

ENGLISH

Peer review pilot exercise,  
Paris, December 4-6 2013

**NON PAPER**  
(Proposed by France)

### **Introduction**

The (attached) report on the pilot exercise illustrating a possible concept of a peer review mechanism in the framework of the BTWC was drafted by France as the host country and promoter of this initiative under its sole responsibility. It took into account the input of experts that participated in the exercise.

It is noteworthy that it was made clear from the start that the participation of experts in this pilot exercise did not, in itself, imply endorsement of the peer review concept by their country of belonging. This remains valid.

#### **1. Background**

At the Seventh Review Conference of the Biological and Toxin Weapons Convention (BTWC) in December 2011, a working paper (BWC/CONF/VII/WP.28) submitted by France sought to initiate debate on the potential of developing a Peer Review system for the BTWC to build confidence in the implementation of the Convention.

Enhancing national implementation, improving confidence amongst States parties through increased transparency, sharing good practices, providing the opportunity to develop international cooperation, while fully respecting national sovereignty, are the main expected benefits of this proposed peer review mechanism.

The proposed peer review mechanism can be seen as a response to the recommendations of the 7<sup>th</sup> RevCon final document under the point III) E. 24 (a) which read as follows: *“The Conference decides that the following topics will be addressed under the Standing Agenda Item on strengthening national implementation: [...] ways and means to enhance national implementation, sharing best practices and experiences, including the voluntary exchange of information among State Parties on their national implementation, enforcement of national legislation, strengthening of national institutions and coordination among national law enforcement institutions”*.

## **2. Development and illustration of the concept**

Since the 2011 paper, the peer review concept was refined based on various consultations with BTWC member States. In comparison with the concept defined in the 2011 paper, a choice was made towards greater flexibility in the purpose and parameters of the proposed mechanism.

In order to provide representatives of the BTWC community a “real-life” experience of the concept, France has organized a peer review pilot exercise from December 4 to 6 2013 in Paris.

A large panel of experts, coming from 9 countries (Canada, China, Germany, India, Mexico, Morocco, Switzerland, the United Kingdom, the United States) participated in this pilot exercise.

Several topics related to the national implementation of the Biological Weapons Convention were presented and illustrated with two on-site visits (Biological Emergency intervention Unit of Institut Pasteur and the ANSES Animal Health Laboratory in Maisons-Alfort). The format and calendar of this exercise implied that a choice in the topics had to be made. As a consequence, some topics that the experts would have wished to hear about could not be presented. Three topics were chosen for this first exercise.

Discussions around the presentations were very active and demonstrated a strong involvement from the participating experts.

### 3. Next steps

France hopes that the organization of the peer review pilot exercise has played its role in dispelling possible concerns about the possible nature, scope and methods of a proposed peer review mechanism. It was also important, in so doing, to establish the wide degree of autonomy that BTWC States Parties would enjoy in defining the scope and purpose of a peer review that they could undertake to organize.

There would be great interest in seeing other BTWC States Parties organize an exercise in order to offer their own approach of such a possible mechanism. Such an initiative could contribute to broaden the understanding of the concept and facilitate its adaptation to the needs and realities of the BTWC membership.

Eventually, the aim of the work undertaken in this field remains, naturally, to prepare the ground for the possible consideration, at the eighth BTWC Revcon (2016), of establishing such a voluntary mechanism within the BTWC framework.



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### Peer review pilot exercise Report

#### Introduction

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Enhancing national implementation, improving confidence amongst States parties through increased transparency, sharing good practices, providing the opportunity to develop international cooperation, while fully respecting national sovereignty, were the main expected benefits of this proposed peer review mechanism.

A “pilot-exercise” was organized in Paris from 4 to 6 December 2013 in order to illustrate a possible concept of this mechanism proposed by France, as it had evolved since its initial presentation.

Discussions around the presentations were very active and demonstrated a strong involvement from the participating experts. The exercise was carried out along the following program and topics :

#### **1. French implementation system of the BWC**

##### *a) The national system of biosafety and biosecurity*

The French National Agency for Medicines and Health Products Safety (Agence nationale de sécurité du médicament et des produits de santé, ANSM) presented the national authorization and control system for manipulating dangerous pathogens. A specific French regulation established in 2001 a list of microorganisms and toxins (MOT). Activities (detention, acquisition, transport, use, etc....) on these MOT are subject to prior authorization. Each

activity shall be covered by a licence, which is granted to a holder. The holder of a detention license is regularly inspected, by the Agency.

- Ways in which the system presented was viewed as contributing to the implementation of the BTWC

The MOT legislation which was presented addresses several of the biosecurity issues discussed at BTWC meetings.

The licensing system seems to be a relevant system according to invited experts. Licensing the laboratories working on dangerous pathogens and ensuring that these labs have taken adequate biosafety and biosecurity measures contributes to the implementation of the Convention. This system is aimed at establishing national controls to ensure that biological agents are used only for peaceful and prophylactic purposes, in accordance with the provisions of the Convention and is aimed at knowing where the relevant pathogens are stocked and handled and to ensure that they are safe and secure. Moreover, different license for different activities enable controls over all aspects of pathogens in France.

The experts expressed the view that the French system seems appropriate and contributes effectively and positively to the implementation of the Convention.

This system was illustrated with two on-site visits, which were highly appreciated. Some experts noted that site-visits were an important complement to the presentation because it allowed them to see how the regulations functioned in actual practice.

- Possible room for improvement identified by the participants

In the licensing process authorizing individuals to manipulate dangerous pathogens, some experts recommended to include some degree of evaluation on criminal history, serious mental health issues for example and periodically update the data.

A very wide scope is left to labs and institutes to determine the adequacy of their own biosafety and biosecurity practices. Some experts consider that a common biosafety/biosecurity standard might facilitate implementation.

More interactions with other departments in charge of controlling dangerous pathogens such as the dual-use item service for exports and the ministry of agriculture for instance. Considering a list of animal pathogens to complete the list of human pathogens might be useful.

Some experts consider that the added-value of French regulation to the European regulation may be difficult to evaluate without providing a more detailed overview of European regulations to clarify the relationship between the two.

Some experts suggested that developing education on BTWC and its relevance to the requirements of biosafety and biosecurity might help the implementation of the Convention.

An annual report may be established with all the concerned actors.

- Assessment of the presentation

The invited experts underlined that this presentation improved their understanding of the French legislation within the French legislative framework. It was also seen as providing excellent information on how MOT agents are overseen.

According to participants, it was very informative and transparent. The highly-detailed presentation helped build confidence in this aspect of French BTWC implementation, which created a favorable context for national cooperation.

The opportunity for questions and discussion was particularly appreciated.

#### *b) The national export control system*

The Ministry of Industrial renewal and more specifically the Dual-use items service (*Ministère du redressement productif, service des biens à double usage*) presented the national export control system focusing on licensing procedures for dual-use biological materials and related equipment. The Deputy head of the Strategic Affairs and Disarmament Department of the French Ministry of Foreign affairs presented the Interagency committee for dual use items.

- Ways in which the system presented was viewed as contributing to the implementation of the BTWC

According to the experts, this presentation highlighted that the French system is a functional control system that fulfills BTWC exports requirements.

Regulation includes equipment, pathogens, toxins and intangible technology. The catch-all provision put in place is critical. The “end user certificate” could be a tool that may be used in other countries. Paper work for industry is simplified.

The export system was known by staff working in laboratories.

The license processing, the interministerial process, an effective interministerial committee, which have the possibility to lead to denials ensure that risks of proliferation are mitigated while illustrating the absence of impediment on exchanges for peaceful purposes.

Several experts mentioned this system as possible model.

- Possible room for improvement identified by the participants

Detailed information about the possible technology applications as well as importers and end-users is needed to provide a reliable export license. It was suggested that in case of doubt, or on a random basis a verification of the end-user could be organized (for instance by sending someone from the local Embassy).

Outreach towards academia and industry was not mentioned in the presentation but is seen as critical to some experts.

More coordination with other agencies, especially on MOT, could be possible.

Keeping the dual-use items list updated seems difficult.

- Assessment of the presentation

Experts consider that a good description was made of the full programme in place to implement the BTWC. The presentation covered a large range of issues related to export controls and the inherent national tensions involved between trade promotion and controls. It highlighted different aspects of the French national procedures. More information about the training of customs would have been appreciated.

### *c) The awareness-raising policy*

The National Institute for health and medical research presented the teaching and training course in France in the field of biosafety and biosecurity. The biosafety and biosecurity training was also illustrated by the French Military Health Service. A panorama including a project of French guidelines for education and training in biosafety and biosecurity as well as courses and workshops was presented.



- Ways in which the system presented was viewed as contributing to the implementation of the BTWC

Most experts expressed a very positive view on this approach and described steps taken by France as reasonable and constructive. According to the experts, awareness-raising starting at university level and enhancing self-regulation efforts to establish a culture of responsibility among the scientists is a very interesting approach. Courses and training delivered by people from different background (military, scientists) are very important to ensure a good national coordination and a concerted policy.

This presentation on awareness-raising of scientists about the dual-use dilemma might be very helpful for other State Parties. The new national technical guidelines being created could be used as an international best practice.

The experience of a pilot dual-use questionnaire submitted prior to start research that might be of a dual-use nature was described as a good tool.

Some aspects of this policy may be useful for other countries.

- Possible room for improvement identified by the participants

The top-down approach regulation must be complemented by outreach and education.

Experts expressed the wish to know more about the next steps taken by France in this field.

They suggested that a dual-use training in cooperation with biosafety and biosecurity standards or other biosecurity requirements could be considered.

It was also deemed that some emergency training exercises prepared and planned by joint teams could be an opportunity to confirm the processes, share experience and check the level of preparedness.

Various experts also stressed that deeper collaboration with academics, other governments, NGOs and relevant organisms could be helpful. The appointment of a point of contact within the government for institutions and scientists could be good to create a relationship between government and academia.

Codes of conduct for scientists, discussed within the BTWC, might also be a good approach. Presenting the French policy in Geneva (side-event, working paper...) at the meeting of experts could help increase discussions on this topic.

## 2. Global assessment of the peer review pilot exercise

### *a) Presentation of France's National system*

Overall this pilot exercise was assessed as an excellent approach in bringing closer and explaining the particularities of the French legislative system relevant to the BTWC. Visits of some affected laboratories were deemed very helpful to illustrate the implementation of the regulation and its implications on the field. The opportunity to be able to talk to the staff of the labs was particularly appreciated.

While some experts suggested that presentations from additional ministries may have been useful, other experts considered that, given the limitation of time and the nature of this exercise, it would not have been possible to cover the entire Convention. Other experts suggested that the opposite approach could be beneficial: that is, to focus even more narrowly on a single aspect of implementation (e.g. biosecurity oversight, or export controls) in order to bring together a group of participants with greater collective expertise in a single area and enable them to explore more deeply the issue.

This program highlighted that each country follows its own way in implementing the Convention according to its own government structure and the national decision-making bodies. There are many ways to implement the BTWC.

Some experts consider that even though this exercise was interesting, the most effective and direct way of strengthening national implementation by States Parties would be the conclusion of a protocol with an effective and practical verification regime. Others were skeptical on the feasibility of such an approach. The question of the role of a peer review mechanism in the framework of the BTWC remains open. According to some experts, this mechanism has its own limitations and could be a voluntary transparency tool between a group of countries. Some experts felt that the peer review approach could be a powerful tool for strengthening national implementation, both through feedback to the host State (from experts), and by allowing experts from other States to compare experiences and approaches in a way that goes beyond examining the text of laws and regulations and beyond sharing experience about the actual challenges linked to the implementation of such documents.

*b) A tool for transparency and strengthening confidence*

This exercise was seen as a very useful means to strengthen confidence between States Parties in specific aspects of BTWC implementation. Some experts considered that this exercise matches with the request of several States Parties asking for better information on national implementation and particularly on national legislation.

*c) A tool for sharing good practices*

The transparent program demonstrates, according to some experts, the French national commitment to implement the BTWC.

This exercise is considered by most experts as a very helpful exercise in order to get a better implementation of the Convention by sharing good practices. It also gives indication on what needs improvement.

For some experts, the presentations could be a starting point of international cooperation that would contribute to strengthen protection, prevention and action capabilities. This exercise gave the opportunity to share good practices and establish contacts between different agencies while respecting the States sovereignty.

According to some experts, some excellent practices were identified and could be adopted as best practices, improving the implementation of other States Parties. In other cases, some gaps were identified through the question and answer time at the end of the presentations, which could help France to improve its own implementation of the Convention.

*d) Room for improvement for next peer review exercise identified by the participants*

Some experts consider that other States parties organizing a peer review might focus on other aspects of the national implementation of the BTWC and might include more aspects touching on other articles of the BTWC (such as response to alleged use, cooperation) as well as continue exchanges with updates on articles III and IV.

An additional contribution could be to share best practices through sharing in-use tools which will contribute to enhance the global implementation of the Convention.

