ANNUAL REPORT OF THE SASA GM INSPECTORATE

GM Inspection and Enforcement Activities

Covering the period 1 April 2005 to 31 March 2006

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1. SUMMARY

1.1 The GM Inspectorate is based at the Scottish Agricultural Science Agency (SASA) and has authority under part VI of the Environmental Protection Act 1990 for inspection and enforcement of the release and marketing of genetically modified organisms (GMOs) under EU Directive 2001/18 in Scotland.

1.2 This is the sixth report of the GM Inspectorate since taking over responsibility from the HSE for inspection and enforcement functions in May 2000. The report covers the period 1 April 2005 and 31 March 2006.

1.3 The report describes the three main work areas of the GM Inspectorate; (1) inspection of research and developments trial sites where GMOs have been authorised for release, (2) management audits of deliberate release consent holders and (3) audits of seed merchants and importers to ensure they are taking appropriate steps to prevent the adventitious presence of GM events in conventional seed. This work is undertaken to ensure compliance of the GM legislation covering the release and marketing of GMOs as set out in the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations (2002) and Environmental Protection Act (1990). The GM Inspectorate is also responsible for identifying and investigating potential infringements of this legislation on a case-by-case basis, and take action as appropriate.

1.4 There have been no field releases of GM crop plants that have been approved for either research trials or for cultivation during the reporting year.

1.5 A major component of the Inspectorate's duties was completed during the year, namely checking compliance for releasing GM oilseed rape under research trial conditions in accordance with part B consents under EU Directive 2001/18/EC. During the year oversight of the final phase of post-trial monitoring of oilseed rape sites was concluded. This involved inspections of two former release sites. A further five sites under rotational restrictions, were checked to ensure an appropriate follow-on crop was being grown until the sites are allowed to be brought back to normal cultivation. In all cases the conditions of the consents were met. No issues of harm to human health or the environment were identified. As of 9 March 2006, post-harvest monitoring has finished on all former oilseed rape research trial sites in Scotland.

1.6 The only monitoring work that remains in this area of work is the oversight of crop-rotation restrictions that applies to a potato research consent which will finish in the autumn of 2007.

1.7 In connection, with deliberate releases a postal management audit was conducted on a Scottish consent holder. The audit provided assurance that the consent holder had implemented appropriate management procedures to ensure post-trial monitoring and reporting is undertaken in accordance with the consent conditions.

1.8 SASA and SEERAD's ongoing seed monitoring programme continued throughout the year. The scope of the audit programme is determined by an assessment of which crops are at risk of acquiring adventitious GM presence, based upon GM releases worldwide, the biology of the crops involved, and the implications for UK crops. Biannual surveys of the Scottish seed industry are undertaken jointly in the spring and autumn. These surveys indicated that imported seed of crops species, currently considered to be at risk (beet, oilseed rape, maize and some related species to oilseed rape and beet) was traded by c. 38 % of the merchants, processors or packers (MPP) registered in Scotland.

1.9 Whilst the majority of Scottish seed merchants did not import seed directly into Scotland, they nevertheless have a duty of care to ensure that non-GM seed was free of unapproved GM events. To establish that reasonable steps had been taken to achieve this, the Inspectorate visited a selected sample of eight seed merchants and carried out audits during the year. Four audits were conducted for spring-sown crops (oilseed rape, beet and maize) and for winter-sown oilseed rape. On completion of the auditing procedure, the SASA Inspectorate had no reason to suspect the presence of GM material in any of the seed marketed by the eight companies. Reports covering the two audits are given in Annex 2 and 3.

1.10 During the reporting year, no incidents had come to the attention or been reported to the GM Inspectorate. The GM Inspectorate, therefore, had no grounds for carrying out enforcement sampling or testing.

1.11 The GM Inspectorate has regularly commented throughout the year on a range of GM issues from inspection, agronomic and scientific perspectives. These have included marketing consent dossiers, management of former deliberate release sites, development of proposals for the Executive's policy on co-existence measures and evaluation of GM related research proposals.

1.12 The GM Inspectorate participates in a number of enforcement groups that operate at a national and European level. These include the GM Enforcement Liaison Group within the UK which attempt to ensure there is a consistent and effective approach to GM enforcement across government departments and enforcement agencies and the European Enforcement Project (EEP) within Europe. The EEP focuses on contained use and deliberate release issues across European Union (EU), European Economic Area (EEA) and European Free Trade Association (EFTA) members. A member of the GM Inspectorate spoke to their annual meeting on planning enforcement investigations.

1.13 The GM Inspectorate regularly attends relevant conferences to maintain their technical competence and knowledge. Inspectors also attended conferences to discuss co-existence measures to ensure the viability of conventional and organic farming with genetically modified crops.

1.14 SASA's Diagnostics and Molecular Biology Section (DMB) provides a GM diagnostic service for the GM Inspectorate. During the reporting year the Section participated in a number of international projects involving the validation of the GM event T25, a copy number determination in MON 810 Maize and a ring test using GM soybean.

2. INTRODUCTION - THE REGULATORY FRAMEWORK

In the UK the EU Directive 2001/18/EC is implemented via the Environmental Protection Act (1990) and the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002. These provide a statutory safety procedure, involving risk assessment, and the need for prior approval before any GMO can be released or marketed. This is a devolved responsibility. The Executive consents to the release of GM crops for research and development purposes in Scotland. Defra acts as a clearing house for applications for deliberate release; provides the secretariat for the Advisory Committee on Release to the Environment (ACRE) (see below); and co-ordinates the international presentation of UK policy.

The EU Directive recognises two classes of release depending upon their purpose: Part B releases for research and development and Part C releases for placing on the market. In the UK, Part B consents are granted, on a case-by-case basis, after a detailed risk assessment has been submitted to the

Northern Ireland, England, Wales and Scotland GM Unit (NIEWS)[1] in Defra and considered by ACRE, a statutory Advisory Committee, consisting of independent scientific experts who advise on the risks to human health and the environment from the release of GMOs. The committee advises Scottish Ministers on whether an application for a release in Scotland should be allowed. Ministers also take advice from the Health and Safety Executive, the Food Standards Agency and Scottish Natural Heritage as appropriate. Consents set out the conditions and limitations governing releases. Part C releases are granted at the EU level and are effective throughout the EU.

Compliance with the above legislation regulations is established by official inspection, to ensure that releases are being conducted in accordance with the conditions of consents. Non-compliance with consent conditions can lead to enforcement action including, where necessary, the prosecution of consent holders. SASA took responsibility for the inspection and enforcement of the deliberate release and marketing of GMOs in Scotland in May 2000. At that time, the Central Science Laboratory (CSL) was contracted by Defra to carry out the equivalent inspection and enforcement service for England and Wales.

In April 2004, a new approval procedure, under Regulation EC/1829/2003 was introduced. The scope of this regulation is the marketing of any GMO whose produce, or derived products, that are intended for food or feed, including the cultivation of crop plants that are intended for these uses. The majority of marketing applications, will in future, be processed through this new regulation. The regulation provides a single unified approval process for food and feed uses, which will not then require approval under Part C of Directive 2001/18/EC. The initial application is made through the competent authority of a member state but the lead responsibility for processing the applications rests with a central body, the European Food Safety Authority (EFSA). For applications including cultivation an environmental risk assessment in keeping with the requirements of 2001/18/EC is required, and EFSA is obliged to consult the 2001/18 competent authorities concerning environmental risk assessments. The Foods Standards Agency will lead on these applications in the UK, while the role of ACRE is to advise on the environmental risk assessments provided with applications for cultivation. Allied to this regulation are new traceability and labelling rules, EC/1830/2003, which include a threshold of 0.9%, above which the adventitious presence of material from an EU authorised GMO in a non-GM product triggers traceability and labelling of the product.

Enforcement of these regulations (1829/2003 and 1830/2003) in Scotland is the responsibility of Local Authority Environmental Health (food) or Trading Standards (feed) Departments.

3. THE WORK OF THE GM INSPECTORATE DURING THE REPORTING PERIOD

The work plan agreed between the GM Inspectorate and SEERAD covering the period 1 April 2005–31 March 2006 is given in Annex 1 of this report.

The report describes the three main work areas of the GM Inspectorate; (1) inspection of research and developments trial sites where GMOs have been authorised for release, (2) management audits of deliberate consent holders and (3) audits of seed merchants and importers to ensure they are taking appropriate steps to prevent the adventitious presence of GM events in conventional seed. This work is undertaken to ensure compliance of the GM legislation covering the release and marketing of GMOs as set out in the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 and the Environmental Protection Act (1990). It is also the responsibility of the GM Inspectorate to identify and investigate potential infringements of the legislation on a case-by-case basis, and take action as appropriate.

[1] Formerly the Joint Regulatory Authority

3.1 Inspections

Inspections are conducted on GM crop research trials (Part B consents) using a standard operating procedure and a checklist by field inspection, and examination of the site operator's records. They are conducted during an experimental release and for a set period following the termination of the trial to ensure that post-harvest monitoring procedures, such as the control of volunteers or subsequent cropping, are being carried out in accordance with the conditions of a consent.

There is also a period following official monitoring, where cropping is restricted until the site can be returned to a normal agricultural rotation. In these cases the follow-on crops are checked to ensure they are in accordance with the conditions of a consent.

Draft inspection reports are sent to the GM Co-ordination Team of the Scottish Executive after each inspection[2]. Final inspection reports are then placed on the Scottish Executive's website at http://www.scotland.gov.uk/Topics/Environment/15159/16919.

During the reporting period inspections covered three types of GM crop research trials namely, farmscale evaluation, variety and seed registration, and research and development trials and two crop types comprising oilseed rape and potato. As the last active GM trial was terminated on 9 March 2004, annual routine inspections were carried out on two research trials that were under going post-trial monitoring. A further five sites were checked to confirm that the fields met the cropping restrictions set out in the consents before they can return to a normal agricultural rotation. In all cases the Inspectorate could confirm these conditions in the consents had been met. At all these sites no risks to human health and the environment were identified.

These inspections and crop checks complete a significant component of the Inspectorate's duties, namely checking compliance for releasing GM oilseed rape under research trial conditions in accordance with part B consents under EU Directive 2001/18/EC. As of 9 March 2006, post-harvest monitoring has finished on all former oilseed rape research trial sites in Scotland. The only outstanding monitoring that remains in this field of work is oversight of crop-rotation restrictions that apply to a potato research consent which will finish in the autumn of 2007.

3.2 Management audits of consent holders

The GM Inspectorate had an on-going programme to audit current Scottish consent holders. Whereas inspections assess compliance at individual deliberate release sites, auditing the management procedures of consent holders at their headquarters provides an overview of their ability to organise and implement releases throughout the life of a consent. The purpose of these audits is to verify that consent holders are aware of their responsibilities for ensuring that the correct procedures and protocols for conducting GM field trials are in place, and that the conditions of a release are known throughout the management chain. Consent holders are required to show evidence of a duty of care by demonstrating that only materials with modifications covered by the consent are released. Further checks are made on the post-trial monitoring procedures and appropriate post-trial cropping as detailed in the consent. Management audit reports are submitted to the GM Co-ordination Team of Scottish Executive.

[2] The locations of these sites and the inspection reports can be found on the Scottish Executive's Genetic Modification website (http://www.scotland.gov.uk/Topics/Environment/15159/16919).

The GM Inspectorate conducted a postal management audit on a Scottish consent holder that was undergoing post-harvest monitoring for 2 deliberate release sites during the reporting year. On the basis of information provided by the consent holder, the Inspectorate were satisfied that the consent holder had implemented appropriate management action to ensure that post-monitoring, appropriate cropping and reporting is undertaken in accordance with the consent conditions.

This component of the Inspectorate's work has also finished as the relevant consent has expired and the consent holder has submitted a final monitoring report to the Scottish Executive.

3.3 Monitoring the sale of conventional seed that may be at risk from adventitious GM material

Under the Directive 2001/18/EC, GM seeds cannot be sold in Europe unless their GM events have been granted a marketing (Part C) consent. Importers and merchants of non-GM seed must take all reasonable steps to ensure that there is no adventitious presence of unapproved GM events before obtaining or marketing conventional seed. The GM Inspectorate has the statutory powers to enter premises of seed companies and to carry out inspections where it suspects that there may be a possibility that the Environmental Protection Act (1990) and GMO Regulations are not being met.

As a result of finding unapproved, adventitious GM material in non-GM oilseed rape varieties in the spring of 2000, which led to crop destruction, many countries in Europe introduced mechanisms to prevent similar incidents from re-occurring. In the UK, the GM Inspectorates[3] were asked to develop programmes for auditing seed imports for the presence of adventitious GM events in non-GM seed, paying particular attention to imported seed in beet, oilseed rape, maize and soybean.

The scope of the audit programme is determined by an assessment of which crops are at risk of acquiring adventitious GM presence, based upon GM releases worldwide, the biology of the crops involved, and the implications for UK crops. In 2004 the list was extended in Scotland to include species and sub-species that are related to oilseed rape (*Brassica napus, B. rapa, B. juncea and B. oleracea*) and beet *(Beta vulgaris).*

Scottish programmes start by surveying seed merchants to establish which companies are marketing seed of the relevant species and whether they import the seed directly into Scotland. Surveys are then followed up by auditing a selected number of merchants to provide evidence that they have taken appropriate steps to ensure that the seed being marketed does not contain GM material.

Biannual Surveys

Biannual surveys of the Scottish seed industry are conducted jointly by SASA and EPHAS staff in the spring and autumn of each year. All the seed that was surveyed was imported via England. No Soya seed was traded in Scotland.

Spring 2005

On completion of the spring 2005 audit, out of the one hundred and seventy-five Scottish registered seed merchants, processors and packers (MPPs), sixteen had failed to reply. Sixty-

[3] The GM Inspectorate at the Central Science Laboratory (CSL) is contracted by Defra to carry out the equivalent inspection and enforcement service for England and Wales. The CSL GM Inspectorate have an extensive seed audit programme

one (38%) of the MPPs who replied had traded in one or more of the species of interest. Companies that traded in spring crops (including related species) were as follows:

30 in spring oilseed rape
8 in maize,
21 in fodder beet and beetroot
45 in swede
49 in turnip
7 in mustard, and
34 in related *Brassicas*.

Nine MPPs previously known to trade these species no longer did so. Ten MPPs who did not trade in the species of interest, according to the 2004 questionnaires, now do so.

Autumn 2005
On completion of the autumn 2005 audit out of the one hundred and seventy-four MPPs, nineteen had failed to reply. Fifty-eight (37%) of the MPPs who replied had traded in one or more of the species of interest. These were as follows:

35 in winter oilseed rape (swede or turnip)
32 in swede
41 in turnip, and
22 in related *Brassica*s.

Eleven MPPs previously known to trade the species of interest no longer did so. Fourteen MPPs who did not trade in the species of eight seed merchants and carried out audits, which involved follow-up action and cross-interest, according to the 2004, questionnaires now do so.

Seed Audits
During the reporting year, the Inspectorate visited referencing SASA and CSL audit information. Four audits were conducted for spring-sown crops (oilseed rape, beet, maize and related *Brassica*s) and four for winter sown oilseed rape (and related *Brassica*s).

During the audits the CSL GM Inspectorate were able to cross reference the majority of the seedlots investigated during the audit of the Scottish seed merchants (CSL aim to audit c. 90% of seed imported into England). The SASA GM Inspectorate was provided with satisfactory assurances and was satisfied that the seed merchants had demonstrated ‘due diligence’ in obtaining assurances from their suppliers.

The SASA Inspectorate had no reason to suspect the presence of GM material in any of the seed marketed by the eight companies.

The spring 2005 and autumn 2005 seed audit reports are at Annex 2 and 3.

3.4 Case by case investigations of potential enforcement cases

During the year, there have been no incidents that have either come to the attention or been reported of the GM Inspectorate. The GM Inspectorate did not carry out any enforcement sampling or testing.

4. OTHER ACTIVITIES

4.1 Provision of technical support

Throughout the reporting year the GM Inspectorate has been in regular contact with policy divisions of the Scottish Executive (GM Co-ordination Team and EPHAS) and Northern Ireland, England, Wales and Scotland GM Unit (NIEWS) in Defra. The GM Inspectorate has commented throughout the year on applications for consent to market GMOs and issues concerning the management of former release sites. During the year, assistance was given with the development of proposals for the Executive's policy on co-existence measures. The Inspectorate has also commented on Scottish, UK and EU policy documents and legislation. It has also assisted in the evaluation of some GM related research proposals.

4.2 GM Enforcement Liaison Group

The Enforcement of the European GM legislation[4] within the UK is the responsibility of a number of government departments and enforcement agencies. To establish a co-ordinated and consistent approach across government, Defra and the Food Standards Agency, established a working group in October 2004 to discuss enforcement issues and develop proposals for responding to any specific issues, especially the release or marketing of unauthorised GMOs. The SASA GM Inspectorate is a member of this group. Other members include the Scottish Executive and the other Devolved Authorities, the CSL Inspectorate, the Health and Safety Executive, the Local Authorities Co-ordinators of the Regulatory Services (LACORS) and the Association of Port Health Authorities (APHA).

4.3 European Enforcement Project

The GM Inspectorate participates in a European Enforcement Project concerned with inspection and enforcement issues of GMOs in contained use and deliberate release. This group consists of GM Inspectorates from EU (members and applicants), EEA and EFTA States. Whilst funding for the project was formally stopped in June 2003, some of the work of the group has continued including notification of GM incidents in other Member States and publication of scientific papers. A paper on presenting enforcement cases for legal proceedings was given by a member of the SASA Inspectorate at a plenary meeting of the Group in Dublin during 26 and 27 May 2005.

4.4 Conferences

Members of the Inspectorate attended the following conference during the year.

- The Second International Conference on GM and non-GM based agricultural supply chains, 14-15 November 2005, Montpellier (France).

[4] Directive 2001/18/EC on Deliberate into the Environment of GMOs, Regulation on GM Food and Feed EC/1829/2003, Regulation on Traceability and Labelling of GM Food and Feed EC/1830/2003 and Regulation on Transboundary Movement s EC/1496/2003.

5. DETECTION OF GMOs TO UNDERPIN GM INSPECTION AND ENFORCEMENT

SASA's Diagnostics and Molecular Biology Section (DMB) provides a GM diagnostic service for the GM Inspectorate. The presence of GM material in both seed and plant material is detected using qualitative DNA-based (polymerase chain reaction {PCR}) analyses. These tests use a range of primers that detect common elements used in GMOs for both authorised and unauthorised events. Sequence Detection Systems (real-time PCR) are also available for quantitative PCR analyses.

To maintain competence in the field of GM diagnostics the section has participated in the following international projects and ring tests:

- Participated in a validation study for the quantification of T25 Maize using real-time PCR. The ring test was organized by the Community Reference Laboratory (CRL) which validates assays on an EU-wide basis.
- Participated in the 5th International Seed Testing Association (ISTA) Proficiency Test on GMO Testing on Soybean (Glycine Max (L.) Merr)
- Participated in the real-time PCR copy number determination study on samples of MON 810 maize. This EU-wide certification study was organised by the Joint Research Council & the Institute of Reference Material and Measurements.

SASA is a full member of the European Network of GMO laboratories (ENGL) and represents the UK at biannual meetings. ENGL is an enforcement network of GMO laboratories. The network provides up to date and detailed information on GMOs, particularly in the sampling, detection, identification and quantification of GMOs in the environment, food, feed and seeds. Through this group, GM Inspectorate and DMB staff participated in the KeLDA (Kernel Lot Distribution Assessment) project. The results of which have now been published in a paper entitled 'Kernel Lot Distribution Assessment (KeLDA): a study on the distribution of GMO in large soybean shipments' has now been published in the journal: European Food Research and Technology.

During 2006/7 the Section will continue to develop PCR screening methods for the detection of adventitious GMO's in seed and will participate in future validation experiments organised by International Seed Testing Association and the Community Reference Laboratory.

Publications

Paoletti, C., Heissenberger, A., Mazzara, M., Larcher, S., Grazioli, E., Corbisier, P., Hess, N., Berben, G., Lübeck, P. S., De Loose, M., Moran, G., Henry. C., Brera. C., Folch, I., Ovesna, J. and Van den Eede, Guy. (2006). Kernel lot distribution assessment (*KeLDA*): a study on the distribution of GMO in large soybean shipments European Food Research. DOI: 10.1007/s00217-006-0299-8

SASA GM Inspectorate
31 March 2006

WORK PLAN: 1 APRIL 2005 - 31 MARCH 2006

1. Inspections will be conducted on all GMO deliberate release sites in Scotland where there is a requirement for consent holders to conduct for post-harvest monitoring. Provision will be made for emergency and unannounced inspections. Reports in an agreed format will be provided as soon as possible after an inspection.

2. Conduct management audits on Scottish consent holders where there is a requirement to monitor deliberate release trial sites in accordance with their consents.

3. Audit consents holders, when necessary, for GMOs marketed in Scotland under Directive 2001/18/EC.

4. Audit Scottish seed importers and merchants to verify whether they can demonstrate due diligence to ensure the non-GM seed which they import or obtain, and supply, is free of unauthorised GM material.

5. Develop sampling and testing procedures for GM presence in line with the European Commission's recommendations on sampling and detection of GM seeds in seed lots. This includes development of quantitative PCR methods. This work will be done in liaison with SASA's Diagnostic and Molecular Biology Section (DMB), European Enforcement Project - Deliberate Release Group (EEP-DR), European Network of GM Laboratories (ENGL) and the International Seed Testing Association (ISTA).

6. Attendance as required at ACRE meetings.

7. Liaison with the Scottish Executive and the NIEWS GM unit in Defra in the development of standards, technical guidance, risk assessment and publications in connection with inspection and enforcement functions.

8. Institute appropriate actions where breaches of consent have occurred, to remedy the breach and prevent realisation of harm.

9. Participate in the EEP-DR and liaise between this group and the ENGL via DMB.

10. Prepare SOPs for all Inspectorate Activities in line with the Agency's timetable for acquiring ISO 9001 accreditation.

ANNEX 2

SASA BIANNUAL REPORT OF AUDITS ON THE SUPPLY OF CONVENTIONAL SEED TO ASSESS COMPLIANCE WITH PART VI ENVIRONMENTAL PROTECTION ACT 1990 AND THE GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) (SCOTLAND) REGULATIONS 2002

Version: 1
Status: Final

The Scottish Agricultural Science Agency (SASA) audited four Scottish seed merchants during June/July 2005 in order to verify that:

- all reasonable steps had been taken by them to ensure that the seed marketed was free from the presence of adventitious GM material and that,

- the merchants were able to demonstrate due diligence in making sure the seed marketed was compliant with the Council Directive 2001/18/EC and the EU Interim Measures for the adventitious presence of GM material in conventional seed.

The audit covered seed marketed in Scotland the period of autumn 2004 to spring 2005. On completion of the spring 2005 audit out of the 175 MPP* 16 had failed to reply. 61 (38%) of the MPP had traded in one or more of the species of interest (spring crops including related species); 0 in sugar beet, 17 in Fodder beet, 4 other Beta vulgaris crops, 8 in Maize, 30 in Spring Oilseed Rape, 45 other Brassica napus crops, 49 other Brassica rapa crops, 7 in mustard, and 34 in Brassica oleracea crops. No MPPs had traded in soya. Nine MPP previously known to trade the species of interest according to last year's questionnaires no longer did so. Ten MPP who did not trade the species of interest according to the last years questionnaires now do so. The conclusions from the four seed audits are summarised in Table 1 below.

Seed Merchant	**Conclusion of the SASA GM Inspectorate Seed Audit**
• *Agrisource* • *Highland Business Services Ring Ltd* • *Ross Muirhead & Co* • *WN Lindsay Ltd*	*As a result of the audit procedure, seed sold by the merchants listed was found to be in compliance with the European Council Directive 2001/18/EC. There was no evidence to suspect that any of the seed marketed by the merchants was contaminated with the adventitious presence of GM elements.*

Table 1. Conclusions of SASA GM Inspectorate Seed Audit

SASA conducted the seed audit procedure in liaison with the CSL GM Inspectorate who were able to provide details of seed lots imported via, and produced, in England covered by their audit programme. During the audit procedure, which includes cross referencing information provided by the seed merchants with information obtained from CSL, SASA had no reason to suspect the presence of adventitious GM material in any of the seed marketed by the four companies. Therefore all seed encountered in the spring 2005 audit programme was found to be in compliance with the EC Directive 2001/18/EC.

As with previous years, some seed suppliers remain unwilling to supply letters of assurance stating that the CSL GM Inspectorate's guidance for seed importers and producers had been followed. Through close liaison with the CSL, the SASA GM Inspectorate had been informed that these suppliers do in fact provide satisfactory assurance to the CSL GM Inspectorate with regard to the seed production/GM absence. The SASA GM Inspectorate will continue to stress that, whilst GM presence is not covered by the seeds legislation, there is still a need for merchants to obtain appropriate assurance from their suppliers in order to demonstrate their duty of care in supplying seed which is compliant with EC Directive 2001/18/EC.

GM INSPECTORATE
November 2005

ANNEX 3

SASA BIANNUAL REPORT OF AUDITS ON THE SUPPLY OF CONVENTIONAL SEED TO ASSESS COMPLIANCE WITH PART VI ENVIRONMENTAL PROTECTION ACT 1990 AND THE GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) (SCOTLAND) REGULATIONS 2002

Version: 1
Status: Final

The Scottish Agricultural Science Agency (SASA) audited four Scottish seed merchants during November/December 2005 in order to verify that:

- all reasonable steps had been taken by them to ensure that the seed marketed was free from the presence of adventitious GM material and that,

- the merchants were able to demonstrate due diligence in making sure the seed marketed was in compliance with the Council Directive 2001/18/EC and the EU Interim Measures for the adventitious presence of GM material in conventional seed.

The audit covered seed marketed in Scotland during the period spring to autumn 2005. On completion of the autumn 2005 audit out of the 174 *MPP 19 had failed to reply. 58 (37%) of the MPP had traded in one or more of the species of interest (autumn crops including related species); 35 in Winter Oilseed Rape, 32 in other Brassica napus, 41 in other Brassica rapa and 22 in Brassica oleracea crops. Eleven MPP previously known to trade the species of interest according to last year's questionnaires no longer did so. Fourteen MPP who did not trade the species of interest according to the last years questionnaires now do so. The conclusions from the four seed audits are summarised in Table 1 below.

Seed Merchant	**Conclusion of the SASA GM Inspectorate Seed Audit**
• *DM Carnegie* • *Kingdom Agribusiness* • *Lothian Crop Specialists* • *Strathmore Agribusiness*	*As a result of the audit procedure, seed sold by the merchants listed was found to be in compliance with the European Council Directive 2001/18/EC. There was no evidence to suspect that any of the seed marketed by the merchants was contaminated with the adventitious presence of GM elements.*

Table 1. Conclusions of SASA GM Inspectorate Seed Audit

SASA conducted the seed audit procedure in liaison with the CSL GM Inspectorate who were able to provide details for the majority of seed lots imported via, and produced in, England covered by their audit programme. During the audit procedure, which includes cross referencing information provided by the seed merchants with information obtained from CSL, SASA had no reason to suspect the presence of adventitious GM material in any of the seed marketed by the four companies. Therefore all seed encountered in the autumn 2005audit programme was found to be in compliance with the EC Directive 2001/18/EC.

As with previous years, some seed suppliers remain unwilling to supply letters of assurance stating that the CSL GM Inspectorate's guidance for seed importers and producers had been followed. Through close liaison with the CSL, the SASA GM Inspectorate had been informed that these suppliers do in fact provide satisfactory assurance to the CSL GM Inspectorate with regard to the seed production/GM absence. The SASA GM Inspectorate will continue to stress that, whilst GM presence is not covered by the seeds legislation, there is still a need for merchants to obtain appropriate assurance from their suppliers in order to demonstrate their duty of care in supplying seed which is compliant with EC Directive 2001/18/EC.

GM INSPECTORATE
March 2006