

IWG



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IWG – LNCV Biosecurity Workshop and Round Table

***Biosecurity, Biosafety, Human Capital
and the Seventh Review Conference of the Biological
and Toxin Weapons Convention***

18-19 November 2011

Palace Hotel
Como, Italy

Report

Introduction

The Seventh Review Conference has provided pause for thought for many of the broad range of stakeholders who have engaged with biosecurity issues internationally since the last Review Conference of 2006. There is wide agreement that the intersessional process, which emerged out of the ashes of the failed VEREX exercise, has gone some way to prevent against the development and use of bioweapons, particularly in relation to bioterrorism. However, there still remains uncertainty about how to build upon these successes going forward. These discussions have happened in the context of an agreement that there is the requirement for continued, and perhaps increased, state involvement in the provision of institutional and financial support of the ‘web of prevention’ especially in relation to: the development of laboratory biosafety and biosecurity practices and infrastructure globally, science and technology review, international co-operation and support, as well as the education of the scientific community and codes of conduct.

It has become apparent that the typical distinction between ‘government’ and ‘governance’ is increasingly dissolving. Both are needed in the provision of the BTWC. It was highlighted for example, that non-state actors possess expertise and human capacities that may be absent within state governments. Thorough out this conference there was emphasis placed on the increased role that non- state, often transnational actors, are already playing in supporting state obligations under the BTWC.

While the focus on the responsibilities and capabilities of such actors certainly seems appropriate, it is also worth highlighting that this should not be perceived as in any way reducing the obligations of states under the BTWC. There remains a requirement for state executives and departments to think creatively about how current indicatives, especially those of a collaborative and transnational nature, can be better supported. The corollary to this of course being that those actors engaged in the development of the 'web of prevention' also need to try and embed their projects in existing governance frameworks to ensure the sustainability of these projects.

The Workshop, organized by the International Working Group (IWG) and Landau Network-Centro Volta (LNCV) of Como, Italy with the support of CRDF Global, the International Science and Technology Centre and the Department of Energy and Climate Change of the UK, was organized in Como (Italy), in the premises of the Palace Hotel, on 18 and 19 November, 2011.

The 2011 Workshop aimed to wrapping up and updating on key topics related to biosecurity, biosafety and dual use issues, with special regard to the human dimension of these issues, with a particular attention to the perspectives of the major international agreement regarding the prevention of biological weapons, the Biological Weapons Convention that would go into its Seventh Review Conference just weeks after the workshop.

Topics included education & awareness raising, engagement of and outreach to the scientific (academic and professional) communities, S&T review; but also on over viewing the 2nd ISP and the perspectives for the near future. The event hence also provided a useful occasion of informal meeting among biosecurity experts, as well as scientists, just before the BTWC Review Conference.

Session 1- A review of the Second BTWC intersessional process . Roundtable interaction

The first session addressed the history and development of the BTWC regime as well as the increasing role that other stake-holders, in particular the scientific community are playing in the evolution of the convention. There appeared to be a range of opinions on the appropriate role of 'bottom-up' governance activities, particularly with regard to the differing roles they could play in addressing the threat of state and non-state misuse. This served to frame some discussion later in the event.

The failure of the VEREX exercise resulted in a decision to suspend the fifth review conference for one year, with the intention that an agreement would be found. There were concerns at the time that there would be a re-emergence of disagreements around the VEREX issue. In response a decision was taken to start an

intersessional process that would deal with a range of issues in order to achieve agreement and facilitate co-operation. For some this has represents a shift from formal agreements to 'soft governance' by the regime.

In the first round of the intersessional process there was an agreement that biosafety and biosecurity were complementary systems. There was also agreement on the requirement for the development of biosafety within the developing world, which could provide abases of biosecurity. There was also an increased involvement of public health actors. An outcome of this process was the agreement that there was requirement to establish the ISU. In the second round of the process, similar issues were tabled for discussion. However, there was also greater discussion of disease control, as well as assistance and co-operation.

There are concerns that the focus on terrorism in the past decade has led to neglect of the issues of state level compliance, state openness and monitoring, as well as the misuse potential of developments within science and technology. For some members of the arms control community this led to a requirement to evaluate the structure of the of the BTWC process- that reflects the more immediate concern of state level misuse, as apposed to more long term concerns about terrorism.

Such tensions on the BTWC agenda reflect the evolving nature of the BTWC regime. This has led some to argue that there is a requirement to distinguish between BTWC activities proper, and those that were complimentary to the regime- in order to avoid the risk of regime overload.

Such political tensions are perhaps also reflected in the various evaluations of the intersessional process. It has been argued elsewhere that the process was overly selective, ineffective as a decision making process, a weak-ordination mechanism and lack of capacity to provide guidance and assistance. However, it is clear that there were certainly advantages to the approach adopted- including inclusivity and transparency, increased capacity for innovation and increased stake-holder engagement and co-operation. The intersessional process has also benefited from the involvement of international scientific institutions which has led to the emergence of an informal 'scientific advisory network' related to the impact of continued advances in Science and technology. This network had provided independent input on biological and chemical risks. These included Workshops on trends in S&T for 1st and 2nd CWC review conferences. There were also Workshops on trends in S&T for 6th and 7th BWC review conferences as initiative from scientific organizations, with informal ties to the ISU. These events also spawned a series of other initiatives internationally¹

Discussion

Several issues in relation to the intercessional process were identified within the introductory session:

¹ Which the ISU have tracked and recorded on their website: <http://www.unog.ch/bwc/science>

- How flexible the process should be, and how it should be structured.
 - The requirement to identify key issues for discussion
 - Whether the ISP required more decision making powers
 - The requirement for clarity in regard to the role of the ISU- and if necessary a re-evaluation of its remit and institutional and financial support
 - The requirement to agree on key issues to be addressed, it also raised questions about the executive powers of the intercessional process and how this should feed into the review conference.
 - The requirement for the regime to be responsive to developments within science and technology, which are often convergent in nature.
 - The question of whether it was necessary to institutionalise the growing involvement of stakeholders with the process was raised with reference to the possibility that this could perhaps lead to the exclusion of some actors. Later in the conference reference would also be made to the problem that NGO's looking for financial support don't necessarily fit institutional funding criteria currently
 - Someone also discussed the potential political issues associated with expanding the ISU's mandate, even if the institution has universal support.
 - It was argued that presently the ISU is set up as an administrative support institution; it has no political role in its mandate. Expansion of the ISU remit will potentially raise political questions, such as whether it is too western centric. If its personnel expands will have to see a broader representation

The requirement to address the threat of state level programmes as well as the threat of terrorism was also raised. It was argued that the treaty currently lack state compliance measures, and that this issue has been largely ignored for a decade.

Session Two : The Science and Technology Review: A Roundtable Interaction

In session two of the workshop, the focus of discussion was the process of science and technology review. Several states have proposed to review the existing system, which has historically been based primarily on

individual state submissions² to the review conference. In recent years there have also been a patchwork of studies produced by nongovernmental stakeholders as well as the background papers by the ISU, and presentations at the series of 'Meetings of Experts'³. It was highlighted that there was a requirement to reflect upon:

- why the review process was important,
- the nature of the mandate of the science and technology review as well as the flexibility of the agenda.
- who should participate as well as the usefulness of a chairperson within the process.

the process in terms of policy inputs and outputs.

It was argued that S and T reviews can be understood to serve several purposes

- Identifying if science and technological developments fell within the remit of the general provision in **Article I**.
- Whether or not developments impacted upon the implementation of **Articles III and IV** and **X**

It was pointed out that 'threats' may emerge from both terrorists as well as state programmes. However, the same scientific and technological developments may have different relevance to highly technical state level programmes, non-state actor programmes as well as individual acts of terrorism.

It was argued that fields such as synthetic biology conceivably impact upon an even broader range of articles: II (detection technologies), III (vaccine development), IV (disease surveillance) VI, VII (disease surveillance and reporting, vaccine production) as well as X (surveillance of disease).

Various options for enhancing scientific advice that had been identified in advanced state papers these were:

- One meeting specifically on S&T issues during new ISP
- S&T issues considered as agenda item for each topic discussed in a new ISP
- Expand the ISU with one or more dedicated S&T posts to monitor developments
- Set up a new task group to meet annually to review & report on S&T developments

² 'Initially, the depositary states prepared a review for the benefit of all others. At subsequent review conferences, any state that wished to submit a national paper on relevant advances could do so, and the collated national papers were circulated to all state parties.' see McLeish, Cairtriona, and Ralf Trapp. 2011. "THE LIFE SCIENCES REVOLUTION AND THE BWC." *The Nonproliferation Review* 18 (3): 527-543. doi:10.1080/10736700.2011.618653.

³ See ISU website. <http://www.unog.ch/bwc/science>

- Standing Advisory Panel
- Ad Hoc Advisory Panels
- Open ended S&T forum for discussion (involving academics, industry)
- Mixture of the above

A commonality has been that all proposals suggest some form of annual review. In summing up several key issue areas for a new review process were identified:

- Scientific developments that can contribute to mitigation of misuse as well as misuse.
- Awareness-raising, education and oversight
- Participation of academia, industry, IGOs etc.
- Enabling a Multidisciplinary approach
- Flexibility to respond to 'unpredictability' of scientific research.

Some practical lesson and conclusions were also discussed in relation to the IAP/IUBMB/IUMS workshop held in Beijing, China in 2010. Specifically the importance of providing the appropriate environments to consult the scientific community about the state of science and technological developments. It was also pointed out that these scientists may come from academia, industry and government. It was argued that it is useful to distinguish the ideas of monitoring and evaluation in this context. Furthermore that the engagement in such activities may entail multiple models of discussion, once the purposes of the review process, were defined.

Within this panel there was also reference made to the lessons that could be learned from past experiences with reviews of science and technology reviews in other contexts. It was argued that developments within regulation tend to be incident driven. Technical enquiries into such incidents have had varied levels of success, and perhaps there were lessons to be learnt in the context of the BTWC Science and technology review process. One key lesson identified was that optimal approaches for evaluating science and technological development may not also be the best approach to reassure audiences. This point was made with reference to science and technological reviews that occurred following the space shuttle challenger disaster.

Other suggestions were also made including: the requirement to reflect upon the poor track record of national projections of technology trends and national capabilities, encouraging heterogeneous review teams, as well as more reactive and frequent review. It was also argued that developing the process of S and T review isn't enough and that there is also a requirement to integrate this process into political discourse.

The process of ethical review of developments of science and technology development was also discussed. This was initially with reference to political level ethical review as well as with regard to enabling the identification of ethical issues at the level of the scientist.

Specific reference was made to the European Group on Ethics which is *'an independent, pluralist and multidisciplinary body advising the European Commission on ethics in science and new technologies in connection with Community legislation or policies. The EGE members serve in a personal capacity and are asked to offer independent advice to the Commission'*. There has been neglect of this issue historically by the EGE, but this issue was increasing being discussed in relation to emerging fields, such as synthetic biology. This has led to inclusion of the issue in the most recent EGE opinion on the field of synthetic biology in which a series of recommendations have been made⁴.

However, the engagement of the bioethics community with these issues has not been forthcoming historically and this is reflected in the absence of dual use on ethics syllabuses even in fields which have been a source of misuse concern historically. Further more even fields directly identified as a source of potential misuse do not exhibit increased levels of education about misuse potential. Two central potential obstacles to changing this were identified. The first was the fragmented nature of applied fields institutionally and professionally speaking, the second was also an absence of members of such communities championing education.

Roundtable session

- The question of law enforcement and security co-operation was raised, as well as potential political issues with this
- It was argued that the international law and security community are working together. Interpol have collaborated with the security community. There has also already been co-operation at a national level in the US. This included HHS, AAS and FBI outreach in relation to the DIY bio community as well as in relation to the I-GEM competition.
- The issue of how to evaluate the misuse potential of a field was raised, with reference to the idea that there may be conceptual as well as technical hurdles in the development of technologies.
- It was highlighted that research scientists tend to avoid talking about obstacles. However, in contrast industry tends to be more forthcoming in highlighting potential hurdles in the development of applications.
- It was argued that S and T developments could also strengthen the regime. Reference was made to existing research on microbial forensics. Which involved open and international co-operation.
- The issue of stake-holder co-operation in relation to article 10 was raise

⁴http://ec.europa.eu/bepa/european-group-ethics/docs/publications/round_table_ethical_aspects_of_synthetic_biology.pdf

- It was argued that different forms of expertise, from different stake-holders was perhaps required at different stages of the process. What was clear however, was that there needed to be open channels of communication between all stages and actors within the process
- In relation to a point made in one of the talks there was discussion the potential of a BTWC/CWC gap. This included reference to mid-spectrum 'bio-chemical agents' some of which are used as less than lethal weapons and incapacitants, as well as developments in relation to understandings of bio-regulators.
- It was argued that legally such a gap does not exist, however that it was important to ensure there was no perceived gap.
- The discussion of S and T review, also led to discussion of the prospect and nature of oversight of gene synthesis. It was highlighted that the various forms of review (ethics S and T) may not take into account different national legal/ political/ ethical contexts

Session three: Awareness Raising and Education, Engagement and Outreach. Roundtable interaction.

Within this panel a series of issues were discussed in relation to awareness raising and education amongst scientists and other stakeholders. In essence these discussions focused on the identification of existing gaps in the provision of education, some examples of existing education activities internationally within industry and the scientific community as well as the lessons drawn from these activities going forward.

In several of the talks the importance of taking a multi-step approach within education focused projects was identified. An exemplar project is that of the European Biosecurity Awareness Raising network (EU-BARNET) of which there were 4 stages. These were: gap-analysis, a review stage, an awareness raising stage, as well as a dissemination stage. It was noted that the gap-analysis phase has been conducted with relation specific techno-scientific fields (to allow deeper insight), however the parts of this project was broader in focus.

Experiences in relation to measuring the current low levels of provision of education pointed to the requirement for clearer definitions of terms such as 'biosecurity' which may be understood in reference to a variety of practices in different national contexts. With regard to the scientific community a recurring theme was the requirement to build trust between the various communities involved. In particular misperceptions between scientific, industry, law enforcement and national security communities was discussed.

With specific regard to industry, it was argued that some multinational biopharmaceutical companies have been eager to engage in a series of initiatives these included:

- The development of guidelines for external compliance assurance. Meaning that the company only works with other entities who agreed to adhere to their standards related to biosecurity practice (i.e select agent screening, laboratory biosecurity)
- Engaging with governance activities, such as industry standard setting involvement with a series of international meetings and workshops related to biosecurity issues involving various governance institutions (such as the BTWC) and other stakeholders.
- A focus on development of medical treatments for infectious diseases as related to the idea of improving biosecurity.
- The work of the the gene synthesis industries and international associations⁵ in relation to the gene synthesis in the development of a code of conduct was also discussed. This included a presentation from one of these entities.

A series of other observations were also made with regard to industry.

- It was suggested that there is an unease among industry to be associated with the idea of 'bioweapons' publicly.
- patent expiries and other financial pressures impact upon companies ability to invest into technologies that may improve biosecurity.
- Security issues may be perceived as one of many 'ethical' issues that biomedical companies have to deal with, so this issue may be in competition with others for attention.

Some form of biosecurity/ biosafety certification for companies would be useful- for example upgrading the CEN work shop standardisation agreement (CWA 15793:2011)⁶ to an International Organisation for Standardisation standards

Within this panel reference was also made to the activities of the FBI in the US in relation to the implementing article IV of the BTWC. It was highlighted that this organisation had played a leading role in engagement with the scientific community, specifically in relation the field of Synthetic Biology and that this was reflected in the FBI representation on the US review conference delegation.

⁵ <http://www.ia-sb.eu/go/synthetic-biology/>

⁶ See: <http://www.cen.eu/CEN/sectors/technicalcommitteesworkshops/workshops/Pages/ws31.aspx>

A recurring theme within this panel was the requirement for these various communities to share information and expertise relevant to awareness raising and education practices. The Virtual Biosecurity Centre website⁷ was advocated as a 'one stop shop' for biosecurity information which could perhaps be suitable forum such activity.

The idea of networks was also repeatedly referred to and in the final talk of the session some reflections on such an approach to governance were provided. It was highlighted that a diverse and historically discreet range of state departments , as well as institutions have engaged in different activities related to predicting, preventing, mitigating and responding to risks associated with pathogens, . Good networks were characterised as dynamic and resilient structures, which could overcome cross-cutting issues that other approaches to governance might struggle to deal with.

Discussion

- It was highlighted that even where there was space for biosecurity education on syllabi that was little appropriate expertise within institutions to provide education, particularly at masters level.
- With regard to the Moroccan experience it was argued that coming to agreements about definitions of key terms, including translations between French and English, had been an important stage in encouraging other actors to engage with the issue.
- It was also suggested that 'gap-analysis' should also identify sources of funding for future education projects.
- There was discussion as to whether industry involved in iGem could also share educational materials.
- There was also discussion as to whether dual-use education developed in a military context (as in Serbia) could be useful in a civilian context. There was agreement that this seemed feasible.
- The issue of low awareness in government about the issue in many states was raised.
- There was discussion of the requirement for the FBI to continue to build relationships with the FDA in regard to concerns about other scientific fields such as agro-biology. Reference was made to co-operation of the HHS and FBI in this regard.

⁷ www.virtualbiosecuritycenter.org

- There was also discussion of whether the FBI would be interested in more intelligence led engagement with the dual-use issue.
- There was discussion of the impossibility of policing the practices of Synthetic Biology, to ensure its only conducted at known, or licenced premises, particularly as scientific and technical capabilities continue to disseminate.
 - o This was identified as an argument for increased awareness raising and education to foster appropriate norms within the community
- There was discussion about the recent shortening of the US select-agent list, and the possible ways in which this could be interpreted by observers and stakeholders
- IT was pointed out that the CWA standard was and international and not just a European agreement. In response to these comments, it was argued that states must reflect upon how they can influence industry, and the ISO may be one approach.
- It was also argued that discussions thus far were emphasising the role of industry in the implementation of the BTWC, which was a state responsibility.
- With relation to Synthetic Biology several issue were raised: First, there was discussion about the requirement of US and European co-operation of pathogen DNA databases. The possibility of yearly review of pathogen sequences by and expert body was also raised. The question of 'insider' threat within the Gene synthesis industry was also raised. It was pointed out that currently industry were perhaps neglecting 'insider threat', with their continued focus on 'outsider threat'.

Session IV: Global Co-operation in Science and Security.

In this session discussion focussed on international collaboration around the globe between scientists and other stakeholders in pursuit of global biosecurity, with reference to the provision of international assistance in achieving this aim.

The work of the International Science and Technology Centre was introduced. This organisation coordinated and implemented efforts to provide opportunities for peaceful applications of research, including sensitive CBRN fields, in some countries of the Former Soviet Union. This has included support of research into disease diagnostics and surveillance. The ISTC is also involved in the implementation of laboratory biosecurity and biosafety initiatives internationally. However, in recent years the ISTC has faced substantial withdrawal of financial support.

There was also discussion of the Biological Engagement Program, which runs out of the US Department of State. This programme developed a library of educational materials based on international best practices which provide specific training designed for a variety of personnel including: policy makers, top management, bio-risk management advisers (also called biosafety officers), scientific and/or laboratory management. There was also discussion of the outreach to Pakistan as part of the work of the International Biological Threat Reduction programme⁸. It was also highlighted that research at Sandia national laboratories were developing technologies that improve the biosafety of diagnostics outside of laboratory settings.

There was also discussion of the EU CBRN Risk Mitigation Centres of Excellence Initiative⁹. In the talk the structure composition and structure of this international network was discussed. The purposes of the centres of excellence project is to:

- optimize the sharing and use of CBRN capabilities;
- collect and share best practices;
- establish a cooperation process between network members to detect issues and design solutions;
and
- identify, collect and deploy resources efficiently.

In the following talk there was discussion of a recently developed Masters course in Neuroscience and Biotechnology, funded by the Tempus European Programme. The aim of the ISIS is to develop multiple masters programmes in Euro-Mediterranean countries, which will include a module on the regulation and ethics. This module will be compulsory for all of those participating in the masters, regardless of the field of study chosen within the programme. Within this talk there was emphasis placed on the potential importance of the Bologna process¹⁰ as a means to encourage European wide integration of biosecurity education into university course.

Discussion

- The question of the relevance of ethics education to the work of the ISTC was raised. It was highlighted that the ISTC normally follow the directions of the collaborative partners. However the issue element could be incorporated and indeed was interrelated with the idea of laboratory biosafety and biosecurity.

⁸ <http://biosecurity.sandia.gov/>

⁹ <http://lab.unicri.it/centers-of-excellence.html>

¹⁰ <http://www.ond.vlaanderen.be/hogeronderwijs/bologna/about/>

- With regard to lessons learned in international collaboration in the development of security and safety, it was highlighted that it was important for funding institutions to remain involved in the implementation process, to ensure that funding achieved the intended impacts.
 - o The importance of state involvement in the implementation of these projects to ensure sustainability. However it was also argued that state governments are sometimes corrupt.
- There was an enquiry into whether Sandia National Laboratory had developed metrics for measuring the success of dual-use education and training.
 - o There were basic longitudinal metrics in use which were under development.
- It was highlighted that there was value in the 'adult education' style of educational materials.
- There was discussion of how the COE interacts with member organisations, such as the OPWC in regard to defining common areas of interest. The question the of state of implementation of this project was also raised

Closing remarks

In summing up some pertinent observations were made with relation to the discussions over the previous two days. It has been widely agreed that the process has been useful and should continue. However questions remained about the structure of this process as well as the relationship between intersessional process and the review process of the BTWC. These issues revolve around questions about the informal advisory community that has developed during the intersessional process can be complemented, and continue contribute in an appropriate and efficient way in the evolving regime.

Some common issues alluded to throughout the workshop with regard to goals of increasing biosecurity and biosafety were:

- Existing knowledge silos within the broader biosecurity community. Particularly with regard to sharing knowledge gained from experiences with the various stages of the policy process from inception to evaluation.
- The mismatch between institutional funding criteria and new collaborative governance approaches, how to ensure that stand-alone projects were sustainable
- The requirement for strong networks in developing and maintaining capacity to deal with biosecurity issues.

- Questions about how best to implement and sustain educational programmes in industry as well as the scientific community . Including options to pursue this at national, regional and international level.

In the context of any developments that come out of the Seventh Review Conference of the BTWC, it is worth highlighting that the ability of governance structures to address these issues should be seen as important criteria to evaluate the progress of the regime.