The Scottish Parliament

Environment and Rural Development Committee

27th Meeting, 2004

Wednesday 10 November 2004

The Committee will meet at 11.00 am in Committee Room 5.

1. **Subordinate legislation:** The Committee will consider the following negative instruments—

   the Genetically Modified Organisms (Traceability and Labelling) (Scotland) Regulations 2004 (SSI 2004/438);

   the Genetically Modified Organisms (Deliberate Release) (Scotland) Amendment Regulations 2004 (SSI 2004/439);

   the Plant Health (Great Britain) Amendment (Scotland) Order 2004 (SSI 2004/440); and

   the Avian Influenza (Survey Powers) (Scotland) Regulations 2004 (SSI 2004/453).

2. **Work programme:** The Committee will consider its forward work programme.

3. **Budget process 2005-06 (in private):** The Committee will consider a draft report.

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The following papers are attached:

Agenda Item 1	
the Genetically Modified Organisms (Traceability and Labelling) (Scotland) Regulations 2004 (SSI 2004/438)	ERD/S2/04/27/1a
the Genetically Modified Organisms (Deliberate Release) (Scotland) Amendment Regulations 2004 (SSI 2004/439)	ERD/S2/04/27/1b
the Plant Health (Great Britain) Amendment (Scotland) Order 2004 (SSI 2004/440)	ERD/S2/04/27/1c
the Avian Influenza (Survey Powers) (Scotland) Regulations 2004 (SSI 2004/453)	ERD/S2/04/27/1d
Extract from the Subordinate Legislation Committee's 38th Report	ERD/S2/04/27/1e
Agenda Item 2	
A paper from the Convener is attached (*for members only*)	ERD/S2/04/27/2a
Agenda Item 3	
A draft report (*for members only*)	ERD/S2/04/27/3a

Agenda Item 1
Environment and Rural Development Committee

10 November 2004
ERD/S2/04/27/1a&b

FINAL REGULATORY IMPACT ASSESSMENT

THE GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) (SCOTLAND) (AMENDMENT) REGULATIONS 2004
&
THE GENETICALLY MODIFIED ORGANISMS (TRACEABILITY AND LABELLING) (SCOTLAND) REGULATIONS 2004

Summary

This Regulatory Impact Assessment covers two EC Regulations on genetically modified food and feed, and on the labelling and traceability of genetically modified organisms. The regulations have been in place since 18 April 2004 and are directly applicable in member states. No flexibility is permitted in relation to the provisions of the regulations. Member states are only required to adopt legislation to provide for the enforcement of the EC regulations.

The traceability and labelling of GMOs regulation introduced a requirement for information to be transmitted through the food and animal feed chains regarding the use of GMOs and ingredients produced from GMOs. The GM food and feed regulation introduced a centralised safety assessment for GMOs via the European Food Safety Authority and extended the previous GM labelling regulations to include a wider range of products. In response to continued consumer demand for non-GM ingredients, food manufacturers and retailers have continued to seek non-GM supplies and therefore have effectively by-passed the need to comply with the requirements of the regulations. Costs incurred by the industry therefore relate to the setting up and maintaining of non-GM supply systems rather than costs incurred in complying with the regulations. Feed manufacturers have chosen to label feed as containing GM ingredients recognising that certain components of feed are likely to be derived from GM crops.

The aim of this RIA is to determine the impact of these regulations and not the impact of non-GM systems as a consequence of the regulations.

1. Title of proposals

1.1 Regulation (EC) No 1829/2003[1] of the European Parliament and of the Council on genetically modified food and feed.

1.2 Regulation (EC) No 1830/2003[2] of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

1.3 During EU negotiations, the Food Standards Agency (FSA) led on the first proposal and the Department for Environment, Food and Rural Affairs (Defra) on the second. It is more transparent to discuss the impact of such closely linked measures in one document.

[1] OJ L 268, 18.10.2003, p.1
[2] OJ L 268, 18.10.2003, p.24

2. Purpose and intended effect of measures

(i) Objective

2.1 Regulation (EC) 1829/2003 – the **Food and Feed Regulation** - lays down specific Community procedures and provisions for the assessment, authorisation, supervision and labelling of genetically modified (GM) food and feed. Its objective is to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumers' interests in relation to GM food and feed, whilst ensuring the effective functioning of the internal market. The Regulation has introduced a centralised assessment procedure for the approval of GM food and feed. From 18 April 2004, such assessment is carried out through the European Food Safety Authority (EFSA) rather than by individual member states, as before that date. This measure will impact on individual member states and the biotechnology industry. It has also introduced new labelling rules for GM animal feed and extended the range of GM food ingredients which will need to be labelled. These labelling measures will impact on a wide range of businesses in relation to the agriculture, food, feed, retail and hospitality sectors. However, such businesses are already subject to a wide range of information requirements under general food law and specific product legislation.

2.2 Regulation (EC) 1830/2003 – the **Traceability and Labelling Regulation** establishes a harmonised EU framework for the traceability and identification, including labelling, of any product consisting of or containing genetically modified organisms (GMOs) and traceability of food and feed produced from GMOs at all stages of the production and distribution chain. Its objective is to facilitate consumer choice and risk management in relation to such products. Traceability systems have already been in place for a variety of food products, either under voluntary arrangements or under requirements set out in general food law or in accordance with specific product control regimes, including the existing regime for the control of GMOs. The Traceability and Labelling Regulation further specifies particular traceability and labelling requirements in relation to GM products.

(ii) Devolution

2.3 Both Regulations apply to the whole of the UK.

(iii) Background

Why GM products are regulated in the EU

2.4 GM products are addressed in EU legislation for three main reasons:

- **Safety**: any possible risks to human health and the environment from GMOs must be properly assessed, managed and communicated to the public. Specific legislation has been in place in the EU since 1990 to ensure that any GM product is thoroughly assessed before being placed on the European Community market. Products that do not meet the relevant safety criteria are not allowed to be sold. Most countries in the world that produce or import GM products have similar

systems of safety assessment. International agreements, such as the Codex Alimentarius or the Cartagena Protocol on Biosafety, lay down common minimum standards of assessment and information. However, such agreements recognise that specific measures may be justified in particular countries or economic areas, for example because an importing country may have significantly different natural habitats and wildlife from an exporting country. Consequently, the EU has its own Community-wide system for assessing and approving any locally produced or imported GM product, including products that have already been authorised in a country outside the Community for the purpose of that country's own domestic legislation.

- **Consumer choice**: consumers should have appropriate and reliable information about the GM content of products. Labelling, or other clearly displayed information, is intended mainly to inform the person who buys or consumes a particular product ("the final consumer") about particular characteristics that may affect his or her individual choice of what to buy. Informing consumers of the GM content of products helps to inform the choice of those who wish to avoid, or possibly to seek out, products with such content as a matter of individual choice. Any GM content must conform to regulatory requirements as regards safety. The veracity of labelling is underpinned by traceability, which means the ability to trace and follow a product through all stages of production, processing and distribution. Most traceability systems include a documentary audit trail that passes along the supply chain from one operator to the next. The specific requirements for GMOs are explained below.

- **Fair competition**: under EC legislation, GM products should be able to be sold and used anywhere in the EU provided they meet, and continue to meet, approval and safety criteria. Approval of a GM product under the relevant EU legislation provides access to the whole of the Community market. Member states may not restrict the sale and use of an approved product without being able to bring forward and sustain evidence of a significant adverse risk to human health or the environment.

The previous regulatory regime

2.5 A generic Directive - 2001/18/EC on the deliberate release into the environment of GMOs[3] - sets out common approval, safety, fair competition and public information standards for any GM product marketed in the EU. It strengthened the requirements in its predecessor Directive – 90/220 – which it replaced. It also provides for mandatory traceability and labelling of GMOs as such or in any product. The fundamental requirement of the Directive is that no product that consists of or contains GMOs may be placed on the Community market without a specific consent based on a thorough assessment of any possible risks to human health and the environment. Conditions of use and management may be placed on any consent and all products must be subject to appropriate post-market monitoring requirements to ensure that the original risk assessment remains valid.The EC Novel Foods Regulation (No. 258/97), adopted in May 1997, introduced a mandatory assessment and authorisation procedure for novel (including GM) foods and novel ingredients, as

[3] OJ L 106, 17.4.2001, p.1

a derogation from Directive 90/220.This Regulation lays down procedures which must be observed before the above foods and ingredients may be placed on the Community market for the first time. These are based on the principle that the products in question must not present a danger to, or mislead, the consumer.

2.6 Directive 2001/18/EC sets out the basic common principles against which any proposed GM product must be assessed. However, more specific and detailed factors, going beyond these common principles, may be relevant to particular products, such as food ingredients. The Directive therefore allows such products to be considered under separate sectoral legislation which covers these wider factors whilst at the same time ensuring that its requirements reflecting for example, environmental risk assessment are at least equivalent to those in the Directive. The detailed terms of any product exemption or derogation must be set out in a separate regulation. The new GM Food and Feed Regulation is one such measure.

2.7 In addition to the labelling requirements laid down in Regulation EC No. 258/97, detailed labelling rules for GM ingredients were also set out in three further measures: EC Regulations 1139/98[4], 49/2000[5] and 50/2000[6].

2.8 For the purposes of comparing the previous provisions in the Novel Foods Regulation with those in the new EC Regulations, there are three main points to note which applied in previous legislation:

- the labelling requirements applied to food ingredients (where novel DNA or protein was present), with a 1% threshold below which products did have to be labelled if, and only if, any incidental GM presence in the ingredient can shown to be "adventitious", that is, accidental and technically unavoidable;
- risk assessment was conducted by Member States;
- there were no specific requirements for feed beyond those applying under Directive 2001/18.

Response of the food and feed industry

2.9 Since the initial introduction of the labelling requirements in Directive 90/220, Directive 2001/18/EC and the EC Regulation 258/97, the food industry has shown a strong preference to source ingredients from alternative non-GM suppliers rather than continue to use ingredients which would require labelling. This has happened despite the fact that GM varieties of two major agricultural commodities – soy and maize – were among the first to be widely adopted, rapidly securing a large share of

[4] OJ L159, 3.6.98, p.4 and OJ L 190, 4.7.98, p.86
[5] OJ L6, 11.1.2000, p.13
[6] OJ L47, 11.1.2000, p.15 and OJ L 47, 19.2.2000, p.34

production in the most important export origins [7], most notably GM soy which by 2002/03 accounted for close to 60% of global exports [8].

2.10 As derivatives of soy and maize are used extensively in food production, avoiding GM varieties required the UK food industry to substitute alternative ingredients or develop systems of "identity preservation" in an effort to maintain the integrity of non-GM food production within a commodity system which was substantially GM by the late 1990s [9]. However, by volume, approximately 80% of the soy imported into the EU – equivalent to some 12 million tonnes of a total of 15 million tonnes of soybeans [10]- is for use in animal feed, which was not required to be labelled under the previous legislation. However, whilst there were no legislative requirements, there were various demands from retailers in terms of supplying non-GM feed materials. Similarly, the oil fraction (about 18% of the total by volume [11]) was not required to be labelled under the previous regime as it did not contain detectable DNA. This has meant that, before 18 April 2004, the volumes of soy derivatives that the industry needed to replace or source under special "identity preserved" systems to avoid GM labelling were relatively small, and were mainly food ingredients derived from soy protein. The additional costs of identity preservation were absorbed by the industry.

2.11 As stated above, the new labelling requirements require food ingredients derived from GM sources to be labelled, whether the DNA is detectable or not, and require feed to be labelled. Since 18 April 2004, in response to the regulations the food industry has maintained its previous position and continued to source non-GM supplies. There is therefore no indication that GM ingredients are being used in the food chain and the food supply chain does not therefore have to label products containing GM ingredients. The feed industry has indicated that some components of animal feed are derived from GM sources and therefore the industry will be labelling animal feed as GM.

The need for change

2.12 The EU legislative framework described above has, on several occasions, been revised and adapted since 1990 to keep pace with technical developments, to

[7] See Chapter 3 *"The Areas of GM crops Under Cultivation",* in ***Supply chain impacts of further regulation of products consisting of, containing or derived from genetically modified organisms"*** **LMC International**, September 2003. http://www.defra.gov.uk/environment/gm/research/epg-1-5-212.htm

[8] Three origins – the US, Argentina and Brazil – accounted for over 90% of total global exports of soy in 2002/03, with the US individually accounting for 50% of total exports, Brazil 30% and Argentina 14%. Given that the share of GM varieties in total production was 75% in the US, 20% in Brazil and 99% in Argentina in the same year, this suggests that global exports of GM varieties were likely to be approaching 60% of total exports. See Executive Summary, Chapter 1 and Chapter 3 of **LMC International** study for full details. http://www.defra.gov.uk/environment/gm/research/epg-1-5-212.htm

[9] See Chapter 5, in **LMC International**, http://www.defra.gov.uk/environment/gm/research/epg-1-5-212.htm.

[10] EU imports of soybeans are about 15 mn tonnes p.a. with a further import requirement of 14 mn tonnes of soybean meal – See **LMC International** Chapter 2, Table 2.1 http://www.defra.gov.uk/environment/gm/research/epg-1-5-212.htm

[11] The remaining 2% approx. is soy lecithin. This, like oil, was not covered under the previous regulations.

respond to demands for greater transparency, openness and to provide more detailed scrutiny of particular products, such as food and feed, to which GM technology may be applied.

2.13 Following the adoption of Directive 2001/18/EC in 2001, the Commission saw a need to propose further GM regulation, to respond to two related pressures:

- **i) public confidence**: some Member States considered further measures on traceability and labelling of GMOs, going beyond Directive 2001/18/EC, were necessary to restore public confidence in the regulation of GM crops and food. Directive 2001/18/EC provides for mandatory labelling of any GM product and also requires that Member States must take measures to ensure the traceability, at all stages of the placing on the market, of GMOs authorised under the Directive. However, on adoption of the Directive, a number of Member States (not including the UK) expressed two main concerns. Firstly, they thought the traceability rules should be made more specific in a way that would ensure harmonised requirements throughout the Community. Second, as Directive 2001/18/EC and EC Regulation 258/97 only applies to products containing detectable GM protein or DNA, it was thought that requirements should also be extended to products derived from a GM source but not containing detectable protein or DNA. A few Member States (whose concern did not receive widespread support) also considered that there should be labelling requirements on products in which GM technology had been used at any stage in the production process (such as meat from livestock fed on GM feed).

- **ii) trade tensions**: the consequence of i) was a so-called “de facto moratorium”, starting in 1998, under which the EU decision-making process on new GM products froze, creating trade tensions, particularly with the US. Some GM soy and maize products for import and use in food had received approval before 1998, but there were no further approvals until 2004 when the new GM regulations were in place. The lack of recent new EU approvals has created a disparity with the situation in third countries, such as the US, Argentina and Canada, where several more new GM varieties have been approved for commercial use since 1998. Some of these GMOs have got to the stage of having received a positive risk assessment from the relevant Community authorities, but not to the stage of final authorisation. The major agricultural exporting countries that have approved GMOs on which the EU has not yet taken a decision claim that the failure by the EU to take decisions amounts to a trade restraint. This is illustrated particularly in the case of maize, where some 18 GM varieties have been approved in the US, but only 4 have been approved in the EU. The US has claimed that this has resulted in the loss to them of some $300m a year in maize exports.

2.14 The Commission’s proposals for further legislation were put forward in July 2001 with a view to unblocking the approvals impasse and raising the level of public confidence in GM regulation, principally through measures seeking to extend consumer choice over a wider range of products. The main measures included in the Commission’s original proposal were:

- more specific traceability and labelling requirements

- the extension of controls to cover products derived from a GM source as well as those consisting of or containing GMOs
- a 1% threshold for the adventitious presence of GM material in products, below which traceability, labelling and other requirements would not apply
- centralisation of the assessment of GM food and feed under EFSA

2.15 Following amendments in negotiations, these proposals were adopted by the EU Council of Ministers and the European Parliament in 2003. The main change from the original proposals was to reduce the 1% threshold to 0.9% in the case of GMOs authorised in the EU. This reduction represents a compromise as some member states would have preferred a lower threshold while others wanted to maintain the 1% threshold. A new threshold of 0.5% was introduced for unapproved of GMOs caught up in the decision-making impasse that have received a positive EU risk assessment. Both Regulations have applied fully in Member States from 18 April 2004.

2.16 During negotiations, the UK expressed several concerns about both sets of Regulations and voted against their adoption on three main grounds:

- the enforceability of requirements applying to products derived from GMOs where no GM protein or DNA is detectable
- the practical basis for the umbrella thresholds of 0.9% and 0.5%
- the consistency of the requirements of the Regulations with the Cartagena Protocol on Biosafety.

It should be stressed that the UK's position was not based on opposition to the principle of mandatory traceability and labelling of GMOs. The UK actively supports this principle and was the first large EU Member State to implement Directive 2001/18, providing for mandatory traceability and labelling. The main concern was that the practical implications of the Regulations required further consideration to ensure maximum benefit for consumers.

Risk assessment

2.17 The new legislation aims to increase public confidence and reduce trade tensions by seeking a balanced package of measures dealing with safety, consumer choice and the practical consequences of trade in GM products. The basis for the legislation is part of the UK policy on GM crops and was the cornerstone of the Secretary of State's statement on GM crops in March 2004 which made clear the Government's commitment to safety and consumer choice. The risk of deteriorating public confidence and increasing trade tension are therefore the risks that justify the Regulations.

2.18 As regards measures to increase public confidence by addressing **safety** issues, the Food and Feed Regulation:

- centralises the consideration and co-ordination of risk assessment issues under the independent European Food Safety Authority (EFSA)
- sets up, for the first time, a specific authorisation and labelling regime for GM feed

- requires that products likely to be used for both feed and food must be assessed together.

2.19 The change in procedure provides a 'one door one key' approach to the safety assessment whereby a single application for authorisation can cover environmental release and clearance for use as a food and feed. One body, EFSA, leads on the safety assessment. This approach does not fundamentally change the principles of risk assessment but increases the efficiency and effectiveness of the delivery of scientific and technical support to ensure these principles are adhered to in the increasingly complex area of the safety of food and feed. Such an approach may also increase the certainty and predictability of the safety regime for companies submitting applications for authorisation for the approval of GM food and feed.

Traceability and labelling of GMOs

2.20 Both regulations enhance **consumer choice** by:

- extending the range of products requiring traceability, labelling and other controls by including products with ingredients derived from a GM source that is not identifiable by analysis ("derived products") as well as products consisting of or containing GMOs.
- Requiring the labelling of GM animal feed for the first time
- requiring operators to keep records for 5 years to allow products to be traced back through the supply chain, if necessary.

2.21 The main differences between the old and new regimes are summarised in **Annex 1.** These new aspects will benefit final consumers by providing more information about the use of GM ingredients in food. In the case of animal feed, the final consumer will be the livestock producer as the Regulations do not require the traceability and labelling of, for example, meat from animals fed on GM feed.

2.22 The benefits of improved consumer information choice are not easily valued as it is not possible directly to observe consumer behaviour in the face of a choice between more or less information on food products and on the origin of ingredients from which they are made. A study commissioned by Defra to ask consumers their willingness to pay for the extension of the labelling regime as required under the new Regulations provides a preliminary indication of consumer support for the extension of the labelling regime and the relatively large premiums that consumers report that they were willing to pay to avoid purchasing food containing GM ingredients. Further initial information from this study is summarised under Benefits in Section 4 of the RIA.

2.23 In summary, the Regulations are intended to address public confidence in GM products and increasing trade tensions by providing consumers with more information on the GM content of the food they are purchasing, including extending the labelling regime to feed, and by improving the approvals process in a way that is compatible with trade rules. By their very nature, the benefits of such measures are difficult to quantify. However quantification of the benefits to consumers of increased

information about the content of the food they purchase has been attempted and is described in Section 4 of the RIA.

(iv) Business sectors affected by the new Regulations

Direct costs

2.24 When assessing the potential impact of the new Regulations on business it is important to recognise that the Regulations are largely an elaboration and consolidation, specifically in relation to GM products, of several requirements already imposed by other existing legislation. Such existing requirements include:

- those of the general EU law, in particular Regulation (EC) No. 178/2002, which establishes the European Food Safety Authority and lays down general procedures in matters of food safety, including the requirement for traceability at all stages of production, processing and distribution of food, feed, food-producing animals and any other substance intended, or expected to be, incorporated into food or feed;
- the traceability and labelling requirements of Directive 2001/18 (which will be partially amended and replaced by the new requirements);
- the requirements for labelling applying to all foodstuffs under Directive 2001/13 on the approximation of the laws of Member States relating to the labelling, presentation and advertising of foodstuffs;
- Directive 89/107/EEC on food additives in foodstuffs;
- Directive 88/388/EEC on flavourings in foodstuffs;
- Council Directive 82/471/EEC on animal nutrition products;
- Council Directive 70/524/EEC on additives in feedingstuffs.

2.25 In addition, several pieces of Community legislation also provide for specific identification systems, such as lot numbering, which may, where appropriate, be used instead of the traceability measures specified in the Traceability and Labelling Regulation. The practical effect of this wide range of existing Community legislation applying particularly to food and feed is that additional burdens posed by the new legislation will be in relation to providing information on the use of GM ingredients. For example, in cases where particular ingredients have to specified on a label, the additional requirement in relation to certain ingredients will be to add the words “derived from GM x” to the labelling indication. In order to comply with regulatory requirements as well as to meet commercial consumer demands, producers, distributors and retailers already specify contracts that require certain information to be passed along the supply chain in order to provide assurance that their own procurement requirements are being met. In relation to adventitious GM presence, such contracts often specify levels well below the new statutory umbrella threshold of 0.9%. The feed industry may incur additional work with suppliers to satisfy the traceability requirements of the new legislation as in some feed supply chains there may be by-products from different industries which are used, and for which information will be required.

2.26 The main concern in relation to the new Regulations is not the additional direct costs that they may impose, but their practicability. This applies particularly to products derived from GMOs but containing no detectable GM presence. Such products are often the result of very long supply chains starting off in third countries where agricultural practices and commodity handling procedures may be different from those expected in the EU. The requirements of the new Regulations only apply

at the point of entry into the Community. Since at present there is no premium to be gained in the EU from marketing GM products, the incentive to provide the correct documentation is not high in cases where there is no means of testing analytically whether documentation should have been provided in cases where it is absent.

2.27 With respect to costs associated with safety assessment procedures, mandatory procedures for release of GMOs into the environment and for GM food and feed are already in place in the EU. Changes in this procedure centralise this through EFSA rather than one Member State taking the lead in the assessment process. The biotechnology industry will need to respond by directing authorisations for GMOs through EFSA. This is not expected to increase the costs to the industry. However, the biotechnology industry will incur additional costs through the new requirement to provide detection methods and reference materials for each GM event. The cost of any approval would be borne only by the biotechnology company marketing the GMO, which may be put to a variety of uses once approved. The current Food Standards Agency tariff for applications for approval made in the UK is £4,000. In future, EFSA would be responsible for incurring the bulk of costs involved in processing applications. These costs are set out in Section 5.4. However, EFSA has not indicated how, or whether, they would operate cost recovery in relation to such costs.

2.28 Labelling provisions will impose some direct costs, although many businesses will already have systems in place for record keeping and providing information to the final consumer. The new regulations will require information to be kept and supplied in relation to a larger range of products. The direct impact of the regulations on different sectors, if the industry chooses to use GM ingredients, will be as follows:

- Feed industry – the cost of maintaining additional information regarding GM material in feed and feed ingredients, passing this information along the feed supply chain, and providing information on GM content through labelling
- Food industry – the cost of maintaining additional information regarding GM material in food and food ingredients, passing this information along the food supply chain, and providing information on GM content through labelling
- Retailers – maintaining additional records regarding GM material in food and food ingredients, and providing information to the final consumer
- Hospitality industry – maintaining additional records regarding GM material, and providing information to the final consumer

2.29 Since the regulations came into effect on 18 April 2004 the food and feed industries have taken different approaches. The food industry is continuing to source non-GM supplies and does not therefore need to comply with the regulations via labelling. The feed industry has reported that it will be labelling animal feed as GM as some of the components of the feed are derived from GM sources. The practicalities and costs of the regulations will be explored in detail in a review of the regulations to be carried out by the Commission in November 2005.

Indirect costs

2.30 Indirect costs will be driven by the response of the food and feed industry to the Regulations. The extension of the labelling regime to derived food ingredients

containing no detectable DNA and to feed, will mean that a much higher volume of products derived from GM varieties of soy and maize will require labelling.

2.31 It is important to emphasise that the industry will only need to incur the additional costs associated with sourcing alternatives supplies of GM derived ingredients if it chooses not to manufacture products which require labelling. However in assessing the expected costs and benefits of the new regulations, indirect costs and benefits need to be considered, including the costs to different industrial sectors in light of their response. In the case of GM labelling, evidence to date suggests that the industry has preferred to avoid the need to label and this is the approach the food industry has continued to adopt. In taking such steps indirect costs are incurred in maintaining and verifying IP systems for example for oil production, separate seed crushing and refining plants are required. Costs incurred will very much depend on demand and therefore market price. Industry may choose to seek alternatives to the main commodity crops and examples are provided in chapter 4 of the LMC report[12].

2.32 To take this into account, the analysis presented in Section 5 of this RIA includes costs to the food and feed manufacturing sector under three alternative scenarios which represent three potential responses to the new regulations. These are:

- (a) avoiding the need to label any products for retail sale as GM by ensuring that all potentially GM products covered by the regime are sourced from non-GM suppliers;
- (b) a shift by manufacturers to include GM ingredients in recognition of the fact that GM agricultural commodities are an established part of the global supply chain. Under this scenario, the costs of the new regulations will simply be the costs of labelling products to indicate that they contain GM ingredients. Products from livestock fed on GM feed would not require labelling, as the provisions of the regulations do not cover this;
- (c) going beyond the requirements of the new regulations in order to remove all GM materials from the food chain in the EU, including feed ingredients [13].

2.33 Since the Regulations came into force in April 2004, we have witnessed two main "themes" of behaviour emerging from sectors affected by the new regulations. The food industry has continued (as before) to adopt the behaviour outlined in scenario (a) i.e. the food industry has continued to source non-GM supplies, in effect bypassing the new rules so products for retail sale do not need to be labelled. As discussed in paragraph 2.1, the new legislation requires the traceability and labelling of GM animal feed for the first time. However, since April 2004, we have not seen any evidence of the feed sector adopting the behaviour of the food industry (scenario

[12] Chapter 4 "*The scope for substituting non-GM alternatives for GM oilseeds and maize in the EU*" in **LMC International**, http://www.defra.gov.uk/environment/gm/research/epg-1-5-212.htm

[13] The main difference between this scenario and the first one is that under the new regulations, meat and other animal products derived from livestock fed on GM feed will not require labelling. However, as ingredients derived form soy and from maize account for a very important share by volume of compound feed, and a high share of these imported ingredients come from origins where GM varieties predominate, if manufacturers/major retailers continue to follow the public mood on GM they may seek to eliminate GM ingredients entirely from the food chain.

(a)). Indeed, the feed industry's response to the regulations so far has been to indicate that it will label all supplies from an unknown origin as "GM", in effect adopting the pattern of behaviour as described in scenario (b) and accepting GM products as part of the supply chain. In addition, we have seen no evidence of scenario (c), except on a small, niche market level.

(vi) Issues of equity and fairness

2.34 As well as assessing the overall costs and benefits of the Regulations, consideration of how these may fall on different sectors within the economy is required.

2.35 It is assumed that all consumers will benefit from improved information on the GM content of foods as information will be publicly available. The distribution of costs associated with the alternative scenarios described in 2.32 above will be considered in Section 5.

3. Options

3.1 The options facing the government are limited to compliance with the requirements, as required by EU law, or non-compliance. However failure to comply would be unlawful and present an unacceptable risk of legal challenge and possible infraction costs and cannot therefore be considered a legitimate option. The regulations have been adopted and there is no scope for flexibility. The requirement now on member states is to provide legislation to enable the regulations to be enforced.

3.2 Compliance with the regulations is therefore the option assessed in this RIA, with the benefits set out in Section 4. However, in order to capture the diverse range of indirect costs to the food and feed industries associated with varying responses to the Regulations, the three alternative scenarios described in Section (v) are considered in Section 5 under Costs. The direct costs will only vary to a limited extent under each scenario.

4. Benefits

4.1 The broad categories of benefits relevant to the Regulations' objectives are:

- **Increased consumer confidence** as a result of (a) establishing traceability systems throughout the food and feed supply chain for GM crops; (b) freedom for consumers to exercise their preferences through the labelling of all GM ingredients used directly in food products; and (c) a centralised and improved procedure for regulation via the European Food Safety Authority. These objectives formed the basis of the Secretary of State's statement in March 2004 which outlined the Government's policy on GM crops and the Government's commitment to safety and consumer choice.
- **Reduced trade tensions** as a result of creating the scope for more products to be approved, where justified on the evidence of risk to human health or the environment, thus reducing the disparity between GM products approved in third country trading partners and in the EU. The US and other countries are

currently pursuing a case in the WTO against the so-called moratorium. Through demonstrating that the EU has effective and operating legislation, the basis for the WTO action is removed, thus reducing the ultimate risk of retaliatory measures should a WTO panel find against the EU. The Commission is defending the current WTO case on the grounds that the EU has a fully effective and operative system of regulation for controlling imports of GM products on a basis that is consistent with relevant international rules and standards. The UK fully supports the Commission's defence. It is possible that the new Regulations may themselves trigger additional complaints from the US and other countries.

4.2 As noted in Section 2, the benefits of reduced trade tensions and of increased public confidence are by their nature very difficult to quantify. However survey methodologies have been developed in recent years by economists to derive estimates of consumer willingness to pay for benefits which are not easily quantifiable, based on presenting consumers with a hypothetical situation in which they are asked to choose how much they are willing to pay for a good which includes among its characteristics the attribute which the researcher is seeking to value. From the analysis of responses, an estimate of the value of the attribute can be derived. Defra commissioned a study using these techniques to provide monetary estimates of the benefits indicated by consumers of the increased information provided by the Regulations.[14] The study is the first quantitative, economic assessment of consumer responses to purchasing foods containing GMOs based on a nationally representative dataset.

The two core questions addressed in the study were:

- What are the benefits of increasing the robustness of the GM food labelling regime?
- What are the benefits of a reduction in GM labelling threshold levels?

Respondents were also asked questions regarding some general issues concerning GMOs in food, including issues of trust and questions about the testing and commercial development of agricultural GMOs.

4.3 Results from the survey indicated that respondents treat GM derived ingredients as no different from GM ingredients, indicating that the extension of labelling requirements to GM derivatives as required by the Regulation was valued by respondents. There was also evidence to suggest statistically significant expressions of willingness to pay (WTP) to avoid purchasing a food product containing GM ingredients. The implication of this finding is that, whilst the introduction of the new labelling regime required by the regulation will generate additional costs, the evidence from the survey is that customers will value the changes introduced.

[14] **Consumer Willingness to pay to reduce GMOs in food and increase the robustness of GM labelling**, D.Rigby, T.Young and M.Burton, University of Manchester, January 2004 http://www.defra.gov.uk/environment/gm/research/reports

4.4 Results from the section of the survey investigating the benefits of reducing GM labelling threshold levels found that consumers did not value the lowering of the threshold of the adventitious GM presence from 1% to 0.9%. Respondents did value lowering the labelling threshold to between 0% and 0.5% levels (although interestingly respondents did not distinguish between threshold levels of 0% and 0.5%). It should be noted, however, that this response was elicited without any consideration of the practical ability of the supply chain to deliver such low thresholds across a very wide range and variety of actual and potential products.

4.5 The results of the survey need to be viewed with some caution given that they are based on asking consumers about a hypothetical situation, and there is evidence that in surveys of this kind consumers do provide much higher values than their actual behaviour demonstrates. As such, the results are not conclusive. It should be stressed that the survey was not carried out to inform any policy decision about the content of the EC regulation or otherwise. As described in section 3, the regulations take direct effect in the UK with no scope for flexibility as regards their implementation. However, the results of the survey are interesting to note in terms of public attitudes towards aspects of GM policy in the UK

5. Costs

5.1 With respect to the public sector, these are:

- the costs of centralising the regulatory system through EFSA;
- enforcement costs for ensuring unauthorised GMOs do not enter the food and feed chain, and GM food and feed is labelled correctly.

5.2 The costs to business will involve:

- the direct costs of maintaining additional information regarding the use of GM material in food/feed and food/feed ingredients, passing this information along the supply chain, and providing information on GM content through labelling;
- the indirect costs for food and feed manufacturers arising from sourcing alternative supplies of GM derived ingredients in order to avoid the need to label products.

Costs to the public sector

(i) The costs of centralising the regulatory system through EFSA

5.3 Detailed quantification of the costs to the public authorities of the safety aspects of the Regulations through a centralised procedure has not been undertaken as, despite the new functions of EFSA, Member States and the Commission still retain a role in relation to key aspects of risk assessments[15] and in the authorisation, risk management, and risk communication processes. It is unlikely that, for the time

[15] For, example, EFSA does not have the option of doing an environmental risk assessment itself in relation to product approvals for seeds or plant propagating material submitted under the Food and Feed Regulation; it must instruct the relevant competent authority of a Member State to do the environmental risk assessment.

being, the change in emphasis in the relationship between these parties will result in significant changes to administrative resource requirements in Member States.

5.4 In presenting its original proposal on the GM Food and Feed Regulation in 2001, the Commission identified the following annual central costs:

Quantification of estimated central administrative costs of safety assessments for the EU (2001)

Activity	**€**	**£**
Meetings of relevant Standing Committee to discuss authorisations	39,000	26,738
Any additional studies required for operation of Regulation	97,500	66,844
Meetings of the Community Reference Laboratory	380,000	260,520
TOTAL	**514,500**	**354,102**

5.5 EFSA itself is funded directly through the European Community with an estimated budget of 29M euros in 2004. Costs attributed to EFSA on GM assessments will depend on how many products are brought forward for approval.

(ii) Enforcement costs

5.6 Enforcement costs are considered in more detail in Section 8.

Business sector costs: (i) direct costs

Traceability systems

5.7 Traceability costs are expected to be low. As discussed in Section 2, this is mainly because the regulations are largely an elaboration and consolidation, specifically in relation to GM products, of several requirements already imposed by existing legislation (paragraphs 2.5-2.7). In addition, several pieces of Community legislation also provide for specific identification systems. Many food and feed manufacturers already have established IP systems in place to guarantee a non-GM supply. In order to comply with these existing requirements producers, distributors and retailers therefore already specify contracts that require certain information to be passed along the supply chain.

5.8 Current traceability costs for the whole UK retail industry – which are driven by the retailers' commitment to demonstrate that they are not using GM ingredients rather than to meet the traceability requirements set out for GM ingredients - are estimated at no more than £5 million p.a., and supermarkets indicated that they are reasonably well prepared to deal with new thresholds without seeing their margins on branded goods suffer[16].

5.9 Generally, the retail sector relies on certification or channelling systems for ensuring that products are sourced with non-GM ingredients. This provides various forms of reassurance about the geographical origins of the raw materials, including

[16] See Chapter 6, *"The Potential Impact of the Proposals on Consumers"* in **LMC International**, http://www.defra.gov.uk/environment/gm/research/epg-1-5-212.htm

certificates that are carried with the crop from the time that it is delivered to the export port to the European processor. These shipments are not necessarily tested for subsequent commingling with GM commodities.

5.10 Among typical units in the catering, restaurant and food service industries, which is much more fragmented than the supermarket industry, the view appears to be that they are too small to afford their own testing procedures and identity preservation systems [17]. Therefore they rely on the word of their suppliers that they have been provided with non-GM ingredients. As a result, these sectors appear not to have incurred any additional costs in meeting current traceability requirements.

5.11 The views among small bakeries, as well as producers of cakes and biscuits, all of whom use ingredients derived from soy and maize, appear to be very similar to those of the catering sector, that is that it is the role of suppliers to ensure product integrity and compliance with the regulations. They do not have facilities with which to trace the origins of their ingredients, and do not therefore incur the associated costs.

5.12 With respect to potential costs to businesses of enforcement and inspection to ensure compliance with the regulations, the expectation is that these will be insignificant because form filling and their storage is already something undertaken by businesses to meet existing regulatory requirements and any inspections will be incorporated within the existing system of visits made by Trade Standards Officers Environmental Health Officers. Furthermore, as there is no immediate prospect of cost recovery, costs will fall to government or local authorities not to business. However, as indicated in Section 8, public sector costs are, in turn, expected to be marginal and to be absorbed within existing expenditure provision.

Labelling and the provision of information to consumers

5.13 The costs for changing labels and providing information to consumers will be contingent on the response of the food and feed manufacturers to the new regulations and the consequent extent to which the labels are required. The food industry has reported that new labelling requirements in addition to those required by these Regulations will add additional costs unless all the required changes can be introduced at the same time. However the food industry has maintained its position of sourcing non-GM supplies and has not therefore needed to change its labels.

Business sector costs: (ii) indirect costs

5.14 The additional costs of sourcing alternative or identity preserved ingredients, which represent indirect costs to the food and feed industries of the regulations, will depend on their response to them. In paragraph 2.32 we considered three alternative scenarios:

(a) Industry avoids the need to label all potentially GM ingredients by sourcing alternative or identity preserved supplies;

[17] *ibid*.

(b) Industry accepts the presence of GM products in the mainstream commodity system and labels all food and feed ingredients accordingly.

(c) Industry goes beyond present labelling requirements in response to the perceived public anti-GM mood and requires all feed ingredients used in the production of livestock products to be sourced from non-GM sources;

We concluded that, since the Regulations came into force in April 2004, the food industry had continued to act in accordance with scenario (a) and that the feed industry had adopted the behaviour of scenario (b). There had been no evidence of scenario (c), except on a small scale. Taking into account this evidence of activity in the food and feed sectors, the following section analyses the costs of scenarios (a) and (c).

Indirect costs under scenarios (a) and (c)

5.15 With respect to scenarios (a) and (c), the main drivers of the additional costs of alternative or identify preserved supplies will be:

- the extent of EU/UK self-sufficiency in the key commodities involved, that is soy and maize, and to a much lesser extent, rapeseed;
- the global availability of non-GM supplies of these commodities;
- the extent to which the EU/UK may, in future, cultivate these commodities;
- EU consumption of the main products for which these commodities are used;
- the scope for substitution of GM by non-GM ingredients from an alternative crop;
- additional costs (testing and documentation) of non-GM identity preservation (IP).

5.16 The LMC report[18] examines these factors in detail. A summary is presented in Annex 3.

5.17 Identity preserved (IP) supply chains for bulk commodities such as soy and maize represent an alternative to sourcing all potentially GM commodities from non-GM origins, and many such IP systems have already been set up [19]. In the LMC report the costs associated with such systems have been used to provide an estimate of the annual costs to the UK industry of establishing a fully IP supply chain, taking account of all transactions from the farm to the final consumer, and assuming that UK costs represent 10% of the EU total. If both scenarios (a) and (c) were to occur hand in hand (assuming no commercial cultivation of GM crops in the EU), it is estimated that the UK share of the wholesale and retail annual IP costs of a non-GM supply chain in the EU would be about £304 million p.a. This is equivalent to 0.22% of the total expenditure in 2002 of £139 billion by UK consumers on food and drink [20]. The pragmatic response of the food industry appears to be sustainable and the new legislation would appear not to introduce additional costs. Costs may vary depending on the demand and supply of the market but these cannot be predicted.

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[18] *ibid.*
[19] Chapter 5 *"The Economics of Segregation and Identify Preservation"* in **LMC International**, http://www.defra.gov.uk/environment/gm/research/epg-1-5-212.htm
[20] Chapter 7 *"An Assessment of the Impact of the Proposed Measures"* in **LMC International**, http://www.defra.gov.uk/environment/gm/research/epg-1-5-212.htm

5.18 The analysis above indicates that under a scenario combining both (a) and (c) the cost of securing sufficient non-GM supplies of three bulk commodities (soybeans, rapeseed, and maize) to meet UK requirements could be as high as £304 million. However, this calculation is based on a hypothetical situation in which both the food and feed sector avoid the use of GM in their supply chains. In practice, however, what we have seen since April 2004 is that, whilst the food manufacturing industry continue to avoid GM (scenario (a)), the feed industry seem to accept GM in their supply chain (scenario (b)). In effect, we have evidence to suggest that scenario (a) is happening in isolation from scenario (c).

5.19 As scenario (a) is occurring in isolation, the cost of £304m quoted above is not an accurate reflection of what has been happening in practice since April 2004. The costs relating to scenario (a) in isolation from scenario (c) would be considerably lower than £304m[21]. As described in section 2, the main change to food labelling introduced by these Regulations relative to previous legislative requirements is the labelling of derived products. Taking this into account, the additional costs for the food industry in scenario (a) should only reflect those costs incurred as a result of tracing or labelling, or sourcing non-GM alternatives, for a small proportion of new, additional products included in the new rules.

5.20 None of the additional supply costs estimated above would be incurred under scenario (b) which assumes that the industries reverse their current policy on avoiding GM labelling and accept the presence of GM soy and maize in the global commodity system.

Costs beyond the UK

5.21 The above costs are presented from a UK perspective, as required in an RIA. However, it is important to note that the regulations will have wider global impacts, as they involve the production and trade of global agricultural commodities. Apart from general considerations about the capacity of developing countries to comply with the regulatory requirements, one significant environmental impact to the regulations is likely to be additional pressure on Brazilian natural habitats to meet EU demands for non-GM soy.[22]

[21] The LMC figure estimated that food produce only represented 32% of £304m, against a share of 58% for feed products: "Under current approvals for growing GM crops in the EU, we estimate that only 32% of all food products derived from the three bulk commodities would be handled by non-GM IP systems, as against a 58% share of feed products". Page 180 in **LMC International**, http://www.defra.gov.uk/environment/gm/research/epg-1-5-212.htm

[22] See the last DFID Country Strategy Paper for Brazil, p.3, which, even in 1998, refers to the particular impact on biodiversity loss of clearance of native tropical savannah vegetation as a result of the introduction of modern large scale agriculture, particularly soy farming. Since 1998 the area planted to soy beans in Brazil has increased by over 40% from about 12 to 17 million hectares in 2002, accounting for nearly 50% of the arable crops grown. The extra capacity has been obtained partly by clearing rain forest areas in the north of the country.

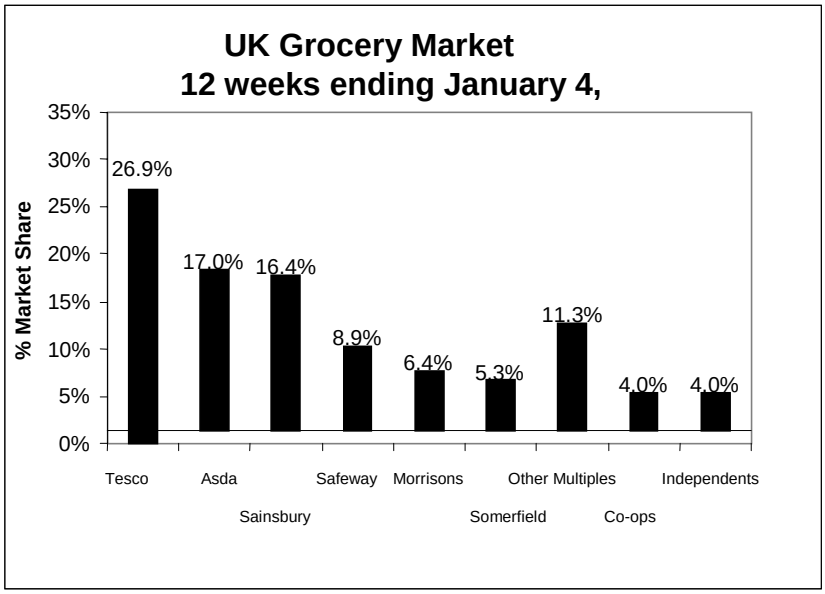
6. Impacts on small business

6.1 Within the baking, catering, restaurant and food service industries are many small units which are highly likely to be using products and ingredients derived from imported soy and maize. Evidence derived in interviews from representatives of these sectors suggests however that the costs of the new regulations associated with traceability are unlikely to fall disproportionately on small businesses. As noted in 5.10 and 5.11, the view in these industries is that it is the role of suppliers to ensure product integrity and compliance with the regulations, and they do not therefore maintain traceability systems of their own but are dependent on the paper audit trail provided. With respect to the costs of enforcement and inspection to ensure compliance, the expectation is that these will be insignificant (see 5.12 above).

7. <u>Competition assessment</u>

Food Retailers

7.1 The latest figures for the relative shares of food retailers in the UK grocery market illustrate that that market for grocery retail is relatively concentrated and the three largest retailers have over 50% market share.



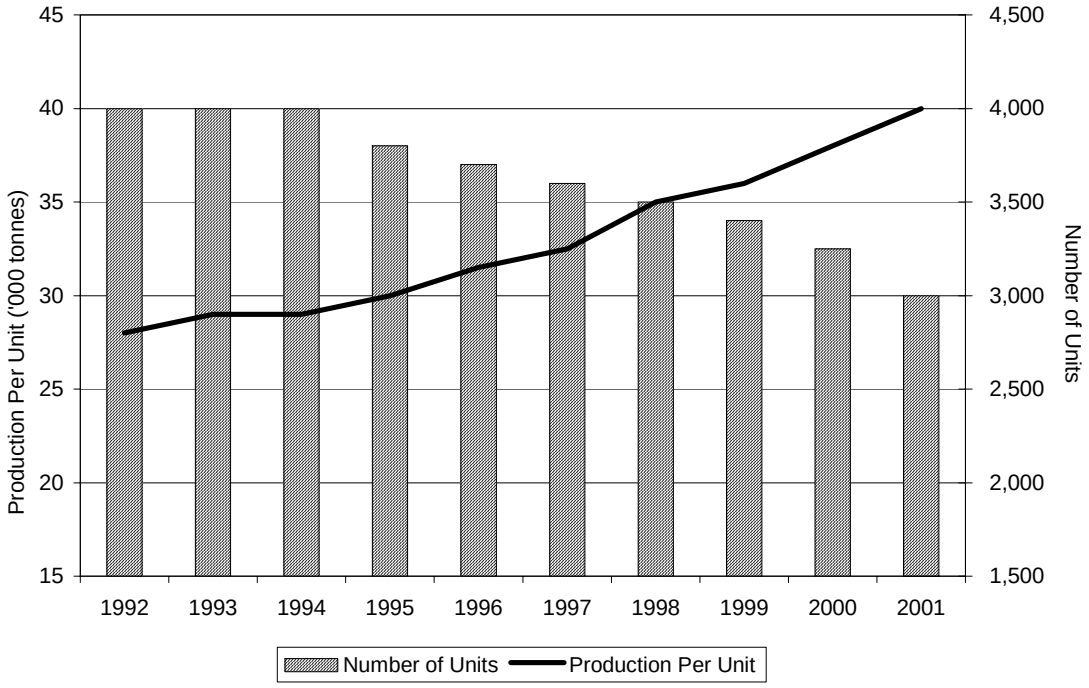
Source: Taylor Nelson Sofres Superpanel

7.2 It is anticipated that the larger retailers will be better able to cope with the new traceability and labelling requirements than their smaller competitors as they already have dedicated supply chains in place to meet the costs of complying with the regulations. Furthermore, the concentration of market power in the retail sector with respect to both suppliers and consumers may mean that retailers will be well placed to pass on any additional costs associated with the regulations up the supply chain to suppliers or downstream to consumers.

Animal feed

7.2 The following table illustrates a decline in the number of feed manufacturing firms in the past ten years reflecting the changes the industry has undergone in response to BSE, and as a result of firms amalgamating and others becoming more specialised in feed production, increase efficiencies or intensification of production. Feed manufacturers could be further squeezed by the pressure of increasingly tight regulation or by the demand to supply non-GM feed, possibly leading to further concentration in these sectors into fewer larger companies.

The Number of EU Compound Feed Plants and Their Average Size



Baking, catering, restaurant and food service industries

7.3 Sections 5 and 6 indicated that the costs of traceability and inspection are not expected to fall disproportionately upon these sectors. The view expressed by representatives of these industries interviewed was that responsibility for meeting the requirements of the regulations would lie with their suppliers.

Farmers

7.4 In the UK there will be no impact on farmers as GM crops are not yet grown commercially. There will be some impact in the future if GM crops are grown commercially but as it is not yet known how extensive GM production will be, an assessment of its effect on the structure of the farming industry is not possible at this time.

8. Enforcement costs and sanctions

8.1 The labelling of GM ingredients in food and feed is to enable end-users to have this information and to be able to make informed choices. This is not a safety

issue given that GMOs undergo a rigorous safety assessment before being approved for food or feed use. The costs therefore allocated by local authorities (who have responsibility for enforcing the regulations) will therefore need to be proportionate to enforcement activities in relation to food safety and protecting human health.

8.2 GM crops are not currently being grown in the UK (and it is unlikely this will occur before 2008) and therefore any GMOs in the UK will be via third country imports. Checking of GMOs is likely therefore to occur at point of entry rather than at point of sale to the end user.

8.3 Since 1999 regulations have been in place requiring the labelling of GM food ingredients. These regulations extend the range of food ingredients to be labelled and include GM animal feed. An EC Food and Veterinary Office mission to the UK in October 2003 was conducted to evaluate the systems in place and the enforcement of the regulations. Local authority activity in monitoring GM ingredients was low recognising that GM labelling is a consumer choice and not a food safety issue, and reflecting the response of the food industry to sourcing non-GM ingredients. Testing and monitoring in relation to these new regulations will vary from one authority to another. Some authorities may choose to set up testing facilities and adopt extensive monitoring programmes while others may choose to limit their activities in this area. For enforcement of these regulations, one County Council which is specifically setting up facilities for testing, and estimates an annual running cost of £50K. However LACORS has indicated that this example is one end of the spectrum and that they are not expecting other authorities to act in this way. Total revenue expenditure is expected to be £8.5bn for local authorities in Scotland in 2004/5 of which in the region of £96 million is expected to be spent on food law enforcement. Although information on how much in total will specifically be spent on enforcement of these regulations, enforcement activity will be considered as part of the Commission's review of the regulations in November 2005 and local authorities are being encouraged to collate information in relation to expenditure.

8.4 The main costs of enforcing the new Regulations are identified as:

- the cost of testing products for GM content
- the cost of monitoring the accuracy of traceability and labelling
- the cost of imposing penalties for non-compliance

8.5 It is assumed that the greatest burden of enforcement will fall on Local Authorities who are responsible for monitoring and enforcing compliance with food labelling requirements and who will pick up the responsibility for labelling under the new feed labelling requirements. Depending on the Local Authority, responsibility may fall to Trading Standards Officers or Environmental Health Officers.

8.6 The proposed enforcement Regulations introducing penalties and fees for the enforcement of the EC regulations for Scotland imply a hierarchy of offences and penalties, descending from more to less serious. The proposals meet Scottish Executive policy guidelines for offences and penalties and are consistent with legal maxima available under the European Communities Act 1972 and the Food Safety Act 1990. They fall into three broad categories, which are summarised in some detail in **Annex 2**.

8.7 The main principles determining these categories of offences and penalties are:

- **most serious**: sale and use of unauthorised products, particularly food
- **less serious**: failure to comply with requirements for authorised products
- **least serious**: failure to keep proper records

9. Monitoring and review

9.1 Both the Traceability and Labelling and the Food and Feed Regulation contain specific review provisions, on which the Commission is tasked to report to the European Parliament and to the Council by October and November 2005 respectively. Although the review report may cover any aspect of the Regulations, the Commission is specifically asked to report on:

- unique identification requirements for GMOs in bulk shipments of agricultural commodities[23]
- operation of the 0.5% transitional threshold in relation GM food and feed[24]

9.2 During negotiations on the Regulations, the UK expressed particular concerns about:

- the enforceability of requirements applying to products derived from GMOs where no GM protein or DNA is detectable
- the practical basis for the umbrella thresholds of 0.9% and 0.5% for adventitious GM presence established under the Regulations
- the consistency of the requirements for the identification of bulk shipments of GM commodities with the Cartagena Protocol on Biosafety.

10. Consultation

Within government

10.1 The FSA and Defra have developed this RIA in consultation with the devolved administrations and other government departments, including the Cabinet Office Regulatory Impact Unit and the Home Office in respect of proposed offences and penalties.

Public consultation

10.2 Oral and written consultations were carried out with stakeholders in 2001 and 2002 whilst the Regulations were under negotiation at EU level. Formal written consultations revealed widely differing views. On the one hand, there was a concern that the consumer requirements of the Regulations should go a lot further in, for example, setting lower labelling thresholds, or extending requirements to products (such as meat and eggs) produced "with" GMOs. On the other hand, other stakeholders pointed out the practical difficulties of applying the proposals to certain

[23] Traceability and Labelling Regulation, Article 12
[24] Food and Feed Regulation, Article 48

ingredients, which in turn had implications for specifying the possible cost implications.

10.3 Following final adoption of the Regulations, FSA Scotland and the Scottish Executive held a stakeholder meeting in November 2003 with groups representing food and feed manufacturing, farming, enforcement and consumer interests The purpose of the meetings was to consider the detail of the Regulations, in particular those aspects affecting their practical application in Scotland. Similar meetings with a wide range of stakeholders were held in other parts of the UK. The discussions and questions raised at the stakeholder meetings focussed on the scope of the labelling requirements and the lead in time for the manufacturing process. With respect to labelling clarity was specifically sought on fermentation products produced using GM substrates or GM micro organisms. The questions in relation to manufacturing process recognised that many food and feed producers would already have already started the manufacturing process for many products which would not reach the final consumer until after the implementation date for the regulations.

10.4 The FSA and Defra subsequently met the Commission to discuss the key issues raised by stakeholders. The Commission's advice on these issues is reflected in guidance notes, which have been produced separately to accompany the domestic regulations which provide penalties and fees for enforcing the Regulations.

10.5 Particular attention will be paid to the factors in paragraph 9.2 in monitoring and reviewing the UK's practical experience of the operation of the Regulations. The RIA formed part of a consultation package issued to stakeholders in April 2004. The consultation package was sent to approximately 1900 stakeholders and 76 replies were received of which 27 commented on the RIA. Stakeholders were asked whether they agreed with the analysis of costs and benefits presented in the RIA and whether there were any significant areas of benefits and/or costs not covered by the RIA. Responses from stakeholders have been incorporated into this final RIA. Respondents were unable to provide input in relation to direct and indirect costs incurred and have stated that this will be monitored over the forthcoming year. The FSA and Defra have specifically requested information from stakeholders on how the regulations work in practice and the actual costs of complying with the regulations over the forthcoming year to enable the UK to play a full part in the Commission's review of these issues in November 2005.

11. Summary and Recommendations

11.1 The new legislation aims to increase public confidence and reduce trade tensions by seeking a balanced package of measures dealing with safety, consumer choice and the practical consequences of trade in GM products. The risk of deteriorating public confidence and increasing trade tension are therefore the risks that justify the regulations.

11.2 As regards measures to increase public confidence by addressing **safety** issues, the Food and Feed Regulation:

- centralises the consideration and co-ordination of risk assessment issues under the independent European Food Safety Authority (EFSA)

- sets up, for the first time, a specific authorisation and labelling regime for GM feed which requires that products likely to be used for both feed and food must be assessed together.

11.3 **Consumer choice** is provided by:

- extending the range of products requiring traceability, labelling and other controls by including products with ingredients derived from a GM source that is not identifiable by analysis ("derived products") as well as products consisting of or containing GMOs.
- labelling of GM animal feed for the first time
- requiring operators to keep records for 5 years to allow products to be traced back through the supply chain if necessary.

11.4 The Regulations have already been adopted and took direct effect in the UK with no flexibility as regards their implementation, except in relation to penalties for non-compliance. Essentially, therefore, the options facing the Government are limited to compliance with the requirements, as required by EU law, or non-compliance. Compliance with the regulations is the option assessed in this RIA.

11.5 Consideration of the benefits of the regulations, that is improved consumer confidence and a reduction in trade tensions, are not easily valued. A study commissioned by Defra to ask consumers their willingness to pay for lower thresholds for the adventitious presence of GM material in food provided a preliminary valuation of £3.8 billion p.a. However, this result needs to be viewed with some caution given that it is based on asking respondents about a hypothetical situation and there is evidence that they provide much higher values – perhaps more than three times higher - than their actual behaviour demonstrates. Applying a correction of a factor of three would suggest benefits of about £1.3 billion p.a..

11.6 Two types of costs are considered: costs resulting directly from the application of the regulations; and the indirect costs associated with the response of the food industry in sourcing non-GM supplies to satisfy market demand.

11.7 Direct costs considered are the costs of labelling and traceability to the food and feed industry, and the administrative costs associated with the new functions of the EFSA and of enforcement in the UK.

11.8 Overall direct costs are expected to be low. This is mainly because the regulations are largely an elaboration, specifically in relation to GM products, of several requirements already imposed by existing legislation. In addition, several pieces of Community legislation also provide for specific identification systems. In order to comply with these existing requirements producers, distributors and retailers therefore already specify contracts that require certain information to be passed along the supply chain.

11.9 Current traceability costs for the whole UK retail industry – which are driven by the retailers' commitment to demonstrate that they are <u>not</u> using GM ingredients rather than to meet the traceability requirements set out for GM ingredients - are estimated at no more than £5 million p.a. and supermarkets indicated that they are

reasonably well prepared to deal with new thresholds without seeing their margins on branded goods suffer. Within the catering, restaurant and food service industries, which is much more fragmented than the retail industry, operators rely heavily on the word of their suppliers to provide them with ingredients as specified by them, whether GM or non-GM.

11.10 Indirect costs for the food and feed industry are considered to be the additional costs of sourcing alternative or identity preserved ingredients and the extent of these will depend on their own response to the regulations. Since the regulations came into force, we have seen the food manufacturing industry avoiding the need to label GM ingredients in retail products by sourcing alternative or identity preserved supplies. This is largely a continuation of their existing behaviour, although now the industry is also required to label products derived from a GM source, whether or not DNA protein is detectable in the final product. Other products included in the new regulations already required labelling under existing legislation (see section 2). As such, any additional costs incurred by the food manufacturing industry as a result of the new, additional changes brought in by these regulations (either direct costs of labelling and tracing, or indirect costs of sourcing non-GM or IP alternatives) will be restricted to a small range of products. We estimate that these costs will not be substantial to the food manufacturing industry as a whole, although those companies working with derived products will incur magnified costs.

11.12 In the current climate, the priority for supermarkets/ food retailers is to avoid GM supplies of products for retail sale in order to bypass GM labelling requirements, hence scenario (a) (see paragraph 2.32). As the new regulations do **not** extend GM labelling requirements to products produced from livestock reared on GM animal feed, the supermarkets and food retailers have not pressurised the feed and livestock industry to change from their current practice of using GM animal feed. As such, the feed industry has effectively accepted GM products as part of the supply chain (scenario (b) in paragraph 2.32). Under this scenario, there will be no indirect costs associated with sourcing alternative or IP ingredients. There will be only direct costs associated with traceability and labelling requirements. As the majority of operators in the feed industry have adopted this approach to labelling, we do not expect them to incur any additional indirect costs as a result of their stance.

11.13 We have seen, on a small scale, some niche market products emerging that go beyond the present labelling requirements. For example, by requiring that livestock products are sourced from animals fed on non-GM feed. However, there is no evidence that this will or may happen on a larger scale. If this scenario did occur on a wider scale, in conjunction with the scenario described in paragraph 11.12 above, the estimated cost of the wholesale and retail annual IP costs of a non-GM supply chain for the UK would be approx £304 million p.a.

11.14 The food industry has chosen to maintain its position and continue to seek non-GM supplies to satisfy market demand. The feed industry has chosen to label animal feed as GM given that some components of the feed are derived from GM sources. However consideration of the potential sectoral impact of the options analysed in the scenarios above suggests that different sectors within the industry itself might favour alternative responses. For example, the retailers, who have shown themselves on this issue to be highly sensitive to their brand reputation, may seek –

in response to the public mood - to require all feed ingredients used in the production of livestock products to be sourced from non-GM sources, whilst at the same time believing that they have the means through their market position to pass back any costs associated with this strategy to their suppliers. However livestock producers and, behind them, the feed industry - which operate on much lower margins - may try and resist such a strategy and demand that the retailers themselves meet the full costs associated with sourcing non-GM ingredients, which, in the short term at least, might prove not only highly costly to source, but actually impossible, given the large volumes of GM soy and maize already traded with the global commodity system. In these circumstances the retailers might consider changing their public stance on GM rather than incurring very high costs which might prove difficult to pass on to consumers.

11.15 A table summarising costs and benefits is set out below. This shows that the costs – specifically the indirect costs - are very sensitive to the response of the food industry to the new regulations. However preliminary estimates of consumers' willingness to pay for measures to reduce the risk of inadvertently consuming GM products is also shown to be high – several times higher than the costs of supplying them. This suggests that overall the benefits to UK consumers of the Regulations outweigh the total costs.

Summary of Costs and Benefits

	Description	**Value**
Benefits	Improved consumer information	Significant
	Reduced international trade tensions	NA
	Improved efficiency of safety assessment process	NA
Costs	***(i) Direct***	
	Industry implementation of traceability and labelling systems	Limited
	Administration costs associated with EFSA	£40,000 p.a.
	Enforcement costs incurred by Local Authority Trading Standards Officers	Limited
	(ii) Indirect – resulting from the response of the industry to the new regulations	
	(a) the UK food manufacturing industry avoids the need to label all potential GM food ingredients in products for retail sale by sourcing alternative or identity preserved supplies	Some indirect costs incurred for specific additional products covered for the first time in this legislation (e.g. derived products)
	(b) Industry accepts the presence of GM products in the mainstream commodity system (mainly for animal feed) and labels all food and feed ingredients accordingly)	No indirect costs. Direct costs relating to traceability and labelling of GM products incurred.
	(c) the food industry goes beyond present labelling requirements in response to the perceived public anti-GM mood and requires all feed ingredients used in the production of livestock products to be sourced from non-GM sources	In conjunction with (a) above: indirect costs of approx £304 million p.a.

12. Declaration

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

Signed……..

Date

Allan Wilson, Deputy Minister for Environment and Rural Development

Signed……..

Date

Tom McCabe, Deputy Minister for Health and Community Care

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Annex 1

GM FOOD AND FEED LABELLING: EC NOVEL FOODS REGULATIONS (258/97, 1139/98, 49/2000, 50/2000) COMPARED WITH NEW GM FOOD AND FEED REGULATION (1829/2003)

Measure	Example	Novel Foods Regulation	GM Food and Feed Regulation
Labelling of GM derived products (no GM material present)	Highly refined maize oil, rape seed oil, alcoholic beverages	Labelling not required	Labelling required
Labelling of products containing, or consisting of, GM material	Maize, soya bean sprouts, tomato, maize flour	Labelling required	Labelling required
Labelling of foods produced "with" GM technology	Cheese produced with the help of chymosin from GM micro-organisms	Labelling not required	Labelling not required
Labelling of food produced from animals fed GM animal feed	Milk, meat, and eggs	Labelling not required	Labelling not required
Threshold for EU-approved GMOs in products		1%	0.9%
Threshold for non-EU-approved GMOs in products		0%	0.5%, only for a transitional period of 3 years and where GMO has favourable safety assessment from EC Scientific Committee
Food sold in catering outlets	All foods sold if produced from GM source, regardless of whether GM material is present in the food, and including alcohol, and food cooked in oil derived from a GM source	Labelling is optional. Compulsory rules have been applied in the UK where GM material is present in the final food, in line with labelling rules under Novel Foods Regulation	Labelling is optional

Annex 2

NEW EC REGULATIONS: ENFORCEMENT

Hierarchy of offences and penalties proposed for England

Category	Proposed Offence	Proposed Penalty
Most serious	1) Placing food on the market without, or in contravention of, an authorisation under the GM Food and Feed Regulation	1) (a) On conviction on indictment, imprisonment for up to 2 years, or a fine, or both 1) (b) On summary conviction, imprisonment for up to 6 months, or a fine not exceeding level 5 on the standard scale (currently £5000)
	2) Placing feed on the market without, or in contravention of, an authorisation under the GM Food and Feed Regulation	2) (a) On conviction on indictment, imprisonment for up to 2 years, or a fine, or both 2) (b) On summary conviction, imprisonment for up to 3 months, or a fine not exceeding level 5 on the standard scale (currently £5000)
Less serious	3) Failure to comply with specified requirements, including labelling, in relation to food with an authorisation under the GM Food and Feed Regulation	3) On summary conviction, imprisonment for up to 6 months, or a fine not exceeding level 5 on the standard scale (currently £5000), or both 4) On summary conviction, imprisonment for up to 3 months, or a fine not exceeding level 5 on the standard scale (currently £5000), or both
Least serious	4) Failure to comply with specified requirements, including labelling, in relation to feed with an authorisation under the GM Food and Feed Regulation 5) Failure to keep and transmit appropriate records in relation to the requirements of the Traceability and Labelling Regulation	4) and 5) On summary conviction, imprisonment for up to 3 months, or a fine not exceeding level 5 on the standard scale (currently £5000), or both

Annex 3

SUMMARY OF GM PRODUCTS APPROVED, OR BEING CONSIDERED FOR APPROVAL, UNDER EC LEGISLATION

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

Annex 4

Summary of the main factors potentially contributing to the additional costs of using alternative or identity preserved supplies
(*http://www.defra.gov.uk/environment/gm/research/epg-1-5-212.htm)*

Self-sufficiency

- the EU is almost entirely dependent on imports for all its soybean needs;
- the greatest need is for soy meal, in which the EU is only 4% self-sufficient;
- the total EU requirement for soy beans and meal is over 30m tonnes a year;
- the largest usage is in compound animal feed, particularly for pigs and poultry;
- soybean derivatives are an important source of functional food ingredients;
- EU net imports of rapeseed and maize products are, in comparison, small;
- the EU nevertheless has 40% of the global demand for maize gluten feed;
- processed maize products are also an important source of food ingredients;
- the EU is near self-sufficient in rapeseed and oil, but not in rape meal;
- rapeseed oil is imported to some extent for use in functional food ingredients.

Sources of supply

- Brazil is predominantly the current source of supply for non-GM soy;
- 75% of Brazil's beans and 80% of its meal are exported to the EU;
- currently at least 20% of Brazilian soy production is GM;
- the other main sources, USA and Argentina, are largely GM producing;
- USA soy production is nearly 80% GM and Argentina's nearly 100%;
- the US is the largest source of supply for processed maize products;
- over 30% of US maize production is GM;
- Canada is the largest producer of rapeseed products, with about 60% GM.

Scope for substitution

- there is no effective substitute for soybean meal, particularly for pigs and poultry;
- while domestic/EU varieties of rapeseed remain non-GM, domestically produced rapeseed oil can substitute for soy oil in all major end food uses. However, it cannot be used for feed as the nutritional profile is different;
- the substitution of the large range of soybean derivatives in food and feed uses will provide more of a challenge for the food industry. Most notably, 15 million tonnes of non-GM soybeans will be needed annually to meet EU lecithin requirements. This is equivalent to the entire volume of annual imports of soybeans in to the EU.
- wheat and potato starch could replace maize products in some food applications but cost would be prohibitive for its substitution in the feed sector.

Subordinate Legislation Committee
Extract of 38th Report, 2004

The Committee reports to the Parliament as follows—

1. At its meeting on 2nd November 2004 the Committee determined that it did not need to draw the attention of the Parliament to the instruments listed in the Annexe to this report on any of the grounds within its remit.

2. The report is also addressed to the following committees as the lead committees for the instruments specified:

Environment and Rural Development	SSI 2004/453

Instruments subject to annulment

The Avian Influenza (Survey Powers) (Scotland) Regulations 2004 **(SSI 2004/453)**

Background

3. These Regulations confer powers of entry etc on local authority and government inspectors to enable surveys of the incidence of avian influenza to be carried out. They supplement Commission Decision 2004/630/EC. The Regulations are a temporary measure that will cease to have effect on 16 March 2005.

4. The Regulations breach the 21-day rule but the Committee accepted that, for the reasons set out in the letter to the Presiding Officer, this was unavoidable.

Question 1

5. The Committee asked the Executive why any definition of "person" on page 2 was considered necessary given the definition in Schedule 1 to the Interpretation Act 1978. This provides that ""person" includes a body of persons corporate or unincorporate". This appeared to the Committee to do all that is necessary. The Committee also noted that it is not usual to include a definition of the word "person" in legislation except where it is intended for policy reasons specifically to confine the definition to one or other category. This does not seem to be the case in the present instance. Furthermore, in the context of the exceptions mentioned in the definition namely regulation 4(1)(g) and 6(3) "person" can in the Committee's view only be a natural person.

Response 1

6. The Executive in reply states that it wished to make it clear that in regulations 4(1)(g) and 6(3), 'person' did not include a body corporate. The Executive considers that the form of words adopted has the equivalent effect

to a phrase such as ""person", in regulations 4(1)(g) and 6(3), does not include a body corporate" but additionally makes it clear to those affected by the instrument that all the offences created by regulations 6(1) and (2) can be committed by bodies corporate. The reply is reproduced at Appendix 4.

Report 1

7. "Person" is defined in Schedule 1 of the Interpretation Act 1978 as including bodies corporate or unincorporate. This definition automatically applies horizontally to all relevant legislation (which in this instance includes the above Regulations as they are made under section 2(2) of the European Communities Act 1972) unless the context otherwise requires. The Committee therefore remained unclear as to why the Executive thought it necessary to include a definition in the Regulations.

8. The context of regulation 6(3) clearly indicates that the definition of "person" in the Interpretation Act could not apply. "Person" in that regulation could not be other than a natural person.

9. It is not considered to be good practice to re-enact without good reason definitions that are contained in the 1978 Act (or, if relevant, the Scotland Act 1998 (Transitory and Transitional Provisions) (Publication and Interpretation etc. of Acts of the Scottish Parliament) Order 1999 (SI 1999/1379)). In the Committee's opinion, failure to follow this rule can cause confusion and therefore does not comply with proper legislative practice. The Committee is satisfied, however, that the error does not adversely affect the instrument in any way. **The Committee draws the attention of the lead committee and the Parliament to this instrument on the grounds of failure to follow proper legislative practice.**

Question 2

10. The Committee noted that, although the Decision appeared to apply to wild birds as well as to captive species, the Regulations apply only to captive birds by virtue of the definition of "bird" in regulation 2 (page 1). The Committee asked the Executive how it proposes that the obligations in relation to wild birds will be fulfilled given that no Transposition Note has been provided and the Executive Note is silent on the point.

Report 2

11. **The Executive has supplied a full and helpful explanation that the Committee draws to the attention of the lead committee and the Parliament.** The Committee observes that the position would have been clearer had a Transposition Note been supplied or the Executive Note contained the relevant information.

Appendix 4

THE AVIAN INFLUENZA (SURVEY POWERS) (SCOTLAND) REGULATIONS 2004, (SSI 2004/453)

On 26th October the Subordinate Legislation Committee considered the above instrument and sought an explanation of the following matters:-

1. The Committee asked the Executive to explain the purpose of the definition of the word "person" given the definition of the word in Schedule 1 to the Interpretation Act 1978;

2. The Committee asked the Executive for information as to how the Decision is to be implemented in respect of wild birds.

The Scottish Executive Environment and Rural Affairs Department responds as follows:-

1. The Executive wished to make it clear that in regulations 4(1)(g) and 6(3), 'person' did not include a body corporate. The Executive considers that the form of words adopted has the equivalent effect to a phrase such as ""person", in regulations 4(1)(g) and 6(3), does not include a body corporate" but additionally makes it clear to those affected by the instrument that all the offences created by regulations 6(1) and (2) can be committed by bodies corporate.

2. The need for the survey, and the funding for it, were agreed by Commission Decision 2004/111/EC on 29 January 2004 (published in the Official Journal L 32 of 5 February 2004, page 20). This Decision was amended twice, firstly by Commission Decision 2004/615/EC on 23 July 2004 (published in Official Journal L 278 of 27 August 2004, Annex page 61 refers); and secondly by Commission Decision 2004/630/EC (published in Official Journal L 287 of 8 September 2004, page 7). The latter forms the basis of the powers taken under the SSI.

In Decision 2004/615/EC, the Commission set out its requirements and guidelines on how the survey was to be designed and implemented. Decision 2004/615/EC amended the guidelines for the survey by adding an Annex. In paragraph 3 of the Annex the Commission narrated that one of the objectives of the programme was "to continue surveillance for avian influenza *on a voluntary basis* in wild birds". Part C1 of the Annex makes it clear that sampling of wild birds is to be carried out on a voluntary basis. A survey plan, based on these instructions, was submitted to the Commission and received approval in article 1 of Decision 2004/630/EC, as meeting the requirements of Decision 2004/111/EC as amended by Decision 2004/615/EC.