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"Derived-No-Effect-Levels" (DNEL)

Occupational exposure limit values (OELV) are fixed in current Occupational Safety and Health (OSH) law (basing on Article 137 of the EC Treaty).

OSH law is not <u>directly</u> affected by REACH, but: Role of DNEL would need to be defined precisely in OSH law.

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Already existing problem: different national OELV and no formal harmonisation procedure on EU level as with classification and labelling.

New problem added: different DNEL by different registrants

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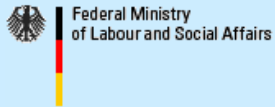
To what extent are OELV mandatory in Member States?

How will DNEL fit in different legal systems?

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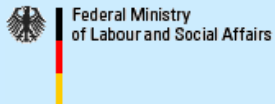
Deduction of DNEL for instance on the basis of subacute toxicity data is possible in principle and a desirable element of REACH.

However REACH stipulates different DNEL – inhalative/dermal; workers/consumers

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Deduction of DNEL is a task of registrants and not of scientific committees – this is a new element in line with the basic principle of REACH:

shift of burden to industry

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But:

Is the deduction of DNEL simple enough so that the system will work?

Is it enough to evaluate 5 % of the dossiers and therewith the soundness of DNEL deductions?

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OELV so far only exist for a very limited number of substances – but under REACH, DNEL will finally be available for approximately **10.000** substances.

What can be proposed for the **20.000** substances in the tonnage range from 1 to 10 tons per year which are also sold on the market?

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Should the scientific committees responsible for the deduction of OELV focus on substances for which no DNEL will be derived under REACH in the future?

1. substances not manufactured or imported but occuring in the workplace, i.e. welding fumes, wood dust, silica dust etc.
2. low tonnage substances (< 10 tons per year)
3. intermediates

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Open questions (solutions?)

- EU process for harmonising OELV

- EU process for harmonising DNEL

- EU concept for OELV and DNEL (hierarchy…)

- EU concept for inclusion of DNEL in work place risk assessment

- EU concept for providing adequate protection of workers without limit values