THE DESIGN OF NATIONAL MECHANISMS TO MAINTAIN THE SECURITY AND OVERSIGHT OF PATHOGENIC MICROORGANISMS AND TOXINS

Prepared by the United Kingdom

Introduction

1. This paper sets out UK views on core elements needed for effective national measures that ensure the security and oversight of toxins and microorganisms pathogenic to humans, animals and plants. It also includes in the Annex a summary of the biosecurity and biosafety legislation which is applied in the UK. These views may be of interest to States Parties that do not have similar measures in place, or that are contemplating amending or extending their own controls in these areas. Although national legislative and control regimes do not always have universal applicability, the UK believes that in this case there is sufficient commonality of the problems, and of the possible regulatory approaches to addressing them, to allow identification of the key principles and possible legislative approaches.

“Biosecurity”

2. The UK understands that ‘biosecurity’ measures are those designed to prevent the unauthorised acquisition of pathogens, toxins or other bioactive substances of biological origin - specifically to prevent their potential misuse inconsistent with the provisions of the BTWC. ‘Biosecurity’ is thus distinct from ‘biocontainment’, that is, the measures intended to prevent the unwanted or accidental release of biological material from a ‘controlled environment’ that could lead to disease in humans, animals or plants. In many countries, biocontainment measures are stipulated and monitored by legislation or regulations administered under the headings of, for example, health and safety, public health or agriculture.

Legislation

3. The UK believes that some States Parties may have limited numbers and types of facilities handling pathogens and toxins of key concern. In such cases, such facilities may be largely under direct or indirect control by the government, which may therefore not find it necessary
to enact legislation in order to ensure that biosecurity measures are in place. In other countries, including the UK, the broad range of owners and operators of such facilities and the wider extent of the legitimate work undertaken (and, therefore, the greater number of targets for unauthorised acquisition) is such that legislation is likely to be necessary to ensure that effective biosecurity measures are fully adopted and implemented nationally. In this situation, relying on facilities to self-regulate biosecurity is likely to be an inadequate approach, and government-based formal oversight arrangements based on legislation would be necessary.

4. Legislation aimed primarily at health and safety, biocontainment in public health or agriculture, or the protection of the environment, may also contain provisions that provide directly or indirectly for the maintenance of security and oversight of pathogenic micro-organisms and toxins. However, since biosecurity is not the intended focus of such laws and regulations, new legislation or regulation may also be needed to complete a State Party’s regulatory and oversight system. One factor that needs to be considered here is how best to introduce biosecurity standards to complement existing biocontainment measures.

(i) National mechanisms to establish and maintain the security and oversight of pathogenic micro-organisms and toxins

5. An effective national regulatory and oversight regime for biosecurity will need provisions in two main categories:

- **regulatory determinants** of which pathogens and toxins should be controlled, what premises (and activities underway within) are covered and what measures must be instituted at them; and,
- **oversight mechanisms** to allow government to be confident that these steps have been taken and to maintain oversight of activities at such premises.

These provisions are expanded below:

**Regulatory determinants**

6. The central provision of a regulatory system, which in many States Parties would need to be created by domestic legislation (see above), would be:

- a government regulatory function or dedicated regulatory authority responsible for administering and enforcing the legislative regime (clearly established set of civil offences with a system of penalties for infringement);
- a list of pathogens and of toxins to which the regulations apply (or criteria/means to identify agents of concern) - facilities keeping or using any of these pathogens or toxins would be subject to the regulatory system;
- a requirement for all such facilities to implement measures to ensure the physical security of any buildings or sites in which listed pathogens and toxins are located or housed;
- a requirement for measures to be taken by the facility to ensure that access to the listed pathogens and toxins is available only to people with legitimate reasons for access, and only in circumstances that ensure the security of the pathogens and toxins;
- a specification of offences for individuals and bodies corporate for non-compliance with these provisions, and of penalties for indicted individuals.
7. A number of other features may also be considered, though in each case the benefits of increased security would have to be balanced against the potential administrative and financial burden for the facilities and for government regulatory authorities. These are:

- the designation of facility personnel responsible for ensuring that the regulations are implemented;
- a requirement on the operator of any facility to notify the regulatory authority before any listed pathogen or toxin is kept or used for the first time;
- a licensing system for notified laboratories;
- provisions and administrative mechanisms for review and, if necessary, amendment of the control list, both for deletions and additions in light of changing circumstances.

Oversight measures

8. To ensure that biosecurity measures are fully and consistently implemented in facilities, including those that are not under government control, a governmental oversight mechanism is likely to be necessary. It may need the following features:

- a requirement for the regulatory authority to be notified of names and addresses of facilities keeping or using any controlled pathogens or toxin;
- powers for the authority to inspect and search facilities and individuals, to instruct work to stop, to remove agents or order them to be destroyed, and to restrict specified individuals from access to the pathogens or toxins;
- appropriately trained and resourced officials, in the regulatory authority or under contract to it, who are empowered by the legislation to inspect facilities, make assessments, and take any enforcement actions.

9. In addition, the oversight mechanism may benefit from the following (though as for ‘regulatory determinants’ above, in each case the benefits of increased security would have to be balanced against the assessed risks and the potential administrative burden for the facilities and for government):

- the notification to the regulatory authority of arrangements made for security and of individuals who have access to pathogens and toxins;
- additional details in notifications of possession, such as:
  - identification of the room(s) in which the pathogens and toxins are to be kept or used;
  - identification of any building or site of which the facility forms part;
  - notification of the types and quantities of listed agents held or used, and details of their disposal or transfer to other sites, including end-users;
  - other particulars that may be thought necessary.
  - internal and international transfer of pathogens and toxins. (for international transfer issues see the companion document BWC/MSP.2003/MX/WP.8 entitled BWTC Implementing and Penal Legislation: Core Elements.

10. However, it should be appreciated that additional controls would place further burdens on the regulator as well as those required to notify. How such information is stored and used is crucial.
Annex

Summary of relevant UK security and biosafety legislation

1. The current controls in the UK, with the exception of the Anti-Terrorism, Crime and Security Act 2001, are primarily in place to deal with health, safety and environmental issues rather than security. It is also helpful to keep in mind the division of departmental responsibilities within the machinery of government in the United Kingdom. The national regulatory agency, the Health and Safety Executive, is responsible for the regulation of almost all the risks to health and safety arising from work activity in Britain. Its mission is to protect people’s health and safety by ensuring risks in the changing workplace are properly controlled. The Home Office in this context deals with security issues and is the lead government department for implementation of the Anti-Terrorism, Crime and Security Act 2001. Some of the agricultural and veterinary regulations are the responsibility of the devolved administrations for Scotland and Northern Ireland.

2. The provisions set out in Part 7 (and Schedules 5 and 6) of the Anti-Terrorism, Crime and Security Act 2001 place an obligation on managers of laboratories and other premises holding stocks of specified disease-causing micro-organisms and toxins to notify the police that they are holding materials listed under Schedule 5 of the Act, and to comply with any reasonable security requirements which they may impose. It also requires managers of laboratories and other premises, to furnish the police, on request, with details of persons with access to any of the specified dangerous substances held there. The Home Secretary is given power to direct that a named individual must not be allowed access to such disease strains or the premises in which they are held. There is a right of appeal to a specially constituted tribunal, the Pathogens Access Appeal Commission (PAAC). The Act provides for its extension to animal or plant pathogens, pests or toxic chemicals subject to the provisions in section 75 (3) and (4).

3. The Biological Agents Directive (2000/54/EC) outlines requirements relating to the protection of workers from risks related to exposure to biological agents at work. The Directive includes a duty to notify the competent authority of an intention to work with certain groups of biological agents and, in some cases, specific biological agents. The Directive is implemented in the UK via the Control of Substances Hazardous to Health Regulations (COSHH); the Health and Safety Executive (HSE) is the Competent Authority.

4. COSHH requires that certain activities involving biological agents should be notified to HSE. Notification is required if there is an intention to use a biological agent from a particular hazard group, other than Hazard Group 1, for the first time at a premises. Notification of each subsequent use of a new biological agent from a list outlined in the legislation (i.e. Hazard Group 3 and 4 agents and a few Hazard Group 2 agents) is also required. The information provided includes the:

- name and address of the employer and the address where the biological agent will be stored;
- the identity of the biological agent and the results of the risk assessment; and
- the preventative and protective measures that will be taken to ensure the health and safety of employees.
5. HSE’s Biological Agents Unit is responsible for collecting this information. It is used to inform the planning of preventative inspections of these premises. As the duties in COSHH were not retrospective when it was introduced in 1985, HSE does not have information on every laboratory working on pathogens in the UK. Recently, HSE has carried out further work to identify laboratories working on significant human pathogens and HSE has the opportunity to obtain additional information on premises when it investigates health and safety incidents that have occurred in the UK.

6. There are similar legal requirements of notification with respect to premises and activities involving GMOs in containment facilities. The Genetically Modified Organisms (Contained Use) Regulations 2000 form the legal basis for these requirements.

7. The Importation of Animal Pathogens Order 1980 (IAPO) as amended prohibits the importation from third countries of animal pathogens (agents that may cause disease in farmed livestock or poultry) and carriers of such animal pathogens, except under licence. Licences are conditional and lay down requirements for such matters as the preparation of the material to be imported prior to importation and its handling and disposal at the laboratory of destination. Restrictions are also placed on domestic transfers of imported material through conditions in import licences. Licensing under IAPO is administered by the Department for Environment, Food and Rural Affairs in England, The Scottish Executive Environment and Rural Affairs Department in Scotland and by the Agriculture and Rural Affairs Department of the National Assembly for Wales in Wales. Separate but similar legislation and arrangements apply in Northern Ireland.

8. The Specified Animal Pathogens Order 1998 (SAPO) prohibits the possession or the introduction into any animal or bird of any of the animal pathogens listed in Part I of the Schedule to the Order and the possession of any carrier containing such a pathogen, except under licence. These are mainly agents that can cause serious exotic diseases of economic importance in farmed livestock and poultry, some of which can affect humans. No licence is required to possess the pathogen listed in Part II of the Schedule but its introduction into any animal or bird is prohibited except under licence. Restrictions are also placed on domestic transfers of specified animal pathogens or carriers through conditions in licences granted to those in possession of such material under SAPO.

9. Licences that authorise the possession of specified animal pathogens under SAPO are only issued where laboratories have the necessary operating procedures and facilities to ensure the safe containment, handling and disposal of the pathogens concerned. Licensing under SAPO is administered by the Department for Environment, Food and Rural Affairs in England, The Scottish Executive Environment and Rural Affairs Department in Scotland and by the Agriculture and Rural Affairs Department of the National Assembly for Wales in Wales. Separate but similar legislation and arrangements apply in Northern Ireland.

10. The Plant Health (Great Britain) Order 1993 (as amended) SI 1993/1320
Under the above the import, movement and keeping of certain plants, plant pests (including pathogens) and other material which poses a risk to plant health is prohibited. However, the Order makes provision, subject to detailed quarantine and containment conditions, for trials, scientific or varietal selection work on plant pests, etc, which would otherwise be prohibited to be carried out under licence in accordance with Commission Directive 95/44/EC.
11. Licensing is administered by the Department for Environment, Food and Rural Affairs in England and Wales and by The Scottish Executive Environment and Rural Affairs Department in Scotland. Licences authorising the import and/or possession of prohibited plant pests etc are only issued where premises have the necessary operating procedures and facilities to ensure the safe containment, handling and disposal of the material concerned. Separate but similar legislation and arrangements apply in Northern Ireland.