nature biotechnology

Letters may be edited for space and clarity.
They should be addressed to:
Correspondence
Nature Biotechnology
345 Park Avenue South
New York, NY 10010-1707, USA
or sent by e-mail to biotech@natureny.com
Please include your telephone and fax numbers.

## Bioweapons protocol update

*To the editor:*

As one of the UK government officials involved in the Ad Hoc Group in Geneva negotiating a Protocol to strengthen the 1975 Biological and Toxin Weapons Convention (BTWC), I welcome the support for this objective shown by Richard Sullivan and Sebastian Gorka in your August issue[1]. We have consulted widely with UK industry and academia over the past six years, including practical work on mock inspections and visits at industrial sites. The two authors of the article are clearly aligning themselves with the widespread consensus that some regime based on declarations and on-site measures must be in place as a matter of urgency. I certainly agree with these authors that industry and academia must be proactive, but I would like to clarify the provisions in the rolling text—the draft Protocol—currently under discussion at Geneva.

First, Sullivan and Gorka mention proposals calling for investigation of illegal transfers, but none appear in the rolling text. They are probably referring to proposals for a mechanism to allow investigation of a decision taken by a State Party to deny an export where it judges that another State Party may use the item in a biological weapons program, which would of course be illegal under the Convention. These proposals are heavily disputed, and the UK is concerned that the resulting investigations could undermine the Convention itself, because they could run counter to the requirements of Article III that a State Party must prevent such exports. We certainly would not propose restriction of exports of equipment or materials, only retrospective annual notification of the transfer of limited types of equipment, mostly those related to aerobiology.

Second, the Protocol does not call for routine inspections; instead there are procedures for a limited number (no more than 100) of visits to facilities worldwide, selected at random, which are intended to provide greater levels of transparency and increase confidence in the accuracy of declarations. All access in such visits is at the discretion of the visited State Party, and there is no provision for sampling or off-site analysis.

Third, the Convention does not have "adequate legal processes already in place to allow a challenge visit." Under Article VI of the Convention, an investigation into noncompliance could take place, but only if approved by the UN Security Council. Nor are there in situ capabilities, such as a trained and equipped readily available inspectorate, for launching immediate investigations into cases of noncompliance. One of the key aims of the Protocol is to remedy this deficiency.

Fourth, the 21 measures identified by VEREX only provided a starting point for the work of the Ad Hoc Group on compliance measures; the Protocol's Annexes dealing with provisions for on-site activities do include observation, interviews, sampling, and auditing—measures first identified in VEREX. Sullivan and Gorka state that the VEREX measures can be effectively "distilled down to two measures; site surveillance and export surveillance." The VEREX report in fact noted that the most promising measures in combination were declarations and on-site activities.

Fifth, it is misleading to refer to "signature" lists of agents or equipment; it has certainly been the UK's view, and that of other participating states, that such lists are only for the purpose of declarations. One of the declaration triggers under consideration deals with work with listed agents and toxins; this would call for declarations of specified production, aerobiological, and GM activities. Declarations are about transparency around particularly relevant and specialized capabilities and knowledge, they are not a mechanism providing for detailed audits of activities; and, given the proposed rules governing visits, there will be no "costly or intrusive surveillance into confidential industry data" bases either. In any case, the type of work involved with listed agents that is specified in the declaration trigger is only likely to be found at specialized laboratories studying dangerous diseases in a public health, veterinary, or phytosanitary context, or as part of the national biodefense program. Although the numbers of facilities declared will depend on the list of agents finally agreed, we assess that about 10 facilities would be captured in the UK by the trigger.

Sixth, the presence or absence of containment equipment is not an issue in investigations; investigating teams may note the presence of fermenters or other items of "key equipment," but there is nothing in the Protocol that obliges them to disregard noncontained equipment. The more important question is what such equipment has been used for, and this will be the focus in any noncompliance investigation at a facility. The declaration format being proposed only asks facilities to indicate whether items are operated under specified levels of containment—simple yes/no questions apply.

Seventh, using existing regulatory frameworks (GMP and health and safety) can play a part in the BTWC compliance process; they are very useful in providing context and confirmatory information during on-site activities. However, the value that can be placed upon assertions about GMP procedures really depends upon a State Party's intentions toward its compliance with the Convention. Therefore, such statements cannot act as a substitute for firsthand evidence gathered by an independent, internationally based regime focused on BTWC compliance.

Finally, notwithstanding the chemical industry's help and encouragement during the development of the CWC (Chemical Weapons Convention), "managed access" was not in fact developed by industry. UK government officials pioneered this technique initially in 1989–1990 during the CWC negotiations to check that the UK could live with intrusive challenge inspections at nuclear weapons–related and other sensitive defense facilities; the concept was developed further and included in the CWC's Verification Annex.

*John R. Walker*
*Arms Control and*
*Disarmament Research Unit*
*Foreign and Commonwealth Office*
*London, UK*
*(acdru.fco@gtnet.gov.uk)*

1. Sullivan, R. & Gorka, S. *Nat. Biotechnol.* **18**, 806 (2000).

## Errata

On p. 912 of the September issue, Cambridge Drug Discovery (Cambridge, UK) was incorrectly cited as the acquisition target of Millennium Pharmaceuticals (Cambridge, MA). Cambridge Discovery Chemistry (Cambridge, UK) was the company that was acquired. In the same issue, on p. 940, the caption for Figure 2 should have read "Negative questions are reverse scored in this graph so that in each case more positive or pro-biotechnology responses are toward the left" rather than "toward the right." Also, on p. 1013, the accompanying images for Nonlinear Dynamics' Phoretix Array[2] and BioDiscovery's AutoGene software were reversed. On p. 1025 of the October issue, Alan Dove (not Natalie DeWitt) authored "A snare for the weak."