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Organization**

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**Assessment of chemical risks for human health:
training and capacity building sub-regional
workshop for Estonia, Latvia and Lithuania**

Vilnius, Lithuania, 14–15 October 2015

Report

ABSTRACT

The use of chemical risk assessment as a basis for advising governments on the development of policies to prevent the negative impact of chemicals on health, and on planning and evaluating risk-reduction measures to this end, is more and more common. Strengthening capacity at the national and subregional levels in a coherent, coordinated, and resource-efficient way is crucial to enabling the translation of relevant knowledge gathered by WHO and EU into policy and action. During the subregional training and capacity building workshop for Estonia, Latvia and Lithuania held in Vilnius, Lithuania, on 14-15 October 2015, available methods of assessing chemical risks and the feasibility of implementing them in the countries were introduced and discussed. Gaps and needs related to building capacity at the national and subregional levels were also addressed.

KEYWORDS

CHEMICAL SAFETY
RISK ASSESSMENT
HAZARDOUS SUBSTANCES
RAPID RISK ASSESSMENT

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CONTENTS

INTRODUCTION	1
Opening of the workshop	1
Scope and Purpose	1
WHO METHODOLOGY FOR ASSESSING CUMULATIVE CHEMICAL RISKS TO HUMAN HEALTH... 2	
WHO/International Programme on Chemical Safety (IPCS) framework on risk assessment of combined exposure to multiple chemicals	2
CUMULATIVE RISK ASSESSMENT: CHALLENGES AND OPPORTUNITIES FOR IMPLEMENTATION AT THE NATIONAL LEVEL (WORKING-GROUP DISCUSSIONS)	3
ASSESSMENT OF CHEMICAL SAFETY WITHIN THE FRAME OF EU LEGISLATION (REACH).....	4
RAPID RISK ASSESSMENT OF EMERGENCY SITUATIONS INVOLVING CHEMICALS	5
STRENGTHENING CAPACITY FOR THE IMPLEMENTATION OF CHEMICAL-RISK ASSESSMENT (ROUND-TABLE DISCUSSION)	6
CONCLUSIONS AND RECOMMENDATIONS	7
ANNEX 1. PROGRAMME	8
ANNEX 2. PARTICIPANTS	9

INTRODUCTION

The subregional training and capacity building workshop for Estonia, Latvia and Lithuania, held in Vilnius, Lithuania, on 14–15 October 2015, was organized within the framework of the Biennial Collaborative Agreements for 2014-2015 between Estonia, Latvia and Lithuania and WHO. A high-level representative of the Ministry of Health of Lithuania, 26 experts from the target countries (Estonia, Latvia and Lithuania) took part, as well as WHO temporary advisers and WHO staff.

The workshop was organized within the framework of the Biennial Collaborative Agreements between WHO and Estonia, Latvia and Lithuania for 2014-2015, and supported by the Ministry for the Environment, Nature Conservation, Building and Nuclear Safety of Germany.

Opening of the workshop

Audrius Sceponevicius, Director, Department of Public Health, Ministry of Health of Lithuania, opened the meeting. In welcoming the participants, he stressed the importance of the meeting for Lithuania where the development of the chemical sector – a leading branch of the economy – should not create unacceptable risks for human health and the environment. On behalf of the participants and WHO, Ingrida Zurlyte, Head, WHO Country Office, Lithuania, thanked the Ministry of Health of Lithuania for its support in organizing the meeting and wished the participants a productive meeting.

Romualdas Sabaliauskas, Director, Centre for Health Education and Disease, Vilnius, Lithuania, was elected as Chairman; Jolita Kruopiene, Senior Researcher, and Jolanta Dvarioniene, Senior Researcher, Institute of Environmental Engineering, Kaunas Technology University, were elected as Rapporteurs.

Scope and Purpose

The aim of the meeting was to:

- introduce and demonstrate the applicability of the WHO framework for the assessment of combined exposure to multiple chemicals;
- provide an update on the European Union (EU) risk-assessment requirements relating to the registration, evaluation and notification of chemicals;
- provide information on the development of rapid risk assessment methods in EU and the WHO European Region.

The provisional programme (Annex 1) was adopted by the participants (Annex 2).

Currently, the methods used to assess combined exposure to multiple chemicals (WHO) and chemical safety (EU) (in compliance with EU regulation EC/1907/2006 “Registration, Evaluation, Authorisation and Restriction of Chemical substances” (REACH)) and to carry out rapid risk assessment during chemical emergencies (WHO, EU) include the same elements (hazard and exposure assessment, risk characterization and evaluation), the methodology chosen being determined by the purpose of the risk assessment. During the workshop, in discussing a coherent joint approach to building the capacity necessary for risk assessment at the national level, the relevant WHO recommendations and EU requirements were taken into consideration. It was noted

that risk assessment was not an aim in itself but a process towards characterizing a risk and deciding on measures to reduce it. Policy-making is based on the evidence provided by risk assessments. There are weighty arguments for harmonizing the approaches to risk communication and risk assessment at the national, regional and global levels in order to avoid contradictory information.

WHO METHODOLOGY FOR ASSESSING CUMULATIVE CHEMICAL RISKS TO HUMAN HEALTH

WHO/International Programme on Chemical Safety (IPCS) framework on risk assessment of combined exposure to multiple chemicals¹

The presentation included: an explanation of the terminology related to the different types of exposure (aggregated, cumulative and combined); an introduction to the basic postulates of toxicology; a description of the tiered approach to assessing combined exposure to multiple chemicals recommended by WHO/IPCS, including a demonstration of its applicability in the case of risks caused by carbamates; and, information about the step-by-step assessment of hazards/exposure and the databases available for this purpose, as well as for calculating the risks for different population groups, children and adults, and evaluating the risks to combined exposure.

Issues addressed during the ensuing discussion included the criteria for choosing either a risk-evaluation approach, for example, the use of a reference value (such as, acceptable daily intake (ADI), tolerable daily intake (TDI), acute reference dose (ARfD), acceptable operator exposure level (AOEL), based on the no observed adverse effect level (NOAEL)/lowest observed adverse effect level (LOAEL) and the safety factor), or the benchmark dose (BMD). Most legislation requires the use of a reference value (resulting in a hazard index or % reference value). An alternative approach – for example, the evaluation of substances already on the market, or for which regulation is not strictly limited to NOAEL-based reference values – is to use BMD as the point of departure for risk assessment. The margin of exposure between BMD and exposure should be considered safe (in most cases, at least a factor 100).

Another important aspect is the choice of safety factors (or margins of exposure) for carcinogens (groups 1A and 1B), mutagens and reproductive toxicants, and other highly toxic chemicals; for example, in countries where scientific data has confirmed a link between higher levels of neurobehavioural disorders in children and lead exposure, stricter safety factors could be applied,

Applying the WHO framework has many advantages. For example, risk assessment can be carried out with limited data at the national level, in combination with those available in relevant international databases, and risk-reduction measures can be decided at all stages of the assessment.

The participants carried out a risk-assessment exercise, using a training module developed by the Netherlands National Institute for Public Health and the Environment (RIVM). The case study dealt with 10 crop-protection products (CPPs) that can affect the central nervous system. These CPPs, which share some structural similarities, have been detected in fruits and vegetables, as well as in drinking water. CPPs have a broad range of use. Based on information on the hazards of CPPs and exposure to them via water and food, the participants calculated the hazards quotient for individual

¹ Meek M E (Bette), Boobis AR, Crofton KM, Heinemeyer G, Van Raaij M, Vickers C. Risk assessment of combined exposure to multiple chemicals: a WHO/IPCS framework. *Regulatory Toxicology and Pharmacology*. 2011;60: S1-S14 (http://ac.els-cdn.com/S0273230011000638/1-s2.0-S0273230011000638-main.pdf?_tid=c3f2326c-9b69-11e5-88c5-00000aacb35d&acdnat=1449331606_1947609f7fe28452e527aaff03f419c2, accessed 5 December 2015).

CPPs and the hazards index for the combined exposure of children and adults at Tier 0, Tier 1 and Tier 2 levels.

Current developments in cumulative risk assessment in EU included the implementation of scientific projects aimed at the further development of combined-exposure risk assessment, the results of which were outlined during the workshop. The driving motive behind this research was EC Regulation 1107/2009 on plant protection products (PPP) and its requirements to ensure the safety of PPP residues for human health, taking into account known cumulative and synergistic effects, and to develop a methodology for the assessment of these effects. Studies within the project, Aggregate and Cumulative Risk of Pesticides: an On-Line Integrated Strategy (ACROPOLIS), have resulted in the development published guidance in which a framework for performing probabilistic dietary exposure assessments (both single and multiple compounds) has been established.² In the guidance, optimistic and pessimistic model runs are proposed with the aim of estimating, respectively, the possible lower and upper exposure ranges in a population. Testing these models leads to the conclusion that a “realistic” scenario, combining the available optimistic and pessimistic options, should be developed. This is one of the aims of the EuroMix project (A tiered strategy for risk assessment of mixtures of multiple chemicals), which was launched in 2015. This project will also deliver a refined grouping strategy for cumulative assessment and a globally harmonized approach to testing chemical mixtures in silico and in vitro.

CUMULATIVE RISK ASSESSMENT: CHALLENGES AND OPPORTUNITIES FOR IMPLEMENTATION AT THE NATIONAL LEVEL (WORKING-GROUP DISCUSSIONS)

In working groups, the participants discussed the following questions.

- What are the main gaps limiting risk assessment and what are the priorities?
- What kind of information is available at the national level and what kind of information can be obtained from international databases?
- Is it feasible to implement cumulative risk assessment at the national level?

In Estonia and Latvia, food safety is the main priority for the assessment of combined exposure to chemicals because of the high level of public concern about this area. In this connection, many data on the chemical contamination of food are available at the national level. Another priority is consumer safety though the available data on exposure assessment in this area are limited and there is a lack of resources to generate them. A lack of human biomonitoring data is one of the factors limiting the assessment of cumulative exposure and its related risks.

In Lithuania, risk assessment is carried out by various institutions, such as the health and environmental authorities and the Plant Protection Service. Their legal bases and mandates vary as do the methods they use. For example, the Environmental Protection Agency has a high level of responsibility in the area of chemicals, which includes dealing with issues related to the REACH regulation, the health authorities are responsible for the safety of biocides, residues in food, and the management of emergency situations, and the Plant Protection Service assesses the cumulative risks of complex PPPs comprising more than one active substance. Companies are responsible for the

² Guidance on the use of probabilistic methodology for modelling dietary exposure to pesticide residues. EFSA Journal. 2012;10(10):2839 (<http://www.efsa.europa.eu/en/efsajournal/pub/2839>, accessed 15 December 2015).

provision of information about chemicals, according to legislation, as well as risk assessment at the workplace.

In conducting risk assessments, information about chemicals hazards is taken mainly from international databases (European Chemicals Agency (ECHA), European Food Safety Authority (EFSA), WHO, etc.). Local data are used for exposure assessment: food safety is the area in which monitoring is most developed; data on air, water and soil pollution are also collected, but to a limited degree.

Lithuania is a member of the European Network on Biomonitoring and, though development in this area is underway, not many data are available yet; it is anticipated that more exposure-assessment data will be generated in the near future.

In addition to food and consumer products, which were recognized as priority areas for cumulative risk assessment by the Estonian and Latvian representatives during the workshop, the Lithuanian representatives considered it important to assess the cumulative risks of indoor pollution, especially for the most vulnerable population groups, such as children and elderly people.

More attention should be paid to strengthening capacity in the area of chemical risk and safety evaluation at the national level in all countries. For example, in Lithuania, the lack of data and other information necessary to fulfil the REACH requirements related to restriction of hazardous substances limits the country's possibility of influencing the restriction process at the EU level.

ASSESSMENT OF CHEMICAL SAFETY WITHIN THE FRAME OF EU LEGISLATION (REACH)

The presentation focused on the assessment of chemical safety within REACH, which was developed to: protect human health and the environment; enforce substitution of the most hazardous chemicals; enhance competitiveness and innovation; and promote the development of alternative methods of assessing substance hazards. As of May 2013, 20 318 substances had been registered under REACH by 41 718 registrants.

Specific attention was paid to the responsibilities of the different players involved in implementing REACH. Producers or importers of chemical substances are obliged to register them, providing information on their tonnage and risks to human health and the environment (for example, ecotoxicity). These companies should ensure the implementation of risk communication and protective measures in the supply chain and at their facilities and workplaces. They are also responsible for applying for authorizations.

As the registration centre, the European Chemicals Agency (ECHA) checks applications for completeness and compliance, develops testing proposals, and evaluates the registration dossiers. At least 5% of all registered dossiers need to be checked for compliance by the ECHA.

REACH is enforced under the supervision of the national authorities. Governments are responsible for ensuring screening, evaluating and identifying substances, and for regulating those of concern. It was noted that the authorization and restriction of substances are legal instruments for use in minimizing the risks.

Currently, 163 substances of very high concern (SVHC) – such as, carcinogens (categories 1A or 1B), mutagenic and reprotoxic (CMR) chemicals; persistent, bioaccumulative and toxic (PBT) substances and very persistent and very bioaccumulative (vPvB) substances; and potential endocrine-disrupting

chemicals (EDCs), PBT and vPvB – are included in ECHA’s Candidate List of SVHC and 31 SVHC are listed in Annex XIV of the REACH regulation. To ensure a higher level of protection of human health and the environment, ECHA developed the SVHC Roadmap to 2020 and is leading its implementation process.

The experience of the German Environment Agency (UBA) in substance evaluation under REACH and in regulatory activities (for example, the preparation of proposals for authorization or restriction of 4,4'-[(isopropylidene)bis(p-phenyleneoxy)]diphthalic dianhydride (BPADA) and perfluorinated alkyl substances) was used to demonstrate to the participants how REACH works.

The objectives of the SVHC Road Map to 2020 are challenging and all Member States should contribute to the process of achieving them. UBA is willing to support the Baltic countries in building capacity for and gathering experience in substance evaluation, for example through cooperation projects, exchange of staff, etc.

In all of the countries represented in the workshop, the chemical industry plays some role in economic development. The largest chemical companies in Lithuania are the producers of fertilizers and refinery and construction materials. Many other companies use chemical substances, for example, in producing textiles and processing metal. In Latvia, pharmaceutical and industrial companies produce organic compounds, which play the main role in the chemical market. In Estonia, where the chemical industry is less developed, there are some small or medium-sized enterprises that produce or use chemical substances.

Based on Germany’s experience, society has a significant role to play in facilitating substitutions. National authorities use television and the information resources of their institutions for consumer protection to draw the public’s attention to information about SVHC, for example, on ECHA’s website, in publications, etc. If the general public is well-informed about chemical risks, it can help to influence the phasing out of hazardous substances and the use of safer alternatives. In the United Kingdom, the public is receptive to the information provided and the alternatives promoted by ECHA. In Lithuania, the national authorities are responsible for informing the public about chemical risks.

RAPID RISK ASSESSMENT OF EMERGENCY SITUATIONS INVOLVING CHEMICALS

The implementation of both the International Health Regulations (IHR) and EU Decision 1082/2013/EU on serious cross-border threats to health requires rapid risk assessment.

Decision 1082/2013/EU requires the notification, ad-hoc monitoring and assessment of chemical risks, as well as the coordination of public health measures following serious cross-border threats to health as a result of biological, chemical and environmental events, and events of unknown origin. It applies to all EU Member States and is comparable to IHR.

Several projects (Alerting, Reporting and Surveillance System for Chemical Health Threats (ASHT), European Chemical Emergency Network (ECHEMNET), etc.) have been implemented at the EU level to provide a scientific basis for enforcing the Decision.

As a first step, European and global media monitoring systems and reporting systems of other sectors were used to collect information on different kinds of events. Subsequently, EU-wide reporting systems, such as the Rapid Alerting System for Chemicals (RASCHEM) and the Early

Warning Response System (EWRS), were created by the appropriate EU authorities. All of this action has helped in the development of rapid-risk-assessment tools and procedures under the Decision.

When risk assessments related to a serious cross-border threat to health fall outside the mandates of EU agencies, the European Commission requests expert groups to carry them out.

Four documents are required to support the management of public health events: (i) a hazard statement outlining the key aspects of the event; (ii) a summary of the key injuries related to the threat (case definition); (iii) a chemical-emergency risk-management (CERM) monograph, including the hazard statement, the case definition and a rapid risk assessment; and (iv) a rapid risk assessment derived from the hazard statement, the case definition, and the opinions expressed in the CERM monograph and of experts involved. According to Decision 1082/2013/EU, each Member State is required to create the necessary capacities for emergency situations. The health sector should be involved in assessing the risks and communicating information about them to the public.

A common approach is applied for rapid risk assessment and the following data are included in the relevant documents: event-control data; hazard data; exposure data; clinical case data; public health factors; cross-sectoral factors; societal factors; and risk characterization. However, in comparison to classic risk assessment, rapid risk assessment has some specific characteristics: for example, it is often associated with greater uncertainty because of the short delivery time required (24–36 hours), which limits the opportunity to engage with experts and generate new data. Despite this, rapid risk assessment has to be solid, reproducible and transparent, and the language used must be easy for risk managers to understand with a view to decision-making.

Group work on the rapid risk assessment of an explosion in a chemical factory helped the participants to learn more about the application of rapid-risk-assessment methods and the preparation of relevant documents. Using what they had learned, the participants discussed the immediate and longer-term public health risks associated with exposure to toxic ingredients and what could be done to reduce the risk of further exposure.

The participants highlighted the role of poisons centres and laboratories in assessing risks and in deciding on the preventive and recovery measures to be taken in emergency situations.

STRENGTHENING CAPACITY FOR THE IMPLEMENTATION OF CHEMICAL-RISK ASSESSMENT (ROUND-TABLE DISCUSSION)

During the round-table discussion, the participants provided feedback on the training they had received. They found the information presented and the exercises carried out in the three areas – risk of combined exposure to multiple chemicals, chemical safety assessment for the purposes of REACH, and rapid risk assessment – very interesting and felt that it would prove very useful in practice, especially in evaluating the risks of persistent organic pollutants (POPs) and other substances of high concern.

The problems of sharing responsibilities among the different agencies and ministries involved in chemical safety, and of their achieving an effective cooperation, were highlighted. For example, in Lithuania, the Ministry of Health is responsible for public health issues, while various institutions are responsible for chemical risk assessment. In emergency situations, some institutions are responsible for conducting risk assessments or coordinating response; others for on-the-scene measurements. It is of paramount importance to combine these resources and ensure effective communication.

Another topic addressed was the role of the health sector in chemical management. As a result, areas of chemical management relevant to health authorities were identified, including information-gathering on the impact of chemicals on health, exposure assessment and human biomonitoring, and the development of recommendations aimed at protecting vulnerable population groups, especially children, from the negative impact of chemicals. The participants were of the common opinion that a wider implementation of human biomonitoring in assessing exposure to chemicals and the creation of the appropriate capacity were necessary.

The cumulative risk assessment of indoor air pollution, consumer products and food, with the main focus on risks created by POPs and EDCs, was identified as a priority in all three countries.

CONCLUSIONS AND RECOMMENDATIONS

The following were the conclusions and recommendations of the workshop.

- The organization of multicountry workshops and the sharing of experience and expertise would help strengthen cooperation between neighbouring countries and facilitate capacity building and networking at the subregional level.
- The knowledge shared and practical experience gained during the workshop in the areas of cumulative-risk assessment, chemical-safety assessment under REACH, and rapid risk assessment during emergency situations involving chemicals were important to facilitating the application of risk assessment at the national level.
- The practical experience in risk assessment gained during the workshop can be used in relevant daily activities.
- International databases are important sources of information on chemical hazards, such as NOAEL/LOAEL values and dose-response relationship, whereas the data necessary for exposure assessment should be collected at the national level. The establishment of appropriate monitoring programmes should be considered to ensure the collection of exposure data; gathering available data in a format applicable to risk assessment can be explored at the initial stage.
- Priority areas for implementing WHO methods of assessing the risk of combined exposures to multiple chemicals in participating countries are indoor air, food, and consumer products with a focus on POPs and EDCs.
- Human biomonitoring data are important for the assessment of human exposure to cumulative chemicals: widening human biomonitoring programmes and capacity building in the relevant areas should be considered.
- The health sector's important role in chemical management can strongly benefit chemical safety, particularly through:
 - evidence-gathering on the impact of chemicals on health;
 - the assessment of exposure involving the use of human biomonitoring;
 - risk assessment; and
 - the provision of advice on recommendations aimed at the protection of vulnerable population groups, especially children, from the negative influence of chemicals.

Annex 1. Programme

Wednesday, 14 October 2015

08:30 – 09:00	Registration
Session 1 09:00 – 10:00	Welcome address (<i>Mr Audrius Sceponavicius, Director, Department of Public Health, Ministry of Health of Lithuania; Ms Ingrida Zurlyte, Head, WHO Country Office in Lithuania</i>) Introduction of the participants Selection of Chair Scope and purpose of the meeting (<i>Dr Irina Zastenskaya, WHO European Centre for Environment and Health</i>) Human health risk assessment in chemicals safety agenda (<i>Dr Irina Zastenskaya, WHO European Centre for Environment and Health</i>)
Session 2 10:30 – 16:30	WHO methodology for assessment of chemical cumulative risks for human health (<i>Dr Coen Graven, National Institute for Public Health and the Environment, Ministry of Health, Welfare and Sport, Netherlands</i>) Introduction and training on WHO framework for assessment of risks of combined exposure to multiple chemicals
Session 3 16:30 -17:30	Cumulative risk assessment: challenges and opportunities for implementation at the national level (working-group discussion)
17:30 – 18:00	Wrap-up of the day

Thursday, 15 October 2015

Session 4 09:00 – 12:00	Assessment of chemical safety in the frame of the European Union legislation (REACH) (<i>Dr Christoph Schulte, UBA, Ministry for the Environment, Nature Conservation Building and Nuclear Safety, Germany</i>) Scope of risk assessment under European Union chemical legislation Introduction of EU methodologies for the risks and chemical safety assessment The concept of substances of very high concern for the environment (PBT, vPvB, Endocrine Disruptors) Analysing different options for risk management, and follow up: The SVHC-roadmap 2020 of REACH
Session 5 13:00 – 15:00	Rapid risk assessment of emergency situations with involvement of chemicals (<i>Professor Raquel Duarte-Davidson, WHO Collaborating Centre, Chemical and Poisons Department, Public Health England</i>)
Session 6 15:00 – 16:00	Needs for strengthening capacity necessary for the implementation of chemical risk assessment (round-table discussion) Challenges, opportunities and needs for implementation of the chemicals risks assessment in the countries Holistic approach to implementation of chemical risk assessment and synergy between WHO and EU approaches to the risk assessment Reporting on results of round-table discussion
Session 7 16:00 – 16:30	Closing session Wrap-up of the meeting, next steps and closure

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