VISITS: AN ESSENTIAL AND EFFECTIVE PILLAR

by

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Introduction

1. Intense debate has continued during the past year, both in the Ad Hoc Group (AHG) and elsewhere, about the role of visits in the future Protocol to strengthen the Biological and Toxin Weapons Convention (BTWC). There are now clear signs that an increasing number of States Parties see visits as a key element in the future verification regime.

2. The original European Union (EU) working paper1 at the 1994 Special Conference of States Parties to the BTWC entitled 'Proposals for a Mandate for an Ad Hoc Working Group on Verification' stated:

> *"4. The objective of the Ad Hoc Working Group on Verification shall be to draft a verification protocol, drawing on the VEREX Final Report as appropriate, establishing a mandatory regime...*
>
> *Such a regime shall include the following basic elements:*
>
> - *off-site measures, including national declarations...*
> - *on-site measures such as information visits to declared facilities, short-notice inspections, and investigations of allegations of use..."*

The role of visits was reaffirmed in the EU Common Position2 of March 1998, which bound the 15 Member States and was supported and adopted by 14 associated and other European countries. More recently, in July 1998, a working paper3 submitted by a different 29 states - Argentina, Australia, Austria, Belgium, Bulgaria, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, New Zealand, Norway, Poland, Portugal, Republic of Korea, Romania, Slovakia, Spain, Sweden, Switzerland, Turkey, United Kingdom and the United States - embracing States Parties from around the world - saw the central and essential elements of the Protocol as comprising:

> *"Declarations of a range of facilities and activities of potential relevance under the Convention so as to enhance transparency;*
>
> *Provisions for visits to facilities in order to promote accurate and complete declarations and thus further enhance transparency and confidence.*
>
> *Provisions for rapid and effective investigations into concerns over non-compliance, including both facility and field investigations; and*
>
> *A cost-effective and independent organization, including a small permanent staff, capable of implementing the Protocol effectively."*

3. Despite this growing consensus, some doubts have been expressed about the effectiveness of visits and there has been the discordant voice of some of the industry trade associations -- especially within the USA pharmaceutical industry -- which, whilst supporting the strengthening of the BTWC, express antagonism4 to the idea of visits even though it is already a highly regulated and frequently inspected industry. As the AHG enters its final phase of negotiations, it is timely to re-examine the role of visits in the future regime **as it is currently emerging**. It is essential in doing this that attention is focused on the **actual** regime and **not** on previous, now outdated, concepts of what the regime might be. The necessity for non-challenge visits5 was addressed in Briefing Paper No. 2, and the implications for the biotechnology and pharmaceutical industry of the Chemical Weapons Convention6 and the strengthened BTWC7 were considered in Briefing Papers No. 11 and No. 17 respectively.

4. This Briefing Paper examines the role and effectiveness of visits as these are emerging from the current negotiations and in the light of the experience being gained in trial visits carried out by several developed States Parties and their likely infrequency based on studies of the probable size of the future BTWC Organization. It is concluded that visits are both an essential and an effective pillar of the strengthened BTWC regime which ensure accurate and complete declarations which thereby build transparency and confidence in compliance, and that their benefits far outweigh the slight additional burden on an already highly regulated and inspected industry.

The draft Protocol

5. The AHG successfully transitioned in July 1997 to the negotiation of the rolling text of the draft Protocol. The sixth draft was issued8 in October 1998. In addition, the Friends of the Chair (FOCs) have started to produce versions of the text in which they have made transparent proposals (using strike-through text to indicate deletions and bold text to indicate added new text) as to how the rolling text might be modified in order to resolve some of the remaining issues. These texts prepared by the Friends of the Chair thus provide an insight into the way in which the Protocol is likely to develop. The modified rolling text taken from these FOC papers, which are contained in Annex IV to the procedural report, are used as the basis for the discussion in this Briefing Paper. The text in Annex IV on Article III D. Declarations, prepared by the FOC on Measures to Promote Compliance, is reproduced in full in the Annex to this Briefing Paper. Whilst the FOCs papers use strike-through text to indicate deletions and bold text to indicate additions, the clean text is used in this Briefing Paper in the interests of clarity and in order to facilitate understanding. In addition the terms Technical Secretariat and Executive Council have been used throughout in the interests of clarity rather than reproducing the terms Technical [Secretariat][Body] and [Executive][Consultative] Council.

6. The current draft Protocol contains essentially three different types of visits -- voluntary request visits (to facilities to be declared), random visits (to declared facilities), clarification visits to declared facilities and to facilities which should have been declared -- each with a different yet important role that is **directly** related to declarations. It needs to be stressed that visits are concerned with declarations and with compliance with the Protocol -- and are **not** addressing compliance with the Convention. All are non accusatory and non confrontational and none are associated with any consideration of whether or not the facility

was in compliance with the Convention. The different roles of the three types of visits can be shown diagrammatically:
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7. As visits will only be to declared facilities or to facilities that should have been declared and will be carried out to ensure that declarations are accurate and consistent with the obligations undertaken by States Parties to the Protocol, it is clear that declarations and visits are intimately interrelated. It is therefore necessary to consider what is -- and what is not -- likely to be declared before considering visits in depth.

Declarations

8. It has to be emphasised that the aim is to have declarations of those facilities and activities of **greatest** relevance to the Convention and **not** to require declarations of all facilities and activities of **possible** relevance to the Convention. The latter approach would inevitably lead to information overload, inaccurate or incomplete declarations and an ineffective regime. It is also apparent from the footnote to the title of *Appendix D Information to be provided in declarations of other facilities* in the July 1998 draft Protocol[9] that neither commercial proprietary information or national security information will be required in declarations as the footnote states:

> *"**Declared information will be passed to all States Parties to the Protocol. Accordingly, the design of the declaration formats is intended to avoid reference to confidential proprietary information or national security information**..."*

This exclusion of commercially sensitive information was also stated in the Austrian/UK contribution[10] to the EU seminar for the pharmaceutical industry on 13 May 1998 which said that *"All are agreed that the forms should be simple and straightforward and should not seek any information which would be considered commercially sensitive."* Although the Declaration Appendices have been modified and the footnote no longer appears in the current draft Protocol, it is clear from the formats in the current draft, which are broadly similar to those in the earlier draft which bore the footnote, that the intention to avoid reference to commercial proprietary information or national security information remains.

9. The Friend of the Chair's paper11 on Article III requires submission of declarations under the following headings:

"*I. SUBMISSION OF DECLARATIONS*

INITIAL DECLARATIONS

(A) Past Offensive and/or Defensive Programmes
[(B) National Legislation and Regulations...]

ANNUAL DECLARATIONS

(C) Current Defensive Programmes
(D) Vaccine Production Facilities

(E) Maximum Biological Containment/Biosafety Level 4 Facilities
(F) High Biological Containment/Biosafety Level 3 (BL3) Facilities
(G) Work with Listed Agents and/or Toxins
[(H) Other Production Facilities]
[(I) Other Facilities...]
[(J) Transfers...]
[(K) Declarations on the Implementation of Article X of the Convention...]

[NOTIFICATIONS]

[(L) Outbreaks of disease]

It is evident that many of these triggers for declarations have little if any relevance to civil industry.

10. The impact of the triggers that might have relevance to civil industry is further limited because of exceptions and particular requirements that have been built in during the AHG negotiations. Thus, for example, under *"(F) High Biological Containment/Biosafety Level 3 (BL3) Facilities"* the text states that:

> *"Each State Party shall declare, in accordance with paragraph 1 above, each facility which, during the previous calendar year, contained areas protected by high biological containment/Biosafety Level 3 (BL3) [and working with listed agents or toxins]* ***but excluding facilities working purely on the diagnosis of human, animal or plant diseases, or carrying out purely medical treatment activities."*** [Emphasis added]

The impact of such a trigger is greatly reduced by the exclusion shown in bold above.

11. Another example is in the section *"(G) Work with Listed Agents and/or Toxins"* where the text states:

> *"[...A facility* ***should not be declared*** *under paragraph 18 above i****f it works*** *with listed agents and/or toxins* ***only*** *for the purpose of diagnosis of human, animal or plant disease, or for carrying out medical treatment activities, or for testing for food or water hygiene, or for testing the efficacy of antimicrobial preparations, vaccines, toxoids, or immunoglobulin preparations [or for academic research or prophylactic activities].]"* [Emphasis added]

Again, under *"(H) Other Production Facilities"* the text reads:

> *"[...A facility* ***should not be declared*** *under paragraph 21 i****f it was solely used*** *for bioremediation or waste treatment, or for manufacture for sale or use of soap, cosmetics, detergents, fertilizers, or of foods or beverages for humans or animals [, or of single cell proteins].]"* [Emphasis added]

Under "*(I) Other Facilities*" the text reads:

"[...24. Each State Party shall declare, in accordance with paragraph 1 above, each facility which, during the previous calendar year, conducted activities with any biological agent and/or toxin and which also:

[(a) Possessed aerosol test chambers of [0.1][10]m^3 or above for work with microorganisms or toxins;]

(b) Possessed equipment with a capacity of ...litres or more for aerosol dissemination in the open air with a particle mass median diameter not exceeding [10] microns ***excluding those for agricultural, health or environmental use****;* [Emphasis added]

[(c) Conducted [genetic] modification to enhance pathogenicity, virulence, stability or resistance to antibiotics [chemical or physical methods of disinfection, or which altered the host range, the infection route or the ease of identification or diagnosis] [within a high biological containment facility (biosafety level 3) [and had an aggregate production capacity of [100] litres or more on site]].]

12. The presence of such reservations were, without doubt, a major factor in the relatively low numbers of sites which were found to be declarable in a series of surveys by States Parties. A review12 of these national surveys concluded in September 1997:

"The surveys thus far reported have been for developed countries which, with the exception of Canada, have all been located in Europe. The broad conclusion that emerges is that the number of facilities in each country that would need to be declared under triggers chosen to capture those facilities of most relevance to the Convention would be relatively limited ***with numbers of the order of 10s*** *in each country....it is unlikely that in developing countries there would be as many facilities that would need to be declared.."* [Emphasis added]

This assessment of the likely numbers was confirmed by the Austria/UK paper13 presented at the EU seminar for the pharmaceutical industry in May 1998. This stated that *"the number of facilities in individual EU countries that would need to be declared* ***can probably be measured in tens*** *rather than hundreds".* [Emphasis added] The number of facilities to be declared world-wide can thus be estimated14 to be in the order of 1600 to 3200 assuming a figure of 10 to 20 facilities is taken as the average for 160 States Parties. This total is consistent with the number of 2500 facilities estimated by others.15

Visits

14. The Friend of the Chair paper16 in Annex IV on Article III D. Declarations follows Section *I Submission of Declarations,* discussed above, with a second section titled *II. FOLLOW-UP AFTER SUBMISSION OF DECLARATIONS.* This is preceded by an explanatory note which states that:

"(It is suggested to add a new subsection to the section on declarations, which might include the existing proposals for random, clarification and voluntary/request visits, ***since each of these measures relates directly and***

exclusively to declarations. *Other forms of clarification might best be addressed in the section on consultation, clarification and cooperation. Other forms of voluntary visits might be taken up in the specific contexts in which they apply, e.g. cooperation and assistance under Article VII)."* [Emphasis added]

The nature of the follow-up after submission of declarations is set out as follows:

> *[32. In order to ensure that the declarations submitted by States Parties are fully consistent with their obligations set out in this Article, the Technical Secretariat shall:*
>
> > *[(a) Conduct a limited number per year of random visits to declared facilities ...]*
> >
> > *[(b) Analyse the declarations and, if it identifies any ambiguity, uncertainty, anomaly or omission, seek clarification from the State Party concerned...]*
> >
> > *[(c) Provide technical assistance to States Parties to help them compile individual facility and national declarations including, if requested, by means of visiting a State Party...]"*

The headings of the text in this new subsection are as follows:

> *"II. FOLLOW-UP AFTER SUBMISSION OF DECLARATIONS*
>
> > *[(A) [RANDOM VISITS]....]*
> >
> > *[(B) CLARIFICATION PROCEDURES....]*
> >
> > *[(C) [VOLUNTARY REQUEST VISITS]....]*

The use of the term *"Clarification **Procedures**"* [Emphasis added] rather than the previous term *"Clarification Visits"* is a useful step forward as it makes it clear that the intention is to have a process whereby ambiguities, anomalies and omissions **in declarations** can be resolved. This procedure may, as will seen below, result in clarification visits to either declared facilities or to facilities that should have been declared.

15. The text in Annex IV has essentially provision for three types of visits:

a. Voluntary request visits (to facilities to be declared).
b. Random visits (to declared facilities)
c. Clarification procedures/visits to declared facilities and to facilities that should have been declared.

These are **all** non-accusatory, are **not** associated with any consideration of whether or not the facility is in compliance with the Convention and have quite **different** roles. The provisions for each type of visit is considered in turn.

16. **Voluntary request visits.** The proposal is to make provision for each State Party to be able to request the future BTWC Organization to *"undertake visits to facilities on its territory...in order to:*

(a) to help compile individual facility and national declarations

[(b) to resolve a specific concern related to declarations, including any ambiguity;]"

It should be noted that the second purpose is in square brackets as it is closely similar to the purpose of clarification visits. Although not explicitly stated in the text, it appears that the intention of the second purpose is to cover the situation in which a State Party invites the Technical Secretariat to make a visit to a facility in order to demonstrate that its declaration is consistent with its obligations under the Protocol.

17. The language states that "The detailed arrangements for, and contents of, a voluntary visit shall be agreed between the Director General and the State Party concerned." and goes on to state that *"The Director General shall issue a mandate for each visit which shall be completed in cooperation with the State Party to be visited."* The visit plan may identify areas in which the visit team may provide technical assistance; these may include, inter alia, fulfilment of declaration obligations, biosafety standards, and good laboratory or manufacturing practices.

18. **Analysis.** Voluntary request visits have a role in enabling the Organization, at the request of a State Party, to assist the State Party making the request for the visit in compiling its declarations as required by the Protocol. As such they are one way of helping States Parties to meet their obligations under the Protocol. The requesting of such a visit would also add to the building of trust and confidence as it would be evidence that the State Party concerned took its obligations seriously by asking the Organization for assistance in making its declarations. In addition, it would be expected that the number of such voluntary request visits would reduce over time as States Parties gained experience in compiling their national declarations.

Voluntary request visits at the request of the State Party have a far less clear role in regard to resolving specific concerns related to declarations. It would be unrealistic to expect a State Party to invite a visit to a specific facility unless the State Party was confident that its declaration was indeed consistent with its obligations under the Protocol. Consequently, such voluntary request visits will have only a very limited role to play in building transparency and confidence in compliance. It is not seen as a credible approach to expect the Organization to be able to request visits to address ambiguities in declarations using a voluntary, case by case approach as it would not contribute to the building of trust and confidence. Likewise any suggestions that voluntary visits should take place on a bilateral basis, outside the auspices of a future BTWC organization, are retrograde steps as such a bilateral process would add nothing to building confidence between all States Parties to the Protocol that accurate and complete declarations are being submitted.

A regime based on declarations and voluntary visits alone would be ineffective on several grounds:

- Not all States Parties would volunteer such visits
- Those that did offer such visits would limit them to those facilities that the State Party was certain had a declaration that was consistent with the Protocol,
- Visits would be unlikely to be volunteered to all categories of facilities within a State Party
- Visits would be unlikely to be volunteered to any facility within a particular category.

The scope of such voluntary visits would be limited to specific facilities within a few States Parties. There would be no incentive to States Parties in general to ensure that all declarations were accurate and complete as States Parties would know that none of their facilities would be visited unless they volunteered a visits. The net effect of such a regime would be that over time States Parties would decide what they would include in declarations and the situation would approach that which pertains at present in regard to declarations under the Confidence Building Measures (CBMs) in which individual States decide how much or how little information to submit resulting in the very variable and patchy CBM responses. Consequently, the CBMs add little if anything to building confidence and transparency as those States which provide comprehensive information under the CBMs tend to provide information in the public domain anyway about those facilities. Thus a regime based on declarations and voluntary visits alone could well create a false sense of security and would clearly fail to build transparency, trust and confidence.

19. **Random Visits.** The purpose of random visits and their nature are clearly set out and are limited to confirming, in cooperation with the State Party, that declarations are consistent with obligations under the Protocol:

> *"Purpose*
>
> *35. [The Organization] shall conduct...a limited number per year of random visits which shall be non-confrontational and confidence building in nature to declared facilities.* ***These visits shall be limited to confirming in cooperation with the State Party to be visited that declarations are consistent with the obligations under this Protocol****.* [Emphasis added]

This limitation is reaffirmed in the section on the mandate which states that:

> *Mandate*
>
> *39. The Director-General shall...issue a standard mandate for the visit.* ***The mandate shall be confined to confirming that declarations are consistent with the obligations under this Protocol****."* [Emphasis added]

As declaration formats have been designed to avoid reference to confidential proprietary information or national security information, this limitation is a significant safeguard for industry.17

20. The number of random visits to be carried out each year will also be very small, and will be limited for any particular State Party:

"Selection of facilities

37. There shall be ***no more than [50][60] random visits per calendar year distributed equally among the [5] [6] regional groups of State Parties*** *represented in the Executive Council.* ***No State Party shall receive more than [10] random visits in each five year period.*** *The [Organization] shall ensure that, over a five year period, random visits shall be divided between each category of declarable facilities in approximate proportion to the total number of declared facilities in each category."* [Emphasis added]

If it is assumed that there are 160 State Parties spread over five or six regional groups, this would mean that there was an average of about 30 States Parties in each regional group. If there were 60 random visits each year distributed equally amongst six regional groups, this would result in 10 random visits each year in a single regional group. Given that there are an average of about 30 States Parties in each regional group, this would mean that about one out of three States Parties within the regional group might be the subject of a random visit in any one year. As to which of the declared facilities within a State party would receive the random visit, the text makes it clear that the frequency of random visits will reflect the numbers of facilities declared in each of the categories of declared facilities. Such a process would result in an equitable distribution of visits amongst the States Parties yet they would indeed be so infrequent as to impose little additional burden bearing in mind that the purpose is solely to confirm that the declaration, which contains no commercial proprietary information, is indeed consistent with the obligations under the Protocol.

21. In addition, the size of the visit team will be small:

"Designation of visiting team

41. (The size of the visit team shall be kept to the minimum necessary for the proper fulfilment of the mandate, and shall not exceed [4] [6] persons..."

and the duration of the visit would be limited:

"Duration

42. The duration of the visit shall be no more than [2] days unless extended by agreement between the visit team and the visited facility..."

It is thus evident that even if a facility is declared, the likelihood of it being subject to a random visit is small, and that visit will be to confirm the accuracy of its declaration and will be carried out by a small team in a limited period.

22. During any random visit a wide range of precautions to protect commercial proprietary information have been incorporated into the text. These include:

"49. Representatives of the visited State Party and of the facility shall accompany the visit team throughout the duration of the visit to the facility...

56. If any of the principal on-site measures are not possible because of national security, commercial proprietary or health and safety considerations, the visited State Party shall provide other means to demonstrate that the submitted declarations are in compliance with the obligations of this Protocol...

61. The visited State Party shall have the right, in accordance with the obligation to demonstrate compliance and the right, if necessary, to protect sensitive information ...to take specific measures which may include the following:

(a) Removal of sensitive papers from direct view;
(b) Shrouding of sensitive displays, stores and equipment;
(c) Shrouding sensitive pieces of equipment, such as computer or electronic systems;
(d) Logging off of computer systems and turning off data indication 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 contents of sensitive buildings or documents...
(h) The visited State Party may at any time during the visit identify products and processes in which it has a proprietary interest....It may request that if a specific piece of information is released to the team, it should be accorded the most stringent protection measures by the organization."

23. Additionally, it is clear that **there will be no sampling** unless offered by the facility :

*"62. Sampling shall **only** be conducted **if offered by the facility** and deemed useful by the visit team. Any such mutually agreed sampling and analysis shall be performed by facility personnel, but in the presence of the visit team."* [Emphasis added]

24. Finally, even the visit team's report is subject to comment by the facility and access to it is strictly limited:

"68. The draft report shall immediately be submitted to the visited State Party. The visited State Party may make written comments which shall be [annexed to] [included, as appropriate, in] the report.

*69. The visit team shall then submit the final report, **which is confidential,** to the Director-General. The final report should include a summary, stating the general activities undertaken by the visit team and its factual findings related to the declaration obligations of the Protocol. The Director-General shall circulate the summary to all States Parties."*

25. Should following the random visit there be any outstanding questions regarding the declaration, the following provision is made:

"70. In cases where declarations remain inaccurate or incomplete, or where ambiguities remain, the Director-General shall inform the Executive Council which shall consider what, if any, further action is required."

26. *Practice Random Visits.* A number of States have carried out practice random visits and provided reports on these as working papers to the Ad Hoc Group. Given the care with which the draft Protocol text on random visits has been developed, it is not surprising that when tested **in practice** by States Parties it has been found that there is no real threat to commercial proprietary information (CPI). Thus a working paper18 presented at the September/October AHG meeting by Denmark, Finland, Iceland, Norway and Sweden on a practice random visit to a biopharmaceutical production facility concluded:

"15. The facility visited considered that the visit had only limited and acceptable resource implications. Management costs were assessed as insignificant, given the likely scope, length and frequency of such visits.

16. Furthermore, the facility visited considered that the visit did not in any way interfere with or disrupt the daily production.

17. The facility was confident that CPI was adequately protected during the visit..."

In addition, the report also concluded that the random visit was effective in confirming the accuracy of the declaration as:

"18. All questions relating to the facility's declaration were fully clarified. The visiting Team found that the facility could account for all its declared activities and how production was conducted..."

27. Very similar conclusions were reached in a working paper19 presented at the same AHG meeting by Austria which concluded from a practice random visit to a pharmaceutical plant that:

" No risk to lose confidential information was encountered throughout visit."*

28. A more detailed analysis of the reasons for the negligible risk to CPI during a practice visit to a pharmaceutical research facility was given in an earlier working paper20 submitted by the United Kingdom to the January 1998 AHG meeting which stated that:

*"**(e) Confidentiality***

"22. The company protected CPI throughout the visit: at no time did it come close to losing control of CPI. There were six reasons for this. First, the procedures governing the visit made it clear that all on-site activities were subject to managed access. Second, the VT (visiting team) size was limited to three people and was not allowed to sub-divide. This meant that senior site representatives had a complete overview of all the information passed to the VT. Third, preparation and pre-briefing of the company personnel helped ensure that

those involved were better equipped to handle VT requests. Fourth, strict documentation control ensured that no CPI sensitive documents were inadvertently handed over: all non-published company documents were scrutinized by company personnel before they were released. Fifth, the visit's limited duration kept potential exposure to CPI to a minimum and reduced the risk that company personnel might lower their guard. Sixth, repackaging information in summary form to exclude CPI enabled the company to discuss key areas of its activities."

The working paper concluded that:

"(a) No CPI was divulged...due to the use of managed access techniques throughout;"

and that

"(c) The exercise confirmed the potential utility of visits as a means of increasing the understanding of information in a declaration..."

29. These recent findings confirm the experience reported of earlier practical trials carried out and presented to the AHG in earlier sessions. An Australian working paper21 presented in July 1996 on a trial inspection of a biological production facility concluded that:

"The company was satisfied that the inspection team did not interfere with either the research or production activities of the company. It was also satisfied that the inspection team had taken appropriate measures to protect commercially valuable information and data and did not foresee any special difficulties with receiving inspections based on the principles which had been followed in this trial..."

It was also concluded that *"an inspection of this type would provide a high level of assurance in the accuracy of information provided by the company in the questionnaire and in the company's compliance with the BWC".* Similar conclusions are found in a joint Brazil and United Kingdom working paper22 on a joint UK/Brazil practice non-challenge visits which concluded that *"the facility personnel believed the confidentiality concerns could be protected by managed access".*

30. **Analysis.** Random visits are **non accusatory** and have **no** association whatsoever with any consideration as to whether or not the particular facility being visited is in compliance. They will clearly be infrequent, short and carried out by a small team with a mandate limited to confirming that the declaration for a declared site is consistent with the obligations under the Protocol. Given that declarations will not include commercial proprietary or national security information, random visits carried out by members of the future BTWC Organization will present no risk to either commercial proprietary information or to national security information.

In addition, it is apparent that the prospect that a declared site will receive a random visit, albeit very infrequently, will bring significant benefits to the Protocol:

a. First, States Parties will be given an incentive to ensure that all declarations for declared facilities are accurate and complete and no State Party would wish to be found by a random visit to have made an inaccurate or incomplete declaration;

b. Second, over time the increased confidence in the accuracy and completeness of declarations will increase transparency and build confidence in compliance;

c. Third, such random visits to facilities within States Parties will over time ensure that the future BTWC Organization has a better understanding of the approaches taken by that State Party in regard to activities relevant to the Convention. Consequently, the BTWC Organization will be better able to reach more accurate judgements regarding activities within that State Party than if the Organization had never visited that State; and,

d. Finally, a would-be violator of the BTWC would be very unlikely to carry out prohibited activities at a declared facility.

Consequently, random visits although infrequent and entailing the use of only a small amount of the resources of the BTWC Organization are highly effective in ensuring that declarations are accurate and complete thereby ensuring that their contributions to transparency and building confidence are maximised. Random visits are thus a highly cost effective means of strengthening the Convention and building confidence in compliance.

31. **Clarification Procedures.** The language in Annex IV regarding *II. Follow-up after submission of Declarations"* includes the provision that:

> *[32. In order to ensure that the declarations submitted by States Parties are fully consistent with their obligations set out in this Article, the Technical Secretariat shall:...*
>
> > *[(b) Analyse the declarations and, if it identifies any ambiguity, uncertainty, anomaly or omission, seek clarification from the State Party concerned...]*

In addition, provision is made for States Parties to seek clarification either directly or by requesting in writing to the Director-General that the matter be clarified:

> *"If a State Party which has received a copy of a declaration of another State Party identifies in it any ambiguity, uncertainty, anomaly of omission, it may seek clarification directly from the State Party concerned and/or it may submit a written request to the Director-General requesting that the matter be clarified. Upon receipt of such a request, the Director-General shall initiate the clarification process..."*

Such clarification procedures can apply to either declared or facilities that should have been declared.

32. **Declared Facilities.** If the Technical Secretariat through its own examination of declarations or following receipt of a request from a State Party,

"considers that there is any ambiguity, uncertainty, anomaly or omission in a declaration submitted by a State Party it shall in the first instance seek clarification from the State Party concerned. It shall do so in writing. The State Party concerned shall respond in writing within 20 days of receipt of such a written communication."

The text goes on to say that if either the State Party who receives such a request or the Technical Secretariat considers that the matter cannot be resolved through the ordinary channels of communication or that the written response does not resolve the matter, then:

"consultations shall be held at the offices of the National Authority of the State Party. The period of these consultations shall not exceed 48 hours after their commencement. If the State Party, facility concerned and Technical Secretariat agree that such consultations are not needed, then a visit may proceed."

33. **Facilities that should have been declared.** If the Technical Secretariat as a result of its own examination or following receipt of a request from a State Party,

"identifies any facility which it believes meets the criteria for declaration...and that facility has not been declared by a State Party, it shall in the first instance seek clarification from the State Party concerned. It shall do so in writing. The State Party concerned shall respond in writing within 20 days of receipt of such a written communication."

Should a State Party believe such a facility meets the criteria for declaration, then the text requires that *"The State Party shall submit all relevant supporting evidence in its request to the Director-General. Such evidence shall include a precise delimitation of the site where activities that should have been declared are believed to be taking place."*

34. As with the procedure for declared facilities, the text goes on to say that if either the State Party who receives such a request or the Technical Secretariat considers that the matter cannot be resolved through the ordinary channels of communication or that the written response does not resolve the matter, then:

"consultations shall be held at the offices of the National Authority of the State Party. The period of these consultations shall not exceed 48 hours after their commencement."

It then states that

"The State Party, at its discretion, may invite the Technical Secretariat to conduct a visit ...with a view to resolving the declaration anomaly or omission."

The subsequent paragraph then states that

"If the consultation meeting does not resolve the matter, the Technical Secretariat may request that a clarification visit be conducted at the facility in question. Such a visit may only be requested when the Technical Secretariat is satisfied that a visit is justified and that all reasonable steps have been taken to clarify the situation through the processes allowed for under this Article."

Provision is then made for the State Party to be able to refuse a clarification visit if it believes that it has made every reasonable effort to resolve the matter:

> *"If the State Party believes that it has made every reasonable effort to resolve the matter it may refuse the clarification visits requested by the Technical Secretariat. The State Party shall submit a written explanation to the Technical Secretariat within 48 hours of receipt of the notification of the intent to conduct the clarification visit. The Executive Council shall consider such a refusal as soon as possible and decide on any further action."*

35. **Clarification Visits.** The purpose of clarification visits is again directly related to declarations:

> *"Clarification visits: purpose/basic principles*
>
> *81. The Technical Secretariat shall also conduct...visits to facilities of States Parties (hereinafter referred to as 'clarification visits'), [regardless of whether they have been declared or undeclared] in order* ***to resolve any ambiguity, uncertainty, anomaly or omission in the declaration*** *of a State Party...and* ***to promote accuracy and comprehensiveness in future declarations.****"* [Emphasis added]

The text includes examples of such ambiguities as including *"failure to complete all questions in a declaration format; contradictory statements and data in the declaration format; exclusion of information that ought to have been included in the declaration format; or inclusion of information inconsistent with other data available to the Technical Secretariat"* .

36. The direct relationship to declarations is reaffirmed in the mandate for clarification visits:

> *"Mandate*
>
> *92. The Director-General shall [, in consultation with the State Party to be visited,] ..issue a mandate which* ***shall be limited to confirming that declarations are consistent with the obligations under this Protocol and resolving the identified ambiguity, uncertainty, anomaly or omission.****"* [Emphasis added]

37. As with random visits, the number of clarification visits is strictly limited and their impact on any one State Party is also carefully circumscribed unless the State Party has failed to submit its initial declaration:

> *"Numbers of Visits*
>
> *85. In preparing a draft implementation plan of clarification visits, the Technical Secretariat shall ensure that the total number of clarification visits through one fiscal year shall not exceed [20] and that a State Party shall not receive more than two visits through the same fiscal year. However, the limitation of two*

visits per one State Party per fiscal year shall not apply to the State Party which has not submitted its initial declaration..."

The number of visits that a State Party might receive is limited to a maximum of two per year unless the State Party has not declared its initial declaration. The requirement in the text is for declarations to be submitted by States Parties*"not later than [180] days after this Protocol enters into force for it..."* Once a State Party has made its initial declaration then the limitation of two clarification visits a year will apply. In practice, it is clear that most requests for clarification of ambiguities, uncertainties, anomalies and omissions will only occur **after** a State Party has made a declaration. The existence of the limitation provides a useful incentive to States Parties to make their initial declarations and the provision for clarification visits provides a useful safeguard against the possibility that a State Party might fail to submit its initial declarations for an extended period, which if not addressed through clarification visits might result in growing concerns about the lack of transparency regarding activities that should have been declared within that State Party.

38. Furthermore, the size of the visit team will be small:

"99. The size of the visiting team shall be no more than [5] persons... "

and the duration of the visit would be limited:

"98. The period of the visit shall not exceed [48][72] hours....The period of visit may be extended once within the maximum length of ... days by agreement between the visit team and representatives of the visited State Party."

39. As with random visits, precautions to protect commercial proprietary information during a clarification visit have been incorporated into the text. These include:

"96. The visit team may interview facility personnel, audit documentation and records, visually observe the visited facility and carry out other activities as agreed between the visit team and the visited State Party. These activities shall be conducted in accordance with the principle of managed access and after consultations with the visited State Party."

Again, it is clear that **there will be no sampling** unless offered by the facility :

"97. Sampling shall not be conducted ***unless offered by the visited State Party****. Even in a case where sampling is offered, analysis of samples shall be performed in the territory of the visited State Party and under terms agreed by the visited State Party."* [Emphasis added].

40. Finally, there are again mechanisms that provide for rapid comment on the visit team's draft report by the visited State Party and for limiting access to the final report.

"101. Not later than 10 days after the visit, the visit team shall prepare a draft report on the activities conducted by the visit team and the factual findings of the visit team, and transmit it to the visited State Party. The visited State Party may

submit to the Technical Secretariat any written comments on the factual findings not later than 10 days after receipt of the draft report.

102. The visit team shall submit a draft final report to the Director-General no more than 30 days after the visit. Any written comments, which the State Party may make in accordance with paragraph...shall be annexed to it.

104. Unless otherwise specified, final reports shall not be circulated outside the Technical Secretariat...."

41. However, a major difference between clarification and random visits is that the text sets out in some detail how an implementation plan shall be prepared by the Technical Secretariat for clarification visits and this shall be submitted to the Executive Council for consideration at its quarterly meetings at which it shall be adopted unless the Executive Council *"decides against adopting it by [a two-thirds majority][a majority] of its members."* As might be expected, reports of clarification visits are to be made to the Executive Council under certain circumstances.

"[Preparation of implementation plan of clarification visits]

82. In cases where the matter cannot be resolved within [14] days through the consultations ...which may include the consultations in capital..., the Technical Secretariat shall prepare a draft implementation plan of clarification visits listing the facilities of States parties to which the Technical Secretariat considers it necessary to conduct visits in order to ensure accurate declarations....

83. In preparing a draft implementation plan of clarification visits, the Technical secretariat shall pay due regard to the following priorities:

(a) First priority facilities: any facilities of States Parties not having submitted their initial declarations;

(b) Second priority facilities: any undeclared facilities of States Parties having submitted their initial declarations;

(c) Third priority facilities: any declared facilities of States parties.

The draft implementation plan is to be submitted to the Executive Council for examination and consideration at their quarterly sessions. A copy will also go to the State Parties whose facilities are proposed to be visited in the plan as well as to any State Party which may have initiated the request for a clarification visit. After consideration by the Executive Council, the Director-General shall inform all States Parties of the implementation plan of clarification visits after its adoption by the Executive Council.

42. In respect of reporting, provision is made for the Director-General in submitting a final report of the clarification visit to the Executive Council for the Director-General, if he considers it necessary *"that the visited State Party redresses its declaration by revising or supplementing it or submits a new declaration, the Director-General shall include in its final*

report the details of, and reasons for, the points on which the declaration concerned should be redressed or a new declaration should be submitted."

43. Provision is made for the Executive Council to consider reports when:

> *"(a) A clarification visit has been conducted at an undeclared facility;*
>
> *(b) A visited State Party submits comments...dissenting from the factual findings in the final report of a visit to a declared or undeclared facility;*
>
> *(c) The Technical Secretariat or a requesting State Party believes that a clarification visit has not resolved the matter;"*

The text then states

> *"108. In all cases the Executive Council shall [decide on any further action necessary][if it deems appropriate, decide by [a two-third majority][a majority] of its members on necessary measures such as a revision of, or addition to, the declaration concerned or submission of a new declaration and the time limit of its fulfilment.]...."*

44. **Analysis.** Clarification procedures, whether in regard to declared facilities or to facilities that should have been declared, will clearly be focussed on ensuring that declarations are free from ambiguities, uncertainties, anomalies or omissions with the aim of promoting accuracy and comprehensiveness in future declarations. There is no association whatsoever with consideration as to whether or not the facility is in compliance with the Convention. They will be part of a process that would start with an exchange of correspondence that may resolve the matter. If not the next stage would be consultations in the offices of the National Authorities which may again resolve the matter. Only if these earlier stages fail to resolve the matter, will a clarification visit be proposed. States Parties can, if they believe that they have taken all reasonable steps to resolve the matter, refuse such a clarification visit although such a refusal will be reported to the Executive Council to decide on any further action. In addition, all clarification visits will be carried out under an implementation plan which will have been adopted by the Executive Council and the results of the clarification visit in due course will be reported to the Executive Council.

The priority in the implementation plan will focus first on facilities within States Parties that have failed to make their initial declarations, then on facilities that should have been declared within other States Parties and finally on declared facilities of States Parties. This rightly put the onus on States Parties to make their initial declarations, and then to ensure that all facilities which should be declared are indeed declared. Because of the nature and focus of clarification visits on accurate declaration, it can be expected that the number of clarification visits will reduce over time as States Parties gain experience in compiling their national declarations.

Clarification visits are thus concerned with implementation of the Protocol through promoting accurate and complete declarations. They are **not** addressing concerns about compliance with the Convention. They bring significant benefits to the Protocol:

a. First, States Parties will be given an incentive to ensure that their initial declarations are made in a timely way, that their declarations are accurate and complete and that all facilities which should be declared are indeed declared;

b. Second, over time clarification procedures, including clarification visits, will give States Parties an increased confidence in the accuracy and completeness of declarations as ambiguities, uncertainties, anomalies or omissions in declarations will have been successfully addressed thereby increasing transparency and building confidence in compliance; and,

c. Finally, a would-be violator of the BTWC would be very unlikely to carry out prohibited activities at either a declared facility or at one which should have been declared as that facility might be the subject of a clarification visit initiated either by the Technical Secretariat or at the request of another State Party.

Consequently, clarification visits, although likely to decrease in number over time, entailing the use of only a small amount of the resources of the BTWC Organization are highly effective in ensuring that States Parties make their initial declarations and that declarations are indeed accurate and complete thereby increasing the contribution made by declarations to transparency and building confidence in compliance. They consequently complement random visits and are a highly cost effective means of strengthening the Convention and building confidence in compliance.

Discussion

45. It is thus apparent that the three types of visits -- voluntary request visits, random visits, clarification visits to declared facilities and to facilities that should have been declared -- have distinct roles and are complementary. All are concerned with ensuring that declarations are accurate and complete.

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It can be expected that the numbers of voluntary request visits and of clarification visits will decrease over time as States parties gain greater experience in compiling their national declarations and as confidence in compliance with the Protocol and the Convention is built over time, a process which will be significantly enhanced by infrequent random visits equitably spread across all States Parties. The resources required to carry out all three types of visits are small and can be readily accommodated within a future BTWC Organization of some 200 people with an annual budget of some $30 million; they are thus a cost effective means of ensuring that declarations are both accurate and complete.

46. Although some have argued for a regime based on declarations and voluntary visits alone, this would be ineffective when various factors are considered:

- Not all States Parties would volunteer such visits
- Those that did offer such visits would limit them to those facilities that the State Party was certain had a declaration that was consistent with the Protocol,
- Visits would be unlikely to be volunteered to all categories of facilities within a State Party

- Visits would be unlikely to be volunteered to any facility within a particular category.

The scope of such voluntary visits would therefore be limited to specific facilities within a few States Parties. There would be no incentive to States Parties in general to ensure that all declarations were accurate and complete as States Parties would know that none of their facilities would be visited unless they volunteered a visits. The net effect of such a regime would be that over time States Parties would decide what they would include in declarations and the situation would approach that which pertains at present in regard to declarations under the Confidence Building Measures (CBMs) in which individual States decide how much or how little information to submit. The net effect would be to seriously degrade the contribution to be made by declarations to the future regime and would seriously impair the ability of the Protocol to effectively strengthen the Convention. Likewise any suggestions that voluntary visits should take place on a bilateral basis, outside the auspices of a future BTWC organization, are retrograde steps as such a bilateral process would add nothing to building confidence between all States Parties to the Protocol that accurate and complete declarations are being submitted. A regime based on declarations and voluntary visits alone could well create a false sense of security and would clearly fail to build transparency, trust and confidence.

47. Although some have expressed doubts about the benefits of visits, there are strong arguments that visits are an essential component of a strengthened BTWC Protocol and it is apparent that the perceived risks to commercial proprietary information are being overstated and does not reflect the reality of the regime emerging from the AHG negotiations. The debate in the AHG has clearly recognized that the strengthened BTWC Protocol regime must comprise an integrated set of measures and that these measures need to include declarations, visits and investigations together with measures to improve the implementation of Article X of the Convention.

48. Insofar as the perceived risks to commercial proprietary information are concerned, it is apparent that a number of States Parties, particularly in developed European countries where there are significant biotechnology and pharmaceutical industry, have carried out practice random visits and concluded that commercial proprietary information is not put at risk by such visits. A similar more realistic view has recently begun to appear in the United States in an a Policy Forum paper23 on strengthening the BTWC in *Science* by two executives of a vaccine production company. In this it is stated that *"Technologies used to develop and manufacture drugs and vaccines could be used to make biological weapons. Such activities are the reason why certain facilities should be subject to declaration and potential visits."* The article goes on to note that the United States had announced, earlier in 1998, that it would immunize active duty forces against anthrax, and would develop vaccines against other threat agents, and state that:

> *"Our company and selected other biotechnology companies were identified as potential contractors for research, development, or production of these vaccines and would thus be primary targets of compliance investigations under the BTWC."*

and continued:

> *"**As representatives of an industry engaged in defensive programs, we consider such declarations and visits to be non-threatening and manageable**."* [Emphasis added]

They go on to note that:

> *"The risks of losing confidential proprietary business information, genetic material, or proprietary cultures, including the constant threat of corporate espionage, are the day-to-day concerns of industry.* ***The specialized problems associated with a BTWC compliance regime should be easily managed.*** *On-site activities, including access to records relating to fermentation, in-process testing, or other manufacturing procedures; documentation relating to biohazard and occupational safety; and research involving animals are already subject to scrutiny and* ***simply do not pose a threat.****...The concern that some inspectors would be untrustworthy needs to be squarely addressed by diligent security measures that exclude individuals with conflicting interests. But this is everyday practice. There are far greater hazards in normal commercial intercourse." [Emphasis added]*.

They conclude by urging the US industry to recognise *"the importance of strengthening the BTWC and the positive results that would ensure, not on hypothetical and unlikely negative outcomes of a compliance regime."*

49. It is thus becoming apparent that when the actual elements of the strengthened BTWC Protocol are considered or are subjected to practical evaluation, the potential danger to commercial proprietary information are seen to be minimal. Indeed, it is evident that the AHG negotiators are successfully meeting the requirement in their mandate24 that:

> *"Measures should be formulated and implemented in a manner designed to protect sensitive commercial proprietary information and legitimate national security needs."*

whilst devising an efficient and cost-effective integrated regime that will strengthen confidence in compliance with the Convention.

Conclusions

50. Although doubts have been expressed by some, especially within the United States, about possible risks to commercial proprietary information as a result of visits under the future BTWC Protocol, these have not been substantiated by practice visits carried out in several European States which have a significant biotechnological and pharmaceutical industry, nor by those, both in the US and elsewhere, who have carried out analyses of the system of declarations and visits as it is emerging from the Ad Hoc Group negotiations.

51. It is concluded that random and clarification visits together with voluntary request visits all have different yet complementary roles, that are essential and effective, to play in ensuring that declarations are accurate and complete in the strengthened BTWC Protocol thereby enhancing the contribution that declarations make to building transparency and confidence in compliance. They are **non-accusatory** and **non-confrontational** and are **not** associated with any consideration of whether or not a facility is in compliance with the Convention. They

are highly efficient elements of the future regime which strengthen the regime significantly through ensuring accurate declarations yet entail only modest resources.

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