Administrative requirements for a harmonised terminology for classification of anomalies

- **Outline**

  - **Science and objectivity**
  - **Aim of the DevTox Project**
  - **Further reqirements**

Main areas of the DevTox Project

- **Providing public information on current topics in the field of developmental toxicology with a primary emphasis on the harmonization of the nomenclature.**
- **Establishing an electronic database consisting of historical and experimental data for the evaluation and comparison of developmental toxicity studies.**
- **Promoting the harmonization and standardization of nomenclature and diagnostic criteria in the field of developmental toxicology.**

Further requirements for the extension of the DEvTox Projekt

- **Extension of the database in order to record the data of the different developmental studies**
- **Extension of the database in order to record the results of the consensus efforts of scientific criteria for classification**
- **Integration of the database into the EU-regulations for chemicals in order to get an official status**
- **Establishment of an Science Advisory Board**

Science Advisory Board

Functions of a Science Advisory Board could include:

- **reviewing the quality, relevance and transparency of the scientific and technical information of the DevTox Database,**
- **reviewing research programs in conjunction with the DevTox Database,**
- **reviewing generic approaches to regulatory matters including guidelines**
- **advising the responsible institution on scientific matters in developmental toxicology**
- **preparing consensus conferences for important matters of hazard and risk assessment in developmental toxicology**

Organizational Arrangements
Use of a Scientific Review Panel

1. Independent scientific review of risk assessments improves the scientific quality of the assessments and strengthens them against later challenge.

2. Standing and continuing review panels appear to be the most useful review bodies.

3. Review panels are best qualified to give scientific advice when they are composed of scientists who are highly qualified in the appropriate disciplines.

4. Review panels will be most effective if they have the authority to review risk assessments before announcement of the agencies intended regulatory actions.

5. Independent panels with authority to review risk assessments for all agency regulatory decisions, including decisions not to act, are more likely to ensure that agency decisions rest on valid scientific grounds.

6. Written reviews help to ensure agency consideration of scientific criticism.