BIOSAFETY, BIOSECURITY and BIOWEAPONS

Three Agreements on Biotechnology, Health and the Environment, and Their Potential Contributions to Biological Weapons Control

the sunshine project

TWN
THIRD WORLD NETWORK

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the sunshine project

Many biological weapons are rapidly destroyed by bright sunlight. The **Sunshine Project** works to bring facts about biological weapons to light! It is an international non-profit organization with offices in Hamburg, Germany and Austin, Texas, USA. It works against the hostile use of biotechnology in the post-Cold War era. Through its research and publications it seeks to strengthen the global consensus against biological warfare and to ensure that international treaties effectively prevent development and use of biological weapons.

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TWN

Third World Network

Third World Network (TWN) is a network of groups and individuals involved in bringing about a greater articulation of the needs and aspirations and rights of people in the Third World and in promoting a fair distribution of world resources and forms of development which are humane, in harmony with nature, and which fulfills people's needs.

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Contents

1 Introduction

This paper introduces and discusses the provisions of three international agreements related to controlling disease and managing biotechnology risks to protect health and the environment. These are the Cartagena Biosafety Protocol (CBP), the International Plant Protection Convention (IPPC), and the Office International de Epizooties (OIE).[1]

This paper relates these agreements to the Biological Weapons Convention (BWC) and discusses how they can contribute to the prevention of hostile use of biology. The agreements discussed in this paper address issues of biosecurity and biosafety, broadly conceived. They are critical elements of a global biosecurity framework.

Other multilateral activities of relevance to the BWC, for example, the World Health Organization's global health response to the deliberate use of biological weapons, are also treated. They are, however, discussed in lesser detail because the BWC relevance of the OIE and, especially, the CBP and IPPC have been insufficiently discussed, despite the fact that the contribution of these agreements is routinely (but vaguely) mentioned in arms control debate and discussed by States Parties in meetings of the BWC.[2]

A closer look at these agreements is also merited because of the currently poor prospects for progress at the BWC itself. Following the 2001 collapse of negotiations for the BWC Verification Protocol, States Parties agreed to a series of annual and experts' meetings in the lead up to its Sixth Review Conference in 2006.

However, a combination of sensitivities resulting from the failed Protocol, plus the narrow scope of meetings, and resignation before the highly uncooperative stance of the US currently limit the possibility that the meetings will result in binding multilateral measures to strengthen the BWC.

The agreements discussed here also merit more profound consideration because of their critical role in the international regulation of biotechnology. Biological weapons risks posed by the development and dissemination of biotechnology are nearly universally recognized. Yet there is presently very little prospect of reining in these risks through the BWC, whose parties generally recognize the dangers of biotechnology but have been unable to adequately respond.

In contrast, the CBP is the first international agreement specifically developed to address biotechnology risks — to the environment, agriculture, animal and human health — and it possesses a vibrant process. The CBP and the IPPC and OIE are presently developing and implementing enforceable international rules and standards to contain threats, limit harm, and impose liability for damages resulting from biotechnology. These provide opportunities and synergies to strengthen the global ban on biological weapons.

This paper provides a background and a summary of critical provisions of each of the three agreements, indicating actions that can be taken to address biological weapons risks. It also discusses the need for addressing biosecurity and biosafety in a comprehensive framework, and concludes by discussing the need for a binding international instrument on biocontainment facilities.

2 Biosecurity and Biosafety: Two Words, Many Concepts, One Framework

The term "biosafety" shifts in meaning in the diplomatic and scientific context. Its two major usages relates to laboratory containment and to biotechnology hazards.

"Biosecurity" is a closely related term increasingly heard in arms control and in health and agriculture, but which also lacks a consistent usage. In animal health, it sometimes refers to preventative disease management. In Australia and New Zealand, it often refers to invasive alien species, while in the US it is increasingly used in reference to anti-terrorism measures related to agriculture ("farm security"). Still others use biosecurity to refer to access to a safe and appropriate food supply.

Biosafety, as it arose in microbiology, is shorthand for "safety in biological containment". In other biosciences and policy related to genetically modified organisms (GMOs), the term appeared as a contraction of "safety in biotechnology", most often, but not exclusively, in reference to release of GMOs into the open environment. Overlap between the usages has become apparent, and "laboratory biosafety" is now often used to refer to the subset of safety issues specifically related to containment, be it of pathogens, GMOs, or GMO-pathogens.

Confusion about meanings of biosafety and biosecurity in English deepens in translation. The logical translation of biosecurity into Spanish, French, and other Romance languages is the same word as that used for biosafety (*bioseguridad* in Spanish, *biosécurité* in French).

Translators at the UN Food and Agriculture Organization (FAO) were unable to come up with a word for biosecurity in Chinese.[3] Then again, the term did not exist in English until it was coined in independent instances to refer to different aspects of human and environmental safety from biological threats.

We submit that there is little need, conceptually, to differentiate between biosafety and biosecurity and that some meanings of both terms sometimes utilized in arms control[4] are counterproductive because they are too restrictive.

Whether at the BWC, in health, in the laboratory, or in sanitary measures, security and safety are largely synonymous, and in the field or in containment, many of the measures that apply to potentially dangerous pathogens also apply to GMOs (and their products) and, of course, pathogens that are GMOs.

On a very practical level, there may be differences between means to prevent an unintended release into the environment (sometimes referred to as "biosafety") and means to prevent abuse or theft (sometimes referred to as "biosecurity"). But conceptually, legally, and in terms of organization and implementation, there are broad overlapping areas.

A wide and shared conceptual framework that integrates sectoral notions of 'biosafety' and 'biosecurity' is required in order for each sector (agriculture, human and animal health, disarmament, environment) that addresses them to be efficient and effective.

Outside of arms control, but prompted by many of the same concerns, there are a number of efforts presently underway to enhance biosafety and biosecurity. In addition to World Health Assembly (WHA) Resolution 55.16 (discussed on page 38), the World Health Organization (WHO) is revising the interim guidelines of its Laboratory Biosafety Manual, a process relevant to biodefense programs and which has become more important in the international public

eye following the September, 2003 SARS escape from a Singapore BSL-3 laboratory.

The FAO and intergovernmental partners are conducting innovative work in articulating a broad conceptual framework encompassing biosecurity/biosafety issues, and its biosecurity initiative promotes "out of the box" thinking, at least for those approaching from an arms control perspective (see IPFSAPH, below).

Biological weapons experts, who are beginning to articulate links to agreements like the Cartagena Protocol,[5] should embrace this work to broadly conceptualize biosecurity/biosafety and articulate their ideas into that framework, rather than developing *sui generis* definitions of the terms.

Cooperation and the Biosecurity Portal (IPFSAPH)

FAO is leading partners including the OIE, WHO, World Trade Organization (WTO), and the Convention on Biological Diversity (CBD) in work to rationalize the disjointed international biosecurity framework, which is plagued by "sectoral approaches" that have inhibited cooperation between agriculture, health, environment, and disarmament. A loose international framework for biosecurity presently exists in international agreements, principally the standards setting "sisters" (OIE, IPPC, and Codex Alimentarius) plus the CBD, CBP and the BWC.

Biosecurity in Food and Agriculture, an important paper framing these issues was drafted by FAO for its March 2001 Committee on Agriculture Meeting.[6] FAO's Biosecurity working group held an initial international consultation in Thailand in January 2003.

Suggestions made by the United States to the BWC Meeting of Experts in August 2003[7] make curious references to the biosecurity-related work of FAO, WHO, and OIE. These are addressed at the end of

this paper, following detailed discussion of the IPPC, Cartagena Protocol, and OIE.

An early fruit of biosecurity cooperation by intergovernmental bodies is the development of an internet portal (website) to serve as a central access point for regulations, standards, and other information related to food safety, animal and plant disease, introduction of genetically modified organisms and their products, and invasive alien species.

The portal, developed at FAO, would facilitate access to information developed by and collected (generally from Parties) by the IPPC, OIE, Codex Alimentarius, SPS, CBP, and the CBD.

FAO's Biosecurity Portal is officially known as the (ungainly) "International Portal for Food Safety, Plant, and Animal Health" (IPFSAPH). Due to debut in early 2004, the Biosecurity Portal has the potential to pull together access to an enormous range of information relevant to biological weapons control. FAO is planning to train government officials in how to use its resources. The portal will use a controlled and consistent vocabulary, and it is planned to be available in English, Spanish, French, Chinese, and Arabic.

Despite the considerable effort of FAO to centrally index and relate varied biosecurity sources, IPFSAPH's present scope is smaller than it should be. IPFSAPH can include more data and enable examination of more relationships related to disarmament. This could include, for example, information on national laboratory biosafety law and regulations, including restricted access agents, legislation to implement the BWC and other information submitted to the BWC by State Parties, as well as the WHO national preparedness program for deliberate epidemics. Governments and NGOs working on biological weapons issues can reach out to the effort to help it integrate these issues into the portal.

Describing Biosafety and Biosecurity

FAO, 2003, articulation of the biosecurity concept:
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.[8]

Barletta, Sands, Tucker, 2002, biosecurity treaty rationale:
... the United States should promote an international biosecurity convention, which would be distinct from the bioweapons treaty but would complement it by primarily addressing the threat of bioterrorism. In addition, the biosecurity convention should build on the ongoing implementation of the 1992 Biological Diversity Convention and its 2000 Cartagena Protocol on Biosafety, which includes provisions for the safe handling, transfer, and use of genetically modified organisms.[9]

Cartagena Biosafety Protocol, 2000, objective:
In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.[10]

World Conservation Union (IUCN), 1999, definition of "biosecurity threats":
... means those matters or activities which, individually or collectively, may constitute a biological risk to the ecological welfare, or to the well-being of humans, animals or plants, of a country.[11]

At a Glance: Agreements Discussed in this Paper							
Agreement	**Date Of Text**	**Auspices (Secretariat)**	**Governing Body**	**Meetings**	**Budget (US$m03)**	**Staff [12]**	**Parties**
International Plant Protection Convention (IPPC)	1951 1979 1997	FAO (Rome)	Interim Commission on Phytosanitary Measures	Annual	1.1	2.85[13]	124
Office International des Epizooties (OIE)	1924	None (Paris)	International Committee of the OIE	Annual	4.3[14]	23	164
Cartagena Biosafety Protocol (CBP)	2000	UNEP (Montreal)	Conference of the Parties	Annual	2.2	7	79 (As of 12 Jan 04)
Convention on Biological Diversity (CBD)[15]	1992	UNEP (Montreal)	Conference of the Parties	1-2 years	10.4	42	187

3 The Cartagena Biosafety Protocol of the Convention on Biological Diversity

Background

The Cartagena Protocol on Biosafety is the first (only) global agreement on genetically modified organisms. The Protocol's diplomatic origins can be traced to the 1992 Summit of the UN Conference of Environment and Development, held in Rio de Janeiro, Brazil.

The Conference concluded with the adoption of four international agreements on environment, among these the Convention on Biological Diversity (CBD), the objective of which is the conservation and sustainable use of biological diversity and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

In the negotiation of the CBD, sharp lines were drawn between developing countries (where most of the world's biological diversity is located) and governments of the North, whose interest lay in maintaining inexpensive and easy access to biological resources. The late 1980's and early 90's surge of concern in Europe and the US about tropical forests and animals was not necessarily viewed as friendly in biodiverse developing countries.[16]

The authorization of utility patents on DNA, microorganisms, plants and animals in the United States led to bitter battles as biodiverse countries, often backed by NGOs, sought to protect their interests in the face of emerging intellectual property protections that permitted privatization of biological resources (also discussed in the then under-negotiation WTO Agreement).

The compromise that was struck pleased most governments and some environmental NGOs, the latter of which were, at the time, convinced that marketing natural products through "bioprospecting" and other commercial efforts would benefit biodiversity.

Some politically-influential constituencies were less certain, including a number of developing countries, advocates for farmers, opponents of life patenting, and many indigenous peoples. They feared that the CBD's enshrinement of national sovereignty over biological diversity coupled with its provisions on access to and patenting of biodiversity would prove destructive to community rights and resources.[17]

Nearly universal, the CBD has 187 parties. The United States, which signed the CBD in Rio in 1992, remains the only industrialized country that has not ratified it. While the Clinton administration officially supported ratification, a concerted effort was not undertaken in the US Senate. Today, the US retains reservations that the CBD impairs its commercial interests. Despite being only a signatory, the US is a vocal and sometimes aggressive player in CBD negotiations.

The Convention operates under the UN Environment Programme (UNEP), headquartered in Nairobi, Kenya. The CBD Secretariat is located in Montreal, Canada. The CBD Conference of the Parties (COP) takes place every one and a half to two years and informally rotates between major (bio)geographic regions.[18]

A Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) usually meets in Montreal and provides technical input. It and the COP sometimes address topics of relevance to the BWC such as biological control and alien invasive species.

The Cartagena Protocol

The Cartagena Biosafety Protocol on genetically modified organisms prohibits the introduction of a GMO into a country without that coun-

try's consent. It arises from Article 19.3 of the CBD, which instructed the Parties to *"consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity"*.

The road towards the adoption of the Protocol was a bumpy one. The negotiations formally started in 1995 with the adoption of Decision II/5 at the 2nd Conference of the Parties of the CBD in Jakarta, Indonesia. That decision led to the creation an Open-ended Ad Hoc Group on Biosafety, whose mission was to draft a protocol on biosafety.

The negotiations lasted five years and, on several occasions, nearly collapsed. The Protocol is named after the city of Cartagena (Colombia), where it was hoped that the Protocol text would be finished in 1999. However, differences prompted the adjournment of the Cartagena meeting without an agreement. The following year, one was finally reached in Montreal. The Protocol required fifty ratifications for entry into force. With Palau's ratification on June 13, 2003, the Protocol entered into force on September 11, 2003. As of 12 January 2004 there were 79 parties.

During the negotiation of the Protocol, states aligned themselves around two opposing groups. Led by the United States were the major exporters of GMOs for food with allied agricultural exporters whose potential future interests included relatively unrestricted international movement of GMOs. Joining the US were Argentina, Australia, Chile, Canada, and Uruguay, forming the "Miami Group".

Opposing this small but powerful group was the much larger "Like Minded Group of Developing Countries", led by Ethiopia. As potential importers of biotechnology products and hosts of greater part of the world's biodiversity, the Like Minded Group felt vulnerable to the environmental and socio-economic impacts of GMOs and wished to establish a comprehensive regulatory framework. In the endgame of the negotiations, the European Union's position was, generally,

supportive of the Like Minded Group, lending additional pressure to finalize the agreement.

Main features

The Protocol reaffirms the Precautionary Approach, adopted as a principle in the 1992 Rio Declaration on Environment and Development. It mandates that when facing a threat to the environment, the lack of scientific certainty due to insufficient scientific information and knowledge shall not prevent States from taking action in order to avoid or minimize adverse effects of the threat[19]. This approach acquires particular relevance in the case of GMOs, the safety of which is vigorously debated worldwide.

Although the Protocol is basically an environmental instrument, it includes within its objective the protection from possible impacts of GMOs on human health. The Protocol recognizes that there are intrinsic risks associated with GMOs — both to the environment and human health — and promotes biosafety by setting the rules for the safe transfer, handling and use of GMOs, focusing on the transboundary movement of GMOs intended for the release into the environment.[20]

Scope

The scope of the Protocol is limited, reflecting the compromise between opposing groups. It applies the core of its provisions to "living modified organisms" (LMOs)[21] intended for field release, and applies to a different, lesser, extent to other GMOs, such as for those intended for direct use as food or feed. The distinction was made in response to the Miami Group's demand to exclude products derived from GMOs (e.g., oil or starch from genetically modified crops). The Protocol applies mainly to the transboundary movement of all LMOs, and has less restrictive provisions for the transit, handling and use of LMOs.

Also excluded from the main provisions of the Protocol are GMOs that are pharmaceuticals for humans (Art. 5) because it was argued by the Miami Group countries that they are addressed by other international agreements or organizations. This exclusion has yet to take practical effect because presently there are no international agreements that specifically address safety of human pharmaceutical GMOs (e.g., "gene therapy" products, which remain experimental). As a result, many countries, including the Africa Group, maintain that the Cartagena Biosafety Protocol applies to GMO pharmaceuticals in the interim. Biotech pharmaceuticals for animals are covered by the Protocol.

Advanced Informed Agreement (AIA)

The core provision set up by the Protocol is the requirement by the exporter of LMOs to obtain prior advanced informed agreement from the importer before the *"first international transboundary movement of LMOs intended for intentional introduction into the environment of the party of import"* takes place. In other words, it is prohibited for one country to introduce a LMO into another without that country's consent. This requirement means that a party can, legally, refuse the introduction of any LMO that it considers a threat to its biological diversity or human health. Annex I of the Protocol details the minimum information that the exporter must submit to the importer (the notification).

Risk assessment and management

The decisions of importing parties to allow or refuse the introduction of LMOs must be based on risk assessment. The Protocol provides the guidelines that the assessments must follow. The assessment must take into consideration the information provided by the exporter as well as the other scientific evidence available *"in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biodiversity, taking also into account risks to human health."* (Art. 15). Annex III of the Protocol provides guide-

lines and methodologies for conducting risk assessments.

Additionally, all Parties are obliged to establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment. Among these, countries must take measures to prevent unintentional transboundary movement of LMOs.

Limited regulations

While the Protocol focuses on the transboundary movement of LMOs intended for planting in fields, it does not exclude from its scope LMOs intended for other uses, such as food and feed, rather, it establishes a less restrictive set of regulations for them.

GMOs that are in transit or intended for contained use (i.e., laboratory utilization) are exempted from the AIA requirement, however, states have the right to regulate the transit of such GMOs through their territories, to require a risk assessment prior the importation of any GMO, and to set standards for contained use (i.e., laboratory biosafety).

GMOs that are intended for direct use as food or feed, or for processing must be labeled indicating that they "may contain" GMOs *"and are not intended for intentional introduction into the environment, as well as a contact point for further information"* (Art. 18).

The Protocol establishes a minimal requirement for all LMOs that countries must approve for domestic use, including placing on the market, whenever those organisms *"may be subject to transboundary movement, as well as for those intended for direct use as food, processing or feed. In such cases, countries must make available the decision by which such use was authorized by the producing country at the "Biosafety Clearing-House"*, an internet based information sharing mechanism (Art. 11).

Annex II of the Protocol lists the minimal information that must be made available at the Biosafety Clearing House, providing potential importers a means to begin their decision-making process on introduction of GMOs within their boundaries

National authorities

Parties are required to designate national authorities responsible to carry out the obligations set up by the Protocol and to serve as liaison with the Secretariat of the Protocol. Parties have to notify the Secretariat the name and contact information of such authorities (Art. 19). Minimally, the national authority must be legally-enabled to carry out the import/export requirements of the Protocol.

While establishing national authorities, many countries, especially developing countries, are setting up more comprehensive domestic biosafety legislation. These processes present opportunities to specifically address the hostile use of GMOs and will lead to the establishment of focal points of expertise in biotechnology risk assessment and management in member states.

In Africa, for example, a Model Law on biosafety to implement the Cartagena Protocol has been developed and adopted by the African Union, for national implementation in member states. This Model Law includes criminal penalties for deliberate abuse of genetically modified organisms.

Secretariat and Conference of the Parties

The governing body of the Protocol is its Conference of Parties, whose responsibility is to review implementation and to take the decisions necessary to promote effective implementation. Only Parties to the Protocol are entitled to fully participate. Non-parties may attend as observers. The Secretariat of the CBD serves also as Secretariat of the Protocol (Art. 31).

Compliance, Liability and Redress

The issues of compliance and of liability for damages resulting from transboundary movement of GMOs were ones on which the Parties could not reach agreement during the negotiation of the Protocol. Instead, they decided to defer until the first COPs (Art. 34 and 27). The first COPs serving as the meeting of the Parties to the Protocol will take place in Kuala Lumpur from 23-27 February 2004, and compliance, liability and redress are on the agenda.[22]

Recommendations

With the entry into force of the Cartagena Protocol, the development of concrete links between it and the BWC has become more possible. The Cartagena Protocol will face challenges in its early meetings, including what promise to be difficult negotiations over liability and redress and the potentially less than constructive participation of some observer countries.

First steps that can be taken by the BWC and/or the Cartagena Protocol include:

Internationally

(a) the Conference of the Parties to the Cartagena Protocol may request observer status for the Protocol at meetings of the Biological Weapons Convention:

- governments should nominate persons with expertise in biological weapons control to the Protocol's Roster of Experts and support their participation in Protocol activities;[23]

- training courses and capacity building for the Cartagena Biosafety Protocol — currently underway on a large scale — should include components on the BWC and biological weapons control;

(b) the Conference of the Parties to the Cartagena Protocol should explore the Protocol's relationships with the BWC by:

- requesting that the Secretariat study how the Protocol's requirements on transboundary movement of LMOs relate to non-proliferation of biological weapons and,

- developing tools to integrate criteria related to the potential for hostile use of LMOs into the process of risk assessment under the Protocol;

(c) likewise, States Parties to the BWC may request the BWC Secretariat to prepare a study on the relationships between the BWC and the Cartagena Protocol.

Nationally, governments may:

(a) assess how financial and technical support for Cartagena Protocol capacity building programs can increase awareness and help countries fulfill obligations under the BWC;

(b) implement the Biosafety Protocol with the provisions of the BWC (particularly Article IV) in mind and, to the maximum extent possible, within a linked legal framework;

(c) adopt biosafety law that establishes criminal penalties for the deliberate abuse (hostile use) of GMOs. These penalties should apply to all persons, including individuals, government officials (in private and official capacities), corporations, and other organizations; and

(d) integrate criteria related to the potential for hostile use of LMOs into the process of risk assessment under the Protocol.

4 The International Plant Protection Convention

Background

The main international phytosanitary (i.e., plant health) agreement, the International Plant Protection Convention (IPPC) was negotiated under the auspices of the United Nations Food and Agriculture Organization (FAO). It seeks international cooperation to prevent the introduction and spread of pests of plants and products and to control such pests.

Adopted in 1951, the IPPC came into force in April 1952. The original Convention was also referred to as "Phytosanitary Certificate", because its main feature was the provision of a form issued by Parties to exporters of plants and plants products to certify that exports were free of organisms designated as plant pests by importing countries.[24]

Since its adoption more than a half-century ago, two major revisions have been made to the text of the Convention. The first revision process started in 1973 and was adopted in 1979. The revision aimed, in essence, to update the terminology of the Convention, to more clearly define the obligations of Parties, and to update the Phytosanitary Certificate.[25] For example, in the 1979 revision, terms such as "pests" and "containers" were defined.

The revised text added a model for a new certificate for "re-export" of plants and plant products (Art. V). This first revision entered into force for all contracting parties in 1991, after it was accepted by two thirds of the parties to the original IPPC.

A second revision process was triggered by the 1994 conclusion of the Uruguay Round of multilateral trade negotiations, which gave rise to the WTO. Along with the creation of the WTO, an Agreement on Sanitary and Phytosanitary Measures — the SPS Agreement — was adopted in 1994.

The SPS Agreement sets the basic rules for food safety and animal and plant health standards with the objective of preventing countries from using sanitary and phytosanitary regulations as trade barriers. It does so by encouraging the development and adoption of international standards, a process known as "harmonization".

Countries retain the right to depart from international standards and adopt their own health regulations but those regulations must be based on science and justified by circumstances.[26]

The standard-setting required by the SPS harmonization process is not carried out by the WTO, but by a set of specialized international agreements. These currently are the standards-setting bodies known as the "three sisters", namely the joint FAO-WHO Codex Alimentarius (food safety), the IPPC (plant health), and the OIE (animal health).[27] New standards-setting bodies may be named, provided that membership in them is open to all WTO members.

The second revision to IPPC was directed specifically to fulfill the new role assigned to it by WTO, particularly standard-setting. The revision negotiations started in 1995 and were concluded in November 1997, when the FAO Conference approved a revised text. This latest text has not entered into force. Like its predecessor, the 1997 IPPC requires acceptance of two-thirds of contracting Parties in order to enter into force. Only 45 countries have done so to date. [28]

An additional problem is that it has proven difficult to reach consensus on how many countries make up the two-thirds required, since the number of parties is in flux. New countries joining the IPPC have usually but not always agreed to accept the new text, while in the

1990s some older state parties disappeared or divided into new ones.

Nevertheless, some provisions from the 1997 version have come into play early because of interim measures adopted by the Parties, including the amendments made to the phytosanitary and re-export certificates; the establishment of an Interim Commission on Phytosanitary Measures (ICPM), the adoption of its terms of reference; and approved interpretations of various articles[29].

Principal Features of the IPPC

(a) Purpose

Defined in Article I, the purpose of the IPPC is *"securing common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control"*. The 1997 version adds text stating that nothing in IPPC will compromise the obligations of parties under other international agreements, a reference to SPS and other WTO obligations.

(b) Scope

The IPPC applies to plants and plant products, as well as storage places, containers, packing material, soil and — in the 1997 version — "any other organism, object or material capable of harboring or spreading pests, deemed to require phytosanitary measures, particularly where international transportation is involved".

Like the 1979 IPPC, the 1997 revision undertook to clarify terms used in the Convention. The 1979 revision added a definition of pest — *"any pathogenic agent, injurious or potentially injurious to plants and plant products"*. This definition was further elaborated in the revised text of 1997, to include also "any species, strain or biotype, animal or pathogenic agent" injurious to plants or plant products.

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The definition of plants was also widened in the 1997 version, adding "germplasm" and extending the scope of protection to wild flora (Art IV). The aim was to provide a comprehensive framework for dealing with issues of plant protection, including aspects of environmental protection.

This new wider scope has increased the relevance of the IPPC to issues such as invasive alien species and biosafety, both of which are also issues addressed under the CBD[30] and are relevant to the BWC.

(c) National Plant Protection Organization (NPPO)

The Convention calls for the designation of a NPPO to be responsible for the core obligations assumed by states under the IPPC, among them (Art. IV):

- inspection of growing plants, areas under cultivation, storage of plant products with the object of reporting pests outbreaks. The 1997 revision added "wild flora" and "laboratories" to the areas under surveillance;

- inspection of consignments of plants and plant products moving in international traffic, to prevent the introduction or spread of pests;

- issuance of phytosanitary certificates to consignments moving in international traffic, regarding their phytosanitary condition;

- making provision for the distribution of information regarding regulated pests and their means of prevention and control;

- research and investigation in the field of plant protection, and the issuance of phytosanitary regulations.

In 1979 the issuance of re-export certificates was added and, in 1997, "the protection of endangered areas and the designation, maintenance

and surveillance of pest free areas and areas of low prevalence", and "the conduct of pest risk assessments" were added. NPPOs are currently registering and reporting pest outbreaks which may be also of relevance to the BWC where under the 1992 Confidence Building Measures (CBMs) an "exchange of information on outbreaks of infectious diseases ... that seem to deviate from the normal pattern"[31] (CBM B) is taking place.

(d) Control over imports

One of the main features of the IPPC is the regulation of Parties' right to control imports of materials that might introduce or spread pests within their territories. The original IPPC text granted Parties the right to:

- place restrictions and requirements on the importation of plants and products;
- prohibit the importation of particular plants and plant products;
- detain particular consignments; and even
- "treat, destroy or refuse entry to particular consignment of plants and products, or require such consignments to be treated or destroyed" (Art. VI of 1959 and 1979 texts).[32]

In 1979, those rights were pared down to allow the destruction and refusal of entry only to consignments that entered in violation of importing country's existing regulations. Parties were also to "list pests the introduction of which is prohibited or restricted because they are of potential economic importance to the country concerned".

The aim of those 1997 changes was to limit Parties' ability to regulate imports under the SPS Agreement. While parties still have the right to adopt phytosanitary measures, including prohibiting or restricting entry of consignments, and to require that consignments be treated

before entrance, a set of limitations has been imposed on exercising those rights. Among them are:

- all actions must be based on phytosanitary measures that are "technically justified";
- parties must publicize their phytosanitary regulations immediately after adoption;
- other parties may request the rationale behind phytosanitary measures, and
- importing countries must report to concerned exporting countries cases of non-compliance with phytosanitary certification.

Under SPS, failure to technically justify phytosanitary measures provides grounds to challenge them (see "US Bioterrorism Law Collides with the WTO", p. 35).

Importation of biological agents is covered under the regulations of importation of plants (Art. VI, VII in the 1997 version). The 1951 text granted the right to countries to make provisions for the importation *"for purposes of scientific research of plants and plant products and of specimens of plants pests and disease causing organisms under conditions affording ample precaution against the risk of spreading plants diseases and pest".*

In 1979 education was added to the purposes for which importation of disease causing organisms, and a reference to biological control was introduced: *"Adequate safeguards likewise need to be taken when introducing biological control agents and organisms claimed to be beneficial".*

In 1997, the purposes for importing biological agents were further widened as was the scope of biological material: *"Nothing in this article shall prevent importing contracting parties from making special provision, subject to adequate safeguards, for the importation, for the purpose of*

*scientific research, education, **or other specific use,** of plants and plant products and **other regulated articles,** and of plant pests."* (Emphasis added on new 1997 additions.)

(e) Standard-setting process

Although a standards process was started within IPPC in 1990 and the first set of international standards were approved in 1993 by a FAO Conference resolution, the standard-setting process is formally established in the (as yet not-in-force) 1997 IPPC revision.[33]

The 1997 version also creates the Commission on Phytosanitary Measures as the IPPC's decision-making organ and the body responsible for the adoption of standards. Membership in the Commission is open to all contracting parties. Because the Commission cannot be officially constituted until the new text enters into force, however, the "Interim Commission on Phytosanitary Measures" (ICPM) serves until the amendments come into force. The ICPM is open to all FAO members, as it was established under the provisions of the FAO Constitution and Basic Texts.

As such, IPPC Parties are not currently obliged to follow the ICPM's international standards, although they are strongly encouraged to do so. A Party may choose to establish protection levels above the international standards, in which case it has to provide scientific justification. In such cases, Parties must also inform other Parties possibly affected by the measures.

This new provision goes along with SPS's requirement that phytosanitary measures be applied for no purpose other than that of ensuring plant health. Indeed, SPS further requires that regulations are applied in such a way that they do not result in unfair or disguised restrictions on trade.

The drafting of the standards themselves can take place at the IPPC's Secretariat, or at any of the expert groups organized by the Secre-

tariat. They may originate as national or regional initiatives. The ICPM reviews draft standards and circulates them among Parties prior to adoption. So far, 19 standards have been adopted by the ICPM, and more are under consideration.

Among the notable adopted standards are No. 3: "Code of Conduct for the import and release of exotic biological control agents", which covers importation of exotic biological control agents capable of self-replication, outlining responsibilities for both importer and exporter countries, before the importation, during the exportation and after the release and No. 11: "Pest Risk Analysis for Quarantine Pests".[34] Drafts currently under consideration include a supplement to No. 11 on genetically modified organisms.

(e) Settlement of Disputes

In the original IPPC, the procedure for settlement of disputes was to request the Director-General of FAO to appoint a committee of experts to consider the question in dispute. The Committee, which would also include representatives from the countries in dispute, would produce a report and send it to the Director-General, who in turn, transmitted it to the parties in dispute and other parties. The Committee's recommendations, while not binding, constituted a basis for renewed consideration by the feuding parties.

The text of 1997 establishes, as first resort (prior to discussion at WTO SPS), an opportunity for the concerned parties to consult among themselves with a view to resolving the dispute. If the dispute cannot be resolved through direct consultation, one of the parties or all parties concerned may request the FAO Director-General to appoint the expert committee. The newly created Commission is charged with the task of approving the rules and procedures that must be followed by any expert committee in the preparation of their report.

Finally, the 1997 text highlights that IPPC settlement of disputes "shall be complementary and not in derogation of the dispute settlement

procedures provided for in other international agreements dealing with trade matters", a clear reference to WTO procedures. The Interim Commission has established a subsidiary body for dispute resolution, although the interest of states parties to date has been rather limited.

Future IPPC Standards

Unlike its "sisters" OIE (1924) and Codex Alimentarius (1964), IPPC is new to setting international standards, having only received a mandate to do so as a result of the SPS agreement. Presently the IPPC adopts an average of two new standards per year. Some Parties (particularly developed countries) wish to increase the Secretariat's budget and staff in order to increase the rate of standard adoption.

Some Parties, such as the US, propose procedures to facilitate adoption of draft standards developed outside of the IPPC. Other Parties prefer a slower approach, in large measure because of the IPPC's relationship to SPS, where many developing countries feel the cards are stacked against them in the event of a dispute with a larger power. Many of the same countries are unenthusiastic about "outsourcing" the standards-drafting process if it affords undue influence to industry, which might develop standards itself and then have them shepherded through the IPPC by a friendly government.

In November 2002, the ICPM polled countries on their suggestions for new international standards.[35] Among the suggestions were new standards on detection, monitoring, and control of a number of pathogens of BW (and economic) concern, including plum pox potyvirus, *Xanthomonas* and *Ralstonia* bacteria, fungi including *Tilletia* (karnal bunt), *Synchytrium endobioticum* (potato wart disease) and types of *Fusarium oxysporum*, as well as insects that are plant pests, such as *Thrips palmi*. The IPPC may also consider specific biotechnology risks, such as adoption of standards on herbicide and insect resistant crops as pests, which presently exist as draft guidelines authored by the

FAO Plant Protection Service.

Of particular interest in limiting broader BW-related risks are IPPC "concept" standards, which relate not to specific pests but to procedures, methods, regulations, and facilities for controlling plant pests more generally. Concept standards have been proposed for identification of plant pests, for monitoring and surveillance, and for high security (i.e., biocontainment) quarantine facilities.

5 Office International Des Epizooties

Background

Based in Paris, the Office International des Epizooties (world animal health organization) focuses on preventing the spread of animal diseases, including zoonoses (animal diseases that can also be transmitted to humans), while enabling international trade of animals and animal products.

OIE came about in the aftermath of a 1920 outbreak of rinderpest in Belgium, which was caused when infected cattle passed through the port of Antwerp. The episode prompted the negotiation of an international agreement that was adopted in 1924 by 28 countries in the League of Nations.

Building on commitments made during the Second World War, at the end of that conflict the United Nations quickly moved to establish two specialized agencies, the Food and Agriculture Organization (FAO, 1945) and the World Health Organization (WHO, 1948).

Both FAO and WHO's functions partially overlap with those of the OIE. This situation prompted initiatives to dissolve the OIE between 1946 and 1951. OIE's role in the modern multilateral framework was clarified in 1952 when it signed a formal agreement with FAO and again in 1960 following an agreement with WHO.

Other international organizations with whom OIE has signed cooperation agreements include: the European Community (1957); the Inter-American Institute for Cooperation on Agriculture (IICA, 1993);

the World Trade Organization (1998); Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA, 1999); Organization of African Unity - Interafrican Bureau for Animal Resources (OAU-IBAR, 2002); World Veterinary Association (WVA, 2002); International Federation for Animal Health (IFAH, 2002), and CAB International (CABI, 2002).

The 1924 Agreement establishing OIE, provided a framework upon which its work has evolved. The obligations contained in the Agreement are basic: the contracting parties agree to the creation of the Office, based in Paris; they establish a decision making body that has authority over the Office; they set up a Committee comprised of delegates of contracting parties; and they create a flexible scheme to make any changes that parties consider necessary, provided it is done by consensus.

The statues for the OIE were appended to the Agreement and outlined the Office's main objectives, elaborated the Committee's rules, and included some additional obligations for contracting parties.

Article 4 of the statutes established the main objectives of the Office as:

(a) To promote and co-ordinate all experimental and other research work concerning the pathology or prophylaxis of contagious diseases of livestock for which international collaboration is deemed desirable.

(b) To collect and bring to the attention of the Governments or their sanitary services, all facts and documents of general interest concerning the spread of epizootic diseases and the means used to control them.

(c) To examine international draft agreements regarding animal sanitary measures and to provide signatory Governments with the means of supervising their enforcement.

In turn, Parties committed themselves to inform the OIE immediately if any outbreaks of rinderpest or foot and mouth disease (FMD) occurred in their territories and to periodically report on the presence and distribution of certain diseases. The list of diseases may be modified by Parties at any time. Additionally, Parties must submit to OIE the regulations they adopt to protect against animal diseases, particularly those that apply to imports (Art. 5).

Thus, the OIE is a versatile organization that works on several fronts simultaneously: it adopts standards on animal health to be applied to international trade of animals and animal products (these are recognized by the WTO SPS Agreement); it collects and disseminates among members information on animal diseases outbreaks; it promotes research on animal diseases and disseminates relevant scientific information; and it provides a framework for international cooperation for the control of animal diseases.

Standards and Manuals

The most important collection of OIE sanitary standards are the Terrestrial Animal Health Code and the Aquatic Animal Health Code, aimed at preventing the introduction of infection agents and diseases pathogenic to animals and humans through the international trade of animals, animal genetic material and animal products. As standards, the codes also have a major role in preventing parties from using animal sanitary measures as trade barriers.

The terrestrial and aquatic codes, as they are known, are periodically updated through revisions carried out by OIE specialist commissions. The commissions are composed of experts in the field, and revisions to the text are approved by OIE's Committee following consultations among delegates. Each code is published in English, Spanish, and French, which are the OIE's only official languages. The Terrestrial Code has been translated into Russian.

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The codes contain a list of definitions, disease notification criteria, procedures for international reporting of diseases, principles for import risk analysis, the organization of import and export procedures. Both codes include a list of priority transmissible animal diseases, but in case of terrestrial animals, they are divided into categories A and B.

In List A are transmissible diseases "which have the potential for very serious and rapid spread". Countries must report the occurrence of these diseases promptly, following the guidelines provided in the Code.

List B includes eighty transmissible diseases that are not regarded as severe a threat for rapid spread as those contained in List A, but which are of economic importance.[36] Parties must report on the status of List B diseases annually following the guidelines provided in the Code. The Acquatic Code lists 35 diseases of fish, molluscs, and crustaceans and also includes reporting requirements.

Emergency reports of List A disease outbreaks filed by the veterinary authorities of member countries are posted by OIE in a weekly publication, *Disease Information*, which is available online.[37] Annual data on outbreaks of List B diseases, including zoonoses such as anthrax, brucella, and types of equine encephalitis, are published in the annual report World Animal Health. A database, Handistat II, lists this information online, but is described as a "prototype" and is not up to date.

OIE List A Diseases
Terrestrial Animal Health Code
Section 1.1, chapter 1.1.2

Foot and mouth disease
Vesicular stomatitis
Swine vesicular disease
Rinderpest
Peste des petits ruminants
Contagious bovine pleuropneumonia
Lumpy skin disease
Rift Valley fever
Bluetongue
Sheep pox
Goat pox
African horse sickness
African swine fever
Classical swine fever
Highly pathogenic avian influenza
Newcastle disease

The Terrestrial Code provides

general standards for risk analysis (for import/export) followed by specific definitions and criteria for each List A and B disease. Both codes contain a series of models of international veterinary certificates, aimed at assisting in the harmonization process mandated by the WTO SPS Agreement.

Additionally, the terrestrial code includes appendices with recommendations for collection and handling of semen and embryos, sanitation of hatcheries and incubators and transport of animals, along with standards for the epidemiological surveillance of some animal diseases. The Aquatic Code also has appendices that include recommendations on health control and hygiene.

Scope

Although OIE focuses on the spread of animal diseases and zoonoses due to international movement of animal and animal products, its scope is wider, to include, besides traditional animal products, biologicals for veterinary use and, in general, any product capable of carrying animal diseases and zoonoses. The Terrestrial Code states (Part 1, Chapter 1.5.1):

All products, including biologicals for veterinary use, derived from animals have some capacity to transmit animal disease. The level of this capacity depends on the inherent nature of the products, their source, the treatment that they might have undergone, and the purpose for which they are intended. Biologicals for in vivo *use in particular will have the highest probability of exposure to animals and as such present the highest risk. Products used for* in vitro *purposes can introduce disease into animal populations through deliberate or inadvertent use* in vivo, *contamination of other biologicals, or spread by other means. Even products for diagnosis and research have the potential for close contact with animals. Exotic micro-organisms, some highly pathogenic, which may be held for research and diagnostic purposes in countries free from infection or the diseases they cause, could possibly contaminate other biological products.*

Veterinary administrations of importing countries shall make available specific procedural requirements for approval or licensing of biologicals for veterinary use. They may limit supply to registered institutions or in vitro *use or for non-veterinary purposes where such assurance cannot be provided.*

The Code addresses biologicals for veterinary use other than veterinary vaccines, including a number of types of laboratory and medical supplies, such as preserved specimens, sera, cell lines, genetically-modified microorganisms (for veterinary use), etc. Countries are charged with carrying out risk analysis for all those products before international trade takes place, for which the manual provides guidelines.

To complement the standards, OIE has also developed two manuals: the Manual of Diagnostic Test and Vaccines for Terrestrial Animals and the Manual of Diagnostic Test for Aquatic Animals. The manuals provide standards for laboratory diagnostic tests and protocols, for the production of biological products for veterinary use, including vaccines; international transfer and laboratory containment of animal pathogens, and laboratory biosafety. These are published in English only.

Both standards and manuals are periodically revised and amended by Specialist Commissions.

Early Warning System

The OIE, FAO and WHO have been working, since the late 90s, on the development of an early warning system to provide alerts on the outbreak (or potential outbreak) of major epizootic diseases such as those on the OIE List A.[38]

Momentum for the system has been built by recent outbreaks of FMD in Europe and also by diseases such as African swine fever, which, the FAO reports, has resulted in the loss of 50% of the West African

pig population between 1996 and 1999. The system is currently called the "Global Information and Early Warning System for Transboundary Animal Disease", and uses the unwieldy acronym "GIEWS-TADs".[39]

In 2003, regional consultations on the system are planned in South Asia and Southeast Asia. The system is also being designed to have predictive capabilities and could also be used to detect and alert in cases of deliberate spread of diseases.

US Bioterrorism Law Collides with the WTO

A showdown looming between the US and countries that export food to it demonstrates how measures intended to limit biological threats can conflict with World Trade Organization (WTO) rules.

Passed in 2002, the US Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) mandates the US Food and Drug Administration (US FDA) to develop rules to register companies exporting food to the US, to require that notification be made to the FDA prior to export, to require new types of (tracking) records to be kept, and to enable the FDA to detain food imports suspected of posing a human or animal health threat.

Detentions can be made on the basis of confidential or classified information. Failure to obey the regulations could lead to US civil and criminal penalties and a ban on future food imports to the US by a violating entity. [40]

The draft FDA regulations are being discussed in sessions of the WTO SPS and it is quite likely that the FDA's rules will run afoul of the WTO. While countries have expressed support for the principle of the US law, many also see the FDA rules as creating "unfair" trade practices that the WTO prohibits. The food focus of the regulations makes them particularly sensitive because of ongoing WTO controversies over farm subsidies that led to the collapse of its September 2003 meeting in Cancun, Mexico.

At the April 2003 session of the SPS Committee, the planned US regulations were roundly criticized by Asian, Latin American, and European countries, many of whom say that the rules appear duplicative and who question if they can distinguish between accidental and deliberate food contamination.[41]

The European Commission's comments on the regulations include poking fun at the FDA's inadequate justifications for the regulations and thinly veiled threats to take the US before a WTO tribunal if the regulations proceed as presently drafted. The EU argues that the law has not been presented in the manner required by the SPS Agreement (including prior performance of a risk assessment) and that the draft regulations impose unfair requirements on imports that are not imposed on domestic producers.[42]

The EU and others also argue that detentions can be of a duration so long that, even if detained shipments are ultimately allowed entry (as is the case nearly 50% of the time under current US sanitary law), they may spoil or miss their market niche (e.g., nouveau wines or seasonal foods). The food industry largely agrees.[43]

However the food import conflict is resolved, the case demonstrates how WTO rules impose significant limits on the ability of WTO members to freely adopt biosecurity measures that impact trade. That is, biosecruity measures that impact saleable items, including intellectual property. And because there are no international biosecurity standards (using "biosecurity" in a typical arms control sense), regulations to protect against bioweapons that impact trade are inherently "higher" than the international norm. Hence, WTO barriers to their implementation are increased.

The situation demonstrates the need to develop agreed international standards to reduce biological weapons risks that would enable consistent and enforceable national legislation.

While the existing standards-setting bodies (Codex, IPPC, and OIE) plus the Cartagena Protocol, which will contain its own liability and

compliance measures, have relevant scientific expertise, they have neither experience nor mandate on security, *per se*. While the BWC does possess mandate, at present, it is actually less well-equipped to establish standards to reduce the risk of a biological weapons attack arriving in commercial disguise.

WHO Resolution on Global Health Response to Deliberate Use of Biological Weapons

On 18 May 2002, the 55th World Health Assembly adopted Resolution WHA55.16 on the "global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radio-nuclear material that affect health".

WHA55.16 contains a provision which may contribute to strengthening the BTWC regime through stronger national implementation, requesting the Director-General: *"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".*

A significant number of requests have been made to the WHO for technical assistance by the health sector of Member States for the assessment of their national preparedness programmes. Based on the mandate provided for in WHA55.16, the WHO initiated a project on "Strengthening National Health Preparedness and Responses to the Deliberate Use of Chemical and Biological Agents" within the WHO's Department of Communicable Disease Surveillance and Response.

As of September 2003, guidelines are being developed to help WHO Member States in assessing their national health preparedness programme on deliberate disease. Based on these guidelines, WHO staff and/or domestic experts will assess the overall structure and performance of preparedness activities in a Member State, making recommendations to the Ministry of Health of Member States.

One important dimension of this assessment framework is national policy. While this will mainly relate to policy and legislation in the health and emergency sector, one part of this assessment could include a review of national legislation to prevent the deliberate use of chemical and biological agents. If the assessment reveals room for strength-

ening BTWC and CWC implementing legislation, such a recommendation could be made to the Member State.

Article IV of the BTWC obliges States Parties to *"take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention"*, but not all States Parties have fulfilled this obligation. Hence, the WHA55.16 process provides for an opportunity to strengthen the global ban on biological (and chemical) weapons by strengthening national legislation.

Implementing national legislation on the chemical and biological weapons bans could contribute to the goal of the WHA55.16 mandate, as it would further build government awareness of biological (and chemical) threats and thus contribute to a stronger commitment to health preparedness in response to the use of biological and chemical weapons.

In most instances, the WHO has been cautious to focus its activities and recommendations on health related issues and to exclude biological disarmament issues from its activities. This appears to be necessary to build confidence in and foster cooperation of many countries on sometimes sensitive health related issues.

In the specific case of WHA55.16, however, it appears to be supportive for the mandated WHO goal to include provisions in its assessment guidelines that may have a beneficial effect from an arms control perspective. This is a particular chance to strengthen the BTWC regime as there appears to be a widespread interest in WHO Member States to receive technical assistance by WHO staff to assess their bioweapons preparedness. This openness and political momentum on the part of of the Member States may ease the way towards stronger national implementation legislation for BTWC (and CWC).

In August 2003, Draft WHO Guidelines on "Preparedness for Deliberate Epidemics" were made available a WHO network of experts ad-

vising and reviewing this project. Based on this draft, it was recommended to the WHO project staff to include an assessment of national legislation to prevent the deliberate use of chemical and biological weapons in its guidelines. Based on expert comments and field tests of the draft guidelines in Member States, the final guidelines will be prepared.

6 Conclusion: Towards a Binding International Instrument on Biocontainment Facilities

Each of the agreements discussed in this paper offers possibilities within its own processes to manage biotechnology dangers and enhance awareness and implementation of the BWC.

Through OIE and IPPC, opportunities exist to develop new international standards on monitoring and management of biotechnology and disease that will reduce risks — by improving detection, integrating bioweapons concerns into risk assessment.

In the case of the Cartagena Biosafety Protocol, we have proposed a number of immediate, concrete actions, most important among them — integrating bioweapons concerns into the risk assessment and legal frameworks that are modified or created by countries that ratify the agreement.

Studies should be immediately performed under the auspices of the Cartagena Protocol and the BWC that assess the relationships and how they can be more mutually supporting.

Looking beyond the individual processes of the IPPC, OIE, BWC, and CBP there are a number of factors mitigating in favor of the creation of a binding international instrument on biocontainment facilities. Biocontainment facilities were largely left out of the Cartagena Protocol by exclusions on its application to GMOs for "contained use", creating a logical need for complementary agreement on biocontainment.

The efforts of the Ad Hoc Group of the BWC to negotiate a binding

protocol to strengthen the BWC, which would have focused in significant measure on such facilities, failed. Apart from some (enforceable) OIE standards of a restricted scope, and WHO's laboratory biosafety guidelines, which are interim and non-binding, biocontainment facilities are not properly addressed in any agreement.

The lack of a binding international instrument on biocontainment has been justified by the argument that regulating the facilities is purely a question of national law. A "Biosecurity Convention" focusing specifically on preventing improper diversion of pathogens has also been suggested. Yet recent cases involving accidents and security failures at biocontainment facilities demonstrate that national law and a simplistic arms control "sectoral" focus on pathogen security are inadequate.

The September, 2003 case of a SARS infection acquired in a Singapore biosafety level 3 facility[44] is one example: The small city-state of Singapore is a global trade and transportation hub. The biocontainment breach in Singapore could have very quickly affected its neighbors or, due to air and sea travel, almost any country in the world.

A 1994 laboratory escape of sabia virus (causative agent of Brazilian Hemmoraghic Fever) in the US demonstrates the same potential.[45] The US anthrax letters of late 2001 utilized a type of anthrax that is likely to have been illicitly acquired in a biocontainment facility. Traces of the anthrax, and innumerable hoax letters, were carried internationally by the postal system, generating problems not only in the United States but across the world.

An interesting paper tabled by the United States at the BWC Meeting of Experts in August 2003 recommends that the BWC *"receive information"* and *"request the WHO, FAO, and OIE to expand or develop, as necessary, their voluntary guidelines for security... "*.[46] The paper conspicuously omits reference to the binding Cartagena Protocol governing transboundary movement of GMOs, and repeatedly terms to the relevant activities of FAO, OIE, and WHO as *"voluntary"*.

As discussed here, the standards-setting activities of IPPC, FAO, and WHO (through Codex) are hardly "voluntary". They are enforced through the WTO SPS Agreement and may be ignored — but at the cost of potentially devastating trade sanctions. As discussed above, one of the US' own bioterrorism laws is encountering difficulties at the WTO, the first of what could become many tests pitting one country's vision of biosecurity against the powerful international trade agreement.

Immediately, the SPS-enforceable standards-setting possibilities at IPPC and OIE, as well as the Cartagena Protocol, present opportunities to reign in risks that the BWC has been unable to address. The trade fight over the US Bioterrorism Act demonstrates that trade agreements are powerful mechanisms for compliance, but the SPS Committee is a trade body and should not have the final say in shaping biological weapons control standards and related measures. The WTO SPS is structured in a way that discourages adoption of national laws impacting trade that are not supported by approved international standards.

An agreement on biocontainment facilities that addresses safety and security should be negotiated under the joint auspices of those international agreements whose purpose directly relates to biosecurity — FAO, WHO, OIE, CBD, and the BWC.

The agreement should complement the Cartagena Protocol by controlling all aspects of "contained use" of GMOs and pathogens, contain relevant standards developed by WHO, FAO, and OIE, and achieve to the maximum extent possible the mandate of the BWC Ad Hoc Group.

The agreement should contain a dispute settlement mechanism providing for physical inspections. Elements of the agreement may be enforceable through existing mechanisms such as WTO SPS (for trade) and the Cartagena Protocol (e.g., for international liability due to containment failure).

Such a broad-based international negotiation is required for the individual pieces — security, health, biodiversity, agriculture — to add up to a whole that achieves biosecurity and biosafety.

ENDNOTES

1 Established by the International Agreement of 25 January 1924.

2 See, for example, Working paper by Mexico and Peru, BWC/CONF.V/COW/WP.26 or Background Paper on *New Scientific and Technological Developments Relevant to the [BTWC] Convention*, BWC/CONF.V/4/Add.1.

3 FAO 2003. *Biosecurity in Food and Agriculture*, Discussion Paper (COAG/2003/9), Committee on Agriculture, 17th Session, Rome, April.

4 In, for example, *The Design of National Mechanisms to Maintain the Security and Oversight of Pathogenic Microorganisms and Toxins* (BWC/MSP.2003/MX/WP.7/Rev.1), paper prepared by the United Kingdom for the BWC Experts Group, Geneva, August 2003 (URL: (i) below) and Barletta M. *Biosecurity Measures for Preventing Bioterrorism*, Monterey Institute Center for Nonproliferation Studies, November 2002 (URL: (ii) below) and proposed definitions in VERTIC, *Time to Lay Down the Law*, August 2003 (URL: (iii) below).

(i) http://www.opbw.org/new process/bwc msp.2003 mx wp07 rev.1.pdf

(ii) http://cns.miis.edu/research/cbw/biosec/pdfs/biosec.pdf

(iii) http://www.vertic.org/assets/TimeToLayDownTheLaw.pdf

5 See, for example, Barletta, M. et.al. (2002). *Keeping track of anthrax: The case for a biosecurity convention*, Bulletin of the Atomic Scientists, May/June, or the Bradford University's Genomics Gateway.
http://www.bradford.ac.uk/acad/sbtwc/gateway/index.html

6 FAO 2003. *Biosecurity in Food and Agriculture* (COAG 01/8).

7 See *Security of Dangerous Pathogens and Toxins* (BWC/MSP.2003/MX/WP.5), paper presented by the US at the BWC Meeting of Experts, Geneva, August 2003.
http://www.opbw.org/new_process/bwc_msp.2003_mx_wp05.pdf

8 FAO, Biosecurity for Food and Agriculture, program website.
http://www.fao.org/biosecurity/

9 Barletta, M. *et.al.* 2002. *Keeping track of anthrax.*

10 Cartagena Biosafety Protocol, Article 1.
http: //www.biodiv.org/biosafety/protocol.asp

11 IUCN 1999. Draft IUCN Guidelines for the Prevention of Biodiversity Loss Due to Biological Invasion, Background paper for the Fourth Meeting of the CBD SBSTTA, Montreal, Canada, 21-25 June 1999.

12 Total staff at United Nations "P" or "D" grade.

13 Plus one associate professional position funded by the US and seconded from USDA. Two IPPC staff split their time with other duties at FAO.

14 EUR 3,934,000, at exchange rate of 1 Sept 2003 (EUR 1 = USD 1.099).

15 Parent of the Cartagena Biosafety Protocol.

16 Calls such as that made in 1988, by Jacques Mitterrand, to "internationalize" the Amazon Basin were obviously unhelpful in promoting unity behind a multilateral agreement to protect biodiversity.

17 The CBD's conclusion necessitated the renegotiation of the FAO Undertaking on Plant Genetic Resources for Food and Agriculture, the primary international instrument on agricultural germplasm. The Undertaking had been developed with such resources considered a "common heritage of mankind", rather than subject to state sovereignty. Those negotiations were successfully concluded in 2001 with the adoption of the International Treaty on Plant Genetic Resources for Food and Agriculture. See the website of the Commission on Genetic Resources for Food and Agriculture:
http://www.fao.org/ag/cgrfa/default.htm

18 The next Conference of the Parties will be held in February, 2004 in Kuala Lumpur, Malaysia. The COP has previously met in Nassau (1994), Jakarta (1995), Buenos Aires (1996), Bratislava (1998), Nairobi (2000), and The Hague (2002).

19 *Principle 15 of the Rio Declaration reads: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."* The full text of the Rio Declaration can be found at:
http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm

20 Mauro, F. 2000. Possible Linkages Between the Cartagena Biosafety Protocol and the Biological and Toxin Weapons Convention, Istituto Diplomatico "Mario Toscano", Rome, p. 2.

21 The term "living modified organism" was promoted by countries who considered it more friendly-sounding than "genetically modified organism".

22 See Provisional Agenda, UNEP/CBD/BS/COP-MOP/1/1. http://www.biodiv.org/doc/meeting.asp?wg=MOP-01

23 The Protocol's Roster of Experts was created to identify and provide assistance to countries in their implementation of the Protocol. As of September 2003, of the 491 persons nominated to the Roster, only two indicated bioweapons control expertise among their credentials.
http://bch.biodiv.org/Pilot/Roster/GettingStarted.aspx

24 FAO 2002. *Toward "Safe Trade"*, in Agriculture 21, March 2002. http://www.fao.org/ag/magazine/0203sp2.htm

25 The IPPC's texts are online at http://www.ippc.int.

26 WTO 1998. *Sanitary and Phytosanitary Measures: Introduction. Understanding the WTO Agreement on Sanitary and Phytosanitary Measures.* May, 1998.
http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm

27 Wolff, C. 2001. *Resolving Possible Conflicts Between Domestic and International Biotechnology Regulations and WTO Rules*, paper presented at ICTSD Workshop on Biotechnology, Biosafety and Trade: Issues for Developing Countries. Bellevue, Switzerland 18-20 July 2001. p. 4.

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http://www.oie.int/eng/normes/mcode/a_00004.htm

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38 See http://www.fao.org/DOCREP/004/Y3649E/y3649e05.htm

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BIOSAFETY, BIOSECURITY, AND BIOWEAPONS

Three Agreements on Biotechnology, Health, and the Environment, and Their Potential Contribution to Biological Weapons Control

Biological weapons risks posed by the development and dissemination of biotechnology are nearly universally recognized. Yet there is presently very little prospect of reining in these risks through the Biological Weapons Convention (BWC), whose parties generally recognize the dangers of biotechnology but have been unable to adequately respond.

This booklet introduces and discusses the provisions of three international agreements related to controlling disease and managing biotechnology risks to protect health and the environment:

- the Cartagena Biosafety Protocol (CBP)
- the International Plant Protection Convention (IPPC) and
- the Office International de Epizooties (OIE).

It relates these agreements, which are critical elements of a global biosecurity framework and play a critical role in the international regulation of biotechnology, to the BWC and discusses how they can contribute to the prevention of hostile use of biology.

The CBP and the IPPC and OIE are presently developing and implementing enforceable international rules and standards to contain threats, limit harm, and impose liability for damages resulting from biotechnology. These provide opportunities and synergies to strengthen the global ban on biological weapons.

This paper provides a background and a summary of critical provisions of each of the three agreements, indicating actions that can be taken to address biological weapons risks. It also discusses the need for addressing biosecurity and biosafety in a comprehensive framework, and concludes by discussing the need for a binding international instrument on biocontainment facilities.

Other multilateral activities of relevance to the BWC, for example, the World Health Organization's global health response to the deliberate use of biological weapons, are also treated.