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ELEMENTS OF A POSSIBLE VERIFICATION REGIME IN THE FRAMEWORK
OF THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT,
PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL)
AND TOXIN WEAPONS AND ON THEIR DESTRUCTION (CONVENTION ON
BIOLOGICAL WEAPONS)

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The verification regime to be adopted should promote transparency and be effective, adequate to dispel suspicion and appropriate to deter violators. The verification regime should guarantee that a maximum amount of information can be obtained with a minimum of interference.

In order to implement an effective verification regime, a group of concrete verification measures should be combined with a specific group of principles.

I. PRINCIPLES OF THE VERIFICATION REGIME

1. The verification regime should be based on transparency rather than prohibitions and should be in keeping with the general principles of verification adopted in United Nations General Assembly resolution 43/81 B of 7 December 1988.
2. All matters of importance for the Convention which are verifiable should be declared. Every matter declared should allow for the possibility of verifying the correctness of the data presented.
3. The obligations arising from the declarations to be presented by the States parties should be carefully defined, as well as the deadlines which must be fully and precisely met so as to guarantee confidence in the activities that are carried out.
4. Declarations should be mandatory in nature and any discrepancies, doubts or suspicions raised should be duly clarified. Failure to submit declarations shall be considered a violation of the commitments entered into by States parties and should be examined in accordance with established procedures.

5. The verification regime to be applied should be as economical as possible, should be accessible to all and should not contain discriminatory measures. However, it should contain machinery for access to any activity or facility selected, if necessary.
6. Every validation and inspection activity should be carried out within the framework of a negotiated agreement between the parties involved.

II. MAIN ELEMENTS OF THE VERIFICATION REGIME.

The verification regime should be composed of:

- (a) Lists of biological and toxin agents of major importance for the Convention which are subject to international control;
- (b) Lists of important equipment which is to be subject to controls under the Convention;
- (c) Facilities;
- (d) Declarations;
- (e) Notifications;
- (f) Validation and inspection visits.

A. LIST OF BIOLOGICAL AND TOXIN AGENTS OF MAJOR IMPORTANCE TO BE SUBJECT TO CONTROLS UNDER THE CONVENTION

The first definitive list of biological and toxin agents to be subject to controls under the Convention will have to be approved by the Conference of the States parties on the basis of a proposal to be presented by the Ad Hoc Group of Governmental Experts. The approved definitive list should be subject to periodic review for the purpose of updating by such competent bodies as may be established. The World Health Organization (WHO), the International Office of Epizootics (IOE) and the Food and Agriculture Organization of the United Nations (FAO) could participate in the drafting and updating of these lists.

The list of agents could include the following categories:

1.A. Agents that should be subject to controls

1.A.1. All known or declared agents which have been developed or standardized as biological weapons.

1.A.2. All agents included in risk categories III and IV according to WHO classification principles.

1.A.3. All agents belonging to risk category II that can be used as possible biological weapons and are the object of research or production (diagnostic activities would be excluded).

1.A.4. All agents which are restricted or subject to quarantine measures, are dangerous for animals and plants and do not fall in the above categories.

1.A.5. All manipulated pathogenic agents in risk groups III and IV or International Office of Epizootics list A which display attenuated virulence and can be used as simulators in research, development and production.

1.A.6. All pathogenic agents and toxins which are not fully described in the international literature. This includes new organisms and toxins obtained through genetic manipulation, as well as those which have emerged or have been discovered recently or have been genetically modified and which display recognized pathogenicity.

2.A. List of classic toxins and other chemicals of biological origin

2.A.1. All toxins and chemicals of biological origin with an effective dose of 1 microgram per kg, quantities of which exceed 5.0 milligrams in the reporting year.

2.A.2. All toxins and chemicals of biological origin with an effective dose of 10 micrograms per kg, quantities of which exceed 100 milligrams in the reporting year.

3.A. Agents that should be subject to certain additional restrictions

Biological agents belonging to risk groups III and IV whose location has been fully identified should preferably be examined in the regions concerned. The Convention should permit such activities and subject them to controls when they are carried out in regions in which the agents are not endemic.

In turn, interested States parties to the Convention which have so requested in advance should, in accordance with article X, have access to the results of, and assistance from, the research carried out on this category of agents, under procedures to be established in the Convention itself.

The Convention will also have to set up appropriate machinery to contribute to the pursuit of such research and the dissemination of the results obtained.

4.A. Prions in the research, development or production stage (diagnostic activities are not included)

B. LIST OF IMPORTANT EQUIPMENT TO BE SUBJECT TO CONTROLS UNDER THE CONVENTION

A very special distinctive characteristic of the production of biological warfare agents is that diagnostic, production and research work for peaceful purposes is carried out in facilities with equipment and technologies similar to those that would be used to produce biological agents for military purposes.

In order to avoid ambiguous situations and unilateral restrictions on the export of equipment for facilities that manipulate biological and toxin agents for peaceful purposes, which would run counter to the provisions of article X of the Convention on scientific and technical cooperation and development, it is necessary to draft a list of equipment whose technical characteristics make it possible to create potentialities for the production of biological weapons, and which therefore should be subject to controls under the Convention.

Stocks of such equipment should appear in the declarations made by States parties, and should therefore be subject to identification and examination during the validation or inspection visits.

The definitive list of equipment should be approved by the Conference of the Parties on the basis of a proposal by the Ad Hoc Group of Governmental Experts, and should be systematically updated by such competent bodies as may be established.

C. FACILITIES

Facilities will be subject to controls under the Convention if they manipulate biological or toxin agents or have equipment and carry out activities which are subject to controls under the Convention. Depending on whether facilities are or are not of major importance, they will make the proposed declarations to the body established for this purpose.

Facilities which exclusively carry out diagnostic or therapeutic activities should be exempted from the requirement to make declarations and would only have to notify the national authority of incidents involving any agents subject to controls that they may have and the detection of such agents. The national authority will make a summary report about such events in such facilities to the competent bodies to be established.

The number of facilities to be verified through validation or inspection visits should determine the procedures to be followed in these cases and the cost of the activity, as well as its frequency.

D. DECLARATIONS

Declarations will have to be made annually. Their concrete content can set a standard and give evidence of transparency; they should include all activities of major interest for the Convention, and this would simplify inspection work.

The types and thresholds of diagnostic and research agents, research and development programmes for defence, aerosol production and release to the environment, among others, will define more accurately the type of declaration and the degree of control and periodicity of the visits and inspections which will have to be made in the corresponding facilities.

Taking into account the categories of biological and toxin agents and the activities and equipment subject to controls under the Convention, all the facilities in which they are manipulated should be declared, including the facilities with a specific biosafety level, above all those at levels BL3 or BL4, as well as plants designed to produce vaccines.

The following types of declaration should be prepared:

1. TYPE A declarations

These will be completed by facilities which:

- Manipulate biological and toxin agents included in lists 1.A.1, 1.A.2, 1.A.4, 1.A.5, 1.A.6, 3.A and 4.A mentioned above, regardless of their biosafety level, and even if they are engaged in diagnosis, research or production of vaccines or other biological preparations.
- Manipulate agents on lists 1.A.3 and 1.A.5 which, in addition to diagnosis, are engaged in research or production.
- Manipulate toxins and other chemicals of biological origin included in lists 2.A.1 and 2.A.2 if they exceed the established thresholds or, even if they do not, are working on production or releases to the environment.
- Possess equipment subject to controls under the Convention, regardless of their biosafety level and even if they are engaged in diagnosis, research or production.

This kind of declaration also includes biological defence programmes and all the facilities involved in them, as provided in the confidence-building measures: Measure A, parts 2 (i), 2 (ii) and 2 (iii), and Measure F, as they appear in the annex to the Final Declaration on confidence-building measures adopted by the Third Review Conference.

2. TYPE B declarations

These will be completed by facilities which do not manipulate agents subject to controls but produce vaccines for agents not subject to controls or are engaged in production

of pathogens for release to the environment and possess equipment of importance for the Convention.

E. NOTIFICATIONS

Notifications should supply brief information on certain events which could be of major importance for the Convention. They include:

- Notifications on the release of pathogens to the environment in tests or by accident at the facilities
- Notifications on large-scale civilian and military immunization programmes
- Notifications on outbreaks of diseases provoked by agents subject to controls
- Notifications on national legislation related to the Convention and to biological safety
- Notifications on the past history and outbreaks of infectious or toxin-based diseases, as well as on similar situations that appear to diverge from the normal pattern
- Notifications on military manoeuvres or outdoor tests included in research and development programmes for defence
- Notifications on incidents involving agents subject to controls or their detection in diagnostic facilities.

F. VALIDATION AND INSPECTION VISITS

1. Validation visits

To supplement the yearly declarations and notifications, visits should be paid to validate the content of the declarations.

The following measures would be applied during these visits (both in this section and in the section on inspections, the measures mentioned have been taken from those identified by the VEREX Group):

1. Data on transfers, requests for transfers and production
2. Visual inspection
3. Identification of key equipment.

Validation visits should be made to facilities selected independently of the declaration they have submitted, whether type A or type B, with the verification procedures established always borne in mind.

2. Inspections

Inspections could be divided into routine inspections and challenge inspections.

ROUTINE INSPECTIONS

This kind of inspection should be limited to a strict minimum and applied in those declared facilities which are of greatest importance for the Convention. The secretariat of the body established for the purpose should enjoy a reasonable degree of independence in order to decide which facilities should be liable to this type of inspection, taking into account a series of defined criteria, among which are the following:

- Facilities that participate in military programmes of defence research
- Facilities that genetically manipulate pathogens included in the lists subject to controls
- Facilities that manipulate biological agents included in category 3.A (agents that should be subject to certain additional restrictions) of the list of agents of major importance for the Convention.

The number of such inspections to be carried out each year should be in keeping with a work programme approved to that end by such competent bodies as may be established.

CHALLENGE INSPECTIONS

These will be carried out at the request of a State party if it provides sufficient data, elements or information to substantiate a claim that another State party is carrying out activities in violation of the provisions of the Convention. Such a request should be subject to approval by the international machinery to be established to oversee verification activities.

This kind of inspection would be applied to both declared and undeclared facilities.

Both routine and challenge inspections would include the following measures, in addition to the measures included in the validation visits:

1. Interviews
2. An audit

3. Procurement and identification of samples at the facility
4. Medical examination.

Both validation and inspection visits should be notified to the State party which will receive them at short notice - the minimum required to enable the designated national authority to make the necessary arrangements for the group of inspectors.

All validation and inspection activities should be conducted under a negotiated agreement between the parties involved.

III. MEASURES APPLICABLE UNDER CERTAIN CONDITIONS

The following measures could be applied in military facilities or those that carry out support activities in biological defence programmes:

1. Surveillance using instruments
2. Permanent manned surveillance.

IV. MEASURES WHICH ARE NOT APPLICABLE IN A VERIFICATION REGIME

Among the potential verification measures already identified, there are, in our view, a group which should not be included because they are expensive, intrusive or incapable of resolving ambiguities and could be used for purposes other than those envisaged in the Convention. They are:

1. Satellite surveillance
2. Aircraft surveillance
3. Land-based surveillance
4. Procurement and identification of samples
5. External observation
6. External checking beyond the limits of the facility.

V. CONFIDENCE BUILDING MEASURES

The confidence-building measures adopted at the second and third review Conferences (see BWC/CONF.III/23, annex to the Final Declaration on confidence-building measures) to strengthen the Convention and increase transparency change in significance

once a verification regime is adopted within the framework of the Convention. When this occurs:

Measure A, parts 1, 2 (i), 2 (ii) and 2 (iii) should be included in TYPE A declarations

Measure B should be included in the notifications

Measures C and D should continue to be considered as confidence-building measures

Measure E should be included in the notifications

Measure F should be included in TYPE A declarations

Measure G should be eliminated, since facilities for vaccine production would have to make type A or B declarations depending on the biological and toxin agents they manipulate, whether they are or not subject to controls, and the technical characteristics of their equipment.

We consider it desirable to include the following new confidence-building measure:

- Information on national visits or inspections carried out and their results.
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