

To all those on the list at Annex B

22 November 2001

Dear Consultee

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

1. Following the terrorist attacks on the United States on 11 September and subsequent events, it has become necessary to make urgent amendments to the Genetically Modified Organisms (Contained Use) Regulations 2000 (GMO(CU)). A draft of the proposed Amending Regulations is attached to this letter at Annex A.
2. In view of the urgency associated with amending the Regulations in relation to the Public Register, I should be grateful to receive your reply no later than **7 December 2001**.
3. The Health and Safety Commission (HSC) has a statutory duty to consult to elicit stakeholders' views on proposals. HSC believes that this enables an open and transparent approach to decision-making which is essential if policies and decisions are to have widespread ownership and reflect the needs and aspirations of the people they will affect. The Commission then decides on the best way forward based on an interpretation and analysis of the results of the exercise. The Commission recognises the need to take urgent action on the Public Register and has therefore agreed to a consultation period of two weeks.

Purpose of consultation

4. There is a need to provide a legitimate basis for the use of discretion to withhold information about the contained use of certain genetically modified organisms (GMOs) in the interests of national security. The reason for the change is to prevent terrorists obtaining information which could lead them to sources of GMOs which could be used as biological weapons.

Scope of GMO(CU)

5. GMO(CU) cover the whole of Great Britain ie England, Wales and Scotland. The Scottish Parliament is empowered to make its own regulations on the environmental and public health provisions of the European Directive 98/81/EC

which GMO(CU) implement. However, the Scottish Parliament has not yet sought to exercise this power. Similarly, the National Assembly for Wales may in the future seek and be granted similar powers to those already devolved to Scotland. It too may wish to make separate regulations in due course. GMO(CU) do not apply in Northern Ireland, who have their own equivalent Regulations.

What is the issue we are consulting on?

Withholding information from the Public Register

6. Regulation 24 of GMO(CU) requires the Competent Authority to maintain a Public Register to:

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

In England and Wales, the Competent Authority comprises HSE, the Secretary of State (Department for the Environment, Food and Rural Affairs) and the MAFF Minister. In Scotland, the Competent Authority comprises HSE and the Scottish Ministers.

7. Following external enquiries about the location of genetically modified (GM) anthrax, and in the light of the events which took place on 11 September, the Health and Safety Executive (HSE) took the decision, on 18 October, to withhold temporarily and pending legal advice further access to the Register. The aim was to prevent such information getting into the public domain. The action was taken in the interests of national security and in the light of the present terrorist activity.

8. In order to act quickly, HSE had to close the whole Register (the Register contains information on a range of GMOs from fairly innocuous to very hazardous). This was the only practical thing to do since sifting through the Register to remove dangerous pathogens of interest to terrorists would take a considerable amount of staff time. In addition, there are a number of hard copies of the Register (full copies are held in Bootle and London, all HSE main offices hold copies covering their region, and HSE's Edinburgh office holds an edition covering Scotland); thus sifting and removing would have to be multiplied according to the number of locations and would require planning and co-ordination to ensure consistency.

9. The draft amending regulations attached at Annex A will, amongst other things, contain provisions to achieve this and will:

- allow the Secretary of State to authorise the exclusion from the Public Register: any information, or description of information, which would be contrary to the interests of national security;

- empower the Secretary of State to require the Competent Authority to submit specific descriptions of information to him for his determination as to whether they should be included in the register;
- give any person the opportunity to write to the Secretary of State saying why they think specific information should be excluded from the Register on grounds of national security. In these cases the information will not be included in the Register unless the Secretary of State decides that it should be included.

10. After a review and sift of entries on the Register have been carried out, it is proposed to re-open the Public Register. The re-opened Register would exclude those entries which the Secretary of State had authorised to be omitted. In the meantime, HSE has made arrangements to make available information to any enquirer on a case-by-case basis.

11. Provision in GMO(CU) relating to the Public Register reflects the terms of the underlying European Directive. HSE will therefore be notifying to the European Commission the action it proposes to take on its Public Register.

Who is affected

12. In withholding information from the Public Register the availability of information on notifications will be limited to a certain extent. This is likely to affect non-government organisations and researchers with an interest in the environment and academic institutions who make appointments to view the contents of the register from time to time.

What will happen after this consultation

13. Following this consultation revised proposals will be put to the Health and Safety Commission in mid-December. The draft regulations will then be submitted to the Secretary of State for signature and laying before Parliament before Christmas. It is anticipated that the regulations would then come into force in mid-January.

Regulatory impact assessment

14. A formal regulatory impact assessment has not been made on these proposals because there are no costs to industry, the voluntary sector, charities or consumers arising from these proposals. The benefits cannot be costed, but would be enormous given that the exclusion of certain information from the Public Register would prevent terrorists from obtaining easily information which they could use to obtain GM materials for ulterior motives.

When and where to send your response

15. Given the urgent nature of the proposal the Health and Safety Commission has agreed a short consultation period and your comments are therefore sought by **Friday 7 December 2001**.

16. Please send your response to:

Mrs Jackie Germain
Health and Safety Executive
Health Directorate B
6th Floor, North Wing
2 Southwark Bridge
London SE1 9HS

Tel: 020 7717 6348
Fax: 020 7717 6199
e-mail: jackie.germain@hse.gsi.gov.uk

You may, if you wish, use the questionnaire at Annex C to send in your response.

17. If you reply to this Consultation Document in a personal capacity, rather than as a post holder of an organisation, you should be aware that information you provide may constitute 'personal data' in terms of the Data Protection Act 1998. For the purposes of this Act, HSE is the 'data controller' and will process the data for health, safety and environmental purposes. HSE may disclose this data to any person or organisation for the purposes for which it was collected, or where the Act allows disclosure. You have the right to ask for a copy of the data and to ask for inaccurate data to be corrected.

18. We will acknowledge all responses and give full consideration to the substance of arguments in the development of proposals; we may also contact you again if, for example, we have a query.

Complaints about this consultation

19. If you are not satisfied with the way in which this consultation exercise has been conducted you can complain by contacting Margaret Clare, Health Directorate Division B, Room 6.26, Health and Safety Executive, Rose Court, 2 Southwark Bridge, London SE1 9HS. We aim to reply to all complaints within 10 working days. If you are not satisfied with the outcome of your complaint, you can raise the matter with the Director General of HSE, Timothy Walker at the same address. You can also write to ask your MP to take up the case with us. Your MP may refer the matter to the Parliamentary Commissioner for Administration (the Ombudsman) who will investigate your complaint.

Yours sincerely

Liz Sawyer
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STATUTORY INSTRUMENTS

2001 No.

HEALTH AND SAFETY

The Genetically Modified Organisms

(Contained Use) (Amendment) Regulations 2001

<i>Made-</i>	-	-	-	2001
<i>Laid before Parliament</i>				2001
<i>Coming into force</i>				2002

The Secretary of State, being the Minister designated^(a) under section 2(2) of the European Communities Act 1972^(b) in relation to the control and regulation of genetically modified organisms and in the exercise of the powers conferred on him by the said section 2(2)^(c) and sections 15(1) and (2) and 82(3)(a) of, and paragraphs 15(1) and 16 of Schedule 3 to, the Health and Safety at Work etc. Act 1974^(d) ("the 1974 Act") and of all other powers enabling him in that behalf and for the purpose of giving effect without modifications to proposals submitted to him by the Health and Safety Commission under section 11(2)(d) of the 1974 Act after the carrying out by the said Commission of consultations in accordance with section 50(3) of that Act, hereby makes the following Regulations:

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- (a) S.I. 1991/755.
- (b) 1972 c.68; the enabling powers conferred by section 2(2) were extended by virtue of section 1 of the European Economic Area Act 1993 (c.51).
- (c) As regards Scotland, see also section 57(1) of the Scotland Act 1998 (c. 46), which provides that, despite the transfer to the Scottish Ministers by virtue of that Act of functions in relation to observing and implementing obligations under Community law, any function of a Minister of the Crown in relation to any matter shall continue to be exercisable by him as regards Scotland for the purposes specified in section 2(2) of the European Communities Act 1972.
- (d) 1974 c.37; sections 11(2), 15(1) and 50 were amended by section 116 of, and paragraphs 4, 6 and 16 respectively of Schedule 15 to, the Employment Protection Act 1975 (c.71).

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2001 and shall come into force on 2002.
2. The Genetically Modified Organisms (Contained Use) Regulations 2000(a) shall be amended in accordance with the following provisions of these Regulations.
3. In regulation 22(3), after the words "following information, which" there shall be inserted the words ", subject to regulation 23A,".
4. In regulation 23(3), after the words "following information, which" there shall be inserted the words ", subject to regulation 23A,".
5. After regulation 23, there shall be inserted the following regulation, namely —

"Confidentiality in the interests of national security

23A –(1) There shall be kept confidential 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.

(2) Where the Secretary of State is of the opinion that information referred to in regulation 22(3) should be kept confidential in the interests of national security, that information shall not be disclosed except —

(a) to the extent necessary to evaluate the notification in question; and

(b) to the European Commission.

(3) Where the Secretary of State is of the opinion that information referred to in regulation 23(3) should be kept confidential in the interests of national security, that information shall not be disclosed except to the extent necessary to

(a) S.I. 2000/2831.

enable the competent authority to comply with its obligations under regulation 21(2).

(4) A person who receives information by virtue of paragraph (2)(a) or paragraph (3) shall not use that information except for the purposes of the competent authority."

6. In regulation 24 —

(a) for paragraph (1), there shall be substituted the following paragraph, namely -

"This regulation is subject to regulation 24A.";

(b) in paragraph (2), for the words "register referred to in paragraph (1)", there shall be substituted the words -

"competent authority shall maintain a register of every notification submitted under regulations 9 to 12 and the register";

(c) in paragraph (3), there shall be omitted the words "referred to in paragraph (1)"; and

(d) after paragraph (10), there shall be added the following paragraph, namely

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"(11) In this regulation, "the register" means the register maintained by the competent authority in accordance with paragraph (2).".

7. After regulation 24 there shall be inserted the following regulation, namely —

"Information not to be included in the register

24A.---(1) No information shall be included in the register if and so long as, in

the opinion of the Secretary of State, the inclusion in the register of that information, or information of that description, would be contrary to the interests of national security.

(2) For the purpose of securing the exclusion from the register of information to which paragraph (1) applies, the Secretary of State may give to the competent authority directions -

(a) specifying information, or descriptions of information, to be excluded from the register; or

(b) specifying descriptions of information to be referred to the Secretary of State for his determination.

(3) No information referred to the Secretary of State pursuant to paragraph (2)(b) shall be included in the register until the Secretary of State determines that it should be so included.

(4) The competent authority shall notify the Secretary of State of any information it excludes from the register in accordance with directions given to it under paragraph (2).

(5) A person may give a written notice to the Secretary of State -

(a) specifying information which appears to that person to be information to which paragraph (1) may apply; and

(b) indicating its apparent nature.

(6) If a person gives a written notice pursuant to paragraph (5), at the same time he shall give written notice to the competent authority that he has done so.

(7) No information notified pursuant to paragraph (5) shall be included in the register until the Secretary of State has determined that it shall be so included.

(8) In this regulation, "the register" means the register maintained by the competent authority in accordance with regulation 24(2)."

Signed by authority of the
Secretary of State for Transport
Local Government and the Regions

[Date]

Minister of State
Department of Transport Local
Government and the Regions

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Genetically Modified Organisms (Contained Use) Regulations 2000, S.I. 2000/2831 ("the 2000 Regulations") certain provisions of which implement as respects Great Britain Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms, as amended by Commission Directive 94/51/EC and Council Directive 98/81/EC. The principal amendments are contained in -

(a) regulation 5, which inserts a new regulation, regulation 23A, which makes provision for keeping information confidential in the interests of national security; and

(b) regulation 7, which inserts a new regulation, regulation 24A, which makes provision for the exclusion from the register, maintained in accordance with regulation 24 of the 2000 Regulations, of information where, in the opinion of the Secretary of State, the inclusion of such information on the register would be contrary to the interests of national security.

ANNEX B

LIST OF COMPANIES AND ORGANISATIONS TO BE CONSULTED ON THE PROPOSED GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) (AMENDMENT) REGULATIONS

EMPLOYER ORGANISATIONS

Association of Independent Businesses
British Chambers of Commerce
Confederation of British Industry
Federation of Small Businesses
Association of British Plant Breeders
Bio Industry Association
Brewers and Licensed Retailers Association
British Veterinary Association
Committee of Vice Chancellors and Principals
Food and Drink Federation
National Farmers Union
Water Utilities Association

EMPLOYEE ORGANISATIONS

Trades Union Congress
Association of Teachers and Lecturers
Institution of Professionals, Managers and Specialists
Manufacturing, Science and Finance Union

PROFESSIONAL BODIES & OTHER REPRESENTATIVE BODIES

Campaign for the Freedom of Information
Consumers Association
English Nature
Friends of the Earth
GeneWatch

Green Alliance
Greenpeace
Institute for Animal Health
Institute of Biology
Institute of Occupational Health and Safety
Institute of Occupational Medicine
Institute of Waste Management
Institute of Water & Environment Management
National Consumer Council
National Council of Women
National Institute For Standards and Control
National Institute of Biological Standards
Royal Pharmaceutical Society of Great Britain
Royal Agricultural Society of England

EDUCATIONAL & RESEARCH ESTABLISHMENTS

Advisory Council for Research and Development
Biotechnology and Biological Sciences Research Council
Cancer Research Campaign
Consortium of Local Education Authorities for the Provision of School Science
Council of Science and Technology
Department of Epidemiology and Public Health
Economic and Social Research Council
Imperial Cancer Research Fund
Medical Research Council
National Environment Research Council
Royal College of Physicians
Royal Environmental Health Institute - Scotland
Science Research Council
Scottish Schools Equipment Research Centre

The Association for Science Education

GOVERNMENT DEPARTMENTS AND AGENCIES

Cabinet Office

Central Veterinary Laboratory

Civil Service Occupational Health Service

Defence Evaluation Research Agency

Department for Education and skills

Department of the Environment, Food and Rural Affairs

Department of Health

Department of Trade and Industry

Environment Agency

Foreign and Commonwealth Office

Forestry Commission

Health and Safety Support Division

HM Treasury

Home Office

Laboratory of the Government Chemist

Ministry of Agriculture, Fisheries and Food

Ministry of Defence

Northern Ireland Office

Public Health Laboratory Service

Royal Highland and Agriculture Society of Scotland

Scottish Environment Protection Agency

Scottish National Heritage Agency

Scottish Executive

Veterinary Medicines Directorate

Welsh Development Agency

GM CENTRES

All GM centres involved in activities notified under the GMO(CU)

**PROFORMA FOR COMMENTS ON THE PROPOSALS TO AMEND
THE GENETICALLY MODIFIED ORGANISMS (CONTAINED USE)
REGULATIONS 2000**

We should like you to tell us what you think about the proposals set out in this consultative letter. You are welcome to comment on any aspect of the proposals, but we are particularly interested in your views on those set out in this proforma. You may find it useful to place your comments in the spaces provided, but you are free to submit comments in whatever way you prefer.

We shall acknowledge all responses and give full consideration to them in the development of the proposals. In some instances, we may contact you to discuss your comments further.

The Commission tries to make its consultation procedure as thorough and open as possible. After the close of the consultation period, responses to this consultation letter will be lodged in the Health and Safety Executive's Information Centres where they can be inspected by members of the public or copied to them, on payment of a fee to cover the costs of doing so.

Responses are invited on the basis that anyone submitting them agrees to them being dealt with as described above. Responses, or parts of them, will be withheld from the Information Centres only at the express request of the person submitting them. In such cases, a note will be put in the index to the responses to identify those who have commented but asked for some or all of their views to be kept confidential.

If you are dissatisfied with the way in which this consultation exercise has been carried out, you have the right to complain.

Address

Telephone, fax, e.mail

Please circle the appropriate answer to the following questions, adding comments if you wish. The cited paragraph numbers refer to the main text of the Consultation Letter.

1 Overall clarity of the proposed Regulations (paragraph 9 and Annex A)

Are you satisfied with the clarity of the proposed Regulations?

Yes	Yes with reservations	No
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Please comment, if you wish, on the overall clarity of the proposed Regulations

If you represent an organisation which obtained the Consultation Letter on your own initiative - as opposed to receiving it unsolicited - please give a brief description of the nature, aims and interests of your organisation.

2. Withholding information held on the Public Register for the purposes of national security

Please comment if you wish on the proposal to withhold information held on the Public Register of notified activities under the GMO (Contained Use) Regulations 2000 for the purposes of national security.

3. The Consultation exercise

In your view, how well does the consultation letter represent the different policy issues involved in this matter:

Very well

Well

Not well

Poorly

If you answered 'not well' or 'poorly' how do you suggest things might be improved for the future (please add extra sheets if you wish)

Please return comments to Mrs Jackie Germain

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