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International Governance of Biosecurity and Human Health: Challenges and Opportunities for Coordination and Coherence

1.1 In its engagement and interaction with the international system in support of biosecurity objectives, UK Government needs to be aware of and responsive to the complexity of the governance situation, adopting a comprehensive approach in order to ensure efforts in one area do not conflict with those in others.

1.2 One of the most useful things UK Government can do in its international leadership and support of the rules-based system is to promote the same objectives of coordination and coherence within that arena as it proposes to do nationally, complemented by support for other countries in developing similar biosecurity coordination models.

1.3 Explanation of use of terms:

- International organisation – the focus in this submission is on international inter-governmental organisations that are open for any state to be a member of.
- International regulations – include treaties and conventions (which are legally binding), and standards, guidelines, and declarations (which are voluntary in nature). The focus in this submission is on those that are open for any state to subscribe to.

1.4 Key Points:

Complexity and Coordination

- There is a complex array of international organisations, regulations, and associated governance processes relevant to biosecurity and human health, and there is a need for improved coordination and coherence in UK Government interactions with them.
- This complexity means that there is not always comprehensive awareness of the full range of governance components, nor of interactions between them. It can present significant burdens to countries with limited regulatory capacities.

- UK Government can act to improve coordination between international organisations as they work on biosecurity issues. Achieving greater biosecurity coordination at the international level will support national biosecurity objectives.

Coordination Initiatives as Opportunities to Enhance Biosecurity Governance

- Biosecurity is a prominent example of an area that cuts across the remits of several international organisations, some of which are responding through the creation of cooperative initiatives. UK Government can play a leadership role by affirming the value of such efforts and actively participating in them.

Approaches to Risk Assessment and Analysis

- Several of the relevant international agreements incorporate risk analysis procedures as first step in managing biological risks. Most of these are infrequently updated and slow to respond to changes in the nature of the organisms, tools, techniques, data and knowledge used within the life sciences and biomedical research.
- The Government could support regular evaluation and timely adaptation of such risk analysis procedures, and has a strong science base from which to do so. It can also support capacity building for national implementation of risk analysis requirements.

Benefits of Attaining A Comprehensive Understanding of Biosecurity Governance

- The UK Biological Security Strategy deliberately adopted a broad understanding of biosecurity. This understanding tends not to be reflected in international governance. When engaging internationally on biosecurity, UK Government needs to be clear on how it is understanding and using the term.
- In order to comprehensively understand the range of relevant organisations, regulations and associated governance processes, it is necessary to move beyond a focus on bioweapons and human diseases, because these interact with other areas of biosecurity-relevant governance in significant ways, which can be unintended, unpredictable and problematic.

2. Complexity and Coordination

2.1 Taking the broad definition of biosecurity from the UK Biological Security Strategy – “protection of the UK and UK interests from biological risks... whether these arise naturally, or through the less likely event of an accidental release of hazardous biological material from laboratory facilities, or a deliberate biological attack. These risks could affect humans, animals or plants.” – at least ten international organisations, more than thirty international regulations, and a range of associated governance activities (such as disease surveillance systems, information exchange mechanisms, and laboratory networks) have relevance. Even limiting this to a more specific focus on bioweapons and human infectious disease threats, there are still multiple organisations, regulations and processes in operation.

2.2 Summary details about the main international organisations and regulations are provided in paragraphs 6.1-6.5. (More detailed information can be found in [1]).

2.3 The relevant regulations mostly developed separately within different domains of international law – for example arms control regulations such as the Biological and Toxin Weapons Convention, developed separately from disease control regulations such as the International Health Regulations. This means that while they all have relevance to biosecurity, they often pursue distinct objectives. There is not always a good level of information exchange and communication between these different organisations and processes.

2.4 Different national government departments and agencies tend to participate in, or provide input to, the UK delegations to different international organisations.

2.5 For these, and other, reasons international governance of biosecurity lacks coherence and a more coordinated approach is needed at this level as well as nationally [2].

2.6 A key response to a lack of coherence in international governance is coordination between international organisations where issues cut across their remits. International organisations generally have constitutional mandates to take cooperative action, and there are some relevant examples of coordination initiatives (including those in paragraph 3.2).

2.7 However, there are various challenges to such coordination efforts and there are actions that the UK Government can take to address these individually and in collaboration with international partners. Challenges include:

- Member states do not always support such activities in practice, and organisations will not undertake them without their direction.

- Different bureaucratic structures and working practices among organisations.
- Organisational reluctance to cooperate due to concerns about: encroaching on the jurisdiction of another organisation; taking on additional costs that might be associated with addressing a new issue; or ceding 'control' of an issue to another organisation.
- Lack of coordination among national government departments represented at those organisations [3].

2.8 Recommendations: Improved biosecurity coordination within UK Government should help to address the last of those challenges. Taking a clear position on areas in which inter-organisation cooperation has value, and encouraging support for coordination activities in meetings of the relevant organisations, could address some of the other challenges. Ensuring there is specific resourcing available, for example by provision of expert participants, or additional finance, will also have value.

2.9 A more specific point in regard to international organisation jurisdiction in different areas of biosecurity is that there is a need to establish what will happen, particularly in terms of on-the-ground operational support from the World Health Organisation (WHO) and international NGOs, if an outbreak they are responding to is found to be of deliberate origin [4]. It is currently thought that many would have to withdraw at that point [5]. Similarly, it will be important to know what would happen to support provided by the UK in such a situation, e.g. how would lead responsibility shift, and would a UK rapid response team deployed abroad have to return home?

2.10 Where multiple organisations, regulations and governance processes interact in a particular area – like biosecurity – it can be challenging for any country to maintain awareness of the full set of regulations that apply, let alone keep track of how other states are implementing them, and any additional regional and national requirements. For example, were a country to consider comprehensively a decision about whether to export a genetically engineered bacterium, it would need to take account of at least ten international regulations [6].

2.11 So, while there is a need for new coordination initiatives in biosecurity, there is also a need for caution about regulatory proliferation, which places substantial burdens on many countries and compounds complexity. Many countries already face significant constraints on their active participation in multiple international governance processes. In addition, they can lack capacity for national implementation activities necessary for compliance with multiple international regulations. (This is seen, for example, in relation to the core capacity requirements of the International Health Regulations [7].)

2.12 Recommendations:

- UK Government should continue to: support international efforts to increase capacity of developing countries to effectively participate in international governance processes; share expertise to help develop national implementation capacities; and recognise the importance of regulatory and administrative capacity building for biosecurity within overseas development programmes.
- If the Government takes the actions proposed in the Biological Security Strategy to enhance cross-government and cross-sector coordination, improve capabilities to understand, prevent, detect and respond, and does so in such a way that supports continued growth of the bio-economy, this will provide a practical model that other countries will be able to learn from, adapt and deploy. At this stage, sharing the experience of drawing up the Strategy and providing an accessible overview of Government biosecurity-relevant activities and responsibilities, will be a valuable first step.

2.13 In UK Government interactions with the international system care is needed in regard to how the term biosecurity is understood and operationalised within different areas of governance, for example:

- Biological and Toxin Weapons Convention – in this context biosecurity is largely understood as security of biological materials, data and knowledge, and associated equipment against misuse.
- World Health Organisation – biosecurity is understood within the laboratory context, where it is distinguished from biosafety (though both fall within the term as used in the Strategy). Biosafety referring to protection against accidental release of pathogens; biosecurity to protection of ‘valuable biological materials’ from ‘unauthorised access, loss, theft, misuse, diversion or intentional release’ [8].
- World Animal Health Organisation (OIE) – generally makes a similar distinction as the WHO in the veterinary laboratory context, but also uses biosecurity in a more general sense of protection of animal health from biological threats.
- The Cartagena Protocol on Biosafety to the Convention on Biodiversity – uses biosafety to describe management of risks to the environment and biodiversity from release of living modified organisms.

2.14 The situation is further complicated because some languages do not have separate words for (bio)safety and (bio)security.

3. *Coordination Initiatives as Opportunities to Enhance Biosecurity Governance*

3.1 Biosecurity is a prominent example of an area that cuts across the remit of several international organisations, some of which are responding through the creation of cooperative initiatives. UK Government can play a leadership role by recognising the value of such efforts and actively participating in them.

3.2 Examples include:

- WHO and OIE collaboration on implementation of the International Health Regulations at the Human-Animal Interface - <https://www.who.int/ihr/capacity-strengthening/human-animal-interface/en/>.
- The Standards and Trade Development Facility, a partnership of the Food and Agriculture Organisation (FAO), OIE, World Bank, WHO, and World Trade Organisation (WTO) supporting development of food safety, animal and plant health standards in developing countries - <https://www.standardsfacility.org/>.
- The OIE-FAO Network of expertise on animal influenza - <http://www.offlu.net/>.

4. Approaches to Risk Assessment and Analysis

4.1 Several of the international regulations relevant to biosecurity incorporate risk analysis procedures. The rapidly shifting scientific and technological context can present a challenge to such procedures as the nature of the organisms being assessed alters, and the tools and techniques applied to manipulate them change.

4.2 Risk analysis procedures also remain focused on materials, while data (such as genetic sequence data) plays an increasingly significant role in life sciences and biomedical research.

4.3 Risk analysis processes are, for example, a core part of:

- Codex Alimentarius standards for safety assessment of foods produced using modern biotechnology;
- The WHO's Laboratory Biosafety Manual; and
- Import risk analysis in the OIE's Terrestrial Animal Health Code.

4.4 OIE standards are the more up-to-date of these because they are regularly revised through the work of its specialist commissions. This means, for example, that they already include guidance covering use of bioinformatics, computational genomics and high-throughput sequencing.

4.5 Recommendations:

- The UK could take a leadership role in identifying gaps in international risk analysis processes and setting out work programmes to address them. This can be done in partnership with the academic and private sectors and international partners.
- Similar work updating risk analysis procedures in UK biosecurity relevant regulation is likely to be necessary, and the Government can make use of international meetings to present information about this work.
- Scientific and technological advances can also provide new tools and techniques to assist risk analysis, and this dimension should be supported in international guidance too.

5. Benefits of Obtaining a Comprehensive Understanding of Biosecurity Governance

5.1 The inquiry is focusing on human health and biosecurity, but the Strategy takes a broader view of biosecurity, and adopting a similar approach when seeking to understand the opportunities and challenges of international collaboration will have great value. The governance activities that focus on the human health aspects of biosecurity overlap and interact with a broader set of activities. These connections are not always obvious and interactions can be unintended and unpredictable. Taking a comprehensive view of international biosecurity governance will increase awareness of the full range of relevant activity and help to avoid unintended outcomes. It will help to prevent action taken in one area being in conflict with action taken in another area.

5.2 In addition to the organisations and regulations specific to biosecurity and human health mentioned earlier and in paragraphs 6.1-6.5, examples of biosecurity-relevant activities in other areas include:

- Work to protect **plant and animal health** led by the FAO and OIE: disease outbreaks affecting crops and livestock can disrupt food supplies and impact global public health; historically, biological warfare programmes have included anti-plant and anti-animal components.
- **Conservation of biodiversity:** The Convention on Biological Diversity, its Cartagena Protocol on Biosafety and its Nagoya Protocol on Access to Genetic Resources. Biosafety in the Cartagena Protocol focuses on protection of biodiversity from introduction of living modified organisms, also risks to human health into account. The Nagoya Protocol interacts with international systems that facilitate sharing of viral samples for disease diagnosis and surveillance purposes.
- Various principles relevant to biosecurity can be found in three UNESCO declarations relating to **human rights** and genetic technologies.

- The World Trade Organisation and World Intellectual Property Organisation are the main sources of international governance of **trade and innovation**, including rules on intellectual property rights, which incorporate provisions relating to national security and public health emergencies.

5.3 Recommendation: UK Government should adopt a broad approach to biosecurity in its understanding of and interactions with international governance. This matches the coordination objectives of the Biological Security Strategy, extending coherence to the UK's international collaborations.

6. Summary Information on International Organisations and Regulations Relating to Biosecurity and Human Health

6.1 The Biological and Toxin Weapons Convention (BTWC) prohibits use of biological materials and related equipment for non-peaceful purposes and promotes international cooperation in peaceful uses of biology. There is no international organisation associated with the BTWC. Regular meetings of its states parties consistently reaffirm its applicability to all relevant scientific and technological advances. The BTWC refers to the 1925 Geneva Protocol for its prohibition on use of biological weapons. There is some overlap between the BTWC and the Chemical Weapons Convention, for example in coverage of toxins. United Nations Security Council Resolution 1540, and subsequent resolutions which extend its timeframe, require states to prevent the proliferation of biological weapons to non-state actors.

6.2 The WHO focuses on protecting and strengthening human health. It oversees the International Health Regulations (2005) designed to minimise the risk of international spread of human disease outbreaks while avoiding unnecessary disruption to international travel and trade. WHO also publishes guidance addressing risks from accidental release of pathogens from laboratories and during transportation (the Laboratory Biosafety Manual; and Guidance on Regulations for the Safe Transport of Infectious Substances); and the prevention of access to biological materials by those who intend to cause harm (Laboratory Biosecurity Guidance). It oversees the Pandemic Influenza Preparedness Framework, facilitating sharing of viral samples and access to vaccines. Additionally, it hosts surveillance and response systems such as the Global Outbreak Alert and Response Network, and is supported by an international network of collaborating centres (including 59 based in the UK).

6.3 The Codex Alimentarius Commission, established by WHO and FAO in the 1960s, provides harmonised international food safety standards.

6.4 Many emerging infectious diseases are zoonotic, therefore some of the work of the OIE is relevant to the protection of human health. Like the WHO, OIE oversees disease control regulations, guidance on biosafety and biosecurity in laboratory settings, outbreak reporting mechanisms, disease surveillance systems, and laboratory networks that support its work. Again, UK laboratories are active contributors to these systems. In 2015 OIE published a *Biological Threat Reduction Strategy* that specifically recognises its role in outbreaks of both natural and deliberate origin [9].

6.5 The World Trade Organisation's Sanitary and Phytosanitary Agreement relates to trade standards put in place for the protection of health, limiting such standards to those that are scientifically justified, and referring to the work of the Codex Alimentarius Commission, FAO and OIE as legitimate sources for such standards.

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- [9] <https://www.oie.int/scientific-expertise/biological-threat-reduction/>.