Gaps in the International Governance of Dual-Use Research of Concern

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1. Introduction

Advances in the life sciences and biotechnology offer many benefits and are already proving powerful tools to address global challenges - helping to prevent and treat disease, enhance manufacturing, and tackle hunger.[1] It can also be used to facilitate the acquisition or use of biological weapons. Whilst to a greater or lesser extent almost all modern biology has some potential for misuse to cause harm, a subset of research may be most readily applied for prohibited purposes.

Some countries, such as the US, have developed national oversight and governance options to identify and manage relevant research. Given the increasingly international nature of modern science, more harmonised international action will ultimately be necessary. Several international processes have engaged with these issues including the Biological Weapons Convention and the World Health Organization. Other organisations which might have engaged, such as UNESCO, seem not to have. This paper reviews what these instruments and institutions have, and have not, accomplished. Original research is then presented to explore possible reasons for this action, or inaction, as well as highlighting how key international partners perceive these issues. The paper concludes with a series of recommendations as to how best to fill existing gaps to build a more coherent international governance framework for dual-use research of concern.

For the purposes of this paper, the term:

- Dual-Use Research (DUR) is used in recognition that the life sciences and biotechnology can be used to cause deliberate harm as well as for beneficial purposes. There is broad recognition, including amongst the scientific community, that “almost all advances in life sciences technology pose potential “dual-use” risks”.[2]
- Dual-Use Research of Concern (DURC) covers "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security”.[3] In other words, it is a subset of research most likely to be applied in the acquisition or use of biological weapons.

1 P. Millett, 5 big impacts of synthetic biology on animal health and global biothreats, Biosecure, 7 July 2015, See: http://bit.ly/1HbE0Fw (last accessed 5 December 2016)

2 US National Academies of Sciences (2006). - Globalization, Biosecurity, and the Future of the Life Sciences. National Academies Press, Washington D.C. Available at: http://www.nap.edu/catalog/11567/globalization-biosecurity-and-the-future-of-the-life-sciences

3 United States, United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern, March 2012, http://osp.od.nih.gov/sites/default/files/resources/United_States_Government_Policy_for_Oversight_of_DURC_FINAL_version_032812_1.pdf

2. Dual Use Research and the Biological Weapons Convention

The Biological Weapons Convention (BWC) might be the logical international forum through which to address DURC. The connection between this international instrument and DURC is not a simple as it might appear. The prohibitions of the BWC do not explicitly cover research activities. Those negotiating the treaty were aware of the dual-use nature of much life science research and, in an effort to avoid having to determine exactly what would (and what would not) be permitted under the treaty, addressed only development and subsequent steps in the acquisition of biological weapons. As a result, the term research rarely appeared in official documents generated by the BWC – a practice continued into this century. For example, the term "research" did not appear in the substantive outcome of the treaty's Fifth Review Conference in 2002.[4] This could complicate discussing both DUR and DURC in this forum.

The BWC has more recently begun to discuss research. For example, the term appeared twice in the substantive outcome of the Sixth Review Conference in 2006. It was used in connection with facilitating the peaceful uses of biology and as part of the mandate of the 2007-2010 work programme.[5] These precedents are important. They clarify that the BWC can address research issues.

Over the following five years, states explored several aspects of research related to DUR and DURC. For example:

> *States Parties recognised the value of being informed about advances in bio-science and bio-technology **research** with the potential of use for purposes prohibited by the Convention and the necessity of strengthening ties with the scientific community*.[6]

The 2008 meetings also clarified that measures to implement the BWC should cover the relevant research:

> *Recognizing the value of developing national frameworks for the oversight of science as part of their efforts to exclude the possibility of biological agents or toxins being used as weapons, States Parties should... ensure that oversight measures are balanced and proportional to the risk, to avoid creating undue restrictions on scientific **research**, development, publication and biotechnology*.

The term 'dual-use' also appeared in the report of the 2008 Meeting of States Parties (perhaps for the first time in this forum). In relation to codes of conduct, States Parties undertook to encourage stakeholders to ensure that codes of conduct require those covered to "be alert to potential misuse of **research**, and assess their own research for **dual-use** potential" and "seek to stay informed of literature, guidance, and requirements related to **dual-use research**".

Perhaps of greatest importance for this paper, in connection with the development of codes of conduct, States Parties undertook to "provide concise, practical guidelines, including criteria to define sensitive

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4 Biological Weapons Convention, Final Document of the Fifth Review Conference, BWC/CONF.V/17, United Nations, Geneva, Switzerland, 2002, www.unog.ch/bwc

5 Biological Weapons Convention, Final Document of the Sixth Review Conference, BWC/CONF.VI/6, United Nations, Geneva, Switzerland, 2006, www.unog.ch/bwc

6 Biological Weapons Convention, Report of the 2008 Meeting of States Parties, BWC/MSP/2008/5, United Nations, Geneva, Switzerland, 12 December 2008, www.unog.ch/bwc

research and identify areas of greatest risk". This is explicit recognition of the concepts underpinning DURC that there is a subset of research more likely to be applied for purposes prohibited by the BWC.

3. DURC and the BWC

The Seventh BWC Review Conference at the end of 2011 concluded as US national efforts were ramped up to consider the publication of the two papers containing the mutations able to confer aerosol transmission in mammals to H5N1. This research prompted the US to develop its policies on DURC and stimulated the creation of the term, as it is being used in this paper.

The BWC began to explicitly address DURC the following year. For example at the Meeting of Experts:

- The US provided details of its national efforts to develop guidance for funding and conducting DURC, as well as for institutional oversight of relevant activities;[7]
- The Russian Federation, although not using the term DURC, identified " the most common biological research areas with dual-use potential", including: research in multidrug resistance and/or resistance to other antimicrobials; research aimed at increasing the pathogenicity of microorganisms; 'Avirulence genes' research; research in selection of strains with altered host specificity and/or high pathogenicity; research in immunity overcoming strains; as well as enabling technologies such as in molecular epidemiology, human genomics, synthetic biology and nanotechnology;[8]
- China identified a number of developments in science and technology that could have implications for prohibited activities, including advances in synthetic biology, genomics, systems biology, as well as enabling technologies such as high-throughput platforms, DNA sequencing, and information technology;[9] and
- Australia identified a number of developments that might assist in activities prohibited by the BWC, with a particular focus on those derived from the convergence of chemistry and biology.[10]

On 17 July 2012, two States Parties, the US and the Netherlands, hosted an event entitled "Dual Use Research of Concern: The H5N1 Controversy and its Implications for Science Governance". Presenters from the two countries detailed national efforts to ensure effective oversight of DURC.[11,12]

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7 United States, Developments in Science and Technology, BWC/MSP/2012/MX/WP.6, United Nations, Geneva, Switzerland, 16 July 2012, www.unog.ch/bwc

8 Russian Federation, Review of global developments in the field of biological sciences and biotechnologies in 2011 2012 that are relevant to the BTWC and have dual-use potential, BWC/MSP/2012/MX/WP.10, United Nations, Geneva, Switzerland, 17 July 2012, www.unog.ch/bwc

9 China, The Effect/Impact of Biotechnology Progress on BWC, BWC/MSP/2012/MX/WP.14, United Nations, Geneva, Switzerland, 18 July 2012, www.unog.ch/bwc

10 Australia, The Convergence of Chemistry and Biology: Implications for the Review of Developments in the Field of Science related to the Convention, BWC/MSP/2012/MX/WP.16, United Nations, Geneva, Switzerland, 20 July 2012, www.unog.ch/bwc

11 L. Kerr, The H5N1 Influenza Controversy: Implications for Science Governance, Presentation made on the margins of the 2012 BWC Meeting of Experts, 5 July 2012, see: http://bit.ly/2h7rjW3 (last accessed 5 December 2016)

12 M. Donker, Dual-use research of Concern and biosecurity in the Netherlands, Presentation made on the margins of the 2012 BWC Meeting of Experts, 5 July 2012, see: http://bit.ly/2gv88W9 (last accessed 5 December 2016)

The Report of the 2012 Meeting of States Parties explicitly used the term DURC - expressing support for "enhanced national oversight of dual use research of concern without hampering the fullest possible exchange of knowledge and technology for peaceful purposes".[13]

The following year, States Parties reiterated the value of increased national oversight of DURC and highlighted the possibility of developing international approaches through "the development of oversight frameworks for dual-use research of concern, involving a broad range of stakeholders at the national and international levels".[14]

States Parties also outlined the role the BWC might play in considering DURC. They recognised the need to "work together to... involve a wide range of national and international stakeholders in discussing responses to dual-use research of concern". This suggests the treaty might act as both a convener to bring together all those with a stake in considering DURC, and a forum for the exchange of national experiences, setting the groundwork for a more harmonised international approach.

In 2014, States Parties identified a series of common understandings on DURC, including areas for further work:

> *Research that is identified as being of dual-use concern is often vitally important to science, public health and agriculture, and its findings often contribute meaningfully to the broader base of knowledge that advances scientific and health objectives. States Parties recognised that identifying research as being of dual-use concern does not, in itself, provide sufficient justification for proscribing or restricting its availability, or for preventing its pursuit. Identifying research as being of dual-use concern does necessitate greater national oversight, and for a collaborative and informed assessment of the potential benefits and risks of the research. States Parties noted the value of addressing associated safety and security risks as well as the possible misuse of research results and products. States Parties also noted the value of continued discussion at future meetings on oversight of dual-use research of concern, including specific approaches to: identifying relevant criteria; assessing both risks and possible benefits; and mitigating identified risks*.[15]

A more detailed overview of relevant national measures for dealing with DURC was included in a synthesis of proposals which was annexed to the report and had been produced by the meeting's Chair but failed to find consensus.

In 2015, there was much less focus on DURC – the annual report only captured that the issue had been discussed rather than identifying any new common understandings.[16]

DURC also played a minimal role at the BWC's Eighth Review Conference. The term was not used in

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13 Biological Weapons Convention, Report of the 2012 Meeting of States Parties, BWC/MSP/2012/5, United Nations, Geneva, Switzerland, 19 December 2012, www.unog.ch/bwc

14 Biological Weapons Convention, Report of the 2013 Meeting of States Parties, BWC/MSP/2013/5, United Nations, Geneva, Switzerland, 24 December 2013, www.unog.ch/bwc

15 Biological Weapons Convention, Report of the 2014 Meeting of States Parties, BWC/MSP/2014/5, United Nations, Geneva, Switzerland, 15 December 2014, www.unog.ch/bwc

16 Biological Weapons Convention, Report of the 2015 Meeting of States Parties, BWC/MSP/2015/6, United Nations, Geneva, Switzerland, 22 February 2016, www.unog.ch/bwc

any statement made during the meeting's general debate. Neither the term nor the concept were included in its Final Document.[17]

4. DURC and the WHO

Building on its central role in reviewing the two H5N1 gain-of-function papers early in 2012, the WHO announced its intention to hold an informal consultation on DURC.[18] The consultation was held from 26-28 February 2013 in Geneva, Switzerland.[19] The meeting identified key issues and concerns related to DURC, existing management approaches and gaps to address such concerns, explored possible actions and mechanisms to address the gaps.

Key findings of the consultations included:

- "DURC is an issue for all countries. Scientific research is conducted in virtually all countries and is critical to strengthening global response to all health threats and hazards, including those posed by naturally occurring and by accidentally or intentionally released biological agents";

- "The management of DURC-related risks should take into account all stages of the research cycle, from initial conceptualization and development of a proposal, to provision of funding, to conduct of the research, analysis of results, storage and potential use of material results, including modified biological agents, and dissemination of findings";

- "Some countries and institutions have developed oversight mechanisms to manage DURC-related risks. Many, however, have not done so, owing to competing demands on resources and capacity, limited awareness of the issue, or a perception that it is not relevant to their particular context or priorities. Nonetheless, oversight mechanisms which take into account both the benefits of undertaking such research as well as the risks are important";

- "The development of guiding principles, toolkits, best practices and other forms of technical assistance would help countries formulate their own policies and procedures for managing DURC. Although establishment of a legally binding global agreement or regulation is theoretically possible, such an approach would be expensive, slow, likely impractical and would not necessarily yield the desired benefits";

- "Communication and continuing dialogue across a broad range of sectors and stakeholders are essential to create a culture of responsibility, cooperation and trust. In particular, improving mutual understanding of the various approaches to risk identification and assessment among stakeholders will be critical to establishing that dialogue"; and

- "Awareness-raising, education and training on biosafety, biosecurity and DURC are essential not only for researchers but also for all sectors and stakeholders".

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17 Biological Weapons Convention, Final Document of the Eighth Review Conference, Advance Version, See: http://bit.ly/2gZQei6 (last accessed 5 December 2016)

18 World Health Organisation, Update 1: WHO activities following the 16-17 February 2012 technical consultation meeting, 29 May 2012, see: http://www.who.int/influenza/human_animal_interface/avian_influenza/h5n1_research/update_20120529/en/

19 World Health Organization, Report of the WHO Informal Consultation on Dual Use Research of Concern, 2013, http://www.who.int/csr/durc/durc_feb2013_full_mtg_report.pdf (last accessed 5 December 2016)

The WHO has not held any additional consultations since 2013, neither has it released any additional documentation, but it has been an active participant in relevant BWC meetings.

5. DURC and UNESCO

Another possible venue for international efforts to address DURC might have been the UN's Educational, Scientific and Cultural Organization (UNESCO), which plays a leading role on key bioethics issues. In this context, DURC might have been framed as a facet of responsible research and innovation.

A simple text search of their website for the phrase "Dual Use Research of Concern" made in December 2016 returned no results.[20] If UNESCO have engaged with this issue, there is no evidence on their website.

Furthermore, UNESCO has not been an active in DURC-related discussions in other fora. For example, according to the official Lists of Participants from BWC meetings UNESCO has not participated since at least the Seventh Review Conference in 2011. No List of Participants for the WHO informal consultation on DURC is available.

6. Understanding DURC in international fora

UNESCO

There are indications that UNESCO is aware of dual-use issues in modern biology.[21] It is unclear why they have not engaged more actively with DURC issues. This is particularly perplexing given that UNESCO houses an active bioethics department that plays a leading role in norm-setting in other areas of science policy. It is possible that a lack of funding for work on DURC prompted the organisation to prioritise work in other (funded) areas. There have, however, been signs of broader disagreements on how best to apply bioethics principles in similar areas. For example, decade long efforts to develop a code of ethics for scientists seem to have stalled.[22]

WHO

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20 The UNESCO website was searched using its own Google-powered search engine for the terms "dual use research of concern", "dual-use research of concern", and "DURC". The first two resulted in no returns. The last term had two returns, one resulted from OCR errors misreading words with the letters "dure" in them, the other included an email address that included the term "DURC" but there was no contextual evidence with was connected to issues relevant to this paper. A subsequent open search for all the terms "dual", "use", "research", and "concern", as expected, resulted in multiple returns (1,340 results). A review of the top 50 results identified three links of interest: a proposal to revise the 1974 Recommendation on the Status of Scientific Researchers to include the "improper use of scientific research" with an explicit reference to "dual use for terroristic purposes" (http://bit.ly/2gZrPqj); a presentation on neuroethics that highlighted European Union funding requirements for dual-use science (http://portal.unesco.org/shs/en/files/10965/11818113201Neuroethics_-_Tandon.pdf/Neuroethics+-+Tandon.pdf): and an interview with a leading scientist from Pakistan, who discussed education outreach on dual-use issues for young scientists (http://en.unesco.org/news/zabta-khan-shinwari-ignoring-science-most-unethical-attitude).

21 UNESCO, 21st Session of the International Bioethics Committee, United Nations Educational, Scientific and Cultural Organization, France, September 2014, http://bit.ly/2gZrPqj

22 S. Scholtze, Setting standards for scientists: For almost ten years, COMEST has advised UNESCO on the formulation of ethical guidelines, EMBO Rep. 2006 Jul; 7(Spec No): S65–S67, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1490296/

WHO's reasoning for engaging with DURC issues is more evident. They were already playing a leading role in efforts to address safety and security concerns around gain-of-function research that led to the creation of the DURC concept. Furthermore, the outcome of those discussions could have impeded public health research and development. It might also have impacted the hard-won and recently negotiated Pandemic Influenza Preparedness framework, which included sensitive discussions over access to the benefits derived from sharing samples of pathogens, including research results.

As a result of their role in considering the two original gain-of-function research papers, WHO was mandated to facilitate a broader discussion on the ethical, societal, scientific, security and safety implications of DURC. Having participated in the resulting consultation, the author recalls a lack of diversity of WHO Member States supporting further work in this area. It is possible that a clearer, more broad-based expression of support for work on DURC, ideally through an explicit mandate from the World Health Assembly, might reinvigorate WHO's efforts.

BWC

There are also indications that DURC discussions in the BWC were hampered by too narrow a support for the issue. Whilst the general concept that some DUR might be more likely than others to applied for purposes prohibited by the BWC, the term is rarely used by any country other than the US. It is also noteworthy that efforts to capture more detailed understandings on DURC did not command consensus, even when technical material was fed into the decision-making process.

The BWC's efforts to consider DURC, which were also productive between 2012-2014 now seem to have stalled. This might be in part because, in general, states began to prepare for the review conference - spending less time focusing on technical discussions and refocusing their efforts on broader strategic policy issues. If proximity to the review conference was responsible for a shift in focus, one would expect that DURC would have been raised once again during the general debate, as were other issues where further work was being prioritised, such as in strengthening the treaty's science advice processes. There was no mention of DURC. This suggests that there are other explanations.

Other states seem to have concerns as to the possible objectives of focusing on DURC. For example, the opening statement made by the Group of the Non-Aligned Movement and other States Parties, despite the potential for certain developments in science and technology to be used for purposes prohibited by the BWC, highlighted "the importance of facilitating the fullest possible exchange of relevant technologies".[23] Such a position is to be expected given the groups traditional support for facilitating the peaceful uses of biology and biotechnology. Whilst the dual-use nature of modern life science and biotechnology has been accepted, there is still resistance to taking actions to address these risks, especially if it might limit access to any resources.

Understanding the rationale behind focusing on the free movement of knowledge and technologies during discussions over how best to prevent those same resources being misapplied in the pursuit of biological weapons is important for understanding other countries' views on DURC. Additional information as to what concerns are motivating such statements was provided in the statements made by Brazil, India, Iran and Pakistan.[24,25,26,27]

23 Venezuela, General Statement on behalf of the Non-Aligned Movement and Other States Parties to the BWC, 7 November 2016, http://bit.ly/2gJCnvH (last accessed 5 December 2016)

24 Brazil, General Statement to the 8th Review Conference of the BWC, 7 November 2016, www.unog.ch/bwc (last accessed 7 December 2016)

25 India, General Statement to the 8th Review Conference of the BWC, 7 November 2016, http://bit.ly/2g3MxmE (last accessed 5

Pakistan, for example, noted:

> *We firmly believe that the potential dual-use nature of emerging technologies in itself should not be used as a pretext for proscribing or restricting their availability to developing countries for permitted purposes*.

The specific countries making such statements also provides useful information. Whilst some countries might have political motivations, others, such as India, are poised to become members of precisely the technology control regimes likely to be used to limit access to DURC (if these concerns were well founded). As a result, not only would they be unlikely to be denied access but asking such statements could undermine their efforts to join these groups by questioning their commitment to non-proliferation. This suggests that in least some cases, there could be substantive, as opposed to politically-motivated concerns.

Some countries, therefore, seem to be genuinely sceptical of the motivations behind efforts to address DURC, suspecting it might be an attempt to impose blanket restrictions over the movement of goods and knowledge important for development, agriculture, health and the bioeconomy. Overcoming these concerns, and demonstrating the benign nature of interest in DURC will likely require dedicated and sustained outreach. It will be increasingly important have to explore collectively how to make mutually reinforcing efforts to build capacity to deal with disease and efforts to govern the resources that might be used in pursuit of biological weapons.

7. National views on DURC in countries other than the US

In addition to statements and documents submitted to the BWC, there are a number of initiatives, reports, publications and guidance that have provided insights into how issues around DURC are seen elsewhere in the world (Annex). A review of this material quickly highlights the diversity of opinion around the world on DURC. Some states find a DURC-based approach useful. Some seem to prefer to focus on broader DUR issues. Most do not seem to have a view on DURC at all. In general, there is a paucity of DURC-specific information in the literature. Where views are expressed, they tend to originate from academia and their impact on national decision-making is unclear. As a result, a simple literature review did not provide sufficient insights into international views on DURC.

To supplement the existing knowledge base, the author circulated a DURC-specific questionnaire to national technical experts from key BWC delegations.[28] Although experts provided information in a personal capacity, all of the individuals participating were involved in national decision-making and were well placed to be able to reflect national thinking.[29]

December 2016)

26 Iran, General Statement to the 8th Review Conference of the BWC, 8 November 2016, http://bit.ly/2g3MxmE (last accessed 5 December 2016)

27 Pakistan, General Statement to the 8th Review Conference of the BWC, 7 November 2016, http://bit.ly/2g3LCTf (last accessed 5 December 2016)

28 Questionnaires were provided to national technical experts from: Australia, Belgium, Canada, Finland, France, Georgia, Germany, Hungary, India, Indonesia, Ireland, Italy, Japan, Kenya, Liberia, Malaysia, Mali, Mexico, Netherlands, Norway, Pakistan, Portugal, Russia, Sierra Leone, Spain, Switzerland, Ukraine, and the United Kingdom.

29 The views expressed by the experts questioned were provided in an individual capacity and do not necessarily represent views of their countries.

Of the 28 delegations approached, eight replied. This provides valuable new insights into international views of DURC. Whilst such a low return rate is not unusual, it might be indicative of how DURC is viewed (or more accurately not viewed) elsewhere in the world. Almost all of the information obtained came from Europe and North America. Only one reply came from Asia and none from Africa. This conforms to general perceptions that biosecurity is viewed as a lower priority in many developing countries than in developed countries.

<u>On the scope of DURC</u>

- A Portuguese expert suggested that DURC was more readily translated into concrete governance frameworks than broader efforts to consider DUR, as it was easier to define relevant research.
- Experts from other countries also saw addressing DURC as a useful approach, for example, those from the UK felt:

  > *DURC is a useful concept for recognising and considering the risks for misuse of some DUR (and the benefits), and for oversight and developing strategies to mitigate those risks. It should inform the conduct of science in an ethical and responsible manner, and help scientists to recognise that not everyone is necessarily interested in or motivated by the benevolent or peaceful applications of the research they undertake. Thus, even though the aims of researchers may be entirely benevolent and worthy, in a minority of cases the results of research may assist others who wish to use science to cause harm.*

- An expert from Pakistan suggested "It is important to keep a balance between beneficial scientific technology and responsible security and to assess the risks and benefits of life sciences research
- Experts from other countries saw value in exploring DURC for specific purposes. Swiss experts, for example, thought it was particularly useful for engaging with, and raising awareness amongst, the scientific community. UK experts shared similar views, suggesting that it would make a useful addition to the agendas of scientific meetings and conferences and saw value in professional scientific bodies engaging more proactively with these issues.
- There were other applications some experts felt were less valuable. The Swiss expert suggested DURC might not be suitable for regulatory approaches as DURC was *"*not useful in terms of creating lists (pathogens, experiments) that will never adequately address the dual use problem. Dual use education should be much more than ticking off boxes for peace of mind. Dual use education should be a thinking process of each and every researcher*"*.
- A desire to continue to focus more broadly was also expressed by the UK experts:

  > *…while it is helpful to identify the particular areas of research which are likely to be considered DURC (e.g., gain of function, etc.), it would be undesirable to limit consideration of DURC only to a small subset of life-sciences research on pathogens, with the implication thereby that other types of research do not need to be considered for DU potential*.

- The Swiss expert felt governance efforts should focus on the intent behind the scientific activity rather specific types of research or work with particular pathogens. This was a view shared by an expert from Germany, who suggested that restricting DURC to a subset of pathogens was counter-productive. They felt that DURC was drawing too much focus from broader dual-use

risks.

- One expert from Germany did not think that DURC was a useful concept:

> *Firstly, Article I of the BWC does - explicitly - not address research. Secondly, the BWC defines prohibited activities with regard to the intended purpose. The intended purpose of a final product of research to be prohibited must be development, production, storage, acquisition or retaining of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes. Research itself, even when resulting in a dual use product or technique, is not covered by the BWC if the product is not intended for non-peaceful purposes*.

<u>On the relationship between DUR and DURC</u>

- Two experts from the UK suggested:

> *...dual-use research (DUR) refers to legitimate research undertaken for peaceful purposes that nevertheless produces knowledge or technologies that could be used (or misused) by those seeking to develop or proliferate CBW, or more generally cause harm*.

They continued:

> *DUR may become 'of concern' (i.e., DURC) when, for example: the danger presented by the misapplication of the dual-use knowledge or technology generated significantly outweighs the benevolent or legitimate benefits it brings; and/or, its nature makes it highly likely that it will be malignly applied with significant undesirable consequences. The designation of DUR as DURC may occur at the outset of the research (if its dangerous nature can be reasonably anticipated), or at any subsequent point as knowledge and technology emerges*.

- A similar explanation was provided by an expert from Pakistan:

Dual Use Research is any life sciences research with both good and bad potentials whereas Dual Use Research of Concern refers to the specific portion of life sciences research with more potential for misuse posing a serious threat to public safety or national security. In other words, certain areas of life sciences research have a higher potential for misuse than others.

- In Spain, DURC is framed as an issue for national security and the national technical expert described it as the part of "dual-use research that poses a threat to elements of national security".
- A Canadian expert suggested that rather than being framed as separate issues, that DUR and DURC were part of a spectrum: "I would think that this is a matter of degree. In some spectrum, if the dual-use risks are harsh enough, we would call it DURC". Experts from the Netherlands expressed similar views, indicating "there is no straight line between what is DUR and what is DURC".
- A Portuguese expert highlighted that DURC is an element of DUR and that "DUR is a more generic concept, DURC is more pragmatic and specific".
- A national expert from Switzerland agreed "DUR might encompass most research activities in the life sciences, whereas DURC limits this extremely broad scope of imaginable things to a very small subset. This subset is still dual use in nature".
- A German expert noted that DUR effectively already identified a subset of research that was of

concern for security reasons. As such, they suggested "any line drawn between DUR and DURC is artificial and is a mind-set that is fluctuating with changing perceptions and assessments of risks and threats".

On relevant national measures

- No specific national definition or law, regulations or guidance was identified by experts from Germany, the Netherlands, Pakistan, Spain, Switzerland and Portugal.
  - ➔ In Portugal DURC is related to the biosecurity committees within institutions and informal bottom-up awareness-raising activities.
  - ➔ In Switzerland, an expert felt that DURC was addressed through biosafety and biosecurity measures.
  - ➔ In Pakistan, an expert felt that DURC was addressed through laws and regulations to implement a number of international agreements.
  - ➔ Germany requires all research involving genetic modification to go through a risk assessment and any research involving parts from an organism requiring BSL3 or BSL4 containment needs a specific license.
  - ➔ The Dutch experts indicated that they did not base their oversight efforts around a specific DURC definition and did not specifically differentiate between the two concepts. The Dutch experts also indicated that DURC could be covered by export controls.
- The experts from the UK explained that "apart from existing Health & Safety and GM regulations, and dual-use export control legislation, there are no laws or regulations specific to DURC". They continued:

  > *The approach has primarily focussed on a system of self-governance by the scientific community rather than additional regulations, which it is felt will provide the most effective means of managing risks of misuse. Initiatives by the academic community, Learned Societies and Professional Bodies, nationally and internationally, to provide education, training and awareness of DURC and in promoting responsible research are encouraged.*

  The UK experts concluded "individual research establishments may have local procedures for consideration of the potential for DURC in their research programmes, and local oversight in respect of external publication of research outputs".
- The Canadian expert recognised that "some amount of supervision (government or institutional) is key".

On international consideration of DURC

- Several experts connected DURC with international disarmament, arms control and non-proliferation agreements:
  - ➔ A Spanish expert felt that DURC was already being addressed in international WMD forums (such as the BWC and UNSCR 1540) but that "it may take a lot of time to reach an agreement on what is DURC and what is only dual-use research".
  - ➔ Dutch experts also felt that technical issues "including DURC is subject to the BWC". The UK experts agreed "since DURC is potentially relevant to the proliferation and development of CBW, especially novel and more effective weapons agents, it must be recognised and

considered in relevant international arms control and non-proliferation forums".

➔ An expert from Pakistan highlighted the important role such treaties play in embedding such concepts into national laws and regulations:

> *Conventions such as BWC can play important role in efforts relevant to broad discussions over DURC, incorporation of this concept in the framework of non-proliferation conventions and its integration by the state parties at the national level*.

They advocated for a more active role for the United Nations, which "must play its role in expanding the reach of DURC concept worldwide (UNHCR 1540 could be one example)".

- Dutch experts also highlighted that discussions on DURC were occurring in other forums, including those for biosafety and biosecurity. They noted that related issues "are being discussed within the EBRF (European Biosecurity Regulators Forum), but also in the IEGBBR", the International Expert Group on Biosafety and Biosecurity Regulation.
- An expert from Pakistan noted the work being done in the WHO on these issues and felt that both health and security processes might work together "to harmonize and increase oversight of DURC concept based on integration of emerging technologies with dual use potential. One example of this is CRISPR".
- The Pakistani, Portuguese and UK experts felt a common understanding on the use of DURC concepts would be of valuable and that a much broader discussion would be constructive.
  - ➔ The Portuguese expert suggested that such a discussion "should be based on prospective analysis, qualitative research, science and technology reviews [conducted] on a permanent basis" and include the UN, WHO, OIE, FAO, OPCW, BWC ISU, Academies of Sciences, as well as a more public component involving the media (through both traditional media and online).
  - ➔ The UK experts suggested "international discussions can hopefully provide guiding principles with flexibility to inform and assist national implementation". They noted that international discussions held to date "have identified key issues, sectors and stakeholders, as well as some potential actions that could contribute to dealing with DURC, but have not agreed specific steps to take the issues forward".
  - ➔ An expert from Pakistan felt that "The fast pace of advancement in life sciences linked with rise in Biotechnology and innovations has increased the risk of misuse and degree of unpredictability thus increasing the need for expanding the horizon of DURC".
- Experts from other countries did not think such a common understanding would be useful, noting the context-specific nature of DURC. The Dutch experts indicated "there is no straight line between what is DUR and what is DURC. This depends on many parameters including the pathogen, research set-up, etc.". An expert from Canada suggested that as DURC might "arise in many different fields general guidance might be more useful" than a common understanding (definition) over what DURC covers.
- Experts from several countries suggested that the US definition for DURC would likely have a notable impact on international efforts to consider the most appropriate approaches for addressing DUR issues and could complicate efforts to explore alternative avenues.

<u>Other reflections on DURC</u>

- A Canadian expert stressed the importance of re-framing DURC so that it does not appear to

require a choice between security interests and development interests.

- The expert from Portugal highlighted "a big gap of knowledge about the concept of DURC". They also noted that identifying a specific piece of research as DURC can potentially be counter-productive by increasing the risk of its application for prohibited purposes: "I think there could be problems related with the 'awareness dilemma' when you make people think about dual use when they don't think about it, you multiply the risk of misuse". On balance, the Portuguese expert believed that the benefits offered by wider-scale appreciation of DURC risks outweighed the potential security implications.
- The Portuguese expert also noted that many of the terms used in both DUR and DURC are not readily translated into other languages and cause difficulties in identifying terms that make technical and linguistic sense at the same time.
- An expert from Pakistan suggested that more work is needed to capture the diversity of views on DURC around the world. They suggested:

  > *International conferences could serve the purpose to some extent. Also, awareness surveys in collaboration with important international organizations and DURC experts in various countries could be a way to capture the opinion of scientific community*.

- The experts from the UK highlighted:

  > *Another factor to consider is the promulgation of the knowledge or technology generated by DURC; since such research is not in and of itself illegal (e.g., the scope of DURC does not include, for example, research deliberately undertaken for offensive CBW development or proliferation purposes, in contravention of the CWC or BTWC), if the promulgation of its outputs to those who may misapply them can be effectively prevented, there may very good reasons why the research should be allowed to proceed – i.e., the 'C' of DURC has been nullified if not removed. Such effective prevention of the promulgation of DURC knowledge or technologies will, of course, only be possible in a small subset of the totality of life sciences and chemistry research undertaken*.

- The UK experts also noted:

  > *To date, the concept of DURC seems to have been applied primarily to the life sciences and in the context of BW, but in our view it is also applicable to chemistry (especially with the convergence of chemistry with biology) and indeed probably in most areas of scientific and technological endeavour*.

8. Recommendations

Based upon the analysis of existing efforts and the views of experts from other countries detailed in this paper, there is a need:

1. **For a deliberate and sustained effort to increase the number and diversity of states interested in, and willing to champion DURC issues**. It will be important to establish how development and security are complementary, feeding into a mutually reinforcing cycle, rather than representing a zero sum game where every security gain comes with a development cost. Widespread global investment in the bioeconomy might provide a useful starting point. There is also a need to expand the number of languages being used to discuss DURC and to ensure the existence of sufficient opportunities for technical discussions that could lead to the organic

evolution of the necessary technical terms in other languages.

2. **To revisit the rationale behind addressing DURC.** Whilst US discussions have been protracted and comprehensive, very little has been done elsewhere. The case now needs to be made internationally in such a way that it engenders genuine buy-in, rather than appearing to be a push for the rest of the world to adopt US-developed rules. This would go a long way to addressing suspicions as the motives behind focusing on DURC. In particular it will be important to make a better case for linking DURC to DUR and how dealing with the output of research is a natural extension of the spectrum of measures used to manage biosecurity risks.
3. **For further international discussions on the desirability of dealing with DURC.** Such a process could usefully build on past work but should also address underlying issues, such as whether the benefits from greater awareness of dual-use outweigh risks associated with identifying the potential to misuse specific research to cause harm. Such discussions should be the result of collaboration between the science and security sectors (i.e. be hosted jointly by some or all of the international processes discussed in this paper). An ultimate goal of this process could be to identify specific practical steps for further action to address DURC.
4. **To initiate a broader international consultation on relevant technical issues**, such as:

   ➔ How best to identify what subset of DUR might received greater oversight through DURC governance measures - options for both guidance-based and regulatory approaches will likely need to be explored;

   ➔ Whether concepts of DURC might be expanded for use in other S&T disciplines or policy processes, in particular its potential applicability for chemical weapons; and

   ➔ How to address DURC through existing rules and regulations, highlighting how, for example, existing institutional research committees and outreach and awareness-raising efforts can be expanded to address DURC.

   Given the outcome of these discussions, the US may need to revisit its own approaches and could likely generate valuable buy-in to such discussions by indicating its willingness to do so from the outset

5. **To find DURC issues a natural home in a larger, more sustainable process**. At present, none of the international processes discussed in this paper seem to be ready to perform such a role. Whilst this paper identifies a number of ways in which these fora might be change to make them more suitable hosts for addressing DURC in the longer term, the GHSA might provide a better short to medium term alternative, perhaps through the Prevent 3 action package on Biosafety and Biosecurity.

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ANNEX

Initiatives, reports, publications and guidance that provide insights into how issues around DURC are seen elsewhere in the world[30]

- The September 2013 Wilton Park conference in the UK on Dual-use biology: how to balance open science with security, see: https://www.wiltonpark.org.uk/wp-content/uploads/WP1260-Report.pdf and the speech given by the UK's chief scientific advisor, see: https://www.gov.uk/government/speeches/dual-use-biology-how-to-balance-open-science-with-security
- The December 2013 report of the Biosecurity Committee of the Royal Netherlands Academy of Arts and Sciences, to provide advice to the Dutch government on the oversight of dual-use life science research, see https://www.knaw.nl/shared/resources/actueel/publicaties/pdf/advies-biosecurity-engels-web
- The December 2014 Herrenhausen Symposium in Hanover, Germany on Dual Use Research on Microbes: Biosafety, Biosecurity, Responsibility, see: https://www.volkswagenstiftung.de/dualuseresearch.html
- The June 2015 EU-funded Satori report on Principles and Approaches in Ethics Assessment:

Dual-use in research, see: http://satoriproject.eu/media/1.g-Dual-use-in-research.pdf

- The July 2015 BBSRC, MRC and Wellcome Trust position statement on dual use research of concern and research misuse, see: https://wellcome.ac.uk/sites/default/files/wtp059491.pdf
- The November 2015 Nuffield Council on Bioethics background paper on Dual Use in Biology and Biomedicine, see: http://nuffieldbioethics.org/wp-content/uploads/Background-paper-2016-Dual-use.pdf
- The German Society for Virology in cooperation with the German Association for the Control of Viral Diseases have constituted a DURC committee to contribute to ongoing debates around risk-benefit analysis, changes to regulatory regimes and opportunities for self-regulation, see: http://www.g-f-v.org/kommission_durc

30 This list is not intended to be exhaustive but should provide an indication of the type of activities being conducted and illustrate that a range of views on DURC exist.