

Toxicological Information- und Data Network - A European Challenge?

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DOCUMENTATION OF PRODUCTDATA FOR RISK PREVENTION

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The proper documentation and assessment of health impairments of chemical products or substances is based in similar manner on the data about clinical symptoms/signs and exposure and the complete and exact product data set. Especially in case of poisonings, which often were emergencies, advisors in the centres or toxicologists have to have rapid access to formulations of products involved in computer assisted product data bases. Otherwise wrong or dangerous advice, misinterpretation of the product's health impairment and false toxicovigilance measures can be initiated. Knowing this, the German legislator create requirements for product and case data bases.

German Regulatory Measures:

Under the regulations of the German Chemicals Act physicians, who are consulted for treatment or evaluation of sequelae of diseases, are requested to report health effects from real or suspected exposures to chemical substances. The BgVV was designated as the Documentation and Assessment Centre for Poisonings. As the most important pre-condition, in different regulations, manufacturers or distributors of products are obliged to submit formulations of chemical products (1990), cosmetics (1998) and biocidal preparations (2002) to the BgVV to provide the German PCCs with product data information. They again have been put under obligation to assist the BgVV by submission of data on health hazards resulting from their work. So we started the German toxicological information and data-network under regulatory measures already in 1990.

The Process of Product documentation

Before products launch the German market, manufacturers/distributors of dangerous substances and cosmetic products are obliged to submit their formulations to the BgVV. In addition industry sends up to 2,000 product formulations per year on a voluntary basis. The main part of the dangerous formulations and voluntary reports were send by form. Through initiatives of the BgVV and Industrial Associations more than 90% of the cosmetic preparations now we easily transfer by electronic data exchange. The non-electronical data is collected by documentalists into the BgVV product database and linked with definite product categories, which were approved in the TDI-precursor research project EVA (Data Collection and Data Analysis in Cases of Poisoning in the Poison Information and Treatment Centres in the Federal Republic of Germany) 1991-1994. Additionally the product data set is linked and supplemented with e.g synonyms, CAS-number, R/S-phrases, first aid measures etc. and merged with the electronical cosmetic data set for rapid data exchange. The data base is unloaded monthly for PCC updates on CD-ROM. Since 2001 the German PCCs

receive more than 130,000 product records for their data bases. The machine readable BgVV product data set allows extensive analysis and can be linked with cases of poisonings. Therefore the BgVV data set is primarily qualified for product monitoring activities for risk prevention.

Product Monitoring

A: General Aspects:

Product Information System: As a consequence of documentation and evaluation of health hazards, a "Toxicovigilance" procedure for rapid information to industry, ministries and industrial associations on the health risks of products utilizing the base of immediate and summarised reports has been inaugurated in 1998 under the following criteria: 1) In the case of serious health effects from acute or chronic product exposures the information is immediately directed to the producers, distributors, associations and the government. 2) The producers are informed on health effects in relation with their products annually in a summarized form to enable them to improve their product safety (responsible care). *Results:* From 1998 -2000 we had 10 immediate reports. The periodically summarised reports were sent to more than 170 manufactures/distributors. These reports led to additional warnings, classification and labelling (e.g. benzalkonium chloride corrosive > 7.5%) and promoted the development of substitutes.

Product labelling: A general BgVV analysis of the product labels especially in the fast-growing and fluctuating international markets of household and cosmetic products has shown, that there must be better information on the labels and packages to identify the real trade-name in emergencies and side-effects of products. To improve the product identification on the basis of the true trade name, the BgVV has initiated investigations to preserve an "Easy-to-Identify Area" on the labels of consumer products in close proximity to the barcode. *Results:* The German Standardization Committee has drafted a proposal for a European standardization project (CEN) in 2002.

B: Products at Risk:

Paints, solvents, glues and pesticides: To evaluate the circumstances of exposures during accidents, a study was initiated to collect data describing the circumstances of exposures to a number of selected chemical products. Cases to be studied are selected from the reports sent to the BgVV, and questionnaires are to be filled out by the exposed persons to collect product related data: *Results of the exposure study :* In the first half year of the study in 2002 we collected 141 cases (82 cases we got by the routine reports of the physicians), 53 cases were sent by specialists in Environmental Medicine and 6 patients reported their cases themselves. Most of the cases could be referred to the path of exposure „inhalation“ and the product-groups "solvents" (60 cases). Pesticides were most frequent (N = 45). The majority of the exposures were acute with a wide variation of exposure scenarios.

Hydrocarbons: Since lamp oils involve the highest risk of severe health effects in infants and small children due to household chemicals in Germany, the BgVV initiated different measures for risk minimisation: child-resistant closures, warnings, new R 65-Phrase, EC-standardisation of oil-lamps in accordance with the competent ministries, which at least led to sale restrictions from July 1, 2000 onwards in all EU countries. This has consequently led to the introduction of lamp oil substitutes into the

German and EU market. To follow the consequences, a BgVV monitory study "Dangerous Lamp Oils" was initiated in conjunction with 450 German Childrens' Hospitals. *Results of the lamp oil study:* Data have shown that the exchange of paraffins by fatty acid esters obviously leads to a marked reduction of risk.

Products at risk for the elderly: Some cases of mistaken, but fatal, ingestion of chemical preparations, namely detergents and disinfectants, have shown that elderly persons may represent a population at risk, particularly for confused persons.

Results: With a round table of experts the BgVV discussed products at risk and appropriate measures to be initiated for risk reduction. For personnel in hospitals/nursing homes/ elderly residentials tailor made information was spread in five different languages.

Conclusions:

Knowledge of substances gained by systematic documentation and analysis of adverse effects of chemicals in humans due to poisonings via a powerful product data base is a valuable tool for a realistic assessment. This instrument can also serve as a basis for classification and labelling of hazardous products and substances, give arguments for educational advertising and create the basis for co-operation with PCCs, manufacturers/distributors, industrial associations and ministries. Although the BgVV product data monitoring system with more than 130,000 product-files is incomplete in a terms of a national product register, it serves as an excellent instrument to create hypotheses, to initiate single risk reduction activities and to perform additional studies for a better and precise risk characterisation. To link these German activities with other European Centres, at least in the sense of a rapid information system, this should be proximate essential step in human risk reduction strategies.