



A CIVIL SOCIETY RESPONSE TO THE CHALLENGES OF REGULATING BIOSECURITY

*Global Networking to Promote Biosecurity and Limit Dual-Use Risks
Como, Italy – Friday, 12 November 2010*

Good afternoon everyone. My name is Scott Spence. I am the Senior Legal Officer at VERTIC and work primarily in our National Implementation Measures Programme. I'd like to extend a special thanks to the Landau Network-Centro Volta for inviting me to participate in this workshop-round table, as well as the CRDF, ISTC, DECC and the Italian Ministry of Foreign Affairs.

INTRODUCTION

I've been asked to speak about legal implementation challenges in the context of promoting biosecurity and limiting dual-use risks associated with biological materials. I'll first share some notes from the field on assisting governments to strengthen their legislative frameworks for implementation of the Biological Weapons Convention (BWC) and UN Security Council Resolution 1540, including effective biosecurity measures. I'll then describe VERTIC's National Implementation Measures Programme, and finally conclude with thoughts on how civil society actors can contribute to the ongoing construction of a global network committed to ensuring that dual-use biological materials and technology are only used for peaceful purposes.

CHALLENGES IN IMPLEMENTATION

One of the main challenges to effectively regulating biological materials is the absence of an intergovernmental organisation, such as an OPCW or IAEA, to oversee and support comprehensive, centralised implementation of the BWC, including legislative assistance. These organisations' legal offices, for example, have prepared

guidance materials and carried out legal drafting workshops and follow-up activities for governments around the world, with the power of stable budgets and staff behind them.

An OPBW was not meant to be, however, for the BWC. We are all familiar with the consequences of the collapse of the BWC Protocol negotiations in 2001 and the subsequent intersessional processes devoted to examining, among other topics, national implementation of the Convention. In addition to saving the BWC regime from uncertainty and irrelevance, the annual sets of Meetings of Experts and States Parties since 2003 have engaged civil society in novel and exciting ways. They have also provided an opportunity for civil society actors to engage with States more directly on activities that have historically been associated with intergovernmental organisations.

But implementation of the Convention is not only complicated by an institutional deficit, it also faces:

- the lack of universality in the BWC membership and a perception in non-States Parties that they do not have to implement effective controls on biological materials (“We don’t have biological weapons”);
- a lack of awareness of the BWC and Security Council Resolution 1540 and their requirements and obligations, as well as a lack of political will to implement these instruments at the national level;
- limited or no technical, human or financial capacity for drafting implementing laws and regulations, training relevant officials, or enforcement;
- difficulty maintaining momentum in the implementation process due to government official turnover, elections and changes in government, or internal or external conflicts; and
- competing legislative, parliamentary, budgetary or economic priorities.

Challenges to legal implementation of the BWC and regulation of biological materials also vary regionally. In South and Central Asia, some States have little to no legislation to control even the most basic activities involving biological agents and toxins while other States have more robust biosecurity regulatory environments.

These examples appear to reflect two predominant trends: the impact of war and strife on the ability of a State to have a functioning legal system, alongside a legacy of Soviet 'anti-plague' stations and biological weapons programmes which necessitated legal measures to protect personnel and the environment.

In the Middle East and North Africa (MENA) region, there is some movement towards a more robust biosecurity regulatory environment, but the progress is slow and uneven. In East Asia and the Pacific, there is movement towards a more robust biosecurity regulatory environment, particularly in the larger countries, but the smaller, lightly populated Pacific Islands nations perceive the risk of proliferation of biological weapons or risk posed by weak biosecurity frameworks to be negligible or at least, less urgent than other, competing priorities.

In sub-Saharan Africa, South Africa has superior legislation and there is progress in some other countries in the region. However, most have little to no law in force to prevent the proliferation of biological weapons, including biosecurity measures and export/import controls. A small number of sub-Saharan countries do, however, criminalize terrorist offenses involving biological agents. Many African countries are more concerned about the impact of genetically modified organisms (GMOs) on their agricultural sectors and so less priority has been given to laboratory biosecurity and other measures to control pathogenic agents.

As you might expect given the European Union's strong role in BW nonproliferation efforts, there is significant movement towards a more robust biosecurity regulatory environment in most of Europe and Eurasia. Nevertheless, many countries in both regions appear to require additional laboratory biosecurity measures, including some of the most advanced European economies.

Finally, the picture in the Americas is uneven: regional leaders include Argentina, Brazil, Canada, Cuba and the United States, while other countries have some controls over activities involving microorganisms or related biological products, including laboratory biosafety measures and transfers controls, on which more robust biosecurity legislative frameworks could be built. Some of the Caribbean States have adopted short and simple, but effective, laws to implement the BWC, which suggests

that they have a higher degree of awareness of the threat of biological weapons proliferation. On the other hand, there are several States throughout the region with inadequate legislation in force to prevent the proliferation of biological weapons, including provisions criminalizing biological weapons and basic controls over microorganisms.

VERTIC AND THE NIM PROGRAMME

To respond to the challenges I've just described, VERTIC has developed a National Implementation Measures or NIM Programme, largely but not completely focused on the BWC. The Programme is our newest and builds upon an earlier VERTIC project of more limited scope, which was merged with work I had started carrying out as Interpol's Biocriminalization Project Manager in 2006. The NIM Programme was developed to assist States in understanding what measures are required at the national level to comply with the prohibitions in a range of nuclear, biological and chemical weapons treaties and UN Security Council resolutions and how to implement them. With funding from the governments of Canada, the United Kingdom, and the United States, we now have a staff of four, as well as a consultant assisting us with our MENA portfolio.

The Programme has four objectives. First, we are in the process of preparing comprehensive analyses of the existing legislation in countries around the world for the implementation of the BWC and related provisions of UN Security Council Resolution 1540. To date, we have completed 107 surveys. The results of our analysis are on the screen and underline the enormous amount of legislative drafting that remains to be done. Second, based on our gap analyses, we provide direct legislative drafting assistance, or other forms of assistance, including remote reviews of draft legislation, legal advice, or information exchanges. Because we are fully funded, we do not charge governments for our services. We have provided direct assistance to nearly 20 countries in the last two years alone and we are currently responding to a sharp increase in expressions of interest.

Third, in order to carry out this assistance, we have developed an 'Implementation Kit' – the first of its kind for the BWC. It consists of fact sheets on the Convention and the establishment of National Authorities; our *Sample Act* for national

implementation of the Convention; *Regulatory Guidelines* to further implement the Convention; and legislation survey templates. All of this material is available in several languages on our website's NIM Programme pages. The *Sample Act* and *Regulatory Guidelines* devote considerable space to biosecurity including licensing, inspections, enforcement mechanisms and transfers controls for particularly dangerous biological agents and toxins and dual-use biological equipment.

Finally, the NIM Programme team also spends a considerable amount of time engaging in outreach – this includes staff participation in symposia, conferences, and workshops, and, of course, participation in the BWC Meetings of Experts and States Parties. We also promote universalisation of the BWC and the establishment of National Authorities.

BUILDING A GLOBAL NETWORK

So how do we go about creating a global network that cuts across science, ethics, law and security? I would submit that the VERTIC NIM Programme's experience with legislative assistance provides an example. We recognise the importance of partnering with intergovernmental organisations; international, regional and subregional organizations; governments; industry; scientists; academia and other members of civil society. Indeed, VERTIC is in communication on a continual basis with several governments, including our funders and the G8 Global Partnership group of States; the OPCW, IAEA, and BWC Implementation Support Unit (BWC ISU); the UN Security Council's 1540 Committee and its experts; the International Committee of the Red Cross; the OSCE; and the European Union and its constituent components including the Council and the Commission and the Joint Action staff at UNODA.

Our ties with other civil society members are necessarily strong and co-ordinated through the BioWeapons Prevention Project (BWPP). BWPP is a global network of civil society actors dedicated to the permanent elimination of biological weapons and of the possibility of their re-emergence. It was launched in 2003 by a group of non-governmental organizations concerned at the failure of governments after 2001 to fortify the norm against the weaponization of disease. BWPP monitors governmental and other activities relevant to the treaties that codify that norm. Its current projects include preparing daily reports of the BWC intersessional meetings and the

Bioweapons Monitor, which aims to generate transparency about BWC implementation and compliance, starting with four countries with an advanced biotechnology sector, drawn from different geographic regions. The first Monitor will be launched this December at the BWC Meeting of States Parties in Geneva.

VERTIC's partnering with governments includes speaking at events that they organise, advising them on how to improve their national implementing legislation for the BWC (and CWC) and working with their national champions to raise awareness within their ministries of these Conventions. We work with Governments to draft new legislation and liaise with them until its final adoption. We also liaise regularly with the IAEA, OPCW and the BWC ISU, as the intergovernmental organizations with primary responsibility for supporting the respective NBC weapons treaties, to inform them of our work with governments on national implementing legislation under the NIM Programme and to co-ordinate assistance activities and follow-up. This spirit of co-operation extends to the 1540 Committee, the ICRC, the G8 Global Partnership, the EU and the OSCE as we all seek to avoid duplication while ensuring that efforts to promote the non-proliferation of biological weapons are strengthened.

The lack of an international secretariat in the guise of an OPBW is being filled by the co-ordinating role of the BWC ISU; engagement in their respective fields from intergovernmental organisations such as WHO, OIE, FAO, WCO and Interpol; the legislative assistance programme from VERTIC; and the outreach and research activities being carried out by the BioWeapons Prevention Project network members mentioned above. There are numerous other projects being undertaken by civil society actors in the areas of codes of conduct; education for scientists on the BWC; laboratory training and skills development by laboratories, universities and governments; industry engagement; and training on law enforcement and public health co-operation and disease surveillance. We will be hearing more about many of these efforts this weekend. The BWC ISU has described implementation of the Convention in its fullest sense as a global network activity in which civil society actors play a major, and I would argue, indispensable, role. And this work cuts across science, ethics, law and security.

There are strengths and weaknesses to this network approach. The strengths are that civil society action can be nimble and certainly more affordable than a large secretariat. Due to funder requirements, our actions are increasingly goal-oriented and time-bound, i.e. we work to achieve certain results within a specified period. Many of us have worked and been trained in government or in the treaty organisations and therefore have a deep understanding of the treaties, issues, and the people involved in their implementation.

Nevertheless, there are several weaknesses in this network approach: funding cycles for civil society can be unpredictable and the loss or shrinkage of an important civil society actor can disrupt new assistance activities, delay crucial follow-up, and curtail information and outreach exchanges and activities. Additionally, some governments may simply be unwilling to work with civil society actors for historical or political reasons. This can be particularly problematic for the BWC where many capacity-building and assistance activities are carried out by organisations such as VERTIC.

I am confident, however, that the non-proliferation community – and this includes intergovernmental organisations; international, regional and subregional organisations; and governments – is becoming increasingly comfortable and familiar with the elevated level of involvement of civil society actors in the implementation of the BWC treaty regime. This comes with the responsibility, however, for us to be highly competent and effective, discrete and professional, and aware of the limits of what we can reasonably accomplish with States. Thank you.

Contact details

Scott Spence
Senior Legal Officer

VERTIC
Development House
56-64 Leonard Street
London EC2A 4LT
United Kingdom

E: scott.spence@vertic.org
M: + 31 628 798 339
W: www.vertic.org/NIM

/...

Measures to implement the BWC and BW-related provisions of UNSCR 1540

<i>Measures (as at 12 October 2010)</i>	<i>States with measure</i>	<i>% out of 107 surveys</i>
DEFINITIONS		
Biological weapon	8	7%
CRIMES		
Develop biological weapons and penalties	20	19%
Manufacture/produce biological weapons and penalties	36	34%
Acquire biological weapons and penalties	30	28%
Stockpile/store biological weapons and penalties	24	22%
Possess/retain biological weapons and penalties	30	28%
Transfer biological weapons and penalties	34	32%
Use biological weapons and penalties	32	30%
Engage in activities involving dangerous biological agents or toxins without authorisation/in violation of the conditions of an authorisation and penalties	26	24%
Transfer dangerous biological agents or toxins without authorisation/to unauthorised persons and penalties	39	36%
CONTROL LISTS		
Control lists for dangerous biological agents and toxins	27	25%
Control lists for dual-use biological equipment and related technology	18	17%
PREVENTATIVE MEASURES		
Measures to account for production	9	8%
Measures to account for use	11	10%
Measures to account for storage	7	7%
Measures to account for transport	12	11%
Measures to secure production	7	7%
Measures to secure use	9	8%
Measures to secure storage	12	11%
Measures to secure transport	21	20%
Regulations for physical protection of facilities which produce, use or store dangerous biological agents or toxins and related penalties	6	6%
Regulations for physical protection of dangerous biological agents and toxins and related penalties	6	6%
Authorisation of activities involving dangerous biological agents or toxins	33	31%
National licensing authority	26	24%
Regulations for genetic engineering work	34	32%
TRANSFER CONTROLS		
Authorisation for exports and imports of dangerous biological agents and toxins	58	54%
Export/import control authority	39	36%
End-user controls for dangerous biological agents and toxins	22	21%
Transit control over dangerous biological agents and toxins	24	22%
Trans-shipment control over dangerous biological agents and toxins	6	6%
Re-export control over dangerous biological agents and toxins	17	16%
Export control over dangerous biological agents and toxins	39	36%
Import control over dangerous biological agents and toxins	44	41%