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 7µg/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/m^3 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/m³
Asbestos	77536-66-4, 12172-73-5, 77536-67-5, 12001-29-5, 12001-28-4, 77536-68-6	0.1 fibre/cm³
Benzene	71-43-2	3.25 mg/m³
Vinyl chloride monomer	75-01-4	7.77 mg/m³
Hardwood dust		5.0 mg/m³

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/m³
Aluminium silicate fibres (Refractory ceramic fibres)	142844-00-6	0.3 fibre/ml
Beryllium and inorganic compounds	7440-41-7	0.0002 mg/m³
Bromoethylene (vinyl bromide)	593-60-2	4.4 mg/m³
1,3-butadiene	106-99-0	2.2 mg/m³
Cadmium and inorganic compounds	7440-43-9	0.001 mg/m³
Chromium VI	7440-47-3, 1333-82-0	0.025 mg/m³
1,2-dibromoethane (ethylene dibromide)	106-93-4	0.8 mg/m³
1,2-dichloroethane (ethylene dichloride)	107-06-2	8.2 mg/m³
Diesel engine exhaust emissions		0.1 mg/m³
Epichlorohydrin	106-89-8	1.9 mg/m³
Ethylene oxide	75-21-8	1.8 mg/m³
Formaldehyde	50-00-0	0.369 mg/m³
Hardwood dust*		3 mg/m³
Hydrazine	302-01-2	0.013 mg/m³
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/m³
2-Nitropropane	79-46-9	18 mg/m³
Propylene oxide (1,2-epoxypropane)	75-56-9	2.4 mg/m³
Respirable crystalline silica	14808-60-7, 14464-46-1, 15468-32-3	0.1 mg/m³
o-Toluidine	95-53-4	0.5 mg/m³
Trichloroethylene	79-01-6	54.7 mg/m³
Vinyl chloride monomer*	75-01-4	2.6 mg/m³

* 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 **CH**emicals), 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/m³	DNEL (workers, long-term exposure) mg/m³
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-pyrolidone (NMP), a reprotoxic solvent[1]. 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.

References

ECHA (2012) Workshop 'Chemicals at the workplace: REACH and OSH in practice', Helsinki, 3 October 2012. https://echa.europa.eu/-/chemicals-at-the-workplace-reach-and-osh-in-practice

ECHA (2014) Information on chemicals: adopted opinions on restriction proposals, Helsinki, European Chemicals Agency. https://echa.europa.eu/previous-consultations-on-restriction-proposals

ECHA (2017) Information on chemicals: registered substances, Helsinki, European Chemicals Agency. http://echa.europa.eu/information-on-chemicals/registered-substances

European Commission (2013) Methodology for the Derivation of Occupational Exposure Limits, Scientific Committee on Occupational Exposure Limits (SCOEL), Version 7. http://ec.europa.eu/social/BlobServlet?docId=4526&langId=en

ETUC (2014) The EU has to act now to improve occupational health and safety, ETUC Resolution adopted by the Executive Committee of 2-3 December 2014. https://www.etuc.org/documents/etuc-resolution-eu-has-act-now-improve-occupational-health-and-safety#.WjDv8EqnHcs

ETUI (2012) Workers and chemicals: 8th ETUI seminar, Brussels, 26-28 June 2012. http://www.etui.org/Events/Workers-and-chemicals-8th-ETUI-seminar

EU-OSHA (1999) Exploratory survey of occupational exposure limits for carcinogens, mutagens and reprotoxic substances at EU Member States level, Bilbao, European Agency for Safety and Health at Work. https://osha.europa.eu/en/publications/reports/548OELs

IFA (2017) GESTIS - International limit values for chemical agents (Occupational exposure limits, OELs), Berlin, Deutsche Gesetzliche Unfallversicherung. http://www.dguv.de/ifa/gestis/gestis-internationale-grenzwerte-fuer-chemische-substanzen-limit-values-for-chemical-agents/index-2.jsp

Musu T. (2013) Revision of the Carcinogens Directive: anything happening?, HesaMag, 08, 21-24.

Pronk M.E.J. (2014) Overview of methodologies for the derivation of Occupational Exposure Limits for non-threshold carcinogens in the EU, RIVM Letter Report 2014- 0153, Bilthoven, National Institute for Public Health and the Environment.

Püringer J. (2011) Derived Minimal Effect Levels (DMELs): Defizite ein Jahre nach der REACH-Registrierungspflicht, Gefahrstoffe-Reinhaltung der Luft, 71 (11-12), 471-479.

Safe Work Australia (2013) Workplace exposure standards for airborne contaminants, Canberra, Safe Work Australia. https://www.safeworkaustralia.gov.au/system/files/documents/1705/workplace-exposure-standards-airborne-contaminants-v2.pdf

Shenck L. *et al.* (2008) Occupational exposure limits: a comparative study, Regulatory Toxicology and Pharmacology, 50 (2), 261-270.

Schenk L. and Johanson G. (2011) A quantitative comparison of the safety margins in the European indicative occupational exposure limits and the derived no-effect levels for workers under REACH, Toxicological sciences, 121 (2), 408-416.

Schenk L., Palmen N. and Theodori D. (2014) Evaluation of worker inhalation DNELs, RIVM Letter Report 110001001/2014, Bilthoven, National Institute for Public Health and the Environment. https://www.rivm.nl/bibliotheek/rapporten/110001001.pdf

Takahashi K. and Higashi T. (2006) The development and regulation of occupational exposure limits in Japan, Regulatory Toxicology and Pharmacology, 46 (2), 120-125.

Tynkkynen S., Santonen T. and Stockmann-Juvala H. (2015) A comparison of REACH-derived no-effect levels for workers with EU indicative occupational exposure limit values and national limit values in Finland, The Annals of Occupational Hygiene, 59 (4), 401–415.

Van den Abeele E. (2014) The EU's REFIT strategy: a new bureaucracy in the service of competitiveness?, Working Paper 2014.05, Brussels, ETUI.

Vogel L. (2015) The machinery of occupational safety and health policy in the European Union: history, institutions, actors, Brussels, ETUI.

Vogel L. and Van den Abeele E. (2010) Better regulation: a critical assessment, Report 113, Brussels, ETUI.

Walters D., Grodzki K. and Walters S. (2003) The role of occupational exposure limits in the health and safety systems of EU Member States, Research Report 172, Sudbury, Health and Safety Executive. http://www.hse.gov.uk/research/rrpdf/rr172.pdf

Wriedt H. (2016) Carcinogens that should be subject to binding limits on workers' exposure, Report 136, Brussels, ETUI.

All links were checked on 24.07.2018.