

Annex 6 – Draft full Regulatory Impact Assessment

DRAFT FINAL REGULATORY IMPACT ASSESSMENT

EU REGULATIONS ON GENETICALLY MODIFIED FOOD AND FEED AND ON TRACEABILITY AND LABELLING OF GENETICALLY MODIFIED ORGANISMS

1. Title of measures

1.1 Regulation (EC) No 1829/2003¹ of the European Parliament and of the Council on genetically modified food and feed.

1.2 Regulation (EC) No 1830/2003² 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.

2. Purpose and intended effect

(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 will introduce a centralised assessment procedure for the approval of GM food and feed. From 18 April 2004, such assessment will be 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 will also introduce new labelling rules for GM animal feed and extend 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 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 are,

¹ OJ L 268, 18.10.2003, p.1

² OJ L 268, 18.10.2003, p.24

however, already 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, including via labelling supported by traceability. 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 with regulatory requirements as regards safety, including the requirement that no GMO for food or feed use with a significant risk of allergenic or toxic effects can be sold. 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 existing regulatory regime

2.5 A generic Directive - 2001/18/EC on the deliberate release into the environment of GMOs³ - sets out common approval, safety, fair competition and public information standards for any GM product marketed in the EU. It strengthens the requirements in its predecessor Directive – 90/220 – which it replaced. It also provides for mandatory traceability and labelling of GMOs as 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 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 were also set out in three further measures: EC Regulations 1139/98⁴, 49/2000⁵ and 50/2000⁶.

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

³ OJ L 106, 17.4.2001, p.1

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

- the labelling requirements apply to food ingredients, with a 1% threshold below which products do not 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 is conducted by Member States;
- there are no specific requirements for feed beyond those applying under Directive 2001/18.

Response of the food industry

2.9 Since the initial introduction of the labelling requirements in Directive 90/220, Directive 2001/18 and the Novel Foods Regulation, 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 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 has not required labelling under the requirements to date. Similarly, the oil fraction (about 18% of the total by volume ¹¹) does not require labelling under the existing regime as it does not contain detectable DNA. This has meant that, to date, the volumes of soy derivatives that the industry has needed to replace or source under special “identity preserved” systems to avoid GM labelling have been relatively small, and have been mainly food ingredients derived from soy protein. The additional costs of identity preservation have been absorbed by the industry.

2.11 As stated above, the new labelling requirements will require food ingredients derived from GM sources to be labelled, whether the DNA is detectable or not, and will require feed to be labelled. The potential response of the food and feed industry

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.

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.

⁹ See Chapter 5, in **LMC International, *ibid.***

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 *ibid.***, Chapter 2, Table 2.1

¹¹ The remaining 2% approx. is soy lecithin. This, like oil, is not covered under existing regulations, however this will change under the new regime.

to the new requirements is outlined in this section under (v) *Business sectors affected* and set out in more detail under Costs in Section 5 of the RIA.

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 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, were necessary to restore public confidence in the regulation of GM crops and food. Directive 2001/18 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 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 also 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). The Member States demanding further legislation formed a blocking minority which considered that the decision-making process under Directive 2001/18 should be suspended until further legislation meeting their concerns had been adopted.
- **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 have been no further approvals, to date, since then. As these products were approved before the Novel Foods Regulation took effect, specific labelling requirements for their use in food were introduced by EC Regulation 49/2000. 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 have 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 amendment 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 and to reduce from 1% to 0.5% the separate threshold for the toleration of unapproved of GMOs caught up in the decision-making impasse that have received a positive EU risk assessment. Both new Regulations are intended to apply fully in Member States from April 2004.

2.16 During negotiations, the UK expressed several concerns about the 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.

(iv) 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 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, will lead 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.

2.20 The likelihood of **consumers** inadvertently consuming GM products is addressed in both Regulations by:

- lowering from 1% to 0.9% the threshold above which the adventitious presence of material from an EU authorised GMO in a non-GM product triggers traceability and labelling of the product;
- 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.

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. However, an as yet uncompleted 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 The Regulations address the need to provide a framework to support the proper functioning of international trade by firstly requiring that detectable GMOs as, or in, products, and entering the market as commodities or other goods, should be traceable and identifiable via a system of unique identification codes reflecting international standards. Secondly, the Regulations allow a transitional threshold of 0.5%, applying for three years, below which adventitious presence of some unapproved GMOs is tolerated in food or feed products subject to certain safety conditions. This is in recognition of the fact that the so-called moratorium on approvals within the EU has delayed further decisions on whether to approve certain imports of GM products already approved in third countries.

2.24 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.

(v) Business sectors affected by the new Regulations

Direct costs

2.25 When assessing the potential impact of the new Regulations on business it is important to stress that any additional direct costs arising specifically from the Regulations themselves are likely to be marginal. This is mainly because the Regulations are largely an elaboration, 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.

2.26 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 any additional burden posed by the new legislation is likely to be small. For example, in cases where particular ingredients have to be specified on a label, the only additional requirement in relation to certain ingredients will be to add the words “derived from GM x” to the labelling indication. Furthermore, 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%.

2.27 The main concern in relation to the new Regulations is not the small 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. There is therefore a risk that consumers will not be provided with reliable information, which could amount to fraud.

2.28 Despite these considerable caveats, the Regulations will impose some new costs on a range of business sectors, most notably the food and feed industries. However there will be no direct impact on farmers within the UK unless GM crops are grown commercially in the UK. As set out in paragraphs 2.9 and 2.10, exposure to GM products in the UK market is predominantly via imports of soy and maize and derivatives of these commodities, which are imported in volumes of millions of tonnes. Costs to the food and feed industries which import these products will be both direct and indirect – direct costs will result from the need to maintain records and provide information to consumers; indirect costs will be driven by the response of the industry to the Regulations, as discussed below.

2.29 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. 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.

2.30 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 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

Indirect costs

2.31 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.

2.32 The opportunity for the EU food and feed industry to secure entirely non-GM supplies of soy to meet current demand - and thus avoid the need to label food and feed ingredients as GM – is likely to be very limited without additional costs, given the EU's dependency on the world export market for 90% of its soybean demand, and some 95% of soybean meal. Market constraints also suggest that sourcing non-GM food and feed ingredients derived from maize would be a challenge for the EU industry¹². There is more market flexibility with respect to edible oils, as these are highly substitutable in many end uses and the EU is well supplied with alternatives, most notably rapeseed oil which is produced domestically, providing food manufacturers with an opportunity to “opt out” of using soy oil (or indeed maize oil, though this does not in fact account for an important share of EU oil demand) at minimal cost¹³. However other important soy derivatives, including lecithin, an emulsifier widely used in processed food products, cannot so easily be substituted, limiting the opportunities for the food industry to reduce its use of such ingredients to avoid labelling without incurring some additional cost. The implications for the industry are discussed in Section 5.

2.33 It is important to emphasise that the industry will only need to incur the additional costs associated with sourcing alternative supplies of GM derived ingredients if it chooses not to manufacture products which require labelling. However in assessing the expected costs and benefits of new regulations, indirect costs and benefits need to be considered, including the costs to different industrial

¹² See Chapter 4 “*The scope for substituting non-GM alternatives for GM oilseeds and maize in the*”, in **LMC International**, *ibid.*

¹³ See Chapter 2, Part 1: *Oilseed products in the EU Food and feed chain - Soybean oil: end uses in the feed, food and technical sectors*, in **LMC International**, *ibid.*

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. Some manufacturers and retailers have removed all GM ingredients from their products, even those which under current regulations would not require labelling, suggesting that the industry believes that any additional costs incurred to date have been offset by other benefits – perhaps those of consumer confidence and brand reputation¹⁴.

2.34 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 as GM by ensuring that all potentially GM products covered by the regime are sourced from non-GM suppliers;
- (b) going beyond the requirements of the new regulations in order to remove all GM materials from the food chain in the EU, including feed ingredients¹⁵;
- (c) a shift by manufactures 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.

(vi) Issues of equity and fairness

2.35 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.

2.36 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 2.34 above will be considered in Section 5.

3. Options

3.1 The preceding discussion indicates that alternative outcomes in terms of the costs and benefits of the new regulations will not result from alternative options for government action but as a result of the chosen response of the food and feed industries to the regulations. It is also important to note that the Regulations have been finally adopted and will take direct effect in the UK with no scope for flexibility as regards their implementation, except in relation to penalties for non-compliance (see Section 8). The UK presented options in the initial and partial RIAs that were used during negotiations which are now over. As described above, the Regulations were adopted despite the UK voting against them. The legal nature of the measures

¹⁴ See Chapter 6 “*Potential impacts of the proposals on consumers*”, **LMC International**, *ibid*.

¹⁵ 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 s 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 form the food chain.

means that some implementation options that are relevant to other EU measures, such as pursuing their provisions through a code of practice, are not available in this case.

3.2 Essentially, therefore, 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.

3.3 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 procedure for regulation via the European Food Safety Authority
- **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.

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.¹⁶ Defra has commissioned a study using these techniques to provide monetary estimates of the benefits indicated by consumers of the increased information provided by the Regulations.¹⁷ The study, which has not yet been finalised, is the first quantitative, economic assessment of consumer responses to purchasing foods containing GMOs based on a nationally representative dataset.

4.3 Preliminary 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, with evidence of statistically significant and high median 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 it will deliver significant benefits to consumers, although estimates regarding the size of these effects could not be reliably derived from the data set.

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. The sample mean WTP to obtain the lower threshold (0% to 0.5%) was about 7%, as expressed as a percentage of weekly expenditure on purchases of food and alcoholic drinks. With average household expenditure of £42 per week on food and drink, a WTP of 7% corresponds to about £3 per week per household, or about £3.8 billion p.a. for all UK households.

4.5 These results 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 – perhaps even greater than three times higher¹⁸ - than their actual behaviour demonstrates. Applying a correction of a factor of three would suggest benefits of about £1.3 billion p.a..

5. Costs

5.1 With respect to the public sector, these are:

¹⁶ For more information on these techniques, which are referred to as “stated preference techniques”, **Economic Valuation with Stated Preference Techniques: A Summary Guide** at <http://www.dft.gov.uk>

¹⁷ **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

¹⁸ See Section 2.2, *ibid*.

- 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 GM material in feed and feed ingredients, passing this information along the feed 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

5.4 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 assessments¹⁹ and in the authorisation, risk management, and risk communication processes. It is unlikely that, for the time being, the change in emphasis in the relationship between these parties will result in significant changes to administrative resource requirements in Member States.

5.5 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

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

If 10% of these costs are assigned to the UK, this gives a total of just over £35,000 p.a..

(ii) Enforcement costs

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

¹⁹ 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.

Business sector costs: (i) direct costs

Traceability systems

5.7 Traceability costs are expected to be low or even insignificant. As discussed in Section 2, 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.

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 suffer²⁰.

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 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 systems²¹. Therefore they rely heavily 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. Perhaps because cases where companies have been challenged about the GM content of their food and drink are not common, there is not undue concern about implementing current regulations or about the introduction of tighter rules, as long as enforcement procedures do not change.

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

²⁰ See Chapter 6, "The Potential Impact of the Proposals on Consumers" in **LMC International**, *ibid.*.

²¹ *ibid.*

by businesses to meet existing regulatory requirements and any inspections will be incorporated within the existing system of visits made by Trade Standards 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 they labels are required. However even where manufacturers chose to label, the costs involved are likely to be small as most products already have to meet general or other specific labelling requirements about their content and composition.

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. Here we consider three alternative scenarios:

- (a) the food manufacturing industry avoids the need to label all potentially GM ingredients by sourcing alternative or identity preserved supplies;
- (b) 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;
- (c) the food and feed industry accept the presence of GM products in the mainstream commodity system and label all food and feed ingredients accordingly.

Indirect costs under scenarios (a) and (b)

5.15 With respect to scenarios (a) and (b), 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 report²² examines these factors in detail, from which the following broad evaluation can be made:

Self-sufficiency

- the EU is almost entirely dependent on imports for all its soybean needs;

²² *ibid.*

- 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 uses;
- 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 the EU's 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 applications

5.17 The above analysis suggests that the greatest challenge to the food and feed industry under scenarios (a) and (b) is the availability and integrity of supplies of non-GM soy from Brazil. At their present volume, and even assuming exports were entirely non-GM, Brazilian exports would be insufficient to meet EU demand for non-GM soybeans for both food and feed uses. However even on the assumption that over the medium to long term Brazilian production of soybeans increased rapidly and exports of non-GM soybeans were sufficient to meet demand in the EU, it is estimated that the EU industry would still have to pay an additional £140 million per annum to secure these supplies²³.

5.18 Identity preserved (IP) supply chains for 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 up²⁴. The costs associated with such systems have been used to provide an estimate of the annual costs to the UK

²³ This would be in order to cover the extra storage costs and financing needed to bridge the period from October to February when, at present, the US is the main global soybean supplier (75%-80% GM) to the EU. See **LMC International**, Chapter 4.

²⁴ Chapter 5 "*The Economics of Segregation and Identify Preservation*" in **LMC International**, *ibid.*.

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. Under current conditions of 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., equivalent to 0.22% of the total expenditure in 2002 of £139 billion by UK consumers on food and drink²⁵.

5.19 In summary, the analysis indicates that under either scenario (a) or (b) the cost of securing sufficient supplies of non-GM soybeans to meet UK requirements could be £304 million.

5.20 However, it is worth noting that under scenario (a) the industry might prefer to adopt an alternative strategy of replacing soy lecithin with lecithin from alternative sources, such as sunflower, rapeseed, maize or rice bran oils, or of sourcing the product from other major producers of non-GM soy, notably India and China²⁶. There is evidence to suggest that this is already occurring and it is likely to be given more urgency by the new regulations. Such alternatives will be adopted to the extent that they are cheaper than the IP alternative, and so the figure of £304 million should be considered an upper limit on the indirect costs of scenario (a).

5.21 None of the additional supply costs estimated above would be incurred under scenario (c) 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.

The sectoral distribution of indirect costs under scenarios (a) and (b)

5.22 Up until now the indirect costs of the regulations have been considered as costs to the food and feed industries – but a critical issue is to what extent will these be passed on to other sectors of the economy, including consumers.

5.23 An issue which will impact significantly upon the sectoral distribution of the indirect costs of IP is which among the final processed products will bear the brunt of the extra costs of the IP system. For oilseeds the options would be the oil, meal or the high value derivatives such as lecithin. For maize, the relevant products are the starch fraction, or the gluten feed and meal or the high value fermentation derivatives.

5.24 Under scenario (a), the new regulations will require GM feed ingredients to be identified only at the level of feed and not in the meat or milk produced using the feed, while the proposals will require all the GM food ingredients to be identified. Thus it seems likely that the premia for non-GM products in food uses will tend to be higher than those on non-GM ingredients in feed applications. An indication of the likelihood of this happening is provided by the fact that the market, in order to meet current demand for non-GM ingredients in advance of the new regulations, is already demanding a 60% premium for non-GM premium lecithin delivered to the UK. This is three times the 20% premium currently paid for non-GM meal supplied under a strict

²⁵ Chapter 7 “An Assessment of the Impact of the Proposed Measures” in **LMC International**, *ibid.*.

²⁶ Though major producers of soybeans, neither China nor India are exporters of soybeans because of the extent of internal demand for the commodity.

IP system. It should be noted too that the opportunity for the costs to be absorbed directly by the oil fraction of soybeans will be limited because the demand for soybean oil is highly price elastic, that is, the availability of alternative oils means that demand falls away rapidly in the face of a higher price.

5.25 Despite the likelihood of an uneven distribution of IP costs on food ingredients, it seems unlikely that the additional cost would be passed on to consumers by manufacturers. Lecithin represents such a tiny percentage of the total cost of food production that manufacturers may simply absorb the extra costs. Chocolate production illustrates this – lecithin is used in minute volumes as an emulsifier in chocolate. However the price of cocoa beans – which accounts for at least 20% by volume of chocolate production and can be as high as 70% - represents a much more significant concern to manufacturers than the cost of lecithin given its potential impact on total production costs.

5.26 Under scenario (b) the likelihood of costs being passed on to consumers would be much greater. The opportunity for feed manufacturers and livestock producers to absorb the IP costs of feed ingredients is limited by the fact that the proportion of the cost of compound feed that is accounted for by soybean meal and maize gluten feed alone is likely to be 20-25%. IP costs would therefore add a few percentage points to the cost of compound feed. Feed typically accounts for over half the wholesale value of poultry production. If the additional costs of non-GM soybean meal were 10-25% higher than that for GM meal, then reliance on non-GM meal would correspond to an increase of 1-2% in the wholesale price of poultry. In relation to supermarket margins, this is sufficiently large to suggest that the additional costs might be passed on to consumers.

5.27 An alternative outcome might be a squeeze on the margins of poultry suppliers, or on those of the compound feed industry itself. This would be likely to have an impact on the market structure of these sectors. The compound feed sector for example tends to be characterised by local, regionally based firms. Within the EU there were 3,000 units in operation in 2001, with an average size of production unit of 40,000 tonnes p.a.. A squeeze on margins might well lead to greater consolidation of the sector.

5.28 The potential sectoral impact of the scenarios analysed above suggests that different sectors within the food and feed industry might favour alternative responses to the new regulations. For example, the retailers, who have shown themselves on this issue to be highly sensitive to their brand reputation, may – in response to the public mood - favour scenario (b), that is to require all feed ingredients 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 suppliers²⁷. 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, but actually impossible to source, given the large volumes of GM soy and

²⁷ Section 7 below provides an overview of the structure of the retail industry. This indicates that the three largest retailers have a combined market share of over 50%.

maize already traded with the global commodity system. In these circumstances the retailers might consider changing their public stance on GM, the scenario (c) considered above, rather than incurring high costs which might prove difficult to pass on to consumers.

Costs beyond the UK

5.29 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.²⁸

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. With respect to the costs of enforcement and inspection to ensure compliance, the expectation is that these will be insignificant (see 5.12 above).

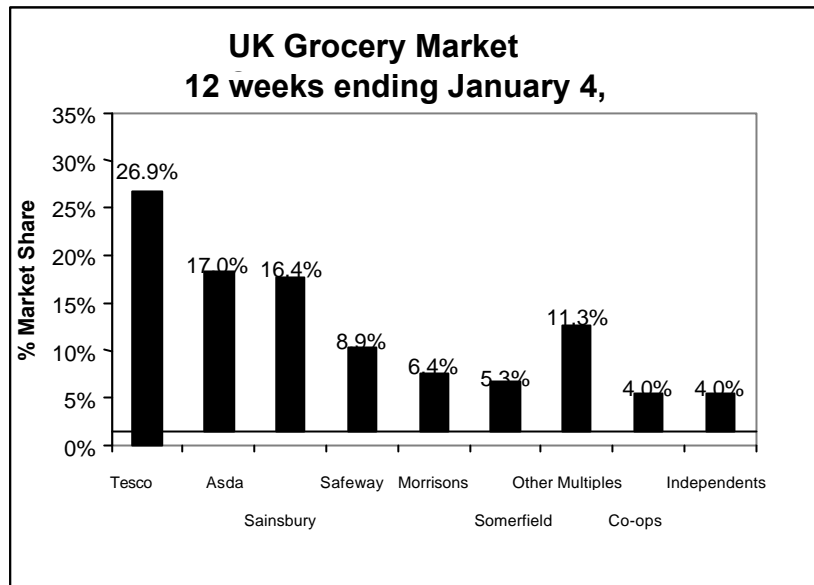
6.2 Within the feed and livestock sectors, where there are still many relatively small operators, the additional costs associated with a move away from GM ingredients in all feed ingredients, as described under scenario (b) in Section 5 above, could lead to significant new pressures on the profit margins of small operators.

7. Competition assessment

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.

²⁸ 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.

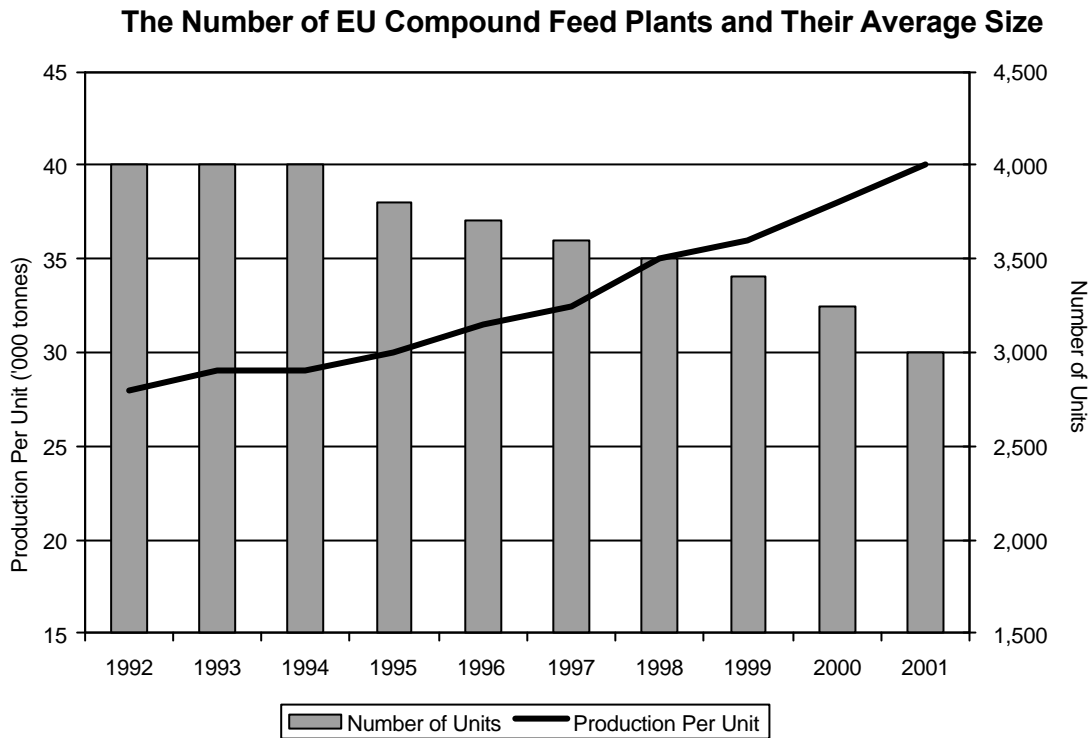


Source: Taylor Nelson Sofres Superpanel

7.1 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.



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 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

8.2 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 Port Health Authorities.

8.3 However, the costs of enforcement are expected to increase only marginally as the standards set become tighter as local authority trading standards officers may be able to monitor compliance with the new regulations within their existing programme of visits. Furthermore, the cost of sample analysis for GM ingredients should remain consistent with the current costs of testing. This is because it will not be possible to test, using analytical methods, the additional products derived from GMOs covered by the new regulations as they do not contain any GM material. In these circumstances only a paper audit trail can verify the origin of these products.

8.4 Consistent with the principle of a risk-based approach, the proposed enforcement Regulations for England imply a hierarchy of offences and penalties, descending from more to less serious. The proposals meet Home Office policy guidelines for offences and penalties and are consistent with legal maxima available under the European Communities Act 1972 and the Food Safety Act 1999. They fall into three broad categories, which are summarised in some detail in **Annex 2**.

8.5 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

8.6 A hierarchy of offences and penalties based on these principles would give the courts a flexible range of punitive and deterrent options, which could be applied proportionately in particular cases. For example, in the event of an operator failing to keep records of the use of unauthorised GMOs, consideration of the most serious level of available punishment would be relevant. However, if the offence committed by an operator was keeping records of authorised GM products for only four of the five years required under the Traceability and Labelling Regulation, consideration of only the least serious category of penalties would be likely to be appropriate.

8.7 Taking account of the above factors, it is estimated that the costs of enforcement in relation to GM products sold to consumers would rise from a current total for the UK of about £225,000 a year to about £400,000 a year. The additional costs of £175,000 are accounted for by the rise in inspections that would be required to cover the larger range of products covered under the new regulatory regime. (principally animal feed and food and feed products with ingredients derived from but containing no detectable GM material).

9. Monitoring and review

9.1 Before the Regulations can apply in Member States, the Commission is required to produce:

- detailed implementing rules and guidance on the presentation of applications under the Food and Feed Regulation²⁹

²⁹ Food and Feed Regulation, Articles 5 and 17

- technical guidance on sampling and testing to facilitate effective compliance with the Regulations, and a co-ordinated approach between Member States³⁰

9.2 Work on these measures is still under way. Given their importance to the effective, equitable and transparent operation of the Regulations, the UK is playing a full part in their development. The Commission's drafts of these measures are being circulated to stakeholders with the draft guidance accompanying this draft RIA.

9.3 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 respectively October and November 2005. 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 commodities³¹
- operation of the 0.5% transitional threshold in relation GM food and feed³²

9.4 The UK Government will play a full part in contributing to the Commission's review on these key issues.

9.5 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.

9.6 Particular attention will be paid to these factors in monitoring and reviewing the UK's practical experience of the operation of the Regulations, including the distributional and competitive issues identified above.

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

³⁰ Traceability and Labelling Regulation, Article 9

³¹ Traceability and Labelling Regulation, Article 12

³² Food and Feed Regulation, Article 48

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

10.3 Following final adoption of the Regulations, the FSA and Defra held a series of seven small stakeholder meetings in October and November 2003 with groups representing food and feed manufacturing, farming, biotechnology, enforcement, consumer and environmental interests. The purpose of the meetings was to consider the detail of the Regulations, in particular those aspects affecting their practical application in 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 the draft guidance accompanying this RIA.

10.5 In considering the draft RIA, stakeholders are being asked to comment on the regulatory impacts identified and to provide further information, particularly in relation to costs, if necessary.

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 The likelihood of **consumers** inadvertently consuming GM products is addressed in both Regulations by:

- lowering from 1% to 0.9% the threshold above which the adventitious presence of material from an EU authorised GMO in a non-GM product triggers traceability and labelling of the product;
- 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 will take 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. An as yet uncompleted 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. However, as the behaviour of the food industry cannot be known for certain in advance of the regulations being implemented, three alternative scenarios – and their implications for the indirect costs of the regulations – are assessed in the analysis.

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 European Food Safety Authority and of enforcement in the UK.

11.8 Overall direct costs are expected to be low or even insignificant. 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 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. 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. These operators do not therefore expect to incur any additional costs of their own as a result of the new regulations.

11.10 Direct administrative costs are also expected to be low. The UK share of the central administrative costs of safety assessments are estimated to be about £40,000 p.a.. Enforcement costs are estimated at about £400,000 year, or about £175,000 a year more than the estimated current costs of enforcing regulations in relation to GM products sold to consumers.

11.11 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. It is estimated that:

- if the UK food manufacturing industry avoids the need to label all potentially GM ingredients by sourcing alternative or identity preserved supplies, the cost will be £304 million p.a. at the most;
- if 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, the cost p.a. will be at least £304 million p.a.;
- if the food and feed industry reverses its current anti-GM position, accepts the presence of GM products in the mainstream commodity system and labels all food and feed ingredients accordingly, there will be no indirect costs associated with sourcing alternative or IP ingredients.

11.12 What the food and feed industry choose to do will depend on its own assessment of the costs and benefits of the options it faces. 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.

11.13 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, even in the face of potential costs to the industry of more than £300 million p.a., outweigh the total costs.

Summary of Costs and Benefits

	Description	Value
Benefits	Improved consumer information	Significant, with a value greater than £1 billion p.a.
	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	£400,000 p.a.
	(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 potentially GM food ingredients by sourcing alternative or identity preserved supplies	Max. £304 million p.a.
	(b) 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	At least £304 million p.a.
(c) the food and feed industry reverses its current anti-GM position, accepts the presence of GM products in the mainstream commodity system and labels all food and feed ingredients accordingly	No indirect costs	

12. Declaration

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

Signed.....

Date

Elliot Morley, Minister for Environment and Agri-Environment

Melanie Johnson, Parliamentary Under-Secretary of State for Public Health

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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]

NEW EC REGULATIONS: ENFORCEMENT

Hierarchy of offences and penalties proposed for England

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

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

1) GM agricultural crop products approved for Community use under EC legislation (Directive 90/220) on the deliberate release into the environment of GMOs

Product	Company	Uses	Description/reference	Date of approval	Consent issued by
Soya	Monsanto	Import only	Herbicide tolerant. C/UK/94/M3/1	April 1996	UK
Maize	Ciba-Giegy (now Syngenta)	As any other maize, including cultivation	Bt-176. Herbicide tolerant and insect resistant. C/F/94/11-03	January 1997	France
Oilseed rape	AgrEvo (now Bayer)	Import only	Topaz 19/2. Herbicide tolerant. C/UK/95/M5/1	April 1998	UK
Maize	AgrEvo (now Bayer)	As any other maize, including cultivation	Line T25. Herbicide tolerant. C/F/95/12/07	April 1998	France
Maize	Monsanto	As any other maize, including cultivation	MON 810. Insect resistant. C/F/95/12-02	April 1998	France
Maize	Northrup King (now Syngenta)	Import only	Bt-11. Herbicide tolerant and insect resistant. C/UK/96/M4/1	April 1998	UK

Notes:

1) The Commission and EU Member States also reached agreement on the approval of the import and cultivation of two kinds of herbicide tolerant oilseed rape (MS1, RF1 and MS1, RF2) but the lead Member State, France, did not issue the consent.

2) Commercial cultivation of the herbicide tolerant crops noted above is still dependent on separate seed listing and pesticides consents being obtained.

3) Food uses of the soya [and maize] product[s] listed above were approved under Directive 90/220 on the deliberate release into the environment of GMOs before the EC Novel Foods Regulation (258/97) took effect. Directive 90/220 was replaced by Directive 2001/18 in October 2002.

4) An imported tomato paste derived from GM tomatoes and produced by Zeneca Plant Science was approved for food use in the UK in February 1995, on the advice of the Advisory Committee on Novel Foods and Processes and also before the application of EC Regulation 258/97. This product is no longer commercially available.

5) From April 2004, all GM products for food and feed uses will be considered under the new GM Food and Feed legislation (EC Regulation 1829/2003)

2) GM food ingredients derived from GM crops, notified under the EC Novel Foods Regulation 258/97, and cleared for use on the Community market

Product	Company	Description	Notification
Rape oil	AgrEvo (now Bayer)	TOPAS 19/2. Processed oil.	June 1997
Rape oil	Plant Genetic Systems (now Bayer)	Processed oil from (i) male sterile MS1Bn (B91-4) oilseed rape line and all conventional crosses, and (ii) fertility restorer RF2Bn (B94-2) oilseed rape line and all conventional crosses, and (iii) hybrid combination MS1XRF2.	June 1997
Rape oil	Monsanto	Line GT73. Refined oil from glyphosate tolerant oilseed rape	November 1997
Maize products	Monsanto	Line MON810. Food and food ingredients produced from maize flour, maize gluten, maize semolina, maize starch, maize glucose, and maize oil derived from the progeny of MON810 maize.	December 1997
Maize products	AgrEvo (now Bayer)	Event T25. Products obtained from GM maize tolerant to glufosinate ammonium herbicide (Event T25) and all the varieties derived therefrom, consisting of: (i) Starch and all its derivatives (ii) crude and refined oil (iii) all heat processed or fermented products obtained from hominys, grits and flour (dry milled fragments)	January 1997
Maize products	Novartis	Line 2044. Food and food ingredient products derived from the original transformant Bt11 crossed with the Northrup King Company inbred line No. 2044 (maize), as well as from any inbred and hybrid lines derived from it and containing the introduced genes.	January 1997
Maize products	Pioneer	Line MON809. Novel foods and novel food ingredients produced from MON809 maize.	October 1998
Rape oil	AgrEvo	GS 40/90. Processed oil form GM oilseed rape derived from Falcon GS 40/90	October 1999
Rape oil	AgrEvo (now Bayer)	Processed oil from GM oilseed rape derived from Liberator L62	October 1999
Rape oil	Plant Genetic Systems (now Bayer)	Processed oil form GM oilseed rape derived from: (i) the male sterile MS8(DBN 230-0028) oilseed rape line and all conventional crosses (ii) the fertility restorer RF (DBN212-0005) oilseed rape line and all conventional crosses, and (iii) the hybrid combination MS8 x RF3	October 1999
Riboflavin	F. Hoffman La Roche	Riboflavin from <i>Bacillus subtilis</i> as nutrient	March 2000
Cottonseed oil	Monsanto	Line 1445. Cottonseed oil from herbicide tolerant cotton	December 2002
Cottonseed oil	Monsanto	Line 531. Cottonseed oil from insect resistant cotton	December 2002

Note: All these products were approved under a “simplified procedure” under the Novel Foods Regulation 258/97. The procedure allows companies only to notify the authorities that products are “substantial equivalent” to their non-GM counterparts, provided a national food assessment body confirms this assessment. The simplified procedure has been abandoned under the new GM Food and Feed Regulation

3) GM agricultural crop products being considered for approval under EC legislation (Directive 2001/18) on the deliberate release into the environment of GMOs

Product	Company	Uses	Description/reference	Lead EU member
Oilseed rape	Monsanto	Import only	Event GT73. Herbicide tolerant. C/NL/98/11	Netherlands
Oilseed rape	Bayer	Import only	Line T45. Herbicide tolerant. C/GB/99/M5/2	UK
Maize	Monsanto	Import only	Event NK603. Herbicide tolerant. C/ES/00/01	Spain
Maize	Monsanto	Import only	Line NK603x MON810. Herbicide tolerant and insect resistant. C/GB/02/M3/3	UK
Maize	Pioneer/ Mycogen	Import only	Line 1507. Herbicide tolerant and insect resistant. C/NL/00/10	Netherlands
Maize	Monsanto	Import only	MON836 x MON810. Insect resistant. C/DE/02/9	Germany
Soybean	Bayer	Import only	A2704 and A5547-127. Herbicide tolerant. C/BE/98/01	Belgium
Cotton	Stoneville Pedigreed Seed Co	Import only	BXN cotton lines 10215 & 10222. Herbicide tolerant. C/ES/99/01	Spain
Rice	Bayer	Import only	Event LL Rice 62. Herbicide tolerant. C/GB/03/M5/3	UK
Maize	Pioneer/ Mycogen	As any other maize	Line 1507. Herbicide tolerant and insect resistant. C/ES/01/01	Spain
Maize	Syngenta	As any other maize	Bt11. Insect resistant. C/FR/96/05/10	France
Maize	Monsanto	As any other maize	Line NK603. Herbicide tolerant. C/ES/03/01	Spain
Oilseed rape	Bayer	As any other oilseed rape	Ms8xRf3. Herbicide tolerant. C/BE/96/01	Belgium
Oilseed Rape	Bayer	As any other oilseed rape	GS40/90pHoe6/Ac. Herbicide tolerant. C/DE/96/5	Germany
Oilseed rape	Bayer	As any other oilseed rape	pHoe6/Ac. Herbicide tolerant. C/DE/98/6	Germany
Sugar Beet	Monsanto/ Syngenta	As any other sugar beet	Event T9100152. Herbicide tolerant. C/BE/99/01	Belgium
Sugar beet	Monsanto	As any other sugar beet	Event H7-1. Herbicide tolerant. C/DE/00/8	Germany
Fodder beet	DLF/ Monsanto/ Danisco	As any other sugar beet	Line A5/15. Herbicide tolerant. C/DK/97/01	Denmark
Potato	Amylogene	As any other industrial starch potato	EH92-527-1. Modified starch content. C/SE/96/3501	Sweden
Cotton	Monsanto	As any other cotton	Event 1445. Herbicide tolerant. C/ES/97/01	Spain
Cotton	Monsanto	As any other cotton	Line 531. Insect resistant. C/ES/96/02	Spain

4) GM products being considered for approval under EC novel foods legislation (EC Regulation 258/97)

Product	Company	Description	Lead Member State
Maize	Monsanto	Line GA21. Herbicide tolerant	Netherlands
Maize	Novartis	Bt11. Insect resistant sweet maize	Netherlands
Maize	Monsanto	Line NK603. Herbicide tolerant	Netherlands
Maize	Pioneer	Line 1507. Insect resistant	Netherlands
Maize	Monsanto	Line MON 863 and maize hybrid MON 810 x MON863. Herbicide tolerant and insect resistant	Germany
Maize	Monsanto	GA21xMON 810. Herbicide tolerant and insect resistant	Netherlands
Soybean	Plant Genetic Systems (now Bayer)	Liberty Link. Herbicide resistant	Belgium
Sugar Beet	Monsant/ Novartis	Roundup Ready. Herbicide tolerant	Netherlands