AD HOC GROUP OF GOVERNMENTAL EXPERTS TO IDENTIFY AND EXAMINE POTENTIAL VERIFICATION MEASURES FROM A SCIENTIFIC AND TECHNICAL STANDPOINT

REPORT

Geneva, 1993

Your Excellency,

The Third Review Conference (September 1991) of the Biological Weapons Convention decided to establish an Ad Hoc Group of Governmental Experts, open to all States Parties, to identify and examine potential verification measures from a scientific and technical standpoint.

The Group held four sessions in Geneva: 30 March - 10 April 1992; 23 November - 4 December 1992; 24 May-4 June 1993; and 13-24 September 1993.

As a result of its deliberations, the Group had identified in all 21 potential measures. Based on the examination and evaluation of the measures against the criteria given in the mandate, the Group considered, from a scientific and technical standpoint, that some of the verification measures would contribute to strengthening the effectiveness and improve the implementation of the Convention, also recognizing that appropriate and effective verification could reinforce the Convention.

In accordance with the decision of the Third Review Conference, which requested the report of the Group be circulated to all States Parties for their consideration, I have the honour to transmit herewith the attached Report on the work of the Group. According to the decision of the Third Review Conference, if a majority of States Parties ask for the convening of a conference to examine the report, by submitting a proposal to this effect to the Depositary Governments, such a conference will be convened. In such a case the Conference shall decide on any further action.

Please accept, your Excellency, the assurances of my highest consideration.

Tibor Tóth
Chairman
Ad Hoc Group of Governmental Experts
to Identify and Examine Potential Verification
Measures from a Scientific and Technical Standpoint

H.E. Minister for Foreign Affairs Ministry of Foreign Affairs

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AD HOC GROUP OF GOVERNMENTAL EXPERTS TO IDENTIFY AND EXAMINE POTENTIAL VERIFICATION MEASURES FROM A

BWC/CONF.III/VEREX/8 24 September 1993

SCIENTIFIC AND TECHNICAL STANDPOINT ORIGINAL: ENGLISH

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SUMMARY REPORT

INTRODUCTION

- 1. The Third Review Conference (September 1991) of the Biological Weapons Convention agreed to establish an Ad Hoc Group of Governmental Experts, open to all States Parties to identify and examine potential verification measures from a scientific and technical standpoint.
- 2. The mandate of the Group was as follows:

AThe Conference, determined to strengthen the effectiveness and improve the implementation of the Convention and recognizing that effective verification could reinforce the Convention, decided to establish an Ad Hoc Group of Governmental Experts open to all States Parties to identify and examine potential verification measures from a scientific and technical standpoint.

AThe Group shall meet in Geneva for the period 30 March to 10 April 1992. The Group will hold additional meetings as appropriate to complete its work as soon as possible, preferably before the end of 1993. In accordance with the agreement reached at the Preparatory Committee, the Group shall be chaired by Ambassador Tibor Tóth (Hungary) who shall be assisted by two Vice-Chairmen to be elected by the States Parties participating in the first meeting.

AThe Group shall seek to identify measures which could determine:

- Whether a State Party is developing, producing, stockpiling, acquiring or retaining microbial or other biological agents or toxins, of types and in quantities that have no justification for prophylactic, protective or peaceful purposes;
- Whether a State Party is developing, producing, stockpiling, acquiring or retaining weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

ASuch measures could be addressed singly or in combination. Specifically, the Group shall seek to evaluate potential verification measures, taking into account the broad range of types and quantities of microbial and other biological agents and toxins, whether naturally occurring or altered which are capable of being used as means of warfare.

ATo these ends the Group could examine potential verification measures in terms of the following main criteria:

- Their strengths and weaknesses based on, but not limited to, the amount and quality of information they provide, and fail to provide;
- Their ability to differentiate between prohibited and permitted activities;
- Their technology, material, manpower and equipment requirements;
- Their financial, legal, safety and organizational implications;
- Their impact on scientific research, scientific cooperation, industrial development and other permitted activities, and their implications for the confidentiality of commercial proprietary information.

Aln examining potential verification measures, the Group should take into account data and other information relevant to the Convention provided by the States Parties.

AThe Group shall adopt by consensus a report taking into account views expressed in the course of its work. The report of the Group shall be a description of its work on the identification and examination of potential verification measures from a scientific and technical standpoint, according to this mandate.

AThe report of the Group shall be circulated to all States Parties for their consideration. If a majority of States Parties ask for the convening of a conference to examine the report, by submitting a proposal to this effect to the Depositary Governments, such a conference will be convened. In such a case the conference shall decide on any further action. The conference shall be preceded by a preparatory committee.≅

- 3. The Group held four sessions, from which three Summaries and a Procedural Report were produced and annexed as part of this Summary Report:
 - VEREX 1 30 March-10 April 1992 (Identification of measures; Annex I);
 - VEREX 2 23 November-4 December 1992 (Examination of measures; Annex II);
 - VEREX 3 24 May-4 June 1993 (Evaluation of measures; Annex III);
 - VEREX 4 13-24 September 1993 (Preparation of the report; Annex IV);

4. During its first session the Group identified in all 21 potential measures suggested by individual delegations under the three broad areas of development, acquisition and production, and stockpiling and retaining, for later examination and evaluation against the mandate criteria. They were included in a list. The inclusion of a measure in this list constituted no judgement by the Group as to the usefulness of the potential measure in relation to the objectives stated in the mandate. Some potential measures included in the list were considered as individual measures which might be applied individually or with other individual measures in each category. Measures were divided as follows: off-site and on-site. They were grouped in a Chairman=s paper in seven broad categories for the purpose of later examination and evaluation:

Off-site Measures:

- Information Monitoring: surveillance of publications; surveillance of legislation; data on transfers, transfer requests and production multilateral information sharing.
- Data exchange: declarations; Notifications.
- Remote Sensing: surveillance by satellite; surveillance by aircraft; ground-based surveillance.
- Inspections: sampling and identification; observation; auditing.

On-site Measures:

- Exchange visits: international arrangements.
- Inspections:

 interviewing;
 visual inspections;
 identification of key equipment;
 auditing;

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sampling and identification; medical examination.

- Continuous monitoring: by instruments; by personnel.
- 5. During the second session, the Group decided to modify the list of measures identified at the first session. The new list agreed upon by consensus is included in Annex II, pages 131-133.
- 6. Each measure was examined according to the mandate in order to determine: AWhether a State Party is developing, producing, stockpiling, acquiring or retaining microbial or other biological agents or toxins, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes. ⊆. Similarly, measures were examined to determine: AWhether a State Party was developing, producing, stockpiling, acquiring or retaining weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict ⊆.
- 7. A methodology for detailed examination of measures was agreed by the Group which included a definition, a description of the characteristics and technologies in terms of the state-of-the-art, the capabilities and limitations, and a discussion of potential interaction with other measures.
- 8. A number of national and background papers were presented by participants. Each measure was fully described and introduced for group discussion by a rapporteur (Annex II, pages 52-122). In all cases potential interaction with other measures was identified. Moderators, (Annex II, pages 127-133) designated by the Chairman, prepared discussion papers in the three broad areas of development, production and stockpiling to assist in the evaluation. The examinations represented a technical summary of the key factors to consider. These consensus summaries discussed extensively by the Group, formed the basis of consolidated texts which could be used as a starting point for evaluation (Annex II, pages 46-148 and Annex III, pages 149-327).

EVALUATION OF MEASURES SINGLY

9. Each potential measure identified in the examination phase was evaluated singly in accordance with the mandate, i.e. its strengths and weaknesses based on, but not limited to, the amount and quality of information it provides, and fails to provide; the ability to differentiate between prohibited and permitted activities; the ability to resolve ambiguities about compliance; the technology, material, manpower and equipment requirements; the financial, legal, safety and organizational implications; and the impact on scientific research, scientific cooperation, industrial development and other permitted activities, and the implication on scientific research, scientific cooperation, industrial development and other permitted activities, and its implications for the confidentiality of commercial proprietary information. On the basis of the Introduction submitted by the rapporteur, the Group discussed and evaluated the measures at both formal and informal meetings and adopted by consensus an evaluation report on each measure. Summaries of the Group—s work in relation to the individual measures are

contained in a shortened form in a table attached to this report. The complete summaries of the examination and the evaluation can be found in the Summaries of Annex II, pages 52-122 and Annex III, pages 154-273.

EVALUATION OF MEASURES IN COMBINATION

- 10. While recognizing the possible utility of other methodologies, the Group agreed to use one methodology to assess illustrative but not exhaustive examples of measures in combination. Although the Group recognized that a large number of combinations were possible, the systematic evaluation of all possible combinations was considered to be impractical without prejudice to any future ideas that may evolve on the subject. The Group agreed that, in general, the capabilities and limitations of a combination of measures equal the sums of the capabilities and limitations of the single measures involved in the combination. This cumulative effect of measures in combination was not addressed. The analysis was intended to investigate whether, in particular cases, the application of measures in combination produces enhanced capabilities and limitations that differ from a simple accumulation of the capabilities and limitations of the single measures involved (synergy).
- 11. The following five combinations were proposed as examples to illustrate the evaluation of enhanced capabilities and limitations of measures in combinations:
 - Declarations/Multilateral information sharing/ Satellite surveillance/Visual inspection
 - Information monitoring (surveillance of publications/ surveillance of legislation/data on transfers, transfer requests and production/multilateral informationsharing/exchange visits)
 - On-site inspection (interviewing/visual inspections; identification of key equipment/auditing/sampling and identification)
 - Declarations/Multilateral information-sharing/
 On-site visual inspection
 - Declarations/Information monitoring.
- 12. The enumeration of these combinations was not meant to represent a proposal for combinations that would serve as a verification regime, since this is not part of the mandate of the Group (Annex III, pages 272-273). It was agreed that, in principle, States Parties could submit additional contributions related to the evaluation of measures in combination for consideration. In this context, the view was expressed that declarations and on-site inspections might be further considered

at a later stage. The Group discussed and evaluated the examples of measures in combination and adopted a report by consensus (Annex III, pages 150-153).

- 13. All rapporteurs have identified off-site and on-site measures which interact with the single measures. The capabilities of single measures might be enhanced if they are combined with other off-site measures and other on-site measures.
- 14. The measure ADeclarations was most frequently identified for application in combination with other measures. The most frequently identified on-site measures in combination were on-site inspections (interviewing, visual inspection, identification of key equipment, sampling and identification, auditing). This does not mean that all the measures in parenthesis above always would be included in an on-site inspection.

OTHER ASPECTS

- 15. The 21 measures were grouped under the three broad areas of prohibition of Article 1 of the Convention (development; acquisition or production; stockpiling or retaining). Some measures were found to be useful for all three areas of prohibition, whereas some measures were considered useful only for one or two of the areas (Annex III, page 271; BWC/CONF.III/VEREX/6/WP.176).
- 16. The Group decided by consensus to include a paper recording the results of consultations on the question of types and quantities of agents. These results could be further considered at a later stage (Annex III, page 153; BWC/CONF.III/VEREX/6). According to the paper, agreed lists, which are difficult to construct at this stage, are a prerequisite to the implementation of many potential verification measures.
- 17. Some national background and rapporteur=s papers mentioned that microbial or other biological agents or toxins can be disseminated by weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.
- 18. In the course of an informal meeting, delegations discussed the experiences gained by the three countries concerned from two trial inspections carried out by the Netherlands and Canada, and the UK, respectively. Two working papers on trial inspections were submitted ABilateral Trial Inspection in Large Vaccine Facility≅ (BWC/CONF.III/VEREX/6/WP.112) by the Netherlands and Canada, and AUK Practice Inspection: Pharmaceutical Pilot Plant≅ (BWC/CONF.III/VEREX/6/WP.141) by the United Kingdom. While work would be required on the question of protection of CPI in order to achieve consensus, the countries concerned in two national trial inspections informed delegations of their national findings that the access given had not compromised commercial confidentiality.
- 19. The Group examined the potential verification measures in terms, *inter alia*, of their impact on scientific research, scientific cooperation, industrial development and other permitted activities. In that context, delegations recalled Article X of the Convention according to which States Parties Aundertake to facilitate, and have the right to participate in the fullest possible exchange of equipment,

materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes and the related provisions of the Final Document of the Third Review Conference. In particular those on the examination of means of improving related institutional mechanisms and those on the adoption of positive measures to promote technology transfer, consistent with all the other Articles of the Convention. Delegations recalled as well that the provisions of the Convention should not be used to impose restrictions and/or limitations on the transfer for purposes consistent with the objectives and the provisions of the Convention.

CONCLUSIONS

- 20. The Group identified, examined and evaluated from a scientific and technical standpoint in all 21 potential verification measures as well as some suggested examples of combinations of measures. Several of the measures evaluated singly have been identified as being closely related.
- 21. The findings of the identification, examination and evaluation of the 21 potential verification measures against the agreed mandate criteria indicated that capabilities and limitations existed for each measure in varying degrees, although reliance could not be placed on any single measure by itself to determine whether a State Party is developing, producing, stockpiling, acquiring or retaining: microbial or other biological agents or toxins, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes or; weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes.
- 22. Certain current scientific and technical shortcomings of some measures were appreciated. These included the acknowledgment that some technologies associated with particular measures are limited by the commercial availability of equipment, materials and stages of development.
- 23. The identified verification measures cover a variety of non-intrusive and intrusive measures. The Group described the capabilities and limitations of the measures and evaluated the impact on scientific research, scientific cooperation, industrial development and other permitted activities and their implications for the confidentiality of commercial proprietary information from a scientific and technical standpoint only. Some measures were considered inherently not capable by themselves of differentiating between prohibited and permitted activities.
- 24. It was difficult to assess accurately the feasibility and the effectiveness of all the 21 measures within the context and criteria laid down in the mandate for the Group. Concerns were expressed over the financial implications and the technical difficulties in the identification of biological agents.
- 25. Concern was also expressed that the implementation of any measure should ensure that sensitive commercial proprietary information and national security needs are protected. The issue of protection of CPI, some aspects of which were addressed in a preliminary way, needs further consideration at a later stage consistent with the effective verification needs of the BWC.

- 26. Taking into account already existing lists for different purposes (Annex III, pages 266-267; BWC/CONF.III/VEREX/6), illustrative lists of agents could be developed to support particular potential verification measures. Under the measure of ADeclarations≘, data on production, including amounts of agents produced, may be collected. Under the measure of AData on transfers, Transfer requests and on Production≘, data may provide background information for inspections and for other measures.
- 27. The development of equipment and technologies, which is difficult for some applications, is important to meet the needs of some discussed measures, and could support the technical applicability of these measures in the future.
- 28. Some of the measures which were identified were also subjected to an illustrative but not exhaustive evaluation of combinations of measures.
- 29. Some measures in combination may enhance the capabilities and/or reduce the limitations of the individual measures. However, some limitations inherent in individual measures could not be removed and in some cases combinations of measures may result in enhanced limitations. In certain cases the enhanced capabilities produced by combinations differ from a simple accumulation of the capabilities of the single measures thus creating synergy. Even if a combination does not create any synergies there will still be a cumulative effect of both capabilities and limitations.
- 30. Important positive and negative synergies which were not identified in the evaluation may exist for each of the combinations examined. From a technical standpoint some combinations of some potential verification measures including both off-site and on-site measures could provide information which could be useful for the main objective of the BWC.
- 31. The Ad Hoc Group of Governmental Experts concluded that potential verification measures as identified and evaluated could be useful to varying degrees in enhancing confidence, through increased transparency, that States Parties were fulfilling their obligations under the BWC. While it was agreed that reliance could not be placed on any single measure to differentiate conclusively between prohibited and permitted activity and to resolve ambiguities about compliance, it was also agreed that the measures could provide information of varying utility in strengthening the BWC. It was recognized that there remain a number of further technical questions to be addressed such as identity of agent, types and quantities, in the context of any future work. Some measure in combination could provide enhanced capabilities by increasing, for example, the focus and improving the quality of information, thereby improving the possibility of differentiating between prohibited and permitted activities and of resolving ambiguities about compliance.
- 32. Based on the examination and evaluation of the measures described above against the criteria given in the mandate, the Group considered, from the scientific and technical standpoint, that some of the potential verification measures would contribute to strengthening the effectiveness and improve the implementation of the Convention, also recognizing that appropriate and effective verification could reinforce the Convention.

DISPOSITION OF THE REPORT

33. The Ad Hoc Group of Governmental Experts recalled that the Third Review Conference had decided the following with regard to the disposition of the work of the Group:

AThe report of the Group shall be circulated to all States Parties for their consideration. If a majority of States Parties ask for the convening of a conference to examine the report, by submitting a proposal to this effect to the Depositary Governments, such a conference will be convened. In such a case the conference shall decide on any further action. The conference shall be preceded by a preparatory committee.≅

Attachment to the Summary Report

(Table)

During Verex 3, all 21 potential verification measures, identified during Verex 1 and examined during Verex 2, were evaluated by the group. To evaluate these measures an agreed methodology was applied based on the six mandate criteria. The criteria for evaluating the measures are:

- 1. Strengths and weaknesses based on but not limited to the amount and quality of information they provide and fail to provide.
- 2. Ability to differentiate between prohibited and permitted activities.
- 3. Ability to resolve ambiguities about compliance.
- 4. Their technological, material, manpower and equipment requirements.
- 5. Their financial, legal, safety and organizational implications.
- 6. Their impact on scientific research, scientific cooperation, industrial development and other permitted activities; and their implications for the confidentiality of Commercial Proprietary Information (CPI).

The first three criteria mainly represent the effectiveness of individual measures; the second three mainly represent their requirements and their impact. According to these criteria, capabilities and limitations were considered.

A general observation was made that reliance could not be placed on any single measures by itself to differentiate conclusively between prohibited and permitted activity or resolve ambiguities about compliance. The attached table is an extract of the complete evaluations made by rapporteurs during Verex 3, which can be found in Annex III.

TABLE

Measure	Definition	EVALUATION (Capabilities and Limitations) Criteria 1-3 ¹ Criteria 4-6 ²	
Surveillance of publications	Selective scanning and analysis of publicly available printed matter and of the media with special attention to scientific literature related to activities in the biological field. VEREX/9, Annex II, p.54)	It could provide useful information on relevant activities in State Party, but consistency in quantity and quality may vary. It may help in the selection of sites for inspections and in focusing ongoing inspection activities. The information provides only a partial picture of activities. This focusing could be done by using key identifiers. Not all types of relevant information are necessarily published. (VEREX/9, Annex III, p. 154 etc.)	If focused this measure need not be very costly. Some personnel with specific expertise and a computer data base would be needed. Translation services might be costly. The low level of intrusiveness of this measure is an advantage.
Surveillance of legislation	Collecting and analysing of information with regard to legislation that exists in relation to the BWC or other areas of interest. VEREX/9, Annex II, p. 56	Could provide information on relevant activities of States Parties. However, the absence of legislation is not an indication of non-compliance. It may help in the selection of sites for inspections and in focusing ongoing inspection activities. The amount of information could be very large and the quantity varies per State. May help explain the nature of dual purpose activities. (VEREX/9, Annex III, p. 156, etc.)	This measure need not be very costly. Although the precise requirements pertaining to this measure still need to be determined, an investment in a computer/data base is needed. Translation costs may be substantial. Limited impact, if any, on permitted activities.
Data on transfers, transfer requests and on production	Collection and analysis of national export and import data, available or specifically requested, government and industrial production statistics, culture collection records and similar information. There may or there may not be an agreed standard for the availability of the nature of the information. (VEREX/9, Annex II, p. 57)	It may be a background for further investigation. It may well be an effective measure if combined with other measures. It may help in the selection of sites for inspections and in focusing ongoing inspection activities. Because of the large amount of information available, a focused survey may be necessary. This focusing could be done by using key identifiers to be determined. Information may be outdated quickly. The amount and quality of information may differ per Sate. May help in the analysis of dual purpose activities. (VEREX/9, Annex III, p.	If focused need not be very costly. Not all information may be freely accessible. Some personnel with specific expertise and a computer data base would be needed. Confidentiality concerns need to be considered. Data analysis and a continuing survey could be costly. There are no technological requirements. Material and manpower requirements are

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Measure	Definition	EVALUATION (Capabilities and Limitations) Criteria 1-3 ¹ Criteria 4-6 ²	
		158, etc.)	limited. In some cases the legal implications should be considered.
Multilateral information sharing	The use of any voluntary international provision or exchange of information on medical, veterinary, agricultural, environmental safety standards, defence and waste management issues, etc., relating to materials and activities of potential relevance to the BWC. Such information sharing on a voluntary basis may or may not have an agreed standard for the nature of the information to be provided. (VEREX/9, Annex II, p. 58)	May well be an effective measure if combined with other measures. May help explain the nature of dual purpose activities and provide indications of non-declared activities. However this measure depends on the willingness of a State Party to provide information. The information may be inaccurate and generate unwarranted concerns. (VEREX/9, Annex III, p. 160, etc.)	If focused this measure is not very costly. The precise requirements of this measure still need to be determined. A computer/data base is needed. Legal implications and confidentiality concerns need to be considered; access to CPI can be defined.
Exchange visits (off site)	Visits of experts arranged for scientific purposes by one country to comparable facilities of another country (States Parties) under bilateral or multilateral agreements. Exchange visits need not be restricted to declared facilities. (VEREX/9, Annex III, p. 162)	It can provide a mechanism of transfer of technical information for a given area of study. The scope of the agreement will largely determine the amount and quality of the information exchanged. It may serve best as an enhanced CBM, expanding openness and transparency. Information is generally limited to scientific matters and in limited area specified in agreement. (VEREX/9, Annex III, p. 162, etc.)	The potential loss of proprietary information is of concern. Financial costs could be a limiting factor. Legal factors such as rights of the exchange scientists and the protection of proprietary information must be considered. Visitor safety should be insured.
Declarations	Mandatory, periodic reporting on a regular basis of information considered to be of relevance for verification of the BWC. The nature of the events/items/facilities to be declared has yet to be fully defined. Notifications were considered to be a subset of declarations, concerned with the	Provides a base line of information regarding all three areas of development, production and stockpiling. There is a need to consider in more detail exactly what items/events should be declared. Examination of declarations could disclose irregularities. They give a nation the opportunity to explain actions or events to States Parties which may otherwise cause compliance concerns. Information may be inaccurate or	The technology, material and equipment requirements would be low. Manpower requirements, financial costs, legal implications and the impact on CPI would depend highly on the nature of the items/events that should be declared. Manpower needs for processing returns

Measure	Definition	EVALUATION (Capabilities and I Criteria 1-3 ¹ Cri	Limitations) iteria 4-6 ²
	reporting of new or unforeseen events or forecast of events in order to preempt compliance concerns. (VEREX/9, Annex III, p. 166)	manipulated, and it is unlikely that any nation would declare a prohibited activity. A non-declaration of a facility known by other means could give rise to compliance concerns. Declarations may give an uneven picture of activity. (VEREX/9, Annex III, p. 166, etc.)	may be substantial. A central processing body may be required to correlate and analyse data.
Surveillance by satellite	A variety of techniques operated by an artificial body placed in orbit around the earth or other planet that enable, to varying degrees, the detection, description, measurement or identification of some property of an object of interest without actually coming into physical contact with the object. (VEREX/9, Annex II, p.67)	It has a broad area coverage, bu the possibility of detecting non-compliance with the Convention when it occurs or resolve ambiguities about compliance is low. Lack of information on distinct external signatures of microbiological activities. It might provide validation of information from other sources. The performance of optical, infra-red and multi-spectral sensors can be affected by daylight, meteorological and atmospheric conditions, in addition to inherent technical limitations with respect to Aresolution≅. SAR has a 24-hour all-weather capability, interrupted only by extreme weather conditions such as hurricanes. (VEREX/9, Annex III, p. 174, etc.)	A dedicated system would be very costly. All services may be obtained commercially, precluding the need for an autonomous capability. The measure requires digital tape data, hardware and software as well as trained personnel. Some state-owned satellite enterprises apply limitations to the availability of imagery on their own country, at the present time. Manipulation and enhancement of digital data requires commercially-available specialized hardware and software, and trained personnel.
Surveillance by aircraft	A variety of techniques operated by manned and unmanned aerial vehicles, including airplanes, helicopters, airships and balloons that enable, to varying degrees, the detection, description, measurement or identification of some property of an object of interest without actually coming into physical contact with the object. (VEREX/9, Annex II, p. 73)	The assessed possibility that it will detect non-compliance with the Convention or resolve ambiguities about compliance was low. It might provide data of a quality that could be used to distinguish between prohibited and permitted activities at an open-air test facility. There is lack of information on distinct external signatures. There is inherent delay/warning. It can be affected by daylight, meteorological and atmospheric conditions. It may be very difficult to draw conclusions on the results of air samples about the source of material collected and	Legal implications, particularly those related to national sovereignty, and collection of information unrelated to the goals and objectives of the BWC would need to be addressed. The requirements for specialized equipment and personnel could pose considerable financial costs.

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Measure	Definition	EVALUATION (Capabilities and Limitations) Criteria 1-3 ¹ Criteria 4-6 ²	
		about compliance. (VEREX/9, Annex III, p. 181, etc.)	
Ground- based surveillance (off site)	Surveillance of a site of interest at some agreed perimeter surrounding a site or many kilometers distance either by remote sensing or by visual inspection. (VEREX/9, Annex II, p. 79)	Sensing of open air test sites may be technically feasible and reasonable but there are only very rare cases where specially tailored g round-based surveillance may have some special value for the monitoring of large enterprises. It may assist targeting for inspections. Effluence of biological substances from sites of concern may be unlikely. No ability to resolve ambiguities or differentiate between permitted and prohibited activities. Optical and spectroscopic methods are not capable of identifying biological agents; generic bio-sensors are not available for all biological agents. (VEREX/9.Annex III, p. 191, etc.)	Sensitivity is limited. Availability of high specific detection probe is limited. In particular, a large variety of recognition materials are required. This measure could be intrusive and, if not focused, expensive. Specialists for interpretation of data required. Surveillance would have to be based on international agreement. Impact on CPI unlikely. May require safety control areas. Sensor techniques for surveillance of sites from distance not available; spectroscopic methods are not able to identify specific biological agents; sensitivity of biosensors requires combination with a step for sample collection.
Sampling and identification (off site)	To take samples of the area in the vicinity of a declared or undeclared facility without penetrating its boundary. (VEREX/9, Annex II, p. 83)c	The measure will usually provide information of rather poor quality, as the probability of obtaining a relevant sample is low. Using this measure alone can result in ambiguities, as e.g., the origin of any agent isolated may not be possible to clarify, and the risk of false positive as well as false negative tests may be very high. Different interpretations of the information are possible. Ability to differentiate between permitted and prohibited activities as well as resolving ambiguities is low. Could be of value in connection with open air sites. (VEREX/9, Annex III, p. 197, etc.)	The costs will depend on the total number of inspections and subsequent number of samples. Small inspection teams will be required, but the chain of custody and laboratory analysis would be labour intensive. Safety problems for inspectors are generally low, except for open air test sites. Assays for identification are not developed for some agents. Minimal impact on permitted activities and CPI.

Measure	Definition	EVALUATION (Capabilities and Limitations) Criteria 1-3 ¹ Criteria 4-6 ²	
Observation (off site)	Monitoring a site to get a sense of activities being carried out in the facility and also to get acquainted with the external characteristics of the facility. (VEREX/9, Annex III, p. 201)	The precision of the information about activities at the site is low, but it can provide a general view of the site=s characteristics. A good deal of information could be obtained about local diseases and epidemics or migration of inhabitants and environmental damage caused by the activity of the site. Its capability to distinguish between prohibited and permitted activities may be low. Also by itself it cannot determine compliance. If supplemented with on-site measures, however, it may resolve some ambiguities. (VEREX/9, Annex III, p. 201, etc.)	The technology and material requirements are generally low. Manpower will play a crucial role. Access in some States may require national legislation. Long-term physical presence of observers could be costly and may also have public relations implications. Poor weather conditions, darkness and obscuring mass could impose limitations. Impact on CPI is low.
Auditing (off site)	The critical examination, outside a facility boundary, in accordance with agreed standards and criteria, of documentary records, electronically-held data and manuals, to assess consistency of matters recorded and material account with declared purposes and permitted activity. (VEREX/9, Annex III, p. 204)	Substantial quantities of information from many sources exist; data are available on production, stockpiling and possibly development and contribute to the build-up of a picture of normal activity. Data could be highly focused and directed towards specific concerns. The scope and depth of information off site may be insufficient to make any meaningful conclusions. Standards of record keeping vary. Seems to have value as a verification measure in a limited range of circumstances, and could be considered not as a primary measure but rather as a follow-up event. (VEREX/9, Annex III, p. 204, etc.)	Technical and material requirements are minimal. Source information could have some impact on CPI. While source information could have commercial and proprietary value, procedures may be adopted that could reduce the risks of comprising commercially sensitive information. Broad range of knowledge required by auditors. Potentially some legal issues, i.e., may require consideration of national legislation and regulations.
Exchange visits - international arrangements	Visits of experts arranged for scientific purposes by one country to comparable facilities of another country (States Parties) under bilateral or multilateral agreements. Exchange visits need not be restricted to declared facilities. (VEREX/9, Annex III,	It can provide a mechanism of transfer of technical information for a given area. Some difficulties exist in implementation on a multilateral basis. The scope of the agreement can impact the amount and the quality of information. This measure is unlikely to differentiate between permitted and prohibited activities and resolve ambiguities about compliance, this measure would	The possible loss of proprietary information is of concern. Existing international organizations may support exchange programmes. Cost and legal implications could be limiting factors. Exchange visits are voluntary and

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Measure	Definition	EVALUATION (Capabilities and Limitations) Criteria 1-3 ¹ Criteria 4-6 ²	
	p. 208)	serve best as an enhanced CBM, expanding openness and transparency. The non-intrusive nature of this measure and the capability of less developed countries to acquire technical information through this mechanism is a unique capability. (VEREX/9, Annex III, p. 208, etc.)	reciprocal, these need not disrupt scientific programme activities.
Interviewing (on site)	One of the measures of fact-finding for onsite inspection. It is conducted with the personnel of the site. The objective is to gain information about the nature, scale and scope of the activities and also to assess the overall function of the site. (VEREX/9, Annex III, p. 213)	A considerable amount of information may be established. Depends on access of personnel to information. The accuracy of the information is highly dependent upon the cooperation of personnel. The possibility of giving false information weakens the differentiation between permitted and prohibited activities. Its ability to resolve ambiguities about compliance is low, but may contribute to an overall judgment. (VEREX/9, Annex III, p. 213, etc.)	It does not require specific material or technology. It requires trained, qualified experts and interpreters. It may interrupt the normal work of the site. There is the possibility of leakage of CPI. It could be costly. Access to facilities in some states may require national legislation.
Visual inspection (on site)	Aimed at acquiring a general view of the site, facilities, equipment, materials and the degree of protection, safety measures and the peaceful activities which are being carried out. It includes taking note of the specificities and the characteristics of the equipment and the instruments. (VEREX/9, Annex III, p. 217)	A large amount of information can be obtained, limited by the degree of access. May provide information on prohibited activities. But the dual-purpose nature of equipment may complicate interpretation of information and ability to resolve ambiguities about compliance. May provide information on production capacity and general capabilities. May provide information on possible undeclared activities, but it is unlikely to provide information on removed equipment. (VEREX/9, Annex III, p. 217, etc.)	It has a low capital investment requirement. The quality of the manpower available is of particular importance. CPI may be disclosed; contamination risk might be a limiting factor. It may cause an interruption of the routine work at the site and commercial confidentiality may be at risk. Inspector training is required and, in some facilities, in some States, may require national legislation.
Identification of key equipment	An essential part of identification of key equipment on site is to confirm a facility=s declaration and help to ensure that the	Can provide substantial amounts of high-quality information, if carried out by experienced specialists. Properly trained individuals may not be available immediately. Assessment of	There may be legal problems. Safety of inspectors must be considered. Proprietary information may be

Measure	Definition	EVALUATION (Capabilities and I Criteria 1-3 ¹	Limitations) iteria 4-6 ²
(on site)	equipment is not used for prohibited activities. (VEREX/9, Annex III, p. 221)	facilities= capabilities is possible. The vast majority of key equipment in biological facilities is of dual-use nature. Portable equipment can be moved out of a facility to deceive inspectors. Lack of equipment or combination of equipment as well as capacity could be used as one important indicator when it comes to differentiate activities, but equipment is mostly of dual-use nature. (VEREX/9, Annex III, p.221, etc.)	negatively affected. Financial implications should be taken into consideration. Costs can be high if a large number of inspections are carried out. Legal problems may be connected with on-site inspections as such and with the confidentiality of information obtained.
Auditing (on site)	The examination within a facility boundary, in accordance with agreed standards and criteria, of documentary records, electronically held data and manuals, to assess consistency of matters recorded and materials accounted with declared purposes and permitted activity. (VEREX/9, Annex III, p. 224)	Able to provide evidence on the linkage between events, people, activities and facilities and allow the testing of consistency and coherence. On its own would be unlikely to enable distinctions between prohibited and permitted activities and to resolve ambiguities about compliance. Unlikely to differentiate between prohibited and permitted activities and to resolve ambiguities about compliance. (VEREX/9, Annex III, p. 224, etc.)	Technological and material requirements are minimal. A broad range of knowledge is required. Procedures may be required to reduce the risks of compromising information. Commercial or other legitimate sensitivities may preclude access to all material in any one situation. Cost and national legislation and regulations may be limiting factors. Could cause some disturbance to staff.
Sampling and identification (on site)	The act of taking samples on the inspected site, analysing these samples either on the site using appropriate methods or to transfer these samples from the site for identification or further investigation in appropriate laboratories. (VEREX/9, Annex III, p. 228)	It could provide key information to resolve certain ambiguities about compliance because of the possibility of identifying the nature of an agent. Can provide information of significant quality and quantity, in particular because of the possibility of obtaining an independent confirmation of analytical results in the event that findings are disputed. A negative result does not neces sarily rule out prohibited activities and may not resolve all cases of non-compliance ambiguities. The efficiency of this measure would be enhanced from a prior indication of	Currently available material would allow many of the on-site presumptive tests to be performed. There is a need to establish infrastructure for training and deployment of inspectors. Creation and maintenance of a sophisticated field laboratory or an independent laboratory could be very costly. There is a risk of loss of CPI, but the use of equipment

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Measure	Definition	EVALUATION (Capabilities and Limitations) Criteria 1-3 ¹ Criteria 4-6 ²	
		the agents one is looking for. Ambiguous results would be reduced if more than one analytical technique and several samples from the same site were used. There is a need for an environmental profile of the site. Key issues are the chain of custody and the use of good sampling and identification practices (GSIP) (VEREX/9, Annex III, p. 228)	and methodology from the site could reduce the costs and protect confidentiality. The need to preserve intellectual, individual and commercial proprietary rights in the case of legitimate activities, means the obligation to use special technical and legal procedures for processing samples, particularly if there are grounds for removing samples from the site for subsequent analysis.
Medical examination (on site)	The collection of information about the activities of a facility by auditing medical and occupational health records of the work force; examination of recent and past cases of diseases; taking and analyzing body fluids and other clinical materials; and surveying the immunological status of the work force versus epidemiological background data. (VEREX/9, Annex III, p. 238)	By its ability to detect human exposure to agents of concern, medical examination may be a useful measure. Possibility of incorrect or falsified reported epidemiological data or medical records. Reference laboratory analysis can be expected to detect and identify an agent of concern. Examination of meticulous bona fide records could help determine prohibited activity. Low significance of immunological tests for endemic diseases, common epidemics or mass immunization with the same type of agent could prevent association with BW activity. (VEREX/9, Annex III, p. 238, etc.)	There is a potential impact on human rights for legal, ethnic, religious or personal reasons. Sensitive laboratory methods do not exist for rapid detection and identification on site for most agents. Very few medical samples can be tested on site, and transport of samples and chain of custody could require material and logistical support. Will require highly qualified specialists. Confirmatory off-site laboratory analysis could be costly. Exposure is possible and liability costs may result. Considerable impact could result from false positive information.
Continuous monitoring by	Activity conducted on a continuing basis using devices or instruments with the specific role of monitoring ongoing	It is technically applicable at any facility. Ability to differentiate between prohibited and permitted activities is low because it is unlikely to determine the purpose of a dual-use	Many in-and on-line monitors are commercially available. Some monitor devices might not operate without the

Measure	Definition	EVALUATION (Capabilities and I Criteria 1-3 ¹ Cr	Limitations) iteria 4-6 ²
instruments (on site)	processes, parameters or agents, occurring in key equipment of a particular facility, and/or storage rooms or special storage facility, or testing areas. (VEREX/9, Annex III, p. 247)	process solely by data collection. No existing instrumentation is sensitive or specific enough to independently identify non-compliance through the measurement of process parameters, or identification of agents. (VEREX/9, Annex III, p. 246, etc.)	continuous assistance of personnel. Possibly needs high investment development and operation costs. Specific antibodies as well as probes are available for several but not all agents or toxins. The technology would need further development. The measure would pose risk to intellectual rights and CPI. Risk of contamination and/or disruption of batch or continuous processes.
Continuous monitoring by personnel (on site)	Activity conducted on a continuing basis using observers or other highly qualified experts with the specific role of monitoring ongoing processes, parameters or agents, occurring in key equipment of a particular facility, and/or storage rooms or special storage facility, or testing areas. (VEREX/9, Annex III, p. 254)	Provides a fairly high degree of knowledge on the general activities undertaken at a facility. Specialized personnel could assist in differentiating between permitted and prohibited activity. However, on its own it is unlikely to determine the purpose of a dual-use process. Specificity of current methods could limit the quality of information. (VEREX/9, Annex III, p. 254, etc.)	Communication, language and cultural difficulties might occur. Costs may be very high, legal implications substantial and the risk of interference with permitted activities and infringement of commercial proprietary rights considerable. May cause contamination of processes. Personnel may need to be immunized against BTW agents or local diseases.

- 1. Criteria 1-3:
- 1. Strengths and weaknesses based on but not limited to the amount and quality of information they provide and fail to provide.
- 2. Ability to differentiate between prohibited and permitted activities.
- 3. Ability to resolve ambiguities about compliance.
- 2. Criteria 4-6:
- 4. Their technological, material, manpower and equipment requirements.
- 5. Their financial, legal, safety and organizational implications.

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6. Their impact on scientific research, scientific cooperation, industrial development and other permitted activities; and their implications for the confidentiality of CPI.

ANNEX I

VEREX 1 SUMMARY

AD HOC GROUP OF GOVERNMENTAL EXPERTS BWC/CONF.III/VEREX/2
TO IDENTIFY AND EXAMINE POTENTIAL 13 April 1992
VERIFICATION MEASURES FROM A

SCIENTIFIC AND TECHNICAL STANDPOINT ORIGINAL; ENGLISH

Geneva, 30 March - 10 April 1992

Summary of the work of the Ad Hoc Grou p for the period 30 March to 10 April 1992

1. The Final Declaration of the Third Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, in the section dealing with the review of Article V of the Convention, contained the following decision:

AThe Conference, determined to strengthen the effectiveness and improve the implementation of the Convention and recognizing that effective verification could reinforce the Convention, decides to establish an Ad Hoc Group of Governmental Experts open to all States Parties to identify and examine potential verification measures from a scientific and technical standpoint.

AThe Group shall meet in Geneva for the period 30 March to 10 April 1992. The Group will hold additional meetings as appropriate to complete its work as soon as possible, preferably before the end of 1993. In accordance with the agreement reached at the Preparatory Committee, the Group shall be chaired by Ambassador Tibor Tóth (Hungary) who shall be assisted by two Vice-Chairmen to be elected by the States Parties participating in the first meeting.

AThe Group shall seek to identify measures which could determine:

- Whether a State Party is developing, producing, stockpiling, acquiring or retaining microbial or other biological agents or toxins, of types and in quantities that have no justification for prophylactic, protective or peaceful purposes;
- Whether a State Party is developing, producing, stockpiling, acquiring or retaining weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

ASuch measures could be addressed singly or in combination. Specifically, the Group shall seek to evaluate potential verification measures, taking into account the broad range of types

and quantities of microbial and other biological agents and toxins, whether naturally occurring or altered, which are capable of being used as means of warfare.

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ATo these ends the Group could examine potential verification measures in terms of the following main criteria:

- Their strengths and weaknesses based on, but not limited to, the amount and quality of information they provide, and fail to provide;
- Their ability to differentiate between prohibited and permitted activities;
- Their ability to resolve ambiguities about compliance;
- Their technology, material, manpower and equipment requirements;
- Their financial, legal, safety and organizational implications;
- Their impact on scientific research, scientific cooperation, industrial development and other permitted activities, and their implications for the confidentiality of commercial proprietary information.

AIn examining potential verification measures, the Group should take into account data and other information relevant to the Convention provided by the States Parties.

AThe Group shall adopt by consensus a report taking into account views expressed in the course of its work. The report of the Group shall be a description of its work on the identification and examination of potential verification measures from a scientific and technical standpoint, according to this mandate.

AThe report of the Group shall be circulated to all States Parties for their consideration. If a majority of States Parties ask for the convening of a conference to examine the report, by submitting a proposal to this effect to the Depositary Governments, such a conference will be convened. In such a case the conference shall decide on any further action. The conference shall be preceded by a preparatory committee.≅

2. The Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint held its first session at Geneva from 30 March to 10 April 1992, under the Chairmanship of Ambassador Tibor Tóth (Hungary). During that period the Group held 18 meetings and 7 informal meetings. The Chairman also conducted a series of informal

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consultations during the same period. The following 53 States Parties to the Convention participated in the session of the Group: Argentina, Australia, Austria, Belgium, Bolivia, Brazil, Bulgaria, Canada, Chile, China, Cuba, Czech and Slovak Federal Republic, Denmark, Finland, France, Germany, Greece, Hungary, India, Indonesia, Iran (Islamic Republic of), Iraq, Ireland, Italy, Japan, Kenya, Malta, Mexico, Netherlands, New Zealand, Nigeria, Norway, Pakistan, Panama, Peru, Philippines, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Senegal, Spain, Sri Lanka,

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Sweden, Switzerland, Thailand, Turkey, United Kingdom of Great Britain and Northern Ireland, United States of America, Venezuela, Yugoslavia, Zimbabwe.

- 3. Representatives of two specialized agencies the World Health Organization (WHO) and the United Nations Industrial Development Organization (UNIDO) also participated as observers in the meeting, upon invitation of the Chairman.
- 4. To assist the Chairman in his work, and as provided for in the decision of the Third Review Conference, the Group, at its 10th meeting on 6 April, elected Ambassador Gérard Errera (France) and Dr. Amir E. Saghafinia (Iran, Islamic Republic of) as its Vice-Chairmen.
- 5. At its first meeting, on 30 March, the Group adopted its agenda as well as a timetable for the first week (30 March 3 April). The agenda is attached to the present summary as Annex III.
- 6. In pursuance of its mandate, and in accordance with its timetable, the Group, during the first week, undertook a structured general discussion of the relevant issues on, *inter alia*, background information, objectives for BWC verification, elements of a BW programme, possible besons from other disarmament and arms limitation regimes, and types of information relevant for verification. In the course of those discussions, several delegations presented national papers which were subsequently circulated as working papers of the Ad Hoc Group. A number of background papers were also circulated at the request of delegations. A list of documents is attached to the present summary as Annex IV.
- 7. At its 9th meeting, on 3 April, the Group adopted a timetable for the second week (6-10 April). For that period, the timetable provided for the identification and compilation of potential verification measures from a scientific and technical standpoint.
- 8. Following the adoption of the timetable for the second week, it was agreed, upon the suggestion of the Chairman, to designate the following experts to assist in the task of identifying and compiling potential verification measures grouped under the three broad areas of <u>development</u>, acquisition or production and stockpiling or retaining.

Development

Moderator: Mr. Patrice Binder (France)

Assisted by: Mr. Vladimir Betina (Czech and Slovak Federal Republic)

Mr. Ashok Kapur (India)

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Acquisition or production

Moderator: Mr. Ake Bovallius (Sweden)

Assisted by: Mr. Jan L.F. Gerbrandy (Netherlands)

Mr. Marian Negut (Romania)

Stockpiling or retaining

Moderator: Mr. Roque Monteleone Neto (Brazil)

Assisted by: Mr. Lloyd White (Canada)

Mr. O.B. Oshodi (Nigeria)

- 9. The Group proceeded, in accordance with its mandate and its timetable, to identify and compile lists of potential verification measures which may determine whether a State Party is:
 - <u>developing</u> microbial or other biological <u>agents</u> or <u>toxins</u>, of types and in quantities that have no justification for prophylactic, protective or peaceful purposes;
 - developing weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict;
 - acquiring or producing microbial or other biological agents or toxins, of types and in quantities that have no justification for prophylactic, protective or peaceful purposes;

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- <u>acquiring or producing weapons, equipment or means of delivery</u> designed to use such agents or toxins for hostile purposes or in armed conflict;
- <u>stockpiling or retaining</u> microbial or other biological <u>agents or toxins</u>, of types and in quantities that have no justification for prophylactic, protective or peaceful purposes;
- <u>stockpiling</u> or retaining weapons, equipment or means of <u>delivery</u> designed to use such agents or toxins for hostile purposes or in armed conflict.
- 10. The measures identified were compiled into lists of potential verification measures in the three broad areas of <u>development</u>, <u>acquisition or production</u>, and <u>stockpiling or retaining</u>. The three lists contained in Annex I to the present summary are indicative and need further discussion. The measures included in the respective lists were integrated by the Chairman into a ACompiled List of Potential Verification Measures≅, which is attached to the present summary as Annex II.

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- 11. At its 15th meeting, on 8 April, the Group began a general discussion on how to examine and evaluate the measures identified and compiled.
- 12. The Group decided to continue its work and, in accordance with its mandate, examine and evaluate the identified potential verification measures from a scientific and technical standpoint. The basis for the examination will be the lists of identified potential verification measures contained in Annex I to the present summary, together with any agreed future changes to the lists. To this end the Group shall meet in Geneva for the period 23 November to 4 December 1992.

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Annex I

IDENTIFICATION OF POTENTIAL VERIFICATION MEASURES¹

The three lists contained in the present annex are indicative and need further discussion.

DEVELOPMENT OF AGENTS AND TOXINS AND OF WEAPONS, EQUIPMENT AND MEANS OF DELIVERY

I. OFF-SITE MEASURES

1. INFORMATION MONITORING

- 1.1 SURVEILLANCE OF PUBLICATIONS (scientific and military literature, reports of symposiums, patents ...)
- 1.2 SURVEILLANCE OF LEGISLATION (on handling and transfers of agents and equipment, licensing, production and use of biological agents and related products, ...)
- 1.3 DATA ON TRANSFERS AND TRANSFER REQUESTS (import and export of agents, equipment, know how, technology, personnel ...) AND ON PRODUCTION
- 1.4 MULTILATERAL INFORMATION SHARING (surveillance of outbreaks and their control using declarations, data banks ...-, international cooperation ...)

¹ Some illustrative possible areas could be discussed from a technical and scientific standpoint in accordance with the mandate criteria together with the proposed measures. Definitions of these elements and guidelines could be discussed during the next steps.

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2. DATA EXCHANGE

- 2.1 DECLARATIONS (on agents², facilities³, equipment⁴, programmes⁵, transfers import-export of agents, equipment, know-how, technology, personnel ... manufacturing ...)
- 2.2 NOTIFICATIONS (on changes in declared activities, unusual activities, accidental releases, outbreaks, military exercises ...)

 $^{^{2}}$ Illustrative lists and quantity thresholds could be elaborated

³ A selection could be made according to criteria to be discussed (e.g. biosafety levels, activities, materials handled ...).

⁴ Illustrative lists could be elaborated (e.g. fermenters, aerosol testing chambers, centrifuge, freeze - drying ...).

⁵ Description of programmes (goals, authority in charge, relationship with military institutions, amount and origin of funds): e.g. programmes on increase of virulence and toxicity, challenge-testing on animals (vaccination, aerosols ...), aerosol dissemination, use of containment units, evaluation of methods for environmental decontamination, microencapsulation....

3. REMOTE SENSING

- 3.1 SURVEILLANCE BY SATELLITE (infrared, radar or visual surveillance of facilities, environment ...)
- 3.2 SURVEILLANCE BY AIRCRAFT (infrared, radar, laser or visual surveillance of facilities, environment, outdoor testing ...)
- 3.3 GROUND BASED SURVEILLANCE (instrumental, visual surveillance of facilities, environment, outdoor testing ...)

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4. INSPECTIONS⁶

- 4.1 SAMPLING AND IDENTIFICATION⁷ (air, water, soil, appropriate biological specimens from animals, plants, in vicinity ...)
- 4.2 OBSERVATION (outdoor facilities, outdoor testing, military, medical, pharmaceutical, agricultural, industrial activities ...)

Inspections could be of routine character or at short notice, and could apply to declared and/or undeclared facilities

Preparation for inspections could be examined in the next steps. (E.g. arrangements for access, time limits, preliminary questionnaires ...).

Object of inspection could be: conformity with declarations; investigation of complaints, unusual outbreaks or accidental releases \dots .

Possibility or not to take samples from site, analysis on/off site, possibility to use reference techniques and/or laboratories

4.3 AUDITING (copy of records, manuals for training or use, safety regulations - according to official manuals, special instructions ...-, financial documents, programmes, questioning of local inhabitants ...)

3. REMOTE SENSING

- 3.1 SURVEILLANCE BY SATELLITE (infrared, radar or visual surveillance of facilities, environment, weapons test areas ...)
- 3.2 SURVEILLANCE BY AIRCRAFT (infrared, radar, laser or visual surveillance of facilities, environment, traffic and shipping activities, weapons test areas ...)
- 3.3 GROUND BASED SURVEILLANCE (instrumental, visual surveillance of facilities, environment, traffic and shipping activities, weapons test areas ...)

4. INSPECTIONS⁶

⁶ Object of inspection could be: conformity with declarations, investigation of complaints, unusual outbreaks or accidental releases. Inspections could be of routine character or at short notice, and could apply to declared and/or undeclared facilities.

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- 4.1 SAMPLING AND IDENTIFICATION⁷ (air, water, soil, appropriate biological specimens from animals, plants, in the vicinity, weapons test areas ...)
- 4.2 OBSERVATION (facilities⁸, military activities, special transport equipment, flash protection, spraying sites ...)
- 4.3 AUDITING (copies of records, manuals for safety, security and training, financial documents, commercial orders/sales records ...)

 $^{^{7}}$ Possibility or not to take samples from site, analysis on/off site, possibility to use reference techniques and/or laboratories

⁸ Cold rooms, presence of filtration units, sewage tanks and treatment facilities for air, water, detection and alarm systems, aerial spraying sites, area decontamination equipment, medical facilities, security arrangements, meteorological stations, protective measures for personnel

II. ON-SITE MEASURES

1. EXCHANGE VISITS

1.1 INTERNATIONAL ARRANGEMENTS (visits by industrial personnel, inspectors, engineers, equipment experts ...)

2. INSPECTIONS

- 2.1 INTERVIEWING (staff, authorities ...)
- 2.2 VISUAL INSPECTION (facilities, equipment, storage capacity, transport/storage containers, enhanced security measures, specialized bunkers, other appropriately designed storage structures ...)
- 2.3 IDENTIFICATION OF KEY EQUIPMENT (systems, apparatus, containment, munitions and delivery systems, weapons filling equipment, aerosol spray equipment ...)
- 2.4 AUDITING (records, safety regulations, manuals for safety, security and training, financial documents, vaccinations, commercial orders/sales records ...)
- 2.5 SAMPLING AND IDENTIFICATION (air, water, soil, surfaces, sewage, filters, appropriate biological specimens from animals and plants, weapons analysis by non-destructive methods, e.g. X-ray, acoustic resonance, pulse echo ...)
- 2.6 MEDICAL EXAMINATION (clinical investigation, investigation of staff health records, body fluids and tissues of personnel ...)

3. CONTINUOUS MONITORING

- 3.1 BY INSTRUMENTS (automatic sampling, video recording ...)
- 3.2 BY PERSONNEL (posting of observers, inspectors, personnel with appropriate expertise ..)

3. REMOTE SENSING

- 3.1 SURVEILLANCE BY SATELLITE (infrared, radar or visual surveillance of facilities, environment, weapons test areas ...)
- 3.2 SURVEILLANCE BY AIRCRAFT (infrared, radar, laser or visual surveillance of facilities, environment, traffic and shipping activities, weapons test areas ...)
- 3.3 GROUND BASED SURVEILLANCE (instrumental, visual surveillance of facilities, environment, traffic and shipping activities, weapons test areas ...)

4. INSPECTIONS⁶

- 4.1 SAMPLING AND IDENTIFICATION⁷ (air, water, soil, appropriate biological specimens from animals, plants, in the vicinity, weapons test areas ...)
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- 4.3 AUDITING (copies of records, manuals for safety, security and training, financial documents, commercial orders/sales records ...)

⁶ Object of inspection could be: conformity with declarations, investigation of complaints, unusual outbreaks or accidental releases. Inspections could be of routine character or at short notice, and could apply to declared and/or undeclared facilities.

 $^{^{7}\,}$ Possibility or not to take samples from site, analysis on/off site, possibility to use reference techniques and/or laboratories

⁸ Cold rooms, presence of filtration units, sewage tanks and treatment facilities for air, water, detection and alarm systems, aerial spraying sites, area decontamination equipment, medical facilities, security arrangements, meteorological stations, protective measures for personnel

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II. ON-SITE MEASURES

1. EXCHANGE VISITS

1.1 INTERNATIONAL ARRANGEMENTS (visits by industrial personnel, inspectors, engineers, equipment experts ...)

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- 4.2 OBSERVATION (facilities⁸, military activities, special transport equipment, flash protection, spraying sites ...)
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 $^{^7\,}$ Possibility or not to take samples from site, analysis on/off site, possibility to use reference techniques and/or laboratories

⁸ Cold rooms, presence of filtration units, sewage tanks and treatment facilities for air, water, detection and alarm systems, aerial spraying sites, area decontamination equipment, medical facilities, security arrangements, meteorological stations, protective measures for personnel

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- 2.5 SAMPLING AND IDENTIFICATION (air, water, soil, surfaces, sewage, filters, appropriate biological specimens from animals and plants, weapons analysis by non-destructive methods, e.g. X-ray, acoustic resonance, pulse echo ...)
- 2.6 MEDICAL EXAMINATION (clinical investigation, investigation of staff health records, body fluids and tissues of personnel ...)

3. CONTINUOUS MONITORING

- 3.1 BY INSTRUMENTS (automatic sampling, video recording ...)
- 3.2 BY PERSONNEL (posting of observers, inspectors, personnel with appropriate expertise ..)

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3. REMOTE SENSING

- 3.1 SURVEILLANCE BY SATELLITE (infrared, radar or visual surveillance of facilities, environment, weapons test areas ...)
- 3.2 SURVEILLANCE BY AIRCRAFT (infrared, radar, laser or visual surveillance of facilities, environment, traffic and shipping activities, weapons test areas ...)
- 3.3 GROUND BASED SURVEILLANCE (instrumental, visual surveillance of facilities, environment, traffic and shipping activities, weapons test areas ...)

4. INSPECTIONS⁶

- 4.1 SAMPLING AND IDENTIFICATION⁷ (air, water, soil, appropriate biological specimens from animals, plants, in the vicinity, weapons test areas ...)
- 4.2 OBSERVATION (facilities⁸, military activities, special transport equipment, flash protection, spraying sites ...)

⁶ Object of inspection could be: conformity with declarations, investigation of complaints, unusual outbreaks or accidental releases. Inspections could be of routine character or at short notice, and could apply to declared and/or undeclared facilities.

 $^{^{7}\,}$ Possibility or not to take samples from site, analysis on/off site, possibility to use reference techniques and/or laboratories

⁸ Cold rooms, presence of filtration units, sewage tanks and treatment facilities for air, water, detection and alarm systems, aerial spraying sites, area decontamination equipment, medical facilities, security arrangements, meteorological stations, protective measures for personnel

4.3 AUDITING (copies of records, manuals for safety, security and training, financial documents, commercial orders/sales records ...)

II. ON-SITE MEASURES

1. EXCHANGE VISITS

1.1 INTERNATIONAL ARRANGEMENTS (visits by industrial personnel, inspectors, engineers, equipment experts ...)

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- 2.5 SAMPLING AND IDENTIFICATION (air, water, soil, surfaces, sewage, filters, appropriate biological specimens from animals and plants, weapons analysis by non-destructive methods, e.g. X-ray, acoustic resonance, pulse echo ...)
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3. CONTINUOUS MONITORING

- 3.1 BY INSTRUMENTS (automatic sampling, video recording ...)
- 3.2 BY PERSONNEL (posting of observers, inspectors, personnel with appropriate expertise ..)

Annex IV

<u>List of documents submitted to the first session,</u> 30 March - 10 April 1992

Doc. Symbol <u>Title</u>

BWC/CONF.III/VEREX/1 Agenda

BWC/CONF.III/VEREX/2 Summary of the work of the Ad Hoc Group for the

period 30 March to 10 April 1992

Working Papers

BWC/CONF.III/VEREX/WP.1 Working paper submitted by the United Kingdom,

entitled AVerification of the BWC: Possible

Directions≅

BWC/CONF.III/VEREX/WP.2 Working paper submitted by France, entitled AGroup

of Experts on the Verification of the Biological

Weapons Convention≅

(available in English and French)

BWC/CONF.III/VEREX/WP.2/Corr.1 Corrigendum

(French only)

BWC/CONF.III/VEREX/WP.3 Working paper submitted by the Netherlands, entitled

ADiscussion Paper≅

BWC/CONF.III/VEREX/WP.4 Working paper submitted by Germany, entitled

AOptions for the Verification of the BWC≅

BWC/CONF.III/VEREX/WP.5 Working paper submitted by the United Kingdom,

entitled AUN Special Commission BW Inspections in Iraq: Lessons for the Ad Hoc Experts—Group on

Verification≅

BWC/CONF.III/VEREX/WP.6 Working paper submitted by the United States,

entitled AMicroorganisms and Toxins: A Brief

Overview≅

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BWC/CONF.III/VEREX/WP.7 Working paper submitted by the United States,

entitled ABiotechnology: An Overview of Techniques, Research and Applications≅

BWC/CONF.III/VEREX/WP.8 Working paper submitted by the United States,

entitled AVerification Measures: Goals and

Purposes≅

BWC/CONF.III/VEREX/WP.9 Working paper submitted by the United States,

entitled AThe Nature of Biological Defense≅

BWC/CONF.III/VEREX/WP.10 Working paper submitted by Australia, entitled AThe

Biological Weapons Convention: A possible

verification regime_≃

BWC/CONF.III/VEREX/WP.11 Working paper submitted by Sweden, entitled

AOutline for a systematic approach on technical verification measures and their applications for the

BTWC≅

BWC/CONF.III/VEREX/WP.11/ Revised version of appendices in Swedish

APPENDICES/Rev. 1 Working paper

BWC/CONF.III/VEREX/WP.12 Working paper submitted by the Czech and Slovak

Federal Republic, entitled AVerification regime of the

 $BWC \simeq$

BWC/CONF.III/VEREX/WP.13 Working paper submitted by France, entitled

AAgents potentiallement militarisables: Essai de

typologie≅

BWC/CONF.III/VEREX/WP.14 Working paper submitted by Portugal, entitled

ATypes of information relevant for verification ∈

BWC/CONF.III/VEREX/WP.15 Working paper submitted by the United States,

entitled AStatement of Dr. Edward J. Lacey, Head of the United States Delegation to the Ad Hoc Group of BWC Governmental Experts on 1 April 1992≘

BWC/CONF.III/VEREX/WP.16 Working paper submitted by the United States,

entitled AAnimal Vaccine Production=

BWC/CONF.III/VEREX/WP.17 Working paper submitted by the United States,

entitled ABrewery Operations≅

BWC./CONF.III/VEREX/WP.18 Working paper submitted by Bulgaria, entitled

AVerification regime of the BWC: Relevance of some information from annual exchange of data in the frames of the BWC for the verification=

BWC/CONF.III/VEREX/WP.19 Working paper submitted by Iraq, entitled AExtracts

from a factual report issued by the Iraqi relevant authorities about the measures taken by Iraq in accordance with Security Council Resolution 687

(1991): >The Biological Aspects=≅

BWC/CONF.III/VEREX/WP.20 Working paper submitted by Sweden, entitled AFirst

step towards a trial inspection of a vaccine

production plant≅

BWC/CONF.III/VEREX/WP.21 Working paper submitted by Iraq, entitled AProposal

for identification of measures which could determine whether a State Party is developing microbial or other biological agents or toxins, of types and in quantities that have no justification for prophylactic,

protective or peaceful purposes≃

BWC/CONF.III/VEREX/WP.22 Working paper submitted by Peru, entitled

AStatement by the Head of the delegation of Peru, Dr. Felix Calderon, to the Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint set up under the Convention on the Prohibition of Bacteriological (Biological) and

Toxin Weapons (1 April 1992)≅

BWC/CONF.III/VEREX/WP.23 Working paper submitted by the Russian Federation,

entitled Alllustrative list of potential biological weapon

agents≅

BWC/CONF.III/VEREX/WP.24 Working paper submitted by Italy, entitled AThe

Biological Weapons Convention, Verification regime:

Some suggested criteria≅

page 44

BWC/CONF.III/VEREX/WP.25 Working paper submitted by Iran, entitled AElements

of biological weapons monitoring systems≅

BWC/CONF.III/VEREX/WP.26 Working paper submitted by Iran, entitled ANatural

biological bomb: A need for biotechnology in

developing countries≅

BWC/CONF.III/VEREX/WP.27 Working paper submitted by Iran, entitled AConcerns

and views of a vaccine producer of the developing

countries≅

BWC/CONF.III/VEREX/WP.28 Working paper submitted by Iran, entitled

AGuidelines to differentiate between prohibited and

permitted activities≅

BWC/CONF.III/VEREX/WP.29 Working paper submitted by India, entitled

AA preliminary approach to the verification regime

for the Biological Weapons Convention≅

BWC/CONF.III/VEREX/WP.30 Working paper submitted by Iran, entitled

AEvaluation of the identified potential verification

measures: A quantitative approach

E

BWC/CONF.III/VEREX/WP.31 Working paper submitted by Canada, entitled

ACapabilities and limitations of overhead remote sensing for verification within the context of the Biological and Toxin Weapons Convention

(BTWC)≃

Conference Room Papers

BWC/CONF.III/VEREX/CRP.1 Provisional Agenda

BWC/CONF.III/VEREX/CRP.2/Rev.2 Tentative Timetable for the first week, 30 March -

April 1992

BWC/CONF.III/VEREX/CRP.3 Tentative Timetable for the second week.

6-10 April 1992

BWC/CONF.III/VEREX/CRP.4/Rev.1 Draft summary of the work of the Ad Hoc Group for

the period 30 March - 10 April 1992

Information Papers

BWC/CONF.III/VEREX/INF.1 List of States Parties

BWC/CONF.III/VEREX/INF.2 Offices of the Ad Hoc Group

BWC/CONF.III/VEREX/INF.3/Rev.1 List of Delegations

BWC/CONF.III/VEREX/INF.4 Mandate of the Ad Hoc Group

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Background documentation

Doc. Symbol	<u>Title</u>	Submitted by
BWC/CONF.III/VEREX/NONE.1	Pugwash Working paper entitled AVerification of biological and toxin weapons disarmament≅	France
BWC/CONF.III/VEREX/NONE.2	Pugwash Working paper entitled AHow to strengthen confidence in the Biological Weapons Convention≅	France
BWC/CONF.III/VEREX/NONE.3	Article from <u>Arms Control and</u> National Security (1990) entitled AChemical and biological warfare≅	France
BWC/CONF.III/VEREX/NONE.4	The Nature of Biological Defence	United Kingdom
BWC/CONF.III/VEREX/NONE.5	The Nature of Biological Warfare Agents	United Kingdom
BWC/CONF.III/VEREX/NONE.6	Article from <u>Jama</u> (1989) enitled AChemical and Biological Warfare≅	France
BWC/CONF.III/VEREX/NONE.7	Article from Jane=s NBC Protection Equipment (1991-1992) entitled ABiological Warfare≅	France
BWC/CONF.III/VEREX/NONE.8	OECD publication (1988) entitled ATrends in Biological and Toxin Weapons≅	France
BWC/CONF.III/VEREX/NONE.9	Paper submitted at a symposium at the Centre des Etudes du Bouchet (28-29 November 1990) entitled	France

	AMesures de protection contre les agents d=origine biologique≅	
BWC/CONF.III/VEREX/NONE.10	Article from <u>Defense Nationale</u> (July 1990) entitled AAgents d=origine biologique: l=evolution du risque≅	France
BWC/CONF.III/VEREX/NONE.11	Article from Médicine et Armées (1990) entitled ABiotechnologies et génétiques dans le concept des nouvelles formes d≟armes biologiques≅	France
BWC/CONF.III/VEREX/NONE.12	Paper submitted at the 3rd National Congress of the Société Française d=Aérobiologie (6·7-8 June 1991) entitled ADetection des agents d=origine biologique potentiellement militarisables≅	France
BWC/CONF.III/VEREX/NONE.13	Article from International Defense Review, 8/1990, entitled ABiological Weapons: How big a threat?≅	France
BWC/CONF.III/VEREX/NONE.14	Article from <u>UNIDIR Newsletter</u> <u>Vol. 4, No. 2</u> (June 1991) entitled APubli cations on Biological Weapons and Disarmament≅	France
BWC/CONF.III/VEREX/NONE.15	Article from Jane=s Intelligence Review (November 1991) entitled ABiological Warfare Developments≅	France
BWC/CONF.III/VEREX/NONE.16	Article from Pacific Research (February 1990) entitled ADisease as a Weapon of War≅	France
BWC/CONF.III/VEREX/NONE.17	Article from New Scientist (21 March 1992) entitled APreventing biological warfare≅	United Kingdom

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BWC/CONF.III/VEREX/NONE.18-20	Withdrawn	
BWC/CONF.III/VEREX/NONE.21	Table entitled Aldentify Measures Examine singly or in combination Assess strengths and weaknesses≅	Canada
BWC/CONF.III/VEREX/NONE.22	Paper entitled ABiological Weapons - Conventions and History≅	Norway
BWC/CONF.III/VEREX/NONE.23	Table enclosing a list of agents	Brazil
BWC/CONF.III/VEREX/NONE.24	Paper entitled AImpact of Verification Inspection on the Biotechnology Industry≅	United Kingdom

ANNEX II

VEREX 2 SUMMARY

1. Criteria 1-3: 1. Strengths and weaknesses based on but not limited to the amount and quality of information they provide and fail to provide.

- 2. Ability to differentiate between prohibited and permitted activities.
- 3. Ability to resolve ambiguities about compliance.
- 2. Criteria 4-6: 4. Their technological, material, manpower and equipment requirements.
 - 5. Their financial, legal, safety and organizational implications.
 - 6. The impact on scientific research, scientific cooperation, industrial development and other permitted activities; and their implications for the confidentiality of CPI.

Ad hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint

BWC/CONF.III/VEREX/4 8 December 1992

ENGLISH only

Second Session Geneva, 23 November - 4 December 1992

Summary of the work of the Ad Hoc Group for the period 23 November to 4 December 1992

- 1. In accordance with the mandate adopted by the Third Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction in 1991 and the agreement reached at the first session of the Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint, the Group held its second session in Geneva from 23 November to 4 December 1992, under the Chairmanship of Ambassador Tibor Tóth (Hungary). Ambassador Gérard Errera (France) and Mr. Hassan Mashhadi (Iran, Islamic Republic of) served as Vice-Chairmen of the Group. During its second session, the Group held 19 meetings and 1 informal meeting. The Chairman also conducted a series of informal consultations during the same period.
- 2. The following 46 States parties to the Convention participated in the session of the Group: Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China, Cuba, Czech and Slovak Federal Republic, Denmark, Ethiopia, Finland, France, Germany, Greece, Hungary, India, Indonesia, Iran (Islamic Republic of), Iraq, Ireland, Italy, Japan, Kenya, Mexico, Netherlands, New Zealand, Nigeria, Norway, Pakistan, Philippines, Poland, Republic of Korea, Romania, Russian Federation, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Thailand, United Kingdom of Great Britain and Northern Ireland, United States of America, Venezuela.
- 3. The representative of the World Health Organization (WHO) also participated as an observer of the meeting, upon invitation of the Chairman.
- 4. The Group was assisted by staff members from the Office for Disarmament Affairs, Mr. Vladimir Bogomolov, Political Affairs Officer, Secretary to the Group and Ms. Jenifer Mackby, Political Affairs Officer, Deputy Secretary.
- 5. At its first meeting, on 23 November, the Group adopted its agenda as well as a programme of work for the session. The agenda and programme of work are attached to the present summary as Annex II. The agenda and the programme of work provided for the examination, the summing up of the examination and the beginning of the evaluation of potential verification measures from a scientific and technical standpoint.

- 6. The following experts continued to assist the Chairman as moderators in the task of examining potential verification measures grouped under the three broad areas: Mr. Patrice Binder (France) development; Mr. Åke Bovallius (Sweden) acquisition or production; Mr. Roque Monteleone Neto (Brazil) stockpiling or retaining. In addition, the moderators were also requested by the Chairman to conduct informal consultations on the following issues: Mr. Binder to carry out a sondage on identified areas of interest needing further elaboration and also on the issue of confidentiality in industry, the results of which are contained in document BWC/CONF.III/VEREX/WP.91 attached to this summary as Annex V; Mr. Bovallius the modalities of reflecting the results of the process of the evaluation; Mr. Monteleone Neto the possible need to modify the list of measures identified at the first session, the results of which were accepted and are contained in document BWC/CONF.III/VEREX/WP.92 attached to this summary as Annex VI.
- 7. The Chairman was further assisted by experts acting in their personal capacity as rapporteurs whose task was to introduce the measure(s) to be examined, the moderate the relevant discussions, and to prepare summaries of the examination of those measures. The list of rapporteurs and the respective measures assigned to them are as follows:

Surveillance of publications Mr. Max Gevers (Netherlands)

Surveillance of legislation Mr. Max Gevers (Netherlands)

Data on transfers and transfer requests and on production

Mr. Max Gevers (Netherlands)

Multilateral information sharing Mr. Max Gevers (Netherlands)

Declarations Mr. Ashok Kapur (India)

Notifications Ms. Annabelle Duncan (Australia)

Surveillance by satellite Mr. Gordon Vachon (Canada)

Surveillance by aircraft Mr. Gordon Vachon (Canada)

Ground-based surveillance Mr. Volker Beck (Germany)

Sampling and identification (off-site) Mr. Åke Bovallius (Sweden)

Observation Mr. A.A. Mohammadi (Iran, Islamic Republic of)

Auditing (off-site) Mr. David O. Arnold-Forster (United Kingdom)

International arrangements Mr. Ashok Kapur (India)

Interviewing Mr. A.A. Mohammadi (Iran, Islamic Republic of)

Visual inspection Mr. A.A. Mohammadi (Iran, Islamic Republic of)

Identification of key equipment Mr. Åke Bovallius (Sweden)

Auditing (on-site) Mr. David O. Arnold-Forster (United Kingdom)

Sampling and identification (on-site) Mr. Patrice Binder (France)

Medical examination Mr. Marian Negut (Romania)

Continuous monitoring by instruments Mr. Roque Monteleone Neto (Brazil)

Continuous monitoring by personnel Mr. Roque Monteleone Neto (Brazil)

- 8. The Chairman also requested Mr. Max Gevers (Netherlands), Mr. Kalyan Banerjee (India) and Mr. Åke Bovallius (Sweden) to conduct consultations on the possible methodology for embarking on the evaluation of the measures examined. As a result of these consultations, the delegations of the Netherlands, India and Sweden presented a working paper (BWC/CONF.III/VEREX/WP.89) aiming at facilitating the work of the Group, and which was agreed upon by the Group as a basis for the evaluation stage. This document is attached to the present Summary as Annex IV.
- 9. At an informal meeting on 2 December 1992 the delegation of the Islamic Republic of Iran presented a quantitative model to evaluate verification measures.
- 10. The delegations of Brazil, France and Sweden proposed, in document BWC/CONF.III/VEREX/WP.90, a possible approach to evaluation.
- 11. The Group proceeded, in accordance with its mandate and the programme of work, to examine the potential verification measures identified during the first session. In the course of those discussions, several delegations presented national papers which were subsequently circulated as working papers of the Group. A number of background papers were also circulated at the request of delegations. A list of documents is attached to the present summary as Annex VII.
- 12. The rapporteurs prepared structured summaries providing a factual description of the examination of the measures. The uniform structure of these summaries is contained in Annex III. These summaries, which are not considered to be exhaustive and might be further specified during evaluation, were thoroughly discussed by the Group, producing consolidated texts to serve as a basis of the beginning of the evaluation. The summaries are contained in Annex I.

- 13. At its 17th meeting, on 3 December, the Group began an evaluation of the measures identified during its first session.
- 14. The Group decided to continue its work and, in accordance with its mandate, to carry on with the evaluation of the identified potential verification measures from a scientific and technical standpoint which had been examined during this session.
- 15. Taking into account the important tasks related to the evaluation of the identified potential verification measures and the limited time periods available for further sessions, the Group was of the view that additional efforts were required to prepare its future work. To this end, the Group entrusted its Chairman:
- to clarify whether moderators and rapporteurs were available to continue to assist the Group in its work,
- to request rapporteurs to prepare informal introductory papers on the respective measures to facilitate their evaluation, and make those papers available before the next session of the Group, if possible,
- to request moderators to prepare informal introductory papers in the context of, <u>inter alia</u>, the three broad areas of development, acquisition or production and stockpiling or retaining to facilitate the evaluation of the measures, and make those papers available before the next session of the Group, if possible,
- to request the Secretary of the Group to provide assistance for the advance circulation of relevant national papers that might be produced before the next session of the Group,
- to hold several informal consultations to prepare for the next session of the Group.

The Group asked its Chairman to conduct consultations on the organization of its work on the basis of document BWC/CONF.III/VEREX/WP.89 and taking into account various additional proposals presented.

16. The Group decided to have its next sessions in Geneva from 24 May to 4 June 1993 and from 13 to 24 September 1993.

Annex I

SUMMARIES OF THE EXAMINATION

INFORMATION MONITORING (Off-Site) (Rapporteur: Mr. Max Gevers)

BWC/CONF.III/VEREX/WP.71/Rev.1

N.B.: The specific aspects mentioned under the general heading A<u>Information Monitoring</u>≅ apply equally to all four subcategories.

Definitions

Information monitoring is the collection, analysis, manipulation or categorization of information, synthesis of already available data on, but not limited to, national export and import records, industrial production, statistics, scientific information and culture collection records, over a period of time, in order to obtain information in relation to biological warfare endeavors.

Monitoring would include surveilling publications, analyzing legislation, reviewing data on transfers and transfer requests and multilateral information sharing. Information would be provided on a voluntary basis, and could include both public and restricted information.

Characteristics and technologies

- Information monitoring could be part of the functions of a proposed independent multilateral body which would have the wider task of verification of the BWC;
- Information which may be <u>indicative</u> of otherwise legitimate dual-purpose activities, that could be diverted to biological weapons purposes or inconsistent with peaceful biological activities:
- Preferably information could assist <u>analysis</u> to highlight dual-purpose activities of potential concern, thus allowing for consultation or elaboration;
- Data of international organizations (WHO, FAO, OIE);
- Necessity to select information and direct it to specific goals: Akey words≅, direct data base searches and may include illustrative lists of agents, equipment and/or activities;
- Is of less intrusive nature than on-site inspections;
- Multitude of different sources;

- Computerized data base; the possibility of establishing an international data base should be considered;
- Necessity to promote universal participation by BWC States Parties in providing information and in information sharing (reference also to CBMs);

N.B.: in case of restricted or classified (sensitive) information: confidentiality to be protected.

Capabilities

- Provides information on activities (official and non-official) in the biological field, taking place on the territory of a State Party;
- May help in establishing patterns of activity;
- Could reveal Atrends≅ and Atrendlike≅ developments;
- Provides background for further investigation, if deemed necessary;
- Could act as support for other types of information;
- Could assist in focussing on targets for inspections;
- May point to information which has been withheld or to other sorts of inconsistencies:

Limitations

- Due to the dual nature of relevant technologies, it may be difficult to distinguish between permitted and prohibited activities of concern;
- If not focussed, it could be expensive, particularly in view of the many different languages, and misleading;
- Might act as a brake on publication;
- Risk of too much information:
- Worldwide and structural examination of identified sources if probably physically impossible;
- Risk of manipulation of information, of misinterpretation, of too much or too little selection:
- Not all information is freely accessible;

- Key word data base searches may miss items, because of national variations on terminology;
- Quantity and quality of information varies per state;
- Particularly applicable to the research, development and production stage;

Potential interaction with other measures

Possibility of overlapping activities with off-site auditing;

May provide a cross-reference on declarations as well as on information provided under CBMs;

Could help in the selection of sites in the conduct of on-site and off-site inspection;

List of documents introduced

- ASome preliminary views on the use of information monitoring in a BWC verification Regime≅ (The Netherlands);
- 2. US statement of 23/11/1992

SURVEILLANCE OF PUBLICATIONS

Definition

Selective scanning and analysis of publicly available printed matter and of the media with special attention to scientific literature related to activities in the biological field;

Characteristics and technologies

- Specific statistical data;
- Press and scientific data bases;
- Records and reports of scientific meetings and congresses;
- Information on vaccine-programmes, other programmes and research concerning pathogenic organisms and toxins directed under high-containment conditions;
- Information on new market products related to rapid identification of toxins and microbial pathogens including WHO risk groups III and IV;

Capabilities

- Scanning could be especially helpful if directed to specific compliance concerns;
- Applicable especially in the research and development stage of biological activities;
- Could assist in identifying inconsistencies;
- Could help in getting a general picture of activities and/or yield specific information on selected sites;
- Could help in obtaining information on abnormal phenomena;

Limitations

- Could be influenced and/or directed by political needs;
- A wealth of information is available, but not in a comprehensive or methodological form;
- Scientific publications usually lag 1-2 years behind the work program;
- Press publications may project a subjective image;
- It provides only a partial picture of activities. Industrial and military activities may be poorly covered;
- Requires specific expertise of knowing what to look for;
- A priori selection of information would be required;

Potential interaction with other measures

- Interaction with publications of the WHO (e.g. on vaccine programs, outbreak of epidemics or national surveillance on reporting systems);
- Interaction with publications listed in facility declaration (CBM-A);

SURVEILLANCE OF LEGISLATION

Definition

Collecting and analyzing of information with regard to legislation that exists in relation to the BWC or other areas of interest.

Characteristics and technologies

- Legislation directly related to biological weapons activities, including enabling legislation with regard to the BWC, or bio-export controls or military appropriation funds;
- Legislation related to biological activities including genetic modification, e.g. to occupational health, environmental and industrial standards and norms (e.g. laboratory and worker safety and related regulation.
 - <u>Comment</u>: Regulations are often issued and anticipated under the umbrella of legislation [i.e. legislation may stay the same, although regulations change periodically]);
- Legislation on export, import and handling or environmental release of biological agents;

Capabilities

- Could suggest priorities in budget allocations;
- Could reveal differences in the application of national legislation and/or regulations in the field of environmental and labour standards;
- Could indicate patterns of a nature that are subject to control in States Parties;

Limitations

- Existence or absence of legislation may not independently provide indications of biological weapons activities;
- Gives information of intentions or pretended intentions, not on factual situations;
- It requires a well established administration;

N.B.: In many aspects, this looks a lot like a reference library on legislation.

Potential interaction with other measures

Data exchange, e.g. declarations; Auditing.

List of documents introduced

ASurveillance of Legislation (WP 34), German Delegation.

DATA ON TRANSFERS AND TRANSFER REQUESTS AND ON PRODUCTION

Definition

Collection and analysis of national export and import data, available or specifically requested, government and industrial production statistics, culture collection records and similar information. There may or may not be an agreed standard for availability of the nature of the information.

Characteristics and technologies

- Information on suppliers and recipients, as already in the public domain (e.g.: trade publications);
- Information on agents and equipment; drafting of specific lists of agents and equipments; the possibility of thresholds and quantities should be considered;
- Information to be supplied by States Parties;
- Confidentiality concerns need to be considered;

Capabilities

- May provide information on production capacity and actual use of this capacity;
- Over time may provide profiles of kinds of activities in a State;

Limitations

- Divergence in information supplied by different states;
- ARecords≅ may be too broadly interpreted;

Potential interaction with other measures

- Annual report of CBMs;
- Could run in parallel with declarations on transfers etc. under any declarations/notifications measure;

List of documents introduced

ABiological agents and dual use biological equipment - Norwegian export control (BWC/CONF.III/VEREX/NONE.33), Delegation of Norway

MULTILATERAL INFORMATION SHARING

Definition

The use of any voluntary international provision or exchange of information on medical, veterinary, agricultural, environmental safety standards, defence and waste management issues, etc., relating to materials and activities of potential relevance to the BWC. Such information sharing on a voluntary basis may or may not have an agreed standard for the nature of the information to be provided. Characteristics and technologies

- Examples of multilateral information sharing are e.g. surveillance of disease outbreaks, information on genetic manipulation and on environmental releases of genetically manipulated organisms. Multilateral information sharing may be carried out on a regional or international basis as one or more States Parties consider appropriate.
- Confidentiality has to be assured;
- It could provide very specific information;
- It could concern information provided by a State about itself or about another State;
- Information supplied by States on potential BW-related activities or unusual occurrences on their own territory or in other States to the proposed inspectorate;
- Information supplied is similar to activities presently taking place in the framework of FAO, WHO and OIE;

Capabilities

- Could provide relevant and detailed information;
- Information on non-declared activities;
- Opens the way to non-routine inspections but without intrusive aspects and to remove doubts (on a consultative or cooperative basis, e.g. fact-finding);
- Could provide information on unusual outbreaks of diseases which might point to accidental releases or use of BW agents

Limitations

- Depends on the willingness of a State to provide information;
- Confidentiality problems;

- Unequal national means, as is a fortiori the case with challenge inspections;
- Inadequacy of information on epidemics;

Potential interaction with other measures

Could help in the selection of a site in the conduct of on-site and off-site inspections;

List of documents introduced

AMultilateral Information Sharing≅ (WP.40), Czech and Slovak Federal Republic.

DECLARATIONS (Off-Site) (Rapporteur: Mr. Ashok Kapur)

(BWC/CONF.III/VEREX/WP.72/Rev.1)

Data exchange is considered as one of the verification measures as well as a potent confidence building measure.

Definitions

<u>Declaration</u>: Mandatory reporting by the State Party, focussed and on a regular basis, e.g. annually, of information and data. The declaration covers the activities of the State within its territory or under its jurisdiction or control anywhere. It may be in the military and public sector, the private sector and R&D activities wherever these may be taking place.

Declarations of States Parties should cover all aspects of BW Convention, i.e. all relevant activities related to or affecting the development, production, stockpiling, acquiring or retaining microbial or other biological agents or toxins.

Characteristics and technologies

Suggested items for declarations include declarations on agents; facilities; equipment; programmes, including spraying programmes; transfers - import-export of agents, equipment, know-how, technology, personnel ... -; manufacturing, and disease outbreaks.

Ideas for declarations can be grouped into four broad concepts: facility concepts, programme concepts, transfer concepts and general concepts. Declarations may build up over time a continuous pattern of activity for each country.

These are possible indicators for use in declarations but it was recognized that this was not an exclusive list and would require further consideration and elaboration. The view was expressed that elaboration of an indicative list of agents could be a useful step. The question of whether lists of agents should be indicative or illustrative was not resolved.

Facility concepts

- 1. All facilities that are associated with or are covered under a biological defence programme.
- All production facilities which are working with risk group III or IV (WHO Biosafety Manual) or with listed agents.
- 3. Vaccine production facilities for animals and humans.
- 4. Production and storage facilities for plant pathogens and biological insecticides the products being used or intended to be used for field use and sites for release of plant pathogens.
- 5. Breeding of vectors in large scale for field use or experimental use.

- 6. Facilities associated with activities of large-scale aerosol generators for microorganisms.
- 7. Facilities utilising listed biological agents and toxins.
- 8. Facilities having aerosol handling capabilities such as aerosol test chambers suitable for use with pathogens or toxins.
- 9. Facilities producing pharmaceuticals by fermentation.
- 10. Facilities containing large-scale microbiological production equipment.
- 11. Greenhouse facilities and animal houses for research, development and production of human, animal and plant pathogens.

Programme concepts:

- 1. Declaration of all military and mass and regular civilian immunization programmes.
- 2. Programmes related to agents threatening flora and fauna which are not present in the geographical region (to cause loss of life, or to produce disease or cause economic damage).
- 3. Any research programme on smallpox (or white pox) virus, either with whole or cloned genes should be declared. A view was also expressed that smallpox virus is one of the most dangerous agents and any research programme and work on it must be declared by the State Party.
- 4. Pest/weed biological control programmes involving aerosol dissemination of biocides.
- 5. National Biological Defence programmes.
- 6. Trials on human and animal vaccines.

Transfer concepts:

Specific dual purpose equipment which is listed.

Import/export of listed human, animal and plant pathogens and toxins.

Transfer of micro-organisms to a country where the outbreak of disease caused by the said organism does not occur.

General concepts:

Legislation and regulation pertaining to BWC and Biosafety.

Funding of programmes or facilities pertaining to BWC.

Declaration of all former offensive and defensive biological programmes.

Disease outbreaks involving listed agents.

Arrangements for public/animal/crop health, especially involving listed agents.

Declaration is a mode of official and formal announcement. However, the technology to prepare, transmit and analyse declarations was not discussed.

Capabilities

Declarations could help focus on other verification measures. It could help to build up a picture of approaches to microbiological work, health and safety in the country against

which other measures could be judged. It may be a low-cost, non-intrusive mode. It should not hamper scientific work. It is a legally binding instrument.

Limitations

Declarations were not seen as a stand alone measure. They could, but not in isolation, provide information relevant to verification of complia nce with the BWC.

There could be confidentiality problems if some of the suggested declarations were allowed to enter the public domain. On the other hand, if one purpose of the declaration is to increase transparency and build confidence, then information gained by the measure must be made available to all States Parties.

Research and Development:

Views were expressed that declarations should be focussed and the cost of declarations kept minimal by ensuring all declarations are relevant to the BWC. With this in mind, a suggestion was made to exclude research programmes from declarations. Research is not specifically referred to by the BWC and the inclusion of data on research programmes could result in large amounts of information if not focussed towards BWC concerns. Confidentiality concerns may also be greatest in the research field.

Production:

Quantities of agents required for legitimate use would vary between organisms. So, careful definition of items to be declared would be required. Thresholds may be a means to facilitate decisions on items to be declared.

Potential interaction with other measures

Declarations were seen as being complementary to information monitoring but not a substitute for it. Declarations may provide information which may be essential in planning on-site and off-site inspections.

Declared information may affect the interpretation of information obtained during inspections.

Data declared on production and stockpiling of large quantities of microorganisms and toxins may also be compared with information obtained by off-site and on-site auditing.

List of documents introduced

India - AData Exchange: 2.1 Declarations ≅, BWC/CONF.III/VEREX/WP.43

<u>Australia</u> - AIntroductory remarks on data exchange notification ≤, BWC/CONF.III/VEREX/WP.42

<u>United Kingdom</u> - AData Exchange as a potential verification measure under the BWC: The philosophy and scope of declarations and notifications_≅, BWC/CONF.III/VEREX/WP.36

<u>United States of America</u> - (a) AEvaluation of the Concept of a list for the BWC≅, BWC/CONF.III/VEREX/WP.45, (b) Statement on Data Exchange by Ambassador Edward J. Lacey

 $\underline{\text{Cuba}}$ - AIndicative list of biological agents and toxins possibly relevant to the BWC \cong , BWC/CONF.III/VEREX/WP.51

<u>Netherlands</u> - AA search for discriminators between permitted and prohibited activities in technical microbiology_{\(\infty\)}, BWC/CONF.III/VEREX/WP.33.

<u>Brazil</u> - APreliminary aspects on the evaluation of the potential verification measures as they were proposed during the first meeting of the governmental expert group <u>≅</u>, BWC/CONF.III/VEREX/WP.54.

NOTIFICATIONS (Off-Site)

(Rapporteur: Ms. Annabelle Duncan)

(BWC/CONF.III/VEREX/WP.73/Rev.1)

Definitions

NOTIFICATIONS - Reporting of new or unforeseen events or forecast of events in order to preempt compliance concerns. Notification may or may not be mandatory.

Characteristics and technologies

Notifications could provide a mechanism whereby clarification of information provided in an annual declaration could be sought.

Notifications could cover private, governmental and military establishments.

It was proposed that notifications of legitimate activities would be designed to provide transparency on two aspects of national activities in case of compliance concerns or unexpected events of possible relevance.

- (a) The facilities which have most of the technological attributes for conducting activities in contravention of the BWC.
- (b) As many as possible of the facilities having several of the capabilities for conducting activities in contravention of the BWC.

Views were expressed that elaboration of an illustrative list of agents could be a useful step. But a view was also expressed that comprehensive lists were not achievable (in light of the large range of possible microbes and toxins of concern together with classification problems and potential application of genetic manipulation techniques).

Possible items/events for inclusion in notification were identified with the caveat that these lists need to be streamlined. Notifications need to be focused and simple providing only data of relevance to the verification compliance with the BWC, particularly because of the need for industrial acceptance.

Suggested events for notification include:

- Disease outbreaks.
- Open air release experiments, e.g. for biological pest control.
- Military exercises which involve BW defense training.
- Accidental release of micro-organisms.
- Discovery of novel pathogenic micro-organisms or toxins.
- Changes to certain categories of declarations, e.g. introduction of mass immunization programs.

- Elaboration of declarations.
- Changes to plans concerning events or activities that may have been subject to forecasts and which therefore require updating.
- Major new scientific developments in gene technology.

These items/events need further elaboration and definition.

State of the art

Capabilities

Notifications could help to focus other verification measures and may help to alleviate concerns of compliance.

Limitations

Notifications were not seen as a stand alone measure; they may not, in isolation, provide verification of compliance with the BWC. They may also give an uneven picture of activity in the biological field in different countries unless they are mandatory.

The success of notification as a verification measure is dependent upon definitions of what is covered.

There could be confidentiality problems if some of the suggested notifications were allowed to enter the public domain. On the other hand, if one purpose of the notification is to increase transparency and build confidence then information gained by the measure must be made available to all States Parties.

The issue of cost was also raised. Notification has often been referred to as a cheaper verification option than some other measures. Is this so?

Potential interactions with other measures

Notifications may be complementary to declarations, enabling elaboration of information provided in declarations.

The two sub-measures of data exchange (notifications and declarations) in combination were also seen as being complementary to information monitoring but not substitutes for it. Lack of agreement between data obtained via monitoring and that provided may give rise to concerns which would need further elaboration and provide the basis for requests to States Parties for explanation.

Notifications may provide information which would be essential in planning on- and off-site inspections.

Information provided in notifications may affect the interpretation of information obtained during inspections.

Data provided on production and stockpiling of large quantities of microorganisms may also be compared with information obtained by on- and off-site auditing.

List of documents introduced

India - Data Exchange 2.1. Declarations - BWC/CONF.III/VEREX/WP.43

Australia - Introductory Remarks on Data Exchange - Notifications - BWC/CONF.III/VEREX/WP.42

UK - Data Exchange as a Potential Verification Measure under the BWC: The Philosophy and Scope of Declarations and Notifications - BWC/CONF.III/VEREX/WP.36

USA - Statement on Data Exchange by Ambassador Edward J. Lacey

United States of America - AEvaluation of the Concept of a List for the $BC \cong -BWC/CONF.III/VEREX/WP.45$

Cuba - BWC/CONF.III/VEREX/WP.51

Germany - National legislation - BWC/CONF.III/VEREX/WP.34

SURVEILLANCE BY SATELLITE (Off-Site)

(Rapporteur: Mr. Gordon Vachon)

(BWC/CONF.III/VEREX/WP.74)

Definitions

Remote sensing: A variety of techniques that enable, to varying degrees, the detection, description, measurement or identification of some property of an object of interest without actually coming into physical contact with the object. Categories of remote sensing techniques or equipment are often described as Aremote sensors= or Asensors=.

<u>Satellite</u>: An artificial body placed in orbit round earth or other planet. A satellite may be described as a Aplatform carrying one or more sensors.

Characteristics and technologies

State-of-the-Art

For the purpose of introducing discussion of developments in the state-of-the-art of satellite remote sensing, remote sensors may be categorized, <u>inter alia</u>, by the following characteristics:

- technology base;
- location of operation;
- operating characteristics (including power requirements, required operator expertise, and maintenance schedules, ...);
- envisioned targets of the sensors;
- explanation of relevant experience with the sensors to date;
-

The discussion focussed on commercially-available, Aoff the shelf≅, space-based sensor imagery.

The sensors mentioned in the examination phase were:

- optical (still photography, video cameras, multi-spectral cameras);
- infrared;
- synthetic aperture radar (SAR);
- remote optical spectroscopy active and passive.

SPOT optical imagery was mentioned as having a ground spatial resolution falling in the range of 5-10 metre resolution (see WP.56). (A variety of other optical techniques was mentioned in WP.46.)

Mention was made of higher resolution /1.7-2.0 metres) optical imagery. ATrade talk \cong suggests that such imagery may be commercially-available, but this remains to be confirmed.

TABLE I
SATELLITE IMAGERY

ТҮРЕ	APPROX. RESOLUTION	AVAILABLE	APPROX. COST
OPTICAL			
(e.g. SPOT,)	5-10 metres	Yes - Panchromatic (one band) - Stereo pairs - Hard copy - Digital	\$4000 ² \$7000 ² \$4000 ² \$4000 ²
(other source ¹)	1.7-2.0 metres	To be confirmed - Panchromatic (one band) - Hard copy - Digital	\$3500- 4000 ² \$3500- 4000 ² \$3500- 4000 ²

Infrared imagery was not discussed in any detail (though briefly mentioned in WP.56 and WP.46).

Synthetic aperture radar (SAR) was briefly discussed, though not in any detail. SAR resolution was described as being larger than 10 metres. Certain general comments appear in the next sections under Acapabilities≅ and Alimitations≅.

Remote optical spectroscopic sensing techniques were mentioned in relation to the analysis of aerosol airborne effluent plumes in the environment (see WP.46).

¹ ATrade talk≅ suggests that such imagery is available, but needs to be confirmed.

² Cost figures approximate and need to be confirmed.

Capabilities

In general, space-based sensor performance was said to be less effective (capable) than airborne sensors, for all the sensors discussed. This usually had to do with the Aresolution (or similar performance criteria) of the sensors. According to the degree of resolution available, the image produced will have varying capabilities of:

- detection (i.e. to discover the presence of an object);
- recognition (i.e. to determine the nature of the object);
- identification (i.e. to identify one or more characteristics of the object);
- description (i.e. to describe some details of the object).

Synthetic aperture radar (SAR) imagery has a lower resolution (i.e. less capable) than optical imagery.

Commercially-available satellite imagery, whether derived from optical or SAR systems, can only pick up large geographical features and large man-made objects, and so are useful for broad area coverage, mapping, and site delineation (see WP.56). They can also pick up road networks; power lines/transmission towers; power plants; changes to sites such as new construction or expansion, over time; and changes to the environment, including changes in natural surface cover and soil, over time. If the imagery mentioned in Table I under Aother source is indeed now commercially available, that might be an interesting addition in terms of the ability to detect, recognize and identify objects or activities of interest.

There is the possibility that accidental releases or seepage from less secure facilities could be detected in certain circumstances (discussed to some extent in WP.46 on remote optical spectroscopy). Imagery can also detect, in certain circumstances, power line connections between facilities; air conditioning machinery; steam heating or coolant conduits, even when buried underground; bunkers; effluent outlets; pipelines; settling or sewage ponds; and other general indicators of activity.

Development:

Insofar as commercially-available satellite imagery may be useful in detecting and monitoring outdoor weapon testing areas, then certain patterns of weapons testing (e.g. sensor grid layouts, animal cages) might be indicative of activities requiring clarification through other measures. This issue needs to be examined further.

Acquisition or Production:

There was little discussion of the capability of space-based remote sensing with regard to detection or monitoring in relation to these prohibited activities. Such surveillance could monitor, over time, related matters such as changes in outdoor storage or dump sites/sewage settling ponds; transportation links; power/heating/cooling lines

Stockpiling or Retaining:

Although space-based remote sensing may be useful in detecting and monitoring weapons storage areas, it remains to be discussed whether any useful indicators can be identified to assist in discriminating between legitimate and illegitimate material or weapon storage. (One suggestion related to air conditioning/refrigeration equipment, but this requires further consideration.)

Imagery compiled over time, whether of a facility/site or of an area, provides a history for future reference purposes. It allows one to look back in time.

Limitations

Some of the consideration of sensor limitations is implicit in the preceding discussion of their capabilities, including in relation to the three categories of prohibited activity.

Optical sensor performance can be significantly degraded by meteorological conditions (daylight, cloud cover, stormy weather, dust storms, etc.), solar altitude (determined by time of day, season of the year, latitude) Atmospheric pollutants can also affect performance. To the very limited extent, at this time, that some sensing techniques are employed to detect and analyse pollutants in the atmosphere - and to the extent any such emissions may be able to be associated with activities of concern to the BTWC, an issue not discussed - there may be some future interest in such techniques. It was also mentioned that the range or standoff distance from such sensors (remote optical spectroscopy, active and passive - see WP.46) to the target must be taken into account, which in itself is not surprising. However, since the current state-of-the-art for remote sensing of effluent plumes is done relatively near the earth=s surface, this suggests limitations on the efficacy of such systems on a satellite platform.

Although SAR is often described as being 24-hour all-weather capable, it is nevertheless an active sensor the signal of which can be disrupted by certain extreme meteorological conditions.

There was no discussion of limitations imposed by data storage/transmission capabilities of space-based systems; nor was there any discussion of the requirements/capabilities/limitations in relation to analysis of the imagery from such systems.

Development:

Buildings and shelters of many types can be imagined into which sensors cannot penetrate. Thus, activities, equipment and materials may not be directly detected when competently contained. To the extent that it was said that complete bio-facilities can be housed in buildings without external indicators, it was generally accepted that space-based sensors would be unlikely to detect suspicious activity without cuing from other sources. Space-based remote sensing appeared to have the least to offer with regard to the detection of offensive research, as that could easily be conducted in small enclosed structures.

Acquisition or Production:

To the extent that these activities could be conducted in completely enclosed buildings exhibiting few if any external indicators, the capability of using space-based sensors to detect activities that someone is determined to hide does not seem very promising at this time. Once again, the possibility of cuing from other sources was mentioned, which might then lead to monitoring of certain facilities, but this issue needs to be examined further.

Stockpiling or Retaining:

The discussion is reflected in the Acapabilities≅ section.

Potential interaction with other measures

In view of the preceding discussion of the capabilities and limitations of current commercially-available space-based imagery, the view was expressed by many participants that the utility of information derived from this measure should be assessed as a complement to information gathered by other measures. It was expressed by many participants that this measure would be particularly useful in the specification of on-site inspection activities. It was mentioned that this measure should be considered in relation to the measure on ground-based remote sensing.

It was mentioned that various arms control agreements make specific <u>provision for non-interference</u> with national and multinational technical means, which are generally understood to include a number of remote sensing techniques including remote sensing from satellites (and aircraft). Space-based remote sensors, to date, have not been explicitly included in the verification regimes of arms control agreements. However, such sensors can at least be seen as complementary to other verification measures.

The CFE Treaty includes provision for the operation of national and multinational technical means of verification, associating the use of such means with A... the purpose of ensuring verification of compliance with the provisions of this Treaty ... in addition to the procedures referred to [elsewhere in the Treaty] ... \approx (Comment; and see WP.67, para. 8.)

Documents introduced

BWC/CONF.III/VEREX/WP.31

ACapabilities and Limitations of Overhead Remote Sensing for Verification within the Context of the Biological and Toxin Weapons Convention (BTWC) (Canada)

BWC/CONF.III/VEREX/WP.46

AThe Possible Relationship of Remote Sensing Technologies to BWC Verification≅ (USA)

BWC/CONF.III/VEREX/WP.56

AAn Introduction to Remote Sensing by Satellite and Aircraft≅

(Canada)

BWC/CONF.III/VEREX/WP.67

AAerial and Space-Based Surveillance in the Context of Arms Control Agreements (Canada)

BWC/CONF.III/VEREX/WP.69

ASatellite and Aerial Surveillance as a Verification Measure for the Biological Convention: Advantages and Limits (France)

Other useful publications

Banner, Allen V., Andrew J. Young, Keith W. Hall. UNIDIR/90/83, United Nations, 1990. Aerial Reconnaissance for Verification of Arms Limitation Agreements: An Introduction. (Comment: This publication explains several technical concepts that are also applicable to space-based sensors.)

SURVEILLANCE BY AIRCRAFT (Off-Site)

(Rapporteur: Mr. Gordon Vachon)

(BWC/CONF.III/VEREX/WP.75)

Definitions

Remote sensing: A variety of techniques that enable, to varying degrees, the detection, description, measurement or identification of some property of an object of interest without actually coming into physical contact with the object. Categories of remote sensing techniques or equipment are often described as Aremote sensors or Asensors.

Aircraft: This term may include:

- aeroplane (mechanically driven winged heavier-than-air flying machine):
- helicopter;
- airship;
- balloon; and
- unmanned aerial vehicles (UAVs) /drones/remotely-piloted vehicles RPVs).

An aircraft may be described as a Aplatform carrying one or more sensors.

Without reference to any operational context, it was also mentioned that gliders and Aultra-light≅ aerial vehicles can be used to carry sensors.

Characteristics and technologies

State-of-the-Art

Prior to discussing technical matters, it was mentioned that the conduct of aerial overflights in a verification context would require the prior permission of the State being overflown.

For the purpose of introducing discussion of developments in the state-of-the-art of airborne remote sensing, remote sensors may be categorized, <u>inter alia</u>, by the following characteristics:

- technology base;
- location of operation;
- operating characteristics (including power requirements, required operator expertise, and maintenance schedules, ...);
- envisioned targets of the sensors;
- explanation of relevant experience with the sensors to date;
- ...

The discussion focussed on commercially-available, Aoff-the-shelf≅, aircraft-borne (airborne) sensor imagery.

The sensors mentioned in the examination phase were:

- optical (still photography, video cameras, multi-spectral cameras);
- infrared;
- synthetic aperture radar (SAR);
- remote optical spectroscopy active and passive.

Aircraft can conceivably carry all of the afore-mentioned sensors simultaneously since space, weight and power requirements can be more easily fulfilled. The airborne sensors can generally achieve higher resolutions (in the case of various sensors, perhaps expressed as other performance criteria) than their commercially-available satellite counterparts due to human interaction and variable altitude capabilities. For example, aircraft are capable of carrying commercially-available:

- (a) optical sensors with a resolution measured in centimetres to tens of centimetres;
- (b) infrared sensors with a resolution measured at approximately half a metre; and
- synthetic aperture radar with a resolution of 3-6 metres (experimental SARs exist with a resolution of 12-3 metres).

The key to any infrared (thermal) sensor is its Adetector≅, which is made of different materials depending on the spectral region within which the detector is to operate. These spectral regions are chosen because therein the atmosphere is largely transparent, allowing radiation from the surface (and objects on the ground/sea) to reach the sensor. Outside of these spectral regions (Awindows≅), atmospheric gases and particles at least partially block the passage of radiation by absorption or scattering. (Atmospheric gases and particles can affect the performance of a variety of active and passive sensors, as discussed in WP.46.)

In discussing infrared systems, two types of Aresolution are important. ASpatial resolution refers to the detector ability to resolve two separate and distinct objects of similar size from each other - similar to what has been discussed elsewhere concerning optical and SAR sensor resolution. AThermal resolution of an infrared sensor refers to the ability to distinguish temperature gradients in the object being observed, and is influenced by the material in, and size of, the detector chip.

Infrared imaging may be conducted using two types of sensors: infrared line scanners (IRLS) or forward looking infrared sensors (FLIR), with each type having particular characteristics suited to particular missions. As a simplification of their respective capabilities, FLIR systems can be used when real-time imagery is required, with the possibility of manipulating the sensor to Aspotlight≅ targets. The imagery is produced in a format similar to that of a video camera. IRLS systems, on the other hand, are usually used when hard copy images or image mensuration are required. There is little or no ability to manipulate the sensor without manipulating the platform.

Capabilities

Although individual sensors may generally be seen as providing more useful information when carried on aircraft versus satellites, it is clear that, in both cases, the comparison is based on the best

commercially-available examples that can be carried on the respective platforms. In other general respects, such as broad area coverage, satellites are generally seen to have the advantage over aircraft.

The resolution of the various commercially-available airborne imaging systems has been mentioned and is indicative of the ability to detect, describe, measure or identify very small natural and manmade objects. The question still needs to be addressed as to whether there are clear indicators such that the enhanced capabilities of airborne sensors (versus space-based sensors) can be put to effective use.

The mix of airborne sensors provides for a wide range of capabilities. The systems (for example, optical systems such as still photography, video cameras - platform mounted or hand-held) can be keyed to provide date/time/location data of the imagery. Although the performance of optical systems is highly dependent on light and meteorological conditions, infrared systems can be used in daylight or at nighttime; can passively detect heat sources (penetrate) haze and smog; and can be used to detect camouflaged or obscured objects (even under forest canopies). Similarly, SARs have a 24-hour all-weather capability.

Multispectral systems (discussed in WP.46) permit imagery to be collected in a number of spectral bands at once. These bands may include wavelengths from ultraviolet, visible, reflected infrared and thermal infrared. By collecting and analyzing images in several spectral bands, it is possible to greatly improve the chances of distinguishing some features (UNIDIR/90/83).

Depending on organizational/operational scenarios and questions relating to the availability and prepositioning of aircraft with appropriate sensors, the response time of aircraft may be considerably faster than reliance upon satellite passes. (However, this advantage must be qualified by the need to provide notification of overflights and of the need to file flight plans, both of which can lead to legitimate or artificial delays.) In addition, aircraft can fly below cloud cover that might frustrate space-based optical sensors.

Development:

Airborne surveillance could be used to monitor, over time, such matters as changes in outdoor storage or dump sites/sewage settling ponds; transportation links; power/heating/cooling lines

Acquisition or Production:

There was no discussion of the capability of airborne remote sensing with regard to detection or monitoring in relation to these prohibited activities. The size and scope of any production activity may be considerably more difficult to conceal than research and development activities. Airborne surveillance could monitor, over time, the same peripheral matters as mentioned at the end of the preceding paragraph.

Stockpiling or Retaining:

Airborne sensing may be useful in detecting and monitoring weapons storage areas, but it remains to be discussed whether any useful indicators can be identified to assist in discriminating between legitimate and illegitimate material or weapon storage. (One suggestion related to air conditioning/refrigeration equipment, but this requires further consideration.)

Imagery compiled over time, whether of a facility/site or of an area, provides a history for future reference purposes. It allows one to look back in time.

Limitations

Some of the discussion of airborne sensor limitations is suggested in the preceding sections on Astate-of-the-art≅ and Acapabilities≅, including in relation to the three categories of prohibited activity.

Buildings and shelters of many types can be imagined into which the sensors cannot penetrate. To the extent that it was said that complete bio-facilities can be housed in buildings without external indicators, then even the highly capable airborne sensors could be defeated in detecting suspicious activity. It was mentioned that cuing from other sources might enhance the probability of successful detection of illegitimate activities by airborne systems, and this aspect needs to be examined further.

One paper (WP.46) mentioned that remote sensing of effluent plumes is done relatively near the earth=s surface - so that the effectiveness of such sensors when carried on airborne platforms would not be as limited (i.e. would be more effective) when compared to satellite platforms. Examples were given in that paper of scenarios in which the sensors can now be useful, given the current state-of-the-art.

There was no discussion of limitations imposed by data storage/transmission capabilities of airborne systems. However, it was said that any such constraints may be much less severe in the case of airborne systems relative to their space-based counterparts. There was only very limited discussion of operational constraints derived from the aircraft=s flight radius or flying characteristics, but these constraints may be circumvented by proper mission-planning. It was mentioned that certain airborne systems provide both real-time and recorded data, not least because of the human presence aboard the platform viewing the target as well as operating the sensors. There was no discussion of the requirements/capabilities/limitations in relation to analysis of imagery from such systems.

Development:

If one assumes that treaty violators would undertake offensive research, and certain development activities, in small enclosed structures having few if any distinctive external characteristics, then this might seriously impact on the effectiveness of airborne sensors in detecting such activities. Furthermore, the inherent delays involved in notifying overflights and filing flight plans could allow ample time for the cessation of outdoor development activities, such as may be involved in weapon testing.

Acquisition or Production:

For the same reasons mentioned in the previous paragraph with regard to hiding such activities in enclosed buildings, similar views may apply to the effectiveness of the sensors in detecting or distinguishing production activities.

Stockpiling or Retaining:

The discussion is reflected in the Acapabilities≅ section.

Potential interaction with other measures

There is a significant qualitative difference between the imagery obtained by airborne sensors and that obtained by space-based sensors. It is possible to envisage airborne imagery as a primary mode of operation in the context of arms control agreements, as in the case of the Open Skies Treaty (mentioned but not discussed in any detail). The view was also expressed that the utility of information derived from this measure should be assessed as a complement to information gathered by other measures. It was further expressed by many participants that this measure may be particularly useful in the specification of on-site inspection activities as well as in direct support to on-site inspection activities. It was suggested that the aerial remote sensing measure could be seen as providing an additional (extra) operational capability to that provided by other measures.

With regard to the question of direct support to on-site inspection activities, the example of the Treaty on Conventional Armed Forces in Europe (CFE Treaty) was provided (see WP.67).

Information with respect to illustrative costs for airborne remote sensing was provided (see WP.63).

Documents introduced

BWC/CONF.III/VEREX/WP.31

ACapabilities and Limitations of Overhead Remote Sensing for Verification within the Context of the Biological and Toxin Weapons Convention (BTWC) (Canada)

BWC/CONF.III/VEREX/WP.46

AThe Possible Relationship of Remote Sensing Technologies to BWC Verification (USA)

BWC/CONF.III/VEREX/WP.56

AAn Introduction to Remote Sensing by Satellite and Aircraft≅ (Canada)

BWC/CONF.III/VEREX/WP.63

AAirborne Remote Sensing: Illustrative Costs≅ (Canada)

BWC/CONF.III/VEREX/WP.67

AAerial and Space-Based Surveillance in the Context of Arms Control Agreements≅

(Canada)

BWC/CONF.III/VEREX/WP.69

ASatellite and Aerial Surveillance as a Verification Measure for the Biological Convention: Advantages and Limits≅ (France)

Other useful publications

Banner, Allen V., Andrew J. Young, Keith W. Hall. UNIDIR/90/83, United Nations, 1990. Aerial Reconnaissance for Verification of Arms Limitation Agreements: An Introduction (Comment: This publication explains several technical concepts that are also applicable to space-based sensors.)

BWC/CONF.III/VEREX/4

GROUND BASED SURVEILLANCE (off site) (Rapporteur: Mr. Volker Beck)

(BWC/CONF.III/VEREX/WP.76)

Definitions

Off-site ground based surveillance:

Surveillance of a site of interest at some agreed perimeter surrounding a site or many klometers distant either by remote sensing or by visual inspection.

Remote sensing:

A variety of techniques that enable, to varying degrees, the detection, description, measurement or identification of some property of an object of interest without coming into physical contact with the object. Categories of remote sensing techniques or equipment are often described as >remote sensors= or >sensors=.

Visual inspection:

Inspection of a site of interest by eye including the use of binoculars.

Biosensors:

Detection and identification equipment consisting of a biological component which is the site of recognition and of a transducer which converts the biological reaction into an electric or optical signal for registration.

Stand-off capability:

Capability of a system to maintain operation without the need of direct physical presence of a person at the site of detection and identification.

Characteristics and technologies

The characteristic of the methods and technologies of off-site ground based surveillance is to enable surveillance of the effluents of a R&D production, stockpile or open air test facilities without intrusive methods or intrusive means.

Off-site ground based surveillance is done at some arbitrary perimeter surrounding a site or many kilometres distant either by remote sensing or by visual inspection.

As far as technical means are used the characteristic is that the equipment is operated without the need for direct physical presence of a person at the site of recognition and identification.

Remote sensors may be categorized, *inter alia*, by the following characteristics:

- technology base
- location of operation
- operating characteristics (including power requirements, required operator expertise and maintenance schedules)
- envisions targets of the sensors
- explanation of relevant experience with the sensor to date.

Available technologies for off-site ground based surveillance of effluents from a site in principle include a broad variety of spectroscopic methods as well as biosensors and equipment for automatic sampling.

Biosensors use antigens, antibodies, enzymes, receptors, membrane structures, DNA probes, etc., as biological recognition components. As transducers around about a dozen of different systems like amperometric and potentiometric electrodes, field electron transistors, piezoelectric crystals, fibre optics, etc., are used.

State of the art

The view expressed on the state of the art techniques for the remote sensing of small chemical molecules or for biological agents include:

Spectroscopic methods:

- passive spectroscopic methods
- radiometry
- thermal imaging
- FTIR (Fourier Transform Infrared)
- passive microwave detection
- multi spectral and hyper spectral analysers
- active spectroscopic methods
- BAGI (Backscatter Absorption Gas Imager)
- DOAS (Differential Optical Absorption Spectrometer)
- RADAR/SAR (Synthetic Aperture Radar)
- LIDAR (Laser Identification and ranging)
- DISC (Differential Scattering LIDAR)
- DIAL (Differential Absorption LIDAR)
- Broadband LIDAR
- Raman LIDAR
- Laser induced fluorescent LIDAR

Biosensors

- Generic sensors

- Specific sensors (immunosensors, bioaffinity sensors)

Automatic sampling equipment

- air samplers
- impingers
- impactors
- cyclone collectors
- liquid samplers
- filtration equipment

Capabilities

Views have been expressed that spectroscopic techniques have been successfully applied to the detection of small, isolated gas phase chemical molecules at trace levels in effluents and that these techniques could possibly be applied to detect if chemicals associated with biological weapons production are released in sufficient quantities and represent a unique signature indicating that biological weapons production is occurring inside a facility. Ultraviolet fluorescent LIDAR has been successfully demonstrated for the detection of proteins associated with biological substances in the environment.

Generic biosensors have been shown to be capable to detect and to identify biological agents with limited specificity in sensitivity ranges from ng to $\Phi g/ml$.

Immunosensors have been shown to be capable to detect and to identify biological agents uniquely specific in sensitivity ranges from ng to $\Phi g/ml$.

A first type of immunosensor is commercially available for laboratory use. The first type of biosensor for field use has been shown by a US company during the 1992 Chemical Defense Exhibition in Stockholm.

A variety of devices and filtration systems for the concentration of biological agents from air and liquids is commercially available with a broad variety and has been shown to be able to support biosensor systems.

Limitations

Biological materials are not small, isolated molecules. They are physically much larger and complex entities. Optical techniques are typically not capable of interacting with such large structures

The presented spectroscopic methods are not able to establish the identity of biological agents. They cannot uniquely identify specific biological substances.

LIDAR and other absorption/fluorescence technique are affected by atmospheric transmissivity of relevant electromagnetic frequencies. This is particularly true in much of the ultraviolet spectrum and also in near and mid-IR frequencies.

Generic biosensors can detect and identify biological agents only with limited specificity.

Immunosensors require for the detection and identification of each and every single biological agent different specific probes

Present sensitivity ranges of biosensors require the combination with a concentration step for the sample. The concentration step must be combined with a transfer in a liquid medium. The stand-off capability of present biosensor systems is limited.

Some views have been expressed that biosensors may not be available commercially before five to ten years or before 15 years as far as DNA probe based sensors will be concerned for the detection and identification of genetically manipulated substances.

Some views have been expressed that the effluent of biological substances from R&D, production and stockpile sites may be extremely unlikely so that remote sensing of these sites will not be beneficial. Remote sensing of open air test sites however may be technically reasonable.

Potential interaction with other measures

Biosensor have been developed for in-process control of fermentation and downstream processes. They may be a helpful tool for continuous monitoring. Spectroscopic sensors have been discussed for surveillance by aircraft and satellite, too.

List of documents introduced

BWC/CONF.III/VEREX/WP.37	Remote Sensing/Ground-based Surveillance (Germany)
BWC/CONF.III/VEREX/WP.44	Ground-based Surveillance (Germany)
BWC/CONF.III/VEREX/WP.46	Technologies to BWC Verification (United States)
BWC/CONF.III/VEREX/WP.65	Continuous Monitoring (Brazil)
BWC/CONF.III/VEREX/WP.66	Continuous Monitoring by Instruments (United States)

Statement on remote sensing by Ambassador Edward Lacey, United States Delegation.

SAMPLING AND IDENTIFICATION (off site) (Rapporteur: Mr. Åke Bovallius

(BWC/CONF.III/VEREX/WP.77/Rev.1)

Definition

Off-site inspections would mean to inspect a declared or undeclared facility without penetrating its boundary.

Off site was clarified to mean *inter alia* the outer boundary of a facility, e.g., close to a facility or outside a specific building, or collection of samples that might circulate beyond the immediate vicinity on the State Party=s territory.

It is essential to chose the most appropriate sampling points and targets which could be:

- air sampling near the facility;
- waste streams near a facility;
- environmental sampling near a facility or a suspected open-air test site or in an area of 100 metres= radius of a site of interest;
- investigation of uncommon disease outbreaks near facilities which might involve epidemiological studies to include taking body fluids of humans or animals as well as samples of vegetation.

Off-site inspection aims at confirmation of declarations, complaints investigation or other relevant purposes

Characteristics and technologies

State of the art

Today a number of sampling techniques and methods of identification are available that could be used for off-site sampling and identification in the vicinity of a facility or a field testing site.

Sampling systems based on direct sampling without pretreatment, inspection, impingement as well as different methods for concentration and filtration are available. For taking air samples a number of commercially available apparatus exist that could be used in this connection. There are also well-established methods for taking surface samples.

For the identification of microorganisms and toxins there are a number of available methods. By combining genetic probes under development with the PCR (polymerase chain reaction) it is possible to achieve very good sensitivity and specificity. As yet these techniques have not been tested extensively on environmental samples. Immunoassays based on polyclonal or monoclonal antibodies are the next most sensitive identification techniques available. For the identification of

toxins, physico-chemical methods like chromatography and spectrometry (GC, HPLC, MS) can be used to screen for positive samples. Cell culture assay techniques can be of value. In general it would be preferable to use at least two independent methods of identification in parallel. Furthermore, basic methods, including traditional culturing techniques for microorganisms are still of value.

In a suspected use situation background, samples from Aclear areas should be taken by identical sampling methods to provide a baseline.

Capabilities

Standardized sampling procedures are crucial as no analysis will be better than the sample and procedure used. The selection of sampling points, sampling techniques, containment and preservation of samples during transport are therefore important. A documented description of the sampling operation, a documented chain of custody and audit trail as well as safe and tamper-resistant transportation containers are vital to the integrity of the sample and the subsequent laboratory analysis.

Samples can be collected as environmental samples (vapours or aerosols, liquid, soil, vegetation, animals, munitions or dissemination devices, used ordnance, etc.) and biomedical samples (from humans or animals).

Off-site sampling and identification would be desirable for production plans and test sites and less desirable for R&D facilities.

It is recommended to take at least three identical samples for each sampling point of which one can be kept by the host facility or State. The other samples would be used for analysis.

Off-site sampling would be less intrusive than on-site sampling and not cause problems with confidentiality.

Off-site sampling near an open-air testing site could be desirable.

Off-site sampling procedures might be considered primarily, as an auxiliary means and a monitoring measure taken, as a rule, parallel to on-side sampling to further specify on-site sampling.

Limitations

Off-site sampling is less preferable than on-site sampling due to the fact that the results of analysis from an off-site sample would be much less reliable and have more ambiguity as evidence for identifying prohibited activities.

A balance has to be found between the value of a sample and intrusiveness.

It is important to know if the agent in question is one naturally occurring in the region or not.

One problem with environmental samples is contaminants in the sample making identification difficult.

An analysis of an air sample will only give information on the presence of agents in the air at the specific time of sampling and no information on past activities.

It is essential to know if the sample contains living or dead organisms as this will influence the way a sample has to be handled, transported and analysed.

The sampling and processing system must in most cases be able to concentrate the microorganisms or toxins from air, liquid or soil to obtain sufficient sensitivity range for the identification methods.

Emission frequency of biological and toxin agents from facilities is regarded as normally low and the possibility to find a released agent is thus small. One exception could be the detection of killed organisms by the PCR techniques in effluents.

The positive identification of a potential BW-agent or toxin in one or several samples off-site would not alone be enough as an indicator of suspected prohibited activities. Other information has to be taken into account, *inter alia* presence of endemic disease in the near surroundings and the permitted activities being carried out by the facility nearby.

The presence of a specific agent in soil samples would need very thorough and careful analysis to be able to, with a high degree of certainty, state where and when the agent might have come from.

Potential interaction with other measures

Off-site inspection aims at confirmation of declarations, complaints investigation or other relevant purposes.

As the presence of an agent in air, liquid or soil samples could be explained by permitted activities or natural occurrence, the measure will not alone give information of such quality that it can be used to distinguish between prohibited and permitted activities. Therefore, other measures will be required.

Off-site sampling could be a predecessor to on-site inspection.

Discussion of relevance for off-site sampling can also be found for the measure remote sensing, e.g., ground base surveillance and when it comes to identification methods under on-site sampling and identification. An illustrative list of agents was also presented which would be of relevance for the choice of identification methods.

List of documents introduced

Italy Off-site and on-site measures,

BWC/CONF/VEREX/WP.35

inspections, sampling and

identification

United States Analysis of biological samples BWC/CONF.III/VEREX/WP48

24 November 1992

Sweden Introduction on off-site verification BWC/CONF.III/VEREX/WP.50

measure, sampling and identification 24 November 1992

Cuba Indicative list of biological agents and BWC/CONF.III/VEREX/WP.51

toxins possibly relevant to the BWC 24 November 1992

United States Biological sample collection, BWC/CONF.III/VEREX/WP.57

preservation and transportation 25 November 1992

RussianRemarks of experts of the Russian

Federation Delegation on the issue of sampling

as a verification method

United States Statement on off-site measures 24 November 1992

Ambassador E.J. Lacey, US delegation

France Sampling and identification BWC/CONF.III/VEREX/WP.68

27 November 1992

United BWC verification measures, technologies BWC/CONF.III/VEREX/WP.52

Kingdom for the identification of BW agents 24 November 1992

Romania Soil sampling BWC/CONF.III/VEREX/WP.70

30 November 1992

Germany Sampling and Identification BWC/CONF.III/VEREX.WP.38

23 November 1992

United Evaluation of the concept of BWC/CONF.III/VEREX.WP.45

States a list for the BWC 24 November 1992

OBSERVATION (off site) (Rapporteur: Mr. A.A.Mohammadi)

(BWC/CONF.III/VEREX/WP.78)

Definitions

Off-site observation is aimed at (a) monitoring a site to get a sense of activities being carried out in the facility and also to get acquainted with the external characteristics of the facility and (b) monitoring continuously through off-site observation the activities complimented by interviewing the local authorities and inhabitants about their observation regarding the activities of the facility.

As to the importance attached to the observation, it is argued that the observer is enabled to get useful information through a relatively less intrusive method and relatively low costs.

Characteristics and technologies

Regarding the technology and method for achieving the task of observation, high technology is not required, but the professional and skillful nature of manpower can play an important role. In comparison with on-site measures, observations seems to be less costly, and since it is not too close to the site, the personal safety is better guaranteed. Observation does not directly interfere with the routine activities of the site and does not interrupt the normal activities of the facility.

The ways to carry out observation could be as follows:

- 1. Level and type of physical protection and security of the site.
- 2. Location of the premises and its distance from residential areas.
- 3. Visible characteristics of the facility which may lead to suspicion that activities prohibited under the BWC are being carried out (e.g., flash protection).
- 4. Type and extent of traffic from and to the site.
- 5. The environmental and topological conditions of the area (e.g., surrounding mountains or the wind direction).
- 6. Photographing the facility it is legally possible.
- 7. Interviewing local authorities and inhabitants about the above-mentioned points, as well as:
- (a) Health care and immunization programmes in that area.
- (b) Incidence of the environmental damage.

(c) Reasons of migration or emigration.

Capabilities

- Provision of some information about the patterns and kinds of activities.
- Less intrusiveness and greater cost-effectiveness of such measure than any on-site inspection activity.
- Its complementary nature with other measures.
- Safeguarding the confidentiality of information.

Limitations

- It might create alarm among the employees and neighbours.
- Any long-term physical presence of observers may have certain legal repercussions.
- It might be difficult to find out whether the facility produces, develops or stockpiles prohibited agents or if it is involved in activities proscribed under the Convention.

Potential interaction with other measures

Possibility of overlapping activities with visual inspection, interviewing, ground-based surveillance and continuous monitoring by personnel.

It was suggested that the external sampling could also be included in the observation, which increases its interaction with the other measures like sampling and identification.

List of documents introduced

Except for the introductory presentation by the Rapporteur, no other paper was presented.

AUDITING (off-site) (Rapporteur: Mr. David O. Arnold - Forster)

(BWC/CONF.III/VEREX/WP.79)

Definition

The examination, outside a facility boundary, in accordance with agreed standards and criteria, of documentary records, electronically-held data and manuals, to assess consistency of matters recorded and material accounted with declared purposes and permitted activity.

Characteristics and Technologies

State of the art

Documentation on activities of relevance to the BWC is already produced in substantial quantities for national and international organizations especially in more developed countries. International inspectors as, for instance, those from the WHO for smallpox stocks and yellow fever vaccine quality control, already examine such reports and returns. Within bilateral arrangements, inspections are equally carried out. National responsibilities of reporting on industry are increasing and spreading because of obligations under health and safety regulations, particularly genetic manipulation, and with increasing acceptance of the advantage of adopting Good Manufacturing Practice.

This means that:

- (a) more information is available for off-site auditing;
- (b) commercial confidentiality concerns can extend to data held by national bodies off site.

Documentation subject to audit off site could, if applicable nationally, include:

- public authority records
- pollution records
- safety records
- national epidemiological collation and surveillance systems
- medical records
- training, safety and procedure manuals
- financial statements and accounts
- shipping and customs logs
- import and export records
- patents
- licences for pharmaceutical products and vaccines

- budget allocations
- annual reports
- statutory returns
- accident and incident reports
- production and acquisition records for agents, raw materials and equipment
- licences for research experiments
- environmental impact statements
- reports from ethical and scientific advisory committees

Auditing has developed into a multi-disciplinary activity, with not only accountancy but forensic, scientific, computer, linguistic and management audit skills available. Technique of random sample or selective audit could save costs and reduce chances of infringing legitimate confidentiality interests, but may increase the chances of evasion remaining undetected.

Auditing could be performed as a single selective activity, though periodic auditing may be considered.

Capabilities

Increasing quantities of information produced for other purposes and increasing audit skills create a larger base on which off-site audit could detect inconsistencies.

Risks to commercial confidentiality exist but are less than on site. Managed access would not have to be applied to information that is publicly or openly available, but only to those records that are kept confidential.

Limitations

The scope and depth of information available off site may be insufficient for an audit team to draw meaningful conclusions.

Commercial confidentiality and individual rights concerns will still apply in some areas, e.g., medical records and proprietary and process technologies.

Standards of record-keeping vary for different subject areas and in different countries around the world.

It would be possible for a violator to maintain two comprehensive sets of records, one false for audit purposes.

Administration delays and time lags in passing facility information to a central system would result in data held off site not reflecting current activity.

Companies would prefer use to be made of existing systems where possible rather than creating whole new ones for the BWC.

Further consultations with industry and other legitimate biological activities need to be coordinated.

Potential interaction with other measures

Auditing is different from information monitoring (Measures I.1.1-4) in that it concerns only objective factual information and is likely to be one off or periodic rather than continuous activity. Nevertheless there is some common ground, for example in the scrutiny of data on transfers.

Auditing would relate to declarations (Measure 2.1) because these would establish bases against which to assess consistency.

Auditing could also relate to off-site sampling and identification because results could be compared for consistency.

The major interaction is likely to be with on-site inspection. Off-site inspection can be useful to conduct investigations with lower risk to commercial information, but if inconsistencies are discovered they would probably have to be pursued on site.

Continuous auditing might be considered as an interaction with continuous monitoring.

List of documents introduced

Apart from the Rapporteur=s introduction and references to auditing in other more general papers, there were no documents introduced on this measure.

INTERNATIONAL ARRANGEMENTS - EXCHANGE VISITS (on site) Rapporteur: Mr. Ashok Kapur)

(BWC/CONF.III/VEREX/WP.80)

Definition

Visits of experts belonging to appropriate scientific disciplines of one country (i.e., a State Party) to facilities of another party to such centres as laboratories or production facilities of another State for scientific purposes under bilateral or multilateral agreement.

Characteristics and technologies

The visits will be on a voluntary and reciprocal basis, with mutual agreement.

It is essentially a confidence-building measure but may be useful as a potential verification method. These should be distinguished from other visits such as inspections. Its main characteristics are:

- mutual agreement
- variable lengths of time
- experts in different fields such as:

agriculture

medicine

veterinary science

microbiology

virology

toxicology/toxinology

biotechnology

engineers of fermentation technology, and equipment and buildings, etc.

immunology

biochemistry

administrators with expertise in science administration and related matters

quality control experts

biosafety

biological defence experts

For the selection of experts, help may be sought from specialized UN agencies like FAO, WHO, UNDP, OIE, etc. The exchange visits may be mediated through:

1. bilateral, or

2. multilateral agreements

Multilateral visits

sponsorship can be through an existing agency or establishment of international organization

development of a cooperative research or production programme

- may include both civilian or military organizations or establishments

may include both civilian or military organizations or establishments

- duration may be for mutually agreed periods.

Capabilities

Exchange visits can also include exchanging locally published or unpublished

materials.

Discussions with scientists, administrators, policy makers and technologists

regarding policies of regulation of bio-technological processes, safety practices, etc.

Direct assessment of the nature of work carried out.

Observations and suggestions for the improvement of safety practices, data storage,

retrieval, etc.

Limitations

It is essentially a confidence-building measure. A multilateral cooperative research programme could be difficult to establish due to varying interests of States Parties. Cost

could be a limiting factor which could be taken into account. The information obtained

could be limited and misleading.

Potential interaction with other measures

It will supplement other measures such as Data Exchange Methods and Multilateral Information

Sharing.

List of documents introduced

BWC/CONF.III/VEREX/WP.53

BWC/CONF.III/VEREX/WP.54

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Statement on Exchange visits by Ambassador E.J. Lacey of USA BWC/CONF.III/VEREX/None.34 - Statement by the Chinese Delegation

INTERVIEWING (on site) (Rapporteur: Mr. A.A. Mohammadi)

(BWC/CONF.III/VEREX/WP.81/Rev.1)

Definition

Interviewing is one of the measures of fact finding for on-site inspection. It is conducted with the personnel of the site. The objective is to gain preliminary information about the nature, scale, and scope of the activities and also to assess the overall function of the site.

Interviewing is considered of value in assessing that activities prohibited under the Convention are not being carried out.

Characteristics and methods

Financial and equipment:

Interviewing seems not to be of financial burden. However, the question of cost effectiveness or otherwise was not addressed at the session. Some recording devices may be required.

Manpower:

It was argued that an interviewer with skill and good technological background is required to conduct the interview. Such a person should be capable of communicating with the interviewees and of encouraging them to give proper answers to the questions. It was therefore suggested that the degree of success of this measure depends highly on the professionalism of the interviewer. In addition, he (she) should be aware of other information about the site as obtained from other measures. The necessity of proper and impartial interpretation should be taken into account.

Capabilities

Possible information provided by interviewing should be as follows:

- the purpose and aims of the facility;
- the military or civilian management of the site;
- the source of the budget of the facility;
- the degree of security measures applied on the personnel and the level and size of containment:
- the presence of locked and hidden rooms to which admission is restricted or prohibited;
- the relationship between the facility and military centres or other facilities;
- the degree of application of GMP, GLP, Biosafety type regulation and national regulation as well as site safety measures;

- regulations permitting or prohibiting the experts to publish their scientific findings;
- the speciality of the experts working on the site;
- any storage of raw material that is out of proportion to or inconsistent with declared work at the facility.

Limitations

- a limiting factor as was discussed during deliberations, was mentioned as lack of cooperation on the side of authorities and staff of the facility;
- they may also be trained to evade the questions; or even they may cooperate but give false information;
- another limiting factor would be the possibility of punitive measures against the interviewee;
- moreover, there is a possibility that some centres may operate under the cover of a
 peaceful purpose and hide the vital part of their operation related to prohibited
 activity from their own personnel except some high-ranking officials. This should be
 related to prior information about the technological capability of the inspected
 country as well as the inspected site;
- it is noteworthy to mention that nobody is allowed to force the staff members to be interviewed in a trial-like manner which may also create panic among people;
- the other limitations are the confidentiality and viability of commercial sites which have to be protected;
- time is also another limiting factor because of lack of cooperation.

Potential interaction with other measures

This measure may have interaction with the following measures:

- information monitoring;
- exchange visits;
- auditing;
- medical examination;
- on-site sampling and identification.

List of documents introduced

AA search for discriminators between permitted and prohibited activities in technical microbiology (The Netherlands, BWC/CONF.III/VEREX/WP.33).

VISUAL INSPECTION (on site) (Rapporteur: Mr. A.a. Mohammadi)

(BWC/CONF.III/VEREX/WP.82/Rev.1)

Definition

Visual inspection is aimed at acquiring a general view of the site, facilities, equipment, materials and the degree of protection, safety measures and the activities which are being carried out.

Taking note of the specifications and the characteristics of the equipment and the instruments.

Characteristics and technologies

On-site visit to facilities and establishments with activities of potential relevance to the objectives of the Convention is generally carried out by various national and international institutions and under different legislation in almost all countries. The inspectors of WHO have already routine visits to biological and industrial centres. These centres and facilities are used to and in practice are under the obligation to accept visits by responsible national authorities, particularly when they implement GMP, GLP and Biosafety type regulations. It can therefore be concluded that such a visual inspection is not uncommon or unusual for such establishments.

In visual inspection the following points could be taken into account:

- 1. Whether there exists any non-declared equipment.
- Whether there is any equipment unrelated to the objective and purpose of the establishment of the site.
- 3. The technical capability and the state of operation of key equipment.
- 4. The degree of safety protection for the personnel at work.
- 5. Any presence of excessive safety measures and specialized engineering control to maintain containment in accordance with national or international standards.
- 6. The degree of access to certain areas and locations by the personnel.
- 7. Alert signals and containment rooms.
- 8. Animal containment sites and the type of animals related to the work of the site.

Capabilities

- Increasing the knowledge of inspectors to the extent that they might be able to trace any possible non-compliance.
- Low intrusiveness and low risk to commercial confidentiality.
- The possibility of corroborating the information obtained through off-site and other measures.
- The possibility of compliance of the facility with the objective of the Convention, particularly when it is in the stage of development, production and stockpiling of biological products.

It can contribute in obtaining information on abnormal activities.

May provide information on production capacity and general capability of the facility.

- Can provide information on possible undeclared activities.

Limitations

- There is the possibility of finding no evidence of displaced key equipment.
- It requires a specific expertise and multidisciplinary teams,
- Dual use nature of equipment may complicate interpretation of information.
- There remains the possibility of compromise of process control information, which is proprietary information, during visual inspection.

Potential interaction with other measures

- multilateral information sharing;
- declaration and notification;
- observation;
 identification of key equipment;
- continuous monitoring;
- exchange visits
- auditing
- interviewing.

List of documents

Good Manufacturing Practice (G.M.P.) Inspectors for Pharmaceutical Products/Value for a BTW Verification Regime (Sweden - BWC/CONF.III/VEREX/WP.62)

Technical Aspects and Possible Schedule for Inspections (France - BWC/CONF.III/VEREX/WP.55)

A Search for Discriminators Between Permitted and Prohibited Activities in Technical Microbiology (The Netherlands - BWC/CONF.III/VEREX/WP.33)

On-site Inspection (OSI): Illustrative Operations and Costs (United States of America - BWC/CONF.III/VEREX/WP.60)

IDENTIFICATION OF KEY EQUIPMENT (On site)

(Rapporteur: Mr. Åke Bovallius)

(BWC/CONF.III/VEREX/WP.83/Rev.1)

Definitions

In the field of development:

The equipment and other items in this area is mainly of <u>dual-use</u> nature. Of particular interest is identification of:

- pilot plant bioreactors (fermenters) and their capacity for cultivation of pathogenic microorganisms and/or production of toxins;
- pilot scale, downstream processing equipment such as centrifugal separators, crossflow filtration apparatus, or freeze dryers;
- inhalation aerosol chambers for studies with aerosolized microorganisms and/or toxins;
- aerosol generating equipment and their capacity for microorganisms and/or toxins;
- equipment that could be used for microencapsulation to stabilize aerosolized microorganisms and/or toxins;
- animal houses and animal rooms used for testing with higher levels of containment;
- equipment for large-scale breeding of inspects;
- equipment for maintaining appropriate containment levels, e.g., equipment for maintaining differential air pressure levels and biological safety cabinets;
- prototypes for means of delivery and weapons under development.

In the field of production and acquisition:

The key equipment in this field is generally of a dual-use nature. Examples of equipment would be:

- bioreactors (fermenters);
- air lift fermenters:
- bioreactors for algae and cyanobacteria (blue-green algae) cultivation;
- separators;
- purification, filtration and concentration equipment;
- air filters:
- freeze- or spray-drying equipment;
- sterilization and decontamination systems;
- dispensing equipment, e.g., for packaging;
- equipment to maintain containment level;
- cell culture equipment for cultivating rickettsia, viruses, animal and plant cells;
- equipment for extracting ricin from castor beans and phase separation devices;
- equipment that could be used for microencapsulation to stabilize aerosolized microorganisms and/or toxins

In the field of stockpiling and retention:

The equipment identified in this area may or may not be of dual use character. Specific key equipment in this field would be:

- equipment for producing or filling of weapons for BW-agents or toxins.
- means of delivery such as weapons or aerosol spray equipment for living BW agents and/or toxins.

Characteristics and technologies

An essential part of an on-site inspection is the assessment of a facility=s capacities and the equipment used to ensure that the equipment is not used for prohibited activities. Another aspect of on-site inspections is to confirm declaration.

State of the art

The different stages in a biotechnical process from raw material, pretreatment, production (use of bioreactor), downstream processing to finished product is characterized by the use of specific equipment. This equipment is generally of a dual use nature. Each type of organism and each type of product requires different and specially designed processes for cultivation and downstream processing.

There are no standard designs for pilot and industrial-scale equipment for the production of dangerous biological substances and most suppliers and end-users have developed their own technologies and concepts to comply with respective national regulations.

Downstream processing depends on whether the product is biomass, extracellular or intracellular substances. Cell separation, concentration and purification are essential steps in downstream processing. Equipment like centrifugal separators and filtration units are common. To stabilize and/or preserve a biological agent or preparation, methods like spray-drying, freeze-drying or microencapsulation can be used.

A specific and exhaustive list of key equipment, their characteristics and location in a facility, might be developed. In the process of identifying key equipment in the fields of development, production, acquisition and stockpiling, international organizations, *inter alia* WHO, might have additional or complementary information.

Capabilities

The identification of key equipment provides information on:

- the scale of capacity to produce biological agents;
- if the equipment is being used under specific containment level;
- if the production equipment (bioreactor, fermenter), is used in the batch or continuous mode;
- if the equipment found complies with declared activities;
- the level of automation in the plant;
- how flexible the plant would be to change from production of one product to another.

Identification of key equipment will form an essential part of an on-site inspection and will give the inspectors important information.

Downstream processing has so many specific characteristics that specialists in the field can, in most cases, identify inconsistencies in declared activities.

Identification of key equipment will enable confirmation of declarations made.

Non-conformity with declaration of equipment in a facility would need clarification.

The presence of certain animals when not relevant in a facility might provide information on non-conformity with declared activities.

Lack of high levels of containment would mean that production of viruses pathogenic for humans, animals and plants from a safety point of view would be very difficult, but production would not be impossible.

Limitations

The identification of key equipment alone might not enable distinguishment between prohibited and permitted activities.

There could be legitimate explanations for large-scale storage of live biological agents and/or toxins, for example agents for insect pest control.

High levels of containment are not globally accepted as a requirement for production of pathogenic microorganisms and/or toxins.

Potential interaction with other measures

Data Exchange (Declarations/Notifications): Data exchange on key equipment can be confirmed during an on-site inspection.

On-site inspection: Identification of key equipment is an essential part of an on-site inspection and thus interacts with other on-site measures, e.g., visual inspection, sampling and identification and auditing.

List of documents introduced

Sweden	Introduction of an on-site	BWC/CONF.III/VEREX/WP.59
	verification measure, identification of	
	key measures	
United	Data exchange as a potential verification	BWC/CONF.III/VEREX/WP.36
Kingdom	measure under the BWC: the philosophy	
	and scope of declarations and notifications	

AUDITING (On-Site) (Rapporteur: Mr. David O. Arnold - Forster)

(BWC/CONF.III/VEREX/WP.84/Rev.1)

Definition

The examination within a facility boundary, in accordance with agreed standards and criteria, of documentary records, electronically held data and manuals, to assess consistency of matters recorded and materials accounted with declared purposes and permitted activity.

Characteristics and technologies

State of the art

Facilities have significant quantities of records stored both on paper and electronically. The prospect of activity of relevance to the BW Convention being conducted without some records is remote.

Development of documentary and electronic data storage may facilitate investigation.

The biotechnology industry in particular is accustomed to reporting and being subject to national inspection and audit on-site.

The state of the art does not yet encompass common international standards of record-keeping. Moves towards these for other purposes such as Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) may increase the production of auditable records.

Capabilities

Facilities cannot operate, except at small scale and low levels of control, without some documentation or recording system. Such information subject to audit on-site could include:

- process records
- production data
- research licences
- workstation records
- financial accounts
- stores issues and receipts
- training and operation manuals
- safety regulations
- work programme instructions
- vaccination records
- sales and enquiries records

- security documents and manuals
- waste discharge records
- transport records
- accident and incident records
- animal registers
- professional and scientific staff recruitment records
- environmental impact statements
- culture collection records
- lists of professional and scientific staff and roles
- quality control records
- pollution records

The adoption of a comprehensive audit approach allows examination of consistency between areas.

The capabilities of on-site audit include intrusive, real-time access to records. (Such intrusion and time sensitivity is not a feature of off-site audit and could enhance the potential of the audit technique on-site.)

Experience with other inspection regimes, for example biosafety inspections, inspections by the US Food and Drug Administration (FDA) and other health and safety agencies and provisions contained in the draft Chemical Weapons Convention, may be relevant when approaching the biotechnology industry.

Limitations

The maintenance of a fabricated set of records may escape audit detection.

Commercial or other legitimate sensitivities preclude comprehensive access to all material in all sites. Research programmes in academic institutions, as well as industry, may be particularly sensitive to audit. Other sensitive commercial information could include, *inter alia*, market opportunities, strategies, market shares, production rates, and potential litigation issues.

Sensitivities were expressed about the risks to proprietary rights and commercial information, although it was suggested that these may be unreasonably high at this early stage of dialogue with industries concerned, before measures to protect confidentiality have been explored with them. Further examination with industry will be needed as a basis for evaluation of this measure.

A managed access approach including random selective sample audit may alleviate the problem of commercial sensitivity, but in doing so may increase the chance of violation remaining undetected.

Whereas a national inspectorate could be subject to safeguards on information divulged and provide for legal compensation payments in the event of unauthorised disclosure, an international BWC audit body might not be under such control. Provisions on confidentiality and safeguards in the draft Chemical Weapons Convention may be relevant in this regard. Potential interaction with other measures

On-site audit is a highly interactive and dynamic measure. Auditors would wish and be able to assess consistency between their own findings and the results of information monitoring and data exchange, off-site and other on-site inspection measures. In some cases, such as medical records, interaction between the audit process and other measures is inevitable. Auditors may need to pursue an audit trail outside the site boundary. On-site audit in the case of compliance concerns should not be carried out without careful site selection and considerable preparatory work beforehand.

List of documents introduced

Apart from the Rapporteur=s introduction and references to auditing in papers on on-site measures in general, no specific documents were tabled on this measure.

SAMPLING AND IDENTIFICATION (On-site)

(Rapporteur: Mr. Patrice Binder)

(BWC/CONF.III/VEREX/WP.85/Rev.1)

On site sampling and identification

The specific aspects covered by the general terms Asampling and identification are the following four sub-items:

- sampling from environment, buildings and from inside and outside equipment at the inspected site,
- analyses for on-site identification using appropriate techniques and equipment,
- packaging samples for transportation,
- analyses for off-site identification in reference laboratories by standard reference methods

Definition

- **on-site**: this expression concerns the localisation of the origin of collected samples,
- sampling: it is the action carried out during inspection which consists in collecting any appropriate pieces of material or product in any place in appropriate quantity and quality which is able to guarantee possible further investigation with appropriate technology for the purpose of the inspection taking due account of respect for the intellectual or industrial property rights (IPR) of the inspected party.
- **identification**: it is the determination of contents in the samples described above, using appropriate methods and technologies for the purpose of the inspection and in respect of the intellectual or industrial property rights (IPR) of the inspected party, with the aim of determining the presence or absence of agents previously declared and/or used in non-compliance with the BW Convention.

A prerequisite for this measure would be to elaborate a manual for sampling and identification describing Agood sampling and identification practices (GSIP), taking into account the recommendations of Agood laboratory practice (GLP) and international regulations for transportation of biological samples.

Characteristics and technologies

sampling:

Sampling should use any appropriate technology available today, realizing that technology could be developed in the future may also be applicable to collect air, liquid and solid material in appropriate

conditions for further methods of analyses. These technologies include air impaction, sampling in liquid or solid medium, filtration and concentration of liquids, swabbing of surfaces and appropriate pieces of possible contaminated soil, leaves and plants, animals.

Capabilities

Samples are collected:

- on equipment used for development, production and/or storage,
- from bulk, raw materials, products in process and final stage, animals and plants used for product testing.
- from natural or artificial environment inside the site: soil inside and outside the buildings, animals and plants at the site.
- from waste and by-products of disposal zones, air filters, and other appropriate sources which could be requested by the inspectors.

Technical requirements:

- sampling should use non contaminated devices, approved methods for labelling, taring, sealing, preservation and transportation.
- sampling by team inspector in presence of staff of the inspected party or reverse.
 Number of equivalent samples in quantity to take into account possible need of confirmation in case of disputes.
- preservation of samples as soon as possible.
- number and volume of samples in quality and quantity just enough for team inspectors= purpose under their mandate, to carry out analyses and to ensure the reliability and confidentiality of this investigation.
- a complete record of sampling handled must be maintained to preserve the integrity and accuracy of any sample analysis.

Limitations

General limitations:

- protection of intellectual and industrial property rights and national heritage.
- a prerequisite is to have indications on the nature of the site and the potential violation before inspection.
- off-site transfers of potentially viable microorganisms, cells or toxins.

Technical limitations

- knowledge of methods of analysis as a prerequisite to sampling.
- possible exposure of personnel to infectious material.
- on-site analysis.

Samples may be analyzed on-site. However, even in such a case a positive showing will necessarily have to be confirmed off-site, especially during a very intrusive inspection. Capabilities

General capabilities:

- in practice, simple, qualitative means requiring little portable equipment will mostly be called for.

Technical requirements:

- standardized protocols and approved methods under GSIP,
- culture medium, portable sterilizers and incubators, portable or immunological tests with or without portable reader, etc.
- assistance from laboratories of the site.
- knowledge of suspected or selected agents is a prerequisite to carry out analyses.
 This could be achieved through illustrative lists.

Limitations

General limitations:

- cost of equipment, transportation and installation of a field laboratory,
- time necessary for very thorough investigation,

Technical limitations:

- sensitivity and selectivity of Ahandle-hand test kits
 <u>=</u> techniques and related methods,
- need to have information on suspected agents or to select a priori agents of concern which should be identified.
- need for technical expertise of personnel conducting tests.
- need to have simultaneously two or more techniques available for each analysis.
- false positive and/or negative responses which may generate political repercussions.
- at a storage area it should be difficult to find an acceptable on-site laboratory.
- nucleic acid probes and PCR technologies are not yet ready as handle-held test kits; possible in a near future, especially with the development of biosensors in the near future; nucleic acid probes to selected agents requires development.
- host country could affect assay, or team=s access to raw data results.
- differentiating between suspect organisms and indigenous organisms requires background information.
- transporting samples.

Transportation of inactivated materials does not require any safety measure other than needed to guarantee reliability of samples during their transfer, an accurate audit trail must be maintained during transportation. The aim is to prevent manipulation of samples during transfer.

However, under special procedures which may be agreed upon, transfer of non-inactivated samples should not be discarded a priori.

Unknown material and non-inactivated materials could be transferred off-site in conformity with international packaging rules for transportation of biological hazardous material.

Capabilities

Technical requirements:

- standardized protocols and approved methods under GSIP.
- sealed boxes are a minimum requirement for this purpose, to meet packaging standards for infectious material (IATA/ICAO).
- preservation protocols would require strict refrigeration measures.

Limitations

General limitation

- duration of transportation
- cost of transportation regarding the need of accompanying staff,
- the possible request of the inspected party to follow the samples.

Technical limitations

- in principle there is no technical limitation for transportation of living or non-living biological materials under international rules, if properly packaged.
- biological toxins could be considered toxic chemicals and some constraints could be applied.
- off-site analysis of samples.

A positive result of on-site analysis in regard to the declared objectives of inspection teach will have to be confirmed independent by expert laboratories which will undertake a complete identification. Off-site analysis would allow use of standardized as well as controlled environments for duplicate analysis to overcome possible ambiguity.

Samples taken will have to be analyzed off-site by at least two different officially-accredited independent laboratories using appropriate analytical techniques.

Participation of representative staff from the inspected site could be requested to control the regularity of analysis and the destruction of remaining samples.

Inactivated samples could be the most useful for each party to solve easily the problems of industrial or commercial confidentiality.

Capabilities

General capabilities:

- possibility to develop any qualitative and quantitative methods.
- approved laboratories for standard analysis able to solve the majority of problems in total impartiality and independence.
- the network of WHO, FAO or other UN certified laboratories could be used in reserve for recourse in the event of an objection or investigation of unusual agents.
- need of high containment laboratories to conduct analysis.

Technical requirements:

- standardized protocols and approved methods under GSIP.
- all techniques previously described above for on-site analysis could be used off-site, together with more sophisticated techniques not available for field use.
- most sensitive techniques using PCR amplification, specific probes if available and validated, and restriction mapping and/or sequencing will be favoured in this respect, even if the samples were inactivated before transportation.
- related technologies as above, plus spectrometry and chromatographic methods, all kinds of electrophoresis, biochemical and immunochemical analysis and animal testing can be performed.
- ideally use of two or more different methods for confirmation or taxonomic classification or chemical identification of agents.
- an illustrative list of suspected agents could be useful to carry out these analyses, although the area of investigation could be extended at any time.

Limitations

General limitation

- the problem of intellectual confidentiality and possible cost are the most critical arguments with regard to these analyses.
- the cost of reference laboratories operated by a possible BW organization needs to be further investigated.
- WHO and FAO laboratories are chartered for health concerns and may not be able to be involved in regular identification processes.

- sub-delegations to other laboratories to search for particular agents could create some difficulties with the inspected party.
- need to have an agreement of the inspected party to extend the area of investigation.
- need to have high containment laboratories to conduct analysis.

Technical limitations:

- inactivated materials could limit the number of different possible methods to carry out analysis

Potential interaction with other measures

The most important other measures related to sampling and identification are the following:

(a) - off-site measures: surveillance of publications,

data on transfers,

multilateral information sharing,

they are useful to provide information on the possible object of analysis;

declarations,

notifications,

- they are a prerequisite in case of conformity verification;

ground based surveillance, sampling and identification,

observation,

(b) - on-site measures: interviewing,

identification of key equipment,

auditing

medical examination

 on-site sampling and subsequent identification is a stage of on-site inspection and all other stages as listed above are pieces of the puzzle which contribute to this purpose;

> continuous monitoring by instrument continuous monitoring by personnel

- they are useful to provide information on the possible object of analysis.

List of documents introduced

BWC/CONF.III/VEREX/WP.38; Sampling and identification; Germany

BWC/CONF.III/VEREX/WP.57; Biological sample collection, preservation and transportation, United States of America

BWC/CONF.III/VEREX/WP.52; BWC measures - technologies for the identification of BW agents, United Kingdom

BWC/CONF.III/VEREX/WP.61; Methods to be used for identification of BW agents and toxins during on-site inspection, Sweden

BWC/CONF.III/VEREX/WP.35; Sampling and identification, Italy

BWC/CONF.III/VEREX/WP.48; Analysis of biological samples, United States of America

BWC/CONF.III/VEREX/None.28; Commercial confidentiality concerns associated with sampling and analysis during on-site inspections under the BWC, United Kingdom

BWC/CONF.III/VEREX/WP.51; Indicative list of biological agents possibly relevant to the BWC, Cuba

BWC/CONF.III/VEREX/WP.55; Technical aspects and possible schedule for inspections; France

BWC/CONF.III/VEREX/WP.68; Introduction on on-site sampling and identification, P. Binder, France

BWC/CONF.III/VEREX/WP.49; Operations and costs: Continuous monitoring arrangements at the Votkinsk machine building plant under the INF Treaty, United States

BWC/CONF.III/VEREX/WP.45; Evaluation of the Concept of a List for the BWC, United States

BWC/CONF.III/VEREX/WP.60; On-site Inspection (OSI): Illustrative Operations and Costs, United States

MEDICAL EXAMINATION (On-site)

(Rapporteur: Mr. Marian Negut)

(BWC/CONF.III/VEREX/WP.86/Rev.1)

Definition

Medical examinations in the context of BWC verification is the collection of information about the activities of a facility by taking and analysing body fluids and other clinical materials, by auditing medical records of the workforce, by surveilling the immunostatus of the workforce versus epidemiological background data and the examination of recent and past cases.

Characteristics and technologies

Medical examination is the basic proof of recent/past contaminations with potential BW-related agents and consists of:

Medical inspections:

- Visiting local medical units and authorities for:
- Questioning about:
 - . local morbidity/mortality rate by infectious diseases (recent/past epidemics, type of epidemic causative agents)
 - . current and special measures of disinfection, pest control
 - . vaccinations (type, frequency)
- Auditing on medical records:

Medical examination of cases

- clinical examination
- laboratory investigation:
 - . haematological
 - . biochemical
 - immunological appropriate to the clinical and epidemiological data
 - microbiological investigation (sampling and identifying by microscopic examination, culturing, immunological, genetical methods common with identification methods) and animal inoculation.

Medical examination of non-diseased person:

- . Interviewing: about recent/past illness, examinations, diagnosis, treatments, vaccinations (clinical history)
- Laboratory investigation: serological examination: if voluntary accepted, or stored blood sample.

On-site veterinary examination (clinical, serological, biochemical, haematological).

Capabilities

- By immunological test conversion can provide evidence of past infection or vaccination.
- Is relevant for evaluating unusual diseases or epidemic outbreaks.
- Get relevant information about potential BW related agents.

Limitations

- Low specificity of some serological examination, in man and animals (if indicated) for common spread diseases due to natural or artificial immunization (vaccination)
- Atypical and unknown medical picture and serological changes determined by genetically modified organisms
- Difficulty in obtaining body fluids and other clinical materials because of legal, religious or personal reasons
- Confidentiality of personal medical records (medical ethical problems)
- Inaccurate or incomplete medical records

Potential interaction with other measures

- Off-site multilateral information sharing
- On-site auditing
- On-site interviewing
- On-site visual inspection
- On-site sampling and identification

List of documents introduced

BWC/CONF.III/VEREX/WP.38; Sampling and Identification, Germany

BWC/CONF.III/VEREX/WP.39; BTWC-on site inspection, medical examination usefulness and limits, Romania

BWC/CONF.III/VEREX/WP.48; Analysis of Biological Samples, United States

BWC/CONF.III/VEREX/WP.71; Summary of the examination: Information Monitoring (On site) BWC/CONF.III/VEREX/WP.57; Biological Sample Collection, Preservation and Transportation, United States

BWC/CONF.III/VEREX/WP.58; Medical examinations during on-site inspection, Finland BWC/CONF.III/VEREX/WP.68; On-site Inspections - sampling and identification, France BWC/CONF.III/VEREX/WP.71; Summary of the examination; Information Monitoring

CONTINUOUS MONITORING BY INSTRUMENTS (On-Site) CONTINUOUS MONITORING BY PERSONNEL (On-Site)

(Rapporteur: Mr. Roque Monteleone - Neto)

(BWC/CONF.III/VEREX/WP.87/Rev.1)

GENERAL INTRODUCTION

The Ad hoc Group of Governmental Experts, during VEREX 1, proposed several possible off-site and on-site verification measures, according to the prohibitions defined in Article I of the BTW Convention: development, acquisition and production, retaining and stockpiling. Continuous monitoring, as an on-site measure, was divided into different possibilities: by instruments and by personnel. The Table below summarizes the possibilities presented at VEREX 1 by the three working areas.

CONTINUOUS MONITORING

by Instruments

D: automatic sampling, long-term recording of process parameters - air filters of hoods or laboratories, sewage tanks or treatment facilities, air, water, fermentation lines ... -, video recording, surveillance of field testing

A/P: monitoring of parameters, video recordings, automatic sampling devices ...

S/R: automatic sampling, video recording ...

by Personnel

D: posting of researchers, observers, inspectors - posting of inspectors at schools for BTW - defence training -, military personnel ...

A/P: posting of inspectors ...

S/R: posting of observers, inspectors, personnel with appropriate expertise ...

D: expert group on development

A/P: expert group on acquisition and production

S/R: expert group on stockpiling and retention

During examination of measures at the current VEREX, two other possibilities of continuous monitoring were introduced: by using laboratory animals (Finland), and by monitoring diseases occurring in humans at a particular facility, through compulsory regular reporting to a BTW organization (Brazil).

CONTINUOUS MONITORING BY INSTRUMENTS

Definition

On-site continuous monitoring by instruments is an activity conducted on a continuing basis using devices or instruments with the specific role of monitoring ongoing processes, parameters, agents or effluents, occurring in key equipment of a particular facility, and/or storage rooms or special storage facility, or testing areas.

Characteristics and Technologies

State of the art

Process Monitoring: Appropriate instrumentation for continuous monitoring currently exists to measure and record process parameters. In line and on-line monitors are routinely used in standard chemical processing, as well as for industrial quality control and good manufacturing practices for biologics and fermentation products, which can provide at regular or random intervals samples to be analyzed.

Detection and Identification: Besides the traditional methods, the identification of microorganisms, viruses and toxins by immunoassays based on antibodies or by nucleic acid related technologies is today the state of the art technique. Polyclonal and monoclonal antibodies are available commercially for several of the biological agents of concern (BWC/CONF.III/VEREX/WP.38).

Other means: Continuous monitoring activity could be performed by video recording cameras and surveillance by closed-circuit television cameras.

Items subject to continuous monitoring by instruments could include:

- agents;
- process parameters, such as temperature, salinity, pH, etc.;
- chemical analysis for microbial degradation residues, microbial metabolites, appropriate feedstocks, and specific toxins;
- effluents:
- general facility activity surveillance (personnel and car or trucks);
- electricity consumption surveillance;
- water consumption surveillance;
- storage rooms;
- testing areas.

The continuous monitoring by instruments could be a regular procedure, or in cases of investigations regarding allegations of non-compliance. In any case, a set of rules of procedure and a facility agreement should be undertaken.

Capabilities

Known agents of concern, ongoing processes, and stocks of biological materials in a particular facility should be detected by personnel using continuous monitoring by instruments.

Rapid development of detection equipment and automatization in microbiology could give better possibilities for continuous monitoring in the near future.

Limitations

At present, no commercially available device is known which might have an integrated capability of sampling and identification, as well as a real-time identification capability.

Confirmation of data results and more sophisticated methods may need to be performed outside the facility or even outside the country where the facility operates.

A high risk to intellectual property rights exists, requiring several safeguards, including precise definition of the circumstances that would trigger this on-site verification measure, and a determination of how long monitoring would last.

The information provided by process parameters analysis and/or continuous monitoring by video recording and television surveillance would only give indirect evidence that a BTW agent had been developed and/or produced or tested.

Equipment and devices to be used in a continuous monitoring activity must be routinely checked, replaced or results recorded by certified personnel.

Information provided must be quickly transmitted, on a confidential basis, and be analyzed by a multidisciplinary team of specialists on a central unit, under an appropriate authority, and integrated with other information which triggered the continuous monitoring activity.

Rules of procedure, such as facility agreement, could determine the operational aspects, confidentiality concerns, including the condition to terminate this activity on a particular facility.

Continuous monitoring of processes and/or agents might be undertaken only if specific agents and/or processes are fully declared.

Contamination and/or disruption of batch or continuous processes might occur, which might lead to legal actions by the institution/laboratory/government under a continuous monitoring activity.

Other limitations similar to those under sampling and identification.

Potential interaction with other measures

Continuous monitoring by instruments interacts with on-site inspections which might trigger its application.

Continuous monitoring by instruments could relate with off-site and on-site sampling and identification because results could be compared for consistency.

Continuous monitoring by instruments also would relate with on-site identification of key equipment which provides the basis for allocation of the types of devices and instruments for parameter process analyses.

List of documents introduced

BWC/CONF.III/VEREX/NONE.28 - Commercial confidentiality concerns associated with sampling and analysis during on-site inspections under the BTWC (United Kingdom).

BWC/CONF.III/VEREX/WP.38 - Sampling and identification (Germany).

BWC/CONF.III/VEREX/WP.41 - On-site measures: Views on the use of Continuous Monitoring (Norway).

BWC/CONF.III/VEREX/WP.48 - Analysis of biological samples (United States of America).

BWC/CONF.III/VEREX/WP.52 - BTWC verification measures - technologies for the identification of BTW agents (United Kingdom).

BWC/CONF.III/VEREX/WP.55 - Technical aspects and possible schedule for inspections (France).

BWC/CONF.III/VEREX/WP.57 - Biological sample collection, preservation and transportation (United States of America).

BWC/CONF.III/VEREX/WP.59/Rev.1 - Introduction of an on-site verification measure, identification of key equipment (Sweden).

BWC/CONF.III/VEREX/WP.62 - Good manufacturing practice (GMP) inspections for pharmaceutical products, value for a BTWC verification regime (Sweden).

BWC/CONF.III/VEREX/WP.65 - Continuous monitoring - Rapporteur=s paper (Brazil).

BWC/CONF.III/VEREX/WP.66 - Continuous monitoring by instruments (United States of America).

BWC/CONF.III/VEREX/Non-paper - Statement on continuous monitoring activities by Ambassador Edward J. Lacey, United States Delegation.

CONTINUOUS MONITORING BY PERSONNEL

Definition

On-site continuous monitoring by personnel is an activity conducted on a continuing basis using observers and other highly qualified experts with the specific role of monitoring ongoing processes, parameters or agents, occurring in key equipment of a particular facility, and/or storage rooms or special storage facility, or testing area.

Characteristics and Technologies

State of the Art

Personnel with various areas of knowledge and expertise, such as bioengineering, bioprocess engineering, detection and handling of biological materials, already exist in several countries, universities, military and civilian institutions. Good manufacturing practice expert personnel, now adopted as a regular procedure in several areas in different countries, could also be included on a team for a continuous monitoring activity by personnel.

Items subject to be continuously monitored by personnel could include:

- identification of previous and new activities and production steps;
- checking the consumption of raw materials, chemicals and reagents;
- checking the integrity of technical installations with respect to normal monitoring equipment, as well as instruments and devices installed for BTW verification purposes;
- documentary and electronically held data.

The continuous monitoring by personnel could be a regular procedure, or in special cases of investigations regarding allegations of non-compliance. In any case, a set of rules of procedure and a facility agreement should be undertaken.

During a continuous monitoring activity, monitoring personnel should be kept in operation 24 hours daily, and the activities be terminated according to specified rules.

Free access, in accordance with safety regulations and facility agreement, at any time, to all areas of the facility for development, production, storage, archives and personnel files should be assured. Interviews will be confidential with all the personnel employed or contracted, and should not be surveyed by representatives from the inspected site.

The monitoring team should be easy to identify, and their presence and purpose should be clearly announced to all the employees and contractors of the facility.

Capabilities

Agents of concern, ongoing processes, and stocks of biological materials, documents, files, electronically held data, as well as checks on traffic activity at a particular facility will be known by the use of continuous monitoring by personnel.

Limitations

A high risk to intellectual property rights exists, which leads to the need to undertake several safeguards on the generated data by this activity, including: precise definition of the circumstances that would trigger this kind of on-site verification measure, and a determination of how long monitoring would last.

Rules of procedure, such as a facility agreement, could determine the operational aspects, confidentiality concerns, including the condition to terminate this activity on a particular facility.

The costs of on-site continuous monitoring by personnel, as opposed to inspection visits, will necessarily be very high.

Continuous monitoring personnel may need to be immunized against possible BTW agents.

Potential interaction with other measures

Continuous monitoring by personnel is associated with continuous monitoring by instruments because of the need for operation, checking, replacement of equipment and devices, and also because it might be one of the triggers for its application.

Continuous monitoring by personnel interacts with on-site inspections which might trigger its application, as an exceptional verification measure.

Continuous monitoring by personnel could relate with off-site and on-site sampling and identification because results could be compared for consistency.

Continuous monitoring by personnel also would relate to on-site identification of key equipment which provides the basis for allocation of the types of devices and instruments for parameter process analyses.

Continuous monitoring could also involve audit activity and thus interact with auditing measures.

List of documents introduced

BWC/CONF.III/VEREX/None.28 - Commercial confidentiality concerns associated with sampling and analysis during on-site inspections under the BTWC. (United Kingdom)

BWC/CONF.III/VEREX/WP.38 - Sampling and identification. (Germany)

BWC/CONF.III/VEREX/WP.41 - On-site measures: Views on the use of Continuous Monitoring. (Norway)

BWC/CONF.III/VEREX/WP.48 - Analysis of biological samples. (United States of America)

BWC/CONF.III/VEREX/WP.49 - Operations and costs: continuous monitoring arrangements at the Votkinsk machine building plant under the INF Treaty. (United States of America)

BWC/CONF.III/VEREX/WP.52 - BTWC verification measures - technologies for the identification of BTW agents. (United Kingdom)

BWC/CONF.III/VEREX/WP.55 - Technical aspects and possible schedule for inspections. (France)

BWC/CONF.III/VEREX/WP.57 - Biological sample collection, preservation and transportation. (United States of America)

BWC/CONF.III/VEREX/WP.59/Rev.1 - Introduction of an on-site verification measure, identification of key equipment. (Sweden)

BWC/CONF.III/VEREX/WP.60 - On-site inspection (OSI): illustrative operations and costs. (United States of America)

BWC/CONF.III/VEREX/WP.62 - Good manufacturing practice (GMP) inspections for pharmaceutical products, value for a BTWC verification regime. (Sweden)

BWC/CONF.III/VEREX/WP.65 - Continuous monitoring - Rapporteur=s paper. (Brazil)

BWC/CONF.III/VEREX/WP.66 - Continuous monitoring by instruments. (United States of America)

BWC/CONF.III/VEREX/Non-paper - Statement on continuous monitoring activities, Ambassador Edward J. Lacey, United States Delegation

Annex II

AGENDA and PROGRAMME OF WORK

Agenda

- 1. Opening of the meeting by the Chairman
- 2. Adoption of Agenda and Programme of Work
- 3. Examination and evaluation, in accordance with the mandate of the Ad hoc Group, of the identified potential verification measures from a scientific and technical standpoint on the basis of the lists of measures contained in Annex I to the summary of the first session of the Ad hoc Group of Governmental Experts (BWC/CONF.III/VEREX/2)
 - a) Examination
 - b) Evaluation
- 4. Other matters, including the question of financial arrangements and of additional sessions
- 5. Consideration and adoption of summary

PROGRAMME OF WORK

FOR THE SECOND SESSION OF THE AD HOC GROUP OF GOVERNMENTAL EXPERTS (23 NOVEMBER - 4 DECEMBER)

Week 1

	23 November	24 November	25 November	26 November	27 November
am.	Opening of the session A. EXAMINATION	II) Data exchange (cont=d)	IV) Inspections (off-site) Moderators: Mr. Binder	V) Exchange visits (cont=d)	VI) Inspections (cont=d)
	I) Information monitoring		Mr. Bovallius Mr. Monteleone Neto		VII Continuous monitoring
	Moderators: Mr. Binder Mr. Bovallius Mr. Monteleone-Neto Introductions: ²		Introductions:		Moderators: Mr. Binder Mr. Bovallius Mr. Monteleone Neto Introductions:
pm.	I) Information monitoring (cont=d) II) Data exchange	III) Remote sensing Moderators: Mr. Binder Mr. Bovallius	IV)Inspection (cont=d) V) Exchange visits	VI) Inspections (on-site) Moderators:	VII) Continuous monitoring (cont=d)
	Moderators : Mr. Binder Mr. Bovallius	Mr. Monteleone Neto Introductions:	Moderators: Mr. Binder Mr. Bovallius Mr. Monteleone Neto	Mr. Binder Mr. Bovallius Mr. Monteleone Neto	

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	Mr. Monteleone Neto		<u>Introductions</u> :	
		<u>Introductions</u> :		
	<u>Introductions</u> :			

PROGRAMME OF WORK

(cont=d)

Week 2

am.	30 November	1 December	2 December	3 December	4 December
	SUMMING UP OF EXAMINATION I) Information monitoring Rapporteurs: II) Data exchange Rapporteurs:	VI) Inspections (on-site) Rapporteurs:	B) BEGINNING OF EVALUATION 1. Surveillance of publications 2. Surveillance of legislation 3. Data on transfers and transfer requests and on production 4. Multilateral information sharing 5. Declarations 6. Notifications Rapporteurs: A	12. Auditing (off-site) 13. International arrangements 14. Interviewing 15. Visual inspection 16. Identification of key equipment Rapporteurs:	Consideration of summary of the work
pm.	III) Remote sensing	VII) Continuous monitoring	7. Surveillance by	17. Auditing (on-site)	Consideration and

 $^{^3}$ Rapporteurs will sum up the discussions of the first week. The Chairman would welcome indications of interest for serving as rapporteur.

 $^{^4\,\}mathrm{Rapporteurs}$ will make an Introduction to each specific measure

Rapporteurs:	Rapporteurs:	satellite 8. Surveillance by	18. Sampling and identification (on-site)	adoption of summary of the work
		aircraft	19. Medical examination	
		9. Ground based	20. Continuous monitor-	
IV) Inspections		surveillance	ing by instruments	
(off-site)		10. Sampling and	21. Continuous monitoring	
		identification (off-site)	by personnel	
Rapporteurs:		11. Observation		
			Rapporteurs:	
V) Exchange visits		Rapporteurs:		
Rapporteurs:				

Annex III

SUMMARIES OF EXAMINATION OF MEASURES TO BE PRESENTED BY THE RAPPORTEURS (STRUCTURAL ELEMENTS)

The summaries should provide a factual description (without any value judgement) of the information contained in the oral contributions, national papers and documents available, arranged according to the following structural elements:

- 1. Definition(s)
- 2. Characteristics and technologies
 - 2.1 State of the Art
 - 2.2 Capabilities (development, production or acquisition, stockpiling or retaining)
 - 2.3 Limitations (development, production or acquisition, stockpiling or retaining)
- 3. Potential interaction with other measures
- 4. List of documents introduced

Annex IV

FOCs ON THE METHODOLOGY FOR THE EVALUATION STAGE

(BWC/CONF.III/VEREX/WP.89)

INDIA, THE NETHERLANDS, SWEDEN

The Netherlands, Indian and Swedish delegations approached several delegations in order to gather views on the methodology to be applied during the evaluation. On the basis of these sondages, and on the basis of the mandate of VEREX, an attempt was made to define the concept Aevaluation ...

Definition

Evaluation is the process of assessing the potential contribution of verification measures to a regime aimed at determining whether a State is performing activities prohibited under art.I of the BWC. The measures could be addressed singly or in combination. The evaluation could take place in terms of the six main criteria described in the mandate.

Different approaches

So far two broad categories of approaches have been put forward, formally or informally. These two approaches are:

- a) a qualitative or verbal approach.
- b) a quantitative approach.

Most delegations that were consulted felt that a verbal approach was adequate during the initial stage of the evaluation, whereas quantitative approach might be of interest for use in a later stage. The quantitative approach seems to be more appropriate for application to some combinations of measures and criteria, than to other combinations of measures and criteria.

A qualitative or verbal approach

Description

A written summary of the exchange of information and views between experts, relating to the application of the mandate criteria to the verification measures (possible modalities: see annex)

Capabilities

- Leaves room to differing views; majority and minority views can be expressed. Discussion can be reflected.
- Chance of misinterpretation of the outcomes will be limited.
- Applicable for all six mandate criteria.

Limitations

- Summary will take at least several pages
- Time-consuming
- Summary will be less concise than in the case of the mathematical approach
- It fails to provide one single answer for each measure-criteria combination

A quantitative approach:

An attempt to express the value of measures in the light of one criteria, or a combination of criteria in a figure by the use of a mathematical model.

Capabilities

- Results might be summarized on one A4 sheet
- If the inputs are correct, it could provide information on how reliable a verification measure is in detecting non-compliance and demonstrating compliance.

Limitations

- difficulties may emerge when VEREX will have to agree on the input values, especially in the case of measures that have hardly been studied scientifically
- might evoke a false sense of objectivity
- results need interpretation

Annex V

FOCs ON THE RESULTS OF THE SONDATE ON IDENTIFIED AREAS OF INTEREST NEEDING FURTHER ELABORATION AND THE ISSUE OF CONFIDENTIALITY IN INDUSTRY

(BWC/CONF.III/VEREX/WP.91*)

FRANCE

A) IDENTIFIED AREAS OF INTEREST NEEDING FURTHER ELABORATION

The VEREX I report had identified 21 measures for verification divided into 7 categories of measures. Annex I of this report listed these measures with some parentheses and footnotes as illustrations of possible applications of these measures. The distribution of key-words and phrases in the categories is the following:

- 1) Information monitoring/scientific and military literature, reports of symposium, patents;
 - handling and transfers of agents, equipment, licensing, produciton and use of biological agents;
 - import-export of agents, equipment, know-how, technology, personnel, manufacturing;
- 2) <u>Data exchange/</u> agents and the problem of illustrative lists, facilities and the problem of their selection, equipment and the problem of illustrative lists, programmes and the question of their description;
- 3) Remote sensing/ infrared, radar or visual surveillance, facilities, environment, outdoor testing;

4) Off-site inspection/ air, water, soil, specimen from animals, plants, in vicinity;

conformity with declarations, investigation of complaints, unusual outbreaks, accidental releases, reference techniques and laboratories, preparation of inspections;

outdoor facilities, testing, military, medical, pharmaceutical, agricultural, industrial activities; records, manuals for training, safety regulations, financial documents, programmes, questioning of local inhabitants;

- 5) <u>Exchange visits</u> increase transparency, invitation of researchers, scientists, engineers, postdoc;
- 6) On-site inspection/ see off-site inspection above, and staff and authorities

vaccinations

surfaces, containers, cultural collection filters, specimen from humans

clinical questioning, medical history, medical and biological background, clinical investigation

7) <u>Continuous monitoring</u>/ automatic sampling, long-term recording, video recording, surveillance of field testing; observers, inspectors, posting of inspectors at schools for BW defence training, military personnel.

All of these key-words and phrases were largely taken into account in the examination phase, and summaries presented by rapporteurs are the demonstration of this. Three points have been the subject of request for clarification or new debate. They are the following:

- it was proposed some additions during the examination phase particularly to clarify the use of terms as $\underline{Aresearchers} \cong \underline{which}$ should be reserved for exchange visits, $\underline{\underline{inspectors}} \cong \underline{which}$ should be reserved for continuous monitoring by personnel.
- the question of <u>illustrative lists</u> (of agents or equipment) was addressed several times during the examination phase. This expert group has taken into account the importance of this question which, as a follow-on to the examination, could be discussed again during the evaluation phase and included, as appropriate, in the intersessional work.

- The VEREX 3 meeting should pay regard, in its discussions, to the issue of possible <u>means of delivery</u> for BW agents, including equipment for weaponization (filling equipment), warheads and long-term storage facilities.

B) ISSUE OF CONFIDENTIALITY IN INDUSTRY

The impact of verification measures was largely addressed during VEREX 2, particularly in terms of industrial and commercial confidentiality. National working papers have been circulated during VEREX 2 but the problem needs to be thoroughly examined during the evaluation phase, in particular to gain more knowledge of the industrialists= perceptions and of the concept of confidentiality, inter alia, with regard to national and international legal constraints, export regulations and manufacturing practices (GMP). An appropriate contribution of industrialists to the intersessional work of the group could be envisaged to improve understanding of this question. To assist in evaluation, some measures could be tried out with industry.

Annex VI

FOCs ON COMPILED LIST OF POTENTIAL VERIFICATION MEASURES

(BWC/CONF.III/VEREX/WP.92)

BRAZIL

The compiled lists below were produced and provided by the Swedish delegation and several delegations were approached to seek their views.

1. INFORMATION MONITORING AND EXCHANGE OF VISITS

- 1.1 Surveillance of publications
- 1.2 Surveillance of legislation
- 1.3 Data on transfers and transfer requests and on production
- 1.4 Exchange visits

2. DECLARATIONS

- 2.1 Declarations
- 2.2 Notifications

3. REMOTE SENSING

- 3.1 Surveillance by satellite
- 3.2 Surveillance by aircraft
- 3.3 Ground-based surveillance

4. INSPECTIONS

- 4.1 On-site interviewing
- 4.2 Visual inspections, including observation
- 4.3 On-site identification of key equipment
- 4.4 Off-site and on-site sampling and identification
- 4.5 Auditing off-site and on-site

5. CONTINUOUS MONITORING

- 5.1 By instruments
- 5.2 By personnel

The first round of consultations were not very broad, but some thoughts brought the following list. Some criteria were agreed: no measures would be deleted and the off-site and on-site measures whenever possible be merged.

1. INFORMATION MONITORING AND EXCHANGE OF VISITS

- 1.1 Surveillance of publications
- 1.2 Surveillance of legislation
- 1.3 Data on transfers and transfer requests and on production
- 1.4 Multilateral information sharing
- 1.5 Exchange visits

2. DECLARATIONS

2.1 Declarations

3. REMOTE SENSING

- 3.1 Surveillance by satellite
- 3.2 Surveillance by aircraft

4. INSPECTIONS (OFF SITE AND ON SITE)

- 4.1 Interviewing
- 4.2 Visual inspections, including observation
- 4.3 Identification of key equipment
- 4.4 Sampling and identification
- 4.5 On-site medical examination
- 4.6 Auditing

5. CONTINUOUS MONITORING

- 5.1 By instruments, including ground based surveillance
- 5.2 By personnel, including continuous auditing

The proposals suggested of having data on transfers and transfer requests and on production be in both areas: information monitoring and exchange of visits, and as one item of content under declarations. Notifications became a special kind of declaration, regarding changes occurring on declared activities and unusual activities. Ground based surveillance be shifted to the content of continuous monitoring by instruments, as well as continuous auditing to continuous monitoring by personnel. However, such points does not represent a consensus or predominant view and many other delegations should be approached on this matter.

After another round of consultations taken with a more broad range of delegations, the only main expressed concern relates to the combination of on-site and off-site measures, at this stage of work, because some criteria might be applicable in different ways if a measure is on-site or off-site :(e.g. legal). So, the following compiled list of measures were accepted:

I. OFF-SITE MEASURES

1. INFORMATION MONITORING

- 1.1 Surveillance of publications
- 1.2 Surveillance of legislation
- 1.3 Data on transfers and transfer requests and on production
- 1.4 Multilateral information sharing
- 1.5 Exchange visits

2. DECLARATIONS

2.1 Declarations (including notifications, data on transfers and transfer requests and on production)

3. REMOTE SENSING

- 3.1 Surveillance by satellite
- 3.2 Surveillance by aircraft
- 3.3 Ground based surveillance

4. INSPECTIONS

- 4.1 Sampling and identification
- 4.2 Observation
- 4.3 Auditing

II ON-SITE MEASURES

1. EXCHANGE VISITS

1.1 International arrangements

2. INSPECTIONS

- 2.1 Interviewing
- 2.2 Visual inspections (including observation and surveillance by aircraft)
- 2.3 Identification of key equipment
- 2.4 Auditing
- 2.5 Sampling and identification
- 2.6 Medical examination

3. CONTINUOUS MONITORING

- 3.1 By instruments (including ground based surveillance)
- 3.2 By personnel

Annex VII

<u>List of documents submitted to the second session</u> <u>23 November - 4 December 1992</u>

Doc. Symbol	<u>Title</u>
BWC/CONF.III/VEREX/3	Agenda
Working Papers	
BWC/CONF.III/VEREX/WP.32	Working paper submitted by the Netherlands, entitled ASome preliminary views on the use of information monitoring in a BWC verification regime≅
BWC/CONF.III/VEREX/WP.33	Working paper submitted by the Netherlands, entitled AA search for discriminators between permitted and prohibited activities in technical microbiology _≅
BWC/CONF.III/VEREX/WP.34	Working paper submitted by Germany entitled ASurveillance of Legislation E
BWC/CONF.III/VEREX/WP.35	Working paper submitted by Italy, entitled AOff-site/on-site Measures: Inspections≅
BWC/CONF.III/VEREX/WP.36	Working paper submitted by the United Kingdom, entitled AData exchange as a potential verification measures under the BWC: The philosophy and scope of declarations and notifications≅
BWC/CONF.III/VEREX/WP.37	Working paper submitted by Germany entitled ARemote sensing: Ground based surveillance≅
BWC/CONF.III/VEREX/WP.38	Working paper submitted by Germany entitle ASampling and Identification≅

BWC/CONF.III/VEREX/WP.39	Working paper submitted by Romania entitled ABTWC-on-site inspection, medical examination usefulness and limits≅
BWC/CONF.III/VEREX/WP.40	Working paper submitted by Czech and Slovak Federal Republic, entitled AIntervention by the delegation of the Czech and Slovak Federal Republic to the sub-item: >Multilateral Information Sharing=≅
BWC/CONF.III/VEREX/WP.41	Working paper submitted by Norway, entitled AOn-site measures: Views on the Use of Continuous Monitoring≅
BWC/CONF.III/VEREX/WP.42	Working paper submitted by Australia, entitled AIntroductory remarks on data exchange notification≅
BWC/CONF.III/VEREX/WP.43	Working paper submitted by India, entitled AData Exchange: 2.1 Declarations ≅
BWC/CONF.III/VEREX/WP.44	Working paper submitted by Germany, entitled AGround Based Surveillance≅
BWC/CONF.III/VEREX/WP.45	Working paper submitted by the United States, entitled AEvaluation of the Concept of a List for the BWC≅
BWC/CONF.III/VEREX/WP.46	Working paper submitted by the United States, entitled AThe Possible Relationship of Remote Sensing Technologies to BWC Verification≅
BWC/CONF.III/VEREX/WP.47	Working paper submitted by the United States, entitled ANondestructive Evaluation Techniques for Chemical Weapons≅
BWC/CONF.III/VEREX/WP.48	Working paper submitted by the United States, entitled AAnalysis of Biological Samples≅
BWC/CONF.III/VEREX/WP.49	Working paper submitted by the United States, entitled AOperations and Costs: Continuous monitoring arrangements at the Votkinsk machine building plant under the INF Treaty≅

BWC/CONF.III/VEREX/WP.50	Working paper submitted by Sweden, entitled AIntroduction on off-site verification measures, sampling and identification iden
BWC/CONF.III/VEREX/WP.51	Working paper submitted by Cuba, entitled AIndicative list of biological agents and toxins possibly relevant to the $BWC_{\widetilde{=}}$
BWC/CONF.III/VEREX/WP.52	Working paper submitted by the United Kingdom, entitled ABWC verification measures - technologies for the identification of BW agents \cong
BWC/CONF.III/VEREX/WP.53	Working paper submitted by India, entitled AII. On site measures≅
BWC/CONF.III/VEREX/WP.54	Working paper submitted by Brazil entitled APreliminary aspects on the evaluation of the potential verification measures as they were proposed during the first meeting of the Governmental Expert Group \cong

BWC/CONF.III/VEREX/WP.55	Working paper submitted by France, entitled ATechnical Aspects and Possible Schedu	ule for Inspections≅
BWC/CONF.III/VEREX/WP.56	Working paper submitted by Canada, entitled AAn Introduction to Remote Sensing by	Satellite and Aircraft≅
BWC/CONF.III/VEREX/WP.57	Working paper submitted by the United States, entitled ABiological Sample Collection Transportation ≡	ı, Preservation and
BWC/CONF.III/VEREX/WP.58	Working paper submitted by Finland, entitled AMedical examinations during on-site in	spection≅
BWC/CONF.III/VEREX/WP.59/ Rev.1 equipment≅	Working paper submitted by Sweden, entitled AIntroduction of an on-site verification measure,	identification of key
BWC/CONF.III/VEREX/WP.60	Working paper submitted by the United States, entitled AOn-site Inspection (OSI): Ill Costs≅	ustrative Operations and
BWC/CONF.III/VEREX/WP.61	Working paper submitted by Sweden, entitled AMethods to be used for identification and toxins during on-site inspection ■	and detection of BW agents
BWC/CONF.III/VEREX/WP.62	Working paper submitted by Sweden, entitled AGood manufacturing practice (GMP) pharmaceutical products, value for a BTWC verification regime≅	inspections for
BWC/CONF.III/VEREX/WP.63	Working paper submitted by Canada, entitled AAirborne remote sensing: illustrative co	osts≅
BWC/CONF.III/VEREX/WP.64	Working paper submitted by Romania, entitled A>Medical Examination as on-site in verification as on-site in verification in the submitted by Romania and the sub	spection measure of
BWC/CONF.III/VEREX/WP.65	Working paper submitted by Brazil, entitled AContinuous Monitoring≅	

BWC/CONF.III/VEREX/WP.66	Working paper submitted by the United States, entitled AContinuous monitoring by Instruments≅
BWC/CONF.III/VEREX/WP.67	Working paper submitted by Canada, entitled AAerial and Space-Based Surveillance in the context of arms control agreements≅

BWC/CONF.III/VEREX/WP.68	Working paper submitted by	France, entitled A	On-site Inspections -	sampling and identification≅

BWC/CONF.III/VEREX/WP.69 Working paper submitted by France, entitled ASatellite and Aerial Surveillance as a Verification Measure for the

Biological (Weapons) Convention: Advantages and Limits≅

BWC/CONF.III/VEREX/WP.70 Working paper submitted by Romania, entitled ASoil Sampling≅

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BWC/CONF.III/VEREX/WP.71/Rev.1 Information Monitoring (Off-site)

(Rapporteur: Mr. Max Gevers)

BWC/CONF.III/VEREX/WP.72/Rev.1 Declarations (Off-site)

(Rapporteur: Mr. Ashok Kapur)

BWC/CONF.III/VEREX/WP.73/Rev.1 Notifications (Off-site)

(Rapporteur: Ms. Annabelle Duncan)

BWC/CONF.III/VEREX/WP.74 Surveillance by satellite (Off-site)

(Rapporteur: Mr. Gordon Vachon)

BWC/CONF.III/VEREX/WP.75 Surveillance by aircraft (Off-site)

(Rapporteur: Mr. Gordon Vachon)

BWC/CONF.III/VEREX/WP.76 Ground-based surveillance (Off-site)

(Rapporteur: Mr. Volker Beck)

BWC/CONF.III/VEREX/WP.77/Rev.1 Sampling and identification (Off-site)

(Rapporteur: Mr. Ake Bovallius)

BWC/CONF.III/VEREX/WP.78 Observation (off-site)

(Rapporteur: Mr. A. A. Mohammadi)

BWC/CONF.III/VEREX/WP.79 Auditing (Off-site)

(Rapporteur: Mr. David O. Arnold-Forster)

BWC/CONF.III/VEREX/WP.80 International arrangements -

Exchange Visits (On-site)

(Rapporteur: Mr. Ashok Kapur)

BWC/CONF.III/VEREX/WP.81/Rev.1 Interviewing (On-site)

(Rapporteur: Mr. A. A. Mohammadi)

BWC/CONF.III/VEREX/WP.82/Rev.1 Visual inspection (On-site)

(Rapporteur: Mr. A. A. Mohammadi

BWC/CONF.III/VEREX/WP.83/Rev.1 Identification of key equipment (On-site)

(Rapporteur: Mr. Ake Bovallius)

BWC/CONF.III/VEREX/WP.84/Rev.1 Auditing (On-site)

(Rapporteur: Mr. David O. Arnold-Forster)

BWC/CONF.III/VEREX/WP.85/Rev.1 Sampling and Identification (On-site)

(Rapporteur: Mr. Patrice Binder)

BWC/CONF.III/VEREX/WP.86/Rev.1 Medical examination (On-site)

(Rapporteur: Mr. Marian Negut)

BWC/CONF.III/VEREX/WP.87/Rev.1 Continuous monitoring by instruments

(On-site)

Continuous monitoring by personnel

(On-site)

(Rapporteur: Mr. Roque Monteleone Neto)

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BWC/CONF.III/VEREX/WP.88 and Corr.1 Working paper by the United States,

entitled Biologically derived toxins:

Quantities for legitimate use≅

BWC/CONF.III/VEREX/WP.89* Working paper submitted by India, the

Netherlands and Sweden, entitled AFOCs on the Methodology for the Evaluation

Stage

BWC/CONF.III/VEREX/WP.90 Working paper submitted by Brazil, France and Sweden, entitled AA Possible Approach to

Evaluation≅

BWC/CONF.III/VEREX/WP.91* Working paper submitted by France entitled AFOCs on the results of the sondage on identified

areas of interest needing further elaboration and the issue of confidentiality in industry

BWC/CONF.III/VEREX/WP.92 Working paper submitted by Brazil entitled AFOCs on compiled list of potential verification

measures≅

BWC/CONF.III/VEREX/WP.93 Working paper submitted by the Russian Federation entitled Aon determining the quantity of microorganisms and toxins required for protective purposes≅ Working paper submitted by Iran (Islamic Republic of) entitled ANeed to Promote Global Health BWC/CONF.III/VEREX/WP.94 for BWC Verification≃ BWC/CONF.III/VEREX/WP.95 Working paper submitted by the United Kingdom entitled ARapporteur=s Introductions: Auditing as an off-site and on-site measures≅ Working paper submitted by the Russian Federation entitled ACertain developments of BWC/CONF.III/VEREX/WP.96 instrumental methods of taking samples and analysis≅ Conference Room Papers BWC/CONF.III/VEREX/CRP.5/Rev.1 Provisional Agenda BWC/CONF.III/VEREX/CRP.6 Tentative Program of Work for the second session of the ad hoc Group of Governmental Experts (23 November -4 December 1992) List of Rapporteurs BWC/CONF.III/VEREX/CRP.7 * * * * * Draft summaries of the examination **Information Monitoring** BWC/CONF.III/VEREX/CRP.8

BWC/CONF.III/VEREX/CRP.9/Rev.2 Declarations

BWC/CONF.III/VEREX/CRP.10 Notifications

BWC/CONF.III/VEREX/CRP.11 Surveillance by satellite

BWC/CONF.III/VEREX/CRP.12 Surveillance by aircraft

BWC/CONF.III/VEREX/CRP.13 Ground-based surveillance

BWC/CONF.III/VEREX/CRP.14 Sampling and identification

BWC/CONF.III/VEREX/CRP.15 Observation

BWC/CONF.III/VEREX/CRP.16 Auditing

BWC/CONF.III/VEREX/CRP.17 International arrangements

BWC/CONF.III/VEREX/CRP.18 Interviewing

BWC/CONF.III/VEREX/CRP.19 Visual inspection

BWC/CONF.III/VEREX/CRP.20 Identification of key equipment

BWC/CONF.III/VEREX/CRP.21/Rev.1 Auditing

BWC/CONF.III/VEREX/CRP.22/Rev.1 Sampling and identification

BWC/CONF.III/VEREX/CRP.23 Medical examination

BWC/CONF.III/VEREX/CRP.24

Continuous monitoring by instruments Continuous monitoring by personnel

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BWC/CONF.III/VEREX/CRP.25/Rev.1

Draft summary of the work of the Ad Hoc Group for the period 23 November to 4 December

1992

Information papers

BWC/CONF.III/VEREX/INF.1/Rev.1

List of States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

BWC/CONF.III/VEREX/INF.5

List of Participants

Miscellaneous papers

BWC/CONF.III/VEREX/Misc.1

Room assignments and telephone numbers

BWC/CONF.III/VEREX/Misc.2/Rev.1

Provisional list of participants

Background	documentation
Dackground	documentation

Submitted by

BWC/CONF.III/VEREX/NONE.25 Decision of the import and export regime of items and technologies under final designation control, as well as on the export control regime for the non-proliferation of nuclear, chemical and biological weapons and of missiles carrying such weapons Romania BWC/CONF.III/VEREX/NONE.26 Report in accordance with the Final Declaration of the Second Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction and Resolution No.44/115C adopted by the General Assembly of the United Nations at its forty-fourth session Romania BWC/CONF.III/VEREX/NONE.27 Vaccine in Japan Japan BWC/CONF.III/VEREX/NONE.28 Commercial confidentiality concerns associated with sampling and analysis during on-site inspections under the **BWC** United Kingdom Statement of information monitoring BWC/CONF.III/VEREX/NONE.29 by Ambassador Edward J. Lacey USA Statement on data exchange BWC/CONF.III/VEREX/NONE.30 by Ambassador Edward J. Lacey **USA** BWC/CONF.III/VEREX/NONE.31 Opening statement

USA

by Ambassador Edward J. Lacey

BWC/CONF.III/VEREX/NONE.32	Elements for ABrainstorming discussion	n with companies: informal translation ≡	Netherlands
BWC/CONF.III/VEREX/NONE.33	Biological agents and dual use biological	al equipment - Norwegian export control	Norway
BWC/CONF.III/VEREX/NONE.34	Statement by the Chinese delegation - 26 November 1992	China	

* * * * *

BWC/CONF.III/VEREX/NONE.35	Ground-based surveillance (Off-site)
BWC/CONF.III/VEREX/NONE.36	Surveillance by satellite (Off-site)
BWC/CONF.III/VEREX/NONE.37	Surveillance by aircraft (Off-site and on-site)
BWC/CONF.III/VEREX/NONE.38	Surveillance of publications (Off-site)
BWC/CONF.III/VEREX/NONE.39	Surveillance of legislation (Off-site)
BWC/CONF.III/VEREX/NONE.40	Data on Transfers and Transfer Requests and on Production (Off-site)
BWC/CONF.III/VEREX/NONE.41	Multilateral information sharing (Off-site)
BWC/CONF.III/VEREX/NONE.42	Identification of key equipment

BWC/CONF.III/VEREX/NONE.43 Medical examination (Off-site)

BWC/CONF.III/VEREX/NONE.44 Auditing (Off-site)

BWC/CONF.III/VEREX/NONE.45 Auditing (On-site)

BWC/CONF.III/VEREX/NONE.46 Notifications (On-site)

BWC/CONF.III/VEREX/NONE.47 Sampling and identification (Off-site)

BWC/CONF.III/VEREX/NONE.48 Observation (Off-site)

BWC/CONF.III/VEREX/NONE.49 Interviewing (On-site)

BWC/CONF.III/VEREX/NONE.50 Visual inspection (On-site)

BWC/CONF.III/VEREX/NONE.51 Continuous monitoring by instruments and by personnel

Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and BWC/CONF.III/VEREX/4/Corr.1 4 February 1993

ENGLISH ONLY

Technical Standpoint

Second Session
Geneva
22 Navarahar 4 Dagar

23 November - 4 December 1992

Summary of the work of the Ad Hoc Group for the period 23 November to 4 December 1992

Corrigendum

Page 24(3),*	<u>Delete</u> existing paragraph.
paragraph 8	Replace with the following:

A8. The Chairman also requested Mr. Max Gevers (Netherlands), and Mr. Kalyan Banerjee (India) and Mr. Ake Bovallius (Sweden) to conduct consultations on the possible methodology for embarking on the evaluation of the measures examined. As a result of these consultations, the delegations of the Netherlands, India and Sweden presented a working paper (BWC/CONF.III/VEREX/WP.89) aiming at facilitating the work of the Group, and which was agreed upon by the Group as a basis for the evaluation stage.≘

Page 26 (5) penultimate

Delete existing paragraph.

AThe Group asked its Chairman to conduct consultations on the organization of its work on the basis of document BWC/CONF.III/VEREX/WP.89* and taking into account various additional proposals presented. This document is attached to the present Summary as Annex $IV.\cong$

Page 127 (82) and 128 (83)

Delete and replace with the following Annex IV.

Annex IV

FOCS ON THE METHODOLOGY FOR THE EVALUATION STAGE

INDIA, THE NETHERLANDS, SWEDEN

The Netherlands, Indian and Swedish delegations approached several delegations in order to gather views on the methodology to be applied during the evaluation. On the basis of these sondages, and on the basis of the mandate of VEREX, an attempt was made to define the concept of evaluation, to summarize the different approaches that have been proposed and to come to a general approach that includes elements of both approaches. To facilitate the work of the Group, the following is suggested:

Definition

^{*} The unbracketed page numbering refers to the consecutive numbering assigned to the Report as a whole. The bracketed numbering refers to the original page number of the document.

Evaluation is the assessment of the potential contribution of verification measures to a process aimed determining whether a State is performing activities prohibited under the BWC.

The measures could be evaluated singly or in combination. The evaluation could take place in terms of the criteria described in the mandate.

Different approaches

So far two broad categories of approaches have been put forward formally or informally.

These two approaches, which are not mutually exclusive, are:

- a) a qualitative approach
- b) a quantitative approach

In discussions a number of capabilities and limitations of both approaches were mentioned. This led to the drafting of the combined approach outlined below, which includes elements of both approaches.

A combined approach

The final product of the evaluation stage of the AAd Hoc Group of Technical Experts≅should be based on a scientific inquiry with a verbal summary and interpretation of the results of the technical evaluation.

Thus, the application of the criteria to the evaluation of each measure should produce results that will include a combination of the technical evaluation, which could consist of a verbal analysis and, if considered useful, a quantitative analysis, combined with a verbal summary. Specifically, as each measure is assessed against the criteria, the final report should include:

- 1. A list of the pros and cons of each measure in the context of their proposed use as verification measures;
- 2. When appropriate, , an analysis based on sensitivity and specificity (a definition of both is given in Annex I) may be useful in evaluating the measures;

- 3. The results of other quantitative analyses if appropriate, may be included;
- 4. An indication of how the measure could be used, including areas of synergy and interaction;
- 5. An assessment to determine if and where further developments may be required, particularly if adequate technical information on measures is not immediately available; and
 - 6. Perhaps, when the balance is clearly against a particular measure, to give it a low status in terms of potential utility.

A verbal approach for preparing the ground for the evaluation stage during this second session

In order to create a starting point for the evaluation during VEREX-III it is suggested to dedicate the time available at the end of VEREX-II to a first reading of the data that VEREX has presently gathered. This may be of use for the process of evaluation.

It is suggested to try to summarize the relevant results of the examination using a format as proposed in arnex II.

These summaries would not present a consensus view.

Annex I

How it works:

Technical reasoning could provide a consistent basis for application of the criteria to the measures and a common understanding of the above-mentioned elements for inclusion in the final report.

Inherent to each measure, or to elements of each measure, is its sensitivity * (amount of information provided) and specificity (quality of information). The evaluation criteria, particularly the first three, provide for an assessment of the quantity and quality of the information that a measure provides. Identification of these specific characteristics of each measure will help in two specific ways:

- -- to determine the ability of each measure or combination of measures to answer questions concerning compliance with the BWC;
- -- to differentiate between legitimate and illegitimate activities.

-- sensitivity: the sensitivity of a measure relates the amount of information a measure provides. Sensitivity is the assessed possibility that a measure will detect non-compliance with the Convention when it occurs.

-- specificity: the specificity of a measure relates to the quality of the information provided by the measure. Specificity is the assessed possibility that a measure will not detect a non-compliance with the Convention when none occurs.

^{*} A general description of each of the two elements in more detail follows:

	CRITERIA	CAPABILITIES AND LIMITATIONS
1.	Amount of information	
	Quality of information	
	Other strengths or weaknesses not covered by other criteria	
2.	Their ability to differentiate between prohibited and permitted activities	
3.	Their ability to resolve ambiguities about compliance	
4.	Technology requirements*	
	Material requirements*	
	Manpower requirements	
	Equipment requirements*	
5.	Financial (Treaty organization, national level, inspected facilities)	
	Legal (international and national level)	
	Safety ((for inspectors, inspected facilities, for environment)	
	Organizational implications (treaty organization, national level)	
6.	Impact on permitted activities	
	Impact on CPI (commercial proprietary information)	

Combinations with other measures that will enhance the effect of the measure above. Listed in order of priority.

1.		
2.		
3		

- What will be required?
 - What is presently available?
 - Which relevant future developments?

BWC/CONF.III/VEREX/9

ANNEX III

VEREX 3 SUMMARY

Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint BWC/CONF.III/VEREX/6 8 June 1993

ENGLISH ONLY

Third Session Geneva, 24 May - 4 June 1993

Summary of the work of the Ad Hoc Group for the period 24 May to 4 June 1993

- 1. In accordance with the mandate adopted by the Third Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction in 1991 and the agreement reached at the second session of the Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint, the Group held its third session in Geneva from 24 May to 4 June 1993, under the Chairmanship of Ambassador Tibor Tóth (Hungary). Ambassador Gérard Errera (France) and Mr. Hassan Mashhadi (Iran, Islamic Republic of) served as Vice-Chairmen of the Group. During its third session, the Group held 17 meetings and 5 informal meetings. The Chairman also conducted a series of informal consultations during the same period.
- 2. The following 42 States Parties to the Convention participated in the session of the Group: Argentina, Australia, Austria, Brazil, Bulgaria, Canada, China,, Cuba, Czech Republic, Finland, France, Germany, Hungary, India, Indonesia, Iran (Islamic Republic of), , Iraq Ireland, Italy, Japan, Luxembourg, Mexico, Netherlands, New Zealand, Nigeria, Norway, Oman, Pakistan, Peru, Poland, Republic of Korea, Romania, Russian Federation, Slovak Republic, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Thailand, United Kingdom of Great Britain and Northern Ireland, United States of America. The list of participants is attached (see Attachment 1).
- 3. The representative of the World Health Organization (WHO) also participated as an observer of the meeting, upon invitation of the Chairman.
- 4. The Group was assisted by staff members from the Officer for Disarmament Affairs, Mr. Timur Alasaniya, Political Affairs Officer, Secretary to the Group and Ms. Olga Sukovic, Senior Political Affairs Officer, Deputy Secretary.
- 5. At its first meeting, on 24 May, the Group adopted its agenda as well as a programme of work for the session. The agenda and programme of work are attached to the present summary as Annex II. The agenda provided for the continuation of evaluation, in accordance with the mandate

of the Ad Hoc Group, of the identified potential verification measures, singly and combination, from a scientific and technical standpoint which had been examined during the second session.

- 6. The following experts continued to assist the Chairman as moderators in the task of evaluating potential verification measures grouped under the three broad areas: Mr. Patrice Binder (France) development; Mr. Åke Bovallius (Sweden) acquisition of production; Mr. Roque Monteleone Neto (Brazil) stockpiling or retaining.
- 7. The Chairman was further assisted by experts acting in their personal capacity as rapporteurs whose task was to introduce the measure(s) to be evaluated, to moderate the relevant discussions, and to prepare reports on the evaluation of those measures. The list of rapporteurs and the respective measures assigned to them are as follows:

Surveillance of publications Mr. Max Gevers

Netherlands

Surveillance of legislation Mr. Max Gevers

Netherlands

Data on transfers, transfer Mr. Max Gevers

requests and on production Netherlands

Multilateral information sharing Mr. Max Gevers

Netherlands

Exchange visits Mr. Thomas Dashiell

(USA)

Declarations Ms. Annabelle Duncan

(Australia)

Surveillance by satellite Mr. Gordon Vachon

(Canada)

Surveillance by aircraft Mr. Gordon Vachon

(Canada)

Ground-based surveillance Mr. Volker Beck

(Germany)

Sampling and identification Mr. Åke Bovallius

(off-site) (Sweden)

Observation Mr. A. A. Mohammadi

(Iran, Islamic Republic of)

Auditing (off-site) Mr. John Noble

(United Kingdom)

International arrangements Mr. Thomas Dashiell

(USA)

Interviewing Mr. A. A. Mohammadi

(Iran, Islamic Republic of)

Visual inspection Mr. A. A. Mohammadi

(Iran, Islamic Republic of)

Identification of key equipment Mr. Åke Bovallius

(Sweden)

Auditing (on-site) Mr. John Noble

(United Kingdom)

Sampling and identification Mr. Patrice Binder

(on-site) (France)

Medical examination Mr. Marian Negut

(Romania)

Continuous monitoring by instruments Mr. Roque Monteleone Neto

(Brazil)

Continuous monitoring by personnel Mr. Roque Monteleone Neto

(Brazil)

- 8. Mr. Åke Bovallius (Sweden) and Mr. Graham Pearson (UK) asked to act as Friends of the Chair on the issue of evaluation measures in combination.
- 9. The Chairman also asked Mr. Volker Beck (Germany) to conduct consultations with a view to identifying an agreed approach to handling the question of possible determination of types and quantities of biological agents.
- 10. The Group proceeded, in accordance with its mandate and the programme of work, to evaluate the potential verification measures identified during the previous sessions. In the course of those discussions, several delegations presented national papers which were subsequently circulated as working papers of the Group. A number of background papers were also circulated at the request of delegations. A list of documents is attached to the present summary as Annex IV.
- 11. On the basis of the Introductions submitted by the rapporteurs, the Group conducted indepth discussion and evaluation of the measures at both formal and informal meetings and adopted by consensus an evaluation report on each measure.

- 12. After the evaluation of measures singly, the Group proceeded to their evaluation in combination. The Group decided to adopt BWC/CONF.III/VEREX/WP.113 "Evaluation of verification measures in combination" as a basis for discussion of the measure on combination methodology (see (Attachment 2). The Group conducted discussion and evaluation of illustrative and non-exhaustive examples of measures in combination and adopted by consensus a report (BWC/CONF.III/VEREX/WP.176). Without prejudice to further contributions. The report is annexed to the Summary in Annex I.
- 13. To date, results of the consultations on the question of types and quantities of agents, which may be further considered at a later stage, are reflected in "Types and Quantities of Microbial and other Biological Agents and Toxins" (BWC/CONF.III/VEREX/WP.175). The Group decided by consensus to include this paper in Annex I of the present Summary.
- 14. In the course of an informal meeting, the group had an exchange of views on the lessons gained from two trial inspections carried out by the Netherlands and Canada, and the UK respectively. Two working papers on trial inspections were submitted "Bilateral Trial Inspection in Large Vaccine Facility" (BWC/CONF.III/VEREX/WP.102) by the Netherlands and Canada, and "UK Practice Inspection: Pharmaceutical Pilot Plant" (BWC/CONF.III/VEREX/WP.141) by the United Kingdom.
- 15. At an informal meeting, the Swiss delegation presented a study on Q-Fever (BWC/CONF.III/VEREX/NONE.52) to illustrate the capabilities of "Sampling and Identification" as a potential verification measure (see Attachment 3).
- 16. A number of national statements were made during the course of VEREX III on its work. In addition, a statement was made by the Non-Aligned and other developing countries participating in the Conference expressing their wish that, in order to arrive at consensus final results, potential verification measures should serve the purpose of strengthening the Biological Weapons Convention (the statement is attached as Attachment 4).
- 17. The Group decided, in accordance with its mandate, to prepare and adopt by consensus at its last session a report on its work. The outline of character, elements and the structure of the report is contained in Annex III of this Summary.
- 18. The Group was of the view that because of the important task related to the adoption at its final session of the report additional efforts were required to prepare a draft of such a report. To this end, the Group entrusted its Chairman to collect possible contributions delegations might wish to make and to prepare, in the course of several informal consultations and Extended Bureau meetings, a draft report which could be circulated in advance of the last session.
- 19. The Group confirmed the decision reached at its second session to meet in Geneva from 13 to 24 September 1993.

Annex I

REPORTS

EVALUATION OF SURVEILLANCE OF PUBLICATIONS (Rapporteur: M. Gevers)

(BWC/CONF.III/VEREX/WP.151)

<u>Effectiveness</u>: Surveillance of publications may well be an effective measure if combined with other measures (e.g. declarations, auditing or other information monitoring measures). It may help in the selection of sites for inspections and in focussing ongoing inspection activities. Because of the large amount of information available, a focussed survey is necessary. This focusing could be done by using key identifiers. At this stage the key identifiers are not yet determined. The low level of intrusiveness of this measure is a considerable advantage.

<u>Costs</u>: If focussed this measure need not be very costly. It does not require large investments. Some personnel with specific expertise and a computer database would be needed.

	CRITERIA	CAPABILITIES	LIMITATIONS
1.	Amount of information	- relevant information is available	- the amount of information is very large, prohibitively if not focussed
	Quality of information	- relevance improves if focussed by key identifiers - could provide useful general information on relevant activities in a State Party - could reveal trends - may be used to target further investigations or inspections	- methodology needs to be refined - provides only a partial picture of activities, not all types of relevant information are necessarily published - not all scientific and technical publications are incorporated in databases - consistency in quantity and quality may vary per region
	Other strengths or weaknesses not covered by other criteria		
2.	Their ability to differentiate between prohibited and permitted activities	 general pattern of activities in a State Party may be construed could assist in identifying inconsistencies may help focus on-site inspections 	- taken alone, this measure could not differentiate between prohibited and permitted activities - work within prohibited activities is not likely to be published
3.	Their ability to resolve ambiguities about compliance	 would highlight dual purpose activities that could merit further investigation relevant publications might also help resolve some specific 	- considerable effort may be needed to prevent missing important items and avoid misinterpretation of facts

		compliance concerns	
4.	Technology requirements	- no requirements	
	Material requirements	- limited requirements	
	Manpower requirements	- limited requirements	- specific expertise of personnel is needed
	Equipment requirements		- computer with on-line connections to major databases
5.	Financial	- focussed surveys need not be very costly	- translation services might be costly
	Legal	- limited implications, if any	
	Safety	- no implications	
	Organizational implications		
6.	Impact on permitted activities	- limited impact, if any	
	Impact on CPI	- no impact	

Combinations with other measures that may enhance the effect of the measure above. Listed in order of priority:

- Other information monitoring measures (surveillance of legislation, data on transfers, transfer requests and production, multilateral information sharing).
- Declarations.
- On-site inspections.
- Auditing (on-site/off-site).

EVALUATION SURVEILLANCE OF LEGISLATION

(Rapporteur: M. Gevers)

(BWC/CONF.III/VEREX/WP.152)

<u>Effectiveness</u>: Surveillance of legislation may well be an effective measure if combined with other measures (e.g. declarations, auditing or other information monitoring measures). It may help in the selection of sites for inspections and in focussing ongoing inspection activities. However, it should be noted that the absence of legislation is not an indication of non-compliance.

<u>Costs</u>: This measure need not be very costly. Although the precise requirements pertaining to this measure still need to be determined, an investment into a good computer/database is needed. Translation costs may be substantial.

	CRITERIA	CAPABILITIES	LIMITATIONS
1.	Amount of information	- relevant information is available	- the amount of information is very large - quantity varies per State
	Quality of information	- could provide information on relevant activities of States Parties	- may not provide an indication of the policy of a country towards the BWC - periodic updating is necessary
	Other strengths or weaknesses not covered by other criteria		
2.	Their ability to differentiate between prohibited and permitted activities	 could help establish pattern of activity in a State Party could suggest priorities in budget allocation may help focus on-site inspections 	 absence of legislation may not be an indication of non-compliance taken alone this measure could not differentiate between permitted and prohibited activities
3.	Their ability to resolve ambiguities about compliance	- may help explain the nature of dual purpose activities	- risk of misinterpretation
4.	Technology requirements	- no requirements	
	Material requirements	- limited requirements	
	Manpower requirements	- limited requirements	- specific expertise of personnel needed
	Equipment requirements		- computer/database

5.	Financial	- a focussed survey should not be very costly	if not focussed, costs of evaluation might be hightranslation costs might be highspecialist expertise is needed
	Legal		
	Safety	- no implications	
	Organizational implications		- a well established administration is required
6.	Impact on permitted activities	- limited impact, if any	
	Impact on CPI	- no impact	

Combinations with other measures that may enhance the effect of the measure above. Listed in order of priority:

- Other information monitoring measures (surveillance of legislation, data on transfers, transfer requests and production, multilateral information sharing).
- Auditing (on-site/off-site).
- Declarations.
- On-site inspections.

EVALUATION DATA ON TRANSFERS, TRANSFER REQUESTS AND PRODUCTION (Rapporteur: M. Gevers)

(BWC/CONF.III/VEREX/WP.153)

Effectiveness: Data on transfers, transfer requests and production may well be an effective measure if combined with other measures (e.g. declarations or other information monitoring measures). It may help in the selection of sites for inspections and in focussing ongoing inspection activities. Because of the large amount of information available, a focussed survey is necessary. This focusing could be done by using key identifiers. At this stage the key identifiers are not yet determined. Not all information may be freely accessible. Confidentiality concerns need to be considered.

<u>Costs</u>: If focussed this measure need not be very costly. This measure does not require large investments. Some personnel with specific expertise and a computer database would be needed.

	CRITERIA	CAPABILITIES	LIMITATIONS
1.	Amount of information	- could provide important relevant information on activities of States Parties	- the amount of information could be very large, prohibitively if not focussed
	Quality of information	- may provide information on dual use activities and on production capacity in the biological realm of State Parties - good quality if focussed by key identifiers - may be a background for further investigation	 key identifiers still have to be determined not all relevant data may be freely accessible the amount and quality of information may differ per State information may be outdated quickly
	Other strengths or weaknesses not covered by other criteria		
2.	Their ability to differentiate between prohibited and permitted activities	- could help establish patterns of activity in a State Party - may help focus on-site inspections	
3.	Their ability to resolve ambiguities about compliance	- may help in the analysis of dual purpose activities	
4.	Technological requirements	-no requirements	
	Material requirements	- limited requirements	
	Manpower requirements	- limited requirements	- specific expertise of personnel

			needed
	Equipment requirements		- computer / database
5.	Financial	- a single focussed survey would not be very costly	- data analysis could be costly - a continuing survey could be more costly
	Legal		- not all information may be freely accessible
	Safety	- no implications	
	Organizational		
6.	Impact on permitted activities	- limited impact, if any	
	Impact on CPI	- access to CPI can be defined	- confidentiality concerns need to be considered

Combinations with other measures that may enhance the effect of the measure above. Listed in order of priority:

- Other information monitoring measures (surveillance of publications, surveillance of legislation, multilateral information sharing).
- Auditing.
- Declarations.
- On-site inspections.

EVALUATION MULTILATERAL INFORMATION SHARING

Rapporteur: M. Gevers

(BWC/CONF.III/VEREX/WP.154)

<u>Effectiveness</u>: Multilateral information sharing may well be an effective measure if combined with other measures (e.g. declarations, remote sensing or other information monitoring measures). It may help in the selection of sites for inspections and in focusing on-site inspection activities.

<u>Costs</u>: This measure need not be very costly. Although the precise requirements pertaining to this measure still need to be determined, an investment into a good computer/database is needed.

	CRITERIA	CAPABILITIES	LIMITATIONS
1.	Amount of information	- relevant information could be made available, including information from international organizations	- the amount of information could be very large, prohibitively if not focussed
	Quality of information	 may provide information on relevant activities in a State Party may be a background for further investigation may provide indications of non-declared activities (e.g. through information on third parties) 	- selection of information is needed - depends on the willingness of a State Party to provide information - there could be a risk of manipulation - the amount and quality of information may differ per State - information may be inaccurate
	Other strengths or weaknesses not covered by other criteria		
2.	Their ability to differentiate between prohibited and permitted activities	- could help establish patterns of activity in a State Party	- taken alone, this measure could not differentiate between prohibited and permitted activities
3.	Their ability to resolve ambiguities about compliance	may help explain the nature of dual purpose activitiesmay help focus on-site inspections	- inaccurate information may generate unwarranted concerns
4.	Technological requirements		
	Material requirements		
	Manpower requirements		
	Equipment requirements		- computer / database
5.	Financial	- if focussed, not very costly	

	Legal		 not all information may be freely accessible legal implications need to be considered
	Safety	- no implications	
	Organizational		- absence of national coordinated efforts may limit the availability of data
6.	Impact on permitted activities	- limited impact, if any	
	Impact on CPI	- access to CPI can be defined	- confidentiality concerns need to be considered

Combinations with other measures that may enhance the effect of the measure above. Listed in order of priority:

- Other information monitoring measures (surveillance of publications, surveillance of legislation, data on transfers, transfer requests and production).
- Declarations.
- On-site inspections.
- Remote sensing.

EVALUATION EXCHANGE VISITS (Off-Site) (Rapporteur: Mr. T. Dashiell)

(BWC/CONF.III/VEREX/WP.155)

Introduction

During VEREX I and II potential verification measures for the Biological and Toxin Weapons Convention (BWC) were identified and examined. This measure generally duplicates the on-site measure "Exchange Visits- International Arrangements" in structure and operation except it is proposed to be conducted off-site. ¹ This should be distinguished from other visits such as inspections.

Definition

Visits of experts arranged for scientific purposes by one country to comparable facilities of another country (States Parties) under bilateral or multilateral agreements. Exchange visits need not be restricted to declared facilities.

Characteristics

Exchange visits have not yet been fully defined, however, the present confidence-building measure agreed at REVCON II may serve as a precedent.

The most extreme application would be development of multilateral agreements to cover all program areas including military defense programs as well as industrial and university areas and opening all areas to exchange visits. The least extreme would be bilateral long-term exchanges made in selected program areas where common scientific interests exist between countries, relevant to the CBMs.

It is generally agreed that visits would be on a voluntary and reciprocal basis with mutual agreement of the areas of interest, selection of personnel and the length of the scientific exchange. Suggestion of technical skills may range from agriculture through medicine and biotechnology to biological defense experts.

Capabilities

Exchange visits can provide a method for information monitoring, however, the other measures proposed for this function may be more useful and cost effective. Exchange visits will more generally provide a mechanism for exchange and acquisition of knowledge between countries

¹ The history of this measure is contained in BWC/CONF.III/VEREX/4, pages 86-88.

interested in a common area of research, development or production. In most cases, specific bilateral arrangements addressing a select area of work would be necessary.

Limitations

A major limitation of exchange visits is the bilateral nature of the effort. Information obtained will not generally be available to all States Parties. Mechanisms will be needed to overcome this difficulty as well as notifications of such official visits to States Parties. Some discussion has indicated that this proposed measure should be considered an enhanced CBM rather than a verification measure.

Interaction With Other Measures

This measure is recognized as not generally being a stand-alone measure but may exhibit some synergy between this measure and declarations, and other measures.

Summary

Exchange visits can provide a mechanism of transfer of technical information for a given area of study. The scope of the agreement will largely determine the amount and quality of the information exchanged. The potential loss of proprietary information is of concern to industry and the academic communities.

From the preliminary evaluation, this measure may serve best as an enhanced CBM, expanding openness and transparency. There is a need to consider whether any added value is obtained by combinations of this measure with other proposed measures.

	CRITERIA	CAPABILITIES	LIMITATIONS
1.	Amount of information	- could be substantive but may depend on length of the visit, type of facility and degree of access	- Information generally limited to scientific matters and in limited area specified in agreements
	Quality of information	- could be of good quality but may depend on length of visit, type of facility and degree of access	
2.	Ability to differentiate	- information accumulated may provide some information on permitted activities at a specific site	- information acquired is insufficient to differentiate alone
3.	Ability to resolve ambiguities about compliance		- unlikely that information acquired will provide more than openness and transparency
4.	Technology requirements	- no limitation on such exchange visits are posed by technology, material or equipment needs	- limitations may exist due to small number of appropriate scientists available for exchange in some countries
5.	Financial	- funding for international	- visit cost and implementing

		exchange programs may be available	mechanism cost could be a limiting factor
	Legal		- legal factors such as rights of exchange scientist and protection of proprietary information must be considered
	Safety		- visitor safety should be insured by proper training and immunization just as the host staff
	Organization	- existing international organizations may support exchange programs	- bilateral agreements relatively simple but limit information dissemination - information limited to subject of agreement
6.	Impact upon permitted activities		
	CPI	- minimal loss anticipated	

Combinations with other measures that may enhance the effect of the measure above. Listed in order of priority.

DECLARATIONS

(Rapporteur: Ms. A. Duncan)

(BWC/CONF.III/VEREX/WP.156)

Introduction

During VEREX I and II potential verification measures for the Biological and Toxin Weapons Convention BWC were identified and examined. The measures were divided into offsite and on-site measures. Declarations were considered to be a major off-site measure from which national profiles or patterns of biological activity could be assessed against other sources of information. Using the declaration mechanism, nations could share information regarding biological activities and could, in effect explain to States Parties activities which may otherwise cause compliance concerns.

It was accepted during the earlier meetings that declarations could not be a stand-alone measure, but that they could interact favourably with other proposed verification measures. At this meeting the nature of the interaction is being considered further.

Definitions

Declarations - mandatory, periodic reporting on a regular basis of information considered to be of relevance for verification of the BWC. The nature of the events/items/facilities to be declared has yet to be fully defined, numerous suggestions were made at VEREX II which will need, eventually to be considered in more detail. It was suggested that there could be two types of declaration, a periodic, national declaration and a specific on-site declaration preceding an inspection.

Notifications were considered to be a subset of declarations concerned with the reporting of new or unforeseen events or forecast of events in order to pre-empt compliance concerns.

Characteristics

Possible items/events for declarations were proposed during VEREX II: (BWC.CONF.III/VEREX/WP.43, BWC/CONF.III/VEREX WP.42, BWC/CONF.III/VEREX/WP.36, BWC/CONF.III/VEREX/WP.72, BWC/CONF.III/VEREX/WP.73/Rev.1). These fall generally into four categories:

- 1. facilities (e.g., those associated with BW defence programmes, vaccine production facilities, etc.);
- 2. programmes (e.g., biological control programmes involving aerosol dissemination of biological agents; trials on human and animal vaccines).
- 3. events (e.g., disease outbreaks, military exercises which involve BW defence training).

4. etc.).	national legal measures (e.g., export controls, occupational health and safety legislation,

Capabilities

Declarations could build up a picture of the approaches to microbiological work, health and safety in a country. This may lead to an understanding of the approaches taken in a country to work on microorganisms and toxins, against which initial judgments of consistency could be made. They could help to put in context other information, providing a basis for discounting incorrect or unsubstantiated reports which might otherwise give rise to costly on-site verification measures.

Declarations could, with other measures, provide a graduated response to compliance concerns. Concerns raised by, for example, detection of activities via remote sensing or information monitoring may be allayed by simple notification in response to a request. When discrepancies persist between the declared information and that obtained by other verification measures, more expensive and time consuming verification measures (e.g., inspections) could be necessary.

It is envisaged that declarations will be important in both the general and focused phases of verification. Thus certain items/events could be declared on a regular basis by all States Parties. Other items/events could be declared (notified) as required, e.g., information regarding key equipment may only be declared in the preparatory stage of a more focused inquiry such as an inspection.

Limitations

A major limitation of declarations is that their utility depends upon their accuracy. No nation would declare a prohibited activity as such, but non-declaration of a facility known by other verification means to exist could give rise to compliance concerns. Thus, declarations alone may not provide verification of the BWC but they are strongly synergistic with other measures.

Declarations may give an uneven picture of activity in the biological field. For example, nations which impose Good Manufacturing Practice (GMP) codes upon industry are likely to have necessary information about their biological industries at hand, whereas those nations where there is little government control or regulation of biological industry may find it more difficult to provide relevant information. This situation should improve as more nations adopt international codes of practice such as GMP.

As one purpose of declarations is to increase transparency, information provided under this measure would need to be made available to all States Parties. Concern was expressed that this could create confidentiality problems for some of the categories of information already suggested as the subject for declarations.

For example releasing the names of personnel employed in a declared facility may result in attacks by animal rights activists or terrorists. Industry may be unwilling to provide commercially sensitive information if it was to be made public. It may be possible to prevent such problems by careful definition of what information is required to be declared, and by ensuring the information is strictly controlled under the BWC.

Sensitivity and specificity

While the sensitivity of declarations alone is low, i.e., declarations alone are not likely to detect non-compliance, the specificity is reasonably high, i.e., they will not detect violations when none occur. On the other hand, all the other measures suggested for verification of the BWC depend to a greater or lesser degree upon information provided by Declarations.

Interactions with other measures

Declarations are not a stand-alone verification measure. Six other verification categories have been proposed, and all of those may interact synergistically with declarations. To allow a more concise assessment of measures in combination, the assessment has been made at the level of categories rather than at the level of individual measures.

Information monitoring: The interaction between information monitoring and declarations may be strongly synergistic. Correlation between declared and monitored data is a good indicator of compliance, whereas a lack of correlation would give rise to concern. It has been suggested that data on transfers, transfer requests and on production should be monitored under information monitoring, and that the same information should form part of a declaration. Discrepancies between the monitored information and the declared information could create concerns which would need further elucidation. This would not necessarily be a bad thing, since it could begin a process which eventually would provide a clearer picture of the degree of a country's compliance with the Convention. Also, in cases of outbreaks of certain diseases, concerns could be allayed by means of declaration (notification) of the outbreak.

Inspections, on and off site: Provision through declaration of background data on a facility could allow more efficient, less time-consuming and less confrontational inspections. Trial inspections of pharmaceutical facilities carried out by the Netherlands/Canada and by the UK (BWC/CONF.III/VEREX/WP.112; BWC/CONF.III/VEREX/WP.147) found that the inspection team benefited from prior declarations. One reason the inspection could be conducted more efficiently was that prior declaration of the function of the facility allowed assessment in advance of the type of expertise required in the inspection team.

Exchange visits: It may be difficult to organise exchange visits to facilities of interest under BWC verification unless such facilities were identified by prior declaration.

Remote sensing: Declarations could be useful in interpreting information obtained by remote sensing.

Continuous monitoring: Information obtained by declaration may be helpful in applying continuous monitoring to a facility.

Further developments required

The major task ahead if declarations are to be used is to elucidate what needs to be declared before implementation. A large list of suggested events for declaration were proposed at

VEREX II. Not all items on the list had unanimous support and many required much more definition to be useful. For example it was suggested that disease outbreaks should be declared but there has, to date, been little discussion of what diseases fall into the category that needs to be declared. Is it particular diseases, or "unusual" disease outbreaks and if the latter, what are "unusual" disease outbreaks?

Summary

Declarations, if properly structured, could be an important mechanism for building up a picture of the biological activities in a nation. They give a nation the opportunity to explain actions or events to States Parties which may otherwise cause compliance concerns. The veracity of such explanations can be judged against the patterns of activity in biological sciences built up over time.

An evaluation of declarations as a verification measure using the six criteria specified in the mandate is given in the accompanying table.

On balance, it would appear from this evaluation that declarations have a high status in terms of potential utility. There is however a need to consider in more detail exactly what items/events should be declared.

	CRITERIA	CAPABILITIES	LIMITATIONS
1	Amount of information	- depends upon how well defined the requirement is, and its scope	- if declarations were not well focused they might result in too much information being supplied and overload of information
	Quality of information	 depends upon how well defined the requirement is, and upon the integrity and capability of the national organization making the declaration potentially this could be very useful if the declarations were well focused treaty guidelines could be developed that would improve that quality of the data returned 	- the quality of the information may vary from country to country - information may be inaccurate or manipulated
2	Ability to differentiate between prohibited and permitted activities	- declarations will provide a baseline of information regarding all three areas of development, production and stockpiling - examination of declarations could disclose irregularities in a country's biological activities suggesting further investigation. Non-	 declarations alone will not enable differentiation between prohibited and permitted activities simply because no nation would declare a prohibited activity virtually all equipment, facilities agents, etc., are of a dual-use character and therefore have no

		declaration of a suspect facility would generate further questions.	unique qualities to associate them with biological weapons
3	Ability to resolve ambiguities about compliance	- declaration may help allay concerns, particularly once regular declarations have built up a pattern of biological activity in a country, against which future activity can be judged	- incomplete or inaccurate dechrations may create new ambiguities which would then require further explanation
4	Technology requirements	low; but a good data base would be required to process informationno new technology/equipment breakthroughs are required	- may be necessary to develop an extensive computer data base programme to develop and compile the declarations
	Material requirements	- low	- no limitations envisaged
	Equipment requirements	- low	- no limitations envisaged
	Manpower requirements	- States Parties to the BWC are obliged to provide annual returns under the CBMs. CBMs are politically binding whereas declarations are envisaged as being mandatory so some States Parties will need more manpower than are currently involved in CBM returns	- to maximize the utility of declarations processing would be required. Manpower needs for processing returns, e.g., translation, distribution, correlating information with that obtained from other sources may be substantial. Expert assessors wold be required
5	Financial	- the cost would depend upon how specific and selective the declarations were. Much of the information likely to be of use in a declaration may be present in many companies, e.g. for regulatory or environmental requirements or public relations purposes	- in some cases resources would need to be established at the national level to prepare declarations with the attendant costs. If an international body were required to process returns, this would impose financial burdens
	Legal	- legal implications are hard to estimate at this stage, but adverse effects can be minimised by choice of items/events that need to be declared	- it is envisaged that Declarations will be mandatory. Some of the suggested items for declarations may cause legal problems that need to be addressed at a national level
	Safety	- no safety problems are envisaged	- nil
	Organizational implications	- at the national level organizational implications should not be large,	- a central processing body may be required to correlate and analyse data

		providing the declarations are well defined and focused. At the international level this issue needs to be addressed	
6	Impact upon permitted activities	- low	
	Impact upon commercial proprietary information (CPI)	- depends upon what is to be included in the declaration. Declarations may or may not cause problems with CPI	- companies may be reluctant to provide commercially sensitive information. Business confidential and proprietary research information may need protection

Combination with other categories of measures that may enhance the effect of declarations. Listed in order of priority.

- <u>Information monitoring</u>. Correlation of information obtained via monitoring and that provided in declarations will be very important in allaying concerns.
- <u>Inspections</u>. Inspections of facilities without the background information provided by Declarations would be more difficult and intrusive.
- <u>Continuous monitoring</u> of a facility implies prior knowledge of the parameters being monitored. This knowledge could be provided via Declarations.
- Remote sensing. Information obtained via remote sensing may give rise to concerns in the absence of Declarations which may not occur if sites/activities are declared.
- Exchange visits. Relevant facilities for exchange visits need to be identified via declarations.

EVALUATION SURVEILLANCE BY SATELLITE (Off site)

(Rapporteur: Mr. Gordon Vachon)

(BWC/CONF.III/VEREX/WP.157)

Definitions

<u>Satellite</u>: An artificial body placed in orbit around the earth or other planet. A satellite may be described as a "platform" carrying one or more sensors.

<u>Sensors</u> Sensors include a variety of techniques that enable to varying degrees, the detection, description, measurement or identification of some property of an object of interest without actually coming into physical contact with the object. Categories of remote sensing techniques or equipment are often described as "remote sensors" or "sensors".

Scope of evaluation of sensors: During the evaluation session, categories of sensors were identified as follows:

- all types of cameras, including television;
- sensors for visible or infrared light;
- radar, and other portions of the electromagnetic spectrum.

Introduction

WP.74 (1 December 1992) provides a consensus summary of the examination of Surveillance by Satellite, and is taken as the starting point for the evaluation.

NONE.36 (3 December 1992) constitutes the first attempt by the Rapporteur to present information in the agreed format for evaluation. It is not a consensus document.

WP.97 (May 1993) constitutes the introduction to further substantive issues bearing on the valuation of this measure, as presented by the Rapporteur. It is not a consensus document.

During discussion of an consultations on this measure, the following points were stressed by a number of delegations:

- Surveillance by satellite is not a stand-alone verification measure, given current commercially-available capabilities. Its utility to verification must be evaluated in combination with other measures.
- In evaluating this measure, due attention must be given to cost effectiveness.
- Cost-effectiveness considerations were said to indicate very limited, if any, utility for this measure at this time as a "general screening" measure, i.e., simply sensing and recording information on a global basis.

- Views were expressed as to the potential utility of this measure, on the basis of current technology, in combination with other verification measures.
- Sensitivity: The assessed possibility that surveillance by satellite will detect a noncompliance with the Convention when it occurs, given the current commerciallyavailable sensors, was said to be low.

	LIMITATIONS
information - traverses area on regular (periodic) basis, so information can be updated and/or stored regularly - provides historical record - variety of information available from a variety of sensors: optical, infrared, radar (SAR), multi- spectral - optical sensors with resolution in	- the performance of optical, infrared and multi-spectral sensors can be affected by daylight, meteorological and atmospheric conditions, in addition to inherent technical limitations with respect to "resolution" - at the current time, exploiting such data is limited to those who have the appropriate technology and equipment

1b.	Quality of information	- optical sensors with resolution in the range of 2-10 metres can distinguish large geographical features as well as objects ranging from certain security enclosures, road networks, other large manmade objects including some details on building exteriors, certain waste treatment tanks/facilities -multi-spectral imagery can provide general information concerning habitation/occupancy, heating/cooling infrastructure, waste treatment - historical data (archives) can be used to detect changes at a site (construction, razing of buildings, active/inactive operation) - can monitor broad levels of external activity	 the performance of optical infrared and multi-spectral sensors can be affected by daylight, meteorological and atmospheric conditions, in addition to inherent technical limitations with respect to "resolution" buildings and shelters can be designed and built to defeat sensors satellite surveillance systems produce images that are inferior to aerial photography for the purpose of detecting and monitoring sites of potential interest under the BTWC
1c.	Other strengths and weaknesses	- satellite imagery can be used for locating sites reported by other sources - imagery might provide tip-offs to suspicious activities, circumstantial evidence of prohibited activities, and validation of information from other sources on the existence of specific facilities	
2.	Ability to differentiate between prohibited and permitted activities	- low	- lack of information on distinct external signatures of microbiological activities (development, production, stockpiling) - unlikely to differentiate, given current commercially-available sensors
3.	Ability to resolve ambiguities about compliance	- low	- see 2, above - unlikely to resolve ambiguities, given current commercially - available sensors
4a.	Technology	- imagery is available in two	- manipulation and enhancement of

	requirements	primary forms: photographic and digital - photographic imagery (positive or negative transparencies and prints) can be easily filed/stored and accessed without complicated specialized equipment - digital products are purchased on a computer-compatible tape CD-ROM, and requires commercially-available computers to retrieve and manipulate the data - digital data can be manipulated and enhanced	digital data requires commercially-available specialized hardware and software, and trained personnel
4b.	Material requirements	 see 4a. above hardware and software are commercially available for the storage, retrieval, manipulation and interpretation of satellite imagery all services may be obtained commercially, precluding the need for an autonomous capability. 	- see 4a above - depending on the capability/autonomy desired, there may be a requirement for an in- house photographic enlarging and printing capability
4c.	Manpower requirements	 training courses for photographic interpretation and for manipulation/interpretation of digital data are commercially available all services may be obtained commercially, precluding the need for an autonomous capability 	- see 4a. above - the man/machine interface for analysis of imagery involves specialised training
4d.	Equipment requirements	- see 4a. and 4b. above	- see 4a. and 4b. above
5a.	Financial	- cost assessment would depend on assumptions made concerning commercial acquisition of some or all services, versus the creation of a small, specialized interpretation unit and data storage - a complete photographic capability including processing printing and enlarging equipment would cost approximately \$30,000-60,000 (Canadian)	- costs as discussed in this section might also be considered to be a "limitation" upon the application of this measure

		- the cost for a computer-based data workstation and related software would be approximately \$25,000-35,000 (Canadian) - digital printers cost approximately \$50,000-100,000 (Canadian) - cost per single image purchased from a commercial enterprise might fall in the range of \$2000-5000 (Canadian) depending on the type of imagery, resolution, and area covered, at current 1993 prices - printing processed imagery on a medium for later use can be done commercially, costing approximately \$500-1000 (Canadian)	
5b.	Legal	- commercial satellite imagery is now available and has been for some years, to all customers (including national governments and international organizations) over most areas of the globe	- some state-owned satellite enterprises apply limitations to the availability of imagery on their own country, at the present time
5c.	Safety	- no implications	-
5d.	Organization	- some or all services related to imagery acquisition and interpretation could be obtained through commercial enterprises	- the timely, flexible and secure access to and interpretation of archived imagery might suggest that consideration be given to a small, dedicated data storage and interpretation capability
6a.	Impact on permitted activities	- no impact in relation to international law	
6b.	Impact on CIP (commercial proprietary information)	- no impact in relation to international law	

Combination with other measures that may enhance the effect of the measure above. Listed in order of priority:

- 1. declarations;
- 2. inspection on site;
- 3. multilateral information sharing.

EVALUATION SURVEILLANCE BY AIRCRAFT (Off-Site and On-Site)

(Rapporteur: Mr. Gordon Vachon)

(BWC/CONF.III/VEREX/WP.158)

DEFINITIONS AND TERMINOLOGY:

Aircraft: This item may include:

- Aeroplane (mechanically driven, winged, heavier-than-air flying machine);
- helicopter;airship;
- balloon; and unmanned aerial vehicles (UAVs)/drones/remotely-piloted vehicles (RPVs).

An aircraft may be described as a "platform" carrying one or more sensors.

Without reference to any operational context, it was also mentioned that gliders and "ultralight" aerial vehicles can be used to carry sensors.

<u>Sensors</u>: Sensors include a variety of techniques that enable, to varying degrees, the detection, description, measurement or identification of some property of an object of interest without actually coming into physical contact with the object. Categories of remote sensing techniques or equipment are often described as "remote sensors" or "sensors".

Aerial remote sensing methods were discussed in the following broadly defined categories:

- aerial photography, using a variety of still and video cameras;
- electro-optical and multi-spectral imagery;
- infrared systems;
- radar systems (SARs and RARs);
- remote spectroscopic measurement systems (passive and active) of effluents;
- air sampling, collection, filtration and concentration.

INTRODUCTION:

WP.75 (2 December 1992) provides a consensus summary of the examination of Surveillance by Aircraft, and is taken as the starting point for the evaluation.

NONE.37 (3 December 1992) constitutes the first attempt by the Rapporteur to present information in the agreed format for evaluation. It is not a consensus document.

WP.98 (May 1993) constitutes the introduction to further substantive issues bearing on the evaluation of this measure, as presented by the Rapporteur. It is not a consensus document.

During the initial discussion of the evaluation of this measure, and during the subsequent consultation, the following points were stressed by a number of delegations:

- Surveillance by aircraft is not a stand-alone verification measure. Its utility to verification must be valuated in combination with other measures.
- In evaluating this measure, due attention must be given to cost-effectiveness.
- With regard to certain concerns expressed about collateral information unrelated to the BTWC that might be collected by airborne sensors, it was suggested that consideration should be given to alternate measures that might be able to perform similar BTWC-related functions without triggering the same degree of concern. Some such potential alternates were suggested:
 - surveillance by satellite
 - off-site inspection measures; and
 - on-site inspection measures.
- It was suggested that "general screening" broad area coverage of States Parties would not be feasible or cost effective.
- Views were expressed as to the potential utility of this measure, on the basis of current technology, in combination with other verification measures.
- Legal and national sovereignty questions were raised, and it was stated that the surveillance by aircraft measure could not be imposed upon States Parties to the BTWC. In response to this, the point was made that, if such a measure were negotiated and agreed by States Parties, then it is clear that the legal and national sovereignty questions would need to have been addressed prior to reaching such an agreement and prior to its implementation.

Sensitivity:

The assessed possibility that surveillance by aircraft will detect non-compliance with the Convention when it occurs was said to be low.

Some sensors, in themselves, may demonstrate both high sensitivity and high specificity. However, it was suggested that the probability of detection of non-compliance behaviour, given the need to obtain overflight permission and to file a flight plan, is low.

	CRITERIA	CAPABILITIES	LIMITATIONS
1.a	Amount of information	- simultaneous coverage possible by a variety of highly sensitive and high specific sensors - airborne sensors benefit from human interaction/direction, including real time monitoring in addition to simultaneous data storage with geocoding and time referencing - sensors provide historical record (archives) that can be used to detect changes at a site (construction, razing) of buildings, active/inactive operation) - airborne platform can carry more sensors than satellite platform, with sensors operating at a higher degree of "resolution" - variety of sensors can detect small geographical features and small man-made objects, including details of building exteriors, security enclosures, and outdoor testing grids and equipment (e.g. with regard to open-air test facilities) - infrared and multispectral sensors can provide detailed information concerning habitation/occupancy, heating/cooling/ventilation infrastructure, waste treatment tanks/facilities - SAR has a 24-hour all weather capability - aircraft platforms can fly below some meteorological atmospheric disturbances	- the performance of optical, infrared and spectroscopic sensors can be affected by daylight, meteorological atmospheric conditions - operation of the aircraft platform could be affected by adverse weather conditions - availability of aircraft and/or sensors could be affected by conflicting operational requirements
1.b	Quality of information	- all sensors provide good quality information - aerial photography produces images that are superior to those obtained from commercially available satellite sensors (centimetres vs. metres) - can provide information on small geographical features and small man-made objects, including details of building exteriors, security enclosures, vehicles, and outdoor testing grids (e.g. with	-trained analysts are required if the information (imagery) is to be used effectively

		regard to open-air test facilities - infrared and multi-spectral sensors provide historical record (archives) that can be used to detect changes at a site (construction, razing) of buildings, active/inactive operation) - can monitor levels and changes in activity - information can be used for detailed mapping and site delineation, and for suggesting relationships between on-site and off-site facilities - optical sensor has higher ground spatial resolution than other airborne sensors might provide data of a quality that could be used to distinguish between prohibited and permitted activities at an open- air test facility	
1.c	Other strengths or weaknesses	- airborne sensors can be used for locating sites (via absolute or relative geo-positioning), and delineating their boundaries, in relation to information provided by other sources; - aircraft can perform ancillary (logistic) functions in relation to off-site observation and on-site inspection measures in the insertion of an inspection team and its equipment; as well as the extraction of the team, equipment and any samples.	
2.	Ability to differentiate between prohibited and permitted activities	- airborne sensors might provide data of a quality that could be used to distinguish between prohibited and permitted activities at an openair test facility -given the current lack of information on distinct external signatures, and delay/warning related to obtaining over-flight permission and the filing of a flight plan, the general assessment of capability as a stand-alone measure was said to be low	-lack of information on distinct external signatures - spectroscopic methods can be spoofed or masked and therefore may have a high false alarm rate - in case of air collection followed by the use of biological detection technologies that are sensitive and highly specific, it may still be very difficult to draw conclusions about the source of the material collected and about compliance - there is inherent delay/warning related to obtaining over-flight permission and the filing of a flight plan

3.	Their ability to resolve ambiguities about compliance	- see 2 above	- see points in 2 above for those sensors that involve air collection or the interrogation of air particles/effluents, , ambiguities likely to persist as to the geographical/facility source of collected or interrogated materials.
4.a	Technology requirements	-a variety of aircraft (platforms) are commercially available for purchase; for long or short term lease; or for lease on a case-by-case basis - a variety of high quality camera systems, thermal infrared system (FLIR) and IRLS) radar systems (SAR and RAR) are commercially available for purchase or lease - aircraft and sensors, as a package, can be configured by a number of companies for sale or lease - photographic imagery can be easily filed/stored and accessed without complicated specialized equipment - digital data interpretation/ analysis involves the use of commercially available hardware and software, in addition to trained personnel	- airborne spectroscopic techniques are at a relatively early stage of development, and they exhibit inherent technical limitations that suggest low utility at this time
4.b	Material requirements	- see 4.a above - all services may be obtained commercially precluding the need for an autonomous capability	- see 4.a above - depending on the capability and degree of autonomy desired, there may be a requirement for an in-house photographic enlarging and printing capability
4.c	Manpower requirements	- training course for image interpretation/ analysis and for manipulation/ interpretation of digital data are commercially available - all services may be obtained commercially, precluding the need for capability	- the flying of aircraft/sensor packages, and the operation of sensors, requires specially-trained aircrew as well as sensor operators - image interpretation/analysis requires specialized training, whether for photographic imagery or digital data (involving different skills)
4.d	Equipment requirements	- see 4.a and 4.b above	- see 4.a and 4.b above

5.a	Financial	-an alternative to the purchase or leasing of aircraft, sensors and imagery interpretation could involve the temporary loan of such capabilities by a State Party, when required; - the cost for a computer-based data workstation and related software would be approximately \$25,000 - \$35,000 (Canadian) - a complete photographic capability including processing, printing and enlarging equipment would cost approximately \$30,000 - \$60,000 (Canadian) - digital printer cost approximately \$50,000 - \$100,000 (Canadian) - illustrative costs of photographic, infrared and radar sensor systems can be found in WP.98	-
5.b	Legal		- national sovereignty implications, and concerns raised about the collection of information unrelated to the goals and objectives of the BTWC, would need to be addressed
5.c	Safety		- the operation of manned aircraft in the proximity of airborne pathogens could pose potential health hazards to aircrew and onboard sensor operators, and to ground crew upon return to a ground base (with aircraft and equipment requiring decontamination) - the operation of airborne LIDAR could pose eye safety hazards in certain circumstances
5.d	Organization	- the question arose as to whether some or all equipment and services might be purchased, or leased commercially, or received on loan from a donating State Party	
6.a	Impact on permitted activities	 physical (visual surveillance is unlikely to have a constraining impact on permitted activities a possible stated requirement for the enhancement of stand-off sensing capabilities might prompt some attention to redressing some 	

		of the current limitations	
6.b	Impact on CPI (Commercial proprietary information)	- the view was expressed that facilities could take appropriate steps to address their concerns about the leakage of CPI from their facilities	- the view was expressed that spectroscopic techniques and air sampling might in certain instances reveal proprietary data related to the industrial chemical or biotechnology process or processes being conducted at a facility

Combination with other measures that may enhance the effect of the measures above. Listed in order of priority:

- 1. declarations;
- 2. inspection on-site;
- 3. multilateral information sharing;
- 4. surveillance by satellite;
- 5. ground-based surveillance off-site;
- 6. sampling and identification off-site;
- 7. observation off-site

EVALUATION GROUND-BASED SURVEILLANCE

(Rapporteur: Mr. Volker Beck)

(BWC/CONF.III/VEREX/WP.159)

Introduction

Off-site ground-based surveillance is the surveillance of a site of interest at some agreed perimeter surrounding a site or many kilometres distant either by remote sensing or by visual inspection.

With respect to remote sensing there are a variety of techniques that enable, to varying degrees, the detection, description, measurement or identification of some property of an object of interest without coming into physical contact with the object. Categories of remote sensing are based on physical, chemical and biological identification system.

Visual inspection means the inspection of a site of interest by eye including use of binoculars.

Characteristics and technologies

The characteristic of the methods and technologies of off-site ground-based surveillance is to enable surveillance of the effluents of a R&D, production, stockpile or open air test facilities without intrusive methods or intrusive means.

Remote sensors used for this purpose may be categorized, *inter alia*, by the following characteristics:

- technology base;
- location of operation;
- operating characteristics (including power requirements, required operator expertise, and maintenance schedules;
- envisioned targets of the sensors;
- explanation of relevant experience with the sensor to date.

Available technologies for off-site ground-based surveillance of effluents from a site in principle include a broad variety of spectroscopic methods as well as biosensors and equipment for automatic sampling.

Biosensors use antigens, antibodies, enzymes, receptors, membrane structures, DNA probes, etc. as biological recognition components. As transducers a dozen of different systems like amperometric and potentiometric electrodies, field electron transistors, piezoelectric crystals,, fiber optics, etc. are used. The views expressed on the state of the art techniques for the remote sensing of small chemical molecules or for biological agents include:

- active and passive spectroscopic methods;
- generic and specific biosensors;
- automatic air and liquid sampling equipment.

Capabilities

- Views have been expressed that spectroscopic techniques have been successfully applied to the detection of <u>small</u>, <u>isolated gas phase chemical molecules</u> at trace levels in effluents and that these techniques could possibly be applied to detect if chemicals <u>associated</u> with biological weapons production are released in sufficient quantities and represent a unique signature indicating that biological weapons production is occurring inside a facility.
- Ultraviolet fluorescent LIDAR has been successfully demonstrated for the detection of a
 proteins associated with biological substances in the environment over ranges of kilometre or
 less.
- Generic biosensors have been shown to be capable to detect and identify biological agents with limited specificity in sensitivity ranges from ng to ug/ml.
- Immunosensors have been shown to be capableof detecting and identifying biological agents uniquely specific in sensitivity ranges from ng to ug/ml.
- A first type of immunosensor is commercially available for laboratory use. The first type of biosensor for field use has been shown by a US company during the 1992 Chemical Defense Exhibition in Stockholm.
- A variety of devices and filtration systems for the concentration of biological agents from air and liquids is commercially available with a broad variety and has been shown to be able to support biosensor systems.

Limitations

- Biological materials are not small, isolated molecules. They are physically much larger and complex entities. Optical techniques are typically not capable of interacting with such large structures.
- The presented spectroscopic methods are not able to establish the identity of biological agents. They cannot uniquely identify specific biological substances.
- Generic biosensors can detect and identify biological agents only with limited specificity.
- Immunosensors require for the detection and identification of each and every single biological agent different specific probes.
- Present sensitivity ranges of biosensors require the combination with a concentration step for the sample. The concentration step must combined with a transfer in a liquid medium.

- The stand-off capability of present biosensor systems is limited.
- Some views have been expressed that biosensors may not be available before 5 to 10 years or before 15 years as far as DNA probe based sensor will be concerned for the detection and identification of genetically manipulated substances.
- Some views have been expressed that the effluent of biological substances from R&D, production and stockpile sites may be unlikely so that remote sensing of this site will not be beneficial because measures such as filtration and decontamination will be used by an offender to prevent routine leaks. Massive leaks such as in accidents will be very rare events. Remote sensing of open air test sites however may be reasonable.

Interaction with other measures

Ground-based surveillance is not a stand-alone measure. There are only very rare cases where specially tailored ground-based surveillance may have some special value for the monitoring of large enterprises. Interactions which may have a synergistic effect with ground-based surveillance are Sampling and Identification, on-site, Declarations and Auditing.

Sampling and Identification, on site:

Results from ground-based surveillance may be a trigger for on-site sampling and identification.

Declarations:

Results from ground-based surveillance may confirm declared activities.

Auditing

Results from ground-based surveillance may be a trigger for on-site auditing.

Technical relation to other measures

Biosensors have been developed for process control of fermentation and downstream processes. They may be a helpful technical tool for continuous monitoring. Spectroscopic sensors have been discussed for surveillance by aircraft and satellite, too.

Evaluation

Evaluation of ground-based surveillance as a stand-alone measure is done in the Annex according to BWC/CONF.III/VEREX/WP.89*.

List of documents introduced

BWC/CONF.III/VEREX/WP.37 Remote Sensing/Ground Based Surveillance (Germany)

BWC/CONF.III/VEREX/WP.44 Ground Based Surveillance (Germany)

BWC/CONF.III/VEREX/WP.46	Technologies to BWC Verification (United States)
BWC/CONF.III/VEREX/WP.65	Continuous Monitoring (Brazil)
BWC/CONF.III/VEREX/WP.66	Continuous Monitoring by Instruments (United States)
BWC/CONF.III/VEREX/WP.76	Ground Based Surveillance (Rapporteur: Volker Beck) Statement on Remote Sensing by Ambassador Edward Lacey, United States Delegation
BWC/CONF.III/VEREX/WP.89*	FOCs on the Methodology for the Evaluation State
BWC/CONF.III/VEREX/WP.114	Evaluation of the Ground-based Surveillance Measure
BWC/CONF.III/VEREX/WP.129	Evaluation Off-Site: Remote Sensing Ground-based

Surveillance (United States)

	CRITERIA	CAPABILITIES	LIMITATIONS
1.	Amount of information	- worldwide surveillance of sources possible	- sensitivity is limited availability of high specific detection probes is limited
	Quality of information		- spectroscopic systems are not able to establish identity of biological agents - risks of misinterpretation by environmental impacts
	Other strengths or weaknesses	- sensing of open air test sites may be technically feasible and reasonable - may assist targeting for inspections	- combination with permanent monitoring of weather data required - effluence of biological substances from sites of concern may be unlikely
2.	Ability to differentiate between prohibited and permitted activities		- no ability to differentiate
3.	Ability to resolve ambiguities about compliance		- no ability by itself, only combined with other measures like declarations or auditing
4.	Technology requirements*	- biosensor technology is available in research and development state - biosensors have very high specificity	- sensor techniques for surveillance of sites from distance not available - spectroscopic methods are not able to identify specific biological agents - sensitivity of biosensors requires combination with a step

			for sample collection
	Material requirements*	- transducer systems are available or under development	- sensor technology requires availability of biological materials for recognition - large variety of recognition materials (antibody, enzymwe, nucleic acid probe, etc.)
	Manpower requirements*	- no permanent operator requirement	- stand-off capability may be limited - scheduled control and maintenance required - specialists for interpretation of data required
	Equipment requirements*	- air and liquid samplers are available	- industrial development required for biosensors
5.	Financial implications	- implication for national or international bodies by poliltical decision	- if not focussed expensive
	Legal implications	- surveillance based on international agreement	- collected information may not be freely accessible
	Safety implications	- not to be expected when using biosensors	- some spectroscopic methods (LIDAR, microwave, etc.) may require safety control areas
	Organizational implications	- national/ international organization can be operated depending on political decision	- organization has to be maintained to control and assist sensing equipment depending on technical requirements -organization of specialists is required for interpretation of collected data
6.	Impact upon permitted activities	- requirement for remote sensing equipment for biological agents for verification will stimulate research	- negative impacts are not expected
	Impact on CPI (commercial propietary information)	- unlikely	

- * Combination with other measures that may enhance the effect of the measure above. Listed in order of priority:
 - Sampling and identification, on-site;
 - Declarations
 - Auditing
- * What will be required?
 - What is presently available?
 - Which relevant future developments?

EVALUATION SAMPLING AND IDENTIFICATION (Off-Site)

(Rapporteur: Mr. Åke Bovallius)

(BWC/CONF.III/VEREX/WP.160)

The measure, sampling and identification, off-site has during VEREX been discussed and characterized, including its capabilities and limitations in the summary of the examination (BWC/CONF.III/VEREX/WP.77/Rev.1) and in the paper (BWC/CONF.III/VEREX/NONE.47. Potential interactions with other measures have also been considered in these examinations. The outline for the evaluation was based on the working paper by India, Netherlands, and Sweden ((BWC/CONF.III/VEREX/WP.89*) which was agreed upon by the Ad Hoc Group at VEREX II. The first step in the evaluation has been to use the formulae in Annex II of WP.89* to summarize the capabilities and limitations of the measure against the six criteria of the mandate.

Today a number of sampling techniques and methods of identification are available that could be used for off-site sampling and identification in the vicinity of a facility or a field testing site.

In conclusion, for the examination phase it was found that the measure will usually provide information of rather poor quality, as the probability of obtaining a relevant sample is low. Using this measure alone can result in ambiguities, as e.g., the origin of any agent isolated may not be possible to clarify. Different interpretations of the information are possible. The ability of the measure to differentiate between permitted and prohibited activities, as well as resolving ambiguities about compliance is therefore low. The measure could be of use in connection with open air test sites. It will have small or no impact on CPI (commercial proprietary information).

	CRITERIA	CAPABILITIES	LIMITATIONS
1.	Amount of information		- the amount of information depends on number of samples collected
	Quality of information		 - the probability of acquiring a meaningful sample is low - difficult to trace the origin of an agent if positive identification is obtained
	Other strengths or weaknesses not covered by other criteria	- of value in connection with open air test sites	- of low value in connection with R&D facilities
2.	Ability to differentiate between prohibited and permitted activities		- not possible to rely on off-site sampling and identification only - the risk of false positive as well as false negative tests may be very high
3.	Ability to resolve ambiguities about		- not possible with this measure alone

	compliance		
4.	Technology requirements	technology for both sampling and identification is available and will improve with time assays exist for the identification of some agents	- assays for identification are not developed for some agents
	Material requirements		
	Manpower requirements*	- small inspection teams will be required	-chain of custody and laboratory analysis would be labour intensive
	Equipment requirements	- standardized sampling and identification procedures could be used. A documented description of the sampling operation, transport and the laboratory analysis is essential and can be performed - for presumptive identification some techniques could be used in the field - special laboratories could be used for more advanced analysis	- portable equipment and backup laboratories are necessary
5.	Financial (treaty organization, national level, inspected facilities)		- the costs will depend on the total number of inspections and subsequent number of samples
	Legal (international and national level)		- legal implications will be focussed on the problems associated with permitting inspection teams to enter the State Party's territory and sample removal and transportation for analysis
	Safety (for inspectors, inspected facilities, for environment)	- safety problems for inspectors are generally low	- safety problems for open air test sites could be high
	Organizational implications (treaty organization, national level)	- organizational implications will be small	
6.	Impact upon permitted activities	- minimal impact	
	Impact on CPI (commercial proprietary information)	- no problems with confidentiality	

Combinations with other measures that may enhance the effect of the measure alone. Listed in order of priority:

- 1 On-site sampling and identification
- 2. Declarations
- 3. Off-site auditing
- 4. Information monitoring

EVALUATION OF OBSERVATION (Off-Site)

(Rapporteur: Mr. A. A. Mohammadi)

(BWC/CONF.III/VEREX/WP.161)

Definitions

Off-site observation is aimed at monitoring a site to get a sense of activities being carried out in the facility and also to get acquainted with the external characteristics of the facility.

- 1. The amount and quality of information: As this measure is being carried out off-site, compared to the on-site measures, the amount of information about the precision of the activities going on in the site is low. But it can provide a general view of the site's characteristics (e.g. location, dimension and size). Moreover, a good deal of information could be obtained about local diseases and epidemics or migration of inhabitants and environmental damages caused by the activities of the site this information could be increased if combined with other measures.
- 2. The ability to differentiate between prohibited and permitted activities and compliance: Since observation is conducted off-site, its capability to distinguish between prohibited and permitted activities may be low. Also by itself it cannot determine compliance. If, however, it is supplemented with on-site measures it may resolve some ambiguities.
- 3. Technology and material requirements: This measure does not require high technology or special materials.
- 4. Manpower and equipment requirement: In observation, manpower plays a crucial role. Observation might require a range of expertise.
- 5. Equipment requirement: The observers may need some equipment such as binoculars, optical cameras and video recorders.
- 6. Legal aspects: To conduct observation, observers may need to stay in the vicinity of the site for a long period of time. They therefore require legal arrangement. In addition, it should not interfere with irrelevant sites and activities.
- 7. Impact on CPI: Since the observation is carried out off-site, the impact on CPI is low.

	CRITERIA	CAPABILITIES	LIMITATIONS
1.	Amount of information	- provides a general view of site above ground and its dimensions and characteristics	
	Quality of information	- low	

	Other strengths or weaknesses not covered by other criteria		
2.	Their ability to differentiate between prohibited and permitted activities	- low	
3.	Their ability to resolve ambiguities about compliance	- low	
4.	Technology requirements	- high technology is not required	
	Material requirements	- no material is required	
	Manpower requirements		could require a range of expertisesize of facility may influence number of personnel
	Equipment requirements	- effectiveness can be enhanced by optical devices and recorders	- poor weather conditions, darkness and obscuring mass could impose limitations
5.	Financial		-it could be costly
	Legal		- access in some States may require national legislation - should not interfere with irrelevant sites and activities
	Safety	- none of the known methods used is of any risk	
	Organizational	- an international o rganization could carry out this measure	
6.	Impact upon permitted activities		- long term physical presence of observers may have public relations implications
	Impact on CPI (commercial proprietary information)	- low	

Combination with other measures that may enhance the effect of the measure above. Listed in order of priorities:

- On-site inspections (auditing, interviewing, visual inspection, identification of key equipment, sampling and identification, and medical examination);
- Declaration;
- Ground based remote sensing;
- Sensing from aircraft and satellite.

THE EVALUATION OF OFF-SITE AUDITING

(Rapporteur: Dr. J. Noble)

(BWC/CONF.III/VEREX/WP.162)

Off-site auditing has been defined (WP.79) as the critical examination outside a facility boundary, in accordance with agreed standards and criteria, of documentary records, electronicallyheld data and manuals, to assess consistency of matters recorded and material accounted with declared purposes and permitted activity.

Extreme application of off-site auditing could involve examination of substantial amounts of data available from national and international sources (public records, financial statements, patents, licenses, budgets, statutory reports, etc.). The amount and quality of data will vary, however, from State to State.

The value of off-site auditing as a verification measure stems from its ability to provide evidence on the linkage between events, people, activities and facilities and to allow the testing of consistency and coherence. When triggered as a result of information gained from other sources, including other verification measures, off-site auditing could be highly focussed and directed towards addressing specific concerns. An audit of medical and pathology reports may have value, for example, in investigations of alleged use or accidental release of biological agents. However, off-site auditing, on its own, would be unlikely to be able to provide sufficient information to differentiate between permitted and prohibited activities or to resolve ambiguities.

A document audit physically divorced from the context in which the documents were derived would considerably reduce the utility of the audit. In such circumstances it may be more likely that detection could be evaded by the maintenance of a duplicate set of documents than would be the case with on-site auditing and on-site inspection.

Of-site auditing, therefore, seems to have value as a verification measure in a limited range of circumstances and could be considered not as a primary measure, but rather as part of a follow-up event.

	CRITERIA	CAPABILITIES	LIMITATIONS
1.	Amount of information	- substantial quantities from many sources including medical and epidemiological	- will vary depending on the State concerned
	Quality of information	 data available on production and stockpiling and possibly also development could contribute to the build-up of a picture of normal activity of a facility and be used to assess overall consistency and coherence 	- will vary depending on the State concerned - out of context may have limited value to verification
	Other strengths or	- data collected could be	

	weaknesses not covered by other criteria	catalogued and placed on a data base for subsequent analysis	
2.	Their ability to differentiate between prohibited and permitted activities		- on its own would be unlikely to enable distinction between prohibited and permitted activities
3.	Their ability to resolve ambiguities about compliance		- on its own would be unlikely to resolve ambiguities about compliance
4.	Technical requirements	- minimal	
	Material requirements	- minimal	
	Manpower requirements		- broad range of knowledge required in, for example, accounting, forensic, process and research - requirement for tecnical interpreters/translators
	Equipment requirements		
5.	Financial		- staff costs and costs of data analysis
	Legal		- potentially some issues, e.g. some information may be protected from release by existing national legislation and regulations
	Safety	- minimal	
	Organizational		- may require the establishment of a dedicated data collection, storage and interpretation capability
6.	Impact upon permitted activities	- minimal	-review of documents may require time of facility staff
	Impact on CPI (commercial proprietary information)	- procedures may be adopted that could reduce the risks of compromising commercially sensitive information	-source information could have commercial and proprietary value

Combination with other measures that may enhance the effect of the measure above. Listed in order of priority:

- Declarations;
- Information monitoring (surveillance of publications, surveillance of legislation, data on transfers and transfer request and on production, multilateral information sharing);

-	On-site inspections (interviewing, visual inspection, identification of key equipment, sampling and identification, and medical examination).	

EXCHANGE VISITS - INTERNATIONAL ARRANGEMENTS (ON-SITE) AS A POTENTIAL VERIFICATION MEASURE FOR THE BWC

(Rapporteur: Mr. T. Dashiell)

(BWC/CONF.III/VEREX/WP.163)

Introduction

During VEREX I and II potential verification measures for the Biological and Toxin Weapons Convention (BWC) were identified and examined. This potential measure, "Exchange Visits - International Arrangements", is a complementary measure to Information Monitoring Exchange visits (Off-site). These should be distinguished from other visits such as inspections.

It is generally accepted during the earlier meetings that this measure could not be considered a stand-alone measure, but that it might interact favorably with other proposed measures.

Definition

Visits of experts arranged for scientific purposes by one country to comparable facilities of another country (States Parties) under bilateral or multilateral agreements. Exchange visits need not be restricted to declared facilities.

Characteristics

Exchange visits have not yet been fully defined, however, the present confidence-building measure agreed at REVCON II may serve as a precedent.

The most extreme application would be development of multilateral agreements to cover all program areas including military defense programs as well as industrial and university areas and opening all areas to exchange visits. The least extreme would be bilateral long-term scientific exchanges made in selected program areas where common scientific interests exist between countries, relevant to the CBMs.

It is generally agreed that visits would be on a voluntary and reciprocal basis with mutual agreement of the areas of interest, selection of personnel and the length of the scientific exchange. Suggestion for technical skills may range from agriculture through medicine and biotechnobgy to biological defense experts.

Capabilities

Exchange visits will provide a mechanism for exchange or acquisition of information and knowledge between countries interested in a common area of research, development, production or storage since it can apply to all areas of concern. In most cases, bilateral agreement may be necessary unless a multilateral agreement can be developed for select areas of work. Due to the widespread, variable and competing interests of States Parties multilateral areas may be very limited.

The purpose of the visit may be a significant factor in the amount and quality of information exchanged. Short visits of a few days duration may provide specific data; however, long term (one year) cooperative R&D programs might provide a more general picture of activities at a given location. It was brought out that the non-intrusive nature of exchange visits and the capability of less developed countries to acquire technical information through this mechanism was a unique capability.

Limitations

A major limitation of exchange visits is the lack of and the difficulties in developing multilateral agreements so that the information could be disseminated to all States Parties. Some discussion has indicated that this proposed measure cannot be considered a verification measure but is in reality an enhanced CBM due to these limitations. A mechanism to implement this measure as a supplement or compliment to the existing CBM will be needed if this measure is to be continued on a neutral basis. Bilateral agreements would probably restrict the information to the parties to the agreement; thus a mechanism which would develop a method to make such information available to all States Parties and a system of reporting to States Parties is needed. A mechanism to notify States Parties of official exchange visits specifically related to BWC verification, with details of personnel, numbers, location and area of interest, is also needed.

Interaction With Other Measures

Exchange visits are recognized as not generally being a stand-alone measure. Some synergy could exist between this measure and declarations based on the fact that declarations would provide a focus to the work ongoing in the declared areas. For example, continuous monitoring by exchange personnel during the visit may provide some interaction with the measure, continuous monitoring by personnel.

Summary

Exchange visits can provide a mechanism of transfer of technical information for a given area. Some difficulties exist in implementation on a multilateral basis. The scope of the agreement can impact the amount and quality of the information. The possible loss of proprietary I formation is of concern to industry and the academic communities.

A preliminary evaluation of the utility of this proposed measure against the six mandate criteria is given in the following table. It appears that alone, this measure would serve best as an enhanced CBM, expanding openness and transparency. There is a need to consider whether added value is obtained by combining this measure with other proposed measures.

	CRITERIA	CAPABILITIES	LIMITATIONS
1.	Amount of information	- could be large but may depend on length of the visit, type of facility and access provided	-type of agreement will influence access and distribution of information acquired

	Quality of information	- may be dependent on type of facility visited, degree of access and length of visit - could be of high quality	- depends on individual skill and training as well as access and nature of the work, development or production
2.	Ability to differentiate between prohibited and permitted activities	- the amount of information accumulated may provide some information on permitted activities	- information acquired by this proposed measure alone is insufficient to differentiate
3.	Ability to resolve ambiguities about compliance		- it is unlikely that sufficient information will be acquired to provide more than openness and transparency increases while not satisfactorily resolving ambiguities
4.	Technology requirements	- there appear to be no limitations on exchange visits posed by the technology, material, or equipment needs	- some limitations may exist due to the small number of appropriate scientists available for exchange in developing countries
5.	Financial	- funding for international exchange programs may be available	- visit cost and implementing mechanism cost could be a limiting factor
	Legal		- some legal factors such as rights of exchange scientist, protection of proprietary information and development of multilateral agreements must be further developed
	Safety		- safety of the visitor should be protected by proper training and immunizations the same as the host staff
	Organization	- existing international organizations may support exchange programs	- simple bilateral agreements are less troublesome but do not yield widespread results as a multilateral agreement might provide - development of multilateral agreements may restrict area of consideration to narrow focus - may be a requirement for an international structure
6.	Impact upon permitted activities	- exchange visits are voluntary and reciprocal, these need not disrupt scientific program activities	
	CPI		-loss of proprietary in formation is the only major concern

Combinations with other measures that may enhance the effect of the measures above. Listed in order of priority

- Declarations;
- On-site inspections;
- Continuous monitoring by personnel;
- Surveillance of publications.

EVALUATION OF ON-SITE INTERVIEWING

(Rapporteur: Mr. A. A. Mohammadi)

(BWC/CONF.III/VEREX/WP.164)

Interviewing is one of the measures of fact-finding for on-site inspection. It is conducted with the personnel of the site. The objective is to gain information about the nature, scale and scope of the activities and also to assess the overall function of the site.

During VEREX II 21 verification measures for the BW Convention were identified and examined by Governmental Experts. At the end of the session, a framework of different criteria for the evaluation of these measures was suggested.

One of these measures was interviewing with personnel which is evaluated based on the proposed criteria.

The amount of information: By interviewing the authorities and personnel of a site, a considerable amount of information can be established, particularly about their work.

The quality of information: Usually ordinary personnel do not have access to the information related to prohibited activity because this type of information is kept confidential. In addition, the accuracy of the information is highly dependent upon the cooperation of personnel. Since many staff do not know the language of the interviewer if he is not from their country, the presence of a qualified interpreter could enhance direct communication.

Ability to differentiate between prohibited and permitted activities: Interviewing can reveal some information about prohibited activities. The possibility of giving false information weakens the differentiation between permitted and prohibited activities. In addition, legitimate activities and dual purpose facilities may provide cover for illegal activities. Its ability to resolve ambiguity about compliance is low, but may contribute to an overall judgement.

<u>Technology</u> and material requirements: Interviewing does not require any specific material or technology, therefore it can be of positive value from a financial point of view.

Manpower requirements: Requires trained, qualified experts and interpreters.

Impact on permitted activity: It may interrupt the normal work of the site.

<u>Conclusion</u>: Considering the above-mentioned information interviewing by itself is not a stand-alone measure but could be useful in combination with other measures.

	CRITERIA	CAPABILITIES	LIMITATIONS
1.	Amount of information	- considerable amount of information could be provided by interviewing the personnel	- the information is highly dependent upon the cooperation and the willingness of the staff and the authorities - it also depends on the accessibility of personnel to information
	Quality of information	- if the managers and staff are interviewed, more precise information could be obtained	- there is the possibility of giving false information by the staff and the managers
	Other strengths or weaknesses not covered by other criteria		
2.	Their ability to differentiate between prohibited and permitted activities	- may reveal some part of prohibited activities	-legitimate activities and dual purpose facilities may provide cover for illegal activities
3.	Their ability to resolve ambiguities about compliance	- low, but may contribute to an overall judgement	
4.	Technology requirements	- no technology is required	
	Material requirements	- no material is required	
	Manpower requirements		- requires trained and qualified experts and interpreters
	Equipment requirements	- recording devices provide interviewers with an historical record of the interviews	-use of recording devices may inhibit interview process
5.	Financial		- it could be costly
	Legal		- access to facilities in some states may require national legislation
	Safety		- local safety regulations may require immunization and mandatory safety training
	Organizational	- an international organization could carry out this measure	
6.	Impact upon permitted activities		- interviewers may need to coordinate their activities with the manager of the facility to minimize interruption - it may interrupt normal activities

Impact on CPI (commercial	 -the possibility of leakage of CPI
proprietary information)	

Combination with other measures that will enhance the effect of the measures above. Listed in order of priority:

- On-site inspections (auditing, visual inspection, identification of key equipment, sampling and identification, and medical examination);
- Declarations;
- Exchange visits.

EVALUATION OF VISUAL INSPECTION (Rapporteur: Mr. A. A. Mohammadi)

(BWC/CONF.III/VEREX/WP.165)

Definition

Visual inspection is aimed at acquiring a general view of the site, facilities, equipment, materials and the degree of protection, safety measures and the peaceful activities which are being carried out.

Taking note of the specificities and the characteristics of the equipment and the instruments.

Amount of information

Conducting visual inspection provides considerable amount of information. in case of no access to some equipments on specific areas, the quantity of information is low.

Quality of information

By visual inspection of the equipment and the facilities of the site, any unusual capacity of key equipment or the presence of instruments not related to the activities of the site can be detected. Moreover, any possible undeclared activity and equipment may be determined. The quality of information could be valuable if combined with other measures such as inspection of key equipment, interviewing and on-site sampling and identification.

Ability to differentiate between prohibited and permitted activity and to resolve ambiguities about compliance

Visual inspection could verify facilities not in compliance with the objectives of the Convention, but there is the possibility of dual use nature of materials and equipment. In such a case the interpretation of information may become complicated.

Technology and material requirements

This measure does not require special materials, technology or equipment.

Manpower requirement

This measure highly depends upon the professionalism and expertise of inspectors who have been trained with respect to the specialty of the inspected site. The impartiality of inspectors is of great value for the implementation of their task.

Financial

Since this measure does not require technology and equipment it has a low capital investment requirement. However, logistical costs associated with visual inspection on site could be high.

Safety

The presence of inspectors on the site may require special safety measures, particularly if they are foreigners. Special care should be taken to avoid any contamination of the site.

Impact on permitted activity and CPI

Visual inspection of the facilities may cause interruption of the routine work of the site. In addition, commercial confidentiality may be at risk.

Conclusion

Considering the limitations and capabilities mentioned above, this measure by itself is of medium value as a verification measure.

	CRITERIA	CAPABILITIES	LIMITATIONS
1.	Amount of information	- a large amount of information depends on the knowledge of inspectors	- the amount of information is related to the degree of access to some equipments or specific areas
1.a	Quality of information	 may provide information on production capacity and general capabilities; may provide information on possible undeclared activities 	- unlikely to provide information on removed key equipments
1.b	Other strengths or weaknesses not covered by other criteria	- can contribute to confirmation of declared activities	
2.	Their ability to differentiate between prohibited and permitted activities	- may provide information on prohibited activity	
3.	Their ability to resolve ambiguities about compliance		- dual purpose nature of equipment may complicate interpretation of information
4.	Technology requirements	- no technology is required	
4.a	Material requirements	- no material is required	
4.b	Manpower requirements	- experts are available	-choice of inspectors must be tailored to the site in question

			and the object of the inspection; -inspectors' training is required and in some cases may be extensive
4.c	Equipment requirements	- it may require recording devices	
5.	Financial		-it could be costly
5.a	Legal (international and national level)		- access to facilities in some states may require national legislation
5.b	Safety		- local safety regulations may require immunization and mandatory safety training; - contamination risk might be a limiting factor to inspect containment area, production equipment, etc.
5.c	Organizational implications	- an international organization can carry out this measure	
6.	Impact upon permitted activities		-risk of interruption of routine work
6.a	Impact on CPI (commercial proprietary information)		-CPI may be disclosed; -some areas of facility may have far less sensitivity to the release of information

Combination with other measures that may enhance the effect of the measures above. Listed in order of priority:

- On-site inspections (auditing, identification of key equipment, interviewing, sampling and identification, and medical examination);
- Declarations;
- Exchange Visits;
- Multilateral information sharing.

EVALUATION IDENTIFICATION OF KEY EQUIPMENT (On site) (Rapporteur Mr. Åke Bovallius)

(BWC/CONF.III/VEREX/WP.166)

The potential verification measure, identification of key equipment, has during VEREX been discussed and characterized, including its capabilities and limitations, in the summary of the examination BWC/CONF.III/VEREX/WP.83/Rev.1) and in the paper (BWC/CONF.III/VEREX/NONE.42). Potential interaction with other measures has also been considered in examination The outline for the evaluation is based on the working paper by India, Netherlands and Sweden (BWC/CONF.III/VEREX/WP.89*) which was agreed upon by the Ad Hoc Group at VEREX II. The first step in the evaluation has been to use the formulae in Annex II of WP.89* to summarise the capabilities and limitations of the measure against the six criteria of the mandate.

Identification of key equipment is an essential part of an on-site inspection to confirm a facility's declaration and help to ensure that the equipment is not used for prohibited activities. The vast majority of key equipment in biological facilities is of dual use nature. The identification of key equipment alone cannot distinguish prohibited from permitted activities. Nonetheless, for the examination phase it was found that the measure can provide a substantial amount of high quality information if inspectors with expertise in the field are used and are given suitable access. The measure is of most value in the area of production and acquisition, and stockpiling and retention, and of less value in the area of development. In some cases it might be possible to differentiate between prohibited and permitted activities, and the ability to resolve ambiguities about compliance may be possible if this measure is coupled to declarations and other on-site measures, e.g., visual inspection sampling and identification and audting. Inspectors needed for this measure could be part of an international organization.

In conclusion, this evaluation has shown that the measure will provide substantial amounts of relevant information and can together with other measures help to distinguish between permitted and prohibited activities. The financial and legal costs could be high if a large number of inspections are to be carried out. Industrial confidentiality of obtained information could be a problem and has to be taken into account.

f information depends of access permitted as that all equipment is identified

	Quality of information	high quality if carried out by experienced specialistsassessment of facilities' capabilities is possible	- portable equipment can be moved out of a facility to deceive inspectors
	Other strengths or weaknesses not covered by other criteria		
2.	Their ability to differentiate between prohibited and permitted activities	- lack of equipment or combination of equipment as well as capacity could be used as one important indicator when it comes to differentiate activities	- equipment is mostly of dual use nature
3.	Their ability to resolve ambiguities above compliance	- biotechnological equipment has so many specific characte ristics that, in most cases, specialists in the field can ensure that equipment is in conformance with declarations	
4.	Technology requirements	- visual inspection	
	Material requirements	- no specific material requirements	
	Manpower requirements	- a few specialists in industrial biotechnological processes are required on an inspection team as well as a couple of specialists in the R&D field	 not all countries currently have experts able to distinguish if key equipment is consistent with declared activities properly trained individuals may not be available immediately
	Equipment requirements	- photographic, audio and video recording equipment could be used and would save time for inspectors,	- equipment that can withstand deconta mination could be needed
5.	Financial (treaty organization, national level, inspected facilities)	- costs might be reduced by use of recording equipment	- costs can be high if a large number of inspections are carried out
			·

	national level)		connected with on-site inspections as such and with the confidentiality of information obtained
	Safety (for inspectors, inspected facilities, for environment)	- vaccines are available for some agents of concern	- safety is connected with the safety of the inspectors. High levels of containment are not globally accepted as a requirement for the production of pathogenic micro-organisms and/or toxins - vaccines are not available for immunization against all agents of concern - sterile requirements in some parts of certain processes must be maintained. This may restrict the inspectors' ability to inspect key equipment
	Organizational implications (treaty organization, national level)	- properly trained experts can be assigned to each on- site inspection team	
6.	Impact on permitted activities		- general problems with on-site inspections of facilities may exist, e.g., interruptions and time lost by the inspected facilities
	Impact on CPI (commercial proprietary information)		- proprietary information may be negatively affected by identification of key equipment configurations

Combinations with measures that may enhance the measure above. Listed in order of priority:

- 1. Declarations;
- 2. On-site visual inspection;
- 3. On-site sampling and identification;
- 4. On-site international arrangements.

EVALUATION AUDITING (On site)

(Rapporteur: Mr. J. Noble)

(BWC/CONF.III/VEREX/WP.167)

On-site auditing has been defined (WP.84/Rev.1) as the examination within a facility boundary, in accordance with agreed standards and criteria, of documentary records, electronically held data and manuals, to assess consistency of matters recorded and materials accounted with declared purposes and permitted activity.

For their normal day-to-day activity and, where appropriate, for national and international regulatory purposes facilities would have substantial quantities of such recorded information. Facilities could not operate, except at very small scale and low levels of hierarchical control, without a documentary recording system. The prospect of permitted activity being conducted without record would be unlikely.

The value of on-site auditing as a verification measure stems from its ability to provide evidence on the linkage between events: people, activities and facilities and to allow the testing of consistency and coherence. A document audit physically divorced from the context in which the documents were derived would considerably reduce the utility of the audit. However, on-site auditing, on its own, would be unlikely to be able to provide sufficient information to differentiate between permitted and prohibited activities or to resolve ambiguities.

Triggered as a result of information gained from other sources, including other verification measures, on-site auditing could be highly focused and directed towards resolving specific concerns. On-site auditing could be considered as one of the major activities of an on-site inspection. It is considered to have a synergistic effect in combination with interviewing, visual inspection, identification of key equipment, sampling and identification, and medical examination, and together with information gained from off-site measures such as information monitoring and declarations could be used by an inspectorate to build up a picture of the normal activity and to assess overall consistency and coherence.

	CRITERIA	CAPABILITIES	LIMITATION
1.	Amount of information	- substantial quantities from many sources	- will vary depending on the facility and State concerned
	Quality of information	 high quality data available on development, production and stockpiling could contribute to the build up of a picture of normal activity of a facility and be used to assess overall 	- will vary depending on the facility and State concerned

		consistency and coherence	
	Other strengths or weaknesses not covered by other criteria	 duplicate documents may be removed from the site data collected could be catalogued and placed on a data base for subsequent analysis 	
2.	Their ability to differentiate between prohibited and permitted activities		- on its own would be unlikely to enable distinctions between prohibited and permitted activities
3.	Their ability to resolve ambiguities about compliance		- on its own would be unlikely to resolve ambiguities about compliance
4.	Technological requirements	- minimal - no new technologies required	
	Material requirements	- minimal	- materials that could withstand decontamination may be needed if removal from containment facilities was required
	Manpower requirements	- form an integral part of the work of inspectors. No additional manpower required	- broad range of knowledge required in, for example, accounting, forensic process and research - requirement for technical interpreters/translators
	Equipment requirements		- may require portable recording equipment
5.	Financial	- little additional cost to on- site inspection	
	Legal		- potentially some issues, e.g., some information may be protected from release by existing national legislation and regulations - access to private industry in some States may require legislation - accountability for lost or compromised information must be

			adequately addressed
	Safety	- minimal	 local safety regulations which may require immunization and mandatory safety training may be necessary to abandon some equipment and material in high containment facilities
	Organizational		- may require the establishment of a dedicated collection, storage and interpretation capability
6.	Impact on permitted activities	 has greatest value when conducted concurrently with normal activity of the facility could be conducted so as to minimise risk of jeopardising research work and product integrity 	- could cause some disturbance to staff at legitimate research and production facilities
	Impact on CPI	- procedures may be adopted that could reduce the risks of compromising commercially sensitive information	- commercial or other legitimate sensitivities may preclude access to all material in any one situation

Combination with other measures that may enhance the effect of the measure above. Listed in order of priority:

- on-site inspections (interviewing, visual inspection, identification of key equipment, sampling and identification, and medical examination);
- declarations;
- information monitoring (surveillance of publications, surveillance of legislation, data on transfers and transfer requests and on production, multilateral information sharing).

EVALUATION SAMPLING AND IDENTIFICATION (On site)

(Rapporteur: Mr. P. Binder)

(BWC/CONF.III/VEREX/WP.168)

Introduction

During VEREX I and II potential measures for the Biological and Toxin Weapons Convention (BWC) were identified and examined. On-site sampling and identification is a part of on-site inspection. Papers about this measure were listed in BWC/CONF.III/VEREX/WP.85/Rev.1. Some additional papers were presented at VEREX III (BWC/CONF.III/VEREX/WP.105, 112, 116, 117, 118, 119, 124, 139, 140, 141). This measure may improve and be improved by other off-site and on-site measures.

Definition

Sampling and identification were defined in BWC/CONF.III/VEREX/WP.85/Rev.1. Briefly, it refers to the act of taking samples on the inspected site, analysing these samples either on the site using appropriate methods or to transfer these samples from the site for identification or further investigations in appropriate laboratories.

Characteristics

This measure is one of the set of on-site inspection measures. It may be en essential component of an inspection process which in some cases would require the results of analyses to support its findings.

The evaluation of this measure should take into account the following considerations:

- the protection of intellectual or commercial proprietary rights must be ensured in carrying out on-site sampling and identification; the inspecting authority is expected to take all appropriate measures to guarantee the confidentiality of the investigation. However, this legitimate concern should not be used as a pretext for concealing prohibited activities.
- the efficiency of this measure would be enhanced if the inspecting authority had a preliminary idea of the agents to search for prior to sampling and analysis, and prepared its equipment accordingly;
- the probability of ambiguous results (e.g., false positive or false negative) would be reduced if more than one analytical technique and several samples from the same site were used;
- the use of equipment and methodology from the site could help reduce the costs and protect confidentiality, but it could also give rise to disputes, which may be eliminated if the inspecting authority used its own equipment and reagents;

- the value of the results would be enhanced if the micro-biological context of the environment of the site was taken into consideration.

Capabilities and limitations

Based on the evaluation criteria defined in the mandate of the Ad Hoc group of experts, the following six features should be noted:

- In terms of the information obtained, the ability of this measure to provide information of
 quality and quantity in a verification process could be significant, in particular because of the
 possibility of obtaining an independent confirmation of analytical results in the event that the
 findings are disputed.
- 2. The ability and potential of this measure to provide data, in some scenarios, to differentiate between permitted and prohibited activities.
- 3. The ability of this measure to provide key information to resolve certain ambiguities about compliance because of the probability with which it can identify the nature of an agent.
- 4. The wealth of techniques that may be used in accordance with approved codes of good practice, involving in particular:
 - the possibility of taking an appropriate number of samples from various sources, in order to ensure the quality of the results;
 - the need for reference data showing the environmental profile on the site;
 - the possibility of performing the wide variety of methods applicable when the agents can be cultivated. The number of such methods can also ensure the quality of the results obtained;
 - the possibility, using genetic and molecular biology methods, of analysing small samples and/or inactivated samples;
 - the need to preserve intellectual, industrial and commercial proprietary rights in the case of legitimate activities, which may mean the obligation to use special technical and legal procedures for processing samples, particularly if there are grounds for removing samples from the site for subsequent analysis.
- 5. The relatively moderate cost of certain analytical techniques;
 - at the legal level, it may be possible to set up structures for the concrete application of this measure;
 - and especially in the context of an inspection, there is no major difficulty involved in organizing the implementation of this measure, for it requires no heavy equipment for

the collection of samples. As for analysis, this may possibly be done with the means available on the site, with portable equipment or by expert reference laboratories.

- 6. The risk of disclosure of key data of intellectual, industrial or commercial value through sample analysis; special provisions could be taken into consideration to reduce this risk.
- 7. Among the possible approaches to check for prohibited activities, there is the possibility of searching for agents of concern during sample analysis. As it can be difficult to identify such agents without any prior indication of which agents one is looking for, it was suggested that illustrative lists of agents could be helpful.

Combination with other measures

The identification of prohibited activities on a site may be facilitated by:

- knowledge about the legitimate activities of the site;
- having some indication beforehand about any agents that might be produced.

Knowledge of the legitimate activities of a site may be obtained through other measures, particularly declarations or information monitoring.

The sampling and identification measure can only provide qualitative information on the agents concerned, even if this information is potentially very precise. Quantitative information may only be gathered in conjunction with other on-site measures, and particularly the identification of key equipment and their characteristics.

The "on-site sampling and identification" measure could be of great added value in combination with other measures.

Remarks

The risk of seeing legitimate information diverted during inspections naturally leads to the question of security of analytical results, which may need to be kept confidential. A precise protocol for sampling and the processing of samples, in keeping with a "good practice guide", must be designed to protect the rightful interest of the inspected party, and it must also provide for a clear "chain of custody" and appropriate penalties in order to limit the risk of uncontrolled disclosure of information unrelated to the object of the verification, in conformity with UN regulations.

	CRITERIA	CAPABILITIES	LIMITATION
1.	Amount of information	- determination of the nature of the agent(s) which the inspection measures are designed to detect - even for a large number of samples analysis of the information should not be difficult	- the preference to plan beforehand which agent or family of agent(s) the inspection be capable of detecting readily ²
	Quality of information	 technological possibility of identifying the nature of the agent(s)³ possibility of using different techniques to increase the credibility of the results obtained use of reference samples and reference procedures (GSIP) give high confidence in the quality of information 	 the need to take an appropriate number of samples to limit the risk of false positive results the need for reference samples which are representative of environmental profile the possible need to inactivate samples before analysis or before removal from the site may limit the number of techniques applicable and ability to detect agents the risk of contamination of samples the samples may degrade in custody chain or while awaiting analysis the risk of misinterpretation of negative results may be due to two possible circumstances the poor quality or poor selection of samples taken the limit of sensitivity of the detection techniques used
	Other strengths or weaknesses not covered by other	- assays of on-site samples may be made on site or after removal from the site	- possible difficulties in cooperation of personnel of the site

It was suggested that an illustrative list of agents could be helpful for the efficiency of sampling and identification and for planning the objective of the inspection beforehand.

This technological possibility is linked to the ability of available technologies to analyse biological substances. It is possible, for example, through genetic analysis combined with other methods, to avoid confusing results from accidental contamination.

	criteria		
2.	Their ability to differentiate between prohibited and permitted activities	non-declared agents can be detected	 in most cases the information supplied is qualitative rather than quantitative a negative result does not necessarily rule out prohibited activities understanding of the limitation of test results is needed to prevent unwarranted conclusions
3.	Their ability to resolve ambiguities about compliance	- measure can possibly provide critical information in the event of ambiguity - ambiguous or disputed results may be clarified by repeated and/or different tests	- the identification of an agent may not resolve all cases of non-compliance ambiguities - negative results of analysis may not necessarily resolve the ambiguities
4.	Technological requirements	- the current availability of a broad spectrum of sampling and identification methods for use with substances even in very low concentration	- it may be necessary to establish proto cols for good sampling and identification practice (GSIP) indicating reference methods, how and in what conditions to use them, and their limitations in particular for inactivated samples ⁴ - updating of these protocols to keep abreast of changing techniques would be important - initial processing may be necessary before some tests can be performed - confirmatory analysis may not be available for on-site identification
	Material requirements	- currently available materials would allow many of the onsite presumptive tests to be performed - rapid technical progress in the biological sciences will further increase these	 some analyses may have to be carried out in one or more outside reference laboratories investigations requiring the use of animals or specific in-vitro cultures may be difficult to carry out on the site

No universal sampling and inactivation technique is available. No single test can be used for identification and false positive/false negative characteristics are not known for some tests.

		capabilities - there are already established reference laboratories which have the materials to perform the analysis of samples taken from the site	
	Manpower requirements	- it would not be difficult to train specialists and technicians in biological and/or forensic fields to collect and package samples, and to perform simple analytical procedures	 there is a need to establish infrastructure for training and deployment of inspectors there is a need to establish chain of custody for transportation of samples taken from the site and for analysis in reference laboratories specialized staff for interpretation of some test results may not be readily available
	Equipment requirements	 a range of sampling and identification equipment is commercially available well-defined standard equipment for transporting biological substances, including air transport (IATA standards) is also available 	 the need for validation and standardisation of sampling, transportation and analytical equipment to be used by inspectors protective equipment and the decontamination or disinfection therefore after use in certain scenarios will be needed
5.	Financial requirements	 possibility of using the laboratories of the inspected site possibility to request assistance of reference laboratories, in particular those of the WHO or FAO, for the analysis of samples removed from the site 5 relatively low cost of simple presumptive analysis and field equipment relatively long life of 	- the budget for the expense of training and deploying inspectors including logistics, may be limited - the design of a sophisticated field laboratory could prove very costly - the creation and maintenance of an independent laboratory solely for the purposes of biological analyses could prove very costly - the budget for analysis in reference laboratories may be limited and may compromise their ability to perform some

May raise the problem of the charter of these organizations which may now allo them to act in this capacity.

		equipment	recommended methods
	Legal requirements (international and national level)	- this measure in some cases can be adapted to suit the circumstances, in keeping with national and international agreements	- this measure in some cases may require adaptation of national legislation in force
	Safety requirements (for inspectors, inspected facilities, for environment)	 safety of inspectors can be accommodated by protective clothing or taking protective or prophlylactic measures, as appropriate the presence of inspectors on a site is unlikely to create any particular safety problem for the site or its environment vaccine are available for some agents of concern 	 the need in certain cases to know beforehand the potential risks associated with the site for safety reasons, it may not be possible to take samples on dangerous sites or sites which do not comply with international safety norms it may not be possible to take samples while the facility is in operation vaccines are not available for all agents of concern
	Organisation implications (treaty organisation, national level)	 the possibility to use in some way infrastructure already established the possibility of in some way, organising procedures under existing international arrangements or using these as models 	- requirements for a certification process for reference laboratories that are used for samples taken and removed from the site
6.	Impact on permitted activities	- none identified	- the measure may interfere (including by accidental contamination) with legitimate development or production processes
	Impact on CPI	- in some cases it might be possible to select technology for sampling and identification which maintain intellectual, industrial or commercial proprietary rights (CPI)	- there is a risk of loss of CPI

Combination with other measures that may enhance the effect of the measure above. Listed in order of priority:

- measures of declaration or information monitoring;
- inspection measures, including *inter alia*:
 - interviews with the staff;
 - visual inspection of the site,;
 - identification of key equipment;
 - auditing;
 - possibly the medical examination of staff;
- continuous monitoring.

EVALUATION MEDICAL EXAMINATION OF VERIFICATION (On site)

(Rapporteur: Mr. M. Negut)

(BWC/CONF.III/VEREX/WP.169)

Introduction

In terms of "on-site" measures of verification, medical examination was defined as a collection of information about the activities of a facility by auditing medical and occupational health records of the work force; examination of recent and past cases of diseases; taking and analysing body fluids/tissue samples; and surveying the immunological status of the work force versus epidemiological background data (BWC/CONF.III/VEREX/WP.86/Rev.1 and BWC/CONF.III/VEREX/WP.136).

Characteristics

Medical examination is the basic proof of recent/past exposure to BW agent and/or immunisation against it and consists of:

- 1. Medical inspection: visits to local medical units and authorities, auditing medical records, information about morbidity/mortality data, epidemiological data, vaccination policy.
- 2. Medical examination of ill and healthy persons by adequate clinical and laboratory investigation (clinical chemistry, hematology, microbiology analysis and immunological tests).
- 3. On-site veterinary examination (clinical chemistry, microbiology, hematology, serology and pathology) (BWC/CONF.III/VEREX/WP.39; BWC/CONF.III/VEREX/WP.58; BWC/CONF.III/VEREX/WP.86/Rev.1; BWC/CONF.III/VEREX/WP.136; and BWC/CONF.III/VEREX/WP.145).

Evaluation criteria

Capabilities

- Medical examination can be a relevant verification measure for development, production and/or stockpiling of a potential BW agent. Medical/occupational records, epidemiological data, clinical and laboratory examination, changes in immunological status versus epidemiological local background, and vaccination policy can provide information on a possible exposure to an agent of concern.
- 2. Qualified medical examiners exist worldwide.
- 3. Reference laboratory analysis can detect micro-organisms and toxins as well as morphological, serological and immunological changes that are relevant to identify a

- causative BW agent. A positive analytical result would be of particular concern if the agent were not endemic in the area.
- 4. Examination of medical and/or occupational health records and proven immunisation of personnel against a BW agent could help to differentiate between permitted and prohibited activities and help to resolve ambiguities about compliance.
- 5. Minimal technology requirements are necessary for examination and auditing and low technology equipment is required for transporting samples safely.
- Medical examination if conducted as targeted activity to a limited group of persons does not have an important financial impact. WHO and highly specialised laboratories could support sample analysis.
- 7. There is a minimal impact on permitted activities and on commercial proprietary information.

Limitations

- 1. There is a potential impact on human rights by medical examination for legal, ethnic, religious or personal reasons.
- Incorrect, incomplete or false medical and epidemiological records create great difficulties in interpreting data. The views were expressed that a surrogate work/force will show no evidence of vaccination against a BW agent.
- 3. Low value of immunological tests in the case of endemic diseases or where there has been mass vaccination for disease.
- 4. Laboratory methods do not exist for rapid detection and identification of all agents of concern and especially genetically modified organisms might not be detected or identified.
- 5. Medical examination requires teams of highly qualified specialists. Including interpreters for medical information, expenses can increase considerably.
- 6. Significant impact on cooperation and industrial development could result if false positive information suggested prohibited BW activity at a facility.
- 7. May be a risk for inspectors from professional exposure.

Interaction with other measures

- 1. The ability to differentiate between prohibited and permitted activities and to resolve ambiguities about compliance besides medical examination requires:
 - information from other measures such as: declaration, notification, on-site auditing, on-site sampling and identification, on-site interviewing.

Conclusions

- 1. By its ability to detect human exposure to agents of concern, medical examination is a useful measure.
- 2. Taking into account major limitations, it is necessary:
 - to establish a protocol defining the accepted terms of medical examination at national level;
 - to ensure protection of an inspection team in high risk conditions;
 - to develop the most adequate techniques for microbiological, serological and immunological detection and identification for a possible exposure to potential BW agents.
- 3. The ability to differentiate between prohibited and permitted activities and to resolve ambiguities about compliance requires interaction with other measures.
 - declarations;
 - notifications:
 - "On site" auditing;
 - "On site" sampling and identification;
 - "On site" interviewing.

	CRITERIA	CAPABILITIES	LIMITATIONS
1.	Amount of information	- clinical picture, patient history and epidemiological records of registered uncommon disease outbreaks can suggest accidental or professionally derived illness by an agent of concern - conversion of the immunological status can reveal past infections or vaccinations when compared to epidemiological background data - reference laboratory analysis in most cases, can be expected to detect and identify an agent of concern	 potential impact to human rights; difficulty in obtaining blood and other body fluids or tissue samples for legal, ethnic, religious or personal reasons medical diagnostic examinations could be restricted for the same above mentioned reasons incomplete reported epidemiological data or medical records research data on animal test at a development or production facility likewise can be destroyed or falsified

	Quality of information	- analytical results may be of special concern if the agent is not endemic in the area	- low significance of immunological tests for endemic diseases due to natural occurrence or artificial immunization - atypical or unknown medical pictures and serological changes determined by genetically modified organisms - examination of a surrogate "work force" will show no evidence of vaccination against or exposure to agents of concern - incorrect or falsified reported epidemiological data or medical records
	Other strengths or weaknesses not covered by other criteria		
2.	Their ability to differentiate between prohibited and permitted activities	- immunisation against BW agents and particular clinical pictures are relevant in uncommon diseases - examination of meticulous bona fide medical and/or occupational health records could help determine prohibited activity	- immunisation of a work force against BW agents may be obscured by mass vaccination of a population against the same agent
3.	Their ability to resolve ambiguities about compliance	 relevant information about BW related agents may be obtained if: typical pathological and immunological changes due to an agent of concern were detected if medical and/or occupational health records and information are authentic 	- common epidemics or mass immunisation with the same type of agent could prevent association with BW activity
4.	Technological requirements	no special requirements for medical inspection and auditing reference - laboratory methods exist	- sensitive laboratory methods do not exist for rapid detection and identification on site of most agents and their induced

		for detecting micro- organisms, toxins and immunological changes as well as for autopsy specimens - low technology equipment is required for transporting samples safely - some assays exist for immunoglobulines to agents of concern	immunological response in human and animals - genetically modified organisms in samples probably would not be detected and identified
	Material requirements	- commonly used in routine medical activities	 very few medical samples can be tested on site transport of samples and maintenance of chain of custody could require material and logistical support
	Manpower requirements	- qualified medical examiners exist worldwide - suitably trained personnel can collect medical, occupational and epidemiological data - properly trained personnel can diagnose disease and take appropriate medical samples on site - suitably trained personnel in specialised reference laboratories can perform analysis	- examination of medical and health records and epidemiological data need time and require highly trained people and interpreters
	Equipment requirements	- minimal equipment is required for obtaining and keeping medical records and epidemiological data - low technology equipment for transporting medical samples safely	- confirmatory analysis of medical samples requires sophisticated equipment available in reference laboratories only
5.	Financial	 medical activity can be limited to a targeted group of persons WHO reference centers and other organisational 	 medical examination teams will require highly qualified specialists translation will be costly confirmatory off site laboratory analysis could be costly in terms of

		laboratories may perform/support some highly specialised activities	manpower and logistical requirements - creation of a new international organisation will be very expensive
	Legal (international and national level)		- a protocol defining the accepted terms of medical examination is necessary to be negotiated at national level in advance - legal restraints limiting access to/or removal of records could exist
	Safety		 risk of exposure is possible considerable liability costs may result considerable repercussions could be expected if a sample is taken for examination and disease is disseminated
	Organisational	- expert organisation for medical examination can be created by international agreement	- expert organisation requires sophisticated expertise
6.	Impact on permitted activities	- minimal impact	- considerable impact could result from false positive information
	Impact on CPI	- minimal impact	

Combination with other measure will enhance the effect of the measure above. Listed in order of priority:

- declarations;
- notifications;
- on-site auditing;
- on-site sampling and identification;
- on-site interviewing.

EVALUATION CONTINUOUS MONITORING BY INSTRUMENTS

(Rapporteur: Mr. Roque Monteleone Neto)

(BWC/CONF.III/VEREX/WP.170)

Introduction

During VEREX I the Ad Hoc Group of Governmental Experts identified Continuous Monitoring as one of the on-site potential verification measures, divided into different modalities: by instruments and by personnel. During VEREX II this measure was specifically addressed by several papers: BWC/CONF.III/VEREX/WP.41 (Norway), BWC/CONF.III/VEREX/WP.49 (USA), BWC/CONF.III/VEREX/WP.65 (Brazil), BWC/CONF.III/VEREX/WP.66 (USA), and BWC/CONF.III/VEREX/Non-paper (Statement of Ambassador Lacey - USA). In addition some other papers mention some aspects related to continuous monitoring, such as BWC/CONF.III/VEREX/WP.76 (Germany), as well as two other possibilities of continuous monitoring that were introduced: by using animals (Finland), and by monitoring diseases occurring in humans at a particular facility, through compulsory regular reporting to a BTW organization (Brazil). The summary of the examination was reported on paper BWC/CONF.III/VEREX/WP.87/Rev.1 (Brazil) and the first approach to the evaluation on BWC/CONF.III/VEREX/NONE.51 (Brazil).

This paper revises BWC/CONF.III/VEREX/NONE.51 (Brazil), based on FOC's paper BWC/CONF.III/VEREX/WP.89 (India, The Netherlands, Sweden), and considers separately continuous monitoring by instruments and continuous monitoring by personnel, due to the differences between these two modalities, according to their different nature and requirements. Nevertheless, it should be kept in mind that continuous monitoring by instruments requires routine checks and replacements by certified personnel; likewise continuous monitoring by personnel includes equipment that might monitor continuously ongoing processes or other activity during its application.

Continuous monitoring by instruments could be a regular procedure, however it is estimated to be more relevant if tailored to certain facilities or specific cases.

Continuous monitoring using animals should be better placed as another measure, because its nature does not meet the criteria established in the definition of continuous monitoring by instruments or by personnel. Continuous monitoring of disease occurring in humans at a particular facility is covered under the combination of measures regarding notifications and medical examination.

Definition

On-site continuous monitoring by instruments is an activity conducted on a continuing basis using devices or instruments with the specific role of monitoring ongoing processes, parameters or events, occurring in key equipment of a particular facility, and/or storage rooms or special storage facility, or testing areas.

Characteristics and Technologies

Appropriate process monitoring instrumentation for continuous monitoring (in-line and on-line currently exists to monitor and record process parameters, which can provide at regular or random intervals samples to be analyzed. On the other hand, the identification of microorganisms, viruses and toxins by immunoassays based on antibodies or by DNA probes is today the state of the art technique. Polyclonal and monoclonal antibodies are available commercially for some of the biological agents of concern, although no sampling-identification or real-time device had yet been developed.

Other means of performing a continuous monitoring by instruments activity could be the use of video recording cameras and surveillance by closed-circuit television cameras.

The identified items subject to continuous monitoring by instruments includes, *inter alia*: agents, process parameters, chemical analysis for microbial degradation residues, microbial metabolites, appropriate feed stocks, and specific toxins, general facility activity surveillance, electricity consumption surveillance, water consumption surveillance, storage rooms, and testing areas.

Capabilities

Known agents of concern, ongoing processes, and stocks of biological materials in a particular facility will be detected by personnel using continuous monitoring by instruments.

Limitations

At present, no commercially available device is known which might have an integrated capability of sampling and identification, as well as real-time identification capability.

A high risk to research and commercial confidentiality may exist, requiring several safeguards, including precise definition of the circumstances that will trigger this modality of on-site verification measure, and for how long.

Confirmation of data results and more sophisticated methods may need to be performed outside the facility or even outside the country where the facility operates, leading to confidentiality concerns for research and commercial activities.

The information provided by process parameters analysis and/or continuous monitoring by video recording and television surveillance would only give indirect evidence of a BTW agent having been developed and/or produced or tested.

Equipment and devices to be used in a continuous monitoring activity must be timely checked, replaced, or its logs be kept by certified personnel.

Information provided must be quickly transmitted, on a confidential basis, and be analyzed by a multidisciplinary team of specialists on a central unit, under an appropriate authority, and integrated with other information that triggered the continuous monitoring activity.

Rules of procedures, such as facility agreements, could determine the operational aspects, confidentiality concerns, including the condition to terminate this activity on a particular facility.

Continuous monitoring of processes and/or agents might be undertaken only if specific agents and/or process are fully declared and/or identified.

Contamination and disruption of batch processes might occur, which might lead to legal actions by the institution/laboratory/government under a continuous monitoring activity.

Other limitations are similar to those under sampling and identification.

Sensitivity and Specificity

The available technology is not sensitive or specific for detection of all agents of concern.

Potential interaction with other measures

Continuous monitoring by instruments interacts with on-site inspections that might trigger its application.

Continuous monitoring by instruments could relate with ground-based surveillance, off-site and on-site sampling and identification, auditing and declarations because results could be compared for consistency.

Continuous monitoring by instruments also would relate with on-site observation, interviewing and identification of key equipment that provides the basis for allocation of the types of devices and instruments for parameter process monitors.

Further Developments Required

Due to the high degree of intrusiveness, the circumstances that might trigger the application of this measure are the major item that deserves further discussions, e.g., if it could be a regular procedure, or in cases of investigations regarding allegation of non-compliance. A set of rules of procedure, that takes into consideration safeguards regarding commercial proprietary rights, as well as harmonization with national constitutional provisions, and a facility agreement format also needs further considerations.

Summary

Continuous monitoring by instruments may be an important measure to be applicable in combination with other measures on very special occasions to monitor compliance and to resolve ambiguities.

The preliminary evaluation of continuous monitoring by instruments using the six criteria specified in the mandate is given as follows:

	CRITERIA	CAPABILITIES	LIMITATIONS
1.	Amount of information	- can provide information on known agents or toxins, ongoing processes, physical, chemical and biological characteristics of the effluents, microbial degradation of residues and production of metabolites, appropriate feed stocks - reasonable amount of information on the general activities taken on a facilitystocks, electricity and water consumption	- decrease in value if information provided is not quickly transmitted and analyzed - if not selective, the large amount of generated information would be cumbersome
	Quality of information	- video recorded tapes provide on- the-spot general information	- information provided by process parameters analysis and/or continuous monitoring by video recording and television surveillance would provide nonspecific information - presently, no methodology is available which would enable realtime, on-the-spot, conclusive identification of all pathogenic microorganisms, viruses, viroids and toxins
	Other strengths or weaknesses not covered by other criteria	- technically applicable at any time to all areas of a facility for development, production or storage	- confirmation of data might need to be performed outside the facility and/or by other methods
2.	Their ability to differentiate between prohibited and permitted activities	- may be able to indicate if an agent or toxin of concern is being developed, processed, or stocked in the object under interrogation, if a specific assay is available	 might not reveal unknown agents or toxins it is unlikely to determine the purpose of a dual-use process solely by data collected
3.	Their ability to resolve ambiguities about compliance		- no existing instrumentation is sensitive or specific enough to independently identify non- compliance through the measurement of process parameters, or identification of agents
4.	Technology requirements	- many in and on-line monitors are commercially available	
	Material requirements	- specific polyclonal and monoclonal	- specific polyclonal and

		antibodies as well as probes are available for several biological agents or toxins or are under development - specific chemical reagents and/or media for traditional identification technologies are commercially available	monoclonal antibodies, as well as probes are not available for several agents
	Manpower requirements	- majority of equipment or devices requires no permanent operators	- some monitor devices and equipment might not operate without the continuous assistance of personnel - equipment and devices require regular maintenance by certified personnel
	Equipment requirements	- automatic video recording, devices and equipment to monitor non- specific ongoing process parameters are commercially available	- real-time sampling and identification equipment need industrial development
5.	Financial		- possibly high investment, development and operation costs
	Legal	- needs a facility agreement - legally binding safeguards regarding data confidentiality	 needs clarification of the situations that might trigger and terminate its application would require harmonization with national constitutional provisions with regard to legal rights and unwarranted searches and seizures
	Safety		- risk of contamination and/or disruption of batch or continuous processes
	Organizational implications	- international organization might be able to receive, analyze and assist such activity	- highly qualified experts are required to observe, analyze data, audit documents and files
6.	Impact on permitted activities	- the need for real-time sampling and identification equipment or devices might stimulate research	- operators need to be convinced and accept the presence of equipment for continuous monitoring - installation and in some cases monitoring and maintenance may cause disruption of permitted activities
	Impact on CPI		- risk to intellectual rights and to proprietary information

Combination with other measures that may enhance the effect of the measure above. Listed in order of priority:

- Observation;
- Interviewing;
- Identification of key equipment;
- Sampling and identification;
- Ground based surveillance;
- Declarations

EVALUATION CONTINUOUS MONITORING BY PERSONNEL

(Rapporteur: Mr. Roque Monteleone Neto)

(BWC/CONF.III/VEREX/WP.171)

Introduction

During VEREX I the Ad Hoc Group of Governmental Experts identified Continuous Monitoring as one of the on-site potential verification measures, divided into different modalities: by instruments and by personnel. During VEREX II this measure was specifically addressed by several papers: BWC/CONF.III/VEREX/WP.41 (Norway), BWC/CONF.III/VEREX/WP.49 (USA), BWC/CONF.III/VEREX/WP.65 (Brazil), BWC/CONF.III/VEREX/WP.66 (USA), and BWC/CONF.III/VEREX/Non-paper (Statement of Ambassador Lacey - USA). In addition some other papers mention some aspects related to continuous monitoring, such as BWC/CONF.III/VEREX/WP.76 (Germany). The summary of the examination was reported on paper BWC/CONF.III/VEREX/WP.87/Rev.1 (Brazil) and the first approach to the evaluation on BWC/CONF.III/VEREX/NONE.51 (Brazil).

This paper revises BWC/CONF.III/VEREX/NONE.51 (Brazil), based on FOC's paper BWC/CONF.III/VEREX/WP.89 (India, The Netherlands, Sweden), which describes the methodology for the evaluation phase, particularly introducing the concepts of sensitivity and specificity. The revision also considers separately continuous monitoring by instruments and continuous monitoring by personnel, due to the differences between these two modalities, according to their different nature and requirements. Nevertheless, it should be kept in mind, that continuous monitoring by instruments requires routine checks and replacements by certified personnel; likewise continuous monitoring by personnel includes equipment that might monitor continuously ongoing processes or other activity during its application.

Definition

On-site continuous monitoring by personnel is an activity conducted on a continuing basis using observers or other highly qualified experts with the specific role of monitoring ongoing processes parameters or agents, occurring in key equipment of a particular facility, and/or storage rooms or special storage facility, or testing areas.

Characteristics and Technologies

Expert personnel in various areas of knowledge, such as bioengineering, bioprocess engineering, detection and handling of biological materials, already exist in several countries, universities, military and civilian institutions. Good manufacturing practice expert personnel, now adopted as a regular procedure in several areas in different countries, could also be included on a team for a continuous monitoring activity by personnel.

The items subject to be continuously monitored by personnel would include: identification of previous and new activities and production steps; checking the consumption of raw materials,

chemicals and reagents; checking the integrity of technical installations with respect to normal monitoring equipment as well as instruments and devices installed for BTW verification purposes.

The continuous monitoring by personnel could be a regular procedure, or used in special cases of investigations regarding allegations of non-compliance. In any case, a set of rules of procedures and a facility agreement should be undertaken.

During a continuous monitoring activity, a personnel system should be kept in operation 24 hours daily, and be terminated according to specified rules.

A free access, at any time, to all points of development, production, storage, archives, personnel files of the facility should be assured, as well as confidential interviews with all the personnel employed or contracted, not to be surveyed by representatives from the inspected site.

The monitoring team should be easy to identify, and their presence and purpose should be clearly announced to all the employees and contractors of the facility.

Capabilities

Agents of concern, ongoing processes, development and production characteristics, and stocks of biological materials, as well as checks on traffic activity at a particular facility will be known by the use of a continuous monitoring by personnel activity.

Limitations

A high risk to research and commercial confidentia lity exist, which leads to the need to undertake several safeguards on the generated data by this activity, including precise definition of the circumstances that will trigger this kind of on-site verification measure, and for how long.

Harmonization with national constitutional provisions with regard to legal rights and unwarranted searches and seizures would be required.

Rules of procedures, such as a facility agreement, could determine the operational aspects, confidentiality concerns, including the condition to terminate this activity on a particular facility.

The costs of on-site continuous monitoring by personnel, as opposed to inspection visits, will necessarily be very high.

Personnel involved in continuous monitoring may require immunization against possible BTW agents.

Potential interaction with other measures

Continuous monitoring by personnel is associated with continuous monitoring by instruments because of the need for operation, checking, replacing equipment and devices, and also because it might be one of the triggers to its application.

Continuous monitoring by personnel interacts with on-site inspections, particularly with visual inspections, interviewing, sampling and identification and identification of key equipment that provides the basis for allocation of the types of devices and instruments for parameter process analyses.

Continuous monitoring by personnel could relate with off-site sampling and identification, ground based surveillance, declarations, and auditing because results could be compared for consistency.

Further Development Required

Due to the high degree of intrusiveness, the circumstances that might trigger the application of this measure are the major item that deserves further discussions, e.g., if it could be a regular procedure, or in cases of investigations regarding allegation of non-compliance. A set of rules of procedure, that takes into consideration safeguards regarding commercial proprietary rights, as well as harmonization with national constitutional provisions, and a facility agreement format needs also further considerations.

Summary

Continuous monitoring by personnel may be an important measure to be applicable in combination with other measures on very special occasions as a component of verification of compliance and to resolve ambiguities.

The preliminary evaluation of continuous monitoring by personnel using the six criteria specified in the mandate is given as follows:

	CRITERIA	CAPABILITIES	LIMITATIONS
1.	- reflect a fairly good overview on the general activities taken on a facility or testing area, stocks, electricity and water consumption		
	Quality of information - fairly high degree of knowledge of the general activities undertaken in the facility		- specificity of current methods
	Other strengths or weaknesses	- technically applicable at any time to all areas of a facility for development, production or storage, archives and personnel files	- confirmation of data might need to be performed outside the facility and/or by other methods
2.	Their ability to differentiate between prohibited and permitted activities	- specialized personnel could assist in differentiating between permitted and prohibited activity	- on its own it is unlikely to determine the purpose of a dual- use process
	Their ability to resolve		

3.	ambiguities about compliance		
4.	Technology requirements	- minimal	
	Material requirements	- minimal	
	Manpower requirements	- personnel with various areas of knowledge and expertise already exist in several countries, universities, military and civilian institutions	- communication, language and cultural difficulties might occur
	Equipment requirements	- minimal	
5.	Financial		- costs may be very high
	Legal	- facility agreement and legally binding safeguards regarding data confidentiality may be arranged	- harmonization with national constitutional provisions with regard to legal rights and unwarranted searches and seizures would be required
	Safety		 - risk of contamination and/or disruption of batch or continuous processes - personnel may need to be immunized against possible BWT agents
	Organizational implications	- capability to receive, analyze and assist such activity may be arranged	
6.	Impact on permitted activities		 may cause contamination and disruption of permitted activities operators need to be convinced and accept the presence of personnel for continuous monitoring
	Impact on CPI		- risk to intellectual rights and to proprietary information

Combination with other measures that may enhance the effect of the measure above. Listed in order of priority:

- Declarations;
- Ground based surveillance;
- Visual inspections;
- Auditing;
- Observation;
- Interviewing;
- Sampling and identification;
- Identification of key equipment;
- Continuous monitoring by instruments.

TYPES AND QUANTITIES OF MICROBIAL AND OTHER BIOLOGICAL AGENTS AND TOXINS

(BWC/CONF.III/VEREX/WP.175)

Mr. Volker Beck

Mandate

The Ad Hoc Group has been asked to

- seek to identify measures which could determine
 - whether a State Party is developing, producing, stockpiling, acquiring or retaining microbial or biological agents or toxins, of types and in quantities that have no justification for prophylactic, protective or peaceful purposes.

Specifically, the Group shall seek to evaluate potential verification measures, taking into account the broad range of types and quantities of microbial and other biological agents and toxins, whether naturally occurring or altered, which are capable of being used as means of warfare.

Based on the mandate, the question of types and quantities is not an isolated problem but is possibly relevant to the ability of a measure to distinguish between compliant and prohibited activity. For this reason, it is not possible for the Ad Hoc Group to discuss types and quantities independently from measures, since these parameters are context dependent.

Requirement

The requirement to discuss the question of types and quantities of agents of concern in the context of identified measures has been already expressed early in the footnotes of Annex I to the Summary of the work of the Ad Hoc Group for the period 30 March to 10 April 1992 (BWC/CONF.III/VEREX/2). During the examination phase of VEREX 2 views were expressed that areas exist that require the support of lists of agents, as for instance, Information Monitoring, Declarations, Notifications, Sampling and Identification. Annex V (Results of the sondage on identified areas of interest needing further elaboration...) of the Summary of the work of the Ad Hoc Group for the period 23 November to 4 December 1992 underlines the importance of the question of illustrative lists. In addition the question of lists of agents and quantities was addressed in isolation from specific possible verification measures in a great number of papers which were submitted to VEREX I, II and III (see Annex).

Character of lists or compilations

The proposals to combine a possible verification measure with a list of agents or of quantities have different rationales. Some measures may not be properly implemented or conducted without a list. For such measures a list is prerequisite. For other measures a list will have only a supportive character.

Information Monitoring, for instance, if not combined with an illustrative list either will create an abundance of information which cannot be handled or will even miss information on activities related to agents of concern. Reliable declarations on the work with certain agents, on transfers or on unusual outbreaks of diseases only can be expected when at least the measure is combined with a list which describes the agents of concern for which certain activities or outbreaks should be declared or notified. For these measures, for instance, a list of agents is prerequisite.

The available technology will allow the identification and detection of increasing numbers of types of microbial and other biological agents and toxins on site. For practical reasons however the number of assays which can be carried to an inspected site will be limited. An illustrative list of agents may help to select assays to be taken on site.

Based on these examples, the capabilities and limitations of lists can be described, *inter alia*, as follows:

capabilities

- * allow to collect and examine relevant data, avoid abundance of information, which is not related to the BWC
- * describe items, for which data are required
- * give advice, for materials to be selected for inspections

limitations

- * can only be illustrative
- * would need revisions based on state of the art knowledge, other sources of information (e.g. WHO) and on industrial development
- * can never become definitive even if the illustrative character or the identified quantities were not changed for a long period.

The matter of lists is not a stand-alone issue but must be considered in conjunction with the measure. However, taking into account the criteria of the mandate the aforementioned capabilities and limitations can also be described against, inter alia, these criteria:

amount of information

- * for some measures the amount of information only can be created based on a list attached to the measure (example: declarations)
- * for some measures the information can be reduced only with list to the amount which is related to the BWC and which can be technically, scientifically and administratively handled (example: surveillance of literature)

- quality of information

- * the quality of information will increase when the requested information can be described in detail with an illustrative list
- other strengths and weaknesses
 - * the strength of an illustrative list is that it describes agents which are identified to be of relevance to the BWC
 - * the weakness of lists is their illustrative character, in that they can only describe agents which, based on certain criteria, can be identified as agents of concern; it cannot be excluded that agents, handled by a proliferant, may not be covered by the list
- ability to differentiate between prohibited and permitted activities and ability to resolve ambiguities about compliance
 - * the application of a list by itself cannot achieve this; however the information that an agent is listed or the information on produced quantities will be supportive background data
 - * in some cases this ability will exist (e.g. smallpox virus)
- technology, material and equipment requirements
 - * not applicable
- manpower requirements
 - * experts are available for elaboration and timely revision of list of agents and quantities
- financial implications
 - * no, as revisions can be done during scheduled BWC Review Conferences
- legal and organizational implications
 - * no, beyond the implications created by a measure itself
- safety implications
 - * none
- impact on permitted activities
 - * there may be impact on permitted activities when a list is attached to particular verification measures

impact on CPI

* none

Possible criteria for the identification of agents of concern

Different lines already exist, such as the ones produced by scientific panels, or which are established parts of international agreements or national laws and regulations:

Thus, based on the 1954 Protocol No. III on the Control of Armaments to the Bruxelles Treaty (WEU-Treaty), the Council of the Western European Union adopted a List of Biological Products. In 1969, the Secretary-General of the United Nations published the report: Chemical and Bacteriological (Biological) Weapons and the Effects of their Possible Use, which contains an annex of Biological Agents Which Can be Used Against Man. Several States have already, for various purposes, drafted lists of agents. The existing lists are based on criteria or designators. Examples of criteria and designators for the development of such lists are described in national and international contexts related to the concerns covered by the BWC:

Para. 58 of the 1969 UN report describes the following requirements as selection criteria for the application of agents in war:

- a) producible in large quantities
- b) easy dissemination even under unfavourable environmental conditions
- c) effective in spite of medical countermeasures
- d) causing large numbers of casualties.

Another example used for the selection of agents for the aforementioned lists is the consideration of the following designators:

- human pathogens:
- 1. an agent has been used in warfare
- 2. an agent has been developed for warfare
- 3. an agent has been sought or acquired by a proliferant
- 4. an agent which could incapacitate or kill and has a short incubation period
- 5. an agent which could be mass-produced
- 6. an agent which is infectious in aerosol form

- 7. an agent to which a population is susceptible.
- animal pathogens:
 - * a mass-producible agent which kills or incapacitates animals to create serious socioeconomic or public health consequences; or
 - * an agent which has been developed for or used in war.
- plant pathogens:
 - * a mass-producible agents, infectious in aerosol form, which damages or kills plants to create serious socio-economic consequences; or
 - * an agent which has been developed for or used in warfare.

So based on the different proposals, extensive measures have already been developed to determine how and which types of agents may be put on illustrative lists of potential BW agents to support verification measures. Taking into account already existing lists, there is no doubt that illustrative lists of agents may be developed to serve particular verification measures.

Possible approaches for the identification of quantities

For determining quantities two approaches are possible. The first approach is, so to speak, an indirect way to solve the problem by defining the militarily relevant quantity of an agent for use in warfare. The United States BWC/CONF.III/VEREX/WP.88 and the Russian BWC/CONF.III/VEREX/WP.93 used this approach. This approach may give rise to lengthy discussions with dissenting opinions about which quantities may be of military relevance. The reason for this is on the one hand that militarily relevant quantities may be highly related to different scenarios and, on the other hand, that the development in biotechnology and genetic engineering has overruled that data which may be available from historic offensive BW programs.

For this reason, a second approach, which sticks to the working of the mandate, should solve the problem. The mandate combines the question of quantities with the justification for prophylactic, protective or peaceful purposes. Once an illustrative list of agents is established, it would be possible to identify the quantities of each agent which are currently produced for justified prophylactic, protective or other peaceful applications. Under the measure of Declarations such data on production may be collected. Under the measure of Data on transfers, on transfer requests and on production, such data may also be collected. The data then could be available as background information for inspections and for other measures supportive to compliance monitoring.

However, there are some cases where microbial and other biological agents and toxins exist which have no commercial or health-care interest and therefore are not subject to production. For such type of agents it may be feasible and reasonable to set thresholds for research, for instance. Smallpox virus is the example which was already mentioned din this context.

BWC/CONF.III/VEREX

Working and None Papers referring to Types and Quantities

BWC/CONF.III/VEREX/WP

2	Group of Experts on the Verification of	the BWC FRANCE
23	Illustrative list of potential BW agents	RUSSIAN FEDERATION
24	The BWC Verification Regime: Some suggested criteria	ITALY
26	Natural biological bomb	IRAN, Islamic Republic of
34	Surveillance of Legislation	GERMANY
45	Evaluation of the Concept of a List for the BWC	USA
51	Indicative list of biological agents and toxins possibly relevant to the BWC	CUBA
88	Biologically derived toxins Quantities for legitimate use	USA
93	On Determining the Quantity of Microorganisms and Toxins Required for Protective Purposes	RUSSIAN FEDERATION
BWC/CONF.	III/VEREX/NONE	
1	Verification of biological and toxin weapons disarmament	FRANCE
5	The nature of biological warfare agents	UNITED KINGDOM
7	Biological Warfare (ex Jane's)	FRANCE
8	Trends in biological and toxin weapons (ex OECD)	FRANCE
11	Biotechnologies et génétique dans le de nouvelles formes d'armes biologique	FRANCE es

15	Biological Warfare Developments (ex Jane's)	FRANCE
16	Diseases as a Weapon of War (ex Pacific Research)	FRANCE
23	List of agents from all NONE papers of VEREX	BRAZIL
25	Romanian import/export regime	ROMANIA
33	Norwegian export control	NORWAY

MEASURES IN COMBINATION

Mr. Åke Bovallius and Mr. G. Pearson (Sweden and United Kingdom)

(BWC/CONF.III/VEREX/WP.176)

A. Background

- 1. The mandate of the Ad Hoc Group of Governmental Experts to evaluate Potential Verification Measures from a Technical and Scientific Standpoint is contained in BWC/CONF.III/VEREX/INF.4.
- 2. The methodology for the evaluation of potential verification measures according to this mandate is contained in working paper no. 89*, agreed upon during VEREX II (BWC/CONF.III/VEREX/WP.89*, 3 December 1992). The rapporteurs have evaluated all the potential verification measures according to this format. Each rapporteur has also identified a non-exhaustive list of possible combination of measures which might enhance the capabilities of each single measure.
- 3. Working paper 113 (BWC/CONF.III/VEREX/WP.113) contains the agreed methodology for the Evaluation of measures in combination. In addition Mr.Å. Bovallius and Mr. G. Pearson were asked to act as Friends of the Chair on measures in combination.
- 4. Brazil, France and the Russian Federation have presented papers (WP.172, WP.173 and WP.174) on evaluation of measures in combination.
- B. The rapporteurs' identification of possible combinations of the potential verification measures
- 1. The rapporteurs' reports show, from a technical and scientific standpoint, that no single measure may be effective by itself to cearly distinguish between permitted and prohibited activities.
- 2. In the reports of the rapporteurs both textual statements, as well as lists of measures in accordance with the format in WP.89*, have identified measures that in combination may give an enhanced effect. Measures in combination may provide enhanced capabilities and thereby enhance the effectiveness of each measure when it is used in combination with others. A list of measures in combination identified by rapporteurs are in Annex.
- 3. Several of those measures evaluated singly have been identified as being closely related. Some evident relations between the potential verification measures were identified in the areas of information monitoring (surveillance of publications, surveillance of legislation, data on transfer, transfer requests and on production, multilateral information sharing) and on-site inspection (interviewing, visual inspection, identification of key equipment, sampling and identification, auditing).

- 4. The rapporteurs' papers show that declarations is the measure that most rapporteurs have chosen as a useful measure in combination. The second most frequently identified group of off-site measures in combination which might enhance the capabilities of the single measure was information monitoring (surveillance of publications, surveillance of legislation, data on transfer, transfer requests and on production, multilateral information sharing).
- 5. All rapporteurs have identified off-site and on-site measures which interact with the single measures. The capabilities of all single measures might be enhanced if they are combined with other off-site measures and other on-site measures.
- 6. The most frequently identified on-site measures in combination were on-site inspections (interviewing, visual inspection, identification of key equipment, sampling and identification, auditing).
- 7. The following examples of measures in combination are cited from the rapporteurs' reports:
- "On-site auditing is considered to have a synergistic effect in combination with interviewing, visual inspection, identification of key equipment, sampling and identification and medical examination and together with information gained from off-site measures such as information monitoring and declarations could be used by an inspectorate to build up a picture of the normal activity and to assess overall consistency and coherence" (WP.167).
- "The interaction between information monitoring and declarations may be strongly synergistic. Correlation between declared and monitored data is a good indicator of compliance, whereas a lack of correlation would give rise to concern" (WP.156).
- "Provisions through declaration of background data on a facility could allow more efficient, less time-consuming and less confrontational inspections" (WP.156).
- "It was also found that when triggered as a result of information gained from other sources, including other verification measures, off-site auditing could be highly focused and directed towards addressing specific concerns" (WP.162).
- "The measure identification of key equipment will provide substantial amounts of relevant information and can together with other measures help to distinguish between permitted and prohibited activities. Industrial confidentiality of obtained information could be a problem and has to be taken into account" (WP.166).

C. Applicability to development, production and stockpiling

During the examination phase of VEREX II it was clear that similar conclusions were reached in all three areas of Development, Production and Acquisition and Stockpiling and Retention. In the moderators' paper BWC/CONF.III/VEREX/NONE.84) the application of measures to the three areas was discussed in one context which shows possible useful combinations,, as follows:

Development

1. According to the Moderators, measures in combination relevant to this area were surveillance of publications, multilateral information sharing, declarations, as well as the measures for on-site inspection and these measures in combination could provide useful information on activities of concern.

Production and acquisition

- 2. Measures in combination identified for this area by the Moderators were declarations, data on transfer, transfer requests and on production, off-site auditing and surveillance by satellite.
- 3. The on-site measures inspections (interviewing, visual inspection, identification of key equipment, sampling and identification and auditing) were considered to be useful together. In special cases some further measures could be useful.

Stockpiling and storage

- 4. Measures in combination identified for this area by the Moderators were the off-site measures surveillance by satellite, auditing, multilateral information sharing, data on transfer, transfer requests and on production and these measures could be useful in combination as a complement to declarations.
- 5. Useful on site measures, identified in this area, include interviewing, visual inspection, identification of key equipment, sampling and identification, auditing and continuous monitoring.

Combination of the three areas development, production and stockpiling

- 6. The following measures were found by the Moderators to be useful for all three areas (development, production and stockpiling): declarations, on-site sampling and identification, interviewing, visual inspection, on-site auditing, medical examination and continuous monitoring by personnel.
- 7. For the development area the following measures were also considered to be useful: multilateral information sharing, surveillance of publications and international arrangements.
- 8. For the production and stockpiling areas the following measures were also considered by the Moderators to be useful: data on transfer, transfer requests and on production, surveillance by satellite, off-site auditing, observation, continuous monitoring by instruments and surveillance by aircraft. Ground-based surveillance could also be useful.
- 9. For the development and production areas, off-site sampling and identification could be useful.

- D. An evaluation of measures in combination
- 1. The mandate charges the Ad Hoc Group to "seek to identify measures that could determine:
 - whether a State Party is developing, producing, acquiring, stockpiling or retaining microbial or other agents or toxins, of types and in quantities that have no justification for prophylactic, protective or peaceful purposes;
 - whether a State Party is developing producing, stockpiling, acquiring or retaining weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

Such measures could be addressed singly or in combination."

- 2. The systematic evaluation of all possible combinations was considered to be impractical.
- 3. In general, the capabilities and limitations of a combination of measures equal the sums of the capabilities and limitations of the single measures involved in the combination. This cumulative effect of measures in combination are not addressed here. The analysis presented in Annex 1 is intended to investigate whether, in particular cases, the application of measures in combination produces enhanced capabilities and limitations that differ from a simple accumulation of the capabilities and limitations of the single measures involved (synergy).
- 4. The analysis in Annex 1 is not aimed at providing a complete evaluation of combinations in terms of the mandate. Its purpose is to provide a number of examples of enhanced effects that the application of measures in combination may yield.
- 5. The following five combinations were proposed as examples to illustrate the evaluation of enhanced capabilities and limitations of measures in combinations:

Combination A. Declarations (6) + Multilateral information sharing (4) + Satellite

surveillance (7) + Visual inspection (15)

Combination B. Information monitoring (1, 2, 3, 4)

Combination C. On-site inspection (14, 15, 16, 17, 18)

Combination D. Declarations (6) + Multilateral information sharing (4) + On-site

visual inspection (15)

Combination E. Declarations (6) + Information monitoring (1, 2, 3, 4)

6. The enumeration of combinations does not represent proposals for combinations that would serve as a verification regime, since this is not part of the mandate of the Group.

- 7. It was agreed that, in principle, States Parties could submit additional contributions related to the evaluation of measures in combination for consideration throughout the duration of the VEREX process.
- 8. Each of the five proposed combinations of measures were evaluated. This evaluation resulted in the identification of examples of enhanced capabilities and enhanced limitations when measures are combined. The evaluation of combinations was illustrative and not exhaustive. Important positive and negative synergies may exist for each of the combinations examined that were not identified in the evaluation.
- 9. The results of the evaluation of the enhanced capabilities and limitations are presented in Annex 1 and indicate that synergistic capabilities and synergistic limitations may occur from the interaction of measures which are not present when measures are evaluated singly.

MEASURES IN COMBINATION

COMBINATION B: INFORMATION MONITORING (1, 2, 3, 4)

- 1. Surveillance of publications (1), surveillance of legislation (2), declarations on transfers, transfer requests (3) and multilateral information monitoring (4) have been evaluated in accordance with WP.113 using the approach in Annex I.
- 2. The following examples of enhanced capabilities have been identified to date:
 - a. (Quality/5) Information monitoring measures in combination may assist in the selection and application of identifers/key words for the analysis of data improving quality and reducing cost.
 - b. (Criteria 3/5) Information monitoring measures may improve identification of dual purpose activities for further examination within their combination. Focusing efforts may result in more relevant data and may reduce cost.
 - c. (Criteria 4) A computer/database to carry out all four information monitoring measures may require little additional resource over that for a single information monitoring measure.
- 3. No examples of enhanced limitations have been identified to date.
- 4. The results are summarized in the WP.89* Annex II format on the next page.

MEASURES IN COMBINATION IDENTIFIED BY RAPPORTEURS

1. Surveillance of publications: Other information monitoring measures **Declarations** On-site inspections Auditing (on-site/off-site) 2. Surveillance of legislation: Other information monitoring measures Auditing (on-site/off-site) Declarations On-site inspections 3. Data on transfer, transfer requests Other information monitoring measures Auditing Declarations On-site inspections 4. Multilateral information sharing: -Other information monitoring measures **Declarations** On-site inspections Remote sensing 5. Exchange visits: **Declarations** 6. Declarations: Information monitoring On-site inspections Continuous monitoring Remote sensing Exchange visits 7. **Declarations** Surveillance by satellite: On-site inspection Multilateral information sharing 8. Surveillance by aircraft: **Declarations** On-site inspections Multilateral information sharing Surveillance by satellite Ground-based surveillance Off-site sampling and identification

Off-site observation

9.	Ground based surveillance:	-	On-site sampling and identification
		-	Declarations
		_	Auditing
10.	Off-site sampling and identification	_	On-site sampling and identification
	1 6	_	Declarations
		_	Off-site auditing
		-	Information monitoring
11.	Observation:	_	On-site inspections
		_	Declarations
		_	Ground based surveillance
		_	Surveillance by satellite
		_	Surveillance by aircraft
			surveinance by uncruit
12.	Off-site auditing:	-	Declarations
		-	Information monitoring
		-	On-site inspections
13.	On-site international arrangements:	_	Declarations
	•	_	On-site inspections
		_	Continuous monitoring by personnel
		_	Surveillance of publications
14.	On-site interviewing:	-	On-site inspections
		-	Declarations
		-	Exchange visits
1.5			
15.	On-site visual inspection:	-	On-site inspections
		-	Declarations
		-	Exchange visits
		-	Multilateral information sharing
16.	On-site identification of		
10.	key equipment:	Declar	ations
	noj odosprimeno.	-	On-site visual inspection
		_	On-site sampling and identification
		_	On-site international arrangements
		_	On-site auditing
		_	On-site interviewing
			Data and transfer, transfer requests and
			on production
			•
17.	On-site auditing:	-	On-site inspections
		-	Declarations
		_	Information monitoring

18. On-site sampling and identification: - Declarations

- On-site inspections

- On-site identification of key equipment

19. On-site medical examination: - Declarations

On-site auditing

- On-site sampling and identification

On-site interviewing

20. Continuous monitoring by

instruments:

- Off-site observation

On-site interviewing

- On-site identification of key equipment

- On-site sampling and identification

- Off-site ground based surveillance

- Declarations

21. Continuous monitoring

by personnel - Declarations

- Off-site ground based surveillance

- On-site visual inspections

On-site auditing

Off-site observation

On-site interviewing

- On-site sampling and identification

- On-site identification of key equipment

- Continuous monitoring by instruments

COMBINATION B: INFORMATION MONITORING (1,2,3,4)

	CRITERIA	ENHANCED CAPABILITIES	ENHANCED LIMITATIONS
1.	Amount of information		
	Quality of information	- may assist in the selection and application of identifiers/cords	
	Other strengths or weaknesses		
2.	Their ability to differentiate between prohibited and permitted activities		
3.	Their ability to resolve ambiguities about compliance	- may improve identification of dual purpose activities for further examination	
4.	Technological requirements		
	Material requirements		
	Manpower requirements		
	Equipment requirements	- a single computer/data base could be used	
5.	Financial	- proper focussing may result in more relevant data and may reduce cost	
	Legal		
	Safety		
	Organizational		
6.	Impact on permitted activities		
	Impact on CPI		

MEASURES IN COMBINATION COMBINATION C: ON-SITE INSPECTION (14, 15, 16, 17, 18)

- 1. On-site interviewing (14), visual inspection, (15), identification of key equipment (16), auditing (17) and sampling and identification (18) have been evaluated in accordance with WP.113 using the approach in Annex I.
- 2. The following examples of enhanced capabilities have been identified to date:
 - a. (Quality) On-site inspection measures in combination may improve the quality of information and reduce the cost; for example, interviewing, visual inspection, identification of key equipment and auditing may reduce the number of samples required to be collected, through identification of key locations at which to collect samples.
 - b. (Quality) On-site inspection measures in combination may provide quantitative information on microorganisms and toxins.
 - c. (Criteria 2) On-site inspection measures in combination may provide improved distinction between permitted and prohibited activities.
 - d. (Criteria 3) On-site inspection measures in combination may provide an improved ability to resolve ambiguities in compliance.
 - e. (Criteria 4) On-site inspection measures in combination may require little additional manpower or skills over that required for a single on-site inspection measure.
 - f. (Criteria 5) On-site inspection measures in combination may require few additional safety requirements over those required for a single -on-site inspection measure.
- 3. The following example of an enhanced limitation has been identified to date:
 - a. (Criteria 6) On-site inspection measure in combination may increase the risk of possible loss of confidential information.
- 4. The results are summarized in the WP.89* Annex II format on the next page.

COMBINATION C: ON-SITE INSPECTION (14, 15, 16, 17, 18)

	CRITERIA	ENHANCED CAPABILITIES	ENHANCED LIMITATIONS
1.	. Amount of information		
	Quality of information	- may improve quality and reduce cost - may provide quantitative information	
	Other strengths or weaknesses		
2.	Their ability to differentiate between prohibited and permitted activities	- may provide improved distinction between permitted and prohibited activities	
3.	Their ability to resolve ambiguities about compliance	- may provide improved ability to resolve ambiguities	
4.	Technological requirements		
	Material requirements		
	Manpower requirements	- may require little additional manpower or skills	
	Equipment requirements		
5.	Financial		
	Legal		
	Safety	- may require few additional safety requirements	
	Organizational		
6.	Impact on permitted activities		- may increase the risk of possible loss of confidential information
	Impact on CPI		

MEASURES IN COMBINATION

COMBINATION A: DECLARATIONS (6) MULTILATERAL INFORMATION SHARING (4), SATELLITE SURVEILLANCE (7) AND VISUAL INSPECTION (15)

- 1. Declarations (6), multilateral information sharing (4), satellite surveillance (7), and visual inspection (15) have been evaluated in accordance with WP.113 using the approach in Annex I.
- 2. The following examples of enhanced capabilities have been identified to date:
 - a. (Quality) Declarations, multilateral information sharing, satellite surveillance and visual inspection may provide indications of undeclared activities.
 - b. (Quality) Declarations, multilateral information sharing, satellite surveillance may, by focusing the visual inspection, improve the quality of information.
 - c. (Other strengths and weaknesses) Cross-checking may confirm certain information and reinforce an apparent need, deriving from information from a single measure, to conduct follow-on examination. Also, cross-checking may remove the concern arising from an individual element of information that, in itself, might have suggested a need for follow-on examination.
 - d. (Criteria 2) Declarations, multilateral information sharing, satellite surveillance and visual inspection may improve the quality of information for identification of dual purpose activities for further examination.
 - e. (Criteria 3) Cross-checking between declarations, multilateral information sharing, satellite surveillance and visual inspection may provide an indicator of compliance, whereas an absence of correlation should require further clarification.
 - f. (Criteria 4) A computer/database to analyze data from declarations and from multilateral information sharing may require little additional resource over that required for either of these measures singly.
 - g. (Criteria 5) Declarations, multilateral information sharing, satellite surveillance and visual inspection may reduce the cost in certain circumstances.
- 3. No examples of enhanced limitations have been identified to date.
- 4. The results are summarized in the WP.89* Annex II format on the next page.

COMBINATION A: DECLARATIONS (6) MULTILATERAL INFORMATION SHARING (4), SATELLITE SURVEILLANCE (7) AND VISUAL INSPECTION (15)

	CRITERIA ENHANCED CAPABILITIES		ENHANCED LIMITATIONS
1.	Amount of information		
	Quality of information	- may indicate undeclared activities - may focus visual inspection	
	Other strengths or weaknesses	- may confirm other information and reinforce need for further examination - may remove concerns arising from other information that may have suggested further examination	
2.	Their ability to differentiate between prohibited and permitted activities	- may improve identification of dual purpose activities for further examination	
3.	Their ability to resolve ambiguities about compliance - cross-checking may provide an indicator of compliance		
4.	Technological requirements		
	Material requirements		
	Manpower requirements		
	Equipment requirements	- a single computer/database could be used	
5.	Financial	- may reduce cost	
	Legal		
	Safety		
	Organizational		
6.	Impact on permitted activities		
	Impact on CPI		

Annex II/4

<u>COMBINATION D: DECLARATIONS (6)</u> MULTILATERAL INFORMATION SHARING (4) AND VISUAL INSPECTION (15)

- 1. Declarations (6), multilateral information sharing (4), and visual inspection (15) have been evaluated in accordance with WP.113 using the approach in Amex I.
- 2. The following examples of enhanced capabilities have been identified to date:
 - a. (Quality) Declarations, multilateral information sharing and visual inspection may provide indications of undeclared activities.
 - b. (Quality) Declarations and multilateral information sharing may, focusing the visual inspection, improve the quality of information and reduce cost.
 - c. (Criteria 2) Declarations, multilateral information sharing and visual inspection may improve identification of dual purpose activities and other items for further examination.
 - d. (Criteria 3) Cross-checking between declarations, multilateral information sharing and visual inspection may provide an indicator of compliance, whereas an absence of correlation should require further clarification.
 - e. (Criteria 4) A computer/database to analyze data from declarations and from multilateral information sharing may require little additional resources over those required for either of these measures singly.
- 3. The following example of an enhanced limitation has been identified to date:
 - a. (Criteria 1) Declarations, multilateral information sharing and visual inspection may inhibit the provision of information.
- 4. The results are summarized in the WP.89* Annex II format on the next page.

\(\scrt{COMBINATION D: DECLARATIONS (6)}\) MULTILATERAL INFORMATION SHARING (4) AND VISUAL INSPECTION (15)

	CRITERIA	ENHANCED CAPABILITIES	ENHANCED LIMITATIONS
1.	Amount of information		- may reduce the provision of information
	Quality of information	- may indicate undeclared activities - may focus visual inspection	
	Other strengths or weaknesses		
2.	Their ability to differentiate between prohibited and permitted activities	- may improve identification of dual purpose activities and other items for further examination	
3.	Their ability to resolve ambiguities about compliance	- cross-checking may provide an indicator of compliance	
4.	Technological requirements		
	Material requirements		
	Manpower requirements		
	Equipment requirements	- a single computer/database could be used	
5.	Financial	- may reduce cost	
	Legal		
	Safety		
	Organizational		
6.	Impact on permitted activities		
	Impact on CPI		

MEASURES IN COMBINATION

COMBINATION E: DECLARATIONS (6) AND INFORMATION MONITORING (1, 2, 3, 4)

- 1. Declarations (6) together with Information Monitoring (Surveillance of publications (1), surveillance of legislation (2), declarations on transfers, transfer requests (3) and multilateral information monitoring (4) have been evaluated in accordance with WP.113 using the approach in Annex I.
- 2. The following examples of enhanced capabilities have been identified to date:
 - a. (Quality/5) Declarations in combination with Information monitoring may assist in the selection and application of identifiers/key words for the analysis of data improving quality and reducing cost.
 - b. (Criteria 3) Cross-checking between declared and monitored data may provide an indicator of compliance, whereas an absence of correlation should require further clarification.
 - c. (Criteria 3) Declarations in combination with Information monitoring may improve identification of dual purpose activities for further examination.
 - d. (Criteria 4) A computer/database to analyze data from declarations and from information monitoring may require little additional resources over those required for declarations or for a single information monitoring measure.
- 3. No examples of enhanced limitations have been identified to date.
- 4. The results are summarized in the WP.89* Annex II format on the next page.

MEASURES IN COMBINATION

$\frac{\text{COMBINATION E: DECLARATIONS (6) AND INFORMATION MONITORING}}{(1,2,3,4)}$

	CRITERIA	ENHANCED CAPABILITIES	ENHANCED LIMITATIONS
1.	Amount of information		
	Quality of information	- may assist in the selection and application of identifiers/cords	
	Other strengths or weaknesses		
2.	Their ability to differentiate between prohibited and permitted activities		
3.	Their ability to resolve ambiguities about compliance	- cross-checking may provide an indicator of compliance - may improve identification of dual purpose activities for further investigation	
4.	Technological requirements		
	Material requirements		
	Manpower requirements		
	Equipment requirements	- a single computer/data base could be used	
5.	Financial	- may reduce cost	
	Legal		
	Safety		
	Organizational		
6.	Impact on permitted activities		
	Impact on CPI		

APPLICATION OF COMBINATION METHODOLOGY

- 1. The procedure being adopted to carry out the combination methodology of WP.113 is as follows:
- a. The capabilities for each measure of the combination will be reviewed to determine whether an enhanced capability results. This will be listed as an enhanced capability in the combination WP..89* Annex II matrix.
- b. The limitations for each measure of the combinations will be reviewed to determine whether the combinations result in the elimination or reduction of the limitations. Any such eliminations or reductions will be included as an enhanced capability in the combination WP.89* Annex II matrix.
- c. The limitations for each measure of the combinations will be reviewed to see whether there are any enhanced limitations. Any such enhanced limitation will be included as such in the WP.89* Annex II matrix.
- 2. In accordance with WP.113 the enhanced capabilities or enhanced limitations listed are those which have resulted from synergy between the individual measures.

Annex II

AGENDA AND PROGRAMME OF WORK

Agenda

- 1. Opening of the meeting by the Chairman.
- 2. Adoption of Agenda and Program of Work.
- 3. Evaluation, in accordance with the mandate of the Ad Hoc Group, of the identified potential verification measures, singly and in combination, from a scientific and technical standpoint which had been examined during the second session.
- 4. Consideration of issues related to VEREX-4, including the final report of the Group.
- 5. Other matters, including the question of financial arrangements.
- 6. Consideration and adoption of the summary of the session.

Draft Program of Work⁶

24 May	25 May	26 May	27 May	28 May
OPENING OF THE SESSION CONTINUATION OF EVALUATION A. Development (Binder) B. Production (Bovallius) C. Stockpiling (Monteleone-Neto)	4. Declarations (Duncan) 7. Surveillance by satellite (Vachon) 8. Surveillance by aircraft (Vachon) 9. Ground-based surveillance (Beck) 10. Sampling and verification (off-site) (Bovallius)	16. Identification of key equipment (Bovallius) 17. Auditing (on-site) 18. Sampling and verification (on-site) (Binder) 19. Medical examinations (Negut) 20. Continuous monitoring by instruments (Monteleone-Neto) 21. Continuous monitoring by personnel (Monteleone-Neto)	Continuation on rapporteurs' drafts Measures 1-10	SUMMING UP OF EVALUATION 1. Surveillance of publications (Gevers) 2. Surveillance of legislation (Gevers) 3. Data on transfers and transfer requests and on production (Gevers) 4. Multilateral information sharing (Gevers)
1. Surveillance of publications (Gevers) 2. Surveillance of legislation (Gevers) 3. Data on transfers and transfer requests and on production (Gevers) 4. Multilateral information sharing (Gevers) 5. Exchange visits	11. Observation (Mohammadi) 12. Auditing (off-site) 13. International arrangements 14. Interviewing (Mohammadi) 15. Visual inspection (Mohammadi)	Measures in combination/ synergium (Bursilius, Pearson)	Measures 11-21	5. Exchange visits 6. Declarations (Duncan) 7. Surveillance by satellite (Vachon) 8. Surveillance by aircraft (Vachon)

31 May	1 June	2 June	3 June	4 June
Consultations on rapporteurs' drafts	CONTINUATIONOF SUMMING UP OF EVALUATION 9. Ground-based surveillance (Beck) 10. Sampling and identification (off-site) (Bovallius) 11. Observation (Mohammadi) 12. Auditing (off-site)	18. Sampling and identification (on-site) (Binder) 19. Medical examination (Negut) 20. Continuous monitoring by instruments (Monteleone-Neto) 21. Continuous monitoring by personnel (Monteleone-Neto)	EXCHANGE OF VIEWS ABOUT VEREX-4 REPORT	CONSIDERATION OF VEREX-3 SUMMARY
Continuation of consultations	13. International arrangements 14. Interviewing (Mohammadi) 15. Visual inspection (Mohammadi)	Measures in combination/ synergium (Bovallius, Pearson)	EXCHANGE OF VIEWS ABOUT VEREX 4 REPORT	CONSIDERATION AND ADOPTION OF VEREX-3 SUMMARY

The Program of Work offers a tentative arrangement that can be handled in a flexible manner. The time allocated to the consideration of agiven measure will depend on the complexity of issues pertaining to its evaluation. The order of considering the measures might be adjusted if the need arises.

31 May	1 June	2 June	3 June	4 June
	16. Identification of key equipment (Bovallius) 17. Auditing (on-site)			

ANNEX III

VEREX Report

- 1. Character of the Report
 - 1.1 Description of the work from a scientific and technical standpoint;
 - 1.2 To be adopted by consensus, taking into account views expressed in the course of its work.
- 2. Elements of the Report
 - 2.1 Summary Report;
 - 2.2 Annex (VEREX 1-3 summaries).
- 3. Summary Report
 - 3.1 Short and readable;
 - 3.2 4-5 pages.
- 4. Structure of the Summary Report
 - 4.1 Introduction;
 - 4.2 Identification and examination;
 - 4.3 Evaluation of measures singly;
 - 4.4 Evaluation of measures in combination;
 - 4.5 Other aspects (three broad areas, types and quantities ...);
 - 4.6 Conclusions.

ANNEX IV

<u>List of documents submitted to the third session</u> 24 May - 4 June 1993

Document symbol	<u>Title</u>
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BWC/CONF.III/VEREX/5 Agenda

BWC/CONF.III/VEREX/6 Summary of the work of the Ad Hoc Group for the

period 24 May to 4 June 1993

Working papers

BWC/CONF.III/VEREX/WP.97 Rapporteur's introduction to the Evaluation, entitled

"Surveillance by Satellite"

Rapporteur: Mr. Gordon Vachon

BWC/CONF.III/VEREX/WP.98 Rapporteur's introduction to the Evaluation, entitled

"Surveillance by Aircraft"

Rapporteur: Mr. Gordon Vachon

BWC/CONF.III/VEREX/WP.99 Working paper submitted by Canada, entitled

"Collateral Analysis and Verification of Biological

and Toxin research in Iraq"

BWC/CONF.III/VEREX/WP.100 Working paper submitted by Canada, entitled

"Collateral Analysis and Verification of Biological and Toxin Research: A Second Case Study"

BWC/CONF.III/VEREX/WP.101 Working paper submitted by Canada, entitled

"Collateral Analysis and Verification of Biological

and Toxin Research: A Third Case Study"

BWC/CONF.III/VEREX/WP.102 Working paper submitted by Canada, entitled

"Collateral Analysis and Verification of Biological

and Toxin Research: the Final Case Study"

BWC/CONF.III/VEREX/WP.103 Working paper submitted by Australia, entitled

"Verification Measure for the BWC"

BWC/CONF.III/VEREX/WP.104 Working paper submitted by the United Kingdom,

entitled "Evaluation Auditing (Off-Site and On-

Site)"

BWC/CONF.III/VEREX/WP.105	Working paper submitted by France, entitled "Evaluation of Sampling and Identification (On-Site)"
BWC/CONF.III/VEREX/WP.106	Working paper submitted by Romania, entitled "Evaluation of Medical Examination (On-Site)"
BWC/CONF.III/VEREX/WP.107	Working paper submitted by Sweden, entitled "Production and Acquisitions"
BWC/CONF.III/VEREX/WP.108	Working paper submitted by Sweden, entitled "Introduction to the Evaluation of Identification of Key Equipment (On-Site)"
BWC/CONF.III/VEREX/WP.109	Working paper submitted by Sweden, entitled "Introduction to the Evaluation of Sampling and Identification (Off-Site)"
BWC/CONF.III/VEREX/WP.110	Rapporteur's introduction to the Evaluation, entitled "Information Monitoring" Rapporteur: Mr. M. Gevers
Add.1	Annexes 4 to 8 of WP.110
BWC/CONF.III/VEREX/WP.111	Rapporteur's introduction to the Evaluation, entitled "Information Monitoring" - A case-study" Rapporteur: Mr. M. Gevers
Corr.1	Modification of title of BWC/CONF.III/VEREX/WP.111
	(Working paper submitted by The Netherlands, entitled "Information Monitoring - a Case-study. A contribution to the evaluation potential verification measures")
BWC/CONF.III/VEREX/WP.112	Working paper submitted by The Netherlands- Canada, entitled "Bilateral Trial Inspection in a Large Vaccine Production Facility. A contribution to the evaluation of potential verification measures"
BWC/CONF.III/VEREX/WP.113	Working paper submitted by the United Kingdom- Sweden, entitled "Evaluation of Verification Measures in Combination"

BWC/CONF.III/VEREX/WP.114	Rapporteur's introduction to the Evaluation, entitled "Ground-Based Surveillance Measures" Rapporteur: Mr. V. Beck
BWC/CONF.III/VEREX/WP.115	Working paper submitted by Germany, entitled "Notification and declarations - Producers of Human Vaccines"
BWC/CONF.III/VEREX/WP.116	Working paper submitted by Germany, entitled "Sampling and Identification - Reference Laboratories"
BWC/CONF.III/VEREX/WP.117	Working paper submitted by Germany, entitled "Sampling and Identification - Data on Reference Strains"
BWC/CONF.III/VEREX/WP.118	Working paper submitted by Germany, entitled "Sampling and Identification - Transport of Toxic and Infectious Samples"
BWC/CONF.III/VEREX/WP.119	Working paper submitted by Germany, entitled "On Determining Types and Quantities of Biological Agents"
BWC/CONF.III/VEREX/WP.120	Rapporteur's introduction to the Evaluation, entitled "Interviewing (On Site)" Rapporteur: Mr. A.A. Mohammadi
BWC/CONF.III/VEREX/WP.121	Rapporteur's introduction to the Evaluation, entitled "Visual Inspection (On-Site)" Rapporteur: Mr. A.A. Mohammadi
BWC/CONF.III/VEREX/WP.122	Working paper submitted by Brazil entitled "Potential Verification Measures - Stockpiling and Storage" (Moderator's paper)
BWC/CONF.III/VEREX/WP.123	Working paper submitted by the United States of America, entitled "On Site Sampling and Identification"
BWC/CONF.III/VEREX/WP.124	Working paper submitted by the United States of America, entitled "Off-Site Sampling and Identification"

BWC/CONF.III/VEREX/WP.125	Working paper submitted by the United States of America, entitled "Evaluation On-Site: Exchange Visits"
BWC/CONF.III/VEREX/WP.126	Working paper submitted by the United States of America, entitled "Evaluation Declarations"
BWC/CONF.III/VEREX/WP.127	Working paper submitted by the United States of America, entitled "Evaluation Off-Site: Remote Sensing, Surveillance by Satellite"
BWC/CONF.III/VEREX/WP.128	Working paper submitted by the United States of America, entitled "Evaluation Off-Site: Remote Sensing, Surveillance by Aircraft"
BWC/CONF.III/VEREX/WP.129	Working paper submitted by the United States of America, entitled "Evaluation Off-Site: Remote Sensing, Ground-Based Surveillance"
BWC/CONF.III/VEREX/WP.130	Working paper submitted by the United States of America, entitled "Off-Site: Observations"
BWC/CONF.III/VEREX/WP.131	Working paper submitted by the United States of America, entitled "Evaluation Off-Site: Auditing"
BWC/CONF.III/VEREX/WP.132	Working paper submitted by the United States of America, entitled "Evaluation On-Site: Interviewing"
BWC/CONF.III/VEREX/WP.133	Working paper submitted by the United States of America, entitled "Evaluation Visual Inspections (On-Site)"
BWC/CONF.III/VEREX/WP.134	Working paper submitted by the United States of America, entitled "On-Site: Identification of Key Equipment"
BWC/CONF.III/VEREX/WP.135	Working paper submitted by the United States of America, entitled "Evaluation On-Site: Auditing"
BWC/CONF.III/VEREX/WP.136	Working paper submitted by the United States of America, entitled "On-Site: Medical Examination"
BWC/CONF.III/VEREX/WP.137	Working paper submitted by the United States of America, entitled "Continuous Monitoring"

BWC/CONF.III/VEREX/WP.138	Rapporteur's introduction to the Evaluation, entitled "Observation (Off-Site)" Rapporteur: A.A. Mohammadi
BWC/CONF.III/VEREX/WP.139	Working paper submitted by Canada, entitled "Potential Verification Measures for the Biological and Toxin Weapons Convention (BTWC): Sampling and Identification"
BWC/CONF.III/VEREX/WP.140	Working paper submitted by the United Kingdom, entitled "On-Site Sampling and Identification in Commercial Sites in BWC Verification"
BWC/CONF.III/VEREX/WP.141	Working paper submitted by the United Kingdom, entitled "UK Practice Inspection: Pharmaceutical Pilot Plant"
BWC/CONF.III/VEREX/WP.142	Working paper submitted by Iran, entitled "Detection and Identification of Biological Agent and Toxins by Instrumental Methods"
BWC/CONF.III/VEREX/WP.143	Working paper submitted by Sweden and the United Kingdom, entitled "Suggested Methodology for Identifying Combinations of Interacting Measures"
BWC/CONF.III/VEREX/WP.144	Working paper submitted by Brazil, entitled "Evaluation: Continuous Monitoring by Instruments and by Personnel" Rapporteur: Mr. R. Monteleone-Neto
BWC/CONF.III/VEREX/WP.145	Working paper submitted by Iran, entitled "Medical Examination"
BWC/CONF.III/VEREX/WP.146	Working paper submitted by France, entitled "Introduction to the Evaluation - Development" Moderator: Mr. P. Binder
BWC/CONF.III/VEREX/WP.147	Working paper submitted by the United Kingdom, entitled "UK Practice Inspection: Pharmaceutical Pilot Plant"
BWC/CONF.III/VEREX/WP.148	Working paper submitted by Sweden and the United Kingdom, entitled "FOCs on the Combination of Interacting Measures - Application of Combination Methodology"

BWC/CONF.III/VEREX/WP.149	Working paper submitted by India, entitled "Introductory Paper by the Indian Delegation - Verification Regimes for BW Agents"
BWC/CONF.III/VEREX/WP.150	Statement of the Non-Aligned and Other Developing Countries Before the Meeting of the Ad Hoc Group
Evaluations of the Measures	
BWC/CONF.III/VEREX/WP.151	Surveillance of Publications Rapporteur: Mr. M. Gevers
BWC/CONF.III/VEREX/WP.152	Surveillance of Legislation Rapporteur: Mr. M. Gevers
BWC/CONF.III/VEREX/WP.153	Data on Transfers, Transfer Requests and Production Rapporteur: Mr. M. Gevers
BWC/CONF.III/VEREX/WP.154	Multilateral Information Sharing Rapporteur: Mr. M. Gevers
BWC/CONF.III/VEREX/WP.155	Exchange Visits (Off-Site) Rapporteur: Mr. T. Dashiell
BWC/CONF.III/VEREX/WP.156	Declarations Rapporteur: Ms. A. Duncan
BWC/CONF.III/VEREX/WP.157	Surveillance by Satellite (Off-Site) Rapporteur: M. G. Vachon
BWC/CONF.III/VEREX/WP.158	Surveillance by Aircraft (Off-Site and On-Site) Rapporteur: Mr. G. Vachon
BWC/CONF.III/VEREX/WP.159	Ground-Based Surveillance Rapporteur: Mr. Volker Beck
BWC/CONF.III/VEREX/WP.160	Sampling and Identification (Off-Site) Rapporteur: Mr. Å. Bovallius
BWC/CONF.III/VEREX/WP.161	Observation (Off-Site) Rapporteur: Mr. A.A. Mohammadi
BWC/CONF.III/VEREX/WP.162	Auditing (Off-Site)

Rapporteur: Mr. J. Noble

BWC/CONF.III/VEREX/WP.163	International Arrangements (On-Site) Rapporteur: Mr. T. Dashiell
BWC/CONF.III/VEREX/WP.164	Interviewing (On Site) Rapporteur: Mr. A.A. Mohammadi
BWC/CONF.III/VEREX/WP.165	Visual Inspection Rapporteur: Mr. A.A. Mohammadi
BWC/CONF.III/VEREX/WP.166	Identification of Key Equipment (On-Site) Rapporteur: Mr. Å. Bovallius
BWC/CONF.III/VEREX/WP.167	Auditing (On-Site) Rapporteur: Mr. J. Noble
BWC/CONF.III/VEREX/WP.168	Sampling and Identification (On-Site) Rapporteur: M. P. Binder
BWC/CONF.III/VEREX/WP.169	Medical Examination of Verification (On-Site) Rapporteur: Mr. N. Negut
BWC/CONF.III/VEREX/WP.170	Continuous Monitoring by Instruments Rapporteur: Mr. R. Monteleone-Neto
BWC/CONF.III/VEREX/WP.171	Continuous Monitoring by Personnel Rapporteur: Mr. R. Monteleone-Neto
*	* * * *
BWC/CONF.III/VEREX/WP.172	The Epidemiological Approach: A way to Find Useful Combinations" Rapporteur: Mr. R. Monteleone-Neto
BWC/CONF.III/VEREX/WP.173	Working paper submitted by France, entitled "Tentative Evaluation of Combinations of Some Off-Site and On-Site Measures"
BWC/CONF.III/VEREX/WP.174	Working paper submitted by the Russian Federation, entitled "Methodology to Examine Potential Verification Measures for Compliance with the Provisions of the BW Convention
BWC/CONF.III/VEREX/WP.175	Working paper submitted by Mr. V. Beck, entitled "Types and Quantities of Microbial and Other Biological Agents and Toxins"

Conference Room Papers

BWC/CONF.III/VEREX/CRP.26 Draft Agenda

BWC/CONF.III/VEREX/CRP.27 Draft Programme of Work

BWC/CONF.III/VEREX/CRP.28 Draft summary of the Work of the Ad Hoc Group

for the Period 24 May to 4 June 1993

Information Papers

BWC/CONF.III/VEREX/INF.1/Rev.2 List of States Parties of the Convention on the

Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin

Weapons and on Their Destruction

BWC/CONF.III/VEREX/INF.6 List of Participants

BWC/CONF.III/VEREX/INF.7 List of Documents submitted to the Third Session,

24 May - 4 June 1993

Miscellaneous Papers

BWC/CONF.III/VEREX/MISC.3 Suggested Schedule for Consultations

BWC/CONF.III/VEREX/MISC.4 Provisional List of Participants

Background documentation submitted by

BWC/CONF.III/VEREX/NONE.52 BWC Verification: Q-fever Switzerland

BWC/CONF.III/VEREX/NONE.53 Suggested Methodology for the Rapporteurs for the

Evaluation of Measures

Sweden and the United Kingdom

BWC/CONF.III/VEREX/NONE.54 Tabulation of interacting measures identified by

rapporteurs in order of priority

Mr. Å. Bovallius and Mr. G. Pearson

Drafts of the Evaluation of the Measures⁷

BWC/CONF.III/VEREX/NONE.55 Draft of the Evaluation Surveillance of Publications

These papers went through several revisions and were issued as Working Papers 151 to 171

Rapporteur: Mr. M. Gevers

BWC/CONF.III/VEREX/NONE.56 Draft of the Evaluation Surveillance of Legislation

Rapporteur: Mr. M. Gevers

BWC/CONF.III/VEREX/NONE.57 Draft of the Evaluation Data on Transfers, Transfer

Requests and Production Rapporteur: Mr. M. Gevers

BWC/CONF.III/VEREX/NONE.58 Draft of the Evaluation Multilateral Information

Sharing

Rapporteur: Mr. M. Gevers

BWC/CONF.III/VEREX/NONE.59 Draft Evaluation of Exchange Visits as a Potential

Verification Measure for the BWC

Rapporteur: Mr. T. Dashiell

BWC/CONF.III/VEREX/NONE.60 Declaration as a Potential Verification for the BWC

Rapporteur: Mr. A. Duncan

BWC/CONF.III/VEREX/NONE.61 Draft Evaluation: Surveillance by Satellite (Off-Site)

Rapporteur: Mr. G. Vachon

BWC/CONF.III/VEREX/NONE.62 Draft Evaluation: Surveillance by Aircraft (Off-Site

and On-Site)

Rapporteur: Mr. G. Vachon

BWC/CONF.III/VEREX/NONE.63 Draft Evaluation of Measure Ground-Based

Surveillance

Rapporteur: Mr. V. Beck

BWC/CONF.III/VEREX/NONE.64 Draft Introduction to the Evaluation of Sampling and

Identification (Off-Site) Rapporteur: Mr. Å. Bovallius

BWC/CONF.III/VEREX/NONE.65 Draft of the Evaluation of Observation

Rapporteur: Mr. A.A. Mohammadi

BWC/CONF.III/VEREX/NONE.66 Draft of the Evaluation of "Off-Site Auditing"

Rapporteur: Mr. J. Noble

BWC/CONF.III/VEREX/NONE.67 Draft Evaluation of Exchange Visits as a Potential

Verification Measure for the BWC

Rapporteur: Mr. T. Dashiell

BWC/CONF.III/VEREX/NONE.68 Draft of the Evaluation of On-Site Interviewing

BWC/CONF.III/VEREX/NONE.69 Draft Evaluation of Visual Inspection

Rapporteur: Mr. A.A. Mohammadi

BWC/CONF.III/VEREX/NONE.70 Draft Introduction to the Evaluation of Identification

of Key Equipment (On-Site) Rapporteur: Mr. Å. Bovallius

BWC/CONF.III/VEREX/NONE.71 Draft of the Evaluation On-Site Auditing

Rapporteur: Mr. J. Noble

BWC/CONF.III/VEREX/NONE.72 Evaluation of the "On-Site Sampling and

Identification Measure" Rapporteur: Mr. P. Binder

BWC/CONF.III/VEREX/NONE.73 Draft of the Evaluation - Medical Examination "On-

Site" Measure of Verification Rapporteur: Mr. M. Negut

BWC/CONF.III/VEREX/NONE.74 Continuous Monitoring by Instruments

Characteristics and Technologies Rapporteur: Mr. R. Monteleone-Neto

BWC/CONF.III/VEREX/NONE.75 Continuous Monitoring by Personnel

Rapporteur: Mr. R. Monteleone-Neto

BWC/CONF.III/VEREX/NONE.76 Examples of Measures in Combination to be

Evaluated in Accordance with WP.113

BWC/CONF.III/VEREX/NONE.77 Measures in Combination

Mr. Å. Bovallius and Mr. G. Pearson

BWC/CONF.III/VEREX/NONE.78 Measures in Combination

Combination B: Information Monitoring (1,2,3,4)

BWC/CONF.III/VEREX/NONE.79 Measures in Combination

Combination C: On-Site Inspection (14, 15, 16, 17,

18)

BWC/CONF.III/VEREX/NONE.80 Measures in Combination

Combination A: Declarations (6), Multilateral Information Sharing (4), Satellite Surveillance (7)

and Visual Inspection (15)

BWC/CONF.III/VEREX/NONE.81 Measures in Combination

Combination D: Declarations (6), Multilateral Information Sharing (4) and Visual Inspection (15)

BWC/CONF.III/VEREX/NONE.82 Measures in Combination

Combination E: Declarations (6) and Information

Monitoring (1,2,3,4)

BWC/CONF.III/VEREX/NONE.83 Types and Quantities of Microbial and other

Biological Agents and Toxins

BWC/CONF.III/VEREX/NONE.84 Development, Production and Acquisition,

Stockpiling and Retention

Moderators: Mr. P. Binder, Mr. Å. Bovallius and

Mr. R. Monteleone-Neto

ATTACHMENT 1

LIST OF PARTICIPANTS

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Mr. Mowafaq Maroki Second Secretary, Permanent Mission

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Mr. Zootomy Arab. Second Secretary, Delegation to the Conference on

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Lic. Sergio Sierra Bernal Primer Secretario, Misión Permanente

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Mr. Jostein Bernhardsen Minister, Permanent Mission

Mr. Bjorn P. Berdal Professor, Norwegian Defence Microbiological

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Mr. Kjell Tormod Pettersen First Secretary, Permanent Mission

OMAN

Mr. Abdullah M. Al-Farsy Permanent Representative

Mr. Mohammed Al-Hassan Second Secretary, Permanent Mission

Mr. Said A.M. Al-Amri Third Secretary, Permanent Mission

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Mr. Ahmad Kamal Head of Delegation, Ambassador, Permanent

Representative

Mr. Shahbaz Counsellor, Permanent Mission

PERU

Sr. Fernando Quir ós Segundo Secretario, Miembro de la Delegación

ante la Conferencia de Desarme

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Miss Lourdes O. Yparraguirre Second Secretary, Permanent Mission

Mr. Calixto V. Espejo Third Secretary, Permanent Mission

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Mr. WI, Sung Lac First Secretary, Permanent Mission

Mr. KIM, Chang Mo Security Policy Division

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Mr. HAHM, Kyung Soo Senior Director, Genetic Engineering Research

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REPUBLIC OF POLAND

Mr. Henryk Pac Counsellor, Permanent Mission

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Mr. Romulus Negut Ambassador, Permanent Representative

Mr. Florin Rosu First Secretary, Permanent Mission

Dr. Marian Negut National Institute of Microbiology "Cantacuzino",

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Mr. Serguei D. Tchouvakhine Head of Delegation, Permanent Mission, Ministry of

Foreign Affairs

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ATTACHMENT 2

(BWC/CONF.III/VEREX/WP.113)

EVALUATION OF VERIFICATION MEASURES IN COMBINATION

Combination methodology

The mandate states: "Such measures could be addressed singly or in combination". After measures have been evaluated singly, it is suggested that the approach to be adopted in considering measures in combination should be as follows:

- a. Rapporteurs will have identified measures which are potential candidates for combinations. In addition, delegations if they wish may bring any proposed combinations for evaluation to Sweden and the UK acting as friends of the Chair.
- b. To qualify as a successful combination, two or more measures when evaluated in combination according to the mandate criteria must result in synergistic value when compared to their value singly. This synergism will be represented by advantages and perhaps disadvantages, in addition to those identified for the measures singly.
 - c. Not all possible combinations of measures need to be evaluated.

ATTACHMENT 3

(BWC/CONF.III/VEREX/NONE.52)

BWC Verification: Q-Fever

1. Introduction

One of the key issues in a possible verification protocol of the BWC is the distinction between those activities that are allowed by the Convention and those that are not. It should be borne in mind that defensive activities are permitted, while offensive activities are not permitted. Offensive activities are the development, production (or acquisition) and the stockpiling (or retention) of agents, toxins, weapons, equipment and means of delivery. Research for defensive purposes such as the identification of agents, the development of protective measures and of vaccines may continue under the rules of the BWC.

For our project we have decided to concentrate on one single bacterial pathogen, *Coxiella burnetii*, the causative agent of Q-fever. We believe that concentration on a single pathogen allows us to identify the basic problems involved in most verification procedures, without setting ourselves the herculean task of studying dozens of different pathogens. Q-fever was chosen for several reasons: it has been on the list of potential B-weapon agents for many years, a great deal of data are accessible in the published biomedical literature and finally it is well known in Switzerland, having caused occasional local outbreaks (Depuis et al., 1987).

2. <u>Assumed conditions pertaining to sampling and identification during on-site inspections</u>

For our project we assume that a site of suspected agent production has been identified by a third party and that it is our task to find out whether the BWC is being violated in that location or not. We will further assume that we will not be permitted to remove any living microorganisms from the site, but only sterile materials, such as samples of fixed microorganisms inactivated by appropriate measures. This assumption is made because we believe that most countries will want to safeguard their industrial and trade secrets and will therefore not allow the export of potentially valuable strains which might be antibiotic producers or attenuated vaccine strains. Another reason for not allowing removal of live microorganisms may be a fear of other countries' infringement of vital national safety concerns of the inspected country. Often countries will not want to give away knowledge of where they stand in the development of defensive measures against biological weapons. The assumptions outlined above are, of course, based on political considerations and may not hold in all situations. It is clear, however, that on-site inspections will mostly be limited in scope by the regulations defined in the BWC and often additionally by the inspected country's reluctance to give unlimited access to outsiders.

A further assumption is made with respect to the amount of laboratory equipment and material that can be brought to the site, where the inspection is going to take place. We will take it for granted that about 1 m³ can be transported to the site, namely about the amount carried in a large car or a small van. It is furthermore assumed that only very limited facilities will be made

available on the premises by the inspected country. No equipment for electrophoresis, PCR etc. shall be assumed to be available on the spot.

3. Basics on Coxiella burnetii

The identification procedures are critically dependent on the microbiological characteristics of Coxiella burnetii. The bacteria of this species are very small and replicate only inside host cells. In the laboratory they are either grown in the yolk sac of embryonated chicken eggs or in mammalian cell cultures. While the cell culture system may be attractive for studies on the biology of the agent, chicken eggs are a simpler system for mass production of rickettsiae. Large amounts of rickettsiae could also be isolated from animal tissues, in particular from placentae. These bacteria form structures able to survive adverse external conditions for very long times. The spore-like structures have been observed to keep alive in soil for one year or more (Williams et al., 1990). The agent is not highly host specific: sheep and other farm animals can all serve as a reservoir for human infections. Transmission between animals is by direct contact or through insects. Humans are most often infected not by insects, but by direct exposure to dust from feces or from contact with placental material. A single airborne bacterium carried with dust particles is thought to be sufficient for infecting a human being and causing pneumonia. After spreading in the body the agent may later occasionally lead to chronic endocarditis. Different strains lead preferentially either to an acute or to a chronic infection. Those causing chronic disease often are more resistant to a series of different antibiotics (Yeaman and Baca, 1991). Depending on where they come from, phase I and phase II organisms can be distinguished (Hackstadt, 1988). Phase I bacteria come from human or animal infections and are themselves highly virulent. They are only weakly antigenic, but this low antigenicity is sufficient to elicit a protective immune response. The low antigenicity is due to a lipopolysaccharide covering the cell surface. Phase II bacteria are virulent and appear after multiple passages in cell cultures or embryonated chicken eggs. Antibodies against phase II bacteria are not strongly protective.

Material for vaccinations is not commercially available, but many attempts at experimental vaccination have been performed (Kazar and Rehacek, 1987). This has mostly been done with formalin or solvent inactivated or also with fractionated bacterial material. Chloroform-methanol extracted residues were shown to be effective both in animal models (Williams et al., 1986) and in human trials. Many years ago Russian scientists developed an attenuated strain of *Coxiella burnetii*, called M-44, but this proved to be rather unreliable as a live vaccine strain (Genig, 1968).

4. On-site sampling and identification

The inspection should start with a visual observation of the facilities and its immediate surroundings. What microbiological laboratory equipment is there? What production equipment is available? It is to be recalled that *Coxiella burnetii* can only be grown either in animal cells or in embryonated eggs. Are there fermenters for animal cells and storage facilities for media and for frozen sera? Are there large incubators for chicken embryos? What facilities are there for separating large amounts of pathogen from host cell components? Are there facilities for extracting large amounts of yolk sac material? Are there facilities for lyophilizing large amounts of cells or tissues? Are large amounts of fixed and inactivated whole cells of *Coxiella burnetii* or various

components of them being stored? What facilities are available for the storage of large amounts of enriched or purified live *Coxiella burnetii*?

For the on-site identification procedures we proposed to take samples of diverse cultures. These should include samples from small and large-scale cultures as well as from storage installations. In view of the limited amount of equipment available at the inspection site, only a tentative identification with relatively crude methods will be attempted. More detailed analyses will be done on fixed material removed from the site. On-site the following analyses will be done:

- 1. Microscopic observation after staining (Gimenez, 1964). This can only be used as a first indication of what pathogen might be present. The cultured animal cells stain green and should show small, red bacterial inclusions. If there are large amounts of embryonated chicken eggs, can one see typical inclusions in smears taken from the yolk sacs?
- 2. Immunofluorescence microscopy. By using several different antibodies it is possible not only to identify *Coxiella burnetii* as a species, but also to distinguish phase I from phase II organisms and furthermore to identify different strains or groups of strains.
- 3. ELISA. The same antibodies can be used as with IF. For this method, both positive and negative controls have to be available on the spot for a reliable assay. Methods 2 and 3 should in general give concordant information, at least when several different antibodies are used.

Further on-site experiments are not feasible, necessary or desirable. In particular on-site animal experiments are thought to be too unreliable to be worth doing, although information on the pathogenicity of the bacteria cultivated on the site would be very useful. For the off-site transportation of material, the bacteria can be fixed for 24 hours at room temperature in 1% formaldehyde. This sterilization procedure has been reported to reduce infectivity by a factor of 10^{11} , reducing it virtually to zero. In the formaldehyde solution the material is quite stable, can be shipped around and stored. For highly sensitive off-site analyses, material should not only be collected from cultures, but also from diverse spots in the buildings. In particular filters of the ventilation or air-conditioning systems are potential sources of microorganisms.

5. Off-site identification

In a well equipped laboratory with appropriately trained personnel, several different highly sensitive tests can be performed on the fixed samples brought from the suspected site of violation of the BWC. The most important test procedures are the following:

- 1. DNA hybridization. Several DNA probes are available for the identification of *Coxiella burnetti* (Mallavia et al., 1990).
 - ELISA as described above.
- 3. PCR. Several different procedures are available for species or strain identification. Based on different plasmids, which have been identified from *Coxiella burnetii*, it is possible to distinguish strains causing acute or chronic disease (Mallavia, 1991). Acute disease is only associated with the presence of plasmic QpH1. PCR requires only very small amounts of samples.

4. RFLP. If enough material is available, this method of DNA analysis produces a large amount of "fingerprint-like data". It will be particularly helpful to study the relatedness of different strains.

6. Evaluation of data

With the proposed procedures it is simple and straight forward to identify *Coxiella burnetii* and distinguish it from other bacteria. This can be achieved already with the on-site examinations outlined above. If large amounts of *Coxiella burnetii* are found, how can it be established whether this is for offensive purposes (in violation of the BWC) or for making a vaccine either for civilian or for military purposes?

It will be very hebful to know if the country in question has an established vaccination program for Q-fever. Possibly WHO has data on this. How many people are routinely being vaccinated in the inspected country? Does this involve the general population, the military or groups that are considered to be specifically at risk? It may be noted that in some countries vaccinations against Q-fever have in fact been carried out. In Australia, several thousand abattoir workers were vaccinated between 1981 and 1986 with inactivated *Coxiella burnetii* (Worswick and Marmion, 1985; Izzo et al., 1988).

If large-scale cultures of *Coxiella burnetii* are made by the inspected country with the purpose of producing an inactivated vaccine, this should be detectable from the storage facilities. The commonly used vaccine is made from formalin-fixed cells, which are subsequently extracted with chloroform-methanol. Presumably this material will be stored around 4°C and not a very low temperature, at which frozen, live bacteria would be kept. The inactivated material can perhaps be distinguished from live bacteria by a specific microscopic technique, but the effectiveness of such an unproven procedure is open to debate. a more clear-cut distinction can most likely be made by electron microscopy, though this may be difficult. Clearly the presence of large amounts of inactivated *Coxiella burnetii* does not manifest an infringement on the BWC.

The situation is more difficult if the inspected country claims that the large-scale production of *Coxiella burnetii* is used to make an attenuated vaccine. In the 1960s an attenuated strain of *Coxiella burnetii*, called M-44, was developed and tested quite successfully in both animal experiments and in trials with humans. This strain or also other attenuated strains do not seem to have been developed or used much since then (Johnson et al., 1977).

If an attempt is made to produce an attenuated vaccine, facilities for large-scale storage of live bacteria would be necessary. These should be looked for and identified. The storage would almost likely be done at -20°C or a still lower temperature. Alternatively lyophilized preparations can be stored at a concentration of about 10¹¹ CFU per mg material. The identification procedures outlined above will easily establish the species. The strain identification can also be done, if the M-44 strain is being used as a live attenuated vaccine strain and if antibodies against that particular strain are available for immunofluorescence and ELISA tests. Unfortunately the M-44 strain cannot be obtained from ATCC. If a new strain has been developed by the inspected country, the situation is more difficult. In this case the inspection team would have to procure both the new vaccine strain and its parent strain. The parent strain will presumably have been used for challenge infections to test the efficacy of the new vaccine strain and should therefore be available. It is proposed that both

strains are subjected to RFLP analysis off-site. It is highly likely that in this analysis differences will be found between the two strains. If this is in fact the case, then it will be possible to decide whether the large amounts of stored live or also lyophilized *Coxiella burnetii* are from the pathogenic parent strain or from the attenuated vaccine strain. In the first case, an infringement of the BWC is highly likely, in the second case not. However, other scenarios cannot be totally excluded. One possibility is that a fraudulent mix-up of strains could have been instigated. A further possibility would be that strains display a certain degree of natural instability, even though there is no indication of this in the literature.

7. Conclusions

For most situations the proposed inspection scheme can identify a violation of the BWC with a high degree of reliability. The posed inspection procedure is quite simple and should be acceptable to most countries. Even if violations under specific circumstances can be missed with this procedure, the mere existence of an internationally accepted verification protocol substantially reduces the temptation of countries to evade the regulations of the BWC.

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ATTACHMENT 4

(BWC/CONF.III/VEREX/WP.150)

STATEMENT OF THE NON-ALIGNED AND OTHER DEVELOPING COUNTRIES
BEFORE THE MEETING OF THE AD HOC GROUP OF GOVERNMENTAL EXPERTS TO
IDENTIFY AND EXAMINE POTENTIAL VERIFICATION MEASURES FROM a
SCIENTIFIC AND TECHNICAL STANDPOINT
GENEVA, 4 JUNE 1993

Mr. Chairman.

At the outset, please allow me, on behalf of the Non-Aligned and Other Developing Countries to express our appreciation for the manner with which you are presiding over the meeting of the Ad Hoc Group of the Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint.

Mr. Chairman.

Bearing in mind that the Ad Hoc Group is now approaching the final stage of its work, the Non-Aligned and Other Developing Countries would like to use this opportunity to solemnly reiterate their commitment to the work of the Ad Hoc Group to identify and examine potential verification measures from a scientific and technical standpoint, as mandated by the Third Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, in 1991. While fully subscribing to this end, the Non-Aligned and Other Developing Countries would like to stress, however, that within the remaining time, the Ad Hoc Group should spare no effort in trying to identify and examine potential verification measures from a scientific and technical standpoint which, in our opinion, should be the least intrusive as possible, while still reliable and capable of deterring any States Parties from engaging in or being involved with activities which run counter to the object and purpose of the Convention In order to do so, it is our considered view that such exercises should, first of all, take into account the existing conditions in all States Parties to the Convention, especially that of the developing countries, thereby avoiding any infringement of their legitimate interests in the field of bio-technological development for peaceful purposes, as well as their national sovereignties, as recognized by international law.

We regret to note that, so far, the exercise carried out in the Ad Hoc Group has concentrated on accommodating the interests of the developed countries. These countries have proven to possess resources, capabilities, expertise and technology enabling them to conduct the work of the Group without due regard to the legitimate interests and concerns expressed by developing countries.

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ANNEX IV

VEREX 4- PROCEDURAL REPORT

Procedural Report

- 1. In accordance with the mandate adopted by the Third Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction in 1991 and the agreement reached at the third session of the Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint, the Group held its fourth session in Geneva from 13-24 September 1993 under the Chairmanship of Ambassador Tibor Tóth (Hungary). Ambassador Gérard Errera (France) and Mr. Ali a. Mohammadi (Iran, Islamic Republic of) served as Vice-Chairmen of the Group. During its fourth session, the Group held 18 meetings and 12 informal meetings. The Chairman also conducted a series of informal consultations during the same period.
- 2. The following 41 States Parties to the Convention participated in the session of the Group: Argentina, Australia, Austria, Brazil, Bulgaria, Canada, Chile, China, Cuba, Czech Republic, Finland, France, Germany, Greece, Hungary, India, Indonesia, Iran (Islamic Republic of), Iraq, Ireland, Italy, Japan, Mexico, Netherlands, New Zealand, Norway, Oman, Pakistan, Republic of Korea, Poland, Romania, Russian Federation, Slovak Republic, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Thailand, United Kingdom of Great Britain and Northern Ireland, United States of America. The list of participants is attached (see Attachment I).
- 3. The representative of the World Health Organization (WHO) also participated as an observer of the meeting, upon invitation of the Chairman.
- 4. The Group was assisted by staff members from the Centre for Disarmament Affairs, Mr. Timur Alasaniya, Political Affairs Officer, Secretary to the Group and Ms. Olga Sukovic, Senior Political Affairs Officer, Deputy Secretary.
- 5. At its first meeting on 13 September, the Group adopted its agenda as well as a programme of work for the session. The agenda and programme of work are attached to the present summary as Attachment II. The agenda provided for the consideration of the Report of the Group in accordance with the mandate of the Ad Hoc Group.
- 6. The following experts assisted the Chairman as Friends of the Chair on different measures: Mr. D.S. Agarwal (India), Mr. V. Beck (Germany), Mr. Å. Bovallius (Sweden), Mr. A.A. Mohammadi (Iran, Islamic Republic of), Mr. R. Monteleone-Neto (Brazil), Mr. G. Vachon (Canada).

ATTACHMENT I

Ad Hoc Group of Governmental BWC/CONF.III/VEREX/INF.8

Experts to Identify and Examine 23 September 1993

Potential Verification Measures

from a Scientific and Original: ENGLISH/FRENCH/

Technical Standpoint SPANISH

Fourth Session

Geneva, 13-24 September 1993

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Ad Hoc Group of Governmental BWC/CONF.III/VEREX/INF.8/Corr.1

Experts to Identify and Examine 24 September 1993

from a Scientific and Original: ENGLISH/FRENCH/

Technical Standpoint SPANISH

Fourth Session Geneva, 13-24 September 1993

Potential Verification Measures

LIST OF PARTICIPANTS

STATES PARTIES

Corrigendum

Page 4, amend the list for FRANCE to read as follows:

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à la Conférence du Désarmement

M. Jean-Luc Florent Premier Secrétaire à la Représentation à la

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M. Nicolas Warnery Sous-Direction du Désarmement

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M. Claude Eon Directeur du Centre d'Etudes du Bouchet, Ministère de la

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Dr. Patrice Binder Médecin en chef des Armées, Chef du groupe

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Col. Jean-Paul Peroz Conseiller Militaire à la Représentation à la

Conférence du Désarmement

Attachment II

AGENDA

- 1. Opening of the meeting by the Chairman.
- 2. Adoption of Agenda and Programme of Work.
- 3. Consideration of the Report of the Group.
- 4. Other matters, including the question of financial arrangements.
- 5. Adoption of the Report of the Group.

PROGRAMME OF WORK

Monday 13 September	11.00 am	Opening of the session. Beginning of consideration of the Report.
	3.00 pm	Continuation of consideration of the Report.
Tuesday 14 September	10.00 am	Continuation of consideration of the Report.
	3.00 pm	Informal consultations.
Wednesday 15 September	10.00 am	Continuation of consideration of the Report.
	3.00 pm	Informal consultations.
Thursday 16 September	10.00 am	Continuation of consideration of the Report.
	3.00 pm	Continuation of consideration of the Report.
Friday 17 September	10.00 am	Informal consultations.
	3.00 pm	Informal consultations.
Monday 20 September	10.00 am	Continuation of consideration of the Report.
	3.00 pm	Continuation of consideration of the Report.
Tuesday 21 September	10.00 a.m	Continuation of consideration of the Report.
	3.00 pm	Continuation of consideration of the Report.
Wednesday 22 September	10.00 am	Continuation of consideration of the Report.
	3.00 pm	Continuation of consideration of the Report.
Thursday 23 September	10.00 am	Other matters.
	3.00 pm	Other matters.
Friday 24 September	10.00 am	Adoption of the Report.
	3.00 pm	Adoption of the Report.
