



Annual report on GM inspection and enforcement activities

01 April 2008 - 31 March 2009

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List of acronyms used

AGMP	Adventitious GM presence
BSPB	British Society of Plant Breeders
CSL	Central Science Laboratory
Defra	Department for Environment, Food and Rural Affairs
EC	European Commission
Fera	Food and Environment Research Agency
GM	Genetically modified
GMI	Inspectorate for deliberate releases of GMOs
GMO	Genetically modified organism
MS	Member State(s) of the European Union
PHSI	Plant Health and Seeds Inspectorate
PVS	Plant Varieties and Seeds Office
QRA	Quantitative risk assessment
SOSR	Spring oilseed rape
the Directive	European Council Directive 2001/18/EC
WOSR	Winter oilseed rape

Executive summary

1. The GM Inspectorate is responsible for enforcement of legislation controlling the deliberate release of genetically modified organisms in England. As there is currently no commercial cultivation of GM crops in England, this concerns small-scale experimental releases and any unauthorised releases. The work is undertaken for the Department for Environment Food & Rural Affairs (Defra). This is the ninth report of the GM Inspectorate covering the period 1st April 2008 to 31st March 2009.
2. In the reporting year the GMI was part of the Central Science Laboratory, which is an executive agency of Defra. On 1st April 2009 CSL merged with Defra Plant Variety Rights Office and Seeds Division, Defra Plant Health Division¹, the Plant Health and Seeds Inspectorate and the Government Decontamination Service to become the Food and Environment Research Agency. Fera has its headquarters at Sand Hutton in York, and the GM Inspectorate is still based there.
3. Fera is an executive agency of Defra, whose over arching purpose is to support and develop a sustainable food chain, a healthy natural environment, and to protect the global community from biological and chemical risks. Fera's role within that is to provide robust evidence, rigorous analysis and professional advice to the UK Government, and national and international organisations in both the public and the private sectors. Further information about Fera is available at: <http://www.fera.defra.gov.uk/>.
4. Within the reporting period there were two GMO deliberate release field trials in England:
 - a) a commercial trial of potatoes genetically modified for resistance to late blight caused by the fungus *Phytophthora infestans*;
 - b) a small-scale proof-of-concept trial for potatoes modified for resistance to potato cyst nematodes (*Globodera* species).
5. Field inspections confirmed that both releases were consistent with the conditions of the consents and that no risks to human health or the environment were identified by release of the GMOs. Five post-trial inspections of former deliberate release trial sites, and three management audits, were carried out in the reporting period. In all cases the consent holders were found to be acting in accordance with the conditions of their respective consents.
6. On behalf of Defra Plant Variety Rights Office and Seeds Division (PVS)², the GM Inspectorate runs a programme of voluntary audits of seed importers and producers. The audits focus on helping companies to be aware of the risks of adventitious GMOs in the seed they import and produce, and discuss how these risks can be managed. The forty-four seed companies that participated in the audits in 2008/09 were found to have acted responsibly in managing the risk of adventitious GM presence in conventional seed they were marketing. Two

¹ With responsibility for plant and bee health.

² From 1st April 2009, part of the Food and Environment Research Agency

additional targeted audits were carried out on new companies. Summary tables of the findings of the audits have been published on the GM Inspectorate website at <http://www.gm-inspectorate.gov.uk/seedAuditProgramme/auditReports.cfm>.

7. Two small investigations have been undertaken in the reporting period. One of these involved a new report of GM fish being offered for sale in England; tests confirmed that the fish were genetically modified. The GM inspectorate also investigated a case of winter oilseed rape that was submitted for UK National List trials and was subsequently found to contain adventitious GM presence. The seed had also been grown in a small private trial in England in 2007/08 and the details surrounding this were also established and appropriate action taken.
8. The formation of Fera brings together the Plant Health and Seeds Inspectorate, the Bee Health Inspectorate and the GM Inspectorate. It is anticipated that this will help realise benefits in minimising the regulatory burden on businesses that Fera regulates. This will be an early priority for Fera.

1. The role of the GM Inspectorate

The GM Inspectorate is responsible for inspection and enforcement of the deliberate release of genetically modified organisms in England. This work is undertaken on behalf of Defra to ensure compliance with legislation concerning the deliberate and unintentional release of genetically modified organisms. Appendix 1 provides details of GM legislation and regulation in the UK. The GMI is responsible for inspection of all GMO deliberate release sites, and for monitoring for adventitious GM presence in conventional seed for marketing and private trials. The GMI is also responsible for investigation of any potential breaches of the GM legislation that may arise in England. These are investigated on a case-by-case basis and action taken as appropriate.

1.1 Experimental (Part B) deliberate release trial sites

One of the primary roles of the GM Inspectorate is to ensure compliance with consents granted under Part B of EC Directive 2001/18/EC³, hereafter called “the Directive”. Part B consents authorise the release of a GMO for “any purpose other than for placing on the market, including for the purposes of scientific research”, this includes, *inter alia*, research, development or demonstration purposes, variety registration, herbicide authorisation, seeds multiplication or biosafety/risk assessment research.

In the UK consent to conduct a Part B trial is issued by Defra in accordance with section 111 of the Environmental Protection Act 1990⁴. Each consent document specifies the limitations and conditions attached to the specific release, including requirements for reporting to the Secretary of State for Environment, Food and Rural Affairs. The limitations and conditions are aimed at ensuring the GMO does not enter the food and feed chain and does not pose any risks to human health or the environment. The GM Inspectorate operates a programme of inspections and audits aimed at establishing that consent holders comply with these terms and conditions, and if not, to take action to correct this.

The GM Inspectorate's programme is achieved by a combination of practical inspection visits at deliberate release trial sites, and audits of consent holders to ensure that they are aware of their responsibilities and discharging their duties appropriately. These activities are described in more detail below. A summary of the inspections and audits completed in 2008-09 is provided in Table 1 in section 2 of this report.

- *Field inspection*

The GMI inspects each deliberate release trial site at least once during the growing season. During inspection visits GM Inspectors must establish that each release is in accordance with the conditions described in the consent, for example the location of the trial site, the area of the GM release, isolation from related crops or wild relatives, the presence and size of pollen barriers (if specified), arrangements for transport and

³ See: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:106:0001:0038:EN:PDF>

⁴ Further information can be found at <http://www.defra.gov.uk/environment/gm/regulation/index.htm>

storage of the GM materials, and control of volunteer plants and/or flowering plants (as applicable).

- *Post-trial monitoring*

The majority of deliberate release consents are issued with specific requirements to monitor the release site following harvest of a trial. The GM Inspectorate visits each former deliberate release site at an appropriate stage in the growing season to ensure that the consent holder is undertaking post-trial monitoring and eliciting appropriate action, when necessary, in accordance with the consent conditions. Responsibilities of the consent holder might include recording and control of plants that emerge at the former trial site, for example from seeds that were shed or potato tubers that were left in the ground (groundkeepers), or restrictions on the follow-on crop(s) that can be grown. The length of the post-trial monitoring period varies depending on the crop that was employed in the trial, but in all cases is designed to ensure that, as far as reasonably possible, no GMOs remain at the release site. Post-trial monitoring must continue until permission is given by Defra to officially terminate the trial.

- *Consent holder audits*

All consent holders are audited to verify they have put procedures and protocols in place to ensure good planning and operation of their GMO field trial(s), and to verify that the conditions laid down in the release consents are known throughout the management chain and effectively implemented *in situ*. During the active trials phase, consent holders are also required to provide evidence to demonstrate that only the GM event(s) covered by the consent is/are released and that no adventitious GMOs are present. 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. Audits are undertaken in advance of planting under all new consents and consents with an active planting programme, whereas consent holders for trials in the post-trial phase are normally audited at the end of the post-trial monitoring season and prior to submission of the annual consent holder monitoring report to Defra.

- *Consent holder monitoring reports*

Under the Directive, consent holder monitoring reports are required annually for all consents until they are officially terminated. A suggested template for these reports is available at http://ec.europa.eu/environment/biotechnology/pdf/dec2003_701.pdf

In the year of release the monitoring report serves to inform Defra whether the trial progressed as planned and to provide a re-evaluation of any risks to human health or the environment posed by the GMO. If the trial did not go as planned, the consent holder must describe what occurred, any mitigating measures that were taken and any additional measures that will be taken in the future, and the reasons for this. Continuation of a multi-year trial would be dependent on annual submission and acceptance (by Defra) of the monitoring reports.

In the post-trial monitoring phase, the report provides Defra with information on the effectiveness of the measures in place to control any plants that emerge at the trial site, including details of the number of plants detected each month on each GMO

area. The consent holder is also required to re-evaluate the monitoring requirements and state whether, in their view, monitoring should be modified or discontinued at the site and the reasons for this. The GM Inspectorate is responsible for administering submission of these reports to Defra.

- *Reporting the GMI field inspection programme*

Draft reports on growing season crop inspection visits are produced and submitted to the consent holder and Defra within an agreed framework of five working days. A period of 20 calendar days then follows in which both parties are given the opportunity to comment on the factual details of the report. Final field inspection reports are then placed on the public register and on the GMI website at: <http://www.gm-inspectorate.gov.uk/deliberateRelease/exptreleases.cfm>.

Reports to Defra on management audits and post-trial monitoring inspections are not currently published. However, this policy is currently under review.

1.2 Adventitious presence of GMOs in conventional seed stocks in England

Whilst genetically modified crops are not currently commercially cultivated in the UK, a number of GM maize varieties are authorised for cultivation in Europe, and GM varieties of other agricultural crops are cultivated worldwide. Experimental work has also been undertaken at the field-trial scale in a number of countries, for a range of different species. There is, therefore, potential for seed to acquire adventitious GM presence either by cross-pollination or admixture. Certified seed production methods employ measures to ensure a specified level of purity of certified seeds, but these are not specifically geared towards ensuring seed is free of AGMP. Current seeds legislation does not lay down specific thresholds for the adventitious presence of authorised GMOs in conventional seed. However, to comply with Directive 2001/18/EC and Regulation (EC) 1830/2003⁵, and since no thresholds are established, seed containing an authorised GMO at any level must be labelled. It is also illegal to market seed containing a GMO that has not been authorised for commercial cultivation in Europe.

GM seeds

Authorised genetically modified crops may be marketed throughout Europe providing the varieties offered for sale have met the requirements for placing on the Common Catalogue of Varieties (see Annex 1). There are currently two consents authorising cultivation of GM maize in the EU, these are MON810⁶ and T25⁷. At present only varieties of MON810 modified for resistance to the European corn borer (*Ostrinia nubilialis*) have been placed on the Common Catalogue⁸. In principle these varieties could be marketed in the UK provided they were correctly labelled, however, to date they are all late-maturing varieties developed for cultivation in areas where the

⁵ See: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0024:0028:EN:PDF>

⁶C/F/95/12/02, Monsanto.

⁷C/F/95/12/07, Bayer CropScience.

⁸As of 1st July 2009 there were more than 70 varieties of maize containing the MON810 event listed in the EC Common Catalogue of Varieties.

European corn borer is present, and they are not suited to cultivation in the shorter UK growing season⁹.

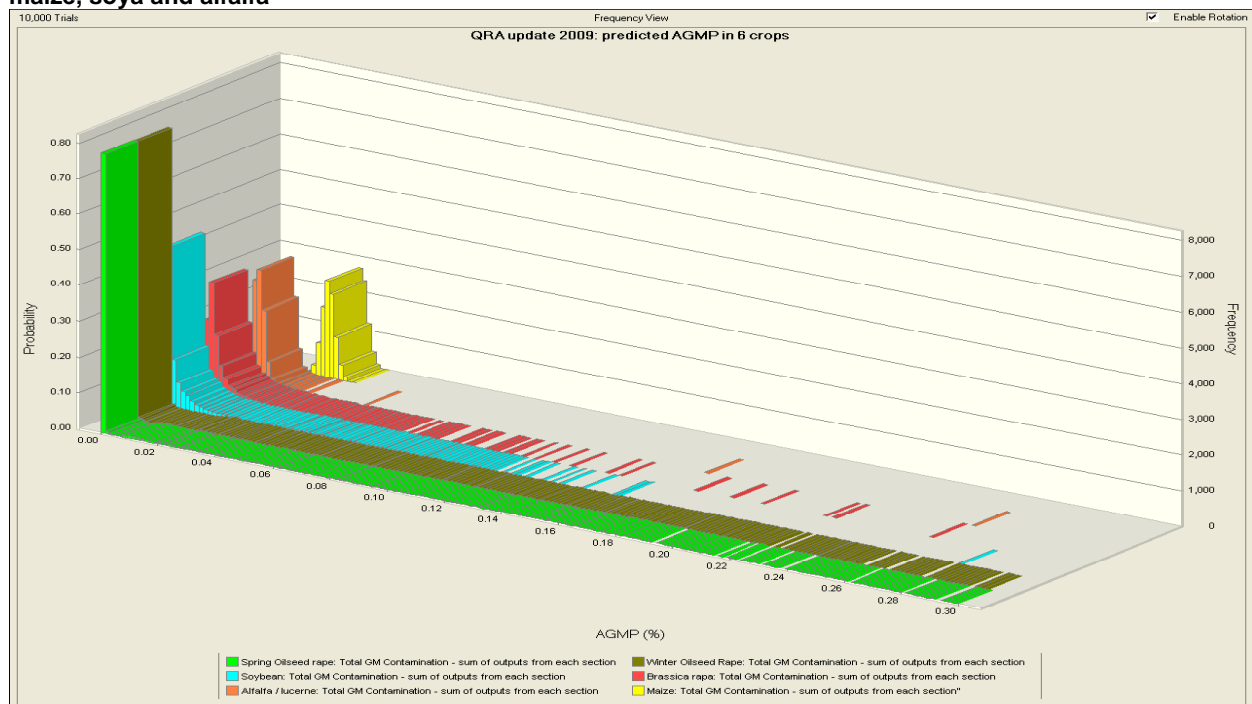
Seed audit programme

In England, it is the role of the GM Inspectorate to ensure that seed producers and importers are aware of the risks of adventitious GM presence in seed they are marketing or trialling, and that they are managing those risks. This is achieved through a programme of voluntary audits that are undertaken on behalf of Defra and Fera's Plant Varieties and Seeds team (PVS) as the competent authority for seed marketing.

Risk assessment

The GM Inspectorate has developed computer-based models for the quantitative assessment of the risks of AGMP in conventional seeds for those key agricultural crops that are known to have been genetically modified¹⁰. The QRA models have been developed in discussion with industry representatives, risk analysis experts and Defra. The models generate probability distributions of relative GM presence based on worldwide GMO activity, crop biology and seed production processes, and produce a set of distributions displaying the relative risks for the major crop species (figure 1).

Figure 1: Predicted distributions of AGMP in seed lots of winter and spring oilseed rape, *Brassica rapa*, maize, soya and alfalfa



⁹In Wales in 2008, a small area of MON810 maize was reportedly grown, although this was never confirmed.

¹⁰*Brassica napus* (winter and spring oilseed rape), *Brassica rapa* (turnips, turnip fodder rape, stubble turnip, etc.), *Zea mays* (maize and sweetcorn), *Glycine max* (soya), *Triticum aestivum* (wheat), *Beta vulgaris* (sugar beet and fodder beet), *Brassica oleracea* (cabbages, kales, cauliflowers etc.), *Medicago sativa* (alfalfa), *Trifolium repens* (white clover), *Lycopersicon lycopersicum* (tomato), *Agrostis stolonifera* (creeping bentgrass).

Figure 1 shows the distribution of AGMP levels predicted by our models for six crops: the height of each peak shows the probability of AGMP occurring, whilst the position along the bottom axis shows the predicted level of AGMP (%). Seed lots of spring and winter oilseed rape (shown as light and dark green, respectively), are predicted to have a high probability of a very low level of AGMP, but this abruptly falls off and is followed by a long tail indicating lower probabilities of elevated levels of AGMP. Conversely, maize seed lots (shown in yellow) display a more compact distribution, with a less abrupt initial decline and without the long tail. Thus, when assessing the relative risk of AGMP for each crop, account must be taken of the profile of the distribution in terms of the maxima and minima of the peaks and the peak heights. Ranking crops according to the risk of AGMP is not a straightforward process and depends to a large extent on the weighting of that risk: are crops that have an occasional high level of AGMP considered more or less risky than those with a persistent low level of AGMP? The GMI presents the model outputs, along with our analysis and interpretation of the data, to PVS who take the final decision on which crops the audit programme should focus on.

The quantitative risk assessments act as a decision support tool and form the basis for policy decisions on which crops should be audited each year. For each crop, the QRA also helps to identify points in its production where risk mitigation could most effectively be focussed. The GM Inspectorate regularly monitors worldwide GMO activity. The QRA models are normally updated every three years, however, if a significant event should occur in the intervening period for any crop, the model for that crop would be updated.

Risk-based audit programme

Each participating company producing or importing seed of interest is audited in detail once every three years. In the intervening years the company is asked to supply basic information about the seed they are marketing (crop type and variety, seedlot reference numbers, amount sold, originator of the seed and country of origin), which is compared with previous audit information. If the new data indicate a possible increase in risk for a particular company, for example if company procedures have changed or seeds have been imported from a new source, they may be asked to submit to a targeted audit. Seed companies that have undergone a detailed or targeted audit receive a full assessment report following their audit, together with recommendations for improving procedures where this is necessary.

Seed audits 2008-09

In 2008-09 the audit programme included seeds of *Zea mays* (maize, including sweetcorn), *Brassica napus* (winter and spring oilseed rape, swede and swede forage rape), *Brassica rapa* (turnip, turnip fodder rape, stubble turnips, pak choi, Chinese cabbage, etc) and *Glycine max* (soya) intended for agricultural and horticultural use and private company trials. Seed material entered into official trials (imported or UK-produced) is separately controlled by Defra PVS, although from 1st April 2009, seeds being placed in UK National List trials will also be included in the GMI audits. A summary of the seed audits completed in 2008-09 is provided in Table 2 in section 2 of this report.

- *Reporting the GMI seed audit programme*

A report on all basic audits is provided to PVS. Reports from detailed audits are presented to the audited company and copied to PVS. Summary tables listing all companies that participated in the seed audit programme are published annually. Each participant company is issued with their summary report and given a period of 20 calendar days in which to comment on the factual details. The seed audit summary reports are then published on the GMI website at: <http://www.gm-inspectorate.gov.uk/seedAuditProgramme/auditReports.cfm>.

- *Seed audit data management*

All data provided to the GM Inspectorate by participants in the seed audit programme are held securely in a bespoke database and are treated as commercial and in confidence. Seed companies participating in the audit can upload data directly if they choose to do so, and access their own data, held in the database via a secure extranet (<https://secure.csl.gov.uk/gmextranet/>).

1.3 Unauthorised GMO releases

The GM Inspectorate is also responsible for investigating any incidents where there has been a reported or suspected release into the environment of any GMO that has not been authorized for release in the UK or Europe. In the current reporting period two incidents have been investigated – further reports of genetically modified *Danio rerio* zebrafish being imported into England, and a small trial of winter oilseed rape that took place in the county of Somerset in 2007/08, which was subsequently found to contain a low level of AGMP.

Enforcement of the Environmental Protection Act 1981

GM Inspectors are appointed under Section 114 of the Environmental Protection Act 1990 (Part VI). The rights of entry of inspection and powers of inspectors are as described in sections 115 to 117 (inclusive) of the Act. A GM inspector may identify a potential breach of the relevant GM legislation in the course of official duties, or they may be notified to the GMI or the regulatory authority by a consent holder, a seed company or a member of the public. The GMI investigates all potential incidents on a case-by-case basis and takes action as appropriate. The GMI does not itself pursue prosecutions when an incident of potential non-compliance is identified; instead, all potential enforcement cases are referred to Defra investigations officers and lawyers for further consideration. No formal investigations were pursued in 2008-09, but please see section 2 of this report for details of potential non-compliances that were identified in connection with GM fish (section 2.2) and planting of seeds with an adventitious GM presence (section 2.4).

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

2.1 Field inspections and consent holder audits undertaken 2008-09

Table 1: Summary of field inspection programme for the 2008-09 financial year

Activity	Number	Consent number and reason for inspection	Outcome
Field inspections	5	06/R42/01 (planting). Potato. Modified for resistance to <i>Phytophthora infestans</i> (late blight)	In all cases the GM Inspectorate was content that the release was consistent with the conditions of the consent and did not identify any risks to human health or the environment posed by the GMO.
		06/R42/01 (growing season)	
		06/R42/01 (harvest)	
		07/R31/01 (planting). Potato. Modified for resistance to potato cyst nematode	
		07/R31/01 (termination of trial following an incident at the trial site)	
Post-trial monitoring inspection	5	01/R4/10/01 (2001)	In all cases the GM Inspectorate was content that monitoring of the former release site was consistent with the conditions of the consent and did not identify any risks to human health or the environment posed by the GMO.
		02/R4/12/01 (2003)	
		06/R42/01 (2007) (x3)	
Consent holder audit	3	BASF	The GM Inspectorate was content with procedures implemented by the consent holders for management of their consents
		University of Leeds	
		Advanced Technologies (Cambridge) Limited (post-trial monitoring only)	
Consent holder monitoring report(s)	2	06/R42/01	Defra was content with the end-of-year reports submitted.
		07/R31/01	

2.2 Suspect genetically modified *Danio rerio* zebrafish

In 2006 the GMI first reported that genetically modified *Danio rerio* zebrafish had been illegally offered for sale in England. At that time action was taken to remove the fish and notices were issued to the ornamental aquatic trade to alert them to the fact that GM fish are not authorised for marketing in the UK or Europe.

Reports of GM fish in 2008-09

In December 2008 a member of the public reported to the GMI that brightly coloured fish described as 'yellow red zebra danios' were on sale in a retail outlet. In collaboration with the Fish Health Inspectorate, the report was followed up. Analytical tests carried out on the fish confirmed that they were genetically modified

to contain genes that express red fluorescent protein¹¹. There are still no authorisations for the marketing of GM fish in Europe, so this remains an illegal activity. Our investigations indicated that the retailer had been supplied with the fish inadvertently. Investigations higher up the supply chain yielded little concrete information and it was not possible to establish contact with the supplier in the far east. A written warning was issued to the retailer and the importer of the fish.

A third information notice was then issued to all retailers and suppliers of ornamental fish registered with the Fish Health Inspectorate (http://www.gm-inspectorate.gov.uk/gmfish/documents/ImportGMfishV3_060109.pdf). The Ornamental Aquatic Trade Association (OATA) also cooperated with the GMI and circulated the notice to all its members. No further reports of GM fish have been received since December 2008. To date, in England, a total of five incidents of marketing GM fish have been reported and actions taken.

2.3 Monitoring adventitious GM presence in conventional seed stocks in England: Audits of seed importers and producers: 2008-2009

Table 2 Summary of seed audit programme for the 2008-2009 financial year (published 12th June 2009)

Audit type	Summary details
Detailed audit	Total number of companies contacted: 32 Reports completed: 14 Companies declining to participate: 8 Companies not marketing any crops of interest: 10 Companies not marketed any new material since last audit: 0
Collection of basic data on seeds marketed	Total number of companies contacted: 21 Reports completed: 17 Companies declining to participate: 1 Companies not marketing any crops of interest: 1 Companies not marketed any new material since last audit: 2
Targeted audit	2

The seed audit programme for 2008-09 was completed in May 2009 and summary reports were published on the GM inspectorate website in June (http://www.gm-inspectorate.gov.uk/seedAuditProgramme/documents/Combined_Seed_audit_summary_tables_2008-09-Final_120609.pdf). Most seed companies participating in the audit were found to have acted responsibly in managing the risk of AGMP in conventional seed. It was not necessary to recall or destroy any marketed seed because of an unauthorised adventitious GM presence. Nine companies known to be marketing seed within scope of the audit programme in England chose not to participate in the programme. Two targeted audits were undertaken in the 2008-09 programme; one of these was a company that was newly identified as importing seeds of maize from the USA for sale in England, and the other was a newly

¹¹Cloned from *Discosoma* spp. coral.

registered seed company that entered material for National List trials that was found to contain an adventitious GM presence (see section 2.4 below).

2.4 Oilseed rape with an adventitious GM presence

2.4.1 National list trials 2008

In September 2008, adventitious presence of the GM trait GT73¹² was detected in a winter oilseed rape (WOSR) candidate for national listing. GT73 oilseed rape is modified to be tolerant to glyphosate-containing herbicides, and although authorised for import and processing¹³ it is not authorised for general cultivation in the EU. The British Society of Plant Breeders, who coordinate the NL trials, had commissioned the testing on the basis of their own internal risk assessment. In England, sowing in NL trials was prevented but the variety had already been sown in a Recommended List trial in Scotland. Further investigation revealed that commercial trials of this and five other varieties with the same GM construct had been sown at sites in Scotland in autumn 2008. The GM Inspectorate for Scotland was responsible for dealing with this incident and their actions are reported at <http://www.sasa.gov.uk/gm/inspectorate/annualreports.cfm>.

In England, all of the seed submitted for NL trials was sent to the GM Inspectorate at Sand Hutton. This seed was sampled¹⁴ and screened for the presence of GM events. These tests indicated the presence of GT73 at a level of 0.05%. The seed was subsequently destroyed by the GMI.

2.4.2 Further investigation

As a result of this incident, the seed company concerned was asked to participate in a GMI seed audit. During the course of the audit and the preceding discussions, it was identified that a small (0.5 hectare) private trial had been sown in Somerset in autumn 2007 using the same WOSR seed as used in the NL trials. The trial had grown to harvest in summer 2008. At the time of planting the trial the company had been unaware that the seeds contained an AGMP. The seed company had also planted a small (0.5 hectare) trial of spring oilseed rape (SOSR) immediately adjacent to the affected WOSR trial. The seed used to plant this SOSR trial has been tested and no AGMP was detected.

The GM Inspectorate conducted a thorough review of the circumstances of the trial. The harvested grain from both trials had been held in store and was sampled to investigate the GM status. The WOSR was found to contain approximately 0.03% GT73, while the SOSR contained a trace of GM DNA of the event GT73. As the SOSR was free of AGMP when planted it was presumed to have acquired the trace of AGMP either by cross-pollination or admixture with the adjacent WOSR crop.

A detailed inspection of the trial site was also undertaken. The trial was sown in a predominantly pastoral area and it is thought that the nearest crop of oilseed rape in 2007/08 was approximately 4 miles away. Forage brassicas had been sown on the

¹² Monsanto Roundup Ready, tolerance to glyphosate.

¹³ Application for renewal of authorisation submitted.

¹⁴ All seed and grain sampling is done according to ISTA rules.

land immediately surrounding the trial, but these were grazed off and did not flower so there were no risks from cross-pollination with these crops. Machinery that was used to sow, spray and harvest the trial had not been shared. Based on the evidence gathered, and considering the very low level of AGMP in the seed that was sown, it was concluded that trial had posed a very low risk to the environment. However, the GMI developed a management and monitoring programme to ensure any volunteer oilseed rape plants that might emerge at the trial site are controlled. It is the responsibility of the seed company concerned to ensure that this monitoring programme is followed. The company was advised that the harvested grain could, in principle, be sold for feed purposes as it contained a GMO authorised for this use in Europe, or the grain could be disposed of. The company chose to dispose of the harvested WOSR and SOSR by sending it for deep burial at an authorised municipal waste site. The GM Inspectorate oversaw disposal of the grain in May 2009.

- *Actions taken as a result of the incident*

The company concerned was completely new to the European seeds industry and the contamination appeared to have occurred inadvertently on their part, largely through ignorance of European laws on GMOs in seeds and the potential risk of AGMP. The company operates a conventional breeding programme that is based in the USA. Through the GM Inspectorate's audit, the company was made aware of the need to assess the risks of AGMP in seed they intend to sow in England. A follow-up (targeted) audit will be conducted in the 2009-10 programme.

Since 2003, seed placed in official trials has not been within scope of the GM Inspectorate seed audit programme¹⁵. The audit programme does cover seed placed in private trials for all companies that are audited, however, newly registered companies and/or companies that have not, to date, marketed seeds in England within scope of the audit programme - such as the company in this incident - would not be covered by the audit programme. Discussions have been held on how to address this gap: in the 2009-10 programme, seeds submitted for official trials will be within scope of the audits and any companies newly registering to enter material into official trials will be referred to the GM Inspectorate and invited to participate in the audit programme.

¹⁵The responsibility of PVS

3. GMO research undertaken 2008 to 2009

3.1 Analysis of field trials management in Member States and prevention of accidental entry into the market place

In September 2007 CSL was commissioned to undertake research into the management of GMO field trials held in the EU member states under Part B of Council Directive 2001/18/EC. The study covered the period from when the Directive came into force in October 2002, to March 2008 and was undertaken for Directorate General Environment of the European Commission. The study was done in collaboration with the Scottish Agricultural Science Agency¹⁶.

The principal aims of the project were:

- i) To get an overview of official measures in place in the EU Member States for the management of field trials, including inspection and control measures by the relevant responsible bodies;
- ii) To assess the effectiveness of these management measures in the prevention of out-crossing from GM crops and other means of GMOs accidentally entering the market place;
- iii) To identify gaps and areas for additional guidance or follow-up work as well as examples of best practice.

Background research

The first step was to develop a searchable database containing details of all Part B notifications submitted under the Directive up to the end of March 2008. A review of current and potential future releases of GMOs in Europe was also conducted. These two steps were necessary to contribute to our understanding of what trials had taken place and the conditions placed on those trials, so that (a) we could target trials to focus on in the MS, and (b) to determine what trials might take place in the future. A review of the management framework in other countries (Australia, New Zealand, Canada and USA) was also carried out for comparison purposes and to identify best practice that could be adapted for use in the EC MS.

Regarding trials management, basic information on the management of GMO field trials was gathered from most EU member states and detailed information was gathered from seven selected¹⁷ member states (France, Germany, Hungary, Spain, Sweden, the Netherlands and the UK). Notifiers who had undertaken field trials in more than one member state also provided data on their experiences. The study covered trials of GM plants only, and the main focus was trials of GM maize, oilseed rape, potato, sugar beet and cotton (although very little information was available on trials of cotton).

The study concluded that, providing inspection and control and good communications between all parties involved in the field trials are maintained and reviewed regularly, there is no reason to believe that the systems currently in place in the MS should not be sufficiently robust to deal with, for example, increased numbers of releases or more complex GMO traits, and to continue to be fit for purpose. A number of

¹⁶ Now Science and Advice for Scottish Agriculture, <http://www.sasa.gov.uk/>

¹⁷ Selected by the European Commission.

recommendations were made to the Commission aimed at facilitating safe trials of GM plants under the Directive in the future.

The full report of the study can be downloaded at http://ec.europa.eu/environment/biotechnology/reports_com_stud.htm.

3.2 Adventitious GM presence arising through use of shared farming machinery, transport and storage equipment

The GMI is working with colleagues in the CSL (now Fera) GMO research team to assess the level of potential AGMP in winter oilseed rape that may arise due to the sharing of farming and transport equipment and storage facilities, between GM and non-GM production streams. The scope of the project includes practical assessment of on-farm processes, from seed sowing through to crop spraying, harvest, transport, drying and storage. The work will quantify sources of AGMP, measure the effects of AGMP mitigation, and collate and model data that can be used for best practice industry guidelines.

Fera is collaborating with a local agricultural college for on-farm aspects of the research. The college provides land for the crops required by the research, and the farming infrastructure required for machinery investigations. The large grain store facility (including grain dryers) at Fera's Sand Hutton site will be used to investigate post-harvest stages of the process. No GM seeds or crops will be used in the study: *Brassica juncea* will be used to investigate potential rates of admixture in oilseed rape.

The research is funded by Defra and will provide further evidence to underpin Defra's strategy on the coexistence of cultivation of GM and other crop types in England. The project commenced in January 2009 and will complete in Autumn 2010.

The project is listed on Defra's GMO research pages at: <http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=15811&FromSearch=Y&Publisher=1&SearchText=cb02049&SortString=ProjectCode&SortOrder=Asc&Paging=10 - Description>.

4. Looking ahead to the 2009 - 2010 reporting year

1. The Food and Environment Research Agency (Fera), was launched on 1st April 2009 as an Executive Agency of the Department for Environment, Food and Rural Affairs (Defra) with the merging of the Central Science Laboratory (CSL) with Plant Health Division (PHD), Plant Health and Seeds Inspectorate (PHSI), the Plant Variety Rights Office and Seeds Division (PVS) and the Government Decontamination Service (GDS). The GM Inspectorate team is now part of Fera's Evidence and Analysis programme.
2. Fera provides robust evidence, rigorous analysis and professional advice, underpinned by world-class research, to help Defra and other customers support and develop a sustainable and secure food chain, a healthy natural environment and protect the global community from chemical, biological, radiological and nuclear (CBRN) or major hazard material (HazMat) incidents. Fera provides operational policy and regulation in support of these activities, particularly in respect of plant health, bee health, crop varieties and seeds. In addition it undertakes and delivers high quality support and input into other regulatory issues relevant to its expertise. Fera provides research and development, advice and services to other public and private sector organisations on a commercial basis. Fera has responsibility to support Government in responding to and recovering from emergency situations, by providing emergency capability, scientific evidence and advice.
3. The creation of Fera brings the Defra Plant Variety Rights Office and Seeds Division (PVS) and the GM Inspectorate into the same Agency. The PVS team sits within a different programme at Fera and remains the customer for the seed audit programme, however, it is anticipated that benefits will be realised from the closer working relationships with the PVS team, and the Plant Health and Seeds Inspectorate. We will look closely at ways to rationalise inspection visits and data requests by sharing information, and at improving how we make information available to regulated businesses.
4. Further information about Fera is available at <http://www.fera.defra.gov.uk/>. The GM Inspectorate website address remains unchanged (<http://www.gm-inspectorate.gov.uk/>), and can be accessed via 'quick links' on the Fera home page.

5. *Hampton Implementation Review*

In 2009, the Department of Business, Innovation and Skills (BIS)¹⁸ will conduct a 'Hampton implementation review' of Fera. The purpose of the review will be to provide Fera and its stakeholders with a structured check on performance against the Hampton¹⁹ principles and the Macrory²⁰ characteristics for the regulation of businesses.

The review of Fera will include the Plant Health and Seeds Inspectorate, the Plant Varieties and Seeds team, and the GM Inspectorate. The Hampton Implementation review team will wish to interview a number of representative stakeholders and regulated businesses during the course of their review. The report will be published by BIS in due course.

¹⁸ BIS was created in June 2009 following a merger of parts of the Department for Enterprise and Regulatory Reform (BERR) with the Department for Innovation, Universities and Skills (DIUS).

¹⁹ Sir Philip Hampton's 2005 review, 'Reducing administrative burdens: effective inspection and enforcement' considered how to reduce unnecessary administration for businesses, without compromising the UK's excellent regulatory regime (<http://www.berr.gov.uk/files/file22988.pdf>)

²⁰ The Macrory Review (2006) looked at the main reasons businesses were not compliant, and what could be done to address the situation. Recommendations from the review aimed to ensure regulators had a set of modern and flexible sanctions to use that were proportionate and appropriate to the risks faced (<http://www.berr.gov.uk/whatwedo/bre/reviewing-regulation/compliance-businesses/page44102.html>)

5. Contact details

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

Or contact us at:
GM Inspectorate
Food and Environment Research Agency
Sand Hutton
York YO41 1LZ, UK

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

- 5.2 For further information on the Fera gemma (genetically modified material analysis) scheme please visit: <http://www.fapas.com/gemma.cfm>
Or contact us at:

FAPAS
Food and Environment Research Agency
Sand Hutton
YORK YO41 1LZ, UK

Telephone: +44 (0) 1904 462100
Fax: +44 (0) 1904 462111 or +44 (0) 1904 462040
Email: info@fapas.com
For test material sales: testmaterials@fapas.com
Web: <http://www.fapas.com/>

- 5.3 For further information about the Fera independent GM testing service please visit: <http://www.fera.defra.gov.uk/foodDrink/foodAnalysis/index.cfm>
Email: foodanalysis@fera.gsi.gov.uk

- 5.4 For information about GMO training courses please visit:
<http://www.fera.defra.gov.uk/training/>

Appendix 1: GM legislation and regulation in the UK

1. European Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EC: its implementation in the UK

- 1.1 In the European Union the deliberate release of GMOs is restricted under EU Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms²¹. This Directive provides a harmonised approach across all the EU member states to the assessment of risks to the environment and to human health in relation to the release and marketing of GMOs. In Great Britain Directive 2001/18/EC has been implemented by the Environmental Protection Act 1990 (Part VI) and regulations made under that Act (e.g. in respect of England, the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443)). The Department for Environment, Food and Rural Affairs (Defra), the Scottish Executive and the National Assembly for Wales have functions and responsibilities in relation to the deliberate release of GMOs.
- 1.2 The regulatory regime for GMOs has two key objectives, to protect human health and the environment and to ensure consumer choice. Enforcement must be effective, proportionate to risk, cost effective and promote public confidence. Under section 114 of the Environmental Protection Act 1990, GM Inspectors (currently there are 4) at Fera are appointed for the purpose of the inspection and enforcement of the legislation concerning deliberate release of GMOs in England. Clinical trials are inspected and enforced by the Health and Safety Executive.
- 1.3 EU Directive 2001/18/EC sets out measures for releasing a GMO for research or development purposes (Part B) and for placing a GMO on the market (Part C). Depending on the intended use of the GMO, an alternative route for commercial release of GMOs is available under EU regulation 1829/2003, (see below). GMOs must not be released into the environment until a thorough assessment of the GMO that is proposed for release has been undertaken. If authorisation is given it will be accompanied by specific conditions detailed within the consent to release the GMO, these are designed to safeguard against any risks to human health and the environment.

UK Competent Authority

- 1.6 In the UK consent to release a GMO under 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

²¹ In the EU, the contained use of genetically modified organisms is controlled by EU Directive 98/81/EC of 26 October 1998 on the contained use of genetically modified micro-organisms, and in the UK the Genetically modified organisms (contained use) regulations 2000 (S.I. 2000/2831), which is enforced by the Health and Safety Executive.

Secretariat to the Advisory Committee on Releases to the Environment (ACRE). ACRE is an independent advisory committee composed of leading scientists whose main function is to advise UK Ministers and the devolved administrations on the risks to human health and the environment from the release and marketing of GMOs²². ACRE reviews all Part B applications for consent to release a GMO and, if satisfied that the proposed release will have no adverse effects on human health or the environment, the Committee will advise that the consent may be issued. ACRE's advice may include recommendations for monitoring following completion of the trial, and other aspects of management of the release. Authorisation to place a GMO on the market under Part C of Directive 2001/18/EC is given at EC level after extensive consultation by the competent authorities of the EU member states. ACRE also reviews and advises on all Part C applications for the UK as well as on the environmental aspects of applications under the GM Food and Feed Regulation 1829/2003.

- 1.7 For more information on the regulatory process see the Defra website at <http://www.defra.gov.uk/environment/gm/regulation/index.htm>.

2. EC Regulation 1829/2003 on genetically modified food and feed

- 2.1 In April 2004 EU regulation EC/1829/2003 on GM food and feed came into force in the European Union. This regulation provides for a single Community procedure for the new authorisation of all food and feed derived from a GMO, of the GMO itself as a food or as a feed, and of food or feed containing the GMO. The European Food Safety Authority²³ manages the application and authorisation procedure centrally. Business operators may now file a single application for the GMO and all its uses; a single risk assessment is performed and a single authorisation is granted for a GMO and all its uses including cultivation, importation and processing into food/feed or industrial products.

- 2.2 The regulation specified a requirement for labelling of all GM food and feed which:

- i) contains or consists of GMOs (e.g. GM soya),
- ii) is produced from GMOs (e.g. glucose syrup from maize starch),
- iii) contains ingredients produced from GMOs (e.g. GM tomato paste).

The regulation makes provisions for tolerance of the technically unavoidable presence of authorised GMOs without the need to label. In England the regulation has been implemented by the Food Safety Act and regulations made under that Act (the Genetically Modified Food (England) Regulations 2004 (S.I. 2004/2335), and the Genetically Modified Animal Feed (England) Regulations 2004 (S.I. 2004/2334)).

- 2.3 The Food Standards Agency has responsibility for this regulation. Local authorities and Port Health authorities are responsible for the enforcement of

²² See <http://www.defra.gov.uk/environment/acre/index.htm>

²³ See http://www.efsa.eu.int/science/gmo/catindex_en.html

food safety and food standards import controls on food products, and they are the appointed enforcement bodies for these Regulations²⁴.

2.4 Applicants seeking authorisation for cultivation of a GM food or feed may still choose to submit a separate application for authorisation to cultivate the GMO under Part C of Directive 2001/18/EC. However, it is anticipated that Part C of Directive 2001/18/EC will be used mainly for applications such as flowers and industrial products that will not enter the food or feed chain.

3. EC Regulation 1830/2003 concerning the traceability and labelling of food and feed products produced from genetically modified organisms and amending 2001/18/EC.

3.1 The EU regulations on traceability and labelling of GMOs came into force in April 2004. This regulation establishes a harmonised EU system of documentation to account for and identify GM products throughout the supply chain, with the objective of facilitating accurate labelling. For certain products, a system of unique identifier codes will be used to allow access to specific information on GMOs from a community register of GM food and feed. In England the regulation has been implemented by the Environmental Protection Act and regulations made under that Act (the Genetically Modified Organisms (Traceability and Labelling) (England) Regulations (S.I. 2004/2412)). Defra has regulatory responsibility for this area and the local authorities and Port Health Authorities are the designated enforcement bodies.

3.2 Full details of regulations 1829/2003 and 1830/2003 can be found on the Food Standards Agency website at <http://www.food.gov.uk/gmfoods/> and http://www.food.gov.uk/gmfoods/gm/gm_labelling.

4. Evaluation of the regulatory framework for the cultivation of GMOs.

4.1 In December 2008, EC DG Environment launched a technical evaluation of the regulatory framework of the cultivation of GMOs under Directive 2001/18/EC on the deliberate release into the environment of GMOs and Regulation (EC) No 1829/2003 on GM food and feed and the marketing of their other uses under the Directive. The aim of the evaluation is to assess to what extent the legislative framework on the cultivation and marketing of GMOs and its implementation to date has achieved its objective of protecting human and animal health, the environment and consumers' interest, while ensuring the effective and efficient functioning of the internal market. The evaluation will cover risk assessment, management and communication, authorisation procedures, national safeguard measures, inspections and controls and confidentiality rules.

4.2 Further information about the review can be found at http://ec.europa.eu/environment/biotechnology/reports_culti.htm.

²⁴ See <http://www.food.gov.uk/enforcement/>

5. Current rules on genetically modified varieties and seeds²⁵

- 5.1 EU legislation on seeds (notably Directive 2002/53/EC on the Common Catalogue of varieties of agricultural plant species and 2002/55/EC on the marketing of vegetable seed) specifies that national authorities that have agreed to the marketing of seed of a certain variety on their territory must notify the acceptance of the variety to the European Commission. To qualify for inclusion in national catalogues varieties must meet defined Community criteria with respect to distinctness, uniformity and stability and, in the case of agricultural species, value for cultivation and use. Once a variety of seed is properly inscribed in a national catalogue, the Commission is informed and is required to inscribe the variety in the Common Catalogue by publication in the Official Journal; once this is done the seed of such a variety can be marketed throughout the EU.
- 5.2 Seed legislation also requires that genetically modified varieties must be authorised in accordance with EU Directive 2001/18/EC before they are included in the Common Catalogue and marketed in the EU²⁶. The Commission examines the information supplied by the Member State as regards inclusion in a national list to ensure it is in compliance with Community legislation and includes the variety concerned in the Common Catalogue of varieties. As of 1st July 2009 there were more than 70 varieties of genetically modified maize MON810 registered in the Common Catalogue.

²⁵ http://ec.europa.eu/food/food/biotechnology/gmfood/qanda_en.htm

²⁶ If the seed is intended for use in food or feed, it can also be authorised in accordance with the GM food and feed Regulation 1829/2003