

## On the Outcome of the German Presidency OEL Conference Summary Comments

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Main differences between OELs and DNELs identified were:

### 1. Safety factors:

- **OEL** have **varying safety factors** which are set based on **expert judgement**, while the procedure for setting **DNELs foresee default values for safety factors**, which can in exceptional cases diverge.

### 2. Criteria for setting limit values:

- **Toxicological criteria for setting OEL and DNEL differ especially for local effects.** This is relevant for example for substances acting locally on skin and the respiratory system, which cause some of the major occupational health problems in the EU (skin and respiratory problems)
- **OELs also include information from the workplace level, such as epidemiological data and results from biological monitoring.**
- Where data are not available, manufacturers set a limit based mainly on structure/effect theoretical models, **DNEL setting foresees the use of QSARs** to reduce animal testing, which is not foreseen for OEL testing, where only toxicological effects in animals or humans are considered.
- **OELs are set for substances of concern at workplaces.** The choice of substances for OEL setting includes different criteria as the number of workers potentially exposed, the levels of exposure, the severity of effects, the degree of toxicological knowledge, etc.
- **The main criterion for setting DNEL according to REACH is the amount of the substance produced/marketed/imported.** The cut-off limit is 10 tons annually, averaged on 3 years. Assessments of how many substances may be concerned range from 10000 to a few hundred, as was assessed by one of the Member states (Poland). There might be considerable national differences, depending on industrial structure of the producers' and import situation.
- **DNEL take into account all exposure routes, while OEL setting is based mainly on inhalative exposure, with additional notifications for sensitization and skin permeability.**
- As they are based on workplace exposure, OELs are normally a single numerical figure applying for all workplaces, only exceptionally are they differentiating by work process (e.g. according to technical feasibility), or group of workers (for example biological limit values for pregnant workers, women, etc..). For one substance there might be several DNELs depending for example on the individual assessment of the producers of the substances, or on the exposure considered (workers, consumers, environment)

### 3. Regulatory framework:

- DNELs are a source of toxicological information, a benchmark level for effects, and an indication for setting risk reduction measures, but not a limit that has the same regulatory application as binding OELs. REACH is applicable without prejudice to OSH legislation.
  - The main target group of REACH regulations are producers/manufacturers and importers and in a limited way also users, while the main target group of OSH are the employers.
- **Consultation and quality assessment**
    - **OELs are being set in an established framework, a thorough toxicological and socio-economic evaluation and consultation** of all concerned parties, such as social partners, and with authorities' involvement.
    - DNELs are being set by individual producers/manufacturers without a consultation process. Much of the information that will be provided by REACH is under the responsibility of the manufacturers and people who sell chemicals and not the authorities. **Only a limited proportion of the dossiers with DNELs will be assessed by the ECHA (EU Chemicals Agency).**
  - **Measurement:**
    - **A lot of experience has been gathered for workplace measurements** of chemicals. Workplace measurement methods and frequencies are partly defined in detail in legislation and guidance and a lot of experience is needed to assess exposures. This experience could be beneficial to the chemicals policy area.
    - There is no system in place for assessing whether the DNELs are for example controllable (to take them as an indication for risk reduction measures it needs to be clarified whether exposure at this level can be assessed (measured)).
  - **Link to risk reduction measures:**
    - **Ample experience on good practice is available for workplace prevention** while risk reduction measures as outlined in REACH are still at a conceptual stage.

A majority of participants agreed on the following **general conclusions and recommendations**:

- **DNEL are still in a “conceptual” phase**, no DNELs have been set yet. Experiences need to be made with DNEL setting, for example how to deal with different DNELs set for one substance or how to deal with differences in OEL and DNEL. Consequently, **the DNEL setting process and guidance might need revision**;
- **DNELs should be revised regularly** as OELs are.
- **The information collected for DNEL setting will be a valuable source for the OEL setting process**, but cannot replace OEL setting. DNELs cannot replace OELs because they are based on different criteria, different exposure routes, different toxicological evaluations, different legislation, different legal application. In the same way, OEL setting cannot replace DNEL setting, which is foreseen for all substances above a certain amount produced/marketed/imported, irrespective

of other criteria of relevance to workplace use. OELs partly include socioeconomic considerations, technical criteria of feasibility and the ability to measure the substance at the level of the OEL.

- **The OELs and DNELs will be complementary.** As based on different legislation, they cannot replace each other. **DNELs are not to be regarded as regulatory in themselves** as opposed to binding OELs and can not replace them.
- Some of the participants raised **concern over the quality assessment of DNELs** and other information provided under REACH. **Proposals to remedy** were:
  - to set up a publicly available database of DNELs published on the ECHA Website.
  - to regularly check and revise these lists for incoherent data (for example different DNELs for the same use by different producers)
  - to foresee revision and adjustment processes for such occasions in guidance and procedures.
- Also, chemicals experts tend to see these issues very much from a substance, toxicological-research point of view, while OSH people see these topics very much from a process, prevention-workplace measures point of view, which includes for example combined exposures of different substances, but also with other risk factors such as thermal risks and physical strain contributing to the uptake of dangerous substances.
- **Risk reduction measures based on DNELs should benefit from OSH good practice and should be compatible with principles applied in workplace prevention.**

Other points mentioned:

- One of the big worries of OSH experts was, along with some of the issues mentioned above, the influence on being able to apply OSH regulations (for example, the hierarchy in control measures or risk assessment or substitution provisions), because something is set elsewhere and accepted by another regulatory body. It was therefore **proposed to mainstream the principles of OSH legislation** (substitution and hierarchy of control measures according to the Chemical agents Directive 98/24) **into guidance for REACH**, and more specifically in DNEL-related guidance.
- OSH regulations foresee taking more than one view into consideration, including at the enterprise level, where OSH experts always have more than one interlocutor with varying expertise. That shapes their communication ability at different levels (you'll have to explain something to an expert or to someone who has no expertise in the topic) and guidance for OSH. **Communication between different parties is essential. It was therefore proposed to base REACH implementation on a broad basis**, for example
  - to include a risk communication expert in the staff list of the ECHA
  - to include worker representatives and OSH experts in the different advisory bodies and groups of the ECHA (for example expertise on workplace risk assessment, OSH prevention, occupational epidemiology, biological monitoring, workplace measurements, etc.)
- The processes for setting limit values, defining acceptable exposure levels and outlining risk reduction measures should be seen as a **cyclic process**, which means that **assessments and procedures need to be regularly revised.**

Experiences on such approaches, for example with risk assessment in occupational health, which aims at continuous improvement of workplace situations, could be beneficial.

- Also, many of the REACH regulations will apply with a certain **delay in time**, which means that there will be none of the announced benefits for still some time ahead.

**The German Ministry for Labor and Social Affairs** who had organized the conference **would like to organize in cooperation with the Agency a follow-up conference on risk reduction measures, possibly under the umbrella of EW 2008.**