

GM Inspectorate
The Food and Environment Research Agency
Environmental Protection Act 1990 Part VI (Genetically Modified Organisms)

Annual Report on GM inspection and enforcement activities
01 April 2010 - 31 March 2011

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List of acronyms used

AGMP	Adventitious GM presence
Defra	Department for Environment, Food and Rural Affairs
EC	European Commission
EFSA	European Food Safety Authority
ERA	Environmental risk assessment
Fera	Food and Environment Research Agency
GM	Genetically modified
GMI	Inspectorate for deliberate releases of GMOs
GMO	Genetically modified organism
MS	Member State(s) of the European Union
QRA	Quantitative risk assessment
the Directive	European Council Directive 2001/18/EC
V&S	Fera's Varieties and Seeds team, the competent authority for seed marketing in England

Executive summary

1. The GM Inspectorate (GMI), based at the Food and Environment Research Agency (Fera), is responsible for enforcement of legislation controlling the deliberate release of genetically modified organisms (GMOs) in England. As there is currently no commercial cultivation of genetically modified (GM) crops in England, this concerns small-scale experimental releases and any unauthorised releases. The work is undertaken for the Department for Environment Food & Rural Affairs (Defra). This is the eleventh report of the GMI covering the period 1st April 2010 to 31st March 2011.
2. Fera is an executive agency of Defra, whose overarching purpose is to support and develop a sustainable food chain, a healthy natural environment, and to protect the global community from biological and chemical risks. Fera's role within that is to provide robust evidence, rigorous analysis and professional advice to the UK Government, and national and international organisations in both the public and the private sectors. Further information about Fera is available at <http://www.fera.defra.gov.uk/>.
3. The GMI is part of Fera's Land Use and Sustainability team, which is in the Plant Protection Programme. The GMI website is available at <http://www.gm-inspectorate.gov.uk/>, and can also be accessed via 'quick links' on the Fera home page (<http://www.fera.defra.gov.uk/>).
4. Within the reporting period there were two GMO deliberate release field trials in England. Both were small scale research trials, one of potatoes modified for control of potato cyst nematodes (*Globodera* species), and the other of potatoes modified for resistance to potato blight, (*Phytophthora infestans*). Field inspections confirmed that the releases were consistent with the conditions of their respective consents and that no risks to human health or the environment were identified by release of the GMOs.
5. Five post-trial inspections of former deliberate release trial sites, and four management audits, were carried out in the reporting period. In all cases the consent holders were found to be acting in accordance with the conditions of their respective consents.
6. A further monitoring inspection was carried out at a former trial site of winter oilseed rape that had previously been found to contain a low level of adventitious GM presence. The management of this unintentional release, which took place in the county of Somerset in 2007/08, was in accordance with the management plan devised by the GM Inspectorate.
7. On behalf of Fera's Variety and Seeds team (V&S), which is the competent authority for seeds marketing in England, the GM Inspectorate runs a programme of voluntary audits of seed importers and producers. The audits focus on helping companies to be aware of the risks of adventitious GMOs in the seed they import and produce, and discuss how these risks can be managed. The 35 companies that participated in the audit programme in 2010-11 were found to have acted responsibly in managing the risk of adventitious GM presence in conventional seed they were marketing. No targeted audits were carried out in this reporting year.

8. Summary tables of the findings of the audits have been published on the GM Inspectorate website at <http://www.gm-inspectorate.gov.uk/seedAuditProgramme/auditReports.cfm>.
9. Two investigations into the unauthorised release of genetically modified *Danio rerio* zebra fish were investigated in the reporting period. No enforcement action was necessary.

1. The role of the GM Inspectorate

The GMI is responsible for inspection and enforcement of the deliberate release of GMOs in England. This work is undertaken on behalf of Defra to ensure compliance with legislation concerning the deliberate and unintentional release of GMOs. Appendix 1 provides details of GM legislation and regulation in the UK. The GMI is responsible for inspection of all GMO deliberate release sites, and for monitoring for adventitious GM presence (AGMP) in conventional seed for marketing and for planting in official and private trials. The GMI is also responsible for investigation of any potential breaches of the GM deliberate release legislation that may arise in England. These are investigated on a case-by-case basis and action taken as appropriate.

1.1 Experimental (Part B) deliberate release trial sites

One of the primary roles of the GMI is to ensure compliance with consents granted under Part B of EC Directive 2001/18/EC¹, hereafter called “the Directive”. Part B consents authorise the release of a GMO for “any purpose other than for placing on the market, including for the purposes of scientific research”, this includes, *inter alia*, research, development or demonstration purposes, variety registration, herbicide authorisation, seeds multiplication or biosafety/risk assessment research.

In the UK, consent to conduct a Part B trial is issued by Defra in accordance with section 111 of the Environmental Protection Act 1990². Each consent document specifies the limitations and conditions attached to the specific release, including requirements for reporting to the Secretary of State for Environment, Food and Rural Affairs. The limitations and conditions are aimed at ensuring the GMO does not enter the food and feed chain and does not pose any risks to human health or the environment. The GMI operates a programme of inspections and audits aimed at establishing that consent holders comply with these terms and conditions, and if not, to take action to correct this.

The GMI's programme is achieved by a combination of practical inspection visits at deliberate release trial sites, and audits of consent holders to ensure that they are aware of their responsibilities and discharging their duties appropriately. These activities are described in more detail below. A summary of the inspections and audits completed in 2010-11 is provided in Table 1 in section 2 of this report.

Field inspection

The GMI inspects each deliberate release trial site at least once during the growing season. During inspection visits GM Inspectors must establish that each release is in accordance with the conditions described in the consent, for example the location of the trial site, the area of the GM release, isolation from related crops or wild relatives, the presence and size of pollen barriers (if specified), arrangements for transport and storage of the GM materials, and control of volunteer plants and/or flowering plants (as applicable).

Post-trial monitoring

The majority of deliberate release consents are issued with specific requirements to monitor the release site following harvest of a trial. The GMI visits each former deliberate release site at an appropriate stage in the growing season to ensure that the consent

¹ See: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:106:0001:0038:EN:PDF>

² Further information can be found at <http://www.defra.gov.uk/environment/gm/regulation/index.htm>

holder is undertaking post-trial monitoring and eliciting appropriate action, when necessary, in accordance with the consent conditions. Responsibilities of the consent holder might include recording and control of plants that emerge at the former trial site, for example from seeds that were shed or potato tubers that were left in the ground (groundkeepers), or restrictions on the follow-on crop(s) that can be grown. The length of the post-trial monitoring period varies depending on the crop that was employed in the trial, but in all cases is designed to ensure that, as far as reasonably possible, no GMOs remain at the release site. Post-trial monitoring must continue until permission is given by Defra to officially terminate the trial.

Consent holder audits

All consent holders are audited to verify they have put procedures and protocols in place to ensure good planning and operation of their GMO field trial(s), and to verify that the conditions laid down in the release consents are known throughout the management chain and effectively implemented *in situ*. During the active trials phase, consent holders are also required to provide evidence to demonstrate that only the GM event(s) covered by the consent is/are released and that no adventitious GMOs are present. Further checks are made on the effectiveness of post-trial management procedures such as monitoring for volunteers and correct post-trial cropping, as detailed in the consent. Audits are undertaken in advance of planting under all new consents and consents with an active planting programme, whereas consent holders for trials in the post-trial phase are normally audited at the end of the post-trial monitoring season and prior to submission of the annual consent holder monitoring report to Defra (see below).

Consent holder monitoring reports

Under the Directive, consent holder monitoring reports are required annually for all consents until they are officially terminated. The European Commission provides a suggested template for these reports at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:254:0021:0028:EN:PDF>.

In the year of release the monitoring report serves to inform Defra whether the trial progressed as planned and to provide a re-evaluation of any risks to human health or the environment posed by the GMO. If the trial did not go as planned, the consent holder must describe what occurred, any mitigating measures that were taken and any additional measures that will be taken in the future, and the reasons for this. Continuation of a multi-year trial would be dependent on annual submission and acceptance (by Defra) of the monitoring reports.

In the post-trial monitoring phase, the report provides Defra with information on the effectiveness of the measures in place to control any plants that emerge at the trial site, including details of the number of plants detected each month on each GMO area. The consent holder is also required to re-evaluate the monitoring requirements and state whether, in their view, monitoring should be modified or discontinued at the site and the reasons for this. The GMI is responsible for administering submission of these reports to Defra.

Reporting the GMI field inspection programme

Draft reports on growing season crop inspection visits are produced and submitted to the consent holder and Defra within an agreed framework of five working days. A period of 20 calendar days then follows in which both parties are given the opportunity to comment on the factual details of the report. Final field inspection reports are then placed on the public

register and on the GMI website at: <http://www.gm-inspectorate.gov.uk/deliberateRelease/exptreleases.cfm>.

Reports to Defra on management audits and post-trial monitoring inspections are not currently published. However, this policy is currently under review.

1.2 Adventitious presence of GMOs in conventional seed stocks in England

Whilst GM crops are not currently commercially cultivated in the UK, two GM maize events and one GM potato event are authorised for cultivation in Europe, and GM varieties of other agricultural crops are cultivated worldwide. Experimental work has also been undertaken at the field-trial scale in a number of countries, for a range of different species. There is, therefore, potential for seed to acquire adventitious GM presence either by cross-pollination or admixture. Certified seed production methods employ measures to ensure a specified level of purity of certified seeds, but these are not specifically geared towards ensuring seed is free of AGMP. Current seeds legislation does not lay down specific thresholds for the adventitious presence of authorised GMOs in conventional seed. However, to comply with Directive 2001/18/EC and Regulation (EC) 1830/2003³, and since no thresholds are established, seed containing an authorised GMO at any level must be labelled. It is also illegal to market seed containing a GMO that has not been authorised for commercial cultivation in Europe.

GM seeds

Authorised GM crops may be marketed throughout Europe providing the varieties offered for sale have met the requirements for placing on the Common Catalogue of Varieties (see Annex 1). There are currently two consents authorising cultivation of GM maize in the EU, these are MON810⁴ and T25⁵, and one consent authorising cultivation of GM potato⁶. At present only varieties of MON810 modified for resistance to the European corn borer (*Ostrinia nubilalis*) have been placed on the Common Catalogue⁷. In principle these varieties could be marketed in the UK provided they were correctly labelled, however, to date they are all late-maturing varieties developed for cultivation in areas where the European corn borer is present, and they are not well suited to cultivation in the shorter UK growing season. The potato will not be grown in the UK because it does not have the required starch processing facilities.

Seed audit programme

In England, it is the role of the GMI to ensure that seed producers and importers are aware of the risks of adventitious GM presence in seed they are marketing or trialling, and that they are managing those risks. This is achieved through a programme of voluntary audits that are undertaken on behalf of Defra and Fera's Varieties and Seeds (V&S) team as the competent authority for seed marketing.

Risk assessment

The GMI has developed computer-based models for the quantitative assessment of the risks of AGMP in conventional seeds for those key agricultural crops that are known to have been genetically modified⁸. The QRA models have been developed in discussion

³ See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0024:0028:EN:PDF> and appendix 1 point 3.

⁴ C/F/95/12/02, Monsanto.

⁵ C/F/95/12/07, Bayer CropScience.

⁶ C/SE/96/3501, BASF Plant Science.

⁷ As of 1st July 2010 there were more than 100 varieties of maize containing the MON810 event listed in the EC Common Catalogue of Varieties.

⁸ *Brassica napus* (winter and spring oilseed rape), *Brassica rapa* (turnips, turnip fodder rape, stubble turnip, etc.), *Zea mays* (maize and sweetcorn), *Glycine max* (soya), *Triticum aestivum* (wheat), *Beta vulgaris* (sugar beet and fodder beet), *Brassica oleracea* (cabbages,

with industry representatives, risk analysis experts and Defra. The models generate probability distributions of relative GM presence based on worldwide GMO activity, crop biology and seed production processes, and produce a set of distributions displaying the relative risks for the major crop species. For a full description of the models and their outputs please refer to the GMI report 2008-09 (http://www.gm-inspectorate.gov.uk/reportsPublications/documents/GMIannualreport2008-09_final.pdf).

Risk-based audit programme

Each participating company producing or importing seed of interest is audited in detail once every three years. In the intervening years the company is asked to supply basic information about the seed they are marketing (crop type and variety, seedlot reference numbers, amount sold, originator of the seed and country of origin), which is compared with previous audit information. If the new data indicate a possible increase in risk for a particular company, for example if their procedures have changed or seeds have been imported from a new source, the company may be asked to participate in a targeted audit. Seed companies that have undergone a detailed or targeted audit receive a full assessment report following their audit, together with recommendations for improving procedures where this is necessary.

Seed audits 2010-11

The risk assessment models were fully updated in 2009 to reassess the risks of AGMP to seeds of key crops, and in 2010-11 the audit programme included seeds of *Zea mays* (maize, including sweetcorn), *Brassica napus* (winter and spring oilseed rape, swede and swede forage rape), *Brassica rapa* (turnip, turnip fodder rape, stubble turnips, pak choi, Chinese cabbage, etc) and *Glycine max* (soya) intended for agricultural and horticultural use, official trials and private company trials. A summary of the seed audits completed in 2010-11 is provided in Table 2 in section 2 of this report.

Reporting the GMI seed audit programme

A report on all basic audits is provided to V&S. Reports from detailed audits are presented to the audited company and copied to V&S. Summary tables listing all companies that participated in the seed audit programme are published annually. Each participant company is issued with their summary report and given a period of 20 calendar days in which to comment on the factual details. The seed audit summary reports are then published on the GMI website at: <http://www.gm-inspectorate.gov.uk/seedAuditProgramme/auditReports.cfm>.

Seed audit data management

All data provided to the GMI by participants in the seed audit programme are held securely in a bespoke database and are treated as commercial and in confidence. Seed companies participating in the audit can upload data directly if they choose to do so, and access their own data, held in the database via a secure extranet (<https://secure.csl.gov.uk/gmextranet/>).

1.3 Unauthorised GMO releases

The GMI is also responsible for investigating any incidents where there has been a reported or suspected release into the environment of any GMO that has not been authorized for release in the UK or Europe. In the current reporting period two incidents of the importation of genetically modified *Danio rerio* zebra fish have been investigated. The fish were intercepted at Border Inspection Posts and were not made available for sale. The fish had been supplied by companies in Sri Lanka and Thailand and were confirmed to be genetically modified by molecular testing undertaken by Fera. As the fish were not placed on the market, and the importing companies cooperated fully with our investigations, no further action was taken.

Enforcement of the Environmental Protection Act 1981

GM Inspectors are appointed under Section 114 of the Environmental Protection Act 1990 (Part VI). The rights of entry of inspection and powers of inspectors are as described in sections 115 to 117 (inclusive) of the Act. A GM inspector may identify a potential breach of the relevant GM legislation in the course of official duties, or they may be notified to the GMI or the regulatory authority by a consent holder, a seed company or a member of the public. The GMI investigates all potential incidents on a case-by-case basis and takes action as appropriate. The GMI does not itself pursue prosecutions when an incident of potential non-compliance is identified; instead, all potential enforcement cases are referred to Defra investigations officers and lawyers for further consideration. No formal investigations were pursued in 2010-11.

2. The work of the GM Inspectorate during the reporting period

2.1 Field inspections and consent holder audits undertaken 2010-11

Table 1: Summary of field inspection programme for the 2010-11 financial year

Activity	Number	Consent number / holder and purpose	Outcome
Field inspections	4	09/R31/01 (growing season/ flowering inspection)	In all cases the GM Inspectorate was content that the release was consistent with the conditions of the consent and did not identify any risks to human health or the environment posed by the GMO
		09/R31/01 (harvest inspection)	
		10/R29/01 (growing season inspection)	
		10/R29/01 (harvest inspection)	
Post-trial monitoring inspection (PTM)	5	01/R4/10 (2001 release)	In all cases the GM Inspectorate was content that the release was consistent with the conditions of the consent and did not identify any risks to human health or the environment posed by the GMO.
		02/R4/12 (2003 release)	
		06/R42/01 (2007 release)	
		06/R42/01 (2008 release)	
		07/R31/01 (2009 release)	
Consent holder audit	4	Advanced Technologies (Cambridge) Ltd.	The GM Inspectorate was content with procedures implemented by the consent holders for management of their consents
		BASF Plant Science GmbH	
		University of Leeds	
		The Sainsbury Laboratory, John Innes Centre	
Consent holder monitoring report(s)	6	01/R4/10 (PTM)	Defra was content with the end-of -year reports submitted by consent holders.
		02/R4/12 (PTM)	
		06/R42/01 (PTM)	
		07/R31/1 (PTM)	
		09/R31/1 (field trial)	
		10/R29/01 (field trial)	
Unauthorised release	1	N/A (unauthorised, therefore no consent number.	The release took place in 2007/8, and was reported in GMI annual report for 2008-2009. An in-year inspection was carried out to ensure the management plan was being adhered to and any volunteer OSR plants controlled. The inspection confirmed this to be the case.

2.2 Monitoring adventitious GM presence in conventional seed stocks in England: Audits of seed importers and producers: 2010-2011

Table 2 Summary of seed audit programme for the 2010-2011 financial year

Audit type	Summary details
Detailed audit	Total number of companies contacted: 10 Reports completed: 9 Companies declining to participate: 0 Companies not marketing any crops of interest: 1
Collection of basic data on seeds marketed	Total number of companies contacted: 48 Reports completed: 26 (excluding non-participant reports) Companies declining to participate: 9 Companies not marketing any crops of interest: 8 Companies changed ownership/no longer trading: 5
Targeted audit	Total number of companies contacted: 2 Reports completed: 0 Companies declining to participate: 0 Companies not marketing any crops of interest: 2 ¹

¹ Both companies no longer trading in crops of interest to the GMI

All data from seed companies was received by August 2011 and summary reports were published on the GM inspectorate website in November 2011 (www.gm-inspectorate.gov.uk/seedAuditProgramme/auditReports.cfm). All seed companies participating in the audit were found to have acted responsibly in managing the risk of AGMP in conventional seed. It was not necessary to recall or destroy any marketed seed because of an unauthorised adventitious GM presence. Nine companies known to be marketing seed within scope of the audit programme in England chose not to participate in the programme. Two targeted audits were scheduled in the 2010-11 programme, but as both companies were no longer marketing or trialling crops of interest to the GMI in England and have no plans to do so in the foreseeable future, it was decided that an audit was not necessary.

3. GMO research undertaken 2010 to 2011

3.1 Defining environmental risk assessment criteria for genetically modified (GM) mammals and birds to be placed on the EU market

In December 2009 Fera, in collaboration with the University of Leeds, was awarded the contract to undertake a review of risk assessment criteria for GM mammals and birds to be placed on the EU market. This is the third⁹ in the series of reviews commissioned to support EFSA in development of its guidance documents for the risk assessment of genetically modified animals. The purpose of this project was to provide EFSA with a scientific and technical report on (1) scientific disciplines and fields of expertise that might feed an environmental risk assessment (ERA) of GM mammals and birds to be commercially released into the EU environment; (2) research institutes and academics having expertise on the subject and on (3) relevant criteria to be considered when performing an environmental risk assessment of GM mammals and birds.

This research was completed in December 2010 and is published on the EFSA website at: <http://www.efsa.europa.eu/en/supporting/pub/107e.htm>

The GM Inspectorate has not participated in any other research projects relating to the release of GMOs in the reporting year.

⁹ EFSA also commissioned "Defining environmental risk assessment criteria for genetically modified (GM) insects to be placed on the EU market".

4. Contact details

- 4.1 For further information on the GM Inspectorate or its activities please visit our website at: <http://www.gm-inspectorate.gov.uk>

Or contact us at:
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Telephone: + 44 (0) 1904 462000
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Email: gm-inspectorate@fera.gsi.gov.uk

- 4.2 For further information on the Fera gemma (genetically modified material analysis) scheme please visit: <http://www.fapas.com/proficiency-testing-schemes/gemma/>

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Web: <http://www.fapas.com/>

- 4.3 For further information about the Fera independent GM testing service please visit: <http://www.fera.defra.gov.uk/foodDrink/foodAnalysis/index.cfm>
Email: foodanalysis@fera.gsi.gov.uk

- 4.4 For information about GMO training courses please visit: <http://www.fera.defra.gov.uk/foodDrink/foodAnalysis/foodAuthenticity.cfm>

Appendix 1: GM legislation and regulation in the UK

1. European Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EC: its implementation in the UK

- 1.1 In the European Union the deliberate release of GMOs is restricted under EU Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms¹⁰. This Directive provides a harmonised approach across all the EU member states to the assessment of risks to the environment and to human health in relation to the release and marketing of GMOs. In Great Britain Directive 2001/18/EC has been implemented by the Environmental Protection Act 1990 (Part VI) and regulations made under that Act (e.g. in respect of England, the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443)). The Department for Environment, Food and Rural Affairs (Defra), the Scottish Executive and the National Assembly for Wales have functions and responsibilities in relation to the deliberate release of GMOs.
- 1.2 The regulatory regime for GMOs has two key objectives, to protect human health and the environment and to ensure consumer choice. Enforcement must be effective, proportionate to risk, cost effective and promote public confidence. Under section 114 of the Environmental Protection Act 1990, GM Inspectors (currently there are 4) at Fera are appointed for the purpose of the inspection and enforcement of the legislation concerning deliberate release of GMOs in England. Clinical trials are inspected and enforced by the Health and Safety Executive.
- 1.3 EU Directive 2001/18/EC sets out measures for releasing a GMO for research or development purposes (Part B) and for placing a GMO on the market (Part C). Depending on the intended use of the GMO, an alternative route for commercial release of GMOs is available under EU regulation 1829/2003, (see below). GMOs must not be released into the environment until a thorough assessment of the GMO that is proposed for release has been undertaken. If authorisation is given it will be accompanied by specific conditions detailed within the consent to release the GMO, these are designed to safeguard against any risks to human health and the environment.

UK Competent Authority

- 1.4 In the UK consent to release a GMO under Directive 2001/18/EC may be obtained by submission of a detailed application, which includes a thorough risk assessment, to the Northern Ireland, England, Wales and Scotland (NIEWS) GM Unit based at Defra. This unit administers all applications (Part B and Part C) for the release of a GMO in the UK and coordinates consultation on applications by other EU Member States. NIEWS also provides the Secretariat to the Advisory Committee on Releases to the Environment (ACRE). ACRE is an independent advisory committee composed of leading scientists whose main function is to advise UK Ministers and the devolved administrations on the risks to human health and the environment from

¹⁰ In the EU, the contained use of genetically modified organisms is controlled by EU Directive 98/81/EC of 26 October 1998 on the contained use of genetically modified micro-organisms, and in the UK the Genetically modified organisms (contained use) regulations 2000 (S.I. 2000/2831), which is enforced by the Health and Safety Executive.

the release and marketing of GMOs¹¹. ACRE reviews all Part B applications for consent to release a GMO and, if satisfied that the proposed release will have no adverse effects on human health or the environment, the Committee will advise that the consent may be issued. ACRE's advice may include recommendations for monitoring following completion of the trial, and other aspects of management of the release. Authorisation to place a GMO on the market under Part C of Directive 2001/18/EC is given at EC level after extensive consultation by the competent authorities of the EU member states. ACRE also reviews and advises on all Part C applications for the UK as well as on the environmental aspects of applications under the GM Food and Feed Regulation 1829/2003.

- 1.5 For more information on the regulatory process see the Defra website at <http://ww2.defra.gov.uk/environment/quality/gm/>

2. EC Regulation 1829/2003 on genetically modified food and feed

- 2.1 In April 2004 EU regulation EC/1829/2003 on GM food and feed came into force in the European Union. This regulation provides for a single Community procedure for the new authorisation of all food and feed derived from a GMO, of the GMO itself as a food or as a feed, and of food or feed containing the GMO. The European Food Safety Authority¹² manages the application and authorisation procedure centrally. Business operators may now file a single application for the GMO and all its uses; a single risk assessment is performed and a single authorisation is granted for a GMO and all its uses including cultivation, importation and processing into food/feed or industrial products.

- 2.2 The regulation specified a requirement for labelling of all GM food and feed which:
- i) contains or consists of GMOs (e.g. GM soya),
 - ii) is produced from GMOs (e.g. glucose syrup from maize starch),
 - iii) contains ingredients produced from GMOs (e.g. GM tomato paste).

The regulation makes provisions for tolerance of the technically unavoidable presence of authorised GMOs without the need to label. In England the regulation has been implemented by the Food Safety Act and regulations made under that Act (the Genetically Modified Food (England) Regulations 2004 (S.I. 2004/2335), and the Genetically Modified Animal Feed (England) Regulations 2004 (S.I. 2004/2334)).

- 2.3 The Food Standards Agency has responsibility for this regulation. Local authorities and Port Health authorities are responsible for the enforcement of food safety and food standards import controls on food products, and they are the appointed enforcement bodies for these Regulations¹³.
- 2.4 Applicants seeking authorisation for cultivation of a GM food or feed may still choose to submit a separate application for authorisation to cultivate the GMO under Part C of Directive 2001/18/EC. However, it is anticipated that Part C of Directive 2001/18/EC will be used mainly for applications such as flowers and industrial products that will not enter the food or feed chain.

¹¹ See <http://www.defra.gov.uk/acre/index.htm>

¹² See <http://www.efsa.europa.eu/en/panels/gmo.htm>

¹³ See <http://www.food.gov.uk/enforcement/>

3. EC Regulation 1830/2003 concerning the traceability and labelling of food and feed products produced from genetically modified organisms and amending 2001/18/EC

3.1 The EU regulations on traceability and labelling of GMOs came into force in April 2004. This regulation establishes a harmonised EU system of documentation to account for and identify GM products throughout the supply chain, with the objective of facilitating accurate labelling. For certain products, a system of unique identifier codes will be used to allow access to specific information on GMOs from a community register of GM food and feed. In England the regulation has been implemented by the Environmental Protection Act and regulations made under that Act (the Genetically Modified Organisms (Traceability and Labelling) (England) Regulations (S.I. 2004/2412)). Defra has regulatory responsibility for this area and the local authorities and Port Health Authorities are the designated enforcement bodies.

3.2 Full details of regulations 1829/2003 and 1830/2003 can be found on the Food Standards Agency website at <http://www.food.gov.uk/gmfoods/> and http://www.food.gov.uk/gmfoods/gm/gm_labelling.

4. Current rules on genetically modified varieties and seeds¹⁴

4.1 EU legislation on seeds (notably Directive 2002/53/EC on the Common Catalogue of varieties of agricultural plant species and 2002/55/EC on the marketing of vegetable seed) specifies that national authorities that have agreed to the marketing of seed of a certain variety on their territory must notify the acceptance of the variety to the European Commission. To qualify for inclusion in national catalogues varieties must meet defined Community criteria with respect to distinctness, uniformity and stability and, in the case of agricultural species, value for cultivation and use. Once a variety of seed is properly inscribed in a national catalogue, the Commission is informed and is required to inscribe the variety in the Common Catalogue by publication in the Official Journal; once this is done the seed of such a variety can be marketed throughout the EU.

4.2 Seed legislation also requires that genetically modified varieties must be authorised in accordance with EU Directive 2001/18/EC before they are included in the Common Catalogue and marketed in the EU¹⁵. The Commission examines the information supplied by the Member State as regards inclusion in a national list to ensure it is in compliance with Community legislation and includes the variety concerned in the Common Catalogue of varieties.

4.3 As of 31st March 2011 three GM events have been authorised for cultivation in the Member States of Europe: maize MON 810, developed by Monsanto to provide resistance to lepidopteran target pests; maize T25, developed by Bayer CropScience, which is tolerant to glufosinate ammonium, and in March 2010 potato EH92-527-1 was authorised, developed by BASF for production of starch for non-food use¹⁶. Of the two maize events, only maize MON810 can be grown in the EU because T25 maize does not have any varieties registered in the Common

¹⁴ http://ec.europa.eu/food/food/biotechnology/gmfood/ganda_en.htm

¹⁵ If the seed is intended for use in food or feed, it can also be authorised in accordance with the GM food and feed Regulation 1829/2003

¹⁶ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:053:0015:0018:EN:PDF> ; C/SE/96/3501; unique identifier BPS-25271-9.

Catalogue. The potato will not be grown in the UK because it does not have the required starch processing facilities.