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## SOME POSSIBLE ELEMENTS IN A VERIFICATION PROTOCOL

### Working Paper submitted by Sweden

#### BACKGROUND

From the work of VEREX it can be concluded that potential verification measures have been comprehensively identified and evaluated from a scientific and technical standpoint and that this part of the governmental experts work now is finished. The results of VEREX is a good base for the further work to develop a legally binding verification protocol.

#### DECLARATION

During VEREX it was found that the effectiveness of some evaluated and examined verification measures could be enhanced if they were combined with other off-site or on-site verification measures. Declarations was the measures most frequently identified for application in combinations with other measures.

As defined during VEREX the verification measure declaration includes notification and data on transfer, transfer requests and on production. With declaration is meant an annual mandatory reporting of data on programmes, facilities and equipment with relevance for the BTWC. A fairly broad range of facilities and activities should be declared as this will give a potential inspectorate a good base from which to make decisions on the need for inspections. A broad declaration system which is well focused will involve national costs for States Parties but could reduce the number of inspections required by the inspectorate thus limiting the cost for the international verification organization. Rules will also have to be elaborated to ensure the confidentiality of information supplied.

The following items could be included:

1. Research and development

Simplified national declaration of facilities, including name, location and indicating work on pathogens and toxins (according to criteria in Annex I). Indicate participation in, or funding by, BTW defence programme. Facilities with appropriate containment level (to be specified in Annex) should also be declared.

2. BTW defence programmes and BTW related military activities

- a. Details on BTW defence programmes today and past activities
- b. Military vaccination programmes
- c. Facilities developing or testing BTW defence equipment

3. Production and acquisition

Declaration including name, location and general description of activities for all facilities, indicate participation in, or funding by, BTW defence programme.

- a. That produce human or animal vaccines
- b. That produce or have appropriate facilities/equipment to be able to produce pathogens and toxins (according to criteria in Annex I)
- c. That work with large scale open air release or have the capability to generate aerosols with relevant particle sizes, of microorganisms or toxins
- d. That produce plant pathogens or biological insecticides
- e. That use or have aerosol test chamber, including explosive test chambers, equal to or larger than one cubic metre for work with pathogenic microorganisms or potent toxins

4. Data of transfer and transfer requests

Export and import of human and animal vaccines against pathogens and toxins (according to criteria in Annex I).

5. Notifications

- a. New immunisation programmes for military personnel
- b. Outbreaks of diseases or intoxications caused by pathogens and toxins (according to criteria in Annex I) that deviate from the normal pattern

ON-SITE INSPECTION

In discussing which verification measures as a minimum that will be required for a verification regime this will depend on: the situation and type of question to be answered, type of facility declared or undeclared and in some cases the sequence and frequency they are

used. When the modalities for verification measures are specified this should be done in such a way so as to ensure that they have no adverse implications for the scope of Article I of the BTWC and so that commercial proprietary information (CPI) is protected as well as legitimate national security needs. The measures evaluated by VEREX can be divided into categories depending on their applicability.

Minimum requirements for a verification regime are a well-focused declaration system, on-site inspections and multilateral information sharing. These measures are required, as there must be a mechanism to verify the accuracy of the information supplied in the declarations and for this some type of on-site inspection is needed. Furthermore on-site inspections of declared facilities will be more effective, better focused and less time consuming if it is based on relevant information about a facility from declarations. One objective of an inspection is to verify that facilities are in compliance with declared activities. The frequency of inspections must take into account: types of facilities, number of facilities, geographical distribution and the size of the inspectorate.

Surveillance, including inspections of facilities/activities, by national authorities for other purposes may also give valuable inputs into a national authority for BTWC verification. The basic measures required for on-site inspections are visual inspection, interviewing, identification of key equipment and auditing. On-site inspections, information visits, could be carried out on a limited scale when it comes to declared facilities. The main part of inspections should be of a short notice type directed towards undeclared facilities or any other facilities/activities of concern. In comparison with the CWC it is proposed that on-site inspections of a routine type for validation of declarations and information gathering for the BTWC should be strongly restricted in frequency and intensity to a small number of inspections/visits per year to keep inspectors and an inspectorate well trained and give them adequate experience but at the same time limiting the costs. To this should be added the need for information sharing between States Parties and to build up a data base with relevant information about facilities/activities.

The mechanism of how an inspection is triggered has to be carefully elaborated. Decisions of an inspectorate should be made independently and based on data from multilateral information sharing, CBMs, declarations and notifications as well as other sources. It could also be on request of a State Party according to a specific procedure and modalities.

When a specific question of concern is raised for a facility/activity or during an on-site inspection the basic verification measures can be complemented by more specific measures that are focused and used to answer specific questions.

On-site inspections play an important role for declared as well as undeclared facilities. More focused measures like sampling and identification on-site can be used for special situations to answer questions of concern. The frequency with which this measure will be used is limited and depends on decisions taken during an on-site inspection. Rules for how and when this measure can be applied have to be elaborated.

In some very special circumstances, for example when non-compliance is suspected, other measures could be considered as well. Inspections/visits by team of experts could also play an important role in investigating unusual diseases outbreaks or intoxications.

#### PROTECTION OF COMMERCIAL INFORMATION

It is important to protect commercial proprietary information (CPI) when implementing verification procedures. An important factor to limit the risk for leakage of CPI during inspections would be the application of sound principles for choosing inspectors and impose a strict code of confidentiality on all non-host personnel involved in the BTWC verification procedures including handling samples, data on-site and off-site. Trial inspections play an important role developing sound principles to protect CPI.

Procedures can be adopted from those developed elsewhere for other international inspections, including managed access, limitations on the number of visits per year, rules defining the conduct of on-site visits, limitations on access to information, etc.

#### ALLEGATION OF USE

The verification protocol should also include procedural and organizational requirements to handle cases of alleged use. The provisions set out in Article VI and VII of the BTWC should then also be taken into account.

A State Party should be able to request an investigation, by the international inspectorate, of alleged use on its own territory or under its jurisdiction and control. The verification organization should be equipped to be able to respond to such a request in an adequate way. After careful analysis of all facts in the case a team of experts with appropriate equipment and mandate could be sent rapidly to the site. The organization should also be able to give information and support to any State Party affected by biological or toxin weapons. It is essential that procedures are worked out that enable a timely access to a site in such a case. Similar procedures as for on-site inspections will play an essential role.

#### DEFINITIONS AND OBJECTIVE CRITERIA

##### Definitions and criteria

During the Ad Hoc Group's work with elaborating a verification protocol the need for clear definitions of terms used in the text will become evident, as the protocol will be legally binding and has to be implemented in national legislation. Such definitions should as stated in the Ad Hoc Group's mandate be limited to specific measures in the verification protocol so that they cannot be interpreted as in any way limiting the scope of the BTWC. For some such terms guidance can be found in other regimes. When a term is to be used by the Ad Hoc Group in a specific situation it should be defined in a clear and unambiguous way.

##### Types and quantities of pathogens and toxins

A list of pathogens and toxins should not in any way be linked to Article I in the BTWC as it will limit the scope of the Convention. Such a list, even an illustrative one, will cause ambiguities about agents that are not on the list. The question of types and quantities of pathogens and toxins is not a simple or isolated matter and should be discussed in connection with specific measures, e.g. declaration/notification. A list of pathogens and toxins cannot be considered as a prerequisite for effective on-site inspections, since the collected information, from several other sources and verification measures, available in a situation relevant for on-site inspection will constitute the basis for the inspectors to request what agents to look for. The organization in charge of the verification regime should be mandated to, if required in each specific case, request what pathogens or toxins, in type and quantity, that are relevant to monitor for and identify, as appropriate, in the case of an on-site inspection of short notice type.

Due to the rapid development in the field of biotechnology and life science it is difficult to construct an illustrative list of pathogens and toxins with relevance for the future. Another rationale could be a list based on properties of pathogens and toxins and derivatives thereof, relevant to consider. It would then be necessary to list relevant properties instead of the organisms judged to be relevant. Criteria can be used as a tool for evaluating pathogens and toxins or properties of these, when establishing a list to be used as one trigger for declarations. (Annex I.) The Ad Hoc Group could use these criteria to prepare such a list of pathogens and toxins to be used as one trigger for declaration. Provisions should be provided in such a list for a regular review e.g. annually.

As stated in the mandate the Ad Hoc Group shall, in the context of where relevant for specific measures designed to strengthen the Convention, consider lists of bacteriological/biological agents and toxins, as well as their threshold quantities. The declaration of quantities of pathogens will though be of limited value. The threshold quantities of pathogens and toxins has to be elaborated in relation to its potential as a warfare agent and to the local factors determining the justifiable quantities for protection and other peaceful purposes. These circumstances indicates that the elaboration of threshold quantities of pathogens and toxins (according to the criteria in Annex I) will be very difficult and should be avoided.

## ORGANIZATION

A Committee of States Parties to the BTWC and a Secretariat will be required. Dispute settlement procedure have to be considered. The Secretariat will gather, analyse and disseminate information made available by States Parties or other organizations. An inspectorate for the BTWC should be limited in size, efficient and cost effective as well as politically independent. The number of inspectors has to be limited according to the expected number of inspections per year. In elaborating the necessary requirements of the verification organization this should be done with the needs of the BTWC primarily in mind and not copied from other regimes. At a later stage any benefits with co-location or cooperation with other disarmament organizations can be discussed.

States Parties should consider to establish National Authorities for BTWC verification, which should cooperate and work closely with the international organization. The details of the institutional structure of the future regime will become clearer when the details of the verification protocol have been elaborated. The measures within the regime will largely dictate which institutional mechanisms are required.

## CONFIDENCE-BUILDING MEASURES

Confidence-building measures are important to create openness and transparency between States Parties.

The information exchange that has taken place so far between States Parties to the BTWC as confidence-building measures has far from resulted in satisfactory participation but it has though resulted in greater openness between States Parties. The extended CBMs that were decided at the 3rd Review Conference can be seen as an improvement in the quality of information to be supplied. Participation must be extended to all States Parties in order to reach the confidence-building aims.

For a credible verification regime a mandatory system is needed. A base for discussions on such a system could be the CBMs decided at the 3rd Review Conference. In order to use some of the current CBMs as one base for elaborating a declaration system, the information to be supplied must be in a suitable format so that it could be verified by inspections. This could mean that the supplied information must be more specific in some cases and also be expanded for some CBMs. A declaration system would also need to expand the amount of information to be declared beyond the CBMs to cover other facilities or areas of concern. Those CBMs not used as a base for a declaration system could be considered to keep as CBMs.

The CBMs, decided by the 3rd Review Conference should be kept intact even if some are used in a mandatory declaration system and verification protocol is agreed. At the 4th Review Conference CBMs and their future role should be discussed in the light of how far the work on a verification protocol then has reached.

Annex I

Possible criteria for pathogens and toxins to be used for declarations

Properties of pathogens and toxins, combinations of agents or agent derivatives which fulfill two or more of the requirements:

1. All biological agents or toxins known to have been used in warfare, standardized and/or manufactured or stored as BTW agents, anywhere, in the past
  2. Can be disseminated on a large scale and retains the main part of its biological activity, protected by microencapsulation or not after aerosolization
  3. Infectious or biologically deleterious via the airborne route and has a short incubation time in man
  4. Will cause large number of casualties when disseminated via aerosol
  5. That will incapacitate/damage or kill animals/livestock or plant/crops to create serious socio-economic or public health consequences
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