

Fifth session  
Geneva, 16-27 September 1996

Working paper submitted by the Friend of the Chair  
on Definitions of Terms and of Objective Criteria

THRESHOLD QUANTITIES

The Group held preliminary discussions of the potential role of threshold quantities for specific measures designed to strengthen the Convention. Further consideration needs to be given to this. Three initial questions have been identified:

- 1) Whether threshold quantities have any role in such measures;
- 2) If they have, what are their potential uses;
- 3) What technical basis should be used to elaborate any thresholds?

With reference to the first question, views were expressed that the application of threshold limits to the possession of biological agents and toxins is not a useful means to strengthen the Convention and could undermine the provisions of Article I; this would clearly be outside the mandate of the Group. Peaceful quantities of an agent cannot be defined independently of the particular circumstances of the use, which means that fixed thresholds cannot be used. There would be a risk of a threshold for work for defence purposes being used to conceal offensive activities. The application of threshold limits could provide inaccurate impressions of the scale of activities at a facility because the self-replicating nature of microorganisms means that an agent amount at or below a threshold could be exceeded within a matter of hours. Finally, even small quantities of biological agents and toxins could, depending upon their intended purpose, violate the object and purpose of the Convention.

Another view was that the establishment of threshold

quantities of biological agents and toxins is essential for an effective verification regime under the BWC. Such threshold limits could in no way contradict the mandate of the Group, since the mandate specifies that the Group shall, inter alia, consider "definitions of terms and objective criteria, such as lists of bacteriological (biological) agents and toxins, their threshold quantities, (emphasis added).....".

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With reference to the second question, one view suggested that the possibility of establishing thresholds for storage of listed biological agents and toxins should be considered by the Group.

Another view was that there should be threshold quantities for biological materials containing listed agents that can be stored at facilities for the purposes of developing and testing means and methods of protection against BW. These thresholds would not cover quantities that are used in day to day work at these and other facilities that produce immune biological, medical and other preparations. This approach is not meant to limit the scope of Article I of the BWC.

On the third question, as to what technical basis could be used for any threshold, the above proposal for threshold quantities for biological materials stored at facilities for the purposes of protection against BW contains the following method of calculation which takes into account the specific concentration of each agent and its virulence:

- select an agent with the highest virulence (for example, pathogen "X" with  $LD_{50} = 40$  cells);
- take a genuinely achievable concentration of the agent in biological material (for example  $10 \cdot 10^9$  cells/ml);
- take the maximum quantity of biological material which can be held at the facility at one time (for example 5 kg);
- calculate the quantity K of  $LD_{50}$  which can be held at the facility at one time (for example,  $K = 5 \cdot 1000 \cdot (10 \cdot 10^9) / 40 = 1,25 \cdot 10^{12} LD_{50}$ )

In order to determine what is the quantity of another biological material containing another agent, or the same one with a different virulence or a different concentration, that can be held at the facility at one time, it is necessary to insert the actual concentration at  $LD_{50}$  of this agent into the following formula:

$M = K.LD_{50}/C.1000$ , where

M is the quantity of biological material containing the agent of a given virulence and concentration which could be held at the facility at one time (kg):

C is the concentration of the agent (cells/ml).

In this context, the starting values for  $LD_{50}$ , concentrations and quantities must be defined by consensus after careful study. It was also suggested that the proposed approach relates only to the listed biological agents. With regard to toxins, that affect humans and animals, as well as biological

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agents and toxins that affect plants, other methodological approaches may be considered.

Views were expressed that the limited relevance of  $LD_{50}$ s (and  $ID_{50}$ s) underscored the lack of utility of threshold quantities in strengthening the Convention:

- $LD_{50}$  values vary greatly with the affected species and route of administration, and the degree of variation between individuals can also vary. This means that widely different amounts of agent are needed for different types of experimentation. Even greater difficulties would be encountered in using virulence and pathogenicity as indicators because these are relative terms.
- For agents that are primarily incapacitating the use of lethal dose regardless of the calculation mode would provide an inappropriate risk assessment.
- The concept of NOAEL (no adverse effect level) is used widely rather than  $LD_{50}$ . It is currently used for the risk assessment of processes and products in regard to the health of humans, animals, plants and environment.

An opinion was expressed that the issue of establishing thresholds for toxins could be addressed separately and some quantitative approaches were proposed.

It was understood that the issue of thresholds for biological agents and toxins needs further consideration by the Group.

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