TERROR
Strengthened preparedness and response to biological and chemical terror attacks

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WP8 Novel Threats

D8.5: Dual-use Technology - Review of currently available dual use guidelines and Report on the results of the questionnaire

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Authors:
Diederik A. Bleijs[1], Saskia A. Rutjes[1,2], Tone Bjordal Johansen[3], Elisabeth H. Madslien[3], Franck Limonier[4], Bernadett Palyi[5], Jozsef Pete[6], Jessica Jones[7]

Affiliations:
[1] Biosecurity Office, National Institute for Public Health and the Environment, Bilthoven, Netherlands
[2] Centre for Infectious Disease Control, National Institute for Public Health and the Environment, Bilthoven, Netherlands
[3] Norwegian Institute of Public Health; Norway
[4] Sciensano; Belgium
[5] National Public Health Centre; Hungary
[6] Government Office of the Capital City Budapest, Unit of Export Control, Hungary
[7] UK Health Security Agency; United Kingdom

Contents

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Terms and abbreviations

Biosecurity	Biosecurity, including Laboratory Biosecurity, refers to the legislative and institutional framework, the principles, technologies and practices that are implemented to secure pathogens, toxins and sensitive technologies and related equipment from unauthorized access, loss, theft, misuse, diversion or intentional release. (1)
BTWC	Biological and Toxin Weapons Convention
CBRN	Chemical, Biological, Radiological or Nuclear
CWC	Chemical Weapons Convention
DU	Dual-use
DURC	Dual-use research of concern
DURC Research	Research methodology to study genomic alternations in pathogens that result in "Gain-of-Function" (e.g., increasing a pathogen's ability to cause disease)
EU	European Union
EBRF	European Biosecurity Regulators Forum
HPAI	High Pathogenic Avian Influenza
IHR	International Health Regulations of the WHO are an instrument of international law that is legally-binding on 196 countries providing an overarching legal framework that defines countries' rights and obligations in handling public health events and emergencies that have the potential to cross borders
IEGBBR	International Experts Group of Biosafety and Biosecurity Regulators
JEE	The Joint External Evaluation is a voluntary, collaborative, multisectoral process to comprehensively assess country capacity to prevent, detect and rapidly respond to public health risks in the framework of the IHR. The JEE helps countries identify their most critical gaps within their human and animal health systems
KNAW	Royal Netherlands Academy of Arts and Sciences

NAS	National Academy of Science
RIVM	National Institute for Public Health and the Environment of the Netherlands
Sensitive technologies and related equipment	Materials, equipment and technology 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.
WOAH	World Organisation for Animal Health
WHO	World Health Organisation
WTRP	Canada's Weapons Threat Reduction Program

Executive summary

Dual-use is defined as knowledge, information, methods, products or technologies generated by peaceful and legitimate research that may be appropriated for non-peaceful or harmful purposes, but that could also be intentionally misused to endanger the health of humans, animals, plants and agriculture, and the environment. In the context of this project, dual-use refers to work in the life sciences, but the principles are also applicable to other scientific fields.

The objective of task 8.3 of Work Package 8 is to pull together the collective knowledge on regulation of dual-use in the biological and chemical research sectors by assessing existing available guidelines and legislation. Although a substantial number of guidance documents on the governance of dual-use are available, export control regulation is often the only legal framework to control dual-use (EU Regulation 2021/821). A specific European dual-use framework, defining the oversight, monitoring, risk assessment, inspection and mitigation for both biological and chemical research sector, in order to prevent misuse of knowledge, information, methods, products or technologies, is currently not in place.

In addition, a survey was performed to identify how EU Member states have organized the governance of dual-use. The survey aimed to collect information on how governments as well as research institutions and organisations in EU Member States govern dual-use research. Due to the lack of information on national contact points for dual-use in both the biological and chemical sector, impacted the proper distribution to relevant stakeholders in a country. This could possibly explain the relatively low response rate across EU-countries leading to a lack of representativeness. Still, the outcome of the survey demonstrates a snapshot of where we are today regarding dual-use regulations and governance in the European countries. Respondents indicated that a European legally binding dual-use framework would be welcomed since it enforces national legally binding requirements. This subsequently will be beneficial for implementation of more strict dual-use measures at the institute level. Based on the information that was collected in the survey, recommendations have been formulated, that should be seen in the context of the evolving response to our developing understanding of dual-use research, and which are listed below.

- Develop a European platform consisting of experts in the field of biosecurity, chemical security and dual-use with delegates from all EU Member States. This European platform may foster a web of policies, approaches and measures that strengthen biosecurity, chemical security and dual-use within Member States. This requires appointing an organization that will be responsible for establishing, hosting and maintaining the platform, in addition to updating information when needed.

Examples of activities that can be initiated by the platform are as follows.

- Keep an up-to-date record of national contact points for biosecurity, chemical security and dual-use, either or not combined with national point of contact, with the aim to facilitate information sharing and support between EU Member States.
- Development of a tool to map all relevant stakeholders in the area of chemical and biological security in a country, including dual-use. This would help in raising awareness and creating insights

into the complexity of the stakeholders arena, supporting commitment from the 'higher decision-making levels', which will be required for strengthening the governance of dual-use.

- Initiate the development of an academic training curriculum for scientists in the life sciences promoting a responsible biological and chemical science research culture. The curriculum should be designed to raise the level of understanding of security aspects in the biological and chemical research sector, including dual-use, and ought to be incorporated into standard educational courses.
- Develop resources, tools and guidelines that need to be easily accessible (e.g. through dedicated digital platform) to all stakeholders in EU Member States.

Joint Action Terror

The European Union (EU) plays an important role in counter-terrorism activities. While primary responsibility for security measures lies with individual Member States, the EU provides a borderless perspective that encourages cooperation and coordination through numerous policy frameworks.

EU Regulation 2022/2371 seeks to build a stronger EU health security framework by improving coordination between the European Commission and other EU agencies (2). The regulation was formally adopted during the lifecycle of Joint Action TERROR and repeals Decision No 1082/2013/EU on serious cross-border threats to health (3). It provides the framework to improve preparedness and to strengthen the response capacities to health emergencies of biological, chemical, environmental, and unknown origin.

The 2009 Commission Working document 'Bridging Security and Health' identified areas that could be strengthened. It states, among other issues, that Member States preparedness in health would benefit from sharing lessons learned and best practices in, among other issues, cross-sectoral support, and coordination.

To support this, Joint Action TERROR's main objectives were to address gaps in health preparedness and to strengthen cross-sectoral work with security, civil protection, and health sectors response to biological and chemical terror attacks.

Joint Action TERROR aimed to build upon work undertaken for the Health Programme and other relevant EU programmes and exercises in particular Joint Action "Strengthened International Health Regulations and Preparedness in the EU" (SHARP) and the Joint Action "Healthy Gateways".

Introduction

Dual-use

Dual-use can be defined as knowledge, information, methods, products or technologies generated by peaceful and legitimate research that may be appropriated for non-peaceful or harmful purposes and thus could be intentionally misused to endanger the health of humans, animals, plants and agriculture, and the environment (4) (5). Dual-use research of concern (DURC) describes research that is conducted for peaceful and beneficial purposes that could easily be misapplied to do harm with no, or only minor, modification (4). In the context of this framework, it refers to work in the life sciences, but the principles are also applicable to other scientific fields as well as the chemical field.

Some examples of DURC of biological agents are the reconstruction of the influenza A/H1N1 virus responsible for the 1918 Spanish flu pandemic (6), synthesis of infectious poliovirus using *in vitro* biochemical manipulation and published structure and nucleotide sequence of the poliovirus genome (7) and the creation of highly pathogenic avian influenza A/H5N1 with enhanced transmissibility in mammals (8) (9). An example of dual-use technology in chemistry is the discovery of the process for synthesizing and mass-producing ammonia which revolutionized agriculture with modern fertilizers but also led to the creation of chemical weapons during World War I. These and other examples have been described in literature reviews "D8.1: State of the art of Synthetic Biology- Literature Review" and "D8.3: Synthetic Opioids- Literature Review" (10) (11) and summarized in the risk and recommendations reports "D8.2: Synthetic Biology- risk assessments and recommendations for future governance guidelines" (12) and "D8.4: Synthetic opioids – risk assessments and recommendations for future governance guidelines" (13).

Some European governments and organisations, particularly universities, research institutes and private sector research, already have legislation, non-binding instruments or guidelines that govern the use of technology and research with dual-use potential, including biosecurity measures. Also, some educational organisations provide training and educational resources in this area. However, there is a lack of oversight and knowledge regarding how this is organized and operated in the different member states within the EU.

Objective

The objective of task 8.3 is to pull together the collective knowledge on regulation of dual-use in the biological and chemical research sectors by assessing existing available guidelines and legislation, including how this is organized in practice and operated in the member states from EU and collaborating countries, governments and organisations. In addition to the desk research, questionnaires have been developed for the biological and chemical sector. For each sector, a questionnaire was designed for either research institutes in public and private research industries, and a questionnaire government entities.

The assessment also addressed legislative aspects of dual-use technology (existing and non-existing) and, where possible, law enforcement agencies were contacted for their input and expertise into this activity. Emphasis on currently existing educational activities and awareness of

biological and chemical security for scientists and students has been made, with the aim to formulate recommendations on the development and use of educational programmes and tools.

The results of the review and questionnaire were used to prepare recommendations for standardized guidance for the governance of dual-use research in both the biological and chemical research sectors.

Methods

A desk research was performed in which relevant available guidelines were reviewed on regulation and governance of dual-use in the biological and chemical research sectors. Internet search was performed using the keywords "biosecurity", "dual-use", "guidance", and "governance", but also expert judgements were performed to gather relevant documents (14) (15). The search covered at least 15 years, and the resulting documents were included and summarized in the results chapter.

Secondly, a questionnaire was developed to gain information on how member states at governmental level as well as research institutions and organisations govern dual-use research. In total four versions of the questionnaire were developed, each tailored for the four different stakeholder categories:

1. B- governmental: governmental organisations (i.e. ministries) in the biology research sector;
2. C- governmental: governmental organisations in the chemical research sector;
3. B- research: organisations, universities and research institutes (including companies) in the biology research sector;
4. C- research: organisations, universities and research institutes (including companies) in the chemical research sector.

The questionnaire built upon a recently developed questionnaire on biosecurity being conducted by RIVM (16), and was aligned with questionnaires developed in Work Package 5 "Preparedness & Response planning to biological and chemical terrorist attacks" and Work Package 6 "Cross-sectoral collaboration: Security, civil protection and health" on order to reduce the number of overall questionnaires within the JA TERROR project. The platform for the questionnaire was the EUSurvey (17), which is the European Commission's official survey management tool.

The questionnaire consisted of several sections focusing on the definition of dual-use research, legislative aspects, and implementation measures and requirements, such as dual-use oversight systems, monitoring, risk assessment, inspections, personnel security and outreach and awareness activities (see appendixes 1-4). The questionnaire was accompanied with a glossary and instructions to fill out the questionnaire.

The questionnaire was distributed to identified contact persons in each of the European countries (see appendix 5). Contact persons were selected either from JA TERROR's competent authorities, National Contact Points of the annual Confidence-Building Measures (CBM) reports of the Biological Weapons Convention (18), or National Contact Points of the Australia Group (19). These contact persons distributed the survey to governmental organisations and research institutes they consider relevant, in the biological and chemical research sector within their respective country. In total 30 countries (see appendix 5) were contacted and the survey was open from April 1st till August 31st, 2024. During this period three reminder emails were sent to the contact persons.

Results

The results of the efforts in task 8.3 are divided into two sections, i.e., overview of relevant guidance documents on dual-use and the results of the questionnaire.

Guidance documents on dual-use

Throughout the recent 15 years a number of relevant guidance documents have been published by different organisations in EU member states, by the EU and by international stakeholders. The identified documents are listed in table 1-3, and brief summaries are given in Appendix 6.

Table 1. Overview of different guidance document on dual-use governance (see also Appendix 6)

Guideline	Organisation	Year	Website
Laboratory biosecurity guidance (1)	World Health Organisation (WHO)	2024	https://www.who.int/publications/i/item/9789240095113
Guidelines, Common Control Lists and Control List Handbooks for chemical and biological trade controls (20)	Australia Group (AG)	2024	https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/control-list-handbooks.html
Global Guidance Framework for the Responsible Use of the Life Sciences: Mitigating Biorisks and Governing Dual-Use Research (4)	World Health Organisation (WHO)	2022	https://www.who.int/publications/i/item/9789240056107
Guidelines for Responsible Conduct in Veterinary Research (21)	World Organisation for Animal Health (WOAH)	2021	https://www.woah.org/app/uploads/2021/03/a-guidelines-veterinary-research.pdf
EU Export Control Regulation (EU) 2021/821 (5)	European Union (EU)	2021	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0821
Governance of Dual-use Research in the Life Sciences: Advancing Global Consensus on Research Oversight (22)	National Academy of Science (NAS)	2018	https://www.nap.edu/catalog/25154/governance-of-dual-use-research-in-the-life-sciences-advancing
Tools for the Identification, Assessment, Management, and Responsible Communication of Dual-use Research of Concern: A Companion Guide (23)	United States of America (USA)	2014	https://www.phe.gov/s3/dualuse/documents/durc-companion-guide.pdf
A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research (24)	European Union (EU)	2010	https://ec.europa.eu/research/participants/data/ref/fp7/89797/improper-use_en.pdf

Especially worth mentioning is the WHO Global Guidance Framework for the Responsible Use of the Life Sciences: Mitigating Biorisks and Governing Dual-Use Research (4) (see Table 1). This document describes the different aspects and stakeholders involved in governing dual-use research and can be scoped to the biology and chemistry research field. Also, the WHO recently published the Laboratory biosecurity guidance in which dual-use research, also referred to as high-consequence research, is included as a relevant component of a total laboratory biosecurity approach (1). The World Organisation for Animal Health (WOAH) published guidelines for responsible conduct in veterinary research, since also these research outputs inherently carry the possibility of unintended consequences and misuse, and therefore have dual-use implications (4). Legally binding and non-binding regulations on export control is covered by EU regulation 2021/821 (5) and the guidelines developed by the Australia Group (AG) (18), respectively. For more examples see Table 1 and Appendix 6.

Table 2. Overview of different code of conducts relevant for biosecurity and dual-use (see also Appendix 6)

Guideline	Organisation	Year	Website
The Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists (25)	Tianjin University	2021	https://www.interacademies.org/sites/default/files/2021-07/Tianjin-Biosecurity-Guidelines-Codes-Conduct.pdf
Dual-use Potential of Life Sciences Research: Code of Conduct for Risk Assessment and Risk Mitigation (27)	Robert Koch Institute's (RKI)	2013	https://www.rki.de/EN/Content/infections/Dual_Use/code_of_conduct.html
Code of Conduct for Biosecurity (28)	Royal Netherlands Academy of Arts and Sciences (KNAW)	2007	https://www.bureaubiosecurity.nl/documenten/knaw-code-of-conduct

Besides these frameworks, also other guidance documents and code of conducts are available. The Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists is a document that aims to promote a culture of responsible science including dual-use aspects of research (25) (see Table 2).

There are also a number of online resources giving an overview of relevant dual-use guidance documents and regulations. The International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR) has published a Compendium of International Oversight Systems of Dual-Use (DU) in Life Sciences in IEGBBR Countries, including the EU, Switzerland, Germany, Denmark, France and the Netherlands (26) (see Table 3).

Table 3. Other relevant online overview resources on dual-use (see also Appendix 6)

Resource title	Organisation(s)	Website
Biosecurity Central (14)	Canada's Weapons Threat Reduction Program (WTRP), World Organisation for Animal Health (WOAH). Georgetown University Center for Global Health Science and Security	https://biosecuritycentral.org/
Biosecurity Resource Toolbox (29)	European Biosecurity Regulators Forum (EBRF)	https://ebrf.eu/toolbox.html
Compendium of International Oversight Systems of Dual-Use (DU) in Life Sciences in IEGBBR Countries (30)	International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR)	https://iegbbr.org/tools.html

Results of questionnaire on dual-use

The four different questionnaires could only be distributed during the end of JA TERROR as a result of the lack of a list of points of contact in each EU country. Therefore, it was difficult to identify relevant contact persons and properly distribute the questionnaire. Out of 30 countries, 14 responded to the survey for governmental organisations in the biological research sector, whereas 8 responded in the chemical research sector. In total 38 institutes of 15 different EU countries filled in the questionnaire for biological research institutes. It should be noted that almost half of the responses (16/38) originated from a single country. As for the chemical research sector, 21 institutes of 9 different EU countries responded to the questionnaire. Out of the 21 responses received, 6 were from a single country.

This questionnaire was not intended to be a check-list, nor an inspection, but rather a probe into best practices. The results reflect the knowledge, experience and role of the respondents and will not give a complete picture of the situation in the countries. A detailed graphic representation of the results of the questionnaires can be found in appendixes 7-10.

Dual-use definition

The definition of dual-use varies between countries, between ministries, between institutes and between disciplines. However, most of the respondents referred to the definition as set out in EU Regulation 2021/821 (5) or as defined by WHO in the Global guidance framework for the responsible use of the life sciences (4).

Law, regulations, and non-binding instruments

Questions in the survey concerned the main national laws and regulations, relevant to dual-use management. Governmental organisations were asked about compliance towards the International Health Regulations (IHR) of the WHO (31). The Joint External Evaluation (JEE) helps countries identify their most critical gaps within their human and animal health systems (32). The initial self-evaluation followed by the in-country evaluation conducted by an external evaluation team are the two phases of a JEE. Self-evaluation was performed in 5/14 and 2/8 countries in respectively the biological and chemical research sector. Only two countries replied that an in-country evaluation was carried out.

Legally-binding instruments on dual-use in the biological and chemical research sector was present in most countries (B: 11/14; C: 7/8) according to governmental organisations. Although a full score should be expected as they are EU countries and should apply to EU regulations. These legally-binding instruments are being implemented in the biological and chemical research sector in respectively 21/38 and 10/21 organisations and universities. Countries that replied that they had legal-binding instruments on dual-use, the primary national law is based on EU Regulation 2021/821 (5) on the control of exports of dual-use items. One country has a specific act on securing specific biological substances, delivery systems and related materials.

Complementary and other laws and regulations on dual-use are found in the implementation law on the Biological Weapons Convention, Contained Use of Genetically Modified Organisms or import laws of biological materials.

Dual-Use Oversight System

In 5/14 and 6/8 countries in respectively the biological and chemical research sector there is a licencing system in place for dual-use activities which mainly are based on EU Regulation 2021/821 (5). Only one country in the biological research sector requires to have a system in place to detect dual-use risks. However, in 23/38 and 8/21 of respectively the biological and chemical research sector responded that they have such a system running.

This suggests that many, but not all institutes and universities have, on a voluntary basis, implemented a system for the detection of potential dual-use risks. Some institutes answered that their research project proposals require evaluation from the Institutional Ethics Committee or that they require to fill-in the Dual-Use Quickscan (33) prior to the start of a research project.

Monitoring and Risk Assessment

Monitoring and performing risk assessments on dual-use aspects is important to mitigate risks. With a few exceptions, at the governmental level there are almost no requirements to perform dual-use risk assessments (B: 3/14; C: 1/8), monitor dual-use risks (B: 2/14; C: 0/8) or have local committees installed tasked on risk assessment and monitoring (B: 0/14; C: 0/8). At the local level, 24/38 and 9/21 respondents in respectively the biological and chemical research sector perform dual-use risk assessments. In more than half of the institutes (19/38 biological research sector and 14/21 chemical research sector) there is no dual-use committee in place within the institution.

Inspection Scheme

Inspections addressing dual-use aspects can be carried out at the governmental level as well as at institutional level (audits). In only 11/38 and 7/21 institutions in respectively the biological and chemical research sector inspections take place. Moreover, according to the responders, inspection reports are often not available, and it is unclear whether there is follow-up in case dual-use aspects arise. The chemical research sector is more regularly inspected when chemicals present are listed on the CWC list (6/8 countries).

Personnel Security Requirements

These questions concern whether there are requirements in place for security screening or assessments of personnel, including students and visitors, handling high risk biologicals or chemicals. At national level, 9/14 and 5/8 countries require to have security screening requirements in place for personnel working with biological and chemical materials in general in respectively the biological and chemical research sector. Whereas, except for one country in the biological research sector, no screening or assessment of personnel is mandatory for performing activities with dual-use potential.

At the institutional level, security requirements and screening of personnel is more often required (B: 24/38; C: 13/21). Some institutes refer to certain security clearance regulations for screening of personnel or their occupational health and safety regulations. The questions whether researchers are sufficiently aware that dual-use risks can occur during the research is positively answered in

17/38 in the biological research and 11/21 chemical research sector. This means that the awareness level of researchers could be improved in order to circumvent potential dual-use risks.

Outreach and Awareness Initiatives

This section of the questionnaire aimed to capture the variety and range of training, outreach and awareness initiatives that can come from either the public or private sector, or some combination of the two. At the governmental level, 5/14 and 4/8 countries in respectively the biological and chemical research sector have national dual-use awareness or training programs in place for researchers and laboratory staff. Only 3/14 in the biological research sector and none in the chemical research sector have these programs also tailored for students. Often the Ministry of Foreign Affairs organises these programs, which are mainly seminars on export control (5).

Outreach activities, such as information workshops and awareness trainings, tend to be similar within institutes in the biological research sector (12/38) than within the chemical research sector (6/21). Awareness initiative for students is often not present. An exemption is that two countries indicate that they perform yearly outreach sessions (1-2 hours) for students within the field of biomedicine, nanotech, medicine, and biotechnology at Master and PhD level. These sessions include an overview of the legislation, as well as a sensitization to the concept of dual-use.

Additional information

These questions aimed to collect any other relevant information regarding dual-use, for example on political will, sustainability, and (structural) budget. Both governmental organisations as well as research institutes at both sectors indicate that there is a lack of structural funding to address dual-use aspects such as risk assessments, mitigation measures, inspections and awareness activities. Among the governmental organisations 5/14 in the biological and 6/8 in the chemical sector are of the opinion that dual-use aspects are regarded as an important issue at the political level within their respective countries.

As also indicated by several responders, without legally binding measures it is hard to implement any stricter dual-use regulation within the institute. Legally binding measures at the EU level would help to introduce national legislation and policy, which could contribute to establish institutional regulations to address and mitigate potential dual-use risks.

Conclusions and recommendations

This report intents to be a snapshot of where we are today regarding dual-use regulations and governances in the European countries and contains recommendations for the future, which should be seen in the context of the evolving response to our developing understanding of dual-use research. Recommendations listed below are based upon feedback on the questionnaires.

Within JA TERROR, several activities were undertaken to make an inventory of the current regulations and governance systems in place for dual-use in the biological and chemical research sectors in European countries. Although a substantial number of guidance documents on the governance of dual-use are available, export control regulation is often the only legal framework to control dual-use (EU Regulation 2021/821).This mechanism regulates export of high-risk biological agents, chemicals, as well as equipment, from EU Members States to non-EU countries (5). The definition of dual-use is based on this regulation as well as on the WHO "Global guidance framework for the responsible use of the life sciences" (4).

Oversight of national dual-use activities is also mainly based on EU Regulation 2021/821 (5), especially in the chemical research sector. However, the correct interpretation of this export regulation in relation to national oversight of dual-use activities is debatable as not all dual-use activities are subject to export control. Strikingly, at governmental level, regulatory requirements are lacking mandating dual-use risk assessments or monitoring dual-use risks. Also, there are no requirements for local safety/ security committees/ officers. The fact that only more than half of the organisations and universities in the biological and the chemical research sector perform dual-use risk assessments, either in the presence or absence of a local committee on dual-use, depicts that even in the absence of legal requirement voluntary action is taken. This is positive, but it's unknown whether this reflects the institutions handling high risk pathogens and/or chemicals. At the same time, this depicts the need to improve awareness and implement regulations in order to govern potential dual-use risks in research.

A specific European dual-use framework, defining the oversight, monitoring, risk assessment, inspection and mitigation for both biological and chemical research sector, in order to prevent misuse of knowledge, information, methods, products or technologies, is currently not in place. The WHO "Global guidance framework for the responsible use of the life sciences" (4) could be a helpful instrument for relevant stakeholders, including governments, as a first step to mitigate potential dual-use risks. A dual-use framework at EU level ought to be developed to both comply with international regulations and documents, and to secure constituents from dual-use related risks mitigation. These gaps and recommendations are in line with the 2019 published report "On the preparation of a biosecurity toolbox to strengthen European biosecurity" (HOME/2019/ISFP/FW/CBRN/0005) (16). The aim of this report was to allow the Commission and Member States to understand current policies of the EU Member States in relation to biosecurity and to evaluate the policies that European Member States should address to mitigate proliferation risks regarding biological materials. The recommendations in this 2019 report focused mainly on biosecurity, but the same conclusions can be draw for the dual-use theme in the biological and chemical research sector as investigated in the current report.

In order to raise awareness on dual-use risk, it is important to conduct outreach activities such as training and education for researchers as well as students in the life sciences. The results of the questionnaire clearly indicate that these activities are largely lacking at both governmental and local level in both sectors. This means that the awareness and knowledge to recognize, signal and act on potential dual-use risks probably is inadequate. Training and education are essential parts in a dual-use framework.

The low number of responses to the questionnaires is probably mainly due to the fact that it was difficult to identify relevant national contact persons and therefore to properly distribute the questionnaires. This was also noted in the 2019 published report "On the preparation of a biosecurity toolbox to strengthen European biosecurity" (HOME/2019/ISFP/FW/CBRN/0005) (16). It was recommended to frequently update the contact list and to stimulate organizational embedding of biosecurity in the EU member states. Based on the responses on the current questionnaire, there still seems to be a lack of coordination and communication between the plethora of national stakeholders within countries, as clear best practices and legislation are largely absent especially at a local level.

Recommendations

- Develop a European platform consisting of experts in the field of biosecurity, chemical security and dual-use with delegates from all EU Member States. This European platform may foster a web of policies, approaches and measures that strengthen biosecurity, chemical security and dual-use within Member States.

The European chemical and biological security platform may facilitate the coordinated development of policies, guidelines and tools required to address the identified gaps in dual-use governance. This requires appointing an organization that will be responsible for establishing, hosting and maintaining the platform, in addition to updating information when needed.

Examples of activities that can be initiated by the platform are as follows.

- Keep an up-to-date record of national contact points biosecurity, chemical security and dual-use, either or not combined in on national point of contact, with the aim to facilitate information sharing and support between EU Member States.

- Development of a tool to map all relevant stakeholders in the area of chemical- and biological security in a country, including dual-use. This would help in raising awareness and creating insights into the complexity of the stakeholders arena, supporting commitment from the 'higher decision-making levels', which will be required for strengthening the governance of dual-use.

- Initiate the development of an academic training curriculum for scientists in the life sciences promoting a responsible biological and chemical science research culture. The curriculum should be designed to raise the level of understanding of security aspects in the biological and chemical research sector, including dual-use, and ought to be incorporated into standard educational courses.

- Developed resources, tools and guidelines that need to be easily accessible (e.g. through dedicated digital platform) to all stakeholders in EU Member States.

Limitations (methodological)

Search results of the literature review are restricted by the search strategy, e.g., selection of search terms, the time frame of the search as well as the inherent limitations of only examining open-source literature.

The absence of national contact points for dual-use, either in the biological or chemical sector, resulted in difficulties to identify relevant contact persons and to properly distribute the questionnaire to relevant stakeholders in a country. In additional there was a relatively low response rate across EU-countries and a lack of representativeness. This has an effect on the interpretation and bias of the results. As an example, for the chemical research sector, 21 institutes responded to the questionnaire of which 6 originated from a single country.

The questionnaire was developed with open answer options as well as with pre-defined response options. This could affect the quality of response and subsequently interpretation of the answers.

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Appendix 1: Questionnaire version for governmental organisations: *Biological research sector*

1. DUAL-USE DEFINITION

The definition of Dual-Use may vary between countries, between ministries, between institutes and between disciplines.

1a. Please provide a definition, if available, of Dual-Use in existing legislation and policies.

2. LAWS, REGULATIONS AND NON-BINDING INSTRUMENTS FOR ADDRESSING DUAL-USE

This question concerns the main national laws and regulations, relevant to Dual-Use management in the biological research sector. Include the corresponding authorities, ministries, and departments (Question 2a). Please also include information on complementary measures relevant to the Dual-Use landscape (Question 2b). Please, if possible, provide website details of the corresponding laws.

2a. Are there legally-binding instruments on Dual-Use in your country? What are the primary national laws and regulations on Dual-Use, and their competent authorities in charge of their implementation? If possible, provide hyperlinks to these laws and regulations.

2b. What are the complementary and other laws and regulations on Dual-Use, and additional authorities in charge of their implementation (for example national, subnational, non-governmental, etc.)? If possible provide hyperlinks to these laws and regulations.

2c. Are there national or international non-binding instruments? If possible, provide hyperlinks to these instruments.

2d. Are any new laws and regulations or non-binding instruments (primary or complementary) in preparation for the biological research sector?

3. INTERNATIONAL HEALTH REGULATIONS

This question concerns compliance to the International Health Regulations (IHR) of the WHO. The IHR are an instrument of international law that is legally-binding on 196 countries providing an overarching legal framework that defines countries' rights and obligations in handling public health events and emergencies that have the potential to cross borders. The Joint External Evaluation (JEE) is a voluntary, collaborative, multisectoral process to comprehensively assess country capacity to prevent, detect and rapidly respond to public health risks in the framework of the IHR. The JEE helps countries identify their most critical gaps within their human and animal health systems. There are two phases of the JEE, which are 1) the initial self-evaluation by your own country, followed by 2) the in-country evaluation conducted by an external evaluation team of subject matter experts.

3a. Has your country conducted the initial self-evaluation? When were these steps carried out?

3b. Has your country conducted the in-country evaluation by an external evaluation team of subject matter experts? When were these steps carried out?

3c. If no to one or both of these steps, are any of these steps currently being planned?

4. SPECIFIC IMPLEMENTION MEASURES AND REQUIREMENTS

4.1 Dual-Use Oversight System

Oversight. Supervision by competent authorities achieved through authorisation processes, i.e. requirements and procedures for obtaining licenses, permits or other types of authorisations, as well as through a program of inspection and monitoring (submission of reports by authorised entities, notifications and similar) that is designed to ensure that the activity is conducted in line with the applicable laws, regulations and any applicable conditions of an issued authorization.

4.1a. Is there a licensing system (national or legal entity) in place for Dual-Use activities? Please provide information on this system for Dual-Use activities.

4.1b. Is there a licensing system (national or legal entity) in place for biologicals (pathogens, GMOs, synthetic biology)? Please provide information on this system for biologicals (pathogens, GMOs, synthetic biology).

4.1c. Does your country require organisations to have a system in place to detect dual-use risks in research? Please shortly describe this system how it functions.

4.2 Monitoring and Risk Assessment

4.2a. Does your country impose/recommend dual-use risk-benefit assessment and risk mitigation?

4.2b. Is there a requirement (legally or non-legally binding) in your country to have a Biorisk Management Advisor that oversees Dual-Use research and/or performs Dual-Use risk assessments?

4.2c. Does your country require organisations to have a local committee monitoring potential Dual-Use research and/or performing risk assessments of Dual-Use research? Please provide information on the requirements for this committee (focus of work, members, etc).

4.2d. Are there national specific approaches or requirements for risk assessments, for example Dual-Use approval? Please provide information on these national specific approaches or requirements for risk assessments.

4.2e. Are the risk assessment reports on Dual-Use of organisations available?

4.3 Inspection Scheme

These questions concern requirements both at a national level (by the dedicated national authority) and at a local level (e.g. biosafety officer). This question concerns requirements both at a national level (by the dedicated national authority) and at a local level (e.g. biosafety officer).

4.3a. What are the national approaches regarding inspections (governmental) or audits (non-governmental body) for Dual-Use?

4.3b. Are inspection reports available?

4.4 Personnel Security Requirements

These questions concern requirements imposed at a national level.

4.4a. Does your country require organisations to have security requirements in place for personnel handling biologicals (pathogens, GMOs, synthetic biology)? Please explain and provide additional information.

4.4b. Does your country require that (i) researchers and laboratory staff handling biologicals, and/or (ii) new staff, students or visitors handling biologicals, and/or (iii) other staff, students or visitors are screened/assessed for possible dual-use concerns (mental condition, personal situation etc.)? Please explain and provide additional information.

4.5 Outreach and Awareness Initiatives

These questions aim to capture the variety and range of training, outreach and awareness initiatives that can come from either the public or private sector, or some combination of the two.

4.5a. Are there national Dual-Use awareness or training programs in place for researchers and laboratory staff? Please elaborate on frequency, kind of personnel being trained, monitoring on trained staff, etc.

4.5b. Do you have national Dual-Use awareness or training programs in place for students? Please elaborate on frequency, kind of personnel being trained, monitoring on trained staff, etc.

4.5c What are the various training, outreach and awareness initiatives on Dual-Use (those not otherwise captured above)?

5. ADDITIONAL INFORMATION

These questions concern other relevant information regarding Dual-Use, for example on political will, sustainability, (structural) budget.

5a. Is there structural funding in your country (national or subnational level) to specifically address Dual-Use aspects (assessment, mitigation, inspection, awareness)? Please explain and provide additional information.

5b. Are Dual-Use aspects considered an important issue at the political level in your country? Please explain and provide additional information.

5c. Are there any other issues regarding Dual-Use technology and research in your country that you would like to mention?

Appendix 2: Questionnaire version for governmental organisations: *Chemical research sector*

1. DUAL-USE DEFINITION

The definition of Dual-Use may vary between countries, between ministries, between institutes and between disciplines.

1a. Please provide a definition, if available, of Dual-Use in existing legislation and policies.

2. LAWS, REGULATIONS AND NON-BINDING INSTRUMENTS FOR ADDRESSING DUAL-USE

This question concerns the main national laws and regulations, relevant to Dual-Use management in the chemical research sector. Include the corresponding authorities, ministries, and departments (Question 2a). Please also include information on complementary measures relevant to the Dual-Use landscape (Question 2b). Please, if possible, provide website details of the corresponding laws.

2a. Are there legally-binding instruments on Dual-Use in your country? What are the primary national laws and regulations on Dual-Use, and their competent authorities in charge of their implementation? If possible, provide hyperlinks to these laws and regulations.

2b. What are the complementary and other laws and regulations on Dual-Use, and additional authorities in charge of their implementation (for example national, subnational, non-governmental, etc.)? If possible provide hyperlinks to these laws and regulations.

2c. Are there national or international non-binding instruments? If possible, provide hyperlinks to these instruments.

2d. Are any new laws and regulations or non-binding instruments (primary or complementary) in preparation for the chemical research sector?

3. INTERNATIONAL HEALTH REGULATIONS

This question concerns compliance to the International Health Regulations (IHR) of the WHO. The IHR are an instrument of international law that is legally-binding on 196 countries providing an overarching legal framework that defines countries' rights and obligations in handling public health events and emergencies that have the potential to cross borders. The Joint External Evaluation (JEE) is a voluntary, collaborative, multisectoral process to comprehensively assess country capacity to prevent, detect and rapidly respond to public health risks in the framework of the IHR. The JEE helps countries identify their most critical gaps within their human and animal health systems. There are two phases of the JEE, which are 1) the initial self-evaluation by your own country, followed by 2) the in-country evaluation conducted by an external evaluation team of subject matter experts.

3a. Has your country conducted the initial self-evaluation? When were these steps carried out?

3b. Has your country conducted the in-country evaluation by an external evaluation team of subject matter experts? When were these steps carried out?

3c. If no to one or both of these steps, are any of these steps currently being planned?

4. SPECIFIC IMPLEMENTION MEASURES AND REQUIREMENTS

4.1 Dual-Use Oversight System

4.1a. Is there a licensing system (national or legal entity) in place for Dual-Use activities? Please provide information on this system for Dual-Use activities.

4.1b. Is there a licensing system (national or legal entity) in place for chemicals (toxins and hazardous chemicals)? Please provide information on this system for chemicals (toxins and hazardous chemicals).

4.1c. Does your country require organisations to have a system in place to detect dual-use risks in research? Please shortly describe this system how it functions.

4.2 Monitoring and Risk Assessment

4.2a. Does your country impose/recommend dual-use risk-benefit assessment and risk mitigation?

4.2b. Is there a requirement (legally or non-legally binding) in your country to have a Chemical Risk Management Advisor that oversees Dual-Use research and/or performs Dual-Use risk assessments?

4.2c. Does your country require organisations to have a local committee monitoring potential Dual-Use research and/or performing risk assessments of Dual-Use research? Please provide information on the requirements for this committee (focus of work, members, etc).

4.2d. Are there national specific approaches or requirements for risk assessments, for example Dual-Use approval? Please provide information on these national specific approaches or requirements for risk assessments.

4.2e. Are the risk assessment reports on Dual-Use of organisations available?

4.3 Inspection Scheme

These questions concern requirements both at a national level (by the dedicated national authority) and at a local level (e.g. biosafety officer). This question concerns requirements both at a national level (by the dedicated national authority) and at a local level (e.g. biosafety officer).

4.3a. What are the national approaches regarding inspections (governmental) or audits (non-governmental body) for Dual-Use?

4.3b. Are inspection reports available?

4.4 Personnel Security Requirements

These questions concern requirements imposed at a national level.

4.4a. Does your country require organisations to have security requirements in place for personnel handling chemicals (toxins and hazardous chemicals)? Please explain and provide additional information.

4.4b. Does your country require that (i) researchers and laboratory staff handling chemicals, and/or (ii) new staff, students or visitors handling chemicals, and/or (iii) other staff, students or visitors are screened/assessed for possible dual-use concerns (mental condition, personal situation etc.)? Please explain and provide additional information.

4.5 Outreach and Awareness Initiatives

These questions aim to capture the variety and range of training, outreach and awareness initiatives that can come from either the public or private sector, or some combination of the two.

4.5a. Are there national Dual-Use awareness or training programs in place for researchers and laboratory staff? Please elaborate on frequency, kind of personnel being trained, monitoring on trained staff, etc.

4.5b. Do you have national Dual-Use awareness or training programs in place for students? Please elaborate on frequency, kind of personnel being trained, monitoring on trained staff, etc.

4.5c What are the various training, outreach and awareness initiatives on Dual-Use (those not otherwise captured above)?

5. ADDITIONAL INFORMATION

These questions concern other relevant information regarding Dual-Use, for example on political will, sustainability, (structural) budget.

5a. Is there structural funding in your country (national or subnational level) to specifically address Dual-Use aspects (assessment, mitigation, inspection, awareness)? Please explain and provide additional information.

5b. Are Dual-Use aspects considered an important issue at the political level in your country? Please explain and provide additional information.

5c. Are there any other issues regarding Dual-Use technology and research in your country that you would like to mention?

Appendix 3: Questionnaire version for organisations, universities and research institutes: *Biological research sector*

1. DUAL-USE DEFINITION

The definition of Dual-Use may vary between countries, between ministries, between institutes and between disciplines.

1a. Please provide a definition, if available, of Dual-Use as applied in your organisation.

1b. Is this definition coming from existing legislation and policies? Please provide information on this legislation/policies.

2. LAWS, REGULATIONS AND NON-BINDING INSTRUMENTS FOR ADDRESSING DUAL-USE

This question concerns the main national laws and regulations, related to Dual-Use management in the biological research sector, that are relevant to your organisation.

2a. Are there legally-binding instruments on Dual-Use in your country that are implemented in your organisation? What are the primary national laws and regulations on Dual-Use, and their competent authorities in charge of their implementation? If possible, provide hyperlinks to these laws and regulations.

2b. Are there national or international non-binding instruments on Dual-Use in your country that are implemented in your organisation? What are the national non-binding instruments on Dual-Use? If possible, provide hyperlinks to these instruments.

2c. Does your organisation follow the international standard for biosafety/biosecurity as layed down in ISO35001:2019 (i.e. CEN workshop agreement CWA15793)?

3. SPECIFIC IMPLEMENTION MEASURES AND REQUIREMENTS

3.1 Dual-Use Oversight System

3.1a. Is there a licensing system (national or legal entity) in place for Dual-Use activities? Please provide information on this system for Dual-Use activities.

3.1b. Is there a licensing system (national or legal entity) in place for biologicals (pathogens, GMOs, synthetic biology)? Please provide information on this system for biologicals (pathogens, GMOs, synthetic biology).

3.1c. Does your organisation have a system in place to detect dual-use risks in research? Please provide information on this system to detect dual-use risks in research.

3.2 Monitoring and Risk Assessment

3.2a. Does your organisation perform dual-use risk-benefit assessment and risk mitigation?

3.2b. Does your organisation have a Biorisk Management Advisor that oversees Dual-Use research and/or performs Dual-Use risk assessments?

3.2c. Does your organisation have a local committee monitoring potential Dual-Use research and/or performing risk assessments of Dual-Use research? Please provide information on this committee (focus of work, members, disciplines involved etc).

3.2d. Are there specific approaches or requirements for risk assessments related to Dual-Use? Please provide information on these specific approaches or requirements for risk assessments related to Dual-Use.

3.2e. Are the risk assessment reports on Dual-Use available?

3.3 Inspection Scheme

These questions concern requirements both at a national level (by the dedicated national authority) and at a local level (e.g. biosafety officer).

3.3a. Has your organisation ever had inspections (governmental) or audits (non-governmental body) specifically addressing Dual-Use aspects? Please provide information on these inspections or audits specifically addressing Dual-Use aspects.

3.3b. Are inspection reports available?

3.3c. Are there specific approaches in your organisation related to inspection of Dual-Use aspects (e.g. internal audits)? Please provide information on these specific approaches in your organisation related to inspection of Dual-Use aspects.

3.4 Personnel Security Requirements

3.4a. Are there security requirements for personnel handling biologicals (pathogens, GMOs, synthetic biology)? Please provide information on security requirements for personnel handling biologicals.

3.4b. Are (i) researchers and laboratory staff handling biologicals, and/or (ii) new staff, students or visitors handling biologicals, and/or (iii) other staff, students or visitors screened/assessed for possible dual-use concerns (mental condition, personal situation etc.)? Please explain and provide additional information.

3.4c. Are researchers sufficiently aware that dual-use risks can occur during the research? Please explain and provide additional information.

3.5 Outreach and Awareness Initiatives

These questions aim to capture the variety and range of training, outreach and awareness initiatives that can come from either the public or private sector, or some combination of the two.

3.5a. Do you have Dual-Use awareness or training programs in place for researchers and laboratory staff? Please elaborate on frequency, kind of personnel being trained, monitoring on trained staff, etc.

3.5b. Do you have Dual-Use awareness or training programs in place for students? Please elaborate on frequency, kind of personnel being trained, monitoring on trained staff, etc.

3.5c What are the various training, outreach and awareness initiatives on Dual-Use (those not otherwise captured above)?

4. ADDITIONAL INFORMATION

4a. Is there funding in your organisation to specifically address Dual-Use aspects (assessment, mitigation, inspection, awareness)? Please explain and provide additional information.

4b. Are there any other issues regarding Dual-Use research in your organisation and in your country that you would like to mention?

Appendix 4: Questionnaire version for organisations, universities and research institutes: *Chemical research sector*

1. DUAL-USE DEFINITION

The definition of Dual-Use may vary between countries, between ministries, between institutes and between disciplines.

1a. Please provide a definition, if available, of Dual-Use as applied in your organisation.

1b. Is this definition coming from existing legislation and policies? Please provide information on this legislation/policies.

2. LAWS, REGULATIONS AND NON-BINDING INSTRUMENTS FOR ADDRESSING DUAL-USE

This question concerns the main national laws and regulations, related to Dual-Use management in the chemical research sector, that are relevant to your organisation.

2a. Are there legally-binding instruments on Dual-Use in your country that are implemented in your organisation? What are the primary national laws and regulations on Dual-Use, and their competent authorities in charge of their implementation? If possible, provide hyperlinks to these laws and regulations.

2b. Are there national or international non-binding instruments on Dual-Use in your country that are implemented in your organisation? What are the national non-binding instruments on Dual-Use? If possible, provide hyperlinks to these instruments.

2c. Does your organisation follow the international standard for biosafety/biosecurity as layed down in ISO35001:2019 (i.e. CEN workshop agreement CWA15793)?

3. SPECIFIC IMPLEMENTION MEASURES AND REQUIREMENTS

3.1 Dual-Use Oversight System

3.1a. Is there a licensing system (national or legal entity) in place for Dual-Use activities? Please provide information on this system for Dual-Use activities.

3.1b. Is there a licensing system (national or legal entity) in place for chemicals (toxins and hazardous chemicals)? Please provide information on this system for chemicals (toxins and hazardous chemicals).

3.1c. Does your organisation have a system in place to detect dual-use risks in research? Please provide information on this system to detect dual-use risks in research.

3.2 Monitoring and Risk Assessment

3.2a. Does your organisation perform dual-use risk-benefit assessment and risk mitigation?

3.2b. Does your organisation have a Chemical Risk Management Advisor that oversees Dual-Use research and/or performs Dual-Use risk assessments?

3.2c. Does your organisation have a local committee monitoring potential Dual-Use research and/or performing risk assessments of Dual-Use research? Please provide information on this committee (focus of work, members, disciplines involved etc).

3.2d. Are there specific approaches or requirements for risk assessments related to Dual-Use? Please provide information on these specific approaches or requirements for risk assessments related to Dual-Use.

3.2e. Are the risk assessment reports on Dual-Use available?

3.3 Inspection Scheme

These questions concern requirements both at a national level (by the dedicated national authority) and at a local level (e.g. biosafety officer).

3.3a. Has your organisation ever had inspections (governmental) or audits (non-governmental body) specifically addressing Dual-Use aspects? Please provide information on these inspections or audits specifically addressing Dual-Use aspects.

3.3b. Are inspection reports available?

3.3c. Are there specific approaches in your organisation related to inspection of Dual-Use aspects (e.g. internal audits)? Please provide information on these specific approaches in your organisation related to inspection of Dual-Use aspects.

3.4 Personnel Security Requirements

3.4a. Are there security requirements for personnel handling chemicals (toxins and hazardous chemicals)? Please provide information on security requirements for personnel handling chemicals.

3.4b. Are (i) researchers and laboratory staff handling chemicals, and/or (ii) new staff, students or visitors handling chemicals, and/or (iii) other staff, students or visitors screened/assessed for possible dual-use concerns (mental condition, personal situation etc.)? Please explain and provide additional information.

3.4c. Are researchers sufficiently aware that dual-use risks can occur during the research? Please explain and provide additional information.

3.5 Outreach and Awareness Initiatives

These questions aim to capture the variety and range of training, outreach and awareness initiatives that can come from either the public or private sector, or some combination of the two.

3.5a. Do you have Dual-Use awareness or training programs in place for researchers and laboratory staff? Please elaborate on frequency, kind of personnel being trained, monitoring on trained staff, etc.

3.5b. Do you have Dual-Use awareness or training programs in place for students? Please elaborate on frequency, kind of personnel being trained, monitoring on trained staff, etc.

3.5c What are the various training, outreach and awareness initiatives on Dual-Use (those not otherwise captured above)?

4. ADDITIONAL INFORMATION

4a. Is there funding in your organisation to specifically address Dual-Use aspects (assessment, mitigation, inspection, awareness)? Please explain and provide additional information.

4b. Are there any other issues regarding Dual-Use research in your organisation and in your country that you would like to mention?

Appendix 5: Consulted European countries

The questionnaire has been sent out to the following European countries:

1. Austria
2. Belgium
3. Bulgaria
4. Croatia
5. Cyprus
6. Czechia
7. Denmark
8. Estonia
9. Finland
10. France
11. Germany
12. Greece
13. Hungary
14. Ireland
15. Italy
16. Latvia
17. Lithuania
18. Luxembourg
19. Malta
20. Netherlands
21. Norway
22. Poland
23. Portugal
24. Romania
25. Slovak Republic
26. Slovenia
27. Spain
28. Sweden
29. Switzerland
30. United Kingdom

Appendix 6: Overview of different guidelines and documents on dual-use

Guidelines

WHO - Laboratory biosecurity guidance (2024).

The WHO laboratory biosecurity guidance follows and complements the revision of the Laboratory biosafety manual, fourth edition and provides principles and measures to prevent lapses and incidents throughout the whole value chain of handling high-consequence biological material, technology and information. The document shares global best practice and covers the biosecurity part of the biological risk management lifecycle, starting from collection, transportation, storage and experiment, and in specific context such as every type of biomedical laboratory, research activities, repository and biobank. It also provides key considerations and best practices for institutional, national and international levels, including regulatory oversight (1).

Australia Group - Guidelines, Common Control Lists and Control List Handbooks for chemical and biological trade controls (2024).

The Australia Group is an informal arrangement which aims to allow exporting or transshipping countries to minimise the risk of assisting chemical and biological weapon (CBW) proliferation. The Australia Group List Control List Handbook serves as a resource tool describing the framework for effective chemical and biological trade controls. It also provides training materials to enhance the capabilities of enforcement officers to identify dual-use materials and equipment in cargo ships. The handbook covers commodities found on each Common Control List and is divided into two volumes: Volume I - Chemical Weapons-Related Common Control Lists and Volume II - Biological Weapons-Related Common Control Lists (20).

WHO - Global Guidance Framework for the Responsible Use of the Life Sciences: Mitigating Biorisks and Governing Dual-Use Research (2022).

The Global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research (the framework) aims to provide values and principles, tools and mechanisms to support Member States and key stakeholders to mitigate and prevent biorisks and govern dual-use research. The document focuses on how responsible research can contribute to prevent and mitigate dual-use risks and raises awareness about the importance of biorisk management in a One health perspective. The framework is primarily intended for those who have responsibilities in the governance of biorisks, such as policy makers and regulators in charge of developing national policies to harness the potential benefits of the life sciences while constraining their risks. The framework is also directed towards scientists and research institutions, educators, trainers,

project management staff, funding bodies, publishers, editors, security actors, the private sector and all relevant stakeholders that are part of the research life cycle. Mitigating biorisks and governing dual-use research is a shared responsibility (4).

WOAH: Guidelines for Responsible Conduct in Veterinary Research (2021).

The purpose of this guidance is to raise awareness about the dual-use potential of research in veterinary settings, supporting veterinary professionals, researchers and other stakeholders to effectively identify, assess and manage dual-use implications. These guidelines are not prescriptive; they do not provide detailed information on what to do but rather aim at providing thought-provoking impulses and encouraging reflection as countries and institutions work towards implementation of their own dual-use guidelines (21).

EU Regulation (EU) 2021/821.

Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items is intended to prevent exported DU items from being used in weapons, or in machines used for making weapons. The regulation is directly applicable throughout the European Union and may be nationally supplemented. The export control is aimed at items for both civil and military purposes that can be used for the development and production of weapons of mass destruction, including biological weapons. European Union export controls reflect commitments agreed upon in key multilateral export control regimes such as the Australia Group, the Wassenaar Arrangement, the Nuclear Suppliers Group and the Missile Technology Control Regime. This regulation is a main legal basis for controls on DU goods in the European Union and sets out the different types of export licenses and sets out the list of goods concerned. The Regulation is binding in its entirety and directly applicable in all Member States. Article 24 of the Regulation sets up a DU Coordination Group bringing together experts from the Commission and Member States to examine any issue concerning the application of export controls with a view to practically improving their consistency and effectiveness throughout the European Union. The group provides a unique forum for exchange of best practices and information between export control officials and forms the basis of a 'European Union network' of export control agencies (5).

National Academy of Science: Governance of Dual-use Research in the Life Sciences: Advancing Global Consensus on Research Oversight (2018).

Between June 10 and 13, 2018, more than 70 participants from 30 different countries and 5 international organizations took part in an international workshop, The Governance of Dual-use Research in the Life Sciences: Advancing Global Consensus on Research Oversight, to promote global dialogue and increased common understandings of the essential elements of governance for such research. Hosted by the Croatian Academy of Sciences and Arts in Zagreb, Croatia, the workshop was a collaboration among the

InterAcademy Partnership, the Croatian Academy, the Croatian Society for Biosafety and Biosecurity, and the U.S. National Academies of Sciences, Engineering, and Medicine. This publication summarizes the presentations and discussions from the workshop (22).

USA: Tools for the Identification, Assessment, Management, and Responsible Communication of Dual-use Research of Concern. A Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual-use Research of Concern (2014).

This Companion Guide comprises a set of tools designed for institutions, principal investigators (PIs), and institutional review entities (IREs) implementing the Policy for Institutional DURC Oversight. However, it is anticipated that much of the guidance embedded in these tools, such as the identification of DURC, risk-benefit assessments, and developing risk mitigation strategies, may also be helpful for Federal agencies in the implementation of the March 2012 DURC Policy. Such guidance may also be applied more broadly to research that is not within the scope of these policies but that may warrant review for dual-use potential and special oversight, and it may be used by others within the scientific community (e.g., journal editors) that are not subject to these policies (23).

EU: A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research (2010).

7th Framework Programme for Research and Technology (European Commission 2013, 18 f.): "A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in European Union funded research": DU is given specific mention in the awarding of research and innovation funding. The strategy outlines the roles and expectations of researchers who apply for funding; the European Union Commission and its subsidiary institutions; the European Union ethics screeners, reviewers and auditors; and the researcher, national contact points, and host institutions. Researchers are to include an assessment of their project for misuse potential and a strategy for safeguards to minimize it, and are assigned responsibility to safeguard their research against risks to society.

The following Report titled "A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research" is based on discussions among 51 Ethics Experts with previous experience in EU Ethics Screening, Review and Audit and was chaired by Johannes Rath. The discussions took place from December 2009 to March 2010 via the SINAPSE system and concluded that: Research misconduct and potential misuse constitute an ethical issue in the context of EU funded research and should be systematically addressed in EU Ethic's oversight (Screening, Review and Audit) (24).

Code of conducts

The Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists (2021).

To promote a culture of responsibility and guard against such misuse, all scientists, research institutions, and governments are encouraged to incorporate elements from the Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists in their national and institutional practices, protocols, and regulations. The ultimate aim is to prevent misuse of bioscience research without hindering beneficial outcomes, in accordance with the articles and norms of the Biological and Toxin Weapons Convention (BWC), and in advancement of progress towards achieving the UN Sustainable Development Goal (25).

RKI - Dual-use Potential of Life Sciences Research: Code of Conduct for Risk Assessment and Risk Mitigation (2013).

This resource is the Robert Koch Institute's (RKI's) Code of Conduct for assessing and mitigating the dual-use potential of research conducted at the RKI. Dual-use potential refers to the potential for certain life sciences research to both contribute to the improvement of society and to potentially be misapplied to the detriment of society and the environment. The RKI aimed to establish a code of conduct that would both preserve the freedom of its researchers while preventing the distribution of data and findings that could harm society or the environment. This code of conduct outlines basic principles for preventing and minimizing dual-use risks, criteria for assessing the dual-use potential of research, a process for evaluating the dual-use potential of research projects, steps for assessing and managing risk, and guidance for developing awareness of the dual-use problem at institutions. We have included this resource in the library to provide institutional officials with an example of an institutional code of conduct for minimizing risk in life science research (27).

KNAW: Code of Conduct for Biosecurity (2007).

This Dutch code of conduct has been developed by the Royal Netherlands Academy of Arts and Sciences (KNAW) and is first known code to set rules to prevent life sciences research or its application from contributing to the misuse of biological agents. These rules apply to a variety of roles and organizations, and organizations may tailor the implementation of those rules to best fit their institution. It raises awareness among professionals in the life sciences of the possible risks of misuse of knowledge from life sciences research. The code of conduct is intended for organisations, institutes and companies that work or deal with high-risk biological agents (28).

Other online overview resources

Biosecurity Central.

Biosecurity Central is a publicly available web-based library that helps users find relevant and reliable sources of information for key areas of biosecurity. The site aims to widely disseminate and share knowledge to help advance biosafety and biosecurity. The library is a searchable and filterable database designed to enable ready access to biosafety and biosecurity resources from around the globe, published by governmental, international, and non-governmental organizations (https://biosecuritycentral.org/). (14)

EBRF Biosecurity Resource Toolbox.

The Biosecurity Resource Toolbox contains 60 resources, of which 27 are related to Biosecurity only, 23 to Biosecurity in combination with Biosafety, and 10 that are related to aspects of dual-use. The type of resources available in the toolbox include interactive tools to mitigate insider threats at strategic and sensitive industries, checklists for the identification of vulnerabilities for strategic industries that house CBRN and dual-use items, and documents related to legislation, guidelines, and best practices concerning biosecurity. The toolbox was created as part of EU project "The preparation of a biosecurity toolbox to strengthen European Biosecurity" with financial support from the European Commission—Directorate General Home Affairs (HOME/2019/ISFP/FW/CBRN/0005 under Framework contract HOME/2014/ISFP/PR/CBRN/0025-Lot 1). (https://ebrf.eu/toolbox.html) (29)

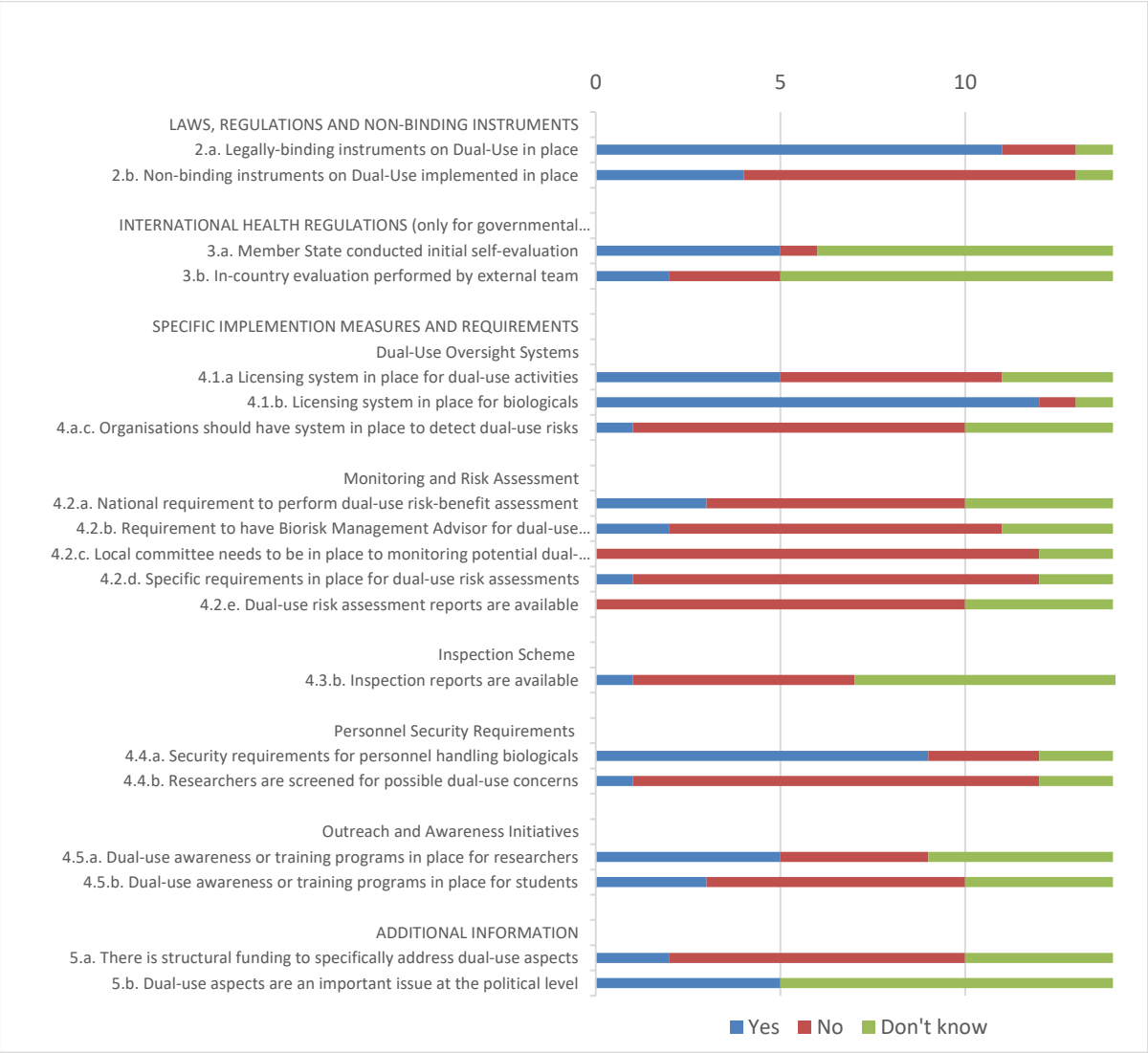
IEGBBR Compendium of International Oversight Systems of Dual-Use (DU) in Life Sciences in IEGBBR Countries (2022).

This review aims to provide an overview of regulatory and non-regulatory oversight, governance frameworks and other measures related to the oversight of DU issues and concerns in the life sciences among the eleven IEGBBR member countries. Categorization of the DU oversight approaches within the review in some cases becomes artificial or contrived, because most of the oversight systems in IEGBBR countries encompass aspects from multiple oversight streams and are highly interwoven. In many cases, the approaches do not fully lend themselves to being compartmentalized in such a way. Nevertheless, the compartmentalization and differentiation of the oversight approaches is done for the purpose of presenting the information in as organized a manner as is possible, as well as to highlight important elements of DU oversight. In compiling and highlighting the approaches for the oversight of DU in IEGBBR countries, the goal is to also provide a description of the spectrum of oversight systems that exist in the IEGBBR countries, in order to understand the international trends in DU oversight. This IEGBBR reference tool can be used by countries that aim to develop or strengthen their national biosafety and biosecurity policies and capacities. It can remove the necessity for extensive legwork prior to the

development and implementation of oversight in countries with an identified need. (https://iegbbr.org/tools.html) (30)

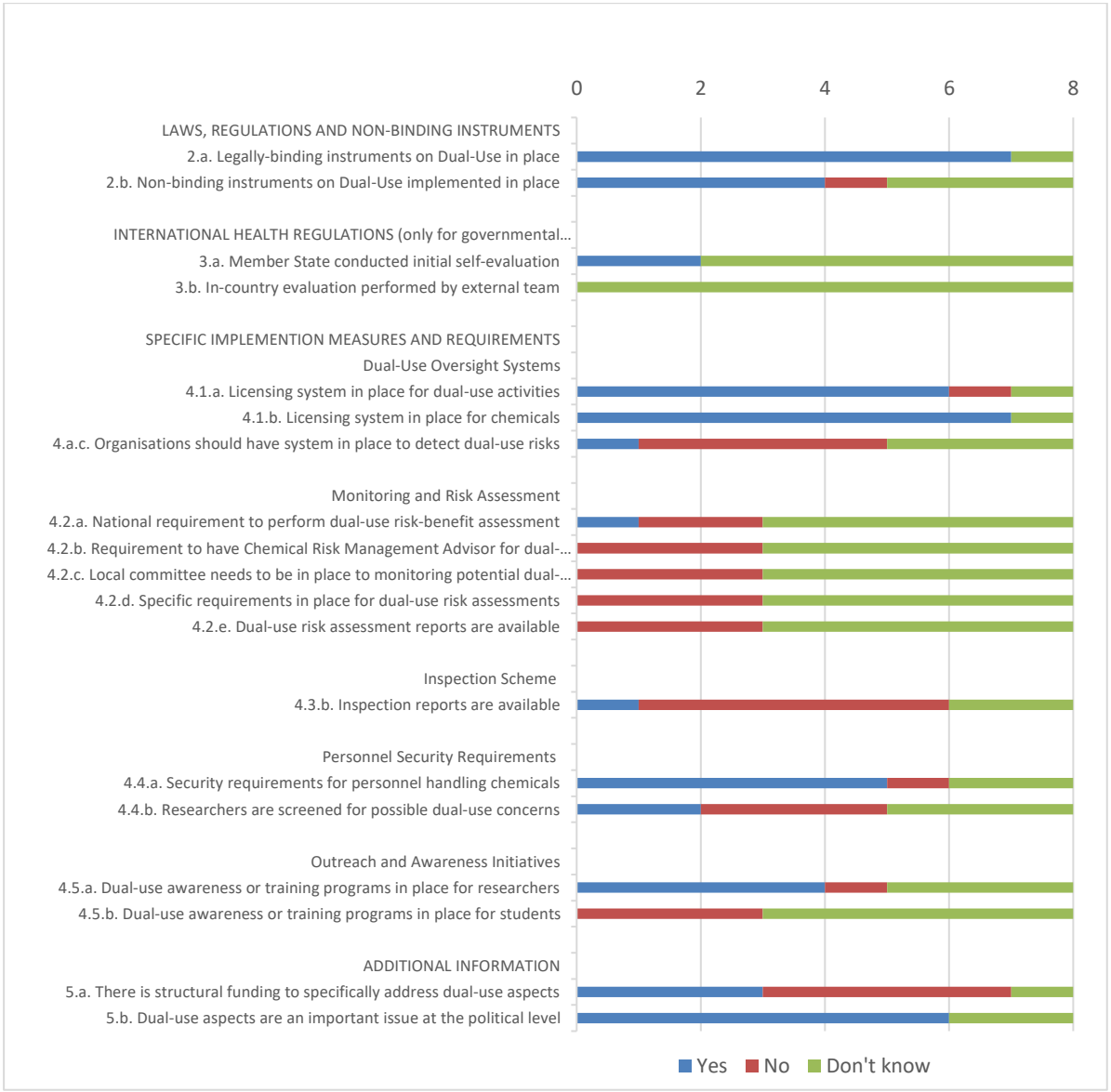
Appendix 7: Results questionnaire version for governmental organisations: *Biological research sector*

In the questionnaire there are some closed and open questions. In this graph only the results of the closed questions are depicted. Responses are collected from all responding governmental organisations in the biological research sector. In total 14 of 30 member states have responded.



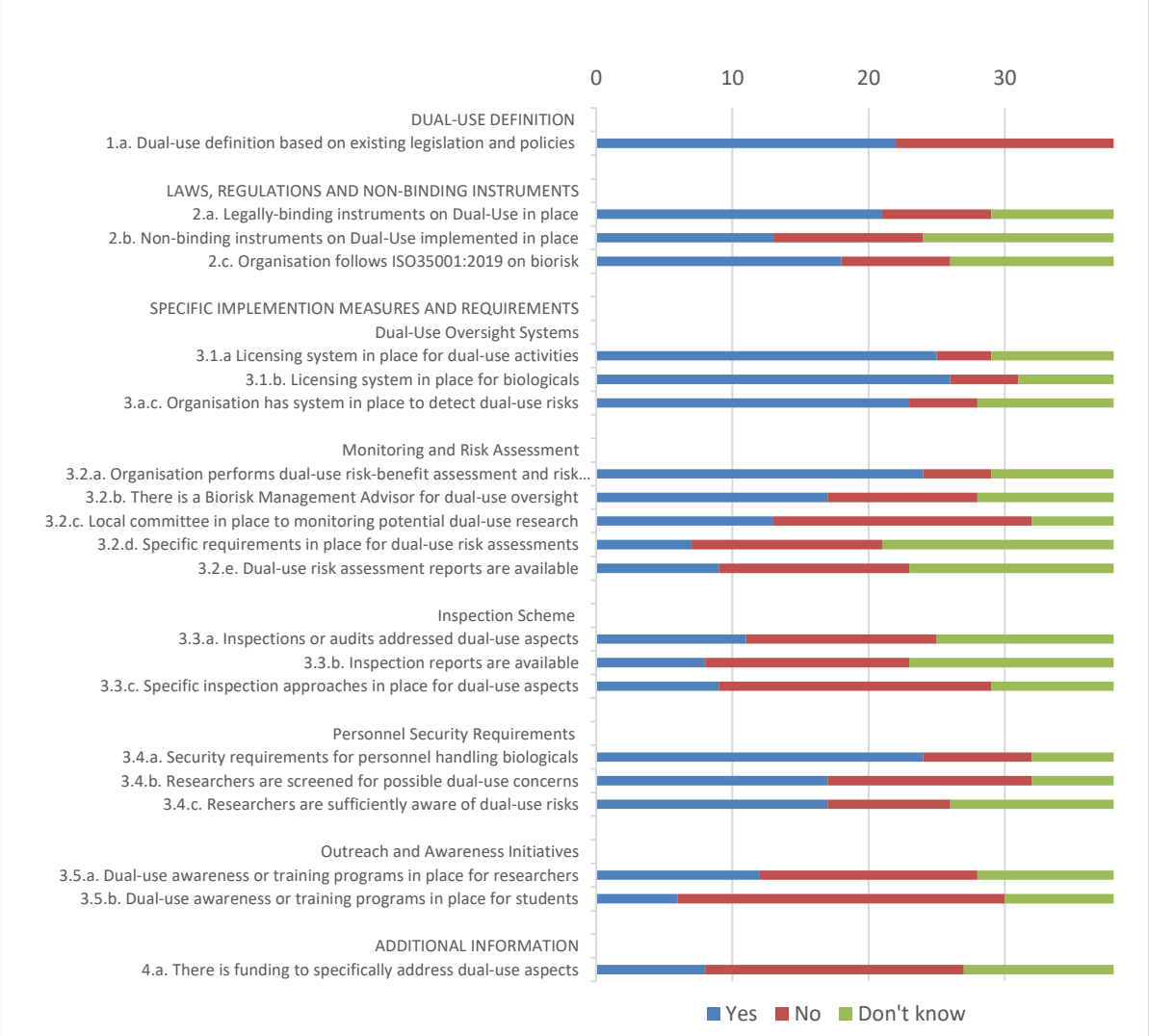
Appendix 8: Results questionnaire version for governmental organisations: *Chemistry research sector*

In the questionnaire there are some closed and open questions. In this graph only the results of the closed questions are depicted. Responses are collected from all responding governmental organisations in the chemical research sector. In total 8 of 30 member states have responded.



Appendix 9: Results questionnaire version for organisations, universities and research institutes: *Biological research sector*

In the questionnaire there are some closed and open questions. In this graph only the results of the closed questions are depicted. Responses are collected from all responding organisations, universities and research institutes in the biological research sector regardless their country. It should be noted that of the 38 responses, 16 of them originated from a single country. In total 15 member states have responded.



Appendix 10: Results questionnaire version for organisations, universities and research institutes: *Chemistry research sector*

In the questionnaire there are some closed and open questions. In this graph only the results of the closed questions are depicted. Responses are collected from all responding organisations, universities and research institutes in the chemical research sector regardless their country. It should be noted that of the 21 responses, 6 of them originated from a single country. In total 9 member states have responded.