



Interim Guidance for National Labour Inspectors on how to use Occupational Exposure Limits (OELs), Derived No Effect Levels (DNELs) and Derived Minimal Effect Levels (DMELs) when assessing effective control of exposure to Chemicals in the workplace

*Senior Labour Inspector's Committee
(SLIC)
SLIC WG CHEMEX*

Adopted at the 69th SLIC Plenary in Luxembourg, 13 November 2015

Table of Contents

1. What are OELs?	3
2. What are DNELs?	4
3. OELs, DNELs and Risk Management measures	6
4. Discussion	7
5. When DNEL is lower than OEL	8
6. When DNEL is higher than OEL	8
7. Where both DNEL and OEL are the same	8
8. Glossary	8
9. Further Information	9

Occupational Exposure Limits (OELs), Derived No Effect Levels (DNELs) and Derived Minimal Effect Levels (DMELs)

What are OELs?

- OELs are established at EU and national level, typically supported by expert independent scientific committees which take into account all available scientific information. OELs are complemented by information on exposure monitoring, such as sampling methodology, measurement methods and measurement systems.
- At EU level, OELs are established in accordance with Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (Chemical Agents Directive)¹ and Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Carcinogens or Mutagens Directive)². They are set further to the advice of the Scientific Committee on Occupational Exposure Limit Values (SCOEL).
-
- There are two different types of OELs set at EU level: Indicative Occupational Exposure Limit Values (IOELVs) established in accordance with the Chemical Agents Directive and, Binding Occupational Exposure Limit Values (BOELVs) established in accordance with the Chemical Agents Directive and also the Carcinogens or Mutagens Directive. A BOELV for asbestos is set in the Exposure to Asbestos at Work Directive (2009/148/EC).
- IOELVs are health-based limit values below which adverse health effects are unlikely to occur for any given substance after short term or daily exposure over a working life time. They are established on the basis of an independent evidence-based scientific assessment of scientific information carried out by SCOEL and take into account the availability of measurement techniques. Where an EU IOELV has been set, Member States are required to establish a national OEL taking into account the EU limit value. Presently, there are about 123 EU IOELVs.
-
- Where an EU BOELV has been set, Member States are required to establish a corresponding national OEL based on, but not exceeding, the EU limit value. BOELVs set in accordance with the Chemical Agents Directive reflect feasibility factors in addition to the factors considered when establishing IOELVs, while maintaining the aim of ensuring the protection of the health of workers.
- Unlike DNELs, OELs are predominantly established for the inhalation route of exposure. They can however indicate that another route of exposure is important; an example is the skin notation applied at EU level. OELs are

¹ Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, OJ L 131, 5.5.1998, p. 11.

² Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, OJ L 158, 30.4.2004, p. 50.

established in order to be practically used and implemented including exposure monitoring measures.

- Member States set national OELs. Obligations for compliance with national OELs differ in the various Member States. National OELs have to be complied with even if the DNEL derived for registration purposes for the same substance is higher.
- The Chemical Agents Directive and the Carcinogens and Mutagens Directive require the employer to assess any risk to the safety and health of workers arising from the presence of hazardous chemicals taking into consideration the type, duration and level of exposure and to ensure that those risks are eliminated or reduced to a minimum by application of a hierarchy of protection and prevention measures, where collective protective measures have priority over individual ones. Employers must also comply with any existing OELs.
-
- Where an OEL established in a Member State has been exceeded, the employer is required under the Chemical Agents Directive (Article 6 (5)) to take immediate steps to remedy the situation, taking into account the nature of the limit. Under the Carcinogens or Mutagens Directive, exposure must not exceed the limit value of a carcinogen as set out in that Directive (Article 5 (4)), and even in presence of such a limit value, the employer is required to ensure that the level of exposure of workers is reduced to as low a level as technically possible (Article 5 (4)).

What are DNELs?

- The REACH Regulation³ introduces a new system of setting exposure reference levels based on human health and environmental effects known as 'Derived No-Effect Levels' (DNELs) for humans and 'Prescribed No-Effect Concentrations' (PNECs) for environmental exposure.
- The term "DNEL" is defined in Annex I to REACH as the level of exposure above which humans should not be exposed.
- DNELs are derived for all relevant routes of exposure i.e. inhalation, dermal and/or oral exposure -both long-term and acute exposure - for workers, as well as for consumers and indirect human exposure via the environment, including certain sub-populations such as children or pregnant women
- DNELs are derived by the registrants (i.e. manufacturers and importers) as part of the REACH registration. DNELs are also set in the framework of authorisation and restriction processes, further to the opinion of the Committee for Risk Assessment (RAC). They are derived when a chemical safety assessment (CSA) is required under REACH which is documented in a Chemical Safety Report (CSR). They are used in risk characterisation, which consists of

³ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p. 1.

the comparison of the exposure of each human population known to be, or likely to be, exposed at the appropriate DNEL

-
- DNELs are derived according to the methodology established by ECHA and they are used in the framework of exposure scenarios to help establish and identify appropriate risk management measures (RMMs). Downstream users have an obligation to apply those RMM measures in order to ensure that the DNEL is not exceeded (adequate control). Each set of operational conditions and exposure will dictate the required RMMs for an identified use.
-
- DNELs should be set out in the manufacturer's/importer's CSR and the extended safety data sheet (SDS) must include the relevant DNELs and existing national OELs, including national OELs set in the absence of EU OELs (section 8 of the SDS)
- The Method for deriving DNELs differs from the methodology used by SCOEL for deriving and establishing OELs. DNELs are derived by the registrant using the tool provided by ECHA (http://www.echa.europa.eu/documents/10162/13655/pg_14_on_hazard_endpoint_en.pdf), where as OEL relies on expert judgement and is thus based on a less prescriptive approach.
- For some substances, a Derived Minimal Effect Level (DMEL) may be assigned, rather than a DNEL. DMELs apply to non-threshold substances for which it was not possible to establish a no-effect level. For these substances, and for substances for which neither DNEL nor DMEL can be assigned, the conditions in the exposure scenario for safe use are based on a qualitative risk assessment. A DMEL is a reference risk level which is considered to be of very low concern. Consequently, as indicated in the European Chemicals Agency (ECHA) Guidance, for carcinogens and mutagens, where a DMEL exists the employer should still comply with the minimisation requirement under the Carcinogens and Mutagens Directive that requires that workplace exposures be avoided or minimised as far as technically feasible, since REACH applies without prejudice to that Directive

OELs, DNELs and Risk Management Measures

- The obligations of employers under the REACH Regulation apply without prejudice to their obligations under the Chemical Agents Directive and the Carcinogens or Mutagens Directive. OELs and DNELs co-exist, and in some circumstances they may apply simultaneously to some work activities
-
- Data gained by measurements of workers' exposure that demonstrate the current level being below the recommended OEL do not relieve the downstream user of the obligation to check if the use of the substance is covered by the supplier's exposure scenario under REACH.
- The implementation of an exposure scenario does not relieve the employer of the obligation to check the effectiveness of the risk control measures under the Chemical Agents Directive or Carcinogens or Mutagens Directive. The key point is that users apply the control measures, risk management measures or conditions of use that will control exposure within the relevant reference level.
-

- DNELs are often, but not always, lower than OELs established at the EU and national level. This is due largely to the difference in scope and methodologies. Another reason may be that updated scientific information became available. In such situations the information may be used for possible revision of the EU or national OEL as appropriate.
-
- As it is the risk management measures (RMMs) that provide protection for workers even if DNELs and OELs are numerically different, it may well be that the RMMs identified by REACH registrants (manufacturers /importers) under REACH and by employers under the Chemical Agents Directive/Carcinogens or Mutagens Directive are broadly comparable for a particular use. If the RMMs do not broadly correspond, then the employer should investigate further how to best fulfil the needs and requirements under the EU legislation.
- Communication up and down the REACH supply chain is encouraged. For further guidance on this issue see Guidance for national labour Inspectors on the interaction of REACH, CAD and CMD, Doc 2229_EN
- Although DNELs and OELs are generally not interchangeable, where an OEL exists, manufacturers and importers can use it as a DNEL with respect to the inhalation route. Moreover, in accordance with Section 0.5. of Annex I to REACH Regulation, where available and appropriate, an assessment carried out under EU legislation shall be taken into account in the development of, and reflected in, the Chemical Safety Report and deviations from such assessments must be justified. Consequently, the existence of an EU IOEL as well as OELs recommended by SCOEL should be taken into account when deriving a DNEL and reflected in the Chemical Safety Report. Any deviation should be justified.

Discussion

Where OELs have, in the past, not provided quantitative information on skin absorption, DNELs could provide a more complete assessment allowing the registrant to better describe what needs to be done to control this route of exposure.

In principle, comparing exposure levels with a DNEL can be useful for downstream users. Whilst there is no direct relationship between a DNEL and an OEL, each is useful in establishing what is needed to secure adequate control of exposure.

'Adequate control' under the REACH Regulation means exposure below a DNEL for humans, or below a Predicted No- Effect Concentration (PNEC), for the relevant environmental 'compartment' (e.g. aquatic/sediment, terrestrial, and atmospheric).

Where both a national OEL and a DNEL (for both the same duration and the same route of exposure) have been derived for a substance, **and the risk management measures in the REACH safety data sheet are significantly more restrictive**, employers continue to remain responsible for the protection of their employees, and should seek to resolve the situation with their suppliers to ensure they achieve control of exposure to the required level which may require the employer to conduct their own chemical safety assessment (CSA).

The situation may arrive when the DNEL is lower than the EU or national OEL, but the RMMs that are recommended in order to comply with that DNEL are less stringent than what is required under the national legislation transposing the CAD or the CMD (for example, individual protective measures are recommended by registrants,

whereas under EU OSH legislation priority is given to collective protection measures). In this case, since REACH Regulation applies without prejudice to EU OSH legislation, the employer is still required to ensure adequate prevention and protection (elimination or reduction of risks to a minimum) by applying the hierarchy of risk control measures established under the CAD and the CMD. Also, in presence of a DMEL, the minimization principle under the CMD continues to apply.

Where both a DNEL and OEL are quoted Inspectors should first establish that they are comparing the quoted limits for the same duration and the OEL and DNEL for inhalation route of exposure. Where this is established the RMM should be capable of achieving the DNEL level of exposure;

When a DNEL is lower than an OEL

The RMM to meet the DNEL should ensure that the OEL is also achieved. If the RMMs do not achieve the DNEL then the User should have contacted their supplier and ensured that their own OSH assessment identifies RMMs that allow them to control exposure below the OEL and bring them into compliance with the legal duties under OSH. Suppliers and Registrants will need to resolve the Issue with the quoted RMMs if they are not capable of achieving the DNEL. They will also have to review the DNEL.

When a DNEL is higher than an OEL

Users are required to control exposure to below the OEL by the OSH legislation. If the RMMs suggested by the supplier achieve DNELs but not the OEL because the DNEL is a higher limit then the user will still need to control exposure to below the OEL in order to comply with their duties under OSH.

Where both the DNEL and OEL is the same

Provided the RMM are effective at controlling exposure to below the DNEL they will also be controlling the level to below the OEL, however, as stated above OSH legislation will put the emphasis on collective measures and engineering control to achieve adequate exposure control so the user will still need to assess this to ensure compliance with their duties under OSH.

As there are no OELs set for Skin absorption or ingestion the same issues do not arise in relation to DNELs. The DNELs for these exposure routes will be the primary limit used to assess the effectiveness of the RMMs and the control of exposure.

Glossary

BOELV – Binding Occupational Exposure Limit
CAD – Chemical Agent Directive (98/24/EC)
CMD – Carcinogen and Mutagen Directive (2004/37/EC)
CSA – Chemical Safety Assessment
DMEL – Derived Minimal Effect Level

DNEL – Derived No Effect Level
IOELV – Indicative Occupational Exposure Limit Value
MS – Member State
OEL – Occupational Exposure Limit
RMM – Risk Management Measure
SCOEL – Scientific Committee on Occupational Exposure Limits
STEL – Short Term Exposure Limit
TWA – Time Weighted Average

Further information:

The European Commission has produced a paper on IOELVs and DNELs. IOELVs set by the European Commission can, in certain circumstances, be used as the exposure reference level for inhalation exposure instead of DNELs in the REACH process.

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_b_en.pdf

The EU document: *Guidance for employers on controlling risks from chemicals - Interface between Chemicals Agents Directive and REACH at the workplace:*
<https://osha.europa.eu/en/topics/ds/materials/reach-guidance-employers.pdf>.

GUIDANCE for National Labour Inspectors on the interaction of the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH) (Regulation (EC) No. 1907/2006), the Chemical Agents Directive (CAD) and the Carcinogens and Mutagens Directive (CMD):

https://circabc.europa.eu/sd/a/8905c619-a5b1-4e65-9a98-2b5e9719473c/SLIC_Guidance%20for%20National%20Labour%20Inspectors%20on%20the%20interaction%20of%20the%20REACH,%20CAD%20and%20CMD_EN.pdf