

Dnels, OELs and workplace safety

Facility managers should carefully examine the situation regarding exposure limit values in their EU member state



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In Europe, safe working conditions in industrial sectors dealing with chemicals are regulated both at the EU and national level. The safe use of chemicals is one of the main objectives of the EU REACH Regulation, and instructions on how to do this must be communicated along the supply chain as part of exposure scenarios. Also, the EU health and safety framework Directive and its fourteenth individual Directive (98/24/EC) define general principles of prevention as well as assigning responsibilities and obligations. EU member states have to enforce compliance with these Directives and have established additional national laws.

The key tool for assessing safe working conditions is occupational exposure limits (OELs), which refer to the airborne concentration of harmful chemical agents. The OEL indicates the maximum concentration of a substance a worker may be exposed to over a working lifetime, without suffering acute or chronic health effects. Under REACH, Dnels (derived no-effect levels), which are the levels of exposure to the substance above which humans should not be exposed, are used to ensure the safe use of chemicals. Sometimes, however, OELs and Dnels are contradictory.

What are Dnels and OELs?

Usually, OELs only consider inhalation exposure. Compliance with the OEL can be monitored by measuring the concentration of chemicals in the air of the work environment. If dermal absorption contributes to systemic effects, an additional skin notation may be assigned identifying the possibility of significant uptake through the skin. For substances demonstrating a high skin uptake, a biological exposure limit may be appropriate. The chemical or its metabolites can then be monitored in biological media



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Exposure limits for the workplace are sometimes contradictory – and employers must decide which they should comply with

such as blood or urine. Other routes of uptake, as well as local effects such as skin irritation, are not considered.

In contrast, Dnels are established for several exposure routes (inhalation, dermal, oral) as well as for different durations (short- and long-term) and different human populations, such as workers and consumers. They provide a more complete assessment of what

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needs to be done to control exposure, but also pose a challenge as it is usually impossible to monitor compliance with oral and dermal Dnels.

Both Dnels and OELs are health-based, which means that exposure to these concentrations of substances in the workplace should not harm health. For substances like non-threshold genotoxic carcinogens, which carry a health risk at any exposure level, risk-based

OELs and derived minimal effect levels (Dmels) can be determined. They indicate a sufficiently low level of risk, and working place concentrations have to be kept as low as technically possible, and always below the OEL or Dmel.

How are exposure limits established?

In general, OELs are established by national and international committees, whereas Dnels are set by substance manufacturers or importers as part of REACH registrations. At European level, OELs are proposed by the European Commission's Scientific Committee for Occupational Exposure Limits. The Committee provides recommendations and opinions requested by the Commission, which then may propose an OEL based on this. The member states can establish additional OELs at the national level. In Germany, OELs are defined by the Committee for Hazardous Materials and are reviewed and updated on the basis of recent developments. OELs can be indicative or binding (see below).

Dnels are non-binding levels and must be included in safety data sheets and the registration dossier's chemical safety

report (CSR). They are based on literature data or studies provided for REACH registration. The registration of chemicals with higher tonnage bands requires more data and leads to a more reliable Dnel. A justification for the derivation of Dnels is given in the CSR. However, this document is not publicly available and quality control by Echa is performed in only 5% of all cases. The derivation of OELs by the Commission's scientific committee includes a public consultation, where interested parties can submit comments and additional data, but the resulting lengthy timescale is a drawback of the in-depth quality assurance and review process.

How can a safe use of chemicals be assured?

The risk to humans can be considered to be adequately controlled if the exposure levels do not exceed the appropriate Dnel or OEL. If this is not the case, appropriate risk minimisation measures and operational conditions must be set by conducting a risk assessment.

Occupational safety requires a risk assessment for all hazardous chemicals, whereas REACH requires one only for substances with production volumes over ten tonnes per year. For REACH, the risk assessment is done by the importer or manufacturer of a substance. They have to document all technical, organisational and worker-related measures required for a safe use of the chemical in the CSR and must communicate this information to downstream users via exposure scenarios in extended safety data sheets (eSDSs). According to Directive 98/24/EC, safe use of chemicals has to be ensured by the employer. They must assess and document the risk for the workers, using supplier information or other available sources, and are obliged to minimise risks posed by dangerous agents. The exact arrangements for these procedures are established by the member states.

The eSDS may suggest risk minimisation measures and operational conditions, but the

employer is still responsible for ensuring the safe use of chemicals in their company. They must replace the more general advice in the eSDS with concrete measures adapted to the local conditions. For example, if the eSDS states "appropriate gloves", the employer must specify material and thickness, and even the make, of gloves which should be used in their facility. Exposure scenarios can provide helpful information, which may be used for risk assessments according to national laws. However, a reassessment of safety measures may be necessary if current work practices are not in line with the eSDS.

What if the OEL and Dnel differ?

OELs and Dnels can be different because of varying experimental methods, substance data or its interpretation. In such cases, employers must decide which they are obligated to comply with.

At EU level, indicative occupational exposure limit values (IOELVs) are set (published in the annexes of Commission Directives 2000/39/EC, 2006/15/EC and 2009/161/EU) and member states must establish national OELs which take them into account. Binding occupational exposure limit values (BOELVs) are listed in Annex I of Directives 98/24/EC, 2003/18/EC and 2004/37/EC and member states must establish national OELs which do not exceed them. In most European countries, the national OELs (for example, AGWs in Germany) are legally binding. An exception is Spain, where the majority of national OELs are non-binding recommendations. Dnels, on the other hand, were originally intended for REACH registration and there is no legal obligation to comply with them. However, they are increasingly considered as an assessment value for risk management.

To illustrate the confusing data situation, take the three substances – ethylbenzene, ethylenediamine and oxalic acid – and the obligations for German employers (see table).

For ethylbenzene, a German AGW (Technical Rules for Hazardous Substances 900), an IOELV and a long-term inhalation

Dnel are all available. The Dnel is stricter than the AGW and the IOELV. As AGWs are legally binding in Germany, they have to be respected, whereas the IOELV is not legally binding. The Dnel is also non-binding, but is in this case lower than the OEL. Therefore, employers are advised to contact the national Committee on Hazardous Substances, which may reassess the OEL. (Other countries should contact their relevant authorities.) In the case of ethylenediamine, no OEL is available and the Dnel acts as a guide to assess whether the current protection measures are adequate. For oxalic acid, the AGW is stricter than the Dnel and the IOELV. Here, the employer has to comply with the AGW.

How is the safe use of chemicals controlled and enforced?

Employers are obliged to document risk assessments; the measures taken to reduce risks and the effectiveness of the measures. Workplace measurements must prove compliance with the OEL. If the workplace air concentration is higher than the OEL, additional safety measures must be implemented and a new risk assessment conducted. Workplace measurements are an instrument for national authorities to monitor compliance with national and European OELs. Depending on the gravity of an infringement, the employer may have to improve or fix current safety measures. They can be fined or, in case of severe violations, may have to stop the production process or even be imprisoned.

Although Dnels are not legally binding, they should be considered for a risk assessment if no OEL is available, to ensure the highest possible level on safety for the workers.

Both OELs and Dnels are intended to ensure safe use of hazardous chemicals. While OELs have been used for decades to evaluate safety in workplaces, Dnels are relatively new. Since OELs are established by authorities and are legally binding, they are still the most important limit value for occupational safety. However, as there are more Dnels than OELs, they may become more important in workplace safety.

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Data situation for three substances with national (AGW) and European (IOELV, Dnel) limit values

Name of chemical	CAS number	Dnel, long-term inhalation, systemic(mg/m ³)	AGW (mg/m ³)	IOELV (mg/m ³)
Ethylbenzene	100-41-4	77	88	442
Ethylenediamine	107-15-3	25	-	-
Oxalic acid	144-62-7	4.03	1	-