



Legislation and Regulations in the Field of Biosafety and Biosecurity in South East Asia

ASEAN Microbial Biotechnology Conference (AMBC)

19-21 February 2014
Bangkok, Thailand



About VERTIC

VERTIC is an independent not-for-profit organization located in London, United Kingdom that promotes the effective verification and implementation of international agreements and related regional and national initiatives.

VERTIC's National Implementation Measures (NIM) Programme advises States on national implementation of the obligations under the BWC, the Chemical Weapons Convention and certain international instruments for nuclear security.



BWC and UNSCR 1540

- The BWC is a multilateral treaty that entered into force on 26 March 1975.
 - It has 170 States Parties and 10 Signatory States.
 - It requires States Parties to adopt measures to prohibit and prevent biological weapons.
-
- United Nations Security Council Resolution 1540 was adopted on 28 April 2004 under Chapter VII of the UN Charter.
 - It is legally binding on all UN Member States.
 - 1540 Committee oversees implementation of the resolution.
 - The 1540 Committee's mandate was extended most recently in 2011 (UNSCR 1977) until 25 April 2021.



National Implementation Measures

- Under Article IV of the BWC and operative paragraphs 2 and 3 of UNSCR 1540, States are required to take national measures, in accordance with their constitutional processes, to prohibit and prevent biological weapons.
- A legislative framework should cover the following areas:
 - 1) Definitions
 - 2) Prohibitions and penalties
 - 3) Jurisdiction
 - 4) Biosafety and biosecurity
 - 5) Transfer control regime
 - 6) Enforcement



National Implementation Measures

- 1) **Definitions** (biological weapon, biological agent, toxin, etc.)

- 2) **Prohibition** of certain activities:
 - development, production, acquisition, stockpiling, retention, direct or indirect transfers, and use of biological weapons
 - preparations (attempts, conspiracy, threats, financing, etc.) related to biological weapons
 - unlicensed activities involving controlled biological agents and toxins (such as anthrax, botulinum, Ebola, plague, salmonella, etc.)

- 3) **Extending the reach** of the prohibitions:
 - to natural and legal persons
 - extraterritorially (e.g. on the basis of nationality of perpetrator, nationality of victim, impact on State interests)



National Implementation Measures

4) **National biosafety and biosecurity** measures play a key role in preventing biological weapons proliferation. Some specific measures could include:

- Adoption of a control (or select) agents list based on threat to public health and safety and national security (e.g. WHO risk-based approach; Australia Group lists for human, animal and plant pathogens and dual-use equipment and related technology)
- Establishing a mechanism for notification of accidents, loss or theft
- Comprehensive record-keeping
- Biosafety and biosecurity training for personnel
- Physically secure labs (externally and internally)
- Personnel background checks
- Secure transportation (approved carriers, secure containers and packaging, labelling, shipment tracking, etc.)



National Implementation Measures

5) Transfer Controls:

- Article III of the BWC requires all States Parties to refrain from transferring biological weapons to anyone and from assisting, encouraging or inducing anyone to manufacture or acquire them.
- Adoption of a control (or select) agents list based on threat to public health and safety and national security (e.g. WHO risk-based approach; Australia Group lists for human, animal and plant pathogens and dual-use equipment and related technology)
- Establish a permit system
- Require an end-user certificate
- Establish effective border controls



National Implementation Measures

6) **Legislative enforcement** to ensure non-proliferation of biological weapons:

- National Authority (and States are strongly encouraged to designate a national point of contact to the BWC's Implementation Support Unit)
- National inspections of laboratories and other facilities where controlled biological agents and toxins may be found (as there is no regime in place for international inspections)
- Training and special powers for law enforcement officials including customs and other border officials, sea and air port authorities
- Disease surveillance; response capability in the event of a natural, accidental or intentional outbreak (and co-operation among law enforcement and health officials)
- International co-operation on judicial and criminal matters



Regional Status of Implementation

- 56 States in Asia
 - 48 BWC States Parties
 - VERTIC legislation surveys for 40 States

- 20 States in South and Southeast Asia

Afghanistan, Bangladesh, Bhutan, Brunei Darussalam, Cambodia, India, Indonesia, Islamic Republic of Iran, Lao PDR, Malaysia, Maldives, Myanmar, Nepal, Pakistan, Philippines, Singapore, Sri Lanka, Thailand, Timor Leste, Vietnam

- 18 States Parties; 2 signatories
 - VERTIC legislation surveys for 18 States
- 170 BWC States Parties in total
 - VERTIC legislation surveys for 141 States



<i>Measures</i>	<i>Asia: Number (%) of 40</i>	<i>Global: Number (%) of 141</i>
DEFINITIONS		
Biological weapon	6 (15%)	15 (11%)
PROHIBITIONS		
Develop biological weapons and penalties	7 (18%)	36 (26%)
Manufacture/produce biological weapons and penalties	13 (33%)	52 (37%)
Acquire biological weapons and penalties	11 (28%)	42 (30%)
Stockpile/store biological weapons and penalties	6 (15%)	34 (24%)
Possess/retain biological weapons and penalties	8 (20%)	43 (30%)
Transfer biological weapons and penalties	13 (33%)	50 (35%)
Use biological weapons and penalties	13 (33%)	50 (35%)
Engage in activities involving dangerous biological agents or toxins without authorisation/in violation of the conditions of an authorisation and penalties	4 (10%)	34 (24%)
Transfer dangerous biological agents or toxins without authorisation/to unauthorised persons and penalties	15 (38%)	56 (40%)



<i>Measures</i>	<i>Asia: Number (%) of 40</i>	<i>Global: Number (%) of 141</i>
CONTROL LISTS		
Control lists for dangerous biological agents and toxins	8 (20%)	33 (23%)
Control lists for dual-use biological equipment and related technology	6 (15%)	24 (17%)
PREVENTATIVE MEASURES		
Measures to account for production	4 (10%)	10 (7%)
Measures to account for use	3 (8%)	16 (11%)
Measures to account for storage	3 (8%)	9 (6%)
Measures to account for transport	3 (8%)	17 (12%)
Measures to secure production	3 (8%)	7 (5%)
Measures to secure use	3 (8%)	11 (8%)
Measures to secure storage	4 (10%)	13 (9%)
Measures to secure transport	4 (10%)	31 (22%)
Regulations for physical protection of facilities which produce, use or store dangerous biological agents or toxins and related penalties	3 (8%)	6 (4%)
Regulations for physical protection of dangerous biological agents and toxins and related penalties	3 (8%)	7 (5%)
Authorisation of activities involving dangerous biological agents or toxins	8 (20%)	42 (30%)
National licensing authority	5 (13%)	30 (21%)
Regulations for genetic engineering work	8 (20%)	53 (38%)



<i>Measures</i>	<i>Asia: Number (%) of 40</i>	<i>Global: Number (%) of 141</i>
TRANSFER CONTROLS		
Authorisation for exports and imports of dangerous biological agents and toxins	25 (63%)	87 (62%)
Export/import control authority	14 (35%)	52 (37%)
End-user controls for dangerous biological agents and toxins	4 (10%)	26 (18%)
Transit control over dangerous biological agents and toxins	9 (23%)	33 (23%)
Trans-shipment control over dangerous biological agents and toxins	4 (10%)	7 (5%)
Re-export control over dangerous biological agents and toxins	6 (15%)	18 (13%)
Export control over dangerous biological agents and toxins	12 (30%)	50 (35%)
Import control over dangerous biological agents and toxins	15 (38%)	62 (44%)

Approaches to National Implementation

- Comprehensive stand-alone BWC law

Antigua and Barbuda, Australia*, Belgium, Brunei-Darussalam, Canada*, Cuba*, Czech Republic*, France, Japan*, Mauritius*, The Netherlands, Russian Federation, Saint Kitts and Nevis, Singapore, United Kingdom, United States

- Law that only contains the necessary penal provisions for the BWC
- Comprehensive law containing penal provisions, biosafety/biosecurity measures, export control provisions and enforcement measures (indicated with *)

- Weapons of Mass Destruction law

Chile, India, South Africa

- Chapter divisions by type of weapon/material (RN, B, C)
- The accountability and security measures are different for each type of regime
- Criminal provisions are separated for each type of weapon
- Transfer permits can be combined for the three regimes

- Implementation through several laws and regulations

H5N1, Erasmus Study & Export Control

- Researchers in the Netherlands have been able to make avian flu transmissible between mammals (Indonesian H5N1 strain used).
- The researchers needed to apply for an export permit before sending their article to the publishers in the United States (because it was an intangible transfer).
- European Union Regulation 428/2009 on ‘setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items and technology’:
 - The Regulation requires an export permit for exports outside of the EU of dual-use items, including exports of technology.
 - Avian flu is one of the animal pathogens listed as a dual-use item, including technology related to avian flu.
- Dutch law implements the EU Regulation at the national level:
 - Decree on Strategic Goods, Law on Strategic Services
 - Law on Economic Offenses

H5N1, Erasmus Study & Export Control

(continued)

- EU Regulation does not require an export permit if the technology in question is ‘basic scientific research’.
 - Definition: ‘experimental or theoretical work undertaken principally to acquire new knowledge of the fundamental principles of phenomena or observable facts, not primarily directed towards a specific practical aim or objective.’
- In Sept 2013 – A Dutch district court approved a government’s decision to require the researcher to obtain export licenses before two research papers were sent outside of the Netherlands for publication.
- The government considered sending the papers to *Science* magazine a form of export requiring official permission.
- The court agreed: this was not basic scientific research but the researchers had “taken steps and made choices that led to entirely new outcomes”



VERTIC's BWC Tools

- ICRC-VERTIC sample legislation: 'A **Model Law**: The Biological and Toxin Weapons Crimes Act'
- VERTIC's '**Sample Act** for National Implementation of the 1972 Biological and Toxin Weapons Convention and Related Requirements of UN Security Council Resolution 1540'
- VERTIC's '**Regulatory Guidelines** for National Implementation of the 1972 Biological and Toxin Weapons Convention and Related Requirements of UN Security Council Resolution 1540'
- VERTIC's '**Guide** to National Implementation of UN Security Council Resolution 1540 (2004)'
- VERTIC's BWC National Implementation **Database** (at www.vertic.org > Programmes > NIM > Biological weapons and materials > BWC Legislation Database)
- We have **fact sheets** on the BWC and on establishing a BWC National Authority
- All are available in various languages at www.vertic.org and on CDs



Contact VERTIC

NIM Programme, NIM@vertic.org

The Verification Research, Training and Information Centre (VERTIC)

Development House, 56-64 Leonard Street

London EC2A 4LT, United Kingdom

Tel +44 20 7065 0880

Fax +44 20 7065 0890

Web www.vertic.org

VERTIC wishes to thank Canada (Global Partnership Program, Foreign Affairs, Trade and Development Canada), the United Kingdom (Strategic Programme Fund, Foreign and Commonwealth Office), the United States (Biosecurity and Chemical Security Engagement Programs, Department of State) for their financial and in-kind support for the NIM programme. The views expressed by VERTIC do not necessarily reflect those of these governments or agencies.