**Ninth Review Conference 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 issues identified in the review of the operation of the Convention as provided for in its Article XII and any possible consensus follow-up action

## Advances in the Field of Biological Science and Technology and Urgent Need to Maximize Their Availability to **Developing Countries**

## Submitted by the Islamic Republic of Iran

- Article XII of the Biological Weapons Convention (BWC) provides that the review of operation of the Convention shall take into account any new scientific and technological (S&T) developments relevant to the Convention.
- While In today's world, pandemic infectious diseases have become a major public health issue and pose a serious threat to human health and safety, advances in science and technology in the life sciences have vast potential for beneficial applications and play a pivotal role in prevention and mitigation of pandemics.
- Advances in vaccine development have wide potential benefits for the mitigation of infectious diseases. Wider availability of vaccines will be a key factor in developing a global response to natural or deliberate infectious disease outbreaks. The development of cheaper and more readily available vaccines is a significant issue for States Parties to the Convention and other related international organizations for the global prevention of diseases.
- 4. Advances in molecular biology, genomics, proteomics, applied biotechnologies, bioinformatics and computational biology, systems biology, synthetic biology and biological engineering, drug discovery and design have led to new pharmaceuticals, diagnostic procedures, preventive strategies and treatment of diseases. Moreover, the researches on the life sciences have contributed to improvements in animal and plant health and food supply. The uses of these tools have led to legitimate and beneficial applications in public health and medicine, agriculture and the environment and other civil sectors.
- 5. During the recent years, biotechnology has made great advances. The development in some areas, such as synthetic biology, genomics and system biology, is especially noticeable. These developments have greatly promoted the improvement of biological sciences, which is of great importance for the elucidation of molecular mechanisms of relevant diseases and design of efficient prevention and treatment strategies. Rational vaccine design depends on an understanding of the pathogenicity of the disease agent and of the host immunological response. Rapid advances in a number of enabling technologies, including the '-omics', bioinformatics, systems biology and immunology have contributed to the development of new strategies and identification of new targets and reduction of the time scale for vaccine development.
- The rapid advances in synthetic biology and genome editing have the potential to revolutionise human, animal and plant health. Synthetic genomics holds the potential to facilitate enormous advances in a variety of disciplines. These include rapid, inexpensive and efficient production of pharmaceuticals, such as vaccines, diagnostics and therapeutics.





Genome editing technology today has widespread applications for peaceful use in various fields including in medical sciences, industry and agriculture. The researchers used synthetic genomics tool to synthesize rapidly and accurately the genes encoding the specific antigens, used in vaccine production. This novel method which used in the production of avian influenza virus H7N9 vaccine and recently in a number of COVID-19 vaccines could potentially enable accelerated responses to future pandemics. This is particularly important to meet the surge capacity required for the production of pandemic vaccines.

- 7. The new methods used in vaccine production, elicits broader spectrum immunity and provides opportunity to be designed, constructed and produced rapidly without biological containment in response to an emerging threat in geographically dispersed facilities. The ability of this method to elicit the production of protective antibodies without biological containment has made possible many potential benefits. Since it contains no genetic material, it cannot infect host species, and would not require expensive high containment facilities for its production.
- 8. Design improvements in fermenters and bioreactors have led to an increase in yield, portability and safety of procedures. Single-use or disposable bioreactor systems have also progressed; these are easily installed, reduce costs, increase product consistency and reduce overall turnaround times. The rocker cell culture bags are suited to cell culture for virus vaccine production as an alternative to traditional methods of growth in embryo eggs. Single-use or disposable components also feature increasingly in downstream processing equipment.
- Efforts to treat cancer with the use of genetic engineering and molecular biotechnology are being intensified. Among various genome editing technologies, Clustered, Regularly Interspaced, Short Palindromic Repeat (CRISPR) technique is the most attractive one and has been widely used for its effectiveness, precision and low cost. CRSPR/Cas tools could enable a level of targeted and efficient genomic manipulation not possible previously. At this time, CRISPR-based tools offer greater precision; allow for multiple simultaneous gene edits as well as changing a single genetic code. CRISPR-based technology gave it potential as a powerful genomic engineering tool also applicable in more complex organisms, including plants, insects, animals and humans. It is now increasingly possible to employ DNA manipulation and gene circuit engineering on mammalian cells, in part through the use of the CRISPER-Cas9 system. This technique is being applied in the treatment of serious diseases, production of new drugs and vaccines and also for other peaceful purposes. The majority of genetic scientists believe that their efforts and researches in the field of genetic engineering and molecular biotechnology can lead to very valuable applications in medical fields which used for the purposes of prevention, diagnosis and treatment of diseases. In recent years, there have also been studies on CRISPR/Cas (such as Cas12b and Cas13a) to develop a DNA detection platform system. Such systems have the advantages of strong specificity, high sensitivity and simple operation. These methods can detect even trace amounts of virus and distinguish between different subtypes or mutations.
- 10. In recent years, a significant part of the discussions on review of S&T developments within the meetings of the Convention have been focused on the potential negative implications of such advances for the Convention and how to minimize the risks. This pessimistic approach to advances in S&T, advocated mainly by developed countries, has not served the interests of the majority of States parties to the Convention. The discussion on how to manage potential risks of S&T developments should never lead to limit or hamper scientific evolution for peaceful purposes and life-saving achievements like vaccine development. Developing countries, in particular, should benefit from advances in technologies which make vaccine production simpler, faster, cheaper and more efficient.
- 11. The review of S&T developments within the context of the Convention should have tangible results for the developing States and should contribute to the fullest exchange of knowledge and technology between developed and developing countries and ensure the unhindered and non-discriminatory flow of science and technology. States Parties have obligation under article X of the Convention to cooperate in contributing to the development and application of scientific discoveries for prevention of disease or for other peaceful purposes. In this regard, the developed States Parties bear a special responsibility.

- 12. The Ninth Review Conference of the Convention should focus on ways and means of maximizing the actual benefits of new scientific and technological advancements in the field of bio sciences, such as approaches for increasing availability and promoting access to and use of the above-mentioned technologies and know-how in developing countries in order to reduce the existing gaps between developing and developed BWC States Parties.
- 13. The management of potential risk of misuse of advances of S&T should not lead to restrictions and/or limitations on transfers of biological agents, toxins, scientific knowledge, technology, equipment and materials for peaceful purposes among the States Parties. Imposition of any restriction on exchange of knowledge, materials and equipment necessary for promoting capacity building in the fields of disease surveillance, detection, diagnosis, and containment of communicable diseases including production of vaccines and other biological material is a violation of obligations under Article X of the Convention.
- 14. The continued research and development in the life sciences is essential to a brighter future for human. Such research activities should be conducted in conformity with national ethics, safety and security considerations as well as international commitments. States parties to the Convention should support the 'culture of responsibility' in the life sciences and encourage professional societies to develop national codes of ethics and policy guidelines in relation to genetically modified organisms to reduce the risks of misuse of this technology. However, such regulatory measures should be undertaken in a manner that does not hamper scientific and technological developments.