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Working paper submitted by Ukraine

THRESHOLD QUANTITIES

**1. Role of threshold quantities**

The determination of threshold quantities of listed micro\_organisms and toxins is viewed as a useful tool in verification of compliance with the BWC. The use of threshold quantities is not aimed at limiting the sphere of application of article I of the BWC, since it is not prohibitive in nature.

**2. Types of threshold quantities and their use**

Two levels of threshold quantities are established for each individual strain (type) of listed micro\_organism or toxin at the monitored facility - lower and upper.

The lower threshold corresponds to the maximum quantity of a pathogenic micro\_organism or toxin of an individual strain (type) which need not be indicated in the annual declarations of activities at a facility monitored under the Convention at which the biological agent in question is produced and/or stored. The maximum current quantity of the listed micro\_organism or toxin in excess of the threshold level is subject to mandatory reporting in the annual declaration.

The upper threshold corresponds to the minimum quantity of a pathogenic micro\_organism or toxin of an individual strain (type) for which prior written authorization is required for production or handling. The authorization places temporal and quantitative limits on the production and use of the biological agent, and also lays down required methods of analysis of the quantity of biological agent and verification of safety conditions.

Any decision to issue a written authorization for the stockpiling of a listed type (strain) of a micro\_organism or toxin in quantities in excess of the threshold level is taken by the Organization in response to a written request from the monitored facility indicating the intended purpose (which must not run counter to the aims of the Convention), and on the basis of a preliminary analysis of the safety conditions at the facility making the request. In the analysis account must be taken of the real likelihood of a violation of the Convention, as well as of accidents, with due regard for all the risks and concern on the part of other States parties as to the activities conducted at the facility.

### **3. Technical basis for determining threshold quantities**

The quantity of listed micro-organisms and toxins is evaluated from the total quantity of infective (incapacitating) doses (ID 50) which produce a reaction in 50 per cent of cases for the most sensitive test subjects and the most common method of infection available at the facility. The lower threshold level for the type of listed micro-organism or toxin is to be taken as the quantity corresponding to the value  $1 \times 10^{13}$  ID 50. The upper threshold level for the type of listed micro-organism or toxin is to be taken as the quantity corresponding to the value  $2 \times 10^{14}$  ID 50.

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