National Implementation Legislation

Lecture No. 20

1. Outline

- Obligations to implement national measures.
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- "Any necessary measures",
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- An elaboration on key aspects of national implementation,
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- Case Study I: Japanese National Implementation,
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- Case Study III. US National Implementation,
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- Model Law and Criminalisation.
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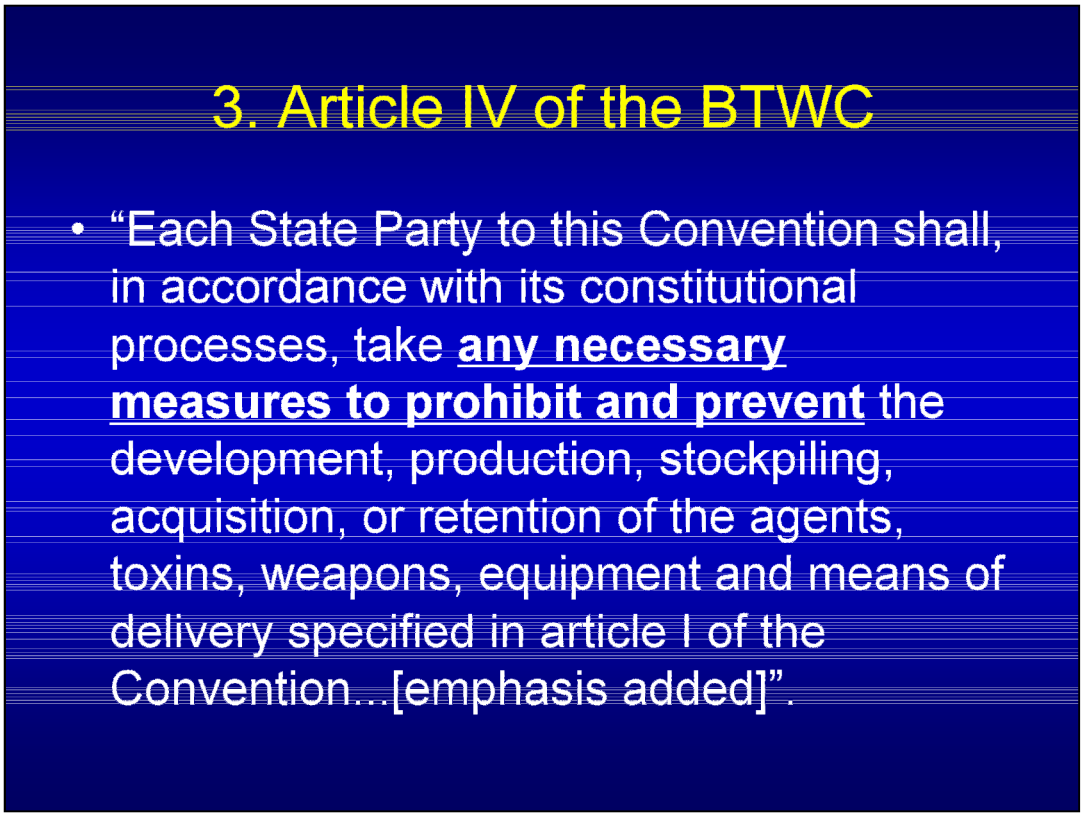
Notes: To be effective international agreements need to be implemented properly in national legislation. If they are not so implemented the "Web of Prevention" will necessarily be weakened. So the lecture begins by outlining what a lawyer would expect to see in national implementation of the BTWC and what was found a VERTIC 2003 survey of national implementation in different countries (see slide 6). Following on from that basis a set of State Party working papers for the Sixth Review Conference of the BTWC in 2006 are used to assess the state of development then, and to conclude developments at the 2007 intersessional meeting on national implementation are reviewed.

2. National Legislation

- National Legislation prohibiting the development, production, stockpiling or otherwise acquiring or retaining BW has become increasingly important since 9-11.
- Many states have constructed or revised their legislation in the 21st century to ensure it is still relevant.
- There has been and increased emphasis on enforcement of such legislation.
- National legislation is a legal process which directly has impacts on individual scientific research and transferring of bioagents. "I didn't know" doesn't help

Notes: Specific legal measures to implement the convention varied, necessarily so because of the differing legal systems used across the globe. Principle here is the distinction between common and civil law traditions, these are neatly explained by the BWPP "Common law states require national legislation to transform international obligations into enforceable national law...States with a civil law tradition, however, may consider treaties they have joined as 'self executing', whereby the text of the accord is automatically incorporated into national law when the agreement enters into force—no additional national measures are necessary to give it effect."



Notes: States Parties to the BTWC are obligated to take measures at the national level under Article IV of the BTWC. Notably this article stipulates that States Parties should take "take any necessary measures to prohibit and prevent". For some states this is an obligation of outcome as the EU has pointed out "Article IV is not simply an obligation of conduct but amounts to an obligation of result.

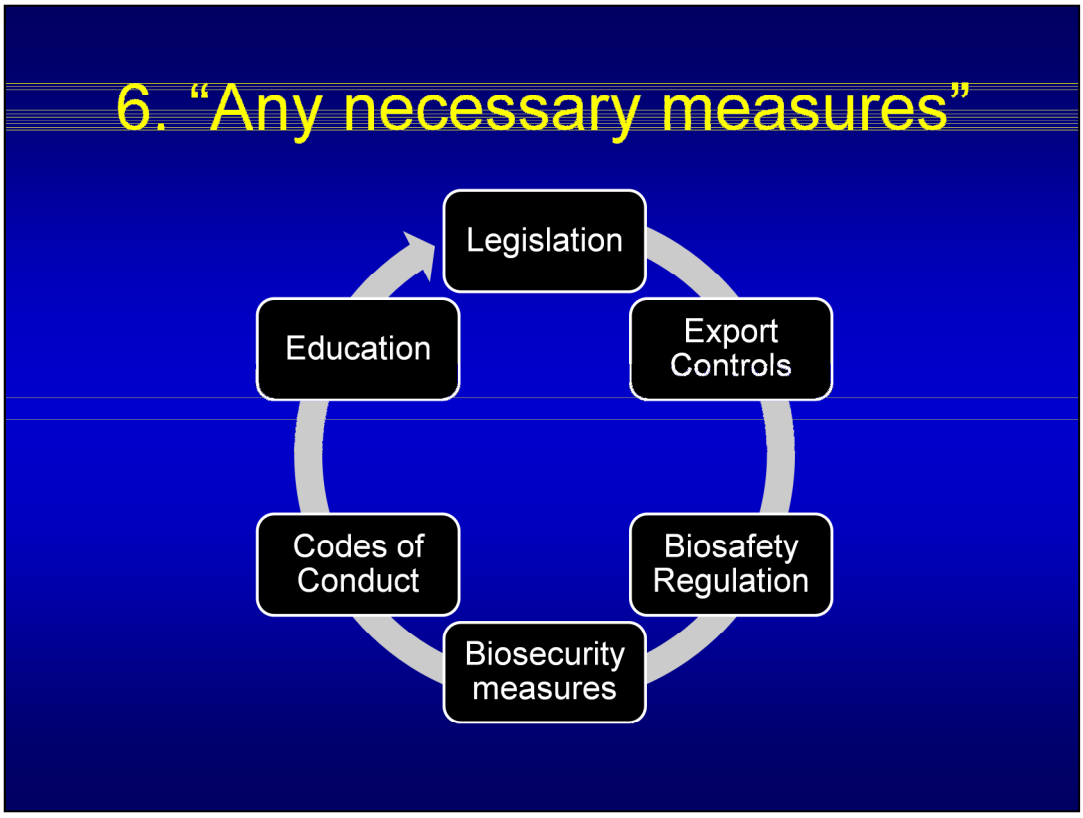
4. Article IV - An Obligation Of Result

- "Article IV is not simply an obligation of conduct but amounts to an obligation of result. It will not be sufficient to introduce mere prohibitions into national law to meet the obligations included in Article IV since States Parties have to take measures 'to prohibit *and prevent*"". [Emphasis in original text]

5. UN Security Council Resolution 1540

- "States shall take and enforce effective measures to establish domestic controls to prevent the proliferation of ... biological weapons and their means of delivery, including by establishing appropriate controls over related materials and to this end shall:
- …(a) Develop and maintain appropriate effective measures to account for and secure such items in production, use, storage or transport;
- (b) Develop and maintain appropriate effective physical protection measures."

Notes: The unprecedented exploitation of UN Chapter VII, 1540 is legally binding upon all states.



Notes: Although there is no one size fits all solution for national implementation and states need to tailor material to the specific linguistic, cultural and legal context, there are several categories of measures which can be undertaken to ensure the peaceful use of biology and biotechnology, including inter alia: National Legislation, Export Controls, Biosafety Regulations, Biosecurity measures, Codes of Conduct and Education.

7. Export Controls

- Changes in technology make export controls more difficult.
- However States have responded to these challenges and many states have updated export control provision and lists of agents and equipment but also “catch all controls” designed to cover “dual use” items.

Notes: In the twenty first century effective biological export controls suffer from a collection of challenges. Although many of these problems are not new, emerging complexities in the international system and the changing nature of science and technology have generated new challenges as well as compounding those problems which have traditionally blighted effective export controls.

8. Biosafety regulation

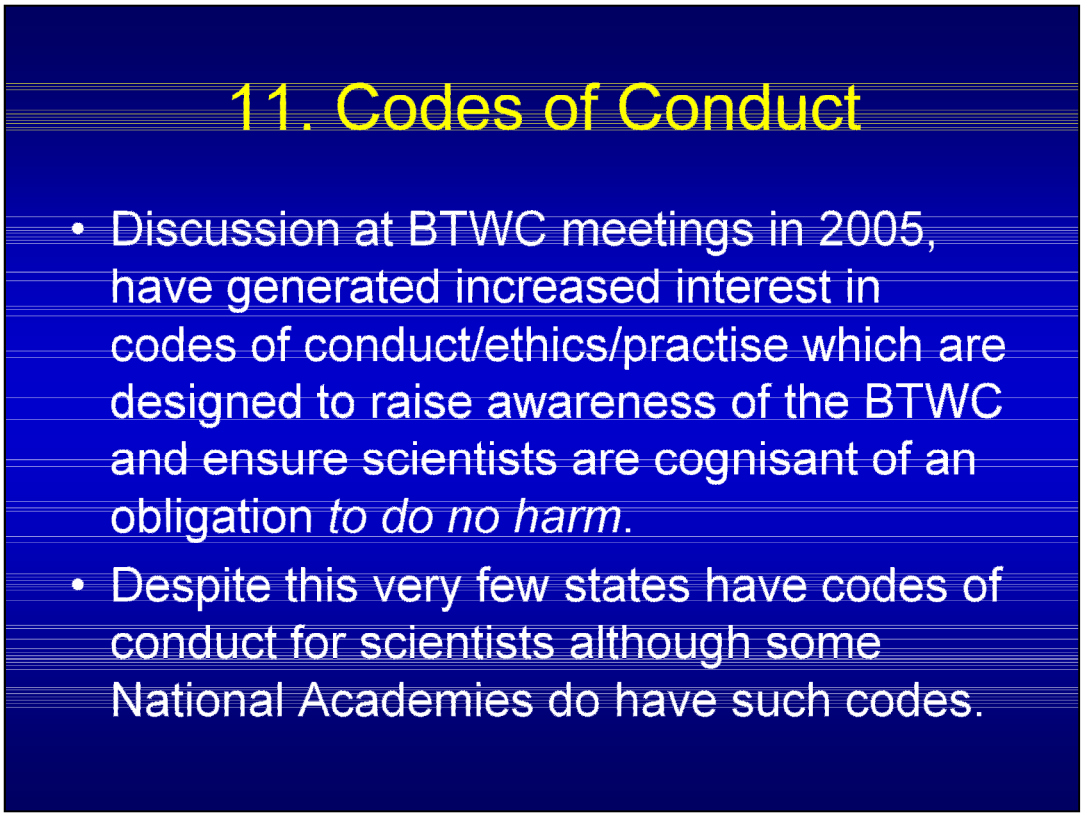
- Biosafety is defined by the WHO as “the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release”.
- Under the UK’s COSHH regulations, for example, this includes: familiarity with Health and Safety Policies; conducting in accordance with regulations; Exercising care in relation to yourself and others who may be affected by your actions (or inactions); and reporting any safety concerns.

9. Biosecurity measures (i)

- Biosecurity in the BTWC is “most commonly used to refer to mechanisms to establish and maintain the security and oversight of pathogenic microorganisms, toxins and relevant resources”.
- Key measures include: Personnel Reliability; Physical Security; Information Technology Security; Material Control and Accountability; Material Transfer Security & Program Management.

10. Biosecurity measures (ii)

"[In 2003] The States Parties agreed ... on the value of the following: The need for comprehensive and concrete national measures to secure pathogen collections and the control of their use for peaceful purposes. There was a general recognition of the value of biosecurity measures and procedures, which will ensure that such dangerous materials are not accessible to persons who might or could misuse them for purposes contrary to the Convention."



The Dutch Ministry of Education, Culture and Science asked the Royal Netherlands Academy of Arts and Sciences (KNAW) to provide it with advice and input for a national Biosecurity Code of Conduct for scientists, as required by the Biological and Toxin Weapons Convention (BTWC), which was ratified in 1972. From page 7 of [Further Inf.2] of the Slide.

12. Education

- Education - Discussion in the BTWC and elsewhere have led to a significant increase in attention devoted to education designed to nurture a culture of responsibility amongst life scientists and ensure awareness of legislation and regulations which govern scientific research.

13. Assessment for National Legislation: EU (Germany) [BWC/CONF.VI/WP.3] (i)

5 general patterns on national legislation on Article I:

1. Often lacks penal codes for breaching obligations,
2. CBN laws cover penal codes as framework legislation,
3. Regulates and controls peaceful use of BW-related materials by licensing permitted activities,
4. Application of prohibitions are limited to domestic territory,
5. Anti-terrorism laws may miss other non-state actors activities.

Notes: The working paper by the EU (presented by Germany) pointed out potential difficulties for implementing Article I and Article III due to the lack of detailed instruction by the texts of those Articles. To give a better illustration the working paper listed up the contents of national implementation measures which have been adopted by the EU countries.

14. Assessment for National Legislation: EU (Germany) [BWC/CONF.VI/WP.3] (ii)

- 3 necessary points to be considered for legislating Article III by.

1. Executing certain type of transferring for peaceful purpose,
2. Specifically identifying list of agents and toxins,
3. "…obligations … not to transfer 'indirectly', and 'not in any way to assist' illegal transport"

15. Detailed Legislative Elements: Japan (BWC/CONF.VI/WP.17)

- **Effective legislative measures to ensure the prohibitions and preventions as required by the Convention**
- **Export Controls**
- **Security and oversight of pathogens and toxins**
- **Enhancing preventive and response capabilities for natural or deliberate epidemics in cooperation with international mechanisms**
- **Education and enlightenment about biological weapon-related issues**

Notes: Based on the understanding at the ISP 2003-2005, the working paper by Japan further elaborated the scope and rationale of: Effective legislative measures; Export controls; Security and oversight of pathogens and toxins; Enhancing preventive and response capabilities for natural or deliberate epidemics in cooperation with international mechanisms; Education and enlightenment about biological weapon-related issues.

16. Japan's National Implementation

- ***Law on Implementing the Convention on Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (1982) revised in 2001***

  prohibits acts from the production, retention, transfer and acquisition of biological or toxin weapons, - and after 2001 - to their use and discharge [see note section]

- ***Foreign Exchange Control Order [Cabinet Order No. 260 1980] based on Foreign Exchange and Foreign Trade Control Law of 1949***

  "The export of certain anti-human, anti-animal and anti-plant pathogens to all countries and areas is subject to permission of the Minister of Economy, Trade and Industry."

- ***The Guidelines for Recombinant DNA Experiments of 2004***,

  "which will be described later, classify genetically modified organisms (GMO) into containment level groups and set, for each group, detailed requirements for laboratory design and safe handling procedures of GMO."

Notes: Japan enhanced the domestic law to make the use of biological weapons liable to indefinite period of imprisonment or for minimum 2 years, or maximum fine of ten million yen [approximately £47,200/$93,000], and shall fine an unlawful discharge of biological agents or toxins with maximum 10 years or minimum 5 years imprisonment, or maximum fine of ten million yen [approximately £47,200/$93,000]. However, difficulties to deal with bioterrorism still remained. Sugishima points out that "a primitive form of biological attack (e.g., contamination of foods with pathogens) like the ones that occurred before the Aum incident, would not be covered by this law."

Notes: It is notable that in the UK approach there has purportedly been an effort to compliment the legislative stick with an educational carrot through a laboratory biosecurity campaign that "has started with a 'hearts and minds' campaign".

18. US National Implementation

- National legislation on **prohibitions** under the BWC includes ***Criminal provisions, Seizure, Security of Dangerous pathogens, and toxins, Export Controls, Sanctions, Foreign assistant restrictions, Cooperative threat reduction, and emergency preparedness and response.*** Specific codes which have been legislated in relation to each of those prohibition measures are listed and illustrated in the working paper provided by the United States at the Meeting of Experts of the BTWC in 2003.
- ***Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188)***

  Codified a list of select agents and toxins by Center for Disease Control and Prevention and a list of live stock select agents toxins by Department of Agriculture.

Notes: VERTIC have been developing model laws and materials to assist states in meeting their obligations under the BTWC Article IV and UNSC Resolution 1540. They have developed a Sample Act for states to use.

20. Harvard Sussex: International Criminalisation

- Harvard Sussex Programme (HSP) are working on an "International Criminalisation" draft Convention.
- Developed "a draft convention that would make it a crime under international law for any person knowingly to develop, produce, acquire, retain, transfer or use biological or chemical weapons or knowingly to order, direct or render substantial assistance to those activities or to threaten to use biological or chemical weapons."

Notes: As part of a joint project the Harvard Sussex have been working on the International Criminalisation for prosecution of "

Sample Questions

1. Describe what legislation has your state undertaken to prevent the development, production, stockpiling or otherwise acquiring or retaining of BW?

2. Describe what legislation has your state undertaken to prevent the export of agents, equipment and expertise which can be considered dual use?

3. Evaluate the guidelines or regulations have your research laboratories or institutions taken to inform individual scientists of their obligation to maintain scientific research as solely peaceful enterprise?

4. As an individual scientist, how can you contribute to the prevention of the misuse of the life sciences? Elements illustrated in slide 7 may be useful here.

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