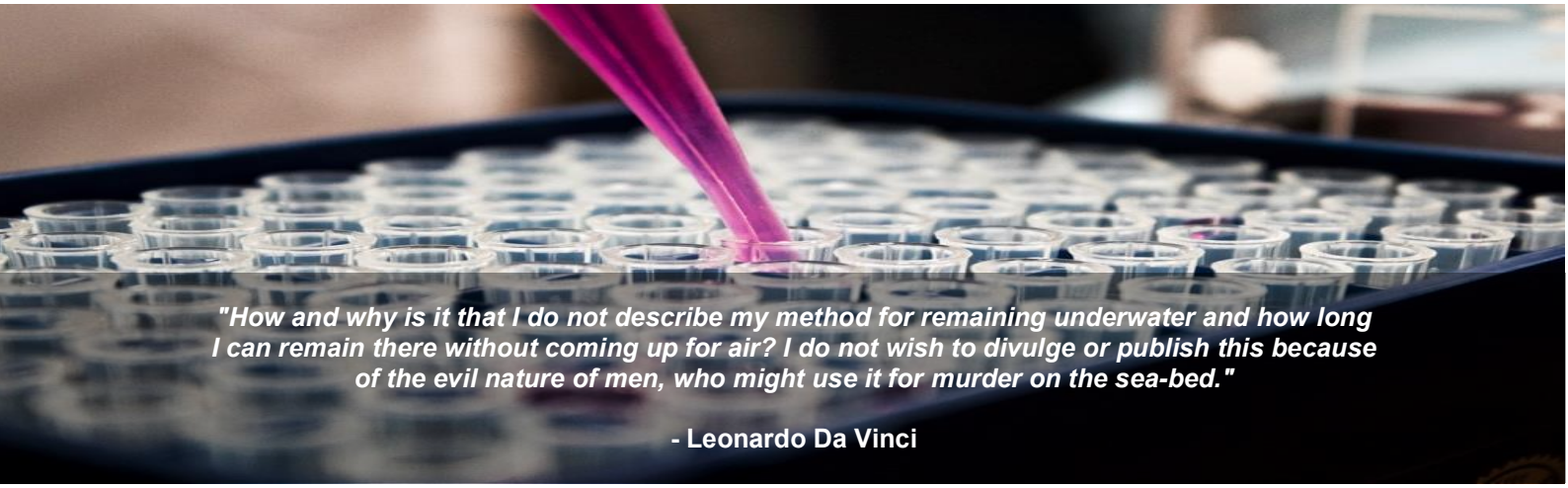
Managing Information Hazards in the Dissemination of Biotechnological Research



EXECUTIVE SUMMARY

This policy brief is addressed to the European Commission's Joint Research Centre (JRC). It highlights the neglect of information hazards in the dissemination of high-risk biotechnological research in policy. To mitigate the problem, this brief recommends expanding the mandate of the EU Ethics Committee via the modification of Directive 2001/20/EC.

INTRODUCTION

Biosecurity risks associated with particular biological materials are well-known and mitigated. For example, securing highly infectious laboratory toxins or preventing the release of invasive species into an ecosystem. Developments in synthetic biology pose unprecedented risks by providing increasingly powerful tools to a myriad of actors, including those who may carry out deliberate biological attacks (National Research Council, 2006; Sandberg and Nelson, 2020). An example includes gene-editing CRISPR kits, which are nowadays so accessible that they can be mailed directly to one's door, allowing the recipient to easily create genetically altered cells (Sneed, 2017).

Information hazards are defined as "a risk that arises from the dissemination of (true) information that may cause harm or enable some agent to cause harm" (Bostrom, 2011, p.2). Current assessments of risks associated with biotechnological progress tend to focus on *material* technological advances. But existing approaches are poorly suited to manage hazardous biological *information* from advances in biotechnology. The dual-use nature of biological information means that potential misuse of such information can have large-scale consequences that are highly neglected in policy and science.

This policy brief proceeds to summarise the problem of biotechnological information hazards by synthesising insights from current scientific literature and drawing on lessons from historical case studies. The brief offers a policy recommendation for the EU Joint Research Centre to decrease information hazards associated with the dissemination of dual-use research of concern (DURC) and suggests sources for further reading.

BIOLOGICAL INFORMATION HAZARDS AND THE DUAL-USE NATURE OF BIOLOGICAL INFORMATION

Biological information cannot be neatly segregated into categories of "safe" and "open" vs. "dangerous" and "secret" (Lewis *et al.*, 2019). Biological information is inherently dual-use: it can be used legitimately by health and security practitioners for beneficial research; yet can equally be used by malicious actors to create deadly biological weapons. The dual use dilemma thus arises because the same scientific research that can be used to benefit humankind can also be used to

cause grave harm. Even an actor that does not desire or intend to misuse an information hazard may nonetheless generate it (ibid), leading to information hazard concerns especially among public health officials and security practitioners.

Biological information hazards are exacerbated by many factors. Firstly, developments in biotechnology have the potential to create both highly lethal, targeted and infectious agents. Deliberately engineered pathogens, for example, could "have the capacity to initiate epidemics on a scale and with a degree of lethality unparalleled in modern history" (Inglesby *et al.*, 2000, p.926). Moreover, scientific knowledge is becoming increasingly accessible as the Internet lowers the barrier for nefarious actors to acquire the know-how to develop bioweapons. In conjunction with rapid development of other technologies, risks such as AI-enabled offensive cyber-attacks may become more prolific, allowing the introduction of malware to disrupt laboratory biosecurity, or allow intruder access to sensitive information (O'Brien and Nelson, 2020). Thus, biological attacks could quickly have a regional or global impact, amplified by global travel and dense populations, leading to potentially catastrophic death tolls as well as political and economic instability (Inglesby *et al.*, 2000; Warmbrod *et al.*, 2020).

Case study 1: Mousepox

Scientific discoveries that might facilitate bioweapons development

In 2001, Australian researchers genetically engineered a strain of mousepox that killed mice vaccinated for ordinary strains of smallpox (Jackson and Ramshaw, 2010). Mousepox is related to smallpox, which incurred death tolls upwards of 300 million in the 20th century (Ochmann and Roser, 2018). The publication prompted a debate on whether the paper should have been published from a standpoint of security given concerns over how the virus might be manipulated by bioterrorists (Selgelid, 2007; Lewis *et al.*, 2019).

Case study 2: Botulinum Toxin H

Being overcautious with information hazards

Botulinum toxin regularly appears on lists of agents of concern, for example the CDC's list of bioterrorism agents (*Bioterrorism Agents/Diseases*, 2019). In 2013, a new subtype of botulinum toxin was discovered. Researchers sought to avoid an information hazard and reduce biorisk associated with the toxin, publishing their findings without the sequence encoding as no antitoxins existed and dual-use concerns were cited alongside the paper (Hooper and Hirsch, 2014). Consequently, restricted access to the toxin and its sequence prevented research groups from developing countermeasures, impacting the ability to develop a treatment (Lewis *et al.*, 2019).

EXISTING REGULATORY FRAMEWORKS ARE SUBOPTIMAL

Case studies demonstrate that over-caution can be counterproductive, impairing emergency response or preventative efforts (Chernov and Sornette, 2016) or impinging the ability of good actors to respond to misuse by bad actors (Lewis *et al.*, 2019). Yet while there are guidelines on how to conduct ethical scientific research, there is a lack of guidelines on the ethical dissemination of scientific knowledge (Dubov, 2014). The few frameworks that do exist poorly manage the responsible communication of dual-use research of concern (DURC), augmenting biological information hazards. These will be discussed in turn.

1) Scientific self-regulation: codes of conduct

Codes of conduct in the context of DURC have been said to promote awareness among scientists about the risks involved with their research (Somerville and Atlas, 2005); increase public trust in the scientific community by ensuring scientists focus on the promotion of human flourishing and the avoidance of harm (Selgelid, 2009); and to avoid government over-regulation and

maintain scientific freedom (ibid). This approach maximally protects the flourishing of science. However, such guidelines are neither internationally uniform, nor legally enforceable (MacIntyre, 2015). Additionally, scientists may lack sufficient expertise to assess the security implications of the nefarious use of scientific discoveries (Miller and Selgelid, 2007). Moreover, self-regulation potentially favours the publication of DURC due to vested interests of the scientific community for free information exchange (Selgelid, 2007; MacIntyre, 2015).

2) The Precautionary Principle

The Precautionary Principle (PP) applies to problems characterised by scientific uncertainty concerning hazards and risks, but it is poorly defined and vague (Kendra and Dyer, 2007). The main critique against the PP is that it is an overly risk-averse interpretation that stifles scientific progress (Sunstein, 2002). The concern is that regulators can justify setting any limit on the dissemination of potential information hazards on the basis of uncertainty about the effects of DURC (Kendra and Dyer, 2007). Yet an overly risk-prone interpretation may lead to DURC becoming more readily available to nefarious actors for misuse, with potentially dire effects on human security, should dangerous biological material (ibid). Most discussions of the PP assume that it tends towards encouraging more risk-aversive behaviour (Hansson, 1999).

Case study 3: SARS

Inappropriate secrecy

Due to Chinese authorities suppressing news of the SARS outbreak in 2002, large-scale preventive measures were delayed for months, leading the WHO to only issue a global warning in mid-March 2003 (Chernov and Sornette, 2016). By then, the virus had resulted in 8098 cases in 26 countries where early preventive action could have significantly reduced international spread (ibid). Though not a direct DURC issue, this case demonstrates that excessive concealment of high-risk biological information can have massive global health consequences.

Debates over the dual use dilemma in the domain of biotechnology have converged on the fact that a more equal balance between the scientific advancement and protecting society from harm must be struck (National Research Council, 2004). Adequate governance is needed, yet stringent regulation or security measures do not necessarily translate to a proportionate increase in security and may significantly impede scientific progress, working contrary to the EU's aim for a more inclusive and transparent science (Selgelid, 2009; Stilgoe, Owen and Macnaghten, 2013; *Citizen science*, 2015).

POLICY RECOMMENDATION: EXPANDING THE MANDATE OF THE EU ETHICS COMMITTEE

The complexity and dual-use dilemmas surrounding biotechnological information means that efficient regulation should focus on the research itself and its dissemination (Samuel *et al.,* 2009). **This policy brief therefore recommends that the Directorate General of the EU Joint Research Centre initiate a modification of Directive 2001/20/EC to expand the mandate of EU Ethics Committees.** The scope of Ethics Committee responsibilities should include assessing the hazard potential of scientific studies and providing recommendations on the process of scientific knowledge dissemination.

Currently, Directive 2001/20/EC states that Ethics Committees are responsible for protecting the rights, safety and well-being of human subjects involved in clinical trials; as well as expressing opinions on the relevance, protocol, suitability of staff, quality of facilities, and completeness of information given to subjects to obtain informed consent before the trial commences (2001).

The mandate of EU Ethics Committees should thus include the following roles, which should be coded into Directive 2001/20/EC in order to mitigate biological information hazards related to

developments in biotechnology (Lewis *et al.*, 2019):

1. Assessing biological information hazard potential before the study is carried out;
2. Assessing the extent to which new information would help good and malicious actors;
3. Disseminating scientific knowledge wisely, in a manner that maximally disadvantages malicious actors.

1. Assessing biological information hazard potential before the study is carried out

Criteria used to evaluate biotechnological DURC should be transparent (Resnik, 2010). Examples of criteria the Ethics Committee may use to assess biological information hazard potential include the following (National Academies of Sciences, Engineering, and Medicine *et al.*, 2017):

- Information can become increasingly hazardous over time as biotechnology becomes increasingly cheap and available. This will make scientific research easier to implement by actors outside of the scientific community. The Committee should evaluate information hazard potential by forecasting the trajectory of biotechnologies and how accessible they will become.
- Information that is high-risk provides previously unknown "pieces of the puzzle" by filling gaps in biotech research. Therefore, information that makes it easier for a potential malicious actor to "solve the puzzle" is more likely to be an information hazard.
- Biological innovations with broad applications are more likely to cause information hazards, as opposed to experimental results.

2. Assessing the extent to which new information would help good and malicious actors

The degree of hazard can be gauged by predicting "worst case scenarios". For example, the knowledge provided by the 2001 mousepox publication also provides a large piece of the puzzle for nefarious actors on how to modify the lethality of the mousepox gene (Selgelid, 2007; Lewis *et al.*, 2019). Hence, if the same gene were to be incorporated into a new smallpox virus, the deliberate release of a vaccine-resistant smallpox would have the potential to become an existential threat to humanity. Thus, the information hazard potential in the case of the mousepox publication is extremely severe.

3. Disseminating scientific knowledge wisely, in a manner that maximally disadvantages malicious actors

Depending on the case, more or less disclosure empowers different malicious actors in different ways. Abstaining from publicising information about *how* biotechnological innovations can be misused or using highly scientific jargon may impose significant barriers to biotechnological misuse (Ouagrham-Gormley, 2014). In more severe cases, it may be that only permitted experts are allowed to view high information hazard publications with strict monitoring of who has accessed the paper, when, and what is done with the information (Steinbruner, 2012).

ADVANTAGES AND CHALLENGES OF THE RECOMMENDATION

A continuous cycle of information gathering and assessment aids the evolution of risk prediction associated with rapid advancements in biotechnology (Dubov, 2014). This approach is incorporated into the policy recommendation as it strikes a ethical expertise required for analysing risks associated with the dissemination of biotechnological DURC. Further, it incorporates a greater number of voices and opinions in regulation of DURC (Dubov, 2014). Consequently, this recommendation strengthens the culture of responsible conduct in the dissemination of DURC (Atlas and Dando, 2006). It also provides clarity on guidelines about the

type of information that would require increased security (Dolgitser, 2007).

There may, however, be adverse effects to academic freedom and scientific progress. Existing incentive structures within academia are such that, despite the high importance of biotechnological research, enhanced oversight may deter scientists from working in such areas if dissemination of their research becomes less certain (Miller and Selgelid, 2007). Difficulties concerning access to knowledge that poses high information hazards remain (Steinbruner, 2012).

CONCLUSION

To summarise, the dual-use dilemma refers to legitimate uses of science and technology (e.g., in medicine) that can be used by malicious actors intending to carry out deliberate biological attacks (e.g., in bioterrorism). Drawing on case studies such as the discovery of the vaccine-resistant mousepox gene and the restricted access to the botulinum toxin and its sequence demonstrate the extent to which information hazards have, to date, been poorly managed.

Yet there is a lack of guidelines on the ethical dissemination of scientific knowledge (Dubov, 2014). Frameworks such as scientific codes of conduct or the Precautionary Principle poorly manage the communication and dissemination of DURC with high information hazard potential.

The complexity and dual-use dilemmas surrounding biotechnological research means that, to mitigate information hazards, efficient regulation should focus on the dissemination of the research itself (Samuel *et al.,* 2009). **This policy brief therefore recommends that the Directorate General of the EU Joint Research Centre initiate a modification of Directive 2001/20/EC to expand the mandate of EU Ethics Committees.** The scope of Ethics Committee responsibilities should include assessing the hazard potential of scientific studies and providing recommendations on the process of scientific knowledge dissemination.

SUGGESTIONS FOR FURTHER READING

Publication	Summary
Sandberg, A., & Nelson, C. (2020). "Who Should We Fear More: Biohackers, Disgruntled Postdocs, or Bad Governments? A Simple Risk Chain Model of Biorisk." Health security.	The authors introduce a risk chain model from bad intentions to consequences. Actors are primarily limited by the most difficult step in the chain. Safeguarding the rarest or difficulty-minimizing information is most important to limiting bad actors in the most crucial step of the risk chain.
Evans, Nicholas G. (2010) "Dual-use bioethics: The nuclear connection." ***Wellcome Trust: Building Sustainable Capacity in Dual-use Bioethics monographs*****. Bradford, University of Bradford.**	The case of nuclear weapons is used as a framework to investigate the dual-use dilemma in the life sciences. The paper provides a historical survey of moral codes in science and their saliency; self- vs. government-regulation; and funding hazards.
Shepherd, S.A. (2003) "How do we define responsible disclosure?" SANS Institute.	This white paper discusses approaches to structures for vulnerability disclosure in IT. It distinguishes between nondisclosure, full disclosure, limited disclosure and responsible disclosure.

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