# UN/SCEGHS/5/INF.10

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (Fifth session, 7-9 July 2003, agenda item 3)

#### **Cooperation with other international organizations**

#### <u>GHS promotion/Information on the outcome of the Fifth Ministerial Conference</u> <u>Environment for Europe</u>

#### Transmitted by the secretariat

1. The fifth Ministerial Conference "Environment for Europe" was held in Kiev, Ukraine, 21-23 May 2003. On this occasion, the GHS was highlighted in two different documents:

- In "Europe's environment", which is the third assessment of the environmental situation of the pan-European region, Chapter 6 on Chemicals, para. 6.6 (entitled "*Three recent initiatives: the EU chemical policy White Paper, the Stockholm Convention on POPs and the Globally harmonized System of Classification and labelling of chemicals (GHS)*" and table 6.5).
- In the Ministerial Declaration, part III entitled "Responses: making it happen", sub-section L on Chemicals, para 55, in which countries of the UNECE region are encouraged to implement the GHS without delay.

2. Relevant extracts from the two documents are highlighted in yellow in the following pages.

## Europe's environment: the third assessment

Summary



• What are the current research priorities: exposure pathways and low dose impacts, or mechanisms of action?

Releases or use of some chemicals have resulted in significant environmental damage (EEA, 2001 — see Box 6.5.). Unlike products such as pharmaceuticals, no premarket toxicity testing was required for most of these and so knowledge about their adverse effects was not available before they were used in large quantities e.g. DDT.

Evidence of dioxins and PCBs in food and livestock feedstuffs (in Belgium in 1999, 2000), phthalates exceeding permitted concentrations in children's toys (in Denmark in 2001, 2002), and flame retardants in human milk (in Sweden in 2000) illustrate the potential for accumulation from low exposures and possible risks.

Clearly, a top priority should be to get basic data on the properties of such substances that are produced and used, and especially those where emissions during production, use or disposal are significant (compared to their hazard potential). Currently industry has to submit notification dossiers for 'new chemicals' e.g. chemicals that were not identified on the European market in 1981. About 300 to 350 new substances are notified every year. The notification dossier should provide information on the substance, e.g. production process, proposed uses, results from analysis of physical and chemical properties, and test reports from toxicological and eco-toxicological assays.

However, even having such basic data cannot exclude the possibility that effects will occur at low doses and/or over a lifelong exposure. The precautionary principle may guide in the direction of reacting on early warnings, but data are still needed to provide a basis for applying the precautionary principle in practice. Having publicly available data and information on the substances in use may allow both the manufacturers, the industrial users (downstream users) and even consumers to take informed decisions on the risk associated with the use of a substance (see Box 6.6.) — little information is currently available about which substances can be safely used.

The European Commission acknowledges that current policies for risk assessment and control of chemicals take too long to implement. It also recognises that the

#### Box 6.5. Association and causality

It is sometimes relatively easy to show that a measure of ill health, e.g. the number of hospital admissions per day, is associated with a possible cause such as the day-to-day variation in levels of air pollutants. To show that a causal relationship exists, a number of guideline tests have been developed. These include the consistency of results between different studies, the way in which the results of different studies fit together (coherence), whether there is a 'dose-response' relationship between the proposed causal factor and the effect, and whether the sequence of events makes sense i.e. the cause always precedes the effect.

Proof of causality is often very difficult to establish, but by the application of these and other criteria, an expert judgement as to whether an association is likely to be causal can often be made. Where effects are likely to be serious and/or irreversible, then a low level of proof as in the 'precautionary principle' may be sufficient to justify the removal or reduction of the probable causes.

Sources: WHO; EEA

current risk assessment process used for 'existing' substances (those declared to be on the market before 1981) is 'slow and resource-intensive and does not allow the system to work efficiently and effectively' (European Commission, 2001). In addition to the proposals contained within the recent EU chemicals policy White Paper (see below), a number of other initiatives have been agreed in recent years that aim to reduce the environmental levels of chemicals (see Table 6.5).

#### 6.6. Three recent initiatives: the EU chemicals policy White Paper, the Stockholm convention on POPs and the globally harmonised system of classification and labelling of chemicals (GHS)

The proposals outlined in the EU chemicals policy White Paper (European Commission, 2001) are among the most significant

#### Box 6.6. Voluntary phase-out of perfluorooctanyl sulphonate production

The oil and water repellent chemical perfluorooctanyl sulphonate (PFOS) was developed in the 1950s and has been used worldwide in a variety of specialist fire-fighting foams and oil and grease-resistant coatings for textiles and paper packaging.

Concerns over the potential health and environmental risks of this and similar chemicals were raised after its recent discovery at low concentrations in human and animal tissues from around the world. Despite there being no unambiguous evidence of toxicity, in a rare precautionary initiative to stop the use of the substance its principal manufacturer announced a voluntary phase-out of production. The move led other makers of similar compounds to launch their own investigations into the environmental fate, transport and effects of perfluorinated substances. A number of manufacturers have since agreed to phase-out these compounds and a subsequent 2002 Danish Environmental Protection Agency study found only three of 21 samples contained PFOS-like compounds. Danish environment minister Hans Christian Schmidt commended the phase-out as a good example of producer responsibility, noting that 'A number of companies have made a conscious choice not to use these problematic chemicals even though they are free to do so' (ENDS, 2002).

#### Table 6.5.

#### Some initiatives for reducing chemicals in the environment

Instrument	Year	Objectives
Montreal protocol	1987	Phase out certain ozone-depleting substances
Responsible care	1989	Industry initiative to promote environmental responsibility via concepts such as: • Sustainable development • Product stewardship • Implementation of good practice • Take-back schemes • Integrated product placement • Development of company pollutant release and transfer registers (PRTRs)
HELCOM convention	1992	Prevent and eliminate pollution to the Baltic Sea
Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal	Text concluded in 1989, and convention entered into force in 1992	Reduce/minimise hazardous wastes at source
OSPAR and HELCOM conventions	1998	Reduce discharges, emissions and losses of hazardous substances to the North Sea to near-zero or background levels by 2020
Rotterdam Convention on Prior Informed Consent	1998	Exporters of hazardous chemicals to get consent of receiving country before delivery
International Council of Chemical Associations (ICCA)	1998	Compiling hazard assessment information on 1 154 HPV chemicals by 2004
UNECE POPs protocol	1998	Reduce air emissions of POPs
UNECE heavy metals protocol	1998	Reduce emissions of cadmium, mercury and lead to 1990 levels
EU water framework directive	2000	An integrated approach to protecting water resources. Defines emission reduction/ elimination targets for a limited number of priority hazardous substances. No comparable legislation currently exists for soils
Stockholm convention on POPs	2001	Elimination of POPs (production and use)
UNEP Global Assessment of Mercury	2001	Review health and environmental impacts of mercury and compile information on control and prevention strategies to potentially form a basis for international action
Globally harmonised system of classification and labelling of chemicals	2002	<ol> <li>To enhance the protection of human health and the environment by providing an internationally comprehensible system for hazard communication</li> <li>To provide a recognised framework for those countries without an existing system</li> <li>To reduce the need for testing and evaluation of chemicals</li> <li>To facilitate international trade in chemicals whose hazards have been properly assessed and identified on an international basis</li> </ol>
Johannesburg summit	2002	Minimise adverse effects of chemicals on health and the environment by 2020. Implement the new globally harmonised classification and labelling system for chemicals by 2008

potential developments for risk assessment and management processes in the European region. The White Paper recognises that the public has a right of access information about the chemicals to which they are exposed (see Box 6.7). It reassesses existing EU directives and amendments and advocates a high level of protection for human health and the environment based on the precautionary principle. The Commission proposes to shift responsibility for generating and assessing data concerning the risks of use of substances onto industry. Downstream users would also be responsible for all aspects of the safety of their products and would have to provide information on use and exposure.

The White Paper sets out a timetable under which 'existing' substances (for which very little risk assessment data exist) would have to undergo assessment. 'Existing' and 'new' substances would be subject to the same risk assessment procedures using a single REACH (registration, evaluation, and authorisation of chemicals) system. The requirements that manufacturers/users of chemicals have to follow will depend on the proven or suspected hazardous properties, uses and exposures of the chemical concerned. The costs of implementing the REACH system have been estimated at between EUR 1.4 billion and EUR 7 billion over 10 years (most probably EUR 3.6 billion (RPA, 2002)). In comparison, EU chemical production in 2001 was valued at EUR 518 billion (CEFIC, 2002). No estimates have yet been made of the external health and environmental costs of chemicals (EEA, 1999), although such estimates are available for the energy and transport sectors (EEA, 2000).

Even though the proposed regime is a substantial improvement over that which currently exists, the new proposals do not go as far as some environmental organisations would like. For example, it has been recommended that: an EU chemicals policy should ensure that transparency of information is guaranteed; persistent and bioaccumulative chemicals should be phased out; the strength of evidence for regulation should be such that 'reasonable doubt' over safety is sufficient to lead to regulatory measures; endocrine disrupting substances should be included in the 'authorisation' procedure; and new non-animal testing techniques awaiting approval are reviewed as a matter of priority (FoE, 2002). Furthermore, the new system operates on

higher volume boundaries to trigger the need for testing than currently in force. There is therefore likely to be a need to check in future regulations that this compromise with industry is not underprotective for new chemicals.

The Stockholm convention on POPs (2001) aims to protect health and the environment through controlling POPs production and emissions. Like the EU chemicals policy White Paper, the concept of precaution as an important element in chemical risk management is acknowledged within the convention (Willis, 2001). For example, whether chemicals proposed as meeting POPs criteria are accepted under the convention is to be decided 'in a precautionary manner'.

Further progress in the protection of the public against chemical hazards and the risk associated with their exposure necessitates that better information on chemicals be made available. The new globally harmonised system of classification and labelling of chemicals (GHS) that was adopted in December 2002 (UNECE, 2002) will dramatically increase the level of information and access to it. Chemicals will be classified according to their potential hazards to humans and the environment. Related information will be communicated and displayed to the public so that appropriate protective measures can be

### Box 6.7. Information for policy-makers and the public: pollutant release inventory initiatives

Pollutant release and transfer registers (PRTRs) are inventories of pollutant releases and transfers to the environment detailed by source. They provide an important means for members of the public to obtain information about the chemicals to which they are exposed, and governments to assess the relative contributions of different emission sources. They therefore enable prioritisation of sources in terms of developing strategies to eliminate or reduce the releases of pollutants, and measurement of progress towards the goal of minimising their emissions.

Increasing numbers of European countries now operate pollutant release inventories, although they often differ both with respect to media covered (air, water, land, waste, etc.) and the threshold and types of chemicals for which reporting is mandatory (OECD, 2000). Regional and international PRTR initiatives have also been developed e.g. OSPAR for emissions to the North Sea, and the pan-European EMEP/Corinair atmospheric emissions inventory.

Recognising both the utility of registers and the need to encourage their development on a national scale, a number of initiatives have been taken to facilitate their introduction in countries currently without release inventories. For example, the UNECE Aarhus convention on access to information, public participation in decision-making and access to justice in environmental matters was adopted in 1998. Under the convention, a working group on pollutant release and transfer registers was established to assist in the implementation of Article 5, establishing public access to information dealing with the environmental release or transfer registers. A protocol concerning implementation of this aspect of the convention has been prepared for the fifth 'Environment for Europe' ministerial conference, Kiev, 2003.

taken. Through the different steps from production, handling and transport to use, chemical products will be marked with universally understandable pictograms. The GHS also includes safety data sheets, presenting standardised content and extended information. The system, called for by the Rio summit in 1992, is now ready to be implemented, as requested at the Johannesburg summit (Article 22(c) of the plan of implementation).

Implementing EU environmental legislation will help the accession countries to meet the challenges in environmental protection. They need to include around 300 pieces of EU environmental law (some of them relevant to chemicals) into their national legislation, as well as to implement and enforce these laws. Most of these countries need to strengthen the environmental administration of ministries and agencies but especially also of local and regional offices.

In order to help the countries, the EU is assisting financially, for example with the LIFE programme, the Phare programme and the instrument for structural policies for preaccession (ISPA); as well as with technical support through the twinning system. Furthermore, the EU has acknowledged

Table 6.6.EU accession countries: transitional periods for<br/>compliance to chemicals-related legislation

Country	Transitional agreement
Estonia	Emissions of volatile organic compounds from petrol storage (until 2006)
Latvia	Emissions of volatile organic compounds from petrol storage (until 2008) Prevention and reduction of environmental pollution by asbestos (until 2004) Health protection of individuals against ionising radiation in relation to medical exposure (until 2005)
Lithuania	Emissions of volatile organic compounds from petrol storage (until 2007)
Poland	Emissions of volatile organic compounds from petrol storage (until 2005) Discharge of dangerous substances into surface water (until 2007) Integrated pollution prevention and control (until 2010) Health protection of individuals against ionising radiation in relation to medical exposure (until 2006)
Slovakia	Emissions of volatile organic compounds from petrol storage (until 2007) Discharge of dangerous substances into surface water (until 2006) Integrated pollution prevention and control (until 2011)
Slovenia	Integrated pollution prevention and control (until 2011)
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Source: European Commission, 2003

some specific problems for which transitional periods are necessary. Table 6.6 shows transitional periods of relevance to chemicals (European Commission, 2003).

Chemicals policy-making is undergoing a period of unprecedented change. It offers the prospect of reducing the risks to human health and the environment from chemicals in Europe and beyond. It can also lay the foundation for a more sustainable approach to the safety of chemicals throughout their entire life cycle and for stimulating innovation through 'greener' chemistry (European Commission, 2001) and other improvements in eco-efficiency. Future generations may therefore avoid paying the price of current deficiencies in chemical policies whilst retaining the benefits of chemical products.

#### 6.7. References

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#### ECE/CEP/94/Rev.1



## FIFTH MINISTERIAL CONFERENCE ENVIRONMENT FOR EUROPE

KIEV, UKRAINE 21-23 May 2003

## DECLARATION

by the Ministers of Environment of the region of the United Nations Economic Commission for Europe (UNECE)



UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE goals. We look forward to the multi-stakeholder conference that will be organized in 2005 within the framework of the EAP Task Force to promote the implementation of the 2000 Almaty Ministerial Conference on Urban Water Sector Reform.

52. We welcome the initiatives and intentions of the countries of South-East Europe and the Mediterranean to promote peaceful and productive cooperation for introduction of integrated water resource management approaches for transboundary waters. In this context, we note the outcomes of the International Conference on "Sustainable Development for Lasting Peace: Shared Water, Shared Future, Shared Knowledge", organized by Greece and the World Bank, in May 2003, as a building block of the Mediterranean Component of the EU Water Initiative.

#### K. Transport, environment and health

53. We will work to implement effectively the newly established Transport, Environment and Health Pan-European Programme, as a successful example of the integration of the environment and public health into sectoral policies, carrying out the activities under the rationalized priorities as outlined in its work plan and ensuring adequate participation of representatives of South-East and East European, Caucasian and Central Asian countries in accordance with the eligibility criteria adopted within WHO and UNECE.

### L. <u>Chemicals</u>

54. We recognize the essential role of sound management of chemicals for sustainable development and for the protection of human health and the environment. We invite all interested States that have not yet ratified or acceded to the Stockholm Convention on Persistent Organic Pollutants and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade to consider doing so.

55. We welcome the adoption in December 2002 of the Globally Harmonized System for the Classification and Labelling of Chemicals. We encourage countries to implement this system without delay to improve the protection of human health and the environment through the sound management of chemicals, with a view to having the system fully operational by 2008. We also note with satisfaction that the WSSD adopted clear targets on chemicals aiming to achieve, by 2020, that chemicals are used and produced in ways that do not lead to significant adverse effects on human health and the environment; of further developing a strategic approach to chemicals management by 2005; and of promoting a reduction of the risks posed by heavy metals and obsolete pesticides that are harmful to human health and the environment. We are fully committed to continue this work, reflecting the decision taken by the UNEP Governing Council earlier this year. We encourage Parties to the Convention on Long-range Transboundary Air Pollution to prepare for the entering into force of the protocol on POPs.

#### M. Biodiversity

56. We recognize the efforts made so far by the Pan-European Biological and Landscape Diversity Strategy (PEBLDS) in its emerging role as an important instrument for the implementation of the Convention on Biological Diversity in the pan-European region and as a vehicle for promoting the integration of biodiversity and landscape concerns in all relevant horizontal and sectoral policies. We, the Ministers and Heads of delegation of States participating in the PEBLDS process, endorse the Resolution on Biodiversity submitted by the PEBLDS