

ENHANCING BIO-SECURITY

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OPENING REMARKS

This paper begins by giving some context to Australia's international obligations and domestic responsibilities. Then, the paper will consider how to differentiate between bio-safety and bio-security. Next it will outline the elements of a bio-security best practice model, ending with some thoughts on how well Australia is doing and possible responses.

INTRODUCTION

Rapid advances in biotechnology over recent decades 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 significantly the potential for biological attack.

The terrorist attacks on 11 September 2001 in the United States and ensuing events brought into focus a new dynamic in international affairs. In quite a new way, terrorism represents a threat to national and international security. The World Trade Center 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 do not appear to be associated with al Qaeda. But it has now become 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.

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While we should not succumb to alarmism; we need to be always vigilant. 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 1925 Geneva Protocol.¹

Despite this prohibition, a number of states continued to make biological weapons covertly, 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 development and use was reinforced in 1972 by the Biological Weapons Convention (BWC).²

The BWC prohibits States Parties from developing, producing, stockpiling or otherwise acquiring or retaining biological weapons and their means of delivery. States Parties to the BWC are under a treaty obligation to prohibit their supply to, or acquisition by all other entities — state and non-state. States Parties are also required to introduce legislation to implement the BWC.

Furthermore, the BWC objectives are complemented in part through the Australia Group,³ established in 1985. The Australia Group is an informal arrangement which aims to allow exporting or trans-shipping countries to minimise the risk of assisting chemical and biological weapon proliferation.

In recent years and with accelerated energy since the terrorist attacks and anthrax incidents in the United States, many countries have moved to strengthen their 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 inter-sessional program of work in the lead up to the next Review Conference in 2006. This program of work covers:

- improving national legislation;
- improving 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
- preparing codes of conduct for scientists.

¹ *Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare*, opened for signature 17 June 1925, 94 LNTS 65 (entered into force 8 February 1928).

² *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, opened for signature 10 April 1972, 1015 UNTS 163 (entered into force 26 March 1975).

³ The development of the Australia Group biological list is discussed in Dr Bob Mathews, 'The Development of the Australia Group Export Control Lists of Biological Pathogens, Toxins and Dual-Use Equipment' in Chapter IV of this volume.

At the BWC Meeting of Experts in Geneva in July 2003, 84 States Parties spent a week discussing bio-security and sharing national strategies. From this work, elements of a best practice bio-security model emerged. The term ‘bio-security’ is used here to describe the prevention of deliberate misuse of biological pathogens and toxins, which is the key issue in this paper, and should not be confused with ‘bio-safety’.

At the subsequent Meeting of BWC States Parties in November of 2003, these States Parties reaffirmed their commitment to BWC obligations; to the introduction of legislation with appropriate penal provisions relating to the misuse of biological materials; and to the establishment and maintenance of security and oversight of dangerous micro-organisms and toxins.

The recently adopted United Nations Security Council resolution 1540, gives weight to the outcomes of the 2003 Meeting of States Parties. The resolution requires all UN Member 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 chemical, biological and radiological materials. Enactment of effective laws is now mandatory under international law and Australia has reported its progress of implementation to the UN as mandated.

There is, clearly, considerable pressure and expectation arising 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 bio-terrorism threat, we are seeking to examine how to better regulate biological research and biotechnology industries. The Department of Foreign Affairs and Trade (DFAT) is working with other government agencies under the umbrella of a Council of Australian Governments (COAG) mandate, which brings together Federal, State and Territory 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.

BIO-SECURITY VERSUS BIO-SAFETY

Many countries, including Australia, have used the term ‘bio-security’ almost synonymously with the term ‘bio-safety’.

First of all, many of the measures currently in place or being developed have been built upon pre-existing bio-safety considerations, where bio-safety 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 discussions of the BWC Meeting of Experts in Geneva in 2003, a uniform definition of the term bio-security was discussed. Along with many like-minded countries, DFAT understands the term bio-security to mean the prevention of deliberate misuse of biological pathogens and toxins, a term, which cannot be simply replaced with bio-safety.

But, bio-security has other meanings in different contexts: the Food and Agriculture Organization (FAO) 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 bio-security is a discipline in its own right: it should not be overshadowed by the common understanding of bio-safety. Standard bio-safety precautions do provide some security measures, such as restricting access to facilities to authorised people; but further measures are required to ensure effective, comprehensive bio-security. We see that the additional features of bio-security over bio-safety are:

- controlling access through knowledge of workers (ie identity and security assessment of those authorised to access relevant biological materials);
- 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 laboratories in the lifetime of a research project.

ELEMENTS OF BIO-SECURITY

BEST PRACTICE

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

1. Established agent control lists;
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;⁴

⁴ See DoHA4 bio-containment 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;⁵
- mandatory background checks;
- a national oversight body;
- 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; and
- an independent investigations process.

DOMESTIC IMPLICATIONS

Effective and efficient implementation of such bio-security 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.

A Legislation

Australia has a body of Federal and State legislation relating to biological activities. Although serving their original purpose well, these laws are many and varied and focus on bio-safety rather than bio-security.

While Australia does have BWC implementing legislation (through the *Crimes (Biological Weapons) Act 1976*), this Act only prohibits certain activities. It does not include measures to prevent certain activities of concern, a problem whose genesis lies partly in the BWC’s lack of a verification regime.⁶ In Australia, the strongest pieces of legislation most relevant to bio-security 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 total number of facilities and biological agents of potential concern in Australia.

Many countries are developing comprehensive regulatory systems for controlling potentially hazardous biological materials. For example, Canada is significantly

⁵ This requires the development of a security standard equivalent to AS2243.3 (2002) ‘Safety in Laboratories: Microbial Aspects and Containment Facilities’.

⁶ Unlike the *Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction*, opened for signature 13 January 1993, 1974 UNTS 45 (entered into force 29 April 1997) (‘Chemical Weapons Convention’) and the *Treaty on the Non-Proliferation of Nuclear Weapons*, opened for signature 1 July 1968, 729 UNTS 161 (entered into force 5 March 1970) (‘Nuclear Non-Proliferation Treaty’).

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 bio-terrorism threats and would be ignoring our obligations under the BWC and United Nations Security Council resolution 1540. An act of bio-terrorism 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 bio-terrorism prevention issue. In progressing best practice bio-security 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, outlined below, provides at least three important benefits to Australia. This line of action would (i) enhance Australia’s national security; (ii) enhance Australia’s bio-security (and, by default, Australia’s bio-safety); and enable Australia to better satisfy its international obligations. The strategy comprises four areas of work.

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 a number of 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 laboratories holding high consequence agents and excluding others would not deliver counter-terrorism 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 bio-security. Further, it would help target enforcement of legislation relevant to Weapons of Mass Destruction (WMD), 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 above.

2 *Control Measures*

These measures could use international best practice and, as a guide, the systems or arrangements already put in place by other countries.

3 *Regulatory Vehicles*

The Australian Quarantine Inspection Service (AQIS) and the Office of the Gene Technology Regulator (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 fine-tuning).

4 *Coordination*

This could take a number of forms ranging from an oversight representative committee as a minimum, through to a legislated new responsible authority or national authority such as foreshadowed in recent legislation in Canada.

With respect to 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 bio-security matters and for outreach programs. Incidentally, this outreach, while primarily domestic in nature, would be expected to flow over into regional outreach because strengthened bio-security in our region would enhance Australia's security.

Turning back to a national authority, this might be established in a similar way to the models provided by 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 to 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.

B *Complementary Voluntary Measures*

1 *Improving Attitudes to Bio-Security*

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 laboratory practices.

Implementation of adequate bio-security is a significant challenge and requires a major change to organisational and workplace culture. During the discussions at the Meetings in Geneva in 2003 it was noted that bio-security is multi-faceted; it cannot be achieved simply with locks and keys; and it is a 'whole-of-life process', covering the acquisition, use, transfer and disposal of materials.⁷ In many ways this is the harder part of achieving good national controls over biological materials because it

⁷ See *Report of the Meeting of the States Parties, Geneva, 10–14 November 2003*, BWC/MSP/2003/4 (26 November 2003) vol I, reproduced in Annex 5 to this volume.

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

2 *Comprehensive Outreach and Education Programs*

Achieving such aims will require active and effective 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) 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 bio-technology industry representative body, AusBiotech, has worked within the International Bio-Industries Federation to develop a Bio-Security 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 the BWC Meetings in 2005, when the BWC Experts work program is to examine the content, promulgation, and adoption of codes of conduct for scientists.

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 bio-security 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 inadequate bio-security measures.

It is a matter of national interest that domestic bio-security arrangements are robust, effective and efficient. 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 bio-security measures as a means to demonstrate to other countries that bio-security is attainable.

Enhancing our domestic arrangements would also enable us to provide better informed guidance in the region, encouraging and assisting our neighbours to review their own national systems and so improve regional security.

PREPARATION EFFORTS TOWARDS BIOLOGICAL THREATS AND IMPLEMENTATION OF BIO-SAFETY & BIO-SECURITY IN INDONESIA

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INTRODUCTION

A Geography, Climate and Population

Indonesia is the largest archipelago in the world, consisting of five major islands, 3000 medium islands and 13 677 small islands, making a total of almost 17 000 islands. The location of Indonesia is between two continents, Asia and Australia, and between two oceans, the Pacific and Indian Oceans.

The total area is 5 193 250 square kilometres with 39 per cent (1 919 443 square kilometres) land and 61 per cent (3 273 807 square kilometres) sea territory. Indonesia has a dry season from June to September and a rainy season from December to March. The range of temperature is from 20–30 degrees Celsius and the humidity ranges from 65 to 90 per cent.

Indonesia is divided into 33 provinces. Every province is headed by a Governor. Provinces in Indonesia are further divided into 441 districts, 5175 sub-districts and 66 721 villages. The total population in 2003–04 was 216 200 000, with a population density of 113 persons per square kilometre.

There are more than 300 ethnic groups in Indonesia, each with different languages. Bahasa Indonesia is the national language used for social and official communication. As far as religion is concerned, 87 per cent of the Indonesian population are Muslim, while other religions include Christianity (Protestant, Roman Catholics), Hinduism and Buddhism.

B 1925 Geneva Protocol, Biological Weapons Convention, and Chemical Weapons Convention

Indonesia has ratified the 1925 Geneva Protocol,¹ the Biological Weapons Convention (BWC),² and the Chemical Weapons Convention (CWC).³ As a follow up

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¹ *Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare*, opened for signature 17 June 1925, 94 LNTS 65 (entered into force 8 February 1928).

² *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, opened for signature 10 April 1972, 1015 UNTS 163 (entered into force 26 March 1975).

action, the Directorate of International Security and Disarmament Affairs (Ministry of Foreign Affairs) functions as the Temporary National Authority (the National Authority will be established by Presidential Regulation).

Members of the Biological Weapons Working Group of the Temporary National Authority are as follows: Ministry of Foreign Affairs, Ministry of Health, Ministry of Defence, Ministry of Agriculture, Armed Forces Head Quarters, National Aerospace and Aviation Agency (LAPAN), National Intelligence Agency (BIN), Indonesian Institute of Sciences (LIPI), Food and Drug Control Agency (BPOM), Ministry of Trade, Ministry of Industry and the Indonesian Police (POLRI).

BIOLOGICAL THREATS IN INDONESIA⁴

According to the World Health Organization (WHO), anthrax, botulism, hemorrhagic fever, smallpox, the plague and tularaemia are considered 'biological threats'. These diseases, other than smallpox, botulism and tularaemia, have occurred in certain regions in Indonesia for many years.

The occurrence of these diseases and other 'emerging infectious diseases' such as tuberculosis, meningitis, HIV-AIDS, malaria, typhoid fever, meningitis, rickettsioses and influenza in our country make it difficult to relate them to bio-terrorism action. However, the Ministry of Health has been preparing and increasing alertness by conducting various measures of early detection and prompt response to anticipate outbreaks of infectious diseases.

A Pattern of Possible 'Biological Threats' in Indonesia

1 Anthrax⁵

According to the Directorate General of Veterinary Production (Ministry of Agriculture), 11 provinces have been infected by anthrax in Indonesia (being Jakarta, West Java, Central Java, West Nusa Tenggara, East Nusa Tenggara, West Sumatra, Jambi, South-East Sulawesi, Central Sulawesi and Papua). However, from those 11 provinces only four provinces reported human cases (being West Java, Central Java, West and East Nusa Tenggara). During the period of 1992–2001, 599 cases (including 10 deaths) of anthrax in humans were reported in Indonesia. The last outbreak of anthrax happened in Babakan Madang (Bogor) in October 2004, where six humans died due to intestinal anthrax.

³ *Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction*, opened for signature 13 January 1993, 1974 UNTS 45 (entered into force 29 April 1997).

⁴ See generally Centre for Data and Information (Indonesian Ministry of Health), *Basic Health Indicators* (2002); World Health Organization Regional Office (Eastern Mediterranean), *Public Information on Biological and Chemical Threats* (2003).

⁵ See generally Sub-Directorate of Zoonosis, Directorate of Animal Resource Diseases Control, Directorate General of Communicable Diseases Control and Environmental Health (Indonesian Ministry of Health), *Guidelines for Managing Anthrax Cases in Indonesia* (2002).

2 *Botulism*

This is a type of food poisoning caused by a neurotoxin (botulin) produced by the growth of *Clostridium botulinum* in improperly canned or preserved foods. According to the Directorate of Surveillance and Food Safety Education (Food and Drug Control Agency) botulism cases have never been reported in Indonesia.

3 *Haemorrhagic Fever*⁶

According to the data from the WHO,⁷ the number of cases of Dengue fever and Dengue haemorrhagic fever in Indonesia from 1985–97 increased significantly, especially in 1996 when the total number cases was 44 650 with a case fatality rate (CFR) of 2.67 per cent. The total cases in 1985 were 13 588 with a CFR of 3.39 per cent, and the total cases in 1997 were 30 730 with a CFR of 2.22 per cent. According to the data from the Directorate General of Communicable Diseases Control and Environmental Health (Ministry of Health) the total cases of Dengue fever and Dengue haemorrhagic fever from all 30 provinces in Indonesia in 2002 was 40 377 with a CFR of 1.3 per cent.

4 *Smallpox*

According to the Directorate General of Communicable Diseases Control and Environmental Health (Ministry of Health), smallpox has not been reported in Indonesia since 1974.

5 *Plague*⁸

Plague entered Indonesia for the first time in 1910 through Surabaya Harbour, East Java, then in 1916 in Semarang, Central Java; in 1923 in Cirebon, West Java; and in 1927 through Tegal, Central Java. During the period of 1910–60, 245 375 cases were reported, with the number of deaths reaching as high as 23 275 in 1934. In 1987, 24 plague cases were reported again in Pasuruan, East Java, and 21 were fatal. The last cases (five bubonic plague cases, with no fatalities) were reported in 1997, also in Pasuruan, East Java. There is a reservoir of plague in the rodent population in Pasuruan which is kept under strict surveillance.

6 *Tularaemia*

According to the Directorate General of Communicable Diseases Control and Environmental Health (Ministry of Health), tularaemia has never been reported in Indonesia.

⁶ See generally Thomas Suroso et al, *Prevention Control of Dengue and Dengue Haemorrhagic Fever* (2003); Directorate General of Communicable Diseases Control and Environmental Health (Indonesian Ministry of Health), *Number of Cases and Deaths of Dengue Haemorrhagic Fever: Provinces and Districts Infected and Incidence Per Year in Indonesia from 1968-2002*.

⁷ World Health Organization Regional Office (South-East Asia), *Prevention and Control of Dengue and Dengue Haemorrhagic Fever* (Publication No 29) (1999).

⁸ See generally Sub-Directorate of Zoonosis, Directorate General of Communicable Diseases Control and Environmental Health (Indonesian Ministry of Health), *Guidelines for Handling the Plague in Indonesia* (2002).

B Pattern of Other 'Emerging Infectious Diseases' in Indonesia

1 Tuberculosis⁹

According to the Directorate General of Communicable Diseases Control and Environmental Health (Ministry of Health), tuberculosis has been reported in all provinces in Indonesia. The number of cases has increased every year from 1997 (33 216 cases), to 2000 (84 591 cases), and 2002 (152 200 cases). Drug resistance is an emerging problem in Indonesia.

2 Malaria¹⁰

Increasing numbers of malaria cases in some places in Indonesia have been reported in the last 10 years. This has been stressed by outbreak reports with some fatal cases of malaria, occurring mostly in 1993 and 1997–98. During the period from 1998–2001, malaria outbreaks in Java-Bali have been reported from Central Java, Yogyakarta, East Java, West Java, and Seribu Islands respectively. In the outer islands of Java-Bali, some outbreaks have been reported from Lampung, South Sumatra, West Sumatra, North Sumatra, and both West and East Nusa Tenggara. Resistance of *Plasmodium falciparum* to chloroquine is found in many provinces especially in the eastern part of the country. Resistance of *Plasmodium vivax* to chloroquine is also found in increasing frequency.

3 HIV-AIDS¹¹

Twenty-three out of 33 provinces in Indonesia have reported cases of HIV infection, and 16 out of those have reported cases of AIDS. The data on AIDS cases was collected through a passive surveillance system, since AIDS has been a reportable disease since 1988 (when the Minister of Health issued an instruction declaring it to be reportable).

In 1987 the first AIDS case was reported from Bali. The case involved a foreign tourist who died after diagnosis. As of 31 December 2003, the cumulative report of cases in Indonesia was 2720 cases of HIV infection, 1371 cases of AIDS, and a total of 479 deaths attributable to AIDS. There are six provinces that reported the high numbers of cases of AIDS. These provinces were Papua (388 cases, representing 28.3 per cent of the total); Jakarta (347 cases, representing 25.31 per cent of the total); East Java (213 cases, representing 15.54 per cent of the total); Bali (76 cases, representing 5.54 per cent of the total); Riau (73 cases, representing 5.32 per cent of the total); and West Java (67 cases, representing 4.89 per cent of the total). Experts have estimated that there are around 120 000 cases of HIV infections in the country.

⁹ See generally Directorate General of Communicable Diseases Control and Environmental Health (Indonesian Ministry of Health), *Report of the Sub-Directorate CDC: Tuberculosis* (2003).

¹⁰ Harijani A Marwoto and Sekar Tuti E Sulaksono, *Increasing of Malaria Cases in Java and the Surrounding Areas* (2003).

¹¹ Directorate General of Communicable Diseases Control and Environmental Health (Indonesian Ministry of Health) and the World Health Organization, *Report on the STI, HIV and AIDS Epidemiology and Consensus on HIV-Cases Estimation of Indonesia in the Year 2001* (2002).

4 *Influenza*¹²

A surveillance study from August 1999 to January 2003 was conducted in clinics at six sentinel locations (Tangerang, Jakarta, Bandung, Yogyakarta, Bali, Makassar). Adults and children (aged 4–14 years) presenting with respiratory symptoms suggestive of influenza were asked to enrol. Nasal and pharyngeal swabs were examined. A total of 3079 specimens were collected from 1544 participants. Influenza infection was confirmed in 172 (11.1 per cent) of volunteers presenting with influenza-like illness. Influenza A (H1N1 and H3N2) and B viruses were detected at all sites. Peak prevalence tended to coincide with the respective rainy seasons regardless of the location. An outbreak of avian influenza occurred in late 2003, but was confirmed only in January 2004. No humans have been infected so far.

5 *Typhoid Fever*

Typhoid fever is an acute, life-threatening febrile illness caused by the bacterium *Salmonella typhi*. In the 1980s, Indonesia was one of the countries with a high incidence of typhoid fever. The results of active surveillance at that time indicated that in a population of 100 000, there were 350 cases in rural areas and 810 in urban areas per year. Typhoid fever cases are reported from all provinces in Indonesia, but accurate data is not available. Every year typhoid fever cases are estimated between 600 000 and 1 300 000, and the number of deaths attributable to the disease is estimated to be 20 000 per year.

6 *Meningitis (Neisseria meningitides)*¹³

Acute meningitis may be caused by any of several bacteria, all of which induce similar disorders. *Haemophilus influenzae* sero type B (Hib) causes meningitis and pneumonia especially in children under two years of age. However, meningococcal meningitis (caused by *Neisseria meningitidis*) is apt to occur in epidemics, and in segregated populations (eg in military installations or boarding schools). In one study in Lombok, West Nusa Tenggara (which has a total population 743 717), active surveillance from January 1999 to December 2002 found that cases of convulsions suspected of meningitis in children aged under two, which were reported and referred to hospital, numbered 640, with a CFR 19.8 per cent.

In 2000 and 2001 an increasing number of cases of meningococcal meningitis caused by *Neisseria meningitidis* serogroup W-135 were observed among pilgrims travelling from Indonesia to Mecca. In the year 2000, the number of Indonesian pilgrims who suffered meningitis in Saudi Arabia was 14, and six people died, and in the year 2001, 18 people suffered meningitis and six people died. Laboratory examinations conducted in 2000 by the Centre for Diseases Control Research and Development at the National Institute of Health Research and Development, and the Directorate General of Communicable Diseases Control and Environmental Health (Ministry of Health) found 10 carrier cases of *Neisseria meningitidis* serogroup

¹² See generally Charmagne G Beckett et al, *Influenza Surveillance in Indonesia: 1999–2003* (2004).

¹³ See generally Muljadi Prijanto dan Yusharmen, 'Vaksin Meningitis Meningokokus Tetraavalen Bagi Jemaah Haji Indonesia' (2002) *Medika* No 6 Tahun XXVIII.

W-135 among 215 pilgrims; in 2001, there were 12 reported carrier cases of the same serogroup W-135 from among 100 pilgrims.

7 *Rickettsioses (Spotted Fever, Murine Typhus and Q Fever)*¹⁴

A serosurvey of wild rodents for rickettsioses was conducted in Java Island, Indonesia between 1993 and 1995. Sera of 327 rats were collected from Jakarta and Boyolali, and the prevalence of antibodies against spotted fever group rickettsia (SFGR) and murine typhus were 128 (39.1 per cent) and 48 (14.7 per cent) respectively. Antibodies against Q fever were not detected in these serum samples. Rickettsial diseases and diseases due to rickettsial-like bacteria are found in Indonesia. Scrub typhus, murine typhus, and Q fever have been investigated and found in Indonesia; however diseases such as those related to the spotted fever group of rickettsiae, trench fever, bartonellosis and ehrlichiosis have never been reported.

8 *Hantaan Virus*¹⁵

Haemorrhagic fever with renal syndrome (HFRS) caused by viruses from genus *Hantavirus*, family *Bunyaviridae*, is one of the important emerging diseases, with a mortality rate ranging from 5–15 per cent. Studies in Indonesia from 1987–97 reported two species of *Hantavirus* in rodents (Hantaan virus and Seoul virus). Hantaan virus in animal reservoirs have been reported in harbours in Indonesia (being Tanjung priok, Sunda Kelapa, Semarang, Makasar and Maumere). Antibodies to this virus are also found in humans in some harbours (being Maumere, Tanjung Priok, Sunda Kelapa, Bali, Batam, East Timor and Irian Jaya).

9 *Nipah Virus*

There was an outbreak of Nipah virus in Malaysia in the late 1990s. Studies of pigs and pig breeders in North Sumatra and Batam Island where there are large projects did not reveal any presence of antibodies against the Nipah virus. However, bats which are suspected as vectors for Nipah virus are found in Indonesia.

INSTITUTIONS WITH CAPACITY TO IDENTIFY PATHOGENIC MICRO-ORGANISMS REGARDED AS 'BIOLOGICAL THREATS' IN INDONESIA

Some institutions with capacity to identify pathogenic micro-organisms regarded as 'biological threats' in Indonesia are as follows:

- Jakarta: National Institute of Health Research and Development (NIHRD) Laboratory; Department of Microbiology, University of Indonesia; United States Naval Medical Research Unit Two (Namru-2) Laboratory; Infectious Disease Hospital Sulianti Saroso; Eijkman Institute Laboratory.

¹⁴ See generally Ima Nurisa Ibrahim et al, 'Serosurvey of Wild Rodents for Rickettsioses (Spotted Fever, Murine typhus and Q fever) in Java Island, Indonesia' (1999) 15 *European Journal of Epidemiology* 89; Allen Richards et al, 'Rickettsial Diseases: Risk for Indonesia' (1995) 23(3) *Bul Penelit Kesehatan*.

¹⁵ See generally Ima Nurisa Ibrahim, 'Hantavirus Penyebab Demam Berdarah dengan Sindrom Renal di Indonesia' (1998) 48 *Kedokt Indonesia*.

- Bogor (West Java): Veterinary Research Centre; Bogor Institute of Agriculture (IPB).
- Bandung (West Java): Bio Farma Laboratory (however WHO suggests this laboratory is only used for vaccine development).
- Surabaya (East Java): Department of Microbiology, Airlangga University; Provincial Health Laboratory; Veterinary Vaccine Institute.

BIO-SAFETY & BIO-SECURITY EFFORTS IN INDONESIA

A *Bio-Safety*

Objective: to reduce or eliminate accidental exposure to or release of potentially hazardous infectious materials.

Strategy: implementing various degrees of laboratory ‘containment’ or safe methods of managing infectious materials in a laboratory setting.

B *Bio-Security*

Objective: to protect biological agents against theft and sabotage.

Strategy: prioritising assets based on consequences of loss; defining unacceptable and acceptable risks by evaluating probabilities and consequences; applying a graded protection approach; and integrating security technologies and procedures across all affected systems.

Components of bio-security: physical security; material control and accountability; personal security; transfer security; information security; and program management.

C *Why Bio-Security Is So Important*

Some of the characteristics of Indonesia require more attention with respect to bio-security. As discussed above, some of the diseases regarded as ‘biological threats’ by the WHO are endemic diseases in certain geographical areas within Indonesia (ie anthrax, Dengue hemorrhagic fever, and plague). The social conditions of a large proportion of the Indonesian population can make them more susceptible to disease (eg low income capacity, poor health facilities and health status). Finally, the actions of separatist or extremist groups in Indonesia may pose a biological threat. For example, such groups may collaborate with ‘insiders’ who work at the laboratories and have the capacity to identify and culture bacteria and viruses with the potential to be used as a biological weapon.

In response to these national bio-security conditions, particular preparation efforts have been taken. National capacity building (personnel, equipment, surveillance, coordination, cooperation and management) has been strengthened. Coordination, cooperation and management have been enhanced both nationally, and amongst regional partners. Indonesia makes use of the network of the Association of Southeast Asian Nations (ASEAN, or ASEAN+3), as well as certain developed countries, to strengthen Indonesia’s capacity to deal with bio-security issues.

D *Some Bio-Safety & Bio-Security Efforts in Indonesia*

Some bio-safety and bio-security efforts in Indonesia include the following:

- Decree of the Minister of Health of the Republic of Indonesia No 1244 of 1994 regarding guidelines on bio-safety in microbiology and bio-medical laboratories;
- Decree of the Minister of Trade and Industry of the Republic of Indonesia No 254/MPP/Kep/2000 regarding the export and import of certain dangerous materials, including chemical and biological agents;
- Training regarding Weapons of Mass Destruction (WMD), April 2003, in Jakarta in collaboration with the United States Embassy in Jakarta;
- Ministry of Science and Technology National Seminar on Bio-Terrorism, July 2003, in Jakarta;
- Centre for Health Emergency Preparedness and Response established by the Ministry of Health;
- National Team for Disaster Management, headed by the Coordinating Minister of People's Welfare;
- Outbreak Response Team established by the Directorate General of Communicable Diseases Control and the National Institute of Health Research and Development in the Ministry of Health; and
- Early Warning and Outbreak Response System (EWORS) established by Directorate General of Communicable Diseases Control and the National Institute of Health Research and Development in the Ministry of Health (WHO Collaborating Centre for Emerging Infectious Diseases).

CHALLENGES AND SOURCES OF POSSIBLE FUTURE THREATS

1 *Geographic Conditions in Indonesia*

Indonesia is the largest archipelago in the world, located between two continents and two oceans, sharing borders with many countries such as Malaysia, East Timor, Papua New Guinea, Singapore, the Philippines, and Australia.

2 *National Efforts and International Cooperation*

Indonesia has to strengthen national capacity building with or without foreign assistance or support. Examples of foreign assistance that may be needed are: training; transfer of knowledge and laboratory equipment; or empowerment of existing resources. Inspection by donor countries is not required. Indonesia has to enhance collaboration and networking with other countries, especially ASEAN countries and developed countries.

3 *Possibilities of Use by Separatist or Extremist Groups and Organisations*

There are separatist movements in Aceh and Papua. There have been bomb explosions in the last three years in Bali, at the Marriot Hotel in Jakarta, and in front of the Australian Embassy in Jakarta, Kuningan. These explosions show that extremist groups are operating now. However, whether there are links between the activities of the separatist movement and the extremist movement is difficult to prove.

4 *Probability of Some Scientists Joining Separatist or Extremist Groups*

Dr Azahari bin Husin, a scientist from Malaysia, is suspected by Indonesian Police of being the designer of the Bali, Marriot Hotel, Jakarta and Kuningan bombs. So far, there is no evidence that biological agents have been used for terrorism in Indonesia.

CONCLUSIONS

Indonesia is a party to the relevant international agreements relating to chemical and biological weapons, and as a follow up action, the Directorate of International Security and Disarmament Affairs of the Ministry of Foreign Affairs functions as the Temporary National Authority.

Indonesia has considered the pattern of possible 'biological threats' posed by anthrax, botulism, haemorrhagic fever, smallpox, the plague and tularaemia, and the pattern of other 'emerging infectious diseases' in Indonesia including tuberculosis, malaria, HIV-AIDS, typhoid fever, meningitis (meningococcus), rickettsioses, Hantaan virus and Nipah virus. There are some institutions with capacity to identify pathogenic micro-organisms located in certain cities, especially in the Java islands.

Efforts made regarding bio-safety and bio-security include implementation of regulations, such as Decrees from the Minister of Health and the Minister of Trade and Industry; training packages regarding WMD; and national seminars on bio-terrorism. National teams for disaster management, emergency preparedness and outbreak response are established by the Directorate General of Communicable Diseases Control and the National Institute of Health Research and Development in the Ministry of Health. Indonesia also seeks to strengthen national capacity building and enhance collaboration and networking with ASEAN and developed countries.

There are some challenges and possible future threats which could be anticipated in our country due to geographic conditions, possible future activities by separatist or extremist groups and the possibility of some scientists joining such groups. National efforts to face these challenges and international cooperation and collaboration need to be intensified.