#### 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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- Consideration of national, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins
- Consideration of oversight, education, awareness raising, and adoption and/or development of codes of conduct with the aim of preventing misuse in the context of advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention

### SYNTHESIS OF CONSIDERATIONS, LESSONS, PERSPECTIVES, RECOMMENDATIONS, CONCLUSIONS AND PROPOSALS DRAWN FROM THE PRESENTATIONS, STATEMENTS, WORKING PAPERS AND INTERVENTIONS ON THE TOPICS UNDER DISCUSSION AT THE MEETING OF EXPERTS

Submitted by the Chairman

## I. National, regional and international measures to improve biosafety and biosecurity, including laboratory safety and security of pathogens and toxins

Concepts and approaches

- 1. In the context of the Convention, States Parties use the terms:
  - (i) *Biosafety* to refer to the principles, technologies, practices and measures implemented to prevent the accidental release of, or unintentional exposure to, biological agents and toxins, and to protect people and the environment from the effects of such release or exposure; and
  - (ii) *Biosecurity* to refer to the protection, control and accountability measures implemented to prevent the unauthorized access, retention, loss, theft, misuse, transfer, diversion or intentional release of biological agents and toxins.

2. Recognising that effective biosafety and biosecurity measures can contribute to efforts to prevent the development, acquisition or use of biological weapons and are an important means of implementing the provisions of the Convention, States Parties should develop and implement biosafety and biosecurity measures that:

- (i) Are based on existing guidance and standards, such as those provided by relevant international and regional organizations (including WHO, OIE and OECD) and professional and scientific bodies (such as the regional biosafety associations);
- (ii) Are practical, sustainable and enforceable, tailored to the specific circumstances, regulatory systems, resources and requirements of the State Party concerned, and readily understood by the relevant personnel;
- (iii) Involve all relevant stakeholders, including government, the scientific community, commercial industry and academia;
- (iv) Address resources relevant to humans, animals and plants;
- (v) Make use of risk management techniques and approaches;
- (vi) Avoid unduly restricting the pursuit of the biological sciences for peaceful purposes in accordance with the provisions of the Convention.

3. As appropriate according to their respective national circumstances, when developing and implementing biosafety and biosecurity measures, States Parties should:

- (i) Create and regularly review a national framework for the supervision and oversight of relevant resources, including by identifying a lead agency or focal point and clearly specifying the mandates of each participating department or agency;
- (ii) Establish effective and efficient accreditation and certification systems for organizations, facilities and individuals engaged in relevant biological research and development;
- (iii) Develop lists of relevant agents, equipment and other resources to be covered by regulation and accreditation;
- (iv) Tailor access control, physical security measures, personnel security, material control and accountability as well as transport and information security to the needs of individual facilities, depending upon the organisms being handled and the work being carried out;
- (v) Cover the full cycle of relevant activities, including production, use, storage, transport, and transfer;
- (vi) Develop compulsory or certified curricula and associated training programmes for relevant personnel, such as biosafety and biosecurity officers;

(vii) Ensure that adequate preparedness and response capacity exists in case of failures in biosafety or biosecurity, possibly through the use of emergency planning.

4. In addition, depending on their national circumstances and legal and constitutional processes, States Parties should consider means to ensure that individual facilities:

- (i) Certify the qualifications, expertise and training of individuals involved in relevant activities, where appropriate through formal security vetting procedures;
- (ii) Require institutional biosafety and biosecurity officers to be responsible for meeting relevant legislation, regulations and guidance;
- (iii) Require senior managers to regularly review safety and security measures and check that all staff are trained in safety and security practices and maintain scrupulous adherence to the relevant procedures.

5. In order to develop relationships with and cooperation among relevant stakeholders, and in the interests of national, regional and international coordination and harmonization, States Parties should:

- (i) Establish and support national and regional biosafety associations or working groups;
- (ii) Develop standing arrangements, using modern communication tools, to inform stakeholders of any changes in legislation, regulations, or guidance;
- (iii) Use relevant regional forums to build networks between stakeholders and support national efforts to improve biosafety and biosecurity measures;
- (iv) Actively engage the private sector, including through the institutional management of facilities involved in relevant activities, as well as technical visits;
- (v) Hold biosafety and biosecurity workshops and seminars, especially at the regional level.

#### Building capacity

6. In order to build their biosafety and biosecurity capacity and improve laboratory safety and security of pathogens and toxins, States Parties should:

 Work with the relevant international organisations such as WHO, FAO and OIE, in particular through their relevant laboratory capacity building programmes, to strengthen the ability and capacity of national public health, veterinary and agricultural services;

- (ii) Facilitate the exchange and sharing of relevant resources by harmonizing national legislative and regulatory regimes dealing with the full spectrum of biological risks, and improving cooperation between government departments and agencies, including those not traditionally involved in arms control;
- (iii) Encourage networking among biosafety and biosecurity professionals both nationally and internationally;
- (iv) Assist in the development and sharing of biosafety and biosecurity training programmes during all stages of education and employment;
- (v) Identify channels and partners to assist in the implementation of efforts to enhance biosafety and biosecurity capacity, including through the relevant professional and scientific organisations.

7. As part of efforts to strengthen implementation of the Convention and promote international cooperation in the biological sciences for peaceful purposes, States Parties in a position to do so should provide, upon request, assistance to other States Parties to build capacity in biosafety and biosecurity, including through:

- (i) Tailoring capacity-building efforts to specific national requirements to help States Parties develop or strengthen relevant capacities according to their needs and priorities;
- (ii) Strengthening laboratory infrastructure, technology, security and management;
- (iii) Developing curricula for primary, secondary and tertiary education and providing ongoing professional training for relevant technical personnel.
- (iv) Adapting efforts to enhance national capabilities in addressing challenges such as emerging and re-emerging diseases to also address biosafety and biosecurity;
- (v) Ensuring that efforts to deal with biosafety and biosecurity also address issues such as building quality, maintenance, sustainability and intangible resources.

#### Risk management

8. Recognising the value of using a risk management approach to developing and implementing effective biosafety and biosecurity measures, States Parties should:

- (i) Base risk assessments on common elements and guidance developed at the international level, implemented nationally and tailored to their specific domestic requirements.
- (ii) Ensure biosafety and biosecurity risk assessments cover risks to humans, animals and plants.

- (iii) Take advantage, where appropriate, of guidance and assistance provided by relevant international organizations, and involve key stakeholders from the scientific and technology communities;
- (iv) Decide on what levels of risk are to be considered acceptable, as zero risk is often unachievable;
- (v) Consider risk management options for people (including personnel, visitors, incident response plan, staff training and developing a biosecurity-conscious culture), material (including supply, control, accountability, and transport security) and information;
- (vi) Develop risk communication strategies to improve communications with stakeholders and the general public.

# II. Oversight, education, awareness raising, and adoption and/or development of codes of conduct with the aim of preventing misuse in the context of advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention

#### Oversight of science

9. Recognizing the value of developing national frameworks for the oversight of science as part of their efforts to exclude the possibility of biological agents or toxins being used as weapons, States Parties should:

- (i) Ensure that oversight measures are balanced and proportional to the risk, to avoid creating undue restrictions on scientific research, development, publication and biotechnology;
- Balance "top-down" government or institutional controls, such as licensing, with "bottom-up" oversight by scientific establishments and scientists themselves, such as peer-review;
- (iii) Involve the relevant stakeholders in all stages of the design and implementation of oversight frameworks, including experts from across government, regulatory authorities, funding bodies, academia (both administrators and practitioners), industry, publishing, social science and ethics, as well as civil society;
- (iv) Ensure that oversight mechanisms do not cause unnecessary burdens, are practical and useable, have meaning for those that will need to use them, and engender a sense of ownership among stakeholders;
- (v) Ensure that oversight mechanisms cover people, resources and knowledge, in both the public and private sectors, throughout the scientific life cycle, including during the proposal, funding, execution and dissemination stages;

- (vi) Adopt measures to protect scientists who raise concerns over activities that might violate the Convention or relevant national legislation or regulations (whistleblowers);
- (vii) Where possible and appropriate, harmonize national, regional and international oversight mechanisms;
- (viii) Regularly review scientific and technological developments relevant to the Convention, and consider creating an international scientific advisory panel to independently analyze such developments.

#### Education and awareness-raising

10. Recognizing the importance of ensuring that those working in the biological sciences are aware of their obligations under the Convention and relevant national legislation and guidelines, have a clear understanding of the content, purpose and foreseeable social, environmental, health and security consequences of their activities, and take a more active role in addressing the threats posed by biological weapons, States Parties should develop, implement and support education and awareness-raising programmes that:

- (i) Involve, and are developed in collaboration with, all relevant stakeholders from both public and private institutions and associations, as well as managers and administrators of universities, research institutions and commercial companies, and individual scientists;
- (ii) Explain the risks associated with the malign use of the biological sciences and biotechnology and the moral and ethical obligations incumbent on those using the biological sciences;
- (iii) Provide guidance on the types of activities which could be contrary to the aims of the Convention and relevant national and international laws and regulations, including on the export and import of biological resources;
- (iv) Are tailored to the target audiences not all stakeholders need to receive the same message.

11. Depending on their national circumstances, in pursuing such programmes States Parties should:

- (i) Establish formal requirements in relevant scientific and engineering training programmes and continuing professional education, such as mandatory seminars, modules or courses;
- (ii) Create accessible teaching materials which address the Convention, relevant national laws and guidelines, and related issues;

- (iii) Use train-the-trainer programmes to ensure that there are sufficient properlyqualified individuals to run education and awareness-raising activities;
- (iv) Make use of, and provide the resources for, seminars, workshops, publications, and audio-visual materials;
- (v) Develop targeted outreach strategies for senior scientists with responsibility for oversight of research or for evaluation of projects or publications;
- (vi) Coordinate outreach activities on the Convention with parallel initiatives in other settings, such as those undertaken on biosafety and biosecurity by WHO, efforts by the United Nations Security Council Resolution1540 Committee, etc;
- (vii) Support regional and international education and awareness-raising activities, and assist and cooperate with other States Parties.

#### Codes of conduct

12. Recognizing that codes of conduct can complement national legislative and regulatory frameworks and help guide scientific research so that it is not misused for prohibited purposes, States Parties should develop strategies to encourage stakeholders – including researchers and other professionals in the life sciences; editors and publishers of life science publications and websites; and organizations, institutions, government agencies, and private companies that conduct, license, fund, facilitate, inspect or evaluate life sciences research or education, or that are involved in the stockpile or transport of dual-use biological agents or toxins – to develop, adopt and promulgate codes of conduct that:

- (i) Cover ethical and moral obligations throughout the scientific life cycle, including during the proposal, funding, execution and dissemination stages;
- (ii) Refer to the Convention and relevant international and national legislation and regulations;
- (iii) Wherever possible, are built on existing arrangements and practices and/or derived from general overarching principles, tailored to precise national or institutional requirements taking into account relevant cultural and social backgrounds.
- (iv) Avoid impeding scientific discovery or placing constraints on research or international cooperation and exchanges for peaceful purposes;
- (v) Provide concise, practical guidelines, including criteria to define sensitive research and identify areas of greatest risk;
- (vi) Include a mechanism for investigating and dealing with possible violations of the code;
- (vii) Continue to be discussed and reviewed at international, regional and national scientific conferences and workshops, as well as in relevant publications.

13. States Parties should encourage stakeholders to ensure that codes of conduct require those to whom they apply to:

- Comply with relevant international and national legislation and regulations, and follow existing basic guidelines and best practices, including in areas such as awareness, safety and security, shipment and transport, education and information, accountability, publication policy, internal and external communication, and oversight;
- (ii) Be alert to potential misuse of research, and assess their own research for dual-use potential;
- (iii) Seek to stay informed of literature, guidance, and requirements related to dual-use research;
- (iv) Educate others, and serve as role models of responsible behaviour;
- (v) Report concerns and possible violations as appropriate.