AD HOC GROUP OF THE STATES PARTIES
TO THE CONVENTION ON THE PROHIBITION
OF THE DEVELOPMENT, PRODUCTION AND
STOCKPILING OF BACTERIOLOGICAL
(BIOLOGICAL) AND TOXIN WEAPONS
AND ON THEIR DESTRUCTION

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THE ROLE AND OBJECTIVES OF INFORMATION VISITS

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INTRODUCTION

1. The nature of BW and its close relationship to legitimate microbiological activity necessitates a fundamentally different approach to the design of effective compliance mechanisms. Although declarations and inspections are essential, a different conceptual framework is required to incorporate these elements into a BTWC compliance protocol. The task is made more demanding by several constraints which further limit the scope for manoeuvre.

2. These constraints include the nature of BW and legitimate microbiological activity, the need to strike the right balance so as to limit the burden on the pharmaceutical and biotechnology industry and to make use of the limited resources that are likely to be available to implement a compliance protocol.

3. It is highly unlikely that agreement could ever be secured for a protocol based exclusively on challenge inspections. The continuing political sensitivities surrounding challenge in the CWC underlines the problem. A mechanism with only a challenge provision would set an unnecessary high threshold for the on-site measures that could be taken to pursue non-compliance concerns. There are also grounds for doubting whether such an arrangement would be as effective as a package of interrelated measures consisting of declarations, short-notice validation/information inspections/visits (subsequently referred to in this paper as visits), challenge inspections and procedures for investigating alleged use.

4. This paper identifies the contributions that visits can make to the strengthening of the Convention, but before considering these in detail it is important to recall the technological environment in which visits would take place.

BIOLOGICAL WEAPONS AND DUAL USE TECHNOLOGY

5. The comparative ease and speed of production of significant quantities of biological warfare agents precludes an approach based on material balances. Significant quantities of biological warfare agents could be produced in a matter of days in the same fermenters used

to produce pharmaceuticals or vaccines. It would thus be fatuous to draw reassurance from setting limits on the quantities of agent held by a State Party. Similarly, it would not be practicable to account for all the growth media used at a facility, although there may be circumstances when the fate of relatively large excesses of media requires explanation. Overall, whilst quantitative statements have a limited role as part of national transparency, a quantitative investigative approach would only rarely be useful in questions of compliance.

6. It is thus not appropriate to think in terms of "routine inspections" as understood in the CWC, CFE and INF Treaties for example. A BW inspection or visit, in contrast, requires a more qualitative approach. In practice this means that inspectors have to make an evaluation of a broad range of interrelated factors such as the scale of specific facilities and the explanations provided for their use. A judgment needs to be formed on whether or not the facilities and activities are consistent with their stated purpose, with descriptions of the development of the site and with the BTWC itself.

7. Microorganisms and toxins are used in a wide range of prophylactic, protective and other peaceful purposes such as veterinary, agricultural, pharmaceutical, and academic. The skills, expertise, equipment and materials that would be of potential relevance for a clandestine offensive BW programme are widely diffused throughout the civil sector. Because an offensive programme could be based solely on dual purpose equipment, no universal unambiguous distinction between permitted and prohibited equipment can be envisaged under the Convention. The number of sites possessing a theoretical potential for offensive BW activities is large. However, in most cases it is not the existence of materials and equipment that is the issue, but rather *how* they are used.

8. In the UK, for example, there are some 300 - 400 BL3 hospital laboratories, but there is nothing to be gained from the compliance perspective from making such small scale diagnostic facilities declarable or available for regular inspection. The same is true for the many academic laboratories which carry out research involving relatively low risk pathogens, and for industrial applications such as brewing where neither the equipment nor the local expertise would be immediately relevant to possible concerns under the Convention. Such facilities would not need to be declared as they would not add anything of specific value to transparency and would flood the system with "noise".

9. Visits, however, would therefore have completely different objectives from those of comparable inspections under other arms control agreements. These objectives relate to both the technical context in which the visits take place as well as their role within the overall compliance protocol.

POTENTIAL BENEFITS OF VISITS

10. Visits have five interrelated benefits:

(i) Providing an opportunity to validate declarations in the context of the site activities and hence encourage States Parties to make accurate declarations;

(ii) Facilitating transparency of national microbiological activities related to the BTWC;

(iii) Providing an understanding of how national safety, genetic engineering, quality control, GMP, etc. rules and regulations operate and how they are implemented in practice;

(iv) Facilitating the relationship between the State Party and the Organization on issues such as national requests for assistance on declarations; and an opportunity to review declaration procedures with individual States Parties;

(v) Contributing to deterring potential proliferators.

11. The key point is that visits are part of an integrated and balanced package of measures, each carefully crafted to complement the other constituent components of the protocol. These components would include: declarations covering military microbiology, BL4 biocontainment laboratories, aerobiology, work with listed agents/toxins and production microbiology, and past activities; challenge inspections in response to specific compliance concerns; investigations of alleged use; and, in order to implement the regime effectively, a professional inspectorate.

(i) Validating declarations in the context of the site activities, hence encouraging States Parties to make accurate declarations.

12. BW visits cannot be limited to "bean counting". Little is achieved, for instance, from only confirming the presence of X fermenters and Y agents or toxins as reported in the site declaration. If such an approach were adopted there is a risk that visits so constrained could give rise to false confidence in compliance thereby leading to complacency as time passes. It is important to guard against the presumption that accurate declarations signify full compliance with the BTWC.

13. Visits should thus not be limited to simple quantitative methods. A much more fruitful approach would see the visit broadly confirm the consistency of the declarations and the extent to which they relate to the activities and development of the site and thus to the purpose of the site as a whole. Placing declarations in the context of the facility would provide higher levels of confidence than merely checking for the presence or absence of specified objects.

14. The possibility that a declared site may be visited will encourage a State Party to ensure accuracy in the compilation of site and national declarations. One of the limitations of the current CBMs is the inability to make formal follow-up enquiries about individual returns, and secure more than a voluntary response. The entire site in which the declarable activity occurs would be open for the visit ie not just the declarable laboratory or production plant.

This will help ensure that there are no relevant activities undeclared within the geographic boundaries of the site, thus avoiding one of the CWC's major limitations.

(ii) Facilitating transparency of national microbiological activities related to the BTWC.

15. As each year goes by inspectors should be able to gain a better appreciation of the nature of microbiological activities, their scope and their potential risk to the Convention in States Parties; they only need to visit a handful of sites in individual states to achieve this. Visits will help put into clearer perspective information gleaned from declarations and public domain information such as company reports, academic literature, national government and non-governmental documents. Both the visits and information will help contribute to greater transparency, and to an understanding of special national features (eg the problems posed for industry by animal rights activists in the UK and the consequent need for extensive physical security). All of these factors will contribute significantly to a broader baseline against which the inspectorate can judge any future compliance concerns.

16. Transparency, especially in BW defence activities, helps enhance the level of confidence that the provisions of the BTWC are being observed. Candour and openness about the history and purpose of facilities and programmes are essential factors in the BTWC protocol. This helps avoid suspicion and reduces the likelihood that ambiguities develop into compliance problems.

(iii) Understanding how national safety, genetic engineering quality control, GMP, etc regulations operate and how they are implemented in practice.

17. The operation of health and safety regulations and product licensing procedures have a direct bearing on the conduct of an inspection. Inspectors need to understand how extensive these arrangements are; for example, those governing standards of containment and genetic engineering. They will need to see how these rules operate in practice since they provide a benchmark against which to judge activities or the design and scale of particular facilities or equipment. They can help the inspectors judge whether information is consistent with declared and stated purpose.

18. Product licensing requirements, GLP and GMP protocols at individual sites can also be used by the inspectors and inspected State Party to help explain site activities. The associated documentation provides collateral for statements made about, and explanations given for, the purpose and use of facilities. Prior knowledge and understanding of the relevant regulations and the way these are implemented puts inspectors in a better position to evaluate the evidence during visits to other sites in a country.

19. In the event of a challenge inspection, prior familiarity with the operation of these rules helps inspectors determine whether genuine safety or regulatory policies are being used to obstruct the investigation; there may also be evidence that they have assumed a new and uncharacteristic stringency. In such circumstances it becomes much more difficult to invoke

national safety regulations as a reason to limit access if inspectors are aware of the rules and regulations and how they are interpreted.

20. The benefits outlined in (ii) and (iii) above are the two strongest arguments in favour of visits. The inspectorate will be able to conduct much more thorough challenge inspections if it has the knowledge and experience gained from earlier visits. This information provides one very helpful yardstick against which to judge facilities, activities and explanations when there is a specific compliance concern under investigation.

(iv) Facilitating the relationship between the State Party and the Organization on issues such as national requests for assistance on declarations, and providing an opportunity to review declarations procedures.

21. The relationship between the State Party and the Agency should not be confrontational. There may be unavoidable national practical difficulties in compiling declarations such as interpreting how the declaration modalities apply to a State Party's specific circumstances. Visits provide an opportunity to discover what the practical difficulties might be. Advice could be offered to the host government's representatives attending the site on the correct interpretation of the modalities. Help could also be made available, through the government, to other sites needing to make declarations. The government itself could be offered assistance in compiling national returns. These benefits will be important for many countries.

22. Declaration modalities might need to be changed in light of practical experience. They may have to respond to changes in administrative and industrial practice; and accommodate new areas of direct relevance to the Convention as technology develops. Visits would provide an opportunity to address these issues with government and facility personnel.

23. Visits may also provide an opportunity for a State Party to seek advice on the practical aspects of health and safety in handling microorganisms and toxins. Inspectors could be trained to give advice on such matters. It has been the experience of national health and safety agencies that in situations where there is a low to moderate microbial hazard, safety can often be markedly improved by raising awareness and by improving appropriate working practices without the need for containment equipment or rooms with inward air flows. Thus, in practice, inspectors may often be able to suggest relatively inexpensive improvements in safety.

(v) Contributing to deterring proliferators.

24. Short notice challenge inspections provide the principal means of deterring non-compliance. The technical realities of BW and the very large number of potential sites means that visits cannot provide the same level of deterrence as challenge inspections of declared and undeclared facilities.

25. The most significant contribution will be their indirect one: they can, by creating a linkage between declarations and individual sites, help enhance transparency and openness, essential prerequisites for confidence in compliance. A proliferating State Party would be confronted with the dilemma of either having to declare all relevant sites or deliberately omitting those working on offensive BW. Under declaring may attract unwelcome international attention which could lead to a challenge inspection.

26. The inspectorate in some circumstances could select a site for a visit which reflected national or international concerns. A low key approach would provide a means to investigate possible problems without the politically charged atmosphere of a challenge inspection.

27. A proliferating State Party might run a greater risk of discovery if it conducted offensive BW activities in a declared site, or incur greater costs in order to create sufficient cover for these activities. If visits are to provide a degree of deterrence in this way, it is essential that they are undertaken at short notice. Any delay will reduce the cost to a proliferating state and the deterrence value of information visits will also be reduced accordingly.

CONCLUSIONS

28. The following factors need to be kept in mind when considering a BTWC compliance protocol. First, the nature of BW means that it is not practicable to approach the design of verification measures purely in terms of quantitative criteria. Prohibition thresholds cannot be used to prevent BW proliferation. Simple “bean counting” of dual use agents and equipment will not strengthen the Convention. Instead, inspectors have to make qualitative judgements about the consistency and plausibility of the information obtained.

29. Second, a protocol based solely on challenge inspection would not be negotiable, nor indeed as effective as an integrated package of measures as outlined here. It would, moreover, be expensive to keep a cadre of full-time inspectors on stand-by against the day that a challenge inspection might be requested.

30. Third, industry has an overriding preference for full-time professional inspectors as they pose a much lesser risk to commercial confidentiality. In fact this is parallelled by a governmental benefit in respect of the protection of national security information.

31. Fourth, full-time inspectors enable the conduct of timely and effective inspections: they also ensure that the system of visits and its attendant benefits are fully exploited. Such inspectors are much more likely to be competent as an organization can better maintain high and uniform approaches. Furthermore, teams can be assembled quickly from a pool of experienced personnel, well-versed in inspection techniques, trained to the same standard, and possessing the necessary vaccinations.

32. The five benefits of visits discussed here are key elements of a broader compliance protocol. They are a response both to the technical factors and requirements for an effective

compliance protocol. Visits should not impose an unreasonable burden on legitimate activities. The numbers of such visits to any one State Party over a given period of time will be limited. It is essential to see visits as part of an integrated package; the benefits are mutually reinforcing, but they will not work in isolation. Their utility must be viewed in conjunction with other elements of the compliance protocol.

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