

Toxicological Information- und Data Network - A European Challenge? Workshop, Berlin 9th - 10th September, 2002

Risk Assessment based on human toxicology data - Co-operations and Structures

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Introduction

Risk can be understood as the result of the probability of the occurrence of an event in comparison to health effects. Chemical risks may be characterised by looking for the circumstances of the contact (exposure) and the toxicologic properties of a substance. In regulatory toxicology, the risks are mainly focused to animal experiments. However, to learn about human risks, it is convincingly needed to look for exposure and effects in humans.

The aim of risk assessment is to secure the population from hazards due to exposures by intended but also from unintended uses. It is therefore of great importance to document the knowledge which can be drawn from the evaluation of human poisonings.

Objectives

In the current project TDI the co-operation between different institutions have been checked, with the aim of reducing risks by an enhancement of knowledge. This is based on a harmonised protocol for reporting data and is planned to be further developed. For this purpose, the structure for identifying health hazards and prevention is explained. Risk evaluation is based on several tasks as shown in figure 1. In general, the duties are arranged as (i) information gathering, (ii) documentation of health effects and their evaluation, and (iii) risk characterisation.

Gathering Information

- Product information, which is needed to identify the toxic relevant substance or the combination of substances of in case of poisonings but also in the prevention of exposures
- substance information, what are the toxicologic properties of a substance and the preferred therapeutic measures
- evaluation of cases to study the most important toxic effects
 - from the calls (poison centres)
 - from reports according to chemical regulations (BGGV)
 - other

Aim: To increase the knowledge and to confirm therapeutic measures.

Method: providing information in co-operation of all the partners involved (Poison centres, manufacturers of products, other agencies)

Documentation of health effects and their evaluation

- standard protocol of cases
- evaluation of frequency of poisoning events
- characterisation of circumstances of toxic exposures

Aim: statistical data on frequency and severity of poisonings, identification of the most important toxic substances

Method: Documentation of poisonings

Risk characterisation and reduction measures

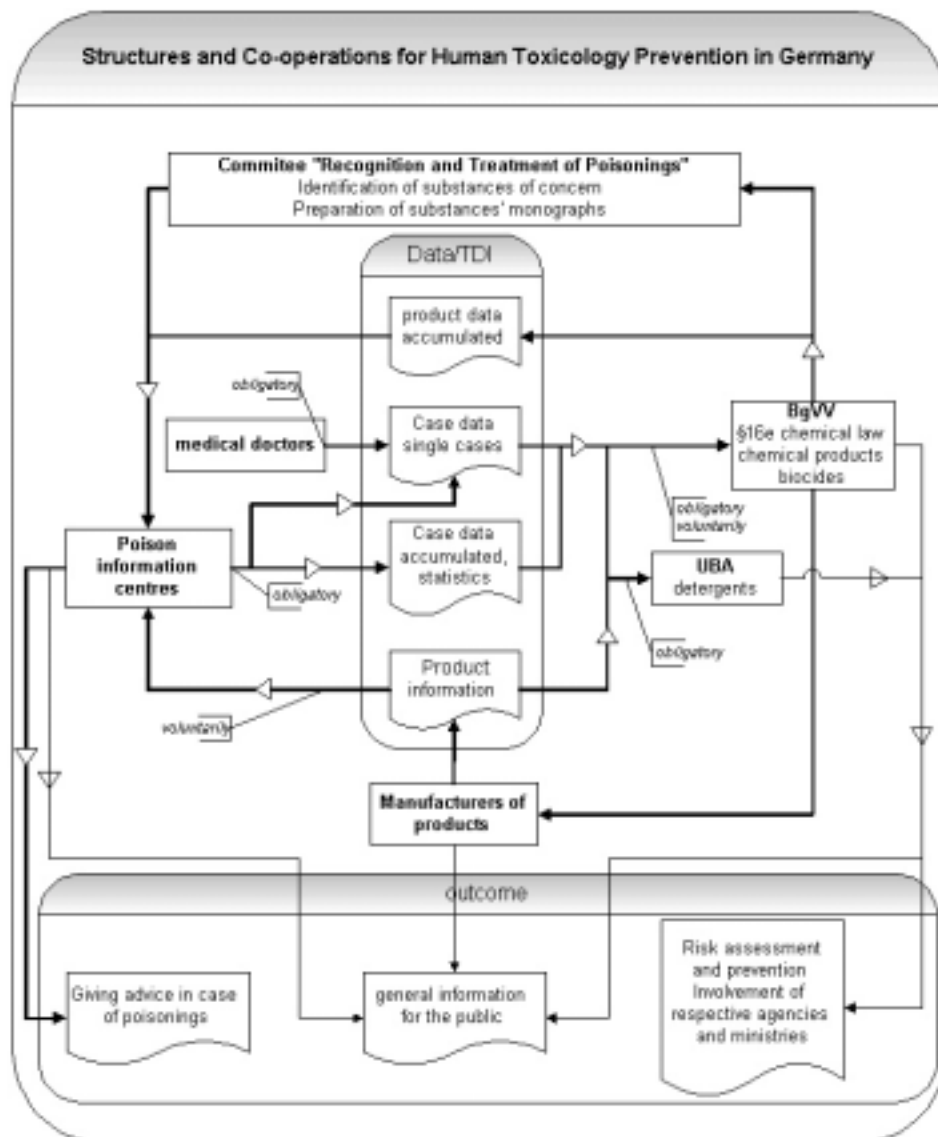
- Identification of substances of concern by evaluations of cases and their occurrence in chemical products
- Information of poison centres
- Co-operation with manufacturers
- Information of the responsible agencies and ministries

Aim: Characterisation of toxic properties in humans of chemical substances
Information of responsible partners

Method: Identification of substances having concern in humans and preparation of substances monographs
Risk assessment reports

Structures

Structures of gathering information in human toxicology in Germany is depicted in the figure. Tree main partners have to be mentioned, 1. the 10 poison centres, 2. the Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV), 3. the Federal Environmental Agency, and, 4. the manufacturers of chemical products.



The endpoint of the work may be defined as the identification and characterisation of a hazardous substance or product for humans.

For this purpose, information on cases where humans develop symptoms from toxic reactions after the exposure to chemicals the data sources and exchange of information should be understood as a cycle where each partner can put information in. Each partner, however, has different tasks. The poison centres will primarily give advice in case of poisonings, they document their cases for statistical and toxicological evaluations. These tasks are laid down in the chemical legislation. The BgVV deals with preventive measures and legislative consequences under the provisions of the chemical law. Due to legislation, the BgVV receives formulations of chemical products and forwards them to the poison centres. It also assesses cases of toxic exposures that are reported from medical doctors directly, by e.g. comparison with poison centre information.

The BgVV also informs the industry as well as the respective ministries about toxic reactions concerning the respective products and ask for preventive measures. Information from poisonings are also used for exposure assessments and risk evaluations in the context of the assessment of chemicals due the existing chemicals regulations.

Manufacturers of chemical products provide information about formulations, on an obligatory basis due to legislation, and, voluntarily. An obligation for notification exist for products classified as corrosive, very toxic, and toxic, as well as for biocidal products.

As a common task, and due to the level of information, all partners work to enhance the knowledge about toxic effects in humans from chemicals. The committee "Recognition and Treatment of Poisonings" identifies substances that have concern and prepares substance monographs for the use in poison centres. Furthermore, the substances are listed in an order of toxicologic relevance as a bases for decision making.

Outcome

For poison centres, this outcome will result in an increased knowledge for giving advice, for the BgVV it means that risks can be better characterized for the initiation of preventive measures. Industry is also able inform their customers about possible hazards. Classification and labelling may also be improved.

The TDI project has been initiated to enhance co-operation, and to harmonize structures and operations between the partners. The first step was to built up a strict and close system for providing information of chemical products. It is planned to expand the system also to substance information and case documentation.