



Annual report on GM inspection and enforcement activities

01 April 2006 - 31 March 2007

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Submitted to the Department for Environment, Food and Rural Affairs October 2007.

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 seventh report of the GM Inspectorate covering the period 1st April 2006 to 31st March 2007.
2. Within the reporting period there were no deliberate release field trials in England. Two new consents were issued for the deliberate release of potatoes genetically modified for resistance to late blight, one of which was planted as scheduled in early April 2007. 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. In January 2007 the GM Inspectorate began investigating reports of genetically modified *Danio rerio* zebrafish fish being sold in the UK. Working with the Fish Health Inspectorate, suspect fish were located at a number of retail outlets in England and Wales. Using a three-stage diagnostic test developed at CSL, the fish were confirmed to be genetically modified in all cases. Importers and retailers have been made aware that no GM fish are authorised for sale in the UK or Europe. Formal enforcement action was not taken in any of the cases identified to date.
4. Sixty three companies were invited to participate in the GM Inspectorate's spring 2006 seed audit programme for adventitious GM presence; thirty two companies were producing seeds of interest and a total of 59 seed audit reports were produced. Twelve companies chose not to participate in the programme. Results of the spring 2006 seed audit programme were published on the GMI website in December 2006.
5. A new risk-based approach to seed auditing was introduced for the 2006/07 programme; the list of crop species identified as being most at risk of adventitious GM presence has been modified and the focus of audits placed on the management of identified risks.. Fifty eight companies were invited to participate in this most recent programme, 46 companies participated and summary tables of the findings will be published on the GMI website in September 2007.

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 EU Directive 2001/18/EC. 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 CSL assumed responsibility for GM inspection and enforcement functions in June 2000; the work of the GM Inspectorate falls into three key areas:
 - a. inspection of GMO deliberate release sites in England;
 - b. audits of deliberate release consent holders;
 - c. monitoring, in England, for adventitious GM presence in conventional seed for marketing.
- 1.4 Within all 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 by a member of the public; a GM inspector may also identify a potential infringement in the course of undertaking statutory work. The GMI investigates these issues on a case-by-case basis and takes action as appropriate.
- 1.5 The GMI is part of CSL's Biotechnology & Molecular Genetics team, a research and development (R&D) team that provides technical support for all GM inspection and enforcement work. The R&D team comprises research scientists whose expertise lies in the development of molecular-based techniques for GMO detection, food and crop authenticity, population genetics and modelling of crop-to-crop gene flow. The R&D team participates in a number of collaborative GM-related projects including the pan-European SIGMEA¹ and Co-Extra² projects. CSL scientists also participate in 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 release incidents that may occur in England.

¹ Sustainable introduction of GM crops into European agriculture (<http://sigmea.dyndns.org/>)

² GM and non-GM supply chains: their co-existence and traceability (<http://www.coextra.eu/>)

- 1.6 The Scottish Agricultural Science Agency (SASA)³ 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 regarding seed audits and reports where seed material crosses borders for production or marketing.
- 1.7 The GM Inspectorate is an active member⁴ of the European GMO Enforcement Project (EEP), a forum for the exchange of information and expertise between GM inspectors in the member states of Europe.
- 1.8 This is the seventh report of the GM Inspectorate covering the period 1st April 2006 through to 31st March 2007.

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

2.1 Experimental (part B) deliberate release trial sites

Active consents

- 2.1.1 The primary role of the GM Inspectorate is the inspection and enforcement of GMO deliberate release trial sites to ensure compliance with consents granted in accordance with section 111 of the Environmental Protection Act 1990. During the reporting period there were no deliberate release trial sites planted in England and therefore no growing crop inspections were conducted (but 2.1.2 below, note added at publication).
- 2.1.2 In December 2006, consent was issued to BASF Plant Science GmbH to carry out deliberate release field trials of potato (*Solanum tuberosum*) genetically modified for resistance to the fungal disease late blight (*Phytophthora infestans*) (consent 06/R42/1)⁵. The consent was issued for five years (five growing seasons) commencing 30th March 2007 and ending 30th November 2011. Consistent with previous releases, the GMI is scheduled to inspect the release at sowing, during the growing season (at flowering), and at harvest.

Note added at publication: the GMO trial went ahead as scheduled and was planted in April 2007. Inspections confirmed that the trial was carried out in accordance with the conditions of the consent. Inspection reports are published on the GMI website at <http://www.gm-inspectorate.gov.uk/deliberateRelease/exptreleases.cfm>. A second consent was issued to BASF in May 2007 (07/R42/01) authorising similar trials over a five-year period at a separate location (see footnote 5); planting under this consent did not go ahead in the 2007 season.

³ <http://www.sasa.gov.uk/gm/inspectorate/index.cfm>

⁴ The Head of the GMI is an elected member of the Steering Committee of EEP

⁵ For details see the Defra website: <http://www.defra.gov.uk/environment/gm/regulation/registers.htm>

Post-trial monitoring

- 2.1.3 When authorisation ('consent') is given to deliberately release a GMO in a field trial, specific conditions are attached which require the consent holder to monitor the release during the trial period and for a specified period after completion of the trial. The 'Schedule' issued with each consent specifies the limitations and conditions of the particular release, including requirements for submission of monitoring reports to the Secretary of State (Defra). The GMI inspects a proportion of former release sites to ensure post-trial management by the consent holder is consistent with consent conditions.
- 2.1.4 Four post-trial inspection visits were made to former GM potato trial sites; two where post-trial volunteer control was an ongoing requirement of consents, and two where restrictions on subsequent cropping still applied. The inspections confirmed that management of the former trial sites was compliant with the conditions specified in the relevant consent documents.

Audits of deliberate release consent holders

- 2.1.5 Deliberate release consent holders are audited by the GMI to verify that they have implemented appropriate management procedures and protocols to ensure the smooth running of the GMO field trial. This includes confirming that the conditions laid down in the consent are known throughout the management chain and are effectively implemented *in situ*, and that arrangements are in place to ensure all material removed during the trial and post-trial periods is stored and/or disposed of correctly.
- 2.1.6 The management audit programme includes consent holders with active consents, i.e. those with release sites currently being used for trials, and those with an ongoing requirement to monitor former trial sites.
- 2.1.7 Two consent holders responsible for a total of 3 consents were audited in the 2006/07 period, this included BASF in preparation for planting their trial under consent 06/R42/01. The GM Inspectorate found that both consent holders had appropriate protocols in place to meet their responsibilities, and that dissemination of information through management chains and the operation of these protocols *in situ* was effective.
- 2.1.8 The holder of consent 06/R42/1 (BASF Plant Science GmbH) was required to provide evidence of duty of care to ensure that the material intended for planting in the trial was consistent with that authorised in the consent. This information was provided in the form of quality assurance procedures for production of GM plant material for release in trials, and analytical test results for the material to be planted. The GMI accepted this information and did not consider it necessary to undertake any independent testing.
- 2.1.9 Management audit reports detailing the evidence provided and the GMI's assessment of compliance for each consent holder were submitted to Defra, providing assurance that deliberate releases were being managed appropriately.

Consent holder monitoring reports

2.1.10 The GMI is responsible for collection and management of all formal monitoring reports required by Defra as part of deliberate release consents. Consent holder reports are checked for completeness and submitted to Defra for approval within an agreed timescale. During the reporting period 2 consent holder monitoring reports were submitted and in all cases, monitoring was consistent with the requirements of the consents.

2.2 Suspect genetically modified *Danio rerio* zebrafish

2.2.1 In November 2004 the GMI reported it had conducted investigations into the alleged, but unsubstantiated, illegal import of genetically modified *Danio rerio* zebrafish⁶. In November 2006 the Dutch authorities reported that brightly coloured zebrafish genetically modified to fluoresce under UV light had been identified for sale in the Netherlands and that appropriate action had been taken; the German authorities reported similar findings shortly after this. The source of the modified fish was thought to be Asia.

2.2.2 Within Great Britain it is an offence for any person to release or market any genetically modified organisms without consent provided under Section 111 of The Environmental Protection Act 1990⁷. There are currently no genetically modified fish authorised for release or marketing in Europe or Great Britain therefore anyone who knowingly releases or markets such fish in Great Britain is committing an offence under The Environmental Protection Act 1990.

2.2.3 In February 2007 a journalist with 'Practical Fishkeeping' magazine reported the sale of brightly coloured *Danio rerio* zebrafish in a number of tropical fish retail outlets in England. The GMI, in collaboration with the Fish Health Inspectorate at Cefas⁸, investigated these claims and at the same time issued a notice to importers and retailers of tropical fish outlining the legal position and requesting them not to import fish meeting the description of 'red danios' or 'coloured danios' pending the outcome of the investigation⁹.

2.2.4 In March 2007 brightly coloured *Danio rerio* zebrafish were obtained from a retail outlet and were confirmed, by tests developed at CSL, to be genetically modified (see section 2.3 below for details of how the test was developed). These fish had been sourced from a breeder in the Czech Republic.

2.2.5 In May 2007 a second notice was issued to importers and retailers of tropical fish confirming that GM fish had been identified in the UK with a description of the fish. This notice informed all importers and retailers that

⁶ <http://www.gm-inspectorate.gov.uk/documents/GMIfinal.pdf>

⁷ Consent issued by the Secretary of State for Defra, the Welsh Assembly Government or the Scottish Executive.

⁸ The Centre for Environment, Fisheries and Aquaculture Science, <http://www.cefas.co.uk/>

⁹ Available at <http://www.gm-inspectorate.gov.uk/gmfish/uktradeintropicalfish.cfm>

“they must not release or market fish meeting the description of coral pink danio or anything sounding similar, e.g. red danio, or any other recently available coloured or fluorescent danio varieties, unless they are certain that these fish are not genetically modified”. The notice explained that, in Great Britain, marketing includes making GM fish available to other persons, whether or not for payment, and that once imported it would be an offence to make available GM fish to anyone else. The notice also advised that monitoring activities were in place and any fish suspected as being genetically modified may be seized, and that anyone appearing to breach these requirements may be prosecuted. The Ornamental Aquatic Trade Association (OATA) was supportive of this initiative.

- 2.2.6 Following the issuing of this second notice, a further three reports of brightly coloured zebrafish were made to the Fish Health and GM Inspectorates. These fish were removed from the retail premises and tests undertaken at CSL confirmed that the fish were genetically modified in all cases. As the fish had already been removed from sale by each of the vendors it was not considered necessary to take formal enforcement action. Each of the incidents was followed up with the individual retailers and the legal position was made clear. Two of the four findings of GM fish were located in Wales and the GMI liaised with the National Assembly for Wales on these particular investigations.
- 2.2.7 Although a formal risk assessment has not been undertaken for UK conditions, it is thought that *Danio rerio* zebrafish would not thrive in the UK if released into ponds or rivers and they are not considered to pose any risk to human health or the environment.
- 2.2.8 The GM Inspectorate and the Fish Health Inspectorate will continue to work with the ornamental aquatic industry directly through organisations such as OATA to monitor and investigate any potential releases in the UK. For regularly updated information regarding GM fish please visit the GM Inspectorate website: <http://www.gm-inspectorate.gov.uk/gmfish/>

2.3 Development of a diagnostic test for genetically modified *Danio rerio* zebrafish

- 2.3.1 Transgenic zebrafish fish have been described in several research papers e.g. Gong *et al.*, (2003) and Wan *et al.*, (2002). The most common fluorescent proteins in these transgenic fish are green fluorescent protein (GFP) and red fluorescent protein (RFP), expressed by *gfp* and *DsRed* genes respectively. Plasmids containing these genes are commercially licensed by Clontech Inc. (USA)¹⁰. At CSL, a diagnostic strategy was developed based on the three tests outlined below. In all cases tests were carried out on tissue taken from fish that had been humanely culled¹¹.

¹⁰ <http://www.clontech.com/>

¹¹ Live fish are held under a Genetically Modified Organisms (Contained Use) licence and the appropriate Home Office licences.

Fluorescence under ultra violet light

Zebrafish containing fluorescent proteins will fluoresce under ultra violet (black) light (wavelength 400 nm – 320 nm) whereas non-GM zebrafish will not fluoresce. This does not confirm that fish are genetically modified as fluorescent dyes may have been absorbed by or fed to the fish. All fish received by the GMI fluoresced under UV (black) light.

Excitation spectra

GFP and RFP fluoresce at 508 and 583 nm respectively given blue light excitation, whereas wild-type *D. rerio* do not fluoresce at these wavelengths. Proteins were extracted from fish tissues and the presence of RFP (and GFP in some cases) was confirmed by measuring the emission spectra. Again, while this gave further indication of a GM event, fluorescent dyes absorbed or fed to the fish could have produced similar results. This test does, nevertheless, give a good indication that GM events may be present. In addition, because GFP, RFP and other fluorescent markers are only known to have been used on separate transformation vectors, it readily indicates the number of possible events present.

Molecular analysis

Polymerase chain reaction tests were developed for *gfp* and *DsRed* genes (two main forms of *DsRed* have been produced and PCR primers for both these forms were used). In addition generic PCR primers for common transgenic elements known to have been used in the development of GM fish were used. PCR tests confirmed that all fish seized by the FHI and GMI were genetically modified. The precise combination of GM events was complex, with some fish containing just RFP and others both RFP and GFP. The fish appear to be distinct from the Glofish®¹² legally marketed in the USA. Further work is being undertaken to characterise in more detail the GFP and RFP events in the fish.

2.4 Adventitious GM presence in conventional seed stocks: monitoring in England

Background to auditing seed producers and importers

- 2.4.1 Seeds of authorised genetically modified varieties may be marketed in the UK and throughout Europe provided they have met the requirements for placing on the Common Catalogue of Varieties (see Annex 1); however, none of the GMO varieties currently authorised are suited to cultivation in the UK. There are no specific measures in EU seeds legislation with respect to the adventitious presence of GMOs in seed, consequently, all seeds marketed for cultivation in the UK must be free of adventitious GM presence (AGMP), and producers and importers of seed material are obliged to take steps to minimise the risk of AGMP in conventional seed before it is placed on the market.
- 2.4.2 On behalf of Defra Plant Variety Rights Office and Seeds Division (PVS), the GM Inspectorate undertakes a programme of voluntary audits with the

¹² <http://www.glofish.com/>

aim of helping companies ensure they are taking appropriate steps to minimise the risks of AGMP in their seed material, and have appropriate supporting documentation in place. The audits include imported or UK-produced seed intended for private company trials but not seed entered into official trials (National List, Descriptive List or Recommended List), which is audited separately by Defra PVS.

2.4.3 The GMI produces guidance documents for each crop species included in the audit programme. These are reviewed at least annually and distributed to all seed producers, importers and suppliers known to market (or to have marketed) seed of the crops scheduled for audit. Guidance has also been developed on managing the risk of AGMP during seed processing for seed producers and importers to forward to their processors. In particular the guidance advises on the key criteria that letters of assurance and analytical testing should meet. Copies of all the guidance documents are available on the GM Inspectorate website at: <http://www.gm-inspectorate.gov.uk/seedAuditProgramme/cropGuidance.cfm>

2.4.4 During this reporting period the GM Inspectorate has conducted two audit programmes, which are summarised individually below. For spring 2006 the established seedlot-based methodology was followed and findings were published in December 2006. The new annual audit programme based on quantitative risk assessment and process management commenced in November 2006 for the 2006/07 financial year. The background to the new approach to audits was provided in the previous GMI annual report (2005/2006), further information is provided in section 2.5 below and in 'question and answer' and crop guidance documents available from the GMI website at: <http://www.gm-inspectorate.gov.uk/seedAuditProgramme>.

Audits of seed importers and producers: Spring 2006 programme ('old' programme)

2.4.5 Participating companies who had marketed seeds of spring oilseed rape, spring brassicas, maize, soya, sugar beet and/or fodder beet in spring 2006 were requested to:

- provide information from their suppliers/growers (usually in the form of letters of assurance) regarding the GM status of their seed;
- be visited by a GM Inspector to discuss the detailed production history of the seed;
- supply details of any analytical test they had undertaken (or commissioned) on the seed.

2.4.6 For each company, information gathered under the above framework collectively formed the basis of an assessment, by the GMI, of the effectiveness with which the risk of AGMP had been managed. If the GM Inspectorate was satisfied that sufficient information had been provided at the time of the audit, and the company had demonstrated that it acted responsibly in managing the risks of AGMP, this was stated clearly in an audit report to Defra PVS.

Summary of Audits for the Spring 2006 programme:

- 2.4.7 During the spring 2006 audit programme the GMI carried out a total of 59 seed audits covering 32 seed importing and/or producing companies. The information is summarised in table 1 below:

Table 1: Summary of the spring 2006 audit programme

Number of companies invited to participate	63
Number of companies with crops of interest that season	32
Number of companies that declined to participate	12
Number of crop-specific reports generated	59

- 2.4.8 All seed companies participating in the audit were found to be taking appropriate steps to manage the risks 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.
- 2.4.9 In addition to the individual company reports submitted to Defra PVS, a summary report for all seed audited during the spring 2006 programme was published on the GMI website. Prior to publication of the reports, seed companies were given 20 calendar days in which to comment on the factual content of the tables and submit any additional comments in relation to specific seed lots. A number of minor comments were received regarding the detail of the summary tables, and these were accepted prior to publication.
- 2.4.10 Summary reports for spring 2006 and previous audit programmes can be viewed at: <http://www.gm-inspectorate.gov.uk/seedAuditProgramme/auditReports.cfm>.

2.5 Audits of seed importers and producers: new programme 2006-2007

- 2.5.1 The new audit approach places emphasis on the management of identified risks. Crops at greatest risk of adventitious GM presence were identified by the 'quantitative risk assessment' models developed by the GMI (as described in the annual report for 2005/06); hence, in the new programme crops of *Brassica napus*, *Brassica rapa*, *Zea mays* and *Glycine max* were identified for audit; crops of *Beta* spp. and *Brassica oleracea* are no longer audited.
- 2.5.2 The most significant practical change in the new risk-management based approach is that audit visits are conducted to ascertain how the company manages the risk of adventitious GM presence as a whole, rather than assessing the provenance of each individual seed lot. In addition, the twice-yearly audit of all seed companies has been re-scheduled such that each participating company producing seed of interest is audited in detail once every three years. In the intervening years the company will be asked to supply basic audit information (crop type and variety, seedlot reference

numbers, amount sold, originator of the seed and country of origin), which will be compared with previous audit information. If the new data indicates a possible increase in risk levels 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.

2.5.3 A summary of these changes and other differences between the 'old' and new risk-based approach to seed audits is provided in table 2 below.

Table 2: Summary of key difference between 'old' and 'new' audit programmes

	Previous audit system	New risk-based system
Approach	<ul style="list-style-type: none"> Qualitative assessment of crop-based risks No clear framework for risk assessment 	<ul style="list-style-type: none"> Strong evidence base Objective assessment of risk Clear risk assessment framework that is transparent, repeatable and applicable in a generic sense to all crop species
Quantification of crop-based risk	Un-quantified	Quantified – crops ranked according to identified risks
Crops audited	<ul style="list-style-type: none"> <i>Zea mays</i>: sweetcorn and maize <i>Brassica napus</i>: e.g. spring and winter oilseed rape <i>Brassica rapa</i>: e.g. turnip, turnip fodder rape <i>Brassica juncea</i>: e.g. brown mustard <i>Brassica oleracea</i>: e.g. cabbage, broccoli, cauliflower <i>Beta vulgaris</i>: e.g. sugar beet and fodder beet <i>Glycine max</i>: soya 	<ul style="list-style-type: none"> <i>Zea mays</i>: sweetcorn and maize <i>Brassica napus</i>: e.g. spring and winter oilseed rape <i>Brassica rapa</i>: e.g. turnip, turnip fodder rape <i>Glycine max</i>: soya <p>This list is kept under review and is open to change in accordance with the risk status of the crops assessed.</p>
Resource use	Resources distributed evenly between all risk areas	Resources targeted to identified areas of higher risk and non-compliant areas
Audit of company policy/procedure	No	Yes
Guidance issued	Yes	Yes
Basic data for imported and marketed seed collected	Yes – twice per year	Yes - annually (based on an April to March financial year)
Frequency of audit visits	Up to twice a year for a company marketing spring and winter crops. (2 audit programmes/ calendar year)	Routine visit for detailed audit once every three years. Additional targeted audits may be necessary if basic data suggests a change in risk level. (1 audit programme/ financial year).
Report provided to Defra	Yes	Yes
Report provided to seed company	No	Yes – for detailed audits a report of the GMI findings and recommendations is supplied to individual companies
Findings published	Yes – summary tables	Yes – summary tables for detailed, targeted and basic audits

Summary of audits conducted under the new 2006-2007 programme:

- 2.5.4 During the audit programme for the 2006-2007 financial year the GM Inspectorate will complete 58 audits of seed importing and/or producing companies, a summary is provided in table 3 below.

Table 3: Summary of audit programme for the 2006-2007 financial year (data as of 31st March 2007)

Audit type	Summary details
Detailed audit	Total number: 12 Reports completed by 31 March: 7 Companies declining to participate: 1 Companies not marketing any crops of interest: 2 Visits completed after 31 March: 2
Basic data collection/ audit	Total number: 46 Reports completed: due for completion July 2007 Companies declining to participate: 11 Companies not marketing any crops of interest: 13 Requests for basic data outstanding: 7
Targeted audit	None necessary

- 2.5.5 It is anticipated that summary tables for the 2006/07 audit will be published in September 2007 on the GM Inspectorate's website at: <http://www.gm-inspectorate.gov.uk/seedAuditProgramme/summaryReports.cfm>. In the usual way, seed companies will be given 20 calendar days prior to publication in which to comment on the factual content of the tables. Participants in this audit will be able to approve their summary reports on-line using the secure extranet facility, if they wish to do so (see 2.5.7 below).
- 2.5.6 All seed companies participating in the audit were found to be taking appropriate steps to manage the risks 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; this is the same number of non-participants as the spring 2006 audit programme.

Electronic management of seed audit data:

- 2.5.7 The secure extranet was developed as an extension of the GM-seed audit information database (GM-SAID) and now forms an essential part of the audit programme. The secure extranet is accessed via the GMI website (<https://secure2.csl.gov.uk/gmextranet/>) and provides seed companies with the facility to submit, electronically, basic data on seeds they have marketed and to view and approve summary tables for publication on-line. Companies can also access reports generated for them following detailed and targeted audits via the secure extranet.
- 2.5.8 A unique username and password was issued to representatives of staff at all participating seed companies during the implementation of the new audit

programme to enable them to access the secure extranet. Tight security measures and restrictions have been put in place to ensure that only authorised persons can access the data; companies who use the secure extranet are only able to access information they themselves have entered and reports relating to their company. In addition, specific representatives of Defra PVS, the GM Inspectorate for Scotland and the National Assembly for Wales have been provided on-line access via the secure extranet, which enables them to view reports only.

3. GMO projects / research undertaken in 2006 to 2007

3.1 In January 2007 CSL won funding to undertake a research project for the European Commission (Directorate General Environment) entitled “Adventitious traces of genetically modified seeds in conventional seed lots: Current situation in member states”. The project was commissioned to provide baseline data required by the European Commission to enable assessment of the possible impact of establishing thresholds for adventitious GM presence in conventional seeds. The main aims of the project were to establish, for maize, oilseed rape and soya:

- The frequency and levels of adventitious traces of GMOs in conventional seed lots that are currently being detected by Member States and what levels of detection are being employed in terms of enforcement.
- The statistical significance of the results taking account of the amount of seed produced (i) regionally/nationally and (ii) imported following production in third countries.

The final project report was submitted to the European Commission in July 2007. It is understood that the European Commission will publish the report in due course.

3.2 CSL continued to participate in the EU-funded Sigma project (Sustainable Introduction of GMOs into European Agriculture, <http://sigmea.dyndns.org/>). CSL participated in two of the work packages of this project:

- Socio-economic dimensions of the adoption of GM crops and their co-existence with other crop systems.
- Development of field-based sampling and testing regimes, using GM maize (MON810) grown in Spain, to detect adventitious GM presence using protein-based test strips and in-field real-time PCR testing technology (‘Smart Cycler’¹³).

Practical work in the Sigma project has now finished and reports will be published in due course.

¹³ <http://www.cepheid.com/>

- 3.3 CSL is also a partner in the EU-funded Coextra project (GM and non-GM supply chains: their coexistence and traceability, <http://www.coextra.eu/>) and is specifically 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.

The Coextra project is due to complete in 2009.

4. Looking ahead to the 2007/2008 reporting year

- 4.1 CSL remains committed to retaining the capacity to respond to any increase in GM activity or any enforcement incidents related to the deliberate release of GMOs; the income base of the team continues to be diversified into related areas to ensure that the team can retain the capacity to deliver and respond as necessary.
- 4.2 The GMI will continue to work with the Fish Health Inspectorate to monitor and investigate any reports of potential breaches of GMO legislation in relation to the marketing of unauthorised genetically modified fish in the UK, and will liaise with the industry to maintain awareness of this issue.
- 4.3 The 2007-2008 programme for auditing seed importers and producers will commence in August 2007 with the issuing of the guidance and supporting documentation. Detailed audit visits will commence in September 2007 and the programme will be completed by the end of March 2008.

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 462741
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
Sand Hutton
YORK YO41 1LZ, UK

Telephone: +44 (0) 1904 462100
Fax: +44 (0) 1904 462111 or +44 (0) 1904 462040
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/>

Email: foodanalysis@csl.gov.uk

Annex 1: GM legislation and regulation in the UK

1. European Council Directive 2001/18/EC 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 organisms¹⁴. 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 also provides the Secretariat to the Advisory Committee on Releases to the

¹⁴ 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.

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 GMOs¹⁵. 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 Authority¹⁶ 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 Regulations¹⁷.
- 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

¹⁵ See <http://www.defra.gov.uk/environment/acre/index.htm>

¹⁶ See http://www.efsa.eu.int/science/gmo/catindex_en.html

¹⁷ See <http://www.food.gov.uk/enforcement/>

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_labelling.

4. Current rules on genetically modified varieties and seeds¹⁸

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 EU¹⁹. 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, 54 varieties of genetically modified maize MON810 are registered in the Common Catalogue.

¹⁸ http://ec.europa.eu/food/food/biotechnology/gmfood/qanda_en.htm

¹⁹ 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