

## **Harmonising OELs and DNELs at European Level - a position paper reflecting the results at the OEL-conference in Dortmund**

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The conference “Occupational Limit Values for Hazardous Substances – Healthy working conditions in a global economy” in Dortmund discussed the relationship of various exposure levels for chemicals at the workplace: the “OELs - occupational exposure limits” from member states or European institutions, “AOELs - acceptable operator exposure levels” for biocides or pesticides, and “DNELs - derived no effects levels” within the framework of the new REACH regulation.

### **Different starting points**

The starting points of these reference values (OEL, DNEL, AOEL) are different, with discussions during the conference focussing mainly on OELs and DNELs. OELs are explicitly developed for occupational safety and health purposes. They are an instrument for authorities, thus having a distinct regulatory function in individual member states, combined with the option to improve compliance by workplace measurements. The IOELVs and BOELVs as established by DG Employment and the SCOEL-Committee in Luxembourg have a similar function assisting the member states in the establishment of their national OELs and supporting harmonisation.

DNELs are primarily not intended to play a role within occupational safety and health regulations. They represent a tool for the chemical safety assessment of chemicals with a production volume of more than 10 tonnes per year. They serve industry to implement risk management measures if the assumed exposure exceeds the DNEL.

Consequently, there are different actors in the establishment of these reference values: national or international scientific committees and regulatory agencies for OELs on one side and industry experts for DNELs on the other.

These differing starting points of OELs and DNELs might result in diverging views on how to integrate both values into the future procedures for setting up occupational safety and health regulations for chemicals in the workplace under the new policy of REACH. An important success of the conference in Dortmund was that the exponents of these different views were brought together and started a dialog.

### **The differences**

There may be differences in the methodology, how a DNEL or an OEL is derived. Particularly, the handling of uncertainty due to incomplete data is often varies. The REACH guidance for DNELs recommends default factors if substance specific data are missing. For OELs some countries apply similar default factors, but most (as well as SCOEL) argue that expert judgment is needed to fill the gap and no defaults are provided.

One speaker presented some comparisons between DNELs and OELs and concluded that numerical differences may be relevant especially for locally acting substances.

In general it may be assumed that the combined expert knowledge of scientific committees establishing OELs provides a more sound standing than the anticipated input into DNEL derivation: the soundness of DNELs may be heterogeneous and sometimes reduced, because they are developed by many different industrial scientists with different experience, less overview for consistency and more subjective influences.

### **The similarities**

Basically DNELs and OELs could be regarded as aiming at the same objective: a concentration which in general would not result in health impairments of workers after occupational exposure. No different levels of protection are obvious from the definitions. Opinions on the adversity of a specific effect and effect size may vary between different OEL-assessors as much as between OEL-assessors and DNEL-assessors. Thus, this criterion would not specifically discriminate OELs from DNELs.

Both reference values will be used for comparison with the actual (measured or modelled) workplace exposure. It will be requested that risk management measures reduce exposure below the DNEL or the OEL, without having regard to their regulatory status and without questioning their soundness. Consequently, even though the origin and method of derivation of DNEL and OEL might be different, their meaning in practice will be very similar.

### **Coexistence of different approaches?**

At the conference, speakers and discussants had different opinions on the coexistence of OELs and DNELs in the future. Some stressed the differences arguing that both types of values have their own role and should be used in parallel. For others it was confusing to be faced with these two values, e.g., in the safety data sheet, without a clear understanding of the difference.

The interference of the two reference values became obvious, when participants of the conference pointed out that in the near future many more DNELs will be produced per year than OELs can be established by SCOEL or the national committees. By this means the DNEL represents a substitute for a missing OEL with identical functions (possibly with reduced soundness). Moreover, risk management measures are not only linked to DNELs as a level of exposure which should not be exceeded, but current approaches in good work practice similarly scale exposure reduction measures to go below the current OEL. If there exists a measurement strategy and workplace measurements are performed, occupational health administrators will indistinctively refer either to a DNEL or an OEL to evaluate health risks at workplaces. Experts in risk communication at the conference clearly indicated that any numerical difference between both values in practice will lead to confusion and distrust.

Therefore, some speakers voted for a substitution of OELs by DNELs on the long run to have just one reference point for the various actions. Many other participants proposed to retain OELs also in future.

However, coexistence of OELs and DNELs will not be useful if numerically different values will be kept and used in parallel. Thus, the conclusion of some participants of the conference that OELs and DNELs should be “used complementary” and “cannot replace each other” has to be supplemented by the demand that current contradictions between the two reference values are reduced or eliminated and that a framework for integration is provided. Specifically, this demand may be transformed into a number of proposed actions and procedural changes:

- Further efforts should be made to harmonise methodologies for OEL derivation internationally (between national countries and experts committees like SCOEL) and to strive for a harmonisation with the DNEL methodology. Even if some expert committees do not support default values as a baseline, a clear and detailed description of their procedures how to handle uncertainty may already help to converge the respective approaches. Similar international harmonisation was achieved for other regulations on chemicals (like the “globally harmonised system” for classification and labelling).
- For substances with local effects apparently different methodologies or different interpretations of adversity exist between some OEL approaches and the DNEL approach. If confirmed, this endpoint would be a specific area for priority harmonisation (national and international OEL- committees and the respective REACH implementation project representatives)
- Existing substances with relevant international differences in the level of their OELs should be selected as high priority substances for harmonisation within Europe. In a global economy with a growing number of mobile workers within the European Community such differences cannot be accepted and weakens the trust in expert judgement.
- For existing substances with similar or identical OELs in the various European countries this OEL (or the lowest if several similar ones are available) should be adopted as DNEL for REACH related assessments and risk reduction measures, if up-to-date data were regarded for the OEL setting. This proposal is justified by the assumed higher quality of expert committee derived OELs, but does not preclude that in individual cases an OEL may be discarded for the use as DNEL if the OEL is obviously flawed.
- For substances with no current OEL but with a DNEL a procedure for possible intervention by scientific committees could be established, possibly via the Helsinki agency ECHA. This may be important in cases, i) where strong concerns are announced by some stakeholder towards a specific DNEL or ii) where conflicting DNELs are established for identical substances or iii) where other priority considerations by national or international scientific committees lead to a re-examination of the DNEL.
- For substances with no current OEL but with a DNEL, a procedure could be established to adopt this DNEL as a national (or European) reference value for worker protection. As DNELs do not have an immediate impact on workplace regulations, a formal procedure has to be implemented to be able to adopt DNELs (case-by-case) as a national regulatory standard.

- For possible adoption of DNELs as national or European standards a procedure has to be established how scientific committees gain access to those data in the chemicals safety report (CSR) which are relevant for DNEL derivation.
- As no DNELs will generally be established for substances with a production volume of less than 10 tonnes per year, these substances may be in special focus of non-industry committees for OEL setting, where relevant exposure is expected.

Even though some participants at the conference argued that currently there exists no experience on DNELs in practice and one should wait for a future point of time for possible action, we consider it highly relevant that procedures as outlined above are initiated now, in order to avoid confusion when REACH is implemented. The mere coexistence of unchanged OEL approaches and the DNEL approach as currently foreseen in RIP 3.2.2 will inevitably result in such problems.

### **Future function of ECHA**

Participants of the conference requested unanimously the publication of a complete list of DNELs via internet by ECHA with special information on those substances where contradictory DNELs were established for one substance. It should not be possible that different DNELs are used as marketing argument to buy certain products with a higher DNEL, possibly leading to lower obligations for exposure reduction measures. Therefore an immediate process to reach consensus has to be initiated, if such multiple DNELs appear in the envisaged ECHA-list.

Moreover, ECHA in cooperation with other stakeholders should identify conflicting values for OELs vs. DNELs and help to initiate and prioritise harmonisation.

Furthermore, ECHA may have an important function in setting up quality standards for DNEL setting and support procedures to check compliance with those quality standards.

From the results of the conference we conclude that many participants are not fully aware of the problems arising if the OEL approach and the DNEL approach lead to inconsistencies. Some activists in practical occupational safety and health argued that limit values are not that important as there are currently only 2-3% of workplaces where workplace measurements have been performed. To correct this misunderstanding it is important to stress that DNELs (as well as OELs) have an important function in inducing risk management measures even without analytical workplace monitoring. Limit values have no stand alone position but have to be integrated into a more complete strategy of occupational safety and health measures. It would be useful to implement such considerations into the strategy of ECHA. Occupational safety and health with regard to chemicals in the workplace is not any more a matter of just national concerns. With REACH, chemical risk assessment, compliance to safety standards and exposure reduction will become increasingly international. Therefore, national activities on occupational safety and health have to be supplemented by harmonisation on the European level and by inclusion of these considerations into REACH procedures. To this end, the conference in Dortmund hopefully was supportive.