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THE CONVENTION ON THE PROHIBITION
OF THE DEVELOPMENT, PRODUCTION
AND STOCKPILING OF
BACTERIOLOGICAL (BIOLOGICAL) AND
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Consideration of the content, promulgation, and adoption of codes of conduct for scientists

THE OVERLAP BETWEEN CODES OF CONDUCT AND LEGISLATION

Prepared by Canada

Introduction

- 1. Codes of conduct can take many forms depending upon the purpose to which they are to be put and the ideals of the individuals who are designing them. In some cases, a code is nothing more than a guide to good scientific practices. In other cases, a code can articulate a moral and ethical system that will act as a framework for guiding a researcher's entire professional life. A question that is worth asking, however, is what is the value of having a code if a State already has comprehensive legislation in place. Assuming that the legislation covers all aspects of what is and is not allowed in the field of biotechnology/biological weapons research, then does a code actually add value? A simple repetition of what is in the legislation, while potentially having a reinforcing effect, may not make much of an impact. On the contrary, if the code is seen as being redundant and repetitive, it may actually make people less receptive to other types of codes that do have value. However, if an appropriate niche can be found for codes of conduct, they can serve as both an independent tool and as a way of strengthening the awareness of, and adherence to, national legislation and regulations by the affected communities.
- 2. This paper will briefly examine one possible niche role for a code of conduct, and how this might fit into the Canadian context given Canada's new legislation, the Biological and Toxin Weapons Convention Implementation Act (BTWCIA). In addition, some elements of the codes currently in use in Canada, which are more thoroughly examined in Canadian Working Papers "X", "Y" and "Z", already fit into this niche area, and will be identified. Finally, the role of reinforcing the existing legislation will be discussed in more detail.

Traffic Lights: Codes as Amber Signals

- 3. One interesting way to look at the issue of legislation and codes of conduct is to examine them using an analogy of traffic lights. As will be well known, traffic lights around the world use essentially the same system, green for go, red for stop and amber as a warning that the lights are about to change. Legislation and regulations can be viewed as being akin to a red light. They generally set out quite specific rules of what, and how, one can or cannot do something (ie: one cannot develop, produce...any microbial agent...for any purpose other than prophylactic or other peaceful purposes). A green light in this context cam be seen as freedom to proceed with research. However there are still agreed upon rules of the road that must follow, a situation which is analogous to that of codes of practices for scientific research. While these types of documents generally do not prohibit any particular form of research, they do set guidelines for biosafety and biosecurity, as well as outlining procedures designed to maximize the efficiency of an organization or project. These practices, while often broadly similar, can differ from place to place, and researchers who may transfer to another institution will be obliged to learn and adhere to the practices at a given location.
- The analogy of the amber light is perhaps the most interesting given the function of this 4. particular signal. An amber light does not necessarily oblige one to stop (depending on the situation), but it warns that such an obligation is close at hand. In addition, the function of an amber signal can be dependant upon the situation. In some ways, a code of conduct could be regarded as the equivalent of an amber light. Certain actions that might be constrained under a code of conduct may not actually be illegal in of themselves, but can come very close to crossing that line. Examples of this might include conflicts of interest or the irresponsible dissemination of knowledge, neither of which are directly prohibited under legislation, but can lead in short measure to activity that is in contravention of the laws of the land. In this sense, a code of conduct can act as a warning signal, indicating that an individual should pay particular attention to an activity such that they do not stray into dangerous territory. In addition, the outreach and communication activities that might accompany the promulgation of a code of conduct would serve as a useful tool to inform researchers and students as to the limits of the legislation as well as the risks of other activities that are not necessarily prohibited. Some examples of these strictures in various codes of conduct will be presented below.

Canada's Legislation: The BTWCIA

5. Before examining the "amber" zone in which codes might be particularly useful, it is worth briefly discussing some of the provision inherent in Canada's legislation, primarily the BTWCIA. This Act (Part 23 of Bill C-7) received Royal Assent on May 6, 2004. The BTWCIA was envisioned to be framework legislation, to streamline existing laws which deal peripherally with BW issues, to provide a more complete legal basis for the regulation of dual-use biological agents, and to establish stricter penalties for contraventions of the BTWC. The Act was designed to parallel the BTWC and to function to ensure clear and total Canadian compliance with all aspects of the BTWC as stated in Section 3:

"The purpose of this Act is to fulfil Canada's obligations under the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological

(Biological) and Toxin Weapons and on their Destruction, which entered into force on March 26, 1975, as amended from time to time pursuant to Article XI of that Convention."

- 6. As such, the primary purpose of the BTWCIA is summed up in Section 6 as follows:
 - (1) No person shall develop, produce, retain, stockpile, otherwise acquire or possess, use or transfer
 - (a) any microbial or other biological agent, or any toxin, for any purpose other than prophylactic, protective or other peaceful purposes; or
 - (b) any weapon, equipment or means of delivery designed to use such an agent or toxin for hostile purposes or in armed conflict.
 - (2) For greater certainty, subsection (1) does not prohibit any program or activity carried out or authorized by Canada and specifically designed to protect or defend humans, animals or plants against the use of any microbial or other biological agent or toxin for hostile purposes or in armed conflict, or to detect or assess the impact of such use.
- 7. Note that the word "use" in the Canadian legislation actually goes beyond the prohibition in the BTWC, but encompasses the prohibition contained in the 1925 Geneva Protocol. The language in Section 6 (1) is quite straightforward in the sense that the provisions are all encompassing. Unfortunately, most microbial agents covered by the BTWC/BTWCIA can be described as dual use, and would therefore have legitimate purposes that make it very difficult to draw the line between what is permitted and prohibited under the Act. To achieve this, there needs to be a precise definition of what is deemed a "prophylactic, protective or other peaceful purpose". In the vast majority of cases, this definition will centre on the determination of intent (although carelessness and/or lack of awareness by scientists or companies may also play a role). The obvious difficultly with identifying intent is the fact that if someone is planning to use an agent or equipment in a prescribed fashion, they are unlikely to announce this fact in advance. Intent may be determined by means of identifying discrepancies between what is allowed and what is declared, with the possibility of having inspections to verify that the declarations are in fact complete and accurate.
- 8. Bringing the BTWCIA into force will therefore require a series of actions for implementation including the following:

Establishment of a Responsible Authority

- 9. This requirement has a fair amount of scope for interpretation and is stated in Section 8 of the BTWCIA as follows:
 - "8. (1) The Minister may designate any person or class of persons to be the responsible authority for the purposes of this Act.
 - (2) The Minister may designate persons or classes of persons to act as representatives of the responsible author"

Creation of Lists

10. In order to fulfill the mandate of the BTWCIA, it may be necessary to draft a list of pathogens and equipment that will be implicated in the act. This is elaborated in Section 20 (a), (f) and (g):

"The Governor in Council may, on the recommendation of the Minister and any other Minister who has powers in relation to biological agents or toxins, make regulations

- (a) defining "biological agent", "microbial agent" and "toxin" for the purposes of this Act;...
- (f) for the purposes of section 17, identifying microbial or other biological agents and toxins and related equipment, and specifying anything that is to be specified by the regulations; and
- (g) generally for carrying out the purposes and provisions of the Convention."

Declarations

11. Once agent/equipment lists (as required) have been established, and relevant institutions identified, the BTWCIA requires that declarations be submitted as specified in Section 17:

"Every person who develops, produces, retains, stockpiles, otherwise acquires or possesses, uses, transfers, exports or imports any microbial or other biological agent, any toxin or any related equipment identified in the regulations shall

- (a) provide such information, at such times and in such form, as may be specified by the regulations, to the responsible authority or to any other portion of the public service of Canada specified by the regulations; and
- (b) keep and maintain in Canada the documents specified by the regulations, at the person's place of business or at such other place as may be designated by the Minister, in the manner and for the period that is specified by the regulations and, on request by the Minister or the responsible authority, provide the documents to the responsible authority or to any other portion of the public service of Canada specified by the regulations."

Inspections

- 12. In order verify that these declarations are accurate, and to check discrepancies, an inspectorate may be designated as explained in Sections 9:
 - "9. The Minister may designate persons or classes of persons as inspectors for the purpose of the enforcement of this Act, and set conditions applicable to the person's inspection activities, after consulting any other Minister who has powers in relation to inspections for biological agents or toxins."

Establishment of Penalties

- 13. Penalties are clearly laid out in the legislation for two types of violations:
 - i Actual violation of the BTWC through development, production, retention, stockpiling, acquisition, possession, use or transfer of BW for non-peaceful, prophylactic or defensive reasons. The penalties are stated in Section 14 (1): *Every person who contravenes section 6 or 7 is guilty of an indictable offence and liable on conviction to a fine not exceeding* \$1,000,000 or to imprisonment for a term not exceeding ten years, or to both.
 - ii Interference with the inspectors in their gathering of information as stated in Section 14 (2): Every person who contravenes section 13 or 17, subsection 18(2) or section 19 or any provision of the regulations is guilty of an offence punishable on summary conviction and liable on conviction to a fine not exceeding \$50,000 or to imprisonment for a term not exceeding two years, or to both.
- 14. The penalties section also has a clause dealing with an offence occurring over a prolonged period as elaborated in Section 15:

Where an offence under this Act is committed or continued on more than one day, the person who committed the offence is liable to be convicted for a separate offence for each day on which the offence is committed or continued.

Elements of Codes in Canada Falling Below the BTWCIA

- 15. The basic prohibition in the BTWCIA is quite straightforward. However, there are a number of areas which, while not directly covered under the BTWCIA or other legislation, may nevertheless constitute a potential danger. These could include actions such as the irresponsible transfer of intangible technology, undertaking work where the identifiable risks clearly outweigh any potential benefits, and compromising one's professional integrity either through the use of false data, conflicts of interest or a lack of due diligence. Attempts to legislate all aspects of one's professional life would be impractical both from an enforcement standpoint (to say nothing about its effects on basic civil liberties) as well as from the perspective of creating a climate whereby research could not be conducted in open, collaborative and efficient manner, thus stifling innovation.
- 16. Codes of conduct, however, can have a greater degree of flexibility and can be applied such that their provisions are not imposed, but can act as guidelines and warnings. Some examples of these warning elements from Canadian codes currently in existence are as follows:
 - i *Balancing risks and benefits:* this is critical particularly with regards to human research, but also in a more general sense of deciding whether the gains from a particular project are worth the potential risks associated with the research.
 - ii Avoidance of conflicts of interest: researchers, research subjects, institutions, and professional bodies must maintain an arm's-length relationship with interests that may

- compromise their independence, objectivity or integrity. In particular, oversight bodies must maintain their independence such that their decisions and recommendations are not unduly influenced by political or financial considerations.
- iii *Pre-Approval of research*: several codes, particularly in the academic field, stress the importance of obtaining approval and peer review of research. Without this check, it is possible that a project could veer into unintended or dangerous territory.
- iv Assumption of professional responsibility: the interpretation of this is often left fairly open, but includes keeping oneself informed about current guidelines and avoiding irresponsible or fraudulent research practices, as well as being aware of what the implications of one's research are, and treating the results accordingly.
- 17. A more detailed analysis of Canada's code of conducts is provided in Working Papers XYZ. In addition, Working Paper ABC provides a listing of where the various Canadian codes of conduct can be found on the internet.

Overlap and Compliment

18. In some cases, codes of conduct can either repeat information also found in legislation, or refer directly to the existing body of laws and regulations. This type of overlap, while somewhat redundant, can nevertheless serve an important function as an additional way to inform people about, and reinforce, the norm against biological weapons that exists both domestically and internationally. Explaining a code and having people agree to adhere to its provisions can allow them to be more personally involved than would be the case if they were simply following legislation imposed by the government in Ottawa. In addition, outreach in conjunction with the promulgation of a code of conduct, both in education institutions as well as in places of work, is an important function that can dramatically increase understanding about both the contents and purpose of a code. If done correctly, this will also help to ensure that governmental legislation and regulations are better understood and fully respected. Working Paper DEF will examine some aspects of codes as an educational outreach tool in more detail.

Conclusions

19. Codes of conduct can have a variety of uses depending on the circumstances for which they are designed. There is no necessity or value in creating an artificial niche for the sake of creating a code of conduct, as this simply adds to the "regulatory" burden that researchers must deal with. However, in those areas where legislation may not be able to cover all the cracks, or where particular vigilance with regard to an activity is seen as important, codes of conduct can act as warning signals to researchers that they should be attentive as to the applications and consequences of their research. This feature, combined with the power of codes to help facilitate the spread of information regarding international norms and government policies, make the endeavour to create effective codes all the more worthwhile.