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Establishing Occupational Exposure Limits

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Establishing Occupational Exposure Limits

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD

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Foreword

The Occupational Exposure Limits (OELs) are set by many international government agencies, as enforceable limits or as guidelines, and by professional organisations. Although various organisations derive OELs, no global harmonised approach for their derivation exists, and nomenclature of the final values differs between jurisdictions/organisations. The OEL project was proposed as a joint project of the Working Party on Hazard Assessment (WPHA) and Working Party on Exposure Assessment (WPEA) in June 2020. The aim of the project was to examine approaches and guidance for OEL development, explore opportunities to harmonise OEL derivation, and identify areas for collaboration related to worker OELs through a case study. The project was led by Health Canada, in collaboration with experts from Canada, Finland, Germany, Japan, the Netherlands and Switzerland.

In order to collect information from countries on policy and scientific approaches used to develop OELs, a survey (Appendix D) was sent to members of the WPHA and WPEA in February 2021. Responses were received from 13 countries/organisations, including Australia, Belgium, Canada, Denmark, European Chemicals Agency (ECHA), Finland, France, Germany, Japan, the Netherlands, Poland, Switzerland, and the United States. The draft report was circulated to the OEL project members in June and then to the WPEA and WPHA in July 2021, and revised by the leads based on comments received. The revised draft was also circulated to the members in November 2021 and then to the WPEA and WPHA in February 2022 for their review and approval.

This report drafted by Health Canada summarises the responses, outlines similarities in approaches, and notes considerations for future OEL development and potential areas for collaboration through case study development. This document is published under the responsibility of the Chemicals and Biotechnology Committee of the OECD.

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List of Abbreviations

ACCSH	Advisory Committee on Construction Safety and Health
ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
AGS	Committee on Hazardous Substances
AL	Administrative Level
ALARA	As Low As Reasonably Achievable
ANSES	French Agency for Food, Environmental and Occupational Health & Safety
BMD	Benchmark dose
BMDL	Benchmark dose level
BMC	Benchmark concentration
DECOS	Dutch Expert Committee on Occupational Safety
DFG	Deutsche Forschungsgemeinschaft
DNEL	Derived No Effect Level
ECEL	Existing Chemical Exposure Limit
ECHA	European Chemicals Agency
LOAEL	Lowest observed adverse effect level
MAC	Poland's Maximum Admissible Concentration
MACOSH	Maritime Advisory Committee for Occupational Safety and Health
NACOSH	National Advisory Committee on Occupational Safety and Health
NCEL	New chemical exposure limit
NEG	Nordic Expert Group
NIOSH	US National Institute for Occupational Safety and Health
NOAEL	No observed adverse effect level
OEL	Occupational exposure limit
OSHA	Occupational Safety and Health Administration
PEL	Permissible exposure limit
POD	Points of departure
QSAR	Quantitative structure-activity relationship
RAC	ECHA Risk Assessment Committee
REL	Recommended Exposure Limit
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RML-CA	Risk Management limit – carcinogens
SCOEL	EU Scientific Committee on Occupational Exposure Limit
SDS	Safety Data Sheets
SER	Socio-Economic Council of the Netherlands
STEL	Short-term exposure limit
SUVA	Swiss Accident Insurance Fund
TWA	Time weighted average
UF	Uncertainty factor
US	United States
WPEA	Working Party on Exposure Assessment
WPHA	Working Party on Hazard Assessment

Executive Summary

Occupational exposure limits (OELs) are derived internationally by many government agencies and professional organisations. The absence of a globally harmonised approach contributes towards differences in derivation approaches and resulting OEL values. The purpose of this report is to summarise the results of a survey of OECD stakeholders on OEL derivation activities, with the goal of highlighting similarities and differences. The report presents roles, responsibilities and scope of the responding organisations; methods of OEL development; successes and challenges of OEL development; and interest in and potential areas of focus for international harmonisation of OELs. The discussions within the report can be used to inform potential priorities or opportunities for international collaboration or case studies.

Roles, responsibility and scope for OEL development. Governance systems for OEL development vary around the world. Some organisations develop OELs, and others directly adopt values from others or use previously-derived OELs as a starting point. In some countries, multiple agencies work together to contribute towards OEL development and governance, and some collaboration between countries is already occurring. Organisations vary in whether they derive OELs that are legally binding. Mandatory OELs are often promulgated after a review process to consider technical feasibility (e.g., measurement and control considerations) and socioeconomic impacts in addition to health-based decisions, whereas non-legally binding OELs are typically derived as health-based guidelines. OEL derivation is often supported by committees that may evaluate scientific, technical, and/or socioeconomic considerations. In addition to participants from government agencies, these committees can include representatives from industry, worker groups, and the scientific community. Further contributions to OEL derivation may also arise from public and stakeholder consultation.

Methods for development and derivation of OELs. Commonalities were observed in the overall scientific process of evaluating health-based considerations, but differences arose in the applications of specific approaches and decisions. Organisations typically derive their OELs for chronic effects as 8-hour time weighted averages (TWAs), with acute effects typically addressed using 15-minute short-term values, and sometimes using a value not to be exceeded at any time (often referred to as a ceiling limit). The endpoints considered for these OELs typically include sensory irritation, systemic effects, and target organ toxicity. Some organisations may exclude certain specific health endpoints, such as carcinogenicity, genotoxicity, reproductive and developmental toxicity, and sensitisation; however, the excluded endpoints vary by organisation. Organisations also generally limit critical effects to endpoints that are relevant to humans. All countries use qualitative hazard notations. The most common notation reflects systemic effects from dermal exposures, and other notations used among organisations address carcinogenicity, skin and respiratory sensitisation, ototoxicity, reproductive toxicity, mutagenicity, and direct dermal toxicity.

Evidence used for deriving OELs is obtained primarily from publicly available data, but unpublished data might also be used by some organisations if from trustworthy sources, and/or if provided by stakeholders, industries, or unions. Human data are used whenever possible, with animal studies used as necessary, and sometimes supplemented by in vitro data. The use of read-across from chemical

analogues and quantitative structure-activity relationship (QSAR) approaches are also employed by some organisations to fill data gaps. Evaluation of data quality and consideration of weight of evidence are performed by organisations; although approaches differ, they tend to evaluate the relevance, reliability, and adequacy of the data. Points of departure (PODs) derived from these studies vary depending on available data. Some organisations will use benchmark dose/concentration approaches to derive a POD if possible. No observed adverse effect levels (NOAELs) (and lowest observed adverse effect levels (LOAELs), whenever necessary) are also used as PODs, either preferentially in some organisations, or limited to instances when benchmark approaches cannot be used in other organisations. Other statistical exposure–response models might be used to derive PODs from epidemiological data.

Uncertainty factors (UFs) that are considered by most of the organisations include inter/intraspecies variation, LOAEL to NOAEL extrapolation, and study duration extrapolation. Some organisations propose numerical values for various UFs while others provide general points regarding the UFs they consider.

Approaches for carcinogenicity vary among organisations; some will use linear approaches for non-threshold carcinogens, whereas other organisations will not perform quantitative analyses for these compounds and instead recommend that exposure be kept to a minimum. Non-linear extrapolation is also employed by some organisations when carcinogenicity appears to result from a threshold mode of action. Where the linear approach is used, 'minimal' or 'acceptable' risk concentrations for carcinogenicity within included organisations range from 1 in 1,000 to 1 in 1,000,000.

Successes and challenges of OEL programme implementation. Survey respondents cited efficient use of resources and stakeholder involvement as main successes of their programmes. Metrics for success that were mentioned included the recognition and uptake of OELs, as well as the decrease in worker exposures to hazardous substances. Challenges stated in surveys included the lack of available data to derive OELs, limitations of older or less protective OELs, regulatory barriers, a lack of alignment with other organisations, adverse impacts on industry stakeholders, and the lack of public understanding of OELs. Most organisations have not performed a formal programme evaluation, but examples of such initiatives included evaluations of reduction in occupational diseases and other post-implementation evaluations of regulatory changes.

Discussion. Many countries are already aligning their work with other OEL-deriving organisations through collaborations and the use of other OELs as starting points for their assessments. Similarities were noted in the overall OEL-deriving processes. For example, the durations for which OELs are derived, broad categories of critical endpoints, the derivation of OELs for threshold effects using a POD divided by uncertainty factors, and the use of hazard notations are common among the organisations responding to the survey. Conversely, differences arose in the breadth of critical endpoints addressed in OEL development and the approaches used for carcinogenicity, preferred PODs and UFs, body of literature used for deriving OELs, and types of hazard notations applied.

Many of the survey respondents were open to harmonising with other organisations. Although adoption of the same OEL value across organisations is likely not possible, due in particular to factors such as feasibility and acceptability of risk, there is an opportunity for harmonisation of risk assessment approaches. A main focus for harmonisation was guidance on OEL-derivation methods, including specific topics such as alignment of the timing of assessments, selection of PODs, confidence assessments, use of epidemiological data, methods of addressing uncertainty, deviation from default approaches, acceptable levels of risk, evaluations of particulates, criteria on differences of OELs from general population assessments, and research into new risk assessment methodologies. Collaboration and harmonisation could also be facilitated by improved information sharing, and could result in decreasing redundancies in work performed across organisations. A key theme in surveys responses

was that increased transparency in the OEL-derivation processes performed by organisations around the world could further improve harmonisation.

Introduction/Background

Increased transparency on approaches used to derive occupational exposure limits (OELs) is of global interest for workplace safety, as it increases their potential use by others. Generally, OELs represent the maximum airborne concentration of a substance to which a worker can be exposed over a period of time without suffering any harmful consequences. OELs are often developed in conjunction with notations to indicate where dermal protection is needed, or where there are effects related to sensitisation or carcinogenicity. OELs are set out by many international government agencies (as enforceable limits and/or as guidelines) and by many professional organisations. The values help employers to protect workers' health from possible risks when using chemicals and determine the effectiveness of existing controls or risk management measures.

Although various organisations and government agencies derive OELs, no global harmonised approach for their derivation exists and OEL values often differ between organisations/agencies. Deveau et al. (2015) cite several possible factors that may contribute to these differences, including varying choices for the Point of Departure (POD) (the basis of a health-based OEL), the timeframe of the literature review, the availability of newer scientific research/modelling methods, choice of uncertainty factors, or consideration of feasibility.

This report captures and examines existing approaches and guidance for OEL development to identify similarities. With increased transparency and understanding of approaches used internationally, the potential to leverage one another's work also increases, which can be particularly useful to countries looking to improve or expand their current work, or for those looking to embark on OEL development. The findings of this report can also be used to inform potential areas of international collaboration or case studies.

The focus of this report is primarily on the development of OELs. Other tools for risk characterization and worker protection exist along the hierarchy of OELs (Laszcz-Davis et al., 2014), including industry-derived exposure guidelines and schemes such as banding approaches. However, these tools are not traditional OELs, and are considered outside of the main focus of this report. This report does include some discussion of Derived No Effect Levels (DNELs), as they were mentioned in survey responses by some participating organisations. DNELs derived using prescriptive guidance set out under Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulations are traditionally considered lower on the hierarchy of OELs, as they originate from European regulatory frameworks and methodology (ECHA, 2012) can vary from traditional national OEL approaches (Schenk and Johanson, 2019). DNELs are also often derived by industries. However, some European organisations who responded to the surveys derive or adopt DNELs as additional instruments for worker protection, using them in combination with OELs, as REACH requires that both values be included in Safety Data Sheets (SDS). Therefore, DNELs are included for discussion in this report where they were mentioned in survey responses from participating organisations. As the surveys were designed specifically for discussion of OELs, some organisations using DNELs may have only focused on OELs in their responses; therefore, discussions of DNELs may not present the full picture of their use by regulatory organisations.

To gather information on approaches and guidance available internationally, a survey was designed and sent to members of the OECD Working Party on Hazard Assessment (WPHA) and the Working Party on Exposure Assessment (WPEA) in February 2021. Responses were received from 27 regulatory agencies in 12 countries (some covering multiple agencies within a country), as well as the European Chemicals Agency. The countries and government agencies that submitted responses are listed in Appendix A. Survey questions are presented in Appendix D, and the responses from each participating organisation have been included in the project member's site (https://community.oecd.org/docs/DOC-192754) (Access is limited to the project members). In some cases, the respondents are tripartite agencies (e.g., Safe Work Australia) or workers' compensation boards that regulate occupational health and safety (e.g., Canadian jurisdictions such as Yukon and British Columbia). The responses were used to inform the analysis discussed in this report. When respondents referred to specific guidance documents from which relevant details could be obtained, information in the guidance documents were used to supplement survey responses.

Roles, responsibilities and scope for OEL development

The governance and systems that are in place to set OELs in Europe, the United States (US), Canada, Japan, and Australia are each unique to their jurisdiction. In many cases, the agencies within a jurisdiction work closely together and inform one another's work. For example, European countries must implement the EU OELs into their national legislation. These EU OELs are presently informed by the scientific opinion of the ECHA Committee for Risk Assessment (RAC) and were formerly informed by the Scientific Committee on Occupational Exposure Limits (SCOEL). Some European countries also work with ECHA RAC in the development of those OELs (e.g., the French Agency for Food, Environmental and Occupational Health & Safety [ANSES] OEL Committee and Nordic Expert Group [NEG] may provide scientific expertise and recommendations during public consultation). That said, many European agencies also have processes to develop and implement OELs beyond those set for the EU, and they work together within their countries (e.g., France's INERIS and ANSES) and between countries to develop OELs. For example, NEG is a forum for collaboration among experts from Sweden, Norway, Finland, and Denmark, and also collaborates closely with the Dutch Expert Committee on Occupational Safety [DECOS]. Further informal international collaboration by DECOS occurs where possible with the US National Institute for Occupational Safety and Health [NIOSH] and France's ANSES. In the US, there are also various government agencies setting OELs, with the US Occupational Safety and Health Administration (OSHA) being the primary regulatory agency setting workplace permissible exposure limits (PELs), EPA setting new chemical exposure limits (NCELs) and existing chemicals exposure limits (ECELs), and NIOSH setting recommended exposure limits (RELs), which may also provide recommended values to a regulatory agencies (OSHA and EPA). In contrast, in Canada, provincial and territorial respondents report each having their own legislation and processes, with little collaboration between agencies to set OELs, although work is underway to explore opportunities for harmonisation.

This section explores the role that different government agencies play in the OEL space (i.e. developing, adopting, or evaluating OELs), the types of OELs developed, and the processes that are in place to support OEL development.

Roles

There are a variety of roles that different government agencies play with respect to OELs. Agencies may develop OELs (i.e., identify a need to develop and set an OEL in their jurisdiction) or adopt OELs from others (i.e., use another OEL directly or as the basis to set an OEL in their jurisdiction).

Many agencies build on the work of others to inform their OEL development. For example, many government agencies that develop OELs (e.g., Denmark, France, the Netherlands, Germany, Switzerland, US EPA, OSHA and NIOSH, ECHA), often use OELs that have been developed by others as a starting point.

Some agencies are responsible for taking limits derived by others and reviewing/adapting them for different purposes (e.g., to make them legally binding). Some OELs that were adopted directly or used as a basis for OEL development referenced in survey responses included, the American Conference of Governmental Industrial Hygienists (ACGIH), the (now disbanded) EU Scientific Committee on Occupational Exposure Limits (SCOEL), ECHA Risk Assessment Committee (RAC), German MAK Commission (also known as Deutsche Forschungsgemeinschaft [DFG]), Dutch Expert Committee on Occupational Safety (DECOS). For example, Safe Work Australia reviews OELs from a list of 'trusted sources' (e.g., ACGIH, German MAK commission, SCOEL, American Industrial Hygiene Association (AIHA), and DECOS). Belgium publishes a list of health-based OELs from specialized institutes/committees (e.g., SCOEL, RAC, ACGIH), which serve as the basis to receive input on these values considering process-technical, measurement-technical, socio-economic or health-based arguments. In Poland, OELs are not adopted from other organisations, however during dossier development, the rationale for OEL values for groups such as ACGIH, MAK Commission and DECOS are reviewed. Canadian provinces and territories that responded to the survey either adopt ACGIH values directly into their regulations or use ACGIH values as the basis for OEL setting.

In Canada, the establishment of OELs varies slightly across jurisdictions. Each of the provinces and territories that responded to the survey indicated that their OEL values were derived from recommendations published by professional organisations, primarily the ACGIH. However, the edition of the ACGIH value being referenced varies across jurisdictions, as presented in Table 1. For example, Alberta derives their OELs using the ACGIH guidelines published in 2006. In contrast, in Quebec, the OELs were established using the 2016 version of the ACGIH recommendations.

Table 1. Year of ACGIH Threshold Limit Values referenced in Canadian legislation

Jurisdiction	Year Referenced from ACGIH
Alberta	2006 edition
British Columbia	N/A – Periodically reviews new values for adoption
Newfoundland	Automatically adopts new values
Nova Scotia	Automatically adopts new values
Ontario	N/A – Periodically reviews new values for adoption
Quebec	2016 edition
Yukon	1986 edition

With the exception of one Canadian jurisdiction that directly references ACGIH values in their regulations, all surveyed agencies post their OELs online and most provide publicly available, documented methods/approaches for the development of OELs which are listed in Appendix B.

Scope and Process

Almost all OELs identified in the survey are legally binding, with the exception of Indicative OELs developed in Europe, Finland, France, Japan, and those developed by ECHA and NIOSH, which are used to inform the development of legally-binding OELs. Non-legally binding OELs are derived as health-based guidelines. Conversely, when an OEL is legally binding, it will generally take into consideration additional factors such as technical feasibility and socio-economic factors. In France, binding OELs are set by decree and indicative (non-binding) OELs are set by an order, with both categories listed in the French labour code. However, the third category of indicative OELs in France not referenced in legislation was published in newsletters between 1982 and 1999. Most countries have clearly defined phases between the scientific review, consideration of technical feasibility and socio-economic impacts. Very few survey respondents have legally binding health-based values (e.g., Australia, Germany and some Canadian jurisdictions including Newfoundland, Nova Scotia and Yukon).

See Appendix C for considerations accounted for in the OEL and enforceability of these OELs for each of the survey respondents.

The survey revealed that the development of OELs is often split into distinct phases: determination of a health-based value, followed by technical and socio-economic considerations. In addition to the interagency/international collaboration identified above, these determinations are supported by scientific review and public/stakeholder consultation.

Scientific Review

A number of Committees have been established to support the scientific review of OELs and may include government representatives as well as members that are external to government (e.g., industry, academics), as shown in Table 2 below. For some agencies, scientific review takes place through peer review (e.g., Safe Work Australia, OSHA, NIOSH).

Table 2. Examples of committees that support the scientific review of OELs

Country	Committee	Membership
France	Expert Committee (CES) on health reference values; two working groups (on biological indicators of exposure and metrology)	ANSES and INERIS
Germany	Subcommittee III Evaluation of Hazardous Substances, a scientific committee of the Committee on Hazardous Substances (AGS) recommends health-based OELs and risk-based OELs to the AGS.	Experts from BAuA are members of the subcommittees of the AGS The AGS consists of representatives of industry, trade unions, authoritative bodies, and the scientific community
Poland	Group of Experts for Chemical Agents and Dust Agents	Headquarters in the Nofer Institute of Occupational Medicine and is affiliated to the Intersectoral Commission for Setting MAC Values, comprising experts from various fields of science.
Switzerland	Swiss OEL Commission (scientific advisory committee)	-
Netherlands	Dutch Expert Committee on Occupational Safety (DECOS) of the Health Council	-

Technical and Socio-Economic Considerations

The consideration of technical and socio-economic impacts often take place at a committee that includes members that are external to government, as shown in Table 3 below.

Table 3. Examples of committees that support the consideration of technical and socio-economic factors

Country	Committee	Role	Membership
Poland	Interdepartmental Commission for	Considers technical feasibility and socio-economic impacts.	Representatives from various ministries,

	Maximum Admissible Concentrations and intensities for agents harmful to health in the working environment	Makes decisions regarding the legislative process in the area of standardisation of admissible concentrations of chemical substances in the working environment.	including ministries responsible for health and labour, representatives of industry, employer organisations, trade unions and research institutes.
France	French Steering Committee on Working Conditions	Presentation of the draft regulation to discuss the effectiveness of the limit values and if necessary, to determine a possible implementation timetable, depending on any technical and economic feasibility problems	-
Germany	Committee on Hazardous Substances (AGS),	Upon request by industry to determine a possible implementation timetable depending on technical feasibility problems for specific uses or sectors.	Experts from BAuA are members of the subcommittees of the AGS The AGS consists of representatives of industry, trade unions, authoritative bodies, and the scientific community.
Netherlands	Socio-Economic Council of the Netherlands (SER)	Advises on the feasibility of the Health Council or RAC recommended OELs for substances with a non-threshold-based OEL	Tripartite[1]
Denmark	National Council for the Working Environment	Discussion takes place to discuss the technical feasibility and socioeconomic impact	Tripartite
Finland	Advisory Committee on Preparation of Occupational Safety Regulations	Makes the final OEL proposal that considers technical and socioeconomic feasibility	Tripartite
Switzerland	Swiss OEL commission	Evaluates science, feasibility and advise of industry	

Public and Stakeholder Consultation

Public consultation is a step that is employed by many countries (e.g., Australia, Belgium, Denmark, ECHA, France, Japanese Administrative Levels (ALs), Switzerland, US EPA Existing Substances programme, OSHA PELs, NIOSH RELs, DECOS health-based OELs, and Canadian provinces of British Columbia, and Quebec).

Targeted consultation with stakeholders is also carried out in some countries. For example, in Switzerland, before releasing a new or changed MAK or BAT, the Swiss Accident Insurance Fund

[1] Representatives of workers, employers, and government authorities

(SUVA) is legally obliged to consult the affected industry. In Canada, Alberta consult with affected stakeholders, and Ontario stakeholders provide feedback on the scientific basis, technical feasibility, and economic impacts of proposed values. In the US, OSHA consults with committees such as Advisory Committee on Construction Safety and Health (ACCSH), the National Advisory Committee on Occupational Safety and Health (NACOSH) and the Maritime Advisory Committee for Occupational Safety and Health (MACOSH) and convenes a Small Business Advisory Review Panel.

Methods for development and derivations of occupational exposure limits

The process of deriving OELs involves many different decision points, each of which may have several options and approaches that could be adopted. Consequently, methods may diverge among different organisations. As expected, the results of the survey indicated differences among countries in each of the various stages of OEL development. The aspects included in the survey, which are discussed throughout this section, include the definitions and scope of OELs (comprising health endpoints, durations of exposure and sampling time, and notations), the nature of data used to develop OELs (including evaluation of quality and weight of evidence), and methodology for deriving OELs (such as selection of points of departure (PODs), adjustment approaches and uncertainty factor application, and approaches for genotoxic carcinogens).

The ACGIH is the primary organisation consulted for assistance in establishing OEL values within Canada. For example, in Alberta, the ACGIH TLVs are implemented for the majority of OEL values, but the province also considers and incorporates guidelines published by other organisations like the NIOSH and the DFG. As the technical aspects of OELs used by Canadian jurisdictions rely on the approaches used by ACGIH in the timeframe relevant to each province, Canadian organisations responding to the survey did not include details related to the methods used to derive OELs. Consequently, this section does not include any discussion of the technical approaches used by Canadian jurisdictions or by the ACGIH TLV Committee. As surveys were only provided to OECD member countries (WPHA and WPEA), a discussion of the OEL approaches used by the ACGIH TLV Committee is considered beyond the scope of this report.

Definitions and Scope of Values

Endpoints included/excluded

When developing OELs, various organisations use different endpoints and critical effects as the basis for deriving their OELs. Endpoints typically included are sensory irritation (ocular, dermal, respiratory), systemic effects and specific target organ toxicity. Some organisations such as in Finland, Switzerland, NIOSH, ANSES and the Health Council of the Netherlands, consider that endpoints can cover all exposure-related adverse health effects (in the workplace) and all diseases, which are clinically diagnosable to assess a causal relationship between exposure and disease. These organisations do not specifically exclude health endpoints. Similarly, the US EPA noted that, for new or existing chemicals, the agency derives OELs for endpoints where potential risks were identified under the conditions of use of the chemical. The critical effects are often identified from studies with effects observed at the lowest exposure (e.g. as identified by Finland), or from exposures that would result in the lowest health-based OEL (e.g. as identified by the Netherlands). In France, critical effects are

chosen from adverse effects deemed relevant, which is generally the first adverse effect that occurs in the exposed population when the dose is increased. OSHA typically assesses the chemical's modes of action (MOA), and the key molecular, biological, pathological, and clinical endpoints that contribute to the health effects of concern. Furthermore, a variety of endpoints are considered for exclusion amongst the organisations for their OEL development, including carcinogenicity, genotoxicity, reproductive and/or developmental toxicity, and sensitisation.

Systemic effects and specific target organ toxicity were stated as endpoints by US EPA, OSHA, Poland, Germany, and ECHA, but were generally applicable endpoints to all organisations establishing OELs. ECHA considered both acute (single exposure) and repeated dose toxicity to target organs.

Some agencies (in Australia, Switzerland and Belgium) review the OEL work of other organisations, adapting them for their jurisdictions, and thus the endpoints they consider are obtained from other trusted international organisations. For example, Belgium uses endpoints from the scientific opinions obtained by SCOEL, RAC and ACGIH, while Australia adapts the work of ACGIH, DFG, SCOEL, AIHA, and the Health Council of the Netherlands. Based on the survey responses, Japan indicated the inclusion/exclusion of endpoints were almost the same as those included/excluded by ACGIH.

Most organisations (e.g. France, Denmark, Germany, ECHA, US EPA, OSHA, and Poland) consider carcinogenicity to be an important endpoint for their OEL development. France and ECHA also consider genotoxicity.

ECHA, US EPA and France consider reproductive/developmental toxicity as endpoints. Poland covers reproductive toxicity as an endpoint but excludes developmental toxicity. In Germany, reproductive toxicity is directly considered for the derivation of an OEL, but developmental toxicity is not. Rather, substances are qualitatively evaluated as to whether developmental toxicity is unlikely to be observed as an endpoint or if it cannot be excluded at the level of the OEL. When damage of the embryo or fetus is considered unlikely to occur at the level of the OEL, the substance is assigned to pregnancy group “Y”. Conversely, when damage of the embryo or fetus cannot be excluded after exposure at the level of the OEL, the substance is assigned to pregnancy group “Z”.

Denmark, ECHA, and France consider sensitisation, allergens and/or sensitisers as endpoints, although France outlines the difficulty associated with defining toxicity and quantifying health risks at low doses for respiratory tract sensitisation. On the other hand, Poland and Germany exclude sensitisation as an endpoint (In Germany’s TRGS 900, compliance with health-based OELs cannot exclude induction of sensitisation, i.e. OELs do not aim to protect against sensitisation). Although Germany excludes sensitisation as an endpoint, skin and respiratory sensitisation are included for notations. Therefore, although some critical effects are excluded as quantitative endpoints (such as sensitisation, carcinogenicity, reproductive and/or developmental toxicity), they may still be evaluated qualitatively (e.g. as notations). In some countries where sensitisation is not an endpoint (e.g., Switzerland), the airborne concentration of the sensitising substance has to be minimized.

Types of OELs derived

Almost all surveyed organisations use 8-hour time weighted averages (8h-TWA), which is the limit of the time-weighted average concentration of a chemical agent in the worker’s breathing zone, over the course of an 8-hour shift. Generally, 8h-TWAs are designed to protect workers exposed regularly and for the duration of a working life, from the chemical in question. Many NIOSH RELs are 10-hour TWAs, (e.g., crystalline silica).

NIOSH specifies that their 8h-TWA Recommended Exposure Limits (RELs) and Risk Management limit – carcinogens (RML-CA) are health protective even if the worker was exposed every day over a 45-year working lifetime. Poland’s Maximum Admissible Concentrations (MACs) are 8h-TWAs to which

workers may be exposed during their whole working life without adverse health effects throughout their lifetimes (e.g. including post-work retirement) or adverse effects on their offspring.

Australia specified that the use of 8h-TWA is for chronic or sub-chronic effects. For existing chemicals, EPA proposes 8-hour Existing Chemical Exposure Limits (ECELs), based on both acute and chronic effects, and cancer.

Most organisations also use short-term exposure limits (STELs), also called “short-term values” (e.g. Denmark, Switzerland, Finland). STELs or short-term values are typically 15-minute averages that shall not be exceeded at any time during the working day. Although most organisations do develop STELs, differences amongst organisations can arise in their recommended application methods. For example, for Poland, 15-minute STELs should not be exceeded more than twice during the work day, at intervals not shorter than one hour. On the other hand, for Finland, 15-minute short-term values should not be exceeded more than four times during the work day, at intervals not shorter than one hour. For Denmark, if no short-term value is established, the value by definition is two times the 8-hour value. In Germany, short-term exposure limits are indirectly included in TRGS 900 (and also in TRGS 910) by multiplying the OEL by excursion factors in order to limit exposure peaks.

Some organisations also establish ‘ceiling’ values or limits (names can differ across organisations), which are established for substances that would need a STEL over short exposure durations (i.e. less than 15 minutes). Ceiling values are typically the maximum concentration of a substance that must not be exceeded at any time, even instantaneously, as it is considered a threat to workers’ health or life. France highlights that ceiling values are recommended for substances that are highly irritating or corrosive, or likely to cause irreversible effects after very short exposures. ECHA highlights that these values might be used, provided appropriate instantaneous measurement techniques are available, such as direct-reading instruments. Australia develops “peak limitations” (i.e., ceiling values) for short-term effects and Belgium develops ceiling limits if proposed during consultation. Germany’s AGS and Denmark did not include ceiling limits in their survey responses.

In addition to 8h-TWA PEL, for some substances, OSHA specifies 8h-TWA Action Levels (AL) in its standards. The action levels are lower, typically by one-half, than the PELs. OSHA specifies certain requirements such as exposure monitoring, medical surveillance, or biological monitoring when the exposure is higher than the AL.

Notations developed

Occupational exposure limits are often associated with advisory or hazard notations to indicate that an adverse health effect may arise from a particular substance. The most common notation developed among organisations is the skin notation (although the notation label used can differ among agencies), which alerts that dermal exposure can cause adverse health effects. All surveyed OECD countries’ organisations use the skin notation (to varying extents) when developing OELs, with the exception of US EPA’s New Chemical Exposure Limits (NCELs) and Existing Chemical Exposure Limits (ECELs).

Another common notation used by many agencies (e.g. in Germany, Japan, Australia, ECHA, and SUVA) is sensitisation (skin and respiratory). In Finland, sensitisation notations from EU legislation (Directive 2004/37/EC) are given to sensitising carcinogens with binding OELs.

Some organisations develop a number of other notations including noise/ototoxicity, carcinogenicity, mutagenicity and reprotoxicity as shown in Table 4 below.

Table 4. Notations used by each of the organisations

Country	Organisation(s) / Committee	Notations

Australia	Safe Work Australia	• Carcinogenicity
		  ○ Category 1A: known to have carcinogenic potential for humans (largely based on human evidence)
		  ○ Category 1B: presumed to have carcinogenic potential for humans (largely based on animal evidence)
		  ○ Category 2: suspected human carcinogen (largely based on animal and/or human data but not sufficiently convincing to be a category 1)
		• Sensitisation
		  ○ Skin sensitisers (DSEN)
		  ▪ A substance is classified as a skin sensitiser; (a) if there is evidence in humans that the substance can lead to sensitisation by skin contact in a substantial number of persons, or (b) if there are positive results from an appropriate animal test
		  ○ Respiratory sensitisers (RSEN)
		  ▪ A substance is classified as a respiratory sensitiser; (a) if there is evidence in humans that the substance can lead to specific respiratory hypersensitivity and/or (b) if there are positive results from an appropriate animal test
		• Skin notation
		  ○ 'Sk': Chemicals where significant absorption and toxicity may occur *via* the dermal route.

Belgium	BE Federal Public Service Employment, Labour and Social Dialogue	• "A" – agent releases gas or vapour which in itself has no physiological effect but can lower the oxygen level in the air. • "C" – agent falls within the scope of title 2 relation to carcinogens, mutagens, and reprotoxic agents (of book VI of the code of well-being at work) • "D" – absorption of the agent (from skin, mucous membranes or eyes) from direct contact or from air • "F" – if exposure of agent is in the form of fibres (length greater than 5 µm, with a diameter less than 3 µm and for which the length / diameter ratio is greater than 3). Fibre concentration is expressed as the number of fibres per cubic meter. • "M" – if exposure exceed limitation value, irritation appears or a danger of acute intoxication. Working process should not allow this level to be exceeded
Denmark	The Danish Working Environment Authority (WEA)	Skin notation

European Union	European Chemicals Agency (ECHA)	• 'Skin' • 'Sensitisation' ○ 'Skin sensitisation', 'Respiratory Sensitisation' • 'Noise'
Finland	Ministry of Social Affairs and Health and Finnish Institute of Occupational Health	• Skin notations • Noise notations • Sensitisation notations from EU legislation (CMD directive) given to sensitising carcinogens with binding OELs

France	French National Institute for Industrial Environment and Risks (INERIS)
	French Agency for Food, Environmental and Occupational Health & Safety (ANSES)
	Ministry of Labour
		• "Skin" notation
		  ○ This reference alerts to the fact that the dermal route of exposure can cause health effect independently of the atmospheric limit values.
		• "Noise" notation
		  ○ Possible ototoxicity for some substances in the event of co-exposure to noise

Germany	Federal Institute for Occupational Safety and Health (BAuA)	• Skin notation ("H") for substances that can easily be absorbed through the skin • Skin sensitisation ("Sh") • Respiratory sensitisation ("Sa") for dermal or respiratory sensitisers.
Japan	Japan Society for Occupational Health	• Skin absorption • Carcinogen • Sensitisers (airway and skin) • Reproductive toxicants
Netherlands	Ministry of Social Affairs and Employment Health Council of the Netherlands Dutch Social and Economic Council Dutch National Institute for Public Health and the Environment	Skin notation ('H') next to OEL when data shows that the substance indicates a substantial contribution of dermal exposure to systemic adverse health effects on which the OEL is based
Poland	Nofer Institute of Occupational Medicine/Group of Experts for Chemical and Dust Agents	• "Skin" notation is mandatory • Not mandatory notations: BEI [2] reprotoxicity, and carcinogenicity

[2] Biomonitoring guidelines included as non-mandatory notations in Poland; however, some other organisations also develop BEIs or equivalent values, but they are not referred to as notations and discussion of them is outside of the scope of the report

Switzerland	Swiss Accident Insurance Fund (SUVA)	• CMR (carcinogenicity, mutagenicity, reproductive) • Skin • Sensitisation • Ototoxicity
United States	Centers for Disease Control and Prevention (CDC), NIOSH U.S. Environmental Protection Agency (US EPA) U.S. Occupational Safety and Health Administration (US OSHA)	NIOSH: skin notations. NIOSH has several skin notation designations: • SK-SYS systemic toxicity after dermal absorption • SK-DIR direct dermal toxicity • SK-SEN sensitising effects after skin exposure • Subnotations of (FATAL) for lethal effects, (IRR) dermal irritation effects, (COR) for corrosive effects on the skin and (ACD) for allergic contact dermatitis • ID(SK) is for insufficient data to assign a skin notation • SK is for chemicals with sufficient data to show that a chemical does not produce systemic, direct or sensitising effects. NIOSH – Ca: chemicals determined to be potential occupational carcinogens or occupational carcinogens distinguish systemic (SYS), direct (DIR), and sensitising (SEN) effects caused by exposure of skin (SK) to chemicals. Chemicals that are highly or extremely toxic and may be potentially lethal or life-threatening following exposures of the skin are designated with the systemic subnotation (FATAL). Potential irritants and corrosive chemicals are indicated by the direct effects subnotations (IRR) and (COR), respectively. EPA: has not developed separate skin notations for NCELs or ECELs OSHA: skin notations for some chemicals, listed in Table Z of 29 CFR 1910.1000, are used as an alert to indicate the need to prevent skin contamination. OSHA does not develop hazard notations. OSHA amended their hazard communication standard (HCS) in 2012 to align with the Globally harmonised system for the classification and labelling of chemicals (GHS), which includes the development of a safety data sheet for hazardous chemicals to provide sections where notations may be reported. Skin notations are used for some chemicals.

How data is evaluated to support and develop OELs

Types of data included in the data search

The majority of the organisations that develop OELs rely on published scientific literature, reviews, and/or reports. Reviews and reports used by agencies are typically from other established bodies, internationally recognized organisations, and/or scientific committees (e.g. AGS, DFG (MAK), DECOS, NEG, ANSES, ATSDR, ACGIH, US NIOSH). Germany, Denmark, and the Netherlands outline that for

their organisations, all individual studies, reviews or reports should rely on open and publicly available data (for transparency reasons).

Some organisations (e.g., Finland, Germany, Switzerland, Poland, ANSES, US EPA, NIOSH, and OSHA) may also examine unpublished studies from trustworthy sources, as well as information from stakeholders, industries or unions (if provided, relevant, and the source of information is indicated). Data from grey literature may also be used to support available information (e.g. US EPA and ANSES).

In addition to published and unpublished studies, NIOSH reports, information from industry and labour organisations used by OSHA, control technology (CT) assessments, engineering control feasibility studies, site visits (conducted by OSHA, NIOSH, or supporting contractors), and OSHA Integrated Management Information System (IMIS) data are all also identified as data sources supporting OELs.

The type of data specified by organisations (e.g. ECHA, ANSES, Finland, Denmark and the Netherlands) included epidemiological and experimental studies (human and/or animal data) and although not explicitly stated, most other organisations are assumed to use relevant human and animal data if it is available. Other types of studies can include case reports and mechanistic (in vivo/ in vitro) studies.

Belgium, Switzerland and Australia's OEL developing organisations rely partly on other organisations' work for the basis of their decision-making processes, including the data sourced from their selected organisations.

How data quality is assessed

Organisations differ in their specific approaches on how they assess data quality of the studies used to derive OELs. In general, when data quality is assessed by organisations, it is done using a scientific evaluation of the relevance, reliability and adequacy. For example, ECHA uses tools such as PRISMA to assess the quality of studies, as well as established ECHA guidance on Information Requirements & Chemical Safety Assessment and SCOEL guidance. Germany uses guidelines from other organisations, particularly OECD or international organisations. Similarly, ANSES takes into account studies conducted according to guidelines (OECD, EPA, etc.) whenever possible.

ANSES provides guidance for assessing data in the Annex of their expert appraisal OEL documents (links to ANSES methodology in Appendix B); this includes guidance on assessing in vivo toxicological studies, epidemiological studies, toxicity studies, in vitro genotoxicity/mutagenicity tests and assessing relevance of articles dealing with dermal absorption. Assessment of toxicity studies and quality can be determined using the Klimisch scoring scheme for animal studies (Annex A3 of ANSES guidance document). The main criteria for evaluating epidemiological studies based on guidance in Annex A2 of the ANSES guidance document is the subpopulation studied is selected to appropriately reflect the reference population, disease and exposure are well defined, other variables that influence risk need to be accounted for, and basic data (such as statistical analyses, number of cases and controls with level of exposure) are reported by authors. In addition, for case-control and cohort epidemiological studies, ANSES analyses biases and confounding factors on the basis of IARC guidance.

OSHA and NIOSH generally perform a review of the methodology (design and conduct of the studies), characterization of exposure during critical periods (as well as dose and adverse effect as specified by NIOSH), sample size/statistical power (degree of certainty and strength of findings, and relevance to the workplace population). While US EPA does not employ a formal systematic review process for the data quality review for new chemicals due to time constraints and limited available data, they do a general review of the quality, relevance and weight of evidence of the included studies in their assessments. For existing chemicals, US EPA conducts a full systematic review with PECO (population, exposure, comparator, and outcome) statements to screen for individual studies' relevance as well as formal evaluation criteria to assess data quality.

SUVA, as well as Finland, Poland and Japan's organisations do not specifically define criteria for their quality assessments. The quality assessment may be done on a more general level or by an expert preparing the documentation (as in Poland's case).

Belgium, Switzerland, Australia and Japan partly use other organisations (as primary data sources) as previously mentioned, in which the primary organisations have already assessed the quality of the data they used. Australia specifies that all data sources included must provide scientific data that is evaluated and sourced from adequate and appropriate studies that are conducted according to international guidelines for toxicological and epidemiological testing of chemicals.

How critical studies are identified, use of human data, read across and QSARs in OEL development

All organisations outline the use of animal data and/or human data for developing OELs. Most OEL-developing bodies indicated higher weight was given to quality human/epidemiological data and the data are more likely to have been obtained from exposure conditions relevant to workers as stated in ECHA's OEL guidance (link to guidance in Appendix B). US EPA, like most organisations, prefers to use available human data for exposure limits for new and existing chemicals but only if a dose-response and POD can be determined from the study.

To identify critical effects, most organisations gather information from a number of possible sources and use a weight of evidence approach (e.g., Finland, SUVA, Poland, Australia, the Netherlands, ECHA, and NIOSH). Given these different sources of information, the weight given to the available evidence will be influenced by factors such as the quality of the data, consistency of results, nature and severity of effects and the relevance of the information for the given endpoint(s) and chemical agent (for example, as identified by ECHA's guidance).

These sources of information to derive OELs differ among organisations. For example, Poland uses published literature, read across from chemical analogues, QSAR (quantitative structure–activity relationships) predictions, data from existing studies, in vitro studies, epidemiological data and human experience. The Health Council of the Netherlands prefers observational studies in the work place, with data on long term exposure and disease that normally manifest after a long latency period (even after retirement). Similarly, ECHA prefers human data obtained from exposure conditions relevant to workers, in vivo data over in vitro data and experimental data over non-testing data. For France, the key studies that are selected according to the chosen critical effect are preferably epidemiological studies of high quality, followed by experimental studies judged to be of high quality.

For EPA's new chemicals, studies that directly measure toxic effects of the chemical (e.g., reproductive toxicity, developmental toxicity) are preferred. Nevertheless, since toxicity data on a new chemical substance may be limited, data on chemical analogues, which may come from relevant studies and endpoints that have been identified in other programmes (e.g., EPA's Integrated Risk Information System or other EPA programme office assessments). Conversely, for existing chemicals that typically have more robust chemical-specific data sets, EPA uses a weight of evidence approach to identify individual adverse health effects (e.g., liver, kidney, etc.) for existing chemical risk evaluations, focusing on sensitive endpoints.

Non-test data include read-across approaches and QSARs. Read-across is used for filling data gaps, when a data rich substance has an OEL and is applied to a data-poor isomer. Only a few organisations surveyed use read-across approaches and QSARs in some cases. These organisations include Finland (only read-across), Germany, ECHA, US EPA and Poland. US EPA does not generally use QSARs to identify a hazard POD. ANSES has not used QSARs or read-across in the development of OELs to date, except for acetic anhydride, where ANSES based the derivation of the OEL on the OEL derived for acetic acid. In Poland, QSAR use is limited for physiochemical properties and is not considered

suitable for complex toxicological properties as they are not fit for classification and labelling or risk assessment. DECOS of the Health Council of the Netherlands does not use QSARs or read-across, as there are 'too many uncertainties in the model'. NIOSH has not to date used QSARs or read-across methods but has active ongoing research of these methods and is very interested in making use of them in the future.

Belgium, SUVA and Australia consider or rely on other committee's comments or decisions when identifying critical effects and key studies. SUVA conducts an independent evaluation and makes their own final decision. Australia considers using the values and parameters from other primary agencies, unless there is variation, at which point a weight of evidence approach evaluating the age of the data, adjustment factors employed, quality of data, secondary data, etc., will be used to derive values. Japan and Denmark do not provide responses on how critical effects/key studies are identified. Germany specified that 'no information on data searches are given'.

Methodology for deriving OELs

Points of Departure selection and modification

For OEL derivation, organisations typically choose POD(s) with consideration for critical endpoints observed in the data (typically epidemiological or animal studies) for which a dose-response can be identified. As previously mentioned, there are a number of different endpoints that could be considered (see 'Endpoints included/excluded' section).

The types of POD selected by different bodies or committees are typically a benchmark dose (BMD), no observed adverse effect level (NOAEL), or lowest observed adverse effect level (LOAEL). The selection of the POD is ultimately based on the data available.

Some organisations have an order of preference of the types of PODs they select. For example, in order of preference, France's OEL committee retains the BMD or the benchmark dose level (BMDL) from the model that best fits the experiment data, followed by "model averaging" when BMD and BMDL values from various models show major differences. Germany's AGS primarily select a NOAEL followed by BMDL, but moving forward, they plan to use the benchmark dose procedure more often. AGS uses the LOAEL approach on a case-by-case basis. Similar to the AGS, ECHA, ANSES, Safe Work Australia, NIOSH, and US EPA consider a NOAEL (LOAEL approach may also be used by ANSES, Safe Work Australia, EPA and NIOSH) but prefer to calculate a BMDL or benchmark concentration (BMC), when the data support a BMD analysis. OSHA relies on statistical exposure-response models based on occupational epidemiological studies.

Once the POD is selected, it may be modified to consider a variety of scenarios including differences in exposure conditions, physical activity, and/or differences in absorption between the experimental animal and the worker.

The surveyed organisations provided various responses on their considerations for the selection and modification of PODs. Belgium stated that for their OEL methodology (including POD selection and modification), they rely on scientific opinions of specialized institutes and committees such as SCOEL, RAC, and ACGIH. Similarly, Finland stated in their response that many of their limit values are based on EU OELs for which the scientific methodology is given, and that their own approaches for OEL setting follow EU methodology. No information was provided in Japan's survey response. Refer to Table 5 for further details on the selection and modification of PODs provided by the organisations.

Table 5. Selection and modification of Points of Departure by various organisations

Country	Organisation(s) /Committee	POD selection	POD modification
Australia	Safe Work Australia	Commonly used PODs are: NOAEC and LOAEC which can use other routes of exposure studies (such as oral, if there are no adequate inhalation studies) BMD/BMC BMD/BMDL approach is most widely used if adequate data is available.	Not specified
Denmark	The Danish Working Environment Authority (WEA)	Depends on the data available. Epidemiological data often used together with animal data.	Not applicable
European Union	European Chemicals Agency (ECHA)	NOAEL, BMD or BMC is calculated where data allows.	ECHA 2019 appendix for deriving OELs does not specifically state how the POD would be modified but they do mention SCOEL's 2017 methodology and ECHA 2012 guidance on information Requirements and Chemical Safety Assessments – ChR.8 dose response characterization for human health SCOEL: may adjust the POD to be relevant to the workers' actual exposure by considering the differences in external and internal exposure between workers and the experimental model (dose metric, exposure regime and physiology, and exposure route for supplementary data)
France	French National Institute for Industrial Environment and Risks (INERIS)	In order of preference: 1. BMD or BMDL from the model that best fit into the experiment data.	When the POD is observed in animal studies, dosimetric adjustments can be applied. The differences in kinetics

	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) Ministry of Labour	2. "model averaging" when the values of BMD and BMDL from various models show major differences (for example, range of extreme values greater than 10) 3. NOAEL followed by LOAEL For choice of level of response (BMR), the committee chose to retain: 1. The value of a BMR in which the observed response was considered abnormal based on biological/toxicological considerations with expert arguments supporting this 2. The BMR values proposed by the European Food and Safety Authority (EFSA) (5 and 10%, for continuous and dichotomous data respectively).	and metabolism of a substance in several species are sometimes corrected by applying an adjustment factor that takes into account, for respiratory exposure, the rate of inhalation (physiological parameter) and distribution coefficients between air and blood (physico-chemical parameters tied to the substance) or physiologically based toxicokinetic models. France considers using the ten Berge equation for duration adjustment when data are available to do so. For gases, when the key study is conducted on animals, the committee applies dosimetric adjustments as described in the US-EPA documents (health effect summary table 1994) to establish OELs. This methodology describes 3 categories of gases but since most substances only have short-term effects, ANSES considers only category 1 when in gas state (gases that are highly water-soluble (> 1000 $mg.L^{-1}$) and/or rapidly irreversibly reactive in respiratory tract tissue).
Germany	Federal Institute for Occupational Safety and Health (BAuA)	Primarily NOAEL followed by BMDL which is going to be used more often. LOAEL used on a case by case basis.	POD modified for: • exposure duration ○ (6 hours/8 hours for inhalation experiments; and/or 7 days per week/5 days per week in case exposure in animal experiment was 7 days per week) • increased respiratory volume (due to

			increased physical activity for workers – for systemic effects only) • For an inhalation study, exposure duration modification of 6h/8h and increased respiratory volume results in an extrapolation of 2 • If data on absorption info is available, differences in absorption are considered • If no info is available on oral absorption, then 100% is assumed
Netherlands	Ministry of Social Affairs and Employment Health Council of the Netherlands Dutch Social and Economic Council Dutch National Institute for Public Health and the Environment	Threshold based OELs – BMD approach according to guideline by EFSA Model averaging methodology to select POD (BMDL)	If no specified data is available, default values are used to extrapolate for instance animal parameters to human parameters (i.e., inhalation volumes, food and water consumption, body weight, surface area) and worker parameters (i.e., working hours/days/weeks/years, average workers' body weight and average workers' inhalation volume).
Poland	Nofer Institute of Occupational Medicine/Group of Experts for Chemical and Dust Agents	NOAEL/NOAEC or LOAEL For irritant substances, the MAC value may be derived from data on the Respiratory Rate Decrease (RD50 – the dose of the irritant absorbed with the inhaled air causing a reduction in respiratory rate to 50% of the baseline value).	Correction factors of uncertainty are applied to calculate the MAC value from the NOAEL
Switzerland	Swiss Accident Insurance Fund (SUVA)	SUVA: MAK – benchmark dose, NOAEL, LOAEL	Case specific, e.g. via specific absorption rates

United States	Centers for Disease Control and Prevention (CDC), NIOSH U.S. Environmental Protection Agency (US EPA) U.S. Occupational Safety and Health Administration (US OSHA)	NIOSH: typically uses BMCLs as a POD, when data support BMD analysis. Other measures of toxicity such as NOAEL and LOAEL are used when data don't support BMD analysis. NIOSH develops or relies on statistical exposure-response models based on occupational epidemiological studies. US EPA: BMD (used mostly for existing chemicals) and NOAEL/LOAEL approaches (used more for new chemicals) OSHA: develops or relies on statistical exposure-response models based on occupational epidemiological studies (the range of observed exposures often overlap with the exposure range of interest for deriving a PEL.)	NIOSH: Adjustments are made depending on the nature of the hazard and available data. US EPA: NCELs and ECELs are adjusted for differences in exposure frequency and duration between animal toxicity studies (or human epidemiological studies as appropriate) and expected/assumed exposure frequency and duration for individuals occupationally exposed. US EPA: NCELs and ECELs consider differences in absorption for situations where studies from a different route of exposure (e.g., oral) are used to set OELs for inhalation exposure. US EPA: Also, a higher ventilation rate is assumed for workers compared with animals. OSHA: Not applicable

Use of uncertainty factors (UFs)

All organisations use uncertainty factors (also referred to as 'assessment factors', 'adjustment factors', and 'variability factors') when deriving OELs for threshold compounds. Generally, the relevant data available for a specific substance needs to be reviewed thoroughly for the establishment of appropriate values for the various uncertainty factors. Uncertainty factors that are considered by most of the organisations include inter/ intraspecies variation, LOAEL to NOAEL extrapolation, and time extrapolation. Some organisations provide numerical values to various uncertainty factors while others provide general points regarding the uncertainty factors they consider. Belgium and Denmark rely on scientific opinions and assessments from other organisations and committees such as SCOEL, ECHA's RAC and ACGIH (only Belgium specifies use of ACGIH). Finland specifies that they follow EU approaches for their derivation methodology. Japan provided no information regarding the use of uncertainty factors. See Table 6 for specific approaches provided by each organisation.

Table 6. Uncertainty factors used to calculate OELs by the various organisations

Country	Organisation(s) /Committee	Uncertainty factors used
Australia	Safe Work Australia	For deriving WES values, the choice of the uncertainty factor will be made by expert judgement and will be dependent on the available data for an individual chemical. A justification for the uncertainty factor will be provided in the evaluation report.
European Union	European Chemicals Agency (ECHA)	Based on SCOEL methodology for derivation of OELs (2017): • Adjustment factors (extrapolation from animals to humans, in case animal data are used) • Variability factors (variability among workers) • Uncertainty factors (considering uncertainties related to individual studies or to a set of studies) Chemical specific data, including an evaluation of the size and quality of the data set, should always be considered first when deciding on AFs. Default AFs should only be used as a last option. The final assessment factor used to address remaining uncertainties is generally seen as a matter of expert judgement.
France	French National Institute for Industrial Environment and Risks (INERIS) French Agency for Food, Environmental and Occupational Health & Safety (ANSES) Ministry of Labour	Referred to as 'adjustment factors' • Pharmacokinetic/pharmacodynamic inter-species differences (AF_A) – value 1 to 10 • toxicokinetic/dynamic inter-individual variability (AF_H) – value 1 to 5 • LOAEL to NOAEL (AF_L) – value 1 to 10 • Differences in length of exposure (AF_S) – value 1 to 10 • Data base quality, difference in exposure pathways (AF_D) – value 1 to 10 • Severity of the effect (AF_D) – value 1 to 10 The final numerical value of the safety factors is considered to be an indicator of confidence in the source study from which the OEL was defined. If the overall factor exceeds 1000 or if more than 3 adjustment factors were applied, the committee considers the study unsuitable for defining an OEL.

Germany	Federal Institute for Occupational Safety and Health (BAuA)	• Time extrapolation systemic and local effects
		  ○ Sub-acute to chronic – 6
		  ○ Sub-chronic to chronic – 2
		  ○ Sub-acute to sub-chronic – 2
		• Inter- and intra- species extrapolation
		  ○ standard factor of 5 for taking into account the entire intra-species and interspecies variability
		  ○ In case of local sensory irritating effects on the upper respiratory tract, factor 3.

Netherlands	Ministry of Social Affairs and Employment Health Council of the Netherlands Dutch Social and Economic Council Dutch National Institute for Public Health and the Environment	• interspecies differences • intraspecies differences • differences in exposure conditions Note: for risk-based OELs for carcinogens no uncertainty factors are used, because of the conservative derivation method
Poland	Nofer Institute of Occupational Medicine/Group of Experts for Chemical and Dust Agents	• interspecies differences and route of administration (route of administration other than inhalation) – to 10; • differences in individual sensitivity – to 2; • transition from short-term to long-term studies – up to 3; • the use of a LOAEL instead of a NOAEL – to 3; • adjustments for incompleteness or poor quality of available data on toxicity – to 5.
Switzerland	Swiss Accident Insurance Fund (SUVA)	Individual assessment factors are used to develop MAK and BAT values
United States	Centers for Disease Control and Prevention (CDC), NIOSH U.S. Environmental Protection Agency (US EPA) U.S. Occupational Safety and Health Administration (US OSHA)	NIOSH: UFs are used to address uncertainty in non-cancer adverse effects and are preferred when data are insufficient to derive substance specific or analogue-specific adjustment factors known as chemical-specific adjustment factors (CSAFs) UFs used include factors each ranging from 1 to 10 for: • for animal-to-human extrapolation • inter-individual variation • shorter-term to longer-term adjustment • NOAEL to LOAEL adjustment • adjustment for database adequacy US EPA: • Interspecies • Intraspecies • LOAEL-to-NOAEL • Subchronic-to-chronic duration OSHA: risk assessment typically provides a central estimate of risk with upper and lower 95th percentiles. OSHA does not typically rely on UFs when deriving

		PELs.

Approach for genotoxic carcinogens

In general, the approach taken for genotoxic carcinogens depends on the MOA of the substance. As indicated by ECHA's OEL guidance (link provided in Appendix B), for most genotoxic carcinogens, the available data are likely to be inadequate for an effective threshold to be identified with sufficient confidence. Therefore, the carcinogenic hazard for these substances is based a non-threshold MOA. The method used to derive a margin or risk for cancer effects due to non-threshold-based genotoxic carcinogens depends on the data available and the quality of such data. For example, ECHA, the Health Council of the Netherlands, Safe Work Australia, AGS, NIOSH, EPA, Poland are amongst the organisations that specify the use of non-threshold linear approaches (or other approaches, based on organisation). As previously mentioned, Belgium relies on the scientific opinions of specialized institutes and committees such as SCOEL, RAC, and ACGIH for their OEL derivation methodology (including approaches for genotoxic carcinogens). Similarly, Finland follows EU methodology for their derivation approaches. Denmark and Japan did not provide answers for this section of the survey. See Table 7 for the summary of approaches used for non-threshold based genotoxic carcinogens for the remaining organisations.

Exposure standards for non-threshold based genotoxic carcinogens are generally at a concentration associated with a specific cancer risk. The methods for determining cancer risk differ across agencies and the selected cancer risk level or margin also differs across agencies (see Table 8 for the cancer risk values for each organisation, if provided).

Some organisations such as SUVA demand minimization of the concentration of non-threshold carcinogens according to "as low as reasonably achievable" (ALARA) principle.

Some organisations (e.g., ECHA, NIOSH, AGS and the Health Council of the Netherlands) indicated in their survey responses or guideline documents that, for some carcinogens (i.e., non-genotoxic) that have sufficient data available, it may be possible to conclude a threshold-based MOA. In this case, threshold approaches would be followed. As outlined by NIOSH in their survey response, in these instances, it would be more appropriate to use non-linear extrapolation, such as a POD/UF approach. For ECHA's threshold approaches, the uncertainties, POD correction and assessment factor application that may be used, must be transparent.

AGS guidance specifies approaches for carcinogens with a sublinear dose–response relationship. ECHA also specifies that if the available data indicate a derivation from linearity, a modification of the default linear approach should be considered. No other organisations provided information specific to carcinogens with a sublinear dose–response relationship.

Table 7. Summary of methodologies for non-threshold based genotoxic carcinogens

Organisation(s) /Committee	Approach	POD	Comments
Safe Work Australia	Linear extrapolation	BMD/BMDL	Rely on already determined BMD/BMDL, cancer slope factors and inhalation unit risk values for genotoxic carcinogens from US EPA
European Union – European Chemicals Agency (ECHA)	Linear extrapolation, Relative and excess risk	For linear extrapolation: T25, BMD10	If the available data indicate a deviation from linearity, a modification of the default linear approach should be considered. When available, good quality human

	(human data)		epidemiological data with sufficient statistical power should be used for excess cancer risk estimation of non-threshold carcinogens
France – French National Institute for Industrial Environment and Risks (INERIS) **French Agency for Food, Environmental and Occupational Health & Safety (ANSES)** **Ministry of Labour**	Different extrapolation models, including linear extrapolation	BMD	Data can come from epidemiological studies or toxicological studies on animals. BMD approach is encouraged in the case of co-existing studies
Germany – Federal Institute for Occupational Safety and Health (BAuA)[3]	Linear extrapolation, Absolute or relative risk (human data)	For linear extrapolation: BMD10, T25	In the case of human data (epidemiological studies), relative risk approach as the preferred option to estimate airborne concentrations at different cancer risk levels
Netherlands – Ministry of Social Affairs and Employment **Health Council of the Netherlands Dutch Social and Economic Council** **Dutch National Institute for Public Health and the Environment[3]**	Linear extrapolation, relative risk (survival analysis) and excess risk	For linear extrapolation: BMD10	The Committee considers the linear extrapolation step in deriving cancer risk values to be sufficiently conservative, so uncertainty factors are not further taken into account. The BMD approach is used when animal data is available. With sufficient human epidemiological data, excess cancer risk can be estimated. The quantitative relationship between the exposure to a compound and the relative risk of cancer that is derived from epidemiological data must be converted into an appropriate measure of risk for deriving a cancer risk value. The Committee uses life tables to calculate an extra risk of cancer.
Poland – Nofer Institute of Occupational Medicine/Group of Experts for Chemical and Dust Agents	Linear extrapolation	-	The “Linearised Multistage Model" has been used extensively.
Switzerland – Swiss Accident Insurance Fund (SUVA) **Secretariat for Economic Affairs (SECO)**	Consideration provided to linear extrapolation	-	Linear extrapolation may be considered, but its application will vary for individual chemicals. For DNELs, the approach depends on the data set, but risk-based approaches are used, if possible.
United States –	NIOSH – linear	EPA –	NIOSH uses linear extrapolation unless

[3] Details obtained from guidance documents referenced in survey, rather than directly from survey responses.

Centers for Disease Control and Prevention (CDC), NIOSH **U.S. Environmental Protection Agency (US EPA)** **U.S. Occupational Safety and Health Administration (US OSHA)**	extrapolation EPA – linear extrapolation OSHA – statistical exposure-response models	BMD/BMDL for linear extrapolation	sufficient data exist to indicate a sub-linear response supported by MOA information. In that case, if data permit, statistical modeling or UF approach may be used. EPA has established methodology that other organisations often refer to for this (such as Safe Work Australia).

Table 8. Target cancer risk levels assigned by the various organisations or committees in the occupational setting

Organisation(s)/Committee	Target cancer risk level (s)	Comments
Safe Work Australia	1 in 100,000	'Minimal' cancer risk level There is still a residual risk at the target level and that PCBUs (person conducting business or undertaking) still have a responsibility to keep concentrations as low as reasonably practicable. The estimated numerical risk at the target concentration will not be published to prevent any misleading indications regarding the accuracy of the risk estimate.
European Union – European Chemicals Agency (ECHA)	-	'No accepted reference cancer risk levels established on an EU-wide basis.'
France – French National Institute for Industrial Environment and Risks (INERIS) **French Agency for Food, Environmental and Occupational Health & Safety (ANSES)** **Ministry of Labour**	1 in 10,000 1 in 100,000 1 in 1,000,000	The committee looks at different quantifications of risk published in literature and based on this data, the OEL is expressed by a scale based on three individual excess risks (of contracting an additional cancer). Individual excess risk is an increase in probability of an individual contracting the health effect in question (cancer) following exposure to the risk factor.
Germany – Federal Institute for Occupational Safety and Health (BAuA)[4]	4 in 10,000	This acceptable risk will be included in revision of TRGS 910 which is planned to be completed in Spring of 2022. Before the 2022 revision of the TRGS 910, the acceptable risk from 2018 was 4 in 100,000. An 'acceptable' risk of 4 in 10,000 was assigned for a transitional period (2013-2018) after the introduction of the concept. Tolerable risk of 4 in 1000 (risk-reduction

[4] Details obtained from guidance documents referenced in survey, rather than directly from survey responses.

		measures possibly needed to keep levels closer to acceptable risk). A concept of graduated measures is proposed that consists of three general levels of risk: High risk (above tolerable risk) Medium risk (between tolerable and acceptable risk) Low risk (below the acceptable risk)
Netherlands – Ministry of Social Affairs and Employment **Health Council of the Netherlands** **Dutch Social and Economic Council** **Dutch National Institute for Public Health and the Environment[3]**	4 in 1000 (prohibitive level) 4 in 100,000 (target level)	Values are based on 40-year of occupational exposure (full working life). Below the level of exposure corresponding to the target risk level, no additional protective measures need to be taken. The prohibitive risk level implies that this level may not be exceeded. Subcommittee assigns OELs at the 'target' level if technically feasible. Otherwise the limit will be between the 'target' level and the 'prohibitive' level.
Poland – Nofer Institute of Occupational Medicine/Group of Experts for Chemical and Dust Agents	Range from 1 in 1000 to 1 in 10,000	For carcinogens, the recommended exposure limits are based on the concept of socially acceptable risk that ranges from 10^{-3} to 10^{-4}, depending on whether the risk is expressed in terms of the incidence of changes in health status during 1 year or during the whole lifetime.
Switzerland – Swiss Accident Insurance Fund (SUVA)	Risk most often falls in range of 1 in 1,000 to 1 in 100,000	Conclusions will vary for individual chemicals, dependent on science, quality of studies and potency of carcinogen.
United States – **Centers for Disease Control and Prevention (CDC), NIOSH** **U.S. Environmental Protection Agency (US EPA)** **U.S. Occupational Safety and Health Administration (US OSHA)**	NIOSH: 1 in 10,000 EPA: 1 in 10,000 to 1 in 1,000,000 OSHA: 1 in 1000	NIOSH: target risk of one excess cancer death per 10,000 workers exposed to the substance for a working lifetime of 45 years" EPA: benchmark risk levels are for new chemicals. Case-specific factors may be considered for selection of level OSHA considers one excess cancer death per 1000 workers to be a significant risk finding

For the derivation and use of OELs, organisations vary in the level of guidance needed and what should be considered. Belgium, Poland and Switzerland specified a high need for guidance. Belgium sees a high need for transparency on residual risk that OELs are associated with, transparency on derivation performed by experts and for legislation to determine how to use OELs, and minimise exposures where OEL is a benchmark that should not be exceeded. Switzerland also sees a high need for guidance on scientific derivation, as well as for the enforcement activities of the inspectorates when it comes to worker DNELs. Poland on the other hand sees a high need for guidance, particularly in the national language. NIOSH and Germany specify that transparency would ensure a consistent derivation of OELs (Germany) and resulting OELs that can be better understood and utilized appropriately (NIOSH).

On the other hand, US EPA suggests that it would be useful to develop flexible international guidance on long-term and short-term exposure limits that can be used in a variety of frameworks (e.g., laws, regulations, etc.) from different jurisdictions. With regard to harmonised methodology approaches, ECHA specifies that this provides a “level playing field” and widens the database of established OELs. Finland sees a medium need for such harmonised approaches. Japan also sees a medium need for guidance since similar studies are evaluated using different weighting, suggesting that there is a need to harmonise how the same studies are evaluated. Japan also suggests guidance for assessment methods for internal exposures, especially for substances where skin exposure is considered.

Successes and challenges of OEL programme implementation

Programme successes

Various types of successes from the implementation of OEL programmes were noted by survey respondents. These included efficiency, stakeholder involvement, recognition and use of values, and worker health protection.

Several organisations mentioned that one success of their OEL programmes was an efficient use of resources. Belgium, Finland, and the Canadian province of Nova Scotia all stated that using existing scientific opinions as starting points for OELs results in maximization of resources. Another Canadian province, Alberta, further mentioned that a success of their programme is not only using established OELs, but also evaluating target OELs for applicability in workplaces.

Stakeholder involvement was also described as a success of the OEL implementation process. The Canadian provinces of Alberta, Quebec, and British Columbia, as well as Switzerland, stated that involving stakeholders in the technical review process improves buy-in of the values. Furthermore, Alberta states that this process allows for the leveraging of stakeholders' expertise. The Netherlands also stated that the availability of public OELs reduces costs for companies, due to a reduced need for industries to derive their own OELs.

Respondents also described that recognition and uptake of their OELs is an indicator of the success of their programmes. The NIOSH and Switzerland stated that their OELs are recognized and well-respected in the occupational health and safety community and by the public, respectively. Moreover, the compendium of NIOSH OELs is the most popular document from the organisation (link provided in Appendix B). Similarly, the Swiss OEL guidance booklet is commonly used in industry (link provided in Appendix B). US EPA also stated that the NCELs have been adopted in worker protection programmes in some industries.

Finally, various aspects of improvement of worker health were stated as indicators of the success of programmes. These included the reduction of worker exposure (Canada [Ontario]), identification of potentially hazardous emission sources and work conditions (Poland), and an increased focus on specific hazardous substances (Denmark). Furthermore, the Netherlands stated the process creates awareness in companies, which Poland stated increases the likelihood of risk control by employers. Poland also stated that their process eliminates reprotoxic substances from the workplace, which supports a pro-family policy.

Programme challenges

Although responding organisations have seen many successes in the adoption of OELs, some challenges to programme implementation continue to occur. These challenges arise from the lack of available data, limitations to risk assessment processes, regulatory issues, alignment with other organisations, impact of OELs on stakeholders, and awareness of public.

The most commonly stated programme challenge was a lack of available data that affected various aspects of the risk assessment process. The US EPA stated that hazard data limitations particularly affect NCELs, which are therefore often based on data for chemical analogues. However, the US EPA also mentioned data limitations for ECELs, particularly in the context of dermal exposure, both from the perspective of reflecting dermal effects in ECELs and measuring dermal exposures. Absence of methods to measure some substances was also stated by Canada (Ontario) as a factor that can present a challenge. Consultation with other organisations was sometimes mentioned as a means of overcoming data availability challenges. For example, Denmark uses external expertise to obtain knowledge about exposure and impact assessment, and the US EPA consults with submitting industries to ensure they use the best available science to establish final NCEL values. The Netherlands stated they are dependent on the input of information for both scientific advice and feasibility. As a means of overcoming challenges in the data gathering process, a project is currently underway to standardise data collection on feasibility.

Additional limitations related to the risk assessment process were noted. NIOSH stated that older OELs may not be based on quantitative risk assessment, as the approaches were only used to support OELs beginning in approximately 1987. Finland also mentioned that socioeconomic challenges or technical feasibility can result in OELs that are less protective than would be appropriate. In these cases, attempts are made to re-evaluate the limits after a few years.

Regulatory issues can also create barriers to, and delays in, the OEL-development process. In Canada, Alberta stated the adoption of OELs is limited by the ability to review and update legislation, and British Columbia stated their OEL-adoption process is very involved and time-consuming. OSHA stated that lengthy periods for developing and issuing standards can be attributed to increased procedural requirements and a rigorous standard of judicial review, and can be further exacerbated by responses to past adverse court decisions. Both OSHA and the Canadian province of Ontario stated that the development of OELs can also be impacted by shifting governmental priorities. Delays can also result when timelines at multiple regulatory levels do not correspond.

Although many organisations ascribed their programme successes to using existing scientific opinions, challenges were also noted. Belgium stated that the reliance on other institutes or committees with which collaboration agreements have not been established can result in challenges, due to a lack of control over the timing of publications by the other organisations. One specific example of this challenge was provided by Finland, who stated that the development of a national OEL might be postponed if an EU-level evaluation of the same chemical is anticipated.

Another reported challenge is the potential impact of OELs on stakeholders. The Canadian provinces of Ontario and Nova Scotia stated that OELs can sometimes have an adverse impact on industry stakeholders, particularly if a substantial change is made or if the OEL is of low feasibility. One approach that Nova Scotia has used to overcome this challenge is to allow impacted industries to apply for a deviation to the regulation for a particular OEL, which may be granted on a case-by-case basis.

Finally, one challenge presented by Switzerland was the lack of understanding and awareness of the public, particularly associated with DNELs. This challenge is ongoing and has not yet been overcome.

Formal programme evaluation

Most organisations stated that they have not performed a formal evaluation of the results of their OEL programme, but brief summaries were provided by four organisations. In Poland, assessments identified that implementations of OELs will be associated with a reduction by 10% in the number of people with occupational diseases. The Netherlands cited two joint publications (Schenk and Palmen, 2013; Schenk et al., 2019) (developed with Sweden) that summarised the results of questionnaires developed to obtain occupational hygienists' input on a newer system that eliminated most existing OELs and placed an increased onus on private industry to derive OELs. Organisations within the Canadian province of Nova Scotia also have data regarding disease claim numbers and compliance with OELs in industries. Moreover, U.S. OSHA conducts "lookback" reviews of existing standards (known as section 610 reviews) designed to evaluate the effectiveness of past rulemakings, including (but not limited to) evaluation of the PEL (OSHA, n.d.).

Discussion

Similarities and differences in approaches to design and implementation

Many countries are already leveraging the work of others, by using existing OELs as a starting point for their own OEL setting and collaborating through formal and informal processes. Some commonly referenced OELs that are used as a basis by many countries include, the American Conference of Governmental Industrial Hygienists (ACGIH), former EU Scientific Committee on Occupational Exposure Limits (SCOEL), ECHA Risk Assessment Committee (RAC), German MAK Commission, and Dutch Expert Committee on Occupational Safety (DECOS), which all derive health-based values. This highlights the value in making health-based OELs (and the methodology for their derivation) publicly available.

Many similarities were noted among countries regarding the derivation and implementation of OELs. All countries predominantly derived 8h-TWA values for chronic and subchronic effects, but also addressed acute toxicity using short-term (typically 15 minute) values, and instantaneous values that are never to be exceeded. These short-term OELs were commonly based on sensory irritation (ocular, dermal, and respiratory), systemic effects, and specific target organ toxicity.

The studies from which critical endpoints are obtained are generally epidemiology and experimental studies published in scientific literature, as well as in agency reviews and reports. The OELs were derived for threshold toxicants by all countries by dividing a POD by uncertainty factors. Finally, all countries use a hazard notation to represent the potential for dermal absorption and/or toxicity; the sole organisation that did not identify a skin notation was the US EPA.

Differences among countries were observed in the ways that certain critical endpoints are addressed in OEL development. Although some organisations quantitatively address carcinogenicity (including genotoxicity), reproductive and developmental toxicity, and sensitisation (respiratory and dermal), other organisations will not use these health outcomes as critical effects, and instead will address them only through the use of hazard notations. In some countries, carcinogens presumed to act via a threshold mode of action will still form the basis of an OEL. In these countries, mutagens or other carcinogens with insufficient evidence of threshold effects will be excluded as the basis of quantitative OELs, with ALARA principles (i.e., recommendations to minimize concentrations of non-threshold carcinogens to levels that are as low as reasonably achievable) instead being recommended. Finally, some countries perform linear extrapolation to derive risk-based values for carcinogens, but this approach is not used by all. Where used, acceptable risk levels vary among organisations.

Although the overall process of deriving OELs for toxicants considered to have a threshold is similar among organisations, countries have different policies in the selection of PODs and uncertainty factors. Most—but not all—organisations mentioned they use BMDL or BMCL values as a POD; however, some organisations prioritize BMD values over NOAELs, whereas others preferentially use NOAELs. The categories of uncertainty factors used differed slightly among organisations; values used for each category also varied, and some organisations provided ranges of values that could be used (with maximum values varying), while others prescribed exact values to be used. Some organisations also

mentioned the possibility of replacing default values by deriving chemical-specific uncertainty factors, when sufficient data are available.

Differences were also noted in the body of literature used to derive OELs. In addition to peer-reviewed published literature, some organisations stated they use grey or unpublished literature if from trustworthy sources. Moreover, and additional sources of data beyond epidemiology and experimental studies are stated as being used by some organisations, particularly when evaluating feasibility of an OEL. Some organisations also use read-across approaches to base their OELs on analog chemicals. Although all organisations assess data quality, many different approaches were used.

Additional hazard notations beyond dermal toxicity are used by some countries, but these vary by organisation. The types of notations mentioned by survey respondents included carcinogenicity, mutagenicity, sensitisation (dermal and respiratory), reproductive toxicity, ototoxicity, and oxygen displacement.

Potential for harmonisation

Despite the differences among countries that were described above, respondents were often open to the potential for harmonisation of approaches for developing OELs with other organisations. In some instances, collaboration are already occurring or being explored. For example, there is US coordination and collaboration between OSHA, US EPA, and NIOSH, and NIOSH is considering further harmonisation with US EPA. Consideration is also being given to harmonisation of reviews and adoption of OELs in Canadian jurisdictions. Positive outcomes were identified from harmonisation initiatives. For example, Belgium stated the EU-level work, including scientific opinions and impact assessments, reduces the workload for Member States.

A main focus for new international harmonisation initiatives was related to guidance on OEL-derivation methods, which is consistent with responses summarised in Section 3 regarding the need for guidance. As stated by Germany, the lack of documentation of methodologies creates a barrier to harmonisation. Areas of guidance that respondents mentioned could be developed for potential harmonisation include:

- Aligning timing of assessments of similar chemicals
- Selection of PODs
- Confidence assessment of PODs and OEL derivations
- Use of epidemiological data
- Methods of addressing uncertainty
- Default approaches, and when and how deviation from defaults is possible and justifiable
- Acceptable levels of cancer risk
- Effects of particles and OELs for particulate forms of substances
- Criteria on how far an OEL should differ from approaches for the general population

A further area for potential harmonisation proposed by respondents was in improved sharing of information. The Netherlands and Finland both stated that an information-sharing mechanism could be helpful in collection of toxicological and epidemiological data used to identify dose–response relationships. Finland further suggested a possible role for cooperation in the evaluation of such data. Switzerland also proposed that organisations transparently sharing the basis of OEL derivations could further contribute to harmonisation efforts. Harmonisation could be facilitated by coordinated exchanges on OEL development, and would have the benefit of saving resources across several organisations. However, the development of new OELs is only one potential area of focus for harmonisation, as the

updating of existing OELs can also be performed. As proposed by Switzerland, another approach is to facilitate an increased frequency of evaluations of the need to update existing OELs, a task necessitated by the ever-increasing development of new knowledge of chemicals and health effects. One proposed approach is to quantify the variability in OELs for different organisations. If large inconsistencies in national OELs are encountered for a substance (e.g., if OELs differ by more than two standard deviations) or an OEL has not been revised for more than 10 years, the need for harmonisation could be triggered. These scenarios would provide the opportunity to combine efforts for updating and harmonising the scientific processes involved in prioritizing OELs for update as well as for deriving OELs.

Another area in which coordinated exchanges and combining of resources could be of potential use is in the area of research into new risk assessment methodologies (e.g., QSAR and read-across) and their applicability for the derivation of OELs. OEL organisations could take part in existing initiatives, such as the Partnership for the Assessment of Risks from Chemicals (PARC) in the EU and the international initiative Accelerating the Pace of Chemical Risk Assessment (APCRA).

Although organisations tended to support the need for harmonisation with respect to development of guidance and sharing of information, the Netherlands stated they did not see a need for harmonisation of OEL values, as they did not think it would be feasible (due to differences in approaches towards socio-economic factors) or necessary. Instead, they suggest that the OECD play a role in increasing awareness among member states about the acceptable risk levels for substances without a safe threshold and encouraging the use of epidemiology data for deriving OELs.

A key theme throughout responses was that increased transparency could further improve harmonisation. This transparency was recommended both in the development of guidance and in the publication of derived OELs. As further highlighted by Germany, the need for transparency is especially warranted in cases where OELs incorporate technical feasibility or socio-economic impacts, rather than derived solely from a health-based perspective.

The most frequent benefit of harmonisation mentioned by respondents was a reduction in redundancy, resulting in both saved time and financial resources; however, additional benefits were noted. One particular benefit stated by the Canadian provinces of Quebec and Nova Scotia is the provision of a standardised level of protection of workers, which Nova Scotia also stated could be benefit employers as their compliance requirements may become standardised.

Conclusion

In conclusion, although the overall OEL-development approaches are similar among respondents, many differences in particular details and decision-making processes can result in diverging OELs. Although standardisation in the form of adoption of the same OEL value is likely not possible due to factors such as feasibility and acceptability of risk, there is opportunity for harmonisation of risk assessment approaches. Potential areas for harmonisation proposed by respondents focus on the development of guidance documents and information-sharing mechanisms. Differences between organisations may continue despite harmonisation of some aspects of developing OELs. As stated by the Canadian province of Quebec, the concerns of organisations may vary due to industrial and institutional specificities. However, effective development of harmonisation processes can reduce redundancies, increase transparency, reduce workload, provide a better understanding of why particular OELs may differ among organisations, and improve consistency in worker protection and compliance requirements of employers.

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Appendix A. Countries/Agencies included in report

Country	Government Agency(s)
Australia	Safe Work Australia
Belgium	BE Federal Public Service Employment, Labour and Social Dialogue
Canada	Alberta Labour and Immigration WorkSafe British Columbia Government of Newfoundland and Labrador Nova Scotia Department of Labor Ontario Ministry of Labour, Training and Skills Development (MLTSD) Québec Labour Standards, Pay Equity and Occupational Health and Safety Board (CNESST) Yukon Workers' Compensation Health and Safety Board *(Note: this does not include all occupational health and safety regulators in Canada that have OELs in their regulations)*
Denmark	The Danish Working Environment Authority (WEA)
European Union	European Chemicals Agency (ECHA)
Finland	Ministry of Social Affairs and Health Finnish Institute of Occupational Health
France	French National Institute for Industrial Environment and Risks (INERIS) French Agency for Food, Environmental and Occupational Health & Safety (ANSES) Ministry of Labour
Germany	Federal Institute for Occupational Safety and Health (BAuA)
Japan	Ministry of Health, Labour and Welfare Japan Society of Occupational Health
Netherlands	Ministry of Social Affairs and Employment Health Council of the Netherlands Dutch Social and Economic Council Dutch National Institute for Public Health and the Environment
Poland	Nofer Institute of Occupational Medicine

Switzerland	State Secretariat for Economic Affairs (SECO) Swiss Accident Insurance Fund (SUVA)
United States	Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH) U.S. Environmental Protection Agency (US EPA) U.S. Occupational Safety and Health Administration (US OSHA)

Appendix B. Hyperlinks to OEL lists and documented methods/approaches

Government Agency(s)	Name of the OEL(s)	Hyperlinks to lists of the OEL values	Hyperlinks to documented methods/approaches for development of OELs
Safe Work Australia	Workplace exposure standards (WES)	https://www.safeworkaustralia.gov.au/doc/workplace-exposure-standards-airborne-contaminants	https://www.safeworkaustralia.gov.au/review-workplace-exposure-standards#review-methodology
Belgium Federal Public Service Employment, Labour and Social Dialogue	Occupational exposure limit values	https://emploi.belgique.be/sites/default/files/content/documents/Bien-%C3%AAtre%20au%20travail/R%C3%A9glementation/Code%20livre%20VI%20titre%201%20Agents%20chimiques.pdf(ANNEX VI.1-1)	https://emploi.belgique.be/fr/procedure-de-consultation-publique-relative-aux-valeurs-limites-dexposition-professionnelle
Canadian jurisdictions: **Alberta Labour and Immigration;** **WorkSafeBC;** **Government of Newfoundland and Labrador; Nova**	Alberta Labour and Immigration: OELs WorkSafeBC: Exposure limits for chemical and biological substances	Alberta Labour and Immigration: www.alberta.ca/ohs-act-regulation-code.aspx (Schedule 1, Table 2) WorkSafeBC: https://www.worksafebc.com/en/resources/health-safety/ohsr-searchable/table-exposure-limits-chemical-biological-substances?lang=en	Alberta Labour and Immigration: N/A WorkSafeBC: N/A Government of Newfoundland and Labrador: N/A – Refer to ACGIH

Scotia Department of Labor; **Ontario Ministry of Labour, Training, Skills and Development (MLTSD);** **Commission des normes, de l'équité, de la santé et de la sécurité du travail (CNESST);** **Yukon Workers' Compensation Health and Safety Bureau**	Government of Newfoundland and Labrador: Threshold Limit Values, Short Term Exposure Values, Ceiling Limits. Nova Scotia Department of Labor: Threshold Limit Values Ontario MLTSD: Time Weighted Average, Short Term Exposure Limit, Ceiling, Excursion limits CNESST: Permissible Exposure Limits Yukon Workers' Compensation Health and Safety Bureau: Permissible Concentration	Government of Newfoundland and Labrador: N/A - Must be purchased through ACGIH Nova Scotia Department of Labor: https://www.novascotia.ca/just/regulations/regs/ohsworkplace.htm#TOC1_2 Ontario MLTSD: https://www.labour.gov.on.ca/english/hs/pubs/oel_table.php CNESST: http://legisquebec.gouv.qc.ca/en/showdoc/cr/S-2.1,%20r.%2013?langCont=fr#sc-nb:1 Yukon Workers' Compensation Health and Safety Bureau: https://www.yukonregs.ca/RegsPublic/Home/Details/5689	Nova Scotia Department of Labor: N/A Ontario MLTSD: N/A CNESST: N/A Yukon Workers' Compensation Health and Safety Bureau: N/A

Danish Working Environment Authority	The translation of the Danish wording is "limit values for the air at work"	https://www.retsinformation.dk/eli/lta/2021/209	Not available
European Chemicals Agency (ECHA)	Occupational Exposure Limits	OELs are in the EU legislation: https://echa.europa.eu/cad-and-cmd-legislation ECHA publishes the opinions it prepares on its website: https://echa.europa.eu/oels-activity-list	Guidance on how to prepare a scientific report for health based exposure limits and OELs at the workplace: https://echa.europa.eu/documents/10162/23036412/ircsa_r8_appendix_oels_en.pdf/f1d45aca-193b-a7f5-55ce-032b3a13f9d8
Ministry of Social Affairs and Health (Finland) **Finnish Institute of Occupational Health**	Binding limit values Concentrations known to be harmful	Binding limit values for carcinogens: https://www.finlex.fi/fi/laki/alkup/2019/20191267 (the values are listed in the appendix (pdf) which can be found on the bottom of the page) Binding limit values for asbestos: https://www.finlex.fi/fi/laki/alkup/2015/20150798 Binding limit values for lead: https://www.finlex.fi/fi/laki/alkup/1993/19931154 Non-binding limit values ("concentrations known to be harmful"): https://finlex.fi/fi/laki/alkup/2020/20200654 (the values are listed in the appendix (pdf) which can be found on the bottom of the page) The OELs are also collected in a booklet/guidance document: https://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/162457/STM_2020_24_J.pdf?sequence=1&isAllowed=y	Many of our limit values are based on the EU OELs for which the scientific approach is given in: https://www.echa.europa.eu/documents/10162/23036412/ircsa_r8_appendix_oels_en.pdf

French National Institute for Industrial Environment and Risks (INERIS) **French Agency for Food, Environmental and Occupational Health & Safety (ANSES)** **Ministry of Labour (France)**	Occupational exposure limits (OELs) and biological limit values (BLVs)	Binding OEL: Décret n° 2012-746 du 9 mai 2012 fixant des valeurs limites d'exposition professionnelle contraignantes pour certains agents chimiques https://sstie.ineris.fr/consultation_document/21257 Indicative OEL: Arrêté du 9 mai 2012 fixant des valeurs limites d'exposition professionnelle indicatives pour certains agents https://sstie.ineris.fr/consultation_document/21893 List of French OEL (binding, indicative and no binding and no indicative): https://www.inrs.fr/dms/inrs/CatalogueOutil/TI-outil65/fichier-VLEP-France-outil65.zip Documentation for OELs and BLVs (French only): https://www.anses.fr/fr/content/les-valeurs-de-r%C3%A9f%C3%A9rence Documentation for BLVs (available in English): https://www.anses.fr/en/content/biological-limit-values-chemicals-used-workplace ANSES Report: https://www.anses.fr/fr/content/avis-du-ces-expertise-en-vue-de-la-fixation-de-valeurs-limites-dexposition-%C3%A0-des-agents	Methodology 2016 (French) (a revision of the methodology is under progress): https://www.anses.fr/fr/system/files/VLEP2016SA0248Ra.pdf Methodology 2013 (old version in English): https://www.anses.fr/en/system/files/VLEP2009sa0339RaEN.pdf OEL Report: https://www.anses.fr/fr/content/avis-du-ces-expertise-en-vue-de-la-fixation-de-valeurs-limites-dexposition-%C3%A0-des-agents

Federal Institute for Occupational Safety and Health (BAuA) (Germany)	Occupational exposure limit (“Arbeitsplatzgrenzwert”; AGW)	https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/TRGS-900.pdf?__blob=publicationFile&v=18 Risk-based OELs for carcinogens (under revision at the moment): https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/TRGS-910.pdf?__blob=publicationFile&v=14 English version of TRGS 910: https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/pdf/TRGS-910.pdf?__blob=publicationFile&v=4	Criteria for development of health-based OEL are laid down in the Announcement on Hazardous Substances 901 (Bekanntmachung für Gefahrstoffe 901; BekGS 901), for which revision is intended: https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/Bekanntmachung-901.pdf?__blob=publicationFile&v=2 Risk-based OELs for carcinogens according to exposure-risk relationships methods are laid down in Annex 3 of TRGS 910, which is under revision at the moment: https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/TRGS-910-Anlage3.pdf?__blob=publicationFile&v=2 English version: https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/pdf/TRGS-910-Annex3.pdf?__blob=publicationFile&v=2 Information on lowering acceptable cancer risk level from 2018 TRGS 910: https://www.baua.de/DE/Aufgaben/Geschaeftsfuehrung-von-Ausschuessen/AGS/pdf/AGS-TRGS-910.pdf?__blob=publicationFile&v=6

Ministry of Health, Labour and Welfare **Japan Society for Occupational Health**	Administrative Levels (AL) Occupational Exposure Limits (OELs)	ALs: https://www.mhlw.go.jp/stf/shingi/2r9852000000w7bi-att/2r9852000000w7nq.pdf (Japanese) OELs (2020-2021): https://www.sanei.or.jp/?mode=view&cid=310	
Ministry of Social Affairs and Employment (the Netherlands) **Health Council of the Netherlands** **Dutch Social and Economic Council** **Dutch National Institute for Public Health and the Environment**	Public OEL (set by the government, binding) Private OEL: for substances for which no public OEL is available, employers have to derive private OELs.	https://wetten.overheid.nl/BWBR0008587/#BijlageXIII	Various reports at https://www.healthcouncil.nl/: • Guideline for the calculation of occupational cancer risk values (2012); Prevention of work-related airway allergies. Recommended occupational exposure limits and periodic screening (2008); • Guideline to the classification of carcinogenic compounds (2010); and, • Principles of deriving health-based occupational exposure limits and recommending classification (work title, in progress, publication expected in 2021) Guidance on how to deal with private OELs: https://www.ser.nl/grenswaarden https://rvs.rivm.nl/normen/werkende https://www.arboportaal.nl/onderwerpen/grenswaardestelsel Guidance for employers, published by the labour inspectorate:

			https://www.zelfinspectie.nl/zelfinspecties/werken-met-gevaarlijke-stoffen including guidance on how to derive private OELs: https://www.inspectieszw.nl/binaries/inspectieszw/documenten/publicaties/2020/04/02/hoe-ga-ik-te-werk-bij-het-vaststellen-van-grenswaarden---bijlage-bij-zelfinspectie-werken-met-gevaarlijke-stoffen/Hoe+ga+ik+te+werk+bij+het+vaststellen+van+grenswaarden+-+bijlage+bij+Zelfinspectie+werken+met+gevaarlijke+stoffen.pdf)
Nofer Institute of Occupational Medicine/Group of Experts for Chemical and Dust Agents (Poland)	Permissible Exposure Limit (Maximum Admissible Concentration)	https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20180001286 (Polish)	Czerczak S, Indulski J, Kowalski Z, Szymczak W. [The methodology for determining occupational and environmental hygiene standards]. Med Pr. 1994;3 Suppl 2:5–88. Polish. Czerczak S. The Principles of Establishing MAC Values of Harmful Chemical Compounds in The Working Environment. 2004, PiMOŚP, vol. 4 (42), 5-18. http://archiwum.ciop.pl/9581.html Skowroń J., Czerczak S.: Rules and recent trends for setting health-based occupational exposure limits for chemicals. Int. J. Occup. Med. Environ. Health 2015;28(2):243–252 https://doi.org/10.13075/ijomeh.1896.00243

			Soćko R., Czerczak S., Kupczewska-Dobecka M. OELs Derivation in Poland and in the Former Eastern Bloc with Reference to Approaches and Practices Applied in the EU. Medycyna Pracy 2015;66(3):383–392 http://medpr.imp.lodz.pl/en. http://dx.doi.org/10.13075/mp.5893.00145 Gromiec J. [Problems Concerning the Integration of "Derived-No-Effect-Levels" (DNELs) into Occupational Safety And Health Regulations]. Problemy związane z wprowadzeniem DNEL (Pochodny Poziom Niepowodujący Zmian) do Prawnego Systemu Ochrony Zdrowia Pracujących. Medycyna Pracy 2008;59(1):65 – 73 Instytut Medycyny Pracy im. prof. J. Nofera w Łodzi http://medpr.imp.lodz.pl http://cybra.p.lodz.pl/Content/9101/Medycyna_Pracy_2008_T_59_nr_1_(65-73).pdf
Swiss Accident Insurance Fund (SUVA) **State Secretariat for Economic**	MAK (Maximale Arbeitsplatz-Konzentration = maximum concentration at the workplace) DNEL	MAK/BAT: www.suva.ch/grenzwerte As Switzerland currently does not provide own DNEL (mainly controls and assess DNEL with SECO-DNEL tool, available at: Occupational Exposure Limits	MAK/BAT: www.suva.ch/grenzwerte DNEL derivation via: https://www.seco.admin.ch/dnel , according to: Guidance on information requirements

Affairs (SECO) (Switzerland)		(DNEL) (admin.ch)) , we compare additionally with international DNEL repository for more than 6000 DNELs at the Gestis-List: www.dguv.de/ifa/gestis/gestis-dnel-liste	and chemical safety assessment. Chapter R.8: Characterisation of dose [concentration]-response for human health: https://echa.europa.eu/documents/10162/13632/information_requirements_r8_en.pdf
Centers for Disease Control and Prevention (CDC), NIOSH (United States)	Recommended Exposure Limit (REL) Risk Management Limit – Carcinogens (RML-CA)	https://www.cdc.gov/niosh/npg https://www.cdc.gov/niosh/docs/2017-100/	How NIOSH conducts risk assessment: https://www.cdc.gov/niosh/topics/riskassessment/how.html NIOSH Chemical Carcinogen Policy: https://www.cdc.gov/niosh/docs/2017-100/default.html NIOSH Practices in Occupational Risk Assessment: https://www.cdc.gov/niosh/docs/2020-106/
U.S. Environmental Protection Agency	New Chemical Exposure Limits (NCELs) Existing Chemical Exposure Limit (ECEL)	New chemicals: NCEL webpage: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/non-confidential-list-tsca-new Existing chemicals: ECELs have not been finalized in regulations to date.	New Chemicals: There is some method information in the boiler plate language for NCELs that are included in section 5(e) orders: https://www.epa.gov/sites/production/files/2015-06/documents/draft_ncel_insert_042115.pdf

U.S. Occupational Safety and Health Administration	Permissible Exposure Limits (PELs)	Permissible Exposure Limits – Annotated Tables: https://www.osha.gov/annotated-pels Occupational Safety and Health Standards (General Industry): https://www.ecfr.gov/cgi-bin/text-idx?SID=56d507286ce8f59c384587e796e5bdbb&mc=true&node=se29.6.1910_11000&rgn=div8 Occupational Safety and Health Standards (Construction): https://www.osha.gov/laws-regs/federalregister/1993-06-30-2 Occupational Safety and Health Standards (Shipyard): https://www.ecfr.gov/cgi-bin/text-idx?SID=56d507286ce8f59c384587e796e5bdbb&mc=true&node=se29.7.1915_11000&rgn=div8	-

Appendix C. Considerations accounted for in the OEL and enforceability

Government Agency	Name of the OEL(s)	Type of OEL	Legally Binding/Non-Binding
Safe Work Australia	Workplace exposure standards (WES)	Health based values	Binding
Belgium Federal Public Service Employment, Labour and Social Dialogue	Occupational exposure limit values	Health based values are used as a starting point for a public consultation. During negotiations, process-technical, measurement-technical, socio-economic or health-based arguments can be introduced.	Binding
Canadian jurisdictions: **Alberta Labour and Immigration;** **WorkSafeBC;** **Government of Newfoundland and Labrador;** **Nova Scotia Department of Labor;** **Ontario Ministry of Labour, Training, Skills and Development (MLTSD);** **Commission des normes, de l'équité, de la santé et de la sécurité du travail (CNESST);**	Alberta Labour and Immigration: OELs WorkSafeBC: Exposure limits for chemical and biological substances Government of Newfoundland and Labrador: Threshold Limit Values, Short Term Exposure Values, Ceiling Limits. Nova Scotia Department of Labor: Threshold Limit Values Ontario MLTSD: Time Weighted Average, Short Term Exposure Limit, Ceiling, Excursion limits	Alberta Labour and Immigration: Considerations in the adoption of OELs include factors such as technical limitations of work site controls, technical limitations of exposure measurement and analytical methods, impact on workplaces and the feasibility to comply. WorkSafeBC: WorkSafeBC reviews the ACGIH TLVs for availability of validated sampling and analytical methods, implementation issues such as technical and economic feasibility and associated health effects. Government of Newfoundland and Labrador: Health based	All are binding

Yukon Workers' Compensation Health and Safety Bureau	CNESST: Permissible Exposure Limits Yukon Workers' Compensation Health and Safety Bureau: Permissible Concentration	Nova Scotia Department of Labor: Health based; however, industries may apply for a deviation where it is difficult/not feasible to comply. Ontario MLTSD: The Ministry consults on the annually recommended updates to the ACGIH OELs. Prior to adopting the OELs in regulation, a consultation process occurs where stakeholders send submissions on the factors influencing compliance to the new OEL in their sector. Submissions can include feedback on the scientific basis for the limits, technical feasibility (e.g. sampling issues, engineering controls) and economic impacts. CNESST: The main factors considered in OEL development are health effects and analytical, economic and technical feasibility. Yukon Workers' Compensation Health and Safety Bureau: Health based	
The Danish Working Environment Authority	The translation of the Danish wording is "limit values for the air at work"	Health based values form the basis for discussions. During tripartite discussions, the technical feasibility and the socioeconomic impact is considered.	Binding

ECHA	Occupational Exposure Limits	Health based values	Non-binding[1]
Ministry of Social Affairs and Health **Finnish Institute of Occupational Health**	Binding limit values Concentrations known to be harmful	Hazard (dose-response), technical feasibility and socio-economic impacts are factored. A majority of the OELs are health-based, but if necessary, the OELs may be adjusted due to technical or socioeconomic challenges.	Binding Non-binding
INERIS/ ANSES/ Ministry of Labour	Occupational exposure limits (OELs) and biological limit values (BLVs)	Health based values form the basis. Consideration of technical feasibility or socio-economic impact are discussed during the stakeholder consultation. The aim of this phase is to discuss the effectiveness of the limit values and if necessary, to determine a possible implementation timetable, depending on any technical and economic feasibility problems.	Binding or Indicative
Federal Institute for Occupational Safety and Health (BAuA)	Occupational exposure limit ("Arbeitsplatzgrenzwert"; AGW)	Health based	Binding
Ministry of Health, Labour and Welfare **Japan Society for Occupational Health**	Administrative Levels (AL) Occupational Exposure Limits (OELs)	ALs: hazard, technical feasibility for the measurement of airborne concentration, socio-economic impact, an overseas trend of OELs, occupational accident OELs: Information not available	ALs are control-binding OELs are non-binding

Ministry of Social Affairs and Employment **Health Council of the Netherlands** **Dutch Social and Economic Council and the Dutch National Institute for Public Health and the Environment**	Public OEL	For substances without a safe threshold (e.g., carcinogens and sensitisers); scientific advice, socio-economic factors and policy factors are strictly separated in three phases. For substances with a threshold, the OEL will be set on the health-based OEL, as recommended by the Health Council or RAC.	Binding
Nofer Institute of Occupational Medicine/Group of Experts for Chemical and Dust Agents	Permissible Exposure Limit (Maximum Admissible Concentration)	In the first step only hazard is factored but next step technical feasibility, socio-economic impacts too.	Binding
State Secretariat for Economic Affairs (SECO) **Swiss Accident Insurance Fund (SUVA)**	MAK, KZGW, BAT (Maximale Arbeitsplatz-Konzentration = maximum concentration at the workplace; Kurzzeitgrenzwert = short-term exposure limit; Biologische Arbeitsstofftoleranzwerte = tolerable biological values).	SUVA is in charge of developing and setting the Swiss MAK/BAT values in coordination with the Swiss OEL commission (Suissepro). As these values are legally binding, the scientific background, the technical feasibility and socio-economic impacts have to be considered.	Binding
U.S. Environmental Protection Agency	New Chemical Exposure Limits (NCELs) Existing Chemical Exposure Limit (ECEL)	New chemicals: provides specifics on the requirements for technical feasibility for the analytical procedure to verify measurement of NCEL concentrations. Existing chemicals: EPA must consider a number of criteria when selecting among the various restrictions under consideration in the rulemaking and develop a statement of effects of the chemical on the health and the environment, the benefits of the chemical substance for various uses, and the reasonably ascertainable	Binding

		economic consequences of the rule, including the effect of the rule on the economy, small business, technical innovation, the environment and public health; and the costs and benefits and cost effectiveness of the proposed action and one or more regulatory alternatives considered by EPA.	
U.S. Occupational Safety and Health Administration	Permissible Exposure Limits (PELs)	Technical and economic feasibility	Binding
Centers for Disease Control and Prevention (CDC), NIOSH	Recommended Exposure Limit (REL) For chemical carcinogens we may use Risk Management Limit – Carcinogens (RML-CA)	Health based; however, in developing RML-CAs, NIOSH does take into account the analytical ability to measure the chemical in the air. In cases where the limit of quantification (LOQ) is higher than the level at which the REL or RML-CA would be set based on risk, NIOSH sets these values at the LOQ. This is in recognition that it is difficult to assess or control a chemical in the air if it cannot be successfully measured.	Non-binding

[1] OELs developed by ECHA-RAC are used by DG EMPL for the decision-making process which includes also other considerations such as socio-economic impact for Indicative or Binding OELs

Appendix D. Survey questions

Establishing Occupational Exposure Limits – Draft Survey

OECD Working Party of Hazard Assessment (WPHA) & Working Party on Exposure Assessment (WPEA)

Many organizations around the world derive occupational exposure limits (OELs), however, no globally harmonized approach for their derivation exists and nomenclature of the final values differs between jurisdictions/organizations of different countries, but sometimes also different values can be used in the same country depending on the purpose. Often guidance and transparency for deriving OELs is available only to a limited extent, the methods for deriving these values often lack details and OEL values often differ between jurisdictions/organizations.

The goal of this survey is to collect experiences amongst countries on policy and scientific approaches used to develop OELs. It includes questions on:

I. General information on respondents;

II. Identification of scope, roles and responsibilities for OEL development;

III. Methods for development and derivations of occupational exposure limits;

IV. Identification of strengths and challenges of the approaches to design and implementation

The survey is designed to capture OEL development activities performed by government agencies; both legally binding and non-binding/recommended values, in the area of industrial chemicals (i.e. excludes pesticides). It is expected that in many countries, WPHA and WPEA members will need to reach out to other government agencies in their countries to solicit input.

The responses to the survey will be used to develop a cross-country summary looking at the different approaches taken by government agencies to develop OELs. This survey is a first step in bringing together international approaches and guidance for OEL development and lessons learned. This activity is not intended to prioritize approaches, or identify the “best” approach, but to better inform intergovernmental discussions and increase awareness of existing government approaches to develop OELs.

Questionnaire

Section I. General information on respondent

Name:

Background of the respondent (e.g. toxicologist, industrial hygienist, policy advisor, etc.):

Organization:

Country:

Email:

Section II. Identification of scope, roles and responsibilities for OEL development

Please provide information on any programmes within your own organization or country/region that develop OELs.

1. Does your organization develop, adopt or control binding or non-binding OELs? If OELs are adopted from others, what organizations are considered 'trusted sources'?
2. What is the name of the OEL(s) developed (e.g. Permissible Exposure Limit, Recommended Exposure Limit)? Please specify if binding or non-binding.
3. What is the name and source of the corresponding policy, legislation, if applicable?
4. Please provide weblinks to lists of the OEL(s) values
5. Are the OELs used for prospective or retrospective risk assessments? Please specify the role how OEL are used, e.g. authorisation of substances or risk characterisations of workplaces, health surveillance, accidental risks etc.
6. Do you publish a list of future priorities for OEL development? If so, please provide hyperlink.
7. Please provide a description of the level of activity (i.e. how many OELs published per year, how recently, how often are existing OELs revisited/updated, what is the average age of the values)?
8. What considerations are factored in the development of OELs? (e.g. hazard, technical feasibility, socio-economic impacts)
9. Is the OEL-List transparent for externals? (i.e. distinguish between the different factors that lead to the values? see previous question)
10. What type of review process is involved? (e.g. public comment, scientific advisory committees)
11. How do you work with other agencies in your region with similar mandates?
12. Are there lists or other regulatory action that triggers the development of an OEL (e.g. SVHC list)?
13. How much workforce is involved in the elaboration of the OEL list? [estimated FTE]

Section III. Methods for development and derivations of occupational exposure limits

1. Please provide web links to documented methods/approaches for development of occupational exposure limits in your organization:
2. Please comment on the definitions and scope of values for OELs that are developed in your organization:
    a. What types of health endpoints are covered? What types of health endpoints are excluded?

   b. Do you use time-weighted averages? Do you derive OELs for long-term exposure, short-term exposure or both?

   c. What notations do you develop?

3. Please comment on how data is evaluated to support and develop OELs in your organization:

   a. What types of data are included in the data search (e.g. published and/or unpublished studies)?

   b. How is data quality assessed? Are there principles or criteria that are followed?

   c. How are the critical effects/key studies identified? Do you follow a weight-of-evidence approach?

   d. Please describe the weighting and frequency of use of human data, read-across and QSARs in the development of OELs

4. Please comment on the methodology for deriving OELs that is used in your organization.

   a. What types of points of departure (POD) are used for OEL derivation (e.g. NOAEL, benchmark dose)? How are the PODs selected?

   b. How is the POD modified to consider differences in exposure conditions, physical activity and/or absorption between the experimental animal and the worker?

   c. Please describe the use of assessment or uncertainty factors in the development of OELs

   d. What is the approach for genotoxic carcinogens?

5. Do you see a guidance need in derivation or use of OEL(s)?, please specify to high, medium, low, and for which OEL(s)

Section IV. Strengths of the approaches and challenges to design and implementation

1. In general, what successes have you observed from the implementation of your OEL program?
2. Were there impediments or factors that delayed action when designing or implementing your program? How did your agency overcome these challenges?
3. Have you tried to formally evaluate the results of this program?

   a. If yes, how has your country evaluated the results (e.g. cost-benefit analysis, compliance)? Please provide examples of quantitative and/or qualitative analyses.

4. Do you see OEL areas where redundant OEL work can be reduced enabling a harmonisation potential?

Appendix E. Survey responses

Original responses to the initial survey are presented on the project community site (https://community.oecd.org/community/oel), which is only accessible to the project members . Discussions in the text of the main document may include information beyond what is presented in the survey results. This occurred when a respondent referred to a published document instead of specifically describing the approaches used within the survey, or when organisations included additional details upon review of draft versions of this report.