



Annual report on GM inspection and enforcement activities

01 April 2005 - 31 March 2006

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Executive summary

1. The GM Inspectorate, based at the Central Science Laboratory in York, is responsible for the inspection and enforcement of the release of genetically modified crops in England. GM inspectors are appointed under part VI of the Environmental Protection Act 1990. The work is undertaken on behalf of the Department for Environment Food and Rural Affairs to ensure compliance, in England, with the legislation concerning the deliberate or unintentional release of genetically modified organisms (GMOs). The statutory work of the GM Inspectorate is underpinned by the expertise and technical know-how of CSL scientists, particularly in sampling and detection methodology for GMOs.
2. During the reporting year, there were no deliberate release trials of GM crops in England or Wales. Nine visits were made to former deliberate release sites to ensure both post-trial monitoring and subsequent cropping restrictions were being observed and checks were made at a further 24 sites for compliance with subsequent cropping restrictions alone. In all cases management of trial sites was in accordance with the requirements of consents. In addition, management audits were satisfactorily completed for 8 consent holders responsible for a total of 10 deliberate release consents.
3. Under the GM Inspectorate's programme of audits of seed producers, importers and suppliers a total of 91 audits were completed, comprising winter oilseed rape (19), spring oilseed rape (9), other Brassica crops (34), sugar beet (4), fodder beet and other Beta species (9), maize and sweetcorn (16). Findings of the audits are summarised and published on the GM Inspectorate website; these show that for two the audit rounds completed in the reporting period, all companies participating in the audit were found to have appropriate measures in place to manage the risks of adventitious GM presence in their seed. As reported last year, 16 companies (out of a total of 56 invited to participate) elected not to participate in the audit; this represents a slight increase in the non-participation rate.
4. No investigations into potential breaches of the GM legislation were necessary in the reporting year. A number of issues have arisen in connection with analytical testing of seed, in particular presentation of PCR test results and changes in the design of PCR primers used to test seed; the implications of these are discussed.
5. A new approach to seed audits is envisaged in the forthcoming year with the introduction of a formalised process for the assessment of the risks of adventitious GM presence in UK seed. This approach will enable audits to be targeted at clearly identified risk areas and is consistent with current government requirements for better regulation. We outline the approach that is being developed and how we envisage a revised seed audit programme will operate. It is anticipated that this will be introduced in October 2006.
6. A new database for the management of information relating to audited seedlots, the seed audit information database (SAID), is now fully in use as a tool of trade

for seed audit work and represents a significant enhancement to the working practices of the seed audit team.

7. Members of the GM Inspectorate have participated in a number of research projects in the last year, three of which have been related to the release of genetically modified organisms and details of these are provided in the report.

1. The role of CSL in GM inspection and enforcement

- 1.1 The GM Inspectorate (GMI), based at the Central Science Laboratory (CSL) in York, is responsible for the 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 The National Assembly for Wales has given CSL separate authority in respect of inspection and enforcement in Wales¹ although there are currently no GM release sites in Wales. The Scottish Agricultural Science Agency (SASA)² is authorised by the Scottish Executive to carry out the equivalent inspection and enforcement activities for Scotland.
- 1.3 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. A wide range of analytical, diagnostic and consultancy services designed to support the international land-based and food industries have arisen from CSL's research.
- 1.4 CSL assumed responsibility for GM inspection and enforcement functions in June 2000³; our work falls into three key areas:
- a) inspection of GMO deliberate release sites in England and Wales;
 - b) management audits of deliberate release consent holders;
 - c) monitoring, in England, for adventitious GM presence in conventional seed stocks and trials seeds.
- 1.5 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 and takes action as appropriate on a case-by-case basis. No infringements of the legislation were identified in this reporting year.
- 1.6 The GMI is part of CSL's Biotechnology & Molecular Genetics team, an 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

¹ <http://new.wales.gov.uk/topics/environmentcountryside/?lang=en>

² <http://www.sasa.gov.uk/gm/inspectorate/index.cfm>

³ This work was formerly undertaken by the Health and Safety Executive

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 SIGMEA⁴ and Co-Extra⁵ 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 GM Inspectorate is able to respond efficiently and appropriately to any GM deliberate release incidents that may occur in England or Wales. A list of GM-related projects ongoing at CSL is given in Annex 2 of this report.

- 1.7 The GMI liases 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. At the European level, the GM Inspectorate is an active member⁶ 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 sixth report of the GM Inspectorate covering the period 1 April 2005 through to 31 March 2006.

⁴ Sustainable introduction of GM crops into European agriculture (<http://sigmea.dyndns.org/>)

⁵ GM and non-GM supply chains: their co-existence and traceability (<http://www.coextra.org/default.html>)

⁶ 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

Active consents

2.1.1 An important function of the GM Inspectorate is to inspect GM crop deliberate release trial sites to ensure compliance with consents granted under EU Directive 2001/18/EC. During the reporting period there were no deliberate release trial sites in England or Wales and therefore no growing crop inspections were conducted.

Post-trial monitoring

2.1.2 Consents to release a GMO are accompanied by specific conditions that require the consent holder to monitor the release during the trial period and, in most cases, for a specified period after completion of the trial. Each deliberate release consent is issued with a Schedule, which specifies limitations and conditions of the consent as appropriate to the particular release and includes 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.

2.1.3 The holder of consent 04/R39/1 for a small-scale research release carried out in 2004, was required to undertake monitoring during the current reporting period before permission to terminate the trial could formally be sought. This consent was designed to evaluate the impact of genetically modified phenazine-expressing *Pseudomonas fluorescens* (a soil bacterium) on other soil-dwelling microorganisms in the rhizosphere of non-GM wheat plants. Wheat plants grown in this release were harvested in 2004 and the site and the surrounding area were being monitored for the presence of GM bacteria prior to termination. During the reporting period the consent holder submitted a formal application to terminate the release based on the results of monitoring at the site; this was granted by the Secretary of State (Defra) in June 2005. There are no further monitoring requirements under this consent and no further releases can be carried out. Details of this consent can be found on the Defra website at <http://www.defra.gov.uk/environment/gm/regulation/consents/index.htm>

2.1.4 Nine post-trial inspection visits were made to former trial sites where post-trial volunteer control was an ongoing requirement of consents, or where restrictions on subsequent cropping still applied. Inspectors verified that management of the former trial sites was compliant with the conditions specified in the appropriate consent document. In addition, to ensure compliance with subsequent cropping conditions at a further 24 former trial sites where post-trial monitoring for volunteer control had been completed, assurance was sought from the respective growers, trials officers and consent holders (as appropriate) that subsequent cropping restrictions were being observed. In all cases it was confirmed that the subsequent

cropping arrangements were in accordance with the consent conditions and inspectors were able to verify that management of the former trial sites was also in accordance with the requirements of the consents.

Management audits of deliberate release consent holders

2.1.5 The Inspectorate continued to undertake management audits of consent holders during the year, although no new trial material was released. The management audit programme includes consent holders with active consents, i.e. those with release sites currently being used for trials (none in this period), and those with an ongoing requirement to monitor former trial sites.

2.1.6 The purpose of the audits is to verify that the correct management procedures and protocols are in place to ensure the appropriate planning and operation of GM field trials. This includes confirming that the conditions laid down in the release consents are known throughout the management chain and are effectively implemented *in situ*, and that all material removed during the trial and post-trial periods is stored and/or disposed of correctly.

2.1.7 Eight consent holders responsible for a total of 10 current experimental consents were audited as part of the programme. Audits focused on a range of issues including soil sampling under consent 04/R39/1 as previously mentioned, the effectiveness of post-trial monitoring for volunteers, analysis of volunteer material where consent conditions required trial sites to be free from GM material, and correct post-trial cropping. Each consent holder provided evidence of their management systems together with appropriate documentation. On the basis of information provided, the GM Inspectorate found that appropriate standards and protocols were in place and that dissemination of information through management chains and the operation of these systems *in situ* was effective.

2.1.8 Management audit reports detailing the evidence provided and the GM Inspectorate's assessment of compliance for each consent holder were submitted to Defra, providing assurance that deliberate releases were being managed appropriately.

Management of consent holder monitoring reports

2.1.9 Under a new agreement with Defra, in this reporting period the GMI assumed responsibility for collection and management of all formal monitoring reports required by the Competent Authority (Secretary of State for Defra) under deliberate release consents. The reports are checked for completeness and submitted to Defra for approval within an agreed timescale. The GM Inspectorate liaised with consent holders and, where practical, coordinated annual management audits to precede the due date for submission of the formal post-trial monitoring reports. During the reporting period 5 consent holder monitoring reports were submitted to Defra and in all cases monitoring was consistent with the requirements of

the consents. In the forthcoming year we anticipate that there will be just one consent holder (two consents) with an ongoing requirement for submission of formal monitoring reports.

2.2 Audits of seed producers and importers

- 2.2.1 Authorised genetically modified varieties may be marketed throughout Europe providing they have met the requirements for placing on the Common Catalogue of Varieties (see Annex 1). Current EU seeds legislation does not, however, describe specific measures with respect to the adventitious presence of GMOs in seed, consequently all seeds marketed for cultivation in the UK must be free of unauthorised adventitious GM presence. There are currently no authorised GMO varieties that are suitable for cultivation in the UK⁷. 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 it is placed on the market.
- 2.2.2 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 to assist them to meet their legal duties; the audits focus on helping companies to ensure that they have taken appropriate steps to manage the risks of adventitious GM presence in their seed material, and have appropriate supporting documentation in place. The audits include seed intended for private company trials. Seed material entered into National List and Recommended List trials (imported or UK-produced) is separately audited by Defra PVS.
- 2.2.3 Crops currently included in the audit are maize (including sweetcorn), oilseed rape (winter and spring) and crops that are related to oilseed rape (*Brassica napus*, *B. rapa*, *B. juncea* and *B. oleracea*), sugar and fodder beet and related crops (*Beta vulgaris* ssp. *cicla* and *B. vulgaris* ssp. *vulgaris*) and soya. These crops have been targeted because genetically modified varieties of these crops are grown both commercially and in deliberate release trials in many seed producing countries around the world, which introduces the risk that the adventitious presence of GM seed in conventional seed of these crops may occur.
- 2.2.4 The audit involves assessment of information provided by seed companies regarding the provenance of seed they are marketing in England. This information may be supplied in the form of letters of assurance detailing the production history of the seed, together with the quality assurance systems or protocols that are in place to manage the risk that adventitious GM presence will be acquired at any stage during production, harvesting and processing. Additional information may also be provided from analytical tests that have been undertaken on seed crops or individual seed lots, e.g. protein-based assays or the polymerase chain reaction

⁷ 31 varieties of genetically modified maize MON 810 are currently registered in the European common catalogue, and three further varieties are pending. These varieties are for production of (insect resistant) grain maize, which is not cultivated in the UK due to agronomic limitations.

(PCR). It is usual for a combination of both letters of assurance and testing results to be presented.

- 2.2.5 GM inspectors review the documentation provided for all seed crops a company has marketed within the scope of the audit programme, and compile a report to PVS. Where the GM Inspectorate is satisfied that, given the information available at the time of the audit, a company has acted responsibly in managing the risks of adventitious GM presence this will be stated clearly in the report. A summary report for seed audited in each of the spring and winter programmes is published on the GMI website.
- 2.2.6 We produce guidance documents for each crop species in the audit programme, these provide seed producers, importers and suppliers with details of the information they should seek to obtain for the seed they are marketing. In particular they advise on the key criteria that letters of assurance and analytical testing should meet. Guidance for seed processors has also been developed. Guidance documents are reviewed twice yearly in advance of the spring and winter audit programmes and are distributed to all seed producers, importers and suppliers know to market (or to have marketed) the crops in the forthcoming audit. Copies of the current crop guidance documents are available on the GM Inspectorate website at <http://www.gm-inspectorate.gov.uk/seedAuditProgramme/cropGuidance.cfm>.

Seed audits

- 2.2.7 During the reporting year the GM Inspectorate carried out a total of 91 seed audits covering 56 seed importing and/or producing companies. The audits fell into the following categories:
- 19 winter oilseed rape
 - 9 spring oilseed rape
 - 34 other Brassica crops
 - 4 sugar beet
 - 9 fodder beet (including other *B. vulgaris* spp)
 - 16 maize / sweet corn
- 2.2.8 Summary tables of the results of the seed audit were published on the GM Inspectorate's website on the 16th June 2005 (2004 winter-sown audit programme) and 9th December 2005 (2005 spring-sown audit programme). 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. No additional comments were received.
- 2.2.9 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. Summary

tables of the seed audit programmes are available at <http://www.gm-inspectorate.gov.uk/seedAuditProgramme/auditReports.cfm>.

2.2.10 Of the 56 companies invited to participate in the audit programme, 16 known to be marketing seed in England were classified as non-participants in the two audit programmes covered by this report.

2.3 Seed audit programme: maintaining current awareness

2.3.1 In 2005 the GM Inspectorate formalised its ongoing programme of monitoring publicly available GM databases and websites by preparing quarterly 'current awareness' reports for Defra. The information gathered in these reports provides a summary of the commercial GM releases and experimental work currently being undertaken worldwide, and ensures that our knowledge of the genetic elements that have been released (and therefore the elements that should be included in seed companies' analytical testing) is up-to-date. Importantly, the reviews also enable us to identify crops that may require a more detailed assessment of risks to UK seed imports.

2.3.2 The current awareness reports cover experimental (deliberate) release, authorised commercial release, and unauthorised (e.g. accidental) release; a news section aims to highlight any significant developments in GM-related issues and flag up any reported incidents of unauthorised GM crop releases. The reports include crops that are grown in the UK, and those where there is a possibility that they may be grown in the UK. Some species are also included because, although they are not grown widely in the UK, they are currently available to the UK amateur market (e.g. sweet potato). Crops such as cotton and rice, which are unlikely to be grown in the UK in the foreseeable future, are not included in these reports unless the risk of admixture with other species is identified. These reports are published on our website at http://www.gm-inspectorate.gov.uk/news_info.cfm.

2.3.3 Although the current audit programme has not been amended as the result of any information collated in these reports, significant elements have been incorporated into the review of the seed audit programme described below.

2.4 Seed audit programme: quantitative risk assessment

2.4.1 Within government the principles of better regulation are driving change in enforcement policy and the 'everyone must be inspected' approach is being superseded by strategies based upon clearly identified risks, which enable the targeting of inspection resources to higher risk and non-compliant areas. This risk management based approach is aimed at reducing the burden on businesses that are consistently compliant with incumbent regulations thereby freeing resources to be targeted where needed, and achieving better regulatory outcomes.

2.4.2 The current seed audit programme is based on assessment of crop-based risks, but these have not been done following a clearly identified

framework, and risks have not been quantified. CSL welcomed the opportunity to develop a more rigorous approach and in February 2006 we undertook a new project to develop a structured framework for identification and characterisation of risks of adventitious GM presence in UK seed stocks, the output of which will be relative ranking of risks on a crop-by-crop basis. These identified risks can then be assessed against Defra's acceptable criteria for risk and will inform policy makers which crops should be included in the audit programme. The ultimate objective of the approach is improved management of risks by better targeting of resources to high-risk areas.

2.4.3 A two-stage risk assessment framework is currently being developed in which intrinsic risks to individual crop species are first assessed on the basis of their biology, crop production characteristics and the global level of GM activity; this will enable identification of higher risk crops to inform basic audit policy. In stage two, risks arising as a result of the country of origin of particular seed lots and GM activity associated with that country will be assessed, together with other factors such as GM activity within the supplying company and knowledge of the UK-based producing or importing company. A probabilistic risk assessment approach is being used to analyse data gathered for each crop, characterise the interactions between data types where appropriate, and ultimately assign overall (relative) risk values. Consistent with government aims, seed audits will then be targeted to where the mixture of crop-based and company-based factors indicate a level of overall risk above that acceptable to Defra.

2.4.4 Our key goals for the project are:

- to provide a strong evidence base for the seed audit programme by developing methodology for objective assessment of the risks to conventional seeds of adventitious GM presence;
- to have a risk assessment framework that is transparent, repeatable and applicable in a generic sense to all crop species;
- to develop an approach to risk assessment that is quantitative and enables relative ranking of crops according to identified risks on a simple scale (e.g. 1 to 10).

2.4.5 The project will initially cover assessment of risks to maize, sugar beet, oilseed rape, turnip, fodder beet, other brassica crops, alfalfa, grasses, clover, soybean, wheat, tomato and potato. These crops have been chosen for assessment because of the level of GM activity worldwide; it is not anticipated that all of these crops will be included in future seed audit programmes, but it is important to establish a baseline assessment for them to enable us to monitor any changes in their risk assessment. A further group of crops has been identified for assessment of risks at a later date, dependent on future GM activity. The risk assessments will be revisited regularly to identify changes in risk values, e.g. as result of a change in GM activity worldwide, or a change in seed production practices.

2.4.6 The seed audit programme itself will change to reflect the new emphasis on management of identified risks; from September 2006 the twice-yearly

audit of all seed companies will be rescheduled such that each company producing seed of interest will be audited every three years. Additional targeted audits will be undertaken on a case-by-case basis where higher risk scenarios are identified. All audited seed companies will receive a full assessment report following their audit, together with recommendations for improving procedures where this is necessary. We will still be seeking basic information on seed marketed from all companies once each year to enable us to maintain good records of seed movements and inform us of potential risk. We hope that seed companies will welcome this new, collaborative approach to management of identified risks and will respond by continuing the high level of participation in the audit programme.

- 2.4.7 Further details of the new programme will be issued to all seed companies in late summer of 2006, and all details will be placed on our website at <http://www.gm-inspectorate.gov.uk/seedAuditProgramme/>.

2.5 Seed audit information database (SAID)

- 2.5.1 Last year we announced that the GM Inspectorate had secured funding for development of a relational, web-enabled database to collate and hold seed audit information. The database has now been designed and developed in-house at CSL by our Information Systems team and has been successfully piloted on a small scale during the winter 2005 audit programme. We are very pleased to report that all inspectors are currently using the new system to complete the spring 2006 audit and are reaping the benefits of this modern, efficient tool of trade.
- 2.5.2 The new database facilitates direct entry of seed lot information either at seed audits or from companies' electronic submissions, and enables automatic cross checking of this information with previous audit records where necessary. The database can quickly be interrogated to facilitate rapid cross checking of individual seed lots, identification of sister or source seed lots, generate seed audit reports and seed audit summary tables as a few examples. Development of the database has also led to improvements in delivery of reports to Defra, as these are now generated automatically and delivered online.
- 2.5.3 Ultimately seed companies will be able to enter their own data and assurance documentation directly through a secure extranet facility should they wish to do so, thus minimising the time that each audit should take and, on some occasions, removing the requirement for an audit visit.
- 2.5.4 We anticipate that the secure extranet will become an essential part of the risk-based audit programme. A number of seed companies have already participated in trials of data submission formats as the first stage towards direct entry of companies' own data. Tight security measures have been put in place to ensure that only authorised persons can access the data. In addition, where companies access the database directly via the secure extranet facility, they will only be able to view the information that they have entered.

2.5.5 Further information on the launch of the secure extranet will be made available during the summer of 2006 in connection with the new audit programme.

3. Technical issues arising during the reporting year

During the reporting year there have been no incidents within the GM deliberate release programme or the seed audit programme that have required investigation. The GM Inspectorate has not carried out any enforcement sampling or testing in the reporting period. A number of technical issues have arisen in connection with the seed audit programme and these are discussed below.

3.1 Reporting of PCR analysis results

3.1.1 Although many seed companies commission PCR analysis of their seed to provide assurance of freedom from adventitious GM presence, it is not a requirement for participation in the audit programme. However, where analytical tests have been undertaken and are presented at an audit, inspectors must examine test certificates and resolve any discrepancies that are identified. A number of problems have emerged over the last year and we have made changes to our seed audit guidance to alert companies to these potential problems. All queries raised by these issues in relation to individual seed lots were satisfactorily concluded by the provision of additional information by seed companies or testing laboratories.

Standards / accreditation

3.1.2 Currently not all PCR certificates presented state whether testing is carried out under recognised standards or accreditation. A number of the common standards / accreditation protocols differ in elements of their statistical analysis and result notation format. Prior knowledge of the standard applied allows inspectors to make a better assessment of the results presented. Our guidance has been amended to clearly request information on the standards / accreditation protocols to which the analysis conforms.

Wording of test results

3.1.3 There has been an increase in the number of PCR test certificates presenting results of quantitative analysis. The format and detail of reporting of these results can vary widely both between and within laboratories. This variation can be either the result of customer specification or, more likely, laboratory/analyst preference. The results themselves are often presented in a generalised shorthand format and lack details of the actual analysis data. Interpretation of these results often requires time-consuming requests for additional information. The need for such requests would be avoided if, for example, the true numerical result of the analysis and the statistical operating parameters were provided.

3.1.4 For example, results with a limit of quantification (LOQ) of 0.1%, but a limit of detection (LOD) of 0.01% are often reported as 'negative <0.1%'. Results presented in this way do not preclude the presence of GM DNA, albeit unquantifiable, below 0.1%. Where such results are presented further information will be needed from the testing laboratory to confirm the GM status of the seed lots. Our guidance has been amended to specify

the types of data required and highlight the importance of including these details with any test results presented.

Use of junction primers

3.1.5 A number of PCR testing laboratories have introduced testing for specific junctions between two GM elements as opposed to the former common practice of testing for individual GM elements in a 'GM screening test'. While these junction tests reduce the likelihood of obtaining false positives, the number of GM lines detected by any one test is also reduced. Our guidance has been amended to suggest that, when commissioning tests, seed companies should specify which GM lines the PCR test should detect.

3.2 'Single marker' issues in PCR testing for GMOs

3.2.1 The majority of PCR test results presented for seed are negative for all elements tested for. However, in a few cases 'single marker' issues occur where only one element is detected when, if a full GM construct were present, a number of elements should be detected. The results might indicate the adventitious presence of GM seeds, or they may be indicative not of GM presence but of environmental contamination in the laboratory or naturally occurring soil micro-organisms on or under the seed coat. The presence of a single GM element detected by a PCR test has been declared to the GMI on a number of occasions over the last six years, each has been satisfactorily investigated and reported in previous annual reports, but not all of these cases were found to be due to environmental contamination.

3.2.2 CSL undertook a review to consider the possible reasons for the occurrence of single markers in PCR tests of seed, the likelihood of each scenario occurring and possible approaches to securing a rapid identification of the source of the single marker in these cases.

3.2.3 We found little evidence to suggest how common, or not, the occurrence of single markers is in routine PCR testing. However, since the review was produced a number of testing laboratories have adapted their testing protocols to rely increasingly on the use of primers detecting junctions between two elements known to occur in commercial GM constructs. These primers are very specific and are not prone to single marker issues - this may be a good indicator that the occurrence of single markers was much more widespread than the few instances we have dealt with would suggest. As discussed in section 3.1.5 above, while this approach removes identification of issues associated with single markers, it does not mean that they are not there and it is possible that contaminants with a GM origin will be missed if this approach is widely adopted, in particular in early breeding stages.

4. GMO research in the reporting year

4.1 GM fish

- 4.1.1 Following an incident in which the suspected import of GM fish was investigated in 2004, we reported last year that we had secured a small amount of funding⁸, to scope the likelihood of the entry of GM fish to the UK, their potential routes of entry, the risks they may pose to the UK, and the ease with which we could develop detection methodology for GM fish.
- 4.1.2 The project was desk-based and involved reviews of published scientific articles, web-based biotech databases, patent databases and grey literature to determine the state of the art with regard to GM fish. We continued our collaboration with the Fish Health Inspectorate (FHI) at the Centre for Environment, Fisheries and Aquaculture Science (Cefas) and meetings were held between CSL and FHI molecular biologists to review detection capability.
- 4.1.3 Aquatic trade can broadly be divided into ornamental and farmed fish; the latter may be farmed for the purposes of providing food or for sport. Currently there are no genetically modified fish authorised for use in either sector in Europe; the illegal occurrence of GM fish in the farmed sectors would potentially present greater environmental concerns than in the (contained) ornamental sector, particularly if traits such as disease resistance or altered temperature tolerance were to be introduced. Literature reviews identified more than 150 GM trait/species combinations involving around 45 species of fin-fish, shellfish and crustaceans. The majority of these modifications were related to fundamental research using tropical species. Marketable spin offs of these have been developed such as zebra fish modified to express a fluorescent protein in their muscle ('GloFishTM'), which are already available on the internet. Also noteworthy is that a significant proportion of modifications involved attempts to improve the aquaculture of edible coldwater species, and three applications for commercial use of (growth-enhanced) farmed GM fish are currently pending.
- 4.1.4 The work was completed in March 2006 and a final report was recently submitted to CSL research directors. It is our intention to publish the report as a review paper in due course. The report will also be placed on the CSL website.

4.2 Monitoring and surveillance of GM crops

The longer-term effects of the release of GMOs are receiving increasing attention from Competent Authorities and the European Commission as authorisations for commercial releases in Europe have gathered slightly more pace. In the reporting year the GM Inspectorate has participated in two research projects focussed on the

⁸ Funding was won from the CSL 'Seedcorn' programme. This is a competitive Defra-funded R&D programme available within CSL to support the development of technologies that will position CSL to meet emerging priorities within Defra, and enable more efficient delivery of existing objectives.

identification and monitoring of longer-term impacts of GMOs, these are discussed below.

4.2.1 Availability and use of general surveillance information for potential changes resulting from GM crop cultivation

4.2.1.1 This project was commissioned by Defra in anticipation of the potential future cultivation of GM crops in the UK, with a view to scoping the availability of environmental monitoring data to support consent holders' post-market monitoring duties under the GM legislation. The objectives were threefold, firstly to identify existing UK environmental monitoring schemes whose data could feed into post-market monitoring programmes for GM crops, secondly to assess the quality of the data and how it might effectively be used in post-market monitoring programmes, and thirdly to design a database to collate and integrate monitoring results supplied by companies marketing GM crops in Europe. The project focussed mainly on GMOs that would be released for cultivation in the EU. The project team comprised the GM Inspectorate, environmental biologists, statisticians and data management experts at CSL.

4.2.1.2 Before reviewing the availability of environmental monitoring data, the generic crop production chain was considered in order to identify potential indicators of environmental change. On the basis of these, environmental monitoring data sets were reviewed and 136 (of hundreds) were selected for detailed review. Each of the datasets was classified in terms of the type of information recorded, frequency, interval, spatial and geographical characteristics, availability of data at national and at regional level and ease of access. Qualitative data gaps were identified and data sets for six key indicators (bird, butterfly and weed populations, pesticide usage, crop cultivation area and river water quality) were analysed statistically to give a measure of their robustness in terms of their ability to detect significant change from baseline levels. A total of seventeen key datasets were identified that will be useful for the post-market monitoring of GM crops. A prototype database was produced to suggest how Defra might ensure these data sets could be made available for monitoring purposes, and how consent holders' monitoring information could be managed most effectively.

4.2.1.3 The final report was submitted to Defra in March 2006 and is currently being peer reviewed. It will be available on the Defra website in due course at http://www2.defra.gov.uk/research/project_data/More.asp?I=CB02042&SCOPE=0&M=PSA&V=PI%3A080A.

4.2.2 Cumulative long-term effects of genetically modified (GM) crops on human/animal health and the environment: risk assessment methodologies

4.2.2.1 Analysis of the cumulative long-term effects of GM crops is an integral requirement of the EU environmental risk assessment process for the deliberate release of GMOs. Current guidance on this provides competent

authorities and applicants with general principles to be followed with respect to the objectives, elements, general principles and methodology. However, to date this has concentrated on the concept of ten year consents and has not examined the longer-term problems which may arise if GM crops are grown on a large scale in many EU countries over several decades.

- 4.2.2.2 In September 2005 CSL, together with RM Consultants Ltd⁹, won a contract to deliver a study for the EU (Environment Directorate) to review risk assessment methodologies for the cumulative long-term effects of GM crops on human/animal health and the environment. This project reviewed existing studies that have investigated the existence or potential for long-term effects of GM crops and assessed the adequacy of existing risk assessment methodologies/protocols to account for such effects, and how these meet the requirements and expectations of EU regulators. Using GM crops currently in the regulatory pipeline as examples, a prototype risk assessment methodology for long term cumulative effects was developed, and risk management measures (including monitoring activities) that might be required to address potential long-term effects were speculated upon.
- 4.2.2.3 The final report was delivered in March 2006 and was recently presented to the Committee of the Competent Authorities dealing with Directive 2001/18/EC. It is understood that this report will be used as an internal reference document for the EU and will not be published.

Annex 2 of this report provides details of other GM-related research ongoing at CSL.

⁹ RM Consultants Ltd, Abingdon, Oxfordshire (<http://www.rmconsultants.co.uk/index.htm>)

5. Other activities

5.1 GM Inspectorate website

- 5.1.1 Development of the seed audit information database (SAID) has necessitated some enhancements to the GMI website to support the secure extranet facility and visitors to the website will notice that the appearance of the site has changed. The focus of the website on our work has been maintained and links are provided to complement the statutory GMI information. The website is accessed at <http://www.gm-inspectorate.gov.uk/>.

5.2 GM Enforcement Liaison Group

- 5.2.1 This group was established by Defra and the Food Standards Agency in 2004. The GM Inspectorate has continued to participate along with representatives of the devolved administrations, the GM Inspectorate for Scotland, the Local Authorities Coordinators of Regulatory Services (LACORS), the Association of Port Health Authorities (APHA) and the Health and Safety Executive. The purpose of the group is to ensure a consistent and effective approach to GM enforcement across government departments and enforcement bodies, and to establish proposed actions that would be taken in response to any specific incidents.
- 5.2.2 The group met once over the past year to discuss actions taken with respect to the Bt10 maize contamination incident in March 2005, enforcement responsibilities, and statutory review of the Food and Feed and Traceability and Labelling regulations (EC/1829/2003 and EC/1830/2003 respectively).

5.3 European Enforcement Project

- 5.3.1 The European Enforcement Project (EEP) constitutes a forum for GMO Inspectors for the exchange of knowledge, information and expertise relating to the contained use and deliberate release of GMOs under incumbent EU legislation.
- 5.3.2 The EEP held its annual conference in Dublin in May 2005. Forty delegates representing eighteen European countries attended, including eleven existing EU member states, the new member states of Slovakia, Slovenia and Hungary, applicant country Bulgaria and other European countries Switzerland, Norway and Iceland. At this meeting, the Head of the GM Inspectorate was elected to the Steering Committee of the project.
- 5.3.3 CSL GM inspectors gave a presentation on seed auditing, explaining the UK approach to monitoring for adventitious GM presence in conventional seed. As part of this presentation we undertook to circulate a questionnaire requesting details of the organisation, legislative framework, scope and funding mechanism of monitoring for adventitious GM presence in each of the EEP member countries.

5.3.4 The information received from the questionnaires was compiled into a report prepared for presentation at the EEP conference in Austria in May 2006. The report will become a reference document, identifying the relevant individual or organisation to be contacted in each member country for information on seed-related GM presence issues. At the meeting in Austria the GMI will also be running a workshop on monitoring oilseed rape deliberate release field trials, and will share with EEP members some of the experience gained from the significant number of deliberate releases of this crop in the UK in the last five years.

5.4 Training activities

The GMI has delivered a number of training programmes in GM inspection and enforcement as outlined below:

- May 2005: GM regulation in the EU, and sampling and testing for GMOs. EC-funded programme with the Turkish Ministry of Agriculture and Rural Affairs.
- October 2005: Inspection and enforcement of the deliberate release of GMOs. Gatsby sponsored Fellow from Uganda visiting the University of Leeds and with interests in the biosafety of GM crops.
- December 2005: Seed sampling methodologies. Delegation of government officials from Georgia.
- January to June 2006: the GM Inspectorate hosted a Korean Government Overseas Fellowship scientist from the Korean Rural Development Administration. The visitor had specific interests in GMO risk assessment and assisted the GMI on a number of R&D projects, and in addition gained experience in practical inspection and auditing procedures.

6. Forward plan 2006-07

- 6.1 The downturn in deliberate release activity has continued and in the forthcoming year, if no new authorisations are granted, there will be just one deliberate release site with an ongoing monitoring requirement. The seed audit programme will be the main focus of the team's regulatory role and establishing the new risk assessment framework and approach to audits will occupy significant amounts of inspectors' time.
- 6.2 CSL is committed to retaining the capacity to respond to any increase in GM activity or any enforcement incidents related to the deliberate release of GMOs. However, in order to manage the current downturn in activity, the income base of the team has deliberately been diversified over the last two years and inspectors now also have other research related roles within the Biotechnology and Molecular Genetics team, and these will continue. The team will continue to collaborate in bids for funding for GM crop related research, particularly in the field of risk assessment.

7. Further information and contact details

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

Or contact us at:

GM Inspectorate
Central Science Laboratory
Sand Hutton
York YO41 1LZ, UK

Telephone: + 44 (0) 1904 462000
Fax: + 44 (0) 1904 462741
Email: gm-inspectorate@csl.gov.uk

7.2 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

7.3 For further information about the CSL independent GM testing service please visit <http://www.csl.gov.uk/prodserv/ana/foodauthentication/foodauthentication.cfm>.

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 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 (5) at CSL are appointed for the purpose of the inspection and enforcement of the legislation concerning deliberate release of GMOs in England and Wales. Clinical trials are inspected and enforced by the Health and Safety Executive. Agreements are in place with Defra and the National Assembly for Wales concerning the functions of the GM Inspectorate.
 - 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

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.

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 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://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 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 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 Regulations¹³.

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

¹² See http://www.efsa.eu.int/science/gmo/catindex_en.html

¹³ See http://www.food.gov.uk/enforcement/imports/enforce_authorities/

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.

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 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 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

¹⁴ http://ec.europa.eu/food/food/biotechnology/gmfood/qanda_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

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, 31 varieties of genetically modified maize MON 810 are registered in the Common Catalogue and three more are pending.

Annex 2: GM research projects ongoing at CSL

In addition to the projects described in section 4 of this report, the following research projects are ongoing at CSL.

All CSL research is undertaken in a manner that is compliant with the Joint Code of Practice for Quality Assurance in Research issued by BBSRC, Defra, FSA and NERC.

Description	Funding body
<p>Quantitative approaches to the risk assessment of GM crops The key aims of the project are:</p> <ol style="list-style-type: none"> 1. To provide a literature review of current knowledge of approaches to quantitative risk assessment, including probabilistic methods and the meta-analysis of combined datasets, and evaluate their potential applicability to risk assessment of GM crops. 2. To carry out case studies aimed at applying probabilistic risk assessment to existing data concerning GM crops, with a view to assessing the feasibility and usefulness of the approach. <p>Work completed March 2006, final report presented to ACRE July 2006; to be published at: http://www2.defra.gov.uk/research/project_data/More.asp?I=CB02040&SCOPE=0&M=PSA&V=PI%3A080A</p>	<p>Defra</p>
<p>Availability and use of general surveillance information for potential changes resulting from GM crop cultivation The key aims of the project are:</p> <ol style="list-style-type: none"> 1. To identify all the existing UK environmental monitoring schemes whose data could feed into the post-market monitoring programmes of GM crops. 2. To assess the quality, quantity and frequency of the data generated in the schemes identified and suggest how data from them could be most effectively used in post-market monitoring programmes to identify unanticipated impacts associated with commercial GM crop releases. 3. To design a database to collate and integrate monitoring results (from general surveillance and case-specific monitoring) supplied by companies who have released a GM crops(s) onto the European market. <p>Work completed and report submitted March 2006, to be published at: http://www2.defra.gov.uk/research/project_data/More.asp?I=CB02042&SCOPE=0&M=PSA&V=PI%3A080A</p>	<p>Defra</p>

<p>A combined protocol for PCR detection of GMOs in seed</p> <p>The key aims of the project are:</p> <ol style="list-style-type: none"> 1. Development, optimisation and assessment of a combined PCR-based approach to seed testing which can provide both % GM seed and % GM DNA results in order to improve the reliability of borderline test decisions and provide results to inform decisions for seed and crop thresholds, which may be expressed differently in legislation. 2. Provide accurate estimates of uncertainty associated with different thresholds and measured % GMO results. <p>Report submitted April 2006, published at: http://www2.defra.gov.uk/research/project_data/More.asp?I=VS0136&SCOPE=0&M=PSA&V=PI%3A080A</p>	<p>Defra</p>
<p>Sustainable introduction of genetically modified crops into European agriculture (SIGMEA)¹⁶</p> <p>The overall objective of SIGMEA is to: “Set up a science-based framework, strategies, methods and tools for assessing the ecological and economical impacts of GM crops and for an effective management of their development within European cropping systems, i.e. to create a practical toolbox.”</p> <p>Further details are at: http://www2.defra.gov.uk/research/project_data/More.asp?I=CB02035&SCOPE=0&M=PSA&V=PI%3A080A</p>	<p>Specific targeted research project funded by the European Commission through the Sixth Framework Programme¹⁷ (Priority: policy oriented research)</p>
<p>GM and non-GM supply chains: their co-existence and traceability (Coextra)¹⁸</p> <p>The main aims of the project are:</p> <ol style="list-style-type: none"> 1. Developing comprehensive tools and methodologies and integrate them along with existing ones into embedded decision-support systems aimed at enabling co-existence between GM and non GM (conventional and organic) crops. 2. Tracing of genetically modified organism (GMO) materials and derived products, along the food and feed chains. 3. Anticipating the future expansion of GMOs in both quantitative as well as qualitative terms. <p>Further details are at: http://www2.defra.gov.uk/research/project_data/More.asp?I=CB02044&SCOPE=0&M=PSA&V=PI%3A080A</p>	<p>Integrated Project funded by the European Commission through the Sixth Framework Programme (Priority: Food Quality and Safety)</p>

¹⁶ <http://sigmea.dyndns.org/>

¹⁷ http://europa.eu.int/comm/research/fp6/index_en.html

¹⁸ <http://www.coextra.org/>

Factors affecting cross-pollination in oilseed rape varieties, particularly of low fertility, growing under typical UK conditions

CSL is a partner in this 4-year field-scale project that is using conventional varieties of oilseed rape to examine the factors that affect levels of cross-pollination between plants growing in adjacent fields and more distant fields under typical UK conditions. The project is examining the effects of percentage male fertility, geographic location, field orientation and size, the role of insects and influence of (same or different crop) barriers on cross-pollination. The output will provide guidance on management options to ensure crop purity is within accepted levels. The Scottish Crops Research Institute leads the project; partners include Rothamsted Research, the National Institute of Agricultural Botany (NIAB), the Agricultural Development and Advisory Service (ADAS) and the Centre for Ecology and Hydrology (CEH Dorset). The project is due to complete at the end of 2006.

Further details are at:

http://www2.defra.gov.uk/research/project_data/More.asp?I=CB02020&SCOPE=0&M=PSA&V=PI%3A080A

Defra