the Council will, as a general rule, take the Commission’s impact assessment as the starting point for their further work. The definition of a ‘substantial’ amendment should be for the respective Institution to determine. This texts thus accords a major margin of discretion to the two institutions. They weigh up the substantial character of an amendment and then decide whether it is appropriate to go ahead with an impact analysis”.

At the time of writing this paper, three batches of proposals for revising the CMD had already been tabled by the Commission and a certain amount of information on the fourth batch was already available. On the other hand, the information available on the possible inclusion of reprotoxic substances is too fragmentary to predict what the Commission’s position will be at the end of the first quarter of 2019. All we know is that different scenarios are being considered.

4. The first batch of proposals: a minimalist approach, greatly improved thanks to the European Parliament

The first batch of proposals for revising the CMD was adopted by the Commission on 13 May 2016. The content was minimalist, not making any amendments to any articles of the existing directive. Its scope was thus not extended to reprotoxic substances. The amendments proposed only referred to Annex I defining the binding OELs and to Annex III containing the list thereof.

As regarded Annex III, the proposal targeted 13 substances. For 2 substances, the amendment involved the revision of existing OELs, while new OELs were introduced for the other 11.

The Commission was convinced that any proposal, however modest, would be approved without substantial amendments by the co-legislators and that its adoption would not involve any major political debates. This turned out not to be the case. It was foiled by the European Parliament's desire to adopt a far more ambitious text on a key issue causing immense social inequalities in health and the leading cause of death associated with working conditions in Europe. The Parliament's Social Affairs Committee appointed the Swedish Socialist MEP Marita Ulvskog as rapporteur. Similarly, each parliamentary group appointed a 'shadow-rapporteur' tasked with monitoring progress. During the first meetings devoted to examining the proposal, MEPs from most of the political groups grasped the importance of the subject and worked to find a consensus on amendments significantly improving the initial proposal.

On 28 February 2017, the Social Affairs Committee approved the report and adopted the various amendments on which broad consensus had been reached. This was all the more noteworthy, given that employer lobbying had done everything to weaken the rapporteur's position. No fewer than 9 European employer organisations⁶ had sent a letter to the various parliamentary groups on 4 January 2017, calling on them to stick to the Commission's minimalist approach. This letter was quick to set forth manifestly untrue counter-claims, in particular stating that the "CMD was originally specifically designed to deal with those carcinogens and mutagens without sound levels of exposure". Although the amendments were ambitious, some 85% of MEPs voted for them. Only two parliamentary groups rejected them: the European Conservatives and Reformists (ECR), a Eurosceptic right-wing group centred around the British conservatives and the Polish Law and Justice Party (PiS), and the extreme right-wing Europe of Nations and Freedom (ENF) centred around the French National Front, the Austrian FPÖ and the Italian Lega Nord. This large majority tipped the balance of power in favour of the European Parliament. The high degree of support for the amendments surprised the Commission which had attempted to portray the Parliament's position as unreasonable

6. The organisations (and their sectors) which signed this letter: Business Europe, CEEMET (metal engineering), CEMBUREAU (cement), ECFIA (insulation wool), Euro-Commerce (distribution), Eurométaux (metalworking), FIEC (construction), IMA-Europe (minerals, particularly active in lobbying for crystalline silica) and the UEAPME (for the SME sector). It should be noted that the CEFIC, the organisation representing chemical sector employers, had nothing to do with this initiative.

and maximalist. It even went as far as stating that the amendments endangered the whole revision of the directive.

The following step was more difficult, as it involved reaching agreement between the Parliament and the Council of Ministers. These negotiations took place mainly between March and June 2017. In the ‘trilogue’ procedures, the Council is represented solely by the State holding the 6-month Council Presidency, in this case Malta. This Presidency has to act within a mandate defined on the basis of an agreement between the various Member States, i.e. parallel negotiations take place in the background.

Within the Committee of Permanent Representatives (COREPER), the Member States discuss the proposal and any amendments, while the Council Presidency negotiates with the representatives of Parliament in the ‘trilogue’. The parliamentary delegation was led by the rapporteur, though all political groups took part in the meetings via their ‘shadow-rapporteurs’. Member States were basically divided into three blocs⁷. A significant group of States was in favour of supporting a major part of the Parliament’s amendments. The States most active in this group were Sweden, France, Germany and Belgium, though, in certain questions, up to a dozen States could be involved. Two States (the United Kingdom and Poland) wanted to uphold the Commission’s minimalist proposals and rejected all of the Parliament’s substantial amendments. They were very often supported by Romania and Finland. The other States took middle-of-the-road positions or did not voice a clear opinion. There was thus no clear majority within the Council⁸. The mandate given to the Maltese Presidency made negotiations very difficult. It basically supported the Commission’s initial proposals without making a specific compromise proposal including the Parliament’s amendments. No substantial amendment made by the European Parliament was accepted by the Council and the Commission showed clear hostility towards the Parliament, making any compromise even more difficult. After three meetings without a result, a final meeting (under the Maltese Presidency which ended on 30 June) was held on 27 June, resulting in a compromise proposal which received COREPER support on 11 July 2017. Overall, this compromise represented an important success for the Parliament and for the group of Member States wishing to adopt more ambitious legislation.

The compromise allowed for the adoption of Directive 2017/2398 of 12 December 2017. This directive will have to be transposed by the Member States no later than 17 January 2020. Its provisions are minimum requirements. Transposition should make it possible to adopt at national level provisions ensuring better prevention of occupational cancers.

On four important points, it is indisputable that this compromise is a major step in the right direction (reprotoxic substances, health screening, OELs for hardwood dust and hexavalent chromium). But no real progress was achieved in crystalline silica, meaning

7. These blocs were not static, i.e. their composition changed over time. Depending on the issue in question, certain States could hold more or less favourable positions regarding the Parliament’s amendments. For instance, the amendment on hexavalent chromium benefited from greater support than that on reprotoxic substances.

8. A qualified majority in the Council needs 55% of Member States, representing at least 65% of the EU population. A blocking minority must include at least four Council members representing more than 35% of the EU population.

that we will have to maintain pressure to get its OEL revised in the near future, thereby preventing thousands of deaths.

Table 1 Summary of the most important amendments discussed

Initial Commission proposal	Amendment proposed by the Parliament	Final compromise between Parliament and Council
No inclusion of reprotoxic substances within the directive' scope	Inclusion of reprotoxic substances within the directive' scope	A new (legally binding) article is inserted into the directive, requiring the Commission to consider the possible inclusion of reprotoxic substances into the directive's scope by Q1 2019 at the latest
No screening of workers' health after the end of exposure to carcinogens and mutagens	Health screening in accordance with conditions to be set by Member States	Health screening in accordance with conditions to be set by Member States and/or prevention agencies
OEL of 25 micrograms/m ³ for hexavalent chromium	OEL of 1 microgram/m ³ for hexavalent chromium	OEL of 5 micrograms/m ³ for hexavalent chromium after a 10-year transition period
OEL of 100 micrograms/m ³ for crystalline silica	OEL of 50 micrograms/m ³ for crystalline silica at the end of a 10-year transition period	OEL of 100 micrograms/m ³ for crystalline silica, but the Commission should consider a reduction when compiling the next report on the directive's application
OEL of 3 mg/m ³ for hardwood dust	OEL of 2 mg/m ³ for hardwood dust	OEL of 2 mg/m ³ for hardwood dust at the end of a 5-year transition period

5. The second batch of proposals: exclusion of diesel engine exhaust emissions

On 11 January 2017, the Commission adopted a proposal for the revision defining the second batch of amendments to the directive. Its scope is even narrower than the first. Although the Commission initially announced that 25 (new or revised) OELs would be proposed in the course of 2016, this second batch refers only to 5, making up a total of 18 OELs in the first two batches.

The approach is again minimalist. The main point at issue in this second batch of proposals concerns diesel engine exhaust emissions. In its preparatory work, the Commission considered including these emissions in Annex I of the directive and defining an OEL in Annex III, thereby opening the door for a more systematic prevention of carcinogenic exposure. This was the main issue at stake in this second batch of proposals, given the number of exposed workers in the European Union (more than 3 million) and the number of cancer deaths caused by this occupational exposure. In the impact assessment presented by the Commission for this second batch, it estimated that 230,000 deaths would occur over the next 60 years without a legislative initiative. This is a very much underestimated figure given that it is based solely on lung cancer deaths. When taking into account the other harmful effects of diesel engine exhaust emissions, the number of avoidable deaths is much higher. The same impact assessment is not very transparent in its argumentation justifying the Commission's backtracking, presenting it as a provisional decision open to re-examination. However, the documents adopted

at a later date by the Commission seem to indicate that it is not intending to take any further initiative in either the 3rd or 4th batch of revision proposals (i.e. within the term of office of the current Commission). Two complementary lines of argumentation were formulated. In its impact assessment, the Commission puts forward a legal argument which in our view is completely illogical. It states that it would be difficult to find a satisfactory legal wording able to distinguish between emissions from new engines and those of older engines. However, such a distinction is irrelevant in the context of the CMD. In practice, workers are exposed to diesel engines corresponding to extremely variable construction standards. The composition of emissions from such engines are not dependent solely on construction standards, but also on a number of other factors such as maintenance, filter systems, combustion temperature, etc. Moreover, for diesel engines used in machines and not vehicles, the latest norms do not apply. The objective of the directive is not to define specific rules on the design of diesel engines, their possible replacement or other measures determined by market rules. The directive needs just to be based on the scientific finding that diesel engine exhaust emissions are carcinogenic. This is the conclusion reached by the International Agency for Research on Cancer (IARC) and recently confirmed by the French Agency for Food, Environmental and Occupational Health Safety (ANSES). Industry lobbying follows a more conventional strategy, sowing doubt through calling for new epidemiological studies. If account is taken of the latency period between occupational exposure and the outbreak of cancer, it is not very likely that we will have any epidemiological studies focused exclusively on workers exposed to the emissions of diesel engines corresponding to the latest norms for the next thirty or forty years. With regard to this issue, the statement of the Scientific Committee on Occupational Exposure Limits (SCOEL) that the emissions of these new technologies cannot be considered as carcinogenic is not based on consistent evidence. The only source cited in the bibliography refers to a report by the Boston-based Health Effects Institute. This refers solely to vehicles meeting the latest norms in force in the United States. The laboratory conditions of this toxicological study differ greatly from the real-life working conditions of workers exposed to diesel engine exhaust emissions in both the United States and the European Union. This report is thus not a relevant document for justifying the SCOEL's affirmation.

The issue of diesel engine exhaust emissions (DEEE) is the most important issue of the amendments adopted by the European Parliament, and will be at the centre of the “trilogue” process initiated in May 2018 under the Bulgarian Presidency and which could continue into the second half of the year under the Austrian Presidency. The Parliament's amendments were once again adopted by an overwhelming majority at the Employment and Social Affairs Committee meeting on 27 March 2018 (41 votes in favour, none against and 7 abstentions). Only two political groups, the ECR (conservative nationalists) and the ENL (extreme right) did not support the amendments resulting from a compromise between all the other groups. Claude Rolin of the European People's Party was the main rapporteur for this second batch, while Marita Ulksvog became the “shadow-rapporteur” of the Socialists and Democrats group. The convergence between these two groups has been decisive in the parliamentary work regarding the first two batches. The main amendments voted by Parliament on the second batch bring DEEE into the scope of the Directive (Annex I), setting OELs for two components of these emissions (elemental carbon and carbon dioxide) in Annex III. The Parliament

also proposes a more precise definition of polycyclic aromatic hydrocarbons (PAHs) for Annex I, the annex determining the scope of the Directive with regard to process exposures. It has also adopted a recital calling on the Commission to include occupational exposure to cytotoxic drugs within the scope of the Directive. From a perspective linking occupational health to gender equality, this amendment is of particular importance.

In the healthcare sector, many drugs have harmful consequences for staff. This is particularly the case of cytostatic substances used to treat cancers (chemotherapy). At all stages – drug preparation, treatment administration, contact with the urine or sweat of patients, waste disposal and laundry cleaning – hazardous exposures can occur if the work is not organized properly. These exposures cause cancer themselves and are reprotoxic (fertility problems, miscarriages, etc.). The staff concerned is predominantly female. While there is a serious underestimation of all occupational cancers, for women, this invisibility is particularly high. Many stereotypes associate cancers with male jobs in traditional industries, a bias also noticeable in the revision of the directive. The majority of the substances considered by the European Commission concern male jobs. This is why the amendment concerning cytostatic drugs would contribute to a better prevention of occupational cancers in highly feminized professions.

6. The third and fourth batches of proposals

The Commission adopted its proposal for the third batch on 5 April 2018 (European Commission 2018). Its content is limited to five substances or groups of substances (cadmium and its inorganic compounds, beryllium and its inorganic compounds, arsenic acid, formaldehyde and MOCA). It reflects the compromises negotiated within the Advisory Committee for Health and Safety with respect to these substances. This text is unlikely to cause much controversy, although some employers' organizations may question the proposed OEL for cadmium and its inorganic compounds. The employer's position is, however, fragile from a legal point of view. It advocates the adoption of a biological limit value, in the knowledge that the CMD does not currently allow for the adoption of binding biological limit values. The European Parliament will adopt its amendments on the third batch in November 2018.

It is too early to know what will be the precise content of the fourth batch. It seems accepted that OELs will be proposed for nickel and its compounds as well as for acrylonitrile, and that the OEL for benzene should be revised. Diesel engine exhaust emissions should also be included in the fourth batch if the Parliament's amendments to the second batch are rejected by the Council.

In fact, the most important legislative debate for 2019 will not concern the fourth batch. It will focus on the regulation of occupational risks related to reprotoxic substances. On the basis of an amendment adopted with the first batch, the Commission is required to submit an impact assessment before the end of the first quarter of 2019. Such an assessment should logically be accompanied by a legislative proposal unless the Commission rejects any change to the CMD in this area. This last hypothesis seems unlikely, especially as, within the Commission itself, several DGs (i.a. Grow and

Environment) are calling for an approach consistent with other Community legislation, i.e. setting the same set of rules for all CMRs. While the negotiations between the Parliament and the Council on the first phase led to a compromise, the Commission surprisingly launched a consultation of the trade unions and employers on 26 July 2017 under Article 154 of the Treaty on the Functioning of the European Union (TFEU). In this new document (European Commission 2017c), the Commission announces that it will not propose a new OEL for hexavalent chromium and that it will keep to the compromise negotiated between Parliament and Council in 2017 despite the high level of residual risk of this OEL. The document does not provide any explanation on how to reach the target of 50 OELs in 2020, merely listing the substances for which OELs will be proposed in the third and fourth batches. The main issue at stake in the upcoming revisions is however not the number of OELs, but concerns two subjects completely ignored in the consultation launched in July.

The inclusion of reprotoxic substances remains a key issue, but there is absolutely no mention of it in the document submitted to the social partner consultation. We will not be going into the importance of this issue as it is the subject of a specific article on page 179.

In its replies to the consultation⁹, the European Trade Union Confederation considers it essential that the European Union adopts a comprehensive strategy for eliminating occupational cancers and not one limited to ad hoc and partial adaptations focused on OELs. Although the consultation ended in December 2017, the Commission has still not adopted a communication based on the results of the consultation.

The other subject involves the way OELs are determined. The approach currently favoured by the Commission involves a cost/benefit analysis. This leads to widely varying protection levels dependent on the substance concerned. For instance, the OEL proposed by the Commission for hexavalent chromium in the first batch of proposals corresponds to a residual risk of one case of lung cancer per 10 exposed workers. Moreover, the Commission's impact assessments are biased insofar as they systematically exclude health impacts other than those related to cancer, as seen for instance in the assessments carried out for crystalline silica. Such an approach is inconsistent, as the majority of carcinogens have other harmful effects. For instance, diesel engine exhaust emissions play a major role in the development of cardiovascular diseases, crystalline silica causes respiratory diseases, beryllium is a sensitizing agent, etc. It is clear that reducing exposure to (and ultimately eliminating) carcinogens has health impacts going beyond that of preventing cancer. It would certainly lead to overall lower morbidity and mortality levels, also among those not directly exposed. A reduction in diesel engine exhaust emissions, for instance, would generally improve air quality. In our view, the cost/benefit methodology is incompatible with TFEU Article 168 which requires that "A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities". This methodology also contradicts one of the fundamental principles of EU health and safety policy, according to which "improvement of workers' safety, hygiene and health at work is an

9. These documents are to be found in the book's annex.

objective which should not be subordinated to purely economic considerations”¹⁰. The Commission itself recognized the importance of this issue in 2007. In the document introducing the second stage of the consultation (2007) of the social partners on revising the CMD¹¹, the Commission wrote: “Nevertheless, scientific, technical and socio-economic data alone will not be sufficient to enable binding limit values to be set for carcinogenic, mutagenic and reprotoxic substances. What is also needed is an appropriate definition by the political authority of the level of risk that can be accepted by society. The Commission is of the opinion that these criteria for setting BOELVs¹² for carcinogenic, mutagenic and reprotoxic substances must be included in any future initiative”. Less than ten years later, against all evidence, the Commission was to state: “There were no significant divergences on the methodologies to be used and the criteria to be set up for the derivation of limit values” (European Commission 2016).

A much more consistent approach used in many Member States involves defining two risk levels: the first which, whatever the case, must never be exceeded; and the second, much lower, which constitutes the target to be achieved. The transition from the one level to the other must be ensured in two complementary ways. On the regulatory side, periodic revisions of OELs are needed to move from the first to the second level, taking account of technological progress. On the corporate side, each company must define concrete plans for minimising exposure, thereby ensuring a planned step-by-step reduction in exposure levels.

7. Conclusions

The various factors subject to the ongoing revision of the CMD were already on the agenda in 2004 when the first phase of social partner consultation was opened. The cumulative delays have had dramatic consequences, helping to aggravate social inequality in health within the European Union. The legislative moratorium adopted in 2013 has nourished the representation of the legal rules governing workers’ health and lives as an administrative burden. The current measures are nothing more than catching-up measures, allowing the CMD to be adapted to the status quo of scientific knowledge of the late 20th century and to the prevention possibilities of that time. In the meantime, new scientific knowledge is appearing, especially in the field of the causes of cancer (carcinogenesis), the role played by epigenetic processes, endocrine disruptors, the transgenerational effects of certain occupational exposures, the risk associated with the nanomaterials now finding their way onto the market, the role of multiple exposures (including interactions between exposures to chemical agents and other carcinogens), research into biomarkers reflecting physical harm to the body before a disease actually breaks out, the importance of working conditions in breaking down immune defences, etc.

10. This recital in the Framework Directive of 12 June 1989 has been acknowledged by the Court of Justice of the European Union as one of the cornerstones of Community legislation on protecting the health and safety of workers (ruling of 12 November 1998, United Kingdom vs. the Council, case C-84/94).

11. This document is available at <http://ec.europa.eu/social/BlobServlet?docId=2179&langId=en>

12. In the Commission document, this acronym stands for “Binding occupational exposure limit values”. These correspond to the OELs in CMD Annex III.

While the current legislative revision is absolutely necessary, it must not block out the need to find legislative responses to a whole range of issues related to emerging risks or to a better understanding of the problems raised. We are only at the start. There is still much work to be done. We need to create a balance of power allowing a comprehensive strategy for eliminating occupational cancers to be defined. This fight goes hand-in-hand with actions to defend the environment against chemical risks. It also has a decisive role to play if we want to combat social inequality in health. Beyond their immediate results, the current intense debates are of great importance in emphasising the political dimension of the fight against cancer.

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Chapter 19

The medium-term perspective: a single OSH Directive for all chemical substances

Henning Wriedt

1. Introduction

Workers in the EU are protected against carcinogenic substances by a special EU occupational safety and health (OSH) directive, the 2004 Carcinogens and Mutagens Directive (CMD, Dir. 2004/37/EC). It was originally based on the 1990 Carcinogens Directive (Dir. 90/394/EEC), which came into force before the 1998 EU Chemical Agents Directive (CAD, Dir. 98/24/EC). The CMD is also partly based on two International Labour Organization (ILO) instruments from 1974: the Occupational Cancer Convention (C139) and the Occupational Cancer Recommendation (R147).

The fact that many EU member states have transposed the CMD and CAD directives into national law via a single regulation is in itself an argument for consolidating them. More important though is the effect of the CMD since it came into force, in particular the way carcinogens have been substituted by less hazardous substances and the degree to which exposure has been reduced. Another issue is whether the CMD can stay abreast of developments in scientific knowledge.

These concerns are illustrated by the following observations:

- Recent attempts to develop more binding occupational exposure limits (BOELs) for the CMD have revealed the very slow progress in reducing exposure levels. These efforts depend on enforcement by authorities, which is often lacking.
- No comprehensive employer data is currently available on the nature, degree and duration of worker exposure to carcinogens and mutagens, even though this is one of the CMD's fundamental requirements and EU member state authorities have the right to request it. This lack of data both hampers scientific research on occupational cancer and restricts further regulatory developments.
- Although OSH regulation on respiratory risks has always been seen as more important than dermal exposure, many chemicals used in the workplace can be absorbed through the skin, suggesting that this issue deserves greater attention.
- The occupational exposure limit (OEL) concept underlying the CMD is outdated as it takes no account of risk-based limits, as introduced in the Netherlands in the mid-1990s and Germany in 2008. Also, only three carcinogens – benzene, hardwood dust, and vinyl chloride monomer – have been assigned binding OELs between 1990 and 2016.

- The recent drafting of recommendations for additional binding OELs for carcinogens has revealed a disturbing fact: no methodology has yet been developed to set binding OELs under the framework defined by the CMD.
- The CMD is still based on assumptions dating back to the 1970s and early-1980s that effect thresholds (the point at which the chemical agent has no adverse health effect) do not exist for carcinogens with genotoxicity (the ability of chemical agents to damage a cell's genetic information) as the mode of action. But since the mid-1980s, evidence has emerged that effect thresholds are likely to exist for certain carcinogens with inflammation-induced modes of action.
- The CMD's scope conflicts with the REACH regulation's scope of substances of very high concern (SVHCs). All carcinogens and mutagens placed on the market are covered by the CMD and, at the same time, are eligible to be SVHCs pursuant to article 57 of REACH. Yet reprotoxic substances and other substances of "equivalent concern" used at the workplace are also eligible as SVHCs under REACH but remain outside the scope of the CMD. There has been no progress in the regulatory efforts that began fifteen years ago to extend the scope of the CMD to reprotoxic substances.
- There are possible overlaps between the REACH regulation and OSH legislation, for example, when it comes to workers' health under the REACH authorisation procedures (REACH Title VII) and restriction procedures (Title VIII). A recent proposal to restrict the use of 1-Methyl-2-pyrrolidone (NMP) revealed conflicts between the two. Solutions are needed to prevent the two regulatory processes interfering with one another. This is not a hypothetical issue: NMP, which can be absorbed through the skin, is a reprotoxic solvent used at work. The aim of the proposed restriction under REACH is to introduce regulatory measures, notably to protect pregnant women and the unborn, but this is not always the right approach for the occupational health and safety issues at stake.
- The binding OELs in the CAD and CMD are supposed to reflect both feasibility factors and health considerations. In other words, binding OELs are designed to both take account of technical and socio-economic considerations on top of health aspects. However, no details are provided on how these considerations should be practically applied when deriving limit values. By contrast, guidance for socio-economic analysis does exist in the REACH regulation.

These observations show that the EU OSH directives on hazardous chemicals need to be modernised and aligned with the REACH regulation.

The following chapter explains how this could be achieved via a consolidated OSH Directive for chemical substances. This would retain the successful parts of the two current directives, while revising or amending the more troubling portions.

2. Approach

The consolidated, single OSH Directive for chemical substances should not be rewritten from scratch. Rather, the revision should take account of approaches from across Europe that might serve as starting points. One such example is the German Hazardous Substance Ordinance, the single regulatory instrument used to transpose both the CAD and the CMD into German law.

2.1 The German Hazardous Substance Ordinance

The 1986 German Hazardous Substance Ordinance, which sets rules on the use of carcinogens in the workplace, was adapted to take account of the EU's 1990 Carcinogens Directive (90/394/EEC). The Ordinance was overhauled when it took on the provisions of the Chemical Agents Directive (98/24/EC). This 2004 revamp set general obligations for all chemical substances within the scope of the CAD, and additional obligations – as laid down in the CMD – for carcinogenic and mutagenic substances.

Talks on extending the CMD to cover reprotoxic substances have gone on since the turn of the millennium. During that time, Germany has extended the rules on carcinogenic and mutagenic substances to include reprotoxic ones. As most reprotoxic substances have effect thresholds for reprotoxicity, the Ordinance's section on carcinogenic, mutagenic, and reprotoxic (CMR) substances exempts the use of these substances if exposure is below a health-based OEL. In such situations, an employer's obligations are limited to those for non-CMR substances.

The substitution obligation is not affected by this qualification: it applies to all CMR substances, irrespective of the existence of an effect threshold. The serious concerns regarding these substances mean that substitution or use in a closed system are considered as safer solutions than exposure minimisation.

One consequence of Germany's extension of the CMD to reprotoxic substances was that existing OELs were checked to see if their values were below the effect threshold. OELs were then derived for relevant reprotoxic substances that did not as yet have them. Ten years without employer complaints about this approach suggests it is a viable solution.

2.2 Outline of a single OSH Directive for chemical substances

2.2.1 Structure

The experience gained in applying the German Hazardous Substance Ordinance can help guide efforts to merge the existing CAD and CMD into a single OSH Directive for chemical substances. This single directive could be based on the structure of the current CAD, with a section on substances of very high concern (SVHCs) that includes any CMD obligations transcending those in the CAD (for details cf. section 2.2.3. below).

The new directive would keep the two obligations establishing inherent safety: substitution obligation and the obligation of use of a closed system if technically possible. The remaining additional obligations would be waived for uses of a substance under certain conditions:

- a health-based OEL exists;
- workplace exposure is below that OEL;
- the effects posed by simultaneous exposure to different substances are taken into account;
- for substances with a skin notation (i.e. absorbable through the skin) and when use does not include manual handling that could lead to repeated or prolonged skin contact.

In addition to a mere consolidation of the current contents of both the CAD and the CMD, certain aspects of both the REACH regulation itself and its outcome could also be incorporated in a single OSH Directive, in particular the information generated by the registration procedure, the notion of SVHCs, and the authorisation procedure.

2.2.2 Scope

The scope of the single OSH Directive would be identical to the existing CAD and CMD, covering substances on the market, substances generated through work activities (so-called process-generated substances) and substances contained in products or in the work environment which are no longer produced or marketed, such as asbestos ('legacy substances'). By contrast, the scope of the REACH regulation is limited only to substances on the market.

The REACH regulation should serve as the template for the SVHC section of the single OSH Directive, irrespective of the overall wider scope of the latter directive. Coverage would be extended by aligning it with art. 57 of the REACH regulation, thus ironing out the differences between the two, while creating new synergies.

It would also mean that the reprotoxic substances in categories 1A and 1B would be included in the SVHC section of the single OSH Directive irrespective of whether they are in the SVHC candidate list under art. 59 of REACH. Substances not classified as CMR 1A or 1B yet raising equivalent concerns could be included in a separate annex similar to Annex I of the current CMD - but only after they have been added to the same REACH candidate list related to concerns over workers' health. This last condition is needed to avoid including SVHCs based on consumer health or environmental aspects rather than workers' health, as those concerns are outside the scope of OSH legislation.

2.2.3 Control measures

Section 2.2.1 refers to specific obligations under the CMD that go beyond the CAD. They include:

- the tiered approach to protection from exposure: substitution, use of a closed system, and exposure minimisation;
- providing information on exposure and related issues to competent authorities upon request;
- training, informing and consulting workers;
- health surveillance both during and after employment;
- keeping records on exposed workers and their health surveillance.

The three elements of the tiered approach on protection from exposure have helped improve the situation with regard to workers' exposure to carcinogens since the mid-1980s, when the content of the CMD was first developed. The ECHA website (available at: <http://echa.europa.eu/information-on-chemicals/registered-substances>), which gathers information on chemicals registered under REACH, shows that some carcinogens have not been registered at all, even though Germany gave them OELs in the 1980s. It is not clear why they disappeared from the European market, but it could in part be due to a successful substitution process. Another possible explanation is a relocation of production and use sites outside the EU, or a phasing-out of uses due to changes in markets and technology. Other carcinogens with technical-based OELs have been registered for use as intermediates only, or under strict control conditions like a closed system. In other words, exposure should have been eliminated completely or at least considerably reduced.

2.2.4 Exposure minimisation and action plans

The absence of reliable exposure information across industry means it is harder to assess the third tier, exposure minimisation. Data, although scarce, indicates falling exposure levels in some sectors. However, that cannot be extrapolated across industry as a whole. Given both the absence of a specific regulatory strategy on exposure minimisation and the precarious level of enforcement in a number of EU member states, some sectors have probably seen little progress on reducing exposure to carcinogens. The Netherlands and Germany have addressed this concern by introducing an additional tool: an action plan in which employers have to describe their intentions on how, by when, and to what extent they plan to further reduce exposure levels¹. Taking the form of an addendum to the documentation of the risk assessment, such an action plan allows worker representatives and labour inspectors to monitor employer compliance on reducing exposure. The obligation to provide such an action plan as part of the risk assessment should be specified in the SVHC section of the single OSH Directive.

2.2.5 Dermal exposure and uptake

For substances that can be absorbed through the skin, certain conditions of use can result in dermal exposure with a higher risk than respiratory exposure, especially with repeated or prolonged skin contact. These substances are tagged with a skin notation, providing key information for the employer's risk assessment.

1. For further details see chapter 9 in this book.

The skin notation is usually available for substances assessed by scientific committees, in particular when it comes to setting an OEL. This information is not part of the classification under the CLP regulation, nor is it easily accessible in the database of REACH-registered substances.

Skin contact with hazardous substances is particularly relevant for manual tasks like construction, work in sheltered workshops or hospitals, cleaning, maintenance and repair work. Manual tasks are more widespread amongst SMEs, which find risk assessment for hazardous substances particularly challenging. So when it comes to specific guidance on protection against dermal exposure, the new OSH directive should provide employers, particularly SMEs, with adequate support to help them comply with their mandatory obligations. One example of such guidance comes from Germany's Technical Rule on risks resulting from skin contact (electronically available at: www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/TRGS-401.html).

Dermal absorption is relevant for many SVHCs as the body can take in the most serious carcinogens and reprotoxic substances through this route.

2.2.6 Compilation of exposure information by EU member states

The current CMD allows EU member state authorities to request exposure information from employers. However, as no government seems to have made use of this possibility, member state reporting requirements to the Commission should be added to a single OSH Directive, thus forcing authorities to collect exposure data for SVHCs. This information would serve two purposes. Firstly, it would help identify sectors or uses with particularly high exposure levels, and could in turn initiate targeted support and enforcement measures. Secondly, it would shed light on progress in exposure reduction, and could thus lead to evidence-based revisions if necessary.

As for SVHCs with an effect threshold, the aim is to keep exposure levels below that limit. Substances should be exempted from the obligation to be covered by an action plan on exposure reduction if a health-based OEL exists and workplace exposure is below that OEL. Those uses should also be excluded from member states' reporting requirements to limit their additional burden.

2.3 SVHCs and risk management instruments

As this publication focuses specifically on carcinogens, the following sections look more closely at the different types of carcinogens and other SVHCs, suggesting appropriate instruments to manage their risks. These include instruments like OELs, the authorisation mechanism of uses foreseen under the REACH regulation, and guidance on specific tasks and uses. The best instrument for the respective exposure situation depends, at least partly, on the characteristics of the SVHCs involved.

2.3.1 Relevant SVHCs

Three types of SVHCs were addressed in section 2.2.2, above: substances on the market, process-generated substances and legacy substances. CMR substances (classes 1A or 1B) produced or imported at volumes over one tonne per year have to be registered under REACH before being marketed. This rule allows regulators to prioritise further action on CMRs according to their production volumes, while letting worker representatives check if CMRs at the workplace are on the market legally.

From a chemical perspective, SVHCs can be present as individual substances or as mixtures of substances. Mixture examples include petroleum and coal stream (PetCo) substances, and several process-generated substances (for further details, see section 2.4.4 below).

SVHCs might have an effect threshold (a point below which the substance does not trigger an adverse health effect) from a toxicological perspective. Current scientific opinion considers that reprotoxic substances have an effect threshold except when they also have carcinogenic properties. By contrast, not having an effect threshold means no exposure threshold has been identified below which the adverse health effect does not occur. Current scientific opinion suggests most carcinogens have no effect threshold.

However, these definitions do not take account of the broad range of scientific complexities. Scientific propositions are based on the current state of knowledge: any regulation that uses them will be affected by potential scientific uncertainties. They will also be affected by the influence that interest groups wield over the regulatory process.

2.3.2 SVHCs with an effect threshold

These provisions should be borne in mind when taking a closer look at the scientific propositions. The European Commission's Scientific Committee on Occupational Exposure Limits (SCOEL) is currently trying to assign carcinogens to one of four categories: without a threshold, situation not clear, practical threshold and true threshold. The German scientific committee looking into exposure-risk-relationships (ERRs) for carcinogens takes a similar route, but with a nuance. Instead of a "practical threshold" category, it uses a "non-linear exposure-risk-relationship" one. For carcinogens in that category, no threshold is assumed: it only has slowly increasing risks below a certain concentration value and a much steeper increase above that value. Thus, the resulting ERR is not linear but takes the shape of a hockey stick.

These two scientific bodies have different assignments for a number of carcinogens. SCOEL considers some carcinogens to have either a true or a practical threshold, which the German committee does not support. These include cadmium compounds, ceramic fibres, nickel compounds and trichloroethylene. By contrast, the German committee assumes a linear ERR for cadmium compounds and ceramic fibres, but a non-linear one for nickel compounds and trichloroethylene.

The two committees agree that there is a threshold for carcinogenicity for at least three substances, namely formaldehyde, propylene oxide, and naphthalene (still classified as C2, naphthalene is therefore outside the scope of the CMD). The German committee has so far identified 24 carcinogens or groups of carcinogens without a threshold: a linear ERR was derived for 18 of them, a non-linear ERR for two and no ERR could be derived for another four. By contrast, thresholds were assigned and health-based OELs were derived for only five carcinogens. Of these, two are considered as threshold ones (formaldehyde, isoprene), whereas for the other three (beryllium, butylene oxide, propylene oxide), the additional cancer risk at the OEL is considered to be so small (i.e. at or below an additional cancer risk of 4:100,000 over 40 years of exposure) that any further exposure reduction would not result in meaningful risk reduction.

2.4 Risk management instruments

2.4.1 OELs

General considerations

OELs serve two main functions as tools for respiratory exposure risk assessment:

- they define the level of protection which should at least be achieved for the design of control measures;
- they are the yardsticks for assessing the effectiveness of control measures and their improvement if need be.

Different types of OELs are defined in the CAD (indicative and binding ones, or IOELs and BOELs, respectively), while the CMD has only binding OELs, and the REACH regulation works with so-called derived no-effect levels, or DNELs.

An OEL can be set differently according to the health hazards of the substance in question. It can be set either for short-term exposure, typically as an average value for 15 minutes (for some substances, it can be a ceiling value that should not be exceeded at all). Or it can be set for long-term exposure, typically as an average value for the duration of a whole shift, i.e. for eight hours. For some substances, both long- and short-term OELs have been derived. For substances where only an eight-hour OEL has been derived, some EU member states have stated that, by default, no short-term exposure should exceed the long-term OEL by a factor of eight. But the eight-hour OEL is relevant for most of them since OELs refer to detrimental long-term health effects.

While some OELs for dermal exposure might be of scientific and regulatory interest, the absence of suitable instruments for monitoring dermal exposure at the workplace means they are not always practical.

OELs for SVHCs

From a scientific point of view, there are obvious ways to set OELs for SVHCs. For SVHCs with an effect threshold, the instrument of choice is a health-based OEL below the effect threshold.

For SVHCs without an effect threshold, like most carcinogens, a risk-based OEL could be the preferred option. This would assume that a consensus could be reached on introducing an overall, substance-independent, risk value for the additional cancer risk on which each OEL were to be based, and the regulatory consequences if exceeded. One obvious action in the case of an OEL being exceeded is the mandatory use of respiratory protective equipment (RPE). By contrast, compliance should not impact the overall obligations to minimise exposure and to write an action plan on future minimisation steps.

But the way forward is more complex from a regulatory context and requires adaptations to current instruments. Although no major changes to the SCOEL methodology are needed to set health-based OELs, member states should no longer be allowed to set higher values than those derived by SCOEL. In other words, health-based values have to be binding, but unlike the current binding OELs, technical or socio-economic factors should not be considered.

A new methodology for establishing binding OELs is needed anyway for carcinogens without a threshold, such as the prototype of non-threshold SVHCs, as the current situation is unsatisfactory. The obvious though challenging way forward under the outline listed above would be a new approach, like the Dutch and the German one, that includes risk-based OELs.

This regulatory approach would leave no room for binding OELs set using technical feasibility or socio-economic considerations. These issues should be covered instead by the REACH regulation's authorisation mechanism. For carcinogens outside the scope of REACH, such as process-generated crystalline silica, a corresponding regulatory mechanism should be set up. Additional details are outlined in section 2.4.3 below.

2.4.2 Number of OELs needed

It should be possible to set OELs for the most relevant CMR substances, even if the classification and labelling information on notified and registered substances (C&L Inventory) on the ECHA website (<http://echa.europa.eu/information-on-chemicals/cl-inventory-database>) suggests otherwise with its huge list of such substances.

However, the information from the C&L Inventory should not be taken at face value. A single OEL would suffice to cover all the compounds in certain groups of substances, such as the different carcinogenic metals and their compounds: arsenic, cadmium, chromium (VI) compounds, cobalt and nickel. By contrast, an OEL would be futile for the coal and petroleum-related products that account for most of the carcinogen entries in the C&L Inventory: other approaches would be needed (see section 2.4.5, below). Of the remaining carcinogenic substances or groups of substances, about 40 are registered under REACH with a full registration of uses that might result in workers' exposure. Another 25 are registered for intermediate use only, or for use under strictly controlled conditions, which is comparable to the way the CMD refers to use in a closed system.

Similarly, the number of OELs needed to cover relevant reprotoxic substances can be estimated. Again, a single OEL might suffice for two groups of substances, lead

compounds and boric acid derivatives. A number of substances are also classified as carcinogens (C 1A / C 1B) and thus do not need to be considered a second time. Of the remaining substances or groups of substances, about 30 have a full REACH registration and about another ten are registered for intermediate use only.

Eight of the reprotoxic substances on the list now have OELs at EU level or are subject to a SCOEL recommendation. SCOEL is still working on recommendations for another two. OELs have been derived for a further four reprotoxic substances in the German list of health-based OELs. The German MAC Commission has made OEL recommendations for an additional four reprotoxic substances. In other words, health-based OELs or recommendations for them are already available for the majority of the most relevant reprotoxic substances. However, this has to be qualified as the scientific committee has warned that there is no certainty that an unborn child would be protected under half of the OELs or recommended OELs.

Only CMRs or groups of CMRs registered under REACH should be considered as relevant in Europe as their annual production or import volume exceeds one tonne. An OEL should be urgently considered only for those with full registration.

2.4.3 Authorisation of SVHCs

The introduction of health- and risk-based binding OELs will have important consequences regardless of their technical or socio-economic feasibility: for some SVHCs there will be certain uses not complying with the binding OEL concerned, though this might not be the case for other uses thereof, while identical or similar uses of other SVHCs will comply with their respective binding OELs.

This situation, where different uses of the same substance result in different exposure levels, given that control measures of the same level of technical feasibility are applied, cannot be reconciled with the current technical-based OELs. These OELs do not distinguish between different uses of a substance. Instead, the resulting binding OEL will most likely be based on a use that creates the highest exposure level over the whole use spectrum. For all other uses, the OEL will apply in spite of lower exposure levels already achieved.

A better regulatory approach in such a situation could be to use the authorisation mechanism of the REACH regulation. That mechanism would allow differentiation between different uses of the same substance, while also facilitating monitoring of company-level efforts regarding substitution, the use of closed systems and exposure minimisation. The specific authorisation conditions (cf. art. 60 of the REACH regulation) could serve a similar purpose to the action plan (cf. section 2.2.4, above), allowing not only labour inspectorates but also workers and their representatives to closely monitor employer compliance with those conditions.

Different scenarios could be established depending on the type of OEL and on compliance with its value:

- For substances with a health-based OEL, the risk of uses with an exposure below the OEL should be qualified as “adequately controlled”. Such uses should thus be exempted from the authorisation mechanism.
- For substances with a risk-based OEL, uses with an exposure below the OEL should be granted a long-term authorisation if the applied occupational safety and health measures conform to good practice, and if the action plan specifies future measures for exposure reduction.
- For substances with a health-based or risk-based OEL, uses with an exposure exceeding the OEL should only be granted a short- or medium-term authorisation if the occupational safety and health measures applied conform to best practice, and the action plan specifies future measures for exposure reduction. In addition, RPE would need to be used by workers, implying that additional breaks and recuperation times would also be needed.

A similar approach should be taken for manual uses of substances that can be absorbed through the skin if they lead to repeated or prolonged skin contact. Those uses should also go through the authorisation mechanism, with authorisation only being granted if the occupational safety and health measures for manual handling conform to best practice and future measures for further reducing or completely avoiding skin contact are specified in an action plan. In addition, personal protective equipment, in particular protective gloves, would have to be worn by workers, again implying that additional breaks would have to be granted on a daily basis. Sufficiently long work phases without wearing gloves also have to be foreseen, so that the prolonged use of protective gloves does not damage the skin.

The approach outlined here, replacing the use of technical-based binding OELs with health-based or risk-based ones plus an authorisation mechanism, would increase pressure to comply with obligations to reduce exposure to SVHCs (which has worked poorly for carcinogens in the past).

One reservation has to be mentioned, though: during the first authorisation procedures under REACH, there were controversies on assessing the economic feasibility of alternative solutions. These controversies need to be resolved before exploring the authorisation mechanism to replace the technical-based OELs referred to above.

2.4.4 Process-generated SVHCs

As mentioned in section 2.3.1, regulation of process-generated substances differs in key respects. Some of these, like diesel engine exhaust emissions (DEEE), silica dust and hardwood dust, are dealt with in the same way as other substances with OELs. Others are seen as mixtures which large numbers of workers could be exposed to. These include polycyclic aromatic hydrocarbons and their nitro-derivatives (PAHs), used mineral oils, polychlorinated dibenzo dioxins and furans (dioxins) and N-nitrosamines.

The situation is more complex for the second group of process-generated mixtures due to the variable composition of their constituents and the differences in their carcinogenic potency. Although OELs have been derived for some individual substances from those groups – e.g. for benzo(a)pyrene and N-nitroso dimethylamine – there are no OELs for each of these groups as a whole. This is not surprising given the differences in the ERRs or the dose-effect curves of the individual substances in each group: the eventual results depend on the mixture's composition and the amounts of the individual substances in it. The composition depends not only on the nature of the generating process but also on key process parameters (temperature, composition of basic substances and presence of specific compounds). It would therefore be of little use to determine a key component and use it as a proxy for the mixture.

From a scientific point of view, any OEL derivation would have to start by identifying the individual constituents to determine their respective amounts in the specific mixture. The ERR (or the dose-effect curve) of that specific mixture could then be calculated without considering any potential interaction between constituents. However, this approach is not viable in practice as the ERR (or the dose-effect curve) has not yet been determined for most of the individual substances in those mixtures. And given the large number of different constituents, it is highly unlikely they will be determined in the foreseeable future.

There is a further complication when it comes to substances for which the exposure risk is through the skin rather than by inhalation: specific solutions on dermal exposure assessment have to be developed for them. This also applies to the petroleum and coal stream substances addressed above: they contain PAHs or other carcinogens to a variable extent, and dermal exposure is also a significant risk.

In other words, assessment tools based solely on scientific evidence, such as OELs, are not an option for such complex mixtures. A different approach is thus required.

2.4.5 Guidelines

Such an approach could consist of guidelines for optimising both the operational conditions of the underlying process and the selection of the most effective control measures. It could be complemented by a more pragmatic assessment tool for the exposure generated during the process. This assessment tool should be scientifically underpinned by the ERR (or the dose-effect curve) of a representative substance for that type of mixture for which sufficient data is available (e.g. benzo(a)pyrene for PAHs, or N-nitroso dimethylamine for N-nitrosamines). But it should also be based on a scientifically informed convention on weight factors for adding up the contribution of the individual constituents.

The guidelines for recommendations on the operational conditions and the control measures should be non-binding to reduce the length of the regulatory process. To give it more legal weight, the Commission should be mandated to include such guidelines in the single OSH directive. The guidelines could also be complemented by the promotion of good practices on the website of the European Agency for Safety and Health at Work in Bilbao.

Guidelines are already available for some processes in certain member states: the UK has operational guidance on coke oven emissions and COSHH essentials on machining with metalworking fluids; Germany has technical rules on processes involving PAHs and N-nitrosamines. EU-level guidelines should build on these existing member state guidelines.

2.4.6 Legacy SVHCs

Restricting certain substances like asbestos does not prevent them being present in the workplace today, nor does authorisation exclude them from tasks beyond those authorised. The past use of certain SVHCs, before restrictions or authorisations were introduced, means they are still present in all sorts of objects and products, from industrial sites to buildings to machinery, vehicles and appliances. A number of tasks involving those objects and products - like maintenance and repairs, demolition, or recycling - will mean exposure to 'legacy substances', such as asbestos, carcinogenic glass fibres, PAHs, lead or other heavy metal pigments, for the foreseeable future.

Although OELs for these substances can help in assessing the risks associated with different tasks, the manual nature of many of these tasks will result in high risks anyway, particularly if the legacy substances are present in relevant concentrations. As in the previous section, specific guidance for such tasks seems similarly warranted as a complementary regulatory tool.

3. Summary

A consolidated, single OSH Directive for chemical substances could do much to address the regulatory shortcomings and deficits outlined in the introduction. The enforcement of certain obligations would also be made easier.

The key aspects of such a consolidated directive are:

- extending the scope of the current CMD to align it with the scope of SVHCs under REACH;
- introducing an action plan as part of the risk assessment for uses of SVHCs with mandatory exposure minimisation;
- introducing regular monitoring and reporting requirements by member states to the Commission on SVHC exposure levels;
- putting a stronger focus on dermal exposure in risk assessment;
- mandating the Commission to issue non-binding guidelines for certain processes and tasks, in particular those involving legacy substances or creating complex process-generated mixtures;
- modernising the outdated OEL concept and basing it solely on health-based and risk-based OELs;
- abandoning technical-based OELs and replacing them, when necessary, with a mechanism tailored to the REACH authorisation process;

- adapting the CMD to state-of-the-art scientific knowledge, in particular by recognising the existence of different modes of actions for carcinogenicity.

A consolidated directive would be improved considerably by prioritising additional OELs for the SVHCs most relevant in the workplace. An initial survey of the relevant ECHA databases suggests a manageable number. Additional needs have been identified for specific assessment tools for certain process-generated carcinogens, such as PAHs, dioxins, and N-nitrosamines, that have a variable composition of constituents. In addition, specific guidance is needed for tasks involving complex mixtures and on protection against dermal exposure.

Part 4

Occupational cancers: recognition and costs

Introduction

Societal awareness of occupational cancers can best be explained using the image of an iceberg: the tip of the iceberg – corresponding to the number of cases of work-related cancer recognised and compensated each year in the EU-28 – represents only around 10% of the actual number of cases assumed to be associated with working conditions. In our industrial societies, the vast majority of occupational cancer cases remain invisible. Although the scale of the problem differs between Member States, cancers of this type are underreported and predominantly ignored throughout the EU.

This invisibility has a knock-on effect on the measures which can be put in place to prevent and avoid these occupational diseases, since it is difficult to organise preventive action (and in particular to improve existing policies) without a clear sense of the magnitude of the problem and its causes.

The Part 4 therefore takes stock of the situation surrounding the recognition of cancers of occupational origin in Europe, with reference to both the obstacles faced and the significant costs incurred by victims, their families and society as a whole.

The first contribution describes how the system for recognising occupational cancers is operated in various European countries, listing virtually every type of cancer (broken down by tumour location and causal agent) currently included on national lists of occupational diseases and therefore presumed – more or less automatically, depending on the country – to be of occupational origin. Alongside the lists, many European countries operate a supplementary “off-list” recognition system which requires sufferers to supply evidence that their cancer is of occupational origin; this is a much more challenging task, and very few succeed in achieving it. Although the recognition rate for occupational cancers varies between Member States, 80% of the cases recognised in most European countries are asbestos-related.

The second contribution digs deeper into the many obstacles encountered in connection with the declaration and recognition of work-related cancers. Cancers are multifactorial diseases, and potential links to the sufferer’s working life can be hard to pinpoint. Tumours of occupational origin rarely differ substantially from those of other origins, and they are often first diagnosed after a latency period lasting up to several decades (20 years on average, and sometimes as long as 40 years). Perhaps more importantly, the doctors who diagnose these cancers are seldom interested in their patients’ work

history, and many of the patients themselves are unaware of the fact that they have been exposed to carcinogens over the course of their working life. Even if these hurdles are cleared and a link is established between a case of cancer and the patient's former working life, research has shown that sufferers do not always exercise their right to compensation; many prefer to devote their energy to fighting the disease and making the most of the time they have left rather than embarking on a legal battle of uncertain outcome to have the cancer recognised and compensated as an occupational disease. Occupational cancers can be described as 'negotiated' diseases on the grounds that not every case of cancer which has been declared as being of occupational origin is automatically recognised as such, and sufferers often have to fight hard to gain recognition of the harm they have suffered. Women in particular face an uphill struggle and find it harder than men to achieve recognition of the occupational origin of their cancers.

The third contribution examines the mismatch between the body of knowledge on the links between work and cancer on the one hand, and exposure in real-life workplaces on the other. Most research studies focus on one carcinogen only, whereas workers in the real world are often exposed to multiple carcinogens at the same time. These multiple exposures become obvious if one considers the variability of activities in the exercise of the same occupation or, as is more and more often the case, the exercise of different occupations during a career. The French courts have recognised several cases of occupational cancer caused by multiple exposures to carcinogens, and changes may ultimately be made at practical and regulatory level with a view to including such cases on registries of occupational diseases.

The final contribution examines the societal costs of occupational cancers. These costs fall into three different categories: direct costs (medical treatments), indirect costs (productivity losses) and human (or intangible) costs associated with deteriorations in patient quality of life. The two independent research studies currently available on this topic agree that the direct and indirect costs of occupational cancers should be estimated in the ballpark of EUR 10 billion per annum for the EU-28, or approximately EUR 300 billion per annum if intangible costs are included. The enormity of these costs (corresponding to around 2% of the EU-28's GDP) should prompt a reaction on the part of political decision-makers, encouraging them to put in place the necessary prevention policies.

Chapter 20

Occupational cancers: what recognition in Europe?

Christine Kieffer

The International Agency for Research on Cancer (IARC) estimated the number of new cases of cancer in the EU-27 at 2.6 million in 2012. Various international studies consider that between 4 and 8.5% of these cancers may be attributable to occupational factors, amounting to roughly 100,000 to 200,000 new cases of work-related cancers in Europe each year.

The link to work is not however easy to identify, for various reasons:

- medically, a tumour due to occupational exposure is indistinguishable from other tumours, and cancers are often multifactorial diseases, making it hard to pinpoint them as work-related;
- these diseases have a long latency period between exposure and the onset of symptoms (20 years on average, but up to 40 years); so it is hard to identify the risk factors and any occupational exposure;
- at the time of diagnosis, doctors tend to pay little heed to the patient's work history.

The above figures raise the issue of recognition of occupational cancers. Assisted by experts from national occupational risk insurance agencies from eleven European countries¹, EUROGIP² has studied the insurance-related aspect of occupational cancers³ in terms of what and how many cancers are apt to be recognized as occupational.

The first thing to say is that the legal concept of an occupational disease is narrower than that of a work-related illness. The occupational nature of a cancer (like any other disease) can be recognized by the national occupational diseases insurance agency if the requirements relating to the nature of the disease, the type of exposure and the job performed are met. The sufferer will be then cared for and compensated in line with prevailing national legislation on compensation for occupational injuries and diseases. But every country has its own criteria and social insurance system.

While in practice a number of cancers are covered in the different countries, the figures for recognized cases lead to the conclusion that occupational cancers are under-reported.

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1. Germany, Austria, Belgium, Denmark, Spain, Finland, France, Italy, Luxembourg, Portugal and Switzerland linked together in the European Forum of the insurance against accidents at work and occupational diseases, www.europeanforum.org.
 2. www.eurogip.fr
 3. The findings of this cooperative survey were published in the report Eurogip (2010).

1. Cancers that could be recognized as occupational

Almost all the European countries in the Eurogip study have a national list of occupational diseases, conferring on them a presumption – of varying conclusiveness according to the country – of occupational origin.

Entering a cancer on a list does not prevent each country from setting its own criteria for its recognition (name of pathology, duration and/or intensity of exposure, list of jobs, etc) and its own method of examination.

The tables below list almost all the cancers currently registered on national lists of occupational diseases by tumour location, broken down by causal agent.

The European Schedule is contained in a Recommendation that has no binding legal effect in EU Member States. It is, however, noteworthy that cancers included in the European Schedule more consistently feature in the various national lists than those that are not. This points to the importance of regular revisions of the European Schedule to prompt movement forward in national systems. The Schedule was last revised in 2003.

Table 1 Cancers that could be recognized under national lists of occupational diseases

Pathology and/or Agent	DE	AT	BE	DK	ES	FI	FR	IT	LU	PT	CH	EU
	Skin cancers											
Arsenic and mineral compounds	●	●	●	●	●	●	●	●	●		●	●
Coal pitch	●	●	●	●	●		●	●	●	●	●	●
Petroleum derivatives	●	●	●	●	●		●	●	●	●	●	
Coal tars	●	●	●	●	●		●	●	●	●	●	●
Coal oils	●	●	●	●	●		●	●	●		●	●
Soot from coal combustion	●	●	●	●	●		●	●	●		●	●
Carbon black	●	●	●	●	●		●		●			
Paraffin and its compounds	●	●	●	●	●				●	●	●	●
Anthracene	●	●	●	●	●		●	●	●	●	●	●
Resins		●			●				●			
Carbazole and its compounds	●	●	●						●			●
Bitumen	●	●	●	●	●			●	●	●	●	●
Ionizing radiation	●	●	●		●			●	●	●	●	●
Mineral oil	●	●		●	●		●			●	●	●
	Bladder cancers											
Aromatic amines and their salts	●	●	●	●	●	●	●	●	●		●	●
N-nitroso-dibutylamine and its salts					●		●			●		
Tars, oils and coal pitch (* except for oils)				● (*)	●		●	● (*)		●		
Soot from coal combustion							●					

Pathology and/or Agent	DE	AT	BE	DK	ES	FI	FR	IT	LU	PT	CH	EU
Bronchopulmonary cancers												
Primary cancer caused by:												
Ionizing radiation	●	●	●		●		●		●	●	●	●
Chromic acid, chromates, alkaline or alkaline earth bichromates, zinc chromates	●	●	●	●	●	●	●	●	●	●	●	●
Tars, oils, coal pitch and soot from coal combustion	●		●	●			●	●	●	●	●	
Inhalation of dust or fumes of arsenic and its compounds	●	●	●	●	●	●	●	●	●		●	●
Inhalation of beryllium dusts	●	●	●	●	●	●		●	●	●	●	●
Inhalation of asbestos dusts	●	●	●	●	●	●	●	●	●	●	●	●
Inhalation of nickel dusts or fumes	●	●	●	●	●	●	●	●	●	●	●	●
Inhalation of iron oxide dusts or fumes							●					
Inhalation of cadmium dusts		●		●	●	●	●	●		●	●	●
Inhalation of cobalt dusts combined with tungsten carbide before sintering				●			●		●	●	●	
Bis(chloromethyl)ether	●	●	●	●	●		●	●				
Malignant degeneration of the lung following:												
Inhalation of asbestos dusts	●	●	●	●	●	●	●	●	●	●	●	●
Silicosis or silicotuberculosis	●	●		●			(1)	●			●	
Bone cancers												
Sarcoma due to ionizing radiation	●		●				●	●	●	●	●	●
Cancer of the ethmoid bone and paranasal sinuses due to wood dusts	●		●	●	●		●	●	●	●	●	●
Cancer of the ethmoid bone and paranasal sinuses due to nickel	●		●	●	●	●	●	●	●	●	●	●
Cancer of the nasal cavities due to chromium	●		●	●	●	●	●	●	●	●	●	
Cancer of the nasal cavities due to leather dusts			●	●	●			●			●	
Leukaemia												
Benzene	●		●	●	●	●	●	●	●	●	●	●
Ionizing radiation	●		●	●	●		●	●	●	●	●	●
Hepatic cancers												
Arsenic and mineral compounds	●		●		●		●	●	●		●	
Vinyl chloride monomer	●		●	●	●	●	●	●	●		●	●
Hepatitis viruses	●		(2)	(3)			●	(4)	(5)			●
Ionizing radiation	●								●			

(1) For primary cancer (2) B, C and delta (3) B and C (4) B and C recognized as work accidents (5) B

Pathology and/or Agent	DE	AT	BE	DK	ES	FI	FR	IT	LU	PT	CH	EU
	Other types of cancers											
Cancers due to inhalation of asbestos dusts (other than lung cancers):												
Cancer of the larynx	●	●	●	●					●	●		●
Pleural mesothelioma	●	●	●	●	●	●	●	●	●	●	●	●
Mesothelioma of the peritoneum	●	●	●	●	●		●	●	●		●	●
Mesothelioma of the pericardium	●	●	●	●	●	●	●	●	●	●	●	
Other cancers:												
Thyroid cancer due to ionizing radiation	●	●	●	●				●	●		●	
Cancer of the larynx/oral cavities due to coal tars/ pitches		●						●	●	●	●	
Cancer of the pancreas due to inhalation of arsenic	●	●							●			
Kidney cancer due to trichloroethylene	●								●			
Cancer of the larynx due to chromium		●			●				●	●		
Lung cancer caused by passive smoke inhalation				●								

Almost every country surveyed also operates a complementary system of recognition under which sufferers must prove the link between their disease and their work activity⁴.

In practice, this off-list system is a residual means of recognition, especially so for cancers, partly because the most numerous types of cancers are usually already listed and partly because the difficulty of producing evidence of the origin of cancers renders the burden of proof harder. Recognized cases not on the prescribed list in 2008 accounted for 1.1% of cancers recognized in Germany, 2.2% in France, but 13% in Italy. This form of recognition is extremely rare for cancers in Switzerland and Austria, and non-existent in Belgium and Luxembourg.

There is little data available on cancers recognized under the off-list system in recent years. In Germany, it almost exclusively concerns skin cancer caused by exposure to ultraviolet radiation, cancer of the oesophagus caused by nitrosamines and lung cancer caused by exposure to 1,3-Propanesultone. In France, by contrast, the sixty-odd cases recognized each year are widely varied. In Denmark, breast cancer due to performing night shift work has been recognizable since 2007 (by the end of 2011, more than a hundred women, mostly hospital sector workers, had received compensation).

In very rare cases the courts have recognized atypical cases of cancers linked to occupational exposures, such as that in Italy in 2012 where a brain tumour was held to be caused by intensive use of a mobile phone.

The last decade has seen few major changes in the cancers appearing on national lists of occupational diseases. Spain and Denmark published new occupational disease lists in 2006 and 2005, respectively, which included new types of cancer or likely occupational carcinogens, while a handful of countries sporadically add a new type of cancer or exposure to their list (skin cancer caused by exposure to ultraviolet radiation was added

4. Apart from Sweden which does not have a mixed system but only a proof-based system, and Spain which has a list system only.

to the German list in January 2015) or amend the regulatory requirements for the recognition of certain cancers (the duration of exposure to certain aromatic amines was reduced for bladder cancer in France in 2012).

2. Detailed figures on occupational cancers

Figures are available on the number of cancers recognized as occupational by national occupational injury and disease insurance organisations. However, the scope of the population insured by these bodies may vary between countries (according to whether they include public sector workers, self-employed workers, etc.).

Table 2 Number of new cancer cases recognized as work-related by the competent insurance organization, 2000-2008, by country

Number of cancers recognized as an occupational disease	2000	2001	2002	2003	2004	2005	2006	2007	2008
Austria	28	29	47	41	53	70	84	76	91
Belgium	114	118	148	178	144	178	245	168	219
Czech Republic	50	55	49	45	26	39	38	37	24
Denmark	154	100	105	110	112	136	135	153	187
France	1 033	1 400	1 511	1 734	1 951	1 856	1 894	2 051	1 898
Germany	-	-	-	-	2 173	2 107	2 194	2 054	2 240
Italy	nd	625	750	755	783	876	911	853	694
Luxembourg	2	6	5	5	10	16	13	15	16
Spain	6	4	14	7	6	13	4	15	62
Sweden	-	-	-	-	-	33	43	34	19
Switzerland	55	56	62	69	89	99	128	116	-

The figures provided by the insurance organizations show an almost across-the-board rise in the number of recognized occupational cancers in all but a few countries. The trends must be interpreted with caution, however, for countries where the absolute number of recognitions is low and where a handful of cases more or less from one year to the next can result in significant variations.

More recent studies of a small number of countries compare the number of declared and recognized occupational cancers with their insured population in 2011 (Eurogip 2015).

Ratios aside, cancers are the only occupational diseases that most countries agree on as being heavily under-reported, mainly due to the long latency period between exposure to the hazard and the onset of symptoms (20-40 years) and their multifactorial nature. These factors make it hard for doctors to establish a cause related to employment (or the past employment of retired sufferers).

Table 3 Declared and recognized cancers relative to the insured population in 2011

Country	Insured population	Applications for recognition	Declarations per 100 000 insured	Recognized cases	Recognitions per 100 000 insured
Denmark	2 676 095	612	23	162	6
France	18 492 444	2 536	14	2 050	11
Germany	40 861 230	8 000	20	2 408	6
Italy	17 294 329	2 272	13	908	5
Spain	15 756 800	Not available	-	75	<1

A distinction has to be made between this aspect of under-reporting and the recognition issue inasmuch as the recognition rates of cancers tend to be higher than other types of occupational disease.

Cancer recognition ratios are comparable for Denmark, Italy and Germany, but twice as high in France. It owes this top position to bronchopulmonary cancers due to asbestos, which are recognized in many more cases in France than in other countries, presumably because the conditions for their recognition in France are rather more open, especially in terms of exposure (no exposure intensity criterion).

Spain stands out for its extremely low recognition ratio; work-related cancers are manifestly under-reported in this country, much more so compared with the other countries surveyed.

Looking at the cancers with the highest recognition rates (in all countries producing statistics per affected organ for 2008), bronchopulmonary cancers - including the pleura - alone account for 86% of recognized cancer cases, trailed far behind by bladder (4%), sinus (3%), blood (2%), and skin (1%) cancers. Recognized work-related cancers affecting other organs account for only 4% of the recognized total (ranging from 0.9% in Belgium to 25% in Denmark).

Since most national statistics allow cases of occupational cancers caused by asbestos to be isolated, it can be concluded that on average 80% of recognized work-related cancers were caused by asbestos dust in 2008 (ranging from 20% in the Czech Republic to 93% in Austria).

3. Conclusions

Data on the recognition of occupational diseases are not enough to account for the real impact of carcinogens in the workplace. Figures on the number of workers exposed (e.g. from CAREX, Sumer ...) are also vital. By contrast, a comparative analysis of data from occupational disease recognition systems is needed to understand the national peculiarities of recognition in a bid to improve their effectiveness.

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Chapter 21

What is stopping the recognition of occupational cancers?

Anne Marchand

There is a wide gap between the fewer-than 2,000 cancer cases recognized as occupational diseases each year in France and the official estimates of 14,000 to 30,000 annual cases of cancers linked to working conditions and work processes (Cancer Plan 2014-2019). This is nothing new: the compensation system has been described as failing in administrative reports going back more than 30 years. So what are the barriers to gaining recognition and compensation for occupational cancers? The survey being carried out since 2002 in the Paris region by Giscop93 (a scientific interest group on occupational cancers in the Seine-Saint-Denis region) offers interesting insights into the reasons for (not) reporting and (non) recognition.

The first, most obvious thing is that occupational cancer sufferers have to know that they may be entitled to compensation. The patent lack of public information on this right, however, is not enough to explain the large-scale failure to claim it: in the first 5 years of the Giscop93 survey, for instance, even when respondents were told of their possible entitlement and had the medical certificate required to put in a claim, 50% of them failed to try and access their right. The introduction of long-term support¹ for these individuals with cancer² has promoted the development of knowledge they could not get any other way.

The context of the disease was quickly seen to be one of the biggest obstacles to claiming the entitlement. To be told that they have cancer is a real “body blow” that knocks the persons concerned sideways, as is extensively reported in the literature. On top of the fatigue caused by treatments and the medication, lives are upheaved and priorities redefined, with more energy put into fighting the disease and making the most of the time remaining than embarking on trying to access a right with a very uncertain outcome.

1. This National Cancer Institute-funded (INCA) intervention research conducted in 2011-2014 aimed to identify factors of social inequality in reporting, recognition and compensation, and ways of reducing them. It was done in collaboration with the Giscop93 team, especially Cécile Durand, Nathalie Ferré and Annie Thébaud-Mony, in partnership with hospital services, the Seine-Saint-Denis primary health insurance fund (CPAM) and a law firm specializing in claims for victims of occupational diseases.
2. The study focused on primary lung cancer sufferers, mostly male (20% female) in manual and clerical job categories (80% of the survey population).

1. The cancer-work link is hard to take on board

But those concerned also seem to have great difficulty in seeing how they can be entitled to compensation for an occupational disease because they cannot take on board the link between cancer and work. There are many reasons for this. Firstly, the characteristics of the disease do not make it easy to see how work might be responsible: being multifactorial, cancer generally carries no specific signature and occurs after a latency period of anything up to several decades, usually around retirement age. Then, too, most of these people were unaware that they might have been exposed to carcinogens during their work activities: these toxicants are almost invariably odourless, invisible and with delayed effects, meaning that they neither saw nor knew about them. Even the most highly-publicized carcinogen – asbestos – is no exception: while (past) workers now know of its hazards, they knew nothing at the time; but they may also simply not have known they were in contact with these mineral fibres which are ingredients of many mixtures like sealants, adhesives, coatings, paints, etc. Even today, there is no centralized, comprehensive inventory on where asbestos is to be found, and workplace health and safety agencies themselves confess that they are unable to trace the risk of cancer. So how could these (former) employees suspect that their present health could be due to their work when the information on the risks they were exposed to was not given to them?

Then, too, those concerned do not always relate well to the prospect of getting compensation for damage done unless the collective aspects of the compensation system are explained to them. Far from it, the prospective personal “benefit” may actually clash with the value systems that underpin their lives. Some, for instance, are unwilling to “ask for charity”, as they see it, after a life of self-reliance, avoiding being beholden to anyone for anything. Others will be deterred by their adult children’s desire to help their parents through the illness as a demonstration of gratitude. Still others will not want to make a claim so as “not to be a drain” on what they know to be a cash-strapped social security system when the costs of their care and treatment are already fully-paid by their health insurance: most do not know that work accidents and recognized occupational diseases are covered by a specific scheme financed in France by employers alone and not from joint employer/employee contributions. For some (former) employees, finding out that there is a law compensating occupational cancers – meaning that society accepts that your work may kill you – is so upsetting that they cannot conceive of their (otherwise nurturing and fulfilling) job being implicated in the occurrence of their illness.

Ultimately, affected individuals who want to claim for their cancer as an occupational disease must be able to build a proper case by providing paper “proof” of their disease and their work. It seems that accessing medical records – although a statutory right – is not easy. Even more difficult is the obtention of that essential document, a medical certificate of occupational disease. Personal beliefs and the culture of the profession (putting lifestyle factors ahead of all other origins), lack of time and training which has not prepared them for it, mean that many doctors will not issue such a certificate, or fail to make it out correctly. The pressures they come under from some employers – in some cases ending in disciplinary proceedings before the general medical council –

compounds this reluctance. And with the onset of the disease occurring years after exposure, victims of an occupational cancer may no longer have their pay stubs and/or employment certificates, the only accepted “proof” of their work activity³.

2. Unsuitable forms of assessment

But even a reported cancer that meets the statutory criteria will not necessarily gain recognition as an “occupational disease”, for the recognition rate for the same disease varies widely even between Funds – from 8 to 80% for some disease conditions according to the chairman of the Occupational Injuries and Diseases Committee (ATMP) established by the National Health Insurance Fund for Employees’ (CNAMTS). Occupational cancer is not a separate medical category, but a disease “negotiated” (Rosental and Omnès 2009) in a highly adversarial setting.

The circumstances under which occupational disease lists are developed – the outcome of bitter, unequal power struggles between representatives of employers, employees and the state – are one illustration of this and a main structural obstacle to the recognition of occupational cancers. There is a huge gap between the state of scientific and medical knowledge and what is actually taken in consideration in the lists evolution. In France, cancer diseases (mostly bronchopulmonary) are included in 22 occupational disease lists (out of 120) and concern only fifteen or so carcinogens – while the IARC identifies 111 “confirmed” human carcinogens and 65 “probable carcinogens” (category 1 and 2A in 2013). Also, the design of these lists is totally unfitted to the real world of work: they disregard the widespread nature of multi-exposure, consider only a single carcinogen, and the often-limited nature of reckonable activities does not correspond to actual work situations and exposure. For example, the reconstruction of the Giscop93 patients’ work histories shows that not all have kept the same job but have in fact had a succession of different employers - up to 30 for some - and so may have been exposed during their actual work activities to cocktails or accumulations of carcinogens: more than two carcinogens in 70%, and more than 5 in 25% of cases. While a complementary system was established in 1993 to try and overcome the limitations of these occupational disease lists – almost 30 years after the European Community recommended it –, it manages to recognize no more than 70 “off-list” cancers a year⁴.

The conditions for Funds’ assessment of cancers as occupational diseases are another reason for the under-recognition of occupational cancers. Firstly, these bodies’ procedures have been “modernized” in a root-and-branch reorganisation that specifically

3. Which immediately rules out any right to compensation for occupational cancer for undocumented workers – who abound in the construction industry - and cash-paid casual workers.
4. The terms of reference of the assessment done by panels of three doctors working in the Occupational Diseases Recognition Regional Committees (CRRMP) are arguably particularly unsuited to the specific characteristics of cancer diseases: with a remit to establish the existence (or otherwise) of “a direct and fundamental link” between the work and the disease, these medical practitioners are more inclined to look for “causal links” - a concept that makes no sense where multifactorial diseases are concerned. As a result, they readily refuse recognition of the occupational origin of a cancer to smokers on the pretext that there is a “non-work-related factor” involved when smoking – while undeniably implicated in the occurrence of cancer – adds to rather than cancels out occupational exposures.

affects the direct interface with users. Their management has been largely computerized or outsourced, while most of the public first-contact points have closed. Insured individuals now have to submit their queries over the Internet or by phone to customer advisors in call centres, where call handlers who are not trained in the difficulties faced by people living with cancer are assessed on the basis of response times. Rather than feeling that they have been treated as sustaining an occupational injury and given caring support in accessing their rights, claimants who are already badly afflicted by disease, rendered insecure by the complexity and lack of transparency of the procedures and the legalistic language of the letters sent out by the Fund may experience these relations as dehumanized and degrading to the point where they drop their claims.

Then, too, the sickness insurance funds are under-resourced and ill-equipped to perform the kind of assessment required for cancers properly within the regulatory 3 - 6-month timeframe: a lengthy and painstaking investigation into all the ins and outs of an entire work history, collating all if any traces of carcinogenic risk in the relevant jobs and firms. This means going back over 20 to 30 years, and it is not uncommon to find that firms and work processes have disappeared or been radically changed. If still in operation, firms take part in the assessment on an adversarial basis, meaning that victims and their employers both make submissions and are told of the facts of any complaint against them. Again, the balance of power between a (past) employee, weakened by illness, with an inexperienced grasp of the terms and nature of the procedure, and an employer's highly-qualified legal department is particularly unequal. While the insurance funds may also look to other sources (health and safety inspectors and safety engineers) to identify potential carcinogenic exposures dating back 30 to 40 years, they also face the gaps in the institutional memory of exposures: if the risk cannot be "established", it will not be recognized. Little surprise, then, that most recognized claims (90% in the Giscop93 survey) are established on the basis of exposure to asbestos, a carcinogen that mobilized widespread labour action and was the focus of a number of studies commensurate with the scale of the health scandal for which industrialists and employers are mainly to blame, facilitated by the shortcomings of the authorities to prevent toxic risks.

These non-reporting and non-recognition factors penalize women even more at all stages. Research on cancer risks – both toxicological and epidemiological studies – has long focused only on male populations. As things go, the Giscop93 experts identifying exposures to carcinogens in the survey patients' work histories find it harder to analyse the work histories of women than men: only 26% of women receive a referral to report their occupational disease (against 64% of men). Asbestos aside, the carcinogens most frequently encountered by women - formaldehyde, chlorinated solvents and passive smoking – are not such as to allow of recognition as a listed disease. Where lists do exist, the limited listing of work activities is patterned on an often inappropriate model of male work. Finally, over and above these structural obstacles to reporting and recognition, women are seen to be "going it alone" more than men in claiming recognition of an occupational disease. As a result, only half of women who reported their cancer as an occupational disease are found to have won recognition compared to 76% of reporting men.

Paradoxically, while women suffer from a lack of recognition of their own occupational cancer, they are the “real” beneficiaries of compensation awarded to their ailing spouses. So short is life expectancy with the disease (50% of patients die within a year of diagnosis) and so protracted are the procedures that the patient often dies before the claim is settled, or even before the occupational disease is reported. It then falls to the spouse to initiate a claim or – in the event – press on with a claim already initiated in the hope of being awarded a portion of the pension the victim would have got if his cancer was recognized as an occupational disease. They then face the same difficulties as encountered by the victim described above but further exacerbated by their bereavement (difficulty making sense of the process, very hard to gain access to medical records).

Seemingly, then, reporting an occupational disease is much less about simple paperwork than “an issue of struggle” to borrow the title of an article on work accidents by the French sociologist Rémi Lenoir. There can only be effective recognition of work cancers through a collective approach, not by dint of individual cases. Likewise, the burden of proving carcinogenic exposures must not lie with the victims of work-related cancers alone. As an issue of struggle, the right to recognition of occupational cancers in the final analysis requires the labour movement to take a long look at its power to act on the combined improvement of cancer compensation and the prevention of occupational cancer risks.

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Chapter 22

Ensuring recognition of the link between cancer and multiple exposures to carcinogens at work

Annie Thébaud-Mony

On 9 April 2014, the Lyon Social Security Affairs Tribunal (TASS) acknowledged that multiple exposures were instrumental in the death from two cancers (pharynx and floor of mouth) of a worker who had worked his entire life as a glassblower. On 5 December 2014, the role of multiple exposures was also recognized in the case of a docker who likewise died of two cancers (kidney and thyroid). Both received posthumous recognition as victims of occupational diseases. On what data and arguments were these rulings based?

1. General scientific principles of how cancers develop

Cancer does not follow the conventional “single cause-single effect” biological model. It is a long process, often spanning several decades of an individual’s life. It develops as serial, simultaneous exposures to carcinogens interact with and are written into the biological development of an individual’s cells. Our current knowledge of carcinogenesis tells us that the mutagenic and carcinogenic damage caused by exposure to multiple carcinogens combine and increase the cancer outcome risk.

Also, a carcinogen does not just attack one single target organ. It is now known that asbestos can be involved in the occurrence of pleural, peritoneal and pericardial mesotheliomas, lung cancer, cancer of the larynx or pharynx, ovarian cancer, stomach cancer, colorectal cancer and more. According to the latest *International Agency for Research on Cancer* monograph (2012), colorectal cancer, for example, is one of the anatomical sites where - when studies were conducted - a statistically significant relationship was found with asbestos exposure.

Finally, cancer has no “signature” from which to “select” some and exclude other causative factors of an individual’s cancer. A cancer sufferer’s history of exposure to carcinogens can be reconstructed using his own experience and knowledge of his employer company’s production process. Rather than establishing a causal link with a specific toxicant, this allows identification of all contaminants that may have caused the individual bodily harm and contributed to the onset of cancer. In a cancer sufferer’s cellular history, each of the different carcinogens to which they have been exposed most likely plays a role - in synergy with the others - in the process that gave rise to and accelerated the development of the particular cancer. The complexity of this process means that an expert cannot claim with absolute certainty that one or more contaminants are to blame rather than any other(s).

2. The state of knowledge of the cancer-work relation

Epidemiology normally concerns itself only with one type of cancer and one substance at a time. One of the few epidemiological studies to consider multiple exposure to carcinogens is that on the incidence of cancer cases among rescue and recovery workers on the World Trade Center site (Ground Zero) after the 9/11 attacks. A 7-year follow-up study of more than 20,000 rescue and recovery workers found a high incidence of cancers involving numerous cancer sites (Solan *et al.* 2013). The epidemiologists link this raised early incidence of cancer cases with multiple exposure to the toxicants in the dust clouds in which these workers operated.

This study aside, epidemiological research on occupational cancers is on the wane. Canada's Toronto-based Occupational Cancer Research Centre has recently highlighted a radical decline in epidemiological studies on the cancer-work relation between 1991 and 2009 (Raj *et al.* 2014). Most of the studies reviewed are single carcinogen studies, focusing only on known carcinogens, even though in this 20-year period, the forms of organization of work and production have changed not only towards greater versatility of workers (including through job flexibility), but also an ever more intensive use of physical and chemical carcinogens.

3. The extent of multiple exposure

The findings of a 12-year survey done by the researchers of the French *scientific interest group on occupational cancers* (Thébaud-Mony 2008) show a widening mismatch between the reality of multiple exposure to carcinogens and the knowledge developed on the relationships between work and cancer.

Multiple exposure can occur within a single occupational activity when a worker is exposed to several carcinogens at once or in very close succession. It is even greater when the whole working life is looked at. Casualization of employment plays a big role here: agency and other contingent workers have a higher likelihood of successive exposure to multiple carcinogens than those in steady employment. Also to be considered are jobs that involve performing a variety of tasks. This is an important factor in multiple exposure of building workers, industrial cleaning and maintenance, agriculture, etc.

Data from the 2010 SUMER survey in France provides some evidence of multiple exposures as part of a single work activity. The percentages relate only to multiple exposure to chemical carcinogens and do not measure combined exposures to a chemical agent and other agents (night work, ionizing radiation, electromagnetic fields, UV, etc.). Based on this data, 1.2% of employees are exposed to at least three carcinogens. The incidence is highest among skilled manual workers (3.6%) and unskilled manual workers (2%), and particularly high in the construction industry (4.8%). Where occupations are concerned, maintenance seems to carry the highest risk of multiple exposure (8.3%). The correlation with company size is also significant: 1.8% in firms with between 1 and 9 employees versus 0.5% in companies with 500 or more employees.

4. Recognition of occupational diseases

In terms of gaining recognition of cancers as occupational diseases, the foregoing argues for very specific treatment in order to identify the “direct and fundamental” link required by the French legislation between multiple, long-term occupational exposures to carcinogens, and cancer. The focus needs to be put not on what are usually inadequate epidemiological data but rather the proven toxicity – and especially the carcinogenicity – of the products to which the person has been exposed in his work.

The lack of a monocausal relationship between a specific exposure and a cancer outcome should under no circumstances be a reason for refusing to recognize cancers as occupational diseases. After all, multicausality is well established for very many occupational diseases (all musculoskeletal disorders, many respiratory diseases). An analysis of health inequalities by occupational groups points to the critical role played by working conditions in these medical conditions.

In both the cases mentioned in the introduction, recognition was not obtained from the regional occupational disease recognition committees (CRRMP¹) following medical and legal assessments, but gained in the courts through legal proceedings. Finding in favour of the Cervantes family in proceedings brought in the TASS, the Lyon court held on 9 April 2014 that: “Mr Cervantes’ simultaneous and/or successive exposure over a period of more than thirty years to multiple toxicants, three of which are major carcinogens (asbestos, PAHs, solvents), interacting with one another increased the risk of developing cancer of the head and neck, and thus may have caused the successively diagnosed and ultimately fatal ‘floor of mouth cancer’ as well as the ‘cancer of the pharynx’.”

The court was also at pains to “point out that the ratio decidendi of the Committees’ (CRRMP) decisions was too cursory to account for the elements of the case that persuaded them to rule out any causal role of work [...] They had before them several scientific opinions, the general gist of which argued in favour of recognition of a causal link, and which deserved to be addressed or at least commented on by them.”

In the case of a docker, Mr Chagnolleau, heard on 5 December 2014, the Nantes TASS found that it had “sufficient evidence to find that Mr Chagnolleau’s multiple exposure to toxicants and carcinogens during his work played a direct and fundamental causal role in the onset of his disease”. That evidence consisted in health and safety committee minutes, the sickness insurance fund’s preventive engineers’ service reports, and a multidisciplinary study on dockers’ occupational exposure to carcinogens highlighting the extent of multiple exposures (Chaumette *et al.* 2014). The TASS also found that “the ratio decidendi of the adjudicating regional committees’ decisions is too cursory to account for the elements of the case that persuaded them to rule out any causal role of work”.

1. France, like most European countries, has a twin-track system for the recognition of occupational diseases: either they are included on a list – or schedule – which confers a presumption of causality; or they are recognized on a case-by-case basis, forcing victims to prove the causal relationship between their working conditions and their disease. CRRMPs are responsible for the second aspect.

Presented with arguments based on the reality of the facts (with which medical experts were unfamiliar) and the state of scientific knowledge, the court thus ruled that these facts should be considered, while questioning the type of expert opinions sought by the CRRMP. Could these two judgments - which may be followed by those in other pending cases – bring about a change in the regulations to include multiple exposure to carcinogens in a list of occupational diseases? Doing so would help ensure recognition of victims' occupational cancer at first instance while still living rather than after a protracted and costly court case conducted not by the victims themselves but more often by the next-of-kin of deceased victims. As it is, victims are deprived of the recognition of the role of work in the development of their cancer, which has not only a financial but also a symbolic impact (see chapter 21).

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Chapter 23

The economic burden of occupational cancers in the European Union

Tony Musu

According to the most recent statistics from the International Agency for Research on Cancer (IARC), there were 2.63 million new cancer cases and 1.28 million cancer deaths in the 28 European Union countries (EU28) in 2012. As regards prevalence, in the same year 7.16 million people in the EU28 were living with a cancer diagnosed in the previous five years (Ferlay *et al.* 2013).

These diseases lead to substantial costs for victims, their families and society as a whole. In a recent study, the social cost of all cancers combined for the EU27 was estimated at EUR 126 billion for 2009 (Luengo-Fernandez *et al.* 2013). Four types of cancer contribute to 44% of these costs: lung cancer (EUR 18.8 billion, 15% of overall cancer costs), breast cancer (EUR 15.0 billion, 12%); colorectal cancer (EUR 13.1 billion, 10%) and prostate cancer (EUR 8.43 billion, 7%).

A certain proportion of all cancers is linked to working conditions. These cancers are particularly shocking as they generally affect people who are involuntarily exposed to carcinogens in the course of their work. Moreover, certain categories of workers are affected much more than others. The risks of exposure to carcinogens for a labourer or nurse are, for example, much higher than for a senior executive, a factor increasing social inequalities in health (Mengeot *et al.* 2014).

Occupational cancers could be avoided if effective prevention actions were implemented to eliminate or reduce such exposure. Likewise, the costs associated with these diseases and deaths could be reduced to the benefit of society as a whole. In order to develop coherent occupational cancer prevention policies, it is particularly important to identify the nature of these costs and understand who bears them, and also to estimate the total amounts involved.

A comprehensive assessment of the cost of occupational cancers in a given country or region necessarily involves two stages. The first is to estimate the number of cancers attributable to occupational exposure. The second is to estimate the various costs associated with each of these cancers. By combining this data, the overall cost of occupational cancers to society can be monetised.

1. Number of occupational cancers

Cancers are multifactorial diseases, with clearly identified risk factors including heredity, lifestyle and environmental and occupational factors. The method generally used to determine the number of cases linked to a particular risk factor is the attributable fraction (AF) method. The attributable fraction can be defined as the percentage of cases of a disease that could have been avoided if there had been no exposure to the suspected risk factor. It reflects the risk of contracting the disease when exposed or not to the risk factor (relative risk) vis-à-vis the proportion of the total population exposed to the risk factor (prevalence of exposure).

The proportion of cancer cases attributable to working conditions varies according to gender and type of cancer. For example, mesotheliomas are almost exclusively occupational in origin (~95%) due to exposure to asbestos, whereas only a very small proportion of kidney cancers (~1%) are seemingly linked to work. However, it is possible to calculate the fraction of all cancers attributable to work.

Table 1 Estimates of cancer cases and cancer deaths attributable to occupational exposure

Author, year	Zone	% of cancer deaths attributable to occupational exposure		% of cancer cases attributable to occupational exposure	
		Men	Women	Men	Women
Vencovsky <i>et al.</i> (2017)	EU-28			6.0-15.0	3.0-7.0
Labrèche <i>et al.</i> (2014)	Quebec (Canada)	11.0-17.3	2.1-3.6	8.3-13.2	1.6-3.3
Rushton <i>et al.</i> (2012)	UK	7.2-9.9	1.7-3.2	4.0-8.4	1.4-3.2
Rushton <i>et al.</i> (2008)	UK	6.0-8.0	1.0-1.5	5.4-6.7	1.0-1.2
Hamalainen <i>et al.</i> (2007)	World	13.8	2.2		
Fritschi & Driscoll (2006)	Australia			10.8	1.8
Deschamps <i>et al.</i> (2006)	France			3.18	
Steenland <i>et al.</i> (2003)	USA	3.3-7.3	0.8-1.0		
Nurminen & Karjalainen (2001)	Finland	13.8	2.2		
Dreyer <i>et al.</i> (1997)	Nordic countries			3	<0.1
Leigh <i>et al.</i> (1997)	USA	6-10			
Doll & Peto (1981)	USA	7.0	1.2		

Source: adapted from Orenstein *et al.* (2010)

Studies conducted in a number of countries estimate that 4% to 12% of all cancer deaths and a high proportion of cancer cases are attributable to occupational exposure (see Table 1). In the early 1980s, British epidemiologists put at 4% (with an uncertainty ranging between 2% and 8%) the fraction of cancer deaths attributable to an occupational cause in the United States (Doll and Peto 1981). This estimate is considered by many to be an underestimate due to the increasing number of carcinogens being identified and recognised by the IARC. More recently, the Rushton team put this attributable fraction at 5.3% for Great Britain in 2005 (8.2% for men and 2.3% for women), while recognising

that this was also an underestimation of the true situation (Rushton *et al.* 2012). The best estimate that is currently generally accepted is based on Finnish studies and puts the fraction of cancer deaths attributable to work at 8.3% (Takala 2015). On this basis, the number of male and female workers who die each year from an occupational cancer in the EU28 can be estimated at over 102 000 (see Table 2 for a breakdown by country). The overall attributable fraction of 8% or above is corroborated by a very recent study on occupational cancers and the associated costs in the EU-28 which indicates that 8% (between 6% and 12%) of all new cancer cases (6% to 15% among men and 3% to 7% among women) could be work-related (Vencovsky *et al.* 2017).

Table 2 Estimate of the annual number of deaths due to occupational cancer in the EU 28

Country	Number of occupational cancer deaths
Austria	1 820
Belgium	2 079
Bulgaria	1 445
Czech Republic	2 238
Croatia	742
Cyprus	179
Denmark	1 242
Estonia	292
Finland	1 135
France	12 035
Germany	17 706
Greece	2 131
Hungary	1 808
Ireland	928
Italy	10 609
Latvia	491
Lithuania	694
Luxembourg	98
Malta	75
Netherlands	3 721
Poland	7 501
Portugal	2 371
Romania	4 233
Slovakia	1 150
Slovenia	442
Spain	9 807
Sweden	2 103
United Kingdom	13 330
Total	102 405

Source: based on 2011 figures and adapted from Takala (2015)

2. Costs associated with a cancer case

There are three main types of cost associated with a cancer case: direct costs, indirect costs and intangible costs (see Table 3). The first category includes all medical and non-medical costs linked to the disease. Direct medical costs include medical visits for diagnosis and monitoring of the disease, hospitalisation costs (surgery, inpatient costs), outpatient care (chemotherapy, radiotherapy, physiotherapy, medical tests), accidents and emergency visits associated with the cancer (for example, bleeding, severe vomiting due to a therapy) and drugs used to treat the cancer. Direct non-medical costs include costs of transport to the hospital or attending doctor, costs of home help, and any costs of moving home or adapting housing.

Table 3 Different types of cost associated with an occupational cancer case

Type of cost		Category	Cost bearer			
			Worker	Family and friends	Employer	State
Direct costs	Medical costs	Medical visits				
		Inpatient care				
		Outpatient care				
		Emergency care				
		Drugs				
	Non-medical costs	Transport				
		Home help				
		Accommodation				
Indirect costs		Productivity loss (morbidity)				
		Productivity loss (mortality)				
		Productivity loss (family and friends)				
Intangible costs		Pain				
		Suffering				
		Grief				
		Loss of self-esteem				

The second category (indirect costs) covers productivity losses due to the morbidity (temporary absence due to sick leave or permanent absence due to work incapacity) as well as productivity losses linked to early mortality (years of work lost at the time of death). The patient's family and friends are often relied upon, spending part of their working (or leisure) time caring for the person suffering from a cancer. This 'informal care' similarly results in productivity losses, particularly for the patient's family and friends and employers who must also be taken into account.

The third category (intangible or human costs) involves the deterioration in the patient's quality of life. Cancers cause pain, suffering, grief and often a loss of self-esteem. Due to their very nature, these costs are difficult to monetise, but 'willingness to pay' methods have been developed for this purpose. These are based on the sums that a population is

willing to pay to avoid a disease or death, and they therefore allow these intangible costs to be considered (EPA 2010).

The cost bearers differ according to the category of costs (see Table 3). The costs borne by workers include some of the direct medical costs, the direct non-medical costs, the net wage losses (difference between lost wages and compensation received) and the costs associated with the deterioration in their quality of life. The patient's family and friends mainly bear wage losses for the time spent on informal care. Employers generally bear the costs of the short- or long-term absenteeism of sick workers (staff turnover, training of replacements, insurance premiums) and the State bears some of the healthcare and social insurance costs and the loss of human capital due to early deaths. The total cost to society as a whole is the net sum of these various costs, i.e. taking into account any transfers between cost bearers.

The costs associated with a cancer case vary according to the location of the cancer. In fact, the cost of treatment differs from one type of cancer to another, as do the survival statistics following first diagnosis. For example, among women, breast cancer has a better 10-year survival prognosis (76%) than lung cancer (12%) (Grosclaude *et al.* 2013). For the same type of cancer, the costs can also vary by country. Accordingly, a case of lung cancer costs EUR 15 per inhabitant and per year in Germany, compared to EUR 2 in Bulgaria (Luengo-Fernandez *et al.* 2013).

3. Estimate of the social cost of occupational cancers in the EU

To our knowledge, two studies are currently available on the cost of occupational cancers for all EU28 countries. They both estimate the current economic burden resulting from past occupational exposure to selected carcinogenic agents. The first study estimates the costs of healthcare and productivity losses to range between €4-7 billion annually for the EU-28. When quality-of-life losses associated with premature deaths and cancer diagnoses are added, the total annual societal impact is estimated to be in the order of €334 (242 - 440) billion (RIVM 2016). The second study commissioned by ETUI puts the direct and indirect annual cost of reported cases of occupational cancer between €4 and €10 billion for the EU-28. When all intangible costs are included in the analysis, the total cost shoots up to between €270 and €610 billion (Vencovsky *et al.* 2017).

Despite the differences in the methodology and the inevitable limitations linked to economic valuations, these results are consistent with each other and give estimates in the same order of magnitude for the sum of direct and indirect costs and for the intangible costs.

These figures are also in line with those produced by Luengo-Fernandez *et al* on the annual costs of cancer in the EU-27, estimated at €129 billion for 2009. It is important to note that this figure covers occupational and non-occupational cancers. In addition, these costs are for direct and indirect costs only and do not include any allowance for intangible costs. Assuming that around 8% of the costs in Luengo-Fernandez study are attributable to occupational cancer suggests that the direct and indirect costs of

occupational cancer were around €10 billion in 2009. This is in line with the annual costs (excluding intangible costs) for the EU-28 calculated by RIVM for 2012 and Vencovsky for 2015.

Whether intangible costs should be quantified or not is debatable. There is an ethical issue in putting a price on workers' loss of quality of life or even on the value of life. This is part of a broader discussion that involves questioning the market rhetoric and the neo-liberal paradigm where all that we value can be monetised.

However, it is important to point out that intangible costs are substantial, and their use is well entrenched in policymaking. Human costs are indeed taken into account in Europe and the United States by the regulatory agencies responsible for developing legislation to reduce risks to humans and the environment from the use of hazardous chemicals (Albertini and Scasny 2014; Woodruff 2015).

4. Conclusions

Occupational cancers are the main cause of work-related mortality in the industrialised countries. Each year they are responsible for the deaths of over 102 000 male and female workers, and for a sizable proportion of the new cancer cases diagnosed in the EU28. The social cost of occupational cancers is significant. It can be roughly estimated at €10 billion per year in the EU28 for direct and indirect costs only and in the order of €300 billion per year when human cost is added. This cost is mostly borne by workers and their families but also by employers and the social security systems in the various Member States. However, occupational cancers and their negative socioeconomic impacts can be avoided if exposure to carcinogens is eliminated or reduced in the workplace. It is high time that policymakers in Europe and around the world finally realised the extent of the problem and the massive impact of inaction in this area of occupational health, and urgently adopt effective policies to prevent occupational cancers.

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Chapter 24

European Trade Union Confederation response to the first stage of consultation with the social partners on possible future reviews of Directive 2004/37/EC¹

Introduction

In the view of the European Trade Union Confederation (ETUC), the current consultation on the revision of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD) represents a positive opportunity to define the positions of the social partners on an issue fundamental to the development of prevention policies in Europe. This consultation should not in any way be used to delay the Commission's adoption of the third and fourth batches of proposals for revising the CMD. Nor should it be used to justify the Commission not taking action on its obligation to explore the possibility of extending the scope of the Directive to include reprotoxic substances by first quarter 2019 as agreed in the first amendment to the CMD². The elements envisaged by the Commission with regard to the first two batches of proposals are covered by the preceding consultation which took place in 2004 and 2007. The Commission has rightly adopted the first two batches of proposals without further consultation of the social partners who significantly contributed to the debates both formally, via the work of the Advisory Committee on Health and Safety at Work, and informally via a number of conferences, publications and contacts with various EU institutions.

In this response, the ETUC would like to discuss crucial issues concerning the revision of the CMD, as well as a number of other issues going beyond this revision and which should help establish a comprehensive strategy for eliminating occupational cancers.

We share the Commission's finding that, in the field of preventing occupational cancers, EU policies up to now have not produced results as encouraging as those in other fields such as the prevention of work-related accidents. A variety of factors explain this finding. The risks arising from exposure to carcinogens and mutagens at work are not immediately visible. The costs of the associated health problems are not or hardly borne by the companies, instead being "outsourced" to the victims, their families and to national social security and healthcare systems. There is a major gap between the cancers recognised as occupational diseases in the various EU Member States and the number of cancers attributable to occupational exposure. The majority of cases are not visible, i.e. problems interrupting or hindering production. Instead, it takes place within the ordinary production context. Absenteeism caused by occupational cancers

1. This response was adopted in September 2017 (note of the publisher).

2. Agreement between the representatives of the European Parliament and the Council on the first amendment of the CMD on 11 July 2017.

does not create great burden for companies exposing their workers to such substances due to the long latency period between exposure and the outbreak of the disease. Most national data and all EU data on cancers contains very little information on patients' occupations. In the majority of Member States, no systematic data exists on exposure to carcinogens or mutagens. Whether such data pertains to the number of exposed workers, the substances to which they are exposed, levels of exposure and available prevention schemes, it is generally scarce, not very systematic and does not constitute a basis for defining adequately targeted strategies. Gender is rarely taken into account in the production of data and in the policies adopted. At EU level, most of the data available is over 20 years' old, having been collected in 15 Member States at that time as part of the CAREX programme.

1. Inclusion of reprotoxic substances within the scope of the CMD

1. The most important issue with regard to the future evolution of the CMD is that of extending its scope to cover reprotoxic substances. It is unacceptable that the Commission's preparatory document makes absolutely no reference to this issue, even though the agreement reached on 11 July 2017 between the European Parliament and the Council introduced a new provision into the CMD, obliging the Commission to give its opinion on such an extension before the end of Q1 2019³. For this deadline to be met, there is no time to be lost.

In the view of the ETUC, the CMD's scope must be extended to include reprotoxic substances. This is also the position of the European Parliament which voted in amendments regarding this issue with an overwhelming majority (some 85% of votes).

1.1 Certain characteristics are shared by carcinogens and mutagens on the one hand and reprotoxic substances on the other. It is these commonalities which justify the workplace prevention of these substances of very high concern being organised in a homogeneous and consistent manner. Whether carcinogens, mutagens or reprotoxic substances, their consequences are extremely serious for human health. They also share the characteristic of having consequences with long latency periods, i.e. the immediate visibility of the risks concerned is greatly reduced. The main interest in extending the scope of the CMD to reprotoxic substances involves organising prevention activities on the basis of the more systematic and tighter requirements set forth in this CMD compared to the vaguer and more general requirements applied to all chemical risks in the context of the Chemical Agents Directive (hereinafter "CAD"). The number of substances involved is considerable: 249 have been identified under the CLP regulation (Regulation (EU) No 1272/2008) as known or presumed reprotoxic substances. However, 134 of these are not subject to the stricter CMD as they are category 1A or 1B reprotoxics only (not also classified as carcinogens or mutagens). Insufficiently controlled, the risks are thought to affect 2 - 3 million workers in Europe. However, this is only an approximate figure, as little to no data on exposure to reprotoxic substances has been collected by Member States.

3. This amendment has been included in the directive 2017/2398 of 12 December 2017 (note of the publisher).

1.2 In all other fields of EU legislation, carcinogens (C), mutagens (M) and reprotoxic (R) substances come under the same legal regime, being defined as CMR substances and belonging to the category of “substances of very high concern” (SVHCs), for which specific and homogeneous legal rules have been defined. This approach – proportionate to the seriousness of the dangers intrinsically linked to the toxicological properties of these substances – is the one used for instance in REACH and in more specific regulations concerning pesticides, cosmetics or biocides. There is no reason for applying a different standard when the health and safety of workers is involved. This alignment with REACH and the other EU legislations on chemicals where C, M and R are treated the same could be seen as a regulatory simplification. It would also improve the synergies between all these legislations.

1.3 The provisions set forth in Directive 92/85 of 19 October 1992 on pregnant workers are insufficient for ensuring effective protection in the field of reproductive health when faced with occupational exposure to chemical substances. These provisions only apply to pregnant workers, and the prevention measures only apply once women have notified their employers of their pregnancy. In practice, such notification rarely occurs before the 10th week of pregnancy. According to a French survey carried out in 2015, 50% of pregnant employees notified their employers of their pregnancy in the 3rd month and 32% in the 2nd month or less, while 17% waited until the 4th, 5th or 6th month. The harmful effects of reprotoxic substances on foetal development is particularly dangerous in the first weeks of pregnancy. On the other hand, the risks associated with occupational exposure to reprotoxic substances do not just involve pregnant women. They just as much affect men and non-pregnant women. Contrary to the other EU directives on health at work, Directive 92/85 does not provide for any consultation of workers’ representatives in assessing risks and prevention measures. This boosts the tendency to consider the protection of pregnant workers as a question concerning individuals in an abnormal situation and not as a collective health issue in all companies. Limiting the specific regulation/legislation on workplace reproductive risks to provisions concerning pregnant workers has two negative aspects: a) it hinders the primary and collective prevention of such risks; and b) there is a risk of discrimination insofar as employers may exclude women from certain activities involving exposure to reprotoxic substances. The right approach for ensuring effective protection of reproductive health for men and women exposed to chemicals at work is therefore the inclusion of reprotoxic substances in the scope of the CMD.

1.4 That’s why several Member States have extended the scope of their national regulations on carcinogens to reprotoxic substances (Austria, Belgium, Czech Republic, Germany, France, Finland). No data exists pointing to such an extension resulting in disproportionate or unrealisable provisions. On the contrary, the small amount of data available suggests that they contribute to more systematic prevention, better targeting workplace reproductive risks. This was exactly one of the conclusions of the study carried out for the Commission in 2013 by the consulting consortium RPA-Milieu.

1.5 Extending the CMD’s scope to reprotoxic substances would also allow the setting of occupational exposure limits (OELs) for a number of these substances. At the request of the ETUC, the European Trade Union Institute compiled a list of 66 substances in 2016

for which it was deemed relevant to define such limits (Wriedt, 2016). There is currently just one binding OEL in the EU legislation governing such substances – for metallic lead and its compounds. The limit⁴ is set at 150 µg/m³. Even at the time of its adoption in 1982, this left extremely high residual risks. At the time, it was presented as a provisional compromise associated with legal constraints then in force. The Commission undertook to revise it five years after the directive’s adoption. This undertaking was not honoured. 36 years’ later, the OEL of 150 µg/m³ remains in force. By way of example, the OEL in Denmark was set to 50 µg/m³ in 2007. On the other hand, in the context of the CAD, indicative limits have been defined for 11 reprotoxic substances. Extending the CMD’s scope would allow these indicative limits to be transposed into binding OELs in Annex III of the CMD. Looking at the national provisions of individual Member States, we note major disparities for both reprotoxic substances and for carcinogens and mutagens. This alone justifies EU action.

1.6 There is currently no EU legislative provision specifically protecting workers against the effects of endocrine disruptors. Without completely solving this problem, extending the CMD’s scope to reprotoxic substances would nevertheless lead to certain endocrine disruptors also being covered (for instance phthalates and bisphenol A).

2. Consistent and transparent criteria for setting OELs: an approach ensuring equivalent protection levels for all workers

2.1 As regards OELs setting, it is crucial to define criteria providing greater transparency and consistency in the legislation. The OELs proposed by the Commission in the first two batches of proposals will not fulfil such criteria. Certain OELs are in contradiction to Article 168 TFEU which stipulates that “a high level of health protection shall be ensured in the definition and implementation of all Union policies and activities”. Certain OELs leave a considerable residual risk. The most glaring case involves chromium VI, for which the limit initially proposed by the Commission corresponded to a residual risk of one case of lung cancer among 10 exposed workers. The document submitted to this consultation of the social partners steers clear of this issue, despite it not being new. In the document introducing the second stage of the consultation (2007) of the social partners on revising the CMD, the Commission wrote: “Nevertheless, scientific, technical and socio-economic data alone will not be sufficient to enable binding limit values to be set for carcinogenic, mutagenic and reprotoxic substances. What is also needed is an appropriate definition by the political authority of the level of risk that can be accepted by society. The Commission is of the opinion that these criteria for setting BOELVs⁵ for carcinogenic, mutagenic and reprotoxic substances must be included in any future initiative.” This issue remains exceedingly relevant. It has not been resolved. This constitutes the main obstacle towards establishing consistent legal rules on OELs.

4. At the same time, a binding biological PbB level was adopted for individual workers: 70 µg Pb/100 ml blood. This level is totally inadequate to ensure effective health protection, as has not been revised for 35 years.

5. In the Commission’s document, this is the abbreviation for “binding occupational exposure limits values”. They correspond to the “occupational exposure limits” (OELs) set forth in Annex III of the CMD.

The absence of any solution is leading to arbitrary decisions where each OEL is defined on a fuzzy basis, a not very transparent mix of economic, technical and health criteria. In practice, what we have today is a cost-benefit approach offering enormous margins of uncertainty and manipulation possibilities which are inherent to the complexity of the issue and the very fragmentary availability of data.

2.2 For the ETUC, health-based OEL should be set whenever possible. In the case of such an OEL being proved technically not feasible, transition periods could be defined.

2.3 Numerous CMR substances are likely to produce harmful effects whatever their level of exposure. For these substances, the lower the level of exposure, the lower the probability of harmful effects. On the basis of the experience gained in several Member States⁶, we are of the opinion that each OEL should be set in a way ensuring that the residual risk of cancer is lower than four cases per thousand exposed workers⁷. This limit should be considered as a binding threshold with no exceptions. Even so, this would still constitute a risk very much higher than that generally used as a basis in public health legislation in various fields. Risk should therefore be reduced to the extent technically feasible. When in one of the Member States, a lower OEL has already been adopted, it should be considered as a strong argument supporting the technical feasibility of that OEL and it should constitute the reference for EU initiative. The target should be that OELs are defined in such a way as not to allow a residual risk of four cases of cancer per 100,000 workers to be exceeded. When the residual risks are between these two levels, we are of the opinion that the following specific provisions will need to be implemented to minimise them:

2.3.1 The CMD must contain a specific obligation to adopt a plan for minimising exposure for all cases where exposure exceeds the residual risk levels of 4 cases of cancer per 100,000 workers.

2.3.2 The Member States and the Commission must encourage sectoral initiatives facilitating the implementation of such plans and must give priority to finding safer substitutes for the CMRs.

2.3.3 The OELs adopted in Annex III of the CMD should fulfil transparency principles, indicating the respective associated residual risk of cancer. This information is important, as it will stimulate research into preventive solutions aimed at eliminating or reducing exposure to CMRs.

2.3.4 The CMD should stipulate that the OELs set forth in Annex III be subject to a revision once every five years.

2.3.5 The medium-term objective of this whole process should be to define homogeneous and consistent levels of health protection in all EU policies, whether

6. We refer here especially to M.E.J. Pronk (*Overview of methodologies for the derivation of Occupational Exposure Limits for non-threshold carcinogens in the EU*, RIVM, 2014).

7. The calculations are based on 40 years of occupational exposure, with standardised working time (8 hours a day, 5 days a week, 48 weeks a year).

they regard food hygiene, the quality of water, road safety, consumer protection or the protection of workers. Reducing social health inequalities implies that workplaces be considered on the same level as living spaces, with no toleration of a level of risk higher than in other contexts.

2.3.6 With a view to completing this revision, there is a need to arrange a cooperation between the expert committees working on OELs in the context of the EU institutions and the committees involved in such work in the individual Member States. A multi-annual plan would allow work to be divided up between these bodies. It should be based on priority criteria taking particular account of the number of workers exposed, the level of the residual risk associated with the OELs, the existence in at least one Member State of an OEL providing a higher level of protection, and the existence of data produced in particular in the context of implementing REACH. Priority lists have already been drawn up by the ETUC and RIVM, the Dutch public health institute. They are more or less convergent, and could serve as the basis for establishing an EU list. Publishing a multi-annual plan containing the complete list and the deadlines by which the OELs are to be defined would greatly heighten the predictability of future legislative developments.

2.3.7 Many CMRs have adverse health effects going beyond cancer and reproductive risks. When determining OELs, account should also be taken of these other risks. In certain cases, this will involve setting a lower OEL than one not taking account of the cancer or reproduction risks. By way of example, the OEL for beryllium must also take account of sensitisation effects, the OEL for diesel engine exhaust emissions must take account of the risk of non-cancer respiratory diseases and cardiovascular diseases, etc. Similarly, when multiple risks exist in the field of reproductive health (for instance, infertility, congenital malformations and childhood cancers), all of these risks should be taken into account.

2.3.8 For all activities related to OELs setting, it is crucial to make better use of the data collected during the implementation of REACH.

2.3.9 The delays which have built up in the definition of OELs have so far prevented an essential issue to be discussed: the determination of harmonised measurement methods. For many OELs, measurement practices diverge from one country to the next. In certain Member States for example, the national authorities tend to prescribe precise methods, while in others the importance of this issue is underestimated.

2.4 We consider that providing an independent scientific expertise for the EU legislative process is a crucial issue for the development of the CMD. Taking into account the experience of the work with SCOEL⁸ recommendations, the Advisory Committee has recently underlined that “The SCOEL members have unmatched expertise in occupational hygiene, toxicology, routes of workplace exposure, epidemiology and workplace measurement techniques, together with experience of process generated substances which are outside the scope of REACH but are highly relevant for OSH. As

8. SCOEL: Scientific Committee on Occupational Exposure Limits.

well as assessing the scientific evidence itself, the SCOEL also runs a public consultation aiming to ensure that all scientifically relevant information is taken into account when forming a recommendation. The Commission must guarantee the respect of conflict of interests' rules." We are also concerned that the Advisory Committee on Health and Safety at Work (ACHS) soon will run out of proposals due to the fact that the Commission has not issued mandates to the SCOEL for a sufficient number of substances.

2.5 Many workers are subject to multiple exposures. It is crucial that prevention plans based on the various data which employers are required to collect pursuant to CMD Article 6 take account of this question. In any event, when a worker is subject to multiple exposures in one activity and OELs exist for at least two of these exposures, the effect of the chemical agents must be considered as cumulative under the following formula $\sum C_i/LV_i \leq 1$ in which C_i represents the concentration of agent i , while LV_i is the limit value (OEL) of agent i . This formula is not applicable when scientific data allows a better exposure assessment.

2.6 It will never be possible to have OELs for all CMRs, and their measurement in workplaces with a wide range of exposure situations (for example in the construction sector, in handling and cleaning work, in transportation, etc.) will not allow all CMR risks to be mapped exactly, taking account of spatial and temporal variations. We consider it important to include both in the CMD and CAD a general provision on the continual reduction of workers' exposure to dust and fumes.

2.7 The Commission's impact assessments for the 1st and 2nd batches of proposals systematically underestimated the expected benefits of the considered policy options, failing to include the reduction of pathologies other than cancer. This is the main difference observed between the impact assessment for the OEL on crystalline silica adopted by the United States (0.05 mg/m³)⁹ and that adopted by the European Union (0.1 mg/m³). The difference is considerable. According to the assessment made by the Occupational Safety and Health Administration (OSHA) in the United States, the choice of an OEL of 0.05 mg/m³ instead of 0.1 mg/m³ will lead to a reduction of lung cancer deaths in the order of 62 people a year and an overall reduction of mortality in the order of 644 people a year when one includes deaths caused by respiratory diseases and non-cancerous kidney diseases. Justifying the proposed BOEL, the European Commission's assessment is limited solely to lung cancers without this choice being truly transparent. Indeed, the table on page 65 of this assessment refers solely to the "total number of attributable deaths".

2.8 Greater transparency would mean that the impact assessments published by the Commission take account not just of the selected policy options but also those rejected and the reasons for such decisions. In practice, the Commission works on a case-by-case basis. In its impact assessment of the 1st batch of proposals, there is no analysis on the different policy options about reprotoxic substances, despite this issue being at the centre of the discussions on the future of the CMD since 2004 and despite the Commission having commissioned a 400-page study on the issue. In other cases, the

9. <https://www.regulations.gov/document?D=OSHA-2010-0034-4247>

Commission provides certain explanations (e.g. with regard to diesel engine exhaust emissions). In our view, any policy option which has been the subject of preparatory work should be explained, with the Commission stating the reasons for not ultimately adopting it. This should certainly be the case when diverging opinions have arisen during the consultation of the social partners or during the discussions within the Advisory Committee for Health and Safety. This would also be necessary when external experts are commissioned to conduct preparatory impact studies.

2.9 When one of the Member States has already set an OEL that is lower than the OEL proposed by the Commission, there should be a requirement in the Impact Assessment to justify the non-adoption of the stricter OEL.

2.10 New entries for the annex I should not be submitted to an impact assessment. The decision-making process is exclusively based on the weight of evidence about the intrinsic toxicological properties of substances generated by a process. The approach must be the same than for harmonized classification in the framework of CLP regulation No 1272/2008.

3. Establishing priority criteria to achieve the target of 50 OELs by 2020

3.1 The ETUC insists that the target of 50 substances in Annex III has to be achieved by 2020. After 2020, the process of setting OELs for CMR's should continue on a dynamic way in order to include most of the substances at the workplace. The criteria we have proposed in the preceding paragraphs are intended to facilitate the adoption of OELs. In addition, the number of OELs for CMRs already defined in at least one Member State is much higher than this total. The more systematic use of data gathered by national bodies would also facilitate the adoption of OELs. The whole body of data gathered in the context of implementing REACH also points to quantitative and qualitative benefits when setting OELs for Annex III. In our view, the three fundamental criteria for determining priorities are as follows: (1) the number of exposed workers in the European Union; (2) the magnitude of the health risks associated with the current level of exposure of these workers; (3) the existence of relevant data for determining OELs for these substances and in particular the existence of an OEL in at least one Member State. The first two criteria take precedence over the third one. With regard to the first two criteria, in our view it is a good idea to take account of the most prevalent exposures among men and among women, as these are not necessarily the same due to both the gendered division of labour and the respective risks. For instance, taking account of occupational exposures linked to breast cancer could possibly lead to priorities which would not appear in a non-gender-based analysis. This criterion also applies to the determination of the relevant process generated substances for Annex I.

3.2 We support the inclusion of 8 substances in batches 3 and 4 as it is proposed by the Commission in the Consultation document. We consider that batch 4 should be expanded in order to reach the target of 50 BOELs in 2020. We attach in annex a list of substances which might be included in batch 4.

4. Revising Annex I

4.1 It is of crucial importance to expand Annex I by including processes concerning the main current exposure situations in the European Union. While the inclusion of crystalline silica represents in itself a major step forward, there remains a lot to do to achieve this target. The priority criteria are as follows: (1) the number of exposed workers; (2) the magnitude of the negative health effects, and (3) the existence of relevant scientific research. In this respect, it is important to include in Annex I all processes for which International Agency for Research on Cancer (IARC) monographs are available. By way of example, exposures caused by the combustion of various materials during firefighting or the multiple exposures of painters to carcinogens should be included in Annex I¹⁰. The differing situations of men and women must also be taken into account when applying criteria (1) and (2). For instance, the exposure of healthcare workers to hazardous drugs constitutes a major risk for women workers with regard to both cancers and reproductive health. In our view, such exposure must be included in Annex I of the 3rd batch of proposals with the following entry : “Work involving exposure to carcinogenic or mutagenic substances resulting from the preparation, administration or disposal of hazardous drugs, including cytotoxic drugs, and work involving exposure to carcinogenic or mutagenic substances in cleaning, transport, laundry and waste disposal of hazardous drugs or materials contaminated by hazardous drugs and in personal care for patients under treatment of hazardous drugs” Apart from diesel engine exhaust emissions, in our view rubber dust and fumes as well as leather dust should also be included in the Commission’s third batch of proposals.

5. Crystalline silica

5.1 The compromise reached between the European Parliament and the Council on crystalline silica requires the Commission to re-examine the OEL defined for this substance. In our opinion, the Commission must immediately start preparatory work for adopting an OEL conforming with article 168 of TFEU requiring a high level of human health protection in the definition and implementation of all Union policies and activities. The new OEL for crystalline silica should be set at 50 µg/m³. Considering the large quantity of exposed workers, it should be one of the priorities in the coming months.

6. Diesel engine exhaust emissions

6.1 We are surprised to find no mention of diesel engine exhaust emissions in the document submitted to the social partners for consultation. In the impact assessment presented by the Commission for the second batch of proposals, it did however indicate that its decision not to include diesel engine exhaust emissions both in Annex I and Annex III was provisional and would be reviewed. In the same impact assessment, the Commission stated that the absence of a legislative initiative would lead to 230,000

10. Such activities are handled in monograph no. 98 published by the IARC in 2010.

deaths over the coming 60 years. This order of magnitude is very much underestimated, given that it is based solely on deaths caused by lung cancer. When taking account of the other adverse health effects of diesel engine exhaust emissions, the number of avoidable deaths is much higher.

6.2 The Commission's observations stated in its impact assessment of the second batch of proposals regarding the difficulty of finding a satisfactory legal formulation are irrelevant in the CMD context. In practice, workers are exposed to diesel engines corresponding to widely varying emission standards. The composition of diesel engine exhaust emissions is not solely dependent on emissions standards applied for their construction, but also varies because several other factors, including maintenance, filter systems, combustion temperature, etc. The goal of the directive is not to define specific rules governing the design of diesel engines, their possible replacement or other measures determined by market rules. It would therefore be a good idea to start out from the scientific finding that diesel engine exhaust emissions are carcinogenic.

6.3 Affirmation of the Scientific Committee on Occupational Exposure Limits (SCOEL) opinion, according to which "exhausts of these new technology diesel engines may not be considered carcinogenic"¹¹, is not based on consistent evidence. The sole source cited in the bibliography refers to the report compiled by the Boston-based Health Effects Institute. This report refers solely to vehicles meeting the latest standards in force in the United States. The laboratory conditions of this toxicological study are very much different to the real-life working conditions of workers currently exposed to diesel engine exhaust emissions both in the United States and in the European Union. This report is thus not a relevant document for justifying the SCOEL's affirmation.

6.4 In our view, the Commission must include diesel engine exhaust emissions as soon as possible in Annex I and in Annex III. The OEL in Annex III should be of 50 µg/m³ calculated on the basis of the concentration of elemental carbon and irrespective of whether the exhaust emissions are from old or new technology diesel engines. Such an OEL has been recently adopted in Germany for diesel engine exhaust emissions. In addition, a provision should be added in the CMD to reduce this OEL to 15 µg/m³ by 2025 in order to take into account epidemiological data. As mentioned by the SCOEL: "although toxicological data supports a threshold (possibly at 0.02 mg DEP¹²/m³ or below, corresponding 0.015 mg EC¹³/m³), epidemiological data suggests significant cancer risks already at and below these exposure levels¹⁴". ETUC will support any amendment of the European Parliament or the Council allowing these targets to be reached in the second batch.

11. SCOEL/OPIN/403 Diesel Engine Exhaust page 10 (December 2016).

12. DEP: Diesel exhaust particulate.

13. EC: elemental carbone.

14. SCOEL/OPIN/403 Diesel Engine Exhaust page 10.

7. Other relevant legislation regarding the protection of workers

7.1 Apart from the revision of the CMD, it would be a good idea to adapt other EU legislation to establish a coherent strategy for fighting occupational cancers.

7.2 Exposure to asbestos remains a priority issue in Europe due to the high number of buildings and equipment containing asbestos. The OEL defined in Directive 2009/148 does not provide a satisfactory level of protection for exposed workers. It would therefore be good to revise this OEL and to define a more effective European strategy on asbestos. Taking into account the development of scientific research, France and the Netherlands have recently revised their national OEL on asbestos with a national BOEL of 0,002 fibers/cm³ in the Netherlands and 0,01 fibers/cm³ in France against the 0,1 fibers/cm³ in the EU directive.

7.3 Directive 2006/25 on the exposure of workers to risks arising from physical agents (artificial optical radiation) excludes solar radiation from its scope of application. However, solar radiation is a major cause of occupational cancers and involves a high percentage of workers. We demand that the Directive's scope of application be revised to include solar radiation (as originally proposed by the Commission). Its exclusion is the result of an amendment adopted by the European Parliament in September 2005.

7.4 In the context of the ongoing revision of Directive 2000/54 on biological agents, account needs to be taken of occupational exposure to biological agents which can lead to cancers or reproductive disorders.

7.5 Directive 2013/35 on electromagnetic fields only takes account of their short-term effects. This approach was defined as provisional and pragmatic at the time the directive was being drafted. In our view, the time has now come to start preparatory work taking account of the long-term effects of electromagnetic fields.

7.6 We also consider it imperative to carry out a review of the radiation protection rules contained in Directive 2013/59/Euratom with regard to workers exposed to ionizing radiation.

7.7 Occupational exposure to radon and radon progeny is also an important cause of work related cancers even at relatively low exposure level. Specific prevention measures for the workers should be addressed in EU legislative instruments.

7.8 Research into night work and posted work points to such work contributing to occupational cancers. This question must also be taken into account in the EU strategy for eliminating occupational cancers.

7.9 In 2008, the Commission launched the first stage of consultation on a possible legislative initiative on environmental tobacco smoke (ETS) at work. The second stage never took place. In October 2013, the Commission stated – in the context of REFIT – that, while the initiative was not being abandoned, the possible adoption of a legislative proposal would depend on future developments. We call on the Commission to state its

intentions in this field. It needs to be checked to what extent an EU legislative initiative would allow the existing national provisions to be upgraded (including the development of e-cigarettes).

7.10 There is a need to improve workers' protection in the EU legislation in three important fields: occupational exposure to nanomaterials, occupational exposure to endocrine disruptors and occupational exposure to pesticides. It should be part of a European strategy against occupational cancer.

8. Catching up and preparing for the future

8.1 We would like to emphasise that the majority of issues discussed in our paper up to now were already on the 2004 agenda put forward on opening the consultation with the social partners on revising the CMD. The cumulative delays have had dramatic consequences, helping to aggravate social health inequality within the European Union. The legislative moratorium adopted in 2013 in the context of the REFIT programme in the field of workplace health was unjustifiable, presenting the legal rules governing workers' health and lives as an administrative burden. The fact that the Commission adopted its first batch of proposals during the Dutch presidency, more than six months before finishing its assessment of the existing directives, shows the extent to which this moratorium was a wrong political decision.

The various CMD aspects on the agenda to be revised by 2020 are nothing but catching-up measures aligning the CMD with the scientific knowledge and with the prevention possibilities of the late 20th century. In the meantime, new scientific knowledge is appearing, especially in the field of the causes of cancer (carcinogenesis), the role played by epigenetic processes, endocrine disruptors, the transgenerational effects of certain occupational exposures, the risk associated with the nanomaterials now finding their way onto the market, the role of multiple exposures (including interactions between exposures to chemical agents and other carcinogens), research into biomarkers reflecting physical harm to the body before a disease actually breaks out, the importance of working conditions in breaking down immune defences, etc. In our response, we have sought to provide urgent responses to problems that should have been resolved more than a decade ago. In our view, the current legislative revision is absolutely necessary. However, it must not block out the need to find legislative responses to a whole range of issues related to emerging risks or to a better understanding of the problems raised. In our view, the European Commission must organise a systematic monitoring of both scientific and regulatory developments allowing us to overcome the challenges in the field of preventing occupational cancers. For our part, we will continue to contribute to the analysis of these issues and to the search for appropriate preventive solutions.

9. Legislation is indispensable, but as yet not sufficient

9.1 The ETUC is convinced that modernising EU legislation on protecting workers against occupational cancers is a pre-condition to any improvement of prevention in this field.

The potential added value of a dynamic EU policy is particularly high, to the extent that preventing occupational cancers relies on synergistic interventions in line with EU competences. An obvious complementarity exists between the rules of the market governing chemical agents and the social rules protecting workers against CMRs. In this respect, we would like to express our concern over the fact that occupational exposure is being neglected in the current procedures accompanying the implementation of the specific regulations on cosmetics and pesticides.

Over and above the indispensable improvements to the legislative framework, it is important to improve cooperation between Member States and EU interventions in the following fields:

9.2 Whatever the legislation, there is always a risk of it remaining a paper tiger when labour inspectorates do not have sufficient resources and competences to enforce compliance. We therefore ask for this aspect to be looked at, in particular by the Senior Labour Inspectors Committee. In addition, it is important to improve cooperation between the departments responsible for enforcing the rules of the market (mainly REACH) and labour inspectorates. The existence of a specific workers' representation for health and safety questions is also a determining factor in the implementation of any regulation. Trade unions and workplace reps have an important role to play here. There are many workers without such representation due to the size of the company they work for or other factors. While this question is obviously not a specific aspect of organising CMR-related prevention, it should be part of any national or European strategy. The development of preventive services with adequate expertise on work related cancers and reproductive risks is also an important challenge. In that field, a better prevention requires a multidisciplinary approach with a cooperation between occupational medicine, toxicology, ergonomics and other specialities.

9.3 Only very few Member States have precise data on workers' exposure to CMR substances. At European level, data on occupational exposures to reproductive risks is completely non-existent, while data on exposure to carcinogens is more than 20 years' old, compiled at the time the European Union was co-financing the Carex programme. The importance of this question was acknowledged in the Commission Communication of 10 January 2017. In our view, it is essential for this acknowledgement to be turned into concrete, systematic and ambitious initiatives. Moreover, the aim of an amendment resulting from the agreement between the European Parliament and the Council on the first batch of proposals was to have Member States collect relevant data in their reports on the Directive's application. It is important that the Commission uses this data to improve the European strategy in this field. The development of databases, involving all the Member States of the EU, as well as, the improvement and transparency of information sources would facilitate the identification of occupations and activities

with higher risk of cancer. It could produce alerts in order to stimulate the research on work related cancers. Databases should identify possible differences between men and women.

9.4 The development of R&D programmes can also help improve the prevention of occupational cancers. Greater attention to occupational exposure and to social health inequality is needed in cancer research programmes co-financed by the EU. Development programmes on ways of substituting CMR substances need to be supported, especially on the basis of sectoral approaches. The work of informing workers and heightening their awareness carried out by the EU-OSHA can also play an important role in improving prevention. The campaign on dangerous substances planned for 2018-19 can play a significant role here. We also support the various initiatives taken in the context of the “Roadmap from Amsterdam to Vienna”.

9.5 In the majority of Member States a marked dividing line currently exists between public health policies and workplace health policies. In particular, cancer statistics and statistics on reproductive risks are insufficient, as they do not allow the occupations of cancer patients and thus of the associated CMR exposure to be identified. There are however positive experiences, such as the NOCCA programme based on the cancer registers of the Nordic countries.

Pro-actively researching the occupational exposure of people suffering from cancer also has the potential to come up with data of use in better targeting prevention, as shown by the OCCAM survey in Italy and the GISCOP93 survey in France. The European Union can base its work on such initiatives, and thus contribute to the production of more systematic data. This would in turn allow policies intended to reduce social health inequality in Europe to be better targeted.

10. The role of social dialogue

10.1 The Commission has asked us whether we would like to see the revision of the CMD taking place within the framework of the social dialogue procedures provided for under TFEU Article 155.

10.2 The ETUC informs the Commission that similar to the process for adopting batch 1 and batch 2 we do not want to launch a negotiation procedure pursuant to Article 155 of the Treaty for the adoption of batch 3 and batch 4 and we urge the Commission to make immediate progress on this. However, this will not rule out our discussing issues together with employers and seeking to find convergent positions on certain questions, as was the case with formaldehyde.

10.3 We consider that social dialogue – whether sectoral or cross industry – can play an important role in implementing a strategy targeting occupational cancers. The European agreement in the hairdressing sector is obviously one example of this. The Commission’s unjustifiable delay in implementing this agreement via a directive is however not an encouraging sign for social dialogue on such issues.

Conclusions

In the view of the ETUC, the Commission must draw its conclusions from the legislative process regarding the first batch of revision proposals. A very large majority of European Parliament parties considered the original Commission proposals as totally insufficient. A significant proportion of the amendments adopted by the European Parliament served in turn as a basis for a compromise within the Council. During the Council discussions, many Member States also supported a more ambitious approach. In the view of the ETUC, this positive experience indicates that more ambitious proposals need to be put forward by the Commission in the next steps of revising the CMD. The Commission should also adopt an open attitude in the “trilogue” with regard to amendments possibly put forward by the European Parliament concerning the second batch of proposals. These would allow the European Union to show that it can positively contribute to improving the working and living conditions of all EU citizens.

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All links were checked on 25.07.2018.

Annex 1

List of potentially relevant carcinogens (or groups of carcinogens) proposed by ETUC for which the derivation of a BOEL under the CMD should be added in batch 4

N°	Substance / group of substances	CAS no.	Classification harmonised (or notified) / Inclusion in annex I of CMD	Registered tonnage band [t/a] / process-generated substance	Comments
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Candidates for batch 4

Process-generated and legacy substances

9	Benzo(a)pyrene (Benzo(def)chrysene)	50-32-8	C 1B, H350	not registered / process-generated / legacy substance	
31	Diesel engine exhaust emissions		annex I (recomm.) IARC: 1 (2013)	Process-generated	
42	Leather dust		IARC: 1 (2012)	Process-generated	
46	N-Nitroso diethanolamine (2,2'-(Nitrosoimino)bisethanol)	1116-54-7	C 1B, H350	Not registered / process-generated	
47	N-Nitroso diethylamine (Diethylnitrosoamine)	55-18-5	Notified: C 1B, H350 IARC 2A (1987)	Not registered / process-generated	
48	N-Nitroso dimethylamine	62-75-9	C 1B, H350	Not registered / process-generated	
49	N-Nitroso di-n-propylamine (Nitrosodipropylamine)	621-64-7	C 1B, H350	Not registered / process-generated	
51	2,3,4,7,8-Pentachlorodibenzo- furan	57117-31-4	IARC: 1 (2012)	Not registered / process-generated	
53	Polychlorinated biphenyls (PCB)	1336-36-3	STOT RE2, H373 IARC: 1 (2016)	Not registered / legacy substance	
61	2,3,7,8-Tetrachlorodibenzo- para-dioxin	1746-01-6	IARC: 1 (2012)	not registered / process-generated	
new 4/17	Welding fumes		IARC: 1 (in prep.)	Process-generated	

Substances classified as C 1A/1B (or due to be classified)

1	Acetaldehyde (ethanal)	75-07-0	C 1B, H350	0 – 10 a)	agreed at RAC-38
5	Anthraquinone	84-65-1	C 1B, H350	1,000 – 10,000	agreed at RAC-35
12	4,4'-Bis(dimethylamino)-4''-(methyldiamino)trityl alcohol	561-41-1	C 1B, H350	10 – 100	
17	2-Chloro-1,3-butadiene (Chloroprene)	126-99-8	C 1B, H350	10,000 – 100,000	
19	α-Chlorotoluene	100-44-7	C 1B, H350	10 – 100	

N°	Substance / group of substances	CAS no.	Classification harmonised (or notified) / Inclusion in annex I of CMD	Registered tonnage band [t/a] / process-generated substance	Comments
21	C.I. Basic Violet 3	548-62-9	C 1B, H350	0 – 10	
22	C.I. Solvent Blue 4	6786-83-0	C 1B, H350	10 – 100	
23	Cobalt compounds classified as C 1B	7646-79-9 10124-43-3	C 1B, H350	1,000 – 10,000	
25	Poly[(aminophenyl)methyl]-aniline (technical MDA)	25214-70-4	C 1B, H350	100 – 1,000 a)	
30	1,2-Dichloropropane	78-87-5	C 1B, H350 IARC: 1 (2016)	1,000 – 10,000 a)	to be included via 9. ATP
new 9/16	1,2-Dihydroxybenzene (pyrocatechol)	120-80-9	C 1B, H350	10,000– 100,000 a)	agreed at RAC-38
32	N,N-Dimethylhydrazine	57-14-7	C 1B, H350	0 – 10	
34	2,3-Epoxypropyl methacrylate (glycidyl methacrylate)	106-91-2	C 1B, H350	1,000 – 10,000	agreed at RAC-35
	Ethylene imine	151-56-4	C 1B, H350	100+ a)	
37	Gallium arsenide	1303-00-0	C 1B, H350	10 – 100	
40	Isoprene (2-Methyl-1,3-butadiene)	78-79-5	C 1B, H350	100,000 – 1,000,000	
43	Methylhydrazine	60-34-4	C 1B, H350	10 – 100 a)	agreed at RAC-34
50	2-Nitrotoluene	88-72-2	C 1B, H350	10 – 100 a)	
	4,4'-Oxydianiline and its salts	101-80-4	C 1B, H350	10 – 100	
52	Phenolphthalein	77-09-8	C 1B, H350	10 – 100	
54	Potassium bromate	7758-01-2	C 1B, H350	0 – 10	
55	1,3-Propanesultone	1120-71-4	C 1B, H350 IARC: 2A (2016)	10 – 109 a)	
	1,3-Propiolactone (3-propanolide)	57-57-8	C 1B, H350	0 – 10	
58	Quinoline	91-22-5	C 1B, H350	100 – 1,000 a)	
60	Styrene oxide ((Epoxyethyl)benzene)	96-09-3	C 1B, H350	100 – 1,000 a)	
68	1,2,3-Trichloropropane	96-18-4	C 1B, H350	1,000 – 10,000	

N°	Substance / group of substances	CAS no.	Classification harmonised (or notified) / Inclusion in annex I of CMD	Registered tonnage band [t/a] / process-generated substance	Comments
CLH process currently under way					
New 2/16	2,2-Bis(bromomethyl)propane-1,3-diol	3296-90-0	Proposed: C 1B, H350	100 – 1,000	2: 1/2017
14	Butanone oxime	96-29-7	Proposed: C 1B, H350	1,000– 10,000	2: 11/2016
New 6/16	Cobalt metal	7440-48-4	Proposed: C 1B, H350	10,000+	2: 4/2016
33	1,4-Dioxane	123-91-1	Proposed: C 1B, H350	1,000+	2: 4/2016
New 4/16	N-(Hydroxymethyl)acrylamide (NMA)	924-42-5	Proposed: C 1B, H350	1,000 – 10,000	2: 4/2016
59	Silicone carbide fibres	409-21-2	Proposed: C 1B, H350 CIRC: 2A (in prep.)	100,000+	2: 2/2015

Numbering of substances

The numbering of substances in the above tables corresponds to the following publication:
www.etui.org/Publications2/Reports/Carcinogens-that-should-be-subject-to-binding-limits-on-workers-exposure

Explanation of notes

Column "Harmonised classification / inclusion in annex I of CMD":
 IARC: IARC classification; year of publication

Column "Registered tonnage band / process-generated substance":
 a) additional registration(s) for "intermediate use only"

Column "Comments":
 re. REACH and CLP processes
 2) CLH process initiated; date of initiation
 ATP: Adaptation to technical progress

Chapter 25

European Trade Union Confederation response to the second stage of consultation with the social partners revisions of Directive 2004/37/EC¹

Key messages

- The revision of the carcinogens and mutagens directive meets fundamental needs and expectations from workers and citizens in the European Union.
- It must be part of a global strategy for elimination work related cancer in Europe. The ETUC urges the Commission to adopt a roadmap in 2018 with different initiatives at EU level. These initiatives should take into account all the occupational risks for women and men, including asbestos and solar UV radiation.
- The scope of application of the directive must be revised including reprotoxins by 2019. It should include different work activities with specific risk of cancer like hairdressing, painting or exposure to cytotoxic substances in the health services.
- 50 binding occupational exposure limits (BOEs) should be set in order to cover the majority of workplace exposures.
- The process for setting BOELs needs to be more consistent and more transparent.

Introduction

The European Trade Union Confederation (ETUC) welcomes the revision of the Carcinogens and Mutagens Directive 2004/37/EC (CMD). After a long period of paralysis, real progress has been achieved with the final adoption of the text of the first revision in October 2017. We hope that the amendments voted by the European Parliament and by the Council of Ministers will improve the second revision during 2018. This important legislation of the European Union meets fundamental needs and expectations of workers and citizens. The recent trade union study on the costs of work related cancer shows that significant cost savings would be realized with better prevention, in particular for workers and their families, national health systems and social security systems (Vencovsky *et al.* 2017).

We are surprised by the fact that most of the proposals made by the Commission do not consider any idea submitted by the social partners. We have the feeling that the documents for the second stage of the consultation were largely written before analysing the different responses. Those responses are mentioned in a purely descriptive way

1. This response was adopted in December 2017.

in the second section of the Consultation Document, but they are not considered as a substantial contribution for improving the EU strategy for eliminating work related cancer.

We consider that the Consultation Document² and the Analytical Document³ prepared by the Commission should have integrated more systematically the amendments adopted by the Parliament and the Council during the discussion of the first batch. Among those amendments, some recitals define important principles which should inform the on-going revision process. We mention only some of them:

- Providing “a consistent level of protection from the risks related to carcinogens and mutagens” (see new recital 1 adopted with batch 1);
- “The limit values set out in this Directive should be revised where necessary in the light of available information, including new scientific and technical data and evidence-based best practices, techniques and protocols for exposure-level measurements at the workplace. That information should, if possible, include data on residual risks to the health of workers and opinions of the Scientific Committee on Occupational Exposure Limits (SCOEL) and of the ACSH. Information related to residual risk, made publicly available at Union level, is valuable for future work to limit risks from occupational exposure to carcinogens and mutagens, including by revising the limit values set out in this Directive. Transparency of such information should be further encouraged » (see new recital 6);
- “Appropriate and consistent data collection by Member States from employers is necessary to ensure the safety and proper care of workers. The Member States are to provide the Commission with information for the purposes of its reports on the implementation of Directive 2004/37/EC. The Commission already supports best practice with regard to data collection in Member States and should propose, as appropriate, further improvements to the data collection required pursuant to Directive 2004/37/EC” (see new recital 8);
- “This Directive strengthens the protection of workers’ health and safety at their workplace. Member States should transpose this Directive into their national law. They should ensure that competent authorities have sufficient numbers of trained staff and other resources necessary to carry out their tasks related to the proper and effective implementation of this Directive, in accordance with national law or practice. Application of this Directive by employers would be facilitated if they had guidance, where relevant, to identify better ways to achieve compliance with this Directive” (see new recital 28).

We are also surprised by the vague wording of many sections of the Commission “Consultation document”. The Document states that “some agents and processes suggested by the workers’ organisations fall outside of the scope of the CMD and thus

2. C(2017) 7466 final, 10 November 2017.

3. SWD(2017) 370 final, 10 November 2017.

are not considered in this consultation paper”. We would like to know which agents and processes are considered in that sentence. If it is about asbestos or electromagnetic fields, the issue is obvious. We never asked the Commission to consider them in the revision of the CMD. If it is about cytotoxic drugs, rubber dust and fumes or leather dust, we are still convinced that they are relevant for the CMD and that their exclusion from the scope of application of the directive reflects a very narrow interpretation of the Annex I.

The Analytical Document does not provide sufficient information on many issues. It does not contain gender disaggregated data. It does not indicate which substances (apart from the nine chemicals already in the pipeline for batch 3 and batch 4) are envisaged for future developments in order to reach the objective of 50 binding occupational exposure limits (BOELs) by 2020. It does not explain the criteria for selecting the 9 agents under consideration. It reflects a poor level of cooperation with Member States, where the processes for setting BOELs for carcinogens, mutagens and reprotoxic substances CMRs are more developed.

We won't repeat all the points already developed in our response for the first stage. We ask the Commission to consider the response for the first stage as a part of our response for the second stage since most of the issues raised by ETUC in September are still pending and should be addressed in future initiatives by the Commission.

1. Scope of application of the directive and annex I

The ETUC insists on including reprotoxins in the scope of application of the directive. This issue was largely explained in the first section of our response to the first stage of consultation.

The revision of annex I is crucial for defining correctly the scope of application of the directive. Annex I is based on the fact that substances are classified only if they are put on the market. When a process is exposing workers to a cancer risk, those process-generated exposures do not necessarily meet the conditions for being classified under the Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation).

In our view, the wording of the directive must be understood taking into account the objectives it pursues and its context. The central objective of the CMD is to protect workers against the risk of occupational cancer. The role of annex I is to fill any potential gap between a narrow scope of application depending exclusively on the criteria laid down by the CLP Regulation and the reality of work activities involving a risk of occupational cancer. For this purpose, Annex I includes “substance, mixture and process”. Part of the added value of a specific workers' protection legislation is to cover situations which cannot be adequately regulated by market rules because they adopt a substance based approach and do not consider work activities as such. There is a large body of scientific evidence indicating that specific work activities must be considered carcinogenic since they imply multiple and complex exposure to carcinogens. In that

perspective, the findings of the International Agency for Research on Cancer (IARC) should be taken into account as an important part of the context of the directive. Some monographs of the IARC identify specific work activities like painting, firefighting, hairdressing, rubber manufacturing, aluminium production, iron and steel founding, printing processes, etc. as exposing workers to the risk of occupational cancer. Other monographs deal with complex process-generated chemicals like mists from strong inorganic acids or coal-tar distillation. If we want to elaborate a “time proof” legislation protecting effectively workers against CMRs, annex I must be heavily revised to take account of all the work activities with a risk of occupational cancer.

In order to make more explicit that approach and avoid any legal uncertainty, we consider that an amendment should be introduced in article 2 of the directive and in the title of annex I. Paragraph 2, a, iii and the title of annex I should add the word “occupational exposure” after “substance, mixture and process”. The new wording would therefore be “substance, mixture, process or occupational exposure”. The introduction of the wording “occupational exposure” would strengthen the link between the CMD, and EU activities based on it, and the IARC systematic programme at international level. “Occupational exposure” would be defined as “specific work activity with an occupational exposure to a complex mixture with carcinogenic, mutagenic or reprotoxic effects on the humans”. Such a revision should be introduced with the batch 3 in 2018. The roadmap of Commission should include a list of “occupational exposures” which are envisaged for annex I and precise deadlines about their inclusion. A first list could be based on the IARC monographs. Other data, like findings from NOCCA (Pukala *et al.* 2009) should be used.

We implore the Commission to be more consistent with the basic principle sustaining that legislation: it is fundamentally a hazard based legislation. This means that legal standards have been designed taking into account the intrinsic properties of determined substances and processes. At that stage, other considerations like socio-economic analysis provided by an impact assessment are completely irrelevant. The adaptation of the scope of application has to be based exclusively on scientific findings about the potential harm of substances and processes. It is a typically hazard-based provision. What matters is that some processes-generated substances are causing cancer. The causal relation must be considered according to the weight of evidence used across EU legislation. Substances and processes are included when they are known to have carcinogenic potential for humans or they are presumed to have carcinogenic potential for humans. A very similar approach is used by the IARC when it classifies substances or processes as “carcinogenic for humans” or “probably carcinogenic for humans”. We do not accept the Commission view that when proposing new processes for annex I, it should be taken into “account an analysis of social, economic and environmental impacts”⁴. If socio-economic considerations might be relevant for adapting annex III, it is not the case for annex I.

4. Consultation Document, page 6. We agree that a socio-economic impact is taken into account for proposing BOELs. Our opposition is about the revision of annex I.

We urge the Commission to consider the revision of Annex I independently from the possibility of setting BOELs in annex III. We don't understand why the documents for the second stage of consultation do not mention at all the important issue of cytotoxic treatments.

2. Revision of Annex III

We agree with the selection of five chemicals for annex III in the third batch and with the first candidate list of four substances for the fourth batch. We consider them only as a minimal list which must be extended to reach the objective of setting 50 BOELs for 2020. The trade union list has been elaborated on the basis of a clear prioritisation criteria. We ask the Commission to consider these chemicals as a priority (Wriedt 2016). Obviously, if during the legislative process, some of those chemicals can be included in the second revision through amendments voted by the European Parliament and the Council of Ministers, we would welcome such developments. It would save lives.

The Commission has the responsibility to avoid any potential bottlenecks in the expertise process contributing to the setting of OELs. We have already expressed our opinions in the current debate on the respective roles of SCOEL⁵ and RAC⁶. We share the views of the Dutch Ministry of Employment in its letter to the Commission of 13 October 2017 that “transferring tasks without adequate measures to ensure the quality and quantity of work and work processes may lead to lesser and less relevant Occupational Exposure Limits being proposed”. In our view, several basic principles should be guaranteed. Any committee involved in scientific expertise for the preparation of BOELs should include independent and recognized experts in all the relevant scientific fields related to workers' protection against chemical risks. There should be a balanced geographical distribution of the members of the committee. The consultation process with the different stakeholders (principally trade unions and employers' organisations) should be organised with sufficient time and full information. The current role of the Advisory Committee for Health and Safety should be maintained and guaranteed. A fruitful cooperation with national bodies involved in setting OELs should also be sustained.

2.1 Define a methodology for setting BOELs for non-threshold CMRs

We regret that the analytical document does not propose any consistent methodology for setting BOELs for non-threshold CMRs. It is a simple list of chemicals with some information on their health impact and their use in Europe. There is a need for defining more precise criteria based on the experience of several Member States as outlined in the second section of our response for the first stage of consultation. We won't repeat our arguments here. They have been extensively developed in the second section of the ETUC response for the first stage of consultation. These must be taken into account as the debate on this important question cannot be permanently procrastinated.

5. SCOEL: Scientific Committee on Occupational Exposure Limits.

6. RAC: Committee for Risk Assessment of the European Chemicals Agency.

In the document introducing the second stage of the consultation (2007) of the social partners on revising the CMD, the Commission wrote: “Nevertheless, scientific, technical and socio-economic data alone will not be sufficient to enable binding limit values to be set for carcinogenic, mutagenic and reprotoxic substances. What is also needed is an appropriate definition by the political authority of the level of risk that can be accepted by society. **The Commission is of the opinion that these criteria for setting BOELVs for carcinogenic, mutagenic and reprotoxic substances must be included in any future initiative**” (our emphasis). Ten years later, this important issue remains unresolved. This constitutes the main obstacle towards establishing consistent legal rules on OELs.

2.2 Lack of transparency of annex III

We would like to express our concern about the lack of transparency of annex III.

In our view, each BOEL should provide consistent and homogeneous information and be structured in 10 sections. Six of those sections are already used in Annex III. Four new sections would provide essential information for the different stakeholders. Our proposal takes into account the new recitals adopted during the legislative process of batch 1 and the experience of several Member States.

1. Name of the agent (as is already the case);
2. EC number (where it is relevant, as is already the case)
3. CAS number (where it is relevant, as is already the case);
4. Binding limit value calculated for 8 hours and, where relevant, for short term (as is already the case);
5. Transitional measures (where relevant, as is already the case);
6. Date of adoption of that limit value (new column);
7. Date of review for that limit value (new column);
8. Residual risk from that limit value as it was evaluated when the limit value was adopted for a non-threshold substance (new column);
9. Skin notation (where it is relevant, as is already the case in part B of Annex III);
10. Measurement methodology (new column).

Introducing those changes would bring positive outcomes:

- Information on residual risk would increase the awareness of the need to avoid exposure or to minimise it when it is not technically possible to avoid it;
- The date of review would increase the predictability of legislative developments among the different stakeholders;
- The definition of measurement methodology would contribute to a consistent application and enforcement of the CMD across Europe and would grant an equal level of protection for workers exposed to the substances with a BOEL. This issue is already considered as an integral part of an EU legislative provision in the case

of asbestos (see article 7 of Directive 2009/148 of 30 November 2009). Taking into account the latest technical expertise, the measurement methodology should help employers and competent authorities to overcome the problem of variability and to use a relatively small number of measurements to demonstrate with a high degree of confidence that workers are unlikely to be exposed to concentrations exceeding the BOELs;

- The date of review should be calculated in principle 5 years after the date of entry into force of the BOEL. It would increase the foresight of legislative changes and facilitate the planning of the different phases for the adoption of BOELs (expertise including cooperation with the Member States, consultation of the Advisory Committee for Health and Safety, impact assessment, etc.)

2.3 Improving the protection of workers exposed to crystalline silica

With more than 5 million workers exposed in the European Union, crystalline silica is a carcinogen for which a review of the recently adopted BOEL is particularly important. We do not believe that new evidence is needed. Existing evidence is easily sufficient to start the work and prepare a new BOEL. There is a common position between ETUC, IndustriAll and the European Federation of Building and Woodworkers which was adopted on 1st March 2017. That common position considers that a BOEL of 0,05 mg/m³ must be introduced in annex III with a transition period during which Member States could apply the BOEL of 0,1 mg/m³. In any case, by 2027, the BOEL of 0,05 mg/m³ should be applied and by 2022 the transition period should be reviewed and possibly shortened in the light of an assessment of workers' exposure in the EU and existing best practices in the various sectors of industry.

3. Enforcement

We consider that the issue of enforcement should be addressed by the Commission. If enforcement is fundamentally a responsibility of each Member State, the experience in other fields of legislation indicates that minimal standards could be defined by the EU legislation in order to guarantee a consistent level of application of the directive. It is already the case in different directives in the field of environmental protection⁷.

4. For a strategic EU roadmap in 2018

The European Commission should adopt in 2018 a strategic roadmap for eliminating work-related cancer. Such a roadmap should clarify the further development of the CMD. It should provide a list of the future agents which will be considered for annex III

7. See, for instance, Directive 2012/18/EU of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC; Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE).

with deadlines. It should set criteria for the setting of BOELs at EU level for non-threshold chemicals.

The roadmap should also consider other legislative initiatives like the revision of the asbestos directive and the revision of the optical radiation directive. Those two revisions must be considered as a priority since a strengthened prevention of asbestos-related cancer and skin cancer would significantly reduce the global burden of work-related cancers. Other legislative instruments in the field of workers protection must be revised. They have been identified in the ETUC response from September 2017 (see section 7). In the case of asbestos, the European Parliament has adopted a resolution on 14 March 2013⁸ with a list of initiatives which should be carried out at EU level. In the case of skin cancer, effective prevention measures can be simple and would strongly reduce the burden of work-related cancer. We fully agree with the findings of the Consensus report on skin cancer published in April 2016 (John *et al.* 2016). One of the main issues raised by the report is the need to revise the optical radiation directive to include solar UV radiation. Since 2014, the German accident social insurance system has carried out dosimetric assessments of outdoor workers⁹. Exposures of up to 5 SED/day are common, compared to a tolerable risk of 1,3 SED/day. For instance, dockworkers' yearly exposure has been measured to be 222 SED, whilst masons/bricklayers have on average an exposure of 435 SED per year. No other occupational carcinogen has such high risk (exceeded threshold-level by 5 times).

The roadmap should take into account progress in scientific knowledge. In particular, we want to mention the need to adopt specific rules for occupational exposures to endocrine disruptors. Those exposures not only affect the health of the exposed workers but also the health of their offspring. The roadmap should deal with the needs of preventing risks from nanomaterials. Other issues have been identified in our response for the first stage of consultation (see point 8 of that response).

The roadmap should integrate a gender perspective. Workplace exposures and their negative health impact can be different for men and women. The gender dimension of preventing work related cancer has been neglected both in legislation and in workplace interventions. Most of the occupational exposures playing a role in breast cancer are not considered a priority for preventative action while breast cancer is with lung cancer among the main causes of death from cancer for women in Europe¹⁰.

The roadmap should combine legislative initiatives with non-legislative action. It should also be aimed at mainstreaming work-related cancer prevention across different EU policies. The collection of relevant data at EU level and an adequate support for

8. See www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2013-0093+0+DOC+XML+Vo//EN

9. See findings from GENESIS-UV: www.dguv.de/ifa/fachinfos/strahlung/genesis-uv/aktuelle-ergebnisse/index-2.jsp

10. According to EUCAN statistics, 90.665 women died from breast cancer in 2012 in the European Union while 81.442 died from lung cancer. According to the ETUI study on the costs of work related cancers, more than 35.000 cases of breast cancer can be attributed to a list of 25 workplace exposures every year in the European Union. Most of them are affecting women (Vencovsky *et al.* 2017).

research in the different relevant fields would be an important contribution to better prevention and a regular evaluation of the effectiveness of policies. In public health, cancer statistics at EU level should integrate information on occupations by gender and by cancer sites using the experience of NOCCA (the Nordic Occupational Cancer project). NOCCA has proven to be a driver for innovative research.

In our view, the future of OSH legislation on chemical risks should be built on a three-level approach:

1. A first block of general obligations as they are defined in the Chemical Agents Directive which needs also some amendments like a general obligation of minimising the exposure to dust and vapour (see ETUC response from September 2017, point 2.6);
2. A second block of stricter obligations as they are defined in the CMD for all the substances of very high concern in an occupational context. In that perspective, the first step should be to include reprotoxicants in 2019. If we consider the five scenarios envisaged by the Commission for the impact assessment study¹¹, we support scenario 2: inclusion of reprotoxic 1A and 1B chemicals in the scope of the CMD with the full application of the existing CMD requirements¹². Other categories of substances should be introduced in the scope of application of those stricter provisions on the basis of their intrinsic toxicological properties. The approach could be quite similar to the application of article 57f in REACH. It should consider, among priorities, the seriousness, the irreversibility and the delay of hazardous effects. Among the substances which meet those conditions, endocrine disruptors, sensitizers, immunotoxic and neurotoxic substances should be considered as a priority during the period 2020-2025. Rather than a case-by-case approach, the preference should go to defining criteria of identification for a category of substances. From that point of view, we consider that the criteria proposed in 2016-2017 by the Commission for the identification of endocrine disruptors in pesticides and biocides are not based on consistent principles of regulatory toxicology. They should reflect the precautionary principle and consider, on the basis of scientific evidence, three categories of endocrine disruptors: known for their effect on humans, presumed for those effects or suspected of them.
3. A third block of specific prohibitions. There is a legal incongruity in the present situation. Specific prohibitions are contained in annex III of the Chemical Agents Directive 98/24 while they are related to carcinogens. Historically, it comes from the fact that the CAD has included the provisions of several former directives. One of them, the Directive 88/364/EEC of 9 June 1988 banned certain specific agents or work activities. Unfortunately, in 30 years, asbestos was the only other carcinogen to have been banned by workers protection legislation (see article 5 of Directive 2009/148 of 30 November 2009). More specific prohibitions of work

11. European Commission, Call for tenders, n° VT/2017/37, p. 13.

12. As soon as reprotoxic substances will be included in the scope of application of the CMD, the BOEL for inorganic lead and its compounds should be revised.

activities which expose workers to certain CMR should be considered in the future without prejudice of other EU provisions on the marketing and use of those CMRs.

We are open to the idea of merging CAD and CMD in a new general directive where the present provisions of CAD would be applied to all workplace hazardous chemical agents and stricter CMD provisions would be applied to workplace ‘very high concern’ agents (CMRs + other categories meeting the above-mentioned criteria). In that case, annex III of the CAD would become an annex of the new Directive.

We are ready to contribute to the preparation of a roadmap with more detailed proposals. We are convinced that it would contribute to reinforcing the consistency of EU action over the long-term. Every stakeholder is convinced that the elimination of work related cancers needs a continuous process involving many different actions and that it should be based on a global strategy.

5. Creating dynamic synergy with market regulation

More coordination with market regulation and its implementation would also significantly increase the effectiveness of a EU strategy against work-related cancer. Both fields of legislation (workers protection and market regulation) are important. They should not be considered as mutually exclusive options.

Better coordination would be beneficial for all. In the authorisation process, when there is a safer alternative for workplace CMRs, that element should justify denying an authorisation for a substance. This has not previously been the case. For instance, authorisation has been granted in November 2016 for lead chromate pigments used for road marking and painting machinery while safer alternatives are available. Since then, around 380 companies have notified their ongoing use of the pigments. In the case of the revision of the CMD, for different substances the limit-values proposed by the Commission do not take into account sufficiently data provided by the registration process in REACH.

The adequacy of testing methods for a correct classification of substances is a basic condition for the good application of both market regulation and workers protection legislation. For instance, several studies indicate that tests required by the REACH do not include a specific analysis of toxic effects on the development of mammary glands¹³. This is a serious gap impeding the identification of all substances that may contribute to the high prevalence of breast cancers.

In the other direction, BOELs proposed by the Commission for the revision of the CMD are not taking into account sufficiently data provided by REACH like DNELs and information on workplace exposure levels.

¹³. See different references in Gray *et al.* (2009).

6. Social dialogue

The ETUC informs the Commission that we do not want to launch a negotiation procedure pursuant to Article 155 of the Treaty for the adoption of batch 3 and batch 4 and we urge the Commission to make immediate progress on this. However, this will not rule out discussing issues together with employers and seeking to find convergent positions on certain questions, as was the case with formaldehyde. We insist that social dialogue – whether sectoral or cross industry – plays an important role in implementing a strategy targeting occupational cancers. The European agreement in the hairdressing sector is obviously one example of this. The Commission’s unacceptable delay in implementing this agreement via a directive is however not an encouraging sign for social dialogue on such issues.

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General conclusions

Tony Musu and Laurent Vogel

Occupational cancers are the primary cause of work-related deaths in our industrialised societies, with more than 100,000 people losing their lives each year through being exposed to carcinogens while at work. Latest estimates set the share of work-related cancers at 8% of all new cancer cases (6 - 12% for men and 3 - 7% for women). These cancers are morally unacceptable, as they could easily have been avoided through adequate prevention measures. They are also unfair. Exposure to carcinogens at work are the cause of major social inequalities in health in Europe, as in the rest of the world. Labourers or nurses are much more likely to contract an occupational cancer than engineers or bankers. Indeed, a socio-occupational map can be drawn for the different types of cancer, tracing them back to these social inequalities. Similarly, if we compare the research budgets assigned to studying respectively genetic factors and occupational factors causing cancer, the former has considerable resources while the latter has to make do on 'peanuts'. In an article published in 2018, Aaron Blair and Lin Fritschi pointed out that, in the fifteen main scientific journals dedicated to cancer, the number of articles relating to occupational cancers "declined dramatically from around 80-90 per year from 1991-2003, to about 30 in 2009"¹. This situation, completely irrational in terms of public health, can be explained by two factors.

First, genetic research is susceptible to commercial appropriation, with its objective not exclusively guided by scientific or public health considerations but also by a desire to gain patents in the field of detecting and treating cancers. When US actress Angelina Jolie decided in 2013 to have her breasts removed following a genetic test pointing to an increased personal risk of breast and ovarian cancer, we saw a sharp rise in the value of Myriad Genetics shares, a company marketing this test on the basis of an exclusive patent for analysing DNA segments. Such private-sector appropriation of biological information implies that the test in question is reserved for the affluent due to its €2,300 price tag.

Second, genetic research in this field contributes to social peace, avoiding having to deal with questions of power in companies, production choices guided by profit or the deliberate neglect of prevention measures.

While not questioning the relevance of genetic research on cancer and its causes, we want to highlight the imbalance between this work considered to be high-priority and research into the role of occupational exposure. This book – while far from being

1. Blair A. and Fritschi L. (2018) Are we doing enough to identify and prioritise occupational carcinogens?, *Occupational and Environmental Medicine*, 75 (8), 543-544.

exhaustive – has looked at various aspects of this research, highlighting in particular the links between this research, the European legislative framework and practical efforts to achieve effective prevention.

The societal cost of occupational cancers is enormous. The study commissioned by our research institute and presented in this book estimates that the total cost of work-related cancers is between €270 and 610 billion a year in the EU-28. The ability to pass on virtually all associated costs to the victims, national social security and public health systems helps reduce to almost zero any motivation for companies to implement effective measures for preventing occupational cancers. On examining risk assessments, we find very little attention accorded to carcinogens and reprotoxic substances. It is therefore particularly important to have a precise, detailed and demanding legislative framework and to regularly adapt it to new data. The directive adopted by the European Union in 1990 played an important role in improving national legislation in Member States, generating a positive momentum which was to last for ten years or so. But then the whole development ground to a halt. During the two terms of office of José Manuel Barroso as head of the European Commission (2004 - 2014), no progress was made at all. This can be seen as part of the more general context of dramatic rises in social inequality, the implementation of ultra-liberal policies which considered many legislative acts (especially those related to employees and their working conditions) as administrative burdens weighing down on company competitiveness and economic growth in Europe. Widening social inequalities in health and resulting in thousands of avoidable deaths, these choices have been disastrous.

Even so, we need to acknowledge that the arrival of Jean-Claude Juncker as President of the European Commission and Marianne Thyssen as Commissioner for Social Affairs has led to significant improvements being made to the Carcinogens Directive. Prompted by certain Member States and the European Trade Union Confederation, the process of revising this directive has gained new impetus. European occupational exposure limits (OELs) have been adopted for commonplace carcinogens such as crystalline silica and hexavalent chromium and will soon be adopted for diesel engine exhaust emissions and formaldehyde. Though the trade union target of achieving binding OELs for at least 50 carcinogens before 2020 will not be achieved, we can be proud of getting some 20 substances covered.

In many occupations, exposure implies a heightened risk of contracting cancer. Moreover, these carcinogens are often to be found away from workplaces, polluting the environment. Similarly, they can be found in products on the market. This ripple effect has already been observed with regard to asbestos and its three waves of possible exposure: in paid work, in unpaid domestic work (for instance washing workclothes, a chore generally done by women) and in the environment. The same three waves can be found with many other carcinogens. Primary prevention at the workplace – with priority given to substitution – involves greatly reducing the carcinogenic burden weighing down on human health.

Such prevention cannot be organised in a piecemeal fashion, company by company. It has to be backed by government programmes promoting substitution and reflecting the

forms of exposure specific to different sectors. Highlighting a necessity common to all occupational health problems, it needs to be based on a threefold process: visualising the invisible, collectivising what *prima facie* appears to be an individual issue, and transforming the needs identified for the defence of occupational health into concrete demands.

In publishing this book, we hope to have contributed to this overall movement. We are convinced that the current state of knowledge allows much more effective preventive action than is currently the case and that we need to bring the regulations governing occupational health up to the same level as those found in other public health fields. We are similarly convinced that trade union mobilisations against occupational cancers act as an impetus for scientific research into the relevant issues, enabling better responses to social needs. Our attitude towards occupational cancers can be seen as a weather vane, reflecting the vision of society that we defend. If we shut our eyes to the inequalities and privileges, this issue is of no great concern. But if we want all inhabitants of our planet to have access to dignified and humane working and living conditions, changing the working conditions becomes a key priority for action.

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Cancer and work **Understanding occupational cancers** **and taking action to eliminate them**

Edited by Tony Musu and Laurent Vogel

Accounting for more than 100,000 deaths a year in the European Union, cancers caused by working conditions constitute the main cause of mortality associated with a lack of prevention. All such cancers could be avoided through eliminating the risks found in production processes, first and foremost through substituting carcinogenic agents and processes.

The potential for preventing occupational cancers and thereby reducing social inequalities in health is immense, but the path is strewn with rocks. Employers are set against any form of workplace control by Labour organisations and public authorities. The cost of occupational cancers is outsourced to victims and public health systems, while their visibility remains weak, even in the medical world. Scientific research is ignoring many dimensions of occupational cancers, especially with regard to women. Indeed, it seems to be a stereotype that only men are affected by occupational cancers.

Reviewing the current state of knowledge, prevention practices, the evolution of European legislation and the recognition of cancers as occupational diseases, this edited volume is published concomitantly with the revision of the European Directive on the protection of workers exposure to carcinogens. Launched in 2016, this revision is expected to continue for several years.

