

Head of Health Directorate, Division B (Biotechnology and Physical Agents) - John Thompson

To all respondents to the Consultative  
Letter on the emergency amendment to  
the Genetically Modified Organisms  
(Contained Use) Regulations 2000

27 February 2002

Dear Respondent

**CONSULTATION ON THE EMERGENCY AMENDMENT OF THE GENETICALLY  
MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS 2000**

Thank you for taking the time to respond to the Consultative Letter on the emergency amendment of the Genetically Modified Organisms (Contained Use) Regulations 2000. We found your comments very useful in helping to formulate the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002. The regulations were made on 16 January and came into force on 8 February 2002. The Minister for Transport, Local Government and the Regions (Alan Whitehead) signed The Genetically Modified Organisms (Contained Use) (Exclusion of Information from the Public Register) (No 1) Direction 2002 on 9 February. This authorised the withholding of information contained in notifications relating to any of the pathogens and toxins listed in Schedule 5 to the Anti-terrorism, Crime and Security Act 2001. The Public Register was re-opened to full public access on 11 February with the withheld items excluded.

I attach a summary of the response to consultation and HSE's response to the views expressed. I hope you will find this helpful.

Yours sincerely

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# **EMERGENCY AMENDMENT OF THE GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS 2000**

## **HSE'S RESPONSE TO CONSULTATION**

### **Consultation process**

1. A consultation letter was sent out on 22 November 2001. In view of the urgency of the proposals, the Health and Safety Commission agreed a two week consultation period. Consultation closed on Friday 7 December 2001, but all responses received up to 10.30 am on Tuesday 11 December 2001 were taken into account in putting final proposals forward to the Commission and the Minister. The Consultation Letter was sent to 850 organisations including employer organisations, employee organisations, professional and other representative bodies, education and research establishments, Government Departments and Agencies, all GM centres, and the Advisory Committees on Genetic Modification and into Releases into the Environment. Publicity was also given to the consultation via a press notice and the Internet.

2. HSE took the responses to the consultation into full account before submitting its proposals to the Health and Safety Commission and the Minister. It also consulted with the other members of the Competent Authorities. Alan Whitehead, Parliamentary Under Secretary of State, Department of Transport Local Government and the Regions signed the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002 (SI 2002/No 63) on 16 January 2002; the Regulations came into force on 8 February 2002. Copies have been sent to the European Commission. On 9 February 2002 the Minister made the Genetically Modified Organisms (Contained Use) (Exclusion of Information from the Public Register) (No 1) Direction 2002. This authorised the withholding of information contained in notifications relating to any of the pathogens and toxins listed in Schedule 5 to the Anti-terrorism, Crime and Security Act 2001 (the 2001 Act).

3. A summary of the response to consultation and HSE's response to the views expressed is given below. Copies of the responses received are available for inspection at HSE's Information Centres at Rose Court, 2 Southwark Bridge, London SE1 9HS; Magdalen House, Stanley Precinct, Bootle, Merseyside L20 3QZ; and Broad Lane, Sheffield S3 7HQ.

4. The vast majority of those who responded were in favour of the proposals. There were 82 responses; a 9.5% response rate:

- ◆ 53 respondents thought the draft regulations were clear; 8 thought they were clear but had reservations; 2 thought they were unclear.
- ◆ 38 made written comments which favoured the proposals, 17 made written comments which favoured the proposals but showed they had reservations, and 6 were against the proposals. 2 responded that the proposals were not relevant to them.
- ◆ 23 respondents thought the Consultation Letter represented the different policy issues very well; 38 well; 0 not well; and 1 poorly.

4. The majority of respondents added written comments, but 16 did not.
5. 15 Consultation Letters were returned to sender.
6. One respondent asked for their comments to be kept confidential.

### **Support for the proposals**

7. 53 respondents made comments which were supportive of the proposals. These came from a wide range of organisations. The comments recognised the need to deal with the terrorist threat.

8. Four respondents saw the proposals as having a benefit of helping to deal with other threats to genetic modification (GM) centres, such as those from activist groups against GM or animal research. One respondent thought that access to sensitive entries on the register should continue to be restricted once the current threat had passed, to avoid misuse of information by other activists. One union thought that employees should be anonymous as well. **HSE response:** *In fact, names of employees and others are not included in the Register anyway.*

9. Two respondents stated that additional security measures or controls should be taken as well. **HSE response:** *Part VII of the Anti-terrorism, Crime and Security Act 2001 (the 2001 Act) requires the increasing of security. Occupiers of premises in which a specified pathogen or toxin is kept or used must notify the Secretary of State initially within a month of the implementation of Part 7 of the Act and again before such a pathogen or toxin is kept or used. The premises must be a discrete area which is secure or capable of being made secure. Police have powers to inspect such premises and to give directions as to their security. Follow-up checks will be made when the work has been done. If the security measures are not taken the Home Office is notified and the power to require the occupier to dispose of the substance(s) could be exercised. Failure to comply is a criminal offence. The Police have power to seize and retain dangerous substances but this would only be done with extreme caution and with professional advice from HSE.*

10. Staff comments from one organisation queried why the information should be available at all. **HSE response:** *It is Government and HSE policy for work on Regulations to be open and transparent. Regulation 24 of the Genetically Modified Organisms (Contained Use) Regulations 2000 (GMO(CU)) requires the Competent Authority to maintain a Public Register (the Register) to:*

- *ensure that the public have access to information on all notified premises and activities;*
- *give the public an opportunity to see information relating to notifications and let the Competent Authority know if they have any comments on control measures and risks of activities.*

*The underlying reason for regulation 24 is Article 19(3) of the Council Directive 90/219/EC on the contained use of genetically modified micro-organisms as amended by Commission Directive 94/51/EC and Council Directive 98/81/EC which GMO(CU) implements in the UK. Article 19(3) states that certain information may 'in no case ..... be kept confidential'.*

## **Respondents' reservations, questions and suggestions**

11. Whilst there was general support for the draft regulations, nevertheless a number of reservations, questions and suggestions were raised.

### Access to the Register

12. Two respondents thought that those accessing the Register should have to identify themselves, and that enquirers should not be allowed to be anonymous. **HSE response:** *At present the Competent Authority does know the identities of those accessing the Register, as they need to make appointments to view the Register. However, HSE is committed to putting the Register onto the Internet (though this is a few months' away) - once this is done it will not be possible to trace who accesses it.*

13. Two respondents suggested that the Competent Authority should notify the GM centre when information was withheld from the Register. **HSE response:** *This will be done.*

14. One commentator suggested that the Competent Authority should notify the GM centre of any enquiries about it prior to the reopening of the Register. **HSE response:** *This suggestion has been overtaken by events, namely the re-opening of the Register.*

15. Three respondents commented on the need to ensure that withholding information did not delay the processing of notifications to the Public Register. **HSE response:** *Withholding information will not in fact delay the notification process.*

16. Three respondents (two of whom made comments against the proposals) commented on the effect on civil liberty and democracy. **HSE response:** *HSE is committed to openness and transparency. This is an unusual, and temporary, step taken in the light of national security with careful consideration being given to the balance between civil liberty and national security. The measure will be reviewed annually.*

17. Three respondents thought that the type of work being done should still be available, even if the details such as location were withheld. **HSE response:** *The Technical Sub-Committee of the Advisory Committee on Genetic Modification (TSC of ACGM) which advised the Secretary of State on which genetically modified (GM) activities and locations should be excluded from the Register agreed with this suggestion and recommended that the Register should list the pathogens on which*

*work is being done in GB, but not their location or the specific activity involved. This has been done.*

18. One respondent was concerned that 'national security' was the grounds for withholding information; their concern was with worker safety, particularly the threats posed by activists. They requested that ACGM should re-examine the changes made at greater leisure to identify whether anything could be done to clarify the circumstances in which material might be withheld from the Register, and to identify whether other measures could be taken to strengthen worker protection. **HSE response:** *HSE appreciates the concerns for workers. The names of employees and others are not included in the Register. Measures being taken under Part 7 of the Anti-terrorism, Crime and Security Act 2001 will mean greater security for premises where pathogens and toxins are kept. This will have the knock-on effect of greater security for those working in those premises. A system of annual review of the list of pathogens excluded from the Register is being put in place - this will include consideration of the matter by ACGM or its sub-committee.*

#### Confidentiality and legitimate access to information

19. Three respondents who favoured the proposals and two against the proposals pointed out that the information was available elsewhere. Several respondents were concerned that the provision in new regulation 23A, which requires information to be kept confidential so long as the Secretary of State is of the opinion that such information should be kept confidential in the interests of national security, would have a detrimental affect on other legitimate use of the information which would be withheld from the Public Register under this provision. Concerns were expressed from a number of viewpoints:

- access would be denied to expert committees whose responsibility it is to ensure safety;
- conflict with international weapons control;
- the need for researchers to keep pace with developments in the science and to obtain scientific data.

**HSE response:** *The primary aim of the Amending Regulations is to ensure that information can be kept off the Register if the Secretary of State considers that the inclusion of the information in the Register would be contrary to the interests of national security (new regulation 24A) - most respondents were in favour of this measure. There would be a lack of consistency in the Regulations if new regulation 23A were not included. This inconsistency would arise because, under new regulation 24A, information which the Secretary of State considered harmful to national security would be kept off the Register (and thus not available to the public). After careful consideration, HSE recommended to the Minister that he sign the regulations containing both new regulations 23A and 24A intact as most respondents were found to be in favour of these proposals. See para 35 for HSE's response on the perceived conflict with international weapons control.*

20. Two organisations recognised the need for information still to be available for evaluation by the Competent Authority and the European Commission (EC), but emphasised that these bodies must keep the information confidential. One commentator sought clarification as to whom exactly in the EC, the information would be disclosed, and another sought clarification on whether the Directive restricted the EC's right to disclose confidential information. **HSE's response:** *HSE will make clear that if information withheld from the Register is divulged to the Commission then such information should be kept confidential. This already happens where any information is forwarded to the Commission in respect of notifications covered by reg 22(2) of GMO(CU) and reg 4(2)(a) of the Environmental Information Regulations 1992.*

### The sift and reopening of the Register

#### *Criteria for removal of entries to the Register*

21. 10 respondents considered that there needed to be criteria for removal of items from the Register. 6 of these respondents specifically argued that the criteria should be contained in the regulations. **HSE's response:** *Experts from the TSC of ACGM considered what should be on the list on 23 January 2002. They advised that information on location of and activities on all pathogens and toxins listed in Schedule 5 of the Anti-terrorism, Crime and Security Act 2001 should be excluded from the Register, but that the Register should contain a list of those pathogens being worked on in GB. These criteria were recommended to the Secretary of State who has issued a Direction to this effect. The measure will be kept under annual review, and it is therefore inappropriate for the criteria for removal of the entries to be contained in the Regulations themselves.*

22. One respondent asked whom the Secretary of State would consult before making a decision on the information to be removed from the Register. Three respondents thought that the Secretary of State should have to justify the information he directed to be excluded from the Register. **HSE response:** *The TSC of ACGM was invited to give their expert opinion to the Secretary of State before he made a decision on what information should be withheld. HSE and the other members of the Competent Authority agree with their recommendations.*

#### *The sift*

23. One respondent suggested that the sift of the register should be done by an expert committee (not civil servants). **HSE response:** *A review was carried out by an expert committee (TSC of ACGM). The sift was done by HSE (who receive notifications and hold the Register) on behalf of the other members of the Competent Authority.*

24. One respondent suggested that the information withheld from the Register should not be restricted to that in Schedule 5 to the Anti-Terrorism, Crime and Security Act. **HSE response:** *It was because the Schedule 5 list might not have been deemed appropriate, that expert advice was sought from TSC of ACGM to ensure*

*that all necessary information was withheld. After considering a range of options from re-opening the Register unabridged, to employing Schedule 5 either alone or with an additional list of pathogens compiled by members, TSC of ACGM recommended that the Schedule 5 list was used.*

25. One respondent had reservations concerning the monitoring systems operating in regard to decisions made to withhold information generally. **HSE response:** *There will be an annual review of the measures. Independent advice will be sought from the Advisory Committee on Genetic Modification and its Technical Sub-Committee will be invited to review the activities which have been withheld from the Register.*

#### *Opening up the Register*

26. Three respondents commented on arrangements for opening up the Register once the terrorist threat had passed; one respondent sought protocols; another felt it should be opened up on freedom of information grounds and a further respondent expressed the hope that it would be opened again. **HSE response:** *HSE is committed to the Government's policy of openness and transparency. The information withheld from the Register will be subject to annual review with the aim of keeping to a minimum information which has to be excluded in the interests of national security. Although details of locations and activities will be withheld, the Register will contain a list of pathogens and toxins on which activities involving genetic modification is being carried out. See also 42 and 48*

27. One respondent asked if there would be protocols and facilities to examine the Register and any hidden entries if sufficient clearance was given. **HSE response:** *No, it will not be possible for members of the public to be able to see information which has been kept off the register on grounds of national security.*

#### Review of the measure

28. 4 respondents expressed the view that there should be a regular review of the measures being taken. **HSE response:** *The measure will be reviewed annually.*

#### **Comments around the working of the revised Register**

29. One respondent emphasised the need for proper controls and inspections to continue to take place and another commented that risk assessments and evaluations should still be required. **HSE response:** *Without question inspections and requirements for risk assessments and evaluations will continue as before.*

30. One respondent expressed the view that the public should be told how many entries were excluded. **HSE response:** *Following the signing of the Direction on 9 February, 42 out of 1128 notified activities have been excluded from the Register.*

## Freedom of information

31. One respondent pointed out that new freedom of information issues would be raised and asked for full weight to be given to the views on this issue. **HSE response:** *There are exemptions covering national security in the non-statutory Code of Practice on Access to Government Information (Exemptions 1(a) and 4(e) which HSE is adhering to until implementation of the Freedom of Information Act comes into force in 2005. The Act also has an exemption relating to national security.*

## Guidance

32. 4 commentators pointed up the need for guidance. **HSE response:** *Guidance is being produced - this will be available as soon as possible.*

## **Reasons commentators were against the proposals**

33. 6 commentators were against the proposals. Their objections were centred on specific issues - some of these issues reflected the reservations felt by those who supported the proposals, but they are included here for completeness.

34. Two commentators pointed out the information was available elsewhere (a point also noted by 3 commentators in favour of the proposals); one commenting that the information would therefore be of little use to terrorists. **HSE response:** *HSE acknowledges that information is available elsewhere, if an effort is made to find it. However, the Public Register is the only place where all the information is collated in one place. In the circumstances surrounding the aftermath of 11 September, the Government cannot be seen to provide a 'route-map' to pathogens which might be of interest to terrorists.*

35. Two commentators considered that the measures would conflict with international efforts to prevent the development of biological weapons under the Biological and Toxin Weapons Convention (BTWC); they believed that the measures could inadvertently create suspicion internationally that the UK was concealing biological weapons development. **HSE response:** *HSE sought advice from the Ministry of Defence's Defence, Science and Technology Laboratory (DSTL) on the question of closure of the Register conflicting with international efforts towards non-proliferation of biological weapons under BTWC. Their advice is that:*

1 *It is difficult to see how the decision of HSE to remove information on GM work from the Public Register could adversely impact on the UK's legally binding or politically binding commitments to the 1972 BTWC.*

2 *The UK is fully committed to providing annual returns of information to other States Parties under the modalities of the Confidence Building Measures (CBM) agreed at the 3rd Review Conference of BTWC in 1991.*

*The information requested under the CBM regime does not include specific information on genetic modification work, but information is volunteered that*

*GM work is carried out. The CBM returns are provided for the information of the other States Parties: there is no requirement under BTWC for the returns to be made publicly available.*

3 *DSTL, who advise MOD on the scientific and technical aspects of the UK's implementation of BTWC, are aware of no requirement under BTWC to disclose information on the premises where GM work is performed, or where any specified type of GM material is held.*

4 *At the Fifth Review conference of BTWC in Geneva, there has been universal condemnation of the recent terrorist attacks with anthrax in the US, and a number of State Parties - including the UK - have proposed that State Parties should review and if necessary reinforce their national legislation and procedures for preventing the acquisition of micro-organisms (and toxins) for other than peaceful purposes. Article IV of the Convention states:*

*'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.'*

*Acquisition would include acquisition by state, or sub-state actors, including terrorists.*

5 *DSTL stated that far from weakening BTWC, the provisions of the new Anti-terrorism, Crime and Security Act are a step to enhancing UK national implementation of the requirements of Article IV of BTWC and thus serving to strengthen the Convention.*

*In the light of the above, the move to close the Register temporarily and legislate for the removal of certain GM items from it, would also serve to strengthen the Convention.)*

36. 3 respondents said that there was no evidence that the anthrax used in the US attacks was GM anthrax. **HSE response:** *Whether or not the anthrax used in the US was GM anthrax, HSE received enquiries relating to the Public Register about anthrax. It was therefore felt prudent to temporarily close the Register and take legal advice on the next best steps.*

37. 3 commentators argued that the broader public interest would be damaged through lack of scrutiny and two others thought that individuals had a right to know what their government and researchers were doing and one feared that public accountability would be permanently eroded. One respondent went on to argue that dangerous experiments should be put to the vote. **HSE response:** *As noted in para 17 above,*

*the Register will list the pathogens on which work is being done in GB on which details of local and specific activity involved have been excluded from the Register, but not their location or the specific activity involved. This will be done. Inspections and requirements for risk assessments and evaluations will continue as before. Annual review of the measure will ensure that the information is put back in the public domain as soon as the terrorist threat is past.*

38. One commentator argued that increasing security on the access to all potentially harmful pathogens would be a better approach. **HSE response:** See para 9 above.

39. One respondent expressed concern that there was no definition of 'security' in the draft regulations; no possibility of challenge; and that 'confidentiality in the interests of national security' meant that even expert committees would be denied access to material. **HSE response:** *No definition of 'security' appears in the Regulations as 'in the interests of national security' is a phrase widely used and accepted. HSE does not consider there is a need for specific provisions to be made for challenge - all citizens are free to write to the Secretary of State and challenge his decisions if they do not agree with them and a person is also free to take such legal action as he/she considers appropriate. HSE sought the advice of the relevant expert committee (TSC of ACGM) before putting recommendations to the Secretary of State on what information should be excluded from the Register. It will seek similar advice when each annual review falls due.*

40. One commentator criticised the consultation document as being more about 'form' than substance and putting the question of clarity of the proposed regulations before the substantive questions. **HSE response:** *HSE used a standard format for the questionnaire attached to the response, which puts clarity of the regulations first. HSE acknowledges, that on reflection, this should not have been the first question posed and that more searching questions could have been asked; this will be borne in mind for future consultation exercises. Nevertheless, the form did not prevent respondents from making their views perfectly clear.*

41. One respondent considered it was not clear whether only GM anthrax would be excluded from the Register. **HSE response:** *The draft regulations did not specifically refer to GM anthrax but any information referred to in regulations 22(3) and 23(3) if, and so long as, the Secretary of State is of the opinion that such information should be kept confidential in the interests of national security.' However, the mention of GM anthrax in the covering letter may have been the reason for some misunderstanding of the intention.*

42. One respondent commented that the proposals did not indicate what provision had been made to return information to the public domain or when. **HSE response:** See para 26 above.

43. One commentator expressed concern that the proposals provided the Secretary of State with unreasonable and virtually unrestricted scope. **HSE response:** As noted

*in paras 21 and 22 above, the Secretary of State has sought expert, independent, advice from the TSC of ACGM before taking a decision on what information should be excluded from the Register. He will continue to take similar advice before reviewing the measure each year.*

44. One respondent considered that the 'sleeper' terrorist threat was just as likely to come from within organisations that developed technology as from outside. **HSE response:** *In addition to the security measures outlined at 9 above, the Anti-terrorism, Crime and Security Act 2001 gives Police powers to carry out background checks on personnel with access to specified pathogens and toxins and if necessary to prevent such access. The Police can require the occupier to supply a list of everyone who has access to the premises together with specified information about them. The occupier then has to ensure that anyone not on the list does not have access (unless exercising a statutory right or duty). Where a check indicates that it would not be in the national interest for a particular person to have access, the Secretary of State is empowered by the Act to issue a notice directing that they shall not have access.*

45. One respondent considered that the restricted time frame for consultation would exclude significant sections of society from being included in resulting decisions. **HSE response:** *Only 4 of about 850 consultees commented on the shortness of the consultation period. HSE consulted widely and received a 10 per cent response which is a good average. The consultation was announced through a press notice and on HSE's web-site to ensure that all interested parties were aware of the proposals. Only one response was received well after the consultation period ended.*

46. One commentator thought it was unreasonable to assume that members of the public would be sufficiently versed in regulatory practices to understand the extent of the implications of the proposal. **HSE response:** *Because of the difficulties experienced by some in interpreting the intention of legal language in draft regulations, HSE was at pains in its consultative letter to make clear the intention and implications of the proposals. The consultation in general received positive feedback. Commentators were very helpful in pointing out the full implications of the proposals and their impact will be explained in the forthcoming guidance.*

47. One commentator suggested that the answer was to destroy the materials or increase security. **HSE response:** *The materials are of great benefit - they are used to advance medical treatment and scientific knowledge. To destroy the materials would therefore be counter-productive to the general benefit of the public at large. Security of premises is being increased under the Anti-terrorism, Crime and Security Act 2001 and the Police are actively advising on improved security measures.*

48. One respondent commented that the Register was an important part of democracy; citizens - especially those who lived near the laboratories concerned - had a right to know what work was permitted to be carried out. **HSE response:** *See para 26 above.*

49. One respondent asked when the Government planned to free up staff time to open the Register excluding items of interest to terrorists. **HSE response:** *It would have been inappropriate for HSE to pre-empt the Secretary of State's Direction by opening up the Register with the sensitive entries excluded before that Direction was issued. The Register was opened immediately after the Minister signed the Direction authorising the removal of entries detailing the location of and activities relating to the list of pathogens and toxins contained in Schedule 5 of the 2001 Act. HSE had put all resources with the specialist knowledge required to maintain the Register into doing preparatory work so that the Register could be opened as soon as the Direction was signed. The Direction could not be made until the Regulations came into force, and was made at the earliest possible opportunity thereafter. The Regulations came into force on 8 February 2002, the Direction was signed by the Minister on 9 February (Saturday) 2002 and the Register opened at 9 am on the next working day - 11 February 2002.*

50. One respondent asked why experiments with GM material were being carried out and who gave authority for them. **HSE response:** *All contained use activities involving GMOs are subject to GMO(CU)2000. Anyone carrying out such work must notify the Competent Authority (DEFRA and HSE for England and Wales and the Scottish Executive and HSE for Scotland) of their intention to use their premises for contained use for the first time; notify class 2, 3 and 4 activities; and must await consent for Class 3 and 4 activities.*

### **Comments on the text of the draft regulations**

51. 11 respondents specifically commented that the draft regulations were clear.

52. 2 respondents specifically commented that the draft regulations were unclear - one because of the legal language, the other because criteria for withholding information were not laid down in the draft regulations. **HSE response:** *HSE lawyers have endeavoured to make the final regulations clear. Guidance to the Regulations will be issued shortly. For comments on criteria see para 21 above.*

### **Comments on the consultation process**

53. Of the 61 respondents who thought the Consultation Letter represented the different policy issues very well or well, 3 made favourable written comments on the clarity of the letter.

54. 4 respondents made specific written comments about the shortness of the consultation time. **HSE response:** *The Health and Safety Commission normally expects a 3 month consultation period. However, in view of the urgency of the proposals following the events on and subsequent to 11 September, the Commission agreed an exceptionally short period of consultation because of the urgency of the issue and the interests of national security. The measure will be subject to annual*

review; consultees are welcome to put forward any views for input to that review to the Biotechnology Policy Unit of HSE at Rose Court, 2 Southwark Bridge, London SE1 9HS.

55. One individual commented that ACGM should have been consulted at an earlier stage. **HSE response:** *ACGM was informed of the temporary closure pending legal advice at their meeting preceding the open meeting on 30 October 2001.*

56. One respondent specifically commented that the consultation letter represented the different policy issues quite well.

57. One commentator suggested that consultation could be improved if HSC made explicit the array of policy implications of the proposals and that this should be supported by independent assessments from a variety of perspectives. **HSE response:** *It would have been impracticable in the time-scales concerned to get any independent assessments before the proposals went out to consultation. Any future policy matters will (as is normal procedure) be put to the ACGM first for independent review. The TSC of ACGM gave an independent assessment of the information to be withheld from the Register before a recommendation was put forward to the Minister.*

#### **Questions and comments not covered elsewhere**

58. A number of comments and questions were raised by commentators.

59. One respondent queried whether the terrorist threat was real. **HSE response:** *Action had to be taken. As can be seen from wider action being taken by the Government, such as the 2001 Act, and measures being taken farther afield, intelligence shows that the threat is real.*

60. One university commented that it was happy with the Competent Authority.

61. One pressure group asked if the production of GM animal feed seeds or other seeds was included. **HSE response:** *No. GM animal feed seeds and other seeds are not covered by GMO(CU).*

62. Three commentators asked what measures were being taken on non-GMOs. **HSE response:** *Measures being taken on non-GMOs are beyond the scope of the Regulations. Where non-GMOs are concerned, HSE is withholding information relating to premises working with the dangerous pathogens listed in Schedule 5 of the Anti-terrorism, Crime and Security Act 2001 and information relating to consignment of those pathogens. This is being done using the exemptions provided in the Code of Practice on Access to Government Information (exemptions 1(a) 'national security' and 4(e) 'safety of the public or buildings' as appropriate).*

63. One respondent commented that disclosure of the more detailed information held by HSE than that which appeared on the Public Register was of at least equal, and often more, importance. **HSE response:** *The Public Register of notifications*

*contains all (non-confidential) information notified on premises and individual activities, including the nature of work to be carried out at premises, the purpose of individual activities and the characteristics of the GMOs involved. Simply to save space, the full risk assessment of an activity is not placed on the Register, but may be viewed on request.*

64. One respondent pointed out that no proposals for breaches of the system were included, and asked if they were already in place. **HSE response:** *The enforcement provisions of the Health and Safety at Work etc. Act 1974 referred to in regulation 26(1)(a) of the Genetically Modified Organisms (Contained Use) Regulations 2000, as amended, will apply in respect of any breach of the provisions contained in those Regulations.*

65. One respondent wanted to know how it was decided that material should be withheld and by whom. **HSE response:** *See para 21 above.*

HSE Biotechnology Policy Unit  
February 2002