

# EUROPEAN BIOSECURITY REGULATORS FORUM (EBRF)

21 June 2016

## Working paper: Securing immaterial technology with dual-use potential

### 1. Background

Biotechnological progress takes place with tremendous pace. This is a positive development resulting in new medicine to cure diseases, vaccines, and solutions to important societal challenges in for example health, agriculture and the environment. However, as with many other technologies, there is also a downside to these developments, namely that technology could be used for nefarious or offensive purposes, for example to develop biological weapons.

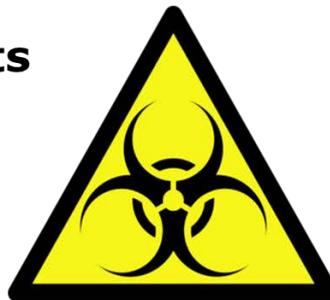
Development of biological weapons requires three components:

- Relevant *biological agents*
- *Equipment*: production machinery and delivery device
- *Immaterial technology*, i.e.: know-how, skills, competencies, and documentation. Please note that in this working paper *technology* only refers to *immaterial* elements and not hardware

## Biological weapons require three components

- **Biological agents**

- virus
- bacteria
- fungi
- toxins



- **Equipment, e.g.**

- fermentors
- freeze dryers
- delivery system

- **Immaterial technology**

- skills
- weaponization
- data
- documentation

“Dual-use” means that a biological agent, a delivery system, related material or immaterial technology can be used for both peaceful and offensive purposes. Dual-use biological agents and equipment are tangible items, and as such, these can be secured by traditional biosecurity approaches: physical security, inventory control, and personnel security etc. This contributes to the prevention of biological threats and increased biosecurity. Dual-use technology, however, is intangible and comprised of the specific know-how, skills and competencies required for weaponizing a biological agent and constructing a complete biological weapon with relevant delivery device. Therefore, immaterial technology is a critical element when it comes to the

# EUROPEAN BIOSECURITY REGULATORS FORUM (EBRF)

prevention of biological weapons research and development – i.e. without the relevant immaterial technology, the threat is significantly reduced, even if a person with hostile intentions should get possession of dual-use biological agents.

In an age when various technologies become more and more accessible to a broader public at a lower cost, often involving the Internet, this raises the important and challenging question: *how to prevent that immaterial technology with dual-use potential becomes accessible for persons, groups or states with offensive intentions?* In recent years, several examples of development of potentially dangerous immaterial technology, i.e. with immediate biological weapons potential, have actualized the issue, and biosecurity professionals, scientists and policy makers have internationally discussed how to regulate or increase awareness in relation to immaterial technology with a serious misuse potential.

## 2. European Biosecurity Regulators Forum – EBRF

The European Biosecurity Regulators Forum – EBRF – is a forum consisting of national biosecurity institutions from: Denmark, France, Germany, The Netherlands, Sweden, Switzerland, and the United Kingdom. The institutions are all government agencies that have a regulatory function in relation to biosecurity, or promote biosecurity regulation in either the human, animal or plant sector. EBRF has its origin in the so-called “B2 Action” of the EU CBRN Action Plan, and the group - before it was termed EBRF - has previously published in 2014 a guideline on best-practices in relation to the securing of biological agents.<sup>1</sup> Following this, and with a European focus, the group decided to address the issue of how to secure immaterial technology, and the aim of this paper is to stimulate discussion that can take further steps to enhanced awareness on responsible science and thereby contributing to immaterial technology not being used for harmful purposes, for example biological weapons development.

## 3. One challenge, many approaches

How to secure immaterial technology is a complex issue. It is, however, an international obligation that states take appropriate measures to secure immaterial technology that can be used to develop biological weapons. This is stipulated in United Nations Security Council Resolution 1540 (UNSCR 1540) of 2004<sup>2</sup>:

“The Security Council [...] Acting under Chapter VII of the Charter of the United Nations, [...] Decides also that all States shall take and enforce effective measures to establish domestic controls to prevent the proliferation of [...] biological weapons and their means of delivery, *including by establishing appropriate controls over related materials*” (own italics).

In UNSCR 1540 “related materials” is defined as materials, equipment and *technology* (own italics) covered by relevant multilateral treaties and arrangements, or included on national control lists, which could be used for the design, development, production or use of [...] biological weapons and their means of delivery.

Some countries have chosen to implement new legislation to address the issue of securing immaterial technology and implement UNSCR 1540, while other countries have published guidelines and best-practices to create awareness amongst scientists and professionals in order to avoid misuse. While many

<sup>1</sup>

[https://www.biosikring.dk/fileadmin/user\\_upload/PDF\\_FILER/External\\_publications/Guidelines\\_for\\_the\\_implementation\\_of\\_Action\\_B2.pdf](https://www.biosikring.dk/fileadmin/user_upload/PDF_FILER/External_publications/Guidelines_for_the_implementation_of_Action_B2.pdf)

<sup>2</sup> [http://www.un.org/en/ga/search/view\\_doc.asp?symbol=S/RES/1540\(2004\)](http://www.un.org/en/ga/search/view_doc.asp?symbol=S/RES/1540(2004))

# EUROPEAN BIOSECURITY REGULATORS FORUM (EBRF)

countries may not have specific legislation with the aim of preventing immaterial technology to be used for biological weapons research and development, it is also characteristic that in many countries there are adjacent legislation, guidelines, ethical codes etc. that address issues regarding safe and secure scientific conduct and technology development. These existing initiatives may form a platform for strengthening awareness on immaterial technologies that may have a security related dual-use potential.

Some countries are of the opinion that legislation increases awareness in the sense that it forces scientists, professionals etc. to think and ask crucial questions concerning potential dual-use implications of their research. Other countries, while focusing on a compliance-based approach, believe that codes of conduct, ethical codes and awareness courses are essential. No matter which approach a country chooses, it is important to remember the wording and intentions of UNSCR 1540 and the BTWC and make sure that technology development takes place in a safe and responsible manner. Basically, the issue is to ensure that security and freedom of research go hand in hand.

 How do we balance security vs. free research and development and assure that we are in accordance with UNSCR 1540 and the BTWC?

- Specific legislation?
- Codes of conduct, awareness courses, screening tools?

## Recommendations

#### 4. Which types of immaterial technology should we be aware of, or regulate?

Many types of biotechnology could have undesired effects, for example for the environment, or for people who work with the substances. Similarly, many technologies could raise various ethical questions. These considerations are important, but not for the scope of this paper. Here the issue is immaterial technologies that have a biological weapons potential. Therefore, this is a *security* challenge. This is very important to consider in order to maintain the right focus and to suggest relevant measures to counter the derived security problems from emerging and novel immaterial technologies. Basically, the criterion for concern is enablement of biological weapons design, research, development, production or use, and this should guide decisions regarding which immaterial technologies are subject to control, codes of conduct and awareness.

Furthermore, it is necessary that researchers, scientists, or policy makers are able to react to security issues related to various immaterial technologies. Research and development in the following areas could pose security issues and should be tied to biological weapons and dual-use awareness:

## EUROPEAN BIOSECURITY REGULATORS FORUM (EBRF)

1. Virulence of pathogens increase
2. Transmissibility of pathogens increase
3. Toxins become more potent
4. Host specificity is altered
5. Resistance of pathogens to medical treatments increases
6. Resistance of pathogens to environmental stress increases
7. Improved methods of dissemination in air, food or water
8. Immune response is compromised
9. New pathogens or toxins arise
10. Extinct pathogens are recreated
11. Diagnostic methods are undermined
12. Other technologies with outcome similar to the above

The above list is not exhaustive and is relevant in relation to both human, animal and plant pathogens that could be used for biological weapons development.

Furthermore, there might also be differences in how grave the misuse and weapons potentials of certain immaterial technologies are. A suggestion could be to divide the misuse potential into the four categories below, ranging from A. as the highest to D. as the lowest. Depending on the classification of the immaterial technology involved, researchers or persons responsible for the technologies would be required to implement relevant security measures:

**A: *Can be used in biological weapons production or use without further modifications***

**B: *Serious potential for misuse in relation to offensive use***

**C: *Less grave and more general dual-use potential***

**D: *No dual-use potential***



Which immaterial technologies require special attention due to security/biological weapons concerns, and can we reach a methodological consensus to identify and assess/categorize these immaterial technologies?

# EUROPEAN BIOSECURITY REGULATORS FORUM (EBRF)

## Recommendations

 Which security measures may, or can we employ?

## Recommendations

### 5. *Who* should assess, regulate or promote awareness of biological weapons relevant immaterial technologies?

An important question is also who, or which agency/institution should assess if certain immaterial technologies have a biological weapons potential, and therefore pose a security concern? This also relates to the issue of reaching the right balance between security and the very beneficial gains from free research and development. Furthermore, it is important to emphasize that security must not compromise legitimate research. Assuming that a project has security implications, when balancing risks against gains, it should be possible to conduct changes in the research set-up that mitigate risks and still achieve the benefits of the research conducted. Only rarely should it be necessary to cancel altogether a research or development project due to security concerns. Nevertheless, disagreement on risks vs. benefits may arise, and then it is necessary to have an independent institution, committee etc. that can decide if a certain project can be realized despite the security implications. Most will probably agree that legitimate research cannot be completely free if there are serious security or ethical problems for society involved.

## EUROPEAN BIOSECURITY REGULATORS FORUM (EBRF)



Which type of authority, agency, committee or entity should be responsible for assessing and weighing the security risks and societal benefits of new biotechnologies?

### 6. International collaboration

Rapid developments in for example biotechnology offer solutions to known problems. At the same time, new challenges arise. It is difficult for one country, and impossible for a single government agency, to have a complete overview of which new technological developments require special attention because of their biological weapons relevance. International cooperation is therefore crucial, both in order to have up to date knowledge, and also to ensure that general technology awareness and legislation in various countries is harmonized. EBRF provides a European platform for exchanging views and information on emerging security threats originating from otherwise beneficial biotechnological research and development. It is, however, also necessary to have a global focus due to the transnational character of biological threats and the rapid flow of information with dual-use implications.



How do we ensure national, regional and global coordination regarding regulation and awareness raising in relation to dual-use technologies that may result in biological security threats?

#### Recommendations

## EUROPEAN BIOSECURITY REGULATORS FORUM (EBRF)



Do we have the necessary international institutional structures? If so, which? Is there a need for new forums to ensure technology awareness, and harmonization of security countermeasures?

**Recommendations**