Animal & Plant Health Agency

**Genetic Modification Inspectorate**
Animal and Plant Health Agency
Email: gm-inspec@apha.gsi.gov.uk
Web: www.gov.uk/apha

## Genetic Modification Inspectorate

Animal and Plant Health Agency

# Annual Report on GMO inspection and enforcement activities in England

01 April 2014 - 31 March 2015

Department for Environment Food & Rural Affairs

Room 11G03, Sand Hutton,
York YO41 1LZ, UK

E-mail gm-inspec@apha.gsi.gov.uk
www.gov.uk/government/collections/guidance-and-reports-on-gm-inspections

APHA is an executive agency, sponsored by the Department for Environment, Food & Rural Affairs

*This page has been left intentionally blank*

## Contents

# Executive summary

1. The European Union (EU) has strict rules governing the release of genetically modified organisms (GMOs)[1] to the environment, and any person or organisation wishing to carry out such a release must obtain formal consent before doing so. The APHA Genetic Modification Inspectorate (GMI) is responsible for the enforcement of GMO deliberate release[2] and marketing legislation 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 the inspection and enforcement work, and related activities, carried out by the GMI during the period 1st April 2014 to 31st March 2015.

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 applicable to their respective release consents. The GMI undertakes this work on behalf of the Department for Environment, Food & Rural Affairs (Defra) GM Policy and Regulation Team.

3. During the reporting period one small-scale research trial of Camelina (*Camelina sativa*), genetically modified to produce omega-3 long-chain polyunsaturated fatty acids, was carried out in England. Growing season inspections confirmed that the release complied with the conditions laid down in the consent, and no risks to human health or environment were identified.

4. The GMI also carried out post-trial inspections of eight former deliberate release trials (three former GM wheat trials and five former GM potato trials), all of which were found to be managed in accordance with the respective release consents. The GMI also undertook four audits to assess the procedures consent holders have in place to manage their releases. In all cases consent holders were found to be acting responsibly and managing their releases and/or former trials sites in accordance with prescribed requirements.

5. As well as to carrying out its statutory inspection and enforcement functions in relation to the deliberate release of GMOs, the GMI has a role in assisting seed companies to comply with their legal obligations not to sow or market unauthorised GMOs. The GMI achieves this by determining which crops are most at risk of adventitious GM presence (AGMP), assessing the controls that UK seed importers and producers have in place to manage this risk, and providing advice on how these controls can be further enhanced, where appropriate. During the reporting year the GMI carried out 14 detailed seed audits and 33 basic seed audits. All the companies that participated in the audit programme were considered to have acted responsibly in managing the risk of AGMP in their seed. No incidents of AGMP were investigated. This seed audit work is undertaken on behalf of Defra's Variety and Seeds (V&S) Policy Team.

[1] Organisms as defined in European Directive 2001/18/EC. (For all relevant legislation see Appendix 1).
[2] 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 GMI also investigated two incidents involving the suspected marketing of GM fish. Currently no GM fish are authorised for commercial sale in the EU, therefore it is illegal to market them. The first incident involved suspect GM black tetra, which were intercepted at a UK Border Inspection Post. Following PCR testing it was concluded that they were not genetically modified but were most likely dyed. The second incident involved a batch of *Danio rerio* zebrafish, advertised for sale as GM fish. A sample of these fish was tested, and it was confirmed that they were genetically modified. Consequently these fish were withdrawn from the market.

7. As well as undertaking inspection and enforcement work, and the auditing of seed companies, the GMI worked on a number of GMO-related projects and studies. These included the continuation of a study looking at the evidence base for the coexistence of GM, conventional and organic crops, participating in an EU-funded project looking at the key steps needed for a Research Area Network to coordinate research on GMOs, and providing expert representation on an EU Coexistence Bureau committee.

8. In September 2014 the Food and Veterinary Office (FVO) of the EU carried out an audit of the GMI as part of a wider evaluation of UK control systems in place for GM food, feed and seed. The audit included an appraisal of the GMI's controls for ensuring that deliberate release trials are correctly managed, and for ensuring that seed companies are adequately managing the properly managing the risk of adventitious GM presence in the seed they handle. Having seen the work carried out by the GMI the FVO concluded that a comprehensive authorisation and control system of GMO field trials is in place in the UK, and the system of auditing seed companies ensures that the requirements relating to unauthorised GMO cultivation are implemented.

# 1. The work of the Genetic Modification Inspectorate

- *The role of the GM Inspectorate*

The GMI for England, based at the Animal and Plant Health Agency, has designated responsibility for ensuring compliance with legislation pertaining to the deliberate release to the environment of genetically modified organisms (GMOs)[3] in England. This legislation is designed to ensure that experimental field trials and commercial releases of GMOs are carried out in such a way as to minimise any risk to human health and the environment.

**The function of the GMI is to enforce EU and UK legislation controlling the safe release to the environment of GMOs.**

Box 1 provides a brief description of what constitutes a GMO.

Box 1 - **what are GMOs?**

Genetically modified organisms (GMOs) are organisms in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination, as defined in Directive 2001/18/EC. Techniques of genetic modification include recombinant nucleic acid techniques, techniques involving the direct introduction of heritable material (e.g. by micro-injection), and cell fusion or hybridisation techniques. Examples of GMOs include oilseed rape modified to tolerate particular herbicides, maize modified to resist insect pests, and fish modified to fluoresce under UV light.

Further information on GMOs can be found at: http://ec.europa.eu/food/plant/gmo/index_en.htm (accessed: 09/04/15).

The GMI has statutory responsibility to:

- Inspect all deliberate releases 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.

This work is undertaken on behalf of the Defra GM Policy Team.

The GMI, as well as carrying out its statutory duties, has responsibility 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 covered under Section 3.

[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)

- *A new home for the GM Inspectorate*

On 1st October 2014 the Genetic Modification Inspectorate (GMI) moved from the Food and Environment Research Agency (Fera) to the Animal and Plant Health Agency (APHA). This move was in anticipation of the privatisation of Fera (now known as Fera Science Ltd.), which was completed on 1 April 2015. APHA is an executive agency of the Department for Environment, Food & Rural Affairs, and was created from the parts of Fera that previously had inspection and enforcement responsibilities (the Plant Health and Seeds Inspectorate, the National Bee Unit and the GMI) and the Animal Health/ Veterinary Laboratories Agency (AH/VLA). APHA provides a robust and resilient home for the GMI. Fera Science Ltd. provides diagnostic support for the GMI.

The physical location of the GMI continues to be the National Agri-food Innovation Campus, near York.

**The National Agri-food Innovation Campus, home of the APHA GM Inspectorate.**

# 2. The GM Inspectorate field inspection programme

## Inspection of GMO field trials

- *The GMI field inspection programme*

The GMI's field inspection programme is designed to ensure that all authorised releases of GMOs to the environment are consistent with the limitations and conditions of their respective consents, and that any potential risks to human health or the environment are kept to a minimum. The GMI achieves this by carrying out audits of the systems consent holders have in place to manage their consents, and by conducting field inspection visits to ensure these systems are properly implemented *in situ* and that any potential risks are kept to a minimum. These management audits and field inspection visits are described in more detail on pages 6 onwards.

During the 2014-15 reporting year there was one experimental release trial of a GMO: *Camelina sativa* modified to produce omega-3 long-chain polyunsaturated fatty acids (see Box 2, below).

**GM *Camelina sativa* plants just coming into flower. This oil-producing crop, genetically modified to produce omega-3 long-chain polyunsaturated fatty acids, has been authorised for experimental release in 2014 and 2015.**

Box 2: **Part B GM trials 2014-15**

In the 2014-15 reporting period there was one Part B (experimental) release in England, as follows:

- Camelina (*Camelina sativa*), modified for the production of omega-3 long-chain polyunsaturated fatty acids - release carried out in spring 2014 by Rothamsted Research (consent 14/R8/01).

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

- Wheat, modified for aphid resistance by production of aphid alarm pheromone - release carried out in 2012 by Rothamsted Research (consent 11/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 Potato Cyst Nematode - releases carried out in 2009 by University of Leeds (consent 09/R31/01);
- Potato, modified to resist late blight - releases carried out in 2007 and 2008 by BASF (consent 06/R42/01).

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

From the time that a consent for the experimental release of a GMO is first issued, to its final termination, GM Inspectors work closely with consent holders to ensure that the requirements and limitations of each consent are understood and adhered to.

Box 3 gives an overview of the process by which the release of GMOs are authorised for release to the environment.

**GM Camelina (*Camelina sativa*) trial undergoing a compliance inspection (left).**

Box 3 – **authorisation process for the release of GMOs:**

Before a GMO can legally be released to the environment in the EU, formal authorisation must be obtained from the relevant authority.

Applications to release a GMO in experimental field trials are considered at national level by the relevant competent authority, which in the case of England is the Department for Environment, Food & Rural Affairs (Defra).

Applications to market a GM product, such as GM seeds for cultivation and food and feed commodities, are assessed and decided upon at EU level. The authorisation process requires that the applicant put forward a comprehensive dossier of information giving details of the genetic modification, the characteristics of the organism, and also a comprehensive risk assessment. The dossier is then evaluated by independent experts to determine any potential risks to human health and the environment, and to assess the suitability of the proposed controls to minimise such risks. Only if the GM organism is considered safe is authorisation granted to release it to the environment, and a consent issued. The schedule to the consent sets out the limitations and conditions that apply to the release. Appendix 1 provides further details of GM legislation and regulation in the UK.

- *Consent holder management audits undertaken in 2014-15*

Before a GMO is released experimentally inspectors carry out an audit of the consent holder to ensure they have appropriate procedures and protocols in place for the safe and effective operation of their deliberate release field trials. Management audits are carried out before the first release, and at the start of each subsequent growing season whilst the consent remains active.

In the case of active releases, audits include comprehensive checks on:

- consent holder administration and infrastructure, to ensure that there are appropriate high-level procedures and protocols in place;
- arrangement and functioning of the management chain, to ensure effective communication from consent holder to site management;
- operational instructions issued to trial site operators and field staff, including verifying that the conditions laid down in the consent are known throughout the management chain so as to be effectively implemented *in situ*;
- systems for receipt, storage, transport and of seed/trials material before planting, and for safe disposal of harvested material;
- monitoring plans during the release period to ensure the limitations and conditions of the consent are met;
- emergency response plans to ensure appropriate and effective measures are in place in the event that something untoward occurs in relation to the release.

The purpose of management audits is also to gain assurance that the consent holder is exercising their duty of care to release only those transformation events covered by their consent. Accordingly, consent holders are required to provide evidence that the GMO matches the description set out in the release application and in the consent conditions, and that no adventitious GMOs are present. Such evidence may be in the form of test results (e.g. PCR testing) and/or as written declarations relating to the production of the GMO and maintaining genetic isolation during the bulking process. Box 4 gives an overview of deliberate release consents.

Box 4 - **deliberate release consents, an overview:**

Experimental GM trials are authorised under Part B of Directive 2001/18/EC, which sets out the rules for deliberate release to 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 pure research, product development, or demonstration purposes. 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 the organism and 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 applicable to the release in order to ensure that any risks of damage to the environment are kept to a minimum. 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.

If the release is in the post-trial phase an assessment is made of the consent holder's systems for monitoring and managing the former release site, including, where appropriate, adhering to subsequent cropping restrictions and ensuring groundkeeper/volunteer management and control.

Following each management audit a draft report is produced setting out the findings of the discussion and detailing any required actions and recommendations. The respective consent holder is given the opportunity to comment on the factual aspects of the report, after which a final version is produced and sent to the Defra GM Team, copied to the consent holder.

During the 2014-15 financial year the GMI conducted four management audits of consent holders. Two audits were in relation to GM Camelina releases (Rothamsted Research, consent 14/R8/01) - one audit carried out in April 2014, prior to the first sowing of the GM crop, and one in March 2015, prior to the sowing of the GM crop that year. The other two audits were in relation to consents in the post-trial phase, namely The Sainsbury Laboratory's GM potato (released under consent 10-R29-01) and BASF's GM potato (released under consent 06-R42-01). See Table 1 on page 14 for more details. In all cases the GM Inspectorate was satisfied that the consent holders had appropriate management procedures in place to ensure that the conditions set out in their respective consents were met.

- *Growing season field inspections undertaken in 2014-15*

The GMI is contracted to inspect each new Part B release at least once during the growing season to ensure compliance with the limitations and conditions of the consent granted for the release. Inspections include checks on the location, layout and dimensions of each trial, the distance from related crops, width and effectiveness of the pollen barrier (where applicable), and the efficacy of consent holder monitoring. Inspections may take place at planting, prior to or during flowering, at harvest and at disposal. Additional visits may be carried out, for example at the time of sowing or at harvest, depending on the findings of earlier inspections and whether there are any identified or potential risks.

**GM Camelina with insect-proof netting, used by the consent holder as an additional precaution to reduce the risk of pollen dissemination during flowering.**

In 2014 one deliberate release trial of a GMO was conducted in England. This was a small-scale research trial of GM *Camelina sativa* (also known as Camelina, gold-of-pleasure, or 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). Camelina is an oil-bearing crop which had been modified by Rothamsted Research to produce omega-3 long-chain polyunsaturated fatty acids (more 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 field inspections of the Camelina release site in May 2014, as the crop was being sown, and at the beginning of June, just prior to flowering. During the July pre-flowering inspection it was noted that the stand density of the pollen barrier was below the minimum specified in the consent, it was therefore necessary to invoke the isolation requirement. This specified that in the absence of an effective pollen barrier a 50 metre (minimum) separation distance must be maintained between the GM trial and any wild or cultivated *Camelina* species. To comply with this requirement the consent holder implemented a management and control strategy which included mowing the 50 metre area surrounding the trial site and carrying out systematic monitoring of this area. At the end of July 2014 the GMI conducted a follow-up inspection visit to assess the procedures the consent holder had put in place to maintain this 50m isolation distance. The visit confirmed that the required separation between the GM trial and related crops and wild plants was being satisfactorily maintained. All three inspection visits to the site confirmed that the release complied with the conditions laid down in the consent, and no risks to human health or environment were identified. (The GMI also carried out a visit to the site in relation to an FVO audit – see Section 6). Following each field inspection a report was sent to the Defra GM Policy and Regulation Team detailing the findings of the visit. All growing season field inspection reports are placed on the GMI website (see: http://www.gm-inspectorate.gov.uk/deliberateRelease/exptreleases.cfm).

**Experimental plots of GM Camelina. The aim of the research is to achieve a sustainable source of omega-3 fish oils for the fish feed industry.**

[4] Further information on this … can be found on Rothamsted Research's website see: http://www.rothamsted.ac.uk/camelina (accessed 09/10/15).

- *Post-trial monitoring inspections undertaken in 2014-15*

As well as specifying conditions relating to the growing crop, the majority of Part B consents have a requirement that consent holders monitor the former GM release site for a specified interval once the GMO has been harvested and/or terminated. The duration of the monitoring period depends on the biology of the plant, the type of GM trait that is involved, and the findings of any previous years' monitoring.

**A GM potato trial during the post-trial period and (inset) during the growing season.**

GM Inspectors undertake visits to all former deliberate release sites that are subject to post-trial conditions as part of the release consent to ensure that consent holders are fulfilling their duties. Such duties typically include recording and controlling any GM plants that either regrow from harvested crops or emerge from shed seed ('volunteers') or, in the case of root crops, such as potatoes, grow from tubers ('groundkeepers'). Consent holders must also ensure any subsequent cropping restrictions are met. The programme of post-trial monitoring is designed to ensure that, as far as reasonably possible, no GMOs remain in the environment once the trial has been completed.

In 2014 the GMI conducted eight post-trial monitoring inspections relating to three consent holders. These comprised of visits to three former GM wheat trials (releases conducted in spring 2012, spring 2013 and autumn 2013) under one consent, and visits to five former GM potato trials (releases conducted in 2007 and 2008, and 2010 to 2012) under two separate consents.

- *Consent holder monitoring reports*

At the end of the season each consent holder is required to submit a monitoring report to the Secretary of State for Environment, Food and Rural Affairs giving details of the risk management measures they have applied, and describing the findings of the release, including an assessment of any risks, or any actual or potential adverse effects, to human health or the environment due to the GMO. These reports are designed to facilitate an assessment of the release to 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. All 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 GM Team for its consideration.

[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).

Once reports are accepted by Defra they are forwarded on to the European Commission.

In the case of releases authorised to take place over more than one year, consent holder growing-season reports help to inform Defra 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.

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

- *Overall findings of the 2014-15 field inspection programme*

Management audits confirmed that all consent holders had suitable procedures in place to manage their consents appropriately. All deliberate release trials of GMOs carried out in 2014-15 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. The GMI and the GM Policy and Regulation Team were content with all end-of-year reports submitted by consent holders.

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

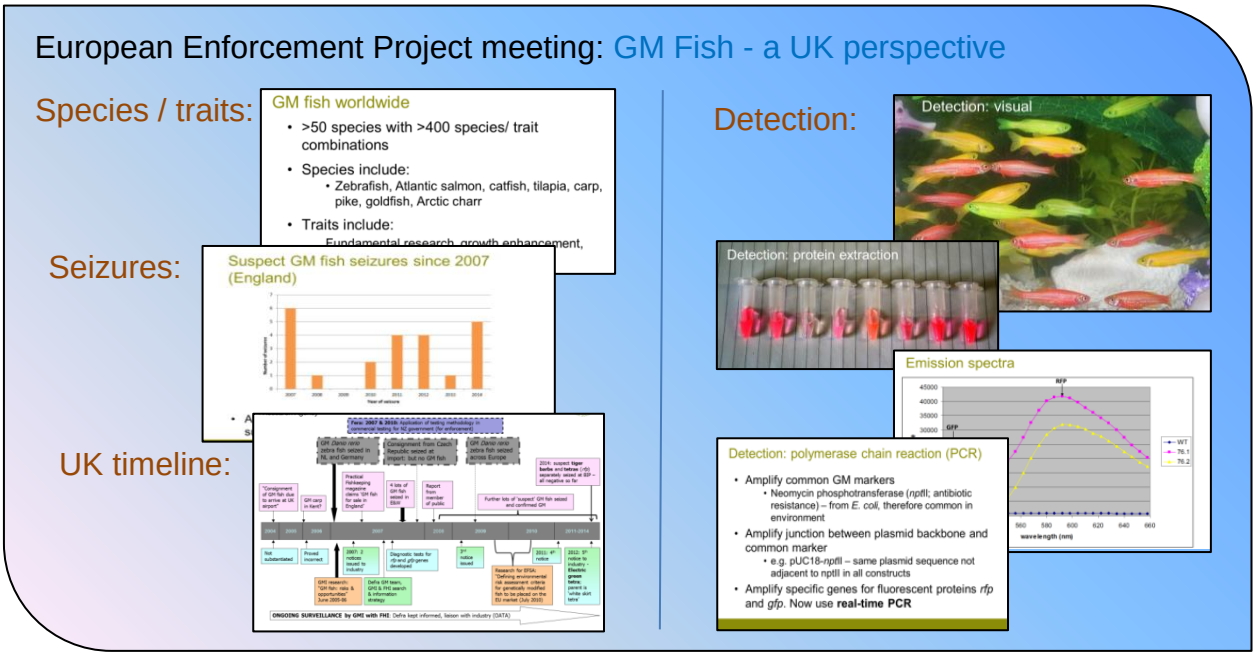
**Table 1 - Summary of GM inspection-related activities carried out in the 2014-15 financial year**

| Activity | Number of inspections | Consent holder / number and type | Outcome |
|---|---|---|---|
| **Field inspections – growing season** | 4 | Rothamsted Research, consent 14/R8/01; crop: Camelina - modified to produce omega 3 oils: (spring 2014 release) | The GM Inspectorate was content that each release was consistent with the 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)** | 8 | Rothamsted Research, consent 11/R8/01; crop: wheat - modified for resistance to aphids: (spring 2012 release) | |
| | | Rothamsted Research, consent 11/R8/01; crop: wheat - modified for resistance to aphids: (spring 2013 release) | |
| | | Rothamsted Research, consent 11/R8/01; crop: wheat - modified for resistance to aphids: (autumn 2013 release) | |
| | | BASF, consent 06/R42/01; crop: potato - modified for resistance to late blight (2008 release) | |
| | | BASF, consent 06/R42/01; crop: potato (2007 release) | |
| | | The Sainsbury Laboratory, consent 10/R29/01; crop: potato – modified for resistance to late blight (2010, 2011 & 2012 releases) | |
| **End of season monitoring reports submitted by consent holders** | 5 | Sainsbury Laboratory (consent 10/R29/01): one combined post-trial monitoring report covering potato releases carried out in 2010, 2011 & 2012. | Defra was content with all end-of-year reports submitted by consent holders. |
| | | BASF (consent 06/R42/01): two post-trial monitoring reports covering releases carried out in 2007 and 2008 | |
| | | Rothamsted Research (consent 11/R8/01): one combined post-trial monitoring report covering wheat releases carried out in 2012 & 2013. | |
| | | Rothamsted Research (consent 14/R8/01): one growing season monitoring report covering a Camelina release carried out in 2014. | |
| **Consent holder management audits** | 4 | Rothamsted Research (consent 14/R8/01): Camelina - modified to produce omega 3 oils (pre-planting management audit for 2014 release – audit undertaken 28/04/14) | The GM Inspectorate was content with the procedures implemented by all consent holders for the management of their respective consents. |
| | | Rothamsted Research (consent 14/R8/01): Camelina - modified to produce omega 3 oils (pre-planting management audit for 2015 release – audit undertaken 03/03/15) | |
| | | The Sainsbury Laboratory, John Innes Centre - consent 10/R29/01; potato (post-trial management audit, 04/03/15) | |
| | | BASF Plant Science GmbH consent 06/R42/01; potato (post-trial management audit, 05/02/15) | |

As well as carrying out consent holder management audits and field inspections the GMI is responsible for providing advice to the Defra GM Policy and Regulation Team on the inspection and enforcement aspects of consent holder deliberate release applications, for managing the receipt and evaluation of consent holder end-of-season reports, and providing expert representation on GM inspection and GM risk-related matters at various meetings and workshops, as appropriate.

- *Other responsibilities relating to the GMI field inspection programme*

**European Enforcement Project participation:**
At the European level, the GMI is an active member of the European Enforcement Project (EEP), a forum for the exchange of information and expertise between official GMO inspection and enforcement bodies operating throughout the EU. A member of the GMI attended the annual EEP meeting in Malmö Sweden, in 2014, and presented an overview of Fera[6]/APHA's experience regarding GM fish, including species and GM traits, GM fish identification, the risk/likelihood of importation to the EU, the UK approach to monitoring and the enforcement of GM regulations, and a UK timeline of incidents (see excerpts from presentation, below).




For more information on the work of the EEP, see the journal Applied Biosafety, April 2015, vol. 20, no. 1, 55-58[7].

**European Coexistence Bureau participation:**
In October 2014 a member of the GMI participated in a workshop organized by the European Coexistence Bureau[8], which is tasked with establishing crop-specific guidelines for the coexistence of GM, conventional and organic crops (see Section 5 for further information).

[6] Note that up to 1 October 2014 the GM Inspectorate was part of the Food and Environment Research Agency (Fera), which has since been privatised and is now Fera Science Ltd.
[7] See: http://intl-apb.sagepub.com/content/20/1/55.full.pdf+html (accessed 09/11/15).
[8] See: http://ecob.jrc.ec.europa.eu/ (accessed 09/11/15)

# 3. The GM Inspectorate seed audit programme

- *Background to audits of non-GM seed for sowing*

Although no GM crops are currently grown commercially in the UK, there are large areas of the world where such crops are cultivated on a commercial basis. As a result there is the potential for non-GM seed to acquire the accidental (adventitious) presence of GMOs, either by cross-pollination or due to admixture. To help safeguard the environment from possible adverse effects of GMOs, EU Directive 2001/18/EC prohibits the import and/or marketing of GM seeds for commercial purposes unless the particular GM line has been assessed and granted the required EU authorisation[9]. Companies importing and/or marketing seed of at-risk species, for planting, must therefore have appropriate controls in place to minimise the risk of adventitious GM Presence (AGMP) in their seed. To help these companies comply with this legislation the GMI undertakes a programme of audits of companies that handle and market non-GM seed (i.e. conventional and organic seed) for cultivation in England. Each audit undertakes a detailed look at all stages of the seed production process (including variety development; sowing; growing and flowering; harvest; transport and storage; and processing), and is used to evaluate the controls the company has in place to minimise the risk of AGMP at each of these stages. The Inspectorate assists audited companies to explore ways in which these controls can be further improved, as appropriate. This work is carried out on behalf of the Defra GM Policy and Regulation Team, which is responsible for upholding GMO deliberate release regulations, and the Defra Variety and Seeds (V&S) Policy, which is responsible for the Seed Marketing Regulations.

**Various types of GM crops are grown throughout the world, meaning that seed companies must have appropriate controls in place to minimize the risk of adventitious GM presence in their seed. In the EU MON810 insect resistant maize is currently the only GM crop that is commercially cultivated.**

The GMI also has a role in raising awareness of the risks posed by GMOs in seed, to help companies know how and where to best target their resources. Box 5, overleaf, gives an overview of EU rules concerning purity standards for seed for sowing, and summarises the aims of the GMI seed audit programme.

[9] 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 (see Appendix 1, Section 6). There are currently three consents authorising cultivation of GM crops in the EU: two for GM maize (MON810 and T25).

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

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, but such rules are not specifically geared towards ensuring a zero presence of GM seeds. Current seeds legislation does not stipulate labelling thresholds for AGMP of authorised GMOs in conventional seed, and nor is there a tolerance 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 that has not been authorised must not be marketed.

The GMI seed audit programme is designed to ensure that the relevant legal requirements are upheld, as well as helping businesses manage and minimise the commercial / reputational risk to them should their conventional seed stocks inadvertently acquire an unwanted GMO content.

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 MON810 maize is very unlikely to be grown in the UK.

- *Seed audits carried out during 2014-15*

The GMI audit programme aims to focus resources as near as possible to the beginning of the seed production/marketing chain, and in this way seek to reduce the burden on the seeds industry as a whole, in accordance with principles of better regulation. We therefore concentrate our activities towards those seed companies that produce seed in England and/or import seed into England from elsewhere, rather than visiting every seed merchant. This approach also ensures we obtain the widest coverage for the smallest outlay in terms of time spent and public expenditure.

During the 2014-15 audit period there were 64 seed companies that qualified for inclusion in GMI's audit programme. No companies were considered to need a Targeted audit. Box 6, overleaf, outlines the three types of audit the GMI undertakes.

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

- Detailed audits: these take place once every three years, and involve a GM Inspector visiting the company and carrying out a thorough assessment of the risk to the company's seed of acquiring AGMP, and the controls in place to minimise these risks. The Inspector then produces a detailed report, which includes recommendations on how the company can enhance their controls, where applicable;
- Basic audits: these take place in the intervening two years and usually involve a telephone-based assessment of the company's practices to determine whether there has been any change in the risk of AGMP 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 for over a year. Targeted audits 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 audit 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, are not sent to the company. A copy of each report is sent to the Defra Variety and Seeds Policy Team.

Using quantitative risk assessment the GMI had previously identified the following crops as being most at risk of AGMP:

- *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.

A summary of the seed audits undertaken is provided in Table 2, below.

**Table 2 - Summary of seed audit programme for the 2014-2015 financial year**

| Audit type | Summary details |
|---|---|
| **Detailed audits** | Companies declining to participate: **4**<br>**Audits undertaken and detailed reports completed: 11** |
| **Basic audits** | Companies declining to participate: **0**<br>Companies not marketing any crops of interest: **4**<br>**Audits undertaken and reports completed: 22**<br>(excluding non-participant reports) |
| **Targeted audits** | No targeted audits were required |

The GMI suggested a number of ways in which individual seed companies could enhance their control of AGMP risk, in the form of minor recommendations. In all cases these recommendations were designed to strengthen the existing protocols and procedures, rather than signifying an underlying lack of control. No major recommendations were made in any of the reports, and the GMI were satisfied that all companies that participated in the 2014-15 audit programme had acted responsibly in the way in which they had managed the risk of AGMP in their seed.

The GMI did not have cause to investigate any GM seed-related incidents in 2014-15; accordingly it was not necessary for the GMI to prohibit the sale of any seed due to the suspected or confirmed presence of an unauthorised GMO, or require the destruction of any seed.

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

# 4. Unauthorised GMO releases

## Unauthorised releases of GMOs

In addition to carrying out GMO field trial inspection visits and auditing seed companies, the GMI has statutory responsibility for investigating any incidents, in England, where there has been a suspected or confirmed infringement of GM deliberate release legislation. Such infringements usually involve the marketing and/or release into the environment of a GMO that has not been granted the necessary authorisation in the UK or Europe. GM Inspectors have the right to exercise certain powers, conferred under Section 125(1) of Part VI of the Environmental Protection Act 1990, which enable them to take samples, collect other evidence and correct any infringements that are likely to pose a risk of harm to the environment. Any potential breaches of GM deliberate release legislation are investigated on a case-by-case basis and action taken as appropriate. Incidents that were investigated in the 2014-15 reported period are detailed below.

- *Potential marketing of GM fish*

Ornamental fish were one of the first GM animals to be marketed to the general public (see Box 7), with fluorescent strains of several species legally available for sale in a number of non-EU countries. In the European Union the release and marketing of GM animals is controlled by the same legislation as that controlling GM crops, and currently, because there are no EU marketing authorisations in place for GM fish, anyone who releases or markets such animals is committing an offence to under Sections 111 and 118 of the Environmental Protection Act 1990. The GMI upholds the legislation in relation to GM fish by liaising with the Fish Health Inspectorate (FHI), whose primary responsibility is to prevent the introduction and spread of fish diseases. FHI officers monitor fish at border inspection posts and retail outlets, and are skilled in recognising fish that differ from the normal types, making this approach an effective monitoring and control strategy. During the 2014-15 reporting period the GMI investigated two incidents relating to the import and potential marketing of suspected GM fish (see overleaf).

Box 7 – **ornamental GM fish:**

Fluorescent GM fish were originally developed as part of a process to engineer fish to detect environmental pollutants and respond in a visible way. This was achieved by adding a gene from a jellyfish (*Aequorea* sp.) into a zebrafish (*Danio rerio*) embryo, allowing it to integrate into the zebrafish's genome. When expressed, the gene produces a green fluorescent protein (GFP), causing the fish to fluoresce under both natural and ultraviolet light. Subsequently it was recognised that there might be interest from the public in buying GM variants which express the protein all the time, hence a number of companies began marketing these GM zebrafish to the ornamental pet trade. Since then several other species of fish have been modified to fluoresce, using genes from jellyfish, coral or anemones to produce different colours. Authorisation for marketing has been granted in a number of countries, including the USA and Taiwan.

***Incident 1*:** In April 2014 a batch of suspected GM black tetra (*Gymnocorymbus* sp., most likely black skirt/black widow tetra *G. ternetzi*) ornamental fish from Thailand were intercepted at a UK Border Inspection Post. Fluorescent black tetras have been commercially available in the USA since around 2012, marketed under the GloFish® brand, and are available in various colours, including bright green, orange, purple, and pink. However, the fish from the intercepted consignment had a pronounced bright pink/red line along their side. Because this was the first interception of suspect GM tetras in the UK, the GMI had little prior knowledge of the appearance of the modified fish, other than images on publically available websites. Comparing the intercepted fish with photographs of GM black tetras (images kindly provided by Yorktown Technologies) led GM Inspectors to consider it likely that the intercepted fish were actually dyed rather than being genetically modified. The definitive way of determining whether fish are genetically modified is to carry out PCR testing, therefore the GMI liaised with Yorktown Technologies in order to obtain positive control material; however, following discussion with the company it was agreed that the appearance of the intercepted fish were markedly different from the ones they market, hence any GM construct was likely to be different and there was little point in applying a GloFish-specific test. Samples of the suspect batch of fish were therefore subjected to a range of generic diagnostic tests (conducted by Fera Science Ltd.), including real-time PCR testing and emission-spectrum analysis at a range of wavelengths. PCR testing was conducted using standard primers for GFP, RFP and endogenous control gene (validated for *Danio rerio*). DNA extracts were analysed alongside control DNA samples containing RFP and GFP genes, DNA from wild type *D. rerio*; and DNA from wild type *Gymnocorymbus ternetzi*. All samples tested negative for the presence of the RFP and GFP transgenes. The level of fluorescence of disrupted fish tissue under UV light was marginally higher in samples from the suspect fish than in the wild type controls, but low compared to RFP positive control samples, and of a different emission spectra profile. Given this, the GMI concluded that, on the balance of evidence, the suspect fish were not genetically modified, and were most likely coloured using a chemical dye.

***Incident 2*:** in March 2015 the GMI received an alert from a member of the public regarding an advertisement on an Internet auction site. The description of the fish in the sale fitted that of some GM fluorescent fish. The GMI contacted the vendor who was found to be a private individual and a visit was carried out by the GMI, accompanied by a member of the Fish Health Inspectorate, to the vendor's residential address to investigate and take samples, as necessary. The vendor stated that he had purchased the parent fish from a pet shop, they had bred, and he was intending to sell the surplus offspring, but he had not so far had any interest and had not sold any of the fish. Visual inspection of the fish, which were identified as zebrafish (*Danio rerio*), indicated that they were genetically modified and, with the vendor's agreement, a sample was taken. The vendor said he was not aware that GM fish were unauthorised for marketing in the EU, and withdrew them from sale. PCR testing by Fera confirmed that the sampled fish were positive for the gene for red fluorescence.

In May 2015, acting on information provided by the would-be online vendor, the GMI visited the original retailer of the parent fish, and discussed the legal situation pertaining to GM fish. The retailer was unaware of the risk of GM fish appearing in shipments. The GMI then spoke to the wholesaler who had initially imported the GM fish, and in this case the company representative was aware of the issue with GM fish, and had removed certain descriptions of Danio varieties associated with genetic modification from their sale lists. He had also alerted their overseas suppliers to the potential problem, but despite requesting them not to supply such fish they appear to have made a late substitution which included GM fish, which the importer had failed to notice.

**GM ornamental fish, *Danio rerio*, modified to fluoresce under UV light. Various forms have been authorised for marketing in several countries around the world, but not in the EU.**

Having traced all known live suspect fish, they were euthanized by the FHI. Given the original importer's awareness of the issue and their attempts to address the problem, the GMI concluded that educating the UK side of the supply chain is not the primary issue; rather the problem is with overseas companies that accidentally or perhaps deliberately include GM fish in their export consignments. The GMI sent an official letter to the importer, reminding them of the risk of GM fish being supplied in consignments of conventional fish and asked them to forward this to their overseas suppliers. As the importers had been unwitting recipients of the GM fish, there was no evidence of intentional marketing having taken place, and all parties co-operated fully with the GMI investigations, no further enforcement action was taken.

Table 3, below, shows details of the interceptions made in 2014-15, and the outcome of the analytical tests performed on them.

**Table 3 – Suspected GM fish intercepted in 2014-2015**

| Fish species | Origin | Date intercepted | Where intercepted | Results of analysis |
|---|---|---|---|---|
| *Gymnocorymbus* sp. (Black tetra or Black Widow tetra) | Thailand | April 2014 | Border Inspection Post (airport) | **Negative** for RFP[10] and GFP[11] transgenes, and according to fluorescence spectra |
| *Danio rerio* (red danio zebrafish) | Unknown | March 2015 | Alert from member of public of suspected sale of fluorescent GM fish on internet | **Positive** for RFP transgene; negative for GFP transgene Fish sampled and PCR tested; confirmed as GMO's and consignment euthanized |

[10] RFP: red fluorescent protein, produced by a gene derived from a coral.
[11] GFP: green fluorescent protein, produced by a gene originally extracted from a jellyfish.

To date the GMI have not encountered any importers, wholesalers or retailers who have knowingly imported and/or marketed GM fish; in all cases importers had ordered standard consignments of ornamental fish, and had unwittingly received a low level presence of GM fish. The nature of the fish import business makes it very difficult for bulk buyers to know what will be in each consignment, as overseas suppliers are not always able to provide exactly what has been ordered. In most cases GM fish are intercepted at Border Inspection Posts, or recognised by importers and retailers and blocked before marketing.

The GMI, in conjunction with the FHI, continues to liaise with the UK aquatic trade with the aim of raising awareness amongst importers and retailers of tropical fish with regard to the illegality of importing GM fish. Further information on the GMI's activities concerning the illegal import and marketing of GM fish can be found at: http://www.gm-inspectorate.gov.uk/gmfish/.

# 5. GMO-related projects, research and studies

**Project work undertaken by the GMI in 2014/2015**

- ***Updating the evidence base on coexistence of GM, conventional and organic crops***

The GMI continued to work on a desk study updating the evidence base on coexistence of GM, conventional and organic crops. The aim of this work, carried out on behalf of the Defra GM Team, is to identify gaps in the coexistence evidence base since Defra published its first draft proposals for managing coexistence in 2006, and where possible to fill these gaps, or recommend where additional research is needed. The study focusses on coexistence for maize, oilseed rape, sugar beet and potatoes - the four crops for which there were applications within the regulatory pipeline and which are important in the UK. The purpose of the review is to ensure that up-to-date and robust evidence is available to inform Government policy on coexistence. The review is expected to be delivered in January 2016.

- ***PreSto GMO ERA-Net project***

The GMI participated in the EC research project 'Preparatory steps towards a GMO research ERA-Net' (PreSto GMO ERA-Net), which aims to lay the groundwork for transnational research into the impacts of GMOs. The overall goal of the project, which brings together a range of stakeholders from EU Member States and the scientific community, is to undertake the key preparatory steps towards the planning and implementation of a European Research Area Network (ERA-Net) for the coordination of research concerning GMOs. Once operational the ERA-Net would streamline transnational studies on the effects of GMOs in the areas of human and animal health, environment and techno-economic impacts. The focus of the ERA-Net would be on GMOs which are intentionally released into the environment and/or used immediately in feed and food applications. The project commenced in September 2013 and is due to be completed by the end of August 2015. For further information on PreSto GMO ERA-Net can be found at: http://www.presto-gmo-era-net.eu/home (accessed 09/11/15). For further information on the GMI's role in this project see the GMI's annual report for 2013-14, available at: http://www.gm-inspectorate.gov.uk/reportsPublications/documents/Annual__Reports/GMIannualreport2013-14_final.pdf (accessed 09/11/15).

## Expert representation

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

During the reporting period the GMI provided UK expert representation as part of a European Coexistence Bureau (ECoB) Technical Working Group for GM cotton. ECoB organises the exchange of technical and scientific information on best agricultural practice for the coexistence of GM, conventional and organic crops, with the overall aim of developing consensus agreement on crop-specific guidelines for coexistence measures. The work of the GMI included participating in the first plenary meeting of the Technical Working Group, held in Seville, Spain, in October 2014, helping contribute towards to a detailed background document covering the biology and cultivation of cotton in the EU, and reviewing the available information on adventitious GM presence in cotton seed production. The second plenary meeting of the Technical Working Group, which established a consensus view on best practice for cotton coexistence, was held in early 2015. The role of the ECoB, and access to coexistence best practice documents can be found at: http://ecob.jrc.ec.europa.eu/ (accessed 09/11/15). The GMI undertook this work on behalf of the Defra GM Policy and Regulation Team.

# 6. Audit of the GMI

- ***Audit of the GMI by the Food and Veterinary Office***

In September 2014 the GMI was the subject of a scheduled audit by the EU Food and Veterinary Office (FVO). The aim of the audit (which also included an assessment of the work undertaken by the Defra GM Policy and Regulation Team and the Food Standards Agency) was to evaluate the control systems in place in the UK for food, feed and seed containing, consisting of, or produced from GMOs. The audit team comprised two FVO auditors and two experts from the Joint Research Centre of the European Commission. This was the first FVO audit that included an evaluation of the UK's controls for the deliberate release of GMOs into the environment.

The audit took place over four days, with GM Inspectors providing a comprehensive account of how the field inspection and seed audit programmes operate to help ensure compliance with GM legislation. FVO auditors also accompanied the GMI on an inspection visit to a GM deliberate release trial site to assess the controls in place and to observe first-hand how official inspection visits are carried out (thanks are due to Rothamsted Research for allowing the use of its GM *Camelina sativa* trial for the inspection, and to its staff for agreeing to take part in the demonstration inspection).

Following the audit the FVO team concluded that, in terms of the experimental release of GMOs, an appropriate system is in place for authorising the deliberate release of GMOs for trial purposes, in line with Directive 2001/18/EC, and there is a comprehensive control system in place regarding GMO field trials. Inspections are undertaken at an appropriate frequency and suitable verification is made to ensure that the conditions of the consent are met.

The official report, published February 2015, concluded that a comprehensive authorisation and control system is in place for UK GMO field trials, and a detailed audit system ensures that the requirements pertaining to unauthorised GMO cultivation are implemented. All systems for managing the deliberate release of GMOs to the environment and minimising the risk of the unauthorised release of GMOs were found to be satisfactory, and no recommendations relating to the work of the GMI were made by the audit team. For a copy of the full report see: http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=3373 (accessed 09/11/15).

# 7. Contact information

**Further information on the GM Inspectorate and its activities can be found on our website, see:**
**http://www.gm-inspectorate.gov.uk**

Or you can contact us at:

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

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

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

For information about the National Agri-food Innovation Campus see:
http://www.ukspa.org.uk/members/nafic

For information about Fera Science Ltd see:
http://fera.co.uk/

# Appendix 1: GM legislation and regulation in the UK/EU

**The key legislation and statutory mechanisms controlling the release or marketing of GMOs and GM products in the EU and UK are described below.**

## EU legislation:

### 1. European Council Directive 2001/18/EC

1.1 In the European Union Council Directive 2001/18/EC[12] is the primary legislation controlling the deliberate release into the environment of GMOs. The aim of Directive 2001/18/EC is to ensure that due attention is given to managing the risks from the deliberate release into the environment of GMOs, and that a harmonised approach exists across all 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 England, Directive 2001/18/EC has been implemented by the Environmental Protection Act 1990 (Part VI) and the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443) made under that Act. The Department for Environment, Food and Rural Affairs (Defra) has functions and responsibilities in relation to the deliberate release of GMOs.

1.2 EC Directive 2001/18/EC sets out measures for releasing a GMO for research or development purposes (Part B of the Directive) 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 has been undertaken. If authorisation is granted it is 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.

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

2.1 In April 2004 EU regulation EC/1829/2003[13] 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 Authority[14] 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 specifies a requirement for the 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).

[12] European Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EC
[13] See http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF
[14] See http://www.efsa.europa.eu/en/panels/gmo.htm

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 food safety and food standards import controls on food products, and they are the appointed enforcement bodies for these Regulations15.

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.**

3.1 EC Regulation 1830/2003[16] 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 and the Food Standards Agency share 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/science/novel/gm/gm-labelling.

**4. UK legislation:**

**The Environmental Protection Act 1990**

4.1 The Environmental Protection Act 1990[17] is the primary legislation that gives the Defra Secretary of State general powers and responsibilities to control the deliberate release of GMOs in England, and to implement Directive 2001/18/EC. Enforcement of GM regulations must be effective, proportionate to risk, cost effective and promote public confidence. Under section 114 of the Environmental Protection Act 1990, GM Inspectors are appointed for the purpose of upholding the legislation concerning

[15] See http://www.food.gov.uk/enforcement/
[16] See http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2003R1830:20081211:EN:PDF
[17] See http://www.legislation.gov.uk/ukpga/1990/43/contents

deliberate release of GMOs in England, including the inspection of GMO release sites. The rights of entry of inspection and powers of inspectors are 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 a breach 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. When an incident of potential non-compliance is identified the GMI does not itself pursue prosecutions; instead, all potential enforcement cases are referred to Defra investigations officers and lawyers for further consideration.

4.2 Currently there are four appointed GM Inspectors, although not all their time is dedicated to dealing with the inspection and enforcement of GMOs, as a certain portion is also spent carrying out other Fera business.

4.3 The Genetically Modified (Deliberate Release) Regulations 2002 supplement the EPA by setting out detailed rules for the implementation of Directive 2001/18/EC, including specific requirements for applications to release GMOs.

Note: Legislation relating to the contained use of GMOs and the use of GMOs in clinical trials is enforced by the Health and Safety Executive (http://www.hse.gov.uk/). The contained use of genetically modified organisms is controlled by EU Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 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).

**5. The UK Competent Authority**

5.1 Defra is the UK competent authority for Directive 2001/18/EC, and it would handle any applications under that legislation for EU approval to release a GMO for commercial marketing. Applications for consent to release a GMO for trial purposes would be handled by the relevant authority in Wales, Scotland or Northern Ireland or by Defra if the intended release site was in England. For both GMO trials or commercial marketing, the application for approval must include a thorough risk assessment and relevant supporting information. UK Ministers and the Devolved Administrations are advised on the potential risks of proposed GMO releases by an independent scientific expert group, the Advisory Committee on Release to the Environment (ACRE)[18]. It reviews all Part B applications for consent to release a GMO and indicates whether adverse effects on human health or the environment are likely to arise. As part of its advice ACRE may recommend risk management conditions for the trial operator to observe, including monitoring procedures following completion of a trial. 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.

[18] https://www.gov.uk/government/organisations/advisory-committee-on-releases-to-the-environment

5.2 For more information on the regulatory process visit the Defra website: https://www.gov.uk/government/policies/making-the-food-and-farming-industry-more-competitive-while-protecting-the-environment/supporting-pages/genetic-modification.

**6. Current rules on genetically modified varieties and seeds**

6.1 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

6.2 EU 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 EU[19]. 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.

6.3 As of 31st March 2015 two GM events are authorised for cultivation in the Member States of Europe: maize MON 810, developed by Monsanto to provide resistance to the European corn borer (*Ostrinia nubilialis*) and maize T25, developed by Bayer CropScience, which is tolerant to glufosinate ammonium. Of these two maize events, only maize MON810 can be grown in the EU because T25 maize does not have any varieties registered on the Common Catalogue. In principle MON810 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 European corn borer is present, and they are not well suited to cultivation in the shorter UK growing season.

Note: GM potato EH92-527-1 (Amflora), developed by BASF for production of starch for non-food use, was approved for marketing in 2010[20], but was withdrawn from the EU market in January 2012.

[19] 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

[20] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:053:0015:0018:EN:PDF; C/SE/96/3501; unique identifier BPS-25271-9.