Position of the Austrian Compensation Board [1] concerning DMELs

REACH Safety Data Sheet and the proposal of DMEL (Derived Minimal Effect Levels): Rejection due to impracticability and due to conflict with the REACH Regulation – Position *)

According to the REACH Regulation, for substances for which no Derived No-Effect Level (DNEL) can be determined – i.e. in particular for genotoxic carcinogens –, a qualitative risk minimisation and risk assessment shall be carried out (Annex I para 6.5). REACH does not provide for the determination of limit values for genotoxic carcinogens and for mutagens (Article 60). Rather, REACH aims to progressively replace carcinogens and other substances of very high concern by suitable alternative substances or technologies (Article 55) by subjecting them to authorisation requirements.

Certain "Guidance Documents on Chemical Safety Assessment" published by the European Chemicals Agency (ECHA), namely Part R.8 and Part B deviate from the abovementioned aim of REACH. Without a legal basis in REACH, these guidance documents lay down the derivation of so called "Derived Minimal Effect Levels" (DMEL) for mutagens and genotoxic carcinogens. The statistical-scientific elements of their derivation are described extensively.

DNEL and DMEL shall not be confused. DNEL ("Derived No-Effect Levels"), as provided for in REACH, are health based limit values. In contrast, **DMEL** ("Derived Minimal Effect Levels") are risk based limit values. It is evident that the knowledge of the exposure–risk relationship (similar to a dose–response relationship) alone is not sufficient to determine a DMEL. Instead, for establishing a risk based limit value e.g. for carcinogens, a decision has to be reached concerning the tolerable reference cancer risk. This decision cannot be taken on a scientific or technical level. It is, rather, a societal issue and requires a decision on a political level.

The Guidance Document R.8 recognises this requirement ("has to be decided on a policy level") but avoids further elaboration and refers to its Annex R.8-14. There, various cancer risks being discussed or seen as tolerable around the world are simply listed. Lifetime cancer risks ranging from 1 in 10,000.000 up to 1 in 1,000 can be found there. In other words, some institutions deem it acceptable that among ten million people exposed to a carcinogen one person develops cancer; other ones deem it tolerable that this happens for one person among thousand.

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[1] *The AUVA (Allgemeine Unfallversicherungsanstalt) is the Austrian Workers' Compensation Board for Occupational Risks for approximately 3 million employed persons, 0.4 million self-employed persons and 1.3 million school children and students. AUVA is entrusted with the prevention of health damages caused by hazardous substances at work. In particular, this includes the prevention of occupational cancer caused by exposure to carcinogenic substances at work. (See also http://www.auva.at/english)*

*) *The items and demands contained in the paper may be of special actuality since the deadline for registration of substances with CMR properties is December 1st 2010. For CMR substances exceeding 10 tons/year a Chemical Safety Report has to be submitted and Exposure Scenarios have to be attached to safety data sheets.*

It is evident and undisputed that the determination of a "DMEL value" requires two specifications: **firstly**, the sufficient knowledge of the exposure-risk relationship (which can be derived scientifically); **secondly**, the decision on the acceptable cancer risk (which can be determined solely politically).

Consequently we can state that the Guidance Document R.8 advocates the determination of DMEL values but misses to determine one of the two indispensable factors, namely the "tolerable" cancer risk. Without it, a DMEL value cannot be determined.

According to Guidance Documents, DMEL values would have to be included in the safety data sheet. Consequently, the responsibility to "choose" a tolerable cancer risk would in practice be shifted to individual enterprises. If a producer – prudently – wants to avoid committing himself, he or she will list DMEL values for several tolerable cancer risks and leave the "choice" to the downstream user. However, enterprises neither have the professional capacity nor the legal competency to assume this far-reaching responsibility (up to claims of compensation by occupational compensation boards). It cannot be accepted that the moral and legal responsibility to decide on cancer risks of third parties is shifted to individual persons or enterprises.

As mentioned, the DMEL concept has no legal basis in the REACH regulation. Therefore, there is no obligation to apply the DMEL concept. Those responsible for developing safety data sheets shall be able to rely on the Guidance Documents. The registrant cannot be expected to legally analyse if a Guidance Document contradicts or exceeds the REACH regulation.

Neither for the chemical industry nor for the numerous enterprises processing chemicals, the DMEL concept according to the Guidance Document is – factually and legally – applicable.

In accordance with the REACH regulation, AUVA therefore proposes to focus on the substitution of carcinogenic and mutagenic substances and/or subjecting them to authorisation requirements. **If at all, DMEL values shall only be determined after consensus has been reached on EU or EEA level which cancer risk arising from handling carcinogens or mutagens is deemed tolerable.**

Furthermore, AUVA reiterates its claim that health and safety of the working population have to be protected to the same degree as the general public. In all example calculations given in the Guidance Document, the "tolerable reference cancer risk" is set ten times higher for occupational exposure than for the general population. This differentiation is resolutely rejected as it is neither factually nor ethically justified[2]. In the view of AUVA, the required EU (or EEA) wide consensus on the societally tolerated cancer risk has to provide for the same level of protection for each group of persons.

Starting from this uniform risk level, for a given substance in a second step different limit values can result, e.g. as a consequence of different exposure times. For example, for the same risk

[2] Additionally this differentiation conflicts with Article 31 of the Charter of Fundamental Rights of the European Union which came into force in December 2009. Article 31 states: Every worker has the right to working conditions which respect his or her health, safety and *dignity*. Article 1 sounds: Human dignity is inviolable. It must be respected and protected.

level, the limit value for a given carcinogen will be lower based on 24 hour exposure (general population) compared to an exposure during working hours. For occupationally exposed persons, the occupational cancer risk would anyway be additional to the cancer risk to which they are subjected as members of the general population.

The more the guidance developed by ECHA becomes an essential tool for the practical application of REACH, the more it is necessary that their contents comply with the aim of the REACH regulation "to ensure a high level of protection of human health" (Article 1). In no case, the Guidance Documents shall contain procedures which contradict REACH or are impracticable. **Therefore it is to be demanded that all provisions in Guidance Documents R.8 and B concerning DMEL values are suspended.**

In the context of the practice of enterprises and authorities, this implies the strong recommendation neither to determine nor to communicate DMEL values for the time being.

Only, after an EU wide decision on the acceptable cancer risk has been reached and published, the determination and communication of DMEL values would be possible. In any case, it would be subsidiary to the aim of substitution and/or authorisation laid down in REACH. As REACH does not provide for limit values for genotoxic carcinogens, even then DMEL values would be specified on a voluntary basis.

Side note on the concept of "acceptable risk" in Germany

The concept of risk based limit values for carcinogenic substances at work (cf. in detail "Announcement 910 on Hazardous Substances"[3] of the Committee on Hazardous Substances [AGS], published by the Federal Ministry of Labour and Social Affairs [BMAS]) distinguishes clearly between a "tolerable risk" and a considerably lower "acceptable risk". If the tolerable risk is exceeded ("red range"), extensive protective measures have to be taken immediately. If the risk is below the acceptable risk ("green range") general hygiene and occupational protection measures (including information and training) are deemed sufficient[4]; in this case, too, substitution efforts are mandatory.

In the range between the higher "tolerable risk" and the lower "acceptable risk" ("yellow range"), the employer must set up a concept of risk control measures describing how in a limited time frame exposure will be reduced below the acceptable risk, and implement this plan.

In contrast, the DMEL concept in the ECHA Guidance Documents rests on a single (as yet un-determined) risk level below which the risk is deemed “adequately controlled”. Of course, for carcinogens a (lower) cancer risk remains even below this acceptable risk. Up to now, the DMEL concept – in contrast to the German model – does not include measures to reduce the risk below the acceptable risk. It therefore does not contribute to reduce cancer risks as far as possible.

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[3] www.baua.de/nn_79754/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/pdf/Announcement-910.pdf (english version)

[4] The acceptable risk for occupational cancer has been consented – after political discussion – in Germany at a value of 4 : 100,000 referring to a working lifetime of 40 years. On the establishment of these reference risk representatives of the chemical industry had a leading role.

How to appraise a given DMEL?

Starting at December 2010[5] the safety data sheet may comprise a DMEL (Derived Minimal Effect Level) in case of a carcinogenic substance or component. As already has been mentioned above every DMEL must be based on a presupposed cancer risk. Nevertheless an acceptable cancer risk is not laid down or even discussed neither in the EU nor in Austria. In Germany (and similarly in the Nederland) an agreement for an acceptable risk of 4 : 100.000 (see footnote 4) has been reached.

It has to be clearly stated that a DMEL without referring to an acceptable risk is of no value and practically cannot be used.

A DMEL based on a higher cancer risk as the one set in Germany cannot be accepted by no means (see footnote 4) due to cultural considerations. It has to be rejected that in the Central European civilization with its traditionally high and elaborated technical standards, to which also Austria is belonging, a higher risk is acceptable than the one which was held for achievable in Germany, even by representatives of the chemical industry.

As there does not exist in Austria any consensus regarding an acceptable reference risk for cancer, there cannot be given any well-based recommendation how to behave in respect of a delivered DMEL.

But is has to be stressed that according the Austrian legislation regarding safety and health at the workplace any exposition to cancer-causing substances has to be minimized by any means, notwithstanding the costs. Low DMEL values could give a strong hint in the legally demanded process of workplace assessment, that the laid down measures[6] should be revised and retouched for achieving a further reduction of exposure.

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[5] Registration deadline for carcinogenic substances with an import or production volume of more than 1 ton per year and registrant. For carcinogenic substances with a volume of more than 10 t/yr a chemical safety report has to be submitted and exposure scenarios have to be attached to the safety data sheet.

[6] In an extended safety data sheet with exposure scenarios there should be included risk management measures. By adhering to these measures the DMEL should not be exceeded. Risk management measures proposed in the exposure scenario must be proven before being applied if they are in accordance with the order of priority of measures given in the Chemical Agents Directive (98/24/EC, Article 6; §§ 42 and 43 ASchG).