Chapter 19
The medium-term perspective: a single OSH Directive for all chemical substances

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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— The occupational exposure limit (OEL) concept underlying the CMD is outdated as it takes no account of risk-based limits, as introduced in the Netherlands in the mid-1990s and Germany in 2008.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 levels[1]. 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 assignations 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 derivates. 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.