BWC - Article IV – Confidence Building Measures

MOT: the French national regulation

Micro-Organisms & Toxins regulation in force

BWC Meetings of Experts – UNODA
MX3 session – Strengthening National Implementation

3 September 2021 - Palais des Nations - Room XIX
Chairman: Mr. Arman Baissuanov of Kazakhstan
MX3 will consider the following topics:

- Measures related to Article IV of the Convention;
- CBM submissions in terms of quantity and quality;
- Various ways to promote transparency and confidence building under the Convention;
- Role of international cooperation and assistance under Article X, in support of strengthening the implementation of the Convention;
- Issues related to Article III, including effective measures of export control, in full conformity with all Articles of the Convention, including Article X.

AGENDA ITEM 4: Measures related to Article IV of the Convention

- Update by the Implementation Support Unit
- BWC/MSP/2020/MX.3/WP.1 - Online training course for Biological Weapons Convention National Contact Points in Southeast Asia: a model approach for other regions - Submitted by Japan
- Technical presentation by Mr. Cyril Stern, France
- Guest of the Meeting Dr. Sonia Drobysz, Verification Research, Training and Information Centre (VERTIC)
- Technical presentation by the Organization of American States (OAS)
- Interventions by States Parties
- Interactive discussion
Micro-Organisms & Toxins (MOTs)

An overview of the French regulation in force
### Examples of legal measures that reflect the CBM in France

#### Purpose

**BWC - Article I & Article IV**

*Biological Agents → prophylactic, protective or other peaceful purposes only + Control measures*

#### National confidence measure

*French defense code - Article L2341-1*

The development, manufacture, possession, storage, transport, acquisition, transfer, import, export, trade and brokering of microbiological agents, other biological agents and toxins are prohibited, whatever their origin and method of production, of types and in quantity not intended for prophylactic, protective or other peaceful purposes.

#### Purpose

**BWC - Article I & Article III → Transfer of agents, toxins, … to other states & organisations**

#### European confidence measure

*COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (Recast) - Art. 6 point 1*

The transit of non-Community dual-use items listed in Annex I may be prohibited by the competent authorities of the Member State where the transit occurs if the items are or may be intended, in their entirety or in part, for uses referred to in Article 4(1). When deciding on such a prohibition the Member States shall take into account their obligations and commitments they have agreed to as parties to international treaties or as members of international non-proliferation regimes.

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**But … how to effectively apply art. IV of the bwc operationally in laboratories?**

……….. simultaneously, how to effectively apply art. X point 2 of the bwc and encourage the activity of biological sciences on highly pathogenic agents while controlling the risks?
Why a specific regulation about Micro-Organisms & Toxins (MOTs)?

But … how to effectively apply art. IV of the bwc operationally in laboratories?

………. simultaneously, how to effectively apply art. X point 2 of the bwc and encourage the activity of biological sciences on highly pathogenic agents while controlling the risks?

◆ What is the typology of biology activities in France?

► Restricted geographic territory
► Multi-sectoral biology activity
► Particularly high density of activities in urban areas
► Activities in national, European and international networks
► Intense research activity through multi-disciplinary teams
► Operators who aim for scientific excellence
► Use of highly pathogenic microorganisms & toxins

The MOT regulation is an operational solution:

- to promote the biorisk management culture through the scientific community in accordance with the terms of the article IV

- to allow the development of the activities in accordance with the terms of the article X
The basic principles of Micro-Organisms & Toxins (MOTs) regulation

1 list of bacteria + viruses & their GMOs + toxins for which a prior authorization regime is in place
+ 6 principles of regulation

1- The authorizations relate to operations (holding - implementation - transfers)

2- Authorizations are granted to identified individuals (applicants then holders)

3- Operations are authorized in identified establishments or between these establishments (transfers)

4- The holders empower identified persons, after agreement from the ANSM, to carry out the authorized operations. MOTs are accessible only to authorized persons

5- Operations are authorized only if the biological risk is safely and securely controlled

6- Any incident / accident and any fact likely to lead to a MOT release must be declared to public health authorities without delay
The control device carried out by the French authorities

- The operator’s activities are checked by 4 integrated layers of control of the biorisk
  - 1- Biorisk assessment on demands
  - 2- Inspection on site (announced or not)
  - 3- Permanent administrative data control
  - 4- Vigilance on signals

- Consequently, the traceability is total on:
  - the biological material itself (nature, quantities, location, etc.)
  - the people who are involved in the authorized operations
  - the operations carried out on site
  - the unwanted events that may occur
The results achieved by the system put in place after 20 years of regulation

Some indicators about the global action capacity per year:

- +/- 1000 authorizations are produced for the detention, the use or the transfer of the MOTs in the national territory or to import or export abroad

- +/- 800 persons are checked to obtain a special clearance to access to the MOTs

- +/- 35 inspections are performed on site (announced or not)

- +/- 40 alert signals are received, analyzed and managed every year

Some side effects of regulations on the behavior of operators in the field:

- The contribution of the scientific community to the MOT regulations and its application is increasingly active

- By its operational aspect, the MOT regulation is a measure of confidence integrating articles IV & X of the convention
Thank you for your attention

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