Working Group on the Strengthening of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

6 December 2023

English only

Third Session Geneva, 4-8 December 2023 Agenda item 6 Identifying, examining and developing specific and effective measures, including possible legally-binding measures, and making recommendations to strengthen and institutionalize the Convention in all its aspects within the mandate of the Working Group

Contemporary problems of verification under the BTWC. Historic work experience of the VEREX and the Ad Hoc Group of States Parties to the BTWC

Submitted by the Russian Federation





BIOLOGICAL WEAPONS CONVENTION

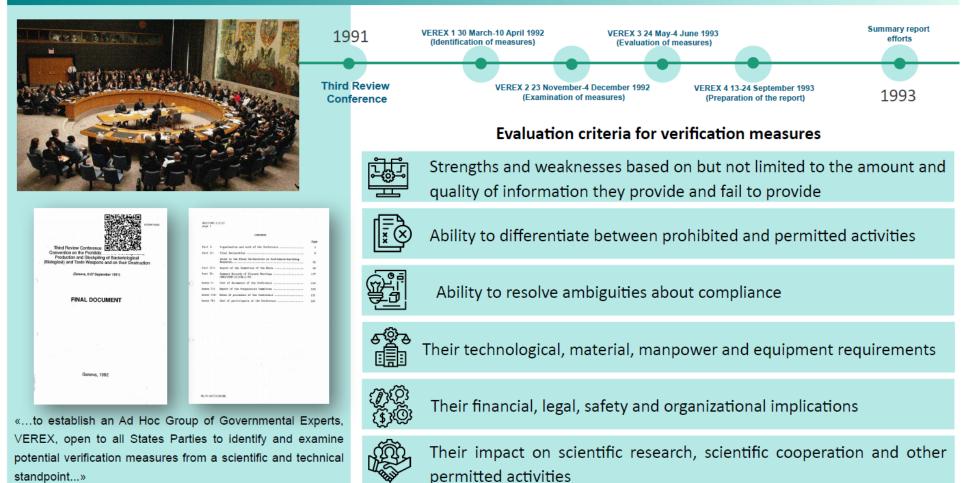
WORKING GROUP ON THE STRENGTHENING OF THE BTWC

Problems of BTWC verification at the present stage.

Historical Perspectives of VEREX and the Ad Hoc Group

Dr. Dmitrii Poklonskii

VEREX GROUP, GOAL-SETTING AND WORKING METHODOLOGY



BWC/WG/3/WP.13

METHODOLOGICAL APPROACHES TO ASSESSING THE EFFECTIVENESS OF VERIFICATION MEASURES



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The quality of information on the use of a verification measure may be examined differently. On the one hand, it may simply be the volume of information, while on the other - it may be understood as a quantity measure of information



Prognosis models have to be developed to quantify criteria 5 and 6 on a number of parameters and subjects for prohibition and their scope have to be specified for criteria 2 and 3

Verification	Relati	ve VM e	ffectiven	ess R	elative V	M costs	ion	Swedish experts evaluation
measures	R&D evalua tion	-facility	Storage facility cvalua- tion	R&D evalua- tion	Prod. facility cvalua- tion			12.8 7.3
Surveillance of publications	8,2	10,7	8,9	12,6	14,0	14,5	- 1	-
Declarations	7,2	7,4,	9,2	15,5	15,9	16.0	- 8	15,0
Notifications	8,6	8,5	11,1	15,5	15,8	15,8	- 8	15,0
Surveillance by satellite	13,4	12,2	11,7	7,2	7,4	7,4	- 8	
Surveillance by aircraft	13,0	112,0	11,5	9,1	8,5	8,6	- 8	14,8
Ground-based surveillance	11,3	11,2	11,6	9,3	9,1	9,1	- 1	11,8
Sampling and identificat (off-site)	ion 12,9	11,9	13,1	6,5	6,0	6,7	- 1	14,6
Observation	12,2	12,2	12,4	10,3	9,7	9,6	- 8	12,3
Auditing (off-site)	11,2	11,4	12,6	11,3	11,0	11,0	- 8	a despert
International arrangements	8,8	12,5	12,7	9,4	10,3	93	- 1	10,7
Interviewing	6,1	7,4	7,4	9,5	9,8	9,1	- 8	5,3
Visual inspection	8,9	74	6,0	9,1	8,7	9,7	- 8	4,7
Identification of key equipment	6,5	5,1	4,4	8,8	8,6	8,5	- 1	3,5
Auditing (off-site)	4,5	5,1	3,5	7,3	6,7	7,2	- 8	5,3
Sampling and identificati (on-site)	on 5,4	5,2	4,5	4,0	4,0	3,9	- 1	2,8
Medical examination	6,8	6,2	8,3	6,8	6,8	6,7		8,5
Continuous monitoring by instruments and personnel	5,3	6,1	3,4	1,8	1.4	1,5		80

Table 1

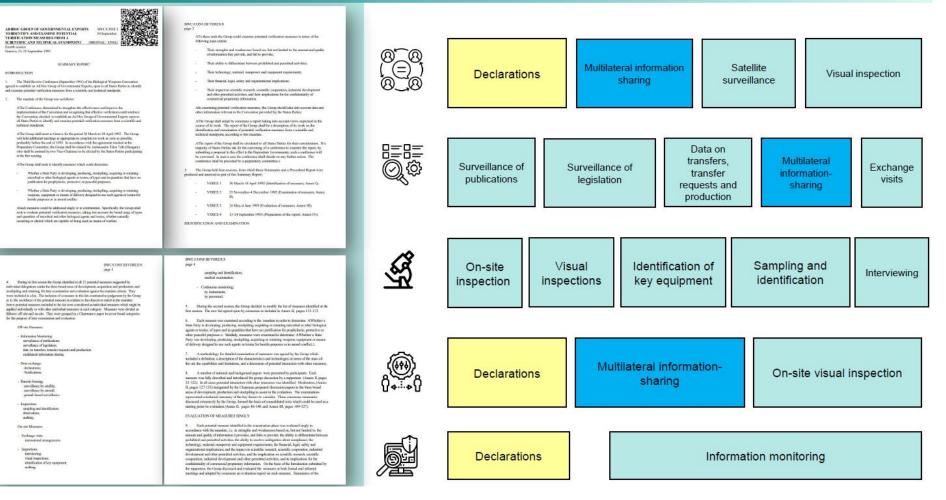
Table 2

VEREX GROUP, VERIFICATION MEASURES

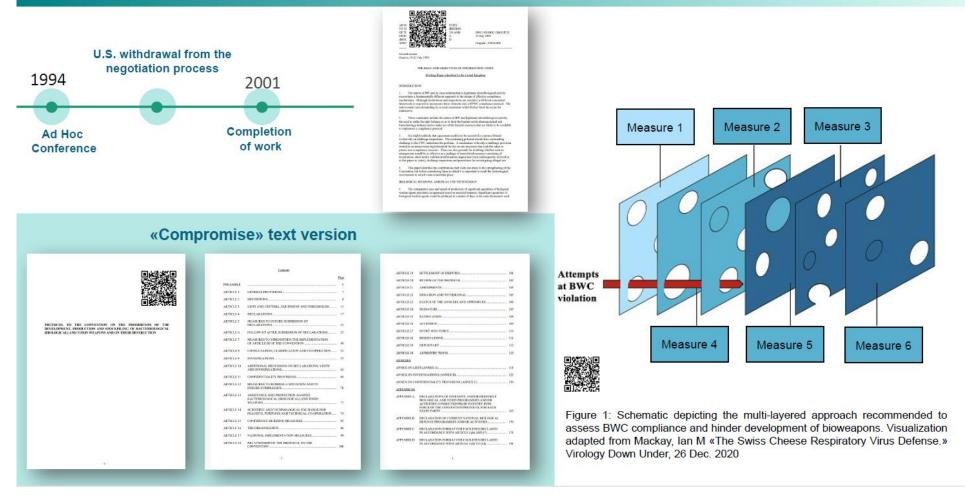
Off-site	2	ရှိသည် ကြည်ကို On-site	A a max capacity the VLIES NATION In the constraints on the Analysis of the constraints on the Analysis and analysis of the VLIES NATION and and analysis of the VLIES NATION and analysis of the VLIES NATIO	PROJECTION CONTENT (Pro) Part Provid	Process the contrast part of t
 Information Monitoring Data exchange Remote sensing 		Č,	Gener, Kisk-Jang-20 menungan series to the law loss in the series of the menungan series to the series of the seri	The second secon	 and yes, "Init figure and the interval titleness," indexing a state of the discount of the discou
ă		 Auditing on-site 	 The NA is the other of flower brief ways to the isometry in the state is the other of the other of the state is the other of the other othe other other other other other other other other other other	Outforwardin'ty inem - Manasar S. HENSY Palant (Semany) - Manasar Manasar S. Hensy Control Hensyllic Manasar S. Hensyllic - M. Alt Hensyllic - M. Alt Hensyllic - Manasar	b. Throughout the form was of the benchest searches, but memory and the searchest searchest searchest searchest throughout the searchest searchest searchest through the searchest searchest searchest through the searchest searchest searchest searchest searchest searchest searchest searchest searchest searchest searchest searchest searchest searchest searchest searchest searchest searchest searchest se
Multilateral information sharing	Surveillance of pub	lications 🕢 Surveillance of legislation	Ber Karles, Kruzzy, Katsian, Kuri, Kurigaram, Kutar, Berning, Katsian, Kuri, Kurigaram, Kutar, Kurigara, Kurisan, Kur	But of the Optimizing But of the Optimizing I have been approximately a second secon	It. A waiting is it is domain a proving a set of the set of t
) Data on transfers, transfer requests and on production	⊖ Exchange visits - int arrangements	ernational Declarations 	A THE GROUP OF THE STATES TARTES	194036/1952 (1967/1921/9411) Janu V Janu V	Heroto TIDC GROUPS (Per 1) Mero Mero
Visual inspection (off-site)	isual inspection (off-site) \bigcirc Surveillance by satellite		The second secon	Angunate for fastic constitutions is the of Point of the Code as a stream of constitution of the Code HERCES I HERCES I HERCES I HERCES IN A STREAM OF THE OFFICE AND A STREAM OF THE HERCES IN A STREAM OF THE OFFICE AND A STREAM OF THE OFFICE AND A STREAM OF THE ADDREAM OF THE OFFICE AND A STREAM OF THE OFFICE AND A STREAM OF THE ADDREAM OF THE OFFICE AND A STREAM OF THE OFFICE AND A STREAM OF THE ADDREAM OF THE OFFICE AND A STREAM OF THE OFFICE AND A STREAM OF THE ADDREAM OF THE OFFICE AND A STREAM OF THE OFFICE AND A STREAM OF THE ADDREAM OF THE OFFICE AND A STREAM OF THE OFFICE AND A STREAM OF THE ADDREAM OF THE OFFICE AND A STREAM OF THE OFFICE AND A STREAM OF THE ADDREAM OF THE OFFICE AND A STREAM OF THE OFFICE AND A STREAM OF THE ADDREAM OF THE OFFICE AND A STREAM OF THE OFFICE AND A STREAM OF THE ADDREAM OF THE OFFICE AND A STREAM	ANNEE DI INVESTIGATIONE 1 FILLE INVESTIGATIONE 1 FILLE INVESTIGATIONE 1 FILLE INVESTIGATIONE 1 FILLE INVESTIGATIONE 1 FILLE INVESTIGATIONE 1 FILLE INVESTIGATIONE 1 CONTINUE OF LIATENCE OF LIATENCE IN 1 CONTINUE OF LIATENCE OF LIATENCE OF LIATENCE IN 1 CONTINUE OF LIATENCE OF LIATENCE IN 1 CONTINUE OF LIATENCE OF LIATENCE OF LIATENCE IN 1 CONTINUE OF LIATENCE OF LIATENCE OF LIATENCE IN 1 CONTINUE OF LIATENCE OF LIATENCE IN 1 CONTINUE OF LIATENCE OF LIATENCE OF LIATENCE IN 1 CONTINUE OF LIATENCE OF LIATENCE OF LIATENCE IN 1 CONTINUE OF LIATENCE OF LIATEN
Sampling and identification (on-site)	\bigcirc Surveillance by air	(off-site)	Net 11 Net 1 Northus Frankrike United to Constant Northus of the Constant Northus of the Constant	 Norto taking, patient, mshipit, or effective apper or meter. International and the other back appears, and the other back appears and a contributed production of the patient of the other back appears. International appearships and appears and	
) Interviewing (on-site)	 Identification of key equipment (on-site 	() Continuous monitoring bu	ARTICLE 1 [DRIVEN, IF INVESTING] 5 ARTICLE 1 [DRIVEN, IF AND RED VEG 7 ARTICLE 1 (DRIVEN, ISA AND RED VEG 7 ARTICLE 1 (DRIVEN, ISA AND RED VEG 7 ARTICLE 1 (DRIVEN, ISA AND RED VEG 16 ARTICLE 1 (DRIVEN, ISA AND RED VEG 16 ARTICLE 1 (DRIVEN, ISA AND RED VEGA 16	 (c) To exclude complexity the possibility of the next of hermitingical biological partial in taking as sequence. (c) but is near sequence. (c) To finitize and three to legist to provide an a to off-head space of sequence and provide space of the sequence of the sequence. (c) To finitize and three to legist to provide an a to finite or off-head space of the sequence. 	
		(\rightarrow) Sampling and identification	ARECLE VI SCENARIO, AND TREPORTORICAL EXCHANGE FOR PRACHEL AREPORT AND TREPORTOR AND TREPORT ARECLE IN THE OPERATION OPERATION OPERATION	(b) compared against and to have the parameter perspect and and to hange it the occurrence and subhorking its of occupants of Theorem Paralises. (6) No Network to use the provisions of the Convention to impose modelutions on the Standards on transfile for paragrams considered with the algorithm and providers of the Convention of the interfile knowledge, including a sphere and an extender.	
Exchange visits (off-site)	(→) Auditing (off-site)	(off-site)	ASHERA INICIAL ALLANDA IL LISTA AND CONTRILLA (ACENTS AND TOXINS)	(d) are Ta easile specific measures to ensure effective and full implementation of Anticle X of the Convention.)	

VEREX GROUP. METHODOLOGICAL ASPECTS OF THE USE OF VERIFICATION MEASURES

6



ACTIVITIES OF THE AD HOC GROUP (AHG). REPORT OF THE AD HOC GROUP

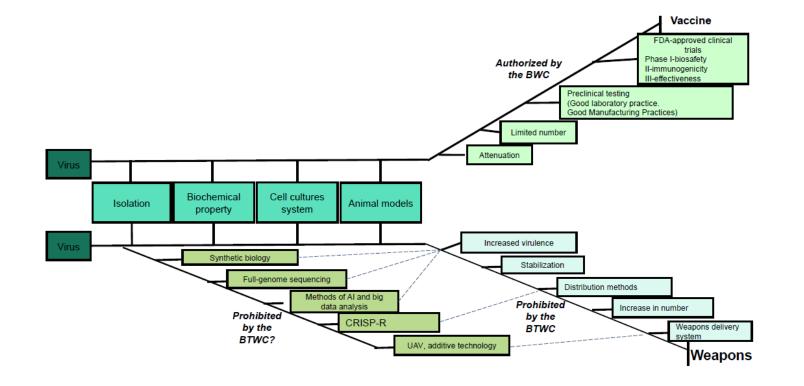


ACTIVITIES OF THE AD HOC GROUP (AHG). PROJECT OF PROTOCOL

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And water And water <t< td=""><td></td><td> All and ansatures i character share has the did if the share of the share share has the share has the share has the share share has the share share has the share share has the share sha</td><td>Surveillance of publications</td><td>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)</td><td>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 focussing ongoing inspection activities. The information provides only a partial picture of activities. This focussing could be done by using key identifiers. Not all types of relevant information are necessarily published. (VEREX/9, Annex III, p. 154 etc.)</td><td>If focussed this measure need not be very costly. Some personnel with specific expertise and a computer database would be needed. Translation services might be costly. The low level of intrusiveness of this measure is an advantage.</td></t<>		 All and ansatures i character share has the did if the share of the share share has the share has the share has the share share has the share share has the share share has the share sha	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 focussing ongoing inspection activities. The information provides only a partial picture of activities. This focussing could be done by using key identifiers. Not all types of relevant information are necessarily published. (VEREX/9, Annex III, p. 154 etc.)	If focussed this measure need not be very costly. Some personnel with specific expertise and a computer database would be needed. Translation services might be costly. The low level of intrusiveness of this measure is an advantage.
Carenda, forbilde resulting due to due to agreed to soil de subsidinguid anteresentation data de data de due due construction de la construction de la construction de la construction de la construction de la construction de la construction de la construction de la construction de la construction d	TIS OF SIMTE	Final Section 1. Section 2. Se	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 focussed this measure is not very costly. The precise requirements of this measure still need to be determined. A computer/ database is needed. Legal implications and confidentiality concerns need to be considered; access to CPI can be defined.
125 100 50% of State Parties reporting 75 50 43 42 39 42 17 21 19 25 17 21 19 51 52 46 41 38 41 25 17 21 19 51 52 46 41 38 41 51 52 50 50 50 50 50 50 50 50 50 50 50 50 50		83 78 80 82 85 92 69 69 65 72 73 78 80 82 85 92 25% of State Parties reporting	Surveillance of legislation	Collecting and analyzing 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 focussing 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 into a computer/ database is needed. Translation costs may be substantial. Limited impact, if any, on permitted activities.
Confidence Building N by 2022, to		reports submitted	Criteria 1 Criteria 4	fail to provide Ability to differentiate betw Ability to resolve ambiguit -6 Their technological, mate Their financial, legal, saf	erial, manpower and equipment requirements. ety and organizational implications. research, scientific cooperation, industrial developn	

VACCINE DEVELOPMENT AND WEAPONS DEVELOPMENT ARE NOT PARALLEL



CURRENT SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENTS AND THEIR POTENTIAL IMPACT ON INTERNATIONAL SECURITY AND DISARMAMENT

Additive manufacturing based on 3-D printing technologies Big data analysis and artificial BIG DATA intelligence technologies

Nanotechnology and materials science

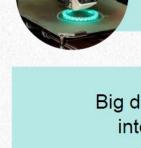
Biological research automation and robotics

9

Report of the Secretary-General



Current developments in science and technology and their impact on international security and disarmament efforts







NEW TECHNOLOGY PLATFORMS IMPACT **ON THE IMPLEMENTATION OF INDIVIDUAL BWC ARTICLES** ⊕⊕⊡ It is necessary to keep track of scientific and technological advances that go far beyond Methodological approaches Article I the traditional understanding of biological weapons, but at the same time reduce to the formation of technical barriers to the development and delivery of BW equipment lists The digitization of biological data and the growing possibilities for DNA sequencing and Article III editing pose serious non-material challenges to existing export control regimes and **=** practices Terms and definitions A number of new technologies raise serious ethical, biosafety and biosecurity issues. It may be necessary to reassess whether states are actually taking «necessary measures Article IV to prohibit and prevent the development, production and stockpiling» of biological weapons Lists of biological agents and toxins New technologies (big data and DNA sequencing) provide a much wider range of Article VI possibilities with which to confirm or refute the validity of alleged violations of the BTWC Threshold quantities of New technologies increase the speed and efficiency of response to disease outbreaks biological materials ್ಠ್ಯಂ Article VII and could also be important in helping states at risk from BWC violations Conducting Digitizing biological data fundamentally changes the way scientists can share Article X inspections and information and collaborate for peaceful purposes audits

TERMS AND DEFINITIONS

11

BWC/WG/3/WP.13





Protection against biological weapons – measures for the prevention, abatement and elimination of the effects of bacteriological (biological) and toxin weapons on humans, animals and plants

Program of protection against biological weapons – a set of research and development activities directed towards the implementation of measures for the prevention, abatement and elimination of the effects of bacteriological (biological) and toxin weapons on humans, animals and plants





Presumed use of a biological weapon – a declaration by a State, based on observation of biological agents, means of delivery and their use, to the effect that biological and/or toxin weapons have been used against it

Terms related to the entire set of verification measures under the Protocol

- >) Terms related to the criteria for evaluating declarations
- \bigcirc Operational terms and definitions applicable in the various sections of the Protocol

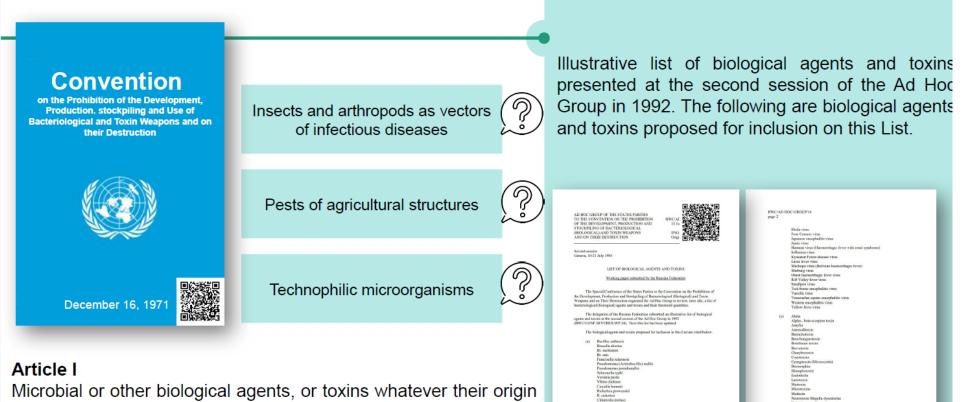
Unusual outbreak of a disease – the emergence and spread of an infectious disease whose origin and clinical characteristics fundamentally distinguish it from other diseases that are typical of a specific locality over a lengthy period of time



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LISTS OF BIOLOGICAL AGENTS AND TOXINS

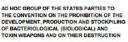
12



Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes

CRITERIA FOR INCLUSION OF MICROORGANISMS AND TOXINS IN THE LIST

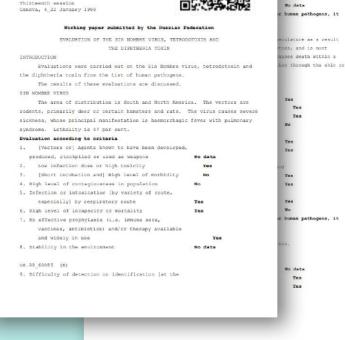
The criteria proposed by the Ad Hoc Group





No data

Thirteenth session



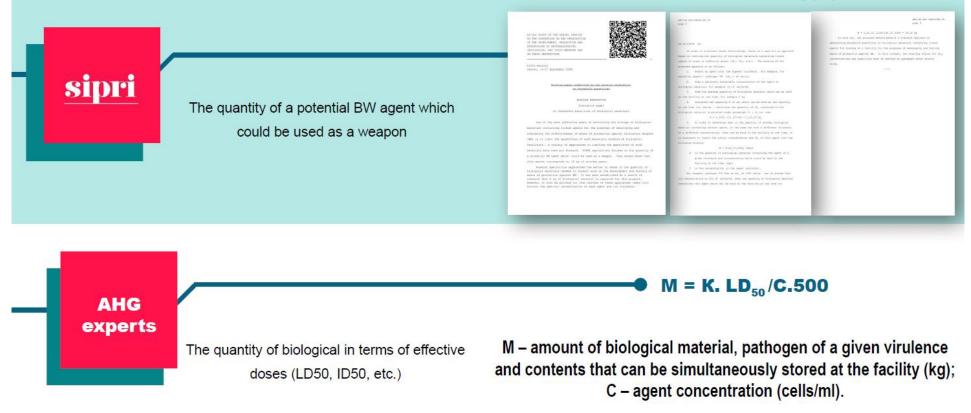
High levels of morbidity and/or infectiousness Infection or intoxication by respiratory route 紫 Low infection dose or high toxicity £33 High level of incapacity or mortality No effective prophylaxis and/or therapy available (4) and widely in use Stability in the environment ١. Difficulty of detection or identification Ease of manufacture, ease of storage, and stability of stockpiles Psychological consequences of the threat of use or any (Æ suspected use Means known to have been used as a weapon or assessed as ٢ weapon



DEFINING THRESHOLD QUANTITIES OF BIOLOGICAL MATERIALS

14

Working paper



KEY EQUIPMENT INFORMATION

Permentation equipment -2-

YES

128 ... 80 ...

Severators

YES

YE8

VES

YES

TE5

Tiltration equipment

Cell disruption equipment

Includes all fermenters, biotescitors, chemostets and continuour-flow forsemention systems mainful for the production of intern-impaired or table for the for the former of the system of the system of the system Egypment for batch fermentation with a reportry of over 00 litres.

Equipment for continuous fermentation with a capatity of over \$0 liters.

Centrifugel separators or tanks for continuous or semi-continuous operation with a separity of over 100 litres per hour.

Botor continuous-flow centrifuges with a capacity of over 100 litres per hour:

Cross-flow targential equipment having a filter area of 5 square metres and above:

Cell disruption equipment negable of continuous operation Authout the percess of seconds and having a flow fate greater than if threes per hour:

15



Marking paper submitted by the Sussian Friezetian The States patties shall submit declarations it accordance with the following formate:

C. French Ices a biological weapons protection programs exist)

Yes/Hp 2. From B

To be completed for feallities participating in a BM protection programs which are carrying out work with any micro-organisms and toning, as well as with materials that imitate their properties; 1. Hene of facility

3. Location (address and geographical location)

1. Ownership (government department or company) 1.List the Miclogical agents and tomins on which work is being carried own

5. Inducts the main arrest of activity in the facility (divilegents of performance and methods, observation, identification, general employations controlology) variance dynamic and other activities related to the perposes of the Convention)

6. Are there areas with a B1-4 containment level? Vee. No. 7. Indicate all equipment present.

141 -. Indicate all equipment present. Temperation equipment Includes all fermenters, bioreactors, chemostats and continuous-flow fermentation systems suitable for the production of micro-organisms or subspyctic cells or for the production of textus. Equipment for betch fermentation with a capacity of over 300 litres. 125 Equipment for constructs fermentation with a capacity of over 50 litrasi 183 ····

Separators Centrifugel separators or tasks for continuous or semi-continuous operation with a capacity of over 100 litres pay hours

185 ···· 10 ···· motor continuous-rico centrifuges with a capacity of over 100 Livro set hour: 185 ···· Filtration equipment

Cross-flow tangential equipment having a filter area of 5 speare metres and above: NES Cell discution equipment

Call distription equipment republe of continuous operation unthing the release of accounts and maring a flow rate greated than in three per hour

Draing equipment Hence-drying, freese-drying and other drying equipment with a contensor capating greater than 5 by per day. TES Hilling equipment Hilling equipment capable of producing grains with a maximum grain size of 10 micross and heving a production capacity of over ... Mg par hour: 188 ····

Necosol chambers Various types of serosol chambers and other equipment for tudy of characteristics of micro-organism estosols, their components, including toxins, or other hological meterisist 183 81

4. Form D To be completed for facilities producing veccines and/or anatoxins to protect homais and enimals against biological agents and toxins included in the List: 1. Went of fecility.

S.Loostion indicess and grographical loostical 3. Types of vaccine produced. L. FORM E.

To be completed for facilities having areas with bicsefety level 4 (BL 4 as specified in the 1950 WHO Laboratory Bicsefetry Hervall. L. HADE OF TROLLLTY

Spray-drying, freeze-drying and other drying equipment with a condensey capacity greater than 5 by per days 728 ···· 80 ···· Hilling equipment Milling equipment sepatcle of producing grains with a maximum grain mize of 10 microim and having a production capacity of over ... Ng par hours

-5-

Taying equipment

1288 Asrosol charDers Terious types of serosol chambers and other equipment for study of characteristics of micro-organism seconds, their components, including toxins, or other biological materials:

302 1. Form C To be completed for facilities as which work is seried our on biological agents and textus included in the list (except for discoverie facilities).

L. Mane of Facility 1.Location (address and geographical location)

1. Deservice (povermient department or company) 4.List the biological epents and toxins on which work is being carried ont

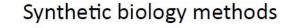
Turlists the main symmet of activity to the facility identicement of preventive spects and methods, cherrenium, identification upsettle manufaction of activity valuatory davidentian and other activities related to the purposes of the (convection)

6. Are there premises with a 51-4 level of bicasfety? Ten/No

2. LOISTIGE (ADDIESS AND Designations location) 2. Donesahip

t. Lebonsonur eres with bicosfery level + (82-4), in substr b. Indicate listed pathogene on which work is being carried out at the facility

4. Inducess the main estats of outivity in the facility developments of potentive parts and methods, observation, descritization) genetic Manipulation secondary tokinology isinfection and other activities related to the purposes of





Directed synthesis methods





Separators





Filtration equipment





CONDUCTING INVESTIGATIONS



Investigation into an alleged breach of obligations under the provisions of the Convention



specific

on-site

sampling and analysis procedures.

The basic principles and procedures for considering requests related to alleged violations of the BTWC have been defined.

The procedure for filing and considering

verification measures.

a complaint (request) has been determined; its contents, as well as the structural elements of the investigation, including



Investigation into the alleged use of biological weapons

At the same time, emphasis is placed on maximum use of the potential of Articles V and VI of the Convention and specific procedures for their implementation are proposed.

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16

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investigating alleged voltations of its provisions. All that is exemis is the spall and the desails of the presentations involved. A possible percedure for tarrying out such investigations agent include the following fastic elements: (A sequent relation to as alleged beach of the convention

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PROTECTING PROPRIETARY INFORMATION DURING INVESTIGATIONS

- (e) In meeting the requirements to provide access, the receiving State Party shall be under the obligation to provide the greatest degree of access possible, taking into account any constitutional obligations it may have with regard to proprietary rights or searches and seizures;
- (f) The receiving State Party shall make every reasonable effort to demonstrate its compliance with the Convention and, to this end, to enable the investigation team to fulfil its mandate.

29. The receiving State Party shall have the right to take measures, as it deems necessary, to protect national security and/or to protect confidential information and data (including commercial proprietary information) in accordance with the provisions of this section and taking into account its obligations under this Protocol. Such measures may include but shall not be limited to the following:

- (a) Removal of sensitive papers from office spaces and direct view;
- (b) Shrouding of sensitive displays, stores, and equipment;
- Shrouding sensitive pieces of equipment, such as computer or electronic systems;
- (d) Logging off of computer systems and turning off data indicating devices;
- (e) Using random selective access techniques whereby the team is requested to select a given percentage or number of buildings of their choice to investigate; the same principle can apply to the interior and content(s) of sensitive buildings or documents;
- (f) Limiting the number of team members who have access to certain buildings, structures or places within the area specified in paragraphs 36 and 39;
- (g) Limiting the viewing angle;
- (h) Limiting the time investigation team members may spend in any area or building;
- (i) At any time during the investigation, notifying the investigation team of the products and processes that involve national security and/or the protection of confidential information and data (including commercial proprietary information) and its rights to an eguard them. It may request that if a specific pace or information is released to the team, it should be accorded the most stringent protection measures in conformity with the confidentiality provisions of this Protocol.

30. If the receiving State Party provides less than full access to places, activities or information, it shall make every reasonable and feasible effort to provide alternative means to demonstrate compliance and to clarify the possible non-compliance concern that generated the investigation. The nature and extent of access, including any alternative means to demonstrate compliance, provided by the receiving State Party, and the extent to which this

- 61 -

enabled the investigation team to fulfil its mandate, shall be recorded factually in the investigation report.

31. These provisions may not be invoked by the receiving State Party to conceal any evasion of its obligations not to engage in activities prohibited under the Convention.

32. The investigation plan shall be handled in accordance with Annex B (80) and (149) to (153).

33. The investigation team shall take into consideration suggested modifications of the investigation plan and proposals which may be made by the receiving State Party, at any stage of the investigation, including the pre-investigation briefing, to ensure, *inter alia*, that sensitive equipment, information or places are protected.

34. The investigation team shall conduct the investigation in the least intrusive manner possible consistent with the effective and timely implementation of its mandate. As a rule, it shall begin with the procedures it deems least intrusive and proceed to more intrusive procedures only as required to fulfil its mandate.

35. If the investigation team considers it necessary in order to fulfil its mandate, the investigation team shall have the right to request clarification in connection with ambiguities that may arise during an investigation. Such requests shall be made promptly to, or through the representative of the receiving State Party. The representative shall make every reasonable effort to provide the investigation team with such clarification as may be necessary to remove the ambiguity.

Field investigations

36. The receiving State Party shall provide access within the investigation area within 48 hours after arrival of the investigation team at the point of entry in order to conduct activities in accordance with this Article and Annex B, Parts A and B for the duration of the investigation as specified in Annex B (73).

37. The receiving State Party shall provide access in accordance with paragraph 28 within the investigation area for the sole purpose of enabling the investigation team to conduct specific on-site activities identified in, and in accordance with Amex B (84) to (111). The extent and nature of access within the investigation area shall be negotiated between the investigation team and the receiving State Party in accordance with paragraphs 28 to 35. Such negotiated access, in accordance with paragraphs 28 to 35, shall allow access to all humans, animals and/or plants that may have been affected by microbial or other biological gents or toxins directly related to the non-compliance concerne being investigated.

38. The access provided for in these paragraphs shall not interfere or impede with any national measures taken to deal with the outbreak of disease.

Facility investigations

39. The receiving State Party shall provide access within the requested and, if different, final perimeter as soon as possible but not later than 108 hours after the notification of the receiving State Party of the request for an investigation in accordance with paragraph 20.

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- Shrouding sensitives pieces of equipment such as computers or electronic systems
- Logging off computer systems and turning off data indicating devices
- Using random selective access techniques whereby the team is requested to select a given percentage or number of building of their choice to investigate; the same principle can apply to the interior and content(s) of sensitive building or documents
- Removal of sensitive papers from direct view

Limiting the time investigation team members may spend in any area or building, while allowing the team to fulfill its mandate

RESULTS OF TWO TRIAL INSPECTIONS IN ACCORDANCE WITH VEREX CRITERIA, RESULTS OF THE WORK OF THE EXPERT GROUP

18

Al four forge of Consensations (prove a Socialized and Consensations) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a Socialized and Consensation) prove a Socialized and Consensation (prove a S

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THE NETHERLANDS - CANADA

Bilateral Trial Europedien in a Large Vacine Prediction Facility A contribution to the evaluation of potential selfication manarrea

A. INTRODUCTION

For a number of matom is wan considered useful to resolve the total inspection in an "instantism" way: Is store model, the scientific bit room for book the impactors and the representatives of the impact fulfilly to should notif roles so various matalists and dataset installs aspect of the impaction.

The resours that this "intervative" model was charact ward (i) this BMC trial imported too first of its list expression by the basis Paulia isochrid; (i) contrary to the short the first this map; CMC trial importance starks, no negotiated shift protect importion protections existed; and (i) the protections (see if an isoli impaction years on a

> compliance assessment Invisionii (a) sofety. (b) teas size and secorts.

proposed precedence, has no evolvate power-all DWC verification measure identified by VEREX, most of which were sell in an nerby stage of development, it was the canadame view data, by using the "generative evolut", On expertise available within the campany analto and or in histor exists.

PRINCIPAL FINIDANS AND CONCLUSIONS
 to this solid impension, the impension sum (IT) was able to determine, in the final

and production moonly more consistent with what one would expect in a vacuproduction field by.

significant diversion of acrivity, equipment or matchial us the production of biological weapons or tanks at the vaccine production facility inspected. A detailed facility declaration and the analysis of off-site information played important

of the impection, the last time the impection will likely take, and the ment focused at efficient the impection effort will be.

6. The nost effective way to their the legitimacy of the full light activity was to perform const-their of the relating to different maps of activity/processing at the facility. This means their verification means were applied to contribution. It was concluded that the contributing of measures would be manufail to an effective on-size impaction.

 During the trial improvion, issues relating to conversial confidentiality did not stand the way of the effective random of the improvian. Some sensitivities were noted, is solutions were at hard.

6. In the case of ambiguides, clasification did rogine preser levels of densil is information provided by the facility. In general, visit did no: lead so problems of connervisi annalosity, although is monoiness required some effort and time to complie the sweeter information. Make a strength of the size of ping terms reserve involvements at the che. There were not strengt several laterer during the impaction.
Is any involve the size of t

 Visual importion (country), applied in surjunction with other resources, was also as investigation of the contractor resources in No couldres relating to confidentially.

A tavailation of key explorent was an input at apart of the declaration prior to the toportion and in the pro-toportion terrifes at the facility. Certain technical (but annicategy) contrains in the qualitation of explorent was speed. Thus, all diffusion territory and or diffusion territory and a stability decreme proved president in the force-toport of explorent to be facility. (a contract toport with the user of such as the stability of compared present to be facility.)

1. Stepping and iterafication was downad with company sees lows. Confidentially common depended way much are the type of winkinguption to the detail and the respective levelspondulipation process as which analyse integration there. See, and all low analysis from the site would have been of great assessme to the company proverse, co-clim analysis regulation would have been provided by the facility had the results of a sampless of more than the means and contention to the greation.

13. Auditing in a particularly important and of the IT. Is previous the basis for transsteading as the different suggest of specials at the facility. It sides provides the apparentity to exploring of transmittening these, as well as of directinging and developed products, with explored auditor instandardal requirements.

12). Motival manifestation was limited during the imposition to the summarized or protocol vacilation memory. Motival essentiation of the inference most laws have quite courly, had it is involved the interruption of the series at equivalence. Theremer, involved assumations of elements in the faulty was carried on or not would be indicated or it remost estimates. he purpose of the two day trial inspection was to evaluate a number of potential verification measures as identified by VEREX

The Mill unclastic in each area are reasoning being. HOTS 4. Access at this perficiency of the off present any performance of the performance of the second second second exception of the off deep least of the second second second exception of the off deep least of the second second second exception of the off deep least of the second second second exception of the off deep least of the second second second exception of the second second second second second second second exception of the second second second second second second second exception of the second second

Constraints for allowing the description and an observed as a second second

c. The laws also to solve matrixing in formation to foreflational probability of the solution of the soluti

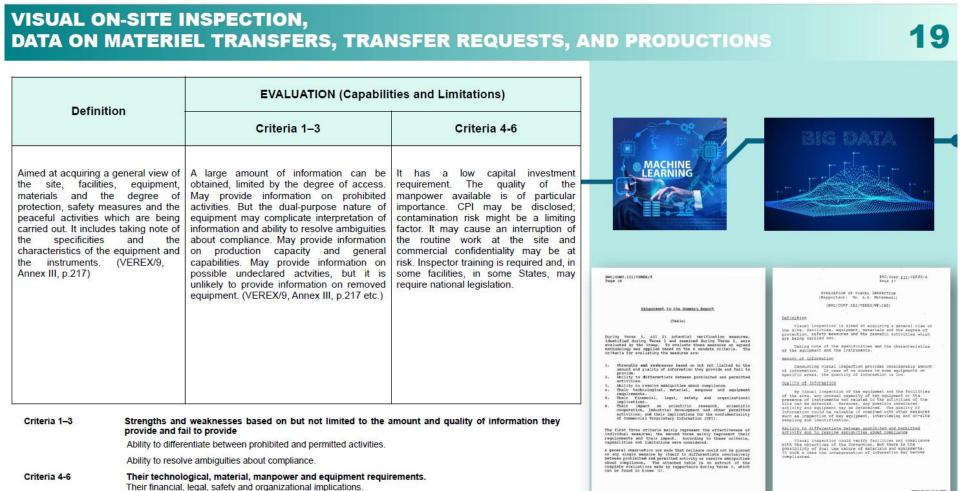
OPELADES ADDISENT TO THE profile Imposition searcetristics in the busilities of the profile imposition searcetristics in the the imposition of the profile imposition of the search of the profile of the profile of the profile imposition of the imposition of the profile imposition of the profile of the imposition of the profile imposition of the profile of the profile of the profile of the profile imposition of the statistic formers. Locaretto an Imposition

 The principal leases here is that further work assis to be derived to be development of BI verification equipment dath as particle SLITE and FCR bits. Where resource of a -2 -

obcieve the work is known title altes (y linguizers shall. Willst loss loss intervent in the same fails. Willst loss intervent semistant is laber alter and a state of the same semistant is laber alter and the same semistant is a same alter will be alter alter alter alter alter will be alter alter alter alter will be alter alter alter alter alter will be alter alter alter alter will be alter alter alter alter alter alter will be alter alter alter alter will be alter alte

as accode a generalization from this particular impedanmergeneral (a) - that is a foundation of the second subjective energeneral (a) - that is a foundation NDD set guidation (berr, be to experiment that much as imposed on the mesible at an test sociality where one slobh espect to constant subjection the second as imposed in entrimetally, and using these void place theoryship matrials of balance.

requirements of the tild observations. Refficient assume marked completions of competitions of the term applied operations of competitions of the term applied operations of competitions of the term of term of term of the term of term of term of term of the term of term Given the nature of health, safety, environmental protection and other regulations governing the pharmaceutical and biotechnology industries, demonstrating compliance with Article I of the BWC is relatively straightforward



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

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BWC/WG/3/WP.13

SAMPLING AND IDENTIFICATION (ON-SITE)

Definition	EVALUATION (Capabilities and Limitations)				
Definition	Criteria 1–3	Criteria 4-6		Next Generation Sequencing	
The act of taking samples on the inspected site, analyzing 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.	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 necessarily rule out prohibited activities and may	Currently available materials 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			Market and the first of the fir
(VEREX/9, Annex III, p.228)	not resolve all cases of non-compliance ambiguities. The efficiency of this measure would be enhanced from a prior indication of the agents one is looking for.	equipment and methodology from the site could reduce the costs and protect confidentiality. The need to preserve			
	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	intellectual, individual and commercial		BNC/COMF.III/VENEX/8 Page 10	BHC/CONF.111/VEMEX/6 Page 78
	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 etc.)	technical and legal procedures for processing samples, particularly if there are grounds for removing samples from the site for subsequent		Allachment to the Busmany Report (Table)	PARTICLY AND INTERFICIENT (CA-File) (Apportant: Nr. 9. Ainder) (Hen/CONY.III/VARK/V9.144) Interdantian
	practices (0511). (*21(232), 11111(*111, p.220 (**.)	analysis.		During Venux 3, all 21 potential verification measures, identified during Teres 1 and exemined during Verex 2, vers evaluated by the Group. To evaluate these measures an agreed methodology was applied based on the 6 sandate criteris. The criteris for evaluating the seasures are	During VEEK 1 and II priorital measures for the Biological and fragmas Convention Dec) were identified effection appetion. Power short this measure were listed in precision repeation. Power short this measure were listed in precision repeation of the state of the state of the listed of the state of the state of the state of the listed of the state of the state of the state of the listed of the state of the state of the state of the state of the state of the state of the state of the state of the listed of the state of t
				 Strongths and machinesses based on but not lighted to the provide. Strongth and the strong provide and fail to provide. Ability to resolve antipulse shown prohibited and permitted ability to resolve antipulse showt compliance. Ability to resolve antipulse showt compliance requirements. 	improve and be improved by other off-site and on-site managing. Befinition Begling and identification were defined in Begling mapping on the improved site, a callying these samples of tabling mapping on the improved site, a callying these samples and the improvement of the sample of the callying these samples and the sample of the improved site.
Criteria 1–3 Strengths and weaknesses based on but not limited to the amount and quality of information they			ŧ 👘	 Teair financial, legal, astety and organizational implifications: an actuality of the second second cooperation, industrial development and other persitted activities and their implications for the coordinaticility of commercial requiring facturation (CHT). The first three criteria milly requests the affectiveness of 	tians angula from the sits for identification or further investigations in groups disk lookstatics. Characterizing This seasons is not the set of co-sits inspection matrices. It may be an execution component of an impertion of support like indicates.
	provide and fail to provide Ability to differentiate between prohibited and permitted activities.			The first three criteris mainly represent the effectiveness of individual measures; the second three sainly represent their requirements and their impact. According to these criteris, capabilities and limitations were considered.	The welcation of this measure should take into account the following considerations:
Abili	lity to resolve ambiguities about compliance.			A general characterion was made that wollaces could not be placed on may single measure by itself to differentiate conclassively between prohibited and permitted activity or resolve ambiguities about compliance. The attached table is an extract of the complete evaluations made by rapporteurs during Yeres 3, which can be found in Armen WI.	 the protection of installectual or conservict projetistary rights must be ensured in carrying out on-tits aspling and identification; the impering surface the superfet fo take all appropriate mession control moments. The confidentiality of the investigation, superative the confidentiality of the investigation, superative the concelling prohibits activities;
	Their technological, material, manpower and equipment requirements. Their financial, legal, safety and organizational implications.				 the efficiency of this measure would be enhanced if the inspecting authority has a preliminary idea of the events to search for price to sampling and analysis, art.
Their impact on scientific research, scientific cooperation, industrial development and other permitted activities; and their implications for the confidentiality of CPI			ľ	- 10 -	Its equipment scoredingty: • type:relative endingency revolts (a.g., f.) or fairs exective walk are endowed if and endingencies of the endowed if and were used; • 238 -

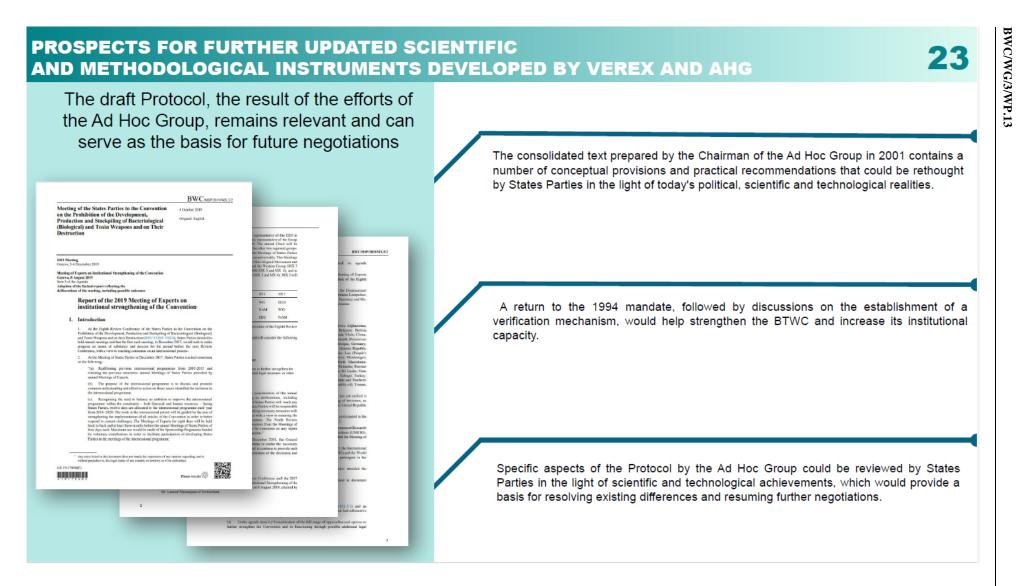
OFF-SITE SAMPLING AND IDENTIFICATION

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	_	

Definition	EVALUATION (Capabilities and Limitations)			
Deminion	Criteria 1–3	Criteria 4–6	PCR Composers	Veiet 1
To take samples of the arr vicinity of a declared or u facility without penetra boundary. (VEREX/9, Annex 1	ndeclared rather poor quality, as the probability of obtaining a relevant sample is low. Using this	inspections and subsequent number of samples. Small inspection teams will be required, but the chain of custody and laboratory analysis would be labor 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.	Terral Cycle	Vicinity Vic
	in connection with open air sites. (VEREX/9, Annex III, p.197 etc.)		BWC/COMP.III/VEMEX/8 Page 10	we/owr.fil/VEREC/4 pape 38 exacling and insyttigation (off-sixe) (Reporter: Nr. As buvilis)
			Attachment to the Summary Report	(BWC/CONF.III/VEREI/NF.TF/Bev.1)
			(Table)	Befinition Off-size inspections would mean to inspect a declared or undeclared facility without perturbing its boundary.
			During Verex 3, all 21 potential verification measures, identified during Verex 1 and examined during Verex 2, vere evaluated by the Group. To evaluate these measures an appred metholology was applied based on the 6 sandate criteria. The criteria for evaluating the measures are:	Offealts was clarified to beam inter alis the outer boundary of a facility, e.g. close to a facility or outside a specific ballding, or collability of samples that algor elevates beyond the immediate vicinity on the fact Party's territory.
			 Strengths and weaknesses based on hot not limited to the amount and quality of inferentian they provide and fail to provide the state of the state of the state of the state activities. Ability to freque satiguities about compliance. They requires antiquities about compliance. They requires the state of the state of the state of the state requirements. The first financial, material, and organizational Their Financial, lead, as fer and organizational 	To is essential to them the most specprists amplify prints and targets minimum reads be: - exists a framework of form of the state of the environmental amplify means of the minimum reads of a site of INTERNET. - INTERNET. - INTERNET.
	ngths and weaknesses based on but not limited to the	amount and quality of information they	 Their impact on scientific research, scientific comparation, industrial development and other permitted activities; and their implications for the confidentiality of Commercial Proprietary Information (CPI). 	complaints investigation or other relevant purposes. Sharacteristics and technologies State of the art
•	provide and fail to provide		The first three criteris 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.	Today a nomber of sampling techniques and methods of identification are available that could be used for off-mite marpling and identification in the wichnity of a facility or a-
	ity to differentiate between prohibited and permitted activities ity to resolve ambiguities about compliance.			field testing sits. Sampling systems based on direct mapping without pretreatment, inpaction, impingement as well as different mathods for concentration and filtration are available. For taking air mapping a number of commercially available
Criteria 4-6 Th		ogical, material, manpower and equipment requirements.		apparatus exist that could be used in this connection. There are also vali-established methods for taking surface samples. For the identification of microorganisms and taxins there is a Waker of available sethods. By combining genetic probes under development with the fet golymanus chain reaction) it
pe		Their impact on scientific research, scientific cooperation, industrial development and other ed activities; and their implications for the confidentiality of CPI		a propriota da anharez very sono soni all'ilizio da ania ania ania ania ania ania ania a

DECLARATIONS FORMAT OF ACTIVITIES OF FOREIGN FACILITIES

Production of the particular strength and the particular strength The	Does the facility use biological agents and toxins which are to be found in
The big ages whether by the Randon Fubrations Bold rap_ DECLARITIN FORMATION Learning of the second secon	of the State Party for the testing of biological agents?
Proof abless of the logit advery of the face face face face in the second sec	Does the facility provide vaccinations for the local population?
Event address of the industry of the indu	Is the facility accessible to health and anidomiclogical monitoring
BSC-10100C 1000 433 pay 1 1. Due de fuilig valet de auvieur de la deraise font de la deraise font de la deraise	Are yearly reports on the work of the facility submitted to the State Party on whose territory the facility is situated?
11. Does the fairing sources for users frame horizontal activities. 12. Does the fairing sources for users frame horizontal activities. 12. The fair of the fairing sources of the fairing the fairing sources of the fairing the fair activity of the fairing sources of the fairing the fair activity of the fairing sources of the fairing th	Are biological agents and toxins exported to the State under whose jurisdiction or control the facility falls?
An for possible will for gut its of sub-open approxity Our Saw Pag	Are the procedures and the quantities of such exports approved by the State Party?





BIOLOGICAL WEAPONS CONVENTION

WORKING GROUP ON THE STRENGTHENING OF THE BTWC

THANK YOU FOR YOUR ATTENTION