



Annual report on GM inspection and enforcement activities

01 April 2007 - 31 March 2008

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Executive summary

1. The GM Inspectorate (GMI) is responsible for enforcement of legislation controlling the deliberate release of genetically modified crops in England. As there is currently no commercial cultivation of GM crops in England, this concerns small-scale experimental releases only. The work is undertaken for the Department for Environment Food & Rural Affairs (Defra). The GMI is based at the Central Science Laboratory (CSL) in York, which is an executive agency of Defra. This is the eighth report of the GM Inspectorate covering the period 1st April 2007 to 31st March 2008.
2. Within the reporting period there was one GMO deliberate release field trial in England of potatoes genetically modified for resistance to late blight caused by the fungus *Phytophthora infestans*. Field inspections confirmed that the release was consistent with the conditions of the consent and that no risks to human health or the environment were identified by release of the GMO. Two post-trial inspections of former deliberate release trial sites, and two 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.
3. On behalf of Defra Plant Variety Rights Office and Seeds Division (PVS), 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. Forty six companies participated in the audit programme for 2006-07, and sixty eight companies participated in the 2007-08 audit programme. The seed companies that participated in the audits were found to have acted responsibly in managing the risk of adventitious GM presence in conventional seed they were marketing. Summary tables of the findings of the audits have been published on the GM Inspectorate website.
4. The Central Science Laboratory is undergoing a merger with Defra Plant Variety Rights Office and Seeds Division and Defra Plant Health Division (which includes the Plant Health and Seeds Inspectorate). The merger will lead to the creation of a new agency for Defra. Whilst the creation of the new Agency will inevitably mean a degree of internal reorganisation, the functional operation of the GM Inspectorate is expected to remain unchanged.

1. The role of the GM Inspectorate

- 1.1 The GM Inspectorate (GMI), based at the Central Science Laboratory (CSL) in York, is responsible for inspection and enforcement of the deliberate release of genetically modified (GM) crops in England. This work is undertaken on behalf of the Department for Environment, Food and Rural Affairs (Defra) to ensure compliance, in England, with the legislation concerning the deliberate or unintentional release of genetically modified organisms (GMOs). Defra is the UK Competent Authority for regulation of the deliberate release of GMOs under EC Directive 2001/18/EC¹. CSL GM inspectors are appointed under Part VI of the Environmental Protection Act 1990 (EPA). Details of GMO legislation in the UK can be found in Annex 1 of this report.
- 1.2 CSL is an executive agency of Defra and specialises in the sciences underpinning agriculture for sustainable crop production, environmental management and conservation, and food safety and quality.
- 1.3 The work of the GM Inspectorate falls into two key areas:
- inspection of GMO deliberate release sites in England and audits of deliberate release consent holders, and
 - monitoring, in England, for adventitious GM presence in conventional seed for marketing
- 1.4 Within both of these areas potential breaches of the relevant GM legislation may occur. These may be notified to the regulatory authority or to the GMI by a consent holder, a seed company or a member of the public; a GM inspector may also identify a potential infringement in the course of official duties. The GMI investigates all of these issues on a case-by-case basis and takes action as appropriate.
- 1.5 The Scottish Agricultural Science Agency (SASA)² is authorised by the Scottish Executive to carry out the equivalent inspection and enforcement activities for Scotland. The GMI liaises closely with the GM Inspectorate at SASA, particularly in sharing information about seed material that crosses borders for production or marketing. Northern Ireland and Wales make their own arrangements.
- 1.6 The GMI is part of the Biotechnology & Molecular Genetics team at CSL. This research and development (R&D) team provides technical support for the GMO inspection and enforcement work. The R&D team comprises research scientists with expertise in the development of molecular-based techniques for GMO detection, crop and food authenticity, population genetics and modelling of crop-to-crop gene flow. The R&D team

¹ Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EC.

² From 1st April 2008 renamed as 'Science and Advice for Scottish Agriculture', <http://www.sasa.gov.uk/gm/inspectorate/index.cfm>

participates in a number of collaborative GM-related projects including the pan-European SIGMEA³ and Co-Extra⁴ projects, also the work of the European Commission Joint Research Centre (JRC) and the European Network of GMO Laboratories (ENGL). The support provided by the R&D team and other CSL scientists ensures that the GMI is able to respond efficiently and appropriately to any GM deliberate and accidental release incidents that occur in England.

- 1.7 The GM Inspectorate is an active member⁵ of the European GMO Enforcement Project (EEP), which is a forum for the exchange of information and expertise between GM inspectors in the Member States of Europe.
- 1.8 This is the eighth report of the GM Inspectorate and covers the period 1st April 2007 to 31st March 2008.

³ Sustainable introduction of GM crops into European agriculture (<http://sigmea.dyndns.org/>)

⁴ GM and non-GM supply chains: their co-existence and traceability (<http://www.coextra.eu/>)

⁵ The Head of the GMI is an elected member of the Steering Committee of EEP

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

2.1 Experimental (Part B) deliberate release trial sites

The primary role of the GM Inspectorate is to ensure compliance with consents granted in accordance with section 111 of the Environmental Protection Act 1990. This is achieved by a combination of practical inspection visits at deliberate release trial sites, and audits of deliberate release consent holders to ensure that they are aware of their responsibilities as the holder of a consent to release a GMO. The limitations and conditions of each deliberate release are specified in the consent document, including requirements for submission of monitoring reports to the Secretary of State (Defra).

The GMI inspects each deliberate release trial at least once during the growing season. During inspection visits GM Inspectors must establish that each release is in accordance with 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).

Draft reports on growing crop inspection visits are produced and submitted to Defra within an agreed framework of five working days. A period of 20 calendar days then follows in which the consent holder and Defra 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 our website at: <http://www.gm-inspectorate.gov.uk/deliberateRelease/exptreleases.cfm>.

- *Consents under which planting could take place in the reporting period*

06/R42/01 (BASF Plant Science GmbH)⁶

During the reporting period one field trial was planted in England under this consent to release potato (*Solanum tuberosum*) genetically modified for resistance to the fungal disease late blight (*Phytophthora infestans*). The trial was planted in April 2007 and inspections carried out at sowing, pre-flowering and harvest confirmed that the trial was carried out in accordance with the conditions of the consent. The inspection reports are published on the GMI website: http://www.gm-inspectorate.gov.uk/deliberateRelease/documents/Inspection_reports_07-08v4.pdf. An additional inspection was necessary at the site following an incident of vandalism; this inspection confirmed that the consent holder's emergency plans were appropriate and had been satisfactorily implemented, and that a clean-up operation had been satisfactorily carried out.

⁶ <http://www.defra.gov.uk/environment/gm/regulation/consents/index.htm>

Note: A second trial was planted under this consent in April 2008. Inspections have been carried out at sowing and at flowering. The inspections confirmed that the trial is being carried out in accordance with the conditions of the consent. These inspection reports are published on the GMI website at <http://www.gm-inspectorate.gov.uk/deliberateRelease/FieldInspectionReports1stApril2008-31stMarch2009.cfm>.

- *Post-trial monitoring*

Most deliberate release consents have specific requirements for the consent holder to monitor the release site after completion of a trial. The GM Inspectorate visits each former deliberate release site at an appropriate stage in the growing season to ensure that post-trial monitoring procedures are being undertaken in accordance with the conditions of the consent. Such procedures might include 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.

In the reporting period two post-trial monitoring inspection visits were conducted at former GM potato trial sites. The inspections confirmed that management of each former trial site was in accordance with the conditions specified in the relevant consent documents.

- *Management audits of deliberate release consent holders*

The purpose of the management audit is to verify that the correct procedures and protocols are in place to ensure good planning and operation of GMO field trials, and to verify that the conditions laid down in the release consents are known throughout the management chain and effectively implemented *in situ*. Consent holders for current field releases are also required to provide evidence to demonstrate that only the GM event(s) covered by the consent is 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.

In the reporting period management audits were conducted for the holders of consent 06/R42/01, and consents 01/R4/10 and 02/R4/12⁷ to review procedures for post-trial monitoring and management. In both cases the consent holders were judged to have appropriate arrangements in place for the management of their consents.

- *Consent holder monitoring reports*

Consent holder monitoring reports are required annually for all consents until they are officially terminated. In the year of the release this is 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 and any additional measures that were taken, also any additional measures that will be taken in the future and the reasons

⁷ Consents 01/R4/10 and 02/R4/12 are held by the same consent holder.

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 consent holder must provide Defra with information on the effectiveness of the measures in place to control any plants that emerged 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 can be modified or discontinued at the site and the reasons for this.

The GM Inspectorate is responsible for administering submission of these reports to Defra. Three consent holder monitoring reports were submitted to Defra in the reporting period (consents 06/R42/01, 01/R4/10 and 02/R4/12). The reports were accepted as meeting the requirements of the respective consents, with no revisions to the risk assessment or trial management measures necessary.

2.2 Suspect genetically modified *Danio rerio* zebrafish

In our 2006-07 annual report, we reported that brightly coloured *Danio rerio* zebrafish had been offered for sale in four separate premises in England and Wales, and that tests undertaken by CSL had confirmed these to be genetically modified. GM fish were also reported in other European Member States (the Netherlands, Germany the Czech Republic), and in New Zealand. Despite a number of reports of sightings of suspect *Danio rerio* fish in aquatic retail outlets in England, no further genetically modified *Danio rerios* have been identified since June 2007. The GM Inspectorate and the Fish Health Inspectorate have a contractual arrangement in place to ensure that any reports of suspect GM *Danio rerio* zebrafish can be investigated and resolved rapidly.

2.3 Monitoring adventitious GM presence in conventional seed stocks in England

Authorised genetically modified 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). At present only varieties of maize line MON810, modified for resistance to the European corn borer (*Ostrinia nubilialis*) have been placed on the Common Catalogue. 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 are not suited to cultivation in the shorter UK growing season.

Current EU seeds legislation does not lay down specific measures for the adventitious presence of GMOs in non-GM seed. As a consequence, all seeds marketed for cultivation in the UK must be free of unauthorised adventitious GMOs. UK producers and importers of seed material are, therefore, legally obliged to take steps to minimise the risk of adventitious GM presence in conventional seed before placing it on the market.

On behalf of Defra Plant Variety Rights Office and Seeds Division (PVS), 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, to discuss how they manage these risks and, if necessary, to identify where improvements in risk management can be made. The audits include seeds of maize (*Zea mays*) including sweetcorn, oilseed rape (*Brassica napus*), *Brassica rapa* and soya (*Glycine max*) intended for agricultural and horticultural use and private company trials. Seed material entered into National List and Recommended List trials (imported or UK-produced) is separately audited by Defra PVS.

Each participating company producing 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 indicates a possible increase in risk for a particular company, for example if company procedures have changed or seeds have been imported from a new source, they may be asked to submit to 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.

- *Audits of seed importers and producers: 2006-2007*

All seed companies participating in the 2006-07 audit were found to have acted responsibly in managing the risk of adventitious GM presence in conventional seed. It was not necessary to recall or destroy any marketed seed because of an unauthorised adventitious GM presence. Twelve companies known to be marketing seed included in the programme in England chose not to participate in the programme.

Table 3: Summary of audit programme for the 2006-2007 financial year (published 20th August 2008)

Audit type	Summary details
Detailed audit	Total number of companies contacted: 12 Reports completed: 9 Companies declining to participate: 2 Companies not marketing any crops of interest: 1
Collection of basic data on seeds marketed	Total number of companies contacted: 46 Reports completed: 32 Companies declining to participate: 10 Companies not marketing any crops of interest: 15 [†]
Targeted audit	None necessary

[†] Includes companies previously audited for extended range of crops under previous risk assessment

- *Audits of seed importers and producers: 2007-2008*

Note added at publication: The seed audit programme for 2007-08 was completed in July 2008. All seed companies participating in the audit were found to have acted responsibly in managing the risk of adventitious GM presence in conventional seed.

It was not necessary to recall or destroy any marketed seed because of an unauthorised adventitious GM presence. Ten companies known to be marketing seed included in the programme in England chose not to participate in the programme. One targeted audit was undertaken on a company that was newly identified as importing seeds of maize from the USA for sale in England.

Table 4: Summary of audit programme for the 2007-2008 financial year (published 28th July 2008)

Audit type	Summary details
Detailed audit	Total number of companies contacted: 13 Reports completed: 11 Companies declining to participate: 1 Companies not marketing any crops of interest: 1
Collection of basic data on seeds marketed	Total number of companies contacted: 36 Reports completed: 47 Companies declining to participate: 9 Companies not marketing any crops of interest: 14 [†]
Targeted audit	1

[†] Includes companies that had supplied data under 2006/07 programme for seed marketed in 2008 growing season

- *Data management*

All data provided to the GM Inspectorate through participation in the seed audit programme is held securely in a bespoke database (the GM-seed audit information database, or 'GM-SAID'), which was designed specifically to support the seed audit programme. Seed companies participating in the audit can access their own data held in the database via a secure extranet. All data is treated as commercial and in confidence.

- *Audits of seed importers and producers: 2008-2009*

The audit programme for 2008-09 is now underway and audit visits will commence in August 2008.

- *Current Awareness of Experimental and Commercial Releases of GM Crops Worldwide*

Our most recent report on the number and types of releases of genetically modified (GM) crops worldwide was provided to Defra in August 2007. The report covered the period April 2006 to August 2007 and provided updated summary information on the commercial and experimental status of GM crops within this period. It also highlighted any significant developments in terms of GM technology and documented any reported unauthorised releases of GM crops. The report can be downloaded from our website at: <http://www.gm-inspectorate.gov.uk/reportsPublications/>.

- *GM Inspectorate Seed Monitoring News*

A newsletter has been developed aimed at seed companies that are invited to participate in the seed audit programme. The newsletter is a six-monthly topical

publication providing current relevant GMO news items and providing a summary of the information included in the current awareness document. A summary of progress with the seed audit programme is also included. The first newsletter was issued in July 2008 and can be downloaded from our website at: http://www.gm-inspectorate.gov.uk/seedAuditProgramme/documents/GMInspectorateNewsletterFinal_July2008.pdf.

3. GMO research undertaken 2007 to 2008

3.1 Co-Extra project

CSL is a partner in the EU-funded Co-Extra project (<http://www.coextra.eu/>). Co-Extra is a research programme on co-existence and traceability. The goal of the project is to support the implementation of coexistence of GM crops and to foster a science-based debate among stakeholders. CSL is contributing to three work packages:

- Graphical description of regional supply chain case studies (sugar beet and rapeseed oil);
- Analysis and development of sampling plans and guidelines;
- Development of on-site detection in both DNA- and protein-based detection approaches; development of quantitative PCR methods to detect GMOs and evaluation of different equipment to increase the accuracy of analysis.

CSL hosted the annual meeting of the Co-Extra project in York in February 2008. This was a project meeting for all the partners, but also included an open session with presentations and discussion on new methods to prevent the admixture of GM to non-GM crops, appropriate approaches to the cost-effective organisation of supply chains, the political and legal aspects of co-existence and economic approaches to co-existence. Information on this event can be found at: (<http://www.coextra.eu/events/event1116.html>).

3.2 Management of GMO field trials

In September 2007 CSL won funding to undertake research for the European Commission (Directorate General Environment) entitled “Analysis of field trials management in Member States and prevention of accidental entry into the marketplace”. The project was commissioned to verify that the EU Member States are adhering to the provisions of EC Directive 2001/18/EC⁸, with respect to Part B releases, and that consent holders are meeting their obligations in accordance with the conditions of consents that have been issued. The principal aims of the project were:

- To get an overview of concrete measures in place in the EU Member States for the management of field trials, including inspection and control measures by the relevant responsible bodies;
- To assess the effectiveness of these management measures in the prevention of out-crossing from GM crops and other means of GMOs accidentally entering the market place;
- To identify gaps and areas for additional guidance or follow-up work as well as examples of best practice.

The work was undertaken in collaboration with the Scottish Agricultural Science Agency. The final report was submitted in July 2008. It is currently being reviewed by the European Commission and will be published in due course.

⁸ Directive 2001/18/EC on the deliberate release into the environment of GMOs

4. Looking ahead to the 2008/2009 reporting year

- 4.1 The Central Science Laboratory is currently undergoing a merger with Defra Plant Variety Rights Office and Seeds Division and Defra Plant Health Division (which includes the Plant Health and Seeds Inspectorate). The merger will lead to the creation of a new agency for Defra. The role of the new agency is: “to provide robust evidence, rigorous analysis and professional advice to Government, international organisations and the private sector, in order to support and develop a sustainable food chain, a healthy natural environment, and to protect the global community from biological and chemical risks”. Whilst the creation of the new Agency will inevitably mean a degree of internal reorganisation, the functional operation of the GM Inspectorate is expected to remain unchanged.
- 4.2 In April 2008 the European Commission held a forum at which they communicated the results of a stakeholder consultation exercise on the impact of setting thresholds for the adventitious presence of authorised GMOs in non-GM seeds. No announcement was made as to when such thresholds might be proposed. The Commission has said that its presentation will be published in due course, and we will create a link to this from the GM Inspectorate website. It is, therefore, anticipated that proposals for thresholds for adventitious GM presence of authorised GMOs might be forthcoming in the not too distant future and that this might have practical implications for the seed audit programme.

5. Contact details

- 5.1 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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York YO41 1LZ, UK

Telephone: + 44 (0) 1904 462000
Fax: + 44 (0) 1904 462250
Email: gm-inspectorate@csl.gov.uk

- 5.2 For further information on the CSL gemma (genetically modified material analysis) scheme please visit: <http://www.fapas.com/gemma.cfm>
Or contact us at:

FAPAS, CSL
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Telephone: +44 (0) 1904 462100
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Email: fapas@csl.gov.uk
For test material sales: fapas.sales@csl.gov.uk

- 5.3 For further information about the CSL independent GM testing service please visit:
<http://www.csl.gov.uk/servicesOverview/foodAnalysis/gmFood.cfm/>

Email: foodanalysis@csl.gov.uk

Annex 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 organisms⁹. 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 (4) at CSL 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 Part B of 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

⁹ 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.

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 the release and marketing of GMOs¹⁰. 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://www.defra.gov.uk/environment/gm/regulation/index.htm>.

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 Authority¹¹ 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 1) contains or consists of GMOs (e.g. GM soya), 2) is produced from GMOs (e.g. glucose syrup from maize starch), or 3) 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 Regulations¹².
- 2.4 Applicants seeking authorisation for cultivation of a GM food or feed may still

¹⁰ See <http://www.defra.gov.uk/environment/acre/index.htm>

¹¹ See http://www.efsa.eu.int/science/gmo/catindex_en.html

¹² See <http://www.food.gov.uk/enforcement/>

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.

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 seeds¹³

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 EU¹⁴. 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. Currently, 74 varieties of genetically modified maize MON810 are registered in the Common Catalogue.

¹³ http://ec.europa.eu/food/food/biotechnology/gmfood/qanda_en.htm

¹⁴ 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