



Mr President, Distinguished Representatives:

The London School of Economics and Political Science greatly appreciates the opportunity to offer this statement.

Universalisation and National Implementation

As noted in a number of the working papers submitted by States Parties, as well as in statements and documents produced by the broader non-governmental community supporting the Convention, the universal adoption of the BTWC by all States is a fundamental element in wholly achieving the Convention's purpose and objectives. And, as also noted, universalisation alone is not sufficient and must be accompanied by full national implementation of the Convention's obligations and provisions by all States Parties.

We firmly support the calls for action on universalisation and national implementation, and endorse the EU Joint Action to promote ratification of and accession to the BTWC by States not Party, and to provide assistance to States Parties for transposing the international obligations of the BTWC into their national legislation and administrative measures.

Operating and Delivering National Legislation

National implementation first and foremost means national legislation. But, of equal importance from a control-system perspective to translating the Convention into national legislation is ensuring an appropriate system is put in place for operating and delivering the aims of that legislation. To develop effective national regimes regulating biological agents and toxins there must be coherence between 1) the standards and objectives outlined in the legislation, 2) the ways of monitoring and gathering information about relevant work with biological agents and toxins within the national territory, and 3) the ways of enforcing and changing behaviour to meet the standards and objectives in the legislation.

In practice this means, firstly—as highlighted in the *EU Paper on Assessment of National Implementation* of the BTWC—that sufficient resources must be devoted to the monitoring and enforcement of the national legislation, and that appropriate expertise is obtained within the implementing authorities.

In addition to this, an effective regulatory regime to implement the BTWC in the national context would also require that a degree of flexibility be built in. Because the risks arising from biological R&D are often difficult to quantify, a certain level of discretion and flexibility must be afforded the regulators and researchers evaluating the risks of projects and programmes. Regulation is not a linear process, whereby rules are made and then enforced. Rather, regulation is a continuous process of rule adjustment and individualisation, rooted in communication and discussion. Encouraging the continuous

process of adjustment and individualisation at the implementation stage is particularly pertinent to regulating rapidly evolving biological R&D.

Key to facilitating such "regulatory conversations" are broad, rather than specific and detailed, regulations that provide a better, more comprehensible guide to behaviour whilst at the same time increasing flexibility and allowing for adjustments to individual circumstances. However, rooting a control system in communication and discussion also raises issues of consistent, fair and objective treatment, and of access, participation and accountability. To be effective, then, as well as acceptable, or indeed legitimate, national legislation implementing the international obligations of the BTWC requires the commitment of regulators and research centres to a meaningful discourse, opportunities for civil society to have appropriate access to the conversations, a balanced distribution of power and authority between the different actors, and, finally, trust and accountability between participants.

Harnessing "Soft Law"

In parallel to formalising the aims of the BTWC through national implementation, it can also be helpful to acknowledge the very important role informal regulatory measures or "soft law" can play in furthering the aims of the Convention and in providing oversight of potential misuse of biological R&D.

There are many different kinds of biological laboratories—they may be situated within universities, public or private institutions, commercial companies, hospitals, or military facilities; they may be very small or very large, or anything in between; they may be working on benign organisms or highly infectious pathogens; they may not be working with whole organisms at all, but with tissue cultures, in-vitro cell systems, small molecules, or gene sequences—and the effectiveness of different regulatory measures or oversight mechanisms will vary depending on the context and configuration of individual laboratories. There is no one-size-fits-all answer to the problem of regulating biological R&D so as to prevent its misapplication.

Regulatory measures that are legally binding have a significant role to play. As an addition to this, however, self-governance by scientific experts and practising researchers can also play an important part. As many scientists repeatedly stress: "You cannot develop regulations fast enough to follow evolving research. It has to be self-policed." Self-governance, or self-policing, can take many forms. Recognising these and finding constructive ways of incorporating concern about potential misuse into the professional norms of biological scientists, their training and research practices, their standard operating procedures and manuals, their peer observation in the laboratory, and their peer review of funding applications, research projects, and publications can be fruitful regulatory measures that also deserve serious consideration.

We thank you for your patience and your attention, and wish you all success in your efforts to relaunch the process of constructive evolution of the BTWC.

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