REGULATORY APPRAISAL

ENVIRONMENTAL PROTECTION, WALES

THE GENETICALLY MODIFIED ORGANISMS (TRANSBOUNDARY MOVEMENTS) (WALES) REGULATIONS 2005

Background

1. 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 Protocol (and the associated EC Regulation) therefore aims to create an enabling environment for the environmentally sound application of biotechnology, especially in those countries without an existing developed domestic framework. The Protocol and the EC Regulation both support the Precautionary Principle.

2. The Cartagena Protocol on Biosafety is a UN Multilateral Environment Agreement designed to secure an adequate level of environmental protection against any possible risks from cross-border movements of GMOs. The Protocol requires each Party to take necessary and appropriate legal, administrative and other measures to implement its obligations.

3. Imports of GMOs into and within the EC are covered by existing legislation, which is in line with the requirements of the Protocol. Existing Community legislation (in the form of Directive 2001/18/EC on the deliberate release into the environment of GMOs, Regulation (EC) No. 1829/2003 on GM food and feed and Regulation (EC) No. 1830/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs) does not contain specific requirements for exports of GMOs to third countries.

4. The Commission considers that the existing legislative framework for the Community is consistent with the relevant provisions of the Protocol, and that no modifications to it are required to implement the Protocol in the Community. 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.

5. 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 are fulfilled.

6. In accordance with the requirements of the Protocol, this new EC Regulation focuses on exporter obligations. In particular, it requires exporters of products consisting of or containing GMOs to supply third countries with the same risk assessment and other information as was supplied when the product was cleared for the EC market. It also obliges the Community to provide information at an international level that is consistent with the requirements of the Protocol's Biosafety Clearing House.

7. These obligations on exporters will enable third countries, before allowing an import of a particular GMO, to perform a risk assessment to identify and evaluate possible adverse effects on the conservation and sustainable use of biological diversity in their country, also taking into account possible risks to human health.

Purpose and intended effect of the measure

8. These Regulations put in place supporting measures for the domestic implementation of Regulation (EC) No 1946/2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms (GMOs) (the EC Regulation).

9. The EC Regulation aims to establish a common system of notification and information for transboundary movements of genetically modified organisms (GMOs). It focuses on exporter obligations, requiring exporters of products consisting of or containing GMOs to supply third countries with the same risk assessment and information as was supplied when the product was cleared for the EC market. This is in accordance with the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, under which, countries have the right to bar imports of live GMOs which they believe carry risks to the environment or human health.

10. The purpose of Regulation 1946/2003 is to ensure that exporters of live GMOs intended for deliberate release in the country of import meet the requirements of the Protocol's Advanced Informed Agreement Procedure. Regulation 1946/2003 also covers the export of GMOs intended for use in food and feed, contained uses of GMOs and the unintentional transboundary movements of GMOs.

11. The Department for Environment, Food and Rural Affairs (Defra) is designated as 'Focal Point' and is responsible for liasing between the UK as a whole (including the Devolved Administrations) and the European Commission. The Assembly is designated as 'Competent Authority', and so is responsible for enforcement of the Regulation in Wales.

12. The Regulations prescribe powers of entry including the power to carry out tests and inspections, to take samples of organisms or substances and require the provision of information. They also provide for criminal offences relating to breach of requirements of the Regulations and provide for a suitable penalties system.

Risk assessment

13. Failure to implement the Cartagena Protocol in Wales would discourage other countries from ratifying the Protocol and implementing its requirements, and thus make uncertain the global status of GM products approved in other countries. Such uncertainty would increase the risk of damage to the environment through lack of evidence about the risks of such products and could have negative consequences for trade and the building of confidence in the safety of the products of new biotechnology. 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.

14. Proceeding with the first intentional transboundary movement of a GMO otherwise than in accordance with the relevant procedures as set out in these Regulations could, as well as aggravating the difficulties of facilitating risk management measures, reduce consumer choice by undermining efforts in countries of import to establish effective traceability and labelling systems for GMOs.

15. Ultimately, failure to implement the regulations in Wales would leave the Assembly open to infraction proceedings brought by the European commission and would mean that our framework for regulating GMO was out of harmony with the European Community and signatories to the Cartagena Protocol.

Options

16. In respect of this legislation, the "Do Nothing" option is not an option, as it would ultimately lead to infraction proceedings against the National Assembly for Wales by the European Commission. Therefore, the "Make the Legislation" option, to implement the changes required to comply with European legislation, is being recommended.

Benefits

17. Compliance with the EC Regulation would mean that the Welsh GMO regulatory framework was consistent with the harmonised system of notification and identification of transboundary movements of GMOs. This system would more effectively achieve the objectives of the Protocol as regards the conservation and sustainable use of biodiversity. It would also provide a coherent and consistent approach to exports and transboundary movements of GMOs, contributing to the effective functioning of the internal market and improving the transparency and security of exports to third countries.

18. The EC Regulation (and the draft Regulations) provides for measures that are mutually supportive of international trade rules. As such, if the Welsh or UK biotech industries were to decide to export GMOs the Regulations would protect exporters from arbitrary decisions on the trade of transboundary movements of GMOs.

19. Establishing an effective system of penalties and offences will encourage compliance with the provisions of the Regulations within Wales and 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.

Costs

20. The EC Regulation applies to the transboundary movements of all GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health. There are specific provisions within the Regulations for products consisting of, or containing GMOs intended for deliberate release into the environment, or GMOs to be used in food,

feed or for processing. At present the UK does not export products that are covered by the EC Regulation. As such, the costs to business (and Government) at time of going to print are zero.

21. As no market currently exists, it is impossible to calculate accurately what the costs will be to business in Wales. The costs set out below are what we envisage would happen in practice if industry began to export GM products. It is assumed that the costs will be the same for the separate sectors of industry (feed, food, pharmaceuticals etc) as the provisions of the EC Regulation do not imply any major differences in the requirements for different products (e.g. food and feed products have similar requirements). The only discrepancies in costs to a business would depend on the size of the company.

22. The costs to business could include, for example:

- administrative costs of notifying the 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) in accordance with Article 4 and Article 12 of the EC Regulation;
- ensuring that the correct information is transmitted to the importer; and
- retaining and maintaining records of documentation.

23. As the Regulations relate to the **first** intentional transboundary movement of a GMO, any costs incurred would be a one-off cost to be determined on a case-by-case basis. The costs relating to the processing of notifications for the first transboundary movement of a GMO and subsequent required activities (e.g. participation in the international information procedure) are expected to be negligible, as companies would already have the information necessary for the accompanying documentation and information to be transmitted from the original authorisation to place a product on the EC market for the first time as set out in Directive 2001/18 and Regulation EC 1829/2003. The EC Regulation does not require any supplementary information to be provided to that required under 2001/18 and Regulation 1829/2003.

24. For large multinationals, it is expected that any additional costs would be marginal. We should note that, relative to the costs incurred by businesses in obtaining the original authorisation for release onto the EC market, any costs relating to the first intentional transboundary movement are marginal by comparison, and unlikely to add any significant further burden on the “owners” of the original authorisation.

25. The proposed Regulations reflect, to a large extent, existing common practice. 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 Protocol and its requirements should not therefore face any new additional burdens compared to what they are already practising. As such, for UK industry the Regulation is relatively manageable within existing frameworks. There should be no major burden on UK business.

26. The main public sector costs of enforcing the new Regulations are identified as:

- the inspection of records;
- the court costs related to cases of non-compliance.

27. As no GM products are currently exported for commercial use by the EU, the focus of inspection will be those records held by companies exporting research material.

28. Enforcement of the Regulations in Wales is at the discretion of the Welsh Assembly Government. The Health and Safety Executive (HSE) have agreed to undertake enforcement at sites/premises in Wales that use GMOs under contained use conditions. This enforcement responsibility will build on the HSE's existing inspection functions for contained uses of GMOs, for which the HSE has quoted a fee of approximately £150 per annum. The HSE will also be undertaking enforcement in/on behalf of the other UK administrations. Local Authorities (for example, Trading Standards Officers or Port Health Authorities) and, where appropriate, the Defra GM Inspectorate (the Central Science Laboratory) will also be involved in enforcement functions, however, this is likely to be discussed and finalised at a later date after discussions with an enforcement liaison group. As there is very little activity that currently takes place that will be affected by these Regulations, the Welsh Assembly Government will not (at this stage) produce guidance on enforcement of these Regulations, although this may be subject to change in the future.

29. The additional burden of Local Authority inspections is unlikely to be directly translated into an increase in public sector costs. This is possible because the extra inspection activities are envisaged to be absorbed within existing inspection regimes and their associated costs. Currently, there are no plans to provide considerable extra resources to enforcement bodies to carry out the additional inspections. Likewise, there are no plans to allow enforcement bodies to recover costs.

Competition Assessment

30. Implementation of the EC Regulation will impact on all businesses and other organisations 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 research organisations making such exports for international information-sharing purposes.

31. The proposed measure is unlikely to result in significant competition impacts in any affected market. 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.

32. It is anticipated that the new Regulations will not cause any major financial or administrative burdens to any business sector in Wales. The Provisions within the draft Regulations will only impose new additional burdens on those business sectors that choose to export GMOs, with specific requirements for products consisting of or containing GMOs intended for deliberate release into the environment, or GMOs to be used in food, feed or for processing.

33. As the UK industry currently exports products that are covered by the EC Regulation, it is impossible to say in advance which business sectors will be affected by the new Regulations in the future. A possible indication of the sectors that may decide to export could be:

    - Feed industry (producers, processors and retailers)
    - Food and drink industry (producers, processors and retailers)
    - Research and academia
    - Pharmaceutical industry
    - Seed industry
    - Agricultural industry (e.g. GM animals)

Monitoring and Review

34. The EC 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.

35. 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.

36. The Assembly will contribute to this review process where appropriate.

Consultation

With Stakeholders

37. The Welsh Assembly Government's public consultation ran from 9 July 2004 to 1 October 2004. A list of consultees is attached at Annex A.

38. Stakeholders were asked to consider:

    - if the offences proposed were appropriate in relation to the requirements of the Regulations;
    - if the analysis of the costs and benefits identified in this Regulatory Appraisal was appropriate; and
    - to identify any areas of costs and/or benefits that had been excluded from the Regulatory Appraisal.

39. Responses were received from the Welsh Local Government Association (WLGA) and National Farmers Union (Wales) (NFU (Wales)). The WLGA

requested further consultation with Local Authorities in the event that any guidance on enforcement of the Regulations is produced in the future; and also requested that any costs incurred through inspections performed by Local Authorities would be met centrally by the Assembly Government.

40. The NFU (Wales) agreed the proposed offences. They also identified that 'common practice' for complying with the Regulations and the costs and benefits of compliance would vary between small and medium enterprises and larger businesses. They requested that a quantitative analysis be undertaken for estimating costs and benefits. They also asked that farmers receive assistance in complying with the Regulations.

41. As no GMOs are grown under deliberate release conditions it is not currently possible to consider what, if any, inspection costs will be incurred by Local Authorities. It is not foreseen that farmers will be subject to any cost implications arising from these Regulations; consequently, performing the quantitative analysis requested by NFU (Wales) is unnecessary.

42. No amendments to the Regulations have been made in light of consultation responses.

With Subject Committee

43. These Regulations were notified to the Environment, Planning and Countryside Committee via the forthcoming list of legislation on 4 February 2004 (EPC(2)-02-02(p.4), item no: 104) and were identified for detailed scrutiny. The Committee scrutinised draft Regulations on 3 November 2004 and approved them without amendment.

Summary and Recommendation

44. 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 (and the associated EC Regulation) therefore aims to create an enabling environment for the environmentally sound application of biotechnology, especially in those countries without an existing developed domestic framework. This new EC Regulation requires exporters of GM products to supply third countries with the same risk assessment and other information as was supplied when the product was cleared for the EC market.

45. The Regulation has already been adopted by the EU and will take direct effect in the UK with no flexibility as regards implementation, except in relation to penalties for non-compliance. Adopting the proposed implementing Regulations in Wales will meet the Assembly's EU obligations with regard to regulating the transboundary movement of GMOs.

ANNEX A

CONSULTATION LIST

AMs	MEPs (Wales)
MPs (Wales)	ADAS Wales
Advisory Committee on Genetic Modification	Advisory Committee on Releases into the Environment
Agriculture and Environment Biotechnology Commission	Brecon Beacons National Park
Campaign for the Protection of Rural Wales	CBI Wales
Coed Cymru	Council of National Parks
Country Land and Business Association (Wales)	Countryside Council for Wales
DARD (NI)	DEFRA
Environment Agency	Farmers' Union of Wales
Federation of Small Businesses	Food Standards Agency (Wales)
Forestry Commission (Wales)	Friends of the Earth (Wales)
GM Co-ordination Team, Edinburgh	GM Free Cymru
Greenpeace	IGER
Mrs J MacDonald	National Assembly for Wales – Brussels Office
National Farmers' Union (Wales)	Organic Farming Centre for Wales
Pembrokeshire Coast National Park Authority	RSPB
SCIMAC	Snowdonia National Park Authority
Soil Association	The Woodland Trust, Lincolnshire
Universities (Wales)	Wales Countryside and Wildlife Link
Wales European Centre	Wales tourist Board
Wales TUC Cymru	Wales Young Farmers' Club
WCVA	Welsh Beekeepers' Association
Welsh Consumer Council	Welsh Development Agency
Welsh Food Alliance	Welsh Institute of Rural Studies
Welsh Local Government Association	Wildlife Trusts
Women in Agriculture	WWF Cymru

ANNEX 1 – Proposed penalties and offences

Statutory Instrument (SI) Provision	EC Provision	Offence	Penalty
Regulation 8(1)(a) and 11(1)	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 11(1)	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 11(1)	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 11(1)	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 11(1)	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 11(1)	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 11(1)	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
Regulation 8(1)(a) and 11(1)	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.
Regulation 8(1)(a) and 11(1)	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.
Regulation 8(1)(a) and 11(1)	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.
Regulation 8(1)(a) and 11(1)	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.
Regulation 8(1)(a) and 11(1)	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 11(3)	No EC Provision: National Competence	Obstructing an inspector in the exercise of a power conferred by regulation 6.	On summary conviction, a fine up to level 5, or imprisonment for up to 3 months, or both.
Regulations 8(1)(c) and 11(3)	No EC Provision: National Competence	Failure to comply with a request made under regulation 7.	On summary conviction, a fine up to level 5, or imprisonment for up to 3 months, or both.
Regulations 8(1)(e) and 11(3)	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)(f) and 11(3)	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).