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RISK ASSESSMENT AT THE NATIONAL INSTITUTE OF PUBLIC HEALTH A MEDICAL TOXICOLOGIST'S VIEW

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Historical perspective

Interdisciplinary Risk Assessment Team

At the National Institute of Public Health (NIPH) a systematic approach to toxicological risk assessment according to international guidelines[1,2] dates back to 1999. At the time, the NIPH was appointed by the Ministry of Health (MH) to take over the coordination of a newly formed risk assessment team consisting of nine professionals from various institutions (NIPH, Institute for Pharmacology and Experimental Toxicology, Institute of Forensic Medicine, Poisons Centre, National Chemical Institute, Public Health Institute Maribor and National Chemicals Bureau) with expertise and/or interest to develop their careers in risk assessment of chemicals. These professionals were to become proficient in all aspects of risk assessment (human health and the environment) by the date of Slovenian entry to the European Union (EU) in 2004. While performing its first task, risk assessment of a herbicide atrazine[3], the team identified a number of problems, such as dissipation of data among various institutions, poor communication within the institutions including lack of systematic data exchange, lack of appropriate models for the estimation of fate and behaviour of chemicals in the local environment, and a serious shortage of financial and manpower resources. Adequate capacity building, improved communication among relevant national institutions including systematic data exchange, and cooperation with other central and eastern European countries in the process of accession to the EU were proposed as short term priority activities.[4] Due to lack of resources, namely a majority of team members working on team tasks on occasional part time (and some of them even on a no–fee) basis, organisational difficulties, and differences of opinion considering further development of the team and its tasks, the team gradually ceased to operate. The NIPH concentrated its manpower resources in its toxicology group which was transformed to a Department of Toxicology in 2004.

Department of Toxicology

Assuring and promoting chemical safety in order to prevent acute and chronic poisoning were prime objectives of the Department of Toxicology. The main activities included risk assessment for human health, public health aspects of toxicovigilance, research, and teaching. Risk assessment procedures were carried out according to current legislation and internationally accepted guidance. We were included in national safety evaluations of consumer products namely food contact materials[5-8], cosmetics and toys, foodstuffs,[9,10] and drinking water.[11] We were also actively involved in European rapid alert systems for food and feed (RASFF), consumer products (RAPEX), and drugs of abuse (EWS EMCDDA).

We proposed a uniform format for the preparation of toxicological risk assessment (http://www.ivz.si/Mp.aspx?ni=124&pi=5&_5_id=257&_5_PageIndex=0&_5_groupId=252&_5_newsCategory=&_5_action=ShowNewsFull&pl=124-5.0).

Within toxicovigilance activities we prepared literature reviews on endocrine disrupting chemicals and proposals for human biomonitoring.[12-15] We analyzed trends of hospitalisation due to poisonings in children and young people from 1999 – 2008 in comparison to the national Poisons Centre enquiries.[16]

In cooperation with and with financial support of the National Fitosanitary Administration we participated in the registration procedure of plant protection products (PPP). Our role included hazard assessment of PPP, risk assessment for operators, workers and bystanders, and assessment of toxicological information, first aid and treatment advice supplied with individual preparations.[17] From 2003 – 2010 we assessed over 150 PPP submitted for registration in Slovenia. We also reviewed draft assessment reports for inclusion of active substances in Annex I of Directive 91/414/EEC and regularly attended Pesticide Risk Assessment Peer Review meetings at the European Food Safety Authority. We took active part in the working party on agricultural questions (Pesticides/PPP) in the process of preparation of regulations concerning placing of PPP on the market, and the Directive for Community action to achieve a sustainable use of pesticides.

Two research projects went on at the department: *Dose response relationship in low dose exposure to atropine and scopolamine in food*[18] and an international project *OSIRIS – Optimized strategies for risk assessment of industrial chemicals through integration of non-test and test information.*[19, 20]

To maintain and develop our own expertise attention was paid to continuous professional development, while we also taught at undergraduate and postgraduate courses nationally and internationally. To increase the awareness of the general public on benefits and risks of chemicals and to promote chemical safety we translated a book, *Poison Paradox,* by the distinguished professor of biochemical toxicology, John Timbrell, into Slovene.[21] We also contributed to the manual for training of PPP salesmen and users.[22] The information on various aspects of chemical safety was regularly placed on our website: http://www.ivz.si/Mp.aspx?ni=22.

At the reorganisation of the NIPH on November 1, 2010, the Department of Toxicology was abolished without any analysis or explanation. The reorganization caused demoralisation and confusion. Staff relocation, dispersion of responsibilities, and delayed communication hindered efficiency and further development.

A view to the future

The Directorate of Public Health at the MH has recently expressed an intent to finance the foundation of a new centre at the NIPH which should aim to:

- identify existent and new environmental risks to human health
- assess the risks
- propose appropriate risk reduction measures
- establish a network of professionals from other institutions involved in various aspects of risk assessment.

We welcome the establishment of an adequately supported **Centre for Risk Assessment** at the NIPH and are proposing the following activities:

- to identify institutions with capacities in risk assessment, i.e. regional public health institutes, academia, private research institutions, as well as, some governmental agencies and inspectorates of the MH, Ministry of Agriculture, Forestry and Food, Ministry of Environment and Spatial Planning and non governmental institutions
- to review »the state of the science/art« in the area of risk assessment procedures of newly emerging and existent chemical, microbiological and physical risks
- to analyse the methodological approaches including deviations from the international guidelines
- to prepare national protocols according to internationally accepted methodologies
- to identify resource gaps
- to develop algorithms of communication among the institutions
- to develop algorithms of systematic data sharing and data exchange
- to define national priorities for risk assessment based on:
  - hazard identification and characterisation
  - exposure assessment using the existent human biomonitoring data, environmental monitoring data and/or mathematical modelling
  - size of the exposed population
  - vulnerability of the exposed population
- to prepare priority risk assessments in order to propose risk reduction measures and to test the effectiveness of the established communication network
- to develop protocols for rapid response in cases of environmental accidents and bioterrorism
- to plan, design and carry out research projects where appropriate
- to maintain the existing and build up new capacities by continuous professional development
- to introduce new methodologies where appropriate
- to cooperate with international networks at the EU and the World Health Organisation level
- to disseminate the information to the public
- to participate in teaching.

Based on acquired knowledge and expertise outlined in historical perspectives, we believe that it is feasible to implement the above plan in four years with a multidisciplinary team of 12 whole time equivalents (WTE) with a relevant background such as biochemistry, biology, chemistry, environmental chemistry, food science, medicine, microbiology, physics, sanitary engineering, veterinary medicine and administrative support (at least 1 WTE). However, establishing an effective network of professionals from other institutions including data sharing and data exchange may present a major challenge and may not be possible on good will and ethical grounds only, but might require legal regulation.

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