

GM Inspectorate
The Food and Environment Research Agency
Environmental Protection Act 1990 Part VI (Genetically Modified Organisms)

Annual Report on GM inspection and enforcement activities
01 April 2009 - 31 March 2010

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List of acronyms used

AGMP	Adventitious GM presence
BSPB	British Society of Plant Breeders
Defra	Department for Environment, Food and Rural Affairs
EC	European Commission
EFSA	European Food Safety Authority
ERA	Environmental risk assessment
Fera	Food and Environment Research Agency
GM	Genetically modified
GMI	Inspectorate for deliberate releases of GMOs
GMO	Genetically modified organism
MS	Member State(s) of the European Union
PHSI	Plant Health and Seeds Inspectorate
QRA	Quantitative risk assessment
SOSR	Spring oilseed rape
the Directive	European Council Directive 2001/18/EC
V&S	Fera's Varieties and Seeds team, the competent authority for seed marketing in England
WOSR	Winter oilseed rape

Executive summary

1. The GM Inspectorate, based at the Food and Environment Research Agency, is responsible for enforcement of legislation controlling the deliberate release of genetically modified organisms in England. As there is currently no commercial cultivation of GM crops in England, this concerns small-scale experimental releases and any unauthorised releases. The work is undertaken for the Department for Environment Food & Rural Affairs. This is the tenth report of the GM Inspectorate covering the period 1st April 2009 to 31st March 2010.
2. Fera is an executive agency of Defra, whose over arching purpose is to support and develop a sustainable food chain, a healthy natural environment, and to protect the global community from biological and chemical risks. Fera's role within that is to provide robust evidence, rigorous analysis and professional advice to the UK Government, and national and international organisations in both the public and the private sectors. Further information about Fera is available at <http://www.fera.defra.gov.uk/>.
3. Within the reporting period there was one GMO deliberate release field trial in England, which was a small-scale proof-of-concept trial for potatoes modified for resistance to potato cyst nematodes (*Globodera* species). Field inspections confirmed that the release was consistent with the conditions of the consent and that no risks to human health or the environment were identified by release of the GMO.
4. Four post-trial inspections of former deliberate release trial sites, and four management audits, were carried out in the reporting period. In all cases the consent holders were found to be acting in accordance with the conditions of their respective consents.
5. A further monitoring inspection was carried out at a former trial site of winter oilseed rape that had previously been found to contain a low level of adventitious GM presence. The management of this unintentional release, which took place in the county of Somerset in 2007/08, was in accordance with the management plan devised by the GM Inspectorate, and no risks to human health or the environment were identified.
6. On behalf of Fera's Variety and Seeds team (V&S), which is the competent authority for seeds marketing in England, the GM Inspectorate runs a programme of voluntary audits of seed importers and producers. The audits focus on helping companies to be aware of the risks of adventitious GMOs in the seed they import and produce, and discuss how these risks can be managed. The 27 seed companies that participated in the audits in 2009-10 were found to have acted responsibly in managing the risk of adventitious GM presence in conventional seed they were marketing.
7. Five additional targeted audits were carried out on new companies (2) and to follow up certain recommendations made to existing companies audited in the previous audit year (3). Summary tables of the findings of the audits have been published on the GM Inspectorate website at <http://www.gm-inspectorate.gov.uk/seedAuditProgramme/auditReports.cfm>.
8. No investigations into the unauthorised release of GMOs were necessary in the reporting period.

1. The role of the GM Inspectorate

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

1.1 Experimental (Part B) deliberate release trial sites

One of the primary roles of the GM Inspectorate is to ensure compliance with consents granted under Part B of EC Directive 2001/18/EC¹, hereafter called “the Directive”. Part B consents authorise the release of a GMO for “any purpose other than for placing on the market, including for the purposes of scientific research”, this includes, *inter alia*, research, development or demonstration purposes, variety registration, herbicide authorisation, seeds multiplication or biosafety/risk assessment research.

In the UK, consent to conduct a Part B trial is issued by Defra in accordance with section 111 of the Environmental Protection Act 1990². Each consent document specifies the limitations and conditions attached to the specific release, including requirements for reporting to the Secretary of State for Environment, Food and Rural Affairs. The limitations and conditions are aimed at ensuring the GMO does not enter the food and feed chain and does not pose any risks to human health or the environment. The GM Inspectorate operates a programme of inspections and audits aimed at establishing that consent holders comply with these terms and conditions, and if not, to take action to correct this.

The GM Inspectorate’s programme is achieved by a combination of practical inspection visits at deliberate release trial sites, and audits of consent holders to ensure that they are aware of their responsibilities and discharging their duties appropriately. These activities are described in more detail below. A summary of the inspections and audits completed in 2009-10 is provided in Table 1 in section 2 of this report.

- *Field inspection*

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

- *Post-trial monitoring*

The majority of deliberate release consents are issued with specific requirements to monitor the release site following harvest of a trial. The GM Inspectorate visits each

¹ See: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:106:0001:0038:EN:PDF>

² Further information can be found at <http://www.defra.gov.uk/environment/gm/regulation/index.htm>

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

- *Consent holder audits*

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

- *Consent holder monitoring reports*

Under the Directive, consent holder monitoring reports are required annually for all consents until they are officially terminated. The European Commission provides a suggested template for these reports at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:254:0021:0028:EN:PDF>.

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

In the post-trial monitoring phase, the report provides Defra with information on the effectiveness of the measures in place to control any plants that emerge at the trial site, including details of the number of plants detected each month on each GMO area. The consent holder is also required to re-evaluate the monitoring requirements and state whether, in their view, monitoring should be modified or discontinued at the site and the reasons for this. The GM Inspectorate is responsible for administering submission of these reports to Defra.

- *Reporting the GMI field inspection programme*

Draft reports on growing season crop inspection visits are produced and submitted to the consent holder and Defra within an agreed framework of five working days. A period of 20 calendar days then follows in which both parties are given the opportunity to comment on

the factual details of the report. Final field inspection reports are then placed on the public register and on the GMI website at:

<http://www.gm-inspectorate.gov.uk/deliberateRelease/exptreleases.cfm>.

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

1.2 Adventitious presence of GMOs in conventional seed stocks in England

Whilst genetically modified crops are not currently commercially cultivated in the UK, a number of GM maize varieties are authorised for cultivation in Europe, and GM varieties of other agricultural crops are cultivated worldwide. Experimental work has also been undertaken at the field-trial scale in a number of countries, for a range of different species. There is, therefore, potential for seed to acquire adventitious GM presence either by cross-pollination or admixture. Certified seed production methods employ measures to ensure a specified level of purity of certified seeds, but these are not specifically geared towards ensuring seed is free of AGMP. Current seeds legislation does not lay down specific thresholds for the adventitious presence of authorised GMOs in conventional seed. However, to comply with Directive 2001/18/EC and Regulation (EC) 1830/2003³, and since no thresholds are established, seed containing an authorised GMO at any level must be labelled. It is also illegal to market seed containing a GMO that has not been authorised for commercial cultivation in Europe.

- *GM seeds*

Authorised genetically modified crops may be marketed throughout Europe providing the varieties offered for sale have met the requirements for placing on the Common Catalogue of Varieties (see Annex 1). There are currently two consents authorising cultivation of GM maize in the EU, these are MON810⁴ and T25⁵. At present only varieties of MON810 modified for resistance to the European corn borer (*Ostrinia nubilialis*) have been placed on the Common Catalogue⁶. In principle these varieties could be marketed in the UK provided they were correctly labelled, however, to date they are all late-maturing varieties developed for cultivation in areas where the European corn borer is present, and they are not well suited to cultivation in the shorter UK growing season.

- *Seed audit programme*

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

- *Risk assessment*

The GM Inspectorate has developed computer-based models for the quantitative assessment of the risks of AGMP in conventional seeds for those key agricultural crops that are known to have been genetically modified⁷. The QRA models have been

³ See: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0024:0028:EN:PDF>

⁴C/F/95/12/02, Monsanto.

⁵C/F/95/12/07, Bayer CropScience.

⁶As of 1st July 2009 there were more than 70 varieties of maize containing the MON810 event listed in the EC Common Catalogue of Varieties.

⁷ *Brassica napus* (winter and spring oilseed rape), *Brassica rapa* (turnips, turnip fodder rape, stubble turnip, etc.), *Zea mays* (maize and sweetcorn), *Glycine max* (soya), *Triticum aestivum* (wheat), *Beta vulgaris* (sugar beet and fodder beet),

developed in discussion with industry representatives, risk analysis experts and Defra. The models generate probability distributions of relative GM presence based on worldwide GMO activity, crop biology and seed production processes, and produce a set of distributions displaying the relative risks for the major crop species. For a full description of the models and their outputs please refer to the GMI report 2008-09 (http://www.gm-inspectorate.gov.uk/reportsPublications/documents/GMIannualreport2008-09_final.pdf).

- *Risk-based audit programme*

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

- *Seed audits 2009-10*

The risk assessment models were fully updated in 2009 to reassess the risks of AGMP to seeds of key crops, and in 2009-10 the audit programme included seeds of *Zea mays* (maize, including sweetcorn), *Brassica napus* (winter and spring oilseed rape, swede and swede forage rape), *Brassica rapa* (turnip, turnip fodder rape, stubble turnips, pak choi, Chinese cabbage, etc) and *Glycine max* (soya) intended for agricultural and horticultural use, official trials and private company trials. A summary of the seed audits completed in 2009-10 is provided in Table 2 in section 2 of this report.

- *Reporting the GMI seed audit programme*

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

- *Seed audit data management*

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

1.3 Unauthorised GMO releases

The GM Inspectorate is also responsible for investigating any incidents where there has been a reported or suspected release into the environment of any GMO that has not been

Brassica oleracea (cabbages, kales, cauliflowers etc.), *Medicago sativa* (alfalfa), *Trifolium repens* (white clover), *Lycopersicon lycopersicum* (tomato), *Agrostis stolonifera* (creeping bentgrass).

authorized for release in the UK or Europe. In the current reporting period it has not been necessary to investigate any incidents of the unauthorised release of GMOs.

- *Enforcement of the Environmental Protection Act 1981*

GM Inspectors are appointed under Section 114 of the Environmental Protection Act 1990 (Part VI). The rights of entry of inspection and powers of inspectors are as described in sections 115 to 117 (inclusive) of the Act. A GM inspector may identify a potential breach of the relevant GM legislation in the course of official duties, or they may be notified to the GMI or the regulatory authority by a consent holder, a seed company or a member of the public. The GMI investigates all potential incidents on a case-by-case basis and takes action as appropriate. The GMI does not itself pursue prosecutions when an incident of potential non-compliance is identified; instead, all potential enforcement cases are referred to Defra investigations officers and lawyers for further consideration. No formal investigations were pursued in 2009-10.

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

2.1 Field inspections and consent holder audits undertaken 2009-10

Table 1: Summary of field inspection programme for the 2009-10 financial year

Activity	Number	Consent number / holder and purpose	Outcome
Field inspections	2	07/R31/01 (planting). Potato modified for resistance to potato cyst nematode	In all cases the GM Inspectorate was content that the release was consistent with the conditions of the consent and did not identify any risks to human health or the environment posed by the GMO.
		07/R31/01 (growing season)	
Post-trial monitoring inspection	4	01/R4/10/01 (2001)	In all cases the GM Inspectorate was content that monitoring of the former release site was consistent with the conditions of the consent and did not identify any risks to human health or the environment posed by the GMO.
		02/R4/12/01 (2003)	
		06/R42/01 (2007)	
		06/R42/01 (2008)	
Consent holder audit	2	University of Leeds (growing season audit)	The GM Inspectorate was content with procedures implemented by the consent holders for management of their consents
		Advanced Technologies (Cambridge) Limited (post-trial monitoring only)	
Consent holder monitoring report(s)	4	01/R4/10/01 (post trial monitoring)	Defra was content with the end-of-year reports submitted.
		02/R4/12/01 (post trial monitoring)	
		06/R42/01 (post trial monitoring)	
		07/R31/01 (field trial)	
Unauthorised release	1	N/A	Reported in GMI annual report 2008-09. An in-year inspection was scheduled to ensure management plan is being adhered to and any volunteer OSR plants controlled. The inspection confirmed this to be the case.

2.2 Monitoring adventitious GM presence in conventional seed stocks in England: Audits of seed importers and producers: 2009-2010

Table 2 Summary of seed audit programme for the 2009-2010 financial year

Audit type	Summary details
Detailed audit	Total number of companies contacted: 8 Reports completed: 8 Companies declining to participate: 0 Companies not marketing any crops of interest: 0
Collection of basic data on seeds marketed	Total number of companies contacted: 41 Reports completed: 27 (including non-participant reports) Companies declining to participate: 10 Companies not marketing any crops of interest: 14
Targeted audit	Total number of companies contacted: 6 Reports completed: 5 Companies declining to participate: 0 Companies not marketing any crops of interest: 1

The seed audit programme for 2009-10 was completed in July 2010 and summary reports were published on the GM inspectorate website in November 2010 (www.gm-inspectorate.gov.uk/seedAuditProgramme/auditReports.cfm). Most seed companies participating in the audit were found to have acted responsibly in managing the risk of AGMP in conventional seed. It was not necessary to recall or destroy any marketed seed because of an unauthorised adventitious GM presence. Ten companies known to be marketing seed within scope of the audit programme in England chose not to participate in the programme. Five targeted audits were undertaken in the 2009-10 programme. Three of these audits were to re-visit companies audited under the 2008/09 programme to monitor progress with recommendations made: all companies were now deemed to be operating in an acceptable manner with regard to AGMP risk management. The other two targeted audits were for companies that have recently commenced activities of interest to the Inspectorate. Both companies were deemed to be acting responsibly in their management of AGMP risk.

3. GMO research undertaken 2009 to 2010

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

Fera has recently completed research for Defra to assess the level of potential AGMP in winter oilseed rape that may arise due to the sharing of farming and transport equipment and storage facilities, between GM and non-GM production streams. The scope of the project included practical assessment of on-farm processes, from seed sowing through to crop spraying, harvest, transport, drying and storage. The research aimed to quantify sources of AGMP, measure the effects of AGMP mitigation, and collate and model data that could be used for best practice industry guidelines.

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

The final report for the research was submitted to Defra in July 2010; it will be published on the Defra website in due course⁸. A paper has recently been submitted to the Journal of Agricultural and Food Chemistry. This research provides further evidence to underpin Defra's strategy on the coexistence of cultivation of GM and other crop types in England.

3.2 Defining environmental risk assessment criteria for genetically modified fishes to be placed on the EU market (CT/EFSA/GMO/2009/01)

In 2009-10 Fera was a partner in a review project carried out on behalf of the European Food Safety Authority to define environmental risk assessment criteria for genetically modified fishes to be placed on the EU market. The project was undertaken in collaboration with Hull International Fisheries Institute, Bournemouth University and the Centre for Environment, Fisheries and Aquaculture Science (Cefas). The purpose of the research was to assist the EFSA GMO Panel⁹ in its work on GM animals, and in particular assessment of the environmental safety of GM animals. The report will be used to support development of EFSA's guidance documents for the risk assessment of genetically modified animals.

Research summary

The most common drivers for the development of GM organisms include enhanced disease resistance, growth and environmental tolerance and production of ornamental fishes. Potentially, the most important routes by which GM fishes can enter the natural waters are escape or deliberate release during transportation, loss from research or experimental facilities, deliberate indiscriminate introductions to improve fishery performance, escape from commercial aquaculture facilities and perhaps vandalism.

⁸ A summary of the project is available on Defra's GMO research pages at: <http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=15811&FromSearch=Y&Publisher=1&SearchText=cb02049&SortString=ProjectCode&SortOrder=Asc&Paging=10 - Description>

⁹ <http://www.efsa.europa.eu/en/panels/gmo.htm>

The potential adverse effects and consequences from the release of genetically modified fishes into the wild vary according to genetic trait, but the main ecological effects are likely to be enhanced competitive abilities in resource acquisition for GM fishes over non-GM fish; increased predation by GM fishes on non-GM fishes; enhanced survival, somatic growth and reproduction of GM fishes over non-GM fishes under the same conditions; and facilitation of GM fish invasion in habitats that limit the non-GM conspecifics. The fish communities into which GM fishes are released is also an important consideration, with more severe effects likely where wild conspecifics are present.

Two complementary approaches were identified to determine the interactions of released GM fishes with non-GM wild fish in the wild: laboratory experiments and field trials using non-GM surrogate fish. Using non-GM surrogates confer a number of advantages, including the wide availability of existing studies on surrogates in wild situations.

A number of characteristics of the receiving aquatic ecosystem were identified as important for undertaking environmental risk assessments on GM fishes. These were used to develop criteria for assessing the potential impact of GM fishes released into the wild, and will help formulate methodologies to assess any impact.

The report was published in July 2010 and is available at:

<http://www.efsa.europa.eu/en/scdocs/scdoc/69e.htm>.

3.3 Defining environmental risk assessment criteria for genetically modified (GM) mammals and birds to be placed on the EU market

In December 2009 Fera, in collaboration with the University of Leeds, was awarded the contract to undertake a review of risk assessment criteria for GM mammals and birds to be placed on the EU market. This is the third¹⁰ in the series of reviews commissioned to support EFSA in development of its guidance documents for the risk assessment of genetically modified animals.

Globally, GM mammals and birds are being developed for a range of purposes, including use as food, pets or for production of pharmaceuticals. The review will provide an analysis of the type of expertise and data required to conduct an environmental risk assessment (ERA) of GM mammals and birds to be commercially released into the EU environment.

The project has developed a searchable database of expertise relevant to an ERA using information collated against scientific disciplines, fields of expertise, research institutes, and academics/experts. In addition a database of GM species and traits where substantial progress has been made towards commercial use has been compiled. Theoretical case studies have been used to allow the development of a comprehensive list of criteria to be considered in an ERA.

The research studies the potential adverse effects of GM mammals and birds on the environment, and identifies their consequences and likelihood of occurrence. Crucial mammal and bird characteristics, baseline information about receiving environments and approaches using modelling and surrogate non-GM species are also evaluated for their utility in an ERA. Consideration is also given to any infectious diseases, or agents, that

¹⁰ EFSA also commissioned "Defining environmental risk assessment criteria for genetically modified (GM) insects to be placed on the EU market".

may be carried by the species and how these may be influenced by the genetic modification.

The report is due for completion in December 2010 and will be published on the EFSA website in due course.

4. Looking ahead to the 2009 - 2010 reporting year

1. The GM Inspectorate team is part of Fera's Land Use and Sustainability programme, which is in Fera's Crop and Food Security Programme. Further information about Fera is available at <http://www.fera.defra.gov.uk/>. The GM Inspectorate website address remains unchanged (<http://www.gm-inspectorate.gov.uk/>), and can be accessed via 'quick links' on the Fera home page.

Hampton Implementation Review

2. In 2009, the Department of Business, Innovation and Skills (BIS)¹¹ conducted a 'Hampton implementation review' of Fera. The purpose of the review was to provide Fera and its stakeholders with a structured check on performance against the Hampton¹² principles and the Macrory¹³ characteristics for the regulation of businesses.
3. The review of Fera included the Plant Health and Seeds Inspectorate, the Varieties and Seeds team, and the GM Inspectorate. The Hampton Implementation team interviewed a number of representative stakeholders and regulated businesses during the course of their review. The report was published on 3rd December 2009. The review team found that Fera demonstrates good compliance with the Hampton criteria in many areas, and has examples of recent good practice in strengthening its performance. Its recent creation provides further opportunities to improve its approach, for example how it shares information and requests data from business. The GMI's seed audits were noted for the clear, evidence-based approach that is taken to underpinning the risk-based audit programme.
4. The review did identify a number of areas where Fera could improve compliance with the Hampton principles for better regulation, and a dedicated project has been established for this purpose. In particular, Fera does not currently publish its own enforcement policy but refers to Defra's; one of the recommendations was that Fera should review its enforcement policy so that it is clear what Fera's own policy is, and the project is looking at this. The full review for Fera, and the Hampton Implementation plan are available at:
<http://www.fera.defra.gov.uk/aboutUs/betterRegulation/index.cfm>.
5. The Hampton Implementation project is one of Fera's Ministerial and strategic targets and is due to be completed in June 2011.

¹¹ BIS was created in June 2009 following a merger of parts of the Department for Enterprise and Regulatory Reform (BERR) with the Department for Innovation, Universities and Skills (DIUS).

¹² Sir Philip Hampton's 2005 review, 'Reducing administrative burdens: effective inspection and enforcement' considered how to reduce unnecessary administration for businesses, without compromising the UK's excellent regulatory regime (<http://www.berr.gov.uk/files/file22988.pdf>)

¹³ The Macrory Review (2006) looked at the main reasons businesses were not compliant, and what could be done to address the situation. Recommendations from the review aimed to ensure regulators had a set of modern and flexible sanctions to use that were proportionate and appropriate to the risks faced (<http://www.berr.gov.uk/whatwedo/bre/reviewing-regulation/compliance-businesses/page44102.html>)

5. Contact details

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

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

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

- 5.2 For further information on the Fera GeMMA (genetically modified material analysis) scheme please visit:
<http://www.fapas.com/proficiency-testing-schemes/gemma/>

Or contact us at:

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

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

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

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

Appendix 1: GM legislation and regulation in the UK

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

- 1.1 In the European Union the deliberate release of GMOs is restricted under EU Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms¹⁴. This Directive provides a harmonised approach across all the EU member states to the assessment of risks to the environment and to human health in relation to the release and marketing of GMOs. In Great Britain Directive 2001/18/EC has been implemented by the Environmental Protection Act 1990 (Part VI) and regulations made under that Act (e.g. in respect of England, the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443)). The Department for Environment, Food and Rural Affairs (Defra), the Scottish Executive and the National Assembly for Wales have functions and responsibilities in relation to the deliberate release of GMOs.
- 1.2 The regulatory regime for GMOs has two key objectives, to protect human health and the environment and to ensure consumer choice. Enforcement must be effective, proportionate to risk, cost effective and promote public confidence. Under section 114 of the Environmental Protection Act 1990, GM Inspectors (currently there are 4) at Fera are appointed for the purpose of the inspection and enforcement of the legislation concerning deliberate release of GMOs in England. Clinical trials are inspected and enforced by the Health and Safety Executive.
- 1.3 EU Directive 2001/18/EC sets out measures for releasing a GMO for research or development purposes (Part B) and for placing a GMO on the market (Part C). Depending on the intended use of the GMO, an alternative route for commercial release of GMOs is available under EU regulation 1829/2003, (see below). GMOs must not be released into the environment until a thorough assessment of the GMO that is proposed for release has been undertaken. If authorisation is given it will be accompanied by specific conditions detailed within the consent to release the GMO, these are designed to safeguard against any risks to human health and the environment.

UK Competent Authority

- 1.4 In the UK consent to release a GMO under Directive 2001/18/EC may be obtained by submission of a detailed application, which includes a thorough risk assessment, to the Northern Ireland, England, Wales and Scotland (NIEWS) GM Unit based at Defra. This unit administers all applications (Part B and Part C) for the release of a GMO in the UK and coordinates consultation on applications by other EU Member States. NIEWS also provides the Secretariat to the Advisory Committee on Releases to the Environment (ACRE). ACRE is an independent advisory committee composed of leading scientists whose main function is to advise UK Ministers and the devolved administrations on the risks to human health and the environment from the release and marketing of GMOs¹⁵. ACRE reviews all Part B

¹⁴ In the EU, the contained use of genetically modified organisms is controlled by EU Directive 98/81/EC of 26 October 1998 on the contained use of genetically modified micro-organisms, and in the UK the Genetically modified organisms (contained use) regulations 2000 (S.I. 2000/2831), which is enforced by the Health and Safety Executive.

¹⁵ See <http://www.defra.gov.uk/acre/index.htm>

applications for consent to release a GMO and, if satisfied that the proposed release will have no adverse effects on human health or the environment, the Committee will advise that the consent may be issued. ACRE's advice may include recommendations for monitoring following completion of the trial, and other aspects of management of the release. Authorisation to place a GMO on the market under Part C of Directive 2001/18/EC is given at EC level after extensive consultation by the competent authorities of the EU member states. ACRE also reviews and advises on all Part C applications for the UK as well as on the environmental aspects of applications under the GM Food and Feed Regulation 1829/2003.

- 1.5 For more information on the regulatory process see the Defra website at <http://ww2.defra.gov.uk/environment/quality/gm/>

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

- 2.1 In April 2004 EU regulation EC/1829/2003 on GM food and feed came into force in the European Union. This regulation provides for a single Community procedure for the new authorisation of all food and feed derived from a GMO, of the GMO itself as a food or as a feed, and of food or feed containing the GMO. The European Food Safety Authority¹⁶ manages the application and authorisation procedure centrally. Business operators may now file a single application for the GMO and all its uses; a single risk assessment is performed and a single authorisation is granted for a GMO and all its uses including cultivation, importation and processing into food/feed or industrial products.

- 2.2 The regulation specified a requirement for labelling of all GM food and feed which:
- i) contains or consists of GMOs (e.g. GM soya),
 - ii) is produced from GMOs (e.g. glucose syrup from maize starch),
 - iii) contains ingredients produced from GMOs (e.g. GM tomato paste).

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

- 2.3 The Food Standards Agency has responsibility for this regulation. Local authorities and Port Health authorities are responsible for the enforcement of food safety and food standards import controls on food products, and they are the appointed enforcement bodies for these Regulations¹⁷.
- 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.

¹⁶ See <http://www.efsa.europa.eu/en/panels/gmo.htm>

¹⁷ See <http://www.food.gov.uk/enforcement/>

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

- 3.1 The EU regulations on traceability and labelling of GMOs came into force in April 2004. This regulation establishes a harmonised EU system of documentation to account for and identify GM products throughout the supply chain, with the objective of facilitating accurate labelling. For certain products, a system of unique identifier codes will be used to allow access to specific information on GMOs from a community register of GM food and feed. In England the regulation has been implemented by the Environmental Protection Act and regulations made under that Act (the Genetically Modified Organisms (Traceability and Labelling) (England) Regulations (S.I. 2004/2412)). Defra has regulatory responsibility for this area and the local authorities and Port Health Authorities are the designated enforcement bodies.
- 3.2 Full details of regulations 1829/2003 and 1830/2003 can be found on the Food Standards Agency website at <http://www.food.gov.uk/gmfoods/> and http://www.food.gov.uk/gmfoods/gm/gm_labelling.

4. Current rules on genetically modified varieties and seeds¹⁸

- 4.1 EU legislation on seeds (notably Directive 2002/53/EC on the Common Catalogue of varieties of agricultural plant species and 2002/55/EC on the marketing of vegetable seed) specifies that national authorities that have agreed to the marketing of seed of a certain variety on their territory must notify the acceptance of the variety to the European Commission. To qualify for inclusion in national catalogues varieties must meet defined Community criteria with respect to distinctness, uniformity and stability and, in the case of agricultural species, value for cultivation and use. Once a variety of seed is properly inscribed in a national catalogue, the Commission is informed and is required to inscribe the variety in the Common Catalogue by publication in the Official Journal; once this is done the seed of such a variety can be marketed throughout the EU.
- 4.2 Seed legislation also requires that genetically modified varieties must be authorised in accordance with EU Directive 2001/18/EC before they are included in the Common Catalogue and marketed in the EU¹⁹. The Commission examines the information supplied by the Member State as regards inclusion in a national list to ensure it is in compliance with Community legislation and includes the variety concerned in the Common Catalogue of varieties. As of 1st July 2009 there were more than 70 varieties of genetically modified maize MON810 registered in the Common Catalogue.

¹⁸ http://ec.europa.eu/food/food/biotechnology/gmfood/ganda_en.htm

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