The Importance of Implementation of the General Purpose Criterion of the Chemical Weapons Convention

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This paper makes an analysis of international developments over the past five years relating to the implementation of the general purpose criterion which is a central element of the Chemical Weapons Convention that ensures that the Convention covers all toxic chemicals. It examines how some of the recent international initiatives that are addressing chemicals that are of potential risk to public health or to the environment might be harnessed to implement the general purpose criterion thereby strengthening the Convention as a counter to the use of Toxic Industrial Chemicals and other chemicals either by States or by sub-State actors such as terrorists.

Keywords: *Chemical Weapons Convention, General Purpose Criterion*

Introduction

A central provision of the Chemical Weapons Convention (CWC) which totally prohibits the development, production, acquisition, storage and use of chemical weapons is the general purpose criterion (GPC) whereby the CWC covers all *"Toxic chemicals and their precursors, except where intended for purposes not prohibited under this Convention, as long as types and quantities are consistent with such purposes."* The implementation of this GPC is placed by Article VI on each State Party which *"shall adopt the necessary measures to ensure that toxic chemicals and their precursors are only developed, produced, otherwise acquired, retained, transferred, or used within its territory or in any other place under its jurisdiction or control for purposes not prohibited under this Convention."*

The CWC entered into force in 1997 and the Organisation for the Prohibition of Chemical Weapons has understandably focused first on the destruction of existing chemical weapons stockpiles and on the verification of the chemicals that are detailed in the Schedules of the Convention. These so-called scheduled chemicals are those chemicals that have previously been used as chemical weapons and they are certainly chemicals that might be used to breach the Convention as they have a proven record as chemical weapons.

The general purpose criterion was wisely drafted by the negotiators of the Convention to cover possible future chemical weapons involving chemicals that are not listed on the Schedules. The verification regime in the Convention also includes provisions for other chemical production facilities – those producing more than 200 tonnes of unscheduled discrete organic chemicals or more than 30 tonnes of an unscheduled discrete organic chemical containing the elements phosphorus, sulphur or fluorine (Part IX of the Verification Annex).

Although the importance of implementing the general purpose criterion has long been recognised by analysts of the CWC and the OPCW, relatively little attention has yet been given to how this might be achieved. As Julian Perry Robinson pointed out in 2000,[1] *"the OPCW Technical Secretariat is sighted only towards those 29 chemicals and 14 families of chemicals that are listed in the CWC Annex on Chemicals"* and *"It is the National Authorities therefore, not the OPCW Technical Secretariat, that are primarily responsible for implementing the general purpose criterion which ... is absolutely vital to the future of the treaty."* It was also encouraging to note that the 1999 Annual Report[2] by the UK National Authority includes mention of the application of the general purpose criterion and concluded that *"National authorities need to consider this situation further."* Subsequent UK Annual Reports have continued to address the general purpose criterion and those for 2001[3] and 2002[4] have recognized

[1] Julian Perry Robinson, *Memorandum submitted by Professor J P Perry Robinson, University of Sussex,* Foreign Affairs Committee, Eighth Report, *Weapons of Mass Destruction,* 25 July 2000, Appendix 29, p. 203.

[2] Department of Trade and Industry, *1999 Annual Report on the operation of the Chemical Weapons Act 1996,* DTI/Pub 4913/2k/6/00/NP, June 2000. This and subsequent annual reports are available at http://www.dti.gov.uk/europeandtrade/non-proliferation/chemical-biological/uk-cwc/page24828.html

[3] Department of Trade and Industry, *Annual Report for 2001 on the operation of the Chemical Weapons Act 1996,* DTI/Pub 6029 1.6k/04/02/NP, April 2002.

[4] Department of Trade and Industry, *Annual Report for 2002 on the operation of the Chemical Weapons Act 1996,* DTI/Pub 6785/1k/7/03/NP, July 2003.

that this has benefits in the context of the threat of chemical terrorism. The Annual Report for 2003[5] for the first time had an entire section entitled the general purpose criterion which included mention that the National Authority had held a meeting to consider the overall regulation of chemicals in the UK. A similar section appeared in the 2004 report[6] which included mention of a seminar held for representatives from industry and academia.

In this paper, an analysis is made of international developments over the past five years and examines how some of the recent international initiatives that are addressing chemicals that are of potential risk to public health or to the environment might be harnessed to implement the general purpose criterion which continues to be a vital element of the Convention.

International developments

There have been two developments during the past five years that underline the central importance of the general purpose criterion and its effective implementation. The first relates to Iraq and the weapons of mass destruction sought by the regime of Saddam Hussein. Although there has been much debate about precisely what capability did Iraq have during the 1980s and 1990s, it is important to recognize that Iraq was seeking chemical weapons to use at a time of their choosing – they were **not**, as was historically the case with most other states which have sought chemical weapons, seeking a **retaliatory** capability.[7] Consequently, there was no requirement, as there is for a retaliatory capability, for agents with long storage lives and toxic chemicals that are more readily available could be used as required. The absence of a stockpile can also been seen as beneficial should an inspection be carried out at short notice.

The second development relates to the concerns that terrorists might choose to use chemicals as a weapon of terror. Again, such use is **not** in **retaliation**, but will be the use of toxic chemicals that are available when required.

Both of these developments reinforce the importance of the general purpose convention as it is this provision in the Chemical Weapons Convention that prohibits the use of toxic chemicals other than for purposes not prohibited under the Convention. It is also being recognized that Toxic Industrial Chemicals (TICs) can present a threat whether used by States or by sub-State actors such as terrorist groups. A United States Chemical and Biological Defense Primer[8] issued in October 2001 includes a tabulation of TICs identified by a UK, US & Canadian International Task Force-25 in 1998 as presenting a high hazard. ITF-25 considered that for a given chemical to present a hazard, the chemical must be present in sufficient quantity in the area of concern, must exhibit sufficient toxicity by inhalation, and must normally exist in a state that could give rise to an inhalation hazard.

Ammonia	Arsine	Boron trichloride	Boron trifluoride
Carbon disulfide	Chlorine	Diborane	Ethylene oxide
Fluorine	Formaldehyde	Hydrogen bromide	Hydrogen chloride
Hydrogen cyanide	Hydrogen fluoride	Hydrogen sulfide	Nitric acid, fuming
Phosgene	Phosphorus trichloride	Sulfur dioxide	Sulfuric acid
Tungsten hexafluoride			

A subsequent International Task Force-40 which reported in 2003 has reviewed, revised and validated the earlier report of ITF-25. ITF-40 agreed that a risk assessment was needed of all High Production Volume (HPV) chemicals on the OECD list and chemicals on the US EPA list – some 5,000 chemicals in all.

The first Review Conference of the Chemical Weapons Convention was held in April/May 2003. In the report[9] prepared by the Scientific Advisory Board (SAB) for the Review Conference, the SAB said:

The SAB is convinced, however, that the number and types of unscheduled chemicals that could cause considerable harm, if they were misused for CW purposes, have expanded significantly. This is the result of recent advances in science and technology.

and went on to say that:

The definition of CW contained in Article II, as well as the provisions of the Schedules of Chemicals, make it clear that the Schedules do not embrace the entire scope of the Convention. The Convention's prohibitions related to "chemical weapons" apply to all toxic chemicals and their precursors, except when intended for purposes not prohibited by the Convention, as long as the types and quantities are consistent with such purposes. Without that broad scope, chemical warfare agents of novel identity (including those which are as yet undisclosed or undiscovered) would remain outside the reach of the Convention.

3.6 The SAB is fully aware of the wisdom of the drafters of the Convention – that international verification procedures complement the obligation of States Parties to take the ne-

[5] Department of Trade and Industry, *Annual Report for 2003 on the operation of the Chemical Weapons Act 1996,* DTI/Pub 7324/2k/06/04/NP, May 2004.

[6] Department of Trade and Industry, *Annual Report for 2004 on the operation of the Chemical Weapons Act 1996,* DTI/Pub 7929/2k/07/05/NP, July 2005.

[7] Graham S. Pearson, *The Search for Iraq's Weapons of Mass Destruction*, Palgrave Macmillan, 2005.

[8] US Department of Defense, *Chemical and Biological Defense Primer,* Prepared by: The Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense, October 2001. Available at http://www.nti.org/e_research/official_docs/dod/2001/1001DOD.pdf#search=%22DOD%20%22Chemical%20and%20Biological%20Defense%20Primer%22%20%22

[9] Organisation for the Prohibition of Chemical Weapons, *Note by Director-General Report of the Scientific Advisory Board on Developments in Science and Technology,* RC-1/DG.2/23 April 2003. This and other OPCW documents are available at http://www.opcw.org

cessary measures to implement the Convention, including legislation in relation to toxic and precursor chemicals. The distinction between scheduled chemicals (i.e. chemicals that need to be declared and that become subject to verification measures) and unscheduled chemicals is a regulatory matter. Wherever this distinguishing line is drawn, there will always be unscheduled chemicals that, if misused, would pose a risk to the Convention. In relation to the verification regime, a certain degree of risk is unavoidable in order to keep verification acceptable, feasible, and affordable. Scientific advances will, however, have an impact on that risk, and therefore they need to be reviewed.

The Director-General in his covering note made the following recommendation to the Review Conference:

the First Review Conference may wish to take note of developments in science and technology in relation to chemicals relevant to the Convention, and may wish to reaffirm that the definition of CW contained in paragraph 1 of Article II continues to ensure all unscheduled chemicals meeting its definitions of "toxic chemical" or "precursor" are covered by the prohibitions of Article I, if they were to be used for CW purposes. In this context, the First Review Conference may also wish to draw the attention of the States Parties to the provisions of paragraph 1 of Article VII, in relation to national implementation measures;

The Review Conference in its Political Declaration[10] stated:

17. The States Parties reaffirm that national implementation measures must reflect all relevant provisions of the Convention and the comprehensive nature of its prohibitions, to ensure that they apply to all toxic chemicals and precursors except where intended for purposes not prohibited under the Convention, as long as their types and quantities are consistent with such purposes.

The Report[11] of the Review Conference included:

7.23 The First Review Conference ***considered*** *the impact of developments in science and technology on the Convention's prohibitions. The definitions contained in Article II, in particular of the terms "chemical weapons" and "chemical weapons production facility", were found to adequately cover these developments and to provide for the application of the Convention's prohibitions to any toxic chemical, except where such a chemical is intended for purposes not prohibited by the Convention, and as long as the types and quantities involved are consistent with such purposes. The First Review Conference* ***noted****, however, that science is rapidly advancing.*

and also went on to include:

7.57 The First Review Conference ***reaffirmed*** *the obligation of the States Parties to adopt the necessary measures to ensure that toxic chemicals and their precursors are developed, produced, otherwise acquired, retained, transferred, or used within their territories or in any other places under their jurisdiction or control, only for purposes not prohibited by the Convention.*

In addition, there have been international developments promoting the sound management of chemicals with the commitment by governments at the World Summit in Johannesburg in 2002 to the aim to achieve, by 2020, the use and production of chemicals in ways that lead to the minimization of significant adverse effects on human health and the environment. As part of that commitment, there is a call to adopt transparent science-based risk assessment procedures and science-based risk management procedures, taking into account the precautionary approach as well the provision of support to developing countries in strengthening their capacity for the sound management of chemicals and hazardous wastes by providing technical and financial assistance. Such an approach requires governments around the world to focus attention on the production and use of chemicals within their countries which may present a hazard to human health or the environment. The relevance of this commitment at the World Summit in 2002 to the international treaty prohibiting chemical weapons is demonstrated by the heading *"Worldwide Toxic Chemicals Ban Agreed"* of one of the articles written at the time.

Toxic chemicals

This article takes a broader look at the international, regional and national initiatives that are addressing chemical safety and the potential risks from chemicals to the environment and/or to the health of the general public or workers.

There are now a number of international organizations which are involved in activities relating to chemical safety. The principal organizations involved can be broadly grouped into international, regional, national and trade associations:

Category of organization	Organization
International	United Nations Environment Programme (UNEP) Chemicals
	International Labour Organisation (ILO)
	Food and Agriculture Organization (FAO)
	World Health Organization (WHO)
	UN International Development Organization (UNIDO)
	UN Institute for Training and Research (UNITAR)
	Organization for Economic Cooperation & Development (OECD)
Regional	European Union (EU)
National	UK Health & Safety Executive (HSE)
	US Environmental Protection Agency (EPA)
Trade Associations	International Council of Chemical Associations (ICCA)
	American Chemical Council (ACC) (previously CMA)
	European Chemical Industry Council (ECIC)
	Japan Chemical Industry Association (JCIA)

[10] Organisation for the Prohibition of Chemical Weapons, *Political Declaration of the First Special Session of the Conference of the States Parties to Review the Operation of the Chemical Weapons Convention (First Review Conference),* RC-1/3, 9 May 2003.

[11] Organisation for the Prohibition of Chemical Weapons, *Report of the First Special Session of the Conference of the States Parties to Review the Operation of the Chemical Weapons Convention (First Review Conference) 28 April-9 May 2003,* RC-1/5, 9 May 2003.

In addition to the above there are programmes and groupings which bring together some of these organizations:

Programme/Grouping	Organizations within Programme/Grouping
International Programme on Chemical Safety (IPCS) established in 1980 (WHO is the executing agency of IPCS)	ILO, UNEP, WHO
Inter-Organization Programme for the Sound Management of Chemicals (IOMC) established in 1995	UNEP, ILO, FAO, WHO, UNIDO, UNITAR, OECD
Intergovernmental Forum on Chemical Safety (IFCS) established in 1994 (WHO is the administering agency)	Mechanism for cooperation between governments and providing a forum where representatives of governments meet with IGOs and NGOs
Strategic Approach to International Chemicals Management (SAICM) adopted in February 2006	UNEP, ICCM (International Conference on Chemicals Management)

Some have been engaged for some decades whilst others have been established following the United Nations Conference on Environment and Development (UNCED) held in Rio de Janeiro in June 1992 (the Earth Summit) and the subsequent World Summit on Sustainable Development (WSSD) held in Johannesburg in August/September 2002. It should be recalled that the six priority programme areas identified under Agenda 21, Chapter 19 *Environmentally sound management of toxic chemicals, including prevention of illegal international traffic in toxic and dangerous products* are:

A) Expanding and accelerating the international assessment of chemical risks;

B) Harmonization of classification and labelling of chemicals;

C) Information exchange on chemicals and chemical risks;

D) Establishment of risk reduction programmes;

E) Strengthening of national capabilities and capacities for management of chemicals; and

F) Prevention of illegal international traffic in toxic and dangerous products.

The IOMC was established in 1995 to serve as a mechanism for coordinating the efforts of intergovernmental organizations in the field of chemical safety. It provides extensive listings of ongoing activities under each of the priority programme areas.

The world growth in trade in the 1960s and 1970s led to increasing attention being given to the potential risks to the environment and to public health from chemicals. The United Nations Environment Programme (UNEP) has over the years had a number of initiatives in relation to chemicals. The UNEP chemicals programme has as its goal the making of the world a safer place from toxic chemicals. This is done by helping governments to take necessary global action for the sound management of chemicals, by promoting the exchange of information on chemicals, and by helping to build the capacities of countries around the world to use chemicals safely.

The World Summit in 2002 agreed[12] to:

Renew the commitment, as advanced in Agenda 21, to sound management of chemicals throughout their life cycle and of hazardous wastes for sustainable development as well as for the protection of human health and the environment, inter alia, aiming to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment, using transparent science-based risk assessment procedures and science-based risk management procedures, taking into account the precautionary approach, as set out in principle 15 of the Rio Declaration on Environment and Development, and support developing countries in strengthening their capacity for the sound management of chemicals and hazardous wastes by providing technical and financial assistance.

Whilst most chemicals are benign in the concentration levels to which we are exposed to them, others present risks to human health or to the environment. Sustainable development requires the global capacity for the sound management of chemicals. National capacities exist within most developed countries, but to a more limited extent elsewhere. One aim in building global capacity is to extend the sound management of chemicals to all countries – that is, to take steps to ensure that all countries have the information necessary, expertise, and resources to manage chemicals safely under the conditions of production or use in that country. A second aim of global capacity is ensuring that the necessary global actions are taken to address risks that are not dealt with by national actions alone.

Expanding access to information and information tools is one of the primary ways in which UNEP helps countries to develop their capabilities in assessing and managing chemical risks. A wide range of information products have been issued by UNEP Chemicals, such as the International Register of Potentially Toxic Chemicals (IRPTC), often with partner organizations such as the International Programme on Chemical Safety (IPCS) and the Organization of Economic Co-operation and Development (OECD).

European Union

The European Union (EU) had identified the potential risks of chemicals as a policy priority in the 1970s and the 1980s which saw the drawing up of EINECS (European Inventory of Existing Commercial Substances) which lists and defines those chemical substances which were deemed to be on the European Union market between 1 January 1971 and 18 September 1981: EINECS is an inventory containing 100,195 substances. Any new chemicals subsequently brought onto the market are included in ELINCS (European

[12] United Nations, *Report of the World Summit on Sustainable Development*, Johannesburg, South Africa, 26 August-4 September 2002, A/CONF.199/20, New York, 2002. Available at http://documents.un.org/default.asp

LIst of New Chemical Substances); this currently comprises some 4000 notifications in total, representing about 2000 substances, which have been notified since 1981 corresponding to about 400 notifications each year. The Fourth Community Action Programme on the Environment (1987–1992) underlined the need for a legislative instrument which would provide a comprehensive structure for the evaluation of the risks posed by "existing chemicals". The development of the legal instruments in the European Union took place in parallel with the development of new initiatives by the OECD which had led to the launching of an extensive programme in 1988 on existing chemicals, an area in which several EU Member States were already active.

European Union Directives require the evaluation and control of the risks to the environment and/or public health of both existing and new chemicals. The European Chemicals Bureau located in Ispra, Italy provides technical support for the development of EU chemicals policy and its website[13] provides information on both existing and new chemicals. The Existing Substances Regulation[14] provides for the evaluation and control of risks posed by existing chemicals in four steps:

Step I Data collection
Step II Priority setting
Step III Risk assessment
Step IV Risk reduction

The data reporting is divided into two broad categories – firstly, data on high production volume (HPV) substances produced or imported in quantities exceeding 1000 tonnes per year, and secondly, data on low production volume (LPV) substances which have been produced or imported in quantities between 10 and 1000 tonnes per year. The data required for HPV chemicals is specified as follows:

Data required for High Production Volume chemicals
Name and EINECS number of the substance
Quantity of the substance produced or imported
Information on the reasonably foreseeable uses of the substance
Data on the physico-chemical properties of the substance
Data on the pathways and environmental fate
Data on the ecotoxicity of the substance
Data on the acute and subacute toxicity of the substance
Data on carcinogenicity, mutagenicity and/or toxicity for reproduction of the substance
Any other indication relevant to the risk evaluation of the substance

The EU Directive makes it clear that industrial and commercial secrecy shall not apply *inter alia* to the name of the substance, the name of the manufacturer, the summary results of the toxicological and ecotoxicological tests.

The toxicity data requirements are comprehensive

Toxicity Data required for High Production Volume chemicals	
5.1	Acute toxicity
5.1.1	Acute oral toxicity
5.1.2	Acute inhalation toxicity
5.1.3	Acute dermal toxicity
5.1.4	Acute toxicity (other routes of administration)
5.2	Corrosiveness and irritation
5.2.1	Skin irritation
5.2.2	Eye irritation
5.3	Sensitization
5.4	Repeated dose toxicity
5.5	Genetic toxicity in vitro
5.6	Genetic toxicity in vivo
5.7	Carcinogenicity
5.8	Toxicity to reproduction
5.9	Other relevant information
5.10	Experience with human exposure

On the basis of the information submitted and on the basis of national lists of priority substances, the Commission shall regularly draw up lists of priority substances or groups of substances *requiring immediate attention because of their potential effects on man or the environment*. These lists are published by the Commission; four such lists have so far been published.[15]

The notification schemes for new substances, manufactured or imported within the EU, were first introduced during the 1970s by individual Member States. The current version is the 7th Amendment[16] to Directive 67/548/EEC which requires the provision of data, with increasing detail, according to the quantity of the substance placed on the market, *viz:* 10 kg, 100 kg, 1000 kg per year per manufacturer with further toxicological and ecotoxicological testing required at quantities exceeding 100 and 1000 tonnes per year.

Type of Notification	Annual Quantity
Level 2 (1000 tonnes)	> 1000 tonnes
Level 1 (100 tonnes)	> 100 tonnes
VIIA	> 1 tonne
VIIB	> 100 kg and 1< tonne
VIIC	> 10 kg and < 100 kg

[13] European Chemicals Bureau website at http://ecb.ei.jrc.it/

[14] European Community, *Council Regulation (EEC) No 793/93 of 23 march 1993 on the evaluation and control of the risks of existing substances,* Available at http://ecb.ei.jrc.it/Directives/793_93.htm

[15] European Community, *Commission Regulation (EC) No 1179/94 of 25 May 1994 concerning the first list of priority substances as foreseen under Council Regulation (EEC) No 793/93*. European Community, *Commission Regulation (EC) No 2268/95 of 27 September 1995 concerning the second list of priority substances as foreseen under Council Regulation (EEC) No 793/93*. European Community, *Commission Regulation (EC) No 143/97 of 27 January 1997 concerning the third list of priority substances as foreseen under Council Regulation (EEC) No 793/93*. . European Community, *Commission Regulation (EC) No 2364/2000 of 25 October 2000 concerning the fourth list of priority substances as foreseen under Council Regulation (EEC) No 793/93*. Available at http://ecb.jrc.it/existing-chemicals/

[16] European Community, *Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.* Available at http://europa.eu.int/eur-lex/en/lif/dat/1992/en_392L0032.html

As an example of the additional data required as the quantity placed on the market increases, the toxicological data requirements are summarised below:

	Toxicological testing	Type of Notification
4.1	Acute Toxicity*	
4.1.1	Administered orally	VIIC, VIIB, VIIA
4.1.2	Administered by inhalation	VIIC, VIIB, VIIA
4.1.3	Administered cutaneously	VIIA
4.1.5	Skin irritation	VIIB, VIIA
4.1.6	Eye irritation	VIIB, VIIA
4.1.7	Skin sensitization	VIIB, VIIA
4.2	Repeated dose**	
4.2.1	Repeated dose toxicity	VIIA
4.3	Other effects	
4.3.1	Mutagenicity	VIIB, VIIA
4.3.2	Screening for toxicity related to reproduction	VIIA
4.3.3	Assessment for toxicokinetic behaviour	VIIA

* For acute toxicity testing at VIIC or VIIB one route of administration is sufficient. Gases should be tested by inhalation. Substances other than gases should be tested by oral administration. At VIIA, substances other than gases shall be administered by at least two routes, one of which should be the oral route. The choice of the second route will depend on the nature of the substance and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route.

** For repeated dose testing, the route of administration should be the most appropriate having regard to the likely route of human exposure, the acute toxicity and the nature of the substance. In the absence of contra-indications the oral route is usually the preferred one.

As the quantity of a new substance increases through Level 1 to Level 2 so the additional toxicological data required converges with the data required for High Production Volume existing substances. The Directive also requires that the substances shall be classified as very toxic, toxic or harmful according to the following criteria:

	Very toxic	Toxic	Harmful
LD_{50} oral in rat, mg/kg body weight	25	25 to 200	200 to 2,000
LD_{50} dermal in rat, mg/kg body weight	50	50 to 400	400 to 2,000
LC_{50} (inhalation) rat, mg/litre/4 hours	0.25	0.25 to 1	1 to 5

The data provided in the new substances notification procedure is used to assign one of the following risk assessments[17] to the new substance:

a) The substance is of no immediate concern

b) The substance is of concern ... assessment revision deferred to tonnage threshold attainment.

c) The substance is of concern ... assessment to be reviewed immediately

d) The substance is of concern ... recommendations for risk reduction to be instigated immediately.

European Union – REACH (Registration, Evaluation and Authorisation of Chemicals)

The current EU legislative framework for chemical substances is a patchwork of many different Directives and Regulations which has developed historically. There are different rules for "existing" and "new" chemicals. However, this system has not produced sufficient information about the effects of the majority of existing chemicals on human health and the environment. The identification and assessment of risks – covering the hazard of a substance as well as exposure of humans and the environment to it – have proved to be slow, as have been the subsequent introduction of risk management measures. The current system has hampered research and innovation, causing the EU chemicals industry to lag behind its counterparts in the US and Japan in this regard.

The current distinction between so-called "existing" and "new" chemicals is based on the cutoff date of 1981. All chemicals that were put on the market before 1981 are called "existing" chemicals. In 1981, they numbered 100,106 different substances. Chemicals introduced to the market after 1981 (about 3000) are termed "new" chemicals. While new chemicals have to be tested before they are placed on the market, there are no such provisions for "existing" chemicals. Thus, although some information exists on the properties and uses of existing substances, there is generally a lack of sufficient information publicly available in order to assess and control these substances effectively.

The current allocation of responsibilities is also not appropriate: public authorities are responsible for undertaking risk assessments of substances rather than the enterprises that manufacture, import or use the substances; and these risk assessments are required to be comprehensive, rather than targeted and use-specific. Since 1993, only 141 high-volume chemicals have been identified for risk assessment and possible recommendations for risk reduction, of which only a limited number (27) have completed the process. Furthermore, current legislation requires the manufacturers and importers of chemicals to provide information, but does not impose similar obligations on downstream users (industrial users and formulators) unless the substance has to be classified and a safety data sheet has to be supplied with it further down the supply chain. Thus, information on uses of substances is difficult to obtain and information about the exposure arising from downstream uses is generally scarce.

On the other hand, new chemicals have to be notified and tested starting from volumes as low as 10 kg per year. This has been a barrier to innovation within the EU chemicals industry by discouraging research and invention of new substances and favouring the development and use of existing substances over new ones.

In a White Paper on the Strategy for a Future Chemicals Policy, published in February 2001 (COM (2001) 88), the Commission outlined the result of a review of the current system and its new strategy for ensuring a high level of che-

[17] European Community, *Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of the risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC*. Available at http://europa.eu.int/eur-lex/en/lif/dat/1993/en_393L0067.html

micals safety and a competitive chemical industry through a system for the **R**egistration, **E**valuation and **A**uthorisation of **Ch**emicals – the REACH system.

The White Paper identified seven objectives that need to be balanced within the overall framework of sustainable development:

– Protection of human health and the environment
– Maintenance and enhancement of the competitiveness of the EU chemical industry
– Prevention of fragmentation of the internal market
– Increased transparency
– Integration with international efforts
– Promotion of non-animal testing
– Conformity with EU international obligations under the WTO.

The intention is that REACH will create a single system for both "existing" and "new" chemicals. Its basic elements are:

1. **Registration** requires manufacturers and importers of chemicals to obtain relevant information on their substances and to use that data to manage them safely.

2. To reduce testing on vertebrate animals, **data sharing** is required for studies on such animals.

3. Better **information** on hazards and risks and how to manage them will be passed down and up the supply chain.

4. Downstream users are brought into the system.

5. The aim of **Evaluation** is to prevent unnecessary testing, by having authorities evaluate the proposals for testing made by industry and to check compliance with the registration requirements, and if not, ask industry for further information. Evaluation also enables authorities to investigate chemicals with potential risks by asking industry for further information. This information may be used later to prepare proposals under Restrictions or Authorisation.

6. Substances with properties of very high concern will be made subject to **authorisation**: Applicants will have to demonstrate that risks associated with uses of these substances are adequately controlled. In this case the Commission will grant an authorisation. Otherwise an authorisation may be granted for uses of these substances if the socio-economic benefits outweigh the risks and there are no suitable alternative substitute substances or technologies.

7. The **Restrictions** provide a procedure to regulate that the manufacture, placing on the market or use of certain dangerous substances shall be either subject to conditions or prohibited. Thus, restrictions act as a safety net to manage Community wide risks that are otherwise not adequately controlled.

8. A **European Chemicals Agency** will manage the technical, scientific and administrative aspects of the REACH system at Community level, aiming to ensure that REACH functions well and has credibility with all stakeholders.

9. A **Classification and labelling inventory** will help promote harmonisation of different classifications of a substance. For substances with carcinogenic, mutagenic properties and those toxic for reproduction (CMRs) as well as respiratory sensitizers there may be a Community wide agreement on the classification by the authorities.

10. **Access to information** rules combine a system of publicly available information over the internet, the current system of requests for access to information and REACH specific rules on the protection of confidential business information.

The adoption of the regulation to implement REACH involves both the Council of Ministers and the European Parliament. The Council reached a political agreement on 13 December 2005 which took into account many amendments proposed by the European Parliament. The proposed changes do not alter the structure of REACH but they lower the information requirements for substances in the 1 to 10 tonne range and increase them for substances of the highest risk, thus providing an incentive to replace such chemicals.

It is anticipated that final agreement will be reached in the second half of 2006 so that REACH will enter into force in 2007.

Organization of Economic Co-operation and Development (OECD)

The 30 nation[18] OECD in 1991 adopted a Council decision/recommendation[19] *considering that strengthened national and co-operative international efforts to investigate systematically and reduce the risks of hazardous existing chemicals will substantially alleviate threats of serious or irreversible damage to the environment and/or the health of the general public or workers ... DECIDES that Member countries shall co-operatively investigate high production volume (HPV) chemicals in order to identify those which are potentially hazardous to the environment and/or to the health of the general public or workers*. In addition, the decision-recommendation *DECIDES that Member countries shall establish or strengthen national programmes aimed at the reduction of risk from existing chemicals to the environment and/or the health of the general public or workers* and *RECOMMENDS that, where appropriate, Member countries undertake concerted activities to reduce the risks of selected chemicals taking into account the entire life cycle of the chemicals. These activities could encompass both regulatory and non-regulatory measures including: the promotion of the use of cleaner products and technologies; emission inventories; product labelling; use limitations; economic incentives; and the phase-out or banning of chemicals*. The decision-recommendation also *INVITES the Secretary-General to take the necessary steps to ensure that this work is carried out in co-operation with other international organi-*

[18] The 30 member States of the OECD are Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea, Luxembourg, Mexico, The Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Spain, Sweden, Switzerland, Turkey, United Kingdom, United States.

[19] OECD, *Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Existing Chemicals,* C(90)163/Final, 31 January 1991. Available at http://www.oecd.org/ehs/CA90163.HTM

zations and, in particular, in collaboration with the UNEP/ IRPTC and the IPCS.

In order to make this task manageable, the OECD decided to concentrate on high production volume (HPV) chemicals – these are chemicals being produced or imported at levels greater than 1000 tonnes per year in at least one OECD country. The chemicals are listed in an OECD list of high production volume chemicals.[20] In addition, the OECD has agreed a minimum set of data in order to determine its potential hazard – the Screening Information Data Set (SIDS).[21] This enables resources to be concentrated on carrying out further work on chemicals of concern.

Using the data from the SIDS, mainly provided by co-operation with the chemical industry, OECD Member countries prepare a SIDS Initial Assessment Report (SIAR) which highlights any potential risk and contains recommendations for further action, if any, on the chemical. The SIAR is discussed at a meeting of experts from all member countries, from other international organizations, and from non-member countries, as nominated by the United Nations International Programme on Chemical Safety (IPCS), as well as representatives of the manufacturing companies. The SIAR, amended as appropriate, is made available world-wide by publication by the International Register of Potentially Toxic Chemicals (IRPTC) of the UNEP Chemicals programme.

International Council of Chemical Associations (ICCA) Global Initiative on HPV Chemicals

The global chemical industry launched a global initiative on High Production Volume (HPV) chemicals on 3 October 1998 at the meeting of the Board of Directors of the ICCA. The goal of this initiative is to prepare harmonized, internationally agreed data sets and initial hazard assessments under the SIDS programme of the OECD. The key element of the ICCA initiative is the improvement of the current database of approximately 1,400 OECD HPV chemicals; such chemicals have to be considered HPV or otherwise of interest in two or more regions (i.e. North America, Europe, or Japan). It is notable that the current ICCA HPV Working List contains several chemicals that appear in Schedule 3 of the CWC such as phosgene, hydrogen cyanide, phosphorus trichloride, phosphorus oxychloride, thionyl chloride, and triethyl phosphite.

National Initiatives

Individual countries such as the United Kingdom and the United States of America have adopted particular national strategies to augment the regional and international initiatives into the evaluation of the risk assessment of chemicals. As an example of a national approach, the United Kingdom has recently published a chemical strategy[22] setting out policies to avoid harm to the environment or to human health through environmental exposure to chemicals. This strategy includes the need for precautionary action for chemicals which are likely to cause serious or irreversible damage to the environment and identifies environmental persistence, tendency to bioaccumulate and toxicity as the properties that are especially important. A Stakeholder Forum was established in 2000 to advise the UK government on establishing criteria for rapidly identifying those chemicals which need a risk management strategy as a matter of urgency. These criteria were agreed in November 2000 in order to trigger a structured review process and provide a fast-track procedure for high risk chemicals. All documents considered by the Stakeholder Forum and all records of its meetings are publicly available on the internet at http:// www.defra.gov.uk/environment/chemicals/csf/papers.htm.

The UK Coordinated Chemical Risk Management Programme was launched in July 2005 to take forward the hazard and risk assessment and risk management of chemicals in the UK in the period leading up to the first assessments under the REACH regulations. The work will largely mirror that which has taken place under the OECD hazard assessment programme and the Existing Substances Regulations (ESR) risk assessment programme. The ESR programme is winding down in the run up to REACH but the UK wishes to ensure that work on existing chemicals continues. Nine chemicals have currently been entered into the programme and it is intended that 10–15 will be considered each year up to the first consideration of chemicals under REACH.

The United States of America in 1998 announced the Chemical Right-to-Know (RTK) Initiative[23] which was the US government response to an Environmental Protection Agency (EPA) study that found that very little basic toxicity information is publicly available on most of the HPV chemicals made and used in the USA. It should be noted that the US definition of HPV chemicals is different from that used in the rest of the world as the US definition is a chemical produced in or imported into the USA in amounts of over a million pounds a year – approximately 444 tonnes. The RTK initiative aims to rapidly test chemicals – using the same tests as in the OECD SIDS – and make the data available to scientists, policy makers, industry and the public. An EPA Chemical Hazard Data Availability Study[24] showed that the US produces or imports close to 3,000 chemicals at over 1 million pound a year yet there was no basic toxicity information publicly available for 43 % of the HPV chemicals produced in the US and that a full set of basic toxicity information is only available for 7 % of these chemicals. The EPA has invited industry chemical manufacturers and importers to participate in a voluntary challenge programme to provide the basic toxicity data on the HPV chemicals they produce. EPA intends that chemicals not adopted in the voluntary programme be tested under the HPV Test Rule. Detailed information on much of this programme is available on the EPA website.

Notification of new chemicals is required in the US under the TSCA (Toxic Substances Control Act) Inventory Update

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[20] The latest list is OECD, *The 1997 OECD List of High Production Volume Chemicals,* Paris, 1997. Available at http://www.oecd.org/ehs/hpv.htm

[21] Information on the SIDS, the SIDS Manual and the current status of SIDS are all available at http:// www.oecd.org/ehs/hpv.htm

[22] Department of the Environment, Transport and the Regions, *Sustainable production and use of chemicals — a strategic approach, The Government's Chemicals Strategy,* London, December 1999. Available at http://www.detr.gov/environment/chemistrat/index.htm

[23] Environmental Protection Agency, *Chemical Right-to-Know Initiative*. Available at http://www.epa.gov/ chemrtk

[24] Environmental Protection Agency, *Chemical Hazard Data Availability Study,* prepared by EPA's Office of Pollution Prevention and Toxics, April 1998. Available at http://www.epa.gov/opptintr/chemtest/hazchem.htm

Rule[25] which requires the reporting of basic data every four years on chemicals produced or imported in an amount exceeding 10,000 pounds (4,540 kilogrammes ~ 4.5 tonnes). Typically data is provided on approximately 9,000 organic substances each four years.

Other initiatives

Although particular attention has been given above to the European Union, OECD and ICCA initiatives demonstrating how there is a concerted effort to obtain data both on existing chemicals and on new chemicals placed on the market, it is evident that there are several global activities which are aimed at taking forward the six priority programme areas of Agenda 21, Chapter 19 so that there is sound management of chemicals worldwide. These include:

a) The International Programme on Chemical Safety (IPCS)[26] established in 1980 with the WHO as its executing agency. The two main roles of IPCS are to:

i. to establish the scientific basis for safe use of chemicals, and

ii. to strengthen national capabilities and capacities for chemical safety

The elements of work include evaluation of chemical risks to human health (preparations and publication of chemicals assessments, development and harmonization of scientifically sound methods for chemicals assessment) as well as capacity building.

b) The Intergovernmental Forum on Chemical Safety (IFCS)[27] established in 1994 which has as one of its functions the identification of priorities for cooperative action on chemical safety particularly taking into account the special needs of developing countries. IFCS has established Priorities for Action[28] for the implementation of the six priority programme areas of Agenda 21 Chapter 19.

c) The Inter-Organization Programme for the Sound Management of Chemicals (IOMC)[29] established in 1995 provides an overarching mechanism to coordinate the efforts of intergovernmental organizations in the assessment and management of chemicals. IOMC compiles summary reports of ongoing activities categorized by the six priority programme areas of Agenda 21 Chapter 19.

d) The Strategic Approach to International Chemicals Management (SAICM)[30] adopted in February 2006 is a policy framework for international action on chemical hazards. The Overarching Policy Strategy sets out the scope of SAICM, the needs it addresses and objectives for risk reduction, knowledge and information, governance, capacity-building and technical cooperation and illegal international traffic.

[25] Environmental Protection Agency, *The TSCA Inventory Update Rule (IUR).* Available at http://www.epa. gov/opptintr/iur98/

[26] Information on IPCS is available at http://www.who.int/pcs/

[27] Information on IFCS is available at http://www.who.int/ifcs/ifcsinfo.htm

[28] Available at http://ww.who.int/ifcs/res_2.htm

[29] Information on IOMC is available at http://www.who.int/iomc

[30] Information on SAIMC is available at http://www.chem.unep.ch/saicm/

Overview

There are already mechanisms in place within nations and regions, such as the European Union which are also reflected in other areas of the world, notably through the OECD and UNEP Chemicals programmes, to respond to the Agenda 21 Chapter 19 priority programme area to expand and accelerate the international assessment of chemical risks. More recently the SAICM initiative which aims by 2020 to ban chemicals that are hazardous to health or to the environment. These programmes ensure that data regarding the risks to public health and to the environment is available for both existing and new chemicals.

The data required increases with the quantity of chemical – using the EU situation as a model, the data requirements are as follows:

Annual quantity	Existing chemicals	New chemicals
> 10 kg and < 100 dag		VIIC
> 100 kg and 1< tonne		VIIB
> 1 tonne		VIIA
10 to 1000 tonnes	Low production volume	
> 100 tonnes		Level 1 (100 tonnes)
> 1000 tonnes	High production volume	Level 2 (1000 tonnes)

It is noted that national schemes, such as that in the United Kingdom, include the establishment of a fast-track procedure for chemicals that present a high risk to public health or to the environment.

Given that the EU now consists of some 25 countries – Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, United Kingdom – and is planned to expand further to include Bulgaria, and Romania with Croatia as a candidate country and that international trade in chemicals will continue to increase, it is reasonable to expect that the EU requirements for toxicity information on both existing and new chemicals will come to be applied to an increasing extent around the world. The SAICM initiative will also seek similar data on the hazards to health of chemicals that will be considered for banning by 2020.

In addition, there is considerable emphasis throughout in making information on the risks posed by chemicals available to the public.

The CWC requirements

The general purpose criterion within the CWC in Article II.1(a) states that *"chemical weapons"* include *"Toxic chemicals and their precursors, except where intended for purposes not prohibited under this Convention, as long as the types and quantities are consistent with such purposes."* As chemical weapons, by their nature, involve toxic chemicals which cause death, temporary incapacitation or permanent

harm to humans or animals, there is clearly a parallel between chemicals which might be used as chemical weapons and existing or new chemicals which are highly toxic – and are the subject of the ongoing national, regional and international initiatives aimed at ensuring the sound management of chemicals and the reduction of risks to human health or the environment.

In considering how National Authorities in the States Parties to the OPCW might implement the general purpose criterion, it is evident that particular attention should be focussed on those chemicals that present the greatest risks to public health and that are available in quantity for purposes not prohibited under the Convention. As traditionally, it has been recognised that for a single attack using chemical weapons, a quantity of about 1 tonne is required, it follows that for a militarily significant capability, a quantity of 300 tonnes or more would be needed. However, it should be noted that the UK/US/CA International Task Force-25 on Toxic Industrial Chemicals (TICs) focused attention on chemicals in excess of 30 tonnes. Consequently it would be appropriate for National Authorities to utilize in respect of existing chemicals, the data emerging from the ongoing international HPV chemicals programme (for chemicals in the US in excess of 444 tonnes per annum and elsewhere in excess of 1000 tonnes per annum) and in respect of new chemicals, the data relating to new substances being placed on the market in quantities in excess of 1 tonne, in order to identify those chemicals that presented the greatest risk to public health. National Authorities could then determine what further action was appropriate to ensure that the national obligations under Article VI.2 of the CWC are being met.

The general purpose criterion also applies to newly encountered hazardous chemicals which might be judged to lack market potential and so fail to enter the reporting systems. Such chemicals may be more toxic than the traditional stockpiled chemical weapon agents – and thus smaller quantities than 300 tonnes may present a risk to the Convention. It is, however, noted that the UK Health & Safety Executive guidance[31] on the notification of new substances states that the regulations apply to anyone who supplies a new substance which "includes selling it, lending it to someone else, passing it on, giving it away or importing it" into the EU. Furthermore, the EU requirements for the notification of new substances do require provision of toxicity information for any new chemical produced in quantities in excess of 10 kg. Whilst it is possible that a significant military quantity (300 tonnes or more for a traditional CW agent – or a smaller quantity for a more toxic novel chemical) of a new chemical that has not been placed on the market could be produced – and thus present a risk to the CWC – it is recognized that the overall trend is increasingly to require the provision of toxicity information on chemicals being produced in a facility for health and safety reasons and for the provision of such information on new chemicals being placed on the market in quantities in excess of 10 kg. National Authorities implementing the general purpose criterion will also need to consider other chemicals, both known and novel, which have not entered the reporting chains in the chemical safety regimes.

From the point of view of the effective implementation of the CWC, there is much to be said for the States Parties individually encouraging both the implementation and extension of the international HPV chemicals programme and the EU REACH programme. The national implementation of the general purpose criterion requires National Authorities to be aware of what toxic chemicals are being produced in what quantity in the country and whether these have the characteristics (toxic gases or toxic volatile liquids) that lend themselves to possible use by terrorists – and to requiring appropriate storage and access controls to such chemicals. For National Authorities in Europe, REACH is seen as being able to provide the basic information that would enable National Authorities to identify and monitor such chemicals as they judged presented a risk of being misused by terrorists – and then requiring additional national security controls of such chemicals and access thereto.

As the general purpose criterion is a central provision in the CWC, it is important that both the fact and the method of its implementation is made generally known. It would be important for National Authorities to report to the OPCW as well as nationally both that they have taken effective action and the nature of this action to implement the general purpose convention thereby strengthening the CWC.

[31] Health & Safety Executive, *The NONS Regulations*. Available at http://www.hse.gov.uk/hthdir/noframes/ nons/nons2.htm

SAŽETAK

Važnost implementacije kriterija opće namjene Konvencije za zabranu kemijskog oružja

G. S. Pearson

U radu se analizira međunarodni razvoj događaja u posljednjih pet godina koji se odnosi na primjenu temeljnih općih kriterija – središnjeg elementa Konvencije za zabranu kemijskog oružja, koji osigurava da Konvencija obuhvaća sve otrovne kemikalije. Rad istražuje neke novije međunarodne inicijative u svezi s kemikalijama koje su potencijalno opasne za javno zdravlje ili okoliš. Takve inicijative mogu dovesti do šire primjene temeljnih općih kriterija te tako osnažiti Konvenciju kao protutežu upotrebi otrovnih industrijskih i drugih kemikalija, bilo od strane država bilo od strane ne-državnih subjekata, kao što su npr. teroristi.

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