ENHANCING BIOSECURITY

Biosecure 2004

23 September 2004

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Opening remarks

At the outset of this presentation, I would like to indicate the topics I will cover this morning.

First of all I want to give us some context so that we have a common understanding of Australia's international obligations and domestic responsibilities. Then, because I suspect there will be a variety of views here, for my purposes today I want to differentiate between biosafety and biosecurity. Next I will outline the elements of a biosecurity best practice model; ending with some thoughts on how well we are doing in Australia and possible responses.

Introduction

Rapid advances in biotechnology over the past decade have brought enormous benefits to medicine, public health, the food industry and agriculture.

At the same time, the rising global risk of terrorism, the increasing sophistication of terrorists, and the rapidly expanding knowledge of biotechnology and people with experience in the biological sciences, has raised the potential for biological attack significantly.

The terrorist attacks on 11 September in the United States and ensuing events brought into focus a new dynamic in international affairs. In a quite new way, terrorism represents a threat to national and international security. The World Trade Centre attacks revealed that some modern terrorists have crossed an important threshold, indicating that they are prepared to inflict a previously unimaginable and indiscriminate level of violence.

The subsequent anthrax letter attacks gave all of us a sense of the terrible immediacy of the threat from biological weapons. For even when they inflict relatively few deaths, biological weapons can create widespread fear, wreaking considerable economic and social damage, attacking a country's normal functioning and its collective confidence.

The perpetrators of the anthrax attacks have not yet been identified and may not be associated with Al-Quaida.

But it is now pretty clear that the terrorists behind the 11 September attacks at least contemplated using chemical and biological weapons. They tried to gain access to hazardous chemical waste products and they tried to obtain crop-dusters, presumably to disperse a chemical or biological agent.

While we should not succumb to alarmism; we need to be always vigilant, although it can be difficult to sift misinformation. But this is not a reason for complacency. It is undeniable that the threat of biological weapons remains a real one which requires a collective counter-response. We are all at risk and we all have a responsibility to assist where we can in the fight to prevent biological terrorism and the proliferation of biological weapons.

International Expectations and Obligations

The international legal regime against biological weapons use, development and acquisition is clear: actual use of biological weapons was outlawed in 1925 through the Geneva Protocol (1925).

Despite this absolute prohibition, a number of states continued to make covertly biological weapons, at times using front companies in third countries to acquire the necessary components on the open commercial market. To some extent international condemnation of biological weapons use and development was reinforced in 1975 by the Biological Weapons Convention (BWC), [of which Australia is an effective member].

The BWC prohibits member states from developing, producing, stockpiling or otherwise acquiring or retaining biological weapons and their means of delivery. States party to the BWC must prohibit their supply to, or acquisition by all other entities—State and non-state. States must also introduce legislation to implement the BWC, a requirement recently re-emphasised by the UNSC resolution 1540.

Furthermore, the BWC objectives are complemented in part through The Australia Group, known as the AG, established in 1985. The AG is an informal arrangement which aims to allow exporting or trans-shipping countries to minimise the risk of assisting chemical and biological weapon (CBW) proliferation.

In recent years and with accelerated energy since the terrorist attacks and anthrax incidents in the US, many countries have moved to strengthen defences against bio-terrorism. There is a greater focus on effective national implementation of treaties, and this is a feature of the new process for strengthening the BWC through its intersessional program of work in the lead up to the next RevCon in 2006.

This program of work covers:

- improved national legislation;
- better national oversight for dangerous pathogens;
- enhancing international capabilities to deal with alleged cases of biological weapons use;
- strengthening and broadening national and international efforts for disease surveillance; and
- codes of conduct for scientists.

At the BWC meeting of Experts in Geneva in July 2003, 84 state parties spent a week discussing biosecurity and sharing national

strategies. From this work elements of a best-practice biosecurity model emerged. The term 'biosecurity' is used here to describe the prevention of deliberate misuse of biological pathogens and toxins, which is the key issue in this talk, and should not be confused with "biosafety".

At the 2003 Meeting of BWC States Parties last November, these States reaffirmed their commitment to: BWC obligations; to the introduction of legislation with appropriate penal powers arising from the misuse of biological materials; and to the establishment and maintenance of security and oversight of dangerous microorganisms and toxins.

The recently adopted UNSC resolution 1540, gives weight to the outcomes of the 2003 Meeting of States Parties. The resolution requires all States to adopt and enforce criminal laws to prohibit the manufacture, acquisition, possession, development, transport, transfer or use of nuclear, chemical or biological weapons and their means of delivery, and requires all states to introduce measures for controlling access to harmful CBR materials. Enactment of effective laws is now mandatory under international law and Australia is expected to report its progress of implementation to the UN in October.

There is, clearly, considerable pressure by and expectation from the international community and in particular our close allies, to implement improved measures to control harmful biological

agents—effective national measures also serve to strengthen regional and international security.

In responding to the heightened bioterrorism threat, we are seeking to examine how to better regulate biotech industries and research. The Department of Foreign Affairs and Trade (DFAT) is working with other government agencies under the umbrella of a COAG mandate, that is the Council of Australian Governments, in a legislative review into the control of hazardous goods which includes, *inter alia*, harmful biological materials—primarily, pathogens and toxins—with a view to ensuring that regulations and controls are effective, consistent and sufficient to prevent the procurement or possession of such goods for illegal purposes. One possible outcome of the review is that provisions will be adopted which ensure that any attempts to procure these materials can be detected early, and that penalties for offences are appropriate.

Biosecurity vs Biosafety

Many countries, including Australia, have used the term "biosecurity" almost synonymously with the term "biosafety".

First of all, many of the measures currently in place or being developed have been built upon pre-existing 'biosafety' considerations, where 'biosafety' refers to measures taken to protect people and the environment from biological pathogens and toxins. It includes workplace health and safety issues and the prevention of the accidental release of biological agents.

On the basis of the BWC Expert Discussions in Geneva last year, a uniform definition of the term biosecurity was discussed. Along with many like minded countries, the Department, understands the term 'biosecurity' to mean the prevention of deliberate misuse of biological pathogens and toxins, a term which cannot be simply replaced with 'biosafety'.

But, 'biosecurity' has other meanings in different contexts: the FAO[1] use it in terms of securing food supplies and within Australian agriculture circles it means protecting the country from exotic pests and diseases through quarantine, surveillance and early detection measures.

We appreciate and support the strong notion that biosecurity is a discipline in its own right: it should not be overshadowed by the common understanding of biosafety. Standard biosafety precautions do provide some security measures, such as restricting access to facilities to authorised people; but further measures are required to ensure effective, comprehensive biosecurity.

We see that the additional features of biosecurity over biosafety are:

- Controlling access through knowledge of workers i.e. identity and security assessment of those authorised to access relevant biological materials;

[1] Food and Agriculture Organisation of the United Nations

- restricting access to material to those people needing it for legitimate use, rather than to those competent in handling the risks; and
- educating legitimate users of the dangers of misuse: instilling an organisational culture of securing materials.

These features need to be applied across all those labs in the lifetime of a research project.

Elements of Biosecuity-Best Practice

At the BWC Experts Meeting in 2003, the core elements of a best-practice biosecurity model were outlined in debate. This is a comprehensive model to prevent misuse of certain biological agents and includes the following ten general elements:

1. Establish agent control list
2. Risk assessments
3. Powers and Penal legislation
4. Site and Sales Security
5. Export Controls
6. Import controls
7. Secure transfers
8. Consequence management

9. Education and outreach

10. A national authority

Fleshing these out, the following activities would be required:

- A list of select agents [see DoHA biocontainment study—laboratory registration review]
- Certain facility registration and control
- A Federal database of names and locations of all registered facilities, including a record of agents and toxins held
- Mandatory security requirements [meed to develop a security standard equivalent to AS2243.3 (2002), Safety in Laboratories – Microbial aspects and containment facilities]
- Mandatory background checks
- A national oversight body [national authority]
- Guidelines for working with select agents
- Risk assessment: vulnerabilities/threat/security/ consequences
- Security plans which must be risk based
- Physical, personnel, information security, procedures/operations
- Professional codes of conduct

- A process by which 'Restricted people' are denied access
- An independent investigations process

Domestic Implications

Effective and efficient implementation of such biosecurity measures depends on a coordinated whole-of-government approach underpinned by three practical pillars, namely:

- comprehensive legislation;
- effective implementation and enforcement arrangements; and
- complementary voluntary activities involving cooperation between governments and facility operators.

Legislation

Australia has a body of Federal and State legislation relating to biological issues. Although serving their original purpose well, these laws are many and varied and focus on biosafety rather than biosecurity.

While Australia does have BWC implementing legislation (through the *Crimes (Biological Weapons) Act 1976*, this Act only prohibits certain acts. It does not include measures to prevent activities of concern, a problem whose genesis is in the BWC itself and this Treaty's lack of a verification regime—unlike the Chemical Weapons Convention (CWC) or the Nuclear Non-Proliferation Treaty (NPT).

The strongest pieces of legislation most relevant to biosecurity are associated with quarantine and genetically modified organisms, [through the *Quarantine Act 1908* and *Gene Technology Act 2000,* respectively]. However, these only apply—and in particular ways—to subsets of the population of facilities and agents of potential concern in Australia.

No doubt most of you are aware that the United States probably now has the most comprehensive regulatory system for controlling potentially hazardous biological materials, with the United Kingdom a fair second. U.S. biosecurity initiatives are also spilling over to other countries with the U.S. expecting and sometimes demanding that its allies do more; even to the extent of withholding transfer of U.S. 'select agents' to uncleared people.

But, be re-assured. I am not advocating that Australia adopts the US approach. Rather, we need a response tailored to our situation in the world.

Many other countries appear to have strong control legal systems, but enforcement is not uniform and thus not necessarily effective despite apparently adequate regulations. Canada is significantly strengthening its controls over potentially hazardous biological materials through the *Biological and Toxic Weapons Convention Implementation Act* (BTWCIA), and, being of a similar size and standing to Australia, is worthy of comparison.

At the extremes, we have the option to do nothing, or alternatively to introduce new legislation that would comprehensively address the problem by overhauling and rationalising existing mandates.

To do nothing would be inconsistent with international trends in the face of growing and credible bioterrorism threats. An act of bioterrorism might not kill many people, but it could have a dramatic impact on the national economy and be the source of panic among the populace and so consequently burden the health sectors with those that may or may not have been exposed to a dangerous biological agent. Both will have to be treated seriously.

The most realistic option associated with any decisive action would be to enhance current regulatory systems to address the bioterrorism prevention issue. In progressing best-practice biosecurity measures through regulatory means, DFAT has always recognised that it is important to adopt a whole-of-government approach, and not to "reinvent the wheel" or duplicate existing structures. Where niche regulation is already in place, the key is to coordinate each element of the national response to make sure there are no gaps and effort is not wasted.

A possible strategy, which I will outline in a moment, provides at least three important benefits to Australia. This line of action would enhance:

- Australia's national security;
- its biosecurity and, by default biosafety, and

- enable Australia to better satisfy its international obligations.

The strategy comprises four areas of work as follows :

(1) Target activities: First of all there is a need to develop a biological agent control list base on risk. The provisional agent control list developed by the COAG Working Group would be a useful starting point for further work, noting that other countries rely more on the Australia Group biological export control list. Secondly, there is a need to register and monitor containment facilities (PC3 and 4 with some screening for PC2) which would also accrue counter-terrorism and BWC benefits. Both are required: limiting a register to those labs holding high consequence agents and excluding others would not deliver CT benefits as terrorists are opportunists—it is likely that they would seek to procure non-listed, yet still infectious agents, from non-registered labs. A register of PC4, PC3 and screened PC2 labs should provide an effective "catch-all" mechanism. This would help focus outreach programs to enhance biosecurity. Further, it would help target enforcement of WMD-relevant legislation (compliance), along with promotion of codes of conduct. This would be in line with international expectation and obligations. In practical terms, this would embrace several of the 'elements' discussed earlier.

(2) Control measures These measures could use best international practice and, as a guide, the systems or arrangements of our major allies.

(3) Regulatory vehicles AQIS and the OGTR are best placed either individually or in tandem to implement improvements. Policy and likely legislative changes would be required, depending on the nature of the improvements, division of responsibilities, and whether a new gap-filling agency, needs to be established. The work of other agencies and control systems eg transport and exports may also be subjected to finetuning; and

(4) Coordination This could take a number of forms ranging from an oversighting representative committee as a minimum, through to a legislated new responsible authority or national authority such as foreshadowed in recent legislation in Canada, and mooted by Indonesia.

Now, I would like to expand that last point. The absence of a coordinating agency reduces the effectiveness of provisions that are developed independently by several agencies. A single agency to coordinate and monitor national BWC compliance should act, also, as a point of contact for facility operators on biosecurity matters and for outreach programs.

Incidentally, this outreach while primarily domestic in nature, would be expected to flow over into regional outreach because strengthened biosecurity in our region would enhance Australia's security.

But turning back to a national authority. This might be established, similar to the models used under the Chemical Weapons

Convention and the Nuclear Non-Proliferation Treaty. The aim of such an agency would not be to duplicate current responsibilities, but rather create a single agency which would have the authority to ensure that all agreed gaps are efficiently closed: some tasks will be undertaken directly by the national authority others will be subsumed into present authorities. In the interests of efficiency and streamlining, such an agency should also be responsible for ensuring that the national measures satisfy international expectations and treaty obligations.

Complementary Voluntary Measures

Improving Attitudes to Biosecurity

While greater regulation can help improve attitudes, the ease with which small quantities of agents and intellectual property may be transferred means there is an equally urgent need for non-government stakeholders to be engaged fully in strengthening lab practices.

Implementation of good biosecurity is a significant challenge and requires a major change to organisational and workplace culture. At the Discussions at the Experts Meeting in 2003 it was noted that: '*biosecurity was multi-faceted and could not be achieved simply with locks and keys and that biosecurity is a 'whole-of-life process',* covering the acquisition, use, transfer and disposal of materials. In many ways this is the harder part of achieving good national controls over biological materials because it requires constant

awareness by both facility operators and regulators, and coordination and maintenance to ensure that exploitable weak links do not develop.

Comprehensive outreach and education programs

Achieving such aims will require strong outreach and information programs by Government. It will need an equally strong commitment from all stakeholders. A central register of facilities capable of undertaking work with pathogens of concern would indeed be a good start for developing an outreach program so that the Government could better identify all relevant laboratories, including all those holding high consequence agents—not just those covered by AQIS and OGTR. However, we await the outcome of the COAG Review of Hazardous Materials (Biologicals) review to see how the education process might be more efficiently and effectively administered.

Other examples of stakeholder-initiated or coordinated activities might include the development, promotion and implementation of complementary codes, standards, benchmarks and guidelines. For example, the Australian biotech industry representative body, AusBiotech, has worked within the International BioIndustries Federation to develop a Biosecurity Policy with view to its adoption by national industry groups.

Such work, with industry taking a leading role, will make an important contribution towards discussion and development of a

code of conduct for scientists at subsequent meetings under BWC auspices specifically in 2005, when the BWC Experts work program is to examine the content, promulgation, and adoption of codes of conduct for scientists.

In conclusion

While Australia appreciates that enacting effective national measures form the backbone of meeting BWC commitments it is important to recognise the tone of international discussions in deciding the direction for a national debate on biosecurity policies and practices. Harmonisation of international practices will help counter would-be terrorists in their quest to procure materials from those countries seen to be a weak link in the overall chain of custody due to poor biosecurity attitudes.

It is a matter of national interest that domestic biosecurity arrangements are robust, effective and cost effective. I am in no doubt that more needs to be done, to which end we need to harness our efforts.

Furthermore, it is in our interests to work collectively towards adopting effective biosecurity measures as a means to demonstrate to other countries that it can be achieved efficiently. This is particularly so in our region where the general attitude to biosecurity is poor. Many countries see no need, resent what they see as Western-biased control regimes and lack both the political will and national resources to implement effective controls.

Enhancing our domestic arrangements would enable us to engage more authoritatively in the region, encouraging and assisting our neighbours to review their own national systems and so improve regional security.