

Risk Assessment Based on Human Toxicology Data - Operations and Structures

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What is Risk Assessment

- **Exposure**
Contact of a Person with a substance
 - intended
 - unintended
 - circumstances
 - doses
- **Hazard**
Toxic properties of the substance
 - signs and symptoms in humans
 - severeness of symptoms

Risk

- Risk can be defined as the probability of the occurrence of health effects in relation to an event of exposure
- Low exposure dose
- Toxicity at high doses } Low risk
- High exposure dose
- Toxicity at low doses } high risk

Getting Information in Toxicology

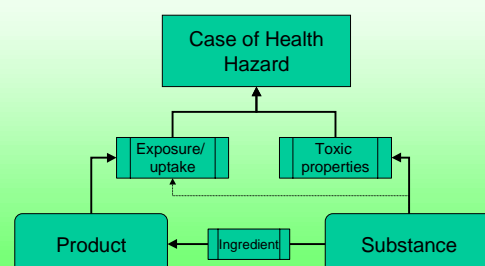
Major questions

- is this substance toxic?
- If **no**, no further evaluation is needed
- If **yes**, the question must be expanded
 - Is there a probability of contact?
 - Are there specific situations for contacts?
 - With which dose might the contact occur?

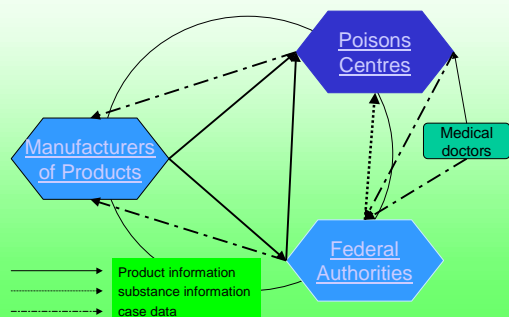
Which information do we need to assess the risk?

- Information about the toxic characteristics of the substance of concern
- Information about products in which the substance occurs as an ingredient
- Statistical and epidemiologic data to evaluate the incidence of poisonings

Structure of Information



Structure of Partners (Germany)



Poisons Centres

Germany has 10 poison centres with different specialisation (childrens, adults, general)

- Poisons Centres give advice to medical personnell and to the public in the case of poisoning
- Poisons centres collect „Experiences“ about toxic cases
- Documentation of poisons centres allow statistical evaluations of the incidences of calls/events

Information Needs of PC's

- Product information
 - ingredients of products (total list)
- Substance information
 - toxic and kinetic properties
 - therapeutic measures
 - clinical testing
- Case information
 - Course of similar cases?

What can Poison Centres provide?

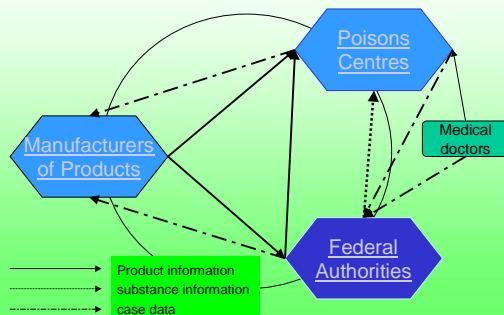
- Evaluations of cases and toxicological evaluations about toxic effects in humans
- Evaluations of severeness of cases
- Statistical material about incidence of cases
 - it should be mentioned that many cases registered are only „calls“ and not „cases“

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Special situation of PC's in Germany

- More than one Poison Centre
 - Need for co-ordination and co-operation
- Work of poison centres is partly regulated by law (chemicals act)
- Different specialisation
- Different coverage

Structure of Partners (Germany)



Federal authorities

- Federal Institute for Health Protection of Consumers and Veterinary Medicine
 Federal Environmental Office
- Competent Authorities for Risk Assessment
 - Involved in Regulations
 - Involved in prevention
 - Information of the public
 - Co-operation with other institutions

What can Authorities provide?

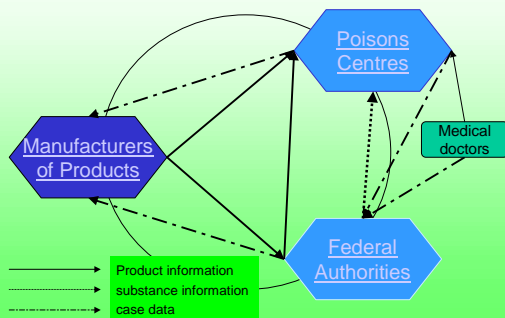
- Information material about substances from toxicological evaluations
- Information about chemical products (in Germany regulated by law)

What do Authorities need?

- Information material about toxic cases
- Statistics about cases

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Structure of Partners (Germany)



Manufacturers and distributors

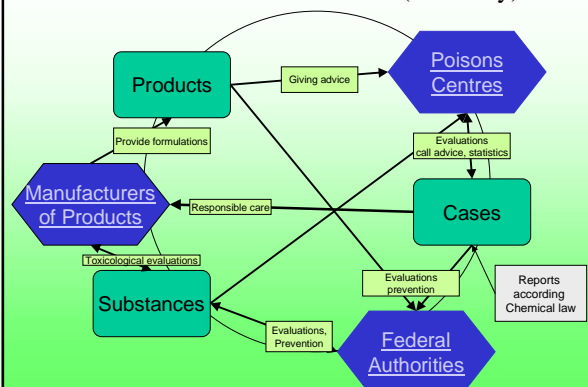
- They produce substances and/or products
 - Product information is confidential
 - Some manufacturers test substance for notification
 - They are responsible for the safety of their products
- Manufacturers are therefore interested in getting information about hazardous effects from their products.

Providing information about substances and products by manufacturers

- Many manufacturers provide information about ingredients of formulations on a voluntary level to the BgVV and PC's
- There is a regulatory obligation to submit formulations classified as very toxic, toxic, corrosive, sensitizing, carcinogenic, mutagenic and teratogenic, as well as for biocides to the BgVV, and for detergents to the UBA.

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Structure of Interest (Germany)



Regulations by Chemicals Act

- Producers must report their formulations to the BgVV, which forwards them to the PC's
- Medical doctors (not PC's) must report cases of poisonings to the BgVV
- PC's report their experiences from their work to the BgVV

Objectives of co-operation (I)

- Providing the information for Poisons Centres needed to give adequate advice
- Providing the information for agencies needed for Risk Assessment
 - Aim: Risk Management Activities
- Providing the information for industry for responsible care
 - immediate measures (responsible care)
 - statistical information (once a year)

Objectives for co-operation (II)

- Evaluations of substances due to human toxicologic needs (poison centre monographs)
- Identifications of substances of concern (for prevention)

co-operation between partners involved in human toxicology in Germany

1. Step: Project „EVA“:

- Development of a common structure for the documentation of cases.
- Classification system for products to enable systematic statistical evaluations of calls

co-operation between partners involved in human toxicology in Germany

2. Step: Project „TDI“:

- Development of a common structure for product information for all german poison centres, and for superior agencies
- Development of rules for exchanging information about substances
- Restructure case documentation and linking them to products.



Some international Projects dealing with Electronic Data Documentation

- **EUROTOXNET** (a standard data format for case documentation and for harmonised annual report)
⇒ EU-harmonised reports
- **ENS-CARE CAP** (a joined project with PC's from Brussels, Lisbon, London, Milan, Lille)
- **INTOX** (worldwide project organised by the WHO-IPCS)
⇒ harmonised documentation of cases, substance monographs, product writer for poison centres)
- **several meetings** have been organised in Lille to discuss co-operation between PC's in Europe concerning data exchange

Value of data transmission?

- Industry don't want multiple partners
- Harmonisation process will be improved due to the characterisation of of data fields and their definitions
 - Standard exchange format for product information
 - Standard exchange format for case data reports to be developed
 - Harmonised annual report?
 - Standards for substance identification