

# **Report on GM Inspection & Enforcement Activities: 2000/2001**

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

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National Assembly for Wales 10 August 2001**

## **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 first for the GM Inspectorate at CSL since taking over the Inspection and Enforcement functions from the Health and Safety Executive in June 2000. Inspection activities have fallen broadly into four categories.

The first and largest of these is the inspection of release sites of GMOs to ensure that there are compliant with the terms of the consents. We have visited 79 sites during the year and all were compliant.

Secondly, we have been auditing the procedures of seed importers, producers and merchants to ensure that due care is being taken not to import or market non-GM seeds that have an adventitious GM presence. The level of care taken by the industry is good and no seed sold to farmers has needed to be recalled or stopped from growing this year because of the presence of unauthorised GM events.

Thirdly, the GM Inspectorate has conducted a number of management audits of GM Deliberate Release consent holders. These audits are 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 were known throughout the management chain and were implemented effectively *in situ*. Some advice was given to consent holders to improve 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 increase in risk or breach of consent conditions, for example the brief ingress of sheep onto a GM release site. These and other issues are explained 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 90/220/EEC (to be replaced by Directive 2001/18/EC) on the Deliberate Release into the Environment of Genetically Modified Organisms. This Directive lays down a set of environmental and human health safety measures in relation to the release and marketing of GMOs. In England the Department for Environment, Food and Rural Affairs 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 the proper consent. Where the releases are for research or development purposes this is covered by Part B of the Directive. Consent for marketing of GMOs is covered by Part C of the Directive and is given at EC level. In the UK Part B consents are given after a detailed risk assessment has been submitted to the Joint Regulatory Authority in DEFRA and assessed by the Advisory Committee on Releases to the Environment (ACRE). If ACRE is satisfied that the proposed release will have no adverse effects 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 conducted.

Under a 3 year Agreement with DEFRA, the CSL GM Inspectorate (see section 3) is the statutory authority<sup>1</sup> for Inspection and Enforcement of the Deliberate Release legislation in England. The Agreement started on 1 June 2000. Prior to this date the Health and Safety Executive carried out inspection and enforcement activities. An Agreement was also set up with the National Assembly for Wales in order to allow CSL to carry out inspections on their behalf. The Scottish Agricultural Science Agency (SASA) is contracted to carry out the equivalent inspection and enforcement role for Scotland.

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<sup>1</sup>Directive 90/220/EEC on the Deliberate Release of GMOs is given effect in the UK by part VI of the Environmental Protection Act 1990 and the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (amended). From June 2000 the GM Inspectorate acted as the delegated statutory authority pursuant to Section 125(1) of the EPA 1990. With the formation of DEFRA the requirement for this authority to be delegated has ceased, and for the remaining period of the current agreement the GM Inspectorate will undertake this role as the statutory authority.

## **2. The work of the GM Inspectorate during the reporting period 1 June 2000 to 31 March 2001**

Inspection and Enforcement has involved four main types of activity:

- the carrying out of inspections of Part B Deliberate Release sites in England and Wales as well as inspections of Part C field releases of GM maize as part of the farm scale evaluations (FSE) programme,
- the audit of seed importers, producers and merchants to ensure that non-GM seed stocks are free from adventitious presence of GM seed,
- 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 GM field releases for both Part B research and development trials and Part C. Reports on inspection visits were produced and submitted to DEFRA within the agreed framework of five working days. All of the inspection reports covering the reporting period are attached for ease of reference at Annex 1 to this report <sup>2</sup>

GM inspectors carry out Part B inspections to ensure compliance with the consent using a checklist of the conditions laid down in the specific consent. The imposition of conditions such as separation distances from other 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 releases of GM crops of winter and spring oilseed rape, sugar beet, fodder beet, potatoes and wheat. These releases were of three types: farm scale evaluations, variety and seed registration trials and company or research institute research and development plots.

Following on from HSE inspections in April and May 2000, 79 Part B release sites were visited out of a total of 121 sites. These figures include the final seven winter oilseed rape sites visited in April 2001. The conditions of the consents were found to have been met in all cases. During the year the GM Inspectorate did not visit a number of sites. This was because they had been visited previously by the HSE or

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<sup>2</sup> The reports will also be placed on the GM Inspectorate web site; anticipated launch 31.10.01

because the trials had been terminated early by the consent holder for various reasons including poor establishment of the crop or, in a few cases, because the plots had been vandalised. The aim of the inspection programme is to visit each release site at least once.

At several sites the imposition of contingency plans<sup>3</sup> had to be confirmed after vandalism and/or premature termination of the trial. The appropriate future monitoring of following crops in 2001 where bolters (pre-flowering or flowering beet plants) had occurred was confirmed in two cases. Six post-trial monitoring inspections were also made of previous release sites in order to check for control of volunteers, as specified in a number of the consents.

In addition, to the Part B releases, seven Part C sites of T25 GM maize were visited. These had been planted under the farm scale evaluation programme and while on site it was noted whether they complied with the SCIMAC code of practice: All were compliant.

Inspectors took strict disease precautions after the beginning of the outbreaks of foot and mouth disease in February 2001. The GM Inspectorate was able to carry out the planned winter crop inspections programme. Inspectors were only prevented from visiting one site, ADAS Rosemaund due to the restrictions. This site was visited subsequently in July 2001.

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

No GM seeds may be imported into Europe for commercial purposes unless the particular GM event concerned has a European marketing consent (Part C approval) under Directive 90/220/EEC. As a consequence, companies importing non-GM seed must ensure that it does not contain the adventitious presence of unapproved GM events. The GM Inspectorate has statutory powers to carry out the necessary inspection of companies importing seed, and enforces the provisions of Directive 90/220/EEC.

The Inspection and Enforcement Agreement with DEFRA (then DETR) was originally intended to include an element of inspection of seed imports such as bulk commodity imports of maize and soya for processing. However events over the summer of 2000 involving some lines of Hyola oilseed rape<sup>4</sup> underlined the need for effective control of seed imports. The GM Inspectorate was heavily involved in the audit of the destruction of the Hyola crops and seed stocks (see section 2.2.1).

As a result of continuing concerns about possible GM presence of seed imported for planting in the UK, the GM Inspectorate was asked to carry out extensive audits of imported seed and additional funding was agreed for this on 22 July 2000. The seed audits have dramatically increased the workload under the Inspection and Enforcement Agreement, especially recently, with the case by case investigation of

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<sup>3</sup> 'Contingency plans' refers to provisions in the consent which set out the actions to be taken in the event of any unexpected effects of the release or if the trial plots are vandalised.

<sup>4</sup> The Hyola incident refers to the situation where adventitious presence of GM oilseed rape seeds was found in non-GM seed supplies. Approximately 500 fields of 'contaminated' seeds were sown in the UK.

individual issues (see sections 2.2.1, 2.2.2 and 2.2.3) and associated follow-up becoming a major component of the workload.

During the reporting year the GM Inspectorate visited seed importing companies and carried out a total of 38 seed audits, which includes some follow-up audits of companies who had significant further imports subsequent to the first audit visit. The audits break down into the following categories:

- 13 winter oilseed rape seeds audits
- 12 spring oilseed rape
- 5 fodder beet
- 6 maize<sup>5</sup>
- 1 sweetcorn
- 1 soya

With respect to imports of sugar beet seed, an audit of British Sugar was conducted. British Sugar handles all imported sugar beet seed: in the year 2000/2001 there were 6 main importing companies.

The seed audits aim to cover as much of a particular crop sown in a season as possible. Resources are therefore targeted at the main seed importers/producers and those crops considered by virtue of their biology or their source to be most at risk of adventitious contamination with GM. In the case of sugar beet the Inspectorate is confident that the audit process covered approaching 100% of the national crop sown in 2001. With more substantive (greater area) crops, such as oilseed rape, the coverage was nearer 60-70% of the imported seed sown.

All companies were found to have adequate procedures in place to comply with the requirements of Directive 90/220/EEC and were taking due steps to avoid the importation or marketing of non-GM seeds containing an adventitious GM presence. No seed sold to farmers has needed to be recalled or stopped from growing because of the presence of unauthorised GM events.

During the reporting year three seed audit issues required significant follow-up work. These were:

*2.2.1 Audit of Advanta in summer 2000 after finding of a low GM presence in Hyola Oilseed Rape seed*

Some batches of seed of the cultivar Hyola were reported to contain an adventitious GM presence. The stocks were produced in Canada in 1998 and imported into the UK. By the time that the GM presence had been confirmed a large amount of the seed had already been sold and sown widely in the UK. Advanta put in place a scheme for tracing the seed and destroying all of the affected crops before they were allowed to flower or set seed. The GM Inspectorate audited the process carried out by Advanta and their verifiers, Crawford & Company. From the evidence presented, the Inspectorate was satisfied that Advanta had traced and destroyed all affected crops before they set seed. The systems already in place to track seed worked well and the

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<sup>5</sup> Most maize and sweet corn audits are completed in April/May and will be covered by the 2001/02 report.

generous compensation paid to farmers encouraged them to participate in the scheme. All seed that had not been sown was re-exported to Canada or destroyed using suitable methods.

### 2.2.2 The presence of 'single markers' in oilseed rape seed samples

Conventional (non-GM) seed consignments are commonly analysed for GM presence by PCR<sup>6</sup> based methods. These look for a panel of DNA sequences that are characteristic (markers) of the genetic modification process. Examples include the presence of commonly used promoter sequences from the cauliflower mosaic virus (CaMV 35S) or *Agrobacterium* (p-nos); selectable marker genes, such as antibiotic resistance (*nptII*); or specific trait genes for herbicide resistance (*pat*, *bar*, *epsps*).

During the seed auditing procedure of winter and spring oilseed rape, PCR test results were revealed that had detected only a 'single marker', for example just p-nos or *npt-II* but with no detection of a transgene or any other characteristic 'GM' sequences. These results are puzzling. They might indicate the adventitious presence of GM seeds although it is difficult to see how single markers like these can occur in the absence of any other characteristic GM sequences/traits. Alternatively, the single marker scenario may be indicative not of GM presence but of bacterial contamination in the laboratory or naturally occurring soil microorganisms on/under the seed coat.

Single markers were detected in seed lots of three breeding lines and two varieties of oilseed rape handled by four different companies. The findings required significant further investigation and action by the GM Inspectorate. Given the uncertainty over whether these seed lots contained a GM presence the companies concerned were instructed not to use the seeds. The whole issue was put to ACRE (Advisory Committee on Releases to the Environment) for expert advice on the significance of these results.

Note added in publication, July 2001: ACRE has now advised that based on the available evidence the ambiguous single marker PCR results are not due to GM presence. The Committee has endorsed a screening procedure to resolve such problems quickly in the future.

### 2.2.3 The low level detection of authorised GM events in maize seed.

In several lots of imported maize seed, detection of a low level (<0.1%) of authorised GM events was reported. In this context an authorised GM event refers to one that has European Part C consent for cultivation under Directive 90/220/EEC. There are three such GM maize events, which are also approved for feed and food uses:

- BT176 – (ref C/F/4/11-3), Bt insect resistance and herbicide tolerance.
- MON810 – (ref C/F/95/12/02), Bt insect resistance
- T25 – (C/F/95/12/07)' Glufosinate herbicide tolerance

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<sup>6</sup> PCR refers to the Polymerase Chain Reaction, which is a sensitive laboratory method to amplify chosen DNA sequences. PCR methods are able to detect very small amounts of target genes or other NA sequences in complex mixtures of other sources of DNA.

The GM Inspectorate confirmed that the testing protocol adopted by the importing company was able to determine firstly, the possible contamination by any GM event and then secondly to distinguish correctly between the presence of unauthorised GM events and the presence of authorised events (authorised within the EU). Given this assurance the GM Inspectorate was satisfied that the low level of GM was due to the presence of approved GM events. In such a situation there is no legal bar to the seed being market within the UK.

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

Several management audits were conducted during the year. The purpose of these audits was to ensure that the correct procedures and protocols were in place during the operation of GM field trials and to ensure the conditions laid down in the release consents were known throughout the management chain and were effectively implemented *in situ*. Secondly, the GM Inspectorate required evidence that consent holders were demonstrating an adequate 'duty of care' to ensure that only those GM events covered by the consent are released.

The standards and reporting structures within the consent holder organisations was generally good. A few recommendations were made, such as adjustment to protocols, as appropriate.

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

In addition to the other duties the GM Inspectorate was asked to investigate three specific incidents that were brought to the attention of the regulatory authorities and for which there might have been a breach of consent or another enforcement issue. The three incidents were:

#### **2.4.1 Release of an unauthorised GM beet line in a Part B field trial of glufosinate-ammonium tolerant sugar beet**

In September 2000 Aventis reported to DEFRA that an unauthorised release of GM sugar beet plants had occurred under consent 00/R33/02 (planted in spring 2000). This was due to the presence of a proportion (approximately 0.5%) of GM beet tolerant to both glufosinate-ammonium and another herbicide, glyphosate. This contamination had become evident when a small proportion of plants in the trial plots survived spray treatment with glyphosate at the end of the trial, thereby showing them to be tolerant to this particular herbicide. Aventis indicated that the unauthorised GM event was likely to be present due to cross-pollination during the production of the beet seed in Germany.

The GM Inspectorate investigated the situation and confirmed that during the year 2000, apart from the original unauthorised planting of double-tolerant GM beet, the conditions of the consent were met fully at all release sites under this consent. Furthermore, an audit visit to Aventis headquarters confirmed the existence of

appropriate paperwork and communication systems to ensure that the conditions specified in the 00/R33/02 consent had been implemented on the ground during the growing season.

The GM Inspectorate visited all the trial sites and confirmed that the plant material had all been properly destroyed or disposed of. The Inspectorate also specified certain follow-up action in 2001 including the development by Aventis of new protocols to ensure that only those transformation events covered by the consent are released plus additional post-trial monitoring in 2001 by Aventis (with confirmation visits by the GM Inspectorate) of all the year 2000 sites from mid May onwards when flowering bolters from re-growth could occur and not just in July and August, as specified in the consent. The CSL GM Inspectorate report concluded that, subject to the follow-up action specified, there was no increased risk to human health and the environment and no further enforcement action was necessary.

#### 2.4.2 Report by members of the public of flowering GM beet at a farm scale evaluation site

The GM beet in the farm scale evaluations programme is being grown under two Part B consents: 99/R22/16 (sugar beet) and 99/R22/17 (fodder beet). It is a condition of these consents that steps are taken to remove the flowering spikes (bolters) of the GM beet plants before flowering – and hence prevent pollen release. However, it is also recognised in the consent that if a bolter is missed and it flowers then action will be taken to increase monitoring of the site.

The GM Inspectorate received reports from two members of the public concerning the presence of a large number of flowering beet plants at a FSE site. The Inspectorate visited the site and confirmed that there were significant numbers of flowering plants present but they were in the non-GM part of the trial of fodder beet and in a neighbouring field of commercial sugar beet. It may have been these flowering plants that were observed by the members of the public. On close inspection of the GM part of the trial one very small flowering GM plant was found between the rows. This plant had previously been removed but had subsequently re-grown and had shed some pollen. The consent holder was informed that they should carry out additional monitoring for volunteers in accordance with the contingency action laid down in the consent.

#### 2.4.3 Inadvertent grazing by sheep of a winter oilseed rape release site, consent 00/R33/07/06

GM Inspectors were alerted following the ingress of sheep onto a farm scale evaluation site of winter oilseed rape at Woodhouse, Leicestershire. A visit to the site was carried out to assess the possible risk to human health and the environment.

Inspection of the site revealed there had been minimal grazing. The sheep had been removed from the site and moved to a site about 10 miles away. The GM Inspectorate was informed that the flock had escaped from the neighbouring field through a hole in the fence, and that this fence would be replaced during the winter. The ewes were present on the FSE site for a very limited period of time and only minimum grazing damage was seen in the crop however, the sheep will have had

opportunity to graze and as such may have ingested GM material. DEFRA made ACRE and the Food Standards Agency aware of the GM Inspectorate's findings, and on the basis of the expert advice of these bodies it was concluded that there were no risks to human health and the environment.

## **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 meeting and comment on release consent applications. One of the more substantive activities has been participation in a European Enforcement Project.

### **2.5.1 Participation in the European Enforcement Project (EEP).**

In April 2000, a European project on the enforcement of GMO legislation was initiated. The project was specifically focused on inspection issues in relation to GM deliberate releases and was attended by inspection personnel from EU member countries as well as Norway and Switzerland. The GM Inspectorate took an active part in the project throughout the year, contributing and sharing information and advice on Inspection and Enforcement matters with members from other European countries. There were three meetings altogether.

The GM Inspectorate participated in joint inspection visits to France, the Netherlands and Germany on oilseed rape, maize and sugar beet crops. The Inspectorate also produced three draft Standard Operating Procedures on field sampling of GM plants as well as providing general information on the UK GM inspection situation.

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

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

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

**Contact number** 01904 462000

**Website** [www.gm-inspections.co.uk](http://www.gm-inspections.co.uk)

**Deliberate Release of Genetically Modified Organisms, Part VI of the Environmental Protection Act 1990**