# 4. Documents from International Organizations (IOs)

States Parties to the BWC are joined in their efforts to govern biological weapons by other international organizations, in accordance with their respective mandates. Documents emanating from these organizations are included in this section. The activities and initiatives of these organizations also serve to strengthen the international norm against the hostile use of disease against humans, animals and plants and thereby fall within the regime to control biological weapons.

Each of these organisations referred to below have made presentations to Meetings of the inter-sessional process and/or Review Conferences. These presentations are available via the ISU website at http://www.unog.ch/bwc

## Food and Agriculture Organization

The Food and Agriculture Organization (FAO) based in Rome is a specialized agency of the United Nations established in 1945. The FAO's mandate is to raise levels of nutrition, improve agricultural productivity, better the lives of rural populations and contribute to the growth of the world economy. The FAO has acknowledged that it has a role in preventing and responding to emergencies that affect food security, including providing early warning, whether the emergencies are caused through natural or deliberate events. The organization has therefore established institutional mechanisms for coordinating emergency assistance. The FAO also hosts the secretariat of the 1952 International Plant Protection Convention (IPPC) (as amended) which is designed to secure action to prevent the introduction and spread of pests of plants and plant products, and to promote appropriate measures for their control.

On 28 June 2011, during the 37th FAO Conference, the 192 Member countries of the UN Food and Agriculture Organization (FAO) adopted a Resolution declaring global freedom from rinderpest, making it the first animal disease to be eliminated thanks to human efforts, and only the second disease of any kind, after smallpox in humans.

Officials from the FAO attended gave presentations at the 2007 Meeting of States Parties on "Current FAO Mechanisms for Dealing with the Deliberate Release of Detrimental Biological Agents" and at the 2008 Meeting of Experts on the "International Plant Protection Convention" Copies of the presentations are on the internet via the ISU website at http://www.unog.ch/bwc. This section of the Briefing Book includes a 2003 FAO document on "Biosecurity in Food and Agriculture".

## International Committee of the Red Cross

The International Committee of the Red Cross (ICRC) is an independent, neutral organization ensuring humanitarian protection and assistance for victims of war and armed violence. Established in 1863, the ICRC is headquartered in Geneva with delegations in around 80 countries and it has more than 12,000 staff. The ICRC's involvement in preventing the hostile application of poisons and disease is long standing; it issued an appeal against the use of poison gas in 1918, during the First World War. Regarding the use of these weapons as abhorrent, the ICRC has argued that "the use of such weapons would contravene existing international treaties and many of the fundamental norms of international humanitarian law".

In September 2002, the ICRC launched an *Appeal on Biotechnology, Weapons and Humanity* to promote consideration of the risks, rules and responsibilities related to advances in biotechnology which may lead to their hostile use.

Following on from this appeal, the ICRC released its principles of practice, *Preventing Hostile Use of the Life Sciences: From Ethics and Law to Best Practice*, in November 2004. Developed through a consultative process with experts in science and policy matters, the principles of practice are designed to form part of a multidisciplinary preventive framework which maximizes the benefits of research in life sciences and its application for humanity, while minimizing the risk of hostile use of advances in this domain. The 2002 appeal and the 2004 principles or practice are included in this section of the Briefing Book.

Representatives from the ICRC attended the 2010 Meeting of Experts and gave a presentation on "Responding to use or alleged use of biological weapons: A reality check". This presentation is available on the BWC's website; http://www.unog.ch/bwc

## Interpol

The International Criminal Police Organization, better known as Interpol, has become an active player in the regime to prevent the hostile use of disease. Interpol was established in 1923 and currently has 188 Member States. Using its perspective as an international law enforcement agency, and concentrating specifically on bioterrorist and other bio-criminal activities, the first ever Interpol Global Conference on Bioterrorism was held in March 2005 at Interpol headquarters in Lyon. The conference brought together senior police officers and counter-terrorism specialists, national and international governmental and non-governmental agencies, scientists and other academics and agreed a programme of work, including developing police training programmes; establishing a resource centre at the disposal of law enforcement worldwide; developing an Incident Response Guide for law enforcement; and enhancing cooperation and understanding between international organizations, including public health officials, customs and law enforcement officials.

As part of its aim to provide regional training for countries in need of capacity-building in the appropriate responses to a bioterrorist incident, Interpol has convened five regional workshops for law enforcements officials in South Africa in November 2005; Singapore in March 2006; Chile in July 2006, Ukraine in November 2006 and Oman in March 2007. Since then they have conducted nine train-the-trainer sessions and four table top exercises. In November 2010, the Dutch National Coordinator for Counterterrorism and Interpol co-organised a global bio-terrorism exercise, *Bioshield Global 2010,* in Utrecht, The Netherlands.

Officials from Interpol have attended and presented at the 2007 Meeting of Experts, on the Bioterrorism Prevention Programme and at the 2010 Meeting of Experts on "After action report Bioterrorism TTEX « BIOSHIELD » Americas region Argentina, 14-16 June 2010", and made statements at the 2007 Meeting of States Parties, the 2008 Meeting of States Parties.

The Final Communiqué of the 1st Interpol Global Conference on Bioterrorism is included in this section of the Briefing Book. Details of how to obtain a copy of the second edition of the Bioterrorism Incident Pre-Planning and Response Guide are available at https://www.interpol.int/Public/BioTerrorism/guide.asp

## Organization for the Prohibition of Chemical Weapons

The Organization for the Prohibition of Chemical Weapons (OPCW) consists of the 188 States Parties (as of 1 October 2011), to the 1993 Chemical Weapons Convention (CWC) which convene as the Conference of the States Parties; the Executive Council; and the

Technical Secretariat. The OPCW is headquartered in The Hague. The relationship between the CWC and the BWC is necessarily close for a number of reasons, not least the overlap between the two treaties regarding toxins and the increasingly blurred lines between chemistry and biology. In addition, Article IX of the BWC calls on its States Parties to "continue negotiations in good faith with a view to reaching early agreement on effective measures" to prohibit chemical weapons, so issues regarding the CWC are formally on the agenda of BWC review conferences.

The CWC stipulates that its States Parties should convene a Review Conference every five years (unlike the BWC, for which five-yearly review conferences only became established practice after the convening of the one review conference mandated by the treaty in 1980). The First CWC Review Conference took place in The Hague in April/May 2003. The Second CWC Review Conference convened in April 2008. As the CWC has an international organization to oversee and assist States Parties' implementation of the treaty (unlike the BWC), the preparations for, and the conduct of, both CWC Review Conferences differed from the BWC Review Conferences. An open-ended working group met periodically throughout the 18 months prior to the First Review Conference and for 21 months prior to the Second Review Conference to prepare its agenda. As part of the preparations for the Second Review Conference the OPCW hosted a meeting between the States Parties to the CWC and representatives of non-governmental organisations (NGOs).

As at the First Review Conference, States Parties at the Second Review Conference reviewed the operation of the CWC thematically, rather than article-by-article as in the BWC. The First CWC Review Conference drew attention to the issues of national implementation and universality and recommended the adoption of action plans to facilitate progress on both issues, which were subsequently adopted by the Executive Council and Conference of the States Parties in October 2003. The action plans incorporate various deadlines and reporting requirements to ensure that political pressure is maintained to promote their objectives. Both action plans have been reviewed at sessions of the Conference of the States Parties in 2007 and 2009 and follow-up decisions have been adopted. The CWC action plans on national implementation and universality, as well as the relevant 2009 decisions, are included in this section of the Briefing Book for reference.

In December 2010, a 14 member Advisory Panel on Future Priorities for the OPCW was established. The Advisory Panel had four plenary sessions between December 2010 and June 2011. On 15 July the Panel presented its report to the Director General of the OPCW, Ambassador Ahmet Üzümcü. The Advisory Panel noted on the subject of convergence between chemistry and biology

> The aims of these advances are plentiful: trying to find new types of medicines for humans and animals, new methods of pest control, enhanced food production, or new means of energy production – to mention just a few may also pose challenges to the way in which the Convention is being implemented. Furthermore, they call for answers with regard to the future relationship between the regimes that govern the ban, respectively, of chemical and biological weapons, and which have evolved separately in recent decades. (para 21-22)

Given the underlying trends in science and technology the Panel went on to recommend that

> the Technical Secretariat should establish a liaison (e.g., a point of contact) with the BWC implementation process. (para 119)

## World Health Organization

The World Health Organization (WHO) is the United Nations specialized agency for health established in April 1948 and based in Geneva. It is governed by its 193 Member States

through the World Health Assembly. The WHO has long been concerned with preventing the hostile exploitation of biology. For example, in 1967 the World Health Assembly resolved that "scientific achievements, and particularly in the field of biology and medicine—that most humane science—should be used only for mankind's benefit, but never to do it any harm." In 1969, the World Health Assembly, requested the WHO Director-General to continue to cooperate with the United Nations Secretary-General on the issue of chemical and biological weapons and the consequences of their possible use. The 1970 *WHO report on Health Aspects of Chemical and Biological Weapons: Report of a WHO Group of Consultants* was the result of that work and echoed the concerns of Member States about the misuse of biology. A revised and updated version of this 1970 report, *Public Health Response to Biological and Chemical Weapons—WHO Guidance* was published in 2004 (see www.who.int/csr/delibepidemics/biochemguide/en/index.html)

In May 2002, the World Health Assembly adopted resolution WHA 55.16 defining a role for WHO in responding to the "natural occurrence, accidental release or deliberate use of biological and chemical agents or radionuclear material that affect health." The WHO Secretariat also established a unit focusing on "preparedness for deliberate epidemics" and a scientific working group on life science research and global health security. In 2008 the WHO produced *Research policy and management of risks in life sciences research for global health security* and in 2010 a guidance document, *Responsible life sciences research for global health security*, provided a biorisk management framework upon which Member States and institutions can consider drawing upon. An extract of that 2010 document is in this book

In 2004, the WHO issued the third edition of its Laboratory Biosafety Manual which for the first time included a section on laboratory biosecurity. An extract of the manual is included in this section of the Briefing Book with a full copy available at www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/) In September 2006, the WHO released *Biorisk Management: Laboratory Biosecurity Guidance,* which elaborates on the biosecurity section of the Laboratory Biosafety Manual by providing more detailed guidance on biosecurity within a biological laboratory and addresses the basic principles and best practices of biosecurity. An extract of that guidance is available in this section of the Briefing Book with a full copy at www.who.int/entity/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

In 2005, WHO Member States unanimously adopted an update to the revised International Health Regulations (IHR). First adopted in 1969 (replacing the 1951 International Sanitary Regulations), the IHR provide an international legal framework for efforts to prevent and control the cross-border spread of communicable diseases. However, under the 1969 IHR, States are only required to notify the WHO if three diseases (cholera, plague and yellow fever) occur on their territory. In 1995, after outbreaks of emerging infectious diseases and the resurgence of existing diseases had rendered the IHR increasingly obsolete, WHO Member States requested a major updating of the regulations to adapt them to the highly mobile, globalized world of the 21st century. After negotiations in 2004 and 2005, the revised IHR text was adopted unanimously by the World Health Assembly at its session in 2005.

The updated regulations depart in important ways from the 1969 version, particularly in their expanded scope and the powers they grant to the WHO Secretariat. Rather than being limited to three diseases, the IHR 2005 require States to notify the WHO of any event that may constitute a "public health emergency of international concern" which is defined as "an extraordinary event which is determined …: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response." The decision of what constitutes a public health emergency of international concern is based on four criteria: (1) the seriousness of the public health impact; (2) the unusual or unexpected nature of the event; (3) the potential for international spread; and (4) the risk of restrictions on international travel or trade.

The IHR 2005 entered into force on 15 June 2007. The first major deadline in IHR (2005) implementation was the 15 June 2009 deadline for all WHO Member States to assess their core capacities. However as that deadline was approaching a pandemic (influenza A, H1N1) was declared. For the first time since their entry into force in 2007, the Regulations were used by the Director-General for the determination of a public health emergency of international concern, setting into motion the mechanisms laid out in the Regulations. In January 2010 the Director General of WHO suggested that the IHR Review Committee should review the functioning of the IHRs in light of the experience gained in the global response to the influenza A (H1N1) pandemic in 2009. The World Health Assembly adopted the report on 20th May 2011. A copy of that report is available via the WHO website: http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_10-en.pdf

The WHO is also charged with overseeing the two authorised stockpiles of the smallpox virus at laboratories in Russia and the USA. In 2005, the WHO established a Global Smallpox Vaccine Reserve with the intention of acquiring 5 million doses to be stored in Geneva and a further 200 million doses to be pledged by States, to facilitate an effective response to a smallpox outbreak (although the disease was declared eradicated in 1980 there is some concern that non-authorised stocks remain and could fall into the wrong hands).

At the 60th World Health Assembly in 2007 adopted resolution WHA60.1 on smallpox eradication: destruction of variola virus stocks requesting that the Director-General undertake a major review in 2010 of the results of the research undertaken, currently under way, and the plans and requirements for further essential research for global public health purposes so that the 64th World Health Assembly in 2011 might reach global consensus on the timing of the destruction of existing variola virus stocks. The resolution

> strongly reaffirmed the decision of previous Assemblies that the remaining stock of smallpox (variola) virus should be destroyed when crucial research based on the virus has been completed. The state of variola virus research will be reviewed at the 67th World Health Assembly in 2014 and in light of that, determining a date for destruction of the remaining virus stocks will be discussed.

## World Organization for Animal Health

The World Organization for Animal Health, formerly known as the Office International des Epizooties (OIE), was established in 1924 and is based in Paris. It currently has 178 Member States. Preventing the spread of animal diseases through international movements is one of the key objectives of the OIE. One of the ways it seeks to achieve this is by publishing international standards and guidelines aimed at preventing the importation of pathogens that are dangerous for animals and humans and strengthening veterinary services so that they can improve their surveillance and response systems. The OIE works in close partnership with the FAO, and together they have developed a joint initiative – the Global Framework for the Progressive Control of Trans-boundary Animal Diseases (GF-TADs).

In May 2001 OIE national delegations unanimously adopted resolution 18/2011 which officially recognised all 198 countries of the world with rinderpest-susceptible animal populations free of the disease. This is the first time that an animal disease has been declared eradicated.

In a special edition of the OIE's *Scientific and Technical Review* on "The spread of pathogens through international trade" (vol 30, number 1), one of the articles addresses the issue of intentional introduction of animal disease as an act of bioterrorism. The authors N.P. Clarke & J.L. Rinderknecht note that biology provides both increased threat of new disease entities and methods for earlier and more effective detection and intervention. This article

can be accessed for free by going to http://www.oie.int/en/publications-and-documentation/scientific-and-technical-review-free-access/list-of-issues/

Included in this section of the Briefing Book is another article from the OIE's *Scientific and Technical Review* on "International organisations and their role in helping to protect the worldwide community against natural and intentional biological disasters".

Officials from the OIE gave presentations or statements to the Meeting of States Parties 2007 and Meeting of Experts in 2009 and 2010.

January 2003

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منظمة الأغذية والزراعة للأمم المتحدة | 联合国粮食及农业组织 | Food and Agriculture Organization of the United Nations | Organisation des Nations Unies pour l'alimentation et l'agriculture | Organización de las Naciones Unidas para la Agricultura y la Alimentación

# COMMITTEE ON AGRICULTURE

## Seventeenth Session

## Rome, 31 March-4 April 2003

## Biosecurity in Food and Agriculture

## Item 9 of the Provisional Agenda

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# I. BACKGROUND

1. National regulatory and export certification systems are being challenged by large increases in the volume of food and agricultural products being traded internationally, by the expanding variety of imported products and by the growing number of countries from which these imports are originating. Increased travel is also creating more pathways to spread pests, diseases and other hazards that are moving faster and further than ever before. Improved coordination is being sought among national bodies responsible for enforcing sanitary, phytosanitary and zoosanitary measures to better protect human, animal and plant life and health without creating unnecessary technical barriers to trade.

2. FAO uses the term, *Biosecurity*, in relation to sanitary, phytosanitary and zoosanitary measures applied in food and agricultural regulatory systems. FAO uses the term synonymously with "*Biosecurity* in food and agriculture". *Biosecurity* is a relatively new concept and a term that is evolving as usage varies among countries with different specialist groups using it in different ways. For FAO, *Biosecurity* broadly describes the process and objective of managing biological risks associated with food and agriculture in a holistic manner.[1]

3. *Biosecurity* measures in agriculture are needed:

i) To protect agricultural production systems, and those dependent on these systems: Producers and others dependent on agriculture can see their livelihood destroyed by animal and plant pests and disease or damage to the environment such as impacts resulting from invasive alien species;

ii) To protect human health and consumer confidence in agricultural products: *Biosecurity* measures are essential to protect consumers–particularly vulnerable groups–that can be exposed to severe health risks, which *Biosecurity* attempts to prevent;

iii) To protect the environment and promote sustainable production: Public awareness of environmental issues and human dependency on biodiversity has resulted in numerous commitments to achieving sustainable development, and achieving these will require an effective approach to *Biosecurity*.

4. *Biosecurity* is a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) that analyse and manage risks in the sectors of food safety, animal life and health, and plant life and health, including associated environmental risk. *Biosecurity* covers the introduction of plant pests, animal pests and diseases, and zoonoses, the introduction and release of genetically modified organisms (GMOs) and their products, and the introduction and management of invasive alien species and genotypes. *Biosecurity* is a holistic concept of direct relevance to the sustainability of agriculture, food safety, and the protection of the environment, including biodiversity.

5. The issues encompassed in *Biosecurity* have traditionally been dealt with in a sectorial manner by means of food safety laws, and animal and plant quarantine and pesticide regulations. Implementation of such laws and regulations has also traditionally been sectorial. Emerging issues of Biosafety[2] and to control the introduction and management of invasive alien species into the environment means that a growing number of issues need to be addressed. This results in

[1] With "agriculture" used in its broadest sense to include agronomy, livestock, forestry, fisheries and related environmental aspects.

[2] The term, "biosafety" refers to the introduction, release and use of genetically modified organisms. The Cartagena Protocol on Biosafety to the CBD applies to "the transboundary movements, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health".

costly regulatory systems that require high investment and recurrent costs (infrastructure and human resources).

6. In recent years, there has been greater recognition of the importance of *Biosecurity* in relation to protection of the environment. In some countries, *Biosecurity* programmes are expanding to include natural ecosystems, including forest and marine ecosystems. The role of traditional *Biosecurity*-related institutions is expanding beyond agricultural production to public health and the environment. Although some of these issues may be outside the core competencies of FAO, they must be addressed in the establishment of sustainable national *Biosecurity* systems. An important factor, which is within FAO's competence, is the heightened attention paid to the environmental impacts of agricultural practices, including increased scrutiny of animal and plant pest and disease control methods.

7. Countries with small economies and limited capacity cannot afford traditional sector-oriented approaches, which are often ill-adapted to their means and circumstances. There is a growing recognition that *Biosecurity* will profit from a more integrated approach. Closer cooperation among institutions responsible for implementing *Biosecurity* and the rationalisation of infrastructures, where appropriate, will benefit, in particular, developing countries and countries with economies in transition. Models to rationalise regulatory functions among sectors in the quest for improved effectiveness and efficiency have appeared in a number of countries. For example, New Zealand has had a Biosecurity Act since 1993 and a Biosecurity Minister and Council since 1999. In Belize, food safety, and animal and plant quarantine and environmental issues, are dealt with by a single authority, the Belize Agricultural and Health Authority.

8. The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization, disciplines SPS measures in relation to international trade. The Codex Alimentarius Commission (Codex), the International Plant Protection Convention (IPPC) and the Office international des epizooties (OIE) provide international standards for food safety, plant health, and animal health, respectively.

9. A further relevant instrument (not yet entered into force) is the Cartagena Protocol, which applies to the transboundary movement, transit, handling and use of Living Genetically Modified Organisms (LMOs). Guidelines on the management of invasive alien species have been developed under the Convention on Biological Diversity (CBD).

10. This group of international agreements, organizations and programmes are part of a loose international framework for *Biosecurity*, and reflect the historically sectorial approach to regulation in this area.

11. FAO has recognized the growing importance of *Biosecurity*, and therefore made it one of the Organization's sixteen Priority Areas for Inter-disciplinary Action (PAIAs). *Biosecurity* was included in the Medium Term Plan to address corporate strategy B, which aims at "*promoting, developing and reinforcing policy and regulatory frameworks for food, agriculture, fisheries and forestry*."[3]

12. *Biosecurity* in Food and Agriculture was discussed by COAG in March 2001, in document COAG/01/8. The Committee appreciated the proactive nature of the document and welcomed the recommendation to convene a consultation to explore *Biosecurity* further. The Committee also appreciated the scope for in-house coordination through the PAIA on *Biosecurity*, in particular to identify possibilities to harmonize, where appropriate, methods of risk analysis, to coordinate capacity building, and to establish a system for the exchange of official information on *Biosecurity*. With the aid of external assistance[4], FAO, through the *Biosecurity* PAIA, undertook

[3] The Strategic Framework for FAO 2000-2015, Food and Agriculture Organization of the United Nations, Rome, 1999.

[4] Financial support from the FAO/Government of the Netherlands partnership programme for international consultation, and financial and in-kind assistance from the USA Government for the information exchange system.

to examine and advance *Biosecurity* in food and agriculture in order to explore possible synergies in relation to standard setting, information exchange and capacity-building.

13. In September 2002, an Inter-agency Meeting on *Biosecurity* in Food and Agriculture[5] discussed the concept and possible mechanisms for cooperation among relevant international organizations. The Inter-agency meeting was followed by an Expert Consultation[6], with the participation of nineteen international experts and resource persons from twelve countries, to explore the relevance of *Biosecurity* in Food and Agriculture, and to advise FAO on modalities for its implementation, particularly in developing countries.

14. In order to broaden awareness of *Biosecurity* and to debate its relevance and practicality more widely, particularly in relation to the needs of developing countries and countries with economies in transition, FAO convened an international Technical Consultation[7] in Bangkok, 13-17 January 2003, with the participation of 38 countries and eight international organizations, including *Codex Alimentarius*, the IPPC, OIE, and the CBD.

15. As information exchange is a common core component of *Biosecurity* sectors, FAO has initiated a project to develop an International Portal for Food Safety and Animal and Plant Health, for the exchange of official *Biosecurity*-related information. This takes the form of a project, implemented in cooperation with other relevant organizations, so as to seek complementarities and synergies, and to avoid duplication.

16. Capacity-building in developing countries and countries with economies in transition has mostly been approached on a sectorial basis. Requests for such assistance have increased substantially over recent years. At the same time, multi-sectorial awareness building has started, through programmes like the FAO Uruguay Round training programme, and various initiatives of WTO and the World Bank, to which the standard-setting organizations have contributed. At the WTO Ministerial meeting in Doha, the Executive Heads of FAO, OIE, WHO, the World Bank and WTO issued a joint communiqué committing their institutions to explore new modes of collaboration to improve the efficiency of their technical assistance programmes on matters related to the SPS Agreement, and to enhance the level and quality of the participation of these countries in international standard setting bodies. The five agencies, including Codex and IPPC, have agreed to establish a Standards and Trade Development Facility.

17. Collaborative efforts to assist developing countries may, in future, also benefit from the participation of international institutions that address biosafety and the introduction and management of invasive alien species.

18. FAO has also developed a programme proposal to address capacity-building in relation to biotechnology, food safety and animal and plant life and health.

# II. OUTCOME OF THE CONSULTATION PROCESS

19. The present document is based on the outcome of a broad consultation process on *Biosecurity*, which included the Inter-agency Meeting, the Expert Consultation, specialized studies and bilateral interaction with interested bodies. The process culminated in the inter-

[5] Delegates from eleven organizations participated in the meeting: the Convention on Biological Diversity (CBD), the World Trade Organisation (WTO), the United Nations Environment Programme (UNEP), the United Nations Industrial Development Organisation (UNIDO), the Organisation for European Economic Cooperation and Development (OECD), *Office international des épizooties* (OIE), the International Plant Protection Convention (IPPC), *Codex Alimentarius*, FAO, the International Plant Genetic Resource Institute (IPGRI), the International Centre for Genetic Engineering (ICGEB).

[6] Report of the Expert Consultation on *Biosecurity* in Food and Agriculture, 10-13 September 2002, FAO, Rome, Italy.

[7] Report of the Technical Consultation on Biological Risk Management in Food and Agriculture, 13-17 January 2003, Bangkok, Thailand.

governmental Technical Consultation, and the following section contains its conclusions and recommendations.

20. The Consultation recognized the advantages of a more coherent, holistic approach to *Biosecurity* that sought synergies between the sectors at national and international levels, without necessarily creating new or unified structures. It further recognized that the integration of various aspects of *Biosecurity* and the institutions involved was occurring in a number of countries. The traditional focus on regulating individual production systems was shifting to one of ensuring confidence in the overall regulatory framework. It noted that many countries, including developing countries and countries with economies in transition, were revising their *Biosecurity* arrangements to take into account the SPS Agreement, at the same time seeking greater efficiencies. The Consultation recognized the valuable contribution of the development of international standards[8], which provided countries, particularly small countries, with a means to achieve *Biosecurity* objectives, while reducing the burden of having to implement national risk assessment and management procedures in each individual case. However, external support for capacity-building in developing countries and countries with economies in transition, to enable them to effect such improvements, including facilitating the development of trade partnerships, was crucial for many countries. It stressed the need to further incorporate developing country perspectives in the development of international standards, in ways that took into account local conditions, and in ways that facilitated their economic development. These included economies characterized by the existence of large numbers of small farmer communities.

21. The Consultation recognized the central role of risk analysis as a framework for *Biosecurity*, including across sectors. There was therefore an opportunity to harmonize terminology and methodology, while respecting the need for individual sectors to tailor risk analysis procedures to the characteristics of the risks involved. It recognized that risk analysis procedures should provide an appropriate basis for *Biosecurity*, while not creating unnecessary barriers to trade. Increased trade was increasing the need for effective risk analysis capacities, including in developing countries and countries with economies in transition, and for bilaterally and multilaterally agreed standards. In this context, many developing countries and countries with economies in transition have insufficient risk analysis capacities to support *Biosecurity* frameworks for both imports and exports. The Consultation recognized that biological risk analysis across sectors necessarily involves the consideration of complex risks and uncertainties associated with them.

22. The Consultation supported the need for a variety of economic analyses in relation to *Biosecurity*. It was suggested that examples be compiled and analysed of where pest eradication campaigns, or the implementation of improved food standards, had resulted in quantifiable export increases. One possible methodology could be developed around an analysis of the values of goods transiting through control and inspection systems, in relation to the costs of such systems. Examples of effective, pooled regional *Biosecurity* standards and procedures were needed. Methodologies were required to document the economic advantages flowing from cross-sectorial cooperation, and of documenting and analysing the costs and the benefits of public-private sector cooperation, as well as where investments in *Biosecurity* measures had been most successful. A further methodology could consider market opportunities in relation to the *Biosecurity* investments that would be required to realize them.

23. The Consultation recognized the central importance of capacity-building, in particular to assist developing countries and countries with economies in transition to establish and sustain their *Biosecurity* systems, to meet international *Biosecurity* standards for food and agriculture, and take advantage of trade opportunities. It welcomed the various initiatives under way. The Consultation stressed that institutional sustainability should be a guiding priority in capacity-building. It was agreed that the IPPC's Phytosanitary Capacity Evaluation model and similar tools

[8] The term "standards" used in this document includes agreed guidelines, recommendations and procedures.

would be useful in the development of *Biosecurity*-wide capacity-building tools, and that relevant international organizations should be associated in such an initiative. The Consultation noted that case studies on institutional development for *Biosecurity* would be valuable, and that governments should take measures to ensure lasting support for their *Biosecurity* organizations.

24. The Consultation supported the development of the International Portal for Food Safety and Animal and Plant Health as a valuable database and information tool for *Biosecurity*, which could help bring together the various sectors involved, nationally and internationally. It should be coordinated with other relevant organizations, so as to add value, avoid duplication, and achieve inter-operability. The Consultation noted that countries needed to improve their internal system for communication and information exchange.

## A. GENERAL RECOMMENDATIONS

25. The Consultation considered the use of the English term, *Biosecurity*, bearing in mind the need for translation and to harmonize terminology. Delegates noted that the term *Biosecurity* is used widely, and that usage varies among countries. They also noted that the term presents translation challenges, particularly for Spanish and French translation[9]. Following considerable discussion on terminology, delegates agreed that the term *Biosecurity* in food and agriculture best describes the concept as used by FAO, and recommended that for the purposes of the Consultation and this report, the English term, *Biosecurity* be used in all languages, and that it be italicized and capitalized, and not be translated.

26. The Consultation considered that *Biosecurity* involves the management of biological risks in a comprehensive manner to achieve food safety, protect animal and plant life and health, protect the environment and contribute to its sustainable use. Achieving *Biosecurity* requires an understanding of, and the ability to analyse diverse and complex risks, and determine and apply measures in a coherent manner while respecting differences among sectors and organizations. Risk analysis[10] is the most important unifying concept across different *Biosecurity* sectors[11]. *Biosecurity* frameworks should not create unjustified barriers to international trade.

27. The Consultation recommended that:

i) Countries should determine the potential for synergies and harmonization within their national and sub-national regulatory frameworks that would result from a holistic and coordinated approach to *Biosecurity*. Policy-makers should recognize the importance of *Biosecurity* as a key element of sustainable development, and the benefits, including in trade that can be gained from comprehensive approaches to *Biosecurity*.

ii) Recognizing the efficiencies that may emanate from regional and sub-regional approaches to risk analysis, particularly in relation to animal and plant life and health, and living modified organisms, countries should also cooperate to address *Biosecurity* issues at regional and sub-regional levels.

iii) Risk analysis and management frameworks are essential to achieve *Biosecurity*. In the past, such frameworks have been mostly sectorial or used to address specific technical issues. In future, such frameworks should seek to improve collaboration among diverse interests and institutions (particularly agriculture, public health, environment, trade, and their associated stakeholders) to achieve *Biosecurity* in a mutually supportive manner, thus avoiding duplication and possible inconsistencies.

[9] The terms "Bioseguridad" and "Biosécurité" have been used in the Cartagena Protocol on Biosafety for the translation of the word "Biosafety" (see footnote 2).

[10] Risk analysis as used in this document includes risk assessment, risk management and risk communication, unless otherwise indicated.

[11] These include, *inter alia*, food safety, plant and animal health and life, and the environment.

iv) General principles for risk analysis for biological risk analysis in food and agriculture are the same, although procedures may differ depending on the hazards addressed. The IPPC, the *Codex* Alimentarius, the OIE, the CBD and its Cartagena Protocol (noting that the Protocol has not yet entered into force), where appropriate, should apply coherent risk analysis methodologies in different sectors by jointly analysing differences and commonalities in approaches, and use of terms in risk analysis.

v) Many developing countries and countries with economies in transition have limited infrastructure and limited capacity to undertake risk analysis, and to enforce risk management decisions. International standards should thus be developed with due consideration of their implications and impacts on developing countries and countries with economies in transition, including the effect on their ability to participate in international trade. The participation of countries in the development of such standards should be supported.

vi) Countries should implement a more coherent and holistic approach to biological risk management in food and agriculture by respective government authorities to strengthen the achievement of common *Biosecurity* objectives.

vii) FAO, in collaboration with relevant international and regional organizations should provide guidance and develop guidelines to assist countries to develop and implement national *Biosecurity* frameworks in harmony with their international obligations.

viii) FAO, in collaboration with other relevant international and regional organizations should consider undertaking further analysis to better understand and advance *Biosecurity*, including:

- analysis of differences, similarities, duplications and gaps, across the various sectors of *Biosecurity*;
- the implications for developing countries and countries with economies in transition of *Biosecurity* standards, procedures and technical regulations; and
- measures required to establish coherent and mutually supportive *Biosecurity* approaches in relation to food safety, animal health and life, plant health and life, and the environment.

## B. CAPACITY BUILDING RECOMMENDATIONS

28. The Consultation stressed the importance of capacity-building as the challenges of *Biosecurity* are increasingly placing demands on countries, with urgent needs in particular areas. The Consultation identified the critical need for capacity-building for developing countries and countries with economies in transition, taking into account both the public and private sector.

29. The Consultation recommended that:

ix) FAO should work with *Codex*, the IPPC, the OIE, the CBD and other relevant international organizations to further develop tools, including tools to extend the Phytosanitary Capacity Evaluation to other sectors, to assist countries analyse their capacity-building needs that take account of the full scope of *Biosecurity*, including the communicational, legal, institutional, scientific and technical aspects.

x) Countries should use the tools developed under the above recommendations or other appropriate methodologies to identify, analyse and integrate their *Biosecurity* capacity building needs and determine priorities.

xi) Donors should base their support for capacity-building activities on this assessment.

xii) In developing capacity-building activities, donors and recipient countries should aim to achieve sustainable improvements in *Biosecurity* systems.

xiii) The roles and responsibilities of both the public and private sectors should be considered in planning *Biosecurity* capacity-building initiatives.

xiv) Appropriate linkages and coordination mechanisms among existing and planned *Biosecurity* capacity-building initiatives should be established to enhance complementarity and avoid duplication of efforts, and to ensure that capacity building is directed at country and regional *Biosecurity* priorities.

xv) FAO, in collaboration with other relevant international organizations, should compile, analyse and summarize examples or cases studies of *inter alia*: economic analysis of *Biosecurity*; establishment of regional *Biosecurity* approaches; and implementation of *Biosecurity* measures, including risk communications measures, and widely share these examples among Member Nations and relevant organizations.

### C. INFORMATION EXCHANGE RECOMMENDATIONS

30. The Consultation stressed the need to share information and to ensure better understanding of the requirements for achieving *Biosecurity*. It endorsed the need for an Internet-based *Biosecurity* Portal to facilitate information exchange on *Biosecurity*. It also recognized the importance of information access and exchange in developing *Biosecurity* capacity.

31. The Consultation recommended that:

xvi) FAO, in collaboration with relevant organizations, should give further support to the development of a publicly accessible, Internet-based *Biosecurity* Portal mechanism for exchange of official information on food safety, and animal and plant health and the environment, which would facilitate improved communication among countries in these sectors, noting the need for this mechanism to complement but not duplicate other relevant information exchange mechanisms. The Portal should be user friendly, demand-driven and linked to other existing relevant portals.

xvii) Countries should be encouraged to develop appropriate mechanisms for information exchange in *Biosecurity*, and to participate in the development of the Portal.

### D. COMMUNICATION RECOMMENDATION

32. The Consultation recommended that:

xviii) Countries should ensure adequate opportunities for appropriate participation by all stakeholders, including members of the public, in addressing *Biosecurity*, and enable them to contribute in meaningful ways to the design and implementation of *Biosecurity* risk management frameworks.

## III. ISSUES THE COMMITTEE MAY WISH TO CONSIDER

33. The Committee may wish to consider the recommendations of the Technical Consultation, as given above, for possible endorsement, and where appropriate give guidance to the secretariat in the area of *Biosecurity*.

# Full text

# APPEAL

## of the International Committee of the Red Cross

## on *Biotechnology, Weapons and Humanity*

Alarmed by the potential hostile uses of biotechnology, **the International Committee of the Red Cross (ICRC) appeals** to:

all political and military authorities to strengthen their commitment to the international humanitarian law norms which prohibit the hostile uses of biological agents, and to work together to subject potentially dangerous biotechnology to effective controls.

the scientific and medical communities, industry and civil society in general to ensure that potentially dangerous biological knowledge and agents be subject to effective controls.

**The ICRC appeals in particular:**

### TO ALL POLITICAL AND MILITARY AUTHORITIES

- To become parties to the 1925 Geneva Protocol and the 1972 Biological Weapons Convention, if they have not already done so, to encourage States which are not parties to become parties, and to lift reservations on use to the 1925 Geneva Protocol,
- To resume with determination efforts to ensure faithful implementation of these treaties and develop appropriate mechanisms to maintain their relevance in the face of scientific developments,
- To adopt stringent national legislation, where it does not yet exist, for implementation of the 1925 Geneva Protocol and the 1972 Biological Weapons Convention, and to enact effective controls on biological agents with potential for abuse,
- To ensure that any person who commits acts prohibited by the above instruments is prosecuted,
- To undertake actions to ensure that the legal norms prohibiting biological warfare are known and respected by members of armed forces,
- To encourage the development of effective codes of conduct by scientific and medical associations and by industry to govern activities and biological agents with potential for abuse, and

- To enhance international cooperation, including through the development of greater international capacity to monitor and respond to outbreaks of infectious disease.

## TO THE SCIENTIFIC AND MEDICAL COMMUNITIES AND TO THE BIOTECHNOLOGY AND PHARMACEUTICAL INDUSTRIES

- To scrutinize all research with potentially dangerous consequences and to ensure it is submitted to rigorous and independent peer review,

- To adopt professional and industrial codes of conduct aimed at preventing the abuse of biological agents,

- To ensure effective regulation of research programs, facilities and biological agents which may lend themselves to misuse, and supervision of individuals with access to sensitive technologies, and

- To support enhanced national and international programs to prevent and respond to the spread of infectious disease.

The ICRC calls on all those addressed here to assume their responsibilities as members of a species whose future may be gravely threatened by abuse of biological knowledge. The ICRC appeals to you to make your contribution to the age-old effort to protect humanity from disease. We urge you to consider the threshold at which we all stand and to remember our common humanity.

The ICRC urges States to adopt at a high political level an international Declaration on "Biotechnology, Weapons and Humanity" containing a renewed commitment to existing norms and specific commitments to future preventive action.

Geneva, September 2002

ICRC International Committee of the Red Cross

# Preventing hostile use of the life sciences: From ethics and law to best practice

**11-11-2004**

**The following "Principles of Practice" incorporate some key points of discussion about ethics relating to life sciences. They apply to all stakeholders in the life sciences. The objective is to build a bridge from pertinent ethics and laws which should prevent poisoning and deliberate spread of infectious disease to best practice within the life science community.**

## Principles and Action Points

### General Principle

Life sciences have been, and must continue to be, of great benefit to humanity. However, the benefits to humanity of any particular development in the life sciences must always outweigh the risks of that development being used to facilitate poisoning and deliberate spread of infectious disease.

### Principles and action points

To minimize the risks of poisoning and deliberate spread of infectious disease resulting from advances in the life sciences, those working in this field should recognise their individual and collective responsibilities, bear in mind certain key principles and take action as appropriate:

## Conflict of interest

1. Preventing advances in the life sciences from being used for poisoning and deliberate spread of infectious disease must always take precedence over personal, commercial or security interests.

**Action points:**

- Encourage education of scientists from undergraduate level onwards about pertinent ethical issues.
- Develop and promote professional ethics and adhere to agreed codes of conduct that may be voluntary, professional or enforced as appropriate.

## Legal responsibilities

2. Research and its application must always be compatible with respect for, and promotion of, national and international laws.

**Action points:**

- Encourage education of scientists from undergraduate level onwards about relevant national and international laws.

- Work with government officials to prevent biological or chemical weapons from being developed, produced, transferred or used and call for governments to fully uphold, implement and strengthen existing and pertinent laws.

## Diligence

3. Undertaking well-intentioned research does not justify neglect of possible hostile use of the outcome.

**Action points:**

- Be diligent in safeguarding legitimate research, whether in academia, industry or defence from being used for any hostile purpose, including the development of chemical or biological weapons.
- Raise concerns with policy-makers an d institutions about existing regulations which may not be adequate for safeguarding legitimate research.

## Governance of research and publication

4. Knowledge gained from research must ultimately become universal for the progress of science; however, the potential for hostile use of some advances in life science and biotechnology may pose a fundamental dilemma about how and when knowledge is made accessible to others.

**Action points:**

- Maintain an open dialogue about and, if possible, define what constitutes'dangerous'research.
- Build a regime of governance of potentially dangerous research and its subsequent publication.

## A culture of transparency

5. Transparency and a culture of dialogue together constitute the most important element in minimising the risk that advances in life sciences will be turned to hostile use.

**Action point:**

- Create and promote a working culture of dialogue and transparency between colleagues about the nature of research undertaken.

## Increasing speed of advances

6. The increasing power and variety of advances in life sciences must be matched by commensurate objective assessments of risk and closer vigilance.

**Action point:**

- Be vigilant with respect to scientific advances that could facilitate poisoning and the deliberate spread of infectious disease.
- Discuss mechanisms that could ensure that the divide between advances in science and advances in its governance and applicable law is minimised.

## A "web of prevention"

7. Minimising the risk of poisoning and deliberate spread of infectious disease require a range of synergistic measures and so is, by necessity, a multidisciplinary endeavour.

**Action points:**

- Encourage and participate in multidisciplinary dialogue and action about the prevention of poisoning and deliberate spread of infectious disease.
- Make the risks of poisoning and deliberate spread of infectious disease comprehensible to actors in related fields and explore ways to work in cooperation to reduce the risks.
- Work with the media with these principles of practice and action points in mind.

## Voicing concern

8. Those working in life sciences who voice concern and take responsible action require and deserve political and professional support and protection.

**Action points:**

- Encourage people who work in the life sciences to voice concern about issues relating to poisoning and the deliberate spread of infectious disease.
- Ensure that adequate mechanisms exist for voicing such concerns without fear of retribution.

## Specific characteristics of biological weapons

9. Because of their particular characteristics, preventing the development, proliferation and use of biological weapons requires a very different approach to preventing the development, proliferation and use of chemical weapons.

**Action point:**

- Develop and promote awareness of the specific risks of the development, proliferation and use of biological weapons and promote preventive strategies.

## "Dual use"

10. Some materials and technologies more than others lend themselves to poisoning and deliberate spread of infectious disease.

**Action point:**

- Be vigilant with respect to and maintain a dialogue about the'dual-use'phenomenon.

## Diffusion of materials and technologies

11. Materials and technologies associated with the life sciences can diffuse rapidly.

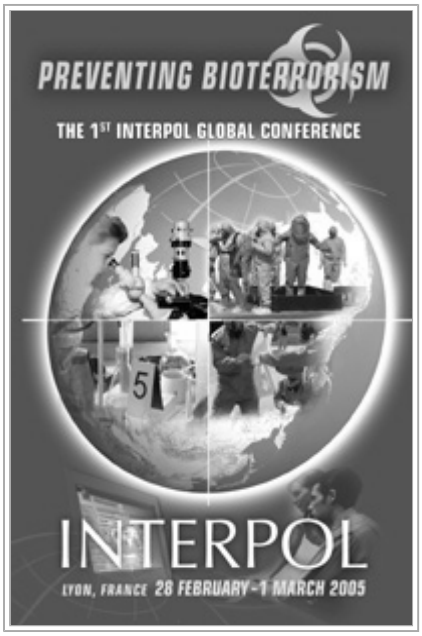
**Action point:**

- Ensure materials and technologies are transferred in a manner that minimises the risk of their use for poisoning and deliberate spread of infectious disease while maximising their potential benefit for humanity.

Bioterrorism

# Final Communiqué

**1st Interpol Global Conference**
Lyon, France, 1-2 March 2005




## Introduction

The 1st Interpol Global Conference on Preventing Bio-terrorism was held in Lyon, France on 1 and 2 March 2005. It was attended by more than 500 delegates from 155 countries, with representatives from the police, scientific and academic communities, as well as delegates from international and non governmental organizations.

## The Conference,

*Recognized* the continuing threat posed by global terrorism and the ongoing need to enhance the co-ordination of effort at national and international levels, in order to strengthen the global response to this serious challenge and threat to international security;

*Acknowledged* that the terrorist use of biological weapons, inter alia, constitutes a serious threat to global security and to the civilian population across the world;

*Agreed* that effective international law enforcement co-ordination and national action is necessary, in partnership with relevant agencies, to recognize, prevent and contain the threat from the terrorist use of biological weapons; and

*Welcomed* the timely Interpol initiative, supported by the Alfred P Sloan Foundation, to improve the understanding, preparedness and capability of law enforcement agencies to tackle bio-terrorism.

In particular, the Conference noted that:

> *Developing* further co-operation between law enforcement agencies, public and animal health authorities and other relevant organizations, nationally and internationally, is essential to address the threat of bio-terrorism; and
>
> *Interpol* has an important role to play in supporting national and international efforts to prevent and investigate terrorism generally, and bio-terrorism particularly.

In this respect, delegates agreed that:

- The Conference had provided a valuable opportunity to improve understanding of the current and future threats posed by bio-terrorism;

- Interpol, as the global police organization, should further promote and enhance co-operation and partnership initiatives between law enforcement and relevant agencies to strengthen the global response to bio-terrorism; and

- Specifically, Interpol should be encouraged to further co-ordinate, develop and enhance the knowledge, training and capability of law enforcement to recognize, prevent, contain and investigate bio-terrorist threats, including by:

    - establishing a resource centre at the disposal of worldwide law enforcement;

    - enhancing co-operation and understanding between international organizations and research centres, including those dealing in genetic engineering;

    - developing an Incident Response Guide; and,

    - providing training and awareness programmes, including Regional workshops;

    - seeking to develop, with law enforcement and relevant agencies, ways of gathering and sharing information concerning the threat of bio-terrorism more effectively.

**News and Media Releases**

- Interpol Conference agrees on measures to fight Bio-Terrorism ar en es fr
- Bio-Terrorism Conference opens with warning of major threat ar en es fr
- Interpol Bio-Terrorism Conference set to be largest ever ar en es fr
- Interpol hosts first global conference on bio-terrorism ar en es fr
- Interpol launches police training programme on bio-terrorism ar en es fr

**Speeches**

- Speech by Jackie Selebi, President, Interpol
- Speech by Ronald K. Noble, Secretary General, Interpol

**See also**

- All Interpol bioterrorism workshops and events
- Minutes ar en es fr
- Presentations
- Final Communiqué ar en es fr
- Steps taken by member countries in response to UNSCR 1540
- National Laws and Measures
- Speakers' CVs
- Conference announcement en es fr
- Photo gallery en es fr
- Agenda (Diffusion - 30/12/2004) ar en es fr (Acrobat files)

OPCW

Conference of the States Parties

Eighth Session
20 – 24 October 2003

C-8/DEC.16
24 October 2003
Original: ENGLISH

# DECISION

## PLAN OF ACTION REGARDING THE IMPLEMENTATION OF ARTICLE VII OBLIGATIONS

**The Conference of the States Parties**,

**Recalling** the recommendations that the First Special Session of the Conference of the States Parties to Review the Operation of the Chemical Weapons Convention (First Review Conference) made on national implementation measures (as covered under agenda item 7(c)(v) of its report, subparagraphs 7.74 to 7.83 of RC-1/5, dated 9 May 2003), in particular the agreement in subparagraph 7.83(h) of that report to develop, at its next regular session, a plan of action based on a recommendation from the Executive Council (hereinafter "the Council") regarding the implementation of obligations under Article VII of the Chemical Weapons Convention (hereinafter "the Convention"), with the objective of fostering the full, effective, and non-discriminatory implementation of the Convention by all States Parties;

**Stressing** the need to fully implement the recommendations of the First Review Conference on national implementation measures;

**Recognising** how important and how urgent it is that States Parties complete their obligations under Article VII to adopt, in accordance with their constitutional processes, the necessary measures to implement the Convention;

**Convinced** that the full and effective implementation of Article VII by all States Parties also contributes to universal adherence to the Convention;

**Concerned** that a large number of States Parties have not yet fulfilled the range of obligations under Article VII, and **recognising** that many of them may have difficulties in doing so; and

**Taking note of** the report by the Director-General to the Eighth Session of the Conference on national implementation measures (C-8/DG.5, dated 18 September 2003, and Add.1, dated 22 October 2003);

**Having received** the recommendation by the Council on the Plan of Action on national implementation measures (EC-M-23/DEC.2, dated 21 October 2003),

**Hereby:**

Identification and analysis of problems and needs (action items for the Technical Secretariat and States Parties)

1. **Requests** the Technical Secretariat (hereinafter "the Secretariat") to intensify its work with those States Parties that have difficulties in adopting the measures required under Article VII, by further identifying, analysing, and addressing those difficulties;

2. **Further requests** the Secretariat to submit to the Thirty-Sixth Session of the Council a report covering, *inter alia*, problems that have been identified, requirements of States Parties for support, the capabilities of the OPCW (that is, both of the Secretariat and of the States Parties) to provide implementation support, and any recommendations relevant to the implementation of the plan of action;

3. **Requests** States Parties seeking assistance of any kind in meeting their national implementation obligations and that have not yet informed the Secretariat of what assistance they require, to do so preferably before 1 March 2004;

Resources for implementation support (action items for the Technical Secretariat and States Parties)

4. **Requests** the Secretariat, within the parameters set by the OPCW Programme and Budget, to offer sustained technical support to States Parties that request it for the establishment and effective functioning of National Authorities, the enactment of national implementing legislation, and the adoption of any administrative measures required in accordance with Article VII;

5. **Welcomes** voluntary contributions from States Parties towards the implementation of this plan of action, and **requests** the Secretariat to implement the plan of action within the resources approved for the OPCW Programme and Budget, together with any voluntary contributions received for national implementation, and in a cost-effective manner;

6. **Encourages** States Parties to lend advice, upon request, to other States Parties in drafting and adopting national measures necessary to implement the Convention, *inter alia* to ensure that the laws reflect the comprehensive nature of the Convention by covering all activities that are to be prohibited or required in accordance with the Convention, and that involve the use of any toxic chemicals and their precursors; to cover the provision of annual declarations on past and anticipated activities; to ensure the implementation of the provisions related to transfers of scheduled chemicals; and to cover the annual submission of information on national protective programmes in accordance with paragraph 4 of Article X;

7. **Requests** States Parties able to provide assistance of any kind towards national implementation in other States Parties to inform the Secretariat, preferably before 1 March 2004, of what they can offer;

8. **Requests** the Secretariat to further develop and improve its implementation support programme, including by mobilising States Parties' efforts so as to provide, upon request and within the limits on available resources, technical assistance and technical evaluations to States Parties in the implementation of the provisions of the Convention, in the areas identified in the section of the report of the First Review Conference on national implementation measures (subparagraph 7.74 to 7.83 of RC-1/5);

9. **Encourages** the Secretariat to identify and, by mutual consent, engage with regional, subregional and other relevant groups of States Parties that can render support to the States Parties concerned in their implementation efforts;

10. **Encourages** the Secretariat and the States Parties to develop partnerships with relevant regional organisations and agencies that could render support to States Parties in their implementation work;

Overall time-frame, intermediate steps, and target date (action items for States Parties)

11. Without prejudice to the timelines set by the Convention, recalling States Parties' obligations under Article VII, and reminding them that it has been more than six years since the entry into force of the Convention, **agrees** that it is imperative that those States Parties that still need to do so take the necessary steps and set realistic target dates for these steps leading to the enactment of the necessary legislation, including penal legislation, and/or the adoption of administrative measures to implement the Convention no later than the Tenth Session of the Conference of the States Parties, scheduled for November 2005;

12. **Calls upon** those States Parties that still need to do so to make every effort to adhere to the overall time-frame established in paragraph 11 above, as well as to the steps and target dates they have established for themselves, and to maintain regular contact with the Secretariat about the implementation of these steps and target dates;

13. **Encourages** States Parties and the Secretariat to take measures to raise awareness of the prohibitions and requirements of the Convention, *inter alia* in their armed forces, in industry, and in their scientific and technological communities;

14. **Underlines** that the steps mentioned in paragraph 11 above should include:

(a) designating or establishing a National Authority and notifying the Secretariat thereof in accordance with Article VII of the Convention, as soon as possible;

(b) taking the steps necessary to enact the legislation, including penal legislation, and/or to adopt the administrative measures States Parties need in order to implement the Convention in accordance with their constitutional processes; and

(c) providing the Secretariat with the full text of their national implementing legislation, including updates, or, in the case of States Parties with a monist legal system, with information on the specific measures they have taken to implement the Convention;

15. **Urges** States Parties that have not yet done so to review their existing regulations in the field of trade in chemicals in order to render them consistent with the object and purpose of the Convention;

Oversight by the Executive Council and the Conference of the States Parties (action items for States Parties and the Technical Secretariat)

16. **Requests** the Secretariat to report to the Ninth Session of the Conference and to every second session of the Council starting with the Thirty-Sixth, in March 2004, on the progress made in implementing this plan of action;

17. **Further requests** the Council to provide guidance to, and to coordinate with, the Secretariat as necessary and to monitor the implementation of this plan of action;

18. **Also requests** States Parties that lend advice, upon request, to other States Parties on the drafting and adopting of national measures to implement the Convention, to keep the OPCW informed of their actions and the results they have achieved; and

19. **Undertakes to review**, at its Ninth Session, the progress made in implementing this plan of action, and to **decide** on any further action needed; and **undertakes to review further**, at its Tenth Session, the status of implementation of Article VII and to **consider** and **decide on** any appropriate measures to be taken, if necessary, in order to ensure compliance by all States Parties with Article VII.

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**ANNEX II ACTION PLAN FOR THE UNIVERSALITY OF THE CHEMICAL WEAPONS CONVENTION: OPCW Executive Council, EC-M-23/DEC.3, dated 24 October 2003**

## DECISION

## ACTION PLAN FOR THE UNIVERSALITY OF THE CHEMICAL WEAPONS CONVENTION

**The Executive Council,**

**Recalling** that the First Special Session of the Conference of the States Parties to Review the Operation of the Chemical Weapons Convention (hereinafter "the First Review Conference") attached great importance to the attainment of universal adherence by States to the Chemical Weapons Convention (hereinafter "the Convention") and **acting upon** the recommendation of the First Review Conference that the Executive Council (hereinafter "the Council"), with the cooperation of the Technical Secretariat, develop and implement a plan of action to further encourage, in a systematic and coordinated manner, adherence to the Convention, and to assist States ready to join the Convention in their national preparations for its implementation;

**Recalling also** resolutions of the United Nations General Assembly which stress the importance of achieving the universality of the Convention;

**Recalling** that the Conference of the States Parties has reviewed annually the progress, and has repeatedly adopted decisions entitled "Recommendation on ensuring the universality of the Chemical Weapons Convention" which, *inter alia*, have urged all States that have neither ratified nor acceded to the Convention to do so without delay;

**Firmly believing** that universality of the Convention is fundamental to the full achievement of its object and purpose;

**Welcoming** the substantial progress made towards universality of the Convention since its entry into force;

**Noting however** that among the States not Party are some whose non-ratification or non-accession is a cause for serious concern;

**Recognising** the positive effects that every new accession or ratification has for international peace and security and for global stability;

**Recalling** the decision of the Council that the OPCW's contribution to global anti-terrorist efforts in the context of the Convention should focus, *inter alia*, on the promotion of universal adherence to the Convention;

**Underlining** the important political, economic, and security benefits of becoming a State Party to the Convention, **recognising** the positive effect of international cooperation (e.g. on Article XI) among the States Parties on universality, **and convinced** that the desire for increased security and the determination to participate fully in the global community are incentives for States not Party to adhere to the Convention;

**Recalling** that States that remain outside the Convention would not be able to take advantage of the benefits that the Convention offers the States Parties;

**Encouraging** States Parties to promote the achievement of the common objectives of the Convention in order to encourage other countries to join the Convention;

**Conscious** of the fact that States Parties can encourage States not Party to adhere to the Convention, **and determined to** take all appropriate steps to intensify bilateral and multilateral efforts towards universality of the Convention; and

**Inspired by** the objective of achieving universal adherence to the Convention ten years after its entry into force;

**Hereby**:

**Urges** the States Parties, in conjunction with the Council and the Technical Secretariat, to undertake further efforts to promote universality of the Convention, including initiatives to address specific regions, sub-regions, or States, and covering all States not Party, in particular those whose non-adherence is a cause of serious concern;

**Strongly supports** the designation of "points of contact" by States Parties, on a voluntary and informal basis, in all regions and sub-regions relevant for the effective promotion of universality, to assist regularly in the implementation of this Action Plan and for the purposes of effective coordination;

**Recommends** that the Director-General should designate an officer of the External Relations Division to act as the focal point within the Technical Secretariat for the implementation of this Action Plan and for the purposes of effective coordination;

**Requests** the Technical Secretariat, having consulted with States Parties, to prepare a comprehensive annual document on planned universality-related activities, and to provide information to the Council on proposed initiatives, including on potential synergies with States Parties willing and able to join in universality-related efforts. The document should contemplate and systematise activities in which the Technical Secretariat has traditionally engaged and, if deemed appropriate, formulate new universality-oriented projects. The document should set indicative targets for increased membership. In particular, the document could include:

(a) measures envisaged by the Technical Secretariat to assist States ready to join the Convention in their national preparations for implementing it;

(b) bilateral assistance visits;

(c) bilateral meetings with States not Party not represented in The Hague, as well as those represented in The Hague, and other activities of participation support and outreach;

(d) regional and sub-regional seminars and workshops;

(e) international cooperation activities which might include States in the process of ratifying or acceding to the Convention;

(f) measures to increase awareness of the Convention, and of the work of the OPCW, including publications in official languages, as well as measures to reach the appropriate audience in States not Party; and

(g) attendance at meetings of, or joint activities with, relevant international and regional organisations;

**Requests** the Technical Secretariat, in support of the document of planned activities, to provide information containing up-to-date details regarding the status of States not Party *vis-à-vis* the Convention, their prospects for adherence, their participation in universality related activities, any significant chemical industry and any other issues relevant to the provisions of the Convention;

**Requests** the Technical Secretariat to implement the document of planned activities within the resources approved for the Organisation's Programme and Budget, together with any voluntary contributions received for universality-related purposes, and in a cost-effective manner;

**Strongly encourages** States Parties to strengthen their efforts in the promotion of universality of the Convention, to actively pursue this objective, as appropriate, in their contacts with States not Party, and to seek the cooperation of relevant international and regional organisations;

**Requests** the Director-General to submit to the Conference at its regular sessions an annual report on the implementation of the Action Plan, and to keep the Council regularly informed, so that the Conference and the Council may review progress and monitor its implementation effectively;
**Requests** that this Action Plan be brought to the attention of the Conference at its Eighth regular session; and

**Recommends** that the Conference decide to review, at its Tenth Session, the implementation of this Action Plan, and take any decisions deemed necessary.

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OPCW

Conference of the States Parties

Fourteenth Session
30 November – 4 December 2009

C-14/DEC.7
2 December 2009
Original: ENGLISH

# DECISION

## UNIVERSALITY OF THE CHEMICAL WEAPONS CONVENTION AND THE FURTHER IMPLEMENTATION OF THE UNIVERSALITY ACTION PLAN

**The Conference of the States Parties,**

**Recognising** the contribution that every new ratification of and accession to the Chemical Weapons Convention (hereinafter "the Convention") makes to the fostering of international peace and security and of global stability;

**Reaffirming** the priority it attaches to the attainment of the universality of the Convention and that the universality of the Convention is fundamental to the achievement of its object and purpose;

**Recalling** that, at its Eighth Session, the Conference of the States Parties (hereinafter "the Conference") noted the action plan for the universality of the Convention, which the Executive Council (hereinafter "the Council") adopted at its Twenty-Third Meeting (EC-M-23/DEC.3, dated 24 October 2003) at the recommendation of the First Special Session of the Conference of the States Parties to Review the Operation of the Chemical Weapons Convention (RC-1/5, dated 9 May 2003);

**Reaffirming also** the importance of all the provisions of the action plan and the measures identified therein for promoting the universality of the Convention, as well as the decisions adopted by the Conference at its Third (C-III/DEC.9, dated 20 November 1998), Fourth (C-IV/DEC.22, dated 2 July 1999), Tenth (C-10/DEC.11, dated 10 November 2005), Eleventh (C-11/DEC.8, dated 7 December 2006), and Twelfth (C-12/DEC.11, dated 9 November 2007) Sessions;

**Recalling** that, at its Twelfth Session, the Conference decided to continue with the action plan and further decided that, at its Fourteenth Session, it would "review the results and implementation of that plan and take any decisions it deems necessary, in particular addressing the status of those States not Party whose non-adherence is a cause for serious concern" (C-12/DEC.11);

**Recalling also** that the Second Special Session of the Conference of the States Parties to Review the Operation of the Chemical Weapons Convention (hereinafter "the Second Review Conference") underlined the fact that the goal of universality shall be pursued by the Technical Secretariat (hereinafter "the Secretariat") as well as the States Parties as a matter of high priority, and acknowledged the efforts made by the States Parties, the policy-making

organs, the Secretariat, and the Director-General to this end (paragraphs 9.12 and 9.13 of RC-2/4, dated 18 April 2008);

**Recalling further** that the Second Review Conference welcomed the decision by the Conference at its Twelfth Session to continue with the action plan for the universality of the Convention (C-12/DEC.11), and also called upon the Secretariat, the Director-General, the policy-making organs and all States Parties in a position to do so to intensify further their efforts with States not Party with a view to achieving full universality at the earliest possible date (paragraph 9.18 of RC-2/4);

**Noting** the annual report on the implementation of the action plan for the universality of the Convention during the period from 19 November 2008 to 11 September 2009, as submitted by the Director-General (EC-58/DG.9 C-14/DG.8, dated 29 September 2009);

**Noting also** with satisfaction that, as a result of the progress achieved since the adoption of the action plan, 33 States have become Party to the Convention, and **noting further** that this reflects a total of 188 States Parties, with seven States remaining to join the Convention, as indicated by the Director-General in EC-58/DG.9 C-14/DG.8;

**Welcoming** the fact that since the Conference met at its Thirteenth Session, four new States have become Party to the Convention, namely the Bahamas (21 May 2009), the Dominican Republic (26 April 2009), Iraq (12 February 2009), and Lebanon (20 December 2008);

**Recognising** the efforts of States Parties and the Secretariat to promote the universality of the Convention; and

**Recalling** that States that remain outside the Convention would not be able to take advantage of the benefits that the Convention offers to States Parties;

**Hereby**:

1. **Calls upon** all the remaining States not Party to ratify or accede to the Chemical Weapons Convention without further delay, thereby confirming their commitment to global peace and security, disarmament, and non-proliferation;

2. **Urges** all States Parties and the Secretariat to continue to intensify their universality-related efforts with a view to increasing the number of States Parties;

3. **Requests** the Director-General to continue his contacts with the States not Party, encouraging them to join the Convention without further delay, and to report on these contacts and the progress made thereon;

4. **Requests** the Secretariat to continue to utilise all available opportunities and resources, including diplomatic channels, international forums, and relevant OPCW meetings and events to advance the objectives of the action plan in accordance with the mandate provided to it in the decisions on universality adopted by the Council and the Conference;

5. **Decides** to continue with the action plan, and **further decides** that, at its Sixteenth Session, it shall review the results and implementation of that plan and take any

decision it deems necessary, in particular addressing the status of those States not Party whose non-adherence is a cause for serious concern; and

6. **Requests** the Secretariat to continue to provide and keep current information on activities related to promoting the universality of the Convention and the progress being made thereon, including in an annual report to the Conference at its Fifteenth Session.

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**OPCW** **Conference of the States Parties**

Fourteenth Session
30 November – 4 December 2009

C-14/DEC.12
4 December 2009
Original: ENGLISH

# DECISION

## ON NATIONAL IMPLEMENTATION MEASURES OF ARTICLE VII OBLIGATIONS

**The Conference of the States Parties,**

**Recalling** the decision adopted at its Thirteenth Session (C-13/DEC.7, dated 5 December 2008), concerning follow-up to the plan of action regarding the implementation of Article VII obligations, adopted by the Conference of the States Parties (hereinafter "the Conference") at its Eighth Session (C-8/DEC.16, dated 24 October 2003) and all related decisions;

**Taking note** of the report of the Director-General on the status of implementation of Article VII of the Chemical Weapons Convention (hereinafter "the Convention") as at 19 August 2009 (C-14/DG.9, dated 21 October 2009), which the Technical Secretariat (hereinafter "the Secretariat") has provided in accordance with paragraph 5 of C-13/DEC.7 and **noting** that different views were expressed by States Parties on the report;

**Recalling** the report of the Second Special Session of the Conference of the States Parties to Review the Operation of the Chemical Weapons Convention (RC-2/4, dated 18 April 2008);

**Acknowledging** the positive impact that tailored and systematic support from States Parties and the Secretariat has in the continued success of the implementation of Article VII obligations, as well as **commending** the provision of assistance, including expertise, and technical support and voluntary contributions, to States Parties upon request;

**Welcoming** the considerable progress made in the implementation of Article VII obligations since the adoption of C-8/DEC.16, and **commending** the efforts of States Parties in this regard;

**Also welcoming** the progress made regarding the designation or establishment of National Authorities;

**Recognising** that further progress is required, as there remains a sizeable number of States Parties that have yet to complete implementation of their Article VII obligations, and **recognising as well** that a number of these States Parties require assistance and technical

support, including some that are encountering difficulties in the process of implementing Article VII;

**Convinced** that the full implementation of Article VII by all States Parties also contributes to universal adherence to the Convention; and

**Strongly reaffirming** the obligation of each State Party to adopt the necessary measures to implement its obligations under the Convention in accordance with its constitutional processes and **also reaffirming** that the full national implementation of the obligations under the Convention is essential for the realisation of the object and purpose of the Convention;

**Hereby**:

1. **Urges** States Parties that have yet to designate or establish a National Authority, and/or that have yet to enact legislation and/or to adopt administrative measures to implement the Convention:

   (a) to notify the Organisation of the designation or establishment of their National Authority; and/or

   (b) to inform the Organisation, on an ongoing basis, as appropriate, with regard to the steps they are taking in accordance with their constitutional processes to enact legislation, including penal legislation, and to adopt administrative measures to implement the Convention;

2. **Requests** all States Parties to inform the Secretariat on an ongoing basis, as appropriate, of any amendments to measures to implement the Convention that had previously been submitted;

3. **Urges** States Parties that have not yet done so to review their existing regulations in the field of trade in chemicals in order to render them consistent with the object and purpose of the Convention;

4. **Encourages** States Parties, in particular those desiring assistance to fulfil their Article VII obligations, to avail themselves of assistance that is offered if they consider it appropriate, and to consult with the Secretariat, and to provide it with details, as appropriate, of their assistance requirements;

5. **Encourages** the Secretariat to continue to provide, upon request, such technical assistance in a tailor-made and systematic manner, to effectively address the needs of those States Parties with a view to addressing their practical national implementation issues and concerns;

6. **Encourages** States Parties to continue offering assistance in implementing Article VII, including, inter alia, through the provision of expertise to States Parties, through the fostering of cooperation within and among regional groups, as well as through making voluntary contributions to the Organisation and any other offers, and to keep the Organisation informed about their activities;

7. **Requests** the Secretariat to provide its annual reports to the Executive Council (hereinafter "the Council") on the status of national implementation measures, and invites the Council to consider and submit the reports referred to in paragraph 8 below to the Conference together with its recommendations, as appropriate;

8. **Invites** the Secretariat to compile two concurrent reports, one of which addresses obligations pursuant to paragraphs 1(a) to 1(c) of Article VII and other obligations, including Article XI(2e), and one which addresses the other national implementation measures, including those contained in the Plan of Action adopted by the Conference at its Eighth Session (C-8/DEC.16), thus all information earlier contained in the annual reports will be contained in the above-mentioned two reports (see the Annex to this decision); and

9. **Requests** the Secretariat to keep current a progress report on the external server of the Organisation.

Annex: Effect on Article VII Reporting of the Decision on National Implementation Measures of Article VII Obligations (C-14/DEC.12, dated 4 December 2009)

## Annex

## EFFECT ON ARTICLE VII REPORTING OF THE DECISION ON NATIONAL IMPLEMENTATION MEASURES OF ARTICLE VII OBLIGATIONS (C-14/DEC.12, DATED 4 DECEMBER 2009)

| | |
|---|---|
| National Authority: | 2nd report |
| Article VII(5) submission: | In both reports (identical) |
| Legislation covers all key areas: | In both reports (identical: only once all key legislative areas of both reports are fully covered the box will be checked) |
| Text of adopted measures provided: | In both reports |
| Measures to control transfers of Scheduled Chemicals | 2nd report |
| Submission of Initial Declarations: | 2nd report |
| Submission in 2010 of ADPA for 2009: | 2nd report |
| Article VI Project: | 2nd report |
| Year(s) of Article X(4) Submissions: | 2nd report |
| Confirmation regarding Article XI(2e) Review: | In both reports (identical) |
| Article I Prohibitions: | 1st report |
| Article I Penalties: | 1st report |
| Extraterritorial Application: | 1st report |
| Definition of Chemical Weapons: | 1st report |
| Schedule 1 Penalties: | Partially in 1st report (sanctions for prohibitions), partially in 2nd report (sanctions for ensuring compliance with regime for industry and transfers) |
| Schedule 2 Penalties: | Partially in 1st (sanctions for transfer prohibitions), partially in 2nd report (sanctions for ensuring compliance with regime for industry and transfers) |
| Schedule 3 Penalties: | Partially in 1st (sanctions for transfer prohibitions), partially in 2nd report (sanctions for ensuring compliance with regime for industry and transfers) |
| Schedule 3 EUC: | 1st report (part of the prohibition-regime) |
| Penalty for Failure to Declare: | 2nd report |

**It is to be noted** that obligations that will be reported on in the second report will remain obligations as such.

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**OPCW** **Technical Secretariat**

Office of the Director-General
S/951/2011
25 July 2011
Original: ENGLISH

## NOTE BY THE DIRECTOR GENERAL

## REPORT OF THE ADVISORY PANEL ON FUTURE PRIORITIES OF THE ORGANISATION FOR THE PROHIBITION OF CHEMICAL WEAPONS

1. The report containing the recommendations agreed upon unanimously by the members of the Advisory Panel on future OPCW priorities is hereby circulated to States Parties. It is hoped that this document will provide a useful basis for States Parties' deliberations on the future of the Organisation.

2. The Advisory Panel was established in December 2010, with a geographically representative group of 14 independent experts on arms control and disarmament, the chemical industry, and science and technology. The work of the Advisory Panel was conducted in a fully independent manner, with individual members serving in their personal capacities. As explained by its Chairman, H.E. Mr Rolf Ekéus of Sweden, in the attached cover letter, the Advisory Panel held four plenary meetings in The Hague, the last of which was conducted from 27 to 29 June 2011, before finalising its report.

3. A list of Advisory Panel members is provided in Annex 3.

Annexes:

Annex 1: Cover Letter to the Director-General from H.E. Mr Rolf Ekéus
Annex 2: Report of the Advisory Panel on Future OPCW Priorities
Annex 3: List of Members of the Advisory Panel on Future OPCW Priorities



CS-2011-6931(E) distributed 25/07/2011

**Annex 1**

## COVER LETTER TO THE DIRECTOR-GENERAL FROM H.E. MR ROLF EKÉUS

International Advisory Panel on the
Future of the OPCW

The Hague/p.t. Stockholm
15 July 2011

Dear Director-General,

In my capacity as Chairman of the International Advisory Panel on Future OPCW Priorities I have the honour to transmit to you a document containing the recommendations agreed upon unanimously by the members of the Panel on the 15 July 2011.

Between 14 December 2010 to 30 June 2011 the Panel members have met in four plenary sessions. I have maintained regular contacts with individual members in between the sessions and intensively so during the period between the ending of the last plenary session and the final moments of concluding the recommendations 15 July. Thus the findings have been subject to careful considerations by all the Panel members. It is my hope that the detailed scrutiny by the participants and the many specific proposals developed in that process by them will serve as something of a reform-agenda for the Participating States when they have to consider the future of the OPCW.

The quality of the recommendations is a reflection of the Panel members' unique skills, far-reaching experience as regards the Chemical Weapons Convention and of their deep engagement in the deliberations of the Panel. In addition it is a pleasure for me to mention the outstanding contributions by all the Panel members. The Panel's consultant, Ralf Trapp, and the secretary Daniel Feakes have both with the quality of their work and and their huge workload been indispensable for the recommendations I can now send to you.

Yours sincerely,

Rolf Ekéus
Chairman
The International Advisory Board
on the Future of the OPCW

His Excellency Ahmet Üzümcü,
Director-General, OPCW.

# Annex 2

## I. INTRODUCTION

1. The Chemical Weapons Convention (the Convention) stands out as a successful model of a multilaterally negotiated non-discriminatory treaty that seeks to eliminate, under international verification, an entire category of weapons of mass destruction. Since its entry into force in 1997, the Convention has become a singular success. It is a cornerstone of the global disarmament and non-proliferation architecture and today has 188 States Parties. The Convention complements the 1925 Geneva Protocol and the 1972 Biological Weapons Convention, and works together with other global disarmament and non-proliferation regimes and initiatives.

2. The Organisation for the Prohibition of Chemical Weapons (OPCW), which is tasked to implement the Convention, is the only genuinely multilateral disarmament body with a global responsibility. It has become a respected international agency and has developed well functioning partnerships with a number of international organisations and agencies that are working towards curbing the proliferation of weapons of mass destruction. The OPCW Technical Secretariat has successfully and effectively carried out the verification measures provided for under the Convention. It has carried out other functions entrusted to it by the Convention, or delegated to it by the Conference of the States Parties, in such areas as assistance and protection against chemical weapons or fostering the international cooperation between States Parties in the peaceful uses of chemistry. The OPCW is the collective property and responsibility of the States Parties but at the same time has become a *global* public good.

3. Fourteen years after the entry into force of the Convention, the final deadline for the completion of the elimination of chemical weapons stockpiles, on 29 April 2012, is approaching. Almost three-quarters of the declared chemical weapons stockpiles have been destroyed and most of the former chemical weapons production facilities have been destroyed or converted for peaceful purposes. Three possessor States Parties have completed the elimination of their chemical weapons stockpiles. There are, however, delays in the elimination of chemical weapons stockpiles in the United States of America and the Russian Federation, that have declared the largest stockpiles and who have both indicated that they will need more time to complete their destruction programmes.

4. Notwithstanding these delays, the OPCW needs to prepare for a transition from mandates and efforts primarily characterised by the elimination of chemical weapons stockpiles and production facilities to an agency that will have as its main task to ensure that the menace of chemical warfare and the use of toxic chemicals for hostile purposes will never reappear, and that international cooperation and assistance in the field of peaceful uses of chemistry can flourish.

5. It is now time for the States Parties and the OPCW collectively to begin addressing this transition. The reduction in the number of chemical weapons destruction facilities in operation and the related drop in verification activity that is anticipated in the coming years will pose serious challenges for the OPCW. Adjustments of programme





priorities, staffing structure, as well as institutional capabilities will be inevitable. This should be change by design, not by default.

6. At the same time, the external environment in which the Convention operates has changed since 1992 when the negotiations of the Convention were concluded. Today's security environment is very different. Science and technology are advancing at an astounding pace, creating new opportunities but also new risks. The size and shape of world's chemical industry are undergoing profound change. All these developments create new conditions within which the Convention has to operate.

7. Consequently, in the autumn of 2010, the OPCW Director-General established an advisory panel of independent experts and requested it to make recommendations for future OPCW priorities, taking into account all relevant developments in international security, chemical industry and science and technology, consistent with the objectives of the Convention. The advisory panel was chaired by Ambassador Rolf Ekéus of Sweden.

8. The advisory panel's purpose has been to develop recommendations that aim at ensuring the relevance and viability of the Convention in the years and decades to come. The advisory panel does not propose amending the Convention or inventing new tasks for the OPCW. This report to the OPCW Director-General contains the conclusions of the advisory panel's deliberations, and its recommendations for how the OPCW and the Convention should adapt to the new challenges.

## II. THE CHANGING ENVIRONMENT

9. The 20th century experienced the horrors of poison gas warfare—the number of victims is impossible to count. Efforts to ban poison gas after its widespread use during World War I led to the 1925 Geneva Protocol for the prohibition of use in war of asphyxiating, poisonous or other gases and of bacteriological methods of warfare. Yet, the gas chambers of the Second World War and the use of poison gas in Africa and in the Far East before and during the Second World War showed the limitations of a ban merely of the use of poison gas. During the Cold War that followed, both the former Soviet Union and the United States entered into an arms race in which both acquired huge chemical weapons stockpiles. These posed considerable threats in response to which bilateral as well as multilateral negotiations began—to control and eventually eliminate them. Then, during the 1980's, chemical weapons were used by Saddam Hussein's regime against Iran and against the Kurds. All these factors and the changing circumstances at the end of the Cold War created a window of opportunity for the adoption in 1992 of the Chemical Weapons Convention, a comprehensive ban not just of the use of chemical weapons, but also of their development, production, acquisition, stockpiling and transfer.

10. The Convention has now been in force for fourteen years. Its implementation, while incomplete, is widely regarded a success. Yet the world in which it is operating has changed, and continues to do so. The conditions that prevailed during its negotiations no longer characterise the environment in which it must function.

11. Firstly, conflict is no longer framed in the context of opposing military alliances in a bipolar world. The number of inter-State conflicts has declined yet the level of

violence has not. The borderlines between war, civil war, large-scale violations of human rights, revolutions and uprisings, insurgencies and terrorism as well as organized crime are blurred. In addition to traditional military forces, more non-State actors have appeared on the battlefield, i.e. paramilitary groups, warlords and their militias and volunteers, mercenaries and private military companies, terrorists and criminal groups. As a consequence, contemporary threat perceptions are also driven by attacks on populations and critical infrastructure, in addition to more traditional state-based threats. Furthermore, there are worries, in such types of conflict and with such actors, that the rules of international law applicable in armed conflict, and in particular the principles and rules of international humanitarian law, may be undermined.

12. Given the specific characteristics of chemical weapons, there may be perceptions that chemical weapons are useful for these contemporary types of violent conflict. Whilst the threat of "traditional" chemical warfare with mass casualties has declined significantly since the implementation of the Convention began, other forms of chemical weapons might appear attractive for their capacity to cause terror, or appear useful in population displacement and social/economic destabilization. The possibility of the malicious use of toxic chemicals has been demonstrated by the Aum Shinrikyo sect in Japan and the detonation of chlorine trucks in Iraq. Such acts of terror cannot be deterred by the fact that the perpetrators may themselves die in the attack.

13. On the other hand, distinctions between law enforcement, counter-terrorism, counter-insurgency and low-intensity warfare may get blurred, and certain types of chemical weapons such as incapacitants may appear to offer tactical solutions to operational scenarios where civilians and combatants cannot easily be separated or distinguished.

14. Secondly, some States have still not formally committed themselves to the prohibition of chemical weapons by ratifying or acceding to the Convention. This implies that quantities of chemical weapons neither declared nor under international control, could be in existence, ready for use and sale. This does not mean that the States concerned would be legally free to use chemical weapons, since customary international law, reflected in the 1925 Geneva Protocol, is binding on all States. Furthermore, the United Nations Security Council, in its resolution 1540 (2004), has obligated all States to adopt and enforce appropriate effective laws which prohibit any non-State actor to manufacture, acquire, possess, develop, transport, transfer or use nuclear, chemical or biological weapons and their means of delivery, in particular for terrorist purposes. Resolution 1540 complements the Convention, although it lacks in certain respects its comprehensive scope and multilateral origins. But, the possibility remains that some States outside the Convention may be ready to resort to chemical warfare.

15. Thirdly, the globalization of the world economy, the emergence of new global actors in addition to States, the growing interdependence of the world as well as the production of and access to energy, food and medicines are fundamentally affecting chemical science and industry. There is a need for ever more advanced chemical technology to satisfy the needs of agricultural growth, economic development and public health, through the production of products such as insecticides, pesticides and medicines for humans and animals.





16. Whereas chemical industry was traditionally concentrated in North America, Western Europe and Japan, the world is now witnessing a migration of chemical production to new locations. Not only the emerging economic powers China, India and Brazil, but also other developing countries in Asia and Latin America, have seen an increase in investment in chemical industry. The industry's goal is to bring manufacturing closer to the raw materials in the Middle East and the huge markets in Asia and in Latin America. Furthermore increasing investment in chemical industry in Africa should be expected given the need of the African continent for agrochemicals, medicine and chemical products for industrial development.

17. These global trends are reflected in the distribution of chemical industry facilities declared to the OPCW by States Parties (see the table below). A comparison of the situation in 2001 (the year for which the OPCW first published a detailed breakdown) and in 2009 (the latest year for which such data are available) shows that, whilst the situation with regard to Schedule 2 and 3 plant sites has remained relatively constant, there is a clear change with regard to States Parties that have Other Chemical Production Facilities (OCPFs) operating on their soil. Whilst their number remained relatively stable in the African, Eastern European and the Western European and Others regional groups, the number of States Parties declaring OCPF plant sites in Asia and the Latin American and Caribbean regional groups more or less tripled over these 9 years.

| | Change in the number of States Parties that have declared facilities, from 2001 to 2010[1] | | |
|---|---|---|---|
| | Schedule 2 | Schedule 3 | OCPF |
| Africa | 0 >> 1 | 1 >> 1 | 4 >> 6 |
| Asia | 5 >> 5 | 6 >> 9 | 7 >> 22 |
| Eastern Europe | 4 >> 9 | 9 >> 9 | 15 >> 18 |
| GRULAC | 3 >> 3 | 4 >> 4 | 5 >> 13 |
| WEOG | 17 >> 20 | 13 >> 13 | 21 >> 21 |

18. This change in the regional distribution of the chemical industry means that more States Parties than in the past have to adopt specific regulatory measures to implement the Convention in their emerging chemical industries. The OPCW should support these countries in their efforts to adopt effective national implementation systems. The change has already led to an increase in the number of States Parties in Asia, Latin America and the Caribbean, and Africa that are liable to receive inspections under the Convention.

19. Accompanying this diffusion of chemical industry into new regions will be the broader dissemination of chemical technology, and a growth in the volume and value of chemical trade. At the same time, the production footprint of chemicals is changing. Production facilities are becoming more versatile, smaller in size, and highly adaptable—offering a range of different chemical products to customer specifications at short notice. Facilities are also becoming less polluting and more energy and material efficient. Alternatively, modern chemical plants can be huge and expansive ("world plants"). This diffusion of the capability to produce a wide range of

[1] Sources: Annual Report of the OPCW for 2001, document C-7/3, dated 10 October 2002 and Draft Annual Report of the OPCW for 2010, document EC-65/CRP.1, dated 4 May 2011.

chemical products will be extremely important for meeting the growing needs of society.

20. All these technological advances are necessary and beneficial for society. Given their dual-use character, they mean that an increasing number of States Parties will have to adopt specific implementation measures in the area of regulating chemical industry and trade. There is also a risk that know-how, materials and equipment could be misused for the acquisition of toxic chemicals for hostile purposes.

21. A fourth, and related, challenge comes from advances in science and technology. A pertinent example is the convergence between chemistry and biology which is particularly visible in the life sciences where researchers are pushing boundaries to better understand the esoteric functioning of biological systems. The aims of these advances are plentiful: trying to find new types of medicines for humans and animals, new methods of pest control, enhanced food production, or new means of energy production – to mention just a few.

22. These scientific advances create expectations for many beneficial applications. But again, they may also pose challenges to the way in which the Convention is being implemented. Furthermore, they call for answers with regard to the future relationship between the regimes that govern the ban, respectively, of chemical and biological weapons, and which have evolved separately in recent decades.

## III. ACHIEVING THE COMPLETE ELIMINATION OF CHEMICAL WEAPONS

23. The core objective of the Chemical Weapons Convention is the complete and permanent elimination of all chemical weapons and their means of production under strict OPCW verification. To achieve this goal, (a) the possessor States Parties are obliged to complete the elimination of their stockpiles and former production facilities by the deadline established by the Convention, (b) the remaining States not Party need to be brought into the Convention and those that possess chemical weapons and/or production facilities must eliminate them in accordance with the provisions of the Convention, and (c) all old and abandoned chemical weapons need to be destroyed. **The OPCW and its Technical Secretariat must retain the competence and resources needed to provide the necessary verification for these disarmament measures, as well as to render technical advice to States Parties when so requested**.

Eliminating all chemical weapons stockpiles

24. The completion of the elimination of the declared stockpiles at the earliest possible date remains the primary task for the OPCW. The delays in the destruction programmes of the United States of America and the Russian Federation beyond the Convention's final deadline in April 2012 are matters of serious concern. The States Parties and the policy making organs need to remain seized of this matter, and adopt the necessary measures to ensure completion of destruction of these stockpiles as early as possible under strict verification.





25. The advisory panel took cognisance of the consultations currently being undertaken by the Chairman of the Executive Council aimed at resolving the legal and political issues caused by these delays. **The advisory panel stressed that determined and relentless efforts needed to be made by the possessor States Parties to rectify the situation at the earliest possible date**.

26. Global chemical weapons disarmament can only be achieved when all States of the world, and in particular those that have chemical weapons capabilities, have joined the Convention and eliminated any CW stockpiles and production facilities in their possession. Striving for universal adherence to the Convention therefore remains a central objective.

27. Efforts must be intensified to persuade the remaining States not Party to join the treaty.[2] This is no longer an issue of political campaigning. With only seven remaining States not Party (signatory States: Israel and Myanmar; non-signatories: Angola, Democratic People's Republic of Korea, Egypt, Somalia and Syrian Arab Republic), the success of universality efforts will depend on a well-tailored approach that takes full account of the specific security, political and economic conditions of each of the remaining States not Party. **The advisory panel strongly encouraged the Director-General to continue to explore in depth the relevant circumstances in each case and to recommend the steps to be taken to achieve universal adherence to the Convention; he should also consider appointing a Special Representative for Universality.**

28. **To achieve universal adherence, all possible avenues (bilateral, regional, international) should be pursued by the OPCW.** The OPCW should continue working with States not Party in a proactive way. It should respond positively to invitations to support initiatives to further the goal of universal adherence to the Convention.

Legacy issues including old and abandoned chemical weapons

29. The States Parties will have to continue dealing with the legacy of past chemical warfare programmes and activities for many years to come. They will continue to discover, recover and destroy old and abandoned chemical weapons left behind on battlefields of former wars and in locations previously associated with their production, storage, testing or disposal.[3] These remnants of previous wars and military preparations pose serious risks to people and the environment. **Therefore, one of the future priorities of the OPCW in the field of chemical weapons destruction will be the destruction of old, and of abandoned chemical weapons**. It is important that these old and abandoned chemical weapons be destroyed as soon as possible and in a manner that is safe for workers, people and the environment.

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2 The Republic of South Sudan became the 193rd Member State of the United Nations on 14 July 2011. With regard to the Convention, the new State can either notify the OPCW through the United Nations that it will join the Convention as a successor State, inheriting the obligations that Sudan has as a State Party, or the new State will have to accede to the Convention.

3 A recent example is the discovery in early July 2011, of an unexploded Iraqi chemical munition dating back to the Iraq-Iran war in the 1980s.

30. With regard to the verification of declarations and the destruction of old and abandoned chemical weapons, the responsibilities of the Technical Secretariat will continue until these remnants of previous programmes and wars have been destroyed. The advisory panel felt that the OPCW should approach these issues from the perspective of facilitating assistance and technical advice for States Parties that need it. The OPCW, for example, could promote studies and surveys into former dumping operations to get a better picture of the situation and the potential risks, and it could promote exchanges and cooperation between States Parties on technical issues related to old and abandoned chemical weapons and their recovery and destruction.

31. Also, sea-dumped chemical weapons will remain a reason for concern with regard to protecting the environment. States Parties are not required and may in their discretion decide whether to declare any such chemical weapons, and whether to apply to them the provisions of the Convention dealing with destruction and verification. As a consequence, the OPCW has had little practical exposure to issues related to sea-dumped chemical weapons. But that does not mean that it can ignore the matter altogether. There may be a need for technical assistance and advice if States Parties request it from or through the OPCW.



Maintaining competence to render technical advice to States Parties regarding chemical weapons issues

32. The continued destruction of chemical weapons under strict international verification, and even beyond the 2012 deadline, as well as of old and abandoned chemical weapons must remain a priority task for the OPCW. Furthermore, there will be a need to monitor the destruction of chemical weapons, declared by States, which have joined the Convention after April 2007[4] or those that could be declared by States, joining the Convention in future. The resources allocated to verification of these destruction operations must be sufficient to meet these requirements.

33. The Technical Secretariat must continue to undertake effective and competent verification with regard to chemical weapons and related facilities, and to render technical assistance and advice to States Parties. It must also remain a source of knowledge, expertise and support to States Parties with regard to issues that may come up as a result of the possible discovery of hitherto-unknown remnants of previous chemical warfare activities. If so requested by States Parties, the OPCW needs to be prepared to provide or arrange assistance for them in such tasks as risk assessment and management, site surveying, recovery, temporary storage, and destruction.

34. The decrease in the verification effort due to the completion of destruction operations at several chemical weapons destruction facilities projected for the coming years must therefore not lead to a loss of competence and capacity to implement all requirements of the Convention with regard to chemical weapons. Considering that there remain many possible forms of misuse of toxic chemicals for non-peaceful purposes—there

[4] According to paragraph 8 of Article IV of the Convention, States which join the Convention 10 years after its entry into force, i.e. after April 2007, should destroy any chemical weapons they may possess as soon as possible, under timelines and verification measures determined by the Executive Council.



continues therefore to be a need to minimize the risk of being unprepared for unforeseen events.

35. Even after the complete elimination of all chemical weapons stockpiles world-wide, **the OPCW should remain the global repository of knowledge and expertise with regard to chemical weapons disarmament, the verification of their non-possession and non-use, and a repository of knowledge about their destruction. The OPCW should find ways of ensuring continuity in its knowledge base and expertise in these areas.**

## IV. UPHOLDING CHEMICAL WEAPONS DISARMAMENT AND PREVENTING NON-STATE ACTORS FROM ACQUIRING TOXIC CHEMICALS FOR HOSTILE PURPOSES

36. To ensure that the threat of chemical warfare will never recur, the States Parties have undertaken, under Article I of the Convention, not to engage in any of the activities prohibited to them under the treaty that could lead to the (re)acquisition and use of chemical weapons, and not to assist, encourage or induce in any way anyone to engage in such activities. States Parties are also required to adopt the necessary measures to ensure that toxic chemicals and their precursors are only used for purposes not prohibited under the Convention.

37. This all requires effective national implementation and enforcement of the Convention's provisions and prohibitions. National implementation also requires the active participation of all stakeholders including the chemical industry, the scientific and technological research community, and the military and police forces. At the international level, it calls for effective verification of compliance by the Technical Secretariat, close cooperation between States Parties, and regular reviews of how these fundamental undertakings are being implemented by the Conference of the States Parties as foreseen under paragraph 20 of Article VIII of the Convention. The Technical Secretariat should effectively coordinate its work with partner organisations which have mandates that relate to the implementation of the Convention.

The General Purpose Criterion

38. The most important legal protection provided by the Convention against the recurrence of chemical weapons is built into the definition of chemical weapons contained in Article II of the Convention: *any* toxic chemical and precursor chemical is to be considered a chemical weapon unless intended for purposes not prohibited by the Convention, as long as its types and quantities are consistent with such purposes (the "general purpose criterion"). The scope of this definition is thus not constrained by the Schedules of Chemicals, and it covers all toxic and precursor chemicals, even those that have yet to be synthesised or discovered. The general purpose criterion has been included by the negotiators so as to ensure that new developments cannot undermine the legal strength of the Convention's prohibitions.

National implementation

39. The goals of the Convention can only be fully achieved if all State Parties respect, realize and comply with their obligations under it. Thus, Articles VI and VII of the Convention require that all States Parties enact and enforce legislation to ensure that

toxic chemicals and their precursors are not used for prohibited purposes. Besides legislation, regulatory and administrative measures must be adopted to enforce the legislation. All States Parties are required to designate or establish a National Authority which must be empowered to work effectively and coordinate its work with other agencies, both nationally and internationally.

40. A key issue in this respect is to implement effective national controls over transfers (exports, imports, transits, transhipments, and re-exports) of relevant chemicals, equipment and technologies. Border control and law enforcement measures need to be applied by States Parties to detect, deter, prevent and combat illicit trafficking and brokering of chemical weapons, and of dual use goods that could be used for chemical weapons purposes. **The OPCW should assist and encourage States Parties in this regard and ensure that there will be a "level playing field" for such controls to avoid loopholes as well as discrimination.**

41. Compliance with the requirements of the Convention cannot merely be achieved by a regulatory approach from governments. It requires support by all stakeholders in chemical industry, research, academia and other relevant sectors of society. To this end, responsible professional conduct needs to be built into their governance systems, and synergies should be sought between the implementation of the Convention, and chemicals management systems such as the Strategic Approach to International Chemicals Management (SAICM) and the Globally Harmonised System of Classification and Labelling (GHS). Important synergies also exist with regard to the European Union's regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), and related initiatives and measures taken in other regions. The chemical industry itself has taken up these governance challenges in its salutary Responsible Care ® programme. All of these measures, in concert with regulatory and enforcement steps taken by governments under the Convention, should lead to the development of a culture of compliance based on adequate laws and regulations and underpinned by self-regulation and conscious participation in the implementation of the requirements of the Convention by all stakeholders.

42. **For the OPCW Technical Secretariat, providing tailored and sustainable technical assistance ("implementation support") to States Parties should therefore remain one of the highest priorities**. Support to build national capacity could include, for example, the strengthening of National Authorities and systems involved in the Convention's implementation. The Technical Secretariat and States Parties with well-developed national implementation systems should actively provide assistance to States Parties with gaps in their national implementation, by offering legislative advice/assistance, financial and technical support. To this end, the Technical Secretariat should continue to develop work plans and provide platforms for exchange and cooperation through the organisation of workshops and meetings.

43. The OPCW should develop and design model structures in support of the strengthening of national capacity to apply the norms of the Convention. The Secretariat can help by providing technical and information support, especially by conducting simulations and assessing how different methodologies may affect implementation efforts of States Parties and verification results, based on declaration data submitted by the States Parties.





44. Much more can be done through regional and global networking, assistance with awareness raising and building stakeholder relations, training of national implementation personnel and the sharing of best practices among States Parties. The Technical Secretariat should continue to help with technical assistance to promote peaceful chemical development among States Parties, and with the assessments of needs so as to better tailor technical assistance to the requirements and conditions of States Parties. Adequate budgetary and human resources for such programmes must be earmarked and the programmes designed so as to enable evaluation against the benchmarks set out in the Action Plan on Article VII.

45. The advisory panel noted that there are concerns in the chemical industry caused by misgivings about the uneven implementation of the Convention by different States Parties which causes gaps in declarations and unequal regulatory treatment of chemical companies in different States Parties. The support and engagement of the industry is essential for the OPCW to effectively implement its duties. Steps must therefore be taken to reinforce confidence of the industry in the Organisation. A non-bureaucratic and constructive partnership should be created, through an ongoing dialogue that respects the mutual needs of confidentiality and trust. The involvement of the National Authorities, with conscious respect for discretion and confidentiality, is essential for creating the broad dialogue that is required. **The Director-General may also consider setting up a group of experts from chemical industry to advise the OPCW on how to better interact with the chemical industry.**

46. A sustainable culture of compliance will require the continued strengthening of the relationship between the Technical Secretariat and the National Authorities—a genuine partnership that builds on national, regional and OPCW-wide networking, and the wide sharing of experiences in the practical implementation of the Convention.

Verification of compliance

47. Preventing the recurrence of the menace of chemical warfare is the second pillar of the Convention. Much progress has been made in setting up an effective verification system to ensure the accuracy of declarations, the completeness of chemical weapons destruction activities, and to provide confidence in the non-production of chemical weapons. The system has been adequate for the initial phase of treaty implementation, which had a strong focus on chemical weapons stockpile declaration and elimination.

48. To ensure the continued viability of the routine verification system under Article VI, the OPCW should now take a forward-looking approach. Verification is more than merely the conduct of inspections and the confirmation of declaration data. It is a process of gathering, validating and evaluating information that allows the independent assessment of how each State Party is implementing the treaty. In an era of globalisation with chemical industry spreading around the globe and chemical trade creating global partnerships and dependencies, and where information about chemical activities is available from an ever-expanding pool of authoritative sources on the Internet, it is difficult to comprehend why the Technical Secretariat does not make better use of open source information, particularly that from company websites and information that is officially provided to other international organizations such as the

UN. States Parties should consider providing additional information on a voluntary basis to reduce the likelihood of inspections at facilities that have no relevance to the Convention. **The policy-making organs of the OPCW should study the matter of using open source information for verification purposes and provide guidance to the Technical Secretariat so as to find acceptable ways to enhance the verification process.**

49. Inspections remain a central aspect of verification. The key to achieving confidence in compliance, however, does not lie solely in inspection numbers. The selection of facilities for inspection is equally important, and should be based on the risk posed to the object and purpose of the Convention, taking due account of the conditions stipulated in the relevant parts of the Convention's Verification Annex. What matters most is the quality of the inspection process. The Convention's general inspection aim under the Convention is to verify that the activities at an inspected facility are consistent with the information provided in declarations.

50. With regard to facilities which produce (process, consume) scheduled chemicals, much experience has been gathered by the OPCW and the conduct of inspections has provided a significant degree of transparency and confidence. Priority should be given to further increasing efficiencies and ensuring the independence and integrity of the verification process.

The Schedules of Chemicals

51. This leads into a consideration of the Schedules of Chemicals, which have remained unchanged since the adoption of the Convention. Given the role that they play in directing routine verification activities in the chemical industry, this constancy has "frozen" much of the industry verification system in the past. The system remains relevant with regard to the verification of non-production of chemical weapons as known from the Cold War. It reflects less and less, however, the emerging threats related to the possibilities of future hostile use of toxic chemicals.[5]

52. The OPCW has yet to review the composition of the Schedules in the light of developments in science, technology and industry. States Parties should be making efforts to update the Schedules to take account of risks that had not been considered in the negotiations as well as economic and verification-related implications, realising that any list-based control system will over time loose its relevance unless it is being regularly updated. **The advisory panel recommends that reviews of the Schedules should be undertaken on a regular basis by the States Parties. Such reviews could take place every fourth or fifth year and be prepared by the scientific unit proposed elsewhere in this report (see paragraph 78), together with the SAB and after consultations with stakeholders.**

[5] Some of the concepts related to the previous text on other organisations having identified toxic chemicals that pose a risk in today's security environment given their toxicological and other properties and their availability in day-to-day life may be taken up in the section on assistance and protection.





Other chemical production facilities (OCPFs)

53. Requirements with regard to industry verification that are not covered by the Schedules are covered by the OCPF verification regime. This category of facilities is perhaps the most diverse with respect to the relevance of individual plant sites to the Convention. Experience gathered by the Technical Secretariat shows that whilst some of the OCPFs pose little or no risk to the object and purpose of the Convention, others are highly relevant to demonstrating that no chemical weapons are being produced. Also, when compared to facilities involved with scheduled chemicals, globalisation and advances in science and technology have the most profound impact in the OCPF category of plant sites. With regard to the verification system as it stands, however, the OCPF regime lacks focus given the very general nature of the data contained in the declarations. For all these reasons, OCPF inspections will remain important to maintaining the relevance of the routine verification system in the future, but should be made more effective. **To this end, the OPCW must find ways of directing inspections more consistently towards facilities of high relevance to the Convention, taking account of the applicable provisions of the Convention with regard to equitable geographic distribution and the overall ceiling of OCPF inspections per year and State Party.**

54. There are, in principle, several options as to how this could be achieved (and they can be combined): more specific data could be required in declarations to better characterise a declared facility and its activities (either within the existing legal framework or after technical change of relevant provisions of Part IX of the Verification Annex); the Technical Secretariat could use data it has acquired in its verification and other activities in addition to those contained in declarations (for example, data from previous inspections); States Parties could submit additional data on their facilities on a voluntary basis to reduce the likelihood of inspections at facilities that have no relevance to the Convention.

55. At the same time, the OPCW should be aware in its evaluation of verification results that mechanisms have been set up in chemical industry, for reasons other than implementing the Convention, that can nevertheless help prevent the misuse of toxic chemicals for hostile purposes. Examples of relevant complementary regulatory measures include the REACH programme in the European Union, and similar initiatives outside of Europe, such as GHS and SAICM. Within industry itself, self-regulatory mechanisms such as Responsible Care®, and the use of industry standards and quality assurance systems aim at enhancing regulatory compliance and responsible behaviour.

Verification tools and procedures

56. Effective verification requires effective verification tools. OPCW inspectors have at their disposal a suite of approved equipment ranging from analytical field instruments and sample collection and preparation kits to different types of non-destructive evaluation equipment, equipment for personal protection, agent detection and safety monitoring, and other tasks. The Technical Secretariat has put in place standard operating procedures to ensure the proper selection, certification and use of this equipment, and it maintains a high standard of training. Furthermore, with the help of

States Parties, the OPCW has set up a fully-validated analytical database of target chemicals for on-site analysis. The OPCW also has established a network of designated laboratories whose professional standard is regularly evaluated in proficiency tests. This network enables the off-site analysis of environmental samples. A similar capability for the analysis of biomedical samples is currently being developed.

57. At the same time, to provide extra protections with regard to confidential information unrelated to chemical weapons, certain practices have been adopted which are incompatible with the privileges and immunities which the Convention accords to inspection teams, or which could otherwise compromise the independence of the verification process (for example: copying of inspector notebooks at the end of an on-site inspection to the inspected State Party in spite of the Convention's stipulation that the records of inspector are inviolable,[6] or restriction of the OPCW analytical database to scheduled chemicals only). Such practices can create scenarios where OPCW inspection teams will lack the ability to detect the presence or absence of certain chemicals relevant to compliance, or where their independence is compromised. **The policy-making organs and the Technical Secretariat should take measures to ensure that the verification processes of the OPCW enjoy the integrity and independence required under the Convention.**

## V. RESOLUTION OF CONCERNS OF POSSIBLE NON-COMPLIANCE

58. Article IX of the Convention provides for a number of mechanisms to address and resolve non-compliance concerns, ranging from bilateral consultations between the parties concerned to mechanisms under the auspices of the Executive Council, and the clarification and resolution of non-compliance concerns by challenge inspection. Allegations about the use of chemical weapons as well as assistance requests in cases of use or threat of use of chemical weapons against a State Party are subject to investigative mechanisms under Articles IX and X of the Convention.

59. Furthermore, there have been situations when States Parties have failed to meet their obligations as a result of a lack of capacity or full understanding of all the requirements of the Convention. The OPCW has dealt with such situations through mechanisms under the Executive Council, subject to review by the Conference of the States Parties, that involved encouragement, transparency measures such as reporting of steps taken to improve the situation, as well as technical assistance by the Technical Secretariat and States Parties when needed.

60. As we move closer towards a world without chemical weapons, but one in which instabilities, threats to national and regional security and conflicts have not ceased, effective means of consultation, cooperation and fact-finding will continue to be essential in order to address and resolve non-compliance concerns within the framework of the Convention.

[6] This was requested by the Executive Council in 1997,at the beginning of the inspection operations when there was limited practical experience with OPCW inspection conduct and protection of confidentiality.





61. The emphasis in resolving non-compliance concerns among States Parties has so far been on bilateral mechanisms. The First and Second Review Conferences (in 2003 and 2008 respectively) recognised the value of such bilateral clarifications and encouraged States Parties to continue resolving concerns about possible non-compliance amongst themselves. It should be noted that such bilateral consultations, whilst they have value for resolving concerns amongst States Parties directly involved, remain non-transparent for other States Parties.

Clarification procedures under the Executive Council

62. Many of the multilateral mechanisms foreseen in Article IX have not been activated since the entry into force of the Convention. Only recently have certain compliance issues been brought before the Executive Council.

63. **It would be desirable for the Executive Council to devote a part of its substantive work to promoting and applying the mechanisms of the Convention to address and resolve concerns about possible non-compliance.** Consistent with the procedures of the Convention, clarification procedures under the Council could involve a whole range of measures from clarification requests through the Council, to the Council requesting the Director-General to establish a group of experts to examine all available information and data relevant to the situation causing the concern, to the possibility that a State Party could request the Council to clarify a situation that has given rise to concerns about its own compliance (the latter could for example be accomplished by an inspection by invitation of a suspected facility or location, to ally concerns and demonstrate that no violation has occurred). **The Conference of the States Parties should strengthen its oversight function, and States Parties should collectively use annual sessions of the Conference to review the compliance status of the Convention.**

Challenge inspection

64. The right of each State Party to request an on-site challenge inspection for clarifying questions concerning possible non-compliance is an ultimate assurance that all States Parties implement their obligations under the Convention. When the Convention was negotiated, great care and attention was given to the formulation of the relevant treaty language in order to make the provisions unambiguous and easy to implement. However, since the entry into force of the Convention, no State Party has requested a challenge inspection. While this reflects a welcome mutual respect among the States Parties and a determination to use whenever possible consensual means to resolve issues, the non-use of challenge inspections might erode its deterrence effect.

65. States Parties should look upon the mechanism of challenge inspections as a necessary safeguard of the Convention that, in order to deter violations, must be operational. The Convention requires that the Director-General inform the Executive Council of situations when a challenge inspection cannot be executed in a timely manner, so that action can be taken to improve the situation. **It is therefore essential that the Technical Secretariat maintain the resources, technical competence, operational readiness and professional skills needed to implement a challenge inspection if one is invoked**.

66. At the same time, the States Parties themselves should further develop and maintain a good understanding of the procedures of challenge inspection. Past experience with national as well as multilateral trial challenge inspections has shown the benefit of such trials for national preparations to receive and effectively conduct a challenge inspection. **The OPCW could help States Parties develop and maintain their practical understanding of these requirements by organizing workshops and exercises.** States Parties should also attempt to finally settle the remaining unresolved issues related to challenge inspection.

Investigations of alleged use of chemical weapons

67. The capacity of the Technical Secretariat to investigate allegations of the use of chemical weapons will likely become more important in the future as new threats relating to the deliberate release of toxic chemicals emerge. These new threats may call for a re-thinking of operational procedures and a review of how the OPCW interacts with host nations, the United Nations and other actors that are likely to appear on the scene of such an event.

68. Maintaining this capacity will be a challenge as it depends on a critical mass of well-trained inspectors with the right mix of technical skills and expertise. As the overall demand for inspectors with chemical weapons expertise and skills related to work in chemical warfare environments declines given the decline in chemical weapons destruction activity, **the Technical Secretariat may have to develop new concepts for how it can maintain readiness to conduct investigations of alleged use** (such as stronger reliance on expertise outside the Inspectorate; more reliance on the Qualified Experts designated by the Director-General for investigations of alleged use, as envisaged by the Convention).

69. With regard to investigations of alleged use by the United Nations Secretary-General in States not Party to the Convention or in territory not under the control of a State Party, it is important that the general provisions contained in the UN-OPCW Relationship Agreement on coordination and cooperation with regard to such investigations be underpinned by operational arrangements and that information is shared on such issues as rosters of experts, laboratories available for off-site analysis, and standard operating procedures. In such events, the OPCW should be able to immediately mobilize and dispatch competent chemical warfare specialists from the Technical Secretariat.

70. The roster of experts and laboratories available to the Secretary-General's investigation mechanism in relation to the 1925 Geneva Protocol, as well as related procedures, have recently been updated. **Close coordination between the OPCW and the United Nations Secretary-General mechanisms will be essential, taking into account that the OPCW provides the primary international investigation mechanism with regard to the alleged use of chemical weapons**. Furthermore, the OPCW - through its network of National Authorities, wide inspection experience, and functioning links with chemical industry - has an unmatched overview of chemical weapons-related capabilities on a global scale. At a minimum, both mechanisms need to be developed towards procedural inter-operability, similar technical and procedural standards and operational coordination.





## VI. MONITORING AND EVALUATING ADVANCES IN SCIENCE AND TECHNOLOGY

71. The Convention's objective—to ban comprehensively and permanently the development, production, possession, transfer and use of chemical weapons—will only be successfully achieved and maintained if advances in science and technology are effectively monitored and evaluated. To achieve this, the OPCW, building on its accomplishments so far, should improve and widen the scope of monitoring and evaluating developments in chemical science and technology and, at the same time, make full use of these developments to improve the quality of its own work. This is recognised by the provisions in Article VIII of the Convention which require the OPCW to consider measures to make use of these advances for verification purposes, the establishment of a Scientific Advisory Board (SAB), and the need to review the impact of these advances on the operation of the Convention through periodic Review Conferences.

72. The OPCW needs good science advice and effective mechanisms to review and evaluate the impact of scientific advances on the Convention. Since its establishment in 1998, the SAB has played an important role in this respect. But there have been deficiencies in how the OPCW has called for science advice as well as how it has incorporated such advice into its operations. There should be more clarity about the purposes of SAB advice to the OPCW, in accordance with the requirements of the Convention and the SAB's terms of reference. The advisory panel suggests that these purposes could include:

- The provision of information and technical assessments to allow the evaluation of risks associated with new chemicals and technologies
- Proposals for the improvement of existing and the adoption of new verification methods and types of inspection equipment
- Advice on the need to adapt verification methods in light of new technological and scientific developments that affect the conduct of verification
- Technical advice in the context of fact-finding measures
- Technical advice on new issues that may affect the operation of the Convention, for example the convergence between chemistry and biology
- Technical advice regarding preparedness for response to releases of toxic chemicals, and with respect to remedial measures after such releases
- Identification of opportunities in science and technology to improve international cooperation among States Parties in the peaceful uses of chemistry
- Sharing of information and experience with regard to technologies for the destruction of (in the future predominantly non-stockpile) chemical weapons.

73. Progress in science and technology affects the Convention in several ways. It can change the technological environment within which the OPCW functions (e.g., in

chemical industry); create new risks for the potential misuse of toxic chemicals; improve means of protection against toxic chemicals; bring about more effective means and methods of verification; and create new opportunities for international cooperation among States Parties in the peaceful uses of chemistry.

74. Firstly, with the finalization of the destruction of existing chemical weapons stockpiles as well as the destruction of old and abandoned chemical weapons, **attention must be directed towards the potential spread of chemical weapons capabilities to governmental and non-governmental actors**. In that context, developments in electronic communications may make chemical weapons information more accessible. Compared to nuclear and certain types of biological weapons, the technological hurdles before the synthesis of toxic chemicals and the improvisation of delivery system are much lower in the case of improvised chemical weapons.

75. At the same time, it is important not to overstate the risks associated with these advances in science and technology—in the absence of dedicated weapons programmes, the various developments of chemical weapons-relevant technology will remain several long and costly steps away from the construction and production of a usable weapon.

76. Secondly, **there should be genuine exchanges involving the technical as well as policy communities of the Convention, including the SAB, government experts and policy makers, to clarify what scientific advice is needed.** There should then also be a strong relationship between the SAB and the wider science, technology and industry communities to ensure that its advice is based on a thorough understanding of what is happening at the frontiers of science and technology.

77. With regard to the chemical sciences community, the OPCW and the SAB have developed a productive relationship with the International Union of Pure and Applied Chemistry (IUAPC), the global international science union in the field of chemistry. It is important to make this partnership constant, both in order to solicit authoritative and broad-based science advice for the OPCW, and to help governance mechanisms within the scientific community to improve awareness of the Convention's goals and requirements and ensure respect for its norms.

78. But even with an expanded role for the SAB and an enhanced relationship with IUPAC, the Organisation's scientific competence must be strengthened further**. Therefore, resources should be set aside for the creation within the Technical Secretariat of adequate capacity to manage and support the systematic monitoring of relevant scientific developments. This could for example be a Science Adviser, or a small unit or part of an office working directly under the guidance of the Director-General and at the same time having access to all Divisions of the Technical Secretariat.** Such a function could also serve as a permanent secretariat of the SAB and assist with the proposing and drafting of the agenda of the SAB and the compilation of documentation on scientific matters under review by the SAB. Furthermore, it could assist the Director-General and the Executive Council in assessing scientific and technological information made available to the Organisation, including the findings of the SAB.





79. A relatively new issue is the convergence between chemistry and biology.[7] This convergence calls for a closer interaction in the implementation of the Convention, and the Biological Weapons Convention. Convergence in the sciences does not in itself lead to convergence of the regimes, but **exchanges of experience and joint technical reviews could be helpful to understand how it affects the implementation of both treaties at the interface between chemistry and biology**. That is particularly pertinent as there is an overlap between the two treaties with regard to the prohibition of toxin weapons.

80. An important partner in these conversations must be the chemical industry. The chemical industry was constructively involved in the design of the Convention's verification regime during the negotiations, and contributed to the preparatory work before the entry into force of the Convention, including by helping with the training of future OPCW inspectors.

## VII. Preparedness for and Response to Events Involving the Release of Toxic Chemicals for Hostile Purposes

81. Article X of the Convention makes provision for the strengthening of national capacities of States Parties to prepare for and respond to attacks with chemical weapons or their threatened use. Article X includes provisions for expert advice though the OPCW on how to enhance national protection against toxic chemicals, and access to the OPCW data bank which contains information on various means of protection against chemical weapons. It also establishes an international response mechanism through the OPCW (directly by States Parties, bilaterally or through the OPCW, as well as by the OPCW itself) to respond to a threat or actual use of chemical weapons and to mitigate the consequences of such attacks. Although these provisions were intended to deal with chemical warfare threats posed by States, they can also be employed if non-State actors such as terrorists use chemical weapons (to be understood as the use of any toxic chemical for hostile purposes).

82. As stated earlier in this report, the threats associated with traditional chemical warfare have been gradually declining after the entry into force of the Convention. At the same time, new risks have emerged. Terrorist organisations have attempted to acquire,

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[7] On the one hand, biological science is increasingly making use of chemistry, to the point where it has become possible to chemically synthesize components of biological systems and simple biological agents such as viruses. The chemical synthesis of more complex living organisms such as bacteria has yet to be accomplished but research to this end is well under way. This trend blurs the borderlines between what should be considered a chemical agent, and what is a biological one. At the same time, the manufacturing of some chemical products makes use of biological processes. Examples include the use of bio-catalysts in chemical synthesis or even the use of living organisms (plants and animals) as production vessels for certain chemical products (for example, certain medicines and biofuels). Similarly, biological systems are used in chemical analysis. Last but not least, the approach in the search for new biologically active chemical compounds (for example medicines or pest control agents) is changing. When in the past, chemical synthesis would provide large numbers of chemical compounds derived from certain lead molecules which would then be screened for their biological effects, the trend is now towards investigating in detail the chemical structure, configuration and functionalities of the biological targets and on that basis to design chemical structures that can specifically interfere with these biological functions. As this approach in the life sciences gains ground, it will increasingly become meaningless from a scientific point of view to distinguish between chemical and biological agents.

and some have actually used, chemical warfare agents and improvised dissemination devices. There have also been concerns about the possible use of toxic chemicals in intra-State conflicts. Assistance and protection no longer aims primarily at saving lives in classic cases of chemical weapons use on the battlefield. Other objectives have become equally if not more pressing: the protection of non-combatants following the deliberate release of toxic chemicals, by whichever actor(s) and in a variety of possible scenarios. This threat is more complex than "traditional" chemical warfare. It can involve chemical, biological, radiological and nuclear (CBRN) materials; it can be instigated by States but also non-State actors such as terrorists; and it is often directed at civilians rather than military forces.

83. The responsibility to counter these new threats lies primarily with governments, who exercise this responsibility within their own jurisdiction as well as collectively in a (sub)regional context and globally under relevant UN Security Council resolutions. Chemical industry also is making its contribution to ensuring the safety and security of its facilities, and voluntary codes of conduct are being put in place worldwide to enhance the safety and security of chemical installations. The OPCW, at the same time, has recognised its responsibility to contribute to the global fight against terrorism. One of its contributions relates to helping States Parties build capacity in the area of prevention and response to deliberate release of toxic chemicals by terrorists, including to possible attacks on chemical installations and transportation.

84. For the development of effective preventive strategies, it is important to recognise a change in the chemical risk spectrum associated with these new threats. Traditional chemical warfare agents are not necessarily the primary concern (although the experience of Tokyo in 1995 has shown they must not be ignored). Terrorist chemical weapons threats are driven by accessibility and opportunity. The deliberate release of toxic industrial chemicals as well as the ad hoc synthesis of chemical agents using readily-available chemicals, including simple household goods, cannot be ignored. Delivery methods may include not only improvised dissemination devices but also attempts to poison food or drinking water. The objective may not be mass casualties but mass terror. Although these threats are much smaller in scale than those of traditional chemcial warfare, in a world of spreading industrial capacity, intensive trade and the broad diffusion of chemistry into daily life, an "all-risks approach" will be needed.

85. In this changing environment, the nature and format of assistance and protection under the Convention should be adapted to meet these new requirements. Building resilience at the local and national level and improving strategic and operational (sub)regional cooperation are of critical importance. The OPCW should contribute to this based upon its competence, its access to expertise of States Parties, and its global reach.

86. **This could, for example, include OPCW support for the establishment, in regions or subregions where such capabilities are lacking, of regional centres to prepare for and respond to threats related to releases of toxic chemicals** (for example, by expert advice, training, or the facilitation of cooperation with other such centres and relevant institutions of other States Parties). Providing assistance and expert advice to





such regional initiatives would enable broader regional buy-in and facilitate donor contributions.

87. With this shift in emphasis towards stronger support for regional, subregional and national preparedness, the future role of the OPCW in response to requests for assistance in case of use or threat of use of chemical weapons should be reviewed. The OPCW mechanism will remain important whenever national and subregional response systems lack capacity, in particular in the event of multiple attacks with toxic chemicals. But any such international assistance can only back up the response at the local level—it is the ability to take effective measures immediately, within hours, that matter in scenarios involving the release of toxic chemicals.

88. To strengthen local, national and regional capacities to prevent, prepare for and respond to chemical incidents, States Parties will require tools (nonbinding guidelines and decision making tools, for example), as well as practical advice that helps them with needs assessment and contingency planning, training and different forms of exercises. The OPCW has already developed a portfolio of programmes and projects in this regard and it should continue offering such measures to States Parties. At the same time, other international and regional organisations are providing similar support, and it is important for the OPCW to coordinate its activities with these other actors. The Technical Secretariat could for example explore the possibilities of cooperation with the World Health Organisation, including, as appropriate, joint workshops, databases and action to support surviving victims.[8]

89. In addition, **the international community will continue to expect the OPCW to maintain the professional competence and operational capability to investigate allegations of the use of chemical weapons**. These issues have already been discussed under heading V. It should be recalled here that the OPCW investigation mechanism is today the primary international mechanism to investigate allegations of the use of chemical weapons.

## VIII. Fostering International Cooperation in the Field of Peaceful Uses of Chemistry

90. Fostering international cooperation in the field of peaceful uses of chemistry is an important goal of the Convention. Article XI sets out the basic principles to this end, and Article VIII assigns responsibility to the Conference of the States Parties to promote international cooperation among States Parties.

91. This objective will gain in importance among OPCW priorities in the future. For many States Parties, it is and will remain a major incentive to stay engaged with the Convention and the OPCW. There are two aspects of international cooperation: not hampering the economic and technological development of the States Parties, and

[8] One of the areas that may require more attention from the OPCW is the treatment of chemical casualties, irrespective of whether they result from the use of chemical weapons, accidents with old and abandoned chemical weapons, terrorist use of toxic chemicals or other incidents. Specific and quite different methodologies are required to save lives immediately after exposure and to manage long term, chronic effects from which many victims are still suffering today. The OPCW is not a medical institution, but it has some relevant expertise.

developing attractive OPCW programmes to promote international cooperation among States Parties.

Transfer controls and the economic and technological development of the States Parties

92. In today's globalised environment, rapidly growing chemical trade is indispensable for economic development. **To ensure that the trade in dual use chemicals, equipment and technologies will only serve legitimate purposes and not contribute to the re-emergence of chemical weapons threats, the OPCW must use its institutional competence to help States Parties implement effective national controls**, without hampering the economic and technological development of all States Parties.

93. Furthermore, **the OPCW should provide assistance to National Authorities to better understand and meet their responsibilities** under the Convention in this regard. For example, the OPCW could develop voluntary guidelines on how best to control chemical trade, offer practical technical assistance to help States Parties adapt these guidelines to their specific national conditions, and provide training, implementation tools and other forms of implementation support.

94. An informal group of 40 States called the Australia Group has, since its inception in 1985, contributed to international security by regulating and controlling exports of chemicals which could be used in the production of chemical weapons. When the Convention was adopted in 1992, a statement was made on behalf of the Group to the effect that, after the entry into force of the Convention and in light of its implementation, each participant in the group would undertake to review the measures they have taken to prevent the spread of chemical substances and equipment for purposes contrary to the objectives of the Convention, with the aim of removing such measures for the benefit of States Parties acting in full compliance with their obligations under the Convention.

95. Today, after 14 years of functioning of the Convention, it can be concluded that the implementation of the Convention has generally met the expectations of its States Parties. The OPCW up to this date has in most cases successfully carried out its duties as defined by the Convention, including the effective prohibition of any transfer of chemical weapons. The remaining tasks are clearly defined (enduring enforcement of the prohibitions with regard to non-transfers of chemical weapons and the undertaking not to assist, encourage or induce any activity prohibited under the Convention; further strengthening of national implementation systems including in the area of transfer controls as required by the Convention; reviews of existing national regulations in the field of trade in chemicals in order to render them consistent with the object and purpose of the Convention). The OPCW appears well equipped and ready to deal with these issues—it has already taken them up in the context of its Article VII Action Plan.

96. To move this process further, **the OPCW could seek to promote dialogue between export licensing organisations and customs authorities where they have not to date interacted and cooperated**, for example to identify elements of the Australia





Group guidelines that can help the National Authorities to better monitor transfers of dual use chemicals of relevance to the Convention.

97. Nevertheless, whether justified or not, the continuation of Australia Group measures vis-à-vis States Parties of the Convention has given rise to resentment. Such resentment is not a healthy or propitious development, and efforts should be made to correct it. A way in which cases of transfer denials might be addressed is through consultation and cooperation within the framework of the OPCW. This has not happened in the past. **The advisory panel recommends an approach whereby any State Party feeling discriminated against over transfer denials could address a complaint to the Director-General, who might use his good offices to bring the parties together to discuss and if possible resolve the matter including by addressing the reasons that have led to the denial. Such a mechanism might increase transparency and help to dispel concerns.**

Fostering international cooperation in the peaceful uses of chemistry

98. With regard to the OPCW's programmes to promote international cooperation in the peaceful uses of chemistry, some progress has been made since the entry into force of the Convention. However, these programme areas have received inadequate resources in the past. With the release of resources from chemical weapons-related verification in the future, greater attention should be provided for the implementation of Articles XI. Effective implementation of this important Article, which involves the entire membership of the Convention, will contribute to the overall objective of enhancing compliance. **To the extent possible, Article XI programmes should not be primarily dependent on voluntary contributions which by nature will be ad hoc, but programmes should be strengthened through the regular OPCW budget as well.**

99. **In developing future cooperation programmes, the OPCW should link these to its own technical competence and strengths. Thereby the OPCW should make full use of its knowledge base and of its networks with National Authorities, various organisations, institutions and experts in the States Parties.** This would give further legitimacy and appeal to these programmes, and make them distinct from international cooperation programmes offered by other international organisations. What the OPCW can bring to the table is its specific technical understanding and competencies related to toxic chemicals, its experience with regard to assisting States Parties with national implementation measures, its ability to network and connect partners, and its global reach.

100. Examples for programme initiatives that draw from these strengths include:

- Improving the regulatory framework in States Parties – technical assistance with regard to legislation, regulations and enforcement;
- Chemical safety and security – development of guidelines for States Parties and help with promoting implementation practices and standards;
- Issues related to facilitating trade in chemicals, chemical equipment and technologies;

- Support to States Parties regarding their efforts to prevent illicit trafficking in chemical dual use goods, including by supporting the work of customs organisations, and export/import licensing;
- Training and exercises related to the issues mentioned above;
- Education and awareness raising with regard to the norms and requirements enshrined in the Convention, the adoption of self-regulatory measures (codes of conduct, guidelines, compliance initiatives in industry and the like), and the promotion of international cooperation in full compliance with the requirements of the Convention.

101. New opportunities for the OPCW have been identified in the Article XI workshop organised by the OPCW in November 2010, and could include *inter alia*:

- Setting up a facility to trace and evaluate incidents involving toxic chemicals;
- Facilitating technology transfers for the development of peaceful uses of chemistry;
- Promoting risk assessment and clean-up programmes related to old and abandoned chemical weapons;
- Promoting risk assessments and other measures related to mitigate the risks regarding sea-dumped chemical weapons;
- Developing other risk assessment and management tools that States Parties could use; and
- Promoting the ethical dimension of chemical weapons disarmament and the rendering of support to initiatives to categorize as a crime against humanity the hostile use of toxic chemicals.

102. Government policies are important in creating and maintaining a regulatory context that invites and accommodates scientific, technological and economic development. **A contribution that the OPCW can make to economic development, therefore, is to help States Parties create and maintain regulatory frameworks that fully implement the Convention thereby furthering conditions for economic development and international exchanges**.

103. **The OPCW should also strengthen its managerial approach towards its international cooperation programmes**. Efforts are needed to develop and use more tailored and reliable tools for assessment of needs, programme impact and results. This will be necessary to ensure that the contribution of the OPCW to international cooperation remains relevant and sustainable for States Parties. Models for such managerial systems and experiences with their application exist in other international technical assistance programmes; these should be looked at with a view to adapting their lessons-learned to the OPCW context.





104. The future OPCW international cooperation programme needs to strike the right balance between programmes to enhance States Parties' capacity with regard to toxic chemicals in general, and their capacity to fully and effectively implement the Convention. Both directions should be pursued in parallel. **The advisory panel recommends that OPCW programmes should be directed towards enhancing and promoting the interaction among National Authorities, and between National Authorities and the OPCW**.

105. As previously discussed, a stronger regional approach would benefit both the States Parties and the OPCW. **Regional or subregional cooperation centres could be set up, perhaps starting with one or more pilot projects, where demand and need exist. This could be done with technical support from the OPCW, in partnership with other international and regional organisations, active participation of the States Parties from the region or subregion, and with voluntary sponsorship by other donors.** These centres would eventually have to become self-sufficient and independent of external financial support to be sustainable. At the same time, they would allow the region or subregion, with advice and technical support from OPCW, to develop projects and cooperation mechanisms among the States Parties of the region or subregion that meet their specific needs and conditions, whilst being able to tap into expertise and support from other States Parties from outside the region.

106. Furthermore, the OPCW's international cooperation programmes need to be developed with the clear understanding that the OPCW is only one of several actors on the international scene that promote cooperation in the field of peaceful uses of chemistry. It is important to embed the OPCW and its international cooperation programmes in that broader domain of international cooperation in the chemical field, through programme coordination, networking, the development of partnerships, and the exploitation of synergies.

## IX. MANAGING THE TRANSITION

107. The OPCW has become the global repository of knowledge and a centre of operational and technical expertise with regard to the prevention of chemical warfare, the elimination of chemical weapons, and international verification. This capacity will also be relevant in the future. Even after all chemical weapons stockpiles have been eliminated, attention needs to be paid to emerging threats associated with the possible hostile use of toxic chemicals. Also, old and abandoned chemical weapons will continue to need to be destroyed subject to the provisions of the Convention. Furthermore, sea-dumped chemical weapons constitute risks to people and the environment and the OPCW can make contributions to mitigating these risks. The sooner the existing chemical weapons stockpiles can be eliminated, the greater the prospects for the OPCW to make its transition to a world without chemical weapons.

108. The adoption of new priorities will require institutional change and managerial adaptation. It is essential for the future of the Convention and the OPCW to find effective and acceptable ways to adapt—the alternative could be institutional fossilisation. The Convention provides sufficient flexibility for institutional change through policy development, decision making by the policy-making organs, gradual modifications of work and operational practices. In doing so, the OPCW should make

full use of principles such as its inclusive approach, transparency, non-discrimination and consensus building.

109. How exactly the new priorities will affect the future size, structure and functioning of the Technical Secretariat goes beyond the scope of this report. The Director-General has appointed a consultant to review the structure of the Technical Secretariat, and to report to him later in 2011. However some general principles should be highlighted, emphasizing that transition and reform should be controlled and gradual.

110. **Institutionally, the OPCW needs to preserve its independence and competence to remain both relevant and credible.** Micromanagement would be counterproductive and should therefore be avoided. Also, the OPCW's staffing levels with regard to qualified and well-trained staff need to be retained above a "critical mass" in relation to all future programme priorities.

111. Changing circumstances and priorities will require some degree of restructuring. It is also apparent that particular vulnerabilities may exist with regard to maintaining an inspectorate that matches the routine tasks in hand after near completion of chemical weapons stockpile elimination, and that is nevertheless strong enough to meet requirements of a less frequent nature such as challenge inspections or investigations of alleged use. **The Technical Secretariat must maintain adequate levels of verification resources to ensure that the destruction of chemical weapons remains subject to international verification as required by the Convention, and to make certain that the verification regime as a whole remains credible**. There will be a need for some flexibility within the structure of the Technical Secretariat to create a reserve that is engaged in routine programme delivery, but that can be relied upon when special demands in the verification areas occur. This will pose managerial challenges with regard to the protection of confidentiality. Robust procedures will be needed to ensure that the OPCW can maintain its high standards in this regard.

112. **Another key requirement is the preservation and expansion of institutional competence, knowledge and professionalism**. The implementation of the OPCW's tenure policy is already under review and it appears that additional flexibility will be required in the manner in which the policy is applied. Learning and training mechanisms should also be further improved.

113. **The shift in priorities may also require a review of the OPCW's budget structure**. The Convention requires that the OPCW divide its budget into two chapters: chapter I for verification costs and chapter II for all other costs including administration. Chapter II contains key elements of programme delivery, including assistance and protection against chemical weapons, implementation support to National Authorities, and international cooperation programmes.

114. Ever since the entry into force of the Convention, practice has been to maintain parity between both Chapters. With the reduction of chemical weapons-related verification activity, this should no longer be so. At the same time, the current budget format combines programme delivery expenses with administrative costs under a single chapter.





115. **The OPCW programme and budget structure should be changed to better reflect the different types of contributions that the OPCW programme outputs make**. These should be clearly separated, to the extent possible, from the administrative costs needed to run the OPCW and to support the work of its policy making organs.

116. With regard to budget allocation, it has already been observed in this report that greater attention should be given to Articles X and XI. In this context, it will be important to ensure that future OPCW programme delivery will not become dependent on voluntary contributions—these are welcome but core business should be funded from the regular budget. At the same time, voluntary contributions by States Parties and other donors such as the EU should be encouraged to expand the possible margins of programme delivery.

117. In this context, **a move to a two-year budget cycle should also be considered, so as to ensure stability and predictability in programme output**. This could be important to increase impact and sustainability of OPCW programmes.

118. Needless to say, States Parties should pay their dues on time. It remains a serious concern that at the end of 2010 a total of 81 States Parties were in arrears with their annual contributions that year. The Working Capital Fund, designed to meet short-term liquidity problems, would allow the OPCW to manage cash flow problems. **The policy making organs should keep this matter under their purview to ensure the timely and effective use of the Working Capital Fund with regard to full programme delivery**.

119. The engagement and contribution of the Convention's stakeholders is becoming ever more important. Their role (with the exception of chemical industry) was limited at the beginning of the Convention's operation—when the focus was on the elimination of State programmes—but is bound to increase and become more critical as the focus moves to prevention and cooperation. More efforts should be made by the OPCW to engage with chemical industry. Also, there have been some initial contacts with the Biological Weapons Convention given the underlying trends in science and technology; these should be strengthened. The **Technical Secretariat should establish a liaison (e.g., a point of contact) with the BWC implementation process**.

120. **Furthermore, a much stronger engagement with civil society will be needed, and the advisory panel supports the Director-General's efforts to enhance public diplomacy by the OPCW**. Externally, what is needed is for the OPCW to further develop an effective networking approach to reach out to the different stakeholder communities, and also to reach back into their expertise as new implementation challenges emerge. Internally, the Technical Secretariat should consider splitting the functions of media relations and public diplomacy.

121. The transition of the OPCW to a renewed set of mandates, new programme priorities and an adapted staffing structure of the Technical Secretariat, create an opportunity to also look carefully at other conditions that affect its work. The Hague as the seat of the OPCW has certain advantages but at the same time lacks the *in-situ* interaction with an international diplomatic and expert community in the arms control, non-

proliferation and disarmament field. It also lacks the presence of a strong NGO community with a focus on disarmament, and the opportunity of a daily interaction with other international agencies that work in fields relevant to the future mission of the OPCW. The OPCW has had to work around these and other constraints. But as the transition to a new mission focus gets under way, States Parties may wish to use this as an opportunity to study how these constraints can be overcome. One option could be to review and if necessary renegotiate aspects of the relationship with the Host Country. Another option, which is not an alternative to the first one, could be creating an OPCW presence in the UN centres where there is a need for joint programming and coordination. **The advisory panel proposes that a full range of options be carefully studied, from the perspective of opportunity costs and benefits, with a particular focus on what sort of environment the OPCW requires for the long-term future**.





**Annex 3**

**LIST OF MEMBERS OF THE ADVISORY ON FUTURE OPCW PRIORITIES**

Chair: H.E. Mr. Rolf Ekéus (Sweden)

H.E. Ms Noor Farida Ariffin (Malaysia)

H.E. Mr Sergei Batsanov (Russian Federation)

H.E. Mr Marcos de Azambuja (Brazil)

Mr Claude Eon (France)

H.E. Mr Roberto Garcia Moritan (Argentina)

Mr Juesheng Gu (China)

H.E. Mr Abuelgasim Idris (Sudan)

H.E. Mr Eric Javits (United States of America)

Ms Patricia Lewis (United Kingdom of Great Britain and Northern Ireland)

H.E. Mr Abdul Minty (South Africa)

Mr Bunro Shiozawa (Japan)

H.E. Mr Rakesh Sood (India)

Mr Ralf Trapp (Germany)

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**FIFTY-FOURTH WORLD HEALTH ASSEMBLY** **WHA54.14**

**Agenda item 13.3** **21 May 2001**

# Global health security: epidemic alert and response

The Fifty-fourth World Health Assembly,

Recalling resolutions WHA48.7 on the International Health Regulations, WHA48.13 on new, emerging and re-emerging infectious diseases, and WHA51.17 on antimicrobial resistance;

Recalling that public health is a priority for development and that combating communicable diseases, which are a major burden in terms of human mortality and morbidity, provides important and immediate opportunities for progress;

Mindful of the globalization of trade and of the movement of people, animals, goods and food products, as well as the speed with which these take place;

Recognizing that, as a result, any upsurge in cases of infectious disease in a given country is potentially of concern for the international community,

1. EXPRESSES its support for:

   (1) ongoing work on the revision of the International Health Regulations, including criteria to define what constitutes a health emergency of international concern;

   (2) development of a global strategy for containment and, where possible, prevention of antimicrobial drug resistance;

   (3) collaboration between WHO and all potential technical partners in the area of epidemic alert and response, including relevant public sectors, intergovernmental organizations, nongovernmental organizations and the private sector;

2. URGES Member States:

   (1) to participate actively in the verification and validation of surveillance data and information concerning health emergencies of international concern, together with WHO and other technical partners;

   (2) to develop and update national preparation and response plans;

(3) to develop training for the staff involved and the exchange of good practice between specialists in response to alerts;

(4) to update regularly information on the resources available for the surveillance and control of infectious diseases;

(5) to designate a focal point for the International Health Regulations;

3. REQUESTS the Director-General:

(1) to devise relevant international tools, and to provide technical support to Member States for developing or strengthening preparedness and response activities against risks posed by biological agents, as an integral part of their emergency management programmes;

(2) to provide technical support to Member States for developing intervention programmes that prevent epidemics and respond to communicable disease threats and emergencies, particularly with regard to epidemiological investigations, laboratory diagnoses and community and clinical management of cases;

(3) to make appropriate arrangements for the development of regional preparedness and response plans;

(4) to provide support to Member States for strengthening their capacity to detect and respond rapidly to communicable disease threats and emergencies, especially by developing the laboratory skills needed for diagnosis and providing training in epidemiological methods for use in the field, particularly in the most exposed countries;

(5) to make available relevant information on public health risks to Member States, relevant intergovernmental organizations and technical partners;

(6) to provide technical support to Member States in the implementation of national efforts to contain and prevent resistance to antimicrobials.

Ninth plenary meeting, 21 May 2001
A54/VR/9

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**FIFTY-FIFTH WORLD HEALTH ASSEMBLY** **WHA55.16**

**Agenda item 13.15** **18 May 2002**

# Global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radionuclear material that affect health

The Fifty-fifth World Health Assembly,

Underlining that the World Health Organization focuses on the possible public health consequences of an incident involving biological and chemical agents and radionuclear material, regardless of whether it is characterized as a natural occurrence, accidental release or a deliberate act;

Having reviewed the report on the deliberate use of biological and chemical agents to cause harm: public health response;[1]

Seriously concerned about threats against civilian populations, including those caused by natural occurrence or accidental release of biological or chemical agents or radionuclear material as well as their deliberate use to cause illness and death in target populations;

Noting that such agents can be disseminated through a range of mechanisms, including the food- and water-supply chains, thereby threatening the integrity of public health systems;

Acknowledging that natural occurrence or accidental release of biological, chemical agents and radionuclear material could have serious global public health implications and jeopardise the public health achievements of the past decades;

Acknowledging also that the local release of biological, chemical and radionuclear material designed to cause harm could have serious global public health implications and jeopardize the public health achievements of the past decades;

Recalling resolution WHA54.14 on global health security: epidemic alert and response, which stresses the need for all Member States to work together, with WHO and with other technical partners, in addressing health emergencies of international concern, and resolution WHA45.32 on the International Programme on Chemical Safety, which emphasized the need to establish or strengthen national and local capacities to respond to chemical incidents;

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[1] Document A55/20.

Recognizing that one of the most effective methods of preparing for deliberately caused disease is to strengthen public health surveillance and response activities for naturally or accidentally occurring diseases,

1. URGES Member States:

(1) to ensure they have in place national disease-surveillance plans which are complementary to regional and global disease-surveillance mechanisms, and to collaborate in the rapid analysis and sharing of surveillance data of international humanitarian concern;

(2) to collaborate and provide mutual support in order to enhance national capacity in field epidemiology, laboratory diagnoses, toxicology and case management;

(3) to treat any deliberate use, including local, of biological and chemical agents and radionuclear attack to cause harm also as a global public health threat, and to respond to such a threat in other countries by sharing expertise, supplies and resources in order rapidly to contain the event and mitigate its effects;

2. REQUESTS the Director-General:

(1) to continue, in consultation with relevant intergovernmental agencies and other international organizations, to strengthen global surveillance of infectious diseases, water quality, and food safety, and related activities such as revision of the International Health Regulations and development of WHO's food safety strategy, by coordinating information gathering on potential health risks and disease outbreaks, data verification, analysis and dissemination, by providing support to laboratory networks, and by making a strong contribution to any international humanitarian response, as required;

(2) to provide tools and support for Member States, particularly developing countries, in strengthening their national health systems, notably with regard to emergency preparedness and response plans, including disease surveillance and toxicology, risk communication, and psychosocial consequences of emergencies;

(3) to continue to issue international guidance and technical information on recommended public health measures to deal with the deliberate use of biological and chemical agents to cause harm, and to make this information available on WHO's web site;

(4) to examine the possible development of new tools, within the mandate of WHO, including modelling of possible scenarios of natural occurrence, accidental release or deliberate use of biological, chemical agents and radionuclear material that affect health, and collective mechanisms concerning the global public health response to contain or mitigate the effects of natural occurrence, accidental release or deliberate use of biological, chemical agents and radionuclear material that affect health.

Ninth plenary meeting, 18 May 2002
A55/VR/9

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# Laboratory biosafety manual

Third edition

**World Health Organization**
Geneva
2004

# 9. Laboratory biosecurity concepts

The *Laboratory biosafety manual* has in the past focused on traditional biosafety guidance for laboratories. The manual emphasizes the use of good microbiological work practices, appropriate containment equipment, proper facility design, operation and maintenance, and administrative considerations to minimize the risk of worker injury or illness. In following these recommendations, the risk to the environment and surrounding community-at-large is also minimized. It has now become necessary to expand this traditional approach to biosafety through the introduction of laboratory biosecurity measures. Global events in the recent past have highlighted the need to protect laboratories and the materials they contain from being intentionally compromised in ways that may harm people, livestock, agriculture or the environment. Before the laboratory biosecurity needs of a facility can be defined, however, it is important to understand the distinction between "laboratory biosafety" and "laboratory biosecurity".

"Laboratory biosafety" is the term used to describe the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release. "Laboratory biosecurity" refers to institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins.

Effective biosafety practices are the very foundation of laboratory biosecurity activities. Through risk assessments, performed as an integral part of an institution's biosafety programme, information is gathered regarding the type of organisms available, their physical location, the personnel who require access to them, and the identification of those responsible for them. This information can be used to assess whether an institution possesses biological materials that are attractive to those who may wish to use them improperly. National standards should be developed that recognize and address the ongoing responsibility of countries and institutions to protect specimens, pathogens and toxins from misuse.

A specific laboratory biosecurity programme must be prepared and implemented for each facility according to the requirements of the facility, the type of laboratory work conducted, and the local conditions. Consequently, laboratory biosecurity activities should be representative of the institution's various needs and should include input from scientific directors, principal investigators, biosafety officers, laboratory

scientific staff, maintenance staff, administrators, information technology staff, and law enforcement agencies and security staff if appropriate.

Laboratory biosecurity measures should be based on a comprehensive programme of accountability for pathogens and toxins that includes an updated inventory with storage location, identification of personnel with access, description of use, documentation of internal and external transfers within and between facilities, and any inactivation and/or disposal of the materials. Likewise, an institutional laboratory biosecurity protocol should be established for identifying, reporting, investigating and remediating breaches in laboratory biosecurity, including discrepancies in inventory results. The involvement and roles and responsibilities of public health and security authorities in the event of a security infraction must be clearly defined.

Laboratory biosecurity training, distinct from laboratory biosafety training, should be provided to all personnel. Such training should help personnel understand the need for protection of such materials and the rationale for the specific biosecurity measures, and should include a review of relevant national standards and institution-specific procedures. Procedures describing the security roles and responsibilities of personnel in the event of a security infraction should also be presented during training.

The professional and ethical suitability for working with dangerous pathogens of all personnel who have regular authorized access to sensitive materials is also central to effective laboratory biosecurity activities.

In summary, security precautions should become a routine part of laboratory work, just as have aseptic techniques and other safe microbiological practices. Laboratory biosecurity measures should not hinder the efficient sharing of reference materials, clinical and epidemiological specimens and related information necessary for clinical or public health investigations. Competent security management should not unduly interfere with the day-to-day activities of scientific personnel or be an impediment to conducting research. Legitimate access to important research and clinical materials must be preserved. Assessment of the suitability of personnel, security-specific training and rigorous adherence to pathogen protection procedures are reasonable means of enhancing laboratory biosecurity. All such efforts must be established and maintained through regular risk and threat assessments, and regular review and updating of procedures. Checks for compliance with these procedures, with clear instructions on roles, responsibilities and remedial actions, should be integral to laboratory biosecurity programmes and national standards for laboratory biosecurity.

**FIFTY-EIGHTH WORLD HEALTH ASSEMBLY** **WHA58.3**

**Agenda item 13.1** **23 May 2005**

# Revision of the International Health Regulations

The Fifty-eighth World Health Assembly,

Having considered the draft revised International Health Regulations;[1]

Having regard to articles 2(*k*), 21(*a*) and 22 of the Constitution of WHO;

Recalling references to the need for revising and updating the International Health Regulations in resolutions WHA48.7 on revision and updating of the International Health Regulations, WHA54.14 on global health security: epidemic alert and response, WHA55.16 on global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radionuclear material that affect health, WHA56.28 on revision of the International Health Regulations, and WHA56.29 on severe acute respiratory syndrome (SARS), with a view to responding to the need to ensure global public health;

Welcoming resolution 58/3 of the United Nations General Assembly on enhancing capacity building in global public health, which underscores the importance of the International Health Regulations and urges that high priority should be given to their revision;

Affirming the continuing importance of WHO's role in global outbreak alert and response to public health events, in accordance with its mandate;

Underscoring the continued importance of the International Health Regulations as the key global instrument for protection against the international spread of disease;

Commending the successful conclusion of the work of the Intergovernmental Working Group on Revision of the International Health Regulations,

[1] See document A58/4.



1. ADOPTS the revised International Health Regulations attached to this resolution, to be referred to as the "International Health Regulations (2005)";

2. CALLS UPON Member States and the Director-General to implement fully the International Health Regulations (2005), in accordance with the purpose and scope set out in Article 2 and the principles embodied in Article 3;

3. DECIDES, for the purposes of paragraph 1 of Article 54 of the International Health Regulations (2005), that States Parties and the Director-General shall submit their first report to the Sixty-first World Health Assembly, and that the Health Assembly shall on that occasion consider the schedule for the submission of further such reports and the first review on the functioning of the Regulations pursuant to paragraph 2 of Article 54;

4. FURTHER DECIDES that, for the purposes of paragraph 1 of Article 14 of the International Health Regulations (2005), the other competent intergovernmental organizations or international bodies with which WHO is expected to cooperate and coordinate its activities, as appropriate, include the following: United Nations, International Labour Organization, Food and Agriculture Organization, International Atomic Energy Agency, International Civil Aviation Organization, International Maritime Organization, International Committee of the Red Cross, International Federation of Red Cross and Red Crescent Societies, International Air Transport Association, International Shipping Federation, and *Office International des Epizooties*;

5. URGES Member States:

(1) to build, strengthen and maintain the capacities required under the International Health Regulations (2005), and to mobilize the resources necessary for that purpose;

(2) to collaborate actively with each other and WHO in accordance with the relevant provisions of the International Health Regulations (2005), so as to ensure their effective implementation;

(3) to provide support to developing countries and countries with economies in transition if they so request in the building, strengthening and maintenance of the public health capacities required under the International Health Regulations (2005);

(4) to take all appropriate measures, pending entry into force of the International Health Regulations (2005), for furthering their purpose and eventual implementation, including development of the necessary public health capacities and legal and administrative provisions, and, in particular, to initiate the process for introducing use of the decision instrument contained in Annex 2;

6. REQUESTS the Director-General:

(1) to give prompt notification of the adoption of the International Health Regulations (2005) in accordance with paragraph 1 of Article 65 thereof;

(2) to inform other competent intergovernmental organizations or international bodies of the adoption of the International Health Regulations (2005) and, as appropriate, to cooperate with them in the updating of their norms and standards and to coordinate with them the activities of WHO under the International Health Regulations (2005) with a view to ensuring the application

of adequate measures for the protection of public health and strengthening of the global public-health response to the international spread of disease;

(3) to transmit to the International Civil Aviation Organization (ICAO) the recommended changes to the Health Part of the Aircraft General Declaration,[1] and, after completion by ICAO of its revision of the Aircraft General Declaration, to inform the Health Assembly and replace Annex 9 of the International Health Regulations (2005) with the Health Part of the Aircraft General Declaration as revised by ICAO;

(4) to build and strengthen the capacities of WHO to perform fully and effectively the functions entrusted to it under the International Health Regulations (2005), in particular through strategic health operations that provide support to countries in detection and assessment of, and response to, public health emergencies;

(5) to collaborate with States Parties to the International Health Regulations (2005), as appropriate, including through the provision or facilitation of technical cooperation and logistical support;

(6) to collaborate with States Parties to the extent possible in the mobilization of financial resources to provide support to developing countries in building, strengthening and maintaining the capacities required under the International Health Regulations (2005);

(7) to draw up, in consultation with Member States, guidelines for the application of health measures at ground crossings in accordance with Article 29 of the International Health Regulations (2005);

(8) to establish the Review Committee of the International Health Regulations (2005) in accordance with Article 50 of these Regulations;

(9) to take steps immediately to prepare guidelines for the implementation and evaluation of the decision instrument contained in the International Health Regulations (2005), including elaboration of a procedure for the review of its functioning, which shall be submitted to the Health Assembly for its consideration pursuant to paragraph 3 of Article 54 of these Regulations;

(10) to take steps to establish an IHR Roster of Experts and to invite proposals for its membership, pursuant to Article 47 of the International Health Regulations (2005).

[1] Document A58/41 Add.2.







# INTERNATIONAL HEALTH REGULATIONS (2005)

## PART I – DEFINITIONS, PURPOSE AND SCOPE, PRINCIPLES AND RESPONSIBLE AUTHORITIES

*Article 1 Definitions*

1. For the purposes of the International Health Regulations (hereinafter the "IHR" or "Regulations"):

"affected" means persons, baggage, cargo, containers, conveyances, goods, postal parcels or human remains that are infected or contaminated, or carry sources of infection or contamination, so as to constitute a public health risk;

"affected area" means a geographical location specifically for which health measures have been recommended by WHO under these Regulations;

"aircraft" means an aircraft making an international voyage;

"airport" means any airport where international flights arrive or depart;

"arrival" of a conveyance means:

(a) in the case of a seagoing vessel, arrival or anchoring in the defined area of a port;

(b) in the case of an aircraft, arrival at an airport;

(c) in the case of an inland navigation vessel on an international voyage, arrival at a point of entry;

(d) in the case of a train or road vehicle, arrival at a point of entry;

"baggage" means the personal effects of a traveller;

"cargo" means goods carried on a conveyance or in a container;

"competent authority" means an authority responsible for the implementation and application of health measures under these Regulations;

"container" means an article of transport equipment:

(a) of a permanent character and accordingly strong enough to be suitable for repeated use;

(b) specially designed to facilitate the carriage of goods by one or more modes of transport, without intermediate reloading;

(c) fitted with devices permitting its ready handling, particularly its transfer from one mode of transport to another; and

(d) specially designed as to be easy to fill and empty;

"container loading area" means a place or facility set aside for containers used in international traffic;

"contamination" means the presence of an infectious or toxic agent or matter on a human or animal body surface, in or on a product prepared for consumption or on other inanimate objects, including conveyances, that may constitute a public health risk;

"conveyance" means an aircraft, ship, train, road vehicle or other means of transport on an international voyage;

"conveyance operator" means a natural or legal person in charge of a conveyance or their agent;

"crew" means persons on board a conveyance who are not passengers;

"decontamination" means a procedure whereby health measures are taken to eliminate an infectious or toxic agent or matter on a human or animal body surface, in or on a product prepared for consumption or on other inanimate objects, including conveyances, that may constitute a public health risk;

"departure" means, for persons, baggage, cargo, conveyances or goods, the act of leaving a territory;

"deratting" means the procedure whereby health measures are taken to control or kill rodent vectors of human disease present in baggage, cargo, containers, conveyances, facilities, goods and postal parcels at the point of entry;

"Director-General" means the Director-General of the World Health Organization;

"disease" means an illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans;

"disinfection" means the procedure whereby health measures are taken to control or kill infectious agents on a human or animal body surface or in or on baggage, cargo, containers, conveyances, goods and postal parcels by direct exposure to chemical or physical agents;

"disinsection" means the procedure whereby health measures are taken to control or kill the insect vectors of human diseases present in baggage, cargo, containers, conveyances, goods and postal parcels;

"event" means a manifestation of disease or an occurrence that creates a potential for disease;

"*free pratique*" means permission for a ship to enter a port, embark or disembark, discharge or load cargo or stores; permission for an aircraft, after landing, to embark or disembark, discharge or load cargo or stores; and permission for a ground transport vehicle, upon arrival, to embark or disembark, discharge or load cargo or stores;

"goods" mean tangible products, including animals and plants, transported on an international voyage, including for utilization on board a conveyance;







"ground crossing" means a point of land entry in a State Party, including one utilized by road vehicles and trains;

"ground transport vehicle" means a motorized conveyance for overland transport on an international voyage, including trains, coaches, lorries and automobiles;

"health measure" means procedures applied to prevent the spread of disease or contamination; a health measure does not include law enforcement or security measures;

"ill person" means an individual suffering from or affected with a physical ailment that may pose a public health risk;

"infection" means the entry and development or multiplication of an infectious agent in the body of humans and animals that may constitute a public health risk;

"inspection" means the examination, by the competent authority or under its supervision, of areas, baggage, containers, conveyances, facilities, goods or postal parcels, including relevant data and documentation, to determine if a public health risk exists;

"international traffic" means the movement of persons, baggage, cargo, containers, conveyances, goods or postal parcels across an international border, including international trade;

"international voyage" means:

(a) in the case of a conveyance, a voyage between points of entry in the territories of more than one State, or a voyage between points of entry in the territory or territories of the same State if the conveyance has contacts with the territory of any other State on its voyage but only as regards those contacts;

(b) in the case of a traveller, a voyage involving entry into the territory of a State other than the territory of the State in which that traveller commences the voyage;

"intrusive" means possibly provoking discomfort through close or intimate contact or questioning;

"invasive" means the puncture or incision of the skin or insertion of an instrument or foreign material into the body or the examination of a body cavity. For the purposes of these Regulations, medical examination of the ear, nose and mouth, temperature assessment using an ear, oral or cutaneous thermometer, or thermal imaging; medical inspection; auscultation; external palpation; retinoscopy; external collection of urine, faeces or saliva samples; external measurement of blood pressure; and electrocardiography shall be considered to be non-invasive;

"isolation" means separation of ill or contaminated persons or affected baggage, containers, conveyances, goods or postal parcels from others in such a manner as to prevent the spread of infection or contamination;

"medical examination" means the preliminary assessment of a person by an authorized health worker or by a person under the direct supervision of the competent authority, to determine the person's health status and potential public health risk to others, and may include the scrutiny of health documents, and a physical examination when justified by the circumstances of the individual case;

"National IHR Focal Point" means the national centre, designated by each State Party, which shall be accessible at all times for communications with WHO IHR Contact Points under these Regulations;

"Organization" or "WHO" means the World Health Organization;

"permanent residence" has the meaning as determined in the national law of the State Party concerned;

"personal data" means any information relating to an identified or identifiable natural person;

"point of entry" means a passage for international entry or exit of travellers, baggage, cargo, containers, conveyances, goods and postal parcels as well as agencies and areas providing services to them on entry or exit;

"port" means a seaport or a port on an inland body of water where ships on an international voyage arrive or depart;

"postal parcel" means an addressed article or package carried internationally by postal or courier services;

"public health emergency of international concern" means an extraordinary event which is determined, as provided in these Regulations:

(i) to constitute a public health risk to other States through the international spread of disease and

(ii) to potentially require a coordinated international response;

"public health observation" means the monitoring of the health status of a traveller over time for the purpose of determining the risk of disease transmission;

"public health risk" means a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger;

"quarantine" means the restriction of activities and/or separation from others of suspect persons who are not ill or of suspect baggage, containers, conveyances or goods in such a manner as to prevent the possible spread of infection or contamination;

"recommendation" and "recommended" refer to temporary or standing recommendations issued under these Regulations;

"reservoir" means an animal, plant or substance in which an infectious agent normally lives and whose presence may constitute a public health risk;

"road vehicle" means a ground transport vehicle other than a train;

"scientific evidence" means information furnishing a level of proof based on the established and accepted methods of science;







"scientific principles" means the accepted fundamental laws and facts of nature known through the methods of science;

"ship" means a seagoing or inland navigation vessel on an international voyage;

"standing recommendation" means non-binding advice issued by WHO for specific ongoing public health risks pursuant to Article 16 regarding appropriate health measures for routine or periodic application needed to prevent or reduce the international spread of disease and minimize interference with international traffic;

"surveillance" means the systematic ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary;

"suspect" means those persons, baggage, cargo, containers, conveyances, goods or postal parcels considered by a State Party as having been exposed, or possibly exposed, to a public health risk and that could be a possible source of spread of disease;

"temporary recommendation" means non-binding advice issued by WHO pursuant to Article 15 for application on a time-limited, risk-specific basis, in response to a public health emergency of international concern, so as to prevent or reduce the international spread of disease and minimize interference with international traffic;

"temporary residence" has the meaning as determined in the national law of the State Party concerned;

"traveller" means a natural person undertaking an international voyage;

"vector" means an insect or other animal which normally transports an infectious agent that constitutes a public health risk;

"verification" means the provision of information by a State Party to WHO confirming the status of an event within the territory or territories of that State Party;

"WHO IHR Contact Point" means the unit within WHO which shall be accessible at all times for communications with the National IHR Focal Point.

2. Unless otherwise specified or determined by the context, reference to these Regulations includes the annexes thereto.

*Article 2 Purpose and scope*

The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.

*Article 3 Principles*

1. The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons.

2. The implementation of these Regulations shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization.

3. The implementation of these Regulations shall be guided by the goal of their universal application for the protection of all people of the world from the international spread of disease.

4. States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to legislate and to implement legislation in pursuance of their health policies. In doing so they should uphold the purpose of these Regulations.

*Article 4 Responsible authorities*

1. Each State Party shall designate or establish a National IHR Focal Point and the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations.

2. National IHR Focal Points shall be accessible at all times for communications with the WHO IHR Contact Points provided for in paragraph 3 of this Article. The functions of National IHR Focal Points shall include:

(a) sending to WHO IHR Contact Points, on behalf of the State Party concerned, urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12; and

(b) disseminating information to, and consolidating input from, relevant sectors of the administration of the State Party concerned, including those responsible for surveillance and reporting, points of entry, public health services, clinics and hospitals and other government departments.

3. WHO shall designate IHR Contact Points, which shall be accessible at all times for communications with National IHR Focal Points. WHO IHR Contact Points shall send urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12, to the National IHR Focal Point of the States Parties concerned. WHO IHR Contact Points may be designated by WHO at the headquarters or at the regional level of the Organization.

4. States Parties shall provide WHO with contact details of their National IHR Focal Point and WHO shall provide States Parties with contact details of WHO IHR Contact Points. These contact details shall be continuously updated and annually confirmed. WHO shall make available to all States Parties the contact details of National IHR Focal Points it receives pursuant to this Article.







## PART II – INFORMATION AND PUBLIC HEALTH RESPONSE

*Article 5 Surveillance*

1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1.

2. Following the assessment referred to in paragraph 2, Part A of Annex 1, a State Party may report to WHO on the basis of a justified need and an implementation plan and, in so doing, obtain an extension of two years in which to fulfil the obligation in paragraph 1 of this Article. In exceptional circumstances, and supported by a new implementation plan, the State Party may request a further extension not exceeding two years from the Director-General, who shall make the decision, taking into account the technical advice of the Committee established under Article 50 (hereinafter the "Review Committee"). After the period mentioned in paragraph 1 of this Article, the State Party that has obtained an extension shall report annually to WHO on progress made towards the full implementation.

3. WHO shall assist States Parties, upon request, to develop, strengthen and maintain the capacities referred to in paragraph 1 of this Article.

4. WHO shall collect information regarding events through its surveillance activities and assess their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Articles 11 and 45 where appropriate.

*Article 6 Notification*

1. Each State Party shall assess events occurring within its territory by using the decision instrument in Annex 2. Each State Party shall notify WHO, by the most efficient means of communication available, by way of the National IHR Focal Point, and within 24 hours of assessment of public health information, of all events which may constitute a public health emergency of international concern within its territory in accordance with the decision instrument, as well as any health measure implemented in response to those events. If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA), WHO shall immediately notify the IAEA.

2. Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern.

*Article 7 Information-sharing during unexpected or unusual public health events*

If a State Party has evidence of an unexpected or unusual public health event within its territory, irrespective of origin or source, which may constitute a public health emergency of international concern, it shall provide to WHO all relevant public health information. In such a case, the provisions of Article 6 shall apply in full.

*Article 8 Consultation*

In the case of events occurring within its territory not requiring notification as provided in Article 6, in particular those events for which there is insufficient information available to complete the decision instrument, a State Party may nevertheless keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate health measures. Such communications shall be treated in accordance with paragraphs 2 to 4 of Article 11. The State Party in whose territory the event has occurred may request WHO assistance to assess any epidemiological evidence obtained by that State Party.

*Article 9 Other reports*

1. WHO may take into account reports from sources other than notifications or consultations and shall assess these reports according to established epidemiological principles and then communicate information on the event to the State Party in whose territory the event is allegedly occurring. Before taking any action based on such reports, WHO shall consult with and attempt to obtain verification from the State Party in whose territory the event is allegedly occurring in accordance with the procedure set forth in Article 10. To this end, WHO shall make the information received available to the States Parties and only where it is duly justified may WHO maintain the confidentiality of the source. This information will be used in accordance with the procedure set forth in Article 11.

2. States Parties shall, as far as practicable, inform WHO within 24 hours of receipt of evidence of a public health risk identified outside their territory that may cause international disease spread, as manifested by exported or imported:

(a) human cases;

(b) vectors which carry infection or contamination; or

(c) goods that are contaminated.

*Article 10 Verification*

1. WHO shall request, in accordance with Article 9, verification from a State Party of reports from sources other than notifications or consultations of events which may constitute a public health emergency of international concern allegedly occurring in the State's territory. In such cases, WHO shall inform the State Party concerned regarding the reports it is seeking to verify.

2. Pursuant to the foregoing paragraph and to Article 9, each State Party, when requested by WHO, shall verify and provide:

(a) within 24 hours, an initial reply to, or acknowledgement of, the request from WHO;

(b) within 24 hours, available public health information on the status of events referred to in WHO's request; and

(c) information to WHO in the context of an assessment under Article 6, including relevant information as described in that Article.







3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall offer to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures. Such activities may include collaboration with other standard-setting organizations and the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.

4. If the State Party does not accept the offer of collaboration, WHO may, when justified by the magnitude of the public health risk, share with other States Parties the information available to it, whilst encouraging the State Party to accept the offer of collaboration by WHO, taking into account the views of the State Party concerned.

*Article 11 Provision of information by WHO*

1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as appropriate, to relevant intergovernmental organizations, as soon as possible and by the most efficient means available, in confidence, such public health information which it has received under Articles 5 to 10 inclusive and which is necessary to enable States Parties to respond to a public health risk. WHO should communicate information to other States Parties that might help them in preventing the occurrence of similar incidents.

2. WHO shall use information received under Articles 6 and 8 and paragraph 2 of Article 9 for verification, assessment and assistance purposes under these Regulations and, unless otherwise agreed with the States Parties referred to in those provisions, shall not make this information generally available to other States Parties, until such time as:

(a) the event is determined to constitute a public health emergency of international concern in accordance with Article 12; or

(b) information evidencing the international spread of the infection or contamination has been confirmed by WHO in accordance with established epidemiological principles; or

(c) there is evidence that:

(i) control measures against the international spread are unlikely to succeed because of the nature of the contamination, disease agent, vector or reservoir; or

(ii) the State Party lacks sufficient operational capacity to carry out necessary measures to prevent further spread of disease; or

(d) the nature and scope of the international movement of travellers, baggage, cargo, containers, conveyances, goods or postal parcels that may be affected by the infection or contamination requires the immediate application of international control measures.

3. WHO shall consult with the State Party in whose territory the event is occurring as to its intent to make information available under this Article.

4. When information received by WHO under paragraph 2 of this Article is made available to States Parties in accordance with these Regulations, WHO may also make it available to the public if

other information about the same event has already become publicly available and there is a need for the dissemination of authoritative and independent information.

*Article 12 Determination of a public health emergency of international concern*

1. The Director-General shall determine, on the basis of the information received, in particular from the State Party within whose territory an event is occurring, whether an event constitutes a public health emergency of international concern in accordance with the criteria and the procedure set out in these Regulations.

2. If the Director-General considers, based on an assessment under these Regulations, that a public health emergency of international concern is occurring, the Director-General shall consult with the State Party in whose territory the event arises regarding this preliminary determination. If the Director-General and the State Party are in agreement regarding this determination, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the "Emergency Committee") on appropriate temporary recommendations.

3. If, following the consultation in paragraph 2 above, the Director-General and the State Party in whose territory the event arises do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern, a determination shall be made in accordance with the procedure set forth in Article 49.

4. In determining whether an event constitutes a public health emergency of international concern, the Director-General shall consider:

(a) information provided by the State Party;

(b) the decision instrument contained in Annex 2;

(c) the advice of the Emergency Committee;

(d) scientific principles as well as the available scientific evidence and other relevant information; and

(e) an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic.

5. If the Director-General, following consultations with the State Party within whose territory the public health emergency of international concern has occurred, considers that a public health emergency of international concern has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49.

*Article 13 Public health response*

1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern as set out in Annex 1. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response capacities.







2 Following the assessment referred to in paragraph 2, Part A of Annex 1, a State Party may report to WHO on the basis of a justified need and an implementation plan and, in so doing, obtain an extension of two years in which to fulfil the obligation in paragraph 1 of this Article. In exceptional circumstances and supported by a new implementation plan, the State Party may request a further extension not exceeding two years from the Director-General, who shall make the decision, taking into account the technical advice of the Review Committee. After the period mentioned in paragraph 1 of this Article, the State Party that has obtained an extension shall report annually to WHO on progress made towards the full implementation.

3. At the request of a State Party, WHO shall collaborate in the response to public health risks and other events by providing technical guidance and assistance and by assessing the effectiveness of the control measures in place, including the mobilization of international teams of experts for on-site assistance, when necessary.

4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern is occurring, it may offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State Party, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.

5. When requested by WHO, States Parties should provide, to the extent possible, support to WHO-coordinated response activities.

6. When requested, WHO shall provide appropriate guidance and assistance to other States Parties affected or threatened by the public health emergency of international concern.

*Article 14 Cooperation of WHO with intergovernmental organizations and international bodies*

1. WHO shall cooperate and coordinate its activities, as appropriate, with other competent intergovernmental organizations or international bodies in the implementation of these Regulations, including through the conclusion of agreements and other similar arrangements.

2. In cases in which notification or verification of, or response to, an event is primarily within the competence of other intergovernmental organizations or international bodies, WHO shall coordinate its activities with such organizations or bodies in order to ensure the application of adequate measures for the protection of public health.

3. Notwithstanding the foregoing, nothing in these Regulations shall preclude or limit the provision by WHO of advice, support, or technical or other assistance for public health purposes.

## PART III – RECOMMENDATIONS

*Article 15 Temporary recommendations*

1. If it has been determined in accordance with Article 12 that a public health emergency of international concern is occurring, the Director-General shall issue temporary recommendations in accordance with the procedure set out in Article 49. Such temporary recommendations may be

modified or extended as appropriate, including after it has been determined that a public health emergency of international concern has ended, at which time other temporary recommendations may be issued as necessary for the purpose of preventing or promptly detecting its recurrence.

2. Temporary recommendations may include health measures to be implemented by the State Party experiencing the public health emergency of international concern, or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.

3. Temporary recommendations may be terminated in accordance with the procedure set out in Article 49 at any time and shall automatically expire three months after their issuance. They may be modified or extended for additional periods of up to three months. Temporary recommendations may not continue beyond the second World Health Assembly after the determination of the public health emergency of international concern to which they relate.

*Article 16 Standing recommendations*

WHO may make standing recommendations of appropriate health measures in accordance with Article 53 for routine or periodic application. Such measures may be applied by States Parties regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels for specific, ongoing public health risks in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic. WHO may, in accordance with Article 53, modify or terminate such recommendations, as appropriate.

*Article 17 Criteria for recommendations*

When issuing, modifying or terminating temporary or standing recommendations, the Director-General shall consider:

(a) the views of the States Parties directly concerned;

(b) the advice of the Emergency Committee or the Review Committee, as the case may be;

(c) scientific principles as well as available scientific evidence and information;

(d) health measures that, on the basis of a risk assessment appropriate to the circumstances, are not more restrictive of international traffic and trade and are not more intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection;

(e) relevant international standards and instruments;

(f) activities undertaken by other relevant intergovernmental organizations and international bodies; and

(g) other appropriate and specific information relevant to the event.

With respect to temporary recommendations, the consideration by the Director-General of subparagraphs (e) and (f) of this Article may be subject to limitations imposed by urgent circumstances.







*Article 18 Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels*

1. Recommendations issued by WHO to States Parties with respect to persons may include the following advice:

– no specific health measures are advised;

– review travel history in affected areas;

– review proof of medical examination and any laboratory analysis;

– require medical examinations;

– review proof of vaccination or other prophylaxis;

– require vaccination or other prophylaxis;

– place suspect persons under public health observation;

– implement quarantine or other health measures for suspect persons;

– implement isolation and treatment where necessary of affected persons;

– implement tracing of contacts of suspect or affected persons;

– refuse entry of suspect and affected persons;

– refuse entry of unaffected persons to affected areas; and

– implement exit screening and/or restrictions on persons from affected areas.

2. Recommendations issued by WHO to States Parties with respect to baggage, cargo, containers, conveyances, goods and postal parcels may include the following advice:

– no specific health measures are advised;

– review manifest and routing;

– implement inspections;

– review proof of measures taken on departure or in transit to eliminate infection or contamination;

– implement treatment of the baggage, cargo, containers, conveyances, goods, postal parcels or human remains to remove infection or contamination, including vectors and reservoirs;

– the use of specific health measures to ensure the safe handling and transport of human remains;

– implement isolation or quarantine;

– seizure and destruction of infected or contaminated or suspect baggage, cargo, containers, conveyances, goods or postal parcels under controlled conditions if no available treatment or process will otherwise be successful; and

– refuse departure or entry.

## PART IV – POINTS OF ENTRY

*Article 19 General obligations*

Each State Party shall, in addition to the other obligations provided for under these Regulations:

(a) ensure that the capacities set forth in Annex 1 for designated points of entry are developed within the timeframe provided in paragraph 1 of Article 5 and paragraph 1 of Article 13;

(b) identify the competent authorities at each designated point of entry in its territory; and

(c) furnish to WHO, as far as practicable, when requested in response to a specific potential public health risk, relevant data concerning sources of infection or contamination, including vectors and reservoirs, at its points of entry, which could result in international disease spread.

*Article 20 Airports and ports*

1. States Parties shall designate the airports and ports that shall develop the capacities provided in Annex 1.

2. States Parties shall ensure that Ship Sanitation Control Exemption Certificates and Ship Sanitation Control Certificates are issued in accordance with the requirements in Article 39 and the model provided in Annex 3.

3. Each State Party shall send to WHO a list of ports authorized to offer:

(a) the issuance of Ship Sanitation Control Certificates and the provision of the services referred to in Annexes 1 and 3; or

(b) the issuance of Ship Sanitation Control Exemption Certificates only; and

(c) extension of the Ship Sanitation Control Exemption Certificate for a period of one month until the arrival of the ship in the port at which the Certificate may be received.

Each State Party shall inform WHO of any changes which may occur to the status of the listed ports. WHO shall publish the information received under this paragraph.

4. WHO may, at the request of the State Party concerned, arrange to certify, after an appropriate investigation, that an airport or port in its territory meets the requirements referred to in paragraphs 1







and 3 of this Article. These certifications may be subject to periodic review by WHO, in consultation with the State Party.

5. WHO, in collaboration with competent intergovernmental organizations and international bodies, shall develop and publish the certification guidelines for airports and ports under this Article. WHO shall also publish a list of certified airports and ports.

*Article 21 Ground crossings*

1. Where justified for public health reasons, a State Party may designate ground crossings that shall develop the capacities provided in Annex 1, taking into consideration:

(a) the volume and frequency of the various types of international traffic, as compared to other points of entry, at a State Party's ground crossings which might be designated; and

(b) the public health risks existing in areas in which the international traffic originates, or through which it passes, prior to arrival at a particular ground crossing.

2. States Parties sharing common borders should consider:

(a) entering into bilateral or multilateral agreements or arrangements concerning prevention or control of international transmission of disease at ground crossings in accordance with Article 57; and

(b) joint designation of adjacent ground crossings for the capacities in Annex 1 in accordance with paragraph 1 of this Article.

*Article 22 Role of competent authorities*

1. The competent authorities shall:

(a) be responsible for monitoring baggage, cargo, containers, conveyances, goods, postal parcels and human remains departing and arriving from affected areas, so that they are maintained in such a condition that they are free of sources of infection or contamination, including vectors and reservoirs;

(b) ensure, as far as practicable, that facilities used by travellers at points of entry are maintained in a sanitary condition and are kept free of sources of infection or contamination, including vectors and reservoirs;

(c) be responsible for the supervision of any deratting, disinfection, disinsection or decontamination of baggage, cargo, containers, conveyances, goods, postal parcels and human remains or sanitary measures for persons, as appropriate under these Regulations;

(d) advise conveyance operators, as far in advance as possible, of their intent to apply control measures to a conveyance, and shall provide, where available, written information concerning the methods to be employed;

(e) be responsible for the supervision of the removal and safe disposal of any contaminated water or food, human or animal dejecta, wastewater and any other contaminated matter from a conveyance;

(f) take all practicable measures consistent with these Regulations to monitor and control the discharge by ships of sewage, refuse, ballast water and other potentially disease-causing matter which might contaminate the waters of a port, river, canal, strait, lake or other international waterway;

(g) be responsible for supervision of service providers for services concerning travellers, baggage, cargo, containers, conveyances, goods, postal parcels and human remains at points of entry, including the conduct of inspections and medical examinations as necessary;

(h) have effective contingency arrangements to deal with an unexpected public health event; and

(i) communicate with the National IHR Focal Point on the relevant public health measures taken pursuant to these Regulations.

2. Health measures recommended by WHO for travellers, baggage, cargo, containers, conveyances, goods, postal parcels and human remains arriving from an affected area may be reapplied on arrival, if there are verifiable indications and/or evidence that the measures applied on departure from the affected area were unsuccessful.

3. Disinsection, deratting, disinfection, decontamination and other sanitary procedures shall be carried out so as to avoid injury and as far as possible discomfort to persons, or damage to the environment in a way which impacts on public health, or damage to baggage, cargo, containers, conveyances, goods and postal parcels.

## PART V – PUBLIC HEALTH MEASURES

### Chapter I – General provisions

*Article 23 Health measures on arrival and departure*

1. Subject to applicable international agreements and relevant articles of these Regulations, a State Party may require for public health purposes, on arrival or departure:

(a) with regard to travellers:

(i) information concerning the traveller's destination so that the traveller may be contacted;

(ii) information concerning the traveller's itinerary to ascertain if there was any travel in or near an affected area or other possible contacts with infection or contamination prior to arrival, as well as review of the traveller's health documents if they are required under these Regulations; and/or







(iii) a non-invasive medical examination which is the least intrusive examination that would achieve the public health objective;

(b) inspection of baggage, cargo, containers, conveyances, goods, postal parcels and human remains.

2. On the basis of evidence of a public health risk obtained through the measures provided in paragraph 1 of this Article, or through other means, States Parties may apply additional health measures, in accordance with these Regulations, in particular, with regard to a suspect or affected traveller, on a case-by-case basis, the least intrusive and invasive medical examination that would achieve the public health objective of preventing the international spread of disease.

3. No medical examination, vaccination, prophylaxis or health measure under these Regulations shall be carried out on travellers without their prior express informed consent or that of their parents or guardians, except as provided in paragraph 2 of Article 31, and in accordance with the law and international obligations of the State Party.

4. Travellers to be vaccinated or offered prophylaxis pursuant to these Regulations, or their parents or guardians, shall be informed of any risk associated with vaccination or with non-vaccination and with the use or non-use of prophylaxis in accordance with the law and international obligations of the State Party. States Parties shall inform medical practitioners of these requirements in accordance with the law of the State Party.

5. Any medical examination, medical procedure, vaccination or other prophylaxis which involves a risk of disease transmission shall only be performed on, or administered to, a traveller in accordance with established national or international safety guidelines and standards so as to minimize such a risk.

### Chapter II – Special provisions for conveyances and conveyance operators

*Article 24 Conveyance operators*

1. States Parties shall take all practicable measures consistent with these Regulations to ensure that conveyance operators:

(a) comply with the health measures recommended by WHO and adopted by the State Party;

(b) inform travellers of the health measures recommended by WHO and adopted by the State Party for application on board; and

(c) permanently keep conveyances for which they are responsible free of sources of infection or contamination, including vectors and reservoirs. The application of measures to control sources of infection or contamination may be required if evidence is found.

2. Specific provisions pertaining to conveyances and conveyance operators under this Article are provided in Annex 4. Specific measures applicable to conveyances and conveyance operators with regard to vector-borne diseases are provided in Annex 5.

*Article 25 Ships and aircraft in transit*

Subject to Articles 27 and 43 or unless authorized by applicable international agreements, no health measure shall be applied by a State Party to:

(a) a ship not coming from an affected area which passes through a maritime canal or waterway in the territory of that State Party on its way to a port in the territory of another State. Any such ship shall be permitted to take on, under the supervision of the competent authority, fuel, water, food and supplies;

(b) a ship which passes through waters within its jurisdiction without calling at a port or on the coast; and

(c) an aircraft in transit at an airport within its jurisdiction, except that the aircraft may be restricted to a particular area of the airport with no embarking and disembarking or loading and discharging. However, any such aircraft shall be permitted to take on, under the supervision of the competent authority, fuel, water, food and supplies.

*Article 26 Civilian lorries, trains and coaches in transit*

Subject to Articles 27 and 43 or unless authorized by applicable international agreements, no health measure shall be applied to a civilian lorry, train or coach not coming from an affected area which passes through a territory without embarking, disembarking, loading or discharging.

*Article 27 Affected conveyances*

1. If clinical signs or symptoms and information based on fact or evidence of a public health risk, including sources of infection and contamination, are found on board a conveyance, the competent authority shall consider the conveyance as affected and may:

(a) disinfect, decontaminate, disinsect or derat the conveyance, as appropriate, or cause these measures to be carried out under its supervision; and

(b) decide in each case the technique employed to secure an adequate level of control of the public health risk as provided in these Regulations. Where there are methods or materials advised by WHO for these procedures, these should be employed, unless the competent authority determines that other methods are as safe and reliable.

The competent authority may implement additional health measures, including isolation of the conveyances, as necessary, to prevent the spread of disease. Such additional measures should be reported to the National IHR Focal Point.

2. If the competent authority for the point of entry is not able to carry out the control measures required under this Article, the affected conveyance may nevertheless be allowed to depart, subject to the following conditions:

(a) the competent authority shall, at the time of departure, inform the competent authority for the next known point of entry of the type of information referred to under subparagraph (b); and







(b) in the case of a ship, the evidence found and the control measures required shall be noted in the Ship Sanitation Control Certificate.

Any such conveyance shall be permitted to take on, under the supervision of the competent authority, fuel, water, food and supplies.

3. A conveyance that has been considered as affected shall cease to be regarded as such when the competent authority is satisfied that:

(a) the measures provided in paragraph 1 of this Article have been effectively carried out; and

(b) there are no conditions on board that could constitute a public health risk.

*Article 28 Ships and aircraft at points of entry*

1. Subject to Article 43 or as provided in applicable international agreements, a ship or an aircraft shall not be prevented for public health reasons from calling at any point of entry. However, if the point of entry is not equipped for applying health measures under these Regulations, the ship or aircraft may be ordered to proceed at its own risk to the nearest suitable point of entry available to it, unless the ship or aircraft has an operational problem which would make this diversion unsafe.

2. Subject to Article 43 or as provided in applicable international agreements, ships or aircraft shall not be refused *free pratique* by States Parties for public health reasons; in particular they shall not be prevented from embarking or disembarking, discharging or loading cargo or stores, or taking on fuel, water, food and supplies. States Parties may subject the granting of *free pratique* to inspection and, if a source of infection or contamination is found on board, the carrying out of necessary disinfection, decontamination, disinsection or deratting, or other measures necessary to prevent the spread of the infection or contamination.

3. Whenever practicable and subject to the previous paragraph, a State Party shall authorize the granting of *free pratique* by radio or other communication means to a ship or an aircraft when, on the basis of information received from it prior to its arrival, the State Party is of the opinion that the arrival of the ship or aircraft will not result in the introduction or spread of disease.

4. Officers in command of ships or pilots in command of aircraft, or their agents, shall make known to the port or airport control as early as possible before arrival at the port or airport of destination any cases of illness indicative of a disease of an infectious nature or evidence of a public health risk on board as soon as such illnesses or public health risks are made known to the officer or pilot. This information must be immediately relayed to the competent authority for the port or airport. In urgent circumstances, such information should be communicated directly by the officers or pilots to the relevant port or airport authority.

5. The following shall apply if a suspect or affected aircraft or ship, for reasons beyond the control of the pilot in command of the aircraft or the officer in command of the ship, lands elsewhere than at the airport at which the aircraft was due to land or berths elsewhere than at the port at which the ship was due to berth:

(a) the pilot in command of the aircraft or the officer in command of the ship or other person in charge shall make every effort to communicate without delay with the nearest competent authority;

(b) as soon as the competent authority has been informed of the landing it may apply health measures recommended by WHO or other health measures provided in these Regulations;

(c) unless required for emergency purposes or for communication with the competent authority, no traveller on board the aircraft or ship shall leave its vicinity and no cargo shall be removed from that vicinity, unless authorized by the competent authority; and

(d) when all health measures required by the competent authority have been completed, the aircraft or ship may, so far as such health measures are concerned, proceed either to the airport or port at which it was due to land or berth, or, if for technical reasons it cannot do so, to a conveniently situated airport or port.

6. Notwithstanding the provisions contained in this Article, the officer in command of a ship or pilot in command of an aircraft may take such emergency measures as may be necessary for the health and safety of travellers on board. He or she shall inform the competent authority as early as possible concerning any measures taken pursuant to this paragraph.

*Article 29 Civilian lorries, trains and coaches at points of entry*

WHO, in consultation with States Parties, shall develop guiding principles for applying health measures to civilian lorries, trains and coaches at points of entry and passing through ground crossings.

## Chapter III – Special provisions for travellers

*Article 30 Travellers under public health observation*

Subject to Article 43 or as authorized in applicable international agreements, a suspect traveller who on arrival is placed under public health observation may continue an international voyage, if the traveller does not pose an imminent public health risk and the State Party informs the competent authority of the point of entry at destination, if known, of the traveller's expected arrival. On arrival, the traveller shall report to that authority.

*Article 31 Health measures relating to entry of travellers*

1. Invasive medical examination, vaccination or other prophylaxis shall not be required as a condition of entry of any traveller to the territory of a State Party, except that, subject to Articles 32, 42 and 45, these Regulations do not preclude States Parties from requiring medical examination, vaccination or other prophylaxis or proof of vaccination or other prophylaxis:

(a) when necessary to determine whether a public health risk exists;

(b) as a condition of entry for any travellers seeking temporary or permanent residence;

(c) as a condition of entry for any travellers pursuant to Article 43 or Annexes 6 and 7; or







(d) which may be carried out pursuant to Article 23.

2. If a traveller for whom a State Party may require a medical examination, vaccination or other prophylaxis under paragraph 1 of this Article fails to consent to any such measure, or refuses to provide the information or the documents referred to in paragraph 1(a) of Article 23, the State Party concerned may, subject to Articles 32, 42 and 45, deny entry to that traveller. If there is evidence of an imminent public health risk, the State Party may, in accordance with its national law and to the extent necessary to control such a risk, compel the traveller to undergo or advise the traveller, pursuant to paragraph 3 of Article 23, to undergo:

(a) the least invasive and intrusive medical examination that would achieve the public health objective;

(b) vaccination or other prophylaxis; or

(c) additional established health measures that prevent or control the spread of disease, including isolation, quarantine or placing the traveller under public health observation.

*Article 32 Treatment of travellers*

In implementing health measures under these Regulations, States Parties shall treat travellers with respect for their dignity, human rights and fundamental freedoms and minimize any discomfort or distress associated with such measures, including by:

(a) treating all travellers with courtesy and respect;

(b) taking into consideration the gender, sociocultural, ethnic or religious concerns of travellers; and

(c) providing or arranging for adequate food and water, appropriate accommodation and clothing, protection for baggage and other possessions, appropriate medical treatment, means of necessary communication if possible in a language that they can understand and other appropriate assistance for travellers who are quarantined, isolated or subject to medical examinations or other procedures for public health purposes.

## Chapter IV – Special provisions for goods, containers and container loading areas

*Article 33 Goods in transit*

Subject to Article 43 or unless authorized by applicable international agreements, goods, other than live animals, in transit without transhipment shall not be subject to health measures under these Regulations or detained for public health purposes.

*Article 34 Container and container loading areas*

1. States Parties shall ensure, as far as practicable, that container shippers use international traffic containers that are kept free from sources of infection or contamination, including vectors and reservoirs, particularly during the course of packing.

2. States Parties shall ensure, as far as practicable, that container loading areas are kept free from sources of infection or contamination, including vectors and reservoirs.

3. Whenever, in the opinion of a State Party, the volume of international container traffic is sufficiently large, the competent authorities shall take all practicable measures consistent with these Regulations, including carrying out inspections, to assess the sanitary condition of container loading areas and containers in order to ensure that the obligations contained in these Regulations are implemented.

4. Facilities for the inspection and isolation of containers shall, as far as practicable, be available at container loading areas.

5. Container consignees and consignors shall make every effort to avoid cross-contamination when multiple-use loading of containers is employed.

## PART VI – HEALTH DOCUMENTS

*Article 35 General rule*

No health documents, other than those provided for under these Regulations or in recommendations issued by WHO, shall be required in international traffic, provided however that this Article shall not apply to travellers seeking temporary or permanent residence, nor shall it apply to document requirements concerning the public health status of goods or cargo in international trade pursuant to applicable international agreements. The competent authority may request travellers to complete contact information forms and questionnaires on the health of travellers, provided that they meet the requirements set out in Article 23.

*Article 36 Certificates of vaccination or other prophylaxis*

1. Vaccines and prophylaxis for travellers administered pursuant to these Regulations, or to recommendations and certificates relating thereto, shall conform to the provisions of Annex 6 and, when applicable, Annex 7 with regard to specific diseases.

2. A traveller in possession of a certificate of vaccination or other prophylaxis issued in conformity with Annex 6 and, when applicable, Annex 7, shall not be denied entry as a consequence of the disease to which the certificate refers, even if coming from an affected area, unless the competent authority has verifiable indications and/or evidence that the vaccination or other prophylaxis was not effective.

*Article 37 Maritime Declaration of Health*

1. The master of a ship, before arrival at its first port of call in the territory of a State Party, shall ascertain the state of health on board, and, except when that State Party does not require it, the master shall, on arrival, or in advance of the vessel's arrival if the vessel is so equipped and the State Party requires such advance delivery, complete and deliver to the competent authority for that port a Maritime Declaration of Health which shall be countersigned by the ship's surgeon, if one is carried.

2. The master of a ship, or the ship's surgeon if one is carried, shall supply any information required by the competent authority as to health conditions on board during an international voyage.







3. A Maritime Declaration of Health shall conform to the model provided in Annex 8.

4. A State Party may decide:

(a) to dispense with the submission of the Maritime Declaration of Health by all arriving ships; or

(b) to require the submission of the Maritime Declaration of Health under a recommendation concerning ships arriving from affected areas or to require it from ships which might otherwise carry infection or contamination.

The State Party shall inform shipping operators or their agents of these requirements.

*Article 38 Health Part of the Aircraft General Declaration*

1. The pilot in command of an aircraft or the pilot's agent, in flight or upon landing at the first airport in the territory of a State Party, shall, to the best of his or her ability, except when that State Party does not require it, complete and deliver to the competent authority for that airport the Health Part of the Aircraft General Declaration which shall conform to the model specified in Annex 9.

2. The pilot in command of an aircraft or the pilot's agent shall supply any information required by the State Party as to health conditions on board during an international voyage and any health measure applied to the aircraft.

3. A State Party may decide:

(a) to dispense with the submission of the Health Part of the Aircraft General Declaration by all arriving aircraft; or

(b) to require the submission of the Health Part of the Aircraft General Declaration under a recommendation concerning aircraft arriving from affected areas or to require it from aircraft which might otherwise carry infection or contamination.

The State Party shall inform aircraft operators or their agents of these requirements.

*Article 39 Ship sanitation certificates*

1. Ship Sanitation Control Exemption Certificates and Ship Sanitation Control Certificates shall be valid for a maximum period of six months. This period may be extended by one month if the inspection or control measures required cannot be accomplished at the port.

2. If a valid Ship Sanitation Control Exemption Certificate or Ship Sanitation Control Certificate is not produced or evidence of a public health risk is found on board a ship, the State Party may proceed as provided in paragraph 1 of Article 27.

3. The certificates referred to in this Article shall conform to the model in Annex 3.

4. Whenever possible, control measures shall be carried out when the ship and holds are empty. In the case of a ship in ballast, they shall be carried out before loading.

5. When control measures are required and have been satisfactorily completed, the competent authority shall issue a Ship Sanitation Control Certificate, noting the evidence found and the control measures taken.

6. The competent authority may issue a Ship Sanitation Control Exemption Certificate at any port specified under Article 20 if it is satisfied that the ship is free of infection and contamination, including vectors and reservoirs. Such a certificate shall normally be issued only if the inspection of the ship has been carried out when the ship and holds are empty or when they contain only ballast or other material, of such a nature or so disposed as to make a thorough inspection of the holds possible.

7. If the conditions under which control measures are carried out are such that, in the opinion of the competent authority for the port where the operation was performed, a satisfactory result cannot be obtained, the competent authority shall make a note to that effect on the Ship Sanitation Control Certificate.

## PART VII – CHARGES

*Article 40 Charges for health measures regarding travellers*

1. Except for travellers seeking temporary or permanent residence, and subject to paragraph 2 of this Article, no charge shall be made by a State Party pursuant to these Regulations for the following measures for the protection of public health:

(a) any medical examination provided for in these Regulations, or any supplementary examination which may be required by that State Party to ascertain the health status of the traveller examined;

(b) any vaccination or other prophylaxis provided to a traveller on arrival that is not a published requirement or is a requirement published less than 10 days prior to provision of the vaccination or other prophylaxis;

(c) appropriate isolation or quarantine requirements of travellers;

(d) any certificate issued to the traveller specifying the measures applied and the date of application; or

(e) any health measures applied to baggage accompanying the traveller.

2. State Parties may charge for health measures other than those referred to in paragraph 1 of this Article, including those primarily for the benefit of the traveller.

3. Where charges are made for applying such health measures to travellers under these Regulations, there shall be in each State Party only one tariff for such charges and every charge shall:

(a) conform to this tariff;

(b) not exceed the actual cost of the service rendered; and

(c) be levied without distinction as to the nationality, domicile or residence of the traveller concerned.







4. The tariff, and any amendment thereto, shall be published at least 10 days in advance of any levy thereunder.

5. Nothing in these Regulations shall preclude States Parties from seeking reimbursement for expenses incurred in providing the health measures in paragraph 1 of this Article:

(a) from conveyance operators or owners with regard to their employees; or

(b) from applicable insurance sources.

6. Under no circumstances shall travellers or conveyance operators be denied the ability to depart from the territory of a State Party pending payment of the charges referred to in paragraphs 1 or 2 of this Article.

*Article 41 Charges for baggage, cargo, containers, conveyances, goods or postal parcels*

1. Where charges are made for applying health measures to baggage, cargo, containers, conveyances, goods or postal parcels under these Regulations, there shall be in each State Party only one tariff for such charges and every charge shall:

(a) conform to this tariff;

(b) not exceed the actual cost of the service rendered; and

(c) be levied without distinction as to the nationality, flag, registry or ownership of the baggage, cargo, containers, conveyances, goods or postal parcels concerned. In particular, there shall be no distinction made between national and foreign baggage, cargo, containers, conveyances, goods or postal parcels.

2. The tariff, and any amendment thereto, shall be published at least 10 days in advance of any levy thereunder.

## PART VIII – GENERAL PROVISIONS

*Article 42 Implementation of health measures*

Health measures taken pursuant to these Regulations shall be initiated and completed without delay, and applied in a transparent and non-discriminatory manner.

*Article 43 Additional health measures*

1. These Regulations shall not preclude States Parties from implementing health measures, in accordance with their relevant national law and obligations under international law, in response to specific public health risks or public health emergencies of international concern, which:

(a) achieve the same or greater level of health protection than WHO recommendations; or

(b) are otherwise prohibited under Article 25, Article 26, paragraphs 1 and 2 of Article 28, Article 30, paragraph 1(c) of Article 31 and Article 33,

provided such measures are otherwise consistent with these Regulations.

Such measures shall not be more restrictive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection.

2. In determining whether to implement the health measures referred to in paragraph 1 of this Article or additional health measures under paragraph 2 of Article 23, paragraph 1 of Article 27, paragraph 2 of Article 28 and paragraph 2(c) of Article 31, States Parties shall base their determinations upon:

(a) scientific principles;

(b) available scientific evidence of a risk to human health, or where such evidence is insufficient, the available information including from WHO and other relevant intergovernmental organizations and international bodies; and

(c) any available specific guidance or advice from WHO.

3. A State Party implementing additional health measures referred to in paragraph 1 of this Article which significantly interfere with international traffic shall provide to WHO the public health rationale and relevant scientific information for it. WHO shall share this information with other States Parties and shall share information regarding the health measures implemented. For the purpose of this Article, significant interference generally means refusal of entry or departure of international travellers, baggage, cargo, containers, conveyances, goods, and the like, or their delay, for more than 24 hours.

4. After assessing information provided pursuant to paragraph 3 and 5 of this Article and other relevant information, WHO may request that the State Party concerned reconsider the application of the measures.

5. A State Party implementing additional health measures referred to in paragraphs 1 and 2 of this Article that significantly interfere with international traffic shall inform WHO, within 48 hours of implementation, of such measures and their health rationale unless these are covered by a temporary or standing recommendation.

6. A State Party implementing a health measure pursuant to paragraph 1 or 2 of this Article shall within three months review such a measure taking into account the advice of WHO and the criteria in paragraph 2 of this Article.

7. Without prejudice to its rights under Article 56, any State Party impacted by a measure taken pursuant to paragraph 1 or 2 of this Article may request the State Party implementing such a measure to consult with it. The purpose of such consultations is to clarify the scientific information and public health rationale underlying the measure and to find a mutually acceptable solution.

8. The provisions of this Article may apply to implementation of measures concerning travellers taking part in mass congregations.







*Article 44 Collaboration and assistance*

1. States Parties shall undertake to collaborate with each other, to the extent possible, in:

(a) the detection and assessment of, and response to, events as provided under these Regulations;

(b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health capacities required under these Regulations;

(c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and

(d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations.

2. WHO shall collaborate with States Parties, upon request, to the extent possible, in:

(a) the evaluation and assessment of their public health capacities in order to facilitate the effective implementation of these Regulations;

(b) the provision or facilitation of technical cooperation and logistical support to States Parties; and

(c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1.

3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies.

*Article 45 Treatment of personal data*

1. Health information collected or received by a State Party pursuant to these Regulations from another State Party or from WHO which refers to an identified or identifiable person shall be kept confidential and processed anonymously as required by national law.

2. Notwithstanding paragraph 1, States Parties may disclose and process personal data where essential for the purposes of assessing and managing a public health risk, but State Parties, in accordance with national law, and WHO must ensure that the personal data are:

(a) processed fairly and lawfully, and not further processed in a way incompatible with that purpose;

(b) adequate, relevant and not excessive in relation to that purpose;

(c) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that data which are inaccurate or incomplete are erased or rectified; and

(d) not kept longer than necessary.

3. Upon request, WHO shall as far as practicable provide an individual with his or her personal data referred to in this Article in an intelligible form, without undue delay or expense and, when necessary, allow for correction.

*Article 46 Transport and handling of biological substances, reagents and materials for diagnostic purposes*

States Parties shall, subject to national law and taking into account relevant international guidelines, facilitate the transport, entry, exit, processing and disposal of biological substances and diagnostic specimens, reagents and other diagnostic materials for verification and public health response purposes under these Regulations.

## PART IX – THE IHR ROSTER OF EXPERTS, THE EMERGENCY COMMITTEE AND THE REVIEW COMMITTEE

### Chapter I – The IHR Roster of Experts

*Article 47 Composition*

The Director-General shall establish a roster composed of experts in all relevant fields of expertise (hereinafter the "IHR Expert Roster"). The Director-General shall appoint the members of the IHR Expert Roster in accordance with the WHO Regulations for Expert Advisory Panels and Committees (hereinafter the "WHO Advisory Panel Regulations"), unless otherwise provided in these Regulations. In addition, the Director-General shall appoint one member at the request of each State Party and, where appropriate, experts proposed by relevant intergovernmental and regional economic integration organizations. Interested States Parties shall notify the Director-General of the qualifications and fields of expertise of each of the experts they propose for membership. The Director-General shall periodically inform the States Parties, and relevant intergovernmental and regional economic integration organizations, of the composition of the IHR Expert Roster.

### Chapter II - The Emergency Committee

*Article 48 Terms of reference and composition*

1. The Director-General shall establish an Emergency Committee that at the request of the Director-General shall provide its views on:

(a) whether an event constitutes a public health emergency of international concern;

(b) the termination of a public health emergency of international concern; and

(c) the proposed issuance, modification, extension or termination of temporary recommendations.

2. The Emergency Committee shall be composed of experts selected by the Director-General from the IHR Expert Roster and, when appropriate, other expert advisory panels of the Organization. The Director-General shall determine the duration of membership with a view to ensuring its continuity in the consideration of a specific event and its consequences. The Director-General shall select the members of the Emergency Committee on the basis of the expertise and experience required for any particular session and with due regard to the principles of equitable geographical representation. At







least one member of the Emergency Committee should be an expert nominated by a State Party within whose territory the event arises.

3. The Director-General may, on his or her own initiative or at the request of the Emergency Committee, appoint one or more technical experts to advise the Committee.

*Article 49 Procedure*

1. The Director-General shall convene meetings of the Emergency Committee by selecting a number of experts from among those referred to in paragraph 2 of Article 48, according to the fields of expertise and experience most relevant to the specific event that is occurring. For the purpose of this Article, "meetings" of the Emergency Committee may include teleconferences, videoconferences or electronic communications.

2. The Director-General shall provide the Emergency Committee with the agenda and any relevant information concerning the event, including information provided by the States Parties, as well as any temporary recommendation that the Director-General proposes for issuance.

3. The Emergency Committee shall elect its Chairperson and prepare following each meeting a brief summary report of its proceedings and deliberations, including any advice on recommendations.

4. The Director-General shall invite the State Party in whose territory the event arises to present its views to the Emergency Committee. To that effect, the Director-General shall notify to it the dates and the agenda of the meeting of the Emergency Committee with as much advance notice as necessary. The State Party concerned, however, may not seek a postponement of the meeting of the Emergency Committee for the purpose of presenting its views thereto.

5. The views of the Emergency Committee shall be forwarded to the Director-General for consideration. The Director-General shall make the final determination on these matters.

6. The Director-General shall communicate to States Parties the determination and the termination of a public health emergency of international concern, any health measure taken by the State Party concerned, any temporary recommendation, and the modification, extension and termination of such recommendations, together with the views of the Emergency Committee. The Director-General shall inform conveyance operators through States Parties and the relevant international agencies of such temporary recommendations, including their modification, extension or termination. The Director-General shall subsequently make such information and recommendations available to the general public.

7. States Parties in whose territories the event has occurred may propose to the Director-General the termination of a public health emergency of international concern and/or the temporary recommendations, and may make a presentation to that effect to the Emergency Committee.

## Chapter III – The Review Committee

*Article 50 Terms of reference and composition*

1. The Director-General shall establish a Review Committee, which shall carry out the following functions:

(a) make technical recommendations to the Director-General regarding amendments to these Regulations;

(b) provide technical advice to the Director-General with respect to standing recommendations, and any modifications or termination thereof;

(c) provide technical advice to the Director-General on any matter referred to it by the Director-General regarding the functioning of these Regulations.

2. The Review Committee shall be considered an expert committee and shall be subject to the WHO Advisory Panel Regulations, unless otherwise provided in this Article.

3. The Members of the Review Committee shall be selected and appointed by the Director-General from among the persons serving on the IHR Expert Roster and, when appropriate, other expert advisory panels of the Organization.

4. The Director-General shall establish the number of members to be invited to a meeting of the Review Committee, determine its date and duration, and convene the Committee.

5. The Director-General shall appoint members to the Review Committee for the duration of the work of a session only.

6. The Director-General shall select the members of the Review Committee on the basis of the principles of equitable geographical representation, gender balance, a balance of experts from developed and developing countries, representation of a diversity of scientific opinion, approaches and practical experience in various parts of the world, and an appropriate interdisciplinary balance.

*Article 51 Conduct of business*

1. Decisions of the Review Committee shall be taken by a majority of the members present and voting.

2. The Director-General shall invite Member States, the United Nations and its specialized agencies and other relevant intergovernmental organizations or nongovernmental organizations in official relations with WHO to designate representatives to attend the Committee sessions. Such representatives may submit memoranda and, with the consent of the Chairperson, make statements on the subjects under discussion. They shall not have the right to vote.

*Article 52 Reports*

1. For each session, the Review Committee shall draw up a report setting forth the Committee's views and advice. This report shall be approved by the Review Committee before the end of the







session. Its views and advice shall not commit the Organization and shall be formulated as advice to the Director-General. The text of the report may not be modified without the Committee's consent.

2. If the Review Committee is not unanimous in its findings, any member shall be entitled to express his or her dissenting professional views in an individual or group report, which shall state the reasons why a divergent opinion is held and shall form part of the Committee's report.

3. The Review Committee's report shall be submitted to the Director-General, who shall communicate its views and advice to the Health Assembly or the Executive Board for their consideration and action.

*Article 53 Procedures for standing recommendations*

When the Director-General considers that a standing recommendation is necessary and appropriate for a specific public health risk, the Director-General shall seek the views of the Review Committee. In addition to the relevant paragraphs of Articles 50 to 52, the following provisions shall apply:

(a) proposals for standing recommendations, their modification or termination may be submitted to the Review Committee by the Director-General or by States Parties through the Director-General;

(b) any State Party may submit relevant information for consideration by the Review Committee;

(c) the Director-General may request any State Party, intergovernmental organization or nongovernmental organization in official relations with WHO to place at the disposal of the Review Committee information in its possession concerning the subject of the proposed standing recommendation as specified by the Review Committee;

(d) the Director-General may, at the request of the Review Committee or on the Director-General's own initiative, appoint one or more technical experts to advise the Review Committee. They shall not have the right to vote;

(e) any report containing the views and advice of the Review Committee regarding standing recommendations shall be forwarded to the Director-General for consideration and decision. The Director-General shall communicate the Review Committee's views and advice to the Health Assembly;

(f) the Director-General shall communicate to States Parties any standing recommendation, as well as the modifications or termination of such recommendations, together with the views of the Review Committee;

(g) standing recommendations shall be submitted by the Director-General to the subsequent Health Assembly for its consideration.

## PART X – FINAL PROVISIONS

*Article 54 Reporting and review*

1. States Parties and the Director-General shall report to the Health Assembly on the implementation of these Regulations as decided by the Health Assembly.

2. The Health Assembly shall periodically review the functioning of these Regulations. To that end it may request the advice of the Review Committee, through the Director-General. The first such review shall take place no later than five years after the entry into force of these Regulations.

3. WHO shall periodically conduct studies to review and evaluate the functioning of Annex 2. The first such review shall commence no later than one year after the entry into force of these Regulations. The results of such reviews shall be submitted to the Health Assembly for its consideration, as appropriate.

*Article 55 Amendments*

1. Amendments to these Regulations may be proposed by any State Party or by the Director-General. Such proposals for amendments shall be submitted to the Health Assembly for its consideration.

2. The text of any proposed amendment shall be communicated to all States Parties by the Director-General at least four months before the Health Assembly at which it is proposed for consideration.

3. Amendments to these Regulations adopted by the Health Assembly pursuant to this Article shall come into force for all States Parties on the same terms, and subject to the same rights and obligations, as provided for in Article 22 of the Constitution of WHO and Articles 59 to 64 of these Regulations.

*Article 56 Settlement of disputes*

1. In the event of a dispute between two or more States Parties concerning the interpretation or application of these Regulations, the States Parties concerned shall seek in the first instance to settle the dispute through negotiation or any other peaceful means of their own choice, including good offices, mediation or conciliation. Failure to reach agreement shall not absolve the parties to the dispute from the responsibility of continuing to seek to resolve it.

2. In the event that the dispute is not settled by the means described under paragraph 1 of this Article, the States Parties concerned may agree to refer the dispute to the Director-General, who shall make every effort to settle it.

3. A State Party may at any time declare in writing to the Director-General that it accepts arbitration as compulsory with regard to all disputes concerning the interpretation or application of these Regulations to which it is a party or with regard to a specific dispute in relation to any other State Party accepting the same obligation. The arbitration shall be conducted in accordance with the Permanent Court of Arbitration Optional Rules for Arbitrating Disputes between Two States applicable at the time a request for arbitration is made. The States Parties that have agreed to accept arbitration as compulsory shall accept the arbitral award as binding and final. The Director-General shall inform the Health Assembly regarding such action as appropriate.







4. Nothing in these Regulations shall impair the rights of States Parties under any international agreement to which they may be parties to resort to the dispute settlement mechanisms of other intergovernmental organizations or established under any international agreement.

5. In the event of a dispute between WHO and one or more States Parties concerning the interpretation or application of these Regulations, the matter shall be submitted to the Health Assembly.

*Article 57 Relationship with other international agreements*

1. States Parties recognize that the IHR and other relevant international agreements should be interpreted so as to be compatible. The provisions of the IHR shall not affect the rights and obligations of any State Party deriving from other international agreements.

2. Subject to paragraph 1 of this Article, nothing in these Regulations shall prevent States Parties having certain interests in common owing to their health, geographical, social or economic conditions, from concluding special treaties or arrangements in order to facilitate the application of these Regulations, and in particular with regard to:

(a) the direct and rapid exchange of public health information between neighbouring territories of different States;

(b) the health measures to be applied to international coastal traffic and to international traffic in waters within their jurisdiction;

(c) the health measures to be applied in contiguous territories of different States at their common frontier;

(d) arrangements for carrying affected persons or affected human remains by means of transport specially adapted for the purpose; and

(e) deratting, disinsection, disinfection, decontamination or other treatment designed to render goods free of disease-causing agents.

3. Without prejudice to their obligations under these Regulations, States Parties that are members of a regional economic integration organization shall apply in their mutual relations the common rules in force in that regional economic integration organization.

*Article 58 International sanitary agreements and regulations*

1. These Regulations, subject to the provisions of Article 62 and the exceptions hereinafter provided, shall replace as between the States bound by these Regulations and as between these States and WHO, the provisions of the following international sanitary agreements and regulations:

(a) International Sanitary Convention, signed in Paris, 21 June 1926;

(b) International Sanitary Convention for Aerial Navigation, signed at The Hague, 12 April 1933;

(c) International Agreement for dispensing with Bills of Health, signed in Paris, 22 December 1934;

(d) International Agreement for dispensing with Consular Visas on Bills of Health, signed in Paris, 22 December 1934;

(e) Convention modifying the International Sanitary Convention of 21 June 1926, signed in Paris, 31 October 1938;

(f) International Sanitary Convention, 1944, modifying the International Sanitary Convention of 21 June 1926, opened for signature in Washington, 15 December 1944;

(g) International Sanitary Convention for Aerial Navigation, 1944, modifying the International Sanitary Convention of 12 April 1933, opened for signature in Washington, 15 December 1944;

(h) Protocol of 23 April 1946 to prolong the International Sanitary Convention, 1944, signed in Washington;

(i) Protocol of 23 April 1946 to prolong the International Sanitary Convention for Aerial Navigation, 1944, signed in Washington;

(j) International Sanitary Regulations, 1951, and the Additional Regulations of 1955, 1956, 1960, 1963 and 1965; and

(k) the International Health Regulations of 1969 and the amendments of 1973 and 1981.

2. The Pan American Sanitary Code, signed at Havana, 14 November 1924, shall remain in force with the exception of Articles 2, 9, 10, 11, 16 to 53 inclusive, 61 and 62, to which the relevant part of paragraph 1 of this Article shall apply.

*Article 59 Entry into force; period for rejection or reservations*

1. The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, these Regulations or an amendment thereto, shall be 18 months from the date of the notification by the Director-General of the adoption of these Regulations or of an amendment to these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.

2. These Regulations shall enter into force 24 months after the date of notification referred to in paragraph 1 of this Article, except for:

(a) a State that has rejected these Regulations or an amendment thereto in accordance with Article 61;

(b) a State that has made a reservation, for which these Regulations shall enter into force as provided in Article 62;







(c) a State that becomes a Member of WHO after the date of the notification by the Director-General referred to in paragraph 1 of this Article, and which is not already a party to these Regulations, for which these Regulations shall enter into force as provided in Article 60; and

(d) a State not a Member of WHO that accepts these Regulations, for which they shall enter into force in accordance with paragraph 1 of Article 64.

3. If a State is not able to adjust its domestic legislative and administrative arrangements fully with these Regulations within the period set out in paragraph 2 of this Article, that State shall submit within the period specified in paragraph 1 of this Article a declaration to the Director-General regarding the outstanding adjustments and achieve them no later than 12 months after the entry into force of these Regulations for that State Party.

*Article 60 New Member States of WHO*

Any State which becomes a Member of WHO after the date of the notification by the Director-General referred to in paragraph 1 of Article 59, and which is not already a party to these Regulations, may communicate its rejection of, or any reservation to, these Regulations within a period of twelve months from the date of the notification to it by the Director-General after becoming a Member of WHO. Unless rejected, these Regulations shall enter into force with respect to that State, subject to the provisions of Articles 62 and 63, upon expiry of that period. In no case shall these Regulations enter into force in respect to that State earlier than 24 months after the date of notification referred to in paragraph 1 of Article 59.

*Article 61 Rejection*

If a State notifies the Director-General of its rejection of these Regulations or of an amendment thereto within the period provided in paragraph 1 of Article 59, these Regulations or the amendment concerned shall not enter into force with respect to that State. Any international sanitary agreement or regulations listed in Article 58 to which such State is already a party shall remain in force as far as such State is concerned.

*Article 62 Reservations*

1. States may make reservations to these Regulations in accordance with this Article. Such reservations shall not be incompatible with the object and purpose of these Regulations.

2. Reservations to these Regulations shall be notified to the Director-General in accordance with paragraph 1 of Article 59 and Article 60, paragraph 1 of Article 63 or paragraph 1 of Article 64, as the case may be. A State not a Member of WHO shall notify the Director-General of any reservation with its notification of acceptance of these Regulations. States formulating reservations should provide the Director-General with reasons for the reservations.

3. A rejection in part of these Regulations shall be considered as a reservation.

4. The Director-General shall, in accordance with paragraph 2 of Article 65, issue notification of each reservation received pursuant to paragraph 2 of this Article. The Director-General shall:

(a) if the reservation was made before the entry into force of these Regulations, request those Member States that have not rejected these Regulations to notify him or her within six months of any objection to the reservation, or

(b) if the reservation was made after the entry into force of these Regulations, request States Parties to notify him or her within six months of any objection to the reservation.

States objecting to a reservation should provide the Director-General with reasons for the objection.

5. After this period, the Director-General shall notify all States Parties of the objections he or she has received with regard to reservations. Unless by the end of six months from the date of the notification referred to in paragraph 4 of this Article a reservation has been objected to by one-third of the States referred to in paragraph 4 of this Article, it shall be deemed to be accepted and these Regulations shall enter into force for the reserving State, subject to the reservation.

6. If at least one-third of the States referred to in paragraph 4 of this Article object to the reservation by the end of six months from the date of the notification referred to in paragraph 4 of this Article, the Director-General shall notify the reserving State with a view to its considering withdrawing the reservation within three months from the date of the notification by the Director-General.

7. The reserving State shall continue to fulfil any obligations corresponding to the subject matter of the reservation, which the State has accepted under any of the international sanitary agreements or regulations listed in Article 58.

8. If the reserving State does not withdraw the reservation within three months from the date of the notification by the Director-General referred to in paragraph 6 of this Article, the Director-General shall seek the view of the Review Committee if the reserving State so requests. The Review Committee shall advise the Director-General as soon as possible and in accordance with Article 50 on the practical impact of the reservation on the operation of these Regulations.

9. The Director-General shall submit the reservation, and the views of the Review Committee if applicable, to the Health Assembly for its consideration. If the Health Assembly, by a majority vote, objects to the reservation on the ground that it is incompatible with the object and purpose of these Regulations, the reservation shall not be accepted and these Regulations shall enter into force for the reserving State only after it withdraws its reservation pursuant to Article 63. If the Health Assembly accepts the reservation, these Regulations shall enter into force for the reserving State, subject to its reservation.

*Article 63 Withdrawal of rejection and reservation*

1. A rejection made under Article 61 may at any time be withdrawn by a State by notifying the Director-General. In such cases, these Regulations shall enter into force with regard to that State upon receipt by the Director-General of the notification, except where the State makes a reservation when withdrawing its rejection, in which case these Regulations shall enter into force as provided in Article 62. In no case shall these Regulations enter into force in respect to that State earlier than 24 months after the date of notification referred to in paragraph 1 of Article 59.







2. The whole or part of any reservation may at any time be withdrawn by the State Party concerned by notifying the Director-General. In such cases, the withdrawal will be effective from the date of receipt by the Director-General of the notification.

*Article 64 States not Members of WHO*

1. Any State not a Member of WHO, which is a party to any international sanitary agreement or regulations listed in Article 58 or to which the Director-General has notified the adoption of these Regulations by the World Health Assembly, may become a party hereto by notifying its acceptance to the Director-General and, subject to the provisions of Article 62, such acceptance shall become effective upon the date of entry into force of these Regulations, or, if such acceptance is notified after that date, three months after the date of receipt by the Director-General of the notification of acceptance.

2. Any State not a Member of WHO which has become a party to these Regulations may at any time withdraw from participation in these Regulations, by means of a notification addressed to the Director-General which shall take effect six months after the Director-General has received it. The State which has withdrawn shall, as from that date, resume application of the provisions of any international sanitary agreement or regulations listed in Article 58 to which it was previously a party.

*Article 65 Notifications by the Director-General*

1. The Director-General shall notify all States Members and Associate Members of WHO, and also other parties to any international sanitary agreement or regulations listed in Article 58, of the adoption by the Health Assembly of these Regulations.

2. The Director-General shall also notify these States, as well as any other State which has become a party to these Regulations or to any amendment to these Regulations, of any notification received by WHO under Articles 60 to 64 respectively, as well as of any decision taken by the Health Assembly under Article 62.

*Article 66 Authentic texts*

1. The Arabic, Chinese, English, French, Russian and Spanish texts of these Regulations shall be equally authentic. The original texts of these Regulations shall be deposited with WHO.

2. The Director-General shall send, with the notification provided in paragraph 1 of Article 59, certified copies of these Regulations to all Members and Associate Members, and also to other parties to any of the international sanitary agreements or regulations listed in Article 58.

3. Upon the entry into force of these Regulations, the Director-General shall deliver certified copies thereof to the Secretary-General of the United Nations for registration in accordance with Article 102 of the Charter of the United Nations.

WHO/CDS/EPR/2006.6

# Biorisk management

# Laboratory biosecurity guidance

September 2006

EPIDEMIC AND PANDEMIC
ALERT AND RESPONSE

World Health Organization

# Abbreviations

**BSL3** Containment laboratory – Biosafety Level 3

**BSL4** Maximum containment laboratory – Biosafety Level 4

**FAO** Food and Agriculture Organization of the United Nations

**GMO** Genetically modified organism

**LBM3** Laboratory biosafety manual, third edition, 2004

**LBG** Biorisk management: laboratory biosecurity guidance, first edition, 2006

**OIE** World Organisation for Animal Health

**VBM** Valuable biological materials

**WHO** World Health Organization

# Definitions

The following terms are defined in the context in which they are used in this document.

**Accountability**
Accountability ensures that valuable biological materials (VBM, see definition below) are controlled and traced as intended, by formally associating the specified materials with the individuals who provide oversight and are held responsible for them.

**Bioethics**
The study of the ethical and moral implications of biological discoveries, biomedical advances, and their applications as in the fields of genetic engineering and drug research (adopted from *1*). In this document, bioethics is one of the three components that contribute to a successful biorisk management culture.

**Biological laboratory**
A facility within which microorganisms, their components or their derivatives are collected handled and/or stored. Biological laboratories include clinical laboratories, diagnostic facilities, regional and/national reference centres, public health laboratories, research centres (academic, pharmaceutical, environmental, etc.) and production facilities (manufacturers of vaccines, pharmaceuticals, large scale GMOs, etc) for human, veterinary and agricultural purposes.

**Biorisk**
The probability or chance that a particular adverse event (in the context of this document: accidental infection or unauthorized access, loss, theft, misuse, diversion or intentional release), possibly leading to harm, will occur.

**Biorisk assessment**
The process to identify acceptable and unacceptable risks (embracing biosafety risks (risks of accidental infection) and laboratory biosecurity risks (risks of unauthorized access, loss, theft, misuse, diversion or intentional release)) and their potential consequences.

**Biorisk management**
The analysis of ways and development of strategies to minimize the likelihood of the occurrence of biorisks. The management of biorisk places responsibility on the facility and its manager (director) to demonstrate that appropriate and valid biorisk reduction (minimization) procedures have been established and are implemented. A biorisk management committee should be established to assist the facility director in identifying, developing and reaching biorisk management goals.

**Biosafety**
Laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release (*2*).

**Code of conduct, code of ethics, code of practice**
Non-legislated guidelines which one or more organizations and individuals voluntarily agree to abide by, that set out the standard of conduct or behavior with respect to a particular activity (adopted from *1*).

**Control**
Control is the combination of engineered and procedural measures that ensure valuable biological material (VBM, see definition below) are used only as intended.

**Dual-use**
Initially used to refer to the aspects of certain materials, information and technologies that are useful in both military and civilian spheres. The expression is increasingly being used to refer not only to military and civilian purposes, but also to harmful misuse and peaceful activities (adopted from *1*).

**Genetically modified organisms (GMO)**
Organisms whose genetic material has been altered using techniques generally known as "recombinant DNA technology". Recombinant DNA technology is the ability to combine DNA molecules from different sources into one molecule in a test tube. GMOs are often not reproducible in nature, and the term generally does not cover organisms whose genetic composition has been altered by conventional cross-breeding or by "mutagenesis" breeding, as these methods predate the discovery (1973) of recombinant DNA techniques.

**Hazard**
A danger or source of danger; the potential to cause harm.

**Laboratory biosecurity**
Laboratory biosecurity describes the protection, control and accountability for valuable biological materials (VBM, see definition below) within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release.

**Misuse**
The misuse of valuable biological materials (VBM, see definition below) describes their inappropriate or illegitimate use, despite existing and subscribed agreements, treaties and conventions (*3*).

**Threat**
The likelihood for an adverse event to occur, as an expression of intention to inflict evil, injury, disruption or damage.

**Transfer of VBM**
Legal and/or administrative policies and procedures relating to the oversight and approval process for the transfer of custody and/or ownership of valuable biological materials (VBM, see definition below) between countries, entities (organizations, institutions, facilities, etc.) or individuals.

**Transport of VBM**
Procedures and practices to correctly categorize, package, document and safely and securely transport valuable biological materials (VBM, see definition below) from one place to another, following applicable national and/or international regulations.

**Valuable biological materials (VBM)**
Biological materials that require (according to their owners, users, custodians, caretakers or regulators) administrative oversight, control, accountability, and specific protective and monitoring measures in laboratories to protect their economic and historical (archival) value, and/or the population from their potential to cause harm. VBM may include pathogens and toxins, as well as non-pathogenic organisms, vaccine strains, foods, genetically modified organisms (GMOs), cell components, genetic elements, and extraterrestrial samples.

# 1. Introduction

*Background*

Disease diagnosis, human or animal sample analysis, epidemiological studies, scientific research, and pharmaceutical developments: all of these activities are carried out in biological laboratories in the private or public sectors. Biological materials are handled worldwide in laboratories for numerous genuine, justifiable and legitimate purposes, where small and large volumes of live microorganisms are replicated, where cellular components are extracted and many other manipulations undertaken for purposes ranging from educational, scientific, medicinal and health-related to mass commercial and/or industrial production. Among them, an unknown number of the facilities, large and small, work with dangerous pathogens or their products every day.

The general public expects laboratory personnel to act responsibly and not to expose the community to biorisks, to follow safe working practices (biosafety) associated with practices that will help keep their work and materials safe and secure (biosecurity), and to follow an ethical code of conduct (bioethics). Often suspicious of work taking place in laboratories, the uninformed public may even feel threatened by the presence of a biological laboratory in their neighborhood. It is the technical and moral duty of laboratory managers and laboratory workers, with the support of national authorities, to reassure the general public, to persuade them that the activities being conducted are beneficial and necessary, and to prove that the biorisks inherent to laboratory work are controlled with appropriate safeguards to meet their expectations.

However, despite advances in technology, the availability of more and more sophisticated instruments for laboratory use, increasingly effective techniques and the availability of personal protective equipment, human error remains one of the most important factors at the origin of accidents. Poor concentration, denial of responsibilities, inappropriate accountability, incomplete record-keeping, suboptimal facility infrastructure, refusal to acknowledge ethical considerations, lack of (or lack of respect for) codes of conduct, etc. may be at the origin of laboratory-acquired infections, loss of material and inappropriate manipulations, or even possibly intentional misbehaviour.

Pathogens and toxins have been used, even in the recent past, to threaten and harm people, to disrupt society, economies and the political status quo (*5*). This has happened in spite of applicable international agreements banning the use of biological agents for malicious use. As those who carry out such acts show disregard for ethical values (*6*), do not respect the right of people to a safe and peaceful life, or do not recognize global treaties and conventions, several regulatory approaches to limit unauthorized access to biological agents and toxins available in biological laboratories are now being carefully considered and implemented worldwide.

Three examples illustrate the need to respond to the international community and articulate biosecurity in the laboratory:

1. Smallpox has been eradicated some 26 years ago. However, its causative agent, variola virus, remains stored in two WHO Collaborating Centres under maximum containment. The accidental or deliberate reintroduction of variola virus into the environment threatens not only public health, but also the economy and political stability of the whole world. For this reason, the known remaining variola virus stocks are subject to WHO scrutiny for the research they are subject to (*7*), and each site is regularly assessed by WHO for its biosafety and laboratory biosecurity (*8*). Despite these existing international arrangements, this guidance document offers an opportunity for further improvement of their working and storage conditions.

2. As the final stages of the poliomyelitis eradication campaign approach, steady progress is being made towards the safe-keeping of facilities containing poliovirus samples and stocks, which will then be advised to decide whether to keep these polioviruses and upgrade their biosafety containment and biosecurity levels and tighten their codes of conduct, transfer their poliovirus samples to a better-equipped reference laboratory, or destroy the remaining stocks. Experience gained and lessons learnt from the containment of variola viruses post eradication offer an invaluable opportunity to plan for the polio post eradication phase and for the development of most appropriate biorisk management plans and goals.

3. Laboratory biosecurity provisions may not have impeded the release of the anthrax letters in the USA in 2001 (*5*). In hindsight however, laboratory biosecurity provisions to write records on research and activity, access shared documentation, consult approved research projects and available results data, may have helped discharge alleged facilities and perpetrators from the list of possible suspects.

Historical awareness of the dual-use (*9*) of agents, equipment and technology, is also considered in the development of laboratory biosecurity guiding principles.

*Current situation*

Facilities containing biological agents may represent tempting procurement opportunities, thus advocacy for security-related scrutiny of biological facilities, their personnel and their visitors is increasing worldwide. In recent years, several countries have developed and implemented laboratory biosecurity legislation to regulate possession, use and access to biological materials to permit their appropriate use.

Despite the advances of some countries, in many other countries and for many laboratories, guidance or specific requirements for the appropriate handling and storage of valuable biological materials (VBM, described below) do not yet exist. This raises the following questions: How are these agents generally kept in such countries? Who has access to them? What kind of research is allowed and conducted with them? Who oversees this research? Who has the ultimate responsibility for these agents? Who should have access to information related to these agents, including research

results and storage details? Should research results be published? Is there a scrutiny for the publication of research data?

Many open questions still remain in the context of laboratory biosecurity, and much still needs to be done to reassure the public, scientists, laboratory managers, regulators, national authorities and the international community that the appropriate measures to prevent, manage, control and minimize the biorisks associated with possessing and handling infectious agents are in place. The biorisk management approach described in this document, encompassing biosafety and laboratory biosecurity, represents a step towards the clarification of these questions.

Globally, one common trend can be identified: rather than providing a prescriptive approach to addressing biosafety and related issues, and requesting compliance with a set of strict rules, the move to a goal-setting approach describing performance expectations for facilities, and placing the responsibility on single facilities to demonstrate that appropriate and valid biorisk minimization measures have been established, is proving very successful. Leaving the choice of procedures, control measures and verification systems to facility managers to ensure that set goals are reached requires the involvement of dedicated managers and of leaders who express appreciation for specific measures, and are instrumental in encouraging and supporting the development of a global biorisk management culture. Indeed it is such a biorisk management culture that the international bioresearch community should strive for.

*International biorisk management*

While an understanding of the need to safeguard VBM is becoming more widespread, universally agreed-upon laboratory biosecurity principles and practices are not. The resulting inconsistencies represent the complexity of the issue and a challenge for the international community to identify what should be addressed and how to respond to real needs. In the framework of public health, the challenge for the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO) and the World Animal Health Organisation (OIE) is to provide Member States with balanced, appropriate and sustainable recommendations that address the biosecurity of biological materials in laboratory environments, expanding the strict mandates of these organizations in the fields of human and animal public health to the area of security, generally associated with entities that have law-enforcement mandates.

International organizations and agreements use the word biosecurity in a variety of contexts and for different purposes, in response to recommendations to protect different assets. FAO and OIE refer to biosecurity in the context of biological and environmental risks associated with food and agriculture, including forestry and fisheries, a sector that covers food safety, and the life and health of plants and animals. The risks include everything from the introduction and release of GMOs and their products, the introduction and spread of invasive alien species, alien genotypes and plant pests, animal pests and diseases and zoonoses, to the erosion of biodiversity, the spread of transboundary cattle diseases, or the preservation of food supplies after production.

The purpose of this document is to define the scope and applicability of "laboratory biosecurity" recommendations, narrowing them strictly to human, veterinary and agricultural laboratory environments. The operational premise for supporting national laboratory biosecurity plans and regulations generally focuses on dangerous pathogens and toxins. In this document, the scope of laboratory biosecurity is broadened by addressing the safekeeping of all *valuable biological materials* (VBM), including not only pathogens and toxins, but also scientifically, historically and economically important biological materials such as collections and reference strains, pathogens and toxins, vaccines and other pharmaceutical products, food products, GMOs, non-pathogenic microorganisms, extraterrestrial samples, cellular components and genetic elements. This is done in order to raise awareness of the need to secure collections of VBM for many reasons, including: for the sake of biology, to preserve biological diversity and endangered species, to perform microbiological studies and better understand the living world and the science behind it; to safeguard resources from which new drugs, vaccines and life-saving materials may be developed, for historical reasons, and to advance the state of knowledge.

*Scope of this document*

This document introduces a new concept and approach to minimize or prevent the occurrence and consequences of human error within the laboratory environment: the biorisk management approach, composed of biosafety, laboratory biosecurity and ethical responsibility.

Biosafety and its internationally acknowledged advantages have already been extensively described in LBM3. Laboratory biosecurity and its as yet poorly appreciated advantages and responsibility in coordinating personnel and scientific activities (research), and code of ethics are discussed here.

Within a comprehensive biorisk management approach, this document aims to define and guide the reader in the field of laboratory biosecurity. It is addressed to laboratories wishing to handle and store VBM, and discusses the legal framework within countries holding and supporting such laboratories. Setting the goal of managing biorisks should drive national authorities, laboratory managers and ultimately laboratory workers to take responsibility in developing the necessary safeguards. This in turn should demonstrate that biorisks in all their potential forms are appropriately addressed, managed and minimized.

*Rationale*

While Member States are expected to address laboratory biosecurity issues in the context of their regional, national and local situations and needs, this document provides guidance to help frame the concepts. A comparative description of biosafety and laboratory biosecurity is provided below for clarification.

Member States are encouraged to introduce these concepts within their local contexts and to develop national frameworks for the security of biological materials they consider valuable, in recognition of the ever-increasing importance of global regulatory harmonization (*10*). In the absence of national regulatory guidance, laboratory managers are encouraged to consider adopting a biorisk management approach adapted to their particular situation and developing guiding principles to be implemented in response to the specific needs of their facilities.

# 2. Laboratory biosecurity as a complement to laboratory biosafety

Laboratory biosafety and biosecurity mitigate different risks, but they share a common goal: keeping VBM safely and securely inside the areas where they are used and stored.

*Laboratory biosafety* (*2*) is the expression used to describe the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release.

A comprehensive biosafety culture translates into the understanding and routine application of a set of safe practices, procedures, actions and habits that protect the people working with biological materials.

Laboratory biosecurity may be addressed through the coordination of administrative, regulatory and physical security procedures and practices implemented in a working environment that utilizes good biosafety practices, and where responsibilities and accountabilities are clearly defined. Biosafety and laboratory biosecurity are complementary. In fact, the implementation of specific biosafety activities already covers some biosecurity aspects. The systematic use of appropriate biosafety principles and practices reduces the risk of accidental exposure and paves the way for reducing the risks of VBM loss, theft or misuse caused by poor management or poor accountability and protection. Laboratory biosecurity should be built upon a firm foundation of good laboratory biosafety.

Through microbiological risk assessments performed as an integral part of an institution's biosafety programme, information is gathered regarding the type of organisms available at a given facility, their physical location, the personnel who require access to them, and the identification of those responsible for them. A laboratory biosecurity risk assessment should further help establish whether this biological material is valuable and warrants security provisions for its protection that may be insufficiently covered through recommended biosafety practices. This approach underlines the need to recognize and address the ongoing responsibility of countries and institutions to ensure the expectation for a safe and secure laboratory environment.

A specific laboratory biosecurity programme, managing the identified biorisks, should be prepared and designed for each facility according to its specific requirements, to the type of laboratory work conducted, and to local and geographical conditions. Laboratory biosecurity activities should be representative of the institution’s various needs and should include input from scientific directors, principal investigators, biosafety officers, laboratory scientific staff, maintenance staff, administrators, information technology staff, law-enforcement agencies and security staff, if appropriate. A sound code of practice should be included for personnel practice.

Laboratory biosecurity measures should be based on a comprehensive programme of accountability for VBM that includes:

1. regularly updated inventories with storage locations,
2. identification and selection of personnel with access,
3. plans of use of VBM,
4. clearance and approval processes,
5. documentation of internal and external transfers within and between facilities, and of any
6. inactivation and/or disposal of the material.

Likewise, institutional laboratory biosecurity protocols should include how to handle breaches or near-breaches in laboratory biosecurity including:

1. incident notification,
2. reporting protocols,
3. investigation reports,
4. recommendations and remedies, and
5. oversight and guidance through the Biosafety Committee.

The protocols should also include how to handle discrepancies in inventory results, and describe the specific training to be offered, and the training that personnel should be required to follow. The involvement, roles and responsibilities of public health and security authorities in the event of a security breach should also be clearly defined. Documenting procedures to manage behaviour and the interaction of workers with the facility and its equipment should also be considered.

These issues should be addressed according to a goal-setting approach to make sure the objective of minimizing biorisks is reached, rather than following a prescriptive approach to demonstrate compliance to a given set of rules. A goal-setting approach furthermore enables facilities to be creative, imaginative and innovative, allowing for responding to unexpected events, and for new findings and considerations to be easily incorporated into existing management systems. Goal-setting principles-based approaches enable staff to deal with the unpredicted and unfamiliar in the most prudent and safe manner until more expert opinion can be obtained.

## *2.1 Commonalities and conflicts: laboratory biosafety vs laboratory biosecurity*

*Commonalities*

Good laboratory biosafety practices reinforce and strengthen laboratory biosecurity systems. Appropriate levels of biosafety may be achieved through carefully designed and implemented work practices, even in modestly-equipped facilities. The biosafety recommendations outlined in LBM3 provide clear levels of protection for VBM. For example self-closing doors, restricted access, physical separation from traffic areas, break-resistant windows and an emergency response plan may all be common to both biosafety and laboratory biosecurity.

LBM3 also advocates a "reliable and adequate electricity supply and emergency lighting" as well as a "stand-by generator". While this helps to ensure the function of critical biosafety equipment (ventilation systems, biological safety cabinets, autoclaves, etc.), it also supports components of physical security systems that may depend on electrical supply.

According to LBM3, the review of research protocols falls under the responsibilities of the biosafety officer and the biosafety committee, by delegation of the director of the facility. This includes risk assessments in consultation with local authorities, national regulatory bodies and the community for contentious or sensitive protocols under discussion. Adding the review of laboratory biosecurity to the existing biosafety mandate for biosafety committees represents a major change and an additional responsibility (*11*). The best advice to these committees is that they should follow transparent processes involving open discussions, and examine moral and ethical considerations before reaching risk management conclusions (*12*). The approval of research protocols should include guidance on how to keep or destroy the developed materials, and the criteria that should be applied before taking a final decision. Scientists for their part should play an active role in decision-making in order to protect intellectual rights and participate in determining the benefits and risks of the research to be undertaken, including protection and access to VBM. Only a well-structured dialogue involving researchers, the biosafety committee and facility managers may ultimately allow a facility to be adequately prepared to best mitigate the consequences of biosecurity breaches that may also result in external criticism.

However, even though biosafety and laboratory biosecurity are in most respects compatible, a number of potential conflicts exist that need to be resolved.


Figure 1. **Biohazard warning sign for laboratory doors**

*Conflicts*

In the absence of careful implementation, various aspects of biosafety may conflict with laboratory biosecurity. For example, controls that reduce unauthorized access might also hinder an emergency response by fire or rescue personnel. Mechanisms need to be established that allow entry by emergency responders but ensure uninterrupted and constant laboratory biosecurity, control, accountability and traceability of VBM. Likewise, staff members must be able to quickly and safely exit a laboratory during an emergency without at the same time allowing unrestricted access to sensitive VBM.

Signage may also represent a potential conflict between biosafety and laboratory biosecurity. In the past, biohazard signs placed on laboratory doors identified the biological agents present in the laboratory. However, as a laboratory biosecurity measure to better protect sensitive VBM, LBM3 now recommends limiting the information on biohazard signs to the laboratory biosafety level, the name and telephone number of the responsible investigator, and emergency contact information (*Fig. 1*).

WHO/HSE/GAR/BDP/2010.2

# Responsible life sciences research for global health security

## A GUIDANCE DOCUMENT

# Acronyms

| | |
|---|---|
| BSL | Biosafety level |
| BWC | Biological and Toxin Weapons Convention |
| BBSRC | Biotechnology and Biological Sciences Research Council (United Kingdom) |
| CDC | Centers for Disease Control and Prevention of the Department of Health and Human Services (United States of America) |
| CSE | Council of Science Editors |
| EC | European Commission of the European Union |
| GMO | Genetically modified organism |
| IAP | InterAcademy Panel |
| ICLS | International Council for the Life Sciences |
| ICSU | International Council for Science |
| IHR | International Health Regulations |
| IUBMB | International Union of Biochemistry and Molecular Biology |
| IUMS | International Union of Microbiological Societies |
| HRS | Health research systems |
| MRC | Medical Research Council (United Kingdom) |
| NGO | Nongovernmental organization |
| NIH | National Institutes of Health of the Department of Health and Human Services (United States of America) |
| NRC | National Research Council of the National Academies (United States of America) |
| NSABB | National Science Advisory Board for Biosecurity (United States of America) |
| PHEIC | Public Health Emergencies of International Concern |
| rDNA | Recombinant DNA |
| RS | Royal Society of the United Kingdom |
| VBM | Valuable biological materials |
| WAME | World Association of Medical Editors |
| WHA | World Health Assembly of the World Health Organization |
| WHO | World Health Organization |

# Definitions

The following terms are defined in the context in which they are used in this document.

**Bioethics** The study of the ethical and moral implications of biological discoveries, biomedical advances and their applications, as in the fields of genetic engineering and drug research (*1*).[1]

**Biological laboratory** A facility within which biological agents, their components or their derivatives, and toxins are collected, handled and/or stored. Biological laboratories include clinical laboratories, diagnostic facilities, regional and national reference centres, public health laboratories, research centres (academic, pharmaceutical, environmental, etc.) and production facilities (the manufacturing of vaccines, pharmaceuticals, large-scale genetically modified organisms, etc.) for human, veterinary and agricultural purposes (*1*).

**Biorisk** The risk (risk is a function of likelihood and consequences) that a particular biological event (in the context of this document: naturally occurring diseases, accidents, unexpected discovery, or deliberate misuse of biological agents and toxins), which may affect adversely the health of human populations, may occur (*1*, *2*). An assessment of these risks can be both quantitative and qualitative.

**Biorisk spectrum** A continuum of biorisks ranging from naturally occurring diseases (chronic and infectious diseases), to accidents, to the deliberate misuse of biological agents and toxins with the intention to cause harm (**Figure 1**) (*2*).

**Biorisk reduction** The reduction of the occurrence of risks associated with exposure to biological agents and toxins, whatever their origin or source, encompassing the full spectrum of biorisks (*2*).

**Laboratory biosafety** The containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents and toxins, or their accidental release (*3*, *4*).

**Laboratory biosecurity** The protection, control and accountability for valuable biological materials[2] within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release (*1*).

**Dual-use life sciences research** Knowledge and technologies generated by legitimate life sciences research that may be appropriated for illegitimate intentions and applications (*2*, *5*).

**Life sciences** All sciences that deal with organisms, including humans, animals and plants, and including but not limited to biology, biotechnology, genomics, proteomics, bioinformatics, pharmaceutical and biomedical research and techniques.

**Global health security** The activities required, both proactive and reactive, to minimize vulnerability to acute public health events that endanger the collective health of populations living across geographical regions and international boundaries (*6*).

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[1] International Futures Program of the Organisation for Economic Co-operation and Development (OECD), Biosecurity oversight and codes (www.biosecuritycodes.org/gloss.htm, accessed October 2010).

[2] Valuable biological materials (VBM) are "Biological materials that require (according to their owners, users, custodians, caretakers or regulators) administrative oversight, control, accountability, and specific protective and monitoring measures in laboratories to protect their economic and historical (archival) value, and/or the population from their potential to cause harm. VBM may include pathogens and toxins, as well as non-pathogenic organisms, vaccine strains, foods, genetically modified organisms (GMOs), cell components, genetic elements, and extraterrestrial samples." (*1*)

**Health research systems** The people, institutions, and activities whose primary purpose in relation to research is to generate high-quality knowledge that can be used to promote, restore and/or maintain the health status of populations; it should include the mechanisms adopted to encourage the utilization of research (*7*).

**Public health** The science and art of preventing disease, prolonging life, and promoting health through the organized efforts and informed choices of society, organizations, public and private, communities and individuals (*8*). Health is defined by the Constitution of the World Health Organization as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

**Research excellence** Research that is of high quality, ethical, rigorous, original and innovative.

# Executive summary

Advances in life sciences research are inextricably linked to improvements in human, plant and animal health. Promotion of excellent, high-quality life sciences research that is conducted responsibly, safely and securely can foster global health security and contribute to economic development, evidence-informed policy making, public trust and confidence in science. Yet opportunities may also be accompanied by risks that need to be acknowledged and addressed. The risks under consideration in this guidance are those associated with accidents, with research that may pose unexpected risks and with the potential deliberate misuse of life sciences research. The opportunities offered by the life sciences are too important for governments and the scientific community (including individual researchers, laboratory managers, research institutions, professional associations, etc.) to leave the attendant risks unaddressed.

The purpose of this guidance is to inform Member States about the risks posed by accidents or the potential deliberate misuse of life sciences research and to propose measures to minimize these risks within the context of promoting and harnessing the power of the life sciences to improve health for all people. Although the issues addressed in this document can potentially interest a quite large audience, the proposed measures and the self-assessment questionnaire are of a public health nature. Health researchers, laboratory managers and research institutions are therefore the primary audience of this guidance.

There is no single solution or system that will suit all countries, institutions or laboratories. Each country or institution that assesses the extent to which it has systems and practices in place to deal with the risks posed by accidents or the potential deliberate misuse of life sciences research will need to decide which measures are most appropriate and relevant according to their own national circumstances and contexts.

However, as recognized by the World Health Assembly in 2002 (Resolution WHA55.16), one of the most effective ways to prepare for deliberately caused disease is to strengthen public health measures for naturally occurring and accidentally occurring diseases. This guidance contributes to the implementation of WHA55.16 and promotes a culture of scientific integrity and excellence, distinguished by openness, honesty, accountability and responsibility. Such a culture is the best protection against the possibility of accidents and deliberate misuse, and the best guarantee of scientific progress and development.

Moreover, countries and institutions may consider drawing on the biorisk management framework for responsible life sciences research developed by this guidance. This integrated framework rests on three pillars supporting public health.

- **Research excellence** – this concerns fostering quality in life sciences activities, which is the basis for developing new treatments and therapeutics, strengthening health research systems, and promoting public health surveillance and response activities. These elements are essential to protecting and improving the health and well-being of all people.

  As such, countries and institutions are invited to:

  — Support capacity development for research as this is essential for reducing health inequalities and for ensuring the proper use of life sciences;
  — Use existing tools and frameworks, such as health research systems (HRS), the WHO strategy on research for health and the International Health Regulations (IHR) as these can provide useful tools for contributing to responsible life sciences research.

- **Ethics** – this involves the promotion of responsible and good research practices, the provision of tools and practices to scientists and institutions that allow them to discuss, analyse and resolve in an open atmosphere the potential dilemmas they may face in their research, including those related to the possibility of accidents or misuse of the life sciences.

  As such, countries and institutions are invited to:

  — Use existing ethical platforms, if appropriate;
  — Promote ethics education and training for students and professionals;
  — Encourage discussion and reflection on research practices;
  — Hold institutions and researchers to account and ensure they are aware of their responsibilities;
  — Ensure institutions and researchers are aware of existing and new legislation, regulations at the country but also at the regional and international levels.

- **Biosafety and laboratory biosecurity** – this concerns the implementation and strengthening of measures and procedures to: minimize the risk of worker exposure to pathogens and infections; protect the environment and the community; and protect, control and account for valuable biological materials (VBM) within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release. Such measures reinforce good research practices and are aimed at ensuring a safe and secure laboratory environment, thereby reducing any potential risks of accidents or deliberate misuse.

  As such, countries and institutions are invited to:

  — Conduct biosafety and laboratory biosecurity risk assessments and, based on these, apply appropriate risk reduction measures;
  — Implement a laboratory biorisk management system;
  — Explore the use of existing biorisk management structures (e.g. laboratory biorisk management adviser and the biosafety committee) to address issues related to the risks posed by life sciences research;
  — Set performance objectives and work on continuous improvement.

A culture of responsible life sciences practice is most likely to result when the leadership within the organization supports and fosters such a management framework.

In implementing the above biorisk management framework for responsible life sciences research, countries and institutions are encouraged to consider:

— Reinforcing public health capacities in terms of research for health, biosafety and laboratory biosecurity management and ethics;
— Investing in training personnel (laboratory staff and researchers) and students in ethics, the responsible conduct of research, and biosafety and laboratory biosecurity.
— Ensuring compliance with biosafety and laboratory biosecurity;
— Seeing multi-stakeholder issues, with different layers of responsibilities and encourage coordination among stakeholders;
— Using existing mechanisms, procedures and systems and reinforce local institutional bodies (if they exist).

Another major component of this guidance is a self-assessment questionnaire, which is intended to help health researchers, laboratory managers, and research institutions identify and build on strengths and address weaknesses in each of the three pillars of the biorisk management framework. Going through this process will provide an assessment of the extent to which systems are in place in the national public health system and individual laboratories to address the risks of accidents and the potential deliberate misuse of science and to identify priority areas where action is necessary to ensure high-quality, safe, secure and responsible research practices across the life sciences.

In general, oversight, safety and public security should be pursued in a manner that maximizes scientific progress and preserves scientific freedom. Any controls over life sciences research need to be proportionate and risk-based, should not unduly hamper the development of the life sciences and should not discourage scientists from working with important pathogens. This requires excellent facilities, and the management of them (including laboratories), leadership with integrity, a robust ethical framework, training and capacity development, institutional development and regular review.

# 1. Introduction

## 1.1 Context, purpose, audience and scope of the guidance

### 1.1.1 Context

When the reconstruction of the 1918 influenza A (H1N1) pandemic virus, also known as the Spanish Flu virus, was published in 2005, many people considered it a remarkable achievement that could help combat future influenza pandemics. At the same time, it raised concerns that the resurrected virus might escape from laboratories (as happened with severe acute respiratory syndrome [SARS] coronavirus in 2003–2004) or that the knowledge gained from this research could be deliberately misused to cause harm. Research-related laboratory accidents have the potential to affect laboratory workers, the environment, and local and more distant communities. The 2001 anthrax letters in the United States of America, which killed five people and infected 22, had a worldwide impact and underscored the role of public health systems in responding to the deliberate misuse of a biological agent (*9*). Other kinds of research misuse that may be dangerous to public health and have a significant economic burden include deliberately neglecting or side-stepping good research practices and codes of conduct, which are meant to ensure standards of ethics, safety and quality (*10*, *11*).

The reconstruction of the 1918 influenza A (H1N1) pandemic virus is one of a few experiments in recent years that have grabbed the media's attention and led to calls for better management of the potential risks associated with accidents or the deliberate misuse of life sciences research. There is a wide recognition that there is no "one size fits all" management measure and that such measures may be issued by different stakeholders. The need to have clear guidelines about what researchers, publishers, funding bodies, governments and other actors are expected to do with research raising possible risks as well as the need to have guidelines to avoid measures that would go beyond what is appropriate, have been emphasized (*12–14*).

The role of WHO in this area has been underlined by several groups, including by the National Research Council of the US National Academies of Sciences in their 2004 seminal report on the subject "Biotechnology Research in an Age of Terrorism: Confronting the Dual-Use Dilemma, also called the "Fink report" (*15*). It has also been noted that WHO as an international organization with direct links to policy makers and having wide acceptance as an authority in preserving public health, is particularly equipped to promote responsible life sciences research. By emphasizing the public health perspective of dual-use issues, this guidance can achieve a broad acceptance of the need to raise awareness in this area and thus be better able to implement the objectives of promoting responsible life sciences research in general on a global level.

A scientific working group, which met in WHO in 2006 to discuss the risks and opportunities of life sciences research for global health security, also underlined the important role of WHO to lead, in coordination with other stakeholders and in line with its public health mandate, global efforts and help maintain effective policies that will maximize the benefits of public health research while minimizing the risks (*2*). Moreover, participants at a WHO workshop on responsible life sciences research also underscored the need to have a foundational document on this topic (see **Annex 3**). As this subject is being addressed by many stakeholders with different interests and agendas, this document provides a unique international public health perspective on this issue, which is important to complement with other policy measures. Such a perspective also provides a platform for discussion.

The importance of a public health perspective on this topic is important for several reasons. The life sciences have the potential to address a host of public health, agricultural and environmental

challenges, making them a key driver of economic growth and an important element of health innovation for developing, as well as for developed countries (*16–19*). It is widely perceived that advances in the life sciences will continue to be significant in this century and that the impact will be similar to that of the life and physical sciences in the 20th century (*20*).

Capacity development for research is necessary for ensuring the proper use of life sciences research and minimizing accidents and potential for deliberate misuse (*21*). Research on conditions affecting the health status of poor people along with access and delivery tools are crucially needed. Despite the substantial increase in funding for research and development (R&D) in developing countries (*22*) and the investment in life sciences R&D expertise by countries such as Brazil, China and India (*22*), only a small proportion of the quadrupling global investments in R&D since 1986 has been spent on diseases affecting poor people (*23*). Over the same time, health status has deteriorated in many developing countries,[1] which are increasingly suffering from the double burden of disease, combining the so-called diseases of poverty (infectious diseases and maternal, perinatal and nutrition conditions) with injuries and chronic noncommunicable diseases such as cancers, diabetes and cardiovascular diseases (*22, 24*).

It is well recognized that more needs to be done to reduce inequities in health conditions among populations, to bridge the technological gap between developed and developing countries (*16, 25*), and to translate new knowledge into health products. Access to biotechnologies therefore remains a major aspect for health development (*18*). The Millennium Development Goals have stressed the important role of the life sciences for human security. Biomedical research and emerging genomics techniques along with international collaboration and partnerships can help to achieve these and other development goals (*26*).

Yet opportunities are often accompanied by a number of risks. Advances in life sciences research and new biotechnologies such as genomics, synthetic biology, stem-cell research, and genetically modified organisms and foods have already raised a series of complex legal, social and ethical issues. In response, many countries have designed and implemented different regulatory frameworks that reflect their own political cultures, national priorities, local contexts and perceptions of risks (*27, 28*). The same country-based approach may be taken for the equally complex and challenging issues around the potential risks of accidents or the deliberate misuse of life sciences research.

The field of public health is concerned with protecting and promoting the health of communities and therefore must give due consideration to both the benefits and the possible risks of life sciences research for public health. At the same time, managing these risks may potentially harm public health if controls on research are so stringent that they stall advances in the life sciences and make international collaboration difficult (*2*). Any controls on life sciences research need, therefore, to be proportionate and balance risks and benefits.

Finding the right balance is essential for several reasons. First, control over research should not unduly hamper the development of the life sciences and should not impede access to biological materials and resources necessary to address public health challenges, including new infectious diseases. A situation that discourages scientists from working with important pathogens should be avoided. At the same time, increasing capacity for the life sciences should be accompanied by the promotion of responsible life sciences management.

Second, strong public confidence in life sciences research needs to be established and continuously nurtured. Research is essential for public health. Communication, international collaboration and openness, which are central to a public health perspective, are indispensable for global health security, scientific discovery and evidence-based measures.

Finally, information on this issue is uneven among Member States. Providing information on this topic to the various ministers of health in WHO Member States will:

- help them to rationally explain the issues to their constituencies and populations;
- help them to inform, educate and advise colleagues in other ministries;
- help them to plan rational and feasible emergency response plans should an adverse event occur;
- better equip them to assess what capabilities (and bioresources, e.g. exotic pathogens) existing within their own countries for the types of potentially dangerous research;
- should Member States be considering national regulations, understanding this issue will help

[1] By 2003, the number of people living in developing countries represented more than 80% of the total world population (*22*).

them formulate workable and effective guidelines and safeguards;
- understanding it will enable them to contribute better to global debate on the topic and, at the same time, bringing with them their own unique perspectives.

### 1.1.2 Purpose and audience

The purpose of this guidance is to inform Member States about the risks posed by accidents or the deliberate misuse of life sciences research and to propose measures to minimize them within the context of promoting and harnessing the power of the life sciences to improve health for all people. This guidance aims at strengthening the culture of scientific integrity and excellence characterized by openness, honesty, accountability and responsibility: such a culture is the best protection against accidents and deliberate misuse, and the best guarantee of scientific progress and development.

This guidance provides Member States with a conceptual framework for individual adaptation according to national circumstances, contexts, needs and capacities. Countries, research institutions, and laboratories are encouraged to review the proposed measures and to adapt them accordingly.

The issues addressed in this document can potentially interest a quite large audience: from policy-makers, relevant national regulatory authorities to scientific community (including researchers, laboratory scientists and managers, research institutions, professional associations, students, educators and journal editors).

However, the measures proposed under the biorisk management framework are of a public health nature and the self-assessment tool has been designed and field-tested within this framework and with the help of health researchers and laboratory managers. Health researchers, laboratory managers and research institutions are therefore the primary audience of this document, noting that the self-assessment questionnaire can be adapted to countries and institutions' needs.

Using this guidance will provide researchers and institutions with:

- a better understanding of the potential risks associated with accidents and the deliberate misuse of life sciences research;
- learn about practical measures that will enable them to manage some of the risks posed by life sciences research;
- assess their needs and capacities using a self-assessment tool to review existing structures and mechanisms and identify potential needs.

### 1.1.3 Scope of the guidance: WHA55.16 and the biorisk management framework for responsible life sciences research

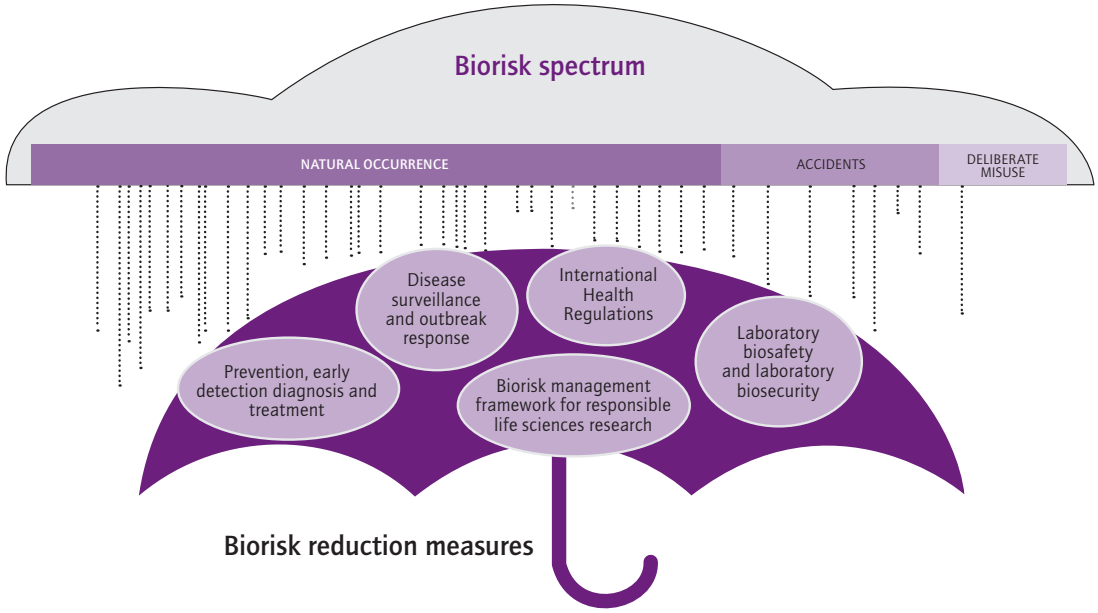
This document complements previous publications on the subject published by WHO (*2*, *5*, *29*) and links up with other areas of work of WHO, in particular, biosafety and laboratory biosecurity, ethics and some areas of work falling under research policy and cooperation. Compared to other documents and approaches published on this subject, the WHO approach is unique because it looks at this issue from a public health angle. As this is a multi-stakeholder issue, policy measures have been proposed by different sectors, including governments, security, academic and private sectors. This guidance, its biorisk framework and its self-assessment tool however only discuss measures based on and supporting public health. Moreover, this document looks at life sciences activities in general and does not focus on a particular field of life sciences. In addition, it takes a country-based approach, noting that over time, comparison and sharing of experiences and best practices of country and institutional approaches can be done at regional and global levels in order to support international cooperation and ensure that no incompatible measures are put forward.

The document and its approach are also to be understood within the context of the World Health Assembly in 2002 (Resolution WHA55.16). As recognized by resolution WHA55.16, one of the most effective ways to prepare for deliberately caused disease is to strengthen public health measures to address naturally occurring and accidentally occurring diseases. While recognizing the important role of other actors, such as the security[1] and academic communities, this guidance has a public health objective and the conceptual framework and measures proposed re-emphasize the WHA55.16 approach.

This guidance has also been developed within the wider context of the "biorisk spectrum" in that it advocates an all-encompassing risk management approach, in accordance with WHA55.16. The continuum of potential natural, accidental or deliberate exposure of humans, animals and/or plants to

[1] See the 1975 Biological Weapons Convention and the United Nations Security Council 1540.

**Figure 1. The biorisk spectrum and biorisk reduction measures**




pathogens or toxins likely to harm public health encompasses the full spectrum of biological risks to global health security (see **Figure 1**) (*2*). Such risks include, for instance, new infectious diseases such as the pandemic influenza A (H1N1) 2009 virus, avian influenza (H5N1) and severe acute respiratory syndrome (SARS), re-emerging diseases and modified strains of long-established diseases (e.g. multi- and extensively drug resistant tuberculosis), laboratory accidents, the unintended consequences of research, lack of awareness, negligence, and the deliberate misuse of life sciences research.

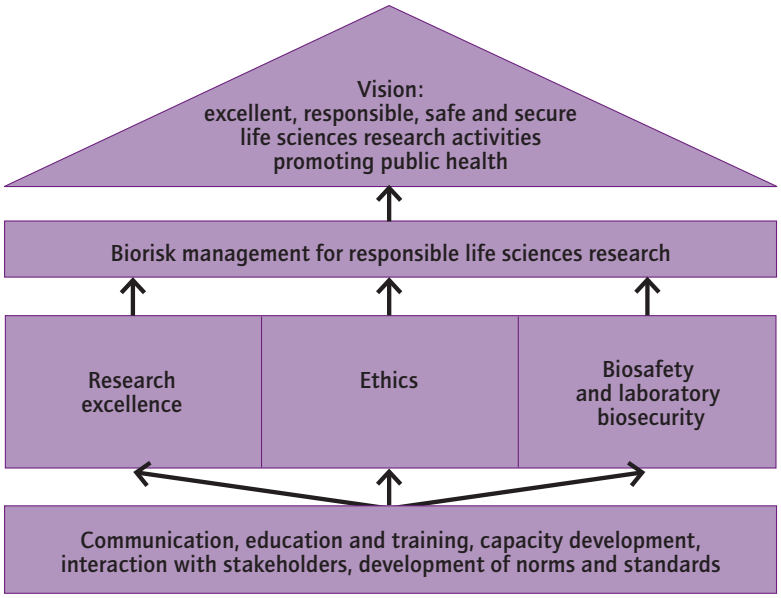
In this guidance, the term "biorisk reduction" is defined as the reduction of the occurrence of risks associated with exposure to biological agents and toxins, whatever their origin or source. Different levels of risk can be assigned across the biorisk spectrum, according to a country's situation or institutional contexts (*2*). Measures put forward using this approach will both help to address the consequences of naturally occurring diseases and reduce the likelihood of accidents or the deliberate misuse of life sciences research.

Responsible life sciences research that is conducted ethically by well-trained professionals in laboratories that have safety and security measures in place, constitutes one public health component of biorisk reduction. Other complementary public health measures that are an integral part of biorisk reduction, but which are not detailed in this guidance, include prevention, early detection, diagnosis and treatment of naturally occurring diseases, disease surveillance, preparedness and outbreak response, compliance with the International Health Regulations (2005),[1] and laboratory biorisk management through biosafety and laboratory biosecurity.

This guidance document focuses on one measure of biorisk reduction, namely the biorisk management framework for responsible life sciences research (see **Figure 2**). The framework focuses on a vision of promoting excellent, high-quality, responsible, safe and secure research, where the results of the research foster advancements in health, economic development, global health security, evidence-informed policy-making, and public trust in science. Underpinning this vision is the importance of managing risks posed by accidents and the deliberate misuse of life sciences research activities through an integrated approach that recommends investing in capacities in three pillars supporting public health: research excellence, ethics, and biosafety and laboratory biosecurity (each pillar is discussed in detail in **Section 3**). At the foundation are several cross-cutting elements: communication, education and training, capacity development, interaction with stakeholders (scientists, publishers and editors, ethicists, national academies of sciences, security communities, gov-

[1] For additional information on the International Health Regulations (http://www.who.int/ihr/en/, accessed October 2010). See also (*9*).

Figure 2. Biorisk management framework for responsible life sciences research




ernments and international organizations), and the development of norms and standards. A self-assessment questionnaire has also been developed and is presented in Section 4 to help countries and institutions assess their strengths and weaknesses and to support implementation of the biorisk management framework. The self-assessment questionnaire is not a tool to evaluate the adequacy of the measures developed by other sectors (security, academia, publishers and editors, etc.) but it recognizes the importance of collaboration between different sectors.

## 1.2 Methodology

A review of the available evidence of the risks and of the policies put forward to manage those risks (see Section 2) has been made by doing a literature review of a variety of different documents. These included peer reviewed journals, background documents, meeting reports, codes of conducts, laws, information shared at international meetings and provided by countries. Most of this information has been collected over the past four years and builds up on previous WHO publications.

Section 3 builds upon the evidence collected in Section 2 and develops a conceptual framework, which was has been presented and discussed at several international meetings. This framework recognizes that "one size does not fit all", and neither should it; that the uniqueness of countries and their specific needs should be identified and met, and that each country would have its own vision on where it wishes to go and how to get there. At the same time, it has to be understood, that in the national and global interest, certain essential standards of the pursuit of science and of scientific research need to be in place: these are the three pillars (research excellence, ethics and biosafety and laboratory biosecurity) and to help evaluating those essential standards, a self-assessment questionnaire has been developed in Section 4 of this guidance.

A first draft document was commented in April/May 2009 by the Guidelines review group. The Guidelines review group workshop on responsible life sciences research was held in Geneva, 22–24 June 2009 to review the content of the document and its implementation (Annexes 2 and 3). The workshop re-emphasizes the importance of the document and its approach. Sections of this guidance have also been reviewed internally with colleagues working on research policy, ethics and on biosafety and laboratory biosecurity (Annex 1).

After the tenure of the Guidelines review group workshop, comments were accommodated and the document was edited. This second draft was sent for peer review in December 2009/January 2010 (Annex 1).

A pilot test of the self-assessment questionnaire presented in Section 4 was conducted in October 2009 with a small group of scientists at the National Institute of Communicable Diseases (NICD), South Africa. It helped to strengthen and refine some of the questions and assess the type of information and results that could be expected from such a questionnaire. Additional pilot tests of the questionnaire will be performed, as appropriate.

As the issues raised in this document are evolving, modifications to this guidance will be made as additional evidence becomes available. This guidance will be reviewed two years after its publication.

### 1.2.1 Terminology

Although the use of the word "biosecurity" is increasing, no universally agreed definition has emerged. As is the case with biosafety, different sectors are using the same word with different

meanings, which in turn may lead to some confusion (*30–32*). Biosecurity was initially used in reference to animal and plant health;[1] more recently, it has been used by public health, academic (*33*), policy and security communities.[2] This guidance uses the WHO concept of "laboratory biosecurity", which is an extension and a complementary dimension of laboratory biosafety (*1*)[3] (see **Section 3.3**). In other words, by implementing good laboratory biosafety practices, laboratories are already implementing some of the requirements of laboratory biosecurity.

There is a similar lack of agreement around the concept of "dual-use research". Several definitions have been put forward, but there is no commonly agreed understanding as to what constitutes dual-use research.[4] Some also argue that the dual-use label is misleading and may cause confusion in regard to certain types of research that nevertheless need to be undertaken for public health. For the purpose of this guidance, dual-use research is understood as knowledge and technologies generated by legitimate life sciences research that may be appropriated for illegitimate intentions and applications. This working definition has to be understood within WHA55.16, whose language has the advantage of focusing more on the action and less on the definition.

This document will refer to the "potential risks posed by accidents or the deliberate misuse of life sciences research". In this guidance, the words "accidents" (or research accidents) reflects the fact that research activities may unexpectedly pose some risks via "accidental" discoveries (such as the mousepox experiment, see **Box 1**). Under this approach, dual-use research can both be associated with "accidents" and risks caused by "deliberate" misuse. This guidance is not specifically concerned with "laboratory accidents", as this important area of work is already being covered by the WHO laboratory biosafety manual (*3*).

## 1.3 Structure of the guidance

This document is organized into four sections. This section provides an overview of the guidance, describing the context, purpose, audience, scope and methodology.

**Section 2** reviews cases of life sciences research that have raised concerns over the past few years and examines the policy options that have been put forward by different stakeholders to address these concerns.

Building on this, **Section 3** describes the three pillars of the guidance's biorisk management framework for responsible life sciences research: research excellence, ethics, and biosafety and laboratory biosecurity. It also shows how the pillars respond to several key issues raised in **Section 2** and how investing in these areas is complementary and self-reinforcing for public health.

**Section 4** presents the main steps for carrying out a self-assessment of national and institutional biorisk management capacity. It includes a questionnaire, which assesses elements of the three pillars, and can be used to inform a tailored approach to implementing the biorisk management framework, adapted to each country's circumstances and needs.

[1] For animal health, biosecurity refers to good hygiene practices that help prevent the emergence and spread of animal diseases. For plant health, biosecurity refers to controls to protect plants against different types of pests but also against animals or practices that could have adverse effects on plants. The Food and Agriculture Organization (FAO) considers biosecurity to be a "strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) that analyse and manage risks in the sectors of food safety, animal life and health, and plant life and health, including associated environmental risk." Biosecurity for agriculture and food production (http://www.fao.org/biosecurity/, accessed October 2010), (http://www.fao.org/ag/agn/agns/meetings_consultations_2003_en.asp,accessed October 2010) and (*34*).

[2] States Parties to the Biological Weapons Convention have also noted their common understanding on "biosafety "and "biosecurity" within the context of the Convention (*35*).

[3] The Organisation for Economic Co-operation and Development (OECD) has also developed best practices guidelines for their Biological Resources Centres (BRCs). OECD refers to biosecurity as the "institutional and personal security measures and procedures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens, or parts of them, and toxin-producing organisms, as well as such toxins that are held, transferred and/or supplied by BRCs". While the OECD and WHO definitions are relatively similar, they differ in their approach because the OECD does not link laboratory biosafety to laboratory biosecurity measures (*36*).

[4] For definitions of dual use, see for instance (*5*, *15*, *37*).

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# International organisations and their role in helping to protect the worldwide community against natural and intentional biological disasters

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**Summary**

Preventing the spread of disease through international movements is one of the key objectives of the World Organisation for Animal Health (OIE). One of the ways it seeks to achieve this is by publishing international standards and guidelines aimed at, *inter alia*, preventing the importation of pathogens that are dangerous for animals and humans and strengthening Veterinary Services so that they can improve their surveillance and response systems. The OIE works in close partnership with the Food and Agriculture Organization of the United Nations (FAO), and together the two organisations have developed a joint initiative – the Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs). Member Countries of these organisations could increase their capacity to manage the risks of disease occurrences, whether natural or deliberately introduced, if they would all strictly implement existing OIE international standards. Compliance with these standards greatly depends on the political willingness of national policy-makers and on a successful transfer of resources to developing countries in support of good governance and appropriate policy implementation. A United Nations Resolution obliging its Member Countries to implement OIE standards could prove invaluable in this respect.

**Keywords**

Agreement on the Application of Sanitary and Phytosanitary Measures – Food and Agriculture Organization of the United Nations – Global Framework for the Progressive Control of Transboundary Animal Diseases – International standard – Surveillance – Transparency – Veterinary Services – World Organisation for Animal Health.

## Introduction

Preventing the spread of animal diseases and zoonoses through international movements is one of the key objectives of both the World Organisation for Animal Health (OIE) and the Food and Agriculture Organization of the United Nations (FAO). The OIE seeks to accomplish this by establishing international standards and guidelines aimed at preventing the importation of pathogens that are dangerous for animals and humans (while avoiding unjustified sanitary barriers) and through the surveillance, notification and control of diseases.

The OIE was founded in 1924, well before the creation of the United Nations. Initially, 28 countries united with a mandate to share information on animal disease outbreaks to allow Member Countries to take the appropriate control measures to protect themselves and to prevent further spread of the disease. There are now 167 OIE Member Countries. Providing a mechanism for prompt reporting of

disease outbreaks/occurrences is still one of the primary roles of the OIE, but the organisation is also recognised as the international standard-setting agency in the area of animal health. OIE standards include:

– procedures for surveillance and prompt reporting of outbreaks of animal diseases and zoonoses

– requirements to be met by Veterinary Services for surveillance, notification, early warning and response, and the chain of command

– requirements that should be met for a country or zone to be defined as free from certain infectious animal diseases and zoonoses

– recommendations for the safe importation of animals, animal products, semen, and embryos

– procedures for the inactivation of infectious agents

– the general provisions that countries should meet to reduce the risk of the spread of infectious animal diseases and zoonoses, including standards on the quality of national Veterinary Services.

These standards are included in various OIE publications, such as the *Terrestrial Animal Health Code (Terrestrial Code)*, the *Aquatic Animal Health Code (Aquatic Code)*, the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual* [3]) and the *Manual of Diagnostic Tests for Aquatic Animals* (the *Aquatic Manual* [2]), the contents of which will be described in more detail later.

The FAO is one of the largest of the specialised United Nations Agencies, the mission of which is to develop agriculture, animal production, fisheries and forestry. In the field of animal production, the FAO Animal Health Service focuses its activities on assisting developing country members to control infectious and parasitic diseases, and to prevent their spread to other countries or regions. Livestock are important in supporting the livelihoods of poor livestock keepers, consumers, traders, and labourers throughout the developing world. Diseases affecting livestock can have a significant impact on animal productivity and production, on trade in live animals, meat and other animal products, on human health (through diseases transmissible from animals to humans), and, consequently, on the overall process of economic development. The activities of the FAO Animal Health Service include the provision of relevant and up-to-date information on:

– selected animal and zoonotic diseases

– the means of, and basic requirements for, the control and management of major animal diseases

– the increasingly important area of safeguarding humans from diseases originating from livestock and/or transmitted through the consumption of animal products.

More recently, the OIE and FAO have been strongly committed to convincing national policy-makers and international donors that the cost of strengthening Veterinary Services so that they can provide better surveillance, early warning systems and management of epizootics, including zoonoses, is negligible compared with the economic losses resulting from the accidental or intentional introduction of infectious animal diseases and zoonoses.

This paper briefly describes the shared objectives of the two organisations before discussing the systems they have in place to achieve these aims and providing details of the standard-setting work of the OIE.

# Common objectives of the OIE and the FAO

The OIE and FAO have certain key objectives in their work for the prevention and control of infectious animal diseases and zoonoses; these main areas of activity are discussed below.

## Transparency in the animal disease situation worldwide

Each OIE Member Country is committed to providing reports to the OIE Animal Health Information Department on its health status regarding significant animal diseases and diseases transmissible to humans; the OIE then disseminates the information to all Member Countries to enable them to take appropriate action and to protect themselves. The FAO stipulates that notification to the OIE is obligatory and provides tools for data capture and reporting. Non-member countries are encouraged to report.

## Collection, analysis and dissemination of veterinary scientific information

Using the FAO network and its own network of internationally recognised scientists, Collaborating Centres and Reference Laboratories, the OIE collects, analyses and publishes the latest scientific information on the control and prevention of important animal diseases, including those transmissible to humans. The FAO serves as a source of expert advice to OIE groups and committees.

## Strengthening of international coordination and cooperation in the control of animal diseases

The FAO implements and/or contributes to the implementation of country or regional projects and

programmes to prevent and control animal diseases by strengthening capacities and emergency preparedness for disease detection, analysis, and reaction. With OIE support, the FAO provides technical expertise to Member Countries (particularly developing countries) requesting assistance with animal disease control and eradication programmes. These activities are performed in coordination with other regional and international organisations, donor countries, and agencies responsible for supporting and funding the control of infectious animal diseases and zoonoses.

### World trade in animals and animal products: protecting animal and human health while avoiding unjustified sanitary barriers

The OIE develops standards for use by its Member Countries to enable them to protect themselves against disease incursions as a result of trade in animals and animal products, while avoiding unjustified sanitary barriers. These standards are developed by experts from the Member Countries and from the OIE network of 170 Collaborating Centres and Reference Laboratories and in collaboration with FAO and FAO/IAEA (International Atomic Energy Agency) Joint Division experts.

In 1995 the standards developed by the OIE were recognised by the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization (WTO). In order to harmonise SPS measures and remove unjustifiable sanitary restrictions to international trade, the Agreement states that Governments should use these international standards, guidelines and recommendations. Its goal is to minimise the risk of importing pathogens and to remove unjustified restrictions to international trade. The Agreement states that while it is the sovereign right of a country to provide an appropriate level of animal and public health protection at its borders, this right is not to be misused for protectionist purposes. An importing country can only apply sanitary measures to imports if a similar level of protection is applied internally and to all imports. Members Countries may introduce standards providing a higher level of protection than that provided by the OIE standards if there is a scientific justification, but these standards must be based on science-based risk analysis.

The FAO is in charge of assisting its Member Countries, particularly the developing countries, to implement international animal health standards. It has undertaken several studies on the cost of complying with the standards established by world bodies and has developed mid- and long-term policy options that countries can use to implement such standards. Moreover, the FAO is committed to developing a systems approach, through national capacity building and performance indicators, to assist countries to attain compliance and improve trade opportunities.

## Towards greater transparency in the animal health situation worldwide

The OIE is the worldwide observatory for animal health. It is supported in this mandate by the FAO. Its key mission is to keep national Veterinary Services and international organisations informed of the appearance and course of epizootics in any country in the world that represent a threat to animal or public health (zoonoses). The system is based on official animal disease information reports that the Veterinary Services of Member Countries have an obligation to submit to the OIE. The use of standard reporting forms ensures that the system is fed with the required data in a standardised format. The strength of the OIE Animal Disease Information System is its 'legal' basis as defined in Chapters 1.1.2 and 1.1.3 of the OIE *Terrestrial Code* and in Chapters 1.1.3 and 1.2.1 of the OIE *Aquatic Code* (6, 7).

The OIE Animal Health Information System has procedures for gathering weekly, annual and biannual animal health data from around the world (the International Monitoring System) and procedures for collecting more urgent information (the International Early Warning System). The International Early Warning System consists of an alert procedure to warn of exceptional epidemiological events (natural or intentional) occurring in Member Countries. Information is aimed at decision-makers and other stakeholders to enable them to take necessary preventive measures. Under this system, the occurrence of a disease, including zoonoses, or any exceptional epidemiological event must be reported as soon as possible (within 24 hours) to the OIE Central Bureau, which then quickly redistributes the information through a variety of channels. Follow-up reports are provided weekly to allow end-users to follow the epidemiological situation as it develops.

To improve the transparency of animal health information, the OIE is also working with the FAO to develop a verification procedure for non-official information from various sources on the existence of disease outbreaks that have not yet been officially notified to the OIE. These processes use different sources of information such as diagnostic results from OIE or FAO Reference Laboratories, scientific papers, field projects, newspapers, the internet, Global Public Health Intelligence (GPHIN), and ProMed.

In addition, in order to improve the control of highly contagious diseases, the FAO and OIE have recently developed a new initiative: the Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs), which is based on a regional approach to animal disease control. The GF-TADs will improve both the quality and quantity of disease information and epidemiological intelligence. An integral aspect of the GF-TADs programme is the Global Early Warning System (GLEWS), which is due to be developed jointly by the FAO, the OIE and the World Health Organization (WHO) as an instrument to assist stakeholders and the international community to predict and prevent livestock animal disease threats through epidemiological analysis and the integration of additional factors that may have an impact on the occurrence and spread of such diseases (e.g. economic factors, civil unrest, climatic changes). The success of this initiative will rely heavily on the sharing of information on animal health and zoonoses in humans among the three organisations. Results of disease information tracking systems will be shared and compared for verification purposes. Through its own Animal Disease Information System the OIE will verify information with the Government representatives of the various Member Countries, thus significantly improving the quality of official information. Similarly, the FAO, through projects and activities in its Member Countries, will also verify the reliability of information and work towards improving transparency. The WHO will also share information gathered by its Global Alert and Response Team and other parties working in the area of zoonotic diseases and veterinary public health.

The expected activities of the GLEWS can be summarised as follows:

– use of designated OIE/FAO Collaborating Centres/Reference Laboratories for specific analysis and modelling trends;

– dissemination of information that complements the OIE Information System;

– dissemination of early warning messages that concentrate on predicting livestock animal disease threats through epidemiological analysis and the integration of additional factors that may have an impact on the occurrence and spread of such diseases;

– design of control strategies;

– development of coordinated responses to animal health and zoonotic emergencies. If consultation among the OIE and FAO shows that an onsite assessment of the situation would be valuable, an urgent field mission may be considered, in consultation with the WHO when relevant. This joint mission would engage the country authorities, especially those of the Ministries of Health and of Agriculture, to obtain a better appreciation of the situation and offer assistance in the formulation of urgent intervention strategies. The joint mission experts would be responsible for briefing supervisors and suggesting a course of action.

While every effort is being made to improve the OIE Animal Health Information System, the major difficulty encountered, as with any international activity, is the quality of the information received, especially information from countries where the Veterinary Services do not comply with OIE standards and do not have adequate resources (e.g. lack of trained veterinarians and epidemiologists, poor equipment and laboratory facilities, inadequate involvement of farmers and other stakeholders in national surveillance systems, and absence of disease control programmes and emergency preparedness plans). In such countries, potentially dangerous situations might go unnoticed or not be dealt with promptly, thereby increasing the risk of disease spreading to other countries.

The OIE has a limited source of emergency funds for use in rapidly assisting Member Countries faced with exceptional epidemiological situations. Typically, these funds are used to immediately send experts from OIE Reference Laboratories or Collaborating Centres to assess the epidemiological situation in the field, and advise national authorities and other international organisations.

The FAO has a well-defined mandate to provide assistance to countries in the field of animal health. One of the key tools it uses to achieve this is its Emergency Prevention System-Livestock (EMPRES-Livestock) programme, which became fully operational in 1994. This system promotes the containment and control of the most serious epizootic diseases of livestock (transboundary animal diseases – TADs), and their progressive elimination on a regional and ultimately a global basis, through international cooperation, involving early warning, early reaction, research, and coordination. EMPRES capitalises on the information provided by the Global Livestock Production and Health Atlas (GLiPHA: www.fao.org/ag/againfo/resources/en/glipha/default.html), which depicts animal population densities, production systems, soil use, and other quantitative information that aids in disease intelligence, ecological understanding, and the development of intervention measures. The EMPRES-Livestock programme focuses on the major epizootic diseases – rinderpest, avian influenza, contagious bovine pleuropneumonia, foot and mouth disease, peste des petits ruminants, Rift Valley fever, Newcastle disease, lumpy skin disease, classical swine fever, and African swine fever. Early warning messages with trend analyses and the potential implications of the disease are posted on the web and distributed via the EMPRES-Livestock mailing list. EMPRES provides training assistance to national epidemiologists and advises on the development of surveillance programmes in the least developed countries.

In the event of a disease emergency and at the request of an FAO Member Country EMPRES can intervene to assist in combating diseases through the FAO's Technical Cooperation Division. Currently, technical cooperation projects (TCPs) are ongoing in over 40 countries, some with regional approaches to disease surveillance and control. While efforts are being made to build capacities in some least-advanced countries, what has been achieved so far has to be further strengthened to better respond to the real needs of many countries, e.g. the need for assistance in improving their national surveillance and monitoring systems and in bringing their contingency plans up to an acceptable level. Furthermore, the available resources must be dramatically increased for tackling emergency situations and to avoid the spread of TADs to other countries.

The warning system operated by the OIE Central Bureau allows Member Countries to react rapidly if the need arises. Member Countries must report any of the following incidents to the OIE Central Bureau within 24 hours:

– the first outbreak of an OIE listed disease

– the re-occurrence of a listed disease following a report declaring that the outbreak has ended

– the first occurrence of a new strain of a pathogen

– the sudden and unexpected increase in the distribution, incidence, morbidity or mortality of a disease prevalent within the country

– an emerging disease with significant morbidity and mortality or zoonotic potential

– evidence of change in the epidemiology of a listed disease (including host range, pathogenicity, strain).

This information is immediately relayed to the other Member Countries as follows:

– by fax or e-mail to countries directly threatened

– through the weekly publication *Disease Information*, available on the OIE website or by mail using the OIE distribution list.

Subsequent to any of the above notifications, Member Countries should send weekly reports by fax or e-mail to provide further information on the evolution of the incident that justified urgent notification.

The FAO obtains additional information from its networks: extensive field activities, Reference Laboratories, rumour-tracking (e.g. GPHIN, ProMed). This information and the resulting analyses are communicated to Member Countries and the OIE either directly or through various channels (FAO-AGA website, EMPRES Bulletin, etc.). As previously mentioned in the above discussion of the GLEWS, a cooperative approach to the information systems is currently being developed between the OIE, FAO and WHO.

These warning systems will provide an improved worldwide surveillance network for the early detection and rapid reporting of any suspicious disease occurrence that is natural or could have its origin in an act of agroterrorism/bioterrorism, i.e. an intentional introduction of pathogens.

Through the International Early Warning System all OIE Member Countries receive alert messages on disease outbreaks, or suspicion thereof, via fax or e-mail. In addition, the OIE annual publication entitled *World Animal Health* provides a wide variety of information on the animal health situation worldwide and reports on the disease control methods Member Countries apply. A selection of all this information is integrated into the World Animal Health Information Database (WAHID) – a regularly updated computerised database available on the OIE website (www.oie.int).

Scientific information is disseminated through other publications, including the OIE *Scientific and Technical Review* (and similar FAO publications), which contains research articles and guidelines of the very highest standard for animal disease control. The FAO also publishes manuals on specific disease recognition, guides on contingency planning, participatory approaches to epidemiology, and booklets on sample collection and submission.

By collecting, processing and disseminating data on animal diseases throughout the world, the OIE and FAO endeavour to ensure transparency in the animal health situation worldwide for the benefit of its Member Countries. The information thus generated is essential for the success of national and regional disease control programmes, for reducing the health risks arising from international movements, and for the early detection of disease attributable to the escape or deliberate introduction of pathogens from acts of bioterrorism.

## Towards improved health safeguards in international trade

The smooth flow of animals and animal products requires:

– the development and adoption by the international community of animal health standards aimed at avoiding the risk of importing and spreading diseases and pathogens transmissible to animals and humans

– the harmonisation, strict implementation, and greater transparency of national animal health regulations applicable to trade in animals and their products so as to avoid unjustified sanitary barriers.

## OIE Standards

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures advocates the use of standards developed under the auspices of the OIE. Various normative works, approved by the OIE International Committee (the OIE's highest authority; every Member Country is represented), are designed to promote the harmonisation of regulations applicable to trade and animal disease control, these are:

– the *Terrestrial Code*

– the *Aquatic Code*

– the *Terrestrial Manual*

– the *Aquatic Manual*.

The *Terrestrial Code* for mammals, birds and bees is developed by the Terrestrial Animal Health Standards Commission, and the *Aquatic Code* is developed by the Aquatic Animal Health Standards Commission (see section entitled Specialist Commissions). The *Codes* contain the requirements for the international movement of animals and animal products and also provide guidelines for disease reporting (see chapters 1.1.2 and 1.1.3 of the *Terrestrial Code* and chapters 1.1.3 and 1.2.1 of the *Aquatic Code* [6, 7]). Both these publications are updated annually and are available in paper and electronic versions (www.oie.int).

The *Terrestrial Manual*, developed by the Biological Standards Commission, and the *Aquatic Manual*, developed by the Aquatic Animal Health Standards Commission, presents standard methods for diagnostic tests and vaccine production to be applied notably in the context of international trade and national animal disease control programmes. Both texts constitute the reference standards for the international harmonisation of the diagnosis of animal diseases and vaccine control; they also contain specific chapters on the following topics:

– sampling methods

– the packaging and transport of samples

– quality management and the biosecurity of veterinary laboratories

– tests for sterility and freedom from contaminants

– human safety in the veterinary microbiology laboratory

– veterinary vaccine production

– disinfection and inactivation procedures

– laboratory methodologies for bacterial antimicrobial susceptibility testing.

In addition to the standards that appear in the *Manuals* the OIE publication *Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases* (1) describes standards for the management and biosecurity of laboratories conducting tests for infectious diseases. It contains technical requirements for these laboratories and includes specific details with respect to test method validation, reference reagents, and laboratory proficiency testing.

The FAO plays a prominent role in providing expertise to the OIE and assisting countries to meet OIE standards through various activities such as national expert capacity building, field projects, and the transfer of technologies and expertise.

## OIE activities

As well as publishing standards and disseminating disease information reported by Member Countries, the OIE now takes a proactive approach to disease reporting and will also report information on confirmed positive results provided by OIE Reference Laboratories (4) or from unofficial sources, such as scientific publications, ProMed and lay publications, after the information has been verified by the Member Country.

In addition to reporting disease occurrence the OIE, through the work of the Scientific Commission for Animal Diseases, develops and updates lists of countries recognised as being free from some serious diseases, most notably foot and mouth disease, bovine spongiform encephalopathy, rinderpest and contagious bovine pleuropneumonia. These lists make a substantial contribution to the health security of international movements.

# Towards objective and impartial expertise in animal health

The International Agreement of 25 January 1924 establishing the OIE made it responsible for promoting and co-ordinating research on the surveillance and control of animal diseases throughout the world. This objective has been attained by the creation of a worldwide animal health network, involving the establishment of Specialist Commissions and Working Groups, the designation of Collaborating Centres and Reference Laboratories, the

organisation of meetings of experts and the continuing publication of scientific articles.

## Specialist Commissions

The four Specialist Commissions study problems of animal disease surveillance and control and questions relating to the harmonisation of international regulations. Members are elected by the representatives of all OIE Member Countries (the International Committee).

The Terrestrial Animal Health Standards Commission contributes to the development, in collaboration with other Specialist Commissions, of the generic and specific chapters in the *Terrestrial Code*. In addition, it promotes the adoption by the International Committee of standards on animal health (including zoonoses), animal welfare, and animal production food safety. It also promotes harmonised surveillance methods and disease control regulations and proposes guidelines and recommendations concerning the trade or international movement of mammals, birds and bees and their products.

The Scientific Commission for Animal Diseases contributes to the development of better strategies and methods for animal disease surveillance and control. The Commission convenes groups of specialists of the highest standard, particularly in the event of an animal health emergency, to verify or evaluate the status of Member Countries in terms of specific animal diseases.

The Biological Standards Commission harmonises methods for the diagnosis of animal diseases and the control of biological products, especially vaccines used for veterinary purposes. The Commission coordinates a programme to develop standard reagents aimed at standardising diagnosis.

The Aquatic Animal Health Standards Commission collects all available information on disease control methods for fish, molluscs and crustaceans. The Commission harmonises rules governing trade in aquaculture products and recommends the optimum diagnostic methods. It also organises scientific meetings on these topics.

All the standards proposed by the various specialist Commissions must be approved by the International Committee before publication. All the standards, recommendations and guidelines of the OIE relating to animal health, zoonoses and international trade in animals and animal products are recognised by the WTO.

## OIE Reference Laboratories and Collaborating Centres

These OIE Reference Laboratories and Collaborating Centres, of which there are 170, covering 92 diseases and topics and located in 31 different countries, provide OIE Member Countries with support and scientific advice on all matters relating to the surveillance and control of animal diseases. This support can take many forms, such as the provision of experts (over 150 world-renowned scientists), the preparation and supply of diagnostic kits or standard reagents, and the organisation of seminars, courses, and scientific meetings.

## Working Groups

Three OIE Working Groups are currently active:

– wildlife diseases

– animal welfare

– animal production food safety.

These Working Groups meet to review progress made in their field and to ensure that the information is made available rapidly to all OIE Member Countries. They also contribute to the organisation of scientific meetings, seminars, workshops and training courses.

The OIE Working Group most concerned with biosafety and biosecurity is the Working Group on Wildlife Diseases (WGWD). This Group collects information on wildlife diseases from Member Countries and urges Member Countries to recognise the importance of wild animals as potential reservoirs (and even as possible targets of deliberately introduced biological agents) when planning responses to outbreaks of disease, exotic or otherwise.

The WGWD has determined that relatively few countries have developed plans for responding to any disease incursions that may affect wild animals. In order to assist OIE Member Countries that may wish to undertake such planning, the WGWD will, in the course of the next 3 years, review preparedness and response plans that already may have been prepared. From these plans the Group will identify the essential major components and information requirements for this planning.

National preparedness for the possible incursion of exotic diseases must include both the preparedness of all the relevant public authorities and stakeholders to intervene and the assembly of up-to-date information on the population size, demography and susceptibility of indigenous wild animal species. It should also include the development of feasible procedures for the early recognition and diagnosis of a disease outbreak, the subsequent prevention of disease transmission between wildlife and domestic livestock and the spread of disease within wild animal populations. Effective planning for responses to an exotic disease incursion must accord to wildlife the same degree of attention that is now given

solely to domestic livestock. A national consultative network of wildlife expertise needs to be created and deployed in order to develop a range of techniques that can be used to reduce the risk of transmission of disease from livestock to wildlife (and *vice versa*) in the event of an exotic disease outbreak. These actions will establish the necessary databases, lines of communication and science-based plans to achieve a high level of preparedness to deal with an exotic disease incursion into a national wildlife population.

The OIE Working Group on Animal Production Food Safety, established between the OIE and high level representatives of the Codex Alimentarius Commission, is responsible for hazards to consumers that are likely to occur during animal production (on the farm). This Working Group also covers intentional actions likely to occur on a farm, e.g. the introduction of zoonotic agents.

During the 72nd General Session of the OIE International Committee in 2004, Member Countries recognised that zoonotic diseases are emerging and re-emerging with great frequency. They indicated their overwhelming support for a greater OIE role in confronting the challenges of such zoonoses. They also recognised the need to co-ordinate activities horizontally, among animal and public health officials and organisations, and vertically, through national, State, and local groups. For this purpose a Resolution (Resolution No. XXIX) was adopted during the 72nd General Session which encouraged further consideration of the OIE's thinking and commitment regarding emerging and re-emerging zoonoses; more specifically, it advocated the following:

– active consideration of this issue as part of the development of the fourth OIE strategic plan (2005-2010)

– the creation of an Ad hoc Group on Emerging Diseases which would work closely with members of the Working Group on Wildlife Diseases, the Working Group on Animal Production Food Safety, the Ad hoc Group on Epidemiology, OIE Reference Laboratories and other relevant bodies or experts (5).

There appears to be little possibility of preventing bioterrorist attacks on domestic animals and the subsequent spill-over into wildlife populations. There is also the risk that wildlife could be the initial target of covert bio-attacks and that infection could then spread into contiguous domestic livestock. Consequently, interdisciplinary and international efforts to increase surveillance and identification of disease pathogens and improved mechanisms for interagency and intergovernmental co-operation and collaboration will be necessary to combat the threat of disease agents likely to be used as a bioweapon.

# Conclusions

If they are correctly implemented the tools currently available through the OIE and FAO can do a lot to increase the ability of Member Countries and of the International Community to protect themselves against the threat of a bioterrorist incident. However, such protection depends on the diligence with which Member Countries follow the existing guidelines and recommendations. The livestock development programmes of the FAO Animal Production and Health Division include recommendations on animal production, health and policy, all of which are invaluable in preparing an effective response to a biological disaster. If these recommendations are implemented alongside OIE guidelines the better prepared a country can be. The OIE guidelines and the benefits they bring can be summarised as follows:

– the OIE standards designed to control disease and to prevent the accidental or intentional introduction of pathogens provide a basis for the harmonisation of national legislation

– the OIE guidelines relating to the biosecurity of laboratories (based on expertise provided from researchers in human and animal health), provide advice on the safe management of biological agents used in those laboratories

– the OIE guidelines, standards and recommendations (and EMPRES principles) relating to surveillance and prompt notification of diseases of domestic livestock and wild animals (including zoonoses) encourage transparency of disease information

– the OIE standards on the quality and evaluation of Veterinary Services can be used to improve the quality and efficiency of Member Countries Veterinary Services, thereby guaranteeing increased vigilance in disease monitoring and surveillance. Compliance with these standards leads to improved early warning and early detection systems, thus ensuring a timely and rapid response to any emergency.

It is plain therefore that effective global biosecurity can only be achieved if all OIE and FAO Member Countries conscientiously comply with the standards and guidelines of the OIE, effectively train stakeholders and ensure the availability of adequate human and material veterinary resources.

Many countries share a common concern about the natural occurrence or deliberate misuse of biological pathogens that can affect public health, food and animal production. Existing methods of disease prevention and containment, regulations, international guidelines and standards are being extended at both national and international levels to improve the ability of countries to prevent, manage and recover from natural, accidental or deliberate introduction

of animal diseases. In this regard there are, at present, substantial differences among countries in the perception of national threat from the deliberate use of pathogenic biological agents. However, significant progress would be made if all Member Countries would strictly implement existing OIE international standards. This is dependent on the political willingness of all national policy-makers and the transfer of resources from developed countries to developing countries in order to support good governance and appropriate policies based on the implementation of existing standards. A Resolution on this voted by the United Nations would provide great support in this respect.

# Les organisations internationales et leur contribution à la protection de la communauté mondiale contre les catastrophes biologiques naturelles et d'origine intentionnelle

B. Vallat, J. Pinto & A. Schudel

**Résumé**

L'un des objectifs fondamentaux de l'Organisation mondiale de la santé animale (OIE) consiste à prévenir la propagation des maladies animales via les mouvements internationaux. L'OIE cherche à atteindre cet objectif notamment en publiant des normes internationales et des lignes directrices visant, entre autres, à prévenir l'importation d'agents pathogènes dangereux pour les animaux et pour l'homme et à renforcer les Services vétérinaires pour qu'ils puissent améliorer leurs systèmes de surveillance et d'interventions. L'OIE travaille en partenariat étroit avec l'Organisation des Nations Unies pour l'alimentation et l'agriculture (FAO), et ensemble, les deux organisations ont élaboré un programme commun – le Cadre global pour le contrôle progressif des maladies animales transfrontalières (GF-TADs). Les Pays membres de ces organisations pourraient accroître leur capacité à gérer les risques d'apparition de maladies, tant naturelles qu'introduites délibérément, si tous appliquaient rigoureusement les normes internationales de l'OIE existantes. Le respect de ces normes dépend en grande partie de la volonté politique des décideurs nationaux et du transfert probant des ressources en faveur des pays en développement à l'appui de la bonne gouvernance et de la mise en œuvre des politiques appropriées. Une résolution des Nations Unies obligeant ses Pays membres à appliquer les normes de l'OIE serait extrêmement utile à cet égard.

**Mots-clés**

Accord sur l'application des mesures sanitaires et phytosanitaires – Cadre mondial pour le contrôle progressif des maladies animales transfrontalières – Norme internationale – Organisation mondiale de la santé animale – Organisation des Nations Unies pour l'alimentation et l'agriculture – Service vétérinaire – Surveillance – Transparence.

# Las organizaciones internacionales y su influencia en la protección de la comunidad internacional contra desastres biológicos de origen natural o intencionado

B. Vallat, J. Pinto & A. Schudel

**Resumen**

Uno de los objetivos básicos de la OIE (Organización Mundial de Sanidad Animal) se cifra en impedir la propagación de enfermedades a consecuencia del movimiento internacional de animales y productos de origen animal. Uno de los métodos que utiliza para ello es la publicación de normas y directrices internacionales destinadas, entre otras cosas, a prevenir la importación de patógenos peligrosos para el hombre y los animales y a fortalecer los Servicios Veterinarios ayudándolos a mejorar sus sistemas de vigilancia y respuesta. La OIE colabora estrechamente con la Organización de las Naciones Unidas para la Agricultura y la Alimentación (FAO), y ambos organismos han puesto en marcha una iniciativa conjunta denominada Programa Global para el Control Progresivo de las Enfermedades Transfronterizas de los Animales (GF-TADs). Si todos los países miembros de ambas organizaciones aplicaran estrictamente las normas internacionales vigentes de la OIE, mejorarían su capacidad para manejar el riesgo de enfermedades, debidas a causas naturales o a actos intencionados. El cumplimiento de esas normas depende en gran medida de la voluntad de los responsables políticos nacionales y de la eficaz transferencia de recursos a los países en desarrollo para apoyar la buena gobernanza y la correcta aplicación de las políticas. En este sentido, una resolución de las Naciones Unidas por la que se obligara a los Estados Miembros a aplicar las normas de la OIE podría resultar de gran ayuda.

**Palabras clave**

Acuerdo sobre las Medidas Sanitarias y Fitosanitarias – Norma internacional – Organización Mundial de Sanidad Animal – Organización de las Naciones Unidas para la Agricultura y la Alimentación – Programa Global para el Control Progresivo de las Enfermedades Transfronterizas de los Animales – Servicio Veterinario – Transparencia – Vigilancia.

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