

Annual Report on GM Inspection & Enforcement Activities: 2001/2002

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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 second 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 consent release sites to ensure that all Part B and Part C (maize FSE) releases are compliant with the relevant terms of the consent. The Inspectorate visited all 137 release sites during the growing season and all were compliant. We also made 51 post-trial inspection visits to current (2001) and previous (2000) release sites for compliance with post trial management conditions. In addition 17 pre-sowing site assessments were made on behalf of DEFRA to carry out a statutory risk assessment of the proposed sites.

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. The level of care taken by the industry is generally very good, and again no seed sold to farmers has been recalled or planting stopped 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. 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 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 (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 the appropriate consent. 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 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 is the statutory authority for Inspection and Enforcement of the Deliberate Release legislation in England. 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. The Scottish Agricultural Science Agency (SASA) is contracted to carry out the equivalent inspection and enforcement role for Scotland.

2. The work of the GM Inspectorate during the reporting period 1 April 2001 to 31 March 2002

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 non-GM seed stocks are free from unauthorised GM events,
- 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 and Part C farm scale evaluation (FSE) trials. Reports on inspection visits were produced and submitted to DEFRA within the agreed framework of five working days. On 26 September 2001 the CSL GM inspectorate website was made available which included all the inspection reports placed on the DEFRA public register since June 2000. Since 26 September all new reports have been placed on the website at <http://www.csl.gov.uk/prodserv/cons/GMI/GMI2.cfm>, following a 20 day comment period from consent holder and DEFRA.

The Inspectorate carries out inspections to ensure compliance with Part B consents using a checklist of the conditions laid down in the specific consent. The imposition of 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 112 Part B release sites were visited at least once during the year. The conditions of the consents were found to have been met in all cases. Two trials were not visited because they had been terminated early by the consent holder due to poor winter establishment of the crop. One site in Wales was visited and found to comply with the notice served by the National Assembly of Wales which prohibited the planting of T25 GM maize in Wales within 200 metres of organic farms, 200 metres of farms growing non-GM sweetcorn, and 80 metres of non-GM forage maize. Contact was maintained throughout the year with consent holders over various matters concerning compliance, including harvest arrangements of related crops within the isolation distances and post trial monitoring of sugar and fodder beet sites.

During the year the GM Inspectorate also visited some of these release sites after harvest or those from previous years to check on post trial consent compliance. Fifty-one of these post-trial inspections were made. Some of these visits were in connection with re-growth of harvested oilseed rape stubble in the autumn (see section 2.4.1. below). Visits were also made to check on ten sites where release of an unauthorised GM beet line in Part B field trials of glufosinate-ammonium tolerant sugar beet had occurred in 2000. (See last year's report). All the sites were found to have no further re-growth of beet plants and correct post trial procedures by the consent holder and delegated trials officers were confirmed.

In addition to the Part B releases, 25 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 policy and regulation unit, the CSL Inspectorate undertook 17 pre-planting site assessment visits to some of the proposed spring oilseed rape and beet 2002 FSE sites. These visits were to check the original risk assessments submitted by the applicant. Factors such as location and size of the site, the description of the site ecosystem and, in particular, 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 risk assessments were confirmed. Details can be found on the DEFRA website at <http://www.defra.gov.uk/environment/fse/siteassess/spring2002.htm>

During the year, GM Inspectors continued to observe strict precautions to avoid disease spread during visits due to the continuing outbreaks of foot and mouth disease. One winter oilseed rape site previously not visited due to visitor restrictions was inspected in July.

2.2 Audits of seed importers and producers

EU legislation requires that no GM seeds may be imported to and/or marketed in the UK for commercial marketing purposes unless the particular GM event concerned has a European marketing consent (Part C approval) under Directive 90/220/EEC (to be replaced by Directive 2001/18/EC). As a consequence, companies importing or producing conventional seed in the UK should take appropriate steps to ensure that it does not contain the adventitious presence of unauthorised GM events.

The GM Inspectorate, as the statutory inspection and enforcement body for England and Wales, liaises with seed importers, producers and merchants to undertake a series 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 have shown due diligence to ensure that the seed they obtain and supply is free of unauthorised GM presence.

At present seven main crop species 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.

In consultation with the seed industry, the GM Inspectorate produces guidance for each crop species audited. This provides a framework against which seed producers and suppliers can compare their own systems to ensure freedom from unauthorised 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.

During the reporting year the GM Inspectorate carried out a total of 46 seed audits of seed importing/producing companies. The audits fall into the following categories:

- 24 winter oilseed rape
- 5 spring oilseed rape
- 3 fodder beet
- 12 maize
- 2 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 adventitious GM presence.

The range of crops to be included in the audit programme will be kept under review, and additional audits may be undertaken as appropriate. The GM Inspectorate may also carry out audits of bulk commodity imports, such as oilseed rape, maize and soya, to check for the presence of unauthorised GM events.

During the reporting year the seed audit issue linked to the presence of ‘single markers’ in oilseed rape seed samples was resolved. This required significant follow-up investigative work for which full details are provided in last year’s report. In July 2001 ACRE advised that, based on the available evidence, the ambiguous single marker PCR results should be adjudged as not being due to GM presence. The Committee endorsed a screening procedure to resolve such problems quickly in the future. This procedure is in place for official testing procedures at CSL.

2.3 Management audits of consent holders

The Inspectorate continued its programme of management audits of consent holders during the year. Consent holders who had active consents, i.e. those with release sites currently being used for trials, were visited and their systems and protocols were inspected. 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.

On the basis of information provided by the consent holder the Inspectorate found the standards, protocols and dissemination of information through the various management chains was generally good. Some minor recommendations for improvements were made.

2.4 Case by case investigation of specific potential enforcement issues

During the year, the GM Inspectorate 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. The incidents were:

2.4.1 Presence of flowering regrowth (stubble)

On 30 November 2001, Friends of the Earth (FOE) wrote to the Secretary of State for the Department for Environment, Food and Rural Affairs (DEFRA) and issued a press release claiming that flowering ‘volunteer’ plants were present on a farmscale GM release site of spring oil seed rape (osr) at Witham on the Hill, Lincolnshire (planted under consent number 00/R33/09, granted to Aventis CropScience UK Ltd). The DEFRA GM policy and regulation unit requested the CSL GM Inspectorate to investigate.

The Inspectorate visited the site on 3 December 2001 and found flowering osr plants at the site occurring on regrowth of the stubble remaining from the harvested crop. No flowering ‘volunteers’ were observed. ‘Volunteer’ plants appear some time after harvest from the seed shed at or prior to harvest. Aventis indicated that stubble remained at three other spring oil seed rape sites. The Inspectorate visited these sites and confirmed the presence of some flowering regrowth at all three sites.

After an assessment of the trial sites and the area within 50 metres of each trial, the Inspectorate concluded that no additional risks to human health and the environment were created by this flowering regrowth: there were no flowering oil seed rape or sexually compatible crops in the neighbourhood of the trials.

The consent holder, Aventis CropScience UK Ltd, was informed of the Inspectorate's findings and reminded of the requirements contained within the consent in respect of post harvest crop management. In consultation with the consent holder, the Inspectorate agreed appropriate precautionary action, and suitable future monitoring plans to be taken at each site. The GM Inspectorate received confirmation in writing from the consent holder of these agreed actions and the future monitoring plans and carried out visits to confirm the action taken.

The Inspectorate considered the flowering regrowth in relation to the consent, particularly in relation to the conditions specified for duration of the trial and for post-trial management of trial sites. The Inspectorate reached the following conclusions:

- Aventis planted and harvested the GM release crop within the stated duration of release (sowing to harvest). The harvest was carried out according to good agricultural practice (GAP): the crops were either harvested directly when they had reached maturity or were sprayed with a herbicide desiccant, which speeds up the ripening of the immature pods so as to advance harvest. By taking either approach, Aventis could reasonably have expected an effective harvest and therefore termination of the release.
- As specified in the consent, Aventis managed the release sites according to Good Agricultural Practice (GAP). In particular:
 - (i) The presence of osr stubble in November, although not common, does occur. Stubble can be left over the winter period until more favourable climatic conditions exist for preparation of the soil for the following crop. It can also help reduce soil erosion due to wind-blow and heavy autumn/winter rainfall. At all four sites at which flowering regrowth was observed, the stubble from the spring oil seed rape crop had been left because the soil was too wet to allow cultivation.
 - (ii) The incorporation of the remaining 'vegetative plant parts' (i.e. the stubble) into the soil as required in the consent, would thus have taken place in accordance with GAP at some time after the report of the flowering incidence.
- Flowering regrowth is not a phenomenon that has been reported in agricultural circles. However, it is reasonable to suppose that the exceptionally mild autumn in 2001 may have contributed to the occurrence of flowering regrowth. From these indications the GM Inspectorate have concluded that the occurrence of flowering regrowth was an exceptional event.
- The consent application and conditions have clear requirements for a monitoring programme for 'volunteers' arising from a spring oil seed rape crop but do not specifically mention or anticipate the occurrence of flowering regrowth. Aventis therefore cannot be said to be in breach of any specific consent conditions by not anticipating the occurrence of flowering regrowth.
- Aventis, once alerted to the occurrence of the flowering regrowth, took appropriate steps to destroy/prevent further regrowth.

In summary the Inspectorate concluded that Aventis had followed GAP and met the conditions of the consent. In the Inspectorate's opinion flowering regrowth of the stubble is an exceptional event that Aventis could not reasonably have been expected

to anticipate. As soon as it was brought to their attention Aventis took immediate action to destroy the re-growth. The risk posed by the flowering re-growth is considered minimal because there were no other flowering osr crops or crops of compatible species in the vicinity of the trials at the time of the incident.

In the light of the findings of flowering regrowth the GM Inspectorate recommended that:

- Aventis reviewed its monitoring strategy to ensure early site assessments after harvest to assist post-trial management of the site.
- Aventis ensured that a more robust notification system between grower and consent holder was introduced to ensure that ‘unexpected events’ such as flowering regrowth are notified in accordance with the general conditions of the Schedule to the consent 00/R33/09.(EPA section 112(5)(a) refers). The management instructions and training provided to growers should be reviewed.
- The GM Policy and Regulation unit together with the Advisory Committee on Releases to the Environment (ACRE) consider reviewing the conditions specified in GM oil seed rape consents and consider the adoption of conditions to address specifically the possibility of flowering regrowth of the GM crop release.

Update 16.07.02

The GM Inspectorate has confirmed that Aventis has taken appropriate action in response to these recommendations: Aventis has reviewed its monitoring programme to ensure that all sites are monitored before the end of October and has issued growers with a new task sheet requiring completion of anticipated cropping plans and expected farming practices for all sites where GM crops have been sown in the previous season in order to target any additional action needed to prevent a recurrence of flowering regrowth (stubble). In addition, Aventis has modified its notification requirements to ensure that growers notify them of any unexpected events occurring at the trial site, including those related to the development of the crop and its agronomy.

At its meeting on 04.07.02, ACRE considered the need to review the conditions specified in GM oil seed rape consents. ACRE agreed that a variation should be inserted for each of the oil seed rape consents to ensure that the consent holder addresses the possible risk of flowering regrowth (stubble).

2.4.2 Presence of cattle on two oil seed rape FSE sites

2.4.2.1 Inadvertent grazing by cattle of a spring oilseed rape release site, consent 00/R33/09 site number 11

During inspection of a site at High Halden, Kent dairy cattle were seen grazing on the non-GM oilseed rape part of the trial. There was also evidence of their previous presence on the GM section of the trial. The consent holder confirmed that the cattle had accidentally been allowed unrestricted access to the trial for a short period. There was evidence of grazing on individual plants in the GM part of the trial. However there was only a short opportunity for grazing which would have minimised any ingestion of GM material. In addition, the cattle were due to enter the ‘over thirty months’ slaughter and disposal scheme and so would not

have entered the human food chain. The Inspectorate therefore concluded that there was no risk to human health or the environment and no further action was required.

2.4.2.2 Inadvertent presence of cattle on a winter oilseed rape release site, consent 00/R33/11 site number 1

During inspection of a site at Lymm, Cheshire observed hoof prints from cattle mainly clustered around a water trough on the non-GM oilseed rape part of the trial. The consent holder confirmed that three months previously the cattle had accidentally broken through an electric fence and strayed onto the trial for a short period until they were removed. At the time of the inspection there was no evidence of grazing on individual plants.

Given the reported minimal time of ingress of the cows onto the trial site coupled with no evidence of damage by grazing, the Inspectorate concluded there was no risk to human health or the environment and no further action was required.

As a result of the two cases above, the GM Inspectorate instructed the consent holder to review its instructions to growers to ensure a more effective line of communication between itself, the growers and the GM Inspectorate so that such events can be reported more effectively in future. In addition during inspection visits the GM Inspectorate now routinely records the presence of any livestock in neighbouring fields, considers the security of any boundaries and advises the consent holder of any potential defects noted.

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. One of the more substantive activities has been participation in a European Enforcement Project (EEP) on Monitoring the Environmental Effects of Genetically modified plants. 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. 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. An extranet set-up during the year to share information between Inspectorates has been invaluable as an early warning of potential GM issues (see section 2.2). In the reporting year there were two conference meetings.

The GM Inspectorate participated in a joint monitoring visit to France on maize and produced a draft Standard Operating Procedure on sampling of seed. It also contributed to mapping of crops in relation to their wild relatives 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:

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