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Genetic Modification Inspectorate Annual Report on GMO inspection and enforcement activities in England

01 April 2015 - 31 March 2016

Date: August 2017

Animal & Plant Health Agency

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Contents

Executive summary

Genetic Modification Inspectorate activities 2015/16

1. The APHA Genetic Modification Inspectorate (GMI) is responsible for the enforcement of legislation relating to the deliberate release[1] and marketing of genetically modified organisms (GMOs) in England, and for the inspection of GMO deliberate release sites to ensure that they comply with conditions laid down in each consent. This report covers inspection and enforcement work, and related activities, carried out by the GMI during the period 1st April 2015 to 31st March 2016.

2. Currently there is no commercial cultivation of GM crops in the UK, therefore the focus of the GMI's statutory inspection and enforcement work has been to ensure that small-scale experimental releases of GMOs are conducted in accordance with the conditions specified in their respective release consents. During the reporting period one small-scale GM research trial was carried out in England, in the form of a release of *Camelina sativa* (camelina) genetically modified to produce omega-3 long-chain polyunsaturated fatty acids. The GMI confirmed that the release complied with the conditions laid down in the consent, and no risks to human health or environment were identified.

3. The GMI carried out post-trial inspections of seven former GM potato trials, all of which were found to be managed in accordance with the respective release consents. In addition, the GMI undertook two management audits to assess the procedures consent holders have in place to manage their releases. In both cases the consent holders were found to be acting responsibly and managing their releases in accordance with prescribed requirements.

4. Separate to its work to ensure the safe deliberate release of GMOs, the GMI has a role in assisting seed companies in ensuring they have appropriate controls in place to minimise the risk of adventitious GM presence (AGMP) in the seed they handle. During the reporting year, as part of this work, the GMI carried out 12 detailed seed audits and 19 basic seed audits. All the companies that participated in the GMI audit programme were considered to have acted responsibly in managing the risk of AGMP in their seed.

5. During the reporting period the GMI investigated seven incidents involving the importation, release and/or marketing of suspected unauthorised GMOs, including: ornamental cotton seed; two varieties of hybrid rape seed; an oilseed rape variety entered into National List variety trials; a consignment of kale seed; and two cases of suspect GM ornamental fish.

[1] This applies to the release of GMOs other than those in clinical trials. Responsibility for enforcing legislation controlling the deliberate release of GMOs in clinical trials (e.g. GM vaccines) is the responsibility of the Health and Safety Executive.

6. The ornamental cotton seed, one of the suspect GM fish cases and the oilseed rape seed in the variety trial were confirmed to have GM presence. For the kale and the hybrid rape seed, further investigations by the GMI revealed that positive GM test results reported by commercial test laboratories, commissioned by the seed producers, were due to the unavoidable presence of common microorganisms, elements of whose DNA are often used in GM constructs. One case of what appeared on visual inspection to be GM fluorescent fish was not confirmed by molecular-based DNA tests.

7. The GMI ensured that the two companies that had unwittingly imported GM seed put appropriate measures in place to remedy the problem, and ensure there was no risk to human health or the environment and no legacy of GM plants remaining in the environment. The GM fish were removed from sale.

8. The GMI provided expert representation at two EU Coexistence Bureau committee meetings, one on the coexistence of GM and non-GM cotton, and one on the coexistence of GM and non-GM potato.

1. The work of the Genetic Modification Inspectorate

The role of the GM Inspectorate

The European Union (EU) has strict rules in place governing the release of genetically modified organisms (GMOs)[2] to the environment, and any organisation wishing to carry out a release must go through a formal process to obtain official consent. The Genetic Modification Inspectorate for England is part of the Animal and Plant Health Agency, and has designated responsibility for ensuring compliance with legislation concerning the deliberate release to the environment of GMOs[3]. This legislation is designed to ensure that experimental field trials of GMOs are carried out in such a way as to minimise any risk to human health or the environment.

The GMI has statutory responsibility to:

- Inspect all deliberate release trials of GMOs, conducted in England, to ensure they are carried out in accordance with the limitations and conditions of their respective consents;
- Investigate any potential breaches of the GM deliberate release legislation, such as the unauthorised release of GMOs; and
- Provide impartial, evidence-based, advice on GMO issues to policy makers and stakeholders.

The GMI undertakes this work on behalf of the Department for Environment, Food & Rural Affairs (Defra) Genetic Resources and GMO Team (Defra GMO Team)

In addition to carrying out its statutory duties, the GMI is responsible for assisting seed companies in their obligation to minimise the risk of adventitious GM presence in conventional and organic seed they produce in England and/or import into England. This work is carried out on behalf of the Defra Variety and Seeds policy team, and is covered in Section 3 of this report.

The GMI is responsible for ensuring compliance with UK legislation controlling the release and marketing of GMOs, thereby minimising any risk to human health and the environment.

[2] Organisms as defined in European Directive 2001/18/EC.
[3] Experimental GMO trials other than clinical trials of GM vaccines, which are the responsibility of the Health and Safety Executive (see: www.hse.gov.uk/biosafety/GMO/index.htm - accessed 09/04/15)

2. The GM Inspectorate field inspection programme

The GMI field inspection programme

- *Inspection of GMO deliberate release field trials*

The GMI's field inspection programme is designed to ensure that GMO deliberate release trials remain consistent with the limitations and conditions of their respective consents, and to make sure any potential risks to human health or the environment are kept to a minimum. To achieve this the GMI undertakes audits of the systems consent holders have in place to manage their releases, and conducts field inspection visits to ensure these systems are properly implemented *in situ*. GMI management audits and field inspections are described in more detail overleaf.

Field inspection of a 2015 GM camelina (*Camelina sativa*) release.

During the 2015-16 reporting year one GMO was released in experimental research trials in England. This was the oil-bearing plant *Camelina sativa*, modified to produce omega-3 long-chain polyunsaturated fatty acids. In addition there were a number GM trials in the post-trial phase of the release (see Box 1).

Box 1: **Part B GM trials 2015-16**

One Part B (experimental) release of a GMO was carried out in England in the 2015-16 reporting period:

- Camelina (*Camelina sativa*), modified for the production of omega-3 long-chain polyunsaturated fatty acids - release carried out in spring 2015 by Rothamsted Research (consent 14/R8/01).

In addition, the following releases were in the post-trial monitoring phase:

- Camelina, modified for the production of omega-3 long-chain polyunsaturated fatty acids - release carried out in 2014 by Rothamsted Research (consent 14/R8/01).
- Potato, modified to resist late blight - releases carried out in 2010, 2011 and 2012 by The Sainsbury Laboratory (consent 10/R29/01);
- Potato, modified to resist late blight - releases carried out in 2007 and 2008 by BASF (consent 06/R42/01).

For further information on consents granted to release genetically modified organisms see: *https://www.gov.uk/government/collections/genetically-modified-organisms-applications-and-consents*

GM Inspectors work closely with consent holders to ensure that the requirements and limitations of their respective consents are understood and adhered to, and releases are carried out in a safe and controlled manner.

GM camelina at the flowering stage.

- *Consent holder management audits undertaken in 2015-16*

Before a GMO is released GM Inspectors undertake an audit of the systems the consent holder will use to manage the release, in order to determine whether they have appropriate arrangements in place to ensure the safe and effective operation of the trial. Such pre-release audits include comprehensive checks on the relevant aspects of administration and infrastructure, details of the management chain, the systems in place for receipt, storage and transport of plant material, plans for planting and safe disposal of material at harvest. The audit also looks at growing-season monitoring plans and how the consent holder would respond if the integrity of the trial were compromised.

Additionally, pre-release management audits look at the safeguards the consent holder has in place to ensure that only those modifications covered by the consent are released. As such, consent holders must provide suitable evidence that the GMO for release matches the description set out in the application for release, and in the consent conditions, and that no adventitious GMOs are present. Evidence may be in the form of the results of analysis (e.g. from PCR testing) and/or in the form of documentation relating to the production of the GMO, including maintaining genetic isolation during initial production, bulking, storage and transport.

In the case of consents that are in the post-trial phase of the release, management audits are carried out prior to the commencement of post-trial monitoring by the consent holder. Such audits are aimed at ensuring consent holders have appropriate policies and procedures in place for managing volunteers and/or groundkeepers, are adhering to subsequent cropping restrictions (as appropriate), and ensuring the limitations and conditions of the consent continue to be met.

Management audits continue to be carried out whilst the consent remains active. Once the GMI is satisfied that the monitoring and control requirements have been fulfilled the consent holder can apply to the Defra GMO Team for termination of the release, which, if granted, means the release site can revert to its normal use.

Following each management audit a detailed report is produced setting out the findings of the audit and specifying any required actions and recommendations. The consent holder and the Defra GMO Team are given the opportunity to comment on the factual aspects of the report, after which a finalised version is sent to both parties.

Box 2 gives a synopsis of deliberate release consents.

Box 2 - **deliberate release consents, an overview:**

Experimental GM trials are authorised under Part B of EC Directive 2001/18/EC, which sets out the rules for deliberate release into the environment of GMOs for any purpose other than for placing on the market, including that of scientific research. Such 'Part B' trials may be undertaken for a variety of reasons, including product development, demonstration purposes or pure research. Approvals to release GMOs are granted by the Secretary of State under authority of the Environmental Protection Act 1990 and the Genetically Modified Organisms (Deliberate Release) Regulations 2002.

Each letter of consent sets out the particulars of the release, including details of the organism and its modification, the maximum size of the release, its location, and its purpose. Included with the letter is a schedule setting out specific limitations and conditions (e.g. setting isolation distance and/or using a pollen barrier) applicable to the release in order to ensure that any risks of damage to the environment are minimised.

The marketing of GMOs takes place under Part C of Directive 2001/18/EC. Applications for approval to market a GM product (including seeds for cultivation, and food or feed use) are assessed and decided upon at EU level.

During the 2015-16 financial year the GMI conducted two consent holder management audits, both of which were in relation to GM potatoes in the post-trial phase of release. The first audit concerned the on-going management of releases carried out in 2007 and 2008 by BASF Plant Science GmbH (consent 06/R42/01); the second audit was in relation to releases carried out in 2010, 2011 and 2012 by The Sainsbury Laboratory (consent 10/R29/01). Table 1 below shows a summary of these management audits. In both cases the GM Inspectorate was satisfied that the consent holders had appropriate procedures in place to ensure that the post-trial management complied with the conditions and limitations set out in their respective consents.

- *Growing season field inspections undertaken in 2015-16*

The GMI is contracted to inspect each new Part B experimental release during the growing season to ensure compliance with the limitations and conditions of the consent for release. Dependent on the type of GMO and the individual consent conditions and limitations, inspections may include checks on the location, layout and dimensions of each trial, the isolation distance from related crops/species, the width of the pollen barrier (where applicable), consent holder monitoring plans, and details of planned agronomic operations (including protocols for sowing, harvest, and crop disposal). Key times for carrying out inspections are at planting, prior to or during flowering, at harvest and at crop disposal. Additional inspection visits may be carried out depending on the findings of earlier inspections and whether there are any identified or potential risks.

In 2015 a single deliberate release trial of a GMO was conducted in England (note: the management audit for this release was conducted in March 2015, and is reported in the GMI 2014-15 annual report). The release was a small-scale research trial of GM *Camelina sativa* (common names: camelina, gold-of-pleasure, and false flax), and was carried out by Rothamsted Research under consent 14/R8/01 (see https://www.gov.uk/government/publications/genetically-modified-organisms-rothamsted-research-14r801). This oil-bearing crop has been modified by Rothamsted Research to produce omega-3 long-chain polyunsaturated fatty acids, commonly known as 'fish oils', through the introduction of the biosynthetic genes comparable to those found in marine microorganisms such as diatoms and microalgae[4].

The GMI carried out a field inspection of the camelina release site in June 2015, just prior to flowering. The visit confirmed that the release was being conducted according to the conditions of the consent, and there were no risks to human health or the environment. Following the inspection a report was sent to the Defra GMO Team detailing the findings of the visit. All growing season field inspection reports are placed on the GMI website (see: https://www.gov.uk/guidance/gm-inspectorate-deliberate-release-inspection-programme#experimental-part-b-releases).

Experimental plots of GM camelina, modified to trial production of a sustainable source of omega-3 'fish oils'.

[4] Further information on this GMO, and the research being undertaken on it, can be found on Rothamsted Research's website see: http://www.rothamsted.ac.uk/camelina (accessed 09/10/16).

- *Post-trial monitoring inspections undertaken in 2015-16*

As well as stipulating conditions relating to the growing crop, experimental release consents often have requirements that apply after the GMO has been harvested and/or terminated. These post-trial specifications generally include a period of monitoring by the consent holder (for example, checking for and controlling volunteers and/or groundkeepers), and usually include cropping restrictions (for example, leaving the site fallow for a specified period and/or not growing specific crops). The purpose of such conditions is to ensure that, as far as reasonably possible, no GMOs remain in the environment once the trial has been completed.

To ensure that consent holders are fulfilling their duties with regard to the post-trial conditions of their releases, GM Inspectors continue to visit all former deliberate release sites that are subject to post-trial conditions.

In 2015 the GMI conducted seven post-trial monitoring inspections relating to three consents. These were comprised of visits to one former GM camelina release (trial undertaken in spring 2014), and visits to five former GM potato trials conducted under two separate consents (releases in 2007 and 2008, and from 2010 to 2012, respectively).

- *Consent holder monitoring reports*

At the end of the growing season consent holders are required to submit a report to the Secretary of State for Environment, Food and Rural Affairs giving details of the monitoring they have carried out, the findings of this monitoring, and any risk-management measures applied. These reports facilitate an assessment of the release, and determine whether the measures informed by the risk assessment were adequate, or whether any amended or additional measures are needed in future to prevent or mitigate risk. In the case of releases authorised to take place over more than one year, consent holder growing-season reports help Defra determine whether it is appropriate for the trial to continue; post-trial monitoring reports provide Defra with information on the effectiveness of the measures in place to control any GM volunteers or groundkeepers.

Consent holder reports are assessed by the GMI to ensure they are in accordance with the requirements of the relevant EC Decision[5], before being sent to the Defra GMO Team for its consideration. The final trial report is forwarded on to the European Commission.

[5] 2003/701/EC: Commission Decision of 29 September 2003 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003D0701&qid=1456833954997&from=EN, accessed 09/10/15).

Following the specified period of post-trial monitoring, and assuming all the consent criteria have been fulfilled, the consent holder can apply to Defra for termination of the release. Once the release has been officially terminated the land upon which the trial took place can revert to its normal use.

Table 1, shows the range of field inspection activities carried out during the reporting period.

Table 1 - Summary of GM inspection-related activities carried out in the 2015-16 financial year

Activity	Number of inspections	Consent holder / number and type	Outcome
Field inspections – growing season	1	Rothamsted Research, consent 14/R8/01; Crop type: Camelina - modified to produce omega 3 oils: (spring 2015 release).	The GM Inspectorate was content that each release was consistent with the limitations and conditions of its respective consent and did not identify any risks to human health or the environment posed by the GMOs.
Field inspections - post-trial monitoring (PTM)	4	Rothamsted Research, consent 14/R8/01; Crop type: Camelina - modified to produce omega 3 oils: (spring 2014 release)	
		BASF, consent 06/R42/01; Crop type: potato - modified for resistance to late blight (2008 release).	
		BASF, consent 06/R42/01; Crop type: potato - modified for resistance to late blight (2007 release).	
		The Sainsbury Laboratory, consent 10/R29/01; Crop type: potato – modified for resistance to late blight (2010, 2011 & 2012 releases).	
End of season monitoring reports submitted by consent holders	5	Rothamsted Research, consent 14/R8/01: one growing season monitoring report covering the Camelina release carried out in 2015.	The GMI and Defra GM Team were content with all end-of-year reports submitted by consent holders.
		Rothamsted Research, consent 14/R8/01: one post-trial monitoring report covering the Camelina release carried out in 2014.	
		BASF, consent 06/R42/01: two post-trial monitoring reports covering potato releases carried out in 2007 and 2008.	
		Sainsbury Laboratory, consent 10/R29/01: one combined post-trial monitoring report covering potato releases carried out in 2010, 2011 & 2012.	
Consent holder management audits	2*	The Sainsbury Laboratory, John Innes Centre - consent 10/R29/01; potato (post-trial management audit, 24/02/16).	The GM Inspectorate was content with the procedures implemented by all consent holders for the management of their respective consents.
		BASF Plant Science GmbH consent 06/R42/01; potato (post-trial management audit, 16/02/16).	

*Note: the management audit for Rothamsted Research consent 14/R8/01 (spring 2016 release) was carried out in April 2016, and will feature in the GM Inspectorate's 2016-17 annual report.

- *Overall findings of the 2015-16 field inspection programme*

Management audits confirmed that all consent holders had suitable procedures in place to manage their releases appropriately. All deliberate release trials of GMOs carried out in 2015-16 were inspected and found to be consistent with the conditions set out in their respective consents; none of the releases were found to pose a risk to human health or the environment. Post-trial monitoring inspections confirmed that all consent holders were effectively managing the post-trial phases of their releases, and the GMI and the Defra GMO Team were content with all end-of-year reports submitted by consent holders.

In conclusion, all consent holders were found to be managing their GMO releases and trials sites in accordance with the conditions of their respective consents.

- *Other activities relating to the GMI's inspection and enforcement function*

In addition to carrying out management audits of consent holder and field inspections of deliberate release trials, the GMI is responsible for providing advice to the Defra GMO Team on inspection and enforcement issues, for managing the receipt and evaluation of consent holder end-of-season reports, and for providing expert representation on GM inspection and GM risk-related matters at stakeholder meetings and workshops, as appropriate.

European Enforcement Project:
The GMI is a member of the European Enforcement Project (EEP) on Contained Use and Deliberate Release of GMOs. This annual gathering provides a forum for discussion and information exchange between official GMO inspection and enforcement bodies operating throughout the EU. The meeting, in June 2015, was attended by the Head of the GMI, who gave a presentation on contingency planning.

Other presentations and topics discussed included an overview of Directive (EC) 2015/412 (establishing the possibility of Member States restricting or prohibiting the cultivation of GMOs in their territory – the 'opt out' clause) and its implementation in Austria; new breeding techniques (specifically CRISPR-Cas, synthetic biology, and the Rapid Trait Development System); the European Food Safety Authority´s role in the risk assessment of GMOs; and inspectors' experiences of inspection in contained use and deliberate release.

European Coexistence Bureau:
In November 2015 the GMI participated in a workshop organised by the European Coexistence Bureau[6], which has the remit of establishing crop-specific guidelines for the coexistence of GM, conventional and organic crops (see Section 5 for further information).

[6] See: http://ecob.jrc.ec.europa.eu/ (accessed 09/11/15)

3. The GM Inspectorate seed audit programme

- *Background to the GMI audit programme*

In the EU there are strict rules[7] governing the release and marketing of GMOs, which specify that before any new GM line can be sold it must be rigorously assessed and shown to be safe to human health and the environment. Only then is the GMO approved for sale. Currently the UK does not grow any GM crops commercially, but there are large areas of the world where such crops are cultivated on a commercial basis, and because of this there is the potential for non-GM seed to acquire the accidental (adventitious) presence of GMOs, either by cross-pollination or due to seed admixture. These GMOs may not have been approved in the EU, therefore UK companies importing and/or marketing seed of at-risk species, for planting, must have appropriate controls in place to minimise the risk of adventitious GM Presence (AGMP) in their seed.

GM varieties of crops such as oilseed rape are grown in many countries around the world. To minimise the risk of adventitious GM presence in seed of at-risk crops UK seed companies must have appropriate controls in place.

To help these companies comply with this legislation the GMI undertakes, on behalf of Defra, a programme of audits of companies that handle and market non-GM seed (i.e. conventional and organic seed) for cultivation in England.

- *What do seed audits involve?*

Each audit visit to a seed company involves looking in detail at the various stages of seed production, including variety development, sowing, growing, harvest, transport and storage, and processing. At each of these stages the risk of adventitious GM presence is explored, as are the controls in place to manage this risk. Where appropriate the GMI helps companies explore ways in which their controls can be further improved. This work is carried out on behalf of the Defra Variety and Seeds policy team, which is responsible for the Seed Marketing Regulations, and the Defra GMO Team, which is responsible for upholding GM legislation.

[7] GM crops may only be grown within the EU if they are authorised for cultivation and the varieties offered for sale have been placed on the Common Catalogue of Varieties. Currently only one GM line is authorised for cultivation in the EU: MON810 maize modified with a cry1A (b) gene which confers resistance to lepidopteran pests (see: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm).

By focusing resources towards the beginning of the seed production/marketing chain the GMI aims to achieve the widest coverage in terms of proportion of eligible seed marketed, whilst reducing the burden on the seeds industry as a whole, in accordance with principles of better regulation. The GMI therefore concentrates its activities towards those seed companies in England that produce and/or import seed, rather than visiting every seed merchant.

Box 5, provides an overview of EU rules concerning purity standards for seed for sowing, and summarises the aims of the GMI seed audit programme.

Box 5 - **GMOs in seed – EU rules and the GMI seed audit programme**

EU seed certification rules prescribe minimum standards for the presence of seed of other species and other varieties in the final product. Current seeds legislation does not stipulate labelling thresholds for AGMP of authorised GMOs in conventional seed, and neither is there an acceptable tolerance level for the presence of unauthorised GMOs. This means that:

- Conventional seed containing any level of a GMO that is authorised for commercial cultivation in Europe must carry a 'GM' label, and;
- Seed containing a GMO, at any level, that has not been authorised, must not be marketed or released to the environment.

The GMI seed audit programme is designed to ensure that the relevant legal requirements are upheld by helping businesses in England manage and minimise the risk of their conventional seed stocks inadvertently acquiring an unauthorised GM presence.

Note: at present only one GM event is authorised for cultivation in the EU: MON810 maize, which confers resistance to lepidopteran pests, particularly the European corn borer (*Ostrinia nubilalis*). However, the European corn borer is not a pest in the UK and the varieties of maize that have been produced with the MON810 event tend not to be suitable for UK conditions. Consequently there is no economic benefit to farmers to grow MON810 maize in the UK.

- *What species do the audits cover?*

Seed of crop species that are at risk of AGMP are determined using quantitative risk assessment modelling. For 2015/16 the most at-risk species were identified as:

- *Brassica napus* (winter and spring oilseed rape, swede, etc.);
- *Brassica rapa* (turnip, turnip fodder rape, stubble turnips, pak choi, etc.);
- *Glycine max* (soya);
- *Zea mays* (maize, including sweetcorn).

GMI audits include seed intended for agricultural and horticultural use, official trials and private company trials.

Because there are currently no thresholds for unauthorised GMOs in conventional seed and there are no statutory rules on how AGMP risk in seed should be managed, participation in the GMI seed audit programme is voluntary. Seed companies are invited to participate in the audit programme as a way of ensuring they are effectively managing the risks of AGMP in their seed. Box 6, below, outlines the three types of audit the GMI undertakes.

Box 6 - **GMI seed audits fall into three categories, as follows:**

- Detailed audits: these are scheduled to take place once every three years, and involve a visit to the company by a GM Inspector who carries out a thorough assessment of the risk of AGMP to the company's seed, and the controls in place to minimise this risk. The Inspector then produces a detailed report, which includes recommendations on how the company can further improve its controls, where applicable. In cases where a significant risk of AGMP is identified, the company may be requested to participate in a Targeted audit, which would normally take place before the next growing season (see below);
- Basic audits: these take place in the intervening two years (between detailed audits) and involve an assessment of the company's practices to determine whether there has been any significant change in risk since the last detailed audit. Change in risk is evaluated in terms of species marketed, countries of origin, and company controls such as GMO testing. Following the audit a short report is produced detailing the findings. If the risk of AGMP is deemed to have increased significantly the GMI may request that the company participates in a Targeted audit;
- Targeted audits are carried out when there is considered to be an elevated risk of AGMP in a company's seed, but the company is not scheduled for a detailed audit. Targeted audits can arise due to the findings of detailed and basic audits, and generally focus on specific risk elements, including whether any previous recommendations relating to these risks have been implemented.

Reports resulting from Detailed and Targeted audits are sent to the company to alert them of any vulnerabilities in terms of AGMP in seed, to inform them of the suitability of their controls, and to give them notice of any recommendations to enhance these controls. Basic audit reports are more formulaic and are not sent to the company. A copy of each report is sent to the Defra Variety and Seeds policy team.

- *Seed audits carried out during 2015-16*

During the 2015-16 audit period there were 55 seed companies in England that were considered eligible for inclusion in GMI's audit programme. No companies were considered to need a Targeted audit. Table 2, overleaf, shows the number and type of seed audits undertaken in 2015/16.

Table 2 - Summary of seed audit programme for the 2015-2016 financial year

Audit type	Summary details
Detailed audits	Audits undertaken and detailed reports completed: **12**
Basic audits	Audits undertaken and reports completed: **19**
Targeted audits	No targeted audits were required
Non-participants	Companies declining to participate**: 7**
No crops of interest	Companies not marketing any crops of interest: **12**

In the audit reports to individual seed companies the GMI made a number of minor recommendations aimed at helping them further improve their management of AGMP risk. In all cases such recommendations were designed to strengthen existing protocols and procedures, rather than signifying an underlying lack of control. No major recommendations were made in any of the audit reports, and the GMI were satisfied that all companies that participated in the 2015-16 audit programme had acted responsibly in the way in which they had managed the risk of AGMP in their seed.

The GMI investigated a number of GM seed-related incidents in 2015-16, and these are described in Section 4, below. It was not, however, necessary for the GMI to prohibit the marketing of any seed of agricultural species due to the suspected or confirmed presence of an unauthorised GMO.

Summary reports are published annually on the GMI website - see: https://www.gov.uk/guidance/gm-inspectorate-seed-audit-programme#audit-summary-reports. These show the seed companies that the GMI have audited, the species of the seed they marketed, the countries of origin of this material, and the overall findings of the audits.

4. Incidents involving unauthorised GMOs

Unauthorised release of GMOs

In addition to auditing seed companies and ensuring experimental field trials comply with their respective consent conditions, the GMI has statutory responsibility to investigate any incidents, in England, where there has been a suspected or confirmed infringement of GM deliberate release legislation. GM Inspectors have a number of powers, conferred under Section 125(1) of Part VI of the Environmental Protection Act 1990, which (for example) grant rights of entry and inspection, enables inspectors to take samples and collect evidence in relation to suspect GMOs, and deal with the cause of any imminent risk to the environment. Breaches or potential breaches of GM deliberate release legislation are investigated on a case-by-case basis and action is taken as appropriate. Incidents that were investigated in the 2015-16 reporting period are detailed below.

Reported contamination of ornamental cotton seed in the UK

In April 2015 the GMI was notified by the Defra GMO Team of an unintentional transboundary movement of GM cotton seed for sowing. The alert came from the Dutch Human Environment and Transport Inspectorate, which had been informed by a Dutch seed company that several seed lots of decorative cotton *Gossypium herbaceum* (an ornamental species of cotton) may contain GM seeds. The Dutch seed company had itself been alerted by a Japanese client, which had detected GM presence using PCR-screening methods. The GMO-containing seed lot was purchased by the Dutch company in China, and 120 kg was shipped to producers of packet seed worldwide.

Testing by the Dutch National Reference Laboratory for GMO analysis detected trace amounts of GM cotton (*Gossypium hirsutum*) line MON531, which is resistant to lepidopteran pests. MON531 is authorised in the EU for food and feed use (authorisation renewed 2015), but not for cultivation. Assessment by the Dutch expert committee on Genetic Modification (COGEM) concluded that there is no risk to human health or to the environment from the GMO, and that cotton (*G. herbaceum* as well as *G. hirsutum*) is extremely unlikely to form viable populations due to the climate of Western Europe.

The GMI contacted the Dutch authorities and it was confirmed that a small quantity (0.34 kg) of the lot had been sent to one company in the UK. Upon confirmation that the seed should not be marketed the UK company sent all unsold seed back to the Dutch company and supplied the GMI with evidence of this transaction. The company had sold 43 packets of this seed, each containing approximately 25 seeds. The company recalled seed from retailers. Advice from the Advisory Committee on Releases to the Environment (ACRE) was that seed presented no risk to health or the environment.

Suspected GM presence in hybrid rape/kale seed for marketing in the UK

In May 2015 the GMI were contacted by a UK seed company which reported that, during routine PCR testing, a gene for neomycin phosphotransferase *NptII* (conferring antibiotic resistance) had been detected in two seed lots of two varieties of "utility rape" (a 'rape/kale' hybrid between *Brassica napus* and *B. oleracea*) produced in New Zealand. *NptII* detection in seed can be due to GM presence or it can be due to the presence naturally occurring *Escherichia coli* or *Streptococcus faecalis* bacteria (both of which contain the *NptII* gene) on the seed coat. Testing (carried out by a laboratory in New Zealand) was negative for a number of other genes and events associated with genetic modification.

Although some seed had already been sold by the UK company, there was no immediate risk of cross-pollination to other compatible crops because the crop requires a vernalisation period before flowering in the second year after sowing. The GMI issued a Prohibition Notice to the UK company to prevent further sales of the seed, and the company confirmed that they were taking steps to trace and recall unsown seed. Subsequent PCR testing commissioned by the company proved negative for *NptII* for both seed lots. A detailed investigation by the GMI, in cooperation with the UK- and New Zealand-based seed companies and the New Zealand laboratory, plus input from UK PCR diagnostic experts, determined that the initial positive *NptII* result was most likely due to bacterial contamination of one of the laboratory's reagents or purification columns, and the original positive results for *Npt*II were not due to AGMP. Based on this conclusion the GMI revoked the Prohibition Notice and allowed the company to recommence marketing of the seed.

GM presence in oilseed rape seed entered in UK National List trials

In October 2015 the GMI was contacted by a UK seed company to report that it had received a positive GM test result for a candidate winter oilseed rape variety that it had entered into UK National List and private trials in England and Scotland. An investigation by the GMI, in cooperation with the company and the Scottish Inspectorate (https://www.sasa.gov.uk/wildlife-environment/gm-services), determined that 25 trial sites were affected in the UK, and that the issue was Europe-wide, with material sown in the Czech Republic, Denmark, France, Germany, Hungary, Poland, Romania, and the Ukraine.

A National List trial site showing one of the affected plots following plant destruction.

The seed in question was produced in France by the parent company and imported into the UK where it was sown in trials around mid-August. Although the seed was PCR tested in France prior to export, the test results were only made available to the UK arm of the company after the seed had been sown. The time of drilling and type of plant meant that there was no risk of the plants flowering until spring 2016, and on the advice of the GMI the company began recalling unsown seed. The company confirmed that all other batches of seed sent for National List trials had tested negative.

The initial positive testing result was not definitive for GM presence, and further testing was carried out which identified the presence of the BXN gene, which is a component of the GM line OXY-235 (developed by Bayer CropScience to confer tolerance to oxynil herbicide, and authorised for cultivation in Canada and Japan, but not authorised for sowing in the EU).Quantitative testing in France confirmed the GM presence to be approximately 0.39%. The French competent authority reported that in the 1990's/early 2000's the site in France where the affected seed was produced had previously been used for the cultivation of 'experimental' lines of oilseed rape, including OXY 235, and this is considered the most likely source of the contamination.

The UK company put forward a management and monitoring plan which included destroying the affected plots and carrying out regular monitoring for oilseed rape regrowth and volunteers. The English and Scottish GM Inspectorates confirmed that the company's plan was appropriate and proportionate, and monitored progress by liaising with the company and trials officers, and by undertaking targeted inspections to ensure compliance. The plan required that monitoring continue up to spring 2017, and that appropriate subsequent crops are planted that allow the use of herbicides designed to kill broad-leaved weeds. The GMI will continue to require the company to undertake monitoring and post-trial treatment until it is clear that there is no realistic likelihood of AGMP in the environment, or in neighbouring/ future crops.

Affected plots were monitored for regrowth and volunteers. The GMI carried out targeted inspections to ensure effective management.

Suspected GM presence in hybrid rape/kale seed for marketing in the UK

In November 2015 a UK seed company reported the detection of CaMV p35S in another batch of fodder kale seed for marketing in the UK. The batch of seed was also positive for native cauliflower mosaic virus DNA (which is the source of most p35S used in genetic constructs) and negative for a range of other GM genes/elements. The GMI assessed the testing regime in respect of all commercial GM oilseed rape lines, and this confirmed that there is no known commercial event that contains p35S without any of the other elements tested for.

Having previously anticipated such so-called 'single marker' test results (report to Defra GMO Team, March 2005) the GMI concluded that, where there was a positive result for CaMV p35S coupled with a positive for a non-GM part of the cauliflower mosaic virus genome (i.e. a sequence that is not used in genetic modification). In the absence of any other markers of genetic modification the GMI concluded that, on the balance of probabilities, the positive result for p35S was from the naturally occurring virus and not from a GM construct. Consequently the company was allowed to recommence marketing.

Potential marketing of GM fish

In late March 2015 the GMI was anonymously sent a link to an internet marketing site calling the GMI's attention to what appeared to be GM fish for sale. Having spoken to the would-be vendor the fish were withdrawn from sale. DNA analysis of a sample of the fish confirmed that they were genetically modified and the remaining fish were surrendered to the GMI. Although the majority of the investigation took place in this reporting period, due to the date of the initial alert a detailed report of the incident appears in the GMI's 2014/15 annual report.

In March 2016, acting on an anonymous call from a member of the public, an Inspector from CEFAS' Fish Health Inspectorate (FHI) visited an aquarists' shop in the Manchester area and observed potential GM red danio zebrafish (*Danio rerio*) fish for sale. The Inspector visited two other aquarist shops in the area and suspect GM fish were seen at one of them. For logistical reasons samples were not taken, therefore the GMI initially telephoned the relevant shops, plus another one which the FHI was unable to visit before close of business. The legal situation regarding the marketing of GM fish was explained to the managers and they were advised to remove from sale any fish that appeared suspect in terms of GM status. A few days later the GMI visited the three aquarist shops in question and took possession of several suspect fish for GM testing.

Testing proved to be negative for all the fish sampled, using both PCR and fluorescence tests, and the GMI informed the retailers of the test outcomes. The GMI, in conjunction with the FHI, continues to liaise with the UK ornamental fish trade in order to raise awareness of the legislation and prevent the marketing of GM fish.

Expert representation undertaken by the GMI in 2015/16

- ***European Coexistence Bureau expert representation***

In April 2015 the GMI provided expert representation on behalf of the UK at a second meeting of the European Coexistence Bureau (ECoB) Technical Working Group for cotton. The ECoB organises the exchange of technical and scientific information on best agricultural practice for the coexistence of GM, conventional and organic crops, with the goal of developing EU consensus on crop-specific guidelines for coexistence measures. The aim of the April meeting was, firstly, to review and analyse contributions towards a background document produced at the previous meeting (first plenary meeting of the Technical Working Group, held in Seville, Spain, in October 2014), covering the biology and cultivation of cotton in the EU, and secondly, agreed a best practice document for coexistence in cotton production on the basis of the agreed information in the background document. Representatives of nine Member States, including the UK, were present at the meeting. The agreed best practice document is currently undergoing the process of European Commission ratification, including stakeholder consultation.

In November 2015 the GMI provided expert representation on behalf of the UK at the first meeting of the ECoB Technical Working Group for potato. Representatives of 18 Member States, including the UK, attended. The meeting explored the biological, agricultural and technological factors influencing coexistence during potato production, as well as reviewing the most recent coexistence research. It also included presentations by specialists from the European Food Safety Authority, the Swedish Board of Agriculture and the Irish Agriculture and Food Development Authority. After agreeing the format of a best practice document and discussing the availability of data sources concerning coexistence in potato production, the ECoB secretariat agreed to circulate an information-gathering template among the members of the working group to obtain up to date background information on current production practices in the different member States. Once contributions are received the ECoB secretariat will prepare the first draft of the background document for consultation, and after finalisation of the consultation process a second plenary meeting (anticipated for April 2016) will be arranged to discuss the production of a best practice document.

The GMI undertakes ECoB work on behalf of the Defra GM Team. For further information on the role of the ECoB, and access to coexistence best practice documents, see: http://ecob.jrc.ec.europa.eu/ (accessed 30/03/16).

6. Contact information

The GMI is located at the National Agri-food Innovation Campus (https://nafic.co.uk/), near York.

Further information on the GM Inspectorate and its activities can be found on the GOV.UK website, see:
https://www.gov.uk/government/collections/guidance-and-reports-on-gm-inspections

Or you can contact us at:

GM Inspectorate
Animal & Plant Health Agency (APHA)
Room 11G03
Sand Hutton
York, YO41 1LZ, UK

Telephone: 020 8026 2466 or 020 8026 2515
Email: gm-inspec@apha.gov.uk

For information on the key legislation and statutory mechanisms controlling the release or marketing of GMOs and GM products in the EU and UK, see the GMI's 2014/15 annual report (in particular Annex 1):
https://www.gov.uk/government/publications/gm-inspectorate-annual-report

For information about the Animal & Plant Health Agency see:
https://www.gov.uk/government/organisations/animal-and-plant-health-agency

For information about the release of GMOs for research purposes, including the application and consent process, see:
https://www.gov.uk/government/collections/genetically-modified-organisms-applications-and-consents

For information on Seed Certification matters see:
https://www.gov.uk/guidance/the-marketing-of-agricultural-and-vegetable-seed-varieties