

# Establishing legislation and regulations

Scott Spence

Programme Director, National Implementation Measures Programme

**Food Defense: The Impact of Chemical and Biological Threats**

10-12 May 2016, Interpol Headquarters

Lyon, France

## Outline

- The legislative framework for food defense from chemical and biological threats: International law & national law
- Which areas of national law are affected?
- Approaches to developing appropriate legislation
- Approaches to achieving inter-agency coordination
- Which approach is best for your country?
- Examples of legislation in force
- Effective practices in legislative implementation
- Lessons learned in legislative implementation
- Useful tools

## The legislative framework: international law

### 1972 Biological Weapons Convention (BWC)

- prohibits the development, production, acquisition, transfer, retention, stockpiling (and use) of biological and toxin weapons

### 1993 Chemical Weapons Convention (CWC)

- prohibits the development, production, stockpiling and use of chemical weapons (toxic chemicals and their precursors, when used for purposes not prohibited under the Convention)

### United Nations Security Council Resolution 1540 (2004)

- requires States to refrain from providing any form of support to non-State actors that attempt to develop, acquire, manufacture, possess, transport, transfer or use nuclear, chemical or biological weapons and their means of delivery

➔ States are required to take and enforce national laws to give effect to their obligations under these instruments

## The legislative framework: national law

### Key elements

- Definitions
- Prohibitions, penalties and alternative criminal liability
- Jurisdiction
- Domestic controls: to account for, secure and physically protect relevant materials; personnel reliability, whistle-blower protection (to mitigate insider threat)
- Transfer controls
- Domestic controls: for monitoring and enforcement
- Co-ordinated emergency preparedness and response

A comprehensive, coherent national legislative framework is essential to prohibit, prevent, detect, respond to and prosecute breaches of food defence involving chemical and biological agents

## Which areas of national law are affected?

- Criminal law
- Export-import, strategic and dangerous goods, customs laws
- Regulatory systems for dual-use materials, including measures to account for and physically protect relevant materials
- Banking laws, financing of terrorism
- Related enforcement measures: criminal procedure laws, etc.
- Related measures to coordinate emergency response

## Approaches to developing appropriate legislation (1/3)

- 1) Standalone biological, chemical (and radiological/nuclear) laws
  - Primarily common law countries have taken this approach (with a few exceptions)
  - Two trends identified:
    - Law that only contains the necessary penal provisions
    - Comprehensive law containing penal provisions, safety/security measures, export control provisions and enforcement measures
  - Pros and cons of this approach?

## Approaches to developing appropriate legislation (2/3)

### 2) A combined 'Weapons of Mass Destruction' law

- Such laws may include the establishment of a 'CBRN National Authority', with roles including risk governance, risk reduction and emergency response
- Some countries have adopted legislation to implement the CWC and BWC in one law and/or have one common authority
- Pros and cons of this approach?

## Approaches to developing appropriate legislation (3/3)

### 3) Implementation through several laws and regulations

- Most European countries (and civil law countries) have adopted this approach
- How does the implementation work ?
  - Criminal provisions: Penal Code or counter-terrorism legislation
  - CB(RN) material safety/security provisions: separate chemical, bio, (nuclear) laws, etc.
  - Export control of dual use items: in export control laws, customs codes or military/sensitive goods/dual-use items legislation
  - Enforcement: through criminal procedure codes, police laws, extradition laws, mutual assistance in criminal matters legislation
- Gaps can be filled with amending legislation:
  - For example, amending the penal code, adopting control lists (preferably through regulation), adopting a CB(RN) material safety/security law, and/or reinforcing the export control regime
- Pros and cons of this approach?



## Approaches to achieving inter-agency coordination

### 1) At the national level

Important to engage all relevant parties in the development of risk mitigation strategies and associated legislation, including police and other first responders

### 2) At the regional and international levels

Helpful to establish MoUs to call upon regional/international assistance and provision of resources (access to services, equipment and personnel)

## Which approach is the best for your country?

- No one size fits all: each State will decide the type of implementing measures it requires and which approach to follow
- Possible to combine various approaches
- What factors should be taken into account when deciding on which approach to follow?
  - Constitutional processes
  - Assessment of international obligations related to UNSCR 1540
  - Assessment of the national and regulatory framework : measures already in place
  - Assessment of the scope of current and future CB(RN) national activities
  - Assessment of the level of detail required in the legislation
  - Actors involved in the drafting process and implementation of the law

## Examples of legislation in force

### Definitions

#### United States

#### Title 18 Part I (Crimes) U.S.C. Chapter 10 (Biological Weapons) Sec. 178 (Definitions)

“As used in this chapter -

(1) the term "biological agent" means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of causing -

(A) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;

(B) **deterioration of food**, water, equipment, supplies, or material of any kind; or

(C) deleterious alteration of the environment”...

See also 7 C.F.R. 331.1, 9 C.F.R. 121.1, 42 C.F.R. 73.1.

## Examples of legislation in force

### Prohibitions, penalties and alternative criminal liability

#### United States

Title 42 (The Public Health and Welfare) U.S.C. Chapter 6A (Public Health Service) Subchapter XII (Safety of Public Water Systems), Part D (Emergency Powers) Sec. 300i-1 (Tampering with public water systems)

#### “(a) Tampering

**Any person who tampers with a public water system** shall be imprisoned for not more than 20 years, or fined in accordance with title 18, or both.

#### (b) Attempt or threat

Any person **who attempts to tamper, or makes a threat to tamper, with a public drinking water system** be imprisoned for not more than 10 years, or fined in accordance with title 18, or both.

#### (c) Civil penalty

The Administrator **may bring a civil action** in the appropriate United States district court (as determined under the provisions of title 28) **against any person who tampers, attempts to tamper, or makes a threat to tamper with a public water system**. The court may impose on such person a civil penalty of not more than \$1,000,000 for such tampering or not more than \$100,000 for such attempt or threat.”

## Examples of legislation in force

### Prohibitions, penalties and alternative criminal liability

#### United States

Title 42 (The Public Health and Welfare) U.S.C. Chapter 6A (Public Health Service) Subchapter XII (Safety of Public Water Systems), Part D (Emergency Powers) Sec. 300i-1 (Tampering with public water systems)

“(d) "Tamper" defined

For purposes of this section, the term "tamper" means –

- (1) to introduce a contaminant into a public water system with the intention of harming persons; or
- (2) to otherwise interfere with the operation of a public water system with the intention of harming persons”.

## Examples of legislation in force

### Prohibitions, penalties and alternative criminal liability

#### United States

#### Title 18 Part I (Crimes) U.S.C. Chapter 3 (Animals, Birds, Fish and Plants) Sec. 43 (Force, violence and threats involving animal enterprises)

“(c) **Restitution.** - An order of restitution under section 3663 or 3663A of this title with respect to a violation of this section may also include restitution -

(1) for the reasonable cost of repeating any experimentation that was interrupted or invalidated as a result of the offense;

(2) **the loss of food production or farm income reasonably attributable to the offense**; and

(3) for any other economic damage resulting from the offense”.



## Examples of legislation in force

### Jurisdiction

#### United States

##### Title 18 Part I (Crimes) U.S.C. Chapter 11B (Chemical Weapons) Sec 229 (Prohibited activities)

“(c) **Jurisdiction.** — Conduct prohibited by subsection (a) is within the jurisdiction of the United States if the prohibited conduct —

- (1) takes place in the United States;
- (2) takes place outside of the United States and is committed by a national of the United States;
- (3) is committed against a national of the United States while the national is outside the United States; or
- (4) is committed against any property that is owned, leased, or used by the United States or by any department or agency of the United States, whether the property is within or outside the United States.”

## Examples of legislation in force

Domestic controls: to account for, secure and physically protect relevant materials; personnel reliability, whistle-blower protection (to mitigate insider threat)

### United States

Title 7 (Agriculture) U.S.C. Chapter 64 Subchapter XIII (Biosecurity) Sec. 3353 (Agricultural biosecurity)

“(b) Guidelines for agricultural biosecurity

(1) In general

The Secretary may award grants to associations of food producers or consortia of such associations for the development and implementation of **educational programs to improve biosecurity on farms** in order to ensure the security of farm facilities **against potential bioterrorist attacks”...**



## Examples of legislation in force

Domestic controls: to account for, secure and physically protect relevant materials; personnel reliability, whistle-blower protection (to mitigate insider threat)

### United States, Department of Health & Human Services, Personnel Reliability

Overview: Personnel are required to be screened prior to being granted access to biological select agents and toxins (BSAT). A Security Risk Assessment (SRA) is one method of evaluating personnel reliability and it is specifically required for those individuals who wish to possess, use, or transfer BSAT. This is completed by the Federal Bureau of Investigation (FBI) in coordination with the Federal Select Agent Program. For Tier 1 BSAT, personnel must also undergo ongoing suitability assessments and the entity has increased responsibilities for personnel monitoring, reporting, and coordination with security and safety officials.

## Examples of legislation in force

### Transfer controls

#### United Kingdom

#### The Export Control Order 2008

Overview: The UK Strategic Export Control Lists form the basis of determining whether any products, software or technology that you intend to export are ‘controlled’ and therefore require an export licence.

The lists include reference to a wide range of items that could be used for military purposes, for torture or capital punishment or for the purposes of developing or manufacturing chemical, biological or nuclear weapons.

## Examples of legislation in force

### Domestic controls: for monitoring and enforcement

#### United States

##### Title 7 (Agriculture) U.S.C. Chapter 109 (Animal Health Protection) Sec. 8319 (Surveillance of zoonotic diseases)

“The Secretary of Health and Human Services, through the Commissioner of Food and Drugs and the Director of the Centers for Disease Control and Prevention, and the Secretary of Agriculture **shall coordinate the surveillance of zoonotic diseases**”.

#### United States

##### Title 18 Part I (Crimes) U.S.C. Chapter 11B (Chemical Weapons) Sec. 229 (Prohibited activities)

##### **Sec. 229E. Requests for military assistance to enforce prohibition in certain emergencies**

"The Attorney General may request the Secretary of Defense to provide assistance under section 382 of title 10 in support of Department of Justice activities relating to the enforcement of section 229 *[on CW prohibitions]* of this title in an emergency situation involving a chemical weapon. The authority to make such a request may be exercised by another official of the Department of Justice in accordance with section 382(f)(2) of title 10.

## Examples of legislation in force

Domestic controls: for monitoring and enforcement

United States

Title 22 (Foreign Relations) U.S.C. Chapter 75 (Chemical Weapons Convention Implementation)  
Sec. 401 (Reports required by the United States National Authority)

(a) Regulations on Recordkeeping. —

(1) Requirements. — The United States National Authority shall ensure that regulations are prescribed that require each person located in the United States who produces, processes, consumes, exports, or imports, or proposes to produce, process, consume, export, or import, a chemical substance that is subject to the Convention to —

(A) maintain and permit access to records related to that production, processing, consumption, export, or import of such substance; and

(B) submit to the Director of the United States National Authority such reports as the United States National Authority may reasonably require to provide to the Organization, pursuant to subparagraph 1(a) of the Annex on Confidentiality of the Convention, the minimum amount of information and data necessary for the timely and efficient conduct by the Organization of its responsibilities under the Convention.



## Examples of legislation in force

Domestic controls: for monitoring and enforcement

United States

Title 18 Part I (Crimes) U.S.C. Chapter 11B (Chemical Weapons) Sec. 229 (Prohibited activities)

### **Subtitle B — Revocations of Export Privileges**

If the President determines, after notice and an opportunity for a hearing in accordance with section 554 of title 5, United States Code, that any person within the United States, or any national of the United States located outside the United States, has **committed any violation** of section 229 of title 18, United States Code, the President may issue an order for the **suspension or revocation of the authority of the person to export from the United States any goods or technology** (as such terms are defined in section 16 of the Export Administration Act of 1979 (50 U.S.C. App. 2415)).

## Examples of legislation in force

### Coordinated emergency preparedness and response

United States

Title 7 (Agriculture) U.S.C. Chapter 64 Subchapter XIII (Biosecurity) Sec. 3354 (Agricultural bioterrorism research and development)

“(a) In general

The Secretary of Agriculture (referred to in this section as the "Secretary") may utilize existing **research authorities and research programs to protect the food supply** of the United States by conducting and supporting research activities to -

- (1) **enhance the capability of the Secretary to respond in a timely manner to emerging or existing bioterrorist threats to the food and agricultural system** of the United States;
- (2) develop new and continue partnerships with institutions of higher education and other institutions to help form stable, long-term **programs to enhance the biosecurity and food safety** of the United States, including the coordination of the development, implementation, and enhancement of diverse capabilities for addressing threats to the nation's agricultural economy and food supply, with special emphasis on planning, training, outreach, and research activities related to vulnerability analyses, incident response, detection, and prevention technologies; ...

## Examples of legislation in force

### Coordinated emergency preparedness and response

United States

Title 7 (Agriculture) U.S.C. Chapter 64 Subchapter XIII (Biosecurity) Sec. 3354 (Agricultural bioterrorism research and development)

- (3) **strengthen coordination with the intelligence community** to better identify research needs and evaluate materials or information acquired by the intelligence community relating to potential threats to United States **agriculture**;
- (4) **expand the involvement of the Secretary with international organizations dealing with plant and animal disease control**;
- (5) continue research to develop **rapid detection field test kits to detect biological threats to plants and animals** and to provide such test kits to State and local agencies preparing for or responding to bioterrorism;
- (6) **develop an agricultural bioterrorism early warning surveillance system** through enhancing the capacity of and coordination between State veterinary diagnostic laboratories, Federal and State agricultural research facilities, and public health agencies; and
- (7) otherwise improve the capacity of the Secretary to protect against the threat of bioterrorism”...

To compare various approaches to national implementation...

1540 legislation database

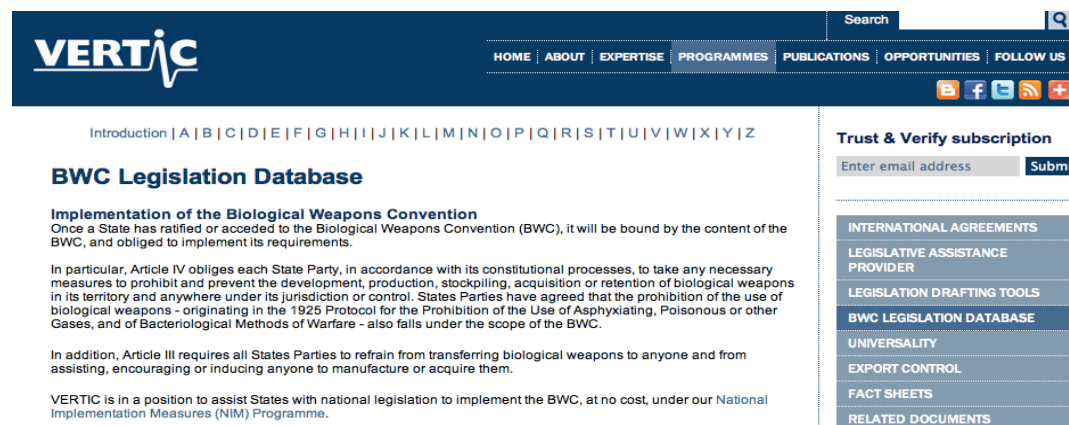
[Main](#) > [National-Implementation](#) > Legislative Database

## List of Legislative Documents

[A](#) [B](#) [C](#) [D](#) [E](#) [F](#) [G](#) [H](#) [I](#) [J](#) [K](#) [L](#) [M](#) [N](#) [O](#) [P](#) [Q](#) [R](#) [S](#) [T](#) [U](#) [V](#) [W](#) [X](#) [Y](#) [Z](#)

[Other Submissions](#)

VERTIC BWC (and nuclear security) legislation databases



The screenshot shows the VERTIC BWC Legislation Database website. The header includes the VERTIC logo, a search bar, and navigation links: HOME, ABOUT, EXPERTISE, PROGRAMMES, PUBLICATIONS, OPPORTUNITIES, and FOLLOW US. Below the header, there is a list of letters for navigation: Introduction | A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z. The main content area is titled "BWC Legislation Database" and contains text about the implementation of the Biological Weapons Convention (BWC). On the right side, there is a "Trust & Verify subscription" form with a "Submit" button and a list of related documents: INTERNATIONAL AGREEMENTS, LEGISLATIVE ASSISTANCE PROVIDER, LEGISLATION DRAFTING TOOLS, BWC LEGISLATION DATABASE, UNIVERSALITY, EXPORT CONTROL, FACT SHEETS, and RELATED DOCUMENTS.



# Effective Practices in Legislative Implementation (1 of 4)



## On the **substance**:

- Identifying international obligations:
  - Review of membership to relevant treaties
  - Consider joining additional treaties and supporting non-legally binding instruments
- Identifying legislative and regulatory needs:
  - Comprehensive review of the existing national legal framework
    - Criminal law and procedure, export/import control law, regulation relating to dual-use materials
  - Gaps and need for additional legislative and regulatory measures
    - Adding the necessary definitions, prohibitions/penalties, jurisdictional measures, safety and security measures, transfer controls and legislative enforcement measures.

# Effective Practices in Legislative Implementation (2 of 4)



## On the **substance**:

- Drafting of additional legislative and regulatory measures
  - Forming a drafting committee with representatives of relevant ministries/institutions
  - Organising drafting workshops
  - Using model legislation and other States' legislation



# Effective Practices in Legislative Implementation (3 of 4)



On the **method**:

- Deciding on the approach:
  - **Comprehensive stand-alone law**
    - Law that only contains the necessary criminal provisions
    - Comprehensive law containing criminal provisions, transfer control measures, safety and security measures, enforcement measures
  - **Weapons of Mass Destruction law**
    - Chapter divisions by type of weapon/material (RN, B, C)
    - Accountability and security measures are different for each type of regime
    - Criminal provisions are separated for each regime
    - Transfer permits can be combined for the three regimes
  - **Implementation through several laws and regulations**

# Effective Practices in Legislative Implementation (4 of 4)



## On the **procedure**:

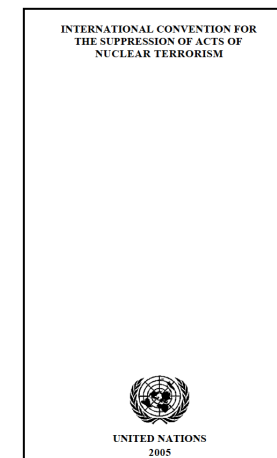
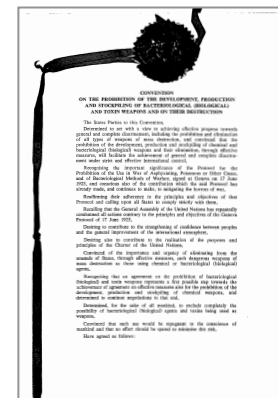
- Identifying relevant institutions/persons:
  - Link roles and responsibilities of national institutions with specific international obligations
  - Focal point in charge of coordinating legislative and regulatory actions
- Identifying possible need for assistance and assistance providers
  - Development of a UNSCR 1540 National Action Plan
- Establishing a timeline for legislative drafting, review and adoption:
  - Review and approval by ministries
  - Review and adoption by legislature
  - Outreach/awareness-raising to relevant national stakeholders

# Lessons Learned in Legislative Implementation (1 of 3)



## On the **substance**:

- Many complex obligations for national legislation drafters
- Difficulty in identifying which obligations are already covered by national legislation
- States are not sure or convinced of the relevance of the measures to them
- Other legislative priorities



# Lessons Learned in Legislative Implementation (2 of 3)



## On the **method**:

- States often wonder what legislative approach is most appropriate and effective for them, based on their national situation and constitutional arrangements
- States often look at other States' approach to legislation, particularly those with a similar legal or industrial background

# Lessons Learned in Legislative Implementation (3 of 3)



## On the **procedure**:

- Difficulties establishing inter-ministerial co-operation and co-ordination – perhaps the biggest hurdle
- Reasonable and realistic timeframes
- Drafting process requires capacity and time
- Co-ordination among assistance providers



## Useful tools

*VERTIC Legislative Guide to National Implementation of UNSCR 1540 (2004)*

*VERTIC Sample Act for National Implementation of the 1972 BTWC and Related Requirements of UNSCR 1540 (2004)*

*VERTIC Regulatory Guidelines for National Implementation of the 1972 BTWC and Related Requirements of UNSCR 1540 (2004)*

*OPCW National Legislation Implementation Kit for the CWC*

*IAEA 2010 Nuclear Law Handbook: Implementing Legislation*

*Indonesia-VERTIC National Legislation Implementation Kit on Nuclear Security*





Thank you

Scott Spence  
Programme Director for National Implementation  
[scott.spence@vertic.org](mailto:scott.spence@vertic.org)

VERTIC (The Verification Research, Training and Information Centre)  
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](http://www.vertic.org) > Programmes > NIM

