

Environmental Protection Act 1990 Part VI (Genetically Modified  
Organisms)

**Annual report on GM inspection &  
enforcement activities**

**April 2003 to March 2004**

**GM Inspectorate**

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## Executive Summary

1. The GM Inspectorate is based at the Central Science Laboratory (CSL)<sup>1</sup> and has authority under part VI of the Environmental Protection Act 1990 for inspection and enforcement of the release and marketing of genetically modified organisms (GMOs) in England. The National Assembly for Wales has given separate authority in respect of inspection and enforcement in Wales<sup>2</sup>.
2. This is the fourth report of the GM Inspectorate since taking over responsibility for inspection and enforcement functions in June 2000. The report covers the period 1 April 2003 through to 31 March 2004.
3. The work of the GM Inspectorate falls into three key areas – 1) inspection of sites where GMOs have been authorised for deliberate release, 2) management audits of deliberate release consent holders and 3) audits of seed producers and importers to ensure they are taking appropriate steps to prevent the adventitious presence of GM events in conventional seed. This work is undertaken to ensure that the legislation concerning the escape or release of GMOs is complied with; it is also the responsibility of the GM Inspectorate to identify where potential breaches of consent conditions or other enforcement issues may have occurred and to investigate these on a case-by-case basis.
4. In the period covered by this report the GM Inspectorate visited all of the current deliberate release trial sites during the growing season to check for compliance with the conditions of the specific consents, this included the last of the winter sown oilseed rape crops for the farm scale evaluation (FSE) trials. In addition we made 79 routine post trial inspection visits to check compliance with post trial management conditions, and a total of 40 visits to sites in connection with specific problems. In autumn 2003 there were no new deliberate release sites for inspection, and in spring 2004 there are only two small-scale deliberate releases. This contrasts significantly with the level of activity in the previous three years. However there is still a substantial level of ongoing post-trial monitoring at many of the former FSE and other trial sites.
5. In connection with the deliberate release sites we have audited holders of consents to release a GMO. These audits provide assurance that the releases are being managed appropriately and in accordance with the conditions of the consent both during the period of the trial and in the post trial phase; essential to this are clear and effective communications, good record keeping and clearly established management procedures – it is the responsibility of the consent holder to ensure that these elements are in place. All consent holders were found to be generally well organised.
6. During this reporting period we have completed 62 audits of conventional seed being marketed by a total of 32 companies. The continued cooperation of the seeds industry is vital to successful completion of the audits. We are pleased to report that, as in previous years, the industry continues to be vigilant and that no seed sold has had to be recalled or planting stopped because of the presence of unauthorised GM events. During the year the Inspectorate has been notified of two cases of a very low level of unauthorised GM presence in seed of oilseed rape. The seed concerned was dealt with appropriately (see

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<sup>1</sup> Central Science Laboratory is an Executive Agency of Defra.

<sup>2</sup> There are currently no GM release sites in Wales.

section 3.3). Results of the spring and autumn seed audit programmes were published on our website in September 2003 and March 2004 respectively.

7. A small number of potential infringements of GM legislation have arisen through the year. These incidents have been investigated thoroughly and are covered in the report. No risks to human health or the environment were identified in any of these cases.

## 1. Introduction

- 1.1 In the European Union (EU) the release of genetically modified organisms (GMOs) is restricted under EU Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms<sup>3</sup>. 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 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), it also makes provisions for labelling and monitoring of commercial releases of GMOs. 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, which are designed to safeguard against any risks to human health and the environment. Consent to place a GMO on the market does not necessarily include cultivation as a crop, it may be issued solely for import and use as food and feed or for industrial use. Under the new EU regulations (footnote 3) different application routes are possible depending on the intended use of the GMO.
- 1.3 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 Environment (ACRE)<sup>4</sup>. ACRE is an independent advisory committee composed of leading scientists whose main function is to give advice to Ministers in the UK and to devolved administrations on the risks to human health and the environment from the release and marketing of GMOs. ACRE reviews all part B applications for consent to release a GMO. If ACRE is satisfied that the proposed release will have no adverse effects on human health or the environment then the Committee will advise that the consent may be issued. The advice will include recommended conditions that should be attached for management of the release, and the recommended monitoring period following completion of the trial. Authorisation to place a GMO on the market (part C) 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 in the UK.
- 1.4 The deliberate release legislation must be monitored and enforced proportionately. Under section 114 of the Environmental Protection Act 1990,

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<sup>3</sup> In April 2004 new EU regulations on GM food and feed (EC/1829/2003) and traceability and labelling of GMOs (EC/1830/2003) came into force in the European Union.

<sup>4</sup> <http://www.defra.gov.uk/acre>

the members of the GM Inspectorate have been appointed as inspectors 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. The GM Inspectorate comprises five full-time staff.

- 1.5 The Scottish Agricultural Science Agency (SASA)<sup>5</sup> is authorised by the Scottish Executive to carry out the equivalent inspection and enforcement role for Scotland.

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<sup>5</sup> <http://www.sasa.gov.uk/gm/inspectorate/index.cfm>

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

The GM Inspectorate has three key areas of work:

- a) inspection of part B 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 non-GM trials seeds.

Within all of these three work areas specific issues relating to potential breaches of the relevant GM legislation may occur. These may be notified to the regulatory authority or to the GM Inspectorate by the consent holder or by a member of the public; a GM Inspector may also identify a potential infringement in the course of undertaking statutory work. The GM Inspectorate investigates these issues on a case-by-case basis and takes action as appropriate.

These areas of work are explained in more detail in the following sections.

### 2.1 Inspections of part B deliberate release sites

- 2.1.1 The GM Inspectorate carries out field inspections to ensure compliance with part B consents. During inspection visits GM Inspectors must establish that each release is in accordance with conditions described in the consent, for example separation distances from related crops, presence and size of pollen barriers, area of GM release and control of volunteers/flowering plants (as applicable). In the period following harvest of experimental releases the GM Inspectorate also visits a proportion of the release sites to ensure that post-trial monitoring procedures, such as control of volunteers or subsequent cropping requirements, are being undertaken in accordance with the conditions of the consent.
- 2.1.2 Draft reports on growing crop inspection visits are produced and submitted to Defra within an agreed framework of five working days. A period of 20 calendar days then follows in which the consent holder and NIEWS have the opportunity to comment on the factual details of the report. Final field inspection reports are then placed on the public register and on our website at: [http://www.csl.gov.uk/prodserv/cons/gm\\_inspectorate.cfm#typesofcrop](http://www.csl.gov.uk/prodserv/cons/gm_inspectorate.cfm#typesofcrop).
- 2.1.3 During the reporting period inspections have covered three types of trials namely the FSE sites, variety and seed registration trials and research and development trials; and eight different crop types - winter and spring oilseed rape, sugar beet, fodder beet, potatoes, barley, wheat and peas.
- 2.1.4 The GM Inspectorate has carried out growing crop inspections of each of the 9 GM field releases for part B research and development trials in England<sup>6</sup> at least once during the year. In addition 5 visits to oversee harvest and/or disposal of trials material were undertaken. The conditions of the consents were confirmed as having been met in all cases. A further two visits to sites where trials had been terminated early due to vandalism confirmed that the appropriate emergency action had been carried out in accordance with the consent conditions.

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<sup>6</sup> There are currently no GMO release sites in Wales.

- 2.1.5 The GM Inspectorate also made 79 routine post-trial inspection visits to previous release sites to check for compliance with post-trial management conditions. A further 40 visits were made in relation to specific investigations, included among these were:
- 14 visits in relation to the findings of additional transformation events in FSE seed material planted in 2002 (sections 3.1 and 3.2 of this report);
  - 10 sites where flowering volunteers had been identified as a potential problem;
  - 3 visits to sites where flowering re-growth had been identified as a problem in 2001 (annual report 2002-03, section 2.4.1);
  - 3 sites where high numbers of sugar beet ground keepers had been noted;
  - 2 sites that had been vandalised in 2002.

At all of the sites no risks to human health or the environment were identified and no further action was taken.

- 2.1.6 As in previous years, successful delivery of our programme of field inspections has been dependent on effective liaison with consent holders over compliance issues such as sowing dates of trials, monitoring requirements during the trial period and arrangements for the disposal of harvested material.

## **2.2 Management audits of consent holders**

- 2.2.1 The Inspectorate has an ongoing programme to audit current consent holders to ensure that they are aware of their responsibilities as the holder of a consent to release a GMO. These audits include all holders of active consents, i.e. those with release sites currently being used for trials, and those who are still required to undertake monitoring at former trial sites.
- 2.2.2 The purpose of the management audit is to verify that the correct procedures and protocols are in place to ensure appropriate planning and operation of GM field trials and to verify that the conditions laid down in the release consents are known throughout the management chain and are effectively implemented *in situ*. Consent holders for current field releases are also required to provide evidence to demonstrate that adequate steps have been taken to ensure that only those GM events covered by the consent are released. Further checks are made on the effectiveness of post-trial management procedures such as monitoring for volunteers and correct post-trial cropping, as detailed in the consent.
- 2.2.3 Ten consent holders responsible for a total of 21 current part B consents were visited to review their management systems and protocols. On the basis of information provided by the consent holder the Inspectorate found that standards, protocols and dissemination of information through the various management chains was generally good although minor improvements were suggested in a number of cases. Management audit reports are submitted to the regulatory authority, to provide assurance that deliberate releases are being managed appropriately; individual reports are not sent to consent holders and are not published on the Inspectorate's website.

## 2.3 Audits of seed importers and producers

- 2.3.1 Under Part VI of the Environmental Protection Act 1990, the importation, acquisition, release or marketing of genetically modified organisms are prohibited unless the requirements for carrying out a risk assessment, giving notification or obtaining a consent are satisfied. Before marketing seed UK producers and importers of seed material should therefore take adequate steps to minimise the risk of adventitious GM presence in conventional seed. The GM Inspectorate conducts audits of seed importers and producers to assist them in meeting these duties. The audits are intended to help companies ensure that they have the appropriate procedures in place and that this is suitably documented. The audit includes seed that is to be marketed for commercial production and seed intended for trial purposes. The audits are undertaken for the Plant Variety Rights Office and Seeds Division (PVS) of Defra.
- 2.3.2 In the reporting year 2003-04 seven crops were included in the audit programme, namely winter and spring oilseed rape, sugar and fodder beet, maize, sweet corn and soya. The audits focus on conventional seed of these crops because GM varieties of these species are grown commercially and/or in GM release trials in many seed producing countries around the world hence there is judged to be an increased risk, relative to other crops, that adventitious GM events may be present.
- 2.3.3 Based on the findings of the review undertaken for PVS by the Inspectorate in the 2002-03 reporting period (GMI annual report 2002-03, section 2.2), the audit programme for 2004-05 will be extended to include species that are related to oilseed rape (*Brassica napus*, *B. rapa*, *B. juncea* and *B. oleracea*) and species that are related to sugar and fodder beet (*Beta vulgaris* ssp. *cicla* and *B. vulgaris* ssp. *vulgaris*). Inclusion of these crops in the audit is based on an assessment of information currently available on the distribution of GM crops and trials in the areas of the world producing these seed crops.
- 2.3.4 The GM Inspectorate undertakes desk studies for PVS to assess the risks of adventitious GM presence in crops that are not covered by the current audit programme. During the reporting period the Inspectorate assessed the potential for adventitious GM presence in grass seed that is produced in or imported into the UK. This assessment was based collectively upon the biology of the grasses, the nature, scale and management of genetic modification work that is being undertaken worldwide on grass species, and the level of trading between the UK and the relevant countries. The study concluded that, at the time it was conducted, there was not a significant risk of adventitious GM presence in grass seed produced in or imported into the UK.
- 2.3.5 **Seed audits.** The audit process involves a systematic assessment of the information presented by seed companies pertaining to the provenance of seed that they are marketing in England (and Wales). This information may be supplied in the form of letters of assurance detailing the production history of the seed, together with the systems or protocols that are in place to minimise the risk that adventitious GM presence will be acquired during production, harvesting and processing. Additional information may also be provided from PCR or other testing that has been undertaken on seed crops or individual lots. It is usual for a combination of both letters of assurance and testing results to be presented.

- 2.3.6 The GM Inspectorate produces guidance documents for each crop species included in the audit programme, these are reviewed twice yearly in advance of the spring and winter audit programmes. Our guidance documents provide seed producers and suppliers with details of the information they should seek to provide to the Inspectorate at an audit. In particular these advise on the key criteria that letters of assurance and PCR testing of seed (in terms of sampling, testing matrices and sensitivity) should meet. Copies of the current crop guidance documents are available on the GMI website at:  
[http://www.csl.gov.uk/prodserv/cons/gm\\_inspectorate.cfm#seedaudit](http://www.csl.gov.uk/prodserv/cons/gm_inspectorate.cfm#seedaudit)
- 2.3.7 During the reporting year the GM Inspectorate carried out a total of 62 seed audits of seed importing/producing companies. The audits fall into the following categories:
- 22 winter oilseed rape
  - 15 spring oilseed rape
  - 5 fodder beet
  - 4 sugar beet
  - 14 maize / sweet corn
  - 2 soya
- 2.3.8 Results of the seed audit were published on the GM Inspectorate's website twice during the year when the 2003 spring and autumn programmes were completed (October 2003 for the spring programme; May 2004 for the winter programme). Prior to publication of the reports, seed companies are given 20 calendar days to comment on the factual content of the tables. The tables for the 2003-04 reporting year are available on our website at:  
[http://www.csl.gov.uk/prodserv/cons/gm\\_inspectorate.cfm#seedaudit](http://www.csl.gov.uk/prodserv/cons/gm_inspectorate.cfm#seedaudit).
- 2.3.9 The GM Inspectorate found that all seed companies were taking appropriate steps to ensure that conventional seed does not contain unauthorised GM presence. There was no requirement for seed sold to farmers or entered into trials to be recalled or destroyed because of an unauthorised adventitious GM presence.

### **3. Case by case investigation of specific potential enforcement issues**

During the reporting year the GM Inspectorate investigated three new incidents that were brought to the attention of the regulatory authorities or were detected by inspectors themselves and for which there might have been a breach of consent or another enforcement issue. The Inspectorate also concluded investigations into two incidents initially reported in previous reports.

#### **3.1 Report on the finding of additional transformation events in oilseed rape material released under consents 00/R33/09 and 98/R19/18**

- 3.1.1 The Inspectorate reported last year on the finding of unauthorised GM elements in GM oilseed rape planted under consents 00/R33/09 and 98/R19/18 (and including consent 00/R14/08 issued in Scotland) (refer to annual report for 2002-03, section 2.4.2). The GM Inspectorate concluded that the planted material did not comply with the consents granted and submitted a report based on its findings to Defra Investigations Branch for further consideration.
- 3.1.2 Defra lawyers concluded that, although a breach of the consents had occurred, these had arisen inadvertently and since the presence of the contaminants did not pose a risk to human health or the environment, no further action would be taken.
- 3.1.3 The GM Inspectorate's report on this case can be found on our website at [http://www.csl.gov.uk/prodserv/cons/gm\\_inspectorate.cfm#inspections](http://www.csl.gov.uk/prodserv/cons/gm_inspectorate.cfm#inspections)

#### **3.2 Report on the finding of additional transformation events in spring oilseed rape material released in 2002 under consent 00/R33/09**

- 3.2.1 Following the incident reported at 3.1 above, Ministers instructed the GM Inspectorate to investigate other seed lots of Ms8xRf3 sown in 2002 as part of the FSE trials, in total this involved 10 sites previously notified by Bayer as 'unaffected' FSE sites. The GM Inspectorate for Scotland carried out a similar investigation as one of the sites involved was located in Scotland.
- 3.2.2 Official testing of seed from two sites in England (sown under 00/R33/09) confirmed the presence of three additional GM sequences (nptII, pNOS and p35S). The consent holder (Bayer CropScience Ltd) subsequently confirmed the findings and agreed that the detection of two of the sequences (nptII and pNOS) was accounted for by the presence in the material of events Ms1, Rf1 and Rf2. The detection of the p35S promoter was stated to be due to the presence of GM event Topas 19/2<sup>7</sup>. Further official testing by the GM Inspectorates in England and Scotland confirmed this.
- 3.2.3 Defra sought advice from ACRE on the possible risks in relation to the presence of Topas 19/2 in this new case. ACRE advised that, irrespective of whether the Topas 19/2 event was present as an admixture of varieties or in the form of gene stacking within a variety, the presence of Topas 19/2 in this

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<sup>7</sup> Topas 19/2 is authorised in Europe for import and processing but not for cultivation.

case did not alter their previous advice on the August 2002 incident in which no risks to human health or to the environment were identified.

- 3.2.4 The Inspectorate carried out monitoring visits with respect to harvest and disposal of seed and post-trial control procedures and was satisfied that procedures were in compliance with the consent conditions. As reported last year, the Inspectorate also carried out official testing of subsequent releases in autumn 2002 and cleared all material for planting. Further verification that measures were in place to ensure the integrity of planting material was obtained from the consent holder for proposed GM releases in autumn 2003 (the 2003 plantings did not go ahead for commercial reasons). No crops of the seed lot concerned have since been grown in the UK.
- 3.2.5 As in the incident reported at 3.1 above, the GM Inspectorate concluded that the planted material did not comply with the consent as granted. A report was produced based on the Inspectorate's findings relating to the case and this was submitted to Defra Investigations Branch for further consideration.
- 3.2.6 Defra lawyers concluded that, although a breach of consent had occurred, this had arisen inadvertently and since the presence of the contaminants did not pose a risk to human health or the environment, no further action would be taken. This decision was taken in October 2003, but publication of the report was delayed as the Procurator Fiscal in Scotland was reviewing a report submitted by the SASA GM Inspectorate in relation to sites in Scotland<sup>8,9</sup>.

### **3.3 Detection of unauthorised GM events in seed**

- 3.3.1 Last year the Inspectorate reported that a seed company had identified one seed lot of a UK produced spring oilseed rape variety as containing a very low level of an unauthorised GM event (GMI report 2002-03, section 2.4.5). The seed in question was destroyed early in the current reporting year and disposal was overseen by the Inspectorate.
- 3.3.2 During the current reporting year another seed company informed the GM Inspectorate that a very low level of an unauthorised GM event had been identified in UK produced seed of oilseed rape. None of the seed had been marketed and the company proposed to destroy the seed. Disposal of the seed was overseen by the GM Inspectorate. The GM Inspectorate undertook a detailed review of the production history of the seed but it was not possible to identify the source of the presence.
- 3.3.3 The GM Inspectorate was also notified of the finding of a very low level of an unauthorised GM event in a small sample of oilseed rape seed that had been imported into the UK for entry into National List trials. The seed in question was never sown and was disposed of under the supervision of the GM Inspectorate. The company concerned decided to discontinue any further work with this variety in the UK. As such a small quantity of seed was

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<sup>8</sup> Note added August 2004: the decision not to take any further action was announced on 4 August 2004 (<http://www.defra.gov.uk/environment/gm/regulation/enforce/index.htm>).

<sup>9</sup> The GM Inspectorate's report on this case can be found on our website at: [http://www.csl.gov.uk/prodserv/cons/gm\\_inspectorate.cfm#inspections](http://www.csl.gov.uk/prodserv/cons/gm_inspectorate.cfm#inspections).

involved and the variety would no longer be used, no further investigation into the source of the GM event was undertaken.

- 3.3.4 In all of the above cases the GM Inspectorate reviewed the systems in place and protocols used by the companies to reduce the risks of adventitious GM presence in UK conventional seed. Considering these systems and the proactive reporting of these findings by the companies, the fact that none of the seed was marketed to growers and that no risks to the environment or human health were identified, no further action was taken against the companies.

### **3.4 Inadvertent planting of unauthorised GM tomato seed**

- 3.4.1 In December 2003 the GM Inspectorate was informed of an incident in which the University of California, USA, had inadvertently circulated tomato seeds containing GM events, and that there was a possibility that some of the material had entered Europe and/or the UK. Release of this material in the UK was subsequently confirmed with the only recipient of the material in the UK being identified as the Eden Project in Cornwall.
- 3.4.2 The tomato cultivar concerned (UC82B) contained the polygalacturonase (PG) gene and the nptII marker gene and had been commercialised in 1996. The variety was approved for food and tomato production in the USA by the USFDA in 1994 and the USDA in 1995. The variety was approved for food consumption by the United Kingdom in 1995 and passed scientific review in the European Union. It was grown commercially in California and sold as tomato paste product in the UK between 1996 and 1999.
- 3.4.3 Eden Project received only 25 seeds of UC82B in 2000; of these 19 were cultivated in 2001, six plants reached maturity and the remainder (13 plants) died due to stem rot. The plants that did survive were pulverized and composted at the end of their life. Six of the original seeds of UC82B were unused and were sent for GM testing at the request of the University of California shortly after the incident had been identified.
- 3.4.4 The GM Inspectorate investigated the matter and established that while the tomato plants had been grown and flowered at one of the biomes at the Eden site and at their nursery, the possibility of cross pollination with other tomato cultivars or other solonaceous species was very low. None of the tomatoes produced at the site in 2001 were used for human or animal consumption.
- 3.4.5 Seed had been collected from the plants grown during 2001 but none of this had been cultivated. As a result of this incident all remaining seed was destroyed. As a precautionary measure any packets of opened tomato seeds that were held on site in December 2003 were also destroyed, thus the only tomato seeds remaining on site following the incident were in packets that had not been opened.
- 3.4.6 All plants and fruit that were grown during 2001 were placed on compost heaps at the end of their life. As a consequence the GM Inspectorate requested that compost heaps and compost used around the site be monitored for the presence of any tomato seedlings that may germinate from the seed contained in the fruits. The Inspectorate requested that any

seedlings found should be destroyed and accurate records kept. No seedlings have been reported to date<sup>10</sup>.

- 3.4.7 No risks to the environment or human health were identified as a result of this incident. The Eden Project was unwittingly involved and has implemented measures to ensure that, as far as possible, the seed it obtains for growing on site is free of any GM presence. No further action will be taken<sup>11</sup>.

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<sup>10</sup> Note added August 2004.

<sup>11</sup> Note added August 2004.

## **4. Other activities**

The Inspectorate has a number of other duties that are undertaken in connection with the statutory duties of inspection and enforcement. These include attendance at all scheduled ACRE meetings as an observer, part of which involves commenting, to NIEWS, on part B and part C applications on aspects of enforcement in the notification documents. In addition we have been involved in discussions on proposals for co-existence arrangements with Defra. We also undertake a number of other related activities, which are outlined below.

### **4.1 European enforcement project**

4.1.1 The Inspectorate continued to participate in the European Enforcement Project (EEP). This project, which ended in June 2003, was specifically focused on inspection issues in relation to GMOs; members included inspection personnel from EU member countries as well as from Norway and Switzerland. A member of the GM Inspectorate attended the final plenary meeting of the project in Thun, Switzerland in May 2003.

4.1.2 In connection with the EEP project, a member from each of the GM Inspectorates for England and Scotland took part in a joint monitoring and sampling visit to Hamburg in Germany. The purpose of the visit was to gain an insight into the sampling activities carried out in other EC countries, to gain experience in the techniques used when sampling bulk grain and to have a better understanding of the techniques they use in PCR analyses. In Germany contained use and deliberate release regulations are enforced on a regional (Länder) basis. There are 16 Länder each with it's own GM Inspectorate, of these Hamburg is the only Inspectorate in Germany that conducts sampling and testing of grain imports. Staff of the Hamburg Inspectorate were the hosts for this very useful and informative visit and both attendees gained a valuable insight into the practical and theoretical aspects of sampling and testing bulk commodities.

4.1.3 In line with the original aims of ensuring consistency in enforcement across the EU, the Inspectorate continues to have independent contact with the network of EEP members to share and seek information on current GM issues.

### **4.2 KeLDA project**

4.2.1 Jointly with the GM Inspectorate for Scotland, the CSL GM Inspectorate has participated in the EU-funded 'KeLDA' (Kernel Lot Distribution Assessment) project over the reporting year. The aim of this project is to gather actual data on the distribution of GM grain in bulk grain lots to enable development and validation of a model that will be informative in the design of sampling regimes for bulk grain loads. The project is run by the EU Joint Research Centre at Ispra (Italy). The role of the GM Inspectorate was to sample three bulk consignments of whole soya at the first entry point to the UK. The samples are then forwarded to the Institute of Reference Materials and Measurements (IRMM) at the Joint Research Centre in Geel (Belgium) to be homogenised and ground. The samples are then returned to researchers at CSL for testing by PCR for the presence of GM events. The UK experienced difficulties in identifying suitable boats to sample as the main UK importer of soya was not willing to participate in the project, and the smaller operators

import material infrequently and often not as whole kernels. However, one company did agree to participate and a boat was sampled in May 2003. A second boat has been identified for sampling in June 2004. Work on this project is due to be completed in December 2004.

### **4.3 Technical support**

**4.3.1** New regulations on traceability and labelling of GMOs and GMO products (regulation (EC) No. 1830/2003) came into force in the EU in April 2004. In preparation for this the European Commission has been developing technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms. Members of the Inspectorate and others at CSL have provided technical support to the UK regulatory authority in developing these guidelines.

### **4.4 Training activities**

**4.4.1** In the latter part of the reporting period the Inspectorate has been making preparations to run a training course entitled "GM Crops: detection, regulation and monitoring". This two-week course is being run jointly by the Central Science Laboratory and the University of Leeds and is funded by the Department for International Development. The course covers the background to GMOs, techniques for making GM plants, the detection of GMOs and their regulation in Europe and the UK. The first course will be run in July with participants from a number of African and South American countries. Many applicants had to be turned away this year so if the course is successful we hope to secure funding to run the course again in future years.

**4.4.2** New Zealand has recently lifted a moratorium on the growing of GM crops and takes a precautionary approach to GMOs. In July 2004 the GM Inspectorate will be providing training in GM inspection and enforcement procedures for a government regulator from New Zealand.

### **4.5 Conferences**

**4.5.1** Quality assurance procedures are an important aspect of the enforcement of GM legislation. The GM Inspectorate at CSL has many measures in place in support of this; in particular there is a requirement on the Inspectorate to have in place a QA system that will demonstrate 'continuity of evidence'. In November 2003 a member of the GM Inspectorate addressed the annual BARQA (British Association of Research Quality Assurance) conference with a paper entitled 'quality issues in the inspection and enforcement of GM regulations'.

## 5. Further information and contact details

For further information on the GM Inspectorate or its activities please visit our website at: [http://www.csl.gov.uk/prodserv/cons/gm\\_inspectorate.cfm](http://www.csl.gov.uk/prodserv/cons/gm_inspectorate.cfm)

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