

ARTICLE X : FURTHER BUILDING BLOCKS

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Introduction

1. The Ad Hoc Group (AHG) of the States Parties to the Biological and Toxin Weapons Convention (BTWC) has the consideration of measures to implement Article X of the Convention as an element of its mandate agreed by the Special Conference in September 1994. The AHG has considered how to address this at each of its substantive meetings with a Friend of the Chair, initially Ambassador Jorge Berguno of Chile and subsequently, Carlos Duarte of Brazil carrying out this responsibility. As progress is being made on the development of the rolling text for the Protocol to strengthen the Convention, it is timely to consider how the implementation of Article X might contribute to the strengthening of the effectiveness of the Convention.

2. Briefing Paper No 6 considered some of the developments that have occurred nationally, regionally and internationally in respect of the use of bacteriological (biological) agents and toxins for peaceful purposes. It noted that there is increasing awareness world-wide because of public health and environmental concerns of the need to control the handling, use, storage and transfer of such biological agents. That paper examined some of the current controls and regulations for biosafety and the international initiatives that are ongoing to strengthen biosafety around the world. These were seen as building blocks which might be considered from a point of view of strengthening the BTWC as well as contributing to the implementation of Article X although care will need to be taken in the Protocol for the AHG to avoid unnecessary duplication with other international activities.

3. This Briefing Paper is complementary to Briefing Paper No 6 as it considers the national regulations in the UK, the EEC and in the United States as well as some other countries in respect of micro-organisms with the aim of providing some further building blocks to be considered in the strengthening of the BTWC and the implementation of Article X of the Convention. The challenging goal continues to be to identify how these other national, regional and international activities can be utilised to contribute to the strengthening of the BTWC.

United Kingdom Regulations

4. There have been tight controls for a number of years in the United Kingdom on the control of human, animal and plant pathogens which have stemmed from concerns about both the health and safety of workers exposed to such pathogens and also the dangers to human health and to the animal and plant environment that could arise should such pathogens be released into the environment. These national controls have in recent years been harmonized with those for elsewhere in Europe through the Directives of the European Community. The UK Regulations for human, animal and plant pathogens are considered in turn; although there are sometimes different Authorities for parts of the United Kingdom such as Scotland, this Briefing Paper in the interests of simplicity has focussed on the regulations for the United Kingdom or for England. A later section addresses the EEC Directives.

5. **Human Pathogens.** The importance of safeguarding workers in the UK from hazards of any kind was taken forward by the Health and Safety at Work Act of 1974. During the 1970s

the UK operated a voluntary system in which a laboratory wishing to work with what was then known as a Category A pathogen was asked to seek clearance from the appropriate Health department which in turn sought advice in appropriate cases, from the expert Dangerous Pathogens Advisory Group. However, in the late 1970s there was an outbreak of smallpox in Birmingham which led the British Government to decide that laboratories intending to hold or handling Category A pathogens should be required by regulations to notify details of the proposed work and provide supporting information.

6. Consequently, on 1 September 1981, the Health and Safety (Dangerous Pathogens) Regulations 1981¹ came into operation requiring the notification to the Health and Safety Executive (HSE) by employers or self-employed persons intending to work with a listed pathogen. Detailed information is required to be provided in writing 30 days in advance that included the name of the person from whom the pathogen will be obtained and the address of the premises from which it will be obtained, where the pathogen was to be kept or handled, the name including, where relevant, the strain of the pathogen, particulars of the work to be undertaken, its proposed dates of commencement and completion and whether the listed pathogen is likely to be propagated, the names, qualifications and relevant experience of the individuals in charge of, supervising or involved in the work. The regulations make it clear that establishments providing a diagnostic facility are also included and that in all cases, the HSE has to be notified of each new project 30 days before work begins. They also require that HSE must be notified 30 days in advance of a transfer of any listed pathogen from one establishment to another with information being provided on the name, including the strain, of the pathogen, the volume of the consignment and the estimated titre of the listed pathogen, the address to which it will be transferred, the name of the carrier, the name of the individual who will accompany the consignment, the route to be taken and the method of transportation. The listed pathogens in the Regulations were all viruses:

- Crimean Haemorrhagic Fever virus (Congo)
- Ebola virus
- Junin Haemorrhagic Fever virus
- Lassa Fever virus
- Machupo Haemorrhagic Fever virus
- Marburg virus
- Rabies virus
- Simian Herpes B virus
- Smallpox virus
- Venezuelan Equine Encephalitis virus.

7. Also in 1981, the earlier Dangerous Pathogens Advisory Group was succeeded by the Advisory Committee on Dangerous Pathogens (ACDP) which is an advisory committee of the UK Health and Safety Commission which also advises Health and Agriculture Ministers. The ACDP early in 1984 introduced a more general categorization of pathogens and by 1990 in a revised edition had set and maintained new practical standards for the safe conduct of laboratory work with infectious agents; however, both of these had the status of guidance supporting the Health and Safety at Work Act 1974. A further revision was produced in 1995² which reflected the need to implement two European Community Directives concerned

¹Health and Safety Executive, *A Guide to the Health and Safety (Dangerous Pathogens) Regulations 1981*, Health and Safety Series Booklet HS(R)12, 1981, Her Majesty's Stationery Office, London.

²Advisory Commission on Dangerous Pathogens, *Categorisation of biological agents according to hazard and categories of containment*, Fourth Edition 1995, Her Majesty's Stationery Office, London, 1995.

with biological agents which had the effect of converting what had hitherto been guidance into law. It is interesting to note that the EEC Directives use the term "biological agent" and not "pathogen" or "infectious agent". The EEC terminology has understandably been adopted in the subsequent UK regulations.

8. New Control of Substances Hazardous to Health (COSHH) Regulations 1994 came into force in January 1995 implementing the first of these Directives (90/679/EEC) by including mandatory control measures for laboratories. The second Directive (93/88/EEC) contained a European Community classification of biological agents capable of causing infection and the 1995 Edition of the ACDP categorization booklet contains the Community classification, with some permissible variations in classification for the UK, as an Approved List of biological agents which has legal status in the UK.

9. The definition of a biological agent in the COSHH 1994 is:

"any micro-organism, cell culture or human endo-parasite, including any which have been genetically modified, which may cause any infection, allergy, toxicity or otherwise create a hazard to human health"

The good management of health and safety is stated in the ACDP 1995 booklet to be a matter of adopting a systematic approach. It lists the elements of COSHH 1994 in relation to biological agents as being:

- a. Risk assessment;*
- b. Prevention of exposure or substitution of an agent with one that is less hazardous (where the nature of the activity permits);*
- c. Selection of control measures;*
- d. Maintenance, examination and test of control measures including, for example, protective equipment such as safety cabinets;*
- e. Provision of information, instruction and training for employees;*
- f. Keeping a list of employees exposed to agents in Group 3 and Group 4;*
- g. Notification of 'first use' of biological agents in Groups 2, 3 and 4;*
- h. Notification of consignment or importation of biological agents listed in Part V of Schedule 9 of COSHH;*
- i. Monitoring of exposure at the workplace (if there is a suitable procedure);*
- j. Health surveillance of employees...;"*

10. Biological agents are categorized into four Hazard Groups defined as follows:

Hazard Group 1: A biological agent unlikely to cause human disease

Hazard Group 2: A biological agent that can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or effective treatment available;

Hazard Group 3: A biological agent that can cause severe human disease and presents a serious hazard to employees; it may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available.

Hazard Group 4: A biological agent that causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

11. The COSHH 1994 require notification at least 30 days in advance of 'first use' of biological agents in Groups 2, 3 and 4. 'First use' is work with or storage of a biological agent where no such work has been conducted before. As the regulation is not retrospective, notification would be required where a new laboratory is set up or an existing laboratory has not worked before with any of the agents in one group or another. In respect of certain of the most dangerous agents (which are defined as agents in Part V of Schedule 9 of COSHH 1994) this new regulation replaces the former requirement of the Health and Safety (Dangerous Pathogens) Regulations 1991 where work with, storage of, consignment of or importation of any of the agents in Part V of Schedule 9 of COSHH 1994 must be notified 30 days in advance. The agents listed in Part V are:

All Hazard Group 4 biological agents

Rabies virus

Simian herpes B virus

Venezuelan equine encephalomyelitis virus

Tick-borne encephalitis group viruses in Group 3

Monkeypox virus

Mopeia virus

It is interesting to note the way in which genetically modified micro-organisms are treated in the ACDP 1995 edition. This notes that

"Genetically modified micro-organisms ('GMMOs' - bacteria, viruses, fungi and parasites), although included in the definition of a biological agent, have not been categorized in the Approved List as it is not practical to do so, there being so many variants of so many different species. GMMOs that have any harmful properties to humans are subject to the controls demanded by COSHH including, for example those concerning laboratory containment. But other regulations also apply..."

12. The principal changes introduced by COSHH 1994 relate to legal requirements for the containment measures that must be used in laboratories and animal rooms and in the industrial use of biological agents.

13. Although the ACDP 1995 booklet is aimed primarily at workplaces where biological agents are handled intentionally ie in diagnostic laboratories, research and industry and focusses on pathogens that present a risk to human health, it notes the following in relation to zoonotic agents ie agents that cause disease in animals):

Zoonotic agents are included in the categorization solely on the basis of their hazard to humans. Other animal pathogens and pathogens of poultry, fish and bees are not listed but it should be noted that some of these can cause serious epizootics and work must be contained safely.

An Appendix (Appendix 20 of ACDP 1995) lists pathogens controlled by the Agriculture and Fisheries Departments in the UK.

14. Animal Pathogens. The aim of British legislation has been to protect livestock in the UK from serious epidemic disease. The Importation of Animal Pathogens Order 1980³ which entered into force on 1 October 1980 prohibits the importation into Great Britain of an animal pathogen or carrier except under the authority of a licence in writing issued by the appropriate Minister and in accordance with the conditions of that licence. Animal pathogen is defined as "any collection or culture of organisms either on its own or in recombinant form of such collection or culture of organisms which may cause disease in animals or poultry", animals is defined as "cattle, sheep, goats and all other ruminating animals, horses and swine" and carrier is defined as "any living creature except man which may carry or transmit an animal pathogen...". If a licence is issued, then this will stipulate the conditions under which animal pathogens or carriers must be transported, handled and kept and how it may be used while in Great Britain. The application form for a licence requires the provision of information including the following:

- A full description of the pathogen including name and strain where known, eg culture collection number etc
- Type, size and number of containers in which the pathogen is to be held
- Volume, weight or number of samples in each container
- The form in which the pathogen will be transported
- The species of animal from which the pathogen is derived
- The name and address of person supplying the pathogen
- Tick any pathogens causing any of the following diseases which are handled at the premises supplying the pathogen.

together with information on

- The address of the premises where the pathogen or carrier will be handled or kept
- The name of the person responsible for the work to be undertaken
- A full description of the work to be carried out on the imported pathogen or carrier.
- The precautions taken at the laboratory to prevent the escape of the pathogen or carrier
- The facilities available for disposing of cultures or other materials which have contained or been in contact with the imported pathogen or carrier.

15. The Specified Animal Pathogens Order (SAPO) 1993⁴ which entered into force on 1 January 1994 implemented the European Community Directive 92/118/EEC laying down animal health and public health requirements governing trade in and imports into the Community. SAPO 1993 prohibits any person in Great Britain from holding or introducing into animals a specified animal pathogen or carrier containing that pathogen except under the

³Statutory Instruments, *The Importation of Animal Pathogens Order 1980*, 1980, No 1212, Her Majesty's Stationery Office, London.

⁴Statutory Instruments, *The Specified Animal Pathogens Order 1993*, 1993, No 3250, Her Majesty's Stationery Office, London.

authority of a licence issued in writing by the appropriate Minister. The specified animal pathogens are those organisms causing serious epidemic diseases of farm livestock. The definition of animal is extended to "any kind of mammal except man and any kind of four-footed beast which is not a mammal", that of poultry to "any species of bird" and disease to "any disease of animals and poultry which may be caused by one or more specified animal pathogens". The specified animal pathogens include the following:

Bacillus anthracis
Brucella melitensis
Brucella ovis
Brucella suis
Equine encephalomyelitis (eastern, western and Venezuelan) viruses
Foot and mouth disease virus
Newcastle disease virus
Rabies virus
Rift Valley Fever virus
Rinderpest virus
Sheep pox, goat pox and horse pox
Swine fever virus

16. Laboratories holding and working with specified animal pathogens are subject to inspection to ensure that the containment conditions meet the requirements for the category of pathogen being held. Such inspections will be made prior to a licence being issued for the specified animal pathogen. These are categorized according to the risk that they pose to livestock and the environment. These categories are **not complementary** to the ACDP classifications (see para 10 above) which are for the protection of employees. The animal pathogen categories are for the purpose of protecting animal health from escapes of organisms from a laboratory and **not** protection of workers in that laboratory. The categories are:

- Group 1:** Disease-producing organism which are enzootic and do not produce notifiable disease.
- Group 2:** Disease producing organisms which are either exotic or produce notifiable disease, but have a low risk of spread from the laboratory.
- Group 3:** Disease producing organism which are either exotic or produce notifiable disease and have a moderate risk of spread from the laboratory.
- Group 4:** Disease producing organisms which are either exotic or produce a notifiable disease and have a high risk of spread from the laboratory.

17. **Plant Pathogens.** The aim of British legislation is to prevent the importation into Great Britain of any plant pathogen or pest that is not already established in Great Britain. As the explanatory leaflet⁵ states there are many plant pests and diseases around the world which, if they were to become established in Great Britain, could cause serious damage to

⁵Ministry of Agriculture, Fisheries and Food, *Explanatory Leaflet on the Issue of Licences for the Import, Movement and keeping of Prohibited Plants, Plant Material, Plant Pests, Soil and Growing Medium*, PHI 1 (rev. 5/97)

crops and plants. It goes on to note that to guard against the spread of harmful organisms, official controls apply to the import, movement, and keeping of plants, plant pests and other material such as soil. These controls are laid down in the Plant Health (Great Britain) Order 1993⁶ which entered into force on 1 June 1993 and prohibits the importing into Great Britain from a third country any infected plants or plant pests. It also prescribes the quarantine and containment conditions to be applied to infected plants and plant pests within Great Britain. Plant pests are defined in the Order as:

""Plant pest" means pests of and harmful organisms liable to infect plants or plant products which belong to the animal or plant kingdoms, or which are viruses, mycoplasmas or other pathogens and includes genetically modified plant pests."

The controlled pathogens and pests may only be imported into Great Britain for experimental purposes under a licence issued by the appropriate Minister.

18. Applications for a licence are required to be submitted at least one month before the licence is required. Issue of the licence will be subject, if necessary, to a prior inspection of the premises in which the material is to be kept. The licence will prescribe conditions that are designed to ensure that the material imported, moved or kept does not pose a risk to plant health. These will include instructions for the safe transport of licensed material, where and how it should be contained and arrangements for its safe disposal. After issue of a licence, licensed premises will be visited to monitor compliance with licence terms and conditions. The frequency of such visits will be influenced by factors such as the plant health risk associated with the type of material imported or kept. It is clear from the Order that inspectors on entering premises "may take with him such other persons, including, but not limited to, representatives of the European Commission, and such equipment and vehicles as are necessary for the exercise of his powers...". The inspector also has rights to sample as the Order states that

"an inspector ... may at all reasonable times ... for any other purpose of this Order, including checking compliance with it, enter any premises, examine and mark any part of the premises or any objects on the premises and examine, take samples of, photograph or mark any plant pest, plant, plant product or other object or anything which has been or may have been in contact therewith;"

19. The Order also requires that an official register be kept containing the name and address of each business, individual or other organisation which applies for registration. Such organisations on the register are required to keep records and these are to be inspected at least once in each calendar year.

20. It is also made clear that although licensed material may be provided to persons or organizations within Great Britain who hold a relevant MAFF (Ministry of Agriculture, Fisheries and Food) licence, such material must not be made available to other persons or organisations without written agreement from the Plant Health Division of MAFF who will make arrangements for the issue of phytosanitary certificates or plant passports or for endorsement of letters of authority.

⁶Statutory Instruments, *The Plant Health (Great Britain) Order 1993*, 1993, No 1320, Her Majesty's Stationery Office, London.

21. The Order also lays down the requirements for the movement of otherwise prohibited material. The principal requirement is for a letter of authority to accompany all material imported under licence; this letter of authority is issued in Great Britain by the relevant Ministry, MAFF. Where material covered by a licence and a letter of authority is imported from another member state in the European Community, it is the responsibility of the licensee, where possible, to have the letter of authority endorsed by the plant health authorities in that member state. In addition, the European Community measures require that in the case of certain plants, plant products and other objects originating in the Community, the material must be accompanied by a plant passport issued under the authority of the plant health services of the exporting member state; the plants to which this requirement applies are listed in Schedule 5, Part A of the Plant Health Order 1993. If certain plants, plant products or other objects are to be introduced from a third country (ie a country outside the Community) then the material must be accompanied wherever possible by a phytosanitary certificate issued in the country of origin; the plants to which this requirement applies are listed in Schedule 5, Part B of the Plant Health Order 1993.

22. The Order also includes the prohibition of the import, movement or keeping of any plant pest which has been genetically modified and any plant material that has been modified such that it contains material derived from a plant pest. Genetically modified plant pests are defined in the Order as:

""genetically modified plant pest" means a plant pest, the genetic component of which has been modified, and includes -

a. organisms and material which contain such a plant pest or parts thereof, and

b. any other modified organisms likely to be injurious to plants..."

The legislation also prohibits any activity that involves genetic modification of a plant pest as it states that:

"No person shall without the authority of an inspector engage in any activity which involves genetic modification of a plant pest or engage in any activity which to his knowledge involves genetically modified plant pests."

The explanatory leaflet notes that with the provision of appropriate safeguards, a plant health licence may be issued to allow genetic modification work with plant pests and for the import, movement and keeping of genetically modified plant pests. It goes on to note that "these strict controls are necessary because the genetic modification process could either alter the pathogenicity of an organism such that it poses a different risk (e.g. altered host range or increases pathogenicity) or produce a plant pathogen (or pest) from material originally of non-pathogenic status."

23. **Analysis.** It is thus apparent that within Great Britain, there are tight controls requiring on-site inspection of all activities involving pathogens that present a risk to humans, animals and to plants. Information about such activities have to be provided to the Government inspectorates responsible for implementation of the national regulations and controls.

European Community Directives

24. The aim of European Community Directives have been to harmonise the various controls that have generally previously operated nationally in member states.

25. **Human Pathogens.** Council Directive 90/679/EEC⁷ addresses the protection of workers from risks related to exposure to biological agents at work. It was issued on 26 November 1990 and requires Member States to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than three years after notification of the Directive to Member States on 29 November 1990. The preamble notes that a Council Resolution of 27 February 1984 on an action programme for safety and health at work provides for the development of protective measures for workers exposed to dangerous agents. The aim of the Directive is "the protection of workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to biological agents at work." Its definition of biological agents is as follows:

"biological agents' shall mean micro-organisms including those that have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity;"

with micro-organism being defined as:

"micro-organism' shall mean a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material;"

The Directive also defines that biological agents shall be classified into four risk groups, according to their level of risk of infection:

- "1. group 1 biological agent means one that is unlikely to cause human disease;*
- 2. group 2 biological agent means one that can cause human disease and might be a hazard to workers; it is unlikely to spread to the community; there is usually effective prophylaxis or treatment available;*
- 3. group 3 biological agent means one that can cause severe human disease and present a serious hazard to workers; it may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available;*
- 4. group 4 biological agent means one that causes severe human disease and is a serious hazard to workers; it may present a high risk of spreading to the community; there is usually no effective prophylaxis or treatment available."*

26. The Directive requires that the possible risks be assessed and determined. If the results of the assessment show that the activity may result in a worker being exposed to a biological agent then various steps shall be taken for the reduction of risks including:

⁷Council Directive, *On the protection of workers from risks related to exposure to biological agents at work*, 26 November 1990, 90/679/EEC, Official Journal of the European Commission, No. L 374/1, 31 December 1990, 1 - 12.

- "a. keeping as low as possible the number of workers exposed or likely to be exposed*
- b. design of work processes and engineering control measures so as to avoid or minimise the release of biological agents into the place of work;*
- c. collective protection measures and/or, where exposure cannot be prevented by other means, individual protective measures;....*
- f. drawing up plans to deal with accidents involving biological agents;*
- g. testing, where it is necessary and technically possible, for the presence, outside the primary physical confinement, of biological agents used at work;..."*

27. Where the assessment reveals a risk to worker's health or safety then employers shall, when requested, make available to the competent authority appropriate information on:

"the results of the assessment;

the activities in which workers have been exposed or may have been exposed to biological agents;...

an emergency plan for the protection of workers from exposure to a group 3 or group 4 biological agent which might result from a loss of physical containment;..."

The Directive also requires that employers shall provide workers and/or their representatives, at their request, with the information listed above. Provision is also made for the supply to the competent authority of the information used for making the assessment.

28. Prior notification to the competent authority is required at least 30 days before the commencement of the use for the first time of:

- group 2 biological agents;
- group 3 biological agents;
- group 4 biological agents;

as well as, subsequently, of each subsequent group 4 biological agent and of any subsequent new group 3 biological agent where the employer himself provisionally classifies that biological agent. The notification shall include:

"a. the name and address of the undertaking and/or the establishment;

b. the name and capabilities of the person responsible for safety and health at work;

c. the results of the assessment...

d. the species of the biological agent;

e. the protection and preventive measures that are envisaged."

29. The Directive lays down three levels of containment measures for laboratories (Annex V) and for industrial processes (Annex VI) carrying out work with group 2, 3 and 4 biological agents.

30. A further Directive 93/88/EEC⁸ amended the earlier Directive 90/679/EEC by providing a Community list of Group 2, Group 3 and Group 4 biological agents. The introductory notes to the list make it clear that only agents known to infect humans are included and animal and plant pathogens which are not known to affect man are excluded. Indicators in the list show cases where the biological agents are likely to cause allergic or toxic reactions, where an effective vaccine is available, or where it is advisable to keep a list of exposed workers for more than 10 years. In addition an asterisk is used to show where certain biological agents classified in group 3 may present a limited risk of infection for workers because they are not normally infectious by the air-borne route as Member States can assess whether, in particular circumstances, some of the containment measures may be dispensed with. The list addresses bacteria, viruses, parasites and fungi which are listed alphabetically showing their respective biological agent classification.

31. Genetically modified organisms are addressed in two Council Directives: 90/219/EEC on contained use⁹ and 90/220/EEC on deliberate release into the environment.¹⁰ Directive 90/219/EEC adopted on 23 April 1990 and to be implemented not later than 23 October 1991 lays down common measures for the contained use of genetically-modified micro-organisms with a view to protecting human health and the environment. It defines "genetically-modified organisms" as being:

a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Within the terms of this definition:

(i) genetic modification occurs at least through the use of the techniques listed in Annex I A, Part 1;

(ii) the techniques listed in Annex I A, Part 2 are not considered to result in genetic modification;

An Annex sets out which genetically modified organisms may be classified as being in Group I -- generally the requirement is that they shall be non-pathogenic - or in Group II described as being other than Group I). Containment measures, described as categories 1, 2 and 3 are required to be adopted to "ensure the protection of the public health of the general population and the environment."

32. Notifications are required to the competent authority prior to an installation being used for the first time for operations involving the contained use of genetically modified micro-

⁸Council Directive, *Amending Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work*, 12 October 1990, 93/88/EEC, Official Journal of the European Commission, No. L 268/71, 29 October 1993, 71 - 82.

⁹Council Directive, *On the contained use of genetically modified organisms*, 23 April 1990, 90/219/EEC, Official Journal of the European Commission, No. L 117/1, 8 May 1990, 1 - 14.

¹⁰Council Directive, *On the deliberate release to the environment of genetically modified organisms*, 23 April 1990, 90/220/EEC, Official Journal of the European Commission, No. L 117/15, 8 May 1990, 15 - 27.

organisms and before the first use of such organisms in Group I and Group II respectively. The information to be provided in the notifications is specified in an Annex to the Directive which requires the following:

description of the nature of the work and the classification of the micro-organism (Group I or II) and the likely scale of the operation;

More detailed information is required before a larger scale operation (known as Type B operations in the Directive) (than one "used for teaching, research, development or non-industrial or non-commercial purposes and which is of a small scale (e.g. 10 litres culture volume of less))" (known as Type A operations in the Directive) involving Group I genetically-modified micro-organisms when the following is required

- *the parental micro-organism(s) used or, where applicable the host-vector system(s) used;*
- *the source(s) and the intended function(s) of the genetic material(s) involved in the manipulation;*
- *identity and characteristics of the genetically modified micro-organism;*
- *the purpose of the contained use including the expected results;*
- *the culture volumes to be used;*
- *a summary of the risk assessment ..."*

In the case of Group II genetically-modified micro-organisms, the same information is required for Type A operations (ie for operations used for teaching, research, development or non-industrial or non-commercial purposes and which is of a small scale (e.g. 10 litres culture volume of less)) together with:

- *descriptions of the section of the installation and the methods for handling the micro-organisms;*
- *description of the predominant meteorological conditions and of the potential sources of danger arising from the location of the installation;*
- *description of the protective and supervisory measures to be applied throughout the duration of the contained use;*
- *the containment category allocated specifying waste treatment provisions and the safety precautions to be adopted.*

33. The Directive in Article 19 addresses the protection of confidential information. It is, however, interesting that if the notifier considers that information, which might harm his competitive position, should be treated as confidential, the Directive states that "Verifiable justification must be given in such cases." Furthermore, the Directive states that:

"In no case may the following information, when submitted according to Articles 8. 9 or 10, be kept confidential:

- *description of the genetically-modified micro-organisms, name and address of the notifier, purpose of contained use, and location of use;*
- *methods and plans for monitoring of the genetically-modified micro-organisms and for emergency response;*

- *the evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.*"

34. Directive 90/220/EEC adopted on 23 April 1990 and to be implemented before 23 October 1991 is aimed at protecting human health and the environment "when carrying out the deliberate release of genetically-modified micro-organisms into the environment" and "when placing on the market products containing, or consisting of, genetically-modified micro-organism intended for subsequent deliberate release into the environment." The definition of genetically-modified micro-organisms is identical to that in Directive 90/219/EEC. However, the requirements for notification are more stringent and the work may only proceed after the written consent of the competent authority has been received. Provision is also made for setting up a system of exchange of the information contained in the notifications between the State in which the proposed release will take place and the European Commission and the other Member States. The provisions for the safeguarding of confidential information in Article 19 are virtually identical to those in the contained use Directive with a closely similar statement of what information "in no case" may be kept confidential.

35. It is interesting to note the type of information which has to be provided, the requirement for "verifiable justification" of any information considered to be confidential, and the clear statement of information that "in no case" may be kept confidential.

36. **Animal Pathogens.** Council Directive 82/894/EEC adopted on 21 December 1982 and to be implemented not later than 1 January 1984 sets out requirements for notification of the outbreak of animal diseases within the European Community.¹¹ Outbreak is defined as:

'outbreak' means the holding or place situated in the territory of the community where animals are assembled and where one or more cases has or have been officially confirmed;

The Directive requires the notification directly to both the Commission and the other member States within 24 hours of the primary outbreak of any of the diseases listed in Annex I of the Directive which have been confirmed. The listed diseases include:

*Foot-and-mouth disease
Rinderpest (cattle plague)
Contagious bovine pleuropneumonia
Bluetongue
Swine vesicular disease
Classical swine fever
African swine fever
Teschen disease (contagious swine paralysis)
Fowl plaque
Newcastle disease*

The information to be provided includes:

(a) Name of disease

¹¹Council Directive, *On the notification of animal diseases within the Community*, 21 December 1982, 82/894/EEC, Official Journal of the European Commission, No. L 378/58, 31 December 1982, 58 - 62.

(b) Type of virus, if appropriate

Date of confirmation

Geographical location of holding

Number of susceptible animals on premises (a) cattle, (b) pigs, (c) sheep, (d) goats, (e) poultry

Number of stock slaughtered (a) cattle, (b) pigs, (c) sheep, (d) goats, (e) poultry

Number of carcasses destroyed (a) cattle, (b) pigs, (c) sheep, (d) goats, (e) poultry

37. Directive 89/662/EEC adopted on 11 December 1989 and to be implemented not later than 31 December 1991 addresses veterinary checks in intra-Community trade¹². The aim is to ensure that veterinary checks are carried out at the place of dispatch only but this implies the harmonization of the basic requirements relating to the safeguarding of public health and animal health. The preamble recognizes that provision needs to be made for the action to be taken when a veterinary check shows that a consignment is irregular so as "to avert any danger where it is found that there has been an outbreak of an epizootic disease, any new serious and contagious disease or other cause likely to constitute a serious hazard to animals or to human health.". The Directive requires that the officials of veterinary departments in the Member States shall be able, in particular, to:

- *carry out inspections of premises, offices, laboratories, installations, means of transport, plant and equipment...*
- *carry out checks on whether staff comply with the requirements laid down in the texts referred to in Annex A;*
- *take samples from products held with a view to being stored or sold, put on the market or transported;*
- *examine documentary or computer material ...;*

38. A further Directive 90/425/EEC adopted on 26 June 1990 and to be implemented not later than 31 December 1991 develops the requirements for veterinary and zootechnical checks for particular species of live animals as well as for products including "Waste (pathogens)".¹³ This includes at Annex C a list of diseases or epizootic diseases, subject to mandatory emergency action, with territorial restrictions (Member States, Regions or Zones):

- *Foot and mouth disease*
- *Classical swine fever*
- *African swine fever*
- *Swine vesicular disease*
- *Newcastle disease*
- *Rinderpest*
- *Peste des petits ruminants*
- *Vesicular stomatitis*
- *Blue tongue*
- *African horse sickness*

¹²Council Directive, *Concerning veterinary checks in intra-Community trade with a view to the completion of the internal market*, 11 December 1989, 89/662/EEC, Official Journal of the European Commission, No. L 395/13, 30 December 1989, 13 - 22.

¹³Council Directive, *Concerning veterinary and zootechnical checks in intra-Community trade in certain live animals and products with a view to the completion of the internal market*, 26 June 1990, 90/425/EEC, Official Journal of the European Commission, No. L 224/29, 18 August 1990, 29 - 41.

- *Viral equine encephalomyelitis*
- *Teschen disease*
- *Avian influenza*
- *Sheep and goat pox*
- *Lumpy skin disease*
- *Rift valley fever*
- *Contagious bovine pleuropneumonia.*

This Directive has virtually identical language to that in 89/662/EEC concerning the rights of the officials of veterinary departments in the Member States.

39. Another Directive 92/118/EEC¹⁴ adopted on 17 December 1992 and to be implemented before 1 January 1994 sets out the animal health and public health requirements governing trade in and imports into the Community of products not subject to the rules laid down in Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC. This Directive includes a useful consolidated version of the Annexes to 89/662/EEC and to 90/425/EEC listing the relevant Council Directives which apply for a wide variety of animals and animal products.

40. **Plant Pathogens.** Directive 95/44/EC adopted on 26 July 1995 and to be implemented on 1 February 1996 establishes the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V of Directive 77/93/EEC may be introduced into or moved within the Community for trial or scientific purposes.¹⁵ This requires that an application shall be submitted to the responsible official bodies prior to the introduction into, or movement within, Member State or relevant protected zones thereof of any such material for any activity for trial or scientific purposes and for work on varietal selection which would involve the use of harmful organisms, plants, plant products or other objects under 77/93/EEC. The Directive specifies that the application shall contain at least:

- *the name and address of the person responsible for the activities*
- *the scientific name or names of the material, including the harmful organism concerned, where appropriate,*
- *the type of material,*
- *the quantity of material,*
- *the place of origin of the material with appropriate documentary evidence for material to be introduced from a third country,*
- *the duration, nature and objectives of the activities envisaged, including at least, a resume of the work and a specification for trial for scientific purposes or work on varietal selections,*
- *the address and description of the specific site or sites for quarantine containment and, where appropriate, for testing,...*

¹⁴Council Directive, *Laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC*, 17 December 1992, 92/118/EEC, Official Journal of the European Commission, No. L 62/49, 15 March 1993, 49 - 68.

¹⁵Commission Directive, *Establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 77/93/EEC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections*, 26 July 1995, 95/44/EC, Official Journal of the European Communities, No. L 184/34, 3 August 1995, 34 - 46.

41. The Directive requires that the responsible official body shall monitor any approved activities and shall ensure that the quarantine containment conditions and other general conditions specified in Annex I are complied with throughout the duration of the activities by examination of the premises and the activities at appropriate times. The general conditions specified in Annex I include:

- * the nature and objectives of the activities shall have been examined,
- * the quarantine containment conditions shall have been inspected,
- * the quantity of material shall be limited to an amount that is adequate for the approved activities and in any case the amount shall not exceed quantities which have been determined with regard to the available quarantine containment facilities,
- * the scientific and technical qualifications of the personnel shall have been examined and approved.

The Annex requires that the quarantine containment conditions shall be sufficient:

"to ensure a safe handling of the material such that any harmful organisms are contained and the risk of spreading such harmful organisms eliminated."

A detailed list of quarantine measures are laid down which have to be considered after assessing the risk of spread of the harmful organisms.

42. The earlier Directive 77/93/EEC adopted on 21 December 1976 and to be implemented within four years addresses protective measures against introduction into the Member States of harmful organisms of plants or plant products.¹⁶ The preamble notes that the International Plant Protection Convention of 6 December 1951 concluded at the United Nations Food and Agricultural Organization and the close cooperation of the States in the European and Mediterranean Plant Protection Organization have already, to a certain extent, resulted in the harmonization of plant-health laws. The term 'harmful organism' is defined in the Directive as being considered to mean:

"pests of plants and of plant products, which belong to the animal or plant kingdoms, or which are viruses, mycoplasmas or other pathogens."

The harmful organisms of plants or plant products are detailed in various Annexes to this Directive:

Annex I A. Harmful organisms whose introduction must be prohibited in all Member States
B. Harmful organisms whose introduction may be prohibited in certain Member States

Annex II A. Harmful organisms whose introduction must be prohibited in all Member States if they are present on certain plants or plant products
B. Harmful organisms whose introduction may be prohibited in certain Member States if they are present on certain plants or plant products

¹⁶Council Directive, *On protective measures against the introduction into the Member States of harmful organisms of plants or plant products*, 21 December 1976, 77/93/EEC, Official Journal of the European Communities, No. L 26/20, 31 January 1977, 20 - 54.

Annex III A. Plants and plant products the introduction of which must be prohibited in all Member States

B. Plants, plant products and other objects the introduction of which maybe prohibited in certain Member States

Annex IV A. Special requirements which must be laid down by all Member States for the introduction of plants, plant products and other objects

B. Special requirements which may be laid down by certain Member States for the introduction of plants and plant products

Annex V Plants, plant products and other objects which must be subjected to a plant health inspection in the country of origin, or the consignor country, before being permitted to enter any of the Member States

This Directive also details the phytosanitary certificate required to accompany plants, plant products or other objects permitted to be introduced. The later Directive 95/44/EC addresses the letter of authority and the plant passport required to accompany approved plants, plant products and other objects approved for movement within or entry into the Community.

43. **Analysis.** It is thus apparent that within the European Community there is widespread harmonization of the regulations controlling human, animal and plant pathogens. As the European Community expands in size the number of States covered by these Directives will be increased. Many of these are aimed at protecting human health and the environment. Information is required to be provided generally for prior approval to the appropriate authorities in the Member States and, to a varying extent, this may be shared with other Member States.

United States of America

44. There is very extensive US documentation relating to regulations for human, animal and plant pathogens. In this Briefing Paper attention is given primarily to controls of pathogens that "have the potential to pose a severe threat to public health and safety." Information is provided on the United States code relating to the regulation of biological products and to the new rules effective 15 April 1997 for the shipping and handling of select agents capable of causing substantial harm to public health.

45. The basic US law on the regulation of biological products is that relating to the Public Health Service¹⁷. In the Section on the regulation of biological products it is made clear that this addresses both intrastate and interstate traffic. This states that:

"No person shall sell, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange from any State or possession into any other State or possession or into any foreign county, or from any foreign country into any State or possession, any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man, unless (1) such virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component

¹⁷United States Code, Title 42 Public Health Service, Part F Licensing of Biological Products and Clinical Laboratories, Subpart I - Biological Products, Section 262 Regulation of Biological Products.

or derivative, allergenic product, or other product has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary as hereinafter authorized, to propagate or manufacture, and prepare such virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product...."

A later section addresses the inspection of such establishments:

"Any officer, agent or employees of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter or exchange in the District of Columbia, or to be sent, carried or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any state or possession."

46. A subsequent section addresses the exportation of a partially processed biological product which is intended for further manufacture into final dosage form outside the United States. This requires submission of an application which shall:

*"(i) describe the partially processed biological product to be exported,
(ii) list each country to which the product is to be exported,
(iii) contain a certification by the applicant that the product will not be exported to a country not listed under clause (ii),
(iv) identify the establishment in which the product is manufactured, and
(v) contain a certification by the applicant that the final product to be developed from the partially processed product is approved in the country to which it is to be exported or approval of the final product is being sought in such country."*

47. The Antiterrorism and Effective Death Penalty Act of 1996¹⁸ introduced in Section 511 Enhanced Penalties and Control of Biological Agents. This states that *"the Congress finds that:*

*(1) Certain biological agents have the potential to pose a severe threat to public health and safety;
(2) Such biological agents can be used as weapons by individuals or organizations for the purpose of domestic or international terrorism or for other criminal purposes;
(3) The transfer and possession of potentially hazardous biological agents should be regulated to protect public health and safety; and
(4) Efforts to protect the public from exposure to such agents should ensure that individuals and groups with legitimate objectives continue to have access to such agents for clinical and research purposes."*

It sets out the requirement that the Secretary of Health and Human Services shall

"establish and maintain a list of each biological agent that has the potential to pose a severe threat to public health and safety"

¹⁸United States, Public Law 104-132, Antiterrorism and Effective Death Penalty Act of 1996, 24 April 1996.

In addition to ensure the regulation of transfers of listed biological agents, *"the Secretary shall, through regulations...provide for:*

- (1) the establishment and enforcement of safety procedures for the transfer of biological agents listed including measures to ensure -
 - (A) proper training and appropriate skills to handle such agents; and*
 - (B) proper laboratory facilities to contain and dispose of such agents;**
- (2) safeguards to prevent access to such agents for use in domestic or international terrorism or for any other criminal purpose;*
- (3) the establishment of procedures to protect the public safety in the event of a transfer or potential transfer of a biological agent in violation of the safety procedures established under paragraph (1) or the safeguards established under paragraph (2); and.*
- (4) appropriate availability of biological agents for research, education and other legitimate purposes."*

48. On 10 June 1996, the proposed rules¹⁹ to achieve the above requirements were promulgated in the Federal Register inviting written comments before 10 July 1996 on the proposed rules. The proposed rule was designed to:

- * Establish a system of safeguards to be followed when specific agents are transported;*
- * Collect and provide information concerning the location where certain potentially hazardous agents are transferred*
- * Track the acquisition and transfer of these specific agents; and*
- * Establish a process for alerting the authorities if an unauthorized attempt is made to acquire these agents.*

A summary of the public comment on the proposed rule and the Department's response together with the final rule were published in the Federal Register of 24 October 1996.²⁰ The final rule has an effective date of 15 April 1997; all transfers of select agents must comply with the complete documentation and registration requirements on or after that date.

49. The final rule includes the following elements:

- Registration of facilities
- Request for agents
- Verification of registration
- Transfer
- Inspections

together with in Appendix A the list of select agents which comprises the following:

"Viruses

1. Crimean-Congo haemorrhagic fever virus

¹⁹United States, Federal Register, Department of Health and Human Services, *Additional Requirements for Facilities Transferring or Receiving Select Infectious Agents*, Proposed Rules, Volume 61, No. 112, Monday 10 June 1996, 29327 - 29333.

²⁰United States, Federal Register, Department of Health and Human Services, *Additional Requirements for Facilities Transferring or Receiving Select Agents*, Rules and Regulations, Volume 61, No. 207, Thursday 24 October 1996, 55190 - 55200.

2. *Eastern Equine Encephalitis virus*
3. *Ebola viruses*
4. *Equine Morbillivirus*
5. *Lassa fever virus*
6. *Marburg virus*
7. *Rift Valley fever virus*
8. *South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)*
9. *Tick-borne encephalitis complex viruses*
10. *Variola major virus (Smallpox virus)*
11. *Venezuelan Equine Encephalitis virus*
12. *Viruses causing hantavirus pulmonary syndrome*
13. *Yellow fever virus*

Bacteria

1. *Bacillus anthracis*
2. *Brucella abortus, B. melitensis, B. suis*
3. *Burkholderia (Pseudomonas) mallei*
4. *Burkholderia (Pseudomonas) pseudomallei*
5. *Clostridium botulinum*
6. *Francisella tularensis*
7. *Yersinia pestis*

Rickettsiae

1. *Coxiella burnetii*
2. *Rickettsia prowazekii*
3. *Rickettsia rickettsii*

Fungi

1. *Coccidioides immitis*

Toxins

1. *Abrin*
2. *Aflatoxins*
3. *Botulinum toxins*
4. *Clostridium perfringens epsilon toxin*
5. *Conotoxins*
6. *Diacetoxyscirpenol*
7. *Ricin*
8. *Saxitoxin*
9. *Shigatoxin*
10. *Staphylococcal enterotoxins*
11. *Tetrodotoxin*
12. *T-2 Toxin*

Recombinant Organisms/Molecules

1. *Genetically modified micro-organisms or genetic elements from organisms in Appendix A, shown to produce or encode for a factor associated with a disease.*
2. *Genetically modified micro-organisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Annex, or their toxic subunits."*

It will be noted that, unsurprisingly, this list contains all the micro-organisms generally included in lists of possible biological warfare agents. Consequently, these US rules are of particular interest when considering measures that might strengthen, or contribute to the strengthening, of the BTWC.

50. The requirements concerning registration require that prior to receiving or transferring a select agent listed in the rule, sufficient information shall be provided that the applicant facility and its laboratory or laboratories are equipped and capable of handling the agents at Biosafety Level (BL) 2, 3 or 4 depending on the agent and the type of work being performed with the agents and the facility shall be inspected. The rule states that the registration can be denied if there is *inter alia* :

Evidence that the facility has or intends to use covered agents in a manner harmful to the health of humans;

The rule also specifies that the requirements for BL - 2, 3 and 4 operations are contained in the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories", Third Edition, May 1993 which is incorporated into the regulation thus transforming its status from guidelines to requirements. This incorporation was one of the public comments on which the Department's response published in the final rule was that:

"Because the BMBL [Biosafety in Microbiological and Biomedical Laboratories] serves as the only nationally and internationally recognized source of for biosafety requirements for laboratories, the final rule retains the incorporation of the BMBL. The BMBL provides the minimum requirements for BL - 2, 3 and 4 laboratories and animal facilities and is readily applicable to a facility registration and inspection process."

The registering entity is required to maintain:

- "(i) A database of all facilities formerly and currently registered as BL 2, 3 or 4 and capable of working with agents in Annex A of this part [of the rule]. The database shall include the name and address of the registered facility...*
- (ii) A copy of each CDC Form EA-101 transmitted by each transferor registered by that registering entity. Such forms shall be made readily available to the Secretary and to appropriate federal law enforcement authorities..."*

51. A request for agents requires the completion, prior to any transfer of any agent in Appendix A, of CDC Form EA-101 for each transfer sought. The information provided must include:

- "(i) The name of the requestor and the requesting facility;*
- (ii) The name of the transferor and the transferring facility*
- (iii) The names of responsible facility officials for both the transferor and requestor..."*

- (iv) *The requesting facility's registration number;*
- (v) *The transferring facility's registration number;*
- (vi) *The name of the agent(s) being shipped;*
- (vii) *The proposed use of the agent(s); and*
- (viii) *The quantity (number of containers and amount per container) of the agent(s) being shipped."*

The form must be signed by both the transferor and requestor and by the responsible facility officials representing both the transferring and receiving facilities.

52. Prior to transferring any agent, the transferor's responsible facility official must verify that the requesting facility has a valid registration, that the requestor is an employee of the requesting facility and that the proposed use of the agent by the requestor is correctly indicated on form CDC EA-101.

53. Provisions are laid down for inspections which state that:

"(1) Registering entities or the Secretary may conduct random or for cause inspections of registered facilities to assure compliance... All Forms CDC EA-101 and records deemed relevant by inspecting officials must be produced upon request to authorized personnel conducting these inspections. Inspections may also include review of the mechanisms developed by a facility to track intrafacility transfers as well as the facility's agent disposal procedures.

(2) In addition, the Secretary may conduct inspections of registering entities and/or any consolidated database... to assure compliance..."

Overall these rules provide a framework which should ensure that the select agents are only held in registered and inspected facilities and that all transfers are between registered facilities and are fully documented and recorded.

54. The CDC/NIH (Centers for Disease Control and Prevention/National Institutes of Health) publication "Biosafety in Microbiological and Biomedical Laboratories"²¹ (BMBL) in its introduction recognises that:

"Microbiological laboratories are special, often unique, work environments that may pose identifiable infectious disease risks to persons in or near them....Published reports around the turn of the century described laboratory-associated cases of typhoid, cholera, glanders, brucellosis and tetanus."

It goes on to say that the third edition of the BMBL continues to:

"specifically describe combinations of microbiological practices, laboratory facilities, and safety equipment, and recommend their use in four categories or biosafety levels of operation with selected agents infectious to humans."

²¹United States Department of Health and Human Services, Centers for Disease Control and Prevention/ National Institutes of Health CDC NIH, "Biosafety in Microbiological and Biomedical Laboratories", HHS Publication No. (CDC) 93-8395, 3rd Edition, May 1993, United States Government Printing Office, Washington, D.C., 1993.

The introduction says that "strict adherence to these guidelines does contribute to a healthier and safer work environment for laboratorians, their co-workers and the surrounding community."

55. The BMBL sets out the criteria for Laboratory Biosafety at levels 1, 2, 3 and 4 and likewise for Vertebrate Animal Biosafety again at levels 1, 2, 3 and 4. It then provides Agent Summary Statements for the various agents which sets out the recommended Biosafety Levels to be used for work involving that agent. In addition, the BMBL includes a useful Appendix E which lists the prohibited animal pathogens which pose a serious disease threat to domestic livestock and poultry. The US Department of Agriculture regulates the importation and interstate shipment of animal pathogens and prohibits the importation, possession or use of certain exotic animal diseases which pose a serious disease threat to domestic livestock and poultry.

56. **Analysis.** It is thus apparent that within the United States there are regulations controlling human and animal pathogens which are aimed at protecting human health and the environment. The handling and transfer of select agents having the potential of posing a serious threat to public health and safety -- which unsurprisingly closely reflect those regarded traditionally as biological warfare agents -- are tightly controlled.

Organization for Economic Co-Operation and Development (OECD)

57. The OECD is an intergovernmental organization established in 1960 with its headquarters in Paris which now has 24 Member countries with advanced market economies²². The OECD Member countries are:

Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, United Kingdom, United States of America.

Its aims and responsibilities are:

- * *Achieving the highest sustainable economic growth and employment;*
- * *Promoting economic and social welfare throughout the OECD region by coordinating policies of its member countries; and*
- * *Stimulating and harmonizing the efforts of member countries in favour of developing countries.*

The OECD Council Decisions are legally binding on Member countries and Council Recommendations which, while not being legally binding, are strong expressions of political will.

58. One of the Committees of the OECD is the Environmental Policy Committee on Environmental Aspects of Biotechnology whose work is intended to further the mutual understanding of national policies and approaches, thus increasing the international use and acceptance of information developed in Member countries. A particular objective is the

²²Dr P W E Kearns et al, *OECD Initiatives on Safety in Biotechnology*, published in Proceedings African Regional Conference for International Cooperation on Safety in Biotechnology, 11 - 14 October 1993, Harare, Zimbabwe.

identification of issues emerging from the use and regulation of recombinant DNA technologies and other modern biotechnologies as well as that of associated products. Particular emphasis is placed on approaches to ensure the safe release of organisms (including genetically modified organisms) to the environment. In the area of environmental health and safety, work is being carried out through the exchange of information on issues relating to environmental releases of organisms derived through biotechnology and through work to develop scientific principles which are valuable in the assessment of safety. A third type of activity is considered to be likely to become increasingly important relating to oversight/regulatory work.

59. Initially the OECD emphasis was towards information exchange and the monitoring of developments in biotechnology regulations. A report on "Recombinant DNA Safety Considerations"²³ was published in 1986 included OECD Guidelines and OECD Council Recommendations that member countries should share information with a view to facilitating international harmonization of approaches to recombinant DNA techniques. This led to a survey "International Survey on Biotechnology Use and Regulations"²⁴ published in 1990 which contained the summarised responses from 20 Member countries (Australia, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom, United States of America) to requests for:

- "- Information on whether and how the OECD Guidelines had been adopted;*
- Information on national guidelines and regulatory developments;*
- Information on environmental releases of genetically modified organisms."*

together with additional information on monitoring programmes for the environmental release of genetically modified organisms (GMOs).

60. The subsequent report published in 1990 provides detailed information on a country by country basis under each of these four headings. Its summary said in respect of the OECD Guidelines that:

"Although there are exceptions, those countries with biotechnology legislation or guidelines generally have found the OECD Guidelines to be useful in the preparation of their own regulatory schemes, and have attempted to harmonize their schemes with the Guidelines. Overall, Member countries' comments were very positive about the Guidelines. If they had not incorporated them by letter, they had very often done so by intent.

The two areas where OECD guidelines had received the greatest attention were in large-scale industrial practice and in the environmental release of GMOs."

On National Guidelines and Regulatory Developments, the report noted that:

²³Organization for Economic Co-Operation and Development (OECD), *Recombinant DNA Safety Considerations*, OECD, Paris, 1986.

²⁴Organization for Economic Co-Operation and Development (OECD), *International Survey on Biotechnology Use and Regulations*, OECD Environment Monographs No. 39, OECD, Paris, November 1990.

Guidelines are being written for the use of biotechnology, particularly in the areas of large-scale contained applications and environmental releases of GMOs. The OECD Guidelines are widely cited as being the basis for new guidelines on large-scale applications....

Member countries are in general concerned about harmonizing their regulatory framework with international standards.

...a biotechnology regulatory infrastructure is being constructed to address classic and current issues arising as the field develops. New issues such as accidental releases of GMOs, contingency plans to deal with escape of GMOs, and disposal of waste related to the use of GMOs are beginning to receive attention....Public participation is also increasingly being integrated into biotechnology regulatory activities.

Considerable detail is provided about releases of GMOs into the environment; 70 per cent of the tests were with modified crop plants. Animal viruses have also been tested.

61. A subsequent OECD report in 1992²⁵ addresses two priority issues concerned with biotechnology industrial production and field experiments in Member countries. First, it elaborates the initial scientific criteria set out in 1986 for the safe development under "Good Industrial Large-Scale Practice" of fermentation derived biotechnology products, and secondly, defines "Good Developmental Principles" for the design of small-scale field research with plants and with micro-organisms with newly introduced traits.

62. **Analysis.** The OECD has recognized the importance of encouraging its Member countries to harmonize their regulations for biotechnology with particular emphasis on guidelines for the safety of work with recombinant DNA. It is evident that the Member countries have accepted this and are working to achieve this goal.

United Nations Industrial Development Organization (UNIDO)

63. Another useful source of information is the Biosafety Information Network and Advisory Service (BINAS) which monitors international developments in regulatory issues in biotechnology as a service of UNIDO. A particularly useful service is the provision on the BINAS website at <http://binas.unido.or.at/binas/home.html> of summaries and full texts of biosafety regulations and guidelines; interestingly, the listing of full texts of biosafety regulations includes under the heading International Conventions the text of only the Biological Weapons Convention. As of 25 February 1998, BINAS offered full texts of the regulations for the following 18 countries:

- * Argentina Plants
- * Brazil
- * Bulgaria Plants
- * People's Republic of China
- * Egypt
- * European Commission
- * India

²⁵Organization for Economic Co-Operation and Development (OECD), *Safety Considerations for Biotechnology 1992*, OECD, Paris, 1992.

- * Japan
 - * Malaysia
 - * Mexico
 - * New Zealand
 - * Nigeria
 - * Norway
 - * The Philippines
 - * Russian Federation
 - * South Africa
 - * Switzerland
 - * Thailand
- Plants

Some are not full texts but summaries and several, as indicated, are concerned only with plants. The others are more general regulations introduced to control genetically modified organisms; as might be expected there are similarities such as appropriate structural arrangements are established; levels of risk established; applications are required with prior approval before the higher risk activities are initiated, etc. There are interesting variations in the detail such as whether the provision of information to the public is mentioned and whether protection of confidential information is addressed. Summary information is provided for several other countries. Some information taken from the BINAS website about the general regulations for some of these 18 countries is summarised below.

64. **China.** The Safety Administration Regulation on Genetic Engineering was issued by order No. 17 of the State Science and Technology Commission of the People's Republic of China on 24 December 1993. It states that:

1. This regulation is aimed at promoting research and development of biotechnology in China, tightening safety control of genetic engineering work, guaranteeing public health of common citizens and genetic engineering workers, preventing environmental pollution, and maintaining ecological balance.

It establishes four safety classes for genetic engineering work according to the potential risk levels:

Safety class I: *genetic engineering work of this class has no threat to human health and ecological environment.*

Safety class II: *genetic engineering work of this class has low level risk to human health and ecological environment.*

Safety class III: *genetic engineering work of this class has intermediate-level risk to human health and ecological environment.*

Safety class IV: *genetic engineering work of this class has high level risk to human health and ecological environment.*

65. Requirements are specified for application and approval procedures:

Institutions carrying out genetic engineering work should submit applications to relevant administrative departments at different levels according to genetic

engineering products' utilization scope and safety class before being approved to kick off.

Institutions carrying out safety class I and safety class II genetic engineering experiment research should get approval from the heads of their institution's administration. The work of safety class III should be examined by chief administrators of the institutions and then be submitted to relevant departments under the State Council for approval. The work of safety class IV should be examined by relevant State Council departments and then be submitted to the national genetic engineering safety committee for approval.

Genetic engineering pilot experiments of safety class I should get approval from chief administrators at the institutional level. The work of safety class II should be approved by responsible State Council departments. The work in safety class III should be approved by relevant State Council departments and be submitted to the national genetic engineering safety committee for record. The work in safety class IV should be examined by relevant State Council departments and submitted to the national genetic engineering safety committee for approval.

Genetic engineering industrial production, release of genetic engineered organisms and utilization of genetic engineering products, if in safety class I to III scope, should be approved by relevant administrative departments under the State Council and submitted to the national genetic engineering safety committee for record. The work in safety class IV should be examined by relevant administrative departments of the State Council and submitted to the national genetic engineering safety committee for approval.

66. **India.** The Department of Biotechnology in the Ministry of Science and Technology issued the Indian Recombinant DNA Safety Guidelines and Regulations in January 1990. These apply to research, manufacture and applications. Four biosafety levels are defined depending on the level of risk with the classification of organisms within these levels being based on pathogenicity, local prevalence of disease and epidemic causing strains in India. The four levels are:

Biosafety Level 1

covers practices, safety equipment and containment installations that are appropriate for undergraduate and secondary education and for teaching laboratories and other facilities in which work is done with defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. No special accommodation or equipment is required, but the laboratory personnel must have specific training and must be supervised by a scientist with general training in microbiology or a related science.

Biosafety Level 2

covers practices, safety equipment and containment installations that are applicable to clinical, diagnostic, teaching and other facilities in which work is done with the broad spectrum of indigenous risk agents associated with human diseases of moderate severity. Laboratory workers are required to have specific training in handling pathogenic agents and to be supervised by competent scientists.

Accommodation and installations, including safety cabinets, are prescribed, especially for handling large amounts and high concentrations of agents and when aerosols are likely to be created. Access to the laboratory is controlled.

Biosafety Level 3

covers practices, safety equipment and containment installations that are applicable to clinical, diagnostic, teaching, research or production facilities in which work is done with indigenous or exotic agents, and the potential for infection by aerosols is real and the disease may have serious or lethal consequences. Personnel are required to have specific training in work with these agents and to be supervised by experienced scientists. Specially designed laboratories and precautions, including the use of safety cabinets, are prescribed, and the access is strictly controlled.

Biosafety Level 4

covers practices, safety equipment and containment installations that are applicable to work with dangerous and exotic agents which pose a high risk of life-threatening disease. Strict training and supervision are required and the work is done in specially designed laboratories under stringent safety conditions, including the use of safety cabinets and special personnel suits. Access is strictly limited. Such facilities may include an area provided with an airlock, exhaust-air filtration units and emergency lighting and communication systems, and where personnel wear one-piece positive-pressure suits.

Principles are set out for Good Large - Scale Practice (GLSP) -- it is noted in the information that these criteria for GLSP organisms are identical with those developed by the OECD.

67. The regulations go on to address the requirements for notification which are defined under 3 categories.

i) Exempt category - (self cloning experiments)

ii) Intimation to competent authority - (e.g. experiments involving nonpathogenic DNA vector systems)

iii) Review and approval of competent authority - (e.g. Toxin gene cloning, antibiotic resistant genes, etc.)

It is also required that an application be made for recognition of the research facility to carry out genetic manipulation to the Department of Environment before the commencement of work using a proforma as detailed in the rules on hazardous microorganisms/genetically engineered organisms notified under the Environmental Protection Act, 1986.

68. The regulations also set out the structural requirements for a four committees which include Institutional Biosafety Committees and a Review Committee on Genetic Manipulation (RCGM) which is an interdepartmental body with a monitoring group:

empowered to visit any facilities where experiments with a biohazard potential are taking place in order to determine that Good Laboratory Practice and conditions of safety are observed. If RCGM has reasons to believe that there is either actual or

potential danger involved in the work carried out by any laboratory (which might or might not have obtained prior clearance for the project), the monitoring group would be empowered to inspect the facility and assess the cause of any real or potential hazard in order to make appropriate recommendations to the RCGM. Thereupon, RCGM is empowered to recommend, based on hazard considerations, the alteration of the course of experiments, or to take steps to cancel the project grant in case of deliberate negligence, or to recommend appropriate actions, where necessary, under the provisions of the Environmental Protection Act (EPA), passed in 1986.

69. **Egypt.** The Biosafety Regulations and Guidelines for Egypt were issued in January 1994 in a document which

"recommends the establishment of a National Biosafety System in Egypt. The purpose is to provide a guide for policy makers to assist the establishment of an appropriate national biosafety framework as no adequate structure currently exists. A national regulatory structure is proposed and biosafety guidelines developed by international organizations are attached. The establishment of such a system will ensure that Biotechnology continues to be safe and does not expose employees, the community and the environment to any possible hazards."

The document makes it clear that:

"Biotechnology refers to any technique that uses living organisms or substances from these organisms to modify or improve quality and product of crops and food, drugs and health care products, vaccines, industrial chemicals and its products. It consists of gradient of technologies ranging from the widely used techniques of traditional biotechnology through modern biotechnology which is based on the new techniques of Recombinant DNA (r - DNA) technology, known as Genetic Engineering."

and goes on to say that:

"Biosafety is one term that is used to describe the policies and procedures adopted to ensure the environmentally safe application of modern biotechnology. It is a term gaining wider currency as more countries seek to benefit from the application of modern science in agriculture, medicine and the environment, without endangering public health or environmental safety."

70. The document suggests a national regulatory structure and provides examples of methods of risk assessment and biosafety guidelines tailored to the Egyptian environment. It is clear that these draw heavily from the US R-DNA Advisory Committee of the National Institute of Health and from the UNIDO developed guidelines for the introduction of genetically modified organisms into the environment. The document also rightly makes it clear that "concern about risks to human health and to the environment is not peculiar to biotechnology."

71. **Malaysia.** The Genetic Modification Advisory Committee (GMAC) of the Ministry of Science, Technology and the Environment, Malaysia has recently (1996 or 1997) issued its National Guidelines for the Release of Genetically Modified Organisms (GMOs) into the Environment. The Introduction states that:

1. The development of techniques in genetic modification which include recombinant DNA technology and cellular techniques of introducing DNA into an organism has resulted in tremendous advances in agriculture, human health and the processing industry.

2. The emergence of genetically modified plants, animals and microorganisms with superior genetic traits and their subsequent release into the environment have currently raised concern among the public at large and highlighted issues regarding safety.

It goes on to say that:

4. The proposed National Guidelines for release of GMOs into the environment have been developed from the existing principles derived from relevant regulations and guidelines at national, regional and international levels.

A list of the international documents taken into account in formulating the guidelines includes the UNEP International Technical Guidelines for Safety in Biotechnology, 1996; Risk Assessment on the Release of Genetically Modified Plants, (MAFF, UK, 1994); Guidelines for Planned Release of Genetically Manipulated Organisms, (GMAC, Australia, 1993); The UNIDO Voluntary Code of Conduct for Release of Organisms into the Environment, 1991; and the Convention on Biological Diversity, 1992.

72. The scope is broad as the guidelines:

21. addresses all institutions and persons researching, developing, using, releasing and the marketing of GMOs and products containing or consisting of GMOs, including GMOs that are imported.

22. covers GMOs at all stages of research, development, use, release and placing on the market. It covers, but is not limited to, genetically modified plants, animals (including for example, insects, mollusks and fish) and microorganisms and products consisting of or containing GMOs.

23. covers safety issues regarding agriculture, public health, the environment and transboundary issues pertaining to release of GMOs and products containing, or consisting of GMOs.

In its principles, it states that assessment and management of risk of the GMOs to agriculture, human health and the environment should be based upon of the following key parameters:

1) Focus on the organisms which should include:

i. characteristics of the parent organism and DNA donor organism which include taxonomy, life cycle, reproductive properties and physiological abilities;...

2) Application or intended use of GMOs: includes physical description of site, containment/ decontamination, monitoring plans, mediation after completion.

The principles also covers provision of information to the public:

National authorities, industry and researchers have a responsibility to disclose or make available safety information to the public. Acceptance of biotechnology products will be enhanced if the information is disclosed and made available to the public, especially the community where the test will occur. There is a need for openness in this process.

In addition, the guidelines make it clear that regional cooperation and the international harmonization of guidelines are important.

73. **Nigeria.** The Guidelines on Biosafety for Nigeria were issued by the Federal Ministry of Agriculture and Natural Resources in March 1994. Annex 1 lists the documents used in developing these guidelines for Nigeria -- these include the UNIDO Voluntary Code of Conduct for the Release of Organisms into the Environment prepared by the UNIDO Secretariat for the Informal UNIDO/WHO/FAO Working Group on Biosafety (July 1991), the OECD Recombinant DNA Safety Considerations (1986), US Department of Agriculture documentation, Canadian and Indian regulations. The purpose of the guidelines is expressed in the introduction as being:

Genetic engineering has introduced a new dimension to biotechnology. With this technology scientists can recombine DNA from different organisms, giving rise to genetically modified organisms (GMOs). rDNA organisms are derived by introducing a small section of DNA from a "donor" organism to a "recipient" organism. The genome of the recipient organism is, therefore, modified. The results of this modification need to be assessed for risks to humanity or the environment before the organism is freely released or deployed. The issues of public and environmental safety concerning every biotechnology product or application must be carefully considered.

A subsequent paragraph sets out the importance of the guidelines:

The need to establish National Biosafety Guidelines is in consonance with the National Policy on Environment and is a first major step in fulfilling the obligations in the handling of biotechnology and the distribution of its benefits that are stipulated in the International Convention on Biological Diversity. Biosafety systems are intended to protect the entire environment of which biodiversity is a component. It also helps to fulfill our obligation under the Environmental Impact Assessment (EIA) Decree No. 86 of 1992, which calls for a precautionary approach to development to ensure that Nigeria is well prepared to manage biohazards.

The guidelines set out the principles for risk assessment and management and sets out the need for a structure comprising a National Biosafety Committee supported by Institutional Biosafety Committees.

74. **Russian Federation.** The Federal Act of the Russian Federation on State regulation of Genetic Engineering Activity was adopted by the State Duma on 5 June 1996 and signed by President Yeltsin on 5 July 1996 as Federal Law No. 86 - F3. The scope of this Act is stated in Article 1 as being:

This Federal Act establishes regulations governing relations in the spheres of the utilization of nature, protection of the environment and assurance of environmental safety arising in connection with the conduct of genetic engineering activity. The Act is not applicable to procedures for the conduct of genetic engineering activity or to the application of genetic engineering techniques to human beings or to tissues or cells in the human organism.

It defines various terms such as genetic engineering as being:

Genetic engineering: all procedures, methods and technologies, including technologies for obtaining recombinant ribonucleic and deoxyribonucleic acids, designed to remove genes from an organism, perform manipulations on genes and introduce them into other organisms;

75. Article 4 addresses the purposes of State regulation in the field of genetic engineering activity and includes:

To define a mechanism to ensure public safety and environmental protection in respect of genetic engineering activity and the application of its results;

Article 5 sets out the main aims of State regulation in the field of genetic engineering activity as including:

Raise living standards and protect human health;

Protect and restore the environment, and preserve biodiversity;

It goes on to say that genetic engineering activity shall be based on the following principles:

The safety of the public (individuals) and of the environment;

The universal accessibility of information on the safety of genetic engineering activity;

Certification of products containing the results of genetic engineering activity, with the requirement that certificates provide full details regarding the methods of obtaining the product in question and regarding its properties.

76. The next Article 6 specifies the types of genetic engineering activity subject to licensing stating that:

Operations in the field of genetic engineering classified as having risk level III or IV shall be undertaken on the basis of authorizations (licences) issued in conformity with the procedures established by law. The following types of genetic engineering activity shall be subject to licensing...

Article 7 addresses the safety regime to be applied to genetic engineering activity and sets out four levels of risk for contained systems:

Risk level I corresponds to activities presenting no danger to human health and is comparable to the level of risk associated with working with non-pathogenic micro-organisms;

Risk level II corresponds to activities presenting an insignificant danger to human health and is comparable to the level of risk associated with activities involving some micro-organisms that are pathogenic under certain conditions;

Risk level III corresponds to activities presenting a moderate risk to human health and is comparable to the level of risk involved in working with micro-organisms potentially capable of transmitting infectious disease;

Risk level IV corresponds to activities presenting a significant risk to human health and is comparable to the level of risk involved in working with pathogens associated with particularly dangerous diseases.

It then specifies levels to be used in two particular cases:

Activities involving micro-organisms in closed systems on a scale reaching beyond the boundaries of laboratory research shall be assigned risk level III or IV.

Genetic engineering activity conducted under the conditions of open systems shall be assigned risk level III or IV.

It is stated that "authorizations (licences) for activities assigned risk levels III and IV shall be issued in conformity with procedures established by the Government of the Russian Federation."

77. Article 10 addresses the guarantee of the universal accessibility of information on the safety of genetic engineering activity stating that:

Information on the safety of genetic engineering activity shall be universally accessible.

Corporations and citizens (individuals) engaging in genetic engineering activity shall be required at the request of interested entities or persons to furnish information on the level of risk of genetic engineering activity and on safety precautions to be taken in its regard. In this connection, information on genetic engineering activity protected by State, official or trade secrecy, shall be furnished in the established manner.

Article 13 addresses international cooperation of the Russian Federation in the field of genetic engineering activity stating that:

The Russian Federation shall enter into international agreements with a view to the further development and consolidation of international cooperation in the field of genetic engineering activity.

78. **South Africa.** The Genetically Modified Organisms Act, 1997, provides measures to promote the responsible development, production, use and application of genetically modified

organisms and established an Executive Council and an Advisory Committee to ensure that genetically modified organisms are appropriate and do not present a hazard to the environment or agricultural production. A memorandum attached to the Bill states that "similar legislation already exists in the USA, UK, Norway, Canada, Australia, New Zealand and the Netherlands." Some of the elements of these regulations use similar language to that used in the European Community regulations. The Act is detailed as applying to:

(a) the genetic modification of organisms;

(b) the development, production, release, use and application of genetically modified organisms (including viruses and bacteriophages); and

(c) the use of gene therapy.

It is made clear that:

a register shall be maintained of all facilities involved in the contained use or the trial release of genetically modified organisms as well as the names and addresses of persons concerned with such contained use or trial release of genetically modified organisms;

notification shall be made of any intended change in the type of activities or release involving genetic modification of organisms being undertaken at facilities for which approval was granted ...;

inspection by an inspector shall be arranged of facilities where activities with or the release of genetically modified organisms are being undertaken;

inspection of all activities as judged necessary, including contained use, trial release and general release to ensure that all terms and conditions attached to a permit issued under this Act are complied with;

A subsequent section makes it clear that if there is reason to believe that there is contravention of the Act, then after obtaining a warrant an inspector may conduct an investigation and may, during normal office hours and without giving prior notice, enter any place or facility:

...(b) to request any information regarding such an activity or process from the owner or person in charge of such place or facility or from any person carrying out or in charge of the carrying out of such activities;

(c) to seize any appliance, book, statement or document and take samples of material or substances which appear to provide proof of a contravention of any provision of this Act; and...

79. The protection of confidential information is also addressed. The Executive Council shall decide, after consultation with the applicant, which information will be kept confidential. However, the Act specifies that *"the following information shall not be kept confidential -*

(a) the description of the genetically modified organisms, the name and address of the applicant, and the purpose of the contained use or release and the location of use;

(b) the methods and plans for the monitoring of the genetically modified organisms and for emergency measures in the case of an accident; and

(c) the evaluation of foreseeable impacts, in particular any pathogenic or ecologically disruptive impacts.

80. **Appreciation.** It is apparent that there are biosafety regulations being introduced by countries around the world which are broadly similar as most recognize the values of adopting harmonized biosafety regulations and guidelines. Although these differ in detail, there is a general move towards categorization of activities involving genetically modified organisms according to the evaluated risks and for those with higher potential risks, requiring prior application and approval which may frequently involve inspection by national authorities. The importance of addressing public concerns is frequently recognised and addressed.

Discussion and Conclusions

81. This Briefing Paper has shown how there are tight controls on pathogens which may cause disease to humans, animal and plants within Great Britain and how these controls are harmonized with the countries within the European Union. Strict controls have been introduced recently in the United States in respect of the handling and transfer of "select agents" having the potential of posing a serious threat to public health and safety -- which unsurprisingly closely reflect those micro-organisms regarded traditionally as biological warfare agents. The emphasis in the OECD on the harmonization of regulations for genetically-modified micro-organisms has been demonstrated and finally, some of the information available from the UNIDO BINAS website has been used to show how the approaches to biosafety in regard to genetically modified organisms around the world have much similarity although they differ in detail.

82. This Briefing Paper is very much complementary to Briefing Paper No. 6 which demonstrated the immense ongoing international activity in all regions of the world to improve biosafety in biotechnology and to build capacity. The regulations described in both Briefing Papers are all driven by an international awareness of the potential dangers to the environment and to public health that may result from the release of micro-organisms into the environment. The requirements are generally for notifications to be made to national authorities which provides relevant information to enable the national authority to consider whether to approve the proposed activity. Inspection provisions are made in many countries to confirm compliance with the regulations or to investigate possible breaches.

83. A summary appreciation of the public health and safety control situation is indicated below:

EXAMPLES OF PUBLIC HEALTH & SAFETY CONTROLS

Material	National		Regional		International	
	Controls	Internal Transfers	Controls	Transfers	Controls	Transfers

Pathogens						
-- Human	UK, US	US	EC	?	?	?
-- Animal	UK	UK	EC	EC	?	?
-- Plant	UK	UK	EC	EC	?	?
Living Modified Organisms (Genetically Modified Organisms)	UK	US (human) UK (animal/plant)	EC OECD Biosafety Guidelines	?	UNEP Biosafety Guidelines	Advance Informed Agreement Protocol

Whilst it appears that there is an international framework for biosafety, this is focussed primarily on genetically modified organisms (GMOs). It is, however, recognised generally that the potential dangers arising from such genetically modified organisms should be based on those for pathogens as the dangers of GMOs are in principle no different from the unmodified organisms. In some countries, such as the United Kingdom, it is clear that the basic controls are specified for pathogens and genetically modified organism are subject to additional requirements for notification and assessment.

84. The developments towards harmonized national and international controls on pathogens and living modified organisms are such that they will contribute to increased international transparency and to improved public confidence that such organisms are being handled and used safely without undue risk to the environment or to public health. A recent article by John Steinbrunner²⁶ has argued that:

"Since access to scientific information and to the pathogens themselves cannot be denied to anyone who seriously pursues it, systematic prevention must be based on strong rules of disclosure. These rules would have two goals: first, to make violations more difficult to conceal, but, second, and beyond that to set affirmative standards for responsible handling of the most dangerous pathogens. Rules of disclosure documenting compliance with those standards would provide continuous positive reassurance that relevant activities were being safely managed and exclusively devoted to legitimate purposes."

He goes on to cite as an example the recent US regulations outlined above (para 47 et seq) in this Briefing Paper and to suggest that this initiative might be developed and extended to the States Parties of the BTWC. This Briefing Paper and Briefing Paper No 6 make it clear that there is already considerable international effort to harmonize national and international regulations relating to pathogens that present danger to public and animal health and to the environment.

85. Such improved transparency and enhanced confidence that pathogenic organisms are being used safely for permitted purposes can contribute to improving international confidence that States are in compliance with the BTWC. It is apparent that in many countries, information is already being collected and submitted to national authorities about activities and facilities handling, using or transferring dangerous pathogens with inspections being

²⁶John D Steinbrunner, "Biological Weapons: A Plague upon All Houses", Foreign Policy, 85- 96, Winter 1997-98.

carried out to confirm that the regulations are being complied with. The relevance of all of this to the negotiations to develop a Protocol to strengthen the BTWC will be evident in that in many countries for public health and environmental safety reasons national authorities are already establishing regulations, collecting relevant information about facilities and activities and inspecting these facilities and activities. The BTWC Protocol is likewise likely to contain declarations and inspections of facilities and activities together with national implementation measures, as well as measures to improve implementation of Articles III and X of the Convention. There is potential for a two way synergy between the strengthening of the BTWC and the strengthening of national procedures for the handling, use and transfer of harmful pathogens for public health and environmental safety. In regard to the strengthening of the implication of Article X of the BTWC, there appears to be scope for measures to facilitate the harmonization of national, regional and international safety rules for pathogens involving both the collection of data and the inspection of facilities thereby enhancing both national public confidence as well as regional and international security. The activities outlined in these two Briefing Papers to enhance safety should be regarded as building blocks that can be drawn upon in devising measures to strengthen the implementation of the BTWC.