

# **Annual Report on GM Inspection & Enforcement Activities: April 2002/March 2003**

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## Executive Summary

The GM Inspectorate at the Central Science Laboratory has authority under part VI of the Environmental Protection Act 1990 for the Inspection and Enforcement of the release and marketing of Genetically Modified Organisms in England. The National Assembly for Wales has given separate authority in respect of inspection and enforcement in Wales.

This report is the third produced by the GM Inspectorate at CSL since taking over the Inspection and Enforcement functions in June 2000.

Inspection activities undertaken remain broadly in four categories.

The first of these categories is the inspection of GM Deliberate Release consent trial sites to ensure that all Part B (research and development and Farm Scale Evaluation (FSE)) releases and all Part C maize (FSE) releases are compliant with the relevant conditions of the consents. The Inspectorate visited all 108 release sites during the growing season to check compliance with the conditions of the specific consents. We also made 60 routine post trial inspection visits to current and previous release sites to check compliance with post trial management conditions, and conducted 8 pre-planting site assessment visits to carry out a statutory risk assessment of proposed trial sites. The Inspectorate made 51 further site visits in relation to specific investigations.

Secondly, we have continued to audit the procedures of seed importers and producers to ensure that due care is being taken not to import or market non-GM seed that has an unauthorised adventitious GM presence. This voluntary cooperation with the GM Inspectorate indicated that the industry continues to be vigilant and the level of care taken continues to be generally very good. As in previous years no seed sold to farmers has had to be recalled or planting stopped because of the presence of unauthorised GM events. One company did identify a single seed lot as possibly containing a very low level of contamination in their own tests, but none of this seed lot had been marketed and it will subsequently be destroyed (see report at 2.4.5 below).

In autumn 2002 summary seed audit tables were published detailing the current and historic information on the seed audits undertaken by the GM Inspectorate since Autumn 2000. A further table of information was published in April 2003 detailing the 2002/3 Winter Oilseed Rape audit details and twice-yearly publications of this information will continue in 2003/4.

Thirdly, the GM Inspectorate has continued to conduct management audits of GM Deliberate Release consent holders. The purpose of these audits is to verify that the correct procedures and protocols are in place during the operation of GM field trials and to ensure that the conditions laid down in release consents are known throughout the management chain and are implemented effectively *in situ*. Individual guidance was given to some consent holders to improve aspects of their reporting structures but all were generally well organised.

Finally, we have been involved in the case-by-case investigation of specific issues where there was a potential breach of consent conditions or other enforcement issue. These investigations are described in more detail in the body of the report.

## 1. Introduction

In the UK the release of GMOs (genetically modified organisms) is restricted under the EU Council Directive 2001/18/EC (previously under directive 90/220/EEC) on the Deliberate Release into the Environment of Genetically Modified Organisms. This Directive lays down a set of environmental and human health and safety measures in relation to the release and marketing of GMOs. In England the Department for Environment, Food and Rural Affairs (Defra) leads on human health and environmental safety of the release and marketing of GMOs, and is the licensing authority. The Scottish Executive and the National Assembly for Wales have the same devolved responsibilities in respect of their own territories.

It is important that the deliberate release legislation is monitored and enforced. GMOs must not be released into the environment without appropriate safeguards provided within the 'consents'. Part B of the Directive covers releases for research or development purposes. Consent for marketing of GMOs is covered by Part C of the Directive and may be given at EC level after extensive consultation by the competent authorities in EU member states. In the UK Part B consents may be given after a detailed application including a risk assessment has been submitted to the Northern Ireland, England, Wales and Scotland (NIEWS) GM Unit which acts as the Secretariat to the Advisory Committee on Releases to the Environment (ACRE). ACRE review all Part B and C consent applications. If ACRE is satisfied that the proposed release will have no adverse affects on human health or the environment then the Committee will advise Ministers that the consent may be issued. Each consent contains detailed conditions that set out exactly how the releases should be managed.

Under a continuing agreement with Defra, the CSL GM Inspectorate remains the statutory authority for Inspection and Enforcement of Deliberate Release legislation in England in relation to all GMO releases with the exception of clinical trials, which are inspected and enforced by the Health and Safety Executive. The current agreement started on 1 June 2000. An agreement is also in place with the National Assembly for Wales for CSL to carry out inspections on its behalf (**There are currently no releases of GM crops in Wales**). The Scottish Agricultural Science Agency (SASA) is authorised by the Scottish Executive to carry out the equivalent inspection and enforcement roles for Scotland.

## **2. The work of the GM Inspectorate during the reporting period 1 April 2002 to 31 March 2003**

Inspection and Enforcement has involved four main types of activity:

- inspection of Part B Deliberate Release sites in England and Wales as well as inspection of Part C field releases of GM maize as part of the farm scale evaluations (FSE) programme,
- the audit of seed importers and producers to ensure that due care is being taken to avoid unauthorised adventitious GM presence in conventional seed stocks,
- management audits of Deliberate Release consent holders and
- case-by-case investigation of specific issues relating to potential breaches of the relevant GM legislation.

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

### **2.1 Inspections of field releases of GMOs**

During this reporting period, the GM Inspectorate has carried out inspections of all the GM field releases for both Part B research and development trials including the winter and spring FSE trials as well as the Part C FSE Maize trials. Reports on inspection visits were produced and submitted to Defra within the agreed framework of five working days. The CSL GM Inspectorate continues to make available all previous (from June 2000) and new reports, placed on the Defra public register, on its website at [http://www.csl.gov.uk/prodserv/cons/gm\\_inspectorate.cfm#typesofcrop](http://www.csl.gov.uk/prodserv/cons/gm_inspectorate.cfm#typesofcrop), following a period of 20 days for comment from the consent holder and NIEWS.

The GM Inspectorate carries out inspections to ensure compliance with Part B consents using a checklist of the conditions laid down in the specific consent. The consent holders compliance with conditions such as separation distances from related crops, presence and size of pollen barriers, area of GM release and control of volunteers/flowering plants are verified.

During the year the GM Inspectorate visited GM releases of winter and spring oilseed rape, sugar beet, fodder beet, potatoes, barley and wheat. These releases were of three types: FSE sites, variety and seed registration trials and research and development plots.

All of the 75 Part B release sites were visited at least once during the year. The conditions of the consents were confirmed as having been met in all cases. There are currently no trial release sites in Wales.

The GM Inspectorate maintained contact throughout the year with consent holders over various matters concerning compliance including the sowing dates of trials, monitoring requirements during the trial period and arrangements for the disposal of harvested material.

During the year the GM Inspectorate also made 60 routine post-trial inspection visits to current and previous release sites to check for compliance with post-trial management conditions. A further 39 site visits were made in relation to specific

investigations. Some of these visits were in connection with the previously investigated incident of re-growth of harvested oilseed rape stubble in the autumn of 2001 (see section 2.4.1 below).

Furthermore the GM Inspectorate also carried out 12 harvest and seed disposal visits in relation to the finding of additional transformation events in FSE seed material (see report at 2.4.2 below).

In addition to the Part B releases, the 33 release sites of T25 GM maize granted commercial release under Part C consent number C/F/95/12/7 were visited during the growing season or at harvest. These had all been planted under the FSE programme: the Inspectorate verified the site location and noted whether or not they complied with the SCIMAC code of practice.

At the request of the Defra GM policy and regulation unit, the CSL Inspectorate undertook 8 pre-planting site assessment visits to some of the proposed winter oilseed rape 2002/3 FSE sites. These visits were to verify the original risk assessments submitted by the consent holder in relation to statements about the location and size of the site and the description of the site ecosystem. Other factors such as whether the trial is situated in an area where that crop is normally grown were considered together with its proximity to sites of special scientific interest (SSSI's). All consent holder risk assessments were confirmed. Details can be found on the DEFRA website at <http://www.defra.gov.uk/environment/gm/fse/siteassess/autumn2002.htm>

## **2.2 Audits of seed importers and producers**

Under EU Council Directive 2001/18/EC (previously directive 90/220/EEC) implemented in the UK by the Environmental Protection Act 1990 (as amended) and the Genetically Modified Organisms (Deliberate Release) Regulations 2002, the release and marketing of genetically modified organisms (GMOs) without the appropriate marketing (Part C) consent is prohibited. Before marketing seed, UK importers and producers of seed material should take appropriate steps to ensure 'due diligence' in minimising the risk of adventitious GM presence in conventional seed.

It is the role of the GM Inspectorate to audit seed importers and producers to ensure that adequate procedures are in place and that appropriate documentation is readily available. The audits may include seed intended for trials purposes.

The GM Inspectorate, as the Statutory inspection and enforcement body for England and Wales continues to liaise with seed importers, producers and merchants in a programme of seed audits. In carrying out seed audits it is the responsibility of the GM Inspectorate to determine whether companies importing and/or producing seed can demonstrate 'due diligence' in guarding against unauthorised adventitious GM presence. The GM Inspectorate may also take samples for testing where there is uncertainty whether the documentation (e.g. letters of assurance or molecular testing results) provides sufficient confidence of compliance with the GM Inspectorate guidance and there is a suspicion of unauthorised adventitious GM presence.

At present seven crops are audited: winter and spring oilseed rape, sugar and fodder beet, maize, sweet corn and soya. These conventional seed crops have been targeted because GM varieties of these species are grown both commercially and in release

trials in many seed producing countries around the world and therefore the adventitious presence of GM seed in conventional seed of these crops may occur. The GM Inspectorate undertook a Defra funded review during the year to identify potential additional crops for inclusion in future audit programmes based on a set of risk assessment criteria.

In consultation with the seed industry, the GM Inspectorate continues to produce guidance documents for each crop species audited. This provides a framework against which seed producers and suppliers can compare their own systems for guarding against unauthorised adventitious GM presence and against which the Inspectorate will check the information provided during an audit. This information may be derived from testing (e.g. PCR testing) or may be supplied in the form of letters of assurance, or a combination of both. Copies of the current crop guidance documents are available on the GMI website at:

[http://www.csl.gov.uk/prodserv/cons/gm\\_inspectorate.cfm#audits](http://www.csl.gov.uk/prodserv/cons/gm_inspectorate.cfm#audits)

During the reporting year the GM Inspectorate carried out a total of 59 seed audits of seed importing/producing companies. The audits fall into the following categories:

- 22 winter oilseed rape
- 11 spring oilseed rape
- 04 fodder beet
- 04 sugar beet
- 14 maize/sweet corn
- 04 soya

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 therefore no requirement for seed sold to farmers or entered into trials to be recalled or destroyed because of an unauthorised adventitious GM presence.

During the reporting year one company informed the GM Inspectorate that it had identified a single seed lot as possibly containing a very low level of GM presence in their own tests. None of this seed lot had been marketed and it will subsequently be destroyed as a precautionary measure (see report at 2.4.5 below).

### **2.3 Management audits of consent holders**

The Inspectorate again continued its programme of management audits of consent holders during the year. Consent holders who had either active consents, i.e. those with release sites currently being used for trials, or those who were still required to monitor former trial sites, were visited to review their management systems and protocols. The purpose of these audit visits was to verify that the correct procedures and protocols are in place to ensure the 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*. At each audit the GM Inspectorate also require the consent holder to provide evidence to demonstrate an adequate 'duty of care' so as to ensure that only those GM events covered by the consent are released. Further checks were made on the effectiveness of post-trial monitoring both for volunteers and for correct post trial cropping.

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. In line with previous audit programmes some minor recommendations for improvements were made.

After the management audit of Aventis CropScience UK Ltd (now Bayer CropScience Ltd) in April 2002 the company confirmed to the Scottish Executive and Defra the finding of unauthorised GM elements in GM oil seed rape planted under consents 00/R33/09 and 98/R19/18 (and including consent 00/R14/08 issued in Scotland) which included both current and previous trial sites plantings. From the information provided by the company it was unclear how the unauthorised elements had arisen and further investigation to confirm this was required (see report at 2.4.2 below).

## **2.4 Case by case investigation of specific potential enforcement issues**

During the year, the GM Inspectorate again investigated several specific 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. These incidents included:

### **2.4.1 Presence of flowering regrowth (stubble) (01/02 Annual report refers)**

#### ***Further update:***

The GM Inspectorate carried out further monitoring inspections to the former spring oilseed rape trial sites where ‘flowering regrowth’ was previously found in November 2001. These visits were to check that the ‘flowering regrowth’ had not resulted in additional volunteers<sup>1</sup>. Each of the sites visited showed no signs of additional volunteers in the areas where flowering regrowth had been present.

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

On 2 August, Aventis CropScienceUK Ltd (now Bayer CropScience Ltd) confirmed to the Scottish Executive and Defra 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). This followed a finding in related seed batches, supplied by Aventis to Scottish Agricultural College (SAC) under consent 00/R14/08, which was detected as a result of testing undertaken as part of SAC’s duty of care to plant only those transformation events covered by the consent.

Aventis indicated that seed derived from the affected batches had been used to plant several farm scale evaluation sites in previous years (2000 and 2001) and had been used for the planting of 14 sites in spring 2002.

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<sup>1</sup> ‘Volunteers’ is the term applied to plants growing from seed shed by plants from a previous crop as they mature or due to losses during harvesting. This seed loss can then give rise to the occurrence of ‘volunteers’ in subsequent crops. Good agricultural practice requires that the numbers of such volunteers arising from shed seed and emerging in subsequent crops be reduced to manageable levels.

The Advisory Committee on Releases to the Environment (ACRE) advised that the risks posed were no different to those posed by the GM crop for which consent had already been granted. The conditions applied to the consent also ensure that the crops are routinely monitored, have separation distances in place and are destroyed after harvest so that they do not enter the human or animal feed chain. The Scientific Steering Committee for the FSEs also confirmed that the unauthorised GM elements would not invalidate the results of the FSEs.

Following the ACRE statement on the risks, the GM Inspectorate put in train additional official measures to monitor the affected crops at harvest and/or disposal of the harvested seed.

The Inspectorate completed its programme of visits to the 'affected sites' sown under consent 00/R33/09 to monitor the disposal of GM seed. The visits took place either at harvest or immediately afterwards to check storage of seed, or at collection of the GM seed for disposal. All the procedures seen were confirmed to have been conducted satisfactorily. The GM Inspectorate visited a proportion of other 'unaffected' FSE oilseed rape sites under consent 00/R33/09 to monitor harvest and/or disposal of seed.

In view of the finding of unauthorised GM elements in this material, the GM Inspectorate concluded that the consent holder had planted material that did not comply with the consent as granted. The GM Inspectorate produced a report on these findings based on a preliminary investigation, which has recently been submitted to Defra Investigations Branch for further consideration.

As part of ACREs statement on consideration of any risks posed by the findings of additional GM events in this trial seed the committee recommended that no new plantings of GM winter oilseed rape should take place until firm assurances regarding the composition and provenance of the trial seed to be used had been provided. As part of an assessment of this trial seed the GM Inspectorate carried out sampling and testing of the seed lots planned to be used by Bayer CropScience Ltd in the Farm Scale Evaluation and Research and Development trials to be sown in autumn 2002.

A copy of the GM Inspectorates report is available at:  
<http://www.csl.gov.uk/prodserv/cons/sup020909.pdf>

The test results indicated that the samples of oilseed rape material contained a range of GM elements (fertility factors, traits and terminator) consistent with the hybrid Ms8xRf3 for which these consents had been granted.

Furthermore the results confirmed the absence of the antibiotic marker kanomycin (nptII) and promoter pNOS and therefore the absence of the GM events Rf1, MS1 and RF2. By considering these results together with information and assurances provided by the consent holder Bayer CropScience Ltd, the GM Inspectorate confirmed that the specified seed lots for the winter trial programme could be planted.

### **2.4.3 Flowering Volunteers**

During post-trial monitoring of oilseed rape sites sown in 2001 under consent 00/R33/09 the GMI found four sites with very low levels of flowering oilseed rape volunteers within the trial area originally planted with GM oilseed rape.

At each of these sites the GM Inspectorate assessed any additional risks posed by the flowering volunteers and agreed action with the consent holder to control the volunteers. At three of the sites the GM Inspectorate concluded that these low levels of isolated flowering volunteers posed no risks to human health or the environment but agreed control measures with the consent holder. As a precautionary step at one site the consent holder agreed to ensure that the area of a current oilseed rape crop growing within 50 metres of the previous trial area would be harvested separately and sent to landfill to prevent it entering the food or feed chain. The GM Inspectorate concluded that once the control measures were implemented at this site that there were no additional risks to human health or the environment. The GM Inspectorate also undertook further monitoring visits to other sites sown under this consent in 2001 and confirmed that no flowering volunteers were present on these sites.

Oilseed rape 'volunteer' plants appear some time after harvest from seed inevitably shed at or prior to harvest and commonly appear growing (and flowering) within the subsequent crop planted on the land<sup>1</sup>. Following normal good agricultural practice (GAP) growers carry out husbandry procedures to minimise the occurrence of 'volunteers' so that the numbers of volunteers arising from shed seed and emerging in subsequent crops be reduced to manageable levels.

Under consents granted for GM plant releases conditions are laid down to minimise the occurrence of 'volunteers' and to control flowering in the following crop.

The GMI carried out a further series of inspections and check visits and confirmed that satisfactory action was taken by the consent holder to control these volunteer populations.

As a result of the finding of flowering volunteer oilseed rape plants on these former trial sites the GM Inspectorate concluded that the management of these volunteer populations by the consent holder did not comply with the consent conditions. The GM Inspectorate produced a report based on these findings that was subsequently submitted to Defra Investigations Branch. Legal Branch then considered a further report on the work undertaken by Investigations Branch. Based on these reports and further comments by the Inspectorate, it was concluded that no further action was appropriate.

#### **2.4.4 Flowering related weeds**

Following a report by Friends of the Earth to Defra recording the presence of 'flowering related weeds' in the trial area of a former winter oilseed rape FSE trial site the GM Inspectorate carried out a post-trial monitoring inspection.

During this inspection the GM Inspectorate observed flowering white mustard (*Sinapsis alba*) plants sown by the grower as a green manure in both the former GM and conventional planting areas. Although white mustard is a related species, spontaneous hybridisations with oilseed rape are not recorded and therefore the presence of this flowering white mustard crop could not pose any risks to human health or the environment.

Both the former GM and conventional crop trial areas contained small volunteer oilseed rape plants varying from seedling to 5<sup>th</sup> true leaf growth stages. These plants were all at a pre-flowering stage and none were seen to have produced flowers.

In addition, three further flowering plant types were later identified from samples taken, during the inspection, within the former GM trial area: - wild radish (*Raphanus raphanistrum*), charlock (*Sinapsis arvensis*) and a further plant type which was identified as a member of the *Cruciferae* family, but given the development stage of the plant it was not possible to produce more definitive identification.

A sample of unsown seed of the green manure crop contained a significant proportion of brown or Chinese mustard (*Brassica juncea*). No brown mustard plants were identified in the trial area but due to the finding of the seeds within the remaining seed the possibility that brown mustard plants were amongst the flowering plant population was considered.

Given that no flowering oilseed rape plants were noted in the former trial area, and that no other flowering oilseed rape or related crops were found in any of the land adjacent to the trial area the GM Inspectorate concluded that there was no risk of cross pollination from GM oilseed rape with any of the flowering plant types found. The GM Inspectorate reported that no risks to human health or the environment were identified.

To verify compliance with the post trial consent conditions the GM Inspectorate requested scientific advice from ACRE on the control of related species. ACRE responded as follows: 'The Committee's summary of the available evidence is that gene flow to wild radish is a very rare event even under favourable conditions and that gene flow from oilseed rape to charlock has not been detected at all despite a number of detailed investigations under field conditions.' In the light of ACRE's advice, the NIEWS GM unit confirmed that charlock and wild radish do not need to be controlled following trials of winter oilseed rape.

As the green manure crop was mown and incorporated before seed formation the GM Inspectorate concluded that there were no implications for post trial monitoring activities. A copy of the GM Inspectorates report is available at: <http://www.csl.gov.uk/prodserv/cons/sup030402.pdf>

#### **2.4.5 The low level detection of unauthorised GM event in oilseed rape seed**

During the year, a company identified one seed lot of a UK produced spring oilseed rape variety as containing a very low level (<0.1%) of an unauthorised GM event. The company took the precautionary approach of informing the GM Inspectorate and proposing the destruction of the entire seed lot. The affected seed will now be destroyed and the Inspectorate will oversee disposal.

The GM Inspectorate also investigated the source of the suspected adventitious GM presence. The detailed production history of the seed and the DNA testing information for the parental material were carefully studied. However it was not possible to identify a source for the presence.

#### **2.4.6 Alleged contaminated Maize seed supplied to members of the public**

A concerned member of the public provided a sample of Maize seed that had been supplied to them by an unknown third party as 'GM maize'. This sample was analysed by the GM Inspectorate against a range of known maize GM elements and markers. All results were negative.

### **2.5 Other activities**

Over this reporting year the GM Inspectorate has been involved in a number of other activities allied to the main Inspection and Enforcement function. These include attendance at ACRE meetings and comment on release consent applications.

The Inspectorate continues to participate in the European Enforcement Project (EEP). This project is specifically focused on inspection issues in relation to GM deliberate releases and is attended by inspection personnel from EU member countries as well as Norway and Switzerland. GM Inspectorate staff attended an EEP meeting in Scotland in order to exchange knowledge and expertise relating to the inspection of deliberate release sites. The visit was structured around presentations and visits to FSE and research and development sites. Topics under discussion included inspection procedures, sampling methods and the use of specific Standard Operating Procedures (SOPs). In addition, a major consent holder gave a presentation of their proposed post-market monitoring plans for oilseed rape. It is hoped that such meetings will facilitate the closer harmonisation of inspection and monitoring of GM releases in EC countries.

The GM Inspectorate contributed to a Department for International Development (DFID) project in the Czech Republic and presented a training course on GM legislation, field trial inspection and seed auditing for the Czech Environmental Inspectorate.

The GM Inspectorate has provided input into the Strategy Unit review paper on Fieldwork: Weighing up the Costs and Benefits of GM crops (full details from <http://www.strategy.gov.uk>) and the AEBC report on Consumer Choice which is currently being produced.

### **3. Further Information and contact details**

For further information on the GM Inspectorate or its activities please contact:

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