Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

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Item 6 of the agenda
Standing agenda item: review of developments in the field of science and technology related to the Convention

Measures for mitigation of risks due to new science and technology developments of relevance to the BWC

Submitted by the European Union

1. As agreed at the Seventh BTWC Review Conference in December 2011 in Geneva, review of developments in the field of science and technology related to the Biological and Toxin Weapons Convention is one of the core issues of the 2012-2015 Intersessional Process.

2. Specific topics set by the Seventh BTWC Review Conference include: (1) possible measures for strengthening national biological risk management in research and development involving new science and technology developments of relevance to the Convention; (2) voluntary codes of conduct and other measures to encourage responsible conduct by scientists, academia and industry; (3) education and awareness-raising about risks and benefits of life sciences and biotechnology.

3. The main goal of this working paper is to share information on illustrative examples of best practices and standards adopted in some EU Member States, which could provide useful benchmarks for other BTWC States Parties. This paper also contributes to information and knowledge sharing on bio-risk management among governments, scientists, officials and civil society.

I. Measures for strengthening national bio-risk management in research and development implemented by the EU Member States

A. The EU engagement in the field of bio-risk management in research and development, including issues addressed by projects under the CBRN Centres of Excellence Initiative

The EU engagement in the field of bio-risk management in research and development under BTWC involves Calls for Projects, announced by EU Instrument for Stability and EU CBRN Risk Mitigation Centres of Excellence. Some of them are listed below.

1. EU Instrument for Stability (IfS)

- "Biosafety and Biosecurity Improvement at the Ukrainian Anti-Plague Station (UAPS) in Simferopol"

2. Projects under the EU CBRN Risk Mitigation Centres of Excellence:

(a) Building capacity to identify and respond to threats from chemical, biological, radiological and nuclear substances (Project 2).

(b) Knowledge development and transfer of best practice on bio-safety/bio-security/bio-risk management (Project 3).

(c) Knowledge development and transfer of best practice on chemical and biological waste management (Project 6).

(d) Guidelines, procedures and standardization on bio-safety/bio-security (Project 7).

(e) Sharing experience between EU and South East Asian countries on the reinforcement of legislations and regulations in the field of bio-safety and bio-security, as well as relevant laboratories management systems through Regional Centre of Excellence (Project 12).

(f) Strengthening laboratory bio-safety and bio-security through development of a laboratory iso-bank system (Project 15).

B. Measures implemented by EU Member States.

Belgium

In Belgium the appointment of a biosafety officer (or biosafety coordinator) and the setting up of a biosafety committee is compulsory for every institution where genetically modified organisms and/or pathogens are contained. It became compulsory when EU Directive 98/81/EC[1] was implemented in the 3 regional Decrees that respectively entered into force in 2001 for the Brussels-Capital region, in 2002 in Wallonia and in 2004 in Flanders. Belgium was one of the few EU Member States that included this obligation in its legislation, thus drawing its inspiration from the United Kingdom where the tasks and duties of the

[1] Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms - http://www.biosafety.be/PDF/98_81.pdf

"biosafety officer" had already been defined by the Health and Safety Executive (HSE). The role and the main task of the biosafety officer and the biosafety committee are defined in the Decrees. Exemption is foreseen for the constitution of a biosafety committee in small laboratories with limited staffing but the appointment of a biosafety officer remains compulsory in any case.

More information on the website of the Biosafety and Biotechnology Unit (SBB) of the Scientific Institute of Public Health (IPH): http://www.biosafety.be/.

France

France adopted a legislation backed by the Public Health Code, which contains biological safety and security requirements for highly pathogenic biological agents. These legally-binding requirements provide the government authorities with full traceability of laboratory activities and the people who undertake them, their objectives and their modalities. The French authorities thus have the means to reduce the risk of misuse as, in particular, traceability is guaranteed when transferring the most virulent strains between laboratories.

This legislation largely draws on the current provisions in the 1961 Single Convention on Narcotic Drugs, which both preserves the sovereignty of each State regarding control and verification/investigation on its territory and provides an international mechanism to trace product transfers as well as international cooperation between countries.

The Netherlands

The Netherlands is currently implementing a coordinated biosecurity regime which seeks to foster expertise on biosecurity in a variety of ways (including a biosecurity toolkit) and which imposes an obligation to report all high-risk biological materials and to appoint a bio-risk professional, who will be responsible for both safety and security. In addition, a number of public institutions have been given funding from the government to enhance security measures.

Portugal

Portugal works towards strengthening the national response to a biological event and the dissemination of biosafety and biosecurity standards, through the coordination of a network involving all the Portuguese BSL-3 Laboratories and the organization of annual workshops on biosafety/biosecurity. The following are examples of practical steps taken by Portuguese laboratories to mitigate bio-risk:

- Biological waste disposal procedures vary according to the biosafety level of the organisms or tissues used. However, all liquid cultures and stocks of microorganisms are inactivated by chemical treatment with 10% household bleach before drain disposal. Biological wastes are sent out to specialized companies for adequate destruction.

- The exits from rooms and buildings are placed nearby them and well signaled.

- Fire extinguishers, safety showers, eyewash stations are examples of security laboratory devices in use in our buildings.

Students and researchers wear safety eyeglasses and protection lab coats.

Spain

1. Law 2/1985 dated 21st January 1985 on Civil Protection and Royal Decrees 407/92 dated 24th April 1992 and 1599/2002 dated 2nd July 2004 created the Regulations for Civil Protection and the General Directorate for Civil Protection and Emergencies, where by the

National System for Civil Protection, dealing with all types of natural disasters and crisis, is articulated at the local, regional and national levels.

The Military Emergency Unit (UME) was created by Royal Decree 416/2006 dated 11th April 2006 to act in the entire Spanish territory in case of natural disasters and in the event of terrorist attacks with nuclear, chemical or biological agents, in accordance with the provisions made in Organic Law 5/2005 of National Defence dated 17th November 2005. The UME is equipped to fulfil its mandate.

Royal Decree 1886/2011 dated 30th December 2011 created the Governmental Commission for National Crisis supported by the Department of Infrastructures and Monitoring of National Crisis (Royal Decree 83/2012 dated 13th January 2012) for an efficient coordination crisis management in Spanish territory.

2. The National Network of Laboratories for Biological Alerts (RE-LAB) was created in February 2009 by Presidential Order PRE/305/2009 dated 18th February 2009 as reinforcement for the National System of Crisis Alert and Control. This network is formed by eight microbiological laboratories specialising in human, animal and plant pathogens. A RE-LAB fundamental mission is the identification and early diagnosis of the potential agent causing the unusual outbreak of the infectious disease and, in particular, those of a terrorist nature. The RE-LAB forms part of the National Working Party for the implementation of CBRN EU Joint Actions.

United Kingdom of Great Britain and Northern Ireland

National approaches to proactive inspection of biocontainment facilities

1. The United Kingdom's Health and Safety Executive (HSE) Biological Agent Unit has developed, and is working to, a programme of proactive inspections of biocontainment facilities that is risk-based. This allows best use of resources and targets efforts on those facilities that represent greatest risk. This type of approach allows HSE to discriminate between sites that operate within the same containment level (CL) categories (CL2 or CL3 or CL4) based upon the activities that are undertaken and on previous evidence of operator performance. It then permits development of risk profiles. These profiles take into account the obvious denominator of the hazard grouping of the biological agent in use, but also consider other factors such as the quantity of agent worked with, the complexity of the operation and the type of work; all of which influence the level of risk. During inspections conducted by the HSE, the operator's performance against a range of set topics are assessed and 'scored' and these data overlay the inherent hazard of the site to augment the risk profile. The overall 'score' influences the frequency of future interventions at that site.

Use of safety performance indicators (SPIs) at Containment Level 4 (CL4)

2. SPIs have been used extensively in several major hazard industries (Nuclear, Oil and Gas, and Chemical) for many years .HSE and interested operators and bodies have developed this type of approach to biorisk management at the UK's biological containment facilities working with biological agents that represent the highest hazards (Hazard Group 4).

3. The approach centres on identifying a range of key elements in biocontainment management that can be measured and analysed to provide leading indicators for when a particular control measure may be in need of attention in order to continue to function as intended and avert an incident that could give rise to a laboratory acquired infection, or a loss of containment. A framework of key indicators that represent the range of control measures (as applying to people, plant, and processes) has been developed and this is already allowing some UK CL4 sites to gain a better insight into the safe operation of their

facilities.

Guidance for contained use activities involving genetic modification

4. The HSE has provided the 'SACGM Compendium of Guidance for contained use activities involving genetic modification' which was prepared in conjunction with the Department for Environment, Food and Rural Affairs and the Scottish Executive Environment and Rural Affairs Department, in consultation with the Scientific Advisory Committee for Genetic Modification (Contained Use) (SACGM). SACGM provides technical and scientific advice to the UK Competent Authorities on all aspects of the risks posed to human health and the environment regarding contained use activities with genetically modified organisms (GMOs). The Compendium is available on the HSE website, and covers such aspects as: legislative requirements and management responsibilities; risk assessments; and containment and control approaches. Guidance is aimed at all those wishing to undertake activities with GMOs in containment, especially those with responsibility for assessing the risks associated with such work, and those who are required to appraise those risk assessments. The guidance represents what is considered to be good practice and is not compulsory. However, if operators follow this guidance they are normally doing enough to comply with UK law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance as illustrating good practice.

5. Some of the UK measures described in Section 2 below in the context of 'other measures to encourage responsible conduct…' also have an aspect of biorisk management since they are oversight mechanisms for research and development including that involving new science and technology developments of relevance to the Convention.

The Academic Technology Approval Scheme (ATAS)

6. ATAS was introduced on 1 November 2007 and is an essential part of the UK's commitment to Counter Proliferation. The ATAS is specifically designed to ensure that those applying for postgraduate study in certain sensitive subjects at UK higher education establishments do not acquire knowledge that could potentially be used in WMD programmes.

C. Elements relevant for possible inclusion in the development of national measures by BTWC States Parties on bio risk management

1. A range of legislative measures and national guidance on their implementation should ideally address the following:

(a) legislative measures to ensure effective control and surveillance over the activities using dangerous human, animal and plant pathogens and toxins;

(b) laboratory bio-risk management drawing on international best practices;

(c) development and maintenance of national capabilities to detect and protect against the misuse of pathogens and toxins;

(d) biosafety and biosecurity education for those working with pathogens and toxins.

2. To ensure effective bio-risk management systems, sustained implementation of both biosafety and biosecurity measures is required. These measures are also mutually reinforcing, but attention must also be paid to the context in which such measures might be required. It is counterproductive, for example, to insist upon high level of containment measures where there is neither the need or national capabilities to sustain them. Developing such systems can of course draw upon following international bio-risk

management guidelines:

(a) WHO International Health Regulations, 2005;

(b) WHO Laboratory Biosafety Manual, 3rd ed.;

(c) WHO Biorisk Management, Laboratory Biosecurity Guidance, 2006;

(d) Laboratory Biorisk Management CWA 15793: 2008.

3. A national laboratory bio-risk management framework could consist of the following specific elements that address both biosafety and biosecuirty aspects. Such elements can include but are not limited to:

(a) A biosafety risk assessment that reviews the nature of the biological material being held and worked upon, and the appropriate measure required to address the safety of the workforce and general population.

(b) An assessment of whether the technical infrastructure is appropriate for the containment levels of laboratories and laboratory safety equipment and personnel protective equipment for the biological agents and toxins that are being worked on or stored;

(c) A biosecurity risk assessment that evaluates the assets of lab activity; environmental threats (criminal, extremist and terrorist activities),

(d) Personnel security: personnel screening/personnel reliability; ensuring that identification badges are worn at all times; controls on visitors;

(e) Oversight and effective management of all work with pathogens and toxins; controls on potentially sensitive information and equipment;

(f) Accountability for all agents held in the laboratory and who has had access to them; effective inventory controls.

(g) Effective physical security, including access control to laboratories limited to designated personnel.

(h) Information security and IT security.

4. Effective and efficient national bio-risk management requires regular reviews and mapping of any capability gaps and identification of any actions required to address any shortcomings. National regulatory authorities should support development of biosafety and biosecurity associations that involve and engage the human, animal and plant health communities.

II. Codes of conduct and other measures to encourage responsible conduct by scientists, academia and industry.

Descriptions of measures that could be an example of possible approaches for BTWC States Parties.

1. Codes of Conduct

Target Group

(a) professionals engaged in the performance of biological, biomedical, biotechnological and other life sciences research

(b) organizations, institutions and companies, which:

(i) conduct life sciences research

(ii) provide education and training in life sciences

(iii) issue permits for life sciences research, fund, facilitate, monitor and evaluate that research

(iv) manage, store, stockpile or transport relevant biological materials or toxins

(c) scientific organizations, professional associations and organizations of employers and employees in the field of life sciences

(d) authors, editors and publishers of life sciences publications and administrators of websites dedicated to life sciences.

Rules of Conduct

(a) raising awareness

(b) research and publication policy

(c) accountability and oversight

(d) internal and external communication

(e) accessibility

(f) shipment and transport

2. Code of Ethics

3. Codes of Practice

4. Responsibilities and Training of PhD Students Regarding Dual Use of Biotechnology

5. Monitoring of Research in Life Sciences, including Dual – Use Research

Measures taken by EU Member States

France

France is in favor of promoting responsibility of scientific laboratory communities through the infra-legislative route by promoting quality management standards. Quality management standards such as ISO/IEC 17025 and ISO 15189, demonstrate the scientists'

expertise, guarantee the reliability of the activities produced and thus determine the level of confidence which the clients can place in the laboratories. These quality management standards, which are supplemented as necessary and based on their specific activities by guidelines and international best practice guides, help ensure that the biological risks are fully under control within the laboratories. They are not only tools of economic cooperation and development (they are proof of the reliability of laboratories and their services), but their implementation improves transparency (laboratories must undergo third-party compliance audits).

The Netherlands

In 2006, in response to debates at BTWC meetings, the Dutch government asked the Royal Netherlands Academy of Arts and Sciences (KNAW) to draw up a Code of Conduct for Biosecurity. The main objective of the Code was to raise general awareness of the subject.

If a Code of Conduct is to have this intended effect, it must engage with relevant scientific, social and political developments and with the day-to-day practice of scientists and their organisations. For that reason relevant actors from science, industry and government have been involved in developing the code from the beginning. With their help, suggestions were made and then translated into issues that could be addressed in the Code of Conduct. This process resulted in the publication of the Dutch Code of Conduct for Biosecurity in 2007. The Code centres on raising awareness; research and publication policy; accountability and oversight; internal and external communication; accessibility; and shipment and transport.

The Code of Conduct has been published in Dutch and English. Working with other parties, KNAW has organised debates with representatives of industry and research-funding organisations. The Code has been used by funding agencies in judging research proposals. Of course a code of conduct cannot prevent abuse of science in all circumstances; other measures are still required. However, as a result of the Code of Conduct, relevant stakeholders are more aware of biosecurity than in the past.

Spain

The Spanish Association of Biosafety (AEBioS) has recently been created with the aim of harmonising the biological containment facilities building and their functioning, in addition to promoting the development of biological safety regulations and associated technology in Spain.

United Kingdom of Great Britain and Northern Ireland

1. The Universal Ethical Code for Scientists is a public statement promulgated by the UK Government Chief Scientific Adviser that sets out values and responsibilities of scientists - anyone whose work uses scientific methods, including social, natural, medical and veterinary sciences, engineering and mathematics. The code has three main aims:

(a) to foster ethical research;

(b) to encourage active reflection among scientists on the implications and impacts of their work; and,

(c) to support communication between scientists and the public on complex and challenging issues.

2. Individuals and institutions are encouraged to adopt and promote these guidelines. It is meant to capture a small number of broad principles that are shared across disciplinary and institutional boundaries.

See http://www.bis.gov.uk/assets/goscience/docs/u/universal-ethical-code-scientists.pdf

3. In 2005, three UK funding bodies that support research in life science subjects, the Biotechnology and Biological Sciences Research Council (BBSRC), the Medical Research Council (MRC) and the Wellcome Trust, each issued position statements on bioterrorism and biomedical research. These cover issues such as: balancing benefit and risk; funding decisions; dissemination of research; international collaboration and training; and promoting research best practice and ensuring public trust. The position statements propose that a system based upon self-governance by the scientific community will ultimately provide the most effective means of managing risks of misuse.

4. The three organisations then issued a joint policy statement 'Managing risks of misuse associated with grant funding activities' – see: http://www.bbsrc.ac.uk/web/FILES/Policies/misuse_of_research_joint.pdf.

The statement was issued in light of public concerns that bioscience research could be misused in the development of bioweapons. It built on existing policies and processes that the Councils and Trust already had in place to ensure that the research they supported met the highest ethical and scientific standards.

5. The BBSRC, MRC and Wellcome Trust agreed changes to their policy statements, guidance and procedures in four areas:

(a) Introduction of a question on grant application forms asking applicants to consider risks of misuse associated with their proposal;

(b) Explicit mention of risks of misuse in guidance to grant referees as an issue to consider;

(c) Development of clear guidance for funding committees on this issue and the process for assessing cases where concerns have been raised; and,

(d) Modification of organisational guidelines on good practice in research to include specific reference to risks of misuse.

6. In the UK Compliance Report for the Seventh Review Conference we noted inter alia that: The UK Ministry of Defence has guidelines to ensure that its biological defence research and development programmes are in compliance with the BTWC. These guidelines codify existing approaches and practices and set out the procedures and responsibilities within the oversight mechanism to ensure that research is consistent with the obligations under the Convention and with relevant domestic law.

European Union

In the context of the ethics review of the EC research funded projects, a specific guidance note has been prepared for the scientific community on misuse of research results. Aspects of research that fall under this category are being reviewed by ethics experts and advice is offered to the researchers on the ways to address these issues during the design and implementation of their research

III. Education and awareness-raising about risk and benefits of life sciences and biotechnology.

A crucial element of risk management in new science and technology developments is awareness-raising and training of scientists, laboratories managers, bio-safety and bio-security professionals. Training should address recipients with both, awareness of biological threats as well as knowledge and hands-on experience in biosafety/biosecurity/biorisk management based on the regional specificity of the natural and deliberate man-made public health risks. Education and awareness-raising measures should ideally:

- monitor relevant developments in bio-security,
- coordinate the publication of information and educational materials, including websites with up-to-date information,
- organize conferences and workshops with interactive elements,
- maintain contacts with relevant actors in the government and civil society
- consult experts who can provide advice on whether the results of potential dual use life science research should be published,
- perform regular evaluations of awareness and technical competence.

The EU engagement in the field of education and awareness-raising about risk and benefits of life sciences and biotechnology, including issues addressed by projects under the CBRN Centres of Excellence Initiative.

The EU engagement in the field of education about bio-risk in life science under BTWC articles involves CoE Calls for Projects, as well. The most relevant topics are listed below.

EU CBRN Risk Mitigation Centres of Excellence projects:

- International Network of universities and institutes for raising awareness on dual-use concerns in bio-technology (Project 18)
- Development of procedures and guidelines to create and improve secure information management systems and data exchange mechanisms for CBRN materials under regulatory control (Project 19).

Possible proposals for consideration at the Meeting of Experts.

- Review of implementation of legislation focused on bio-risk management.
- Initiate discussion on development of a joint curriculum on biosafety, biosecurity and bioethics for life scientists to enhance good practices on a national level.

Measures taken by Member States

France

France recommends that national plans be drawn up to raise awareness among the scientific community according to the following methods:

The States Parties to the Convention are invited to form a national structure responsible for

implementing the scientific community's national awareness plan. This structure would be made up in particular of representatives from the Ministries and agencies responsible for research, from the academic world, from major research organizations and of other stakeholders.

This plan could comprise: criteria for identifying risky research, the establishment of scientific monitoring observatories, the creation of codes of conduct for scientists and manufacturers, information via conferences and workshops as well as through the creation of dedicated websites.

The annual Conference of States Parties could serve as a platform where national organizations could discuss the best practices and draw up guidelines as necessary.

The States Parties could provide a progress report on the implementation of their national plan during the Review Conference.

Promoting responsibility requires awareness as soon as possible. It is therefore essential to include specialized courses in the training programme for scientists and engineers, within which the Convention and the contents of its provisions should be mentioned. The issues of dual use and bioethics should also be dealt with. The course content and implementation timetable should be set up within the framework of the national structure.

Germany

In Germany, education and awareness raising of personnel acting in the wide field of biosciences is regulated by law and other measures. The following describes main training requirements.

(a) Technical laboratory assistants

Education and training of medical technical laboratory assistants and biological technical assistants is regulated in by federal law and regulations of the Federal States.

(i) Medical technical laboratory assistant

The three year education and training is regulated by the Gesetz über technische Assistenten in der Medizin (MTA-Gesetz - MTAG; Law on Technical Assistants in Medicine) of 2 August 1993. MTAG also applies to the education and training of veterinary-medicine laboratory assistants and addresses, inter alia, different areas of specialization including microbiology. Detailed requirements for education are laid down in the Ausbildungs- und Prüfungsverordnung für technische Assistenten in der Medizin (MTA-APrV; Regulation on Training and Examination of Technical assistants in Medicine) of 25 April 1994. MTA-APrV contains detailed curricula for education and training of laboratory assistants which cover, inter alia, the fields of:

- legal provisions in/for medicine in general
- ethics
- specialized legal provisions for jobs in medicine/veterinary medicine
- labour legislation, including prevention of accidents and health and safety measures
- regulations on dangerous goods, radiation protection, etc
- laws and regulations on infectious diseases/animal diseases/food hygiene
- penal and administrative legislation relevant to job description
- political opinion making and action, ongoing relevant political

questions/news.

(ii) Biological technical laboratory assistant

The education of biological technical laboratory assistants is regulated by the Federal State. The education and training period is two or three years depending on different entrance qualifications. Curricula are controlled by Federal States and include similar packages of legislation and job related regulatory information as mentioned above for MTA.

(b) Academic education and training

In principle, German universities are independent in deciding on curricula. However, need exists for following more or less standardized curricula as a result of the Bologna process. In Germany ASIIN e.V., a registered association supported by professional technical and scientific associations, industry and business associations, unions, and universities, develops standardized curricula in engineering, computer science, natural sciences, mathematics, and teaching qualification. ASIIN also acts as accreditation agency for degree programmes (master and bachelor). The ASIIN website describes the supplementary competence requirements for accreditation of bachelor and master degree programmes. In the curriculum of biosciences teaching requirements regarding “Biologische Sicherheit” are mentioned. An unauthorized translation of this part is provided here:

"Biologische Sicherheit” [can be translates to mean biosafety as well as biosecurity] should be an essential part of education in bio-sciences. Therefore, security/safety relevant items should be taught as part of an interdisciplinary approach adapted to the profile of the field of studies:

- introduction to relevant laws and regulations (work protection law, laboratory guidelines, regulation on biological agents, regulation on dangerous goods, genetic engineering legislation, radiation protection legislation, guideline on animal experiments, animal welfare legislation)
- organisation of safety/security and health protection in laboratories
- liability and responsibility
- aspects of safety and protection measures regarding work in laboratories (GLP, instructions for employees, organizational work instructions, infrastructure and equipment)
- risk assessment (biosafety/biosecurity)”

More information on ASIIN and its activities are available on: http://www.asiin-ev.de/pages/en/asiin-e.-v.php

(c) On job training

According to Biostoffverordnung (Biological Agents Ordinance), Sections 10(5) and 12(2):

- 10 (5) Workers shall only be assigned to specific activities involving biological agents of risk group 3 or 4 if they are sufficiently competent and instructed. This shall apply mutatis mutandis to non-specific activities posing similar risk. …
- 12 (2) Workers due to work with biological agents shall be instructed on existing risks and protective measures on the basis of operating instructions. Instruction shall be given orally and with specific reference to the workplace prior to the beginning of work and shall be repeated annually. After the instruction, time and content of the instruction shall be recorded in writing and shall be signed and approved by the trainee.

The Netherlands

The Netherlands has developed a number of instruments to increase knowledge of high-risk (CBRN) materials and security issues relating to these materials, particularly at facilities that use, store or transport them. The main instruments are the online modules entitled, 'It's your business to be sure.' The first module targets security managers, helping them set up workshops on security awareness within their organisations. The second module targets employees, in particular new ones. A special module has been developed for facilities that may be under threat by animal rights extremists. These modules are provided free of charge by the National Coordinator for Counterterrorism and Security and can be found (in Dutch) at www.nederlandtegenterrorisme.nl, the website for the Dutch counterterrorism campaign first launched in 2006. All modules can be customised by the facilities. To improve security awareness and test security performance, a number of Dutch institutions, working with the National Coordinator for Counterterrorism and Security, have subjected their security to 'red teamings', or real-life security tests. Facilities will soon have access to a red teaming toolbox, which they can use to set up their own red-team exercises.

Portugal

Portuguese BSL-3 Laboratories are engaged, at national level, in promoting biosecurity and biosafety through research projects, higher education courses and the organization of an annual Seminar. In addition, many research centres and higher education institutions, such as the National Health Institute "Dr Ricardo Jorge", the University of Lisbon, the Institute of Chemical and Biological Technology and the Institute of Tropical Medicine and Hygiene of the New University of Lisbon, take part in European and international research networks that also focus their work in biosecurity and biosafety (eg. ERIHA – European Research Infrastructure on Highly Pathogenic Agents).

Spain

Several outreach initiatives have been undertaken under the auspices of the Spanish Ministry of Foreign Affairs as part of a more general plan aimed at increasing education and awareness-raising:

Seminars specifically directed to chosen actors whose activities are related to BTWC. The first seminar was addressed to a selected group of Spanish Bio-industries and was focused on the impact that the national implementation of BTWC would have on their activities.

Presentations at plenary sessions of national scientific congresses of Spanish Scientific Societies with the same focus as above, with emphasis on codes of conduct.

United Kingdom of Great Britain and Northern Ireland

The UK has nothing new to add to the information reported in our national Compliance Report at the Seventh Review Conference and in Working Paper 20. We do however include a summary of some relevant points here for ease of reference:

The UK has held several seminars addressing codes of conduct, oversight, education and awareness-raising related to the BTWC. These were attended by representatives from academia, research councils, professional and trade associations and the pharmaceutical and biotechnology industries, and have been reported in Working Papers to BTWC meetings (e.g. BWC/MSP/2008/MX/WP.10). Such events have helped to raise the levels of awareness in the academic and research communities of the risks inherent in dual use biological science, and the responsibility of individuals to prevent misuse; highlight the nature of the Convention's legal prohibitions; and promote the need to address issues such as technology governance on a continuing basis.

The University of Bradford has devoted considerable efforts to developing educational material to support awareness-raising and education. The University's Education Module Resource (EMR), freely available online, offers content that includes history and national implementation of the Biological and Toxin Weapons Convention, dual-use issues in the contemporary life sciences, and responsible conduct in scientific research. The UK Global Partnership Programme is currently funding Bradford University to develop a National Series for a number of specific countries including in the Former Soviet Union. This series includes the essential values of the current EMR, but the themes, contents and learning outcomes for educational contexts are designed to be country specific. The main objective is to provide user friendly educational resources for use in the immediate introduction of short biosecurity education programmes for higher education.

European Union

Specific training activities have to be undertaken in the EU member states in order to increase awareness on the relevant EU legislation (such as the Dual Use regulation etc). These activities are important because a number of researchers ignore their existence as well as the available structures that oversee their implementation and could provide, if appropriately staffed, with the necessary information.

Specific training activities can be organized targeting EC research personnel in order to be able to detect and process proposals that raise such questions.

All activities under point 3 should also extend to disciplines outside life sciences. A few of the protocols we receive that raise misuse issues come from behavioral and social sciences (including in areas related to security related research).

Annex

Existing EU legislation and actions relevant to research on potentially dangerous pathogens as regards biosafety, biosecurity and dual use

The following list aims to provide an overview of EU legislation relevant for the research involving highly pathogenic avian influenza H5N1 virus.

The issues raising concern are on the one hand related to biosafety (containment principles, technologies and practices to prevent unintentional exposure of biological agents or their accidental release, including protection of laboratory workers and the general public) and on the other hand biosecurity (protection, control and accountability for biological materials to prevent their misuse or intentional release) as well as dual use (technology that can be used for both peaceful and military aims, including use of biological information for terrorist purposes). There is obviously some overlap in these concepts.

Harmonized EU legislation is already in place through five sets of Directives addressing 1) biosafety and biosecurity risks related to laboratory handling of avian influenza viruses, 2) the protection of laboratory workers, 3) handling of genetically modified organisms, 4) handling the public health consequences of an incident and 5) dual use matters.

1 Handling of avian influenza virus (veterinary legislation), DG SANCO:

Council Directive 2005/94/EC on Community measures for the control of avian influenza requires that diagnostic procedures, sampling and laboratory testing to detect the presence of avian influenza in poultry or other captive birds or avian influenza virus in mammals are carried out according to the Diagnostic Manual approved by Commission Decision 2006/437/EC). This manual refers to the following minimum safety/containment standards to be applied in diagnostic laboratories:

(a) EU Directives listed in paragraphs 2 and 3.

(b) EN norms:

(i) EN 12128 Biotechnology. Laboratories for research, development and analysis. Containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements

(ii) EN 12738 Biotechnology. Laboratories for research, development and analysis. Guidance for containment of animals inoculated with micro-organisms in experiments

(iii) EN 12740 Biotechnology. Laboratories for research, development and analysis. Guidance for handling, inactivating and testing of waste

(iv) EN 12741 Biotechnology. Laboratories for research, development and analysis. Guidance for biotechnology laboratory operations.

(c) EU reference Laboratory for AI (UK requirements)

(d) International standards and recommendations

Animal health (OIE):

(a) Terrestrial code (20th Edition, 2011, chapter 5.8.) "International transfer and laboratory containment of animal pathogens"

(b) Terrestrial Manual (6th Edition, 2008) chapter 1.1.2.) "Biosafety and biosecurity in the veterinary microbiology laboratory and animal facilities"

Human Health (WHO):

(a) WHO Laboratory Biosafety Manual – 3rd Edition

(b) WHO guidelines for the collection of human specimens for laboratory diagnosis of avian influenza infection

(c) WHO Responsible life sciences research for global health security – a guidance document WHO Geneva 2010

2. Protection of workers and laboratory safety, DG EMPL:

(a) Council Directive 89/391/EEC on the introduction of measures to encourage improvements in safety and health of workers at work .

(b) Directive 2000/54/EC of the European Parliament and of the Council on the protection of workers from risks related to exposure to biological agents at work , containing in particular requirements for laboratories (containment levels 1 to 4).

3. Handling of genetically modified organisms, DG SANCO:

Directive 2009/41/EC of the European Parliament and of the Council on the contained use of genetically modified micro-organisms (recast of Directive 90/219/EEC).

4 Handling the public health consequences of an incident, DG SANCO:

Under Decision 2119/98/EC of the European Parliament and of the Council, a Community Network for epidemiological surveillance and control of communicable diseases is established. Under the provisions of this Decision and its implementing measures, a mechanism is established to report at EU level cases of avian influenza A/H5 or A/H5N1 in humans as well as to oblige Member States to report in case of an emergency situation should rise as a result of an escape of the virus from laboratory premises. In addition to this specific virus other dangerous pathogens, mostly related with potential deliberate threats are addressed under Decision 2119/98/EC (smallpox, anthrax, botulism, tularaemia, plagues, etc.). Finally, in case of such events should happen, Member States have the obligation to share information with each other and the Commission on any health measures planned or undertaken to respond to the event, with the final aim to coordinate a shared approach to minimise the impact of such incidents, in close collaboration with the EU Health Security Committee.

5. Handling dual-use items, DG TRADE, HOME, ENTR:

The Commission Decision 2001/844/EC, ECSC, Euratom, lays out the basic provisions for security and Council Regulation (EC) 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items. This regulation covers both the physical handling of listed pathogens as well as the management of knowledge (for example, sequence information).

(a) Dual-use items are civil goods and technologies which can be used for producing conventional weapons or for producing weapons of mass destruction (nuclear, biological, chemical) and their means of delivery (missiles). Examples can be as diverse as ferment, a machine tool with specific parameters, a chemical product or a virus/pathogen, a navigation system, a specific computer etc.

(b) Export control of dual-use items are concrete means for Member States to ensure that dual use items exported will not contribute to illicit end uses such as the production or delivery of weapons of mass destruction. Export controls enable Member States to

implement several non-proliferation treaties and arrangements to which they are parties and which prohibit the development and production of weapons of mass destruction.

(c) The lists of dual use items subject to export controls are decided in international export control regimes such as:

(i) the Nuclear Suppliers Group, to which the Commission is observer

(ii) the Australia Group (chemical and biological items) to which the Commission is a member

(iii) the Missile Technology Control Regime to which the Commission attends meetings in the Presidency's delegation.

(iv) the Wassenaar Arrangement (export controls of conventional weapons and of dual use goods and technologies) to which the Commission attends meetings in the Presidency's delegation.

(d) These lists are incorporated in annex I of Council Regulation (EC) No 428/2009 . The Regulation is amended by the Council, on the basis of a Commission proposal annually in order to update the control lists following decisions taken in the above mentioned export control regimes.

(e) Export of items listed in the Regulation is submitted to prior authorisation delivered by the EU Member State where the exporter is located (except in the case of EU General Export Authorisation, 6 of which are currently in force for certain limited combinations of items and destinations).

(f) In addition to control on listed items, Member States may also subject exports of non-listed items to an authorisation requirement if the item may be used in a Weapons of Mass Destruction (WMD) or military programme.

6. Handling classified information in RTD funded projects, DG ENTR:

Rules related to the handling of security sensitive RTD actions are to be found in Annex B of the Commission Decision related to the rules on submission, evaluation, selection and award procedures for indirect actions under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities and under the Seventh Framework Programme of the European Atomic Energy Community (Euratom) for nuclear research and training activities (2007-2011) . This Annex also reference the Decision 2001/844/EC, ECSC, EURATOM (see under pt 2) and the Council Regulation (EC) No 428/2009 on the control of experts, transfer, brokering and transit of dual-use items . In addition, all projects that raise issues concerning dual use, undergo an ethics review as described in Annex A of the above mentioned Rules for submission, evaluation, selection and award procedures (see reference No. 15)