Integration of DNEL into Polish regulations for occupational safety and health

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Summary

According to REACH legal text, DNELs should be derived for all substances subject to registration that are placed on market in quantities of 10 tonnes and more per year as a part of chemical safety assessment. DNELs represent a level of exposure above which humans should not be exposed. The purpose of DNELs is to act as benchmark for determining adequate control of exposure for specific scenarios. Since considerable number of scenarios may cover occupational exposure a problem of integrating DNELs into national legislation on occupational safety and health becomes of crucial importance.
In Poland occupational health and safety in chemical and related industries are covered by the Ordinance of the Minister of Health of 30.12.2004 on the protection of health of workers from the risks related to chemical agents at work containing provisions of Council Directive 98/24/EC. According to this document the employer is obliged to assess any risks to the safety and health of workers arising from the presence of chemical agents taking into account, among others, the level, type and duration of exposure as well as appropriate established occupational exposure values. Polish occupational exposure values called Maximum Admissible Concentrations (MAC) are published by the Minister of Labour and Social Policy (based on documented proposals from the Interdepartmental Commission for MACs for Agents Harmful to Health in the Work Environment) and are legally binding. The MACs are very conservative, restrictive and aimed to protect the worker and his descendants from any adverse health effects assuming exposure 40 hr/week for 40 years. Furthermore, there is legislation requiring from the employers to carry out measurements of chemical agents in work environment with frequency depending on a concentration/MAC ratio and keep records of such measurements. The recommended methods of measurements are developed for that purpose in the form of national standards (PN).
Actually, it is hard to compare DNELs to MACs and discuss a possibility to incorporate DNELS into OSH legislation since the available Reference Technical Guidance Document on human health hazard assessment is only a preliminary proposal and no calculated and widely accepted DNEL values are existing. Risk characterization under REACH and exposure assessment under existing OHS legislation seem to be quite similar processeses; in both situations DNELs and MACs, respectively, serve as reference values. However, for any future discussions on a possible role of DNELs all similarities and differences in the process of DNEL and MAC development and setting need to be named and made clear to the possible users.

For chemicals that exhibit a threshold effect the starting point for both DNEL (occupational exposure by inhalation) and MAC is NOAEL (or LOAEL) for the critical effect, preferably from human data or from chronic toxicity inhalation studies on experimental animals. The difference is in the values of assessment (uncertainty) factors reflecting interspecies and intraspecies differences, differences in duration of exposure, issues related to dose-response relationship and quality of data are different and need to be harmonized if consistency of values derived from the same starting point using the same data base is to be achieved. Fortunately, the proposed methodology for deriving DMELs for mutagens and genotoxic carcinogens is in good agreement with that applied in Poland in establishment of MAC values for this group of compounds. It is largely based on linear extrapolation from animal carcinogenity dose-response data to predict a level of exposure that would be associated with a defined low cancer risk in humans (increased lifetime cancer risk in the range of 10^{-3} to 10^{-5}).

Very often raised question is that national lists of OELs include only limited number of compounds when compared to thousands of chemical for which DNELs need to be derived. It, however, should not be a serious problem in Poland. There are over 500 chemicals on the MAC list while no more than 800 ten tonnes/year chemicals were manufactured/imported to Poland in 2004, most of them having MAC values assigned. The Interdepartmental Commission for MACs for Agents Harmful to Health in the Work Environment is able to review appr. 20 documentations of proposed MAC values a year, which would help to fill the possible gap.

Other issue that need to be raised is the quality of the assessment resulting in a DNEL value. MAC documentations are reviewed and toxicity data carefully assessed by the Interdepartmental Commission for MACs for Agents Harmful to Health in the Work Environment composed of the leading specialists in toxicology, occupational pathology and analytical chemistry. It is not clear who would guarantee the quality of assessments resulting in DNELs. DNELs may, therefore, serve as a kind of guidelines, providing orientation for downstream users and preliminary criteria for risk characterization/assessment in cases where no MAC having a sound scientific bases is available. Substances with only DNEL values derived should have been given priority in the activity of the MAC Commission. However, DNELs as tentative criteria for the assessment of long-term occupational exposure in situations, where MAC values are not available need to be formally introduced into Polish OSH legislation. For practical reasons it cannot be done earlier than the first DNEL values will appear and their quality evaluated.

For any criterion of occupational exposure by inhalation (regardless OEL or DNEL) an analytical method is required enabling determination air concentrations of a substance in question. It must be therefore decided who will be responsible for the development and validation of appropriate methods. In Poland, formally, no MAC value is established if no appropriate validated analytical method is available in the form of the national standard enabling determination of compliance . This procedure needs to be extended to possible “DNEL chemicals” taking advantage of capacities of scientific institutions engaged in development of methods for “MAC chemicals”.

Currently Nofer Institute of Occupational Medicine and the Bureau for Chemical Substances and Preparations carry on series of intensive training on REACH

regulations not only for manufacturers/importers of chemicals but also for inspectors from the State Sanitary Inspectorate and the State Labour Inspection which shall result, among others, in better understanding of the DNEL concept and DNEL related issues.

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Polish law on occupational health and safety (OSH)

- **Ordinance of the Minister of Health of 30.12.2004 on the protection of health of workers from the risks related to chemical agents at work**

  (provisions of Directive 98/24/EC)

  The employer is obliged to assess any risk to the safety and health of workers arising from the presence of chemical agents, taking into consideration:

-the circumstances of work including amounts of chemicals

-the level, type and duration of exposure;

-any occupational exposure limit values or biological limit values, if established;

Polish law on occupational health and safety (OSH), cntd

- **Ordinance of the Minister of Health of 20.04.2005 on measurements of harmful agents in work environment**

-the employer is obliged to carry on measurements of harmful agents in work environment and keep measurement records;

-frequency of measurements depend on a concentration/OEL ratio;

-measurements must be carried out using national (PN) or international (ISO, EN) standard methods

Occupational Exposure Limits in Poland

- Maximum Admissible Concentration (MAC)
- Proposed by the MAC Commission, established by the Minister of Labour and Social Policy
- Starting point:

-**NOAEL or LOAEL for substances with systemic activity**

-**human data or RD_{50} for irritants**

- Use of uncertainty factors
- Ceiling MACs for substances highly irritating or dangerous to life
- STEL (2x15 min. during a workshift)
- Analytical method required
- Conservative and restrictive approach

Maximum Admissible Concentration (MAC) - definition

- time-weighted average concentration for a conventional 8-hour workday, to which it is believed that a worker may be exposed throughout his/her whole working life without adverse health effect to himself/herself (also when retired) or his/her descendants

DNELs

- Required for 10 tonnes/yr chemicals
- DNELs (inhalation) for occupational exposure comparable to MACs
- Starting point: NOAEL
- Use of assessment factors
- Only preliminary procedure available
- Quality not known
- Assessment factors differ from uncertainty factors used by the Polish MAC Commission

Derivation of reference values for occupational exposure from NOAEL (LOAEL)

DNEL	(inhalation)	MAC	(Poland)
Assessment	factor	Uncertainty	factor
Interspecies	**AS, 2.5**	**Interspecies and route-to-route extrapolation**	**max.10**
Intraspecies	**5**	**Intraspecies**	**max. 3**
Exposure duration subacute to chronic	**6**	**Exposure duration subacute to chronic**	**max. 3**
Dose response	**1(deviations possible)**	**LOAEL to NOAEL**	**max. 3**
Route-to-route extrapolation	**1(deviations possible)**	**Incompleteness of data**	**max. 5**

Other relevant issues

- Number of 10 tonnes/yr chemicals in Poland: 834 (in 2004)
- Number of MAC values: appr.520, capacity to produce 20 documentations/yr
- Quality of DNELs: need for expert reassessment
- No tradition of „private OELs" in Poland
- Possible status of DNELs: tentative guidelines for chemicals with no MAC values established
- Analytical methods required for determination of compliance (MAC) or RCR (DNEL)

Conclusions

- Intended legal status of DNEL – temporary guidelines for the assessment of risk from chemicals with no MACs
- Assessment factors and uncertainty factors need to be harmonized (e.g. introduction of allometric scaling)
- „DNEL only" chemicals need to be given priority in the activity of the MAC Commission

Conclusions, cntd

- Analytical methods need to be developed and validated for „DNEL chemicals" as it is in case of „MAC" chemicals
- Responsibility for development of appropriate analytical methods should be determined
- Intensive training in REACH legislation including the concept of DNEL needs to be continued