Working Group on the Strengthening of 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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Identifying, examining and developing specific and effective measures, including possible legally-binding measures, and making recommendations to strengthen and institutionalize the Convention in all its aspects within the mandate of the Working Group

Conceptual and methodological aspects of a possible mechanism of verification of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction

Submitted by the Russian Federation

1. Efforts by 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 (BTWC) to create a comprehensive and effective verification regime were officially initiated by the Third Review Conference in 1991, which being «…determined to strengthen the effectiveness and improve the implementation of the Convention and recognizing that effective verification could reinforce the Convention», decided to establish the Ad Hoc Group of Governmental Experts (VEREX) open to all States Parties «to identify and examine potential verification measures from a scientific and technical standpoint…»[1].

2. In 1993, this Group prepared a consensus report which contained 21 verification measures[2]. The experts concluded that the said measures could be useful in enhancing confidence that States Parties were fulfilling their obligations under the BTWC[3].

3. Based on the work of the VEREX Group, in September 1994, the Special Conference of the States Parties to the BTWC was convened, which decided to establish the Ad Hoc Group to consider relevant measures, including verification measures to be incorporated into the legally binding Protocol. The Ad Hoc Group held several meetings and completed its work in 2001 after the United States refused to continue negotiations having failed to agree on the text of the Protocol and to draft the report for submission to the Fifth BTWC Review Conference. However, the Chair of the Group distributed a compromise text[4] which became the basis for further discussions on institutional strengthening of the Convention.

4. As the VEREX Group noted, «…verification of the BTWC poses unique and substantial challenges given the dual-use nature of the materials, equipment, expertise and knowledge required for an offensive biological weapons programme…»[5]. These differences

[1] BWC/CONF.III/23, 1992.
[2] BWC/CONF.III/VEREX/9, 1993.
[3] BWC/CONF.III/VEREX/8, 1993.
[4] BWC/AD HOC GROUP/CRP8, 2001.
[5] BWC/AD HOC GROUP/21, 1995.

are compounded by the progress in such scientific sectors as molecular biology, virology, medicine, veterinary medicine, the pharmaceutical industry and plant science[6].

5. At the same time, the concept of adopting selected "individual" measures for "incremental" strengthening of the existing provisions of the Convention being implemented since 2001 in the BTWC format is difficult to reconcile with revolutionary changes in science and technologies and in ensuring biological security. Summary Report of the 2019 Meeting of Experts on the Institutional Strengthening of the Convention noted that «…the Convention operates in a highly dynamic environment and involves a range of stakeholders including States, industry, academia and civil society. Challenges also relate to the implications of the rapid advances in life sciences and other relevant disciplines…»[7].

6. Thus, the development of synthetic biology and gene-editing technologies rendered possible to synthetize and study new types of biological agents. The use of 3D printing made it possible to produce controllable laboratory equipment, means of delivery and use of biological weapons. The increased e-commerce involving biotechnological and pharmaceutical industries has made export control measures significantly less efficient.

7. Thus, in the context of the BTWC effective operation, it is vital to resume multilateral negotiations aimed at concluding a non-discriminatory, legally binding Protocol dealing with all articles of the Convention in a balanced and comprehensive manner, including verification measures. At the same time, the draft instrument resulting from the efforts of the Ad Hoc Group continues to be relevant and may serve as a basis for future negotiations[8].

8. The consolidated text drafted by the Chair of the Ad Hoc Group in 2001 contains a number of conceptual provisions and practical recommendations which could be revised by the States Parties in light of political and scientific and technological realities of today. At the same time, the return to 1994 mandate followed by the discussion of the verification mechanism would contribute to strengthening of the BTWC and enhancing its institutional potential.

9. Meanwhile, a number of key provisions of the Protocol, including terminology, lists of biological agents and toxins, threshold quantities of biological materials and criteria for their inclusion in the lists, methodological approaches to compiling lists of equipment, conducting inspections and verifications, as well as investigations of possible violations of obligations under the BTWC, will require substantial revision.

10. *Terminology*. Experts of the Ad Hoc Group noted that a common understanding of terms by States Parties both at the stage of the development of the regime for strengthening the Convention and at the stage of control is needed to overcome fundamental differences[9]. To a large extent, that is related to accurate and balanced understanding of the potential of new technologies in the BTWC context. Such technologies could include: additive manufacturing based on 3D printing technologies, Big Data analysis and artificial intelligence technologies, nanotechnologies and materials science, automation of biological research and robotics. In this case, a major part of work with serious implications for biological security has nothing in common with the use of pathogens. Thus, one can see transformation of the concept of "biological threat" which is becoming more complex and includes elements from other areas not related to biotechnology and traditional understanding of biological weapon that requires making relevant changes to concepts and terminology.

11. *Lists of biological agents and toxins*. Wordings of Article I of the Convention that prohibit the use of biological agents and toxins that have no justification for "prophylactic, protective or other peaceful purposes" create an ambiguity and remain open for various interpretations. For example, up to now there is no consensus understanding of whether Article I covers the use of vectors (insects and arthropods – carriers of infectious diseases), crop pests and technophile microorganisms. Lists of biological agents and toxins developed

[6] BWC/MSP/2019/MX5/WP.1, 2019.
[7] BWC/MSP/2019/MX5/2, 2019.
[8] BWC/MSP/2019/MX5/2, 2019.
[9] BWC/AD HOC GROUP/15, 1995.

by the Ad Hoc Group[10] can be used as a basis and reviewed by experts in terms of their universalization.

12. *Criteria for inclusion of microorganisms and toxins in the lists.* Criteria proposed by the Ad Hoc Group on the whole remain relevant today. Selected technical changes could be made to their wordings to reflect the development of the terminological framework in the field of biotechnology, synthetic biology and medicine.

13. *Determination of threshold quantities of biological materials.* Experts of the Ad Hoc Group noted that one of the most effective means of monitoring the storage of biological materials used for the purposes of developing and evaluating the effectiveness of means of protection against biological weapons is to limit the quantities of such materials handled at biological facilities. A variety of approaches to limiting the quantities of such materials have been put forward. For example, specialists of the Stockholm International Peace Research Institute (SIPRI) focused on the quantity of a potential biological weapon (BW) agent which could be used for military purposes. They established that this amount corresponds to 10 kg of biological material. It has been established as a result of research that 5 kg is required for the development and testing of means of protection against BW. However, it must be pointed out that neither of these approaches took into account the specific concentration of each agent and its virulence[11].

14. In order to eliminate these shortcomings, an approach based on limiting the quantity of biological materials containing listed agents in terms of effective doses was proposed (LD_{50}, ID_{50}, etc.). The starting values for LD_{50}, concentrations and quantities were proposed to be defined by agreement after careful study by experts. The said approach based on the calculation of effective doses can be used to determine threshold quantities of new types of biological agents and compounds covered by the BTWC.

15. *Information on key equipment.* Lists of technological equipment presented in the documents of the Ad Hoc Group[12] for facilities participating in a BW protection programme which are carrying out work with any micro-organisms and toxins, as well as with materials that imitate their properties are subject to review by experts in terms of nomenclature. Primarily this is due to the emergence of new technological pathways for receiving micro-organisms and biological substances through methods of synthetic biology and directed synthesis. The performance of the machinery (fermentation equipment, separators, refrigerating, filtration and drying equipment) has been calculated based on threshold quantities of microorganisms (no more than 5 kg) and should also be reviewed.

16. *Conduct of investigations.* The Ad Hoc Group distinguished two types of investigations of possible violations of international norms on the prohibition of biological weapons: (1) investigation of an alleged breach of obligations under the provisions of the Convention, and (2) investigation of the alleged use of biological weapons[13]. The document provided for the procedure for the lodging and consideration of the complaint/request, its contents as well as structural elements of investigation, including specific verification measures in situ, procedures for the sampling and analysis[14]. It also specified the basic principles and procedures for consideration of requests relating to alleged violations of the BTWC[15]. The emphasis was placed on maximizing the potential of Articles V and VI of the Convention, and specific procedures for their implementation were proposed[16]. The methodology of the conduct of investigation proposed by the Ad Hoc Group could be adapted to take into account modern standards of biological sampling, instrumental analytical methods and clinical diagnostics.

[10] BWC/AD HOC GROUP/16, 1995.
[11] BWC/AD HOC GROUP/WP 99, 1996.
[12] BWC/AD HOC GROUP/WP.219, 1997.
[13] BWC/AD HOC GROUP/WP.125, 1997.
[14] BWC/CONF.III/VERSC/WP-96-8, 1997.
[15] BWC/AD HOC GROUP/WP.181, 1997.
[16] BWC/AD HOC GROUP/WP.217, 1997.

17. In this way, specific aspects of the draft protocol prepared by the Ad Hoc Group could be examined by the States Parties in the light of scientific and technological developments, which would provide the basis for resolving existing differences and resuming further negotiations. Failure to continue such discussion increases the risk of the compliance with the BTWC requirements coming short of the scientific and political realities and becoming even more fragmented.