

THE CWC VERIFICATION REGIME: IMPLICATIONS FOR THE BIOTECHNOLOGICAL & PHARMACEUTICAL INDUSTRY

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Introduction

1. The Ad Hoc Group (AHG) of the States Parties to the Biological and Toxin Weapons Convention (BTWC)¹ is considering "*measures to strengthen the effectiveness and improve the implementation of the Convention*" through a legally binding instrument.² The AHG successfully transitioned in July 1997 to consideration of a rolling text for the Protocol which has now developed to contain language, albeit with square brackets indicating alternative views, for most if not all that is required for an effective Protocol.

2. Particular attention is being given by the AHG to devising an integrated regime that is effective in building confidence in compliance by States Parties with the Convention.³ Comprising declarations, visits and investigations as its three main pillars, such an integrated regime would strike a proper balance in the declarations it required from those facilities of particular relevance to the Convention whilst avoiding the unnecessary burden which could result were declarations to be required from all facilities of possible relevance to the Convention. The current draft Protocol⁴ provides for declarations by the following types of microbiological production facility:

(ii) Which produce vaccines [and/or toxoids/anatoxins][licensed by the State Party] for the protection of humans [against listed agents or toxins][with a production capacity as specified in Annex...][with primary production containment];

(iii) Which produce vaccines [and/or toxoids/anatoxins][licensed by the State Party] for the protection of animals [against listed agents or toxins][with a production capacity as specified in Annex...][with primary production containment];

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¹United Nations General Assembly, *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction*, Resolution 2826(XXVI), 16 December 1971.

²United Nations, *Special Conference 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*, Final Report, BWC/SPCONF/1, Geneva, 19 - 30 September 1994.

³Graham S Pearson, *The Strengthened BTWC Protocol : An Integrated Regime*, University of Bradford Briefing Paper No 10, July 1998. Available at <http://www.brad.ac.uk/acad/sbtwc>

⁴The current version of the rolling text is that produced following the January 1998 meeting together with the further changes issued following the March 1998 meeting. United Nations, *Procedural Report of the 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*, BWC/AD HOC GROUP/39, 2 February 1998 and United Nations, *Procedural Report of the 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*, BWC/AD HOC GROUP/40, 17 March 1998. Also available at <http://www.brad.ac.uk/acad/sbtwc>

[(iv) Which produce plant inoculants and/or biological control agent(s) and have a plant quarantine capability [with primary production containment];]

[(viii) Other microbiological production facilities...not working with listed agents which have an aggregate fermenter production capacity of [100][1000]litres or more...

and infrequent non-challenge visits to declared facilities.

3. These proposals have led people within the pharmaceutical and biotechnology-based industry to suggest that a strengthened BTWC would impose a whole new type of burden on the industry. Yet in fact the industry, like the rest of the chemicals industry, falls within the ambit of the 1993 Chemical Weapons Convention (CWC), which entered into force a year ago and currently has 108 States Parties, including all EU Member-States and all other major industrialized countries. Another 60 States have signed but not yet completed the requisite ratification processes. This Briefing Paper sets out some of the key provisions of the CWC, including the verification regime set out in the CWC Verification Annex, the implementation of which is now getting under way in the industry. The Briefing Paper draws lessons from the CWC experience for the strengthening of the BTWC.

Overview of the CWC Verification Regime

4. The verification regime for the CWC is a system operated jointly by, on the one hand, the Technical Secretariat of the CWC's international authority, the Organization for the Prohibition of Chemical Weapons (OPCW) based at The Hague, and, on the other hand, the "*national authorities*" which, under CWC Art VII.4, each State Party is required to designate or establish "*[i]n order to fulfil its obligations under this Convention*". The treaty defines chemical weapons in such a way as to bring within its purview any activity involving toxic chemicals, broadly defined, or substances from which toxic chemicals can be made. Some parts of pharmaceutical and biotechnology-based industry are therefore already experiencing the CWC verification regime. Moreover, the entire industry (except where located within countries not party to the treaty) is subject to the 'challenge inspection' procedures of the regime. The purpose of this Briefing Paper is to outline these CWC-mandated controls on biotechnology.

5. The CWC-verification system has several components.⁵ Some are **inspection activities** of various types. These are the "*verification measures provided for in this Convention*" which the OPCW Technical Secretariat, according to CWC Art VIII.37, must carry out. More specifically, according to CWC Verification Annex Part II.3, these activities are to be performed by the Secretariat's "*designated inspectors and inspection assistants*", and only by them. Other components of the verification system are **declaration activities**: the collection, reporting and processing of specified kinds of information relating to chemical weapons or to

⁵A systemic analysis of the CWC verification regime is contained in the present author's "The Verification System for the Chemical Weapons Convention", in Hague Academy of International Law, *The Convention on the Prohibition and Elimination of Chemical Weapons: A Breakthrough in Multilateral Disarmament*, edited by Daniel Bardonnet (Nijhoff, 1995) pp 489-506.

technologies that could be used to make them. Herein lies a division of labour that underpins the entire verification regime. The National Authorities are responsible for collecting and reporting the information that the Convention obliges States Parties to declare either at regular intervals or when occasion arises, depending on the type of information. The Technical Secretariat is responsible for receiving and processing the declarations and, through the 'routine inspection' procedures, for validating some of them. To be able to make the declarations, the National Authorities must have entered into an intimate monitoring relationship with all relevant parts of their countries' technological base, including civil industry. High standards of monitoring are in principal assured through the relationship of mutual scrutiny between the National Authorities and the Technical Secretariat instituted by the many international procedures of the treaty. Completing the regime is the possibility of short-notice challenge inspection at virtually any location, a threat which the Convention poses so as to deter potentially non-compliant States from exploiting technologies or facilities that lie outside the declarations-bounded domain of routine inspection.

6. In the broad architecture of the CWC verification regime, three principal elements can thus be discerned: mandatory declarations, routine inspection, and challenge inspection. The strength of the overall construct must depend not only on system-design but also on the powers of the system-operators Ð the OPCW Technical Secretariat and the National Authorities Ð and on their respective propensities for collaboration within their assigned division of labour. The prevailing tendency in international relations today is still to minimize the autonomy and capacity for independent action of international organizations such as the OPCW. So, whether CWC-derived controls do or do not come to bear down heavily upon biotechnology would appear, at the present juncture, to depend less on what the OPCW Technical Secretariat does and more on what the National Authorities choose to do. It is important in the present paper, therefore, to identify the role and powers of the National Authorities within the overall regime.

Role and Powers of the Article VII National Authorities

7. The purpose of the verification system is to generate and sustain confidence among the States Parties that they are better off inside the CWC than outside it:⁶ that it is worth their while continuing to pay their membership dues and to accept the constraints and burdens imposed by the treaty. The verification system itself contributes to those burdens, which means that, in principle, there can be both too much and too little verification. This principle was well recognised by the original negotiators of the CWC, and led them to assign a major role to the national authorities within the overall verification regime. Thus, by making individual chemical companies accountable for treaty-compliance, not in the first instance to the OPCW, but to their national authorities, the burden of bureaucracy could be reduced; and any threat that those companies might see to their confidential proprietary information in the requisite accountability could be no different from that to which they were accustomed in

⁶This particular concept of the function of compliance-verification within a multilateral regime of chemical-warfare arms control and disarmament is drawn from earlier studies by the present author including: *Chemical Warfare Arms Control*, London: Taylor & Francis for the Stockholm International Peace Research Institute, 1985 [SIPRI Chemical & Biological Warfare Studies no 2]; 'Verifying a ban on chemical-warfare weapons', *Faraday Discussion Paper* [London: Council for Arms Control] no 12 (1988); and 'Implementing the Chemical Weapons Convention', *International Affairs* [London: Royal Institute of International Affairs] vol 72 no 1 (January 1996) pp 73-89.

other areas of government-industry dealings. To reinforce this particular relative advantage (as compared with alternative forms of verification), the negotiators devised the strict information-confidentiality regime imposed upon States Parties by CWC Art VII.6 and upon the OPCW Technical Secretariat by CWC Art VIII.5 and the Confidentiality Annex.

8. The powers envisaged in the treaty for the National Authorities are extensive in that CWC Art VII.4 assigns to these bodies the responsibility for ensuring that States Parties are fulfilling their obligations. Some States-Parties have established their national authorities within their ministries of economics, trade, industry or commerce; others, within their ministries of foreign affairs; others still, within special commissions. Full implementation of the CWC is proving a slow process, even though the treaty did not enter into force until 29 April 1997, more than four years after it had been opened for signature. It is possible that, despite the educational efforts of the OPCW Preparatory Commission and then the Technical Secretariat, not all States-Parties have yet sufficiently appreciated what is expected of their national authorities. In other respects, too, the 'level playing field' on which the original negotiators sought to ensure that their industries would compete while controlled remains unrealised. This is evident in, for example, the continuing absence of consensus among States-Parties on the "*low concentration*" issue and on the question of which biotechnological-process products should be treated as discrete organic chemicals "*produced by synthesis*". For the time being, it is up to each National Authority to decide for itself the positions on these and other such issues, which it will then implement in its industry. Furthermore, a number of key States-Parties have still to adopt legislation empowering their National Authorities to do what the CWC requires of them. The weight of influence of the National Authorities within the overall regime is therefore not yet as strong as originally intended.

9. Wisely, the original negotiators first devised the procedures whereby the National Authorities and the OPCW Technical Secretariat would be placed in a continuing relationship of mutual scrutiny, and, having done that, chose to leave most of the detailed specification of the duties of the National Authorities to the States Parties. This is so in the case of the most onerous obligation of all, that of CWC Art VI.2. This provision of the treaty requires each State Party to "*adopt the necessary measures to ensure that toxic chemicals and their precursors are only developed, produced, otherwise acquired, retained, transferred, or used within its territory or in any other place under its jurisdiction or control for purposes not prohibited under this Convention.*" Only as regards the chemicals listed in the schedules of the CWC Annex on Chemicals does the provision go on to specify how it is to be implemented. So it is left for individual States-Parties to decide what the "*necessary measures*" should be for the huge multitude of unscheduled chemicals (including toxins and other toxic biotechnological-process products) also subject to the Art VI.2 provision in accordance with what has come to be called its 'general purpose criterion'. This means, in effect, that it is to the National Authorities, not to the OPCW, that the CWC has assigned the task of overseeing implementation of a major provision of the treaty. The same can be said of several other primary obligations of the treaty for which the Technical Secretariat has no assigned role in monitoring compliance. Notable examples of such implementation duties falling by default to the National Authorities include the CWC Art I.1(a) obligation not to "*develop*" chemical weapons and the CWC Art I.1(c) obligation not to "*engage in any military preparations to use chemical weapons*".

10. The extent to which National Authorities have recognised and accepted these default duties is not yet evident from the public record. The Iraq-UNSCOM relationship has no doubt given pause for thought about the propriety and the effectiveness of an international regime becoming significantly dependent upon national agencies; likewise the behaviour of the Soviet Union towards the Biological Weapons Convention. (Iraqi authorities have been deliberately concealing from international inspectors an ambitious biological-weapons programme which the UN Security Council ceasefire resolution had outlawed in 1991, at the close of the Kuwait War. The USSR had continued development of biological weapons even after entry into force of the BTWC, and built large-scale production capacity for the weapons within its civilian pharmaceutical and biotechnology-based industry.) Yet the remedy to compliance-dereliction at high governmental level is surely to strengthen the procedural links between the national and international authorities, not to diminish the role of national agencies. The fact remains that the CWC establishes an expectation that the National Authorities will both be accorded and exercise substantial powers for domestic implementation of the treaty, and that their implementation is subject to international verification.

11. As regards particular default duties, a number of National Authorities have expressly recognised at least the guardianship of the General Purpose Criterion which CWC Art VI.2 implicitly entrusts to them. This can be seen in, for example, the statutory annual report to Parliament of the UK National Authority for 1997.⁷ The Criterion is an element of the CWC regime that is especially pertinent to the present paper, for it is what brings so much of biotechnology-based industry within the ambit of the CWC verification system.

12. The significance of the General Purpose Criterion is described in the following paragraphs. Quite apart from the role of the CWC National Authorities in overseeing its implementation, it is evident from the preceding paragraphs that these bodies are essential to effective relations the OPCW and the States-Parties. A strengthened BTWC will surely also require the creation or designation of counterpart national bodies.

The General Purpose Criterion

13. The General Purpose Criterion is the device which the original negotiators of the CWC copied from the Biological Weapons Convention in order to give adequate scope to their treaty. As set out in CWC Art II.1(a), it defines the objects prohibited by the Convention "chemical weapons" not in terms of intrinsic properties but in terms of purposes for which they exist: *"toxic chemicals and their precursors, except where intended for purposes not prohibited under this Convention, as long as the types and quantities are consistent with such purposes"*. What those purposes may be are listed "rather more specifically than the *"prophylactic, protective or other peaceful purposes"* which the Biological Weapons Convention uses in relation to *"microbial and other biological agents, and toxins whatever their method of production"* in CWC Art II.9,⁸ while in CWC Art II.2

⁷United Kingdom, Secretary of State for Trade and Industry, *1997 Annual Report on the Operation of the Chemical Weapons Act 1996*, February 1998.

⁸CWC Art II.9 reads: *'Purposes Not Prohibited Under this Convention' means:*

a) *Industrial, agricultural, research, medical, pharmaceutical or other peaceful purposes;*

b) *Protective purposes, namely those purposes directly related to protection against toxic chemicals and to protection against chemical weapons;*

"toxic chemical" is defined to mean "any chemical which through its action on life processes can cause death, temporary incapacitation or permanent harm to humans or animals". A chemical weapon in the sense of the CWC is therefore a considerably broader concept than the chemical weapon of, say, common military parlance. Without that breadth, chemical-warfare agents of novel but still-secret chemical identity, or toxic chemicals not yet discovered or made newly accessible through manufacturing innovation, would be unaffected by the strictures of the treaty. The General Purpose Criterion thus allows the Convention to keep up with technological change.

14. No less important, the General Purpose Criterion is also the device that protects beneficent peaceful application of the so-called 'dual use' chemicals. These are the substances which can serve purposes not prohibited under the CWC but which can also be used as chemical-warfare agents, or as precursors in the manufacture of such agents. Examples include such widely and heavily used industrial intermediates as chlorine, phosgene and hydrogen cyanide, which also happen to be first-generation military poison-gases. The General Purpose Criterion operates to permit their industrial use instead of suppressing it, as the disarmament stipulations of the Convention would otherwise demand. Further examples of dual-use chemicals protected by the General Purpose Criterion are to be found within the pharmaceutical industry, including scheduled chemicals, such as 3-quinuclidinyl benzilate and saxitoxin, and unscheduled chemicals, such as the *Clostridium botulinum* toxins.

15. The General Purpose Criterion is restated in the CWC Article VI.2 provision quoted above (in paragraph 9) as a positive obligation upon States Parties to adopt the measures necessary to give it force. As regards unscheduled chemicals, one of the few areas in which the operation of such measures is evident is the work of the Australia Group, which, however, concerns only a limited number of chemicals and is restricted to export controls. As regards scheduled chemicals, Art VI.2 incorporates into the treaty both the Annex on Chemicals and the Verification Annex whereby an agreed international control regime is defined in detail, to be supervised by the OPCW Technical Secretariat. The principal features of this chemical control regime are summarized in Table 1. Article VI.2 is thus the basis for the system of mandatory declarations and routine inspections to which civil chemical industry is subject under the CWC.

Table 1. The chemical control regimes under the CWC

<i>Elements of control regime</i>	<i>For Schedule 1 chemicals</i>	<i>For Schedule 2 chemicals</i>	<i>For Schedule 3 chemicals</i>	<i>For unscheduled discrete organic chemicals</i>

c) *Military purposes not connected with the use of chemical weapons and not dependent on the use of the toxic properties of chemicals as a method of warfare;*
d) *Law enforcement including domestic riot control purposes.*^Ó

<i>Production limit</i>	No more than 1000 kg of all types may be held by a state-party	None specified, but all production must be for, and in quantities consistent with, purposes not prohibited under the Convention		
<i>Data reporting (initial and annual)</i>	Yes: detailed information on production, use, import and export	Yes: for each one, aggregate national data on production, use, import and export	Yes: for each one, aggregate national data on production, import and export	No, except for plant specific data (as with the scheduled chemicals)
<i>Inspection of facilities producing more than threshold quantities</i>	Yes: highly stringent and augmented with instrumented monitoring	Yes	Yes: less stringent	Not until EIF+3 yrs, if then approved by the Conference of the States Parties
<i>Export control</i>	Exports permitted only to states parties, with advance notification of OPCW	End-use certification required until EIF+3 yrs, after which exports permitted only to states parties	End-use certification required; and possibility of other measures after EIF+ 5 yrs	None specified

16. In summary, then, the General Purpose Criterion is vital to the future well-being of the CWC regime. Any neglect over the years ahead could bring obsolescence to the regime, opportunity for camouflaging prohibited activities, and a weakening of the safeguards against ill-considered calls for the suppression of beneficial technologies that happen also to have weapons applications. It is fortunate that the BTWC contains a similar device, and it is vital that nothing in the projected BTWC Protocol be allowed to detract from it. Above all, it is surely essential that such lists as may have to be written into the BTWC Protocol for verification purposes do not come to be seen as limiting the scope of the General Purpose Criterion, and therefore also the scope of the treaty itself.

The Mandatory Declarations

17. The CWC obliges States Parties to submit declarations and notifications of a wide variety of information, some during the period immediately succeeding entry into force of the treaty, some occasionally, and some recurrently. Article III provides for the declarations concerning past chemical-weapons programmes: data on any remaining holdings of chemical weapons, including old or abandoned chemical weapons; on facilities for development, storage, production or destruction of chemical weapons; and also on *"riot control agents"*. These declarations enable the OPCW Technical Secretariat to identify the facilities that the CWC requires be made subject to *"systematic verification"*. Article VI provides for the declarations of industrial rather than chemical-weapons data. The original negotiators intended the declarations of industrial information as means for identifying facilities whose 'dual use' attributes rendered them a particular threat to the *"object and purpose of this Convention"* – in other words facilities that might be especially attractive to potential cheaters seeking to conceal production of chemical-warfare agents behind a façade of legitimate industrial activity, or even facilities that had been deliberately constructed so as to furnish such concealment. Thus identified, the facilities would be subject to a regime of routine inspection intended to reduce their concealment potential and thus drive cheaters out to more exposed venues.

18. For purposes of the Article VI declarations, the CWC Annex on Chemicals sets out three schedules, which together list 43 species or families of chemical: 12 in Schedule 1 (including saxitoxin and ricin, as well as blister and nerve gases and intermediates thereof), 14 in Schedule 2, and 17 in Schedule 3 (including hydrogen cyanide, which as a toxic agent of biological origin is a toxin within the meaning of the Biological Weapons Convention). Of the 43, 27 are precursors and 16 are toxicants. Each of the chemicals has been scheduled because it is deemed to pose a risk to the object and purpose of the Convention, the chemicals in Schedule 1 a *"high"* risk, and those in Schedule 2 a *"significant"* risk. The scheduling also reflects the degree of industrial application of the listed chemicals, those in Schedule 3 being ones *"produced in large commercial quantities"* and those in Schedule 1 *"having little or no use for purposes not prohibited under this Convention"*. The three schedules are in fact negotiated lists, though criteria for adding new chemicals to them, or removing existing ones, are also specified in the Annex on Chemicals. Two categories of declaration are triggered by each schedule, one having to do with the chemicals *per se*, the other with facilities associated with them. The amount of detail required is greatest for Schedule 1 and smallest for Schedule 3, this reflecting the differing stringency of the control regime associated with each schedule. The facilities to be declared are ones in which more than threshold quantities of the chemicals are produced or, for chemicals on Schedules 1 and 2, processed or consumed. The facility declarations also extend, with certain exemptions, to plant sites where *"unscheduled discrete organic chemicals"* are *"produced by synthesis"* in more than threshold quantities. Annual declarations are made in two broad types, one reporting data for the previous year, the other reporting anticipated data for the year ahead. A summary of all these declaration requirements is given in Table 2.

Table 2. Chemical industry declarations required of CWC States-Parties

<i>CWC element</i>	<i>Information to be declared by each State Party</i>	<i>Deadline</i>
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VerAx VII.9-10 VerAx VIII.9-10	Each plant site where there is plant that has produced Schedule 2 or 3 chemicals for chemical-weapons purposes at any time since 1 January 1946	By entry into force (EIF) + 30 days
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<i>CWC element</i>	<i>Information to be declared by each State Party</i>	<i>Deadline</i>
VerAx VI.17-20	<p>Location and details of all facilities approved for production of more than 0.1 kg/yr of Schedule 1 chemicals for research, medical or pharmaceutical purposes.</p> <p>Annual declarations also required: of prior-year production, consumption, storage and transfer, and of projected next-year production.</p>	<p>By EIF + 30 days</p> <p>By year-end + 90 d & year-start - 90 d</p>
VerAx VII.1-2	<p>Aggregate national data on the production, processing, consumption, import and export of Schedule 2 chemicals, for each such chemical during the previous calendar year.</p> <p>Declaration to be repeated annually.</p>	<p>By EIF + 30 days</p> <p>By year-end + 90 d</p>
VerAx VIII.1-2	<p>Aggregate national data on the production, import and export of Schedule 3 chemicals, for each such chemical</p> <p>Declaration to be repeated annually.</p>	<p>By EIF + 30 days</p> <p>By year-end + 90 d</p>
VerAx VII.3-8	<p>Each plant site where Schedule 2 chemicals have recently been, or will next year be, produced, processed or consumed in amounts exceeding 1 ton/yr (or less for three of the chemicals: see Table 3), with details.</p> <p>Annual declarations also required, both of prior-year and of projected next-year activities.</p>	<p>By EIF + 30 days</p> <p>By year-end + 90 d & year-start - 60 d</p>
VerAx VIII.3-8	<p>Each plant site where Schedule 3 chemicals have been or will be produced in amounts exceeding 30 ton/yr, with details.</p> <p>Annual declarations also required, both of prior-year and of projected next-year activities.</p>	<p>By EIF + 30 days</p> <p>By year-end + 90 d & year-start - 60 d</p>

VerAx IX.1-6	<p>For unscheduled discrete organic chemicals, each plant site where more than 200 tons were synthesized during the previous year, unless the chemicals contain P, S or F, in which case the threshold is 30 tons, or unless the chemicals are exclusively explosives or hydrocarbons.</p> <p>The list of sites is to be updated annually.</p>	<p>By EIF + 30 days</p> <p>By yr-start + 90 d</p>
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19. Information contained in the various declarations has the protection from disclosure afforded by CWC Art VIII.5, which states that the OPCW *"shall take every precaution to protect the confidentiality of information on civil and military activities and facilities coming to its knowledge in the implementation of this Convention and, in particular, shall abide by the provisions set forth in the Confidentiality Annex"*. The Confidentiality Annex requires the OPCW Director-General to establish a special regime for protecting confidential information, for which it sets out guidelines. The confidentiality regime that is now in place actually makes it rather difficult for the outside world to know even in broad terms how well the treaty is being implemented, let alone what the content of individual facility declarations, say, might be. If a State-Party wishes any information it declares to the Technical Secretariat to be protected, it simply has to designate it as 'confidential' and indicate which of the three available levels of protection should be applied to it. The Secretariat is then obliged to protect the information accordingly. The Director-General has complained publicly of the tendency of some States Parties to assign unnecessarily high protective markings to some or all of their declarations. The States-Parties themselves, through their National Authorities, are entitled under paragraph 2(b) of the Confidentiality Annex to be *"routinely provided"* with such data as they require *"to be assured of the continued compliance with this Convention by other States Parties"*. This provision goes on to state that such data may include the initial and annual reports and declarations under Articles III, IV, V and VI. According to CWC Art VII.6, it would appear that only people in government who have responsibilities for domestic implementation of the Convention may have access to confidential information supplied under paragraph 2(b).

20. In summary, it is hard to envisage an international verification regime for the CWC which did not pivot on a system for mandatory declarations. What information should actually be declared clearly depends upon prevailing circumstances, meaning that mechanisms for reconsidering and, if necessary, amending the requirements are perhaps no less important within the overall regime. Both these conclusions are applicable also to the projected BTWC verification regime.

The Routine Inspections

21. If the annual quantity of scheduled chemical processed, consumed and/or produced in a declared facility exceeds a specified threshold, the facility becomes liable to routine inspection by the OPCW Technical Secretariat. It is not obvious, in retrospect, that this simple quantitative method for triggering the international inspectorate into action within civil industry is really the best way of ensuring that all industrial 'dual use' facilities that are

especially vulnerable to abuse are brought within the ambit of routine inspection. As set out in the treaty, the trigger is clearly a compromise. The key thing about it is that it is the outcome of international negotiation in which senior representatives of chemical industry, as well as diplomats and chemical-weapons experts, were involved throughout. Important for industry representatives was the willingness of the diplomats first to write into the treaty stringent provisions for safeguarding confidential proprietary information (see paragraphs 7 and 19 above), secondly to accept that the number of routine inspections a State-Party would be required to receive at declared industrial facilities each year would be rather tightly limited, and thirdly to accept that each and every routine inspection could be governed by a "*facility agreement*" that had been negotiated bilaterally between the OPCW Technical Secretariat and the State-Party concerned. These facility agreements limit access by OPCW inspectors solely to those particular areas of a plant site that had been declared as producing, or otherwise handling, a scheduled chemical; the facility agreements preclude access to other areas. Within those parameters, the intrusiveness of routine inspection varies from schedule to schedule. A summary of the facility control regime is given in the Annex.

22. The disclosure of information gathered by the OPCW Technical Secretariat during routine inspections is governed in the first instance by the reporting procedure set out in CWC Verification Annex Part II.60 and 62-65, and thereafter by the confidentiality regime (see paragraph 19 above). During the day following an inspection, the inspectors are to write a preliminary report on a standardized form after they have met to review the inspection with representatives of the inspected facility and the inspected State Party, this also being opportunity for clarifying ambiguities. Attached to the preliminary report is to be a list of all data gathered, samples taken, written information obtained and anything else which the team will be taking off site. A copy of all this is to be given to the inspected State Party. Within the next ten days a final report is to be prepared and sent to the inspected State Party, whose comments, if any, will be annexed to the report when it is transmitted to the Director-General. The latter may, as he thinks fit, seek clarifications from the inspected State Party, and if these prove unsatisfactory the OPCW Executive Council is to be informed without delay. Throughout this process the report is to remain confidential. The Confidentiality Annex, in its paragraph 19, states that if information contained in the report has to be transmitted beyond the inspected State Party and the Technical Secretariat, it may first be "*processed into less sensitive forms*". It was in December 1997 that routine inspection of civil chemical industry commenced, so experience with these various provisions is only now starting to accumulate. There have been slight hitches, but basically the system appears to be working.

23. In summary, the key points to note here are that routine industry inspections under the CWC are carried out relatively infrequently (perhaps once every three years at a particular facility), and that they are tightly circumscribed inspections that are confined to declared areas of plant sites.

Challenge Inspection

24. Routine inspections are not meant to discourage production of chemical weapons or other illicit activities in undeclared facilities, nor can they be expected to deter abuse of declared facilities, such as could conceivably happen if cheaters were to find ways of evading the procedures prescribed for the routine verification regime. Moreover, routine inspections do not allow States Parties much opportunity to demonstrate that particular facilities within

their jurisdiction are not being abused. The challenge inspection provisions of the CWC are intended to serve the first two of these functions. They could also contribute to the third. A State-Party wishing to dispel doubts or allegations concerning its own compliance may, under CWC Art IX.5, seek the assistance of the Executive Council to clarify the situation. It is up to the Council to decide what to do, but among its options will be that of organizing a special inspection by the Technical Secretariat. No challenge inspections have yet been conducted under the CWC. A number of States-Parties have, however, invited the participation of the OPCW Technical Secretariat in practice challenge inspections.

25. The challenge-inspection provisions of the treaty are as follows. When a question of compliance becomes an issue, CWC Art IX.2 requires that the States-Parties concerned first make every effort to resolve the issue among themselves through exchange of information and consultations. If that does not work, the challenge procedures can be invoked. By CWC Art IX.8, *"each State Party has the right to request an on-site challenge inspection of any facility or location...under the jurisdiction or control of any other State Party for the sole purpose of clarifying and resolving any questions concerning possible non-compliance...and to have this inspection conducted anywhere without delay by an inspection team designated by the Director-General ..."*. By CWC Art IX.11(b), the challenged State is obliged *"to provide access within the requested site for the sole purpose of establishing facts relevant to the concern regarding possible non-compliance"*. By CWC Art IX.12, the requesting State may attach an observer to the inspection team whom the challenged State is expected but not obliged to accept. The challenged State is required by CWC Art IX.11(a) *"to make every reasonable effort to demonstrate its compliance with this Convention"*.

26. Three principal limitations are placed upon the challenge-inspection process by the Convention in order to provide protection against abuse. These limitations follow from CWC Art IX.9, which obliges States Parties to keep inspection requests *"within the scope of this Convention"* and to justify their requests by including *"appropriate information"*. The first limitation subjects requests to a filtering mechanism, the so-called 'red light' procedure. By CWC Art IX.17, the OPCW Executive Council, to which the inspection request must be transmitted as well as to the Director-General of the Technical Secretariat, may block inspection if it deems the request to be *"frivolous, abusive or clearly beyond the scope of this Convention"*. Such action requires a three-quarters majority of the Council, and must be taken within 12 hours of the request. The second and third limitations are mandated by CWC Art IX.11(c), which gives the inspected State the *"right to take measures to protect sensitive installations, and to prevent disclosure of confidential information and data, not related to this Convention"*. One such protection is established by the procedures set out in CWC Verification Annex Part X.16-21 which allow for negotiation between the inspection team and the challenged State on where exactly the inspection is to be conducted. This will not prevent access, but it will allow the challenged State the best part of five days to prepare the site for inspection (less if it is a declared site). The second such protection is in the procedures for *"managed access"* set out in Part X.46-52 whereby there may be less than full access to objects within the inspected site. This may be achieved by shrouding items, removing sensitive papers, logging-off computers, agreeing on use of Random Selective Access techniques, and suchlike measures.

27. The reporting procedure for a challenge-inspection team, set out in Verification Annex X.59-61, is somewhat similar to the procedure following routine inspections (see paragraph 22 above), including the requirement that the final report be limited to the factual findings.

The team is most definitely not required to present an assessment of compliance or noncompliance. The final report is, however, to be disseminated to all States Parties -- processed, if necessary, into a less sensitive form -- in preparation for the review of the report which the Executive Council is required to conduct. It will be on the basis of this review that the Council will decide whether further action is or is not necessary.

28. Challenge inspection represents the CWC verification regime at its most intrusive. Like the civil-industry controls, it is a precedent-setting feature of the treaty. Walter Krutzsch and Ralf Trapp⁹ describe how, in the intrusiveness of challenge inspection and in the essentially unlimited range of sites at which it may be applied, it far surpasses such procedures as the 'unannounced inspections' of the IAEA safeguards system, the CSCE inspections, the 'short notice inspections' of the INF treaty and the 'inspections on suspicion' of the CFE treaty. In the limitations placed by the Convention on challenge inspection are to be seen the most delicate of the compromises reached by the original negotiators: a balance between, on the one hand, the effectiveness of the central deterrent against cheating and, on the other hand, the security of information unrelated to the Convention which, for one reason or another, States Parties wish to keep secret. The quest is now to strike such a balance in the "*legally binding instrument*" that is to strengthen the BTWC. The key must surely lie, as it did with the CWC, in the degree to which the routine and the challenge on-site inspection regime can be made to support one another, thereby enhancing their overall deterrent effect.

Legislative and Administrative Machinery

29. Biotechnology is a prime example of 'dual use' technology. The manner in which the CWC addresses dual use thus offers especially relevant guidance, even though the CWC model may not in all respects be a good one.¹⁰ The General Purpose Criterion is, as has been seen earlier in this paper, the central element in the CWC's dual-technology control, and, because the BTWC also relies upon such a criterion, it will also direct the projected BTWC Verification Protocol. The chief problem with the criterion is that, administratively, it is far less easy to implement than, for example, a list-based approach to what is and is not prohibited. The CWC, in its schedules-bounded regime of routine verification, in fact uses a list-based approach as well as the General Purpose Criterion. Its remedy for ensuring that States-Parties do not in consequence come to neglect the criterion is to follow BTWC Art IV. Thus, CWC Art VII.1 opens as follows: "*Each State Party shall, in accordance with its constitutional processes, adopt the necessary measures to implement its obligations under this Convention.*" These obligations of course include the CWC Art VI.2 obligation to implement the General Purpose Criterion (see paragraph 13 above). In contrast to BTWC Art IV, which adds nothing further of substance, CWC Art VII.1 goes on to specify what those "*necessary measures*" must include: "*In particular, [each State Party] shall: (a) Prohibit natural and legal persons anywhere on its territory or in any other place under its jurisdiction as recognized by international law from undertaking any activity prohibited to a State Party under this Convention, including enacting penal legislation with respect to such*

⁹Walter Krutzsch and Ralf Trapp, *A Commentary on the Chemical Weapons Convention*, Nijhoff, 1994, pp.175-76

¹⁰For an incisive account of differences between the chemical and the biological control problem, see John Gee, *ÒA strengthened BWC: lessons to be learned from the Chemical Weapons ConventionÓ*, UNIDIR NewsLetter no 33/96, pp 75-80.

activity; (b) Not permit in any place under its control any activity prohibited to a State Party under this Convention; and (c) Extend its penal legislation enacted under subparagraph (a) to any activity prohibited to a State Party under this Convention undertaken anywhere by natural persons, possessing its nationality, in conformity with international law."

30. While it appears from the declarations under BTWC confidence-building measure "E" that rather few BTWC States Parties have taken any Article IV "necessary measures"¹¹, CWC Article VII cannot so easily be disregarded. In part this is because of the specificity of its provisions. In part, too, the Article has attraction as a means for reinforcing State powers against, for example, chemical terrorism. But there is also recognition that, in the absence of strong and routine national measures, the international CWC regime would be an edifice built upon sand. That much is apparent from study of at least some of the national legislation enacted in accordance with Article VII. In the UK *Chemical Weapons Act 1996*, for example, the general purpose criterion is implemented in full, and the steps now being taken properly to administer the Act include efforts to ensure that the relevant authorities receive the coöperation from the country's science and technology base without which enforcement of the General Purpose Criterion would be a hopelessly optimistic goal. The actual administrative device employed is a National Authority Advisory Committee whose membership includes representation from industry, the universities and professional scientific associations as well as the National Authority itself and other parts of government.

31. The CWC thus demonstrates a strong need to develop BTWC Article IV as has been proposed¹², and thereby, as the mandate of the BTWC Ad Hoc Group puts it, "to improve the implementation of the Convention" of the BTWC.

Conclusion

32. A conclusion to be drawn from the foregoing descriptions is that the CWC verification regime affords useful parallels for the regime now being negotiated for the Biological Weapons Convention, even though some features, such as the chemical-weapons destruction provisions, are unlikely to be inappropriate. The relevant features will include:

- (1) an international organization charged with overseeing implementation of the treaty in a division of labour with national authorities;
- (2) mandatory declarations that ensure continuing oversight of biotechnology by National Authorities that operate under the scrutiny of the international authority; and
- (3) an international on-site-inspection regime wherein challenge and non-challenge visits, the latter linked to the declarations, mutually reinforce one another to the detriment of potential cheaters.

¹¹See Iris Hunger, *Article V: Confidence-Building Measures*, in Graham S Pearson & Malcolm R Dando, *Strengthening the Biological Weapons Convention: Key Points for the Fourth Review Conference*, Quaker UN Office, Geneva, September 1996. Available at <http://www.brad.ac.uk/acad/sbtwc>

¹²Graham S Pearson and Nicholas A Sims, *National Implementation Measures*, University of Bradford, Briefing Paper No 4, January 1998. Available at <http://www.brad.ac.uk/acad/sbtwc>

A strengthened BTWC will require a verification regime in which these features are carefully integrated. It is fitting that the result would resemble the counterpart CWC regime, for there is much in common between biological and chemical weapons. Moreover, given that toxins are covered by both treaties, some overlaps and a consistency in approach are going to be essential.