EXPLANATORY MEMORANDUM TO THE

THE GENETICALLY MODIFIED ORGANISMS (TRANSBOUNDARY MOVEMENTS) (ENGLAND) REGULATIONS 2004

2004/2692

1. This explanatory memorandum has been prepared by the Department for Environment Food and Rural Affairs and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 These Regulations provide for the administration and enforcement (including penalties and offences) of Council Regulation (EC) No. 1946/2003 ("the Council Regulation"), which establishes a common system of notification and information for transboundary movements of genetically modified organisms (GMOs) and ensures coherent implementation of the provisions of the Cartagena Protocol on Biosafety[1].

3. Matters of Special Interest to the Joint Committee on Statutory Instruments

3.1 none

4. Legislative background

4.1 These Regulations are being made in order to provide for the administration and enforcement of Council Regulation (EC) No. 1946/2003 on transboundary movements of genetically modified organisms. The Council Regulation is binding in its entirety and directly applicable in all Member States.

4.2 Article 18 of the Council Regulation requires Member States to lay down rules on penalties applicable to infringements of the Council Regulation and to take all measures necessary to ensure that the provisions of the Council Regulation are adequately enforced.

4.3 The Council Regulation's objective is to establish a common system of notification and information for transboundary movements of genetically modified organisms (GMOs) and to ensure coherent implementation of the provisions of the Cartagena Protocol on Biosafety (a United Nations Multilateral Environment Agreement). The establishment of such systems should ensure an adequate level of protection on the field of the safe transfer, handling and use of GMOs that may have

[1] The Cartagena Protocol on Biosafety is a UN Multilateral Environment Agreement that creates an enabling environment for the environmentally sound application of biotechnology, especially in those countries without an existing developed domestic framework, by establishing minimum standards for the safe transfer, handling, and use of GMOs, with specific focus on transboundary movements of GMOs.

adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

5. Extent

5.1 With the exception of regulation 3(1), which designates a focal point for the UK these Regulations apply to England only.

6. European Convention on Human Rights

6.1 It is the view of Defra that these Regulations are compatible with the Convention rights.

7. Policy Background

7.1 The EC Regulation aims to establish a common system of notification and information for transboundary movements of genetically modified organisms (GMOs) and implements aspects of the Cartagena Protocol on Biosafety that are not already covered by existing EC legislation.

7.2 The Cartagena Protocol requires each Party to take necessary and appropriate legal, administrative and other measures to implement its obligations. Hence, the EC Regulation seeks to implement provisions of the Protocol which are not covered by existing EC legislation.

7.3 Imports of GMOs into and within the EC are covered by existing legislation. However, a common legal framework is needed for exports of GMOs in order to ensure compliance with the obligations in the Protocol regarding transboundary movements of GMOs.

7.4 Directive 2001/18/EC on the deliberate release into the environment of GMOs invited the Commission to bring forward a legislative proposal for implementing the procedures laid down in the Protocol and, in accordance with the Protocol, requiring Community exporters to ensure that requirements of the Cartagena Protocol are fulfilled.

8. Impact

8.1 A Regulatory Impact Assessment (RIA) has been prepared and a copy is attached to this Explanatory Memorandum.

9. Contact

Mr Robin Healey
Head of Regulatory & International GM Policy
Zone 3/F7
Ashdown House
123 Victoria Street
London

SW1E 6DE
Tel: 0207 082 8098
Fax: 0207 082 8086

FINAL REGULATORY IMPACT ASSESSMENT

UK (ENGLAND) ENFORCEMENT ARRANGEMENTS IMPLEMENTING REGULATION (EC) 1946/2003 ON TRANSBOUNDARY MOVEMENTS OF GENETICALLY MODIFIED ORGANISMS IN ENGLAND

Summary

i) This RIA is an impact assessment of the Genetically Modified Organisms (Transboundary Movements) (England) Regulations 2004 (the "domestic Regulations"). The domestic Regulations establish penalties and offences for non-compliance and set out provisions for domestic inspection arrangements related to Regulation (EC) No 1946/2003 on transboundary movements of GMOs (the "Council Regulation").

ii) The domestic Regulations also establish who will enforce the Council Regulation in England and grants powers to those inspectors for the purposes of enforcement. The domestic Regulations designate the Secretary of State for the Department for Environment, Food and Rural Affairs (DEFRA) as the focal point for the UK and as the Competent Authority for England.

iii) This RIA provides a cost-benefit analysis of the arrangements for domestic implementation and enforcement (including arrangements for inspections and the establishment of penalties and offences). As such, the analysis in this RIA is limited to this and is not concerned with the content of the Council Regulation. The provisions of Council Regulation referred to above were the subject of a previous and separate RIA process in 2002.

iv) The Council Regulation applies directly in all Member States, without the need for transposition. However, Member States do have some flexibility in terms of how the rules are enforced in England, such as:

a) the level of penalties and offences established;
b) who carries out the inspections;
c) number of inspections carried out;
d) the proportion of companies being inspected; and
e) level of support businesses are expected to provide for inspectors (e.g. do they have to provide desk facilities).

v) The hierarchy of penalties and offences as provided for in the domestic Regulations are in accordance with the provisions of the Council Regulation which states that "*the penalties provided for must be effective, proportionate and dissuasive*". The penalties meet Home Office policy guidelines for penalties and offences and are consistent with the legal maxima available under the European Communities Act 1972.

vi) In England, the inspection of records will be the responsibility of inspectors appointed as such for the purposes of these Regulations by the Secretary of State for Environment, Food and Rural Affairs. It is envisaged that the majority of enforcements will be carried out by the Health and Safety Executive's (HSE) GM Inspectorate, although the Central Science Laboratory's GM Inspectorate and local authorities will also have a role.

vii) Inspections are likely to be periodic, rather than a frequent occurrence. Defra will liaise with the enforcement bodies about the level of inspections required (e.g. the proportion of exporters being inspected). This will form part of the contract between Defra and HSE and the CSL GM Inspectorate, which will be reviewed on an annual basis.

viii) The only direct costs that businesses and institutions will incur as a result of the domestic Regulations and enforcement arrangements will be:

- costs relating to the storage of information relating to notifications and other documentation; and
- costs relating to staff time spent interacting with the inspectors during a visit.

ix) The domestic enforcement arrangements outlined in this RIA would bring economic, social and environmental benefits such as:

- businesses and institutions will be provided with a clear, centralised legal framework in which to work; and
- supporting the social and environmental objectives of the United Nations Cartagena Protocol.

1. Title of measure

1.1 The Genetically Modified Organisms (Transboundary Movements) (England) Regulations 2004 ("the domestic Regulations").

2. Purpose and intended effect

(i) Objective

2.1 The domestic Regulations put in place supporting measures for the domestic implementation of Regulation (EC) No 1946/2003[2] of the European Parliament and of the Council on transboundary movements of genetically modified organisms (GMOs) ("the Council Regulation").

2.2 The Council Regulation aims to establish a common system of notification and information for transboundary movements of genetically modified organisms (GMOs) and implements aspects of the Cartagena Protocol on Biosafety[3] that are not already covered by existing EC legislation.

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[2] OJ L 287, 05.11.2003, p.1

[3] The Cartagena Protocol on Biosafety is a UN Multilateral Environment Agreement that creates an enabling environment for the environmentally sound application of biotechnology, especially in those countries without an existing developed domestic framework, by establishing minimum standards for the safe transfer, handling, and use of GMOs, with specific focus on transboundary movements of GMOs. A copy of the Protocol can be found at www.biodiv.org/biosafety/default.aspx

2.3 The Council Regulation requires Member States to introduce a proportionate and effective hierarchy of offences and penalties related to the potential seriousness of the failure to comply with the various EU requirements. The domestic Regulations outlined in this document provide for such arrangements.

2.4 The Council Regulation applies DIRECTLY in all Member States without the need for transposition. There is no flexibility for Member States except in arrangements for enforcement. This RIA provides a cost-benefit analysis of the arrangements for domestic implementation and enforcement[4] of the Council Regulation's provisions (including arrangements for inspections and the establishment of penalties and offences). It is not concerned with the content of the Council Regulation itself. The provisions of Council Regulation referred to above were the subject of a previous and separate RIA process in 2002[5]. Details of the Council Regulation are included in these pages for background purposes only.

2.5 The Council Regulation applies to the whole of the UK. However, with the exception of regulation 3(1) which appoints a focal point for the UK, the domestic Regulations apply to England only. Scotland, Wales and Northern Ireland will consult separately on their own proposals.

(ii) Background

2.6 The supervision and control of transboundary movements of GMOs is important both for the protection of the world's biodiversity, the environment in general, and for the protection of human health. The Cartagena Protocol requires each Party to take necessary and appropriate legal, administrative and other measures to implement its obligations. Hence, the Council Regulation seeks to implement provisions of the Protocol which are not covered by existing EC legislation.

2.7 The UK ratified the Cartagena Protocol on 19 November 2003. The UK has been positively engaged with Cartagena throughout its existence and was involved in the four-year long negotiating process that ended with the adoption of the Protocol in January 2000. The UK's positive support of the Protocol has been widely documented amongst stakeholders. The majority of stakeholders have, therefore, been well aware for some time of the Government's intention to ratify fully the Cartagena Protocol's provisions and have been aware of the practical implications. The wide availability of the Protocol's text is witness to this fact. Responsible companies have been working in accordance with Cartagena for some time, in recognition of the future wide spread buy-in across the globe.

The existing regulatory regime & why it needs to change

[4] Enforcement arrangements in the context of this RIA mean inspection arrangements (who inspects, the powers of these inspectors) and penalties and offences for non-compliance with the provisions of Regulation (EC) No 1946/2003 on transboundary movements of GMOs.

[5] See http://www.defra.gov.uk/corporate/consult/cartagena/index.htm

2.8 Imports of GMOs into and within the EC are covered by existing legislation[6]. However, a common legal framework is still needed for exports of GMOs in order to ensure compliance with the obligations in the Protocol regarding transboundary movements of GMOs.

2.9 Directive 2001/18/EC on the deliberate release into the environment of GMOs invited the Commission to bring forward a legislative proposal for implementing the procedures laid down in the Protocol and, in accordance with the Protocol, requiring Community exporters to ensure that all requirements of the Advanced Informed Agreement Procedure[7] are fulfilled. The resulting legislation was Regulation (EC) No 1946/2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms[8].

2.10 The provisions of the Council Regulation apply DIRECTLY in all Member States without the need for transposition. There is no flexibility for Member States except in arrangements for enforcement[9]. As such, this RIA is not concerned with the costs and benefits associated with the provisions of the Council Regulation - it is only concerned with the analysis of impacts that may occur as a result of enforcement and inspection in England – no analysis of the provisions of the Council Regulation is given. More information about the Council Regulation and its provisions is included for background information at Annex 3.

(iii) Risk assessment

2.11 The supervision and control of transboundary movements of GMOs is important both for the protection of the world's biodiversity, the environment in general, and for the protection of human health. At the international level, the most important action we can take with regard to GMOs is to help all countries of the world – developed and developing alike – to reach informed decisions about GMOs.

2.12 The risks of not implementing the Council Regulation through domestic Regulations can be summarised as:

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6 Existing EC legislation includes Directive 2001/18/EC on the deliberate release into the environment of GMOs (OJ L 106, 17.04.2001, p.1), Regulation (EC) No. 1829/2003 on GM food and feed (OJ L 268, 18.10.2003, p.1) and Regulation (EC) No. 1830/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs (OJ L 268, 18.10.2003, p.24)

7 The Advanced Informed Agreement Procedure is set out in Articles 7 to 10 and 12 of the Protocol. Also see Annex 2 of this RIA.

8 OJ L 287, 05.11.2003, p.1

9 About 10% of EU environmental laws take the form of regulations. Regulations are directly binding in Member States and supersede any conflicting national laws. Member states may not transpose the provisions of regulations into national law, even if the national law is identical to the regulation. This ban on transposition arises from the fact that regulations must be applied directly by national courts and national administrative bodies; any transposing national legislation would be in conflict with the particular legal nature of regulations under the EC Treaty. For example, the types of measures which countries will have to take include the appointment of competent authorities to inspect, the publication of guides and notification forms, or the designation of national sanctions for violations of the law.
(Source: http://europa.eu.int/comm/environment/guide/part1.htm)

- The Government sends out a negative message about the UK's commitment to the principles of Cartagena. As a signatory and long-term supporter of Cartagena, this would be inconsistent with the UK's approach to this international agreement;
- Failure to implement Cartagena fully would go against the aims of the Protocol in creating an enabling environment for the environmentally sound application of biotechnology and would damage the effectiveness of the international agreement;
- Countries importing GMOs, including the EC, but particularly developing countries, would be without clear and specific international rules governing informed, evidence based decisions on the import and export of GMOs;
- Businesses and institutions exporting GMOs would be without a clear legal framework in which to operate. This could present such businesses with a risk of not knowing what their responsibilities and requirements were;
- Operators would have no protection from arbitrary trade decisions on their exports;
- Failure by the UK to comply with the requirements of an Council Regulation (including the failure to establish appropriate domestic enforcement arrangements) in England and failure to comply with the requirements as required by EC law presents an unacceptable risk of legal challenge from the Commission and a possible case of infraction[10].

(iv) Business sectors affected by the new Regulations

2.13 Only the impacts on businesses incurred as a direct result of the introduction of domestic enforcement arrangements are discussed in this RIA (i.e. only the impacts that occur as a result of the domestic Regulations).

2.14 A possible indication of the industry sectors that could be affected by the new Regulations could be given if we consider the range of products that may be exported from the UK:

GMOs for deliberate release into the environment:
- GM seeds
- GM animals
- GM plants
- GM flowers (e.g. GM carnations)

GMOs intended for direct use as food or feed, or for processing:
- Food products consisting of or containing GMOs (e.g. GM soy beans)
- Feed products consisting of or containing GMOs (e.g. soya)
- Commodities for processing (e.g. GM rapeseed)

[10] Where a Member State fails to comply with its obligations under the Treaty – for example, by not correctly transposing a directive (or not doing so on time), or by failing to implement it properly. Infraction cases are taken to the European Court of Justice by the Commission for trial if their Reasoned Opinion is not adequately answered. (source: http://www.cabinetoffice.gov.uk/regulation/ria-guidance/content/eu-glossary/index.asp)

GMOs intended for contained use:

- Laboratory products (e.g. GM micro-organisms)
- Pharmaceutical products for animal use[11] (e.g. vaccines)

Possible sectors that could be affected could therefore be:

- Seed industry
- Agricultural industry (e.g. GM animals)
- Feed industry (producers, processors and retailers)
- Food and drink industry (producers, processors and retailers)
- Commodity crop exporters
- Research and academia
- Pharmaceutical industry (not pharmaceuticals for humans)

2.15 No business in the UK currently exports GMOs for commercial purposes. As such, we cannot give an exact figure for how many such companies would be affected. However, a number of UK operators export GMOs for research purposes (e.g. field assessment, laboratory work). These companies will be affected by the new rules.

2.16 The majority of GMOs that are exported for research are kept in containment[12] in the EC. Although these products are kept in containment in the EC, this does not imply that this the GMO's final use. For example, the GMO in containment in Britain may be exported for deliberate release in another country.

2.17 The Health and Safety Executive (HSE) operates and enforces legislation in Great Britain that aims to control the risks to human health and the environment arising from activities involving GMOs in containment under the Genetically Modified Organisms (Contained Use) Regulations 2000[13]. Amongst other provisions, The Genetically Modified Organisms (Contained Use) Regulations 2000 require notification of all premises to HSE before they are used for genetic modification activities for the first time. As such, HSE inspects all premises in Britain that use GMOs in containment. There are currently 544[14] such active premises registered for contained use of GMOs. These businesses and institutions will be required to comply with the new legislation if they export GMOs. As these premises are already inspected by HSE, it is envisaged that HSE will also inspect them in respect of the domestic Regulations (as part of their existing inspection regime). This is discussed in more detail in sections 3 and 8.

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[11] Article 2(2) of the Council Regulation states, "Pharmaceuticals for humans that are addressed by other relevant international agreements or organisations are excluded from the scope of this Regulation".

[12] Containment means that physical, chemical or biological barriers are used to limit contact between GMOs and humans or the environment. Contained Use facilities therefore include; laboratories, animal houses, plant growth rooms and glasshouses, industrial fermenters used for large scale production of enzymes or therapeutics, and facilities to contain genetically modified farm animals.

[13] A summary of the Contained Use legislation can be found at: http://www.hse.gov.uk/infection/gmo/law.htm. Also see http://www.hmso.gov.uk/si/si2000/20002831.htm and the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002 http://www.hmso.gov.uk/si/si2002/20020063.htm.

[14] As at 23/09/2004.

3. Options

3.1 In basic terms the options facing the Government are:

- Do nothing and fail to implement the new legislation in the UK; and
- Implement the new legislation.

3.2 As the Government is required by EC law to comply with the Council Regulation and implement supporting measures through domestic legislation, failing to implement and enforce the new legislation is not a reasonable option. Furthermore, the risks of failing to implement the Council Regulation (as outlined in section 2 of this RIA) are of a significant scale to warrant avoidance. As such, this RIA recommends that the Government implements the Council Regulation by statutory instrument.

3.3 The Council Regulation has been adopted and will take direct effect in Member States from 5 November 2004. Member States have no scope for flexibility as regards implementation, except in relation to the establishment of arrangements for enforcement through domestic legislation. This could include who is appointed as the competent authorities to inspect, the publication of guidance, or the designation of national sanctions for violations of the law. The UK Government therefore has sub-options within its chosen option of complying with the Council Regulation, as outlined below.

(i) Options for penalties and offences

3.4 There are options within the scope of establishing penalties and offences (i.e. the level at which the penalties are set). The hierarchy of offences as provided for in the domestic Regulations are in accordance with the provisions of the Council Regulation which state, "the penalties provided for must be effective, proportionate and dissuasive[15]". The domestic Regulations meet Home Office policy guidelines for penalties and offences and are consistent with the legal maxima available under the European Communities Act 1972.

3.5 The policy reflected in the domestic Regulations is to provide for a hierarchy of offences and penalties related to the potential seriousness of the failure to comply with the various EU requirements. The underlying rationale is that:

- proceeding with the first intentional transboundary movement of a GMO otherwise in accordance with the relevant procedures (e.g. respecting decisions of the Party of import) could constitute a serious potential hazard to human or animal health or to the environment;
- failure to keep proper records and failure to provide the appropriate information to importers in another country is likely to have less serious consequences as it implies that decisions of the importing country have still been respected.

3.6 Taking these principles into account, the proposed offences carry different penalties depending on the nature of the offence. As such, offences relating to failure

[15] Article 18, Regulation (EC) 1946/2003 on transboundary movements of GMOs.

to obtain the necessary authorisations at the first intentional transboundary movement are triable either way and could potentially incur a higher penalty.

3.7 Further details of the penalties and offences are attached at Annex 1.

(ii) Inspection Options

3.8 In enforcing the Council Regulation, Member States have the flexibility to decide on the most appropriate level of inspection and how these inspections are carried out. Member States could choose to have:

- No inspection, but with risk of infraction;
- A light-touch and proportionate approach with periodic inspections;
- Regular, strict inspection of **all** premises.

3.9 The UK Government has decided to go for the second option with periodic inspection of premises, rather than regular strict inspection or no inspections at all. This is proportionate to the current situation in the UK, where, at the time of going to print, the number of transboundary movements of GMOs are relatively low. Furthermore, this approach would mean that enforcement bodies could absorb the new requirements into their existing priority frameworks and workloads.

3.10 If a more draconian approach were adopted with regular, resource-heavy inspections, enforcement bodies could find that these inspections were disproportionately affecting their existing enforcement objectives and priorities. This could have resource and funding implications for both the inspection bodies and central Government.

3.11 No inspection at all would contravene the provisions of the Council Regulation, which states that, "Member States… shall take all measure necessary to ensure that …(the provisions of the Council Regulation) are implemented".

3.12 Defra will liaise with the inspection bodies about the precise level of inspections required in line with current inspection rates (e.g. the proportion of exporting companies and institutions being inspected). This will form part of the contract between Defra and HSE and GM Inspectorate, which will be reviewed on an annual basis.

3.13 Other options surrounding the inspection arrangements include:

- who enforces the domestic Regulations; (e.g. can these inspections be absorbed into existing inspection regimes?)
- number of inspections carried out;
- the proportion of companies being inspected; and
- level of support businesses are expected to provide for inspectors (e.g. do they have to provide desk facilities).

3.14 Since the original consultation on the draft domestic Regulations, the inspection arrangements for these Regulations have been revised and modified, taking into account the views of stakeholders. Inspections will be carried out by different bodies depending on the type of GM product in question or depending on a particular case, as set out below.

3.15 In England, the inspection of records will be the responsibility of inspectors appointed as such for the purposes of the Regulations by the Secretary of State for Environment, Food and Rural Affairs. It is envisaged that the majority of inspections will be carried out by the Health and Safety Executive's (HSE) GM Inspectorate. HSE have responsibility for the contained use of GMOs, in particular the Contained Use Regulations 2000 and already inspect the 544 premises registered for contained use of GMOs. As such, this additional requirements will be absorbed into the **existing** HSE GM inspection regime. This will **minimise** public sector costs. This is discussed in more detail in section 8.

3.16 Any GM product that has **not** been approved for the EC market comes under HSE's jurisdiction, as it will only be allowed to be kept in the EC in containment. As only a handful of products have been approved for the EC market[16] the majority of GMO products in the UK are effectively governed by HSE. It would seem prudent, therefore, for the HSE to be the main body to enforce these domestic Regulations by carrying out inspection of premises. There are currently 544 premises in the UK authorised for the contained use of GMOs. This should give some indication of the level of inspections that HSE may require and the number of firms that will be affected by these Regulations.

3.17 The HSE does not cover GM products that have already been approved for marketing in the EC. For those GM products that are approved for cultivation in the EC, information is kept centrally by the Central Science Laboratory's GM Inspectorate. As such, CSL-GMI will take on responsibility (when instructed to do so by the Secretary of State) for the enforcement of these Regulations in relation to exported GM products that have been approved for cultivation in the EC.

3.18 The domestic Regulations also include provision for local authorities to enforce the Regulations in relation to certain products or circumstances on instruction from the Secretary of State. For example, local authorities would enforce these Regulations in respect of transboundary movements of approved GM products in the food chain, such as a GMO approved for import into the EC, which could be subject to export from the EC. An example could be an operator trading in soya. A UK operator could import soya (i.e. a live GMO) into the EC from Argentina. This soya could then be re-packaged into small batches and sold onto another operator in a third country. Again, this movement of GMOs would be subject to transboundary movements and would not be captured by HSE's remit, but would fall within the remit of local authorities.

3.19 The use of different inspection bodies **should not equate to a duplication of effort**. Indeed, the three inspection bodies mentioned above (HSE, CSL GMI and LA

[16] There are currently (as of 11 Aug 04) only five GM foods that have been authorised for marketing in the EU, these are maize (5 different GM events), oil from cottonseed (2 events) and oilseed rape (7 events), soya (1 event), tomato (1event) and Bacillus subtilis (1 event, used for the production of vitamin B2). These authorisations are for fixed periods, after which renewal may be sought. For up-to-date information please see http://europa.eu.int/comm/food/food/biotechnology/authorisation/list_author_gmo_en.pdf

TSO's) all cover separate business areas and there would be no risk of duplication or overlap.

(iii) Options for individual operators (businesses or institutions)

3.20 In terms of activity at the individual business level, businesses are required to follow the provisions as set out in Chapters II to IV of Council Regulation. These provisions are not repeated in this RIA, although a general overview is given at Annex 3, along with a link to the text of the Council Regulation. Businesses and individuals should refer to the Council Regulation for details of the specific requirements according to the product in question and its intended use.

3.21 Where required, businesses and institutions must maintain and keep records of notifications / documentation for 5 years[17]. As the Council Regulation relates to the **first** intentional transboundary movement of a GMO, any costs incurred would be on a one-off, case-by-case basis – that is, documentation is only required for the first transboundary movement, not every subsequent transboundary movement of a particular product to a specific country of import. Businesses and institutions may be required to show these records to inspectors when they visit their premises. Exporters would be required to absorb additional costs of this storage of information.

3.22 No centralised procedure or pro-forma for the retention of documentation for inspection purposes has been established at present[18]. Recognising the potential costs of setting up and maintaining systems for retention of specific documentation, the Government will take into account potential costs to business in any decision on changes to procedures for storage of information, in order to minimise adverse impacts on businesses affected.

3.23 It will be for individual businesses to determine the most efficient and reliable way to transmit and retain information according to their particular circumstances. The inspection bodies will work with individual businesses and institutions and will advise on specific logistics[19]. These arrangements would be communicated to businesses via inspectors.

3.24 The Council Regulation reflects, to a large extent, existing common practice[20]. Most developed countries already have rules in place for notification procedures and the international exchange of information with which companies should be complying. Institutions and businesses already working within the provisions of the

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[17] E.g. For GMOs intended for deliberate release into the environment, the "exporter shall for a period of five years keep a record of the notification referred to in Article 4 and the acknowledgement of receipt and the decision of the Party, or where appropriate, non-Party of import " (Article 6 of the Council Regulation).

[18] E.g. for notifications, no template of how the information should be presented has been produced. However, businesses are required to provide as a minimum the information as specified in the Council Regulation (Annex I of the Council Regulation in the case of notifications).

[19] An example could be that inspectors advise businesses and operators how and where to keep copies of relevant documentation – does it need to be on site? In what format should it be kept? For how long must it remain on site?

[20] Recognising that the definition of "common practice" entails can differ from operator to operator.

Protocol and its requirements should not therefore face any new additional burdens compared to what they are already practising as part of normal good practice. As such, for UK industry the Council Regulation and the domestic Regulations should be relatively manageable within existing frameworks.

4. Benefits and costs

Benefits

4.1 As this RIA is not concerned with the detail of the Council Regulation, the benefits of complying with the Council Regulation are not analysed. Only the benefits related to enforcement arrangements are discussed.

4.2 The benefits of the do nothing option would be:

(i) Economic:
- No set-up costs for Government (although this could be offset by court costs if the UK were taken to the European Court of Justice as an infraction case);
- No administrative burden for operators.

(ii) Social:
- There would be no social benefits.

(iii) Environmental:
- There would be no environmental benefits.

4.3 The benefits of implementing and enforcing the EC legislation are:

(i) Economic:
- No legal challenge from Commission (and associated court costs);
- Inspections absorbed into existing inspection regimes with multifunction visits inspecting a range of legislation (minimal cost for public sector);
- Exporting businesses and institutions protected from arbitrary trade decisions on exports;
- Businesses and institutions provided with clear, centralised framework in which to work (all operators subject to the same standards).

(ii) Social:
- Establishing an effective system of penalties and offences will encourage compliance with the provisions of the Regulations within the UK. The system would be proportionate in relating the available sentencing tariff to the potential seriousness of possible offences, and would provide clear options to the courts in determining cases;
- Communicating a positive message about the UK Government's commitment to Cartagena;
- Supporting the social objectives of Cartagena.

(iii) Environmental

- Supporting the environmental objectives of Cartagena – mainly being to create an enabling environment for the environmentally sound application of biotechnology.

Costs

4.4 The potential costs to business that arise as a result of enforcement and inspection to ensure compliance with the Council Regulation are expected to be very low.

4.5 The costs relating to the do nothing option would be:

(i) Economic:

- Potential court costs if a case of infraction was brought against the UK Government;
- Businesses exporting GMOs would be without a clear legal framework in which to operate.

(ii) Social:

- The Government sends out a negative message about our commitment to the principles of Cartagena. As a signatory and long-term supporter of Cartagena, this would be inconsistent with the UK's approach to this international agreement;
- Countries importing GMOs, including the EC, but particularly developing countries, would be without clear and specific international rules governing informed, evidence based decisions on the import and export of GMOs.

(iii) Environmental:

- Failure to support the environmental aims of the Protocol in creating an enabling environment for the environmentally sound application of biotechnology.

4.6 The costs of implementing and enforcing the Council Regulation are:

(i) Economic

- Businesses will not be required to provide accommodation for inspectors on visiting their premises. As such, the **only direct costs** that businesses will incur as a result of the inspections will be the costs relating to the **storage of information relating to notifications** and **the costs of staff time for interacting with the inspector during a visit**.

- Businesses will also have to show inspectors that they are complying with the requirements for information to be contained in the documentation accompanying exports of GMOs, although there are no specific requirements for how companies should record this.

- The costs relating to additional administrative burden would be minimised, as the inspection requirements would be absorbed into existing inspection arrangements for the majority of cases – inspectors would already be visiting these premises, enforcing separate but related legislation. Visits would be multi-functional. We could say this option would therefore be **cost neutral**.

(ii) Social

- There would be no social costs relating to this option.

(iii) Environmental
- There would be no environmental costs relating to this option.

4.7 There are additional costs that relate directly to the provisions of the Council Regulation[21]. These are not discussed in this RIA as the focus of this RIA is only the analysis of costs that result from enforcement arrangements, as set out in the domestic Regulations.

4.8 Costs to the public sector are discussed in section 8 under costs of enforcement.

5. Distributional impacts

Business sectors affected

5.1 It is anticipated that the new Regulations will not cause any major financial or administrative burdens to any business sector within the UK.

5.2 Businesses exporting GMOs intended for deliberate release into the environment will incur a higher level of costs relative to those businesses exporting GMOs intended for food, feed or for processing (FFP) or for contained use, for example. This difference occurs because GMOs intended for deliberate release are required by the new rules to comply with notification procedures (see Annex 3), as well as provisions for documentation to accompany GMO exports.

5.3 GMOs for FFP, GMOs in transit and GMOs intended for contained use are not bound by the requirements of the notification procedure on the whole, although third countries have the right to regulate their importation on the basis of domestic legislation.

5.4 For example, with laboratory products for contained use, there would be a small incremental increase in requirements regarding information contained in documentation accompanying the first export[22] and, therefore, no significant increase in cost (this is assuming that the Party of import does not require GMOs destined for contained use should be covered by the AIA procedure). However, seed

[21] These costs could include:
- administrative costs of notifying Parties and non-Parties of import of the first transboundary movement of a GMO intended for deliberate release into the environment;
- costs in staff time with regard decisions on notifications for deliberate releases (especially in cases of non decision)' including waiting periods, delays on authorisations and review periods;
- ensuring completeness and accuracy of the information contained in notifications and accompanying documentation (for which the exporter has responsibility);and
- ensuring that the correct information is transmitted to the importer.

[22] Article 12 of the Council Regulation.

manufacturers that will export seeds for deliberate release into the environment would see a marked increase in requirements. They would, in addition to costs related to accompanying documentation, also have to absorb costs relating to notification procedures, with their associated storage and inspection costs.

5.5 Section 6 discusses differences in costs that may occur as a result of the size of a company.

5.6 As the Regulations will be enforced centrally by central GM inspectorates, there will be consistency of enforcement standards across different geographical locations.

6. Impacts on small businesses

6.1 The majority of businesses that currently export GMOs from the UK are those dealing with GMOs in contained use. A large proportion of these are academic institutions. In terms of the composition of businesses (as opposed to academic institutions) that deal with GMOs for export, we understand that the majority of businesses that are likely to be affected by these Regulations are large multinational firms, although we do recognise that some SMEs will also be affected (although we do not have any exact figures). We would expect individual companies to absorb any additional costs that arise from the establishment of enforcement arrangements themselves (see from paragraph 3.20).

6.2 In previous consultations[23] on the impacts of the EC provisions, some industry groups felt that SMEs would feel the impact of the Council Regulation more than larger businesses. There was concern that the provisions for notifications, associated waiting periods, and maintenance of records could impose new additional administrative burdens for industry, especially those companies and institutions with limited resources[24]. In terms of how disproportionately the domestic Regulations could affect SMEs, these businesses will need to comply with enforcement arrangements and inspections the same as larger companies. However, this should not translate in any additional disproportionate costs for SMEs, as businesses are not required to provide any accommodation for the inspectors (see paragraph 4.6).

6.3 For the large multinationals in the industry the additional costs of storing information for inspection purposes should be easily absorbed. However, it is quite likely that SMEs would experience a larger proportionate effect in relation to their own resources than would larger businesses in terms of this storage provision.

6.4 It is likely that courts will take into account the resources of an individual company when making a judgement on the appropriate form and level of penalty to assign when an offence has been committed. Ultimately it will be for the courts to decide whether an offence has been committed and to assign the appropriate level of penalty.

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[23] The original consultation on the detail of the Council Regulation can be accessed at: http://www.defra.gov.uk/corporate/consult/cartagena/index.htm

[24] In response to the consultation of July-October 2002, the Institute of Directors (IoD) commented that “it is quite likely that SMEs would experience a larger proportionate effect in relation to their own resources than would larger businesses”.

7. Competition Assessment

7.1 Implementation of the Council Regulation will impact on all businesses and other organisations in the EU that export materials consisting of, or containing, GMOs. At present, no such products are exported from the EC for commercial use, so any immediate impact will be restricted to businesses and research organisations making such exports for international information-sharing and research purposes.

7.2 The proposed measure is unlikely to result in significant competition impacts in any affected market, in terms of the impacts that occur as a result of inspection and enforcement. The proposals largely reflect existing common practice, and it is not anticipated that implementation will result in significant additional costs for businesses. Such costs as do result from implementation are thought to be unlikely to affect specific firms within any affected market disproportionately.

8. Enforcement and Sanctions

8.1 The main public sector burdens implied by the new legislation are outlined below, with an indication of who will enforce in practice.

8.2 In England, the inspection of records will be the responsibility of inspectors appointed as such for the purposes of these Regulations by the Secretary of State for Environment, Food and Rural Affairs. It is envisaged that the majority of inspections will be carried out by the Health and Safety Executive's (HSE) GM Inspectorate, although, as described in paragraph 3.8 onwards, there will also be a role for other inspection bodies.

8.3 How the domestic Regulations are enforced on the ground (e.g. the frequency of inspections) will be at the discretion of the Competent Authority (i.e. the Department for the Environment, Food and Rural Affairs in England) in conjunction with the individual enforcement bodies (e.g. GM inspectorate). The additional burden of inspections is unlikely to be directly translated into an increase in public sector costs. This is possible because the extra inspection activities will be absorbed into existing inspection regimes. Currently, there are no plans to provide extra resources to enforcement bodies to carry out the additional inspections. Likewise, there are no plans to allow enforcement bodies to recover costs for these activities. However, this arrangement may be subject to change in the future. The contracts held between Defra and both the HSE GMI and Defra's GMI are reviewed on a yearly basis.

8.4 Consistent with the principle of a risk-based approach, the proposed enforcement Regulations for England imply a hierarchy of offences and penalties, making a distinction between the relative seriousness of an offence. The enforcement Regulations meet Home Office policy guidelines for offences and penalties and are consistent with the legal maxima available under the European Communities Act 1972.

8.5 The most serious penalty relates to offences such as proceeding with the first intentional transboundary movement of GMO otherwise than in accordance with the relevant procedures, including failure to respect decisions of Parties or non-Parties of

import. The other, less serious, level of penalty concerns offences such as failure to keep proper records of notifications; failure to provide specified information; and failure to transmit appropriate information to the Party or non-Party of import. Full details of the proposed penalties and offences for England are attached at Annex 1.

8.6 A hierarchy of offences and penalties based on these principles would give the courts a flexible range of punitive and deterrent options, which could be applied proportionately in particular cases.

8.7 There will be some public sector costs related to imposing penalties for non-compliance, including the related court costs.

9. Monitoring and Review

9.1 The Council Regulation contains specific review provisions that requires Member States to forward to the Commission a report on the implementation of the Regulation at regular intervals, and at least every three years, unless otherwise determined[25].

9.2 In addition, the Commission is required to present the information provided by Member States to the Convention serving as the Meeting of the Parties of the Protocol[26].

9.3 The UK will play a full part in contributing to these review processes.

10. Consultation

Within Government

10.1 Other Government departments and the devolved administrations were consulted during negotiations leading up to final adoption of the Council Regulation. They were also consulted on the attached domestic Regulations.

10.2 This RIA has been completed with input from Cabinet Office Regulatory Impact Unit, Small Business Service, the Bioscience Unit of the Department for Trade and Industry, the Health and Safety Executive and the Office of Fair Trading. The proposed offences and penalties in relation to infringements of the Regulation have been cleared with the Home Office.

Public Consultation

10.3 Oral and written consultations were carried out with stakeholders between July and October 2002 whilst the Council Regulation was under negotiation. Responses to the consultation were few and mainly focused on clarification of statements made within the EC text. No major concerns with the provisions were registered with DEFRA. The original consultation can be accessed at:

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[25] Article 19, Regulation (EC) 1946/2003, OJ L287, 05.11.2003, p.1
[26] Article 19, Regulation (EC) 1946/2003, OJ L287, 05.11.2003, p.1

http://www.defra.gov.uk/corporate/consult/cartagena/index.htm

10.4 A draft of this RIA was consulted on in May 2004, concerning the domestic enforcement arrangements[27]. Stakeholders were asked to comment on the analysis of costs and benefits included in a draft RIA. 157 stakeholders were forwarded a copy of the consultation. Defra received 16 replies. The replies to the consultation were used to inform the revision of the RIA – this document.

10.5 Five respondents made no comments, or only highlighted typographical errors in the consultation documents, which have now been rectified. A number of respondents had queries or comments on the provisions of the EC Council Regulation itself. The majority of respondents thought that the penalties and offences were proportionate or made no comment on their level. However, two respondents considered that the penalties and offences were not stringent enough. The level of penalties has not been amended as a result of these comments. The domestic Regulations are being made under the European Communities Act 1972, which limit the level of penalties that can be imposed. The penalties provided for in these Regulations form part of a hierarchy of offences with the Traceability and Labelling and the Food and Feed Regulations and it is considered that they are both appropriate and proportionate.

10.6 The RIA was revised to provide further clarification of inspection and enforcement arrangements. Stakeholders responded that they wanted to see a more structured analysis of how the enforcement arrangements would work in practice. The revised section 3 on "inspection options" has been written to provide such clarity. In addition, the RIA now acknowledges that non-commercial exports of GMOs from the UK are covered by the new legislation and that, as such, a number of businesses and institutions will be affected by the new Regulations at the time of the Regulations coming into force. This was not made clear in the original draft of the RIA.

10.7 The summary of responses will be published on the Defra website.

11. Recommendation

11.1 The Minister is recommended to sign and approve this RIA.

12. Declaration

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs

Signed: Elliott Morley

Date: 17th October 2004

Elliot Morley, Minister for Environment and Agri-Environment

Contact point:

[27] See http://www.defra.gov.uk/corporate/consult/gm-transboundary/index.htm

Robin Healey
GM Regulation and International
Department for Environment, Food and Rural Affairs
Zone 3/G9
Ashdown House
123 Victoria Street
London SW1E 6DE

Email: Robin.healey@defra.gsi.gov.uk
Tel: 00 44 (0) 20 7082 8098

ANNEX 1 – Proposed penalties and offences

Statutory Instrument (SI) Provision	EC Provision	Offence	Penalty
Regulation 8(1)(a) and 10	Article 5(3) of Regulation 1946/2003	Proceeding with first intentional transboundary movement of GMOs otherwise than in accordance with the relevant procedures.	On summary conviction, a fine up to the statutory maximum, or up to 3 months imprisonment, or both. On indictment, a fine or imprisonment up to 2 years, or both.
Regulation 8(1)(a) and 10	Article 10(1)	Failure to respect any decision on the import of GMOs intended for direct use as food or feed or for processing .	On summary conviction, a fine up to the statutory maximum, or up to 3 months imprisonment, or both. On indictment, a fine or imprisonment up to 2 years, or both.
Regulation 8(1)(a) and 10	Article 10(2)	Proceeding with first export of genetically modified organisms intended for direct use as food or feed or for processing otherwise than in accordance with the relevant procedure.	On summary conviction, a fine up to the statutory maximum, or up to 3 months imprisonment, or both. On indictment, a fine or imprisonment up to 2 years, or both.

Regulation 8(1)(a) and 10	Article 10(3)	Exporting genetically modified organisms without prior import authorisation.	On summary conviction, a fine up to the statutory maximum, or up to 3 months imprisonment, or both. On indictment, a fine or imprisonment up to 2 years, or both.

Statutory Instrument (SI) Provision	EC Provision	Offence	Penalty
Regulation 8(1)(a) and 10	Article 4 of Regulation 1946/2003	Failure by exporter to notify parties and non-parties of import prior to first international transboundary movement of a GMO intended for deliberate release; Failure to provide the minimum specified information in the notification; and Failure to ensure that the information contained in the notification is accurate.	On summary conviction, a fine up to level 5, or imprisonment up to three months, or both.

Regulation 8(1)(a) and 10	Article 6 of Regulation 1946/2003	Failure to keep records of notifications under article 4 of the Council Regulation; acknowledgements of receipt of notifications; and decisions of the Party or non-Party of import; and Failure to send copies of these records to the Competent Authority and to the Commission.	On summary conviction, a fine up to level 5, or imprisonment up to three months, or both.
Regulation 8(1)(a) and 10	Article 7(2) of Regulation 1946/2003	Failure to copy to the Secretariat any reminder sent to Parties or non-Parties of import.	On summary conviction, a fine up to level 5, or imprisonment up to three months, or both.

Statutory Instrument (SI) Provision	EC Provision	Offence	Penalty
Regulations 8(1)(a) and 10	Article 12(1) of Regulation 1946/2003	Failure to ensure that specified information is contained in a document accompanying the GMO; and Failure to ensure that this information is transmitted to the importer.	On summary conviction, a fine up to level 5, or imprisonment up to three months, or both.
Regulations 8(1)(a) and 10	Article 12(2) of Regulation 1946/2003	Failure to supply the specified supplemental information in relation to GMOs intended for direct use as food or feed.	On summary conviction, a fine up to level 5, or imprisonment up to three months, or both.
Regulations 8(1)(a) and 10	Article 12(3) of Regulation 1946/2003	Failure to supply the specified supplemental information in relation to GMOs intended for contained use.	On summary conviction, a fine up to level 5, or imprisonment up to three months, or both.

Regulations 8(1)(a) and 10	Article 12(4) of Regulation 1946/2003	Failure to supply the specified supplemental information in relation to GMOs intended for deliberate release and any other GMOs to which the Council Regulation applies.	On summary conviction, a fine up to level 5, or imprisonment up to three months, or both.
Regulations 8(1)(a) and 10	Article 13 of Regulation 1946/2003	Failure to notify Parties of the transit of genetically modified organisms through their territory.	On summary conviction, a fine up to level 5, or imprisonment up to three months, or both.
Statutory Instrument (SI) Provision	**EC Provision**	**Offence**	**Penalty**
Regulations 8(1)(b) and 10	No EC Provision: National Competence	Obstructing an inspector in the exercise of a power conferred by regulation 4.	On summary conviction, a fine up to level 5, or imprisonment for up to 3 months, or both.
Regulations 8(1)(c) and 10	No EC Provision: National Competence	Failure to comply with a request made under regulation 4(3)(g) or regulation 5.	On summary conviction, a fine up to level 5, or imprisonment for up to 3 months, or both.

Regulations 68(1)(d) and 10	No EC Provision: National Competence	Knowingly or recklessly to make a statement or furnish any information that is false or misleading in a material particular where the statement is made or the information is furnished in purported compliance with: i) Any requirement imposed by the specified Community provisions; or ii) A request of an inspector made for a purpose in connection with the administration or enforcement of these Regulations.	On summary conviction, a fine up to level 5, or imprisonment up to three months, or both.
Regulations 8(1)(e) and 10	No EC Provision: National Competence	Intentionally to make a false entry in any record required to be kept under the Council Regulation.	On summary conviction, a fine up to level 5, or imprisonment up to three months, or both.

ANNEX 2

Advance Informed Agreement (AIA)

The "Advance Informed Agreement" (AIA) procedure applies to the first intentional transboundary movement of GMOs for intentional introduction into the environment of the Party of import. It includes four components: notification by the Party of export or the exporter, acknowledgment of receipt of notification by the Party of import, decision procedure and review of decisions. The purpose of this procedure is to ensure that importing countries have both the opportunity and the capacity to assess risks that may be associated with the GMO before agreeing to its import.

Specifically, the Party of export or the exporter must notify the Party of import by providing a detailed, written description of the GMO in advance of the first shipment. The Party of import is to acknowledge receipt of this information within 90 days. Then, within 270 days of the date of receipt of notification, the Party of import must communicate its decision: (i) approving the import, (ii) prohibiting the import, (iii) requesting additional relevant information, or (iv) extending the 270 days by a defined period of time. Except in a case in which consent is unconditional, in other cases the Party of import must indicate the reasons on which its decisions are based. (see Article 7, Article 8, Article 9, and Article 10)

A Party of import may, at any time, in light of new scientific information, review and change a decision. A Party of export or a notifier may also request the Party of import to review its decisions. (see Article 12)

However, the Protocol's AIA procedure does not apply to certain categories of GMOs:

- GMOs in transit (see Article 6);
- GMOs destined for contained use (Article 6);
- GMOs intended for direct use as food or feed or for processing (see Article 7.3).

It should be noted that, while the Protocol's AIA procedure does not apply to certain categories of GMOs, Parties have the right to regulate the importation on the basis of domestic legislation.

In addition, the Party of import may also specify in advance to the Biosafety Clearing-House that it will exempt certain imports of GMOs from the AIA procedure (see Article 13). Also, the Conference of the Parties serving as the meeting of the Parties to the Protocol may in future decide to exempt additional GMOs from application of the AIA procedure (see Article 7.4).

Annex 3

Provisions of Regulation (EC) No 1946/2003 on transboundary movements of GMOs

In accordance with the requirements of the Protocol, Regulation 1946/2003 ("the Council Regulation") focuses on exporter obligations. Its provisions include two main procedures to control the movement of GMOs from one country to another:

i) A specific **notification procedure** requiring notification to, and the agreement of, the importing country before the export of a GMO (such as a seed) intended for deliberate introduction into the environment may proceed (the Advance Informed Agreement); and

ii) A procedure for information exchange through the **Biosafety Clearing House**

The full text of the Council Regulation can be accessed at:
http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_287/l_28720031105en00010010.pdf