Parallel Session 2

Non-Threshold Carcinogens

1. Identification of methodologies and approaches

Valid documentations are available:

- Risk assessment methodologies & approaches by SCHER, SCCP, SCENIHR (prelim. Report of 24. Oct. 2008)
- IPCS Mode-of Action Framework (different publications)

2. Particular relevant problems

- The threshold concept is generally accepted for nongenotoxic carcinogens and is plausible for certain genotoxic carcinogens
- Carcinogenicity, especially quantitative, generally cannot be predicted based on in vivo data only. They may point to hazard only. Importance of toxicokinetics.
- Dose selection problems important!
- The WoE (weight of evidence) -> MoE approach appears appropriate. But how large should the MoE be?
- BMD / T-25 calculations again depend on the quality of data; they can be used if quanti tative data are needed.
- The current classification system is only hazard-based. This is not the scientific state of the art.

3. Identify best practices

- There are guidance procedures from EFSA, JECFA, IPCS, EPA that can be used.
- Exposure assessment is frequently the weak point (-> other workgroup).
- Case study developments should be enforced.

4. Recommendations to improve practices

- We need an inventory/repository of existing case studies (include- MoA and regulatory status).
- Research in the MoA area should be internationally supported as to contribute to the development of case studies
- The translation of scientific findings into regulation is inadequate and thus necessary

5. Recommendations to be followed up

- The present hazard-based classification system should be re-evaluated to incorporate elements of risk, to the extent possible.
  - Integrate existing elements (such as of EPA, national bodies, SCOEL).
  - A task group should be committed with developing a white paper.
  - Continue a global dialogue, as also GHS is to be addressed.