

Formal Consultative 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 provisional agenda

Respective outstanding questions by the Russian Federation to the United States and to Ukraine concerning the fulfilment of their respective obligations under the Convention in the context of the operation of biological laboratories in Ukraine

Response by the United States of America to the request by the Russian Federation for a Consultative Meeting under Article V of the Biological and Toxin Weapons Convention (BWC)

Submitted by the United States of America

I. Introduction

1. The United States received from the Russian Federation, under cover of a diplomatic note dated June 13, 2022, an Aide Memoire entitled “Questions to the United States regarding compliance with the obligations under the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (BTWC) in the context of the activities of biological laboratories in the territory of Ukraine.” Notwithstanding this title, the document did not contain any actual questions, but rather a series of assertions and mischaracterizations of various documents that the Russian Federation claims to have obtained during Russia’s war against Ukraine (though some of these documents are publicly available).

2. Throughout the Russian Federation’s Aide Memoire, little or no connection is drawn between these assertions and any clearly articulated issues related to compliance with the Convention. It appears that the Russian Federation’s assertions fall into three categories: (1) issues related to U.S. cooperation with public and animal health-related laboratories and institutions in Ukraine; (2) U.S. funding of animal disease surveillance studies that support local and global health objectives in Ukraine; and (3) issues related to a specific U.S. patent that were conclusively addressed by the United States in 2019 in a written response to the Russian Federation.

3. On June 23, the United States responded to the June 13 diplomatic note (and accompanying Aide Memoire) noting that several of the documents appended to the Aide Memoire are “unreadable or virtually unreadable” and requesting that legible documents be provided on an “expedited basis.” Noting that some of the supporting documents were unreadable, the United States indicated that it would respond to Russia’s allegations within 30 days of the receipt of legible documents.

4. On June 28, however, the Russian Federation responded that “since the Russian side has not received substantive answers to its reasonable questions, we will be



forced to launch the procedure for convening a Consultative Meeting of States Parties to the BTWC, as provided for in Article V of the Convention.”

5. On June 29, the Russian Federation informed the United Kingdom and the United States, in their capacity as depositaries, of its request to convene a formal consultative meeting under Article V of the BWC “with a view to resolving the issues with the United States and Ukraine regarding their compliance with their obligations under the BTWC in the context of operation of biological laboratories” in Ukraine.

II. Response to issues raised by the Russian Federation

6. The United States is in full compliance with its obligations under the Convention. The United States unilaterally renounced biological weapons (BW) in 1969 and completed the elimination of its BW program prior to entry into force of the BWC, as reported in Form F of the Confidence-Building Measures. All the biological-related activities of the United States are for peaceful purposes and fully consistent with its obligations under the Convention. This includes the capacity-building programs questioned by the Russian Federation.

7. For more than 30 years, the U.S. Department of Defense (DoD) has implemented the Cooperative Threat Reduction (CTR) Program, initially created to consolidate, secure, and eliminate weapons of mass destruction (WMD)-related materials and infrastructure in states of the former Soviet Union, including the Russian Federation. Today, the DoD CTR Program helps more than 30 partner nations to improve their ability to detect, diagnose, and report infectious disease outbreaks caused by human and animal pathogens and to improve biosafety and biosecurity at facilities that handle those pathogens. The DoD CTR Program provides assistance and capabilities to partners through activities such as workforce development, equipment upgrades, and physical infrastructure projects. CTR-supported laboratories have often proved instrumental in providing critical support during the COVID-19 pandemic, such as diagnostic testing and analyzing of samples, and have led the way in building domestic capacity for enhanced disease monitoring, public and animal health initiatives, and the training of front-line biosecurity experts.

8. The Russian Federation itself was the foundational partner of the DoD CTR Program. Pursuant to the 1992 Agreement Between the United States of America and the Russian Federation Concerning the Safe and Secure Transportation, Storage and Destruction of Weapons and the Prevention of Weapons Proliferation, as amended and extended, the Russian Federation engaged in cooperative activities with the DoD CTR Program for 21 years. These activities included collaborative biological research (such as biosurveillance studies on zoonotic infectious diseases) and laboratory biosafety and biosecurity upgrades. Like those cooperative efforts with the Russian Federation, U.S. cooperation with Ukraine and other countries today is fully consistent with the BWC and is one of the many ways in which the United States fulfills its obligations under the international cooperation and assistance provisions of the Convention (Article X).

9. In advance of the consultative meeting, the United States is providing this written response to the June 13 Aide Memoire of the Russian Federation. At the consultative meeting, U.S. and Ukrainian technical experts will present a more detailed briefing to jointly respond to and rebut Russia’s unfounded assertions.

A. U.S. Cooperation with Laboratories and Institutions in Ukraine

10. In 2005, the United States Department of Defense and the Ukrainian Ministry of Health entered into the Agreement Concerning Cooperation in the Area of Prevention of Proliferation of Technology, Pathogens, and Expertise that could be Used in the Development of Biological Weapons (“the 2005 Agreement”). The 2005 Agreement, which is an implementing agreement for the broader 1993 Agreement between the United States and Ukraine Concerning Assistance to Ukraine in the Elimination of Strategic Nuclear Arms, and the Prevention of Proliferation of Weapons of Mass Destruction, as amended and extended, provides a specific framework for cooperation for the purpose of preventing the proliferation

of technology, pathogens, and expertise that are located at facilities in Ukraine and that could be used in the development of biological weapons. In other words, the purpose of the 2005 Agreement is explicitly to *reduce and eliminate* the risk of biological weapons development and proliferation.

11. Article III of the 2005 Agreement specifies that assistance provided by the DoD to the Ukrainian Ministry of Health “may include, but is not limited to, cooperative biological research, biological threat agent detection and response, and assistance for improving biological material protection, control and accountability in order to reduce the risk of theft or unauthorized use of dangerous pathogens” at certain facilities in Ukraine. This agreement provides the framework for the work of the Biological Threat Reduction Program (BTRP) – a component of the DoD CTR Program – in Ukraine. Such cooperation and assistance contributes to the fulfillment of the United States’ obligations under Article X of the BWC to facilitate “the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes,” and to “cooperate in contributing individually or together with other States . . . to the further development and application of scientific discoveries in the field of bacteriology (biology) for prevention of disease, or for other peaceful purposes.” Many of the activities supported in Ukraine by this program are similar to the cooperative work undertaken for many years with the Russian Federation, particularly collaborative biological research and biosafety and biosecurity upgrades at laboratories, until that cooperation was terminated by Russia.

Russia’s Mischaracterization of the 2005 Agreement

12. In the June 13 Aide Memoire, Russia mischaracterizes several provisions of the 2005 Agreement. For example, Russia claims the 2005 Agreement requires Ukraine to transfer to the United States “all strains collected in Ukraine and data generated by the infectious disease surveillance in that country.” In fact, paragraph 5 of Article IV of the 2005 Agreement makes clear that it only refers to the transfer of “requested copies” of pathogen strains, specifically to permit cooperative research between U.S. and Ukrainian laboratories “for prophylactic, protective, or other peaceful purposes.” Sample transfers under the 2005 Agreement between the United States and Ukraine have been infrequent and always conducted with the consent of the Ukrainian government specifically to support Ukrainian efforts to further sequence, characterize, or identify new and emerging strains of pathogens to inform vaccine or therapeutic efforts to protect the Ukrainian people. Such exchanges of pathogen samples and data are considered essential for international cooperation and to support pandemic preparedness broadly.

13. The Russian Federation similarly mischaracterizes another provision, asserting that “deliverables under the Agreement as well as information on its implementation become sensitive by default” under its Article VII. The 2005 Agreement makes no such blanket determination. What the 2005 Agreement actually stipulates is that *in the event that* information transmitted under it or developed as a result of its implementation is considered by the Department of Defense to be “sensitive,” *or* by the Ukrainian Ministry of Health to be “restricted information,” such information must be clearly designated and marked accordingly, and the recipient has an obligation to handle the information appropriately, as set forth in that Article.

International Cooperation and the BWC Confidence-Building Measures

14. The Russian Federation’s complaint that none of this U.S.-Ukrainian cooperative activity under the CTR program is reported in U.S. submissions under the BWC Confidence-Building Measures (CBMs) is at odds with the actual provisions of the CBMs. Though Russia seems to imply an unspecified sinister motive, the CBMs do not call for reporting on bilateral assistance in areas such as biosafety, biosecurity, and disease surveillance. The CBM regarding biodefense research and development also does not apply, as none of this activity constitutes U.S. research and development to protect against biological weapons. In sum, Russia’s assertions are unsupported by the actual CBM formats and requirements. Moreover, Russia’s criticism of the alleged “secrecy” of U.S.-Ukrainian cooperation is discredited by information provided, and working papers submitted, during

past BWC meetings (see, for example, BWC/MSP/2020/WP.11, “Article X Cooperation and Laboratory Support: The Example of the Biological Threat Reduction Program”; BWC/CNF.VIII/WP.21, “International Activities of Global Partnership Member Countries related to Article X of the Biological and Toxin Weapons Convention”; and BWC/MSP/2015/WP.5, “International Activities of Global Partnership Member Countries related to Article X of the Biological and Toxin Weapons Convention”).

15. The Russian Federation also mischaracterizes a 2018 planning document (contract HDTRA-1-08-D-0007-0004), which it cites as “evidence” that the U.S. DoD has financed “military-biological activities in Ukraine,” with mobile diagnostic capabilities provided to the Ukrainian Ministry of Defense. The activities in question are “military” only in the sense that they are activities performed by the Ministry of Defense and, in fact, U.S. support is provided *only* to enable public health activities performed by that Ministry – not to further its military capabilities. At the request of the Government of Ukraine, the United States provided training and equipment to support the ability of the Regional Sanitary and Epidemiological Departments of the Ministry of Defense to detect, diagnose, and respond to outbreaks of infectious disease. These efforts proved critical in assisting Ukraine to develop and implement a plan to address the COVID-19 outbreak in the region, just as many other governments have leveraged military capabilities in response to COVID-19. This project was later broadened to also support regional laboratories of the State Service of Ukraine for Food Safety and Consumer Protection and the Ministry of Health.

The I. Mechnikov Anti-Plague Scientific Institute

16. The Russian Federation, in referring to what appears to be an internal document of the Ukrainian Ministry of Health (a 2018 report on the I. Mechnikov Anti-Plague Scientific Institute in Odessa), asserts that the laboratory’s pathogen collection “gives the most vivid insight in the scale and focus of the military-biological activities in Ukraine.” It is unclear why the Russian Federation would raise with the United States questions about the management and inventory of a laboratory that is owned and operated by the Ukrainian government. These are matters more properly addressed to Ukraine. From an outside perspective, however, Russia’s claims regarding the pathogens studied and the volume of material held are not credible.

17. The Russian Federation claims that the list of pathogens studied at the Institute “disagrees with the current Ukraine’s health issues.” This claim reveals Russia’s demonstrably flawed judgments about what health issues Ukraine should seek to address, as well as a misconception that a country should only retain and study locally endemic pathogens. Regarding the latter, there is no requirement that research be conducted only on pathogens that currently pose health issues in a country (which would greatly impair international cooperation in combatting diseases); if there were, a great deal of research conducted in the Russian Federation would be problematic for that reason alone. In addition, the pathogens that Russia references are indeed endemic to Ukraine, which demonstrates Russia’s lack of knowledge of the actual biological threats facing people and animals in Ukraine. Anthrax, for example, is an endemic animal disease in Ukraine, and cholera outbreaks continue in Ukraine, with concerns that another outbreak could occur as a result of the war waged by the Russian Federation.

B. U.S. funding of animal disease surveillance projects in Ukraine

18. In its Aide Memoire, the Russian Federation also expresses concern about zoonotic disease surveillance projects funded by BTRP (Risk Assessment of Selected Especially Dangerous Pathogens Potentially Carried by Migratory Birds over Ukraine [UP-4] and Risk of Emerging Infections from Insectivorous Bats in Ukraine and Georgia [P-781]) and incredibly suggests that migratory birds and bats “can be considered as delivery means [for biological weapons].” Neither the United States nor Ukraine is in any way seeking to “weaponize” migratory animals.

19. On the contrary, to prevent the spread of disease, surveillance and studies to better understand the movement of zoonotic pathogens are an important aspect of national

and global health security; in Ukraine's case, these studies are particularly relevant, as several major migratory routes pass over Ukraine. These studies support a long-term international effort encouraged by the World Health Organization to understand the spread of avian influenza around the world. Such research projects are generally funded by BTRP in response to proposals from partner governments; in other words, they are not directed by the United States, but are responsive to the public and animal health priorities of other countries.

20. The majority of all emerging infectious diseases is zoonotic – animal-borne pathogens that enter the human population, sometimes with catastrophic effect. Moreover, the international spread of pathogens that generally do not affect humans, such as Highly Pathogenic Avian Influenza or Newcastle Disease (a highly contagious disease of birds and poultry) can adversely affect a nation's economy, exports, and food supply. The importance of studying the impact of infectious diseases that can be carried by bats and birds is well-understood by experts around the world – including in the Russian Federation, which has also conducted studies into the role of migratory birds as disease vectors.

C. Patent awarded by the U.S. Patent and Trademark Office

21. The Russian Federation asserts that the United States has failed to answer questions previously posed concerning U.S. patent No. 8,967,029 B1 in an Aide Memoire provided in late 2018. A substantive response was in fact provided to the Russian Federation in the form of an Aide Memoire dated February 11, 2019. As was made clear in that response, in the United States, patent rights do not confer a legal right or authorization to produce an invention; patent rights simply serve to give the patent owner the legal means to exclude other parties from taking certain actions with respect to that invention. Additionally, contrary to the claims made in the Russian Federation's June 13 Aide Memoire, the United States has no requirement that a prototype of an invention actually be produced before a patent is awarded, nor a requirement that the person granted the patent use the patent once it is issued. (Subsequent investigation has confirmed that no such device was constructed in the case of this particular patent.)

22. The United States takes seriously its obligations under the BWC and has a comprehensive domestic legal regime to implement its obligations under Article IV of the BWC (See Title 18 U.S. Code, Part I, Chapter 10, Section 175). These laws make clear that, *inter alia*, the development and production of a biological weapon is prohibited under U.S. law, and any violation of those laws is punishable by penalties ranging from fines to imprisonment. The laws are vigorously enforced by the Federal Bureau of Investigation and other law enforcement agencies, and violations are prosecuted by the Department of Justice. Therefore, while an individual may be able to hold a patent for an invention of the type discussed here as a domestic legal matter, it is clear that production of such an invention for use as a weapon would violate the relevant laws implementing the United States' obligations under the BWC and be punishable by fines and/or imprisonment.

23. Furthermore, the decision to issue such a patent does not violate U.S. obligations under the BWC. Significantly, the United States noted in its 2019 response to Russia that, in fact, other States Parties have similarly awarded patents for devices for the delivery of chemical or biological agents for hostile purposes, including the Russian Federation. In light of that practice in multiple States Parties, the United States suggested to Russia that the broader issue of how States Parties deal with patent applications for devices designed for delivery of toxins or biological agents remains relevant and might benefit from further discussions on best practices for identifying and addressing such applications. The Russian Federation never responded to the February 2019 Aide Memoire.

III. Conclusion

24. The assertions made by the Russian Federation in its June 13 Aide Memoire, and which form the basis of its request for an Article V consultative meeting, are unfounded and based upon mischaracterizations of official documents and of legitimate, peaceful scientific studies. The United States remains in full compliance with its obligations under

the Biological and Toxin Weapons Convention. Cooperative efforts by the U.S. Department of Defense with Ukraine and with other countries are fully consistent with the BWC and further the international cooperation and assistance provisions of BWC Article X. Indeed, the COVID-19 pandemic has highlighted the importance of international disease surveillance and the power of open, transparent, and responsible scientific cooperation and collaboration, such as that undertaken by the United States and Ukraine. This negative effect of Russia's disinformation and false allegations comes at a time when the world needs to intensify cooperation on public health to end the COVID-19 pandemic, mitigate current outbreaks, and prevent future ones. The United States intends to continue its cooperative threat reduction efforts with partner countries, and requests that the Russian Federation cease its efforts to impede or malign the cooperative activities in which it once participated and from which it once benefited.
