# Strengthening the Biological Weapons Convention

# Briefing Paper No 4 (Second Series)

# National Measures to Establish and Maintain the Security and Oversight of Pathogenic Microorganisms and Toxins

## April 2003

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**NATIONAL MEASURES TO ESTABLISH AND MAINTAIN THE SECURITY AND OVERSIGHT OF PATHOGENIC MICROORGANISMS AND TOXINS**

by Graham S. Pearson

## Introduction

1. At the Fifth Review Conference of the States Parties to the Biological and Toxin Weapons Convention (BTWC) it was agreed[1]:

> *To hold three annual meetings of the States Parties of one week duration each year commencing in 2003 until the Sixth Review Conference, to be held not later than the end of 2006, to discuss, and* ***promote common understanding and effective action*** *on:*
>
> > *i. The adoption of necessary, national measures to implement the prohibitions set forth in the Convention, including the enactment of penal legislation;*
> >
> > *ii. National mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;*
> >
> > *iii. Enhancing international capabilities for responding to, investigating and mitigating the effects of cases of alleged use of biological or toxin weapons or suspicious outbreaks of disease;*
> >
> > *iv. Strengthening and broadening national and international institutional efforts and existing mechanisms for the surveillance, detection, diagnosis and combating of infectious diseases affecting humans, animals, and plants;*
> >
> > *v. The content, promulgation, and adoption of codes of conduct for scientists.*

and that *"Each meeting of the States Parties will be prepared by a two week meeting of experts."* This Briefing Paper considers the second topic to be addressed in 2003, namely *"National mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;".*

2. In Briefing Paper No. 2[2] it was noted that the annual meeting of States Parties would ideally develop a text that would integrate

> a. the States Parties' verdict on the experts' recommendations, commending those it felt able to approve as promoting best practice,
>
> **and**

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[1]United Nations, *Fifth Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Geneva, 19 November - 7 December 2001 and 11 - 22 November 2002, Final Document, BWC/CONF.V/17, 2002. Available at http://www.opbw.org

[2]Nicholas A. Sims, *The New Multilateral Process For The BTWC: Ambiguities And Opportunities*, University of Bradford, Department of Peace Studies, Briefing Paper No.2 (Second Series), January 2003, paragraph 19. Available at http://www.brad.ac.uk/acad/sbtwc

b. the relevant language in Final Declarations, arranged and tabulated by the secretariat for the meetings of experts and of States Parties.

3. This Briefing Paper provides an input to the meetings of experts and of the States Parties by first collecting the relevant language from Final Declarations regarding security and oversight of pathogenic microorganisms and toxins and then providing an example, drawing on the security and oversight measures for one State Party, of the input that all States Parties should be able to make to the meetings. There is much to be said, as was noted in Briefing Paper No.2[3], for States Parties providing similar information on their national measures for the security and oversight of pathogenic microorganisms and toxins **prior** to the experts meeting.

**The Requirement for National Measures**

4. Article IV of the Biological and Toxin Weapons Convention requires that:

> *Each State Party to this Convention shall, in accordance with its constitutional processes, take any necessary measures to* ***prohibit and prevent*** *the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.* [Emphasis added]

5. Article IV obliges each State Party to ensure national implementation of the prohibitions in the Convention in the broadest possible terms, as the scope clauses at the end of the Article spell out clearly. In considering such national measures, several aspects need to be considered:

a. **Adoption.** All States Parties need to be seen to have adopted effective measures and to be implementing those measures. There is all too little information as to what measures have indeed been adopted by States Parties.

b. **Implementation.** The national measures need to implement the prohibitions of the Convention in Article I -- the basic prohibition -- Article III -- the obligation not to transfer -- and Article IV -- the obligation to *prohibit and prevent.*

c. **Effectiveness.** The national measures need to be comprehensive -- and be coextensive -- with the prohibitions in the Convention. A failure to be coextensive could leave a State Party open to charges of non-compliance.

d. **Applicability.** The national measures need to apply to **all** with no exclusions.

e. **Penal legislation.** The national measures needs to be given teeth -- so that those who do not comply can be appropriately punished. Given the overlap between the BTWC and the Chemical Weapons Convention in the toxin and mid-spectrum region, there is much to be argued for the national measures for the BTWC being enforced by

[3]Nicholas A. Sims, *The New Multilateral Process For The BTWC: Ambiguities And Opportunities*, University of Bradford, Department of Peace Studies, Briefing Paper No.2 (Second Series), January 2003, paragraph 15. Available at http://www.brad.ac.uk/acad/sbtwc

penal legislation which is required for the implementation of the Chemical Weapons Convention.

6. Such national measures to implement the prohibitions in the BTWC are complemented by national measures adopted to enhance security, health and safety and to protect the environment. These complementary measures include:

a. **Containment and operating procedures** for pathogens and toxins.

b. **Control of access** to pathogens and toxins.

c. **Control of transfers** both nationally and internationally.

d. **Control of genetic modification** in regard to both contained use and deliberate release.

7. The effectiveness of such measures are enhanced through effective oversight. Oversight also needs to be taken into account in considering what work should be carried out and what information should be made publicly available:

a. **Oversight of national legislation and regulations.** Attention needs to be given to how the national legislation and regulations are made widely known and implemented effectively.

b. **Oversight of the nature and purpose of proposed work.** Those who are responsible for the approval of proposed work need to be aware of the prohibitions and regulations and need to evaluate whether the proposed work should indeed be carried out. Whilst there is oversight of the safety consequences of proposed work involving genetic modification this generally does not extend to the purpose of the work.

c. **Oversight of publicly available information.** Attention is being given to whether certain information, which might be misused by States non-compliant with the BTWC or by sub-national groups or individuals who wish to use biological agents or toxins for prohibited purposes, should be made publicly available. This parallels in some respects the export controls on intangible technology related to weapons of mass destruction. Both of these trends towards constraint and control of information in the public domain are contrary to the trend for more information to be made publicly available, especially in the life sciences area, because of public concerns.

8. Subsequent sections of this Briefing Paper address the complementary elements to enhance security, health and safety, and protection of the environment using national and regional examples. These complementary elements can be summarised as:

a. National measures to implement the BTWC Convention
b. National measures for health and safety
c. National measures to control genetic modification

Oversight of pathogens and toxins can also be considered as a number of complementary elements:

a. Oversight of national legislation and regulations
b. Oversight of the nature of work and of proposed work
c. Oversight of publicly available information.

**National Measures to Implement the BTWC Convention**

9. States Parties to the BTWC Convention undertake to implement the prohibitions set out in Articles I, III and IV. The basic prohibition in Article I requires that:

> *Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:*
>
> > *(1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;*
> >
> > *(2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.*

Reaffirmations by successive Review Conferences have emphasised the comprehensiveness of the applicability of the Convention. Thus at the Fourth Review Conference, the Article I section of the Final Declaration stated that:

> *5. The Conference also reaffirms that the Convention unequivocally covers all microbial or other biological agents or toxins, naturally or artificially created or altered, as well as their components, whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes.*

and went on to add that:

> *6. The Conference, conscious of apprehensions arising from relevant scientific and technological developments, inter alia, in the fields of microbiology, biotechnology, molecular biology, genetic engineering, and any applications resulting from genome studies, and the possibilities of their use for purposes inconsistent with the objectives and the provisions of the Convention, reaffirms that the undertaking given by the States Parties in Article I applies to all such developments.*

10. Article III of the Convention requires that:

> *Each State Party to this Convention undertakes not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any State, group of States or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in article I of this Convention.*

Successive Review Conferences have affirmed the extent of the Article III prohibition. Thus at the Fourth Review Conference, the Article III section of the Final Declaration stated that:

*The Conference affirms that Article III is sufficiently comprehensive to cover any recipient whatsoever at international, national or subnational levels.*

10. As already noted earlier, Article IV of the Convention obliges each State Party to *take any necessary measures to* ***prohibit and prevent*** the prohibitions in Article I. In the United Kingdom, this was achieved by the Biological Weapons Act 1974[4] which sets out that:

*No person shall develop, produce, stockpile, acquire or retain--*

*(a) any biological agent or toxin of a type and in a quantity that has no justification for prophylactic, protective or other peaceful purposes; or*

*(b) any weapon, equipment, or means of delivery designed to use biological agents or toxins for hostile purposes or in armed conflict.*

It goes on to define biological agent and toxin by stating that:

*In this section--*

*"biological agent" means any microbial or other biological agent; and*
*"toxin" means any toxin, whatever its origin or method of production.*

and then setting out the penalty that:

*Any person contravening this section shall be guilty of an offence and shall, on conviction on indictment, be liable to imprisonment for life.*

It will be noted that the language used in the UK Biological Weapons Act very closely parallels that in Article I of the Convention.

11. The UK implementation of the prohibitions in Article III was outlined in paragraphs 10 to 24 of Briefing Paper No. 12.[5] A new legislative framework for the control of strategic goods and technology has recently been adopted with the enactment of the Export Control Act 2002[6] for which secondary legislation is currently being introduced. This will include new controls on:

a. The electronic transfer abroad of military technology;
b. The transfer by any means of technology related to weapons of mass destruction (WMD), and
c. The provision of WMD related technical assistance.

The new control on the transfer, by any means, of WMD related technology supplements existing end-use controls on the physical export of goods and technology and the electronic

[4]United Kingdom, *Biological Weapons Act 1974*. Available at http://www.opbw.org

[5]Graham S. Pearson, *Article III: Some Building Blocks*, University of Bradford, Department of Peace Studies, Briefing Paper No.12 (First Series), October 1998, paragraphs 10 to 24. Available at http://www.brad.ac.uk /acad/sbtwc

[6]United Kingdom, *Export Control Act 2002*, 2002 Chapter 28. Available at http://www.legislation.hmso.gov. uk/acts/acts2002/20020028.htm

transfer of technology contained in the EC Dual Use Regulation[7]. Transfer by any means includes face-to-face communication, personal demonstration or dissemination of written material. However, the communication of information that is in the public domain, or the placing of this information into the public domain is not covered by this control. These new controls implement a European Joint Action of 22 June 2000[8].

12. Although the BTWC has been in force since 1975 and currently has 146 States Parties and 17 Signatory States, there is little basis for assuming that there is widespread adoption and implementation of national measures by States Parties. As was noted in the Article IV chapter in the Bradford Briefing Book for the Third Review Conference[9], Goldblat and Bernauer had reported in their 1991 UNIDIR Research Paper[10] prepared for the Third Review conference that *"very few"* States Parties had adopted national legislative or administrative measures to implement the Convention. It was impossible in 1991 to ascertain just how few had taken up the invitation to send their legislative or other appropriate texts to the Department for Disarmament Affairs (DDA) - into which the UN Centre for Disarmament had been upgraded in 1983 - because the relevant file had been mislaid in New York.[11] The United Kingdom proposal in 1980 had specified as the designated recipient of such texts, for purposes of consultation, the Research and Reference Collection in the Geneva Unit of the Centre for Disarmament (which could make copies for the Centre's Treaties and Resolutions Section in New York so that duplicate collections could be maintained in both cities); but at the insistence of the Secretariat this provision had been dropped during the First Review Conference - regrettably, as it turned out.[12]

13. The Article IV chapter recalled that the Netherlands had reported[13] at the Second Review Conference despatch of the text of implementing regulations to the UN at the time it ratified the Convention (June 1981). It was thought that only four other States Parties had shared their texts in this way, and Goldblat and Bernauer were able to gather four -- the United Kingdom's *Biological Weapons Act 1974*[14], Australia's *Crimes (Biological Weapons) Act 1976*[15], New Zealand's *New Zealand Nuclear Free Zone, Disarmament, and Arms Control Act 1987*[16] and the United States' *Biological Weapons Anti-Terrorism Act of 1989*[17].

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[7]European Communities, *Council Regulation (EC) No. 1334/2000 of 22 June 2000 setting up a Community regime for the control of exports of dual-use items and technology*, Official Journal of the European Communities, L159/1, 30 June 2000.

[8]European Communities, *Council Joint Action of 22 June 2000 concerning the control of technical assistance related to certain military end-uses (2000/401/CFSP)*, Official Journal of the European Communities, L159/216, 30 June 2000.

[9]Nicholas A. Sims, *Article IV: National Implementation Measures*, in Graham S. Pearson & Malcolm R. Dando (eds), *Strengthening the Biological Weapons Convention: Key Points for the Fourth Review Conference*, University of Bradford, Department of Peace Studies, November 1996. Available at http://www.brad.ac.uk/acad/sbtwc

[10]Jozef Goldblat & Thomas Bernauer, *The Third Review of the Biological Weapons Convention: Issues and Proposals*, UNIDIR Research Paper No. 9 (New York: United Nations, 1991), p.22.

[11]Personal communication, 4 June 1991.

[12]Nicholas A Sims, *The Diplomacy of Biological Disarmament: Vicissitudes of a Treaty in Force, 1975-85*, (London: Macmillan; New York: St. Martin's Press, 1988) pp. 80-81, pp 136-137.

[13]BWC/CONF.II/SR.5 (10 September 1986), paragraph 56. Barend ter Haar (The Netherlands).

[14]United Kingdom, Biological Weapons Act 1974. Available at http://www.opbw.org

[15]Australia, Crimes (Biological Weapons) Act 1976. Available at http://www.opbw.org

[16]Available at http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes

[17]Available as S.993 ENR at http://thomas.loc.gov/cgi-bin/query/D?c101:1:./temp/~c101xk0qsS::

They reproduced them in facsimile as annexes to their Research Paper[18], together with France's pioneering law[19] of 9 June 1972 which had anticipated the Article IV legislation of States Parties at a time when it appeared most unlikely that France would ever accede to the Convention then ready opened for signature. (It did in fact accede in 1984). Belgium's law of 10 July 1978 also deserves honourable mention as having been included *in extenso* in Belgium's national compliance report for the First Review Conference, the only text which was sent forward by the States Parties contributing to that 1979-80 compilation.[20] The interesting process by which, over the years 1972-1978, this Belgian legislation came about has been recounted elsewhere;[21] as (by another author) has the even more protracted legislative process over the period 1973-1989 in the United States.[22]

14. Goldblat and Bernauer expressed themselves forcefully on the lack of attention paid by the overwhelming majority of States Parties to Article IV:

> *Since each State Party must ensure the observance of the BW Convention on its territory and anywhere else under its jurisdiction and control, it is* ***imperative*** *that it take the necessary national measures of legislative, administrative or regulatory nature. Such measures must specify the prohibitions and obligations to be observed by the natural and legal persons of the country concerned, and provide for the prosecution, trial and punishment of offenders.*
>
> *The Parties should* ***commit themselves*** *to send all pertinent information and documentation to the UN Secretariat, as recommended by the First and Second Review Conferences. This material,* ***to be distributed to all Parties****, might serve as an incentive as well as guidelines for those States which have not yet adopted the required national measures.*[23] [Emphasis added]

The Article IV chapter concluded by urging the States Parties at the Fourth Review Conference to adopt language providing stronger encouragement for States Parties to enact national measures.

15. There is little to suggest that the situation has changed substantially during the past decade despite the exhortations at both the Third and the Fourth Review Conferences; the Article IV section of the Final Declaration of the Fourth Review Conference stated that:

> *The Conference underlines the importance of Article IV. It reaffirms the commitment of States Parties to take the necessary national measures under this Article, in accordance with their constitutional processes.*

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[18]Jozef Goldblat & Thomas Bernauer, *The Third Review of the Biological Weapons Convention: Issues and Proposals,* UNIDIR Research Paper No. 9 (New York: United Nations, 1991), pp 62-75.

[19]Law No 72-467, prohibiting the development, production, possession, stockpiling, acquisition and transfer of biological or toxin weapons (9 June 1972).

[20]BWC/CONF. I/4 (20 February 1980), paragraph 30, pp 17-18.

[21]Nicholas A Sims, *The Diplomacy of Biological Disarmament: Vicissitudes of a Treaty in Force, 1975-85,* (London: Macmillan; New York: St. Martin's Press, 1988), pp 81-85.

[22]John Isaacs, *Legislative Needs*, in Susan Wright (ed), *Preventing a Biological Arms Race* (Cambridge, Mass: The MIT Press, 1990) pp 291-299 and legislative texts appended at pp 406-11.

[23]Jozef Goldblat & Thomas Bernauer, *The Third Review of the Biological Weapons Convention: Issues and Proposals,* UNIDIR Research Paper No. 9 (New York: United Nations, 1991), pp 23-24.

The experience in regard to the implementation of the Chemical Weapons Convention through national measures is not encouraging even though the Legal Adviser's Office of the Technical Secretariat has being extremely active in providing assistance to States Parties to enact the necessary legislation. Five years after entry into force, only 42 States Parties (28%) have legislation covering all key areas. For 108 States Parties there is either no legislation in place, or gaps in legislation, or an unknown legislative situation[24].

16. In regard to the BTWC it is strongly recommended, as in Briefing Paper No. 3[25], that the language from previous Review Conference Final Declarations should be used as the basis for the *"conclusions or results"* of the experts meeting and the subsequent meeting of the States Parties. Those meetings would thereby be enabled to take forward the cumulative process of regime-building, through recording agreements among States Parties on common understandings with regard to the implications and implementation of Article IV. Having established this basis, recommendations should be added for promoting best practice, as evaluated by the new process. This will necessarily involve pooling the implementation experience of States Parties, as well as examining the text of their national measures, in the light of the need to capture comprehensively the BTWC prohibitions and to make them effective. It was strongly recommended that all States Parties provide information and copies of their legislation, regulations and other measures relevant to BTWC national implementation to the Secretariat in Geneva **prior** to the experts meeting.

**National Measures for Health and Safety**

17. States have long had measures to protect the health and safety of people as well as measures to protect the health of animals and plants. In the United Kingdom, the basic provisions for health and safety of people are provided by the Health and Safety Act 1974[26] which is *"to make further provision for securing the health, safety and welfare of persons at work, for protecting others against risks to health or safety in connection with the activities of persons at work, for controlling the keeping and use and preventing the unlawful acquisition, possession and use of dangerous substances..."* It sets out the principal provisions of the Act as being:

> *(A) Securing the health, safety and welfare of persons at work;*
> *(B) Protecting persons other than persons at work against risks to health or safety arising out of or in connection with the activities of persons at work;*
> *(C) Controlling the keeping and use of explosive or highly flammable or otherwise dangerous substances, and generally preventing the unlawful acquisition, possession and use of such substances;*

18. A key element in the implementation of the Health and Safety at Work Act is the Control of Substances Hazardous to Health Regulations 2002[27] which are intended to protect both

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[24]Nicholas A. Sims, *The Importance of National Implementing Legislation for the Chemical Weapons Convention*, University of Bradford, Department of Peace Studies, First CWC Review Conference Paper No. 5, April 2003. Available at http://www.brad.ac.uk/acad/scwc

[25]Graham S. Pearson & Nicholas A. Sims, *National Measures to Implement the Prohibitions in the BTWC*, University of Bradford, Department of Peace Studies, Briefing Paper No.3 (Second Series), March 2003. Available at http://www.brad.ac.uk /acad/sbtwc

[26]United Kingdom, *Health and Safety at Work etc Act 1974*, 1974, chapter 37. Available at http://www. healthandsafety.co.uk/haswa.htm

[27]United Kingdom, *Control of Substances Hazardous to Health Regulations, 2002*, Statutory Instrument S.I. 2002/2677. Available at http://www. opbw.org

workers and others who may be exposed from work activities from the risks of hazardous substances. The development of these regulatory measures in respect of biological agents was addressed in paragraphs 5 to 13 of a Briefing Paper issued in March 1998[28]. In the context of the regulations, hazardous substances are anything which can harm health if they are not adequately controlled. Consequently, all pathogens and toxins are covered by these regulations.

19. The 2002 COSHH regulations define *"substance hazardous to health"* as meaning a substance -

> *a. which is listed in Part I of the approved supply list as dangerous for supply ... and for which an indication of danger specified for the substance is very toxic, toxic, harmful, corrosive or irritant;*
>
> *b. for which the Health and Safety Commission has approved a maximum exposure limit or an occupational exposure standard;*
>
> *c. which is a biological agent;*
>
> *d. which is a dust of any kind...;*
>
> *e. which, not being a substance falling within subparagraphs a. to d., because of its chemical or toxicological properties and the way it is used or is present at the workplace creates a risk to health.*

It defines biological agent as:

> *"biological agent" means a micro-organism, cell culture or human endo-parasite, whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health"*

20. The basic approach in regard to substances hazardous to health, including biological agents, adopted in the COSHH regulations comprises of the following elements:

> a. Assessment of risk to health created by work involving substances hazardous to health;
> b. Prevention or control of exposure to substances hazardous to health;
> c. Use of control measures, etc;
> d. Maintainance, examination and testing of control measures;
> e. Monitoring of exposure at the workplace
> f. Health surveillance
> g. Information, instruction and training for persons who may be exposed to substances hazardous to health;
> h. Arrangements to deal with accidents, incidents and emergencies;

Additional requirements apply to work with biological agents including:

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[28]Graham S. Pearson, *Article X: Further Building Blocks*, University of Bradford, Department of Peace Studies, Briefing Paper No.7 (First Series), March 1998, paragraphs 5 - 13. Available at http://www.brad.ac.uk /acad/sbtwc

a. Classification of biological agents;
b. Special control measures for laboratories, animal rooms and industrial processes;
f. List of employees exposed to certain biological agents (in Group 3 and Group 4);
g. Notification of the use of biological agents (in Groups 2, 3 and 4);
h. Notification of the consignment of biological agents (in Group 4);

21. Biological agents are categorized into four hazard Groups:

**Group 1** - unlikely to cause human disease;

**Group 2** - 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 treatment available;

**Group 3** - can cause severe human disease and may be a serious hazard to employees; it may spread to the community, but there is usually effective prophylaxis or treatment available;

**Group 4** - 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.

An approved list of the categorisation to be applied to biological agents is issued by the Health and Safety Executive[29].

22. The regulations also set out the minimum requirements for containment measures in facilities and laboratories handling such biological agents as follows:

(a) level 2 for activities which involve working with a Group 2 biological agent;

(b) level 3 for activities which involve working with a Group 3 biological agent;

(c) level 4 for activities which involve working with a Group 4 biological agent;

(d) level 2 for laboratories which do not intentionally propagate, concentrate or otherwise increase the risk of exposure to a biological agent but work with materials in respect of which it is unlikely that a Group 3 or Group 4 biological agent is present;

(e) level 3 or 4, where appropriate, for laboratories which do not intentionally propagate, concentrate or otherwise increase the risk of exposure to a Group 3 or Group 4 biological agent but where the employer knows, or it is likely, that such a containment level is necessary; and

(f) level 3 for activities where it has not been possible to carry out a conclusive assessment but where there is concern that the activity might involve a serious health risk for employees.

[29]The latest approved list took effect from 1 February 2000 and is available in Health and Safety Executive, Advisory Committee on Dangerous Pathogens, *Second supplement to: Categorisation of biological agents according to hazard and categories of containment.* 2000. Available at http://www.hse.gov.uk/hthdir/noframes/biolhaz.htm

The basic requirement is thus that the containment level must match the hazard grouping of the agent as a minimum.

23. The COSHH 2002 requirements for containment levels include requirements regarding access and safe storage of biological agents as follows:

| Containment measure | 2 | 3 | 4 |
|---|---|---|---|
| Access to be restricted to authorised persons only | Yes | Yes | Yes, via air-lock key procedure |
| Safe storage of biological agents | Yes | Yes | Yes, secure storage |

24. The requirement for keeping a list of employees exposed to agents in Group 3 and Group 4 is detailed as follows:

> ***List of employees exposed to certain biological agents***
>
> *4. - (1) Subject to sub-paragraph (2), every employer shall keep a list of employees exposed to a Group 3 or Group 4 biological agent, indicating the type of work done and, where known, the biological agent to which they have been exposed, and records of exposures, accidents and incidents, as appropriate.*
>
> *(2) Sub-paragraph (1) shall not apply where the results of the risk assessment indicate that -*
>
> *(a) the activity does not involve a deliberate intention to work with or use that biological agent; and*
> *(b) there is no significant risk to the health of employees associated with that biological agent.*
>
> *(3) The employer shall ensure that the list or a copy thereof is kept available in a suitable form for at least 40 years from the date of the last entry made in it.*
>
> *(4) The relevant doctor referred to in regulation 11, and any employee of that employer with specific responsibility for the health and safety of his fellow employees, shall have access to the list.*
>
> *(5) Each employee shall have access to the information on the list which relates to him personally.*

25. The requirement for notification of first use is set out as follows:

> ***Notification of the use of biological agents***
>
> *5. - (1) Subject to sub-paragraphs (7) and (8), an employer shall not use for the first time one or more biological agents in Group 2, 3 or 4 at particular premises for any of the activities listed in paragraph 3(3) unless he has –*

*(a) notified the Executive in writing of his intention to do so at least 20 working days in advance, or such shorter period as the Executive may allow;*
*(b) furnished with that notification the particulars specified in sub-paragraph (5); and*
*(c) received the acknowledgement required by sub-paragraph (4).*

*(2) Subject to sub-paragraphs (7) and (9), an employer shall not use a biological agent which is specified in Part V of this Schedule, except where the use of that agent has been notified to the Executive in accordance with sub-paragraph (1), for any of the activities listed in paragraph 3(3) unless he has -*

*(a) notified the Executive in writing of his intention to do so at least 20 working days in advance, or such shorter period as the Executive may allow;*
*(b) furnished with that notification the particulars specified in sub-paragraph (5); and*
*(c) received the acknowledgement required by sub-paragraph (4).*

*(3) The Executive may accept a single notification under sub-paragraph (2) in respect of the use of more than one biological agent by the same person.*

*(4) Upon receipt of the notification required by sub-paragraph (1) or (2), the Executive shall, within 20 working days -*

*(a) send to the notifier an acknowledgement of receipt; or*
*(b) if the notification does not contain all of the particulars specified in sub-paragraph (5) -*
*(i) inform the notifier in writing of the further particulars required, and*
*(ii) within 10 working days of receipt of those further particulars, send to the notifier an acknowledgement of receipt.*

*(5) The particulars to be included in the notification referred to in sub-paragraphs (1) and (2) shall be -*

*(a) the name and address of the employer and the address of the premises where the biological agent will be stored or used;*
*(b) the name, qualifications and relevant experience of any employee of that employer with specific responsibility for the health and safety of his fellow employees;*
*(c) the results of the risk assessment;*
*(d) the identity of the biological agent and, if the agent does not have an approved classification, the Group to which the agent has been assigned; and*
*(e) the preventive and protective measures that are to be taken.*

*(6) Where there are changes to processes, procedures or the biological agent which are of importance to health or safety at work and which render the original notification invalid the employer shall notify the Executive forthwith in writing of those changes.*

*(7) Sub-paragraphs (1) and (2) shall not apply in relation to a biological agent where an intention to use that biological agent has been previously notified to the Executive*

*in accordance with the Genetically Modified Organisms (Contained Use) Regulations 2000.*

*(8) The requirement in sub-paragraph (1) to notify first use of a biological agent in Group 2 or 3 shall not apply to an employer whose only use of that agent is in relation to the provision of a diagnostic service provided that use will not involve a process likely to propagate, concentrate or otherwise increase the risk of exposure to that agent.*

*(9) The requirement in sub-paragraph (2) to notify use of a biological agent specified in Part V of this Schedule shall not apply to an employer whose only use of that agent is in relation to the provision of a diagnostic service provided that use will not involve a process likely to propagate, concentrate or otherwise increase the risk of exposure to that agent.*

26. The requirement for notification of the consignment of biological agents is set out as:

***Notification of the consignment of biological agents***

*6. - (1) An employer shall not consign a Group 4 biological agent or anything containing, or suspected of containing, such an agent to any other premises, whether or not those premises are under his ownership or control, unless he has notified the Executive in writing of his intention to do so at least 30 days in advance or before such shorter time as the Executive may approve and with that notification has furnished the particulars specified in sub-paragraph (4).*

*(2) Sub-paragraph (1) shall not apply where -*

*(a) the biological agent or material containing or suspected of containing such an agent is being consigned solely for the purpose of diagnosis;*
*(b) material containing or suspected of containing the biological agent is being consigned solely for the purpose of disposal; or*
*(c) the biological agent is or is suspected of being present in a human patient or animal which is being transported for the purpose of medical treatment.*

*(3) Where a Group 4 biological agent is imported into Great Britain, the consignee shall give the notice required by sub-paragraph (1).*

*(4) The particulars to be included in the notification referred to in sub-paragraph (1) shall be –*

*(a) the identity of the biological agent and the volume of the consignment;*
*(b) the name of the consignor;*
*(c) the address of the premises from which it will be transported;*
*(d) the name of the consignee;*
*(e) the address of the premises to which it shall be transported;*
*(f) the name of the transport operator responsible for the transportation;*
*(g) the name of any individual who will accompany the consignment;*
*(h) the method of transportation;*
*(i) the packaging and any containment precautions which will be taken;*
*(j) the route which will be taken; and*

*(k) the proposed date of transportation.*

27. It is thus evident that UK regulations require biological agents to be categorised, for containment provisions including access and safe storage, for lists to be kept of employees exposed to agents in Group 3 or 4, notification of first use of agents in Groups 2, 3 and 4, and notifications of consignments of agents in Group 4.

***Animal Pathogens***

28. Different regulations apply in regard to animal and plant pathogens where the aim is to protect livestock and plants in the UK from disease. The development of these regulatory measures in respect of animal pathogens was addressed in paragraphs 14 to 16 of a Briefing Paper issued in March 1998[30]. The Specified Animal Pathogens Order (SAPO) 1998[31] entered into force on 1 April 1998 prohibits any person in Great Britain from having in his possession any specified animal pathogen or any carrier in which he knows such a pathogen is present except under the authority of a licence issued in writing by the appropriate Minister. The specified animal pathogens are those organisms listed in the Order causing serious epidemic diseases of farm livestock. The definition of disease is extended so as *"to comprise 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*
*Eastern & Western equine encephalomyelitis viruses*
*Foot and mouth disease virus*
*Newcastle disease virus*
*Rabies virus*
*Rift Valley Fever virus*
*Rinderpest virus*
*Sheep pox and goat pox virus*
*Venezuelan equine encephalomyelitis virus*

29. 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 hazard groups for human pathogens (described earlier in this Briefing Paper) 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:

[30]Graham S. Pearson, *Article X: Further Building Blocks*, University of Bradford, Department of Peace Studies, Briefing Paper No.7 (First Series), March 1998, paragraph 14 - 16. Available at http://www.brad.ac.uk/acad/sbtwc

[31]United Kingdom, *The Specified Animal Pathogens Order 1998*, Statutory Instrument S.I. 1998/463. Available at http://www. opbw.org

**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.

*Plant Pathogens*

30. 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. The development of these regulatory measures in respect of plant pathogens was addressed in paragraphs 17 to 22 of a Briefing Paper issued in March 1998[32]. Official controls that apply to the import, movement, and keeping of plants, plant pests and other material such as soil are laid down in the Plant Health (Great Britain) Order 1993[33] 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. 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.

31. 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 an inspector 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

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[32]Graham S. Pearson, *Article X: Further Building Blocks*, University of Bradford, Department of Peace Studies, Briefing Paper No.7 (First Series), March 1998, paragraph 17 - 22. Available at http://www.brad.ac. uk/acad/sbtwc

[33]United Kingdom, *The Plant Health (Great Britain) Order 1993*, Statutory Instrument S.I. 1993/1320. Available at http://www.brad.ac. uk/acad/sbtwc

*"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;"*

32. 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.

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

34. 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 by the relevant Ministry, DEFRA. 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.

35. 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."*

**National Measures to Control Access to Biological Agents and Toxins**

36. Additional requirements addressing the security of biological agents were enacted in the United Kingdom in the *Anti-Terrorism, Crime and Security Act 2001*[34] which includes as *Part 7 Security of Pathogens and Toxins.* This includes the following elements:

a. Duty to notify Secretary of State before keeping or using any dangerous substance;
b. Power to require information about security of dangerous substances;
c. Power to require information about persons with access to dangerous substances;
d. Duty to comply with security directions;
e. Duty to dispose of dangerous substances;
f. Denial of access to dangerous substances;

Part 7 sets out the pathogens and toxins to which these requirements apply as being those pathogens and toxins listed in Schedule 5 to the Act and includes provision for the Secretary of State to add any pathogen or toxin to that Schedule if he is satisfied that the pathogen or toxin is capable of endangering life or causing serious harm to human health. The term *"dangerous substance"* is defined as meaning anything which consists of or includes a substance for the time being mentioned in Schedule 5 as well as anything which is infected with or otherwise carries any such substance.

37. The Act also includes the power to extend the requirements to animal or plant pathogens, pests or toxic chemicals. This extension *may be exercised in relation to any pathogen or pest only if the Secretary of State is satisfied that there is a risk that the pathogen or pest is of a description that could be used to cause:*

*a. widespread damage to property;*
*b. significant disruption to the public; or*
*c. significant alarm to the public.*

In respect of chemicals, this extension *may be exercised in relation to any chemical only if the Secretary of State is satisfied that the chemical is capable of endangering life or causing serious harm to human health.*

38. The detailed provisions include the following:

a. The notification before keeping or using any dangerous substance must:

*(a) identify the premises in which the substance is kept or used;*
*(b) identify any building or site of which the premises form part;*

b. The information about security of dangerous substances includes both

[34]United Kingdom, *Anti-Terrorism, Crime and Security Act 2001.* Available at http://www.opbw.org and at http://www.legislation.hmso.gov.uk/acts/acts2001/10024

*(a) measures taken to ensure the security of any building or site of which the premises form part; and*
*(b) measures taken for the purpose of ensuring access to the substance is given only to those whose activities require access and only in circumstances that ensure the security of the substance.*

c. The information required about persons with access to dangerous substances includes a list of-

*(a) each person who has access to any dangerous substance kept or used there;*
*(b) each person who, in such circumstances as are specified or described in the notice, has access to such part of the premises as is so specified or described;*
*(c) each person who, in such circumstances as are specified or described in the notice, has access to the premises; or*
*(d) each person who, in such circumstances as are specified or described in the notice, has access to any building or site of which the premises form part.*

d. Denial of access to dangerous substances. The provisions set out that *"the Secretary of State may give directions to the occupier of any relevant premises requiring him to secure that the person identified in the directions:*

*(a) is not to have access to any dangerous substance kept or used there;*
*(b) is not to have, in such circumstances (if any) as may be specified or described in the directions, access to such part of the premises as is so specified or described;*
*(c) is not to have, in such circumstances (if any) as may be specified or described in the directions, access to the premises; or*
*(d) is not to have, in such circumstances (if any) as may be specified or described in the directions, access to any building or site of which the premises form part."*

**National Measures to Control Genetic Modification**

39. Examples of regulatory measures relating to genetic modification are the UK Genetically Modified Organisms (Contained Use) Regulations 2000[35] which entered into force on 15 November 2000 and UK Genetically Modified Organisms (Deliberate Release) Regulations

[35]United Kingdom, *Genetically Modified Organisms (Contained Use) Regulations 2000*, Statutory Instrument S.I. 2000/2831. Available at http://www.hmso.gov.uk

2002[36] which entered into force on 17 October 2002. These Regulations implemented in the United Kingdom the corresponding EC Directives 98/81/EC[37] and 2001/19/EC[38].

40. The contained use regulations set out the requirements for:

a. Risk assessment and notification of activities involving genetic modification which include:

i. Notification of the intention to use premises for the first time for activities involving genetic modification;
ii. Notification of class 2 activities involving genetic modification of micro-organisms;
iii. Notification of class 3 or 4 activities involving genetic modification of micro-organisms;

b. Conduct of activities involving genetic modification which includes containment and control measures for activities involving genetic modification of micro-organisms;

The classes of activity involving genetic modification are set out as:

• **Class 1.** *Activities of no or negligible risk for which containment level 1 is appropriate to protect humans and the environment.*
• **Class 2.** *Activities of low risk for which containment level 2 is appropriate to protect humans and the environment.*
• **Class 3.** *Activities of moderate risk for which containment level 3 is appropriate to protect humans and the environment.*
• **Class 4.** *Activities of high risk for which containment level 4 is appropriate to protect humans and the environment.*

The term *"genetic modification"* is defined in relation to an organism as meaning *the altering of the genetic material in that organism in a way that does not occur naturally by mating or natural recombination or both and within the terms of this definition -*

*a. genetic modification occurs at least through the use of the techniques listed in Part I of Schedule 2.*

Part I of Schedule 2 provides examples of techniques constituting genetic modification as being:

*a. recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatsoever means outside an organism, into any virus, bacterial plasmid or other*

[36]United Kingdom, *Genetically Modified Organisms (Deliberate Release) Regulations 2002*, Statutory Instrument S.I. 2002/2443. Available at http://www.opbw.org and at http://www.hmso.gov.uk
[37]European Community, *Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified microorganisms*, Official Journal L 330, 05/12/1998, pp. 13 - 31. Available at http://europa.eu.int
[38]European Community, *Council Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EC*, Official Journal L 106, 17/04/2001, pp. 1 - 39. Available at http://europa.eu.int

*vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;*

*b. techniques involving the direct introduction into an organism of heritable genetic material prepared outside the organism, including micro-injection, macro-injection and micro-encapsulation;*

*c. cell fusion and hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.*

It is pointed out that this list is not exhaustive as any technique which alters the genetic material of an organism by a way that would not occur by natural mating or recombination can result in a genetically modified organism.

41. **Risk Assessment.** The requirement for a risk assessment of activities involving genetically modified microorganisms is that:

*1. No person shall undertake any activity involving genetic modification of microorganisms unless, before commencing that activity, he has ensured that a suitable and sufficient assessment of the risks created thereby to human health and the environment has been carried out.*

*2. The person carrying out an assessment required by paragraph 1 shall take into account the matters set out in Part I of, and include the steps set out in Part II of, Schedule 3.*

The matters set out in Part I of Schedule 3 include: identification of any potentially, harmful effects; characteristics of the proposed activity; the severity of any potentially harmful effects; and the likelihood of them occurring. Part II sets out the steps that must be taken in making the risk assessment which includes the selection of the appropriate containment and control measures for the particular activity.

42. **Safety Committee.** The regulation also requires the establishment of a genetic modification safety committee (GMSC) which is required to review and advise on risk assessments made in accordance with the regulation. The regulation does not detail the composition or function of a GMSC but points out that it should ideally be constituted to represent both the managers and employees with its members being representative of all people having access to the genetic modification facilities or who might otherwise be exposed to such work. Guidance is, however, provided on the experience and knowledge of members of such a GMSC and on the possible constitution and functions.

43. **Emergency plans.** In addition, the regulation requires that:

*1. Where an assessment ... shows that as a result of any reasonably foreseeable accident:*

*a. The health and safety of persons outside the premises in which an activity involving genetic modification is carried on is liable to be seriously effected; or*

*b. There is a risk of serious damage to the environment;*

*the person undertaking that activity shall ensure that, before the activity to which the assessment relates begins, a suitable plan is prepared with a view to securing the health and safety of those persons and the protection of the environment.*

It is further required that:

*4. The person undertaking the activity involving genetic modification which is the subject of the emergency plan shall:*

*a. inform the emergency services and any body or authority liable to be affected by an accident to which the plan relates of the contents of the plan and of any relevant revisions ... and*

*b. make the plan and any such revisions publicly available.*

44. **Notification.** The notification of the intention to use premises for the first time in activities involving genetic modification requires that no such use shall take place until an acknowledgement has been received from the competent authority of the notification[39]. In regard to notifications to carry out class 2 activities, an acknowledgement is required from the competent authority, whilst in respect of notifications to carry out class 3 or 4 activities, prior written consent is required from the competent authority.

45. The regulations also require that a person who undertakes an activity involving genetic modification shall ensure that:

*a. the exposure of humans and the environment to genetically modified micro-organisms is reduced to the lowest level that is reasonably practicable; and*

*b. harm to humans arising from an activity involving genetic modification of organisms other than micro-organisms is reduced to the lowest level that is reasonably practicable;*

It goes on to require that for any activity involving genetic modification of micro-organisms, the measures to be taken to comply with the above requirement shall include the general principles of good microbiological practice and of good occupational safety and hygiene as detailed in Schedule 7 to the regulations.

46. **Public Register.** The regulations also require that a register be maintained of genetic modification activities which shall be open for inspection by members of the public. Provisions are included for the exclusion of certain information regarded as confidential from this register. In addition, an amendment[40] to the regulations which entered into force on 8th February 2002, provides for information to be made confidential in the interests of national security and thus excluded from the public register.

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[39]Current notification requirements are set out in the Advisory Committee on Dangerous Pathogens, *Biological Agents Bulletin No. 6*, March 2003. Available at http://www.doh.gov.uk/acdp/publications.htm

[40]United Kingdom, *Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002*, Statutory Instrument S.I. 2002/63. Available at http://www.opbw.org and at http://www.hmso.gov.uk

**Oversight of National Legislation and Regulations**

47. The effectiveness of national legislation and regulations requires that these are both widely known in the relevant community and implemented effectively. Furthermore, they need to be reviewed periodically to ensure that they continue to be comprehensive and effective.

48. **National Legislation to Implement the BTWC.** Insofar as such national legislation is concerned, although successive Review Conferences have in the Article IV section of their Final Declarations included language along the following lines:

> *The Conference notes the importance of:*
>
> *- Legislative, administrative and other measures designed to enhance domestic compliance with the Convention;*
>
> *- Legislation regarding the physical protection of laboratories and facilities to prevent unauthorized access to and removal of microbial or other biological agents, or toxins:*
>
> *- Inclusion in textbooks and in medical, scientific and military education programmes of information dealing with the prohibitions and provisions contained in the Biological and Toxin Weapons Convention and the Geneva Protocol of 1925.,*

it is far from clear as to what concrete action States Parties have taken to implement these measures. It is unfortunately all too often the situation even in developed countries that students in universities are unaware of the Biological and Toxin Weapons Convention and its prohibitions or of national legislation to implement the Convention. There is little evidence that medical, scientific or military education programmes even in developed countries include information about the prohibitions and provisions of the Convention apart from in specialised courses for those interested in international relations, security and arms control.

49. **National Measures for Health and Safety.** The situation in respect of awareness and implementation of national measures for health and safety is much more satisfactory. This is because the importance of health and safety has been successfully embedded into the national functioning of laboratories and facilities -- with public and media attention being given to prosecutions of those who fail to meet the required health and safety standards. Furthermore, the inspectors of the national health and safety agency -- in the United Kingdom of the Health and Safety Executive -- carry out regular inspections of all facilities -- and have the power, should inadequate health and safety standards be encountered, to issue orders requiring that work in those facilities stops until the health and safety standards have been improved to the satisfaction of the HSE inspectors.

50. In regard to dangerous pathogens, the United Kingdom has established an Advisory Committee on Dangerous Pathogens (ACDP) whose terms of reference[41] are:

[41]Department of Health, Advisory Committee on Dangerous Pathogens (ACDP). Available at http:// www.doh. gov.uk/acdp

*To advise the Health and Safety Commission, the Health and Safety Executive, Health and Agriculture Ministers, and their counterparts under devolution in Scotland, Wales and Northern Ireland, as required, on all aspects of hazards and risks to workers and others from exposure to pathogens.*

The Committee comprises of a Chairman and 17 members: 9 are scientific experts, 4 employer representatives and 4 employee representatives[42]. The Advisory Committee enables the UK Government to draw upon expert scientific knowledge and thereby ensure that new controls and regulations are soundly based and will be effective. Agendas for the ACDP meetings are posted on the web and are annotated after the meetings to give an indication of the outcome[43]. Information about the work of the ACDP and the latest information on pathogens is published in the Biological Agents Bulletin[44].

51. **National Measures to Control Genetic Modification.** The situation in respect of awareness and implementation of national measures for genetic modification is similar to that for national measures for health and safety. This is again because the importance of evaluating the risks to health and safety prior to carrying out genetic modification has been successfully embedded into the national functioning of laboratories and facilities. Furthermore, the inspectors of the national health and safety agency -- in the United Kingdom of the Health and Safety Executive -- carry out regular inspections of facilities engaged in genetic modification as well as giving prior approval of proposed work -- and have the power, should inadequate health and safety standards be encountered, to issue orders requiring that work in those facilities stops until the health and safety standards have been improved to the satisfaction of the HSE inspectors.

50. In regard to genetic modification, the United Kingdom has established an Advisory Committee on Genetic Modification (ACGM) whose terms of reference[45] are:

*To advise the Health and Safety Commission and Executive and the Secretary of State for the Environment, and other Ministers and bodies, as appropriate, on all aspects of the human and environmental safety of the contained use of genetically modified organisms.*

The Committee comprises of a Chairman and 18 members: 10 are independent experts, 4 employer representatives and 4 employee representatives[46]. The ACGM also has a Technical Subcommittee which provides specialised advice to the ACGM on all aspects of the human and environmental safety of the contained use of genetically modified organisms. It advises on the individual activities notified under the GMOs (Contained Use) Regulations and develops and maintains the ACGM Compendium of Guidance. The Advisory Committee enables the UK Government to draw upon expert scientific knowledge and thereby ensure that new controls and regulations are soundly based and will be effective. agendas for the

[42]Department of Health, Advisory Committee on Dangerous Pathogens (ACDP), Membership. Available at http://www.doh.gov.uk/acdp/members.htm

[43]Health and Safety Commission, Advisory Committee on Dangerous Pathogens (ACDP), Agenda. Available at http://www.hse.gov.uk/aboutus/hsc/iacs/acdp/index.htm

[44]Advisory Committee on Dangerous Pathogens, *Biological Agents Bulletin*. Available at http://www.doh.gov.uk/acdp/publications.htm

[45]Health and Safety Executive, Advisory Committee on Genetic Manipulation (ACGM). Available at http://www.hse.gov.uk/aboutus/hsc/iacs/acgm/index.htm

[46]Health and Safety Executive, Advisory Committee on Genetic Manipulation (ACGM). Available at http://www.hse.gov.uk/aboutus/hsc/iacs/acgm/members.htm

ACGM meetings are posted on the web and are annotated somewhat more fully than for the ACDP meetings after the meeting to indicate the outcome[47].

51. A second committee addresses releases to the environment. The Advisory Committee on Releases to the Environment (ACRE)[48] provides advice to the government on the release and marketing of genetically modified organisms within the legislative framework of the UK Environmental Protection Act 1990 and the UK GMO Deliberate Release Regulations 2002 which together implement the European Community Directive 2001/18/EC. The Committee consists of a Chairman and 12 members together with an ex-officio member -- the Chair of the Advisory Committee on Novel Foods and Processes. The agendas and the minutes of meetings are posted on the web[49] and their annual reports and advice on specific cases are also posted[50].

**Oversight of the nature of work and of proposed work**

52. Although there is oversight of proposed work in relation to biological agents, this is entirely focussed on the risks from such work to health and safety and not on whether it is appropriate that such work should be carried out. The scrutiny of proposed work becomes more intense when genetic modification is concerned and particularly when deliberate releases or marketing are being addressed. However, in all these cases the scrutiny is primarily on the risks posed to health and safety and to the environment by the proposed work. It is, however, true that in regard to deliberate releases of genetically modified organisms there is more intense debate about all aspects of the proposed release including why the proposed release should take place. The availability of information on the deliberations of the various advisory committees becomes the greater as one moves from work in relation to biological agents through the contained use of genetic modification and to deliberate releases of genetic modified organisms. This increased scrutiny and availability of information reflects the public awareness and concern which is currently greatest about deliberate releases and least about work with biological agents.

53. The University of Maryland project[51] on Controlling Dangerous Pathogens in reviewing oversight notes the security provisions of the Biological and Toxin Weapons Convention internationally and then recognises that some of the most significant environmental and public health-related controls on pathogens can be found in the European Union. It goes on to consider other oversight provisions in the UK such as those for pathogens and for genetic modification. It notes that the UK has even more extensive oversight arrangements for activities involving animals. These more extensive oversight arrangements reflect public awareness and concern about the use of animals in scientific procedures. This Briefing Paper addresses these oversight arrangements in the next section.

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[47]Health and Safety Executive, Advisory Committee on Genetic Manipulation (ACGM). Available at http://www.hse.gov.uk/aboutus/hsc/iacs/acgm/index.htm

[48]Department of the Environment, Food and Rural Affairs, Advisory Committee on Releases to the Environment (ACRE). Available at http://www.defra.gov.uk/environment/acre/about/tor.htm

[49]Department of the Environment, Food and Rural Affairs, Advisory Committee on Releases to the Environment (ACRE). Available at http://www.defra.gov.uk/environment/acre/meetings/index.htm

[50]Department of the Environment, Food and Rural Affairs, Advisory Committee on Releases to the Environment (ACRE). Available at http://www.defra.gov.uk/environment/acre/pubs.htm

[51]John Steinbruner, Elisa D. Harris, Nancy Gallagher and Stacy Gunther, *Controlling Dangerous Pathogens: A Prototype Protective Oversight System*, 5 February 2003. Available at http://www.puaf.umd.edu/cissm/projects/amcs/amcs.html

53. **Oversight of Activities Involving Animals.** The UK legislation relating to activities involving animals is the Animals (Scientific Procedures) Act 1986[52] which is described on the Home Office website as being widely viewed as the most rigorous piece of legislation of its type in the world. This puts into effect, and in some areas exceeds, the requirements of the European Union Directive 86/609/EEC. The Act recognises that scientific procedures using animals can only be permitted when the benefits that the work is likely to bring (to man, other animals or the environment) outweigh any pain and distress that the animals may experience and where there is no alternative.

54. The Act implements a three level licensing system under which:

a. Those carrying out procedures must hold personal licences, which ensures that those doing the work are qualified and suitable;

b. The programme of work must be authorised in a project licence:

c. The work must also normally take place in a designated user establishment although in specific circumstances, such as a field trial, work can be carried out elsewhere with the Home Secretary's authority.

No work involving animals can take place without prior licensing by the Home Secretary which will often involve a visit by an Animals (Scientific Procedures) Inspector from the Home Office.

55. The 1986 Animals (Scientific Procedures) Act requires that there is also an independent body, the Animal Procedures Committee (APC)[53] whose terms of reference are:

> *To advise the Secretary of State on such matters concerned with the Act and his functions under it as the Committee may determine or as may be referred to the Committee by the Secretary of State.*

In other words, its role is to advise the Home Secretary on matters concerned with the Act and his functions under it, relating to any experimental or other scientific procedure applied to a protected animal and also to examine other related subjects that the Committee considers worthy of further study. The APC currently has 21 members including the Chairman. The membership[54] is posted on the APC website as is a Code of Conduct for the Committee[55] together with the minutes of meetings[56] and its annual report and other products of the Committee. Reports have been made on the effectiveness of the 1986 Act in controlling the use of laboratory animals in the emerging biotechnologies[57] in June 2001 and on what

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[52]United Kingdom, *Animals (Scientific Procedures) Act 1986*, Available at http://www.archive.official-documents.co.uk/document/hoc/321/321-xa.htm

[53]Home Office, Animal Procedures Committee. Available at http://www.apc.gov.uk

[54]Home Office, Animal Procedures Committee, *Current APC Members and Register of Interests.* Available at http://www.apc.gov.uk/members/interest.htm

[55]Home Office, Animal Procedures Committee, *Code of Conduct* Available at http://www.apc.gov.uk/members/concode.htm

[56]Home Office, Animal Procedures Committee, *Minutes of Meetings.* Available at http://www.apc.gov.uk/reference/minutes.htm

[57]Home Office, Animal Procedures Committee, *APC Report on Biotechnology, June 2001*. Available at http://www.apc.gov.uk/reference/biorec.pdf

additional information about animal procedures and individual licenses could or should be made public in an APC Report on Openness[58] in August 2001.

56. In 1998, the Home Secretary decided that an ethical review process should be established and maintained in each designated user establishment within which animal procedures are carried out[59]. From 1 April 1999, the requirement for a local ethical review process would be a standard condition for every designated user and breeding/supplying establishment. The aims of this process are:

> *a. To provide independent ethical advice to the certificate holder, particularly with respect to project licence applications and standards of animal care and welfare.*
>
> *b. To provide support to named people and advice to licensees regarding animal welfare and ethical issues arising from their work.*
>
> *c. To promote the use of ethical analysis to increase awareness of animal welfare issues and develop initiatives leading to the widest possible application of the 3Rs.* [possibilities for reduction, refinement and replacement]

In addition, the process should specifically enable the following:

> *a. Promoting the development and uptake of reduction, replacement and refinement alternatives in animal use, where they exist, and ensuring the availability of relevant sources of information;*
>
> *b. Examining proposed applications for new project licences and amendments to existing licences, with reference to the likely costs to the animals, the expected benefits of the work and how these considerations balance;*
>
> *c. Providing a forum for discussion of issues relating to the use of animals and considering how staff can be kept up to date with relevant ethical advice, best practice, and relevant legislation;*
>
> *d. Undertaking retrospective project reviews and continuing to apply the 3Rs to all projects, throughout their duration;*
>
> *e. Considering the care and accommodation standards applied to all animals in the establishment, including breeding stock, and the humane killing of protected animals;*
>
> *f. Regularly reviewing the establishment's managerial systems, procedures and protocols where these bear on the proper use of animals;*
>
> *g. Advising on how all staff involved with the animals can be appropriately trained and how competence can be ensured.*

[58]Home Office, Animal Procedures Committee, *APC Report on Openness,* August 2001. Available at http://www.apc.gov.uk/reference/openness.pdf

[59]Home Office, *The Ethical Review Process,* 1 April 1998. Available at http://www.homeoffice.gov.uk/erpstatement.html

It is furthermore emphasised that commonly, there should be a promotional role, seeking to educate users (in applying the 3Rs) and non-users (by explaining why and how animals are used), as appropriate. There should be some formal output from the ethical review process for staff and colleagues in the establishment, made as widely available as security and commercial/intellectual confidentiality allow.

57. Supplementary notes on the ethical review process were issued by the Home Office Chief Inspector in December 2000[60]. It is made clear that the requirement is for a process rather than for an event or a committee because the process should be activated when work is at the concept stage, it should inform the planning process, continue once the work is in progress, and reflect upon the lessons learned when the work has been completed. The named veterinary surgeon and the named animal care and welfare officer are expected to be involved in the process as are representatives of personal and project licence holders. In addition, where possible there should also be input from those who do not have responsibilities under the 1986 Act. It is also strongly recommended that, where possible, an external lay member should take part in the ethical review process. A review of the Ethical Review Process was carried out in November 2001 by the Animals (Scientific Procedures) Inspectorate which concluded that the process should be seen as an evolving one and that those involved in ERPs should be made aware of 'best practice'.

58. **Analysis.** It is thus apparent that animal scientific procedures are highly regulated with the requirement for the individual to be licensed as being competent to carry out the work, the specific project licensed and the establishment in which the project is carried out also licensed. There is also a requirement that any proposed project shall have been subjected to an ethical review process. This highly regulated process has emerged largely because of public concerns about the use of animals in scientific procedures. It is for consideration whether the dangers posed by the misuse of pathogenic microorganisms and toxins -- and their expression in public concerns about bioterrorism -- merit consideration of a similar highly regulated framework. There is much to be said for an ethical review process for work on pathogenic microorganisms and toxins in which the possible risks are balanced against the potential benefits -- a risk benefit analysis which is likely to be required in any event for health and safety and environmental reasons -- together with an ethical review in which risks to security, including compliance with the BTWC, and safety should be addressed.

## Oversight of Publicly Available Information

59. Recently, following the attacks of 11 September 2001 and the subsequent anthrax letters in the United States, attention is being given to whether certain information, which might be misused by States non-compliant with the BTWC or by sub-national groups or individuals who wish to use biological agents or toxins for prohibited purposes, should be made publicly available. This parallels in several respects the recent moves towards the control of the transfer of information which might assist a State seeking to acquire biological or toxin weapons which have resulted in several States bringing in controls on the transfer of intangible technology. Such considerations as to whether publicly available information should be limited are contrary to the general trend over the past decade or more which has been towards making more and more information publicly available -- especially in the life

[60]Home Office, *The Local Ethical Review Process, Supplementary Note by the Chief Inspector December 2000*, December 2000. Available at http://www.homeoffice.gov.uk/erp chief.html

sciences and in the area of genetic modification in order to reassure public concerns about the risks associated with such work.

60. **Scientific Openness and National Security.** The United States National Academy of Sciences held a workshop[61] in Washington, D.C., on 9 January 2003 intended to stimulate consideration of the pivotal role of scientific communication in today's society and the ethical responsibility to prevent misuse of published scientific information. Three particular questions were posed[62]:

> a. Should there be restrictions on publication, or other dissemination of biomedical research results -- even when the research is not classified and if so, what criteria should be used and who should decide?
>
> b. Should some aspects of biotechnological research be withheld from publication, such as methods sections or genome sequences, and should publishers agree to publish papers with details omitted?
>
> c. Should we manage access to scientific information and if so, who should be responsible for controlling that access?

In the opening session, the Director of the White House Office of Science and Technology Policy[63] pointed out that modern biotechnology has two aspects -- first the determination of molecular codes and structures and their significance to the organism, and second, the technical procedures used to produce novel organisms based on this knowledge. The first, discovery activity on which the whole field depends for its advance is the one that is the most technically difficult to acquire, whilst the second, the applications phase is easier. He went on to say that the current US national policy is that in National Security Decision Directive 189 issued by President Ronald Reagan on 21 September 1985 which states that "It is the policy of this Administration that, to the maximum extent possible, the products of fundamental research remain unrestricted" and "where the national security requires control the mechanism for control of information generated during federally funded research ... is classification." Furthermore, the policy states that "No restrictions may be placed upon the conduct or reporting of federally funded fundamental research that has not received national security classification, except as provided in applicable U.S. Statutes."

61. The following day, 10 January 2003, saw a meeting by a group of editors in the life sciences to discuss the issues with specific reference to the scientific publication process. A statement emerged from that meeting which has been widely published[64]. This states that:

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[61]National Academy of Science, *Scientific Openness and National Security Workshop*, 9 January 2003. Agenda available at http://www7.nationalacademies.org/pga/Scientific_Openness_Agenda.html

[62]National Academy of Science, Scientific Openness and National Security Workshop, 9 January 2003. Ron Atlas, *Preserving Scientific Integrity and Safeguarding Our Citizens: Challenges for Scientific Publishers in the Age of Bioterrorism.* Available at http://www7.nationalacademies.org/pga/Atlas_Presentation_Sci_Openness.pdf

[63]National Academy of Science, Scientific Openness and National Security Workshop, 9 January 2003. *Remarks by John Marburger, Director, Office of Science and Technology Policy, Executive Office of the President.* Available at http://www7.nationalacademies.org/pga/Marburger_Presentation_Sci_Openness.pdf

[64]*Statement on the Consideration of Biodefence and Biosecurity*, Nature, Vol. 421, 20 February 2003, p. 771.

*Fundamental is a view, shared by nearly all, that there is information that, although we cannot now capture it with lists and definitions, presents enough risk of use by terrorists that it should not be published.*

A number of agreed statements were included:

> ***First:*** *The scientific information published in peer-reviewed research journals carries special status, and confers unique responsibilities on editors and authors. We must protect the integrity of the scientific process by publishing manuscripts of high quality, in sufficient detail to permit reproducibility. Without independent verification -- a requirement for scientific progress -- we can neither advance biomedical research nor provide the knowledge base for building strong biodefence systems.*
>
> ***Second:*** *We recognize that the prospect of bioterrorism has raised legitimate concerns about the potential abuse of published information, but also recognize that research in the very same field will be critical to society in meeting the challenges of defence. We are committed to dealing responsibly and effectively with safety and security issues that may be raised by papers submitted for publication, and to increasing our capacity to identify such issues as they arise.*
>
> ***Third:*** *Scientists and their journals should consider the appropriate level and design of processes to accomplish effective review of papers that raise such security issues. Journals in disciplines that have attracted numbers of such papers have already devised procedures that might be employed as models in considering process design. Some of us represent some of these journals; others among us are committed to the timely implementation of such processes, about which we will notify our readers and authors.*
>
> ***Fourth:*** *We recognize that on occasions an editor may conclude that the potential harm of publication outweighs the potential societal benefits. Under such circumstances, the paper should be modified or not published. Scientific information is also communicated by other means: seminars, meetings, electronic posting, etc. Journals and scientific societies can play an important role in encouraging investigators to communicate results of research in ways that maximize public benefits and minimize risks of misuse.*

In the absence of further detail on precisely how such screening can and will be carried out, it is difficult to assess the effectiveness of the proposed procedures.

62. **Intangible Technology Transfer.** As noted earlier in this Briefing Paper, new controls are being introduced within the European Union on:

> a. The electronic transfer abroad of military technology;
> b. The transfer by any means of technology related to weapons of mass destruction (WMD), and
> c. The provision of WMD related technical assistance.

These new controls on the transfer, by any means, of WMD related technology supplements the existing end-use controls on the physical export of goods and technology and the

electronic transfer of technology contained in the EC Dual Use Regulation[65]. Transfer by any means includes face-to-face communication, personal demonstration or dissemination of written material. Furthermore, in Article 2 of the Regulation, *"export"* is defined as meaning:

> *"transmission of software or technology by electronic media, fax or telephone to a destination outside the Community; this applies to oral transmission of technology by telephone only where the technology is contained in a document the relevant part of which is read out over the telephone, or is described over the telephone in such a way as to achieve substantially the same result; "*

63. The European Joint Action of 22 June 2000[66] requires the export control system within the Community to cover *"technical assistance including oral transfers of technology required to be controlled by the international export control regimes, bodies and treaties for weapons of mass destruction."* It is made clear in Article 4 of the Joint Action that *"technical assistance"* does not apply *"where it takes the form of transferring information that is "in the public domain" or "basic scientific research" as these terms are respectively defined in the international export control regimes, bodies and treaties."* In the UK implementation of the Joint Action, it is made clear that *"in the public domain"* is defined as *"available without restriction upon further dissemination (no account being taken of restrictions arising solely from copyright)"* and *"basic scientific research"* is defined as *"experimental or theoretical work undertaken principally to acquire new knowledge of the fundamental principles of phenomena or observable facts, not primarily directed towards a specific practical aim of objective."*

64. It should, however, be noted that the WMD end-use controls under the EC Dual Use Regulation are all-embracing and apply to physical and electronic transfers of technology as well as to export of goods. There are **no** exemptions for information in the public domain or for basic scientific research with respect to end-use control since all European Member States have agreed that deliberately to send to a known WMD proliferator even a published book or article which might be of use to that WMD programme should require a licence[67].

65. **Publicly Available Information on Genetic Modification.** In contrast to the earlier sections above which both seek to control and restrain information, there are moves in the opposite direction to meet public concerns and anxieties about genetic modification that seek to assure the provision of information to the public. The Earth Summit at Rio de Janeiro in 1992 included agreement of the Rio Declaration on Environment and Development[68] which contained Principle 10:

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[65]European Communities, *Council Regulation (EC) No. 1334/2000 of 22 June 2000 setting up a Community regime for the control of exports of dual-use items and technology*, Official Journal of the European Communities, L159/1, 30 June 2000.

[66]European Communities, *Council Joint Action of 22 June 2000 concerning the control of technical assistance related to certain military end-uses (2000/401/CFSP)*, Official Journal of the European Communities, L159/216, 30 June 2000.

[67]Department of Trade and Industry, See *Annex B, Existing Export Controls*, in *Consultation Document on Draft Orders to be made under the Export Control Act 2002.* Available at http://www.dti.gov.uk/export.control/legislation/pdfs/consultdoc.pdf

[68]United Nations General Assembly, *Report of the United Nations Conference on Environment and Development*, Rio de Janeiro, 3 -14 June 1992, *Annex I Rio Declaration on Environment and Development,* A/CONF.151.26 (Vol.I) 12 August 1992. Available at http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm

*Environmental issues are best handled with the participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by the public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public access and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided.*

*66.* In Europe, Principle 10 has been elaborated in the United Nations Economic Commission for Europe (UNECE) Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters[69] which was adopted on 25 June 1998 in Aarhus, Denmark -- and is known as the Aarhus Convention -- at the Fourth Ministerial Conference in the "Environment for Europe" process.

67. The Convention sets out its objective in Article 1 as being:

*..., each Party shall guarantee the rights of access to information, public participation in decision-making, and access to justice in environmental matters in accordance with the provisions of this Convention.*

In Article 2 on Definitions includes the following: *"environmental information" means any information in written, visual, aural, electronic or any other material form on:*

*a. The state of elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites,* ***biological diversity and its elements, including genetically modified organisms,*** *and the interaction among these elements. ...*

*c. The state of human health and safety, ...* [Emphasis added]

Article 5 on Collection and Dissemination of Environmental Information includes the following:

*Each Party shall ensure that:*

*(c) In the event of any imminent threat to human health or the environment,* ***whether caused by human activities or due to natural causes****, all information which could enable the public to take measures to prevent or mitigate harm arising from the threat and is held by a public authority is disseminated immediately and without delay to members of the public who may be affected.* [Emphasis added]

Article 6 on Public Participation in Decisions on Specific Activities includes the provision that:

*11. Each State Party shall, within the framework of its national law, apply, to the extent feasible and appropriate, provisions of this article on decisions on whether to permit the deliberate release of genetically modified organisms into the environment.*

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[69]United Nations Economic Commission for Europe, *Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters,* done at Aarhus, Denmark, on 25 June 1998. Available at http://www.unece.org/env/pp/cep43e.pdf

68. The Aarhus Convention which required ratification by 16 States for entry into force entered into force on 30 October 2001. In April 2003, it currently has 23 States Parties and a further 21 Signatory States[70]. The States Parties are:

| | | |
|---|---|---|
| Albania | Georgia | Poland |
| Armenia | Hungary | Republic of Moldova |
| Azerbaijan | Italy | Romania |
| Belarus | Kazakhstan | Tajikstan |
| Belgium | Kyrgyzstan | FYR of Macedonia |
| Denmark | Latvia | Turkmenistan |
| Estonia | Lithuania | Ukraine |
| France | Malta | |

69. In June 1998 when the Aarhus Convention was adopted, the signatories agreed the following[71]:

> *Recognize the importance of the application of the provisions of the Convention to deliberate releases of genetically modified organisms into the environment, and request the Parties, at their first meeting to further develop the application of the Convention by means of inter alia more precise provisions, taking into account the work done under the Convention on Biological Diversity which is developing a protocol on biosafety.*

This led to the establishment of a task force on genetically modified organisms (GMOs) to summarise the experience of implementing the provisions of Article 6, Paragraph 11 (reproduced above) and to make recommendations for further action. The task force met twice in 2000 and reported to the second meeting of the signatories which decided that an Intergovernmental Working Group should be established to continue the work of the task force. This Working Group has followed a two track approach, one legally-binding and the other non-legally-binding. At its third meeting on 17-19 June 2002, the Working Group finalized work on a draft decision on GMOs as well as draft guidelines on access to information, public participation and access to justice with respect to genetically modified organisms.

70. The first meeting of the States Parties to the Aarhus Convention in Lucca, Italy on 21-23 October 2002 adopted the decision on GMOs[72] as well as the guidelines[73] without

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[70]United Nations Economic Commission for Europe, *Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, Participants.* Available at http://www.unece.org/env/pp/ctreaty.htm

[71]United Nations Economic Commission for Europe, *Resolution on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters,* Aarhus, Denmark, 23 - 25 June 1998. Available at http://www.unece.org/env/documents/1998/cep/cep.43.add.1.rev.1.e.pdf

[72]United Nations Economic Commission for Europe, Meeting of the Parties to the *Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters,* First meeting, Lucca Italy, 21-23 October 2002, *Draft Decision 1/4 Genetically Modified Organisms*, MP.PP/2002/5, 12 August 2002. Available at http://www.unece.org/env/pp/mop1/decision.1.4.e.doc

[73]United Nations Economic Commission for Europe, Meeting of the Parties to the *Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters,* First meeting, Lucca Italy, 21-23 October 2002, *Draft Guidelines on Access to Information, Public Participation and*

amendments. The decision established a further *"Working Group on Genetically Modified Organisms to examine and build upon the preparatory work undertaken ... regarding possible legally binding options, including a draft amendment of the Convention."* The first meeting of that Working Group took place in Geneva on 9 - 11 April 2003. The guidelines includes among its objectives:

> *c. Encourage the development of a common approach to access to information, public participation and access to justice with respect to GMOs, including on GMO matters which are not explicitly referred to in the Convention.*

and goes on to state that *"The Guidelines provide a non-legally binding and voluntary framework and should be used as examples of good practice."* In regard to the scope of public participation in decision making on specific activities with GMOs, the guidelines state:

> *It is recommended that, in principle, public participation should be provided for in decision-making procedures in all three areas of GMO application, and adapted to the specific requirements of these decision-making procedures and uses:*
>
> *a. Deliberate use;*
> *b. Placing on the market;*
> *c. Contained use.*

It is recommended that public participation should be provided for as appropriate in the following procedures:

> *a. First-time deliberate release into the environment of GMOs in any new location;*
>
> *d. ... the contained use of GMOs in a specific installation where in the event of an accident there would be a risk of serious damage to the environment and/or human health and therefore suitable contingency plans are foreseen.*

The Guidelines also set out in Annex III the information recommended to be available within a public participation process as including:

> *a. A general description of the GMOs;*
> *b. The name and address of the notifier or applicant;*
> *c. The purpose of the proposed activity with the GMOs;*
> *d. Experience gained with deliberate release into the environment of certain GMOs;*
>
> *f. Location of the site where the proposed deliberate release of the GMOs into the environment will take place ...; a description of any emergency response plan;*
> *g. The location of the facility where the contained use of GMOs under the scope of this chapter of the Guidelines will take place, and a description of the specific containment measures ...; a description of any emergency response plan and the possibility for its implementation;*

**Conclusions**

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*Access to Justice with Respect to Genetically Modified Organisms*, MP.PP/2002/6, 15 August 2002. Available at http://www.unece.org/env/pp/mop1/gmo.guidelines.e.doc

71. This Briefing Paper provides an input to the meetings in 2003 of experts and of the States Parties to the Biological and Toxin Weapons Convention considering:

> *National mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins;*

Sections of the Briefing Paper have addressed the complementary elements to enhance security, health and safety, and protection of the environment using national and regional examples. These complementary elements can be summarised as:

a. National measures to implement the BTWC Convention
b. National measures for health and safety
c. National measures to control genetic modification

Oversight of pathogens and toxins is then considered as a number of complementary elements:

a. Oversight of national legislation and regulations
b. Oversight of the nature of work and of proposed work
c. Oversight of publicly available information.

72. It is concluded that all States Parties will have a significant contribution to make to the experts meeting and the subsequent States Parties meeting through the sharing of their national experience, legislation and regulations relating to the implementation of the BTWC Convention, to national measures to protect health and safety from pathogenic microorganisms and toxins, and to national measures to protect health and the environment from genetically modified organisms. They will also have contributions to make from sharing national experience regarding the oversight of such legislation and regulations, of the work involving pathogenic microorganisms and toxins, and of genetic modification as well as the provision of publicly available information.

73. This Briefing Paper shows that there are several relevant European wide regulations and directives relating to many aspects of the security and oversight of pathogenic microorganisms and toxins that will apply not only within the 15 Member States of the European Union but also in the new 10 Member States recently admitted to the Union. Although less attention is paid specifically to toxins, other than as toxic chemicals, than to pathogenic organisms, and there is less oversight or prior approval of work involving pathogenic microorganisms and toxins than there is of work involving genetically-modified organisms, the European framework should nevertheless provide a sound basis for the multilateral consideration of the security and oversight of pathogenic microorganisms and toxins and the identification by the experts and the States Parties of best practice and of which areas require further work -- such as oversight and prior approval of work with pathogenic microorganisms and oversight and constraint of publicly available information -- and what balance needs to be struck given the increasing trend to making more information publicly available, especially in the life sciences, in order to assuage public concerns.

74. **All** States Parties have a real opportunity to move forward decisively by carrying out a similar survey nationally to that provided in this Briefing Paper and submitting this **prior** to the meeting of experts on 18 to 29 August 2003 or **at the very least** bringing such a national survey with them to the experts meeting. The experts could then at that meeting identify best

practice thereby providing a substantive and vital input to the States Parties meeting on 10 - 14 November 2003.