

Check against delivery

Expectations and Concerns
Related to Biosecurity
(discussion paper)

by John Hart
SIPRI*

Presented at: 'Developing a Comprehensive Global Biosecurity Regime'
Organized by Green Cross International and affiliates and hosted by the United
Nations Office at Geneva (UNOG)
8 November 2006
Palais des Nations
Geneva, Switzerland

* The views expressed are the author's and do not necessarily reflect those of SIPRI.

I would like to thank Green Cross International and its affiliates, the United Nations Office at Geneva (UNOG) and, in particular, Dr Paul Walker for providing me the opportunity to be here today to participate in this roundtable discussion. It is not my intention to describe in detail such issues as biosecurity programmes, budgets and legislation. Instead my purpose will be to attempt to identify some of the underlying trends and related concerns *connected to* biosecurity. This is partly to try to promote a discussion of broader expectations, trends and interests. This includes:

- (a) what various institutions and organizations involved in biosecurity wish to achieve (both politically and in terms of specific, operational-level objectives),
- (b) how such goals can be better achieved, and
- (c) how the effectiveness of the results (or processes) can be properly evaluated.

Definition and purpose

The purpose of this meeting is to consider the development of a ‘comprehensive global biosecurity regime’. A number of overlapping efforts have already been carried out in this area. However, just to reiterate some of what would seem to be the basic elements or measures common to any biosecurity regime, one could point to the following:

- (a) agreeing statements of political support which are structured so as to maximize the chances for sustained and effective follow-on measures;
- (b) preparing supporting paperwork, such as case studies, technical papers and policy options papers;
- (c) identifying actors and institutions operating in the field;
- (d) systematically and periodically identifying gaps and overlap among the various types of biosecurity-related activities;
- (e) achieving a better understanding of the general roles assigned to various institutional frameworks in implementing such a regime at the local, state and international levels;
- (f) identifying and providing the required resources;
- (g) identifying mechanisms and common criteria to evaluate the success of such a regime; and
- (h) agreeing common criteria to modify the implementation of such a regime in order to improve its effectiveness.

One cannot discuss biosecurity without also considering biosafety. The two terms have been consistently and increasingly linked. In some cases, discussions on biosafety have been carried out where the actual interest has been more in biosecurity (the opposite might also occur). It should also be noted that in some languages one word can be translated into English as either ‘biosafety’ or ‘biosecurity’ (for example, *биобезопасность* (Russian) and *biosäkerhet* (Swedish)). This may help to explain the increased use of such terms as ‘biorisk’ or ‘biorisk management’.

The World Health Organization (WHO) has defined ‘Laboratory biosafety’ as ‘the containment principles, technologies and practices that are implemented to prevent the unintentional exposure of pathogens and toxins, or their accidental release’.

(*Biorisk Management: Laboratory Biosecurity Guidance* (WHO: Geneva, Sep. 2006), p. iii)

The WHO has defined ‘Laboratory biosecurity’ as ‘the protection, control and accountability for valuable biological materials...within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release’. (*Biorisk Management: Laboratory Biosecurity Guidance* (WHO: Geneva, Sep. 2006), p. iv)

Institutional expectations

‘Biosecurity’ and ‘biosafety’ are used as an umbrella under which a wide variety of activities and expectations fall. Several types of institutions and groups have taken part in activities in these fields. As has often been observed, some of them do not traditionally interact with each other. Perhaps the most notable example is the public health field *versus* the arms control and international security communities.

Each of the various groups has a different perspective, mandate and set of institutional interests. Some institutions might be primarily concerned with possibilities for obtaining improved access to technology and equipment, while others might be more interested in promoting increased transparency in biological defence establishments. Still others are primarily interested in improving disease surveillance and response, pharmaceutical research and development (R&D), developing ethics and codes of conduct, or promoting Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP).

A given biosecurity measure can also be characterized in a manner that helps to ensure that it is included under or excluded from the mandate of an existing body. This is most evident when considering whether an organization that has a competence in either biosecurity or biosafety should become involved in both areas. Although cooperative threat reduction (CTR)-type activities that are designed to prevent ‘brain drain’ are generally considered to be a type of biosecurity measure, such activities can also be characterized as industry subsidies for researchers or research facilities. Some CTR-type programmes, including in the biological field, have been criticized partly on this basis. More generally, there have been difficulties agreeing what the term ‘biosecurity’ outside the laboratory should entail.

The main point here is that there are a variety of institutions involved in biosecurity and biosafety with differing expectations, and whose mandates and activities have not necessarily been linked traditionally. It might therefore be useful to consider further how such differences can affect agreeing and implementing a comprehensive global biosecurity regime.

Threat and risk assessments

One of the more problematic issues of biosecurity is the uncertainty associated with threat and risk assessments. This is especially true in cases where there is little or no historical record to serve as a guide. It is often said that the risk of an attack with biological weapons (BW), including bioterrorism, is ‘low’, but that the consequences of such an attack would be ‘high’ or even catastrophic—either in terms of casualties

and deaths, or in economic damage. The principal mechanism for predicting the future is to look at past experience. However, in the BW field past experience is limited and may not be an accurate predictor of the future. Even quantitative risk assessments have a qualitative element that is produced during the process of selecting risk factors. For example, the numerical value given to a risk factor is almost certainly partly informed by the analyst's 'best judgement'.

One might also wish to consider further how threat perceptions have affected policies to develop a biosecurity regime. For example, the majority of states may not feel themselves to be directly threatened by BW. In Africa it is reasonable to suppose that the principal concern is more on public health than on bioterrorism. Any measures to improve biosecurity should, partly for these reasons, also be carried out in conjunction with biosafety measures. The risk posed by possible diversion of agent strains worldwide should also continue to be considered.

Much of the public consideration of threats and risks has also been carried out on the basis of conflicting information regarding what state and non-state actors' capabilities and intentions are in the BW field. In theory it is not possible to fully assess the capabilities or plans of these actors without access to restricted information derived from law enforcement and intelligence. However, in practice such information may itself be incomplete.

EU institutions and policies

Longstanding challenges associated with the division of authority and allocation of resources among EU states also exist which, in turn, influence the effectiveness of EU programmes in the biosafety and biosecurity fields. Some programmes are pursued at the national level, while others are carried out at the EU level. There is a well-known, longstanding reluctance among EU member states to relinquish national sovereignty in the national security area. The division of responsibility and powers among the constituent EU bodies is a broader issue that may never be resolved to the general satisfaction of those in the Union.

The EU has devoted relatively little attention to prevention measures in the biosecurity field, particularly outside the Union. This is perhaps partly due to the difficulty in measuring success in the absence of bio-incidents in which case the effectiveness of biosecurity programmes would become more evident. In addition, the level of resources, including financial expenditure, may not reflect the actual effectiveness of the biosecurity regime. When attempting to measure the success of a biosecurity regime, at least two broad distinctions should be drawn. One is to achieve specific results or goals, while the other is to engage in activities whose value derives from the process of implementing them (i.e., results *versus* processes).

Priorities

There are also limits to the administrative and other resources that can be allocated by states. Related questions include what constitutes a reasoned and balanced approach to biosecurity for states with limited resources and other pressing concerns, as well as who determines what is 'reasoned' and 'balanced'. There is probably no 'correct' answer such questions. They should nevertheless be periodically considered in terms

of developing common criteria and general understandings, as well as how they relate to specific cases.

Underlying reasons for policy disagreement

It would also perhaps be useful to discuss the underlying reasons for disagreement on language drafted within the framework of the Biological and Toxin Weapons Convention (BTWC) and previous efforts to develop elements of various biosecurity regimes.

'Securitizing' biosafety and public health

A further issue is the extent to which public health issues can or should become 'securitized'. For example, the United States increasingly requires background information on researchers and institutions before it will pursue joint projects with biological facilities in other countries. While similar procedures have been carried out as part of the implementation of CTR programmes, other states, including in the EU appear to be increasingly affected. Such information requirements may be linked to funding grants and appear to be focused on work involving agents that appear on the U.S. Centers for Disease Control and Prevention (CDC) Select Agent list. There is anecdotal evidence that some European facilities have pulled out of joint projects with the U.S. because they have refused to provide some types of information out of concern for privacy rights. EU harmonization of biosecurity standards should nevertheless be carried out. Whether and how national biosecurity standards can be harmonized globally is less clear.

Conclusions

The ability of states to politicize technical issues should not be underestimated. Cooperation on technical issues, including within the field of biosafety, should be quite straightforward to implement. Cooperation on biosecurity measures, by contrast, can encompass politically sensitive issues such as how national biological defence research establishments can or should become engaged in international cooperation projects. The more that public health-related issues become 'securitized', the greater, it would seem, will be the scope for disagreement at the higher political level.

Many of the points raised above have no solution and can only be periodically and systematically considered. This includes consideration of threats posed by non-state actors.

Biosecurity measures must be considered and implemented with the active participation and consultation with those working in the life sciences.

The distinction between a 'biosecurity regime', as opposed to, for example, 'security' or 'security measures' should be clarified.

Achieving a unified overarching global biosecurity strategy is unlikely. Agreement would be achieved using rather broad compromise language. In order to ensure that meaningful measures are taken once such a strategy is agreed, there must be a sufficiently high level of political support and follow-on engagement.

Finally, measures to promote biosecurity and biosafety should be viewed as an opportunity for technical and political cooperation in an area about which there can be little or no disagreement on the broad objectives. Such activities should also be implemented with a view towards strengthening the BTWC regime.

Thank you.