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 µg/m³.

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 reached[2]. 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 conclusions[3].

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.

---

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