



ANNUAL REPORT OF THE SASA GM INSPECTORATE

Covering the period 1 April 2003 to 31 March 2004

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Contents

Section No	Section	Page
	Summary	2
	Background - The Regulatory Framework	4
1	Duty of care	5
2	Inspections:	5
3	Management Audits	6
4	Auditing Marketing Consents	7
5	Auditing Scottish seed importers and seed merchants	7
6	Liaison with the policy divisions of the Scottish Executive and NIEWS, Defra in connection with inspection and enforcement functions	8
7	Case by case Investigations of Specific Potential Enforcement Cases:	9
8	Review of the GM inspection and enforcement regime covering of the deliberate release of genetically modified plants under Part B of the Directive 2001/18/EC	10
9	Participation in the European Enforcement Group	10
10	GM Detection at SASA	11
11	Training	12
Annex 1	Work Plan: 1 April 2002 - 31 March 2003	13
Annex 2	SASA Audit reports on the supply of conventional seed to assess compliance with Part VI of the Environment Protection Act and the GMOs (Deliberate Release) (Scotland) Regulations 2002.	15

SUMMARY

1. *Duty of care*: In August 2002 additional GM material was discovered in some Farmscale Evaluations trials (see Section 7). Since that incident, all GM seed that has been deliberately released in Scotland has been tested to ensure it is free of additional GM material. **This has included material that was released in the spring and autumn of 2003.** In future in all applications for GM research trials, the method of reproduction of the seed, or propagules will be scrutinised by Government before approval will be given.
2. *Inspections*: All the GM active trials and post-release sites were inspected just before or during the reporting year. All former release sites under rotational restrictions, were also checked to ensure an appropriate follow-on crop was being grown. The Inspectorate was satisfied the conditions of the consents were met in all cases. No issues of harm to human health or the environment were identified. **Monitoring these former trial sites will continue until the post-harvest conditions of their consents are fulfilled. As from February 2004, there are no active GM research trials taking place in Scotland.**
3. *Management Audits*: Two audits were conducted during the year. One of these was a joint audit with the CSL GM Inspectorate with a consent holder who has active consents in both England and Scotland. The other was with a Scottish consent holder. In both cases the consent holders had satisfactory standards, implementation of protocols and dissemination of consent conditions throughout the management chain for conducting field trials. Appropriate 'duty of care' procedures were also in place.
4. *Auditing Marketing Consents*: There were no field releases in Scotland of GM plant varieties that had marketing consents during the reporting year. SASA is broadening its expertise for sampling and testing consignments of imported grain. Participation in the European Commission's Institute for Health and Consumer Protection (IHCP) of the Joint Research Centre's (JRC) project for determining the actual distribution of GM material in large kernel lots (KeLDA Project) has continued.
5. *Auditing Scottish seed importers and seed merchants*: SASA and SEERAD's Plants, Horticulture and Potatoes (PHP) branch conduct biannual surveys of the Scottish seed industry jointly in the spring and autumn. These surveys indicated that imported seed of beet, oilseed rape and maize was traded by 53 (c. 27%) of the merchants, processors or packers registered in Scotland and that this seed was imported *via* England. Whilst Scottish seed merchants did not import seed directly into Scotland, they nevertheless had 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 four 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. A report covering the two audits is given in Annex 2. In the spring 2004 audit programme the list of species that are considered to be at risk of containing GM adventitious presence has been extended.

6. Liaison with policy divisions of the Scottish Executive (GM Co-ordination Team and Plants, Horticulture and Seeds Branch) and Northern Ireland, England, Wales and Scotland GM Unit (NIEWS)¹ in Defra concerning inspection and enforcement functions: SASA has regularly commented throughout the year on applications for consent to release GMOs, consent holder's proposals for managing release sites, incidents and alleged breaches of consents. The Inspectorate has also commented on Scottish, UK and EU policy documents and legislation from inspection and science perspectives.
7. Case by case Investigations of Specific Potential Enforcement Cases: In August 2002 the consent holder responsible for 98/R19/18 disclosed to the Regulatory Authorities that seed containing adventitious GM presence had been sown at 25 Farmscale Evaluation sites in England and Scotland between 1999 and 2002. Scottish Ministers asked the GM Inspectorate to investigate whether other seed sown in these trials had also been affected. Samples were taken from the remaining Scottish FSE site, at Newport-on-Tay, which also contained impurities. An additional GM event, Topas 19/2, was found including those previously identified in the initial incident. This event has a marketing consent for import and processing of seed but not for cultivation. ACRE considered the safety implications for all the GM events in these cases and concluded no environmental or human harm resulted from their release. **The Executive forwarded a report, prepared by the GM Inspectorate, on the 27 January 2004 to the Procurator Fiscal.**
8. Review of the GM Inspection and Enforcement regime covering of the deliberate release of genetically modified plants under Part B of the Directive 2001/18/EC: Following the initial discovery above (Section 7), ACRE was asked to review inspection and enforcement for GM Crop research trials. Their review called for more stringent conditions under which seeds, or propagules, are produced as part of all applications. In some cases independent validation by the GM Inspectorate of seed purity will be required. Scottish Ministers have considered the report and have accepted the recommendations in full. **The GM Inspectorate has incorporated the recommendations into their assessments of applications and inspection procedures.**
9. Participation in the European Enforcement Group: The GM Inspectorate is a member a group of European GM Inspectorates (Enforcement Group) that meets to discuss inspection and enforcement issues relating to the Directive 2001/18/EC. The GM Inspectorate attended the annual meeting at Thun, Switzerland in May 2003 and a joint monitoring and sampling visit to Hamburg, Germany in June 2003.
10. GM Detection at SASA:
A validated method for detecting adventitious GM material in growing crops is described (p11). SASA participates in International Seed Testing Association sponsored ring tests for the detection and quantification of GM maize. Development of quantitative PCR tests for GM events in oilseed rape has continued.
11. Training: The GM Inspectorate regularly attends training courses and relevant conferences to maintain their technical competence and knowledge. Training included courtroom skills when giving evidence as expert witnesses. Inspectors also attended

¹ Formerly the Joint Regulatory Authority

conferences on co-existence measures and techniques for post-market monitoring of GM crops.

BACKGROUND - THE REGULATORY FRAMEWORK

The release of Genetically Modified Organisms (GMOs) in the EU is controlled under Directive 2001/18/EC which, in the UK, 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 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)² 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.

As from April 2004, an alternate approval procedure is available, under Regulation (EC) 1829/2003, for the marketing of GM crops whose produce, or derived products, are destined for food and feed. The procedure includes a full assessment of human, animal and environmental safety. An applicant will have the choice of supplying an authorisation for the deliberate release into the environment already obtained under Part C of 2001/18/EC or submission of an environmental risk evaluation, which complies, with the requirements of this directive. 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.

Compliance with these 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 2000. 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.

² Formerly the Joint Regulatory Authority

The work plan agreed between the Inspectorate and SEERAD covering the period 1 April 2003–31 March 2004 is given in Annex 1 of this report.

1. DUTY OF CARE

In August 2002 additional GM material was discovered in some GM spring oilseed rape Farmscale Evaluations trials (see Sections 7). Since that incident, all GM seed that has been deliberately released in Scotland has either been tested, or test results have been verified, by the GM Inspectorate to ensure freedom from additional GM material. This included material that was released in the spring and autumn of 2003 under consents 00/R14/8 and 00/R14/9S. In future, more stringent checking procedures will be introduced whereby more detailed descriptions of the conditions under which seeds, or propagules, are produced as part of all applications for research consents (see Section 8).

2. INSPECTIONS

Inspections were conducted on research and development trials (Part B consents) to ensure compliance with the specific conditions of the consent using a standard operating procedure and a checklist by field inspection, and examination of the site operator's records. Inspections were conducted at different times during the growing season so that a range of conditions could be assessed. Inspection Reports were sent to the GM Co-ordination Team of the Scottish Executive after each inspection². There were no Part C releases of GM crops in Scotland in 2003/2004.

2.1 Active Field Inspections

During the reporting year, inspections were carried out on three different forms of releases for research and development trials (Part B consents): variety and seed testing trials, company or agricultural institute research trials and Farmscale Evaluations. The GM crops that were released during this period were oilseed rape.

Table 1: Inspections of GM field trials from 1 April 2003 to 31 March 2004

Sites with active field trials	5
No. of inspections of active field trial sites	2*
No. of additional inspections	4

*All active trials were inspected during the growing season, however, 3 inspections were prior to 1 April 03.

In many cases follow-up action was not required. Where action was taken, additional information was often sought from consent holders so that the Inspectorate could be satisfied that site operators were complying with the conditions of the relevant consents. In all cases where this was done the consent holders supplied the necessary information.

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/gm/trials.asp>).

Following the final exhumation of a GM seed burial trial in February 2004, there are no active research trials involving the deliberate release of genetically modified crops taking place in Scotland.

2.2 *Post-Harvest Monitoring*

Post-harvest monitoring inspections were conducted to cover the length of time consent holders are responsible for post-release monitoring. The Inspectorate check that post-harvest monitoring is undertaken and that site operators are conducting effective volunteer control. There is also a period following official monitoring, where the use of follow-on crops is restricted until the site can be returned to a normal agricultural rotation. In these cases the follow-on crops are checked to ensure compliance.

Table 2: Inspections undertaken from 1 April 2003 to 31 March 2004

Sites undergoing post-harvest monitoring	11
No. inspections on sites undergoing post-harvest monitoring	11
No. of site checks for appropriate follow-on crops	8

All the post-harvest sites were for previous GM oilseed rape releases. The only exceptions were for two GM potato release sites. In all cases the conditions of the consents were met. No issues of harm to human health or the environment were identified. One of the potato sites was due to be returned to a normal agricultural rotation in the autumn of 2003. Monitoring of the site, conducted by the consent holder, showed that plantlets from true potato seed has continued to emerge after two years from harvesting the crop. The consent holder has agreed to continue to monitor the site until there is sufficient evidence that monitoring can be drawn to a close.

3. **MANAGEMENT AUDITS OF CONSENT HOLDERS**

The GM Inspectorate continued their programme of management audits on 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 the ability to organise and implement releases throughout the life of a consent. The purpose of these audits is to ensure 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. A consent holder must also show a duty of care by demonstrating that only materials with modifications covered by the consent are released.

An audit on a Scottish consent holder was conducted on 5 February 2003. The audit concentrated on post-harvest management procedures of deliberate release sites. The Inspectorate was satisfied that the consent holder had implemented appropriate action to ensure the consent conditions were being met, that these conditions were known and understood by staff throughout the management chain associated with the remaining trial and the maintenance of former deliberate sites. Some procedural recommendations were made for improving the descriptions of observations recorded in the trial diaries. ‘Duty of

care' issues were not audited as seed that was released under consent applications 00/R14/08 and 00/R14/9S was from an identified seedlot. This seed had been tested in the spring of 2002. There was no evidence of additional GM material being present in the seedlot.

A Joint Management Audit was conducted with the CSL GM Inspectorate of a consent holder on 16 July 2003 who had a consent that was active in both England Wales, and Scotland. The consent holder had implemented appropriate action in these territories to ensure that the consent conditions were met. Procedural improvements for the identification of surplus trial seed material, ensuring additional resources would be available for unplanned visits and compliance checks for third party contractors for the disposal of seed, or other material, were recommended.

4. AUDITING MARKETING CONSENTS INCLUDING INSPECTION, SAMPLING AND TESTING OF SHIPMENTS

There were no field releases in Scotland of GM plant varieties that had marketing consents during the reporting year.

The GM Inspectorate has been active in discussing and developing methodologies for sampling bulked commodities e.g. shipments of imported grain both within the UK and with other countries. A substantial portion of this work has been through SASA's participation in the European Commission's Institute for Health and Consumer Protection (IHCP part of the Joint Research Centre's (JRC)) project for determining the distribution of GM material in large kernel lots (KeLDA Project). The project is testing the commonly held assumption that the distribution of GM material within large grain lots is random. A shipment of imported soya grain was sampled and tested in 2003 (see Section 10). A further consignment has been sampled in June 2004 and is being prepared for testing.

5. AUDITING SCOTTISH SEED IMPORTERS AND SEED MERCHANTS

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, before obtaining or marketing conventional seed, that there is no adventitious presence of unapproved GM events. To ensure companies met these responsibilities the GM Inspectorates have a programme 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 soya bean. As of spring 2004, this list has been extended to include additional forage and vegetable types of beet and some *Brassica* species³.

³ In 2003 the UK GM Inspectorates conducted a review of the species at risk of containing an adventitious contamination with GM elements. Additional species were found to be at risk due to recent releases of GM varieties, and/or releases of sexually compatible GM crops, in countries that may supply seed to the UK. There is, therefore, a risk of adventitious GM presence in non-GM seedlots of these species. These include forage and vegetable varieties of *Beta vulgaris* (e.g. Swiss chard, spinach beet, beetroot, mangels, etc.); *Brassica napus* (e.g. salad rape and swede fodder rape, etc.); *Brassica rapa* (e.g. turnip, turnip fodder rape, stubble turnips, pak choi, etc.); *Brassica juncea* (grown for oil seeds); *Brassica oleracea* (e.g. cabbage, kale, cauliflower, broccoli, kohlrabi, Brussels sprouts etc.).

Biannual surveys of the Scottish seed industry are conducted jointly by SASA and SEERAD's Plant, Horticulture and Seeds Branch in the winter and summer of each year. In 2003 these surveys indicated that imported seed of beet, oilseed rape and maize was traded by 53 (c. 27%) of the merchants, processors or packers registered in Scotland and that this seed was imported *via* England. No soya seed was traded in Scotland in 2003. SASA relied upon the results provided by the English GM Inspectorate, which audits seed companies importing or producing seedlots ultimately traded in Scotland. Whilst Scottish seed merchants did not import seed directly into Scotland, they nevertheless had a duty of care to ensure that non-GM seed is free of unapproved GM events. The records of Scottish seed merchants can, therefore, be audited by the SASA GM Inspectorate to verify that the seed merchant took reasonable steps to establish that the seed traded was free of adventitious GM contamination. As a minimum the SASA GM Inspectorate expects Scottish merchants to obtain written assurances from their suppliers that the seed has been produced according to the CSL GM Inspectorate guidance for importers and producers of seed. The SASA GM Inspectorate also confirms that all seedlots can be traced back to an importer, thereby providing a cross-reference with the CSL records.

During the reporting year, the Inspectorate visited eight seed merchants and carried out audits, which involved follow-up action and cross-referencing SASA and CSL audit information. Four audits were conducted for spring-sown crops (oilseed rape, beet and maize) and four 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.

Some merchants were unable to obtain appropriately worded letters of assurance from their suppliers as was found in 2002. This prevents the Inspectorate from concluding that they had taken all reasonable steps to prevent adventitious GM material from being sold in the seed that they are marketing. The trade generally expressed the view that the seed they market is certified and should, therefore, be to an acceptable marketing standard, this approach is cited as the reason why letters of assurance have not been obtained prior to the Inspectorate contacting the merchant. However, through close liaison with the CSL Inspectorate, we know that these suppliers provide satisfactory assurance to CSL with regard to absence of GM material the marketed seed lots.

The spring 2003 and Autumn 2003 Seed audit reports are at Annex 2.

6. LIAISON WITH THE SCOTTISH EXECUTIVE AND NEWS IN THE DEVELOPMENT OF STANDARDS, TECHNICAL GUIDANCE AND PUBLICATIONS IN CONNECTION WITH INSPECTION AND ENFORCEMENT FUNCTIONS

SASA has regularly commented throughout the year on a range of GM issues. These included comments on consent dossiers for the release GMOs (both part B and part C), consent holder's proposals for managing release sites, incidents and alleged breaches of consents. We have also commented on Scottish, UK and EU policy documents and legislation from inspection, agronomic and scientific perspectives.

7. CASE BY CASE INVESTIGATIONS OF POTENTIAL ENFORCEMENT CASES

Adventitious GM presence in a seedlot sown in the Farmscale Evaluation trials under consent 98/R19/18. Following an incident in August 2002 involving the release of unauthorised material at FSE sites, Ministers instructed the GM Inspectorates to investigate other seedlots sown in 2002. The Central Science Laboratory GM Inspectorate for England and Wales undertook a similar investigation. Only one site in Scotland fell into this category which was sown with seedlot E5103.

On 17 September 2002 the Scottish Agricultural Science Agency (SASA) GM Inspectorate drew samples from the harvested seed at the Newport-on-Tay site. The CSL GM Inspectorate secured samples from two sites in England. Official testing of these samples was undertaken on behalf of the Inspectorates. This testing identified the presence of the unauthorised GM elements *nptII*, *Pnos* and CaMV 35S promoter in seed of seedlot E5103.

The consent holder provided a detailed report on 25.06.03 to the Inspectorates, confirming that the GM elements *nptII* (Kanamycin) and CaMV 35S promoter were present as a result of the following GM events: Ms1 (0.1%), Rf1 (0.1%), Rf2 (4.0%), and Topas 19-2 (1.3%). The *Pnos* GM element is also a component of these GM events. The company's test results were consistent with the findings of the GM Inspectorates and provided an explanation of the additional GM elements found in the E5103 seed.

After the reporting of the 2002 case, the Advisory Committee on Releases to the Environment (ACRE) advised on 13.08.02 that the release of the events Ms1, Rf1 and Rf2 does not pose an additional risk to human health or the environment than a conventional oilseed rape variety. On 4.09.03 the Committee considered the additional presence of event Topas 19/2 in lot E5103 in the light of their previous advice. They confirmed that presence of this event, irrespective of whether it formed part of a seed admixture or a combination of stacked genes within a hybrid variety, did not alter their previous assessment that the release represented no increased risk to human health or the environment.

The SASA GM Inspectorate verified that the E5103 material harvested in 2001 and 2002 was appropriately contained, labelled and disposed of to deep landfill. The Inspectorate has verified by post-trial inspection that volunteers of E5103 have been properly controlled and that the follow-on cropping of the release sites was appropriate. No crops of seedlot E5103 have been grown since the harvest of 2002 or are currently being grown in the UK.

On the 27 January 2004 the Executive referred the case to the Procurator Fiscal's Office in Fife for consideration of whether prosecution is appropriate in this particular case.

The company reported to the GM Inspectorate that they are revising their internal quality control and quality assurance procedures to prevent future occurrences of adventitious GM presence in their seedlots. Their procedures shall be subject to future management audits.

8. REVIEW OF THE GM INSPECTION AND ENFORCEMENT REGIME COVERING OF THE DELIBERATE RELEASE OF GENETICALLY MODIFIED PLANTS UNDER PART B OF THE DIRECTIVE 2001/18/EC

Due to effectiveness of the GM Inspectorate's auditing procedures, unauthorised GM material in seed of a GM variety sown in the 2002 spring oilseed rape Farmscale Evaluations trials was discovered in August 2002. Following this initial discovery ACRE were asked to review inspection and enforcement for GM Crop research trials. Their review⁴ called for more stringent conditions to be placed on the assessment of trial material before consents are approved. In particular ACRE will require more detailed descriptions of the conditions under which under which seeds, or propagules, are produced as part of all applications for research consents. In some cases independent validation by the GM Inspectorate of seed purity will be required. ACRE will then recommend different inspection procedures depending on the conditions under which the seeds, or propagules, are produced. The committee recommended that the present rate of site inspections should continue, and that they would advise as part of its routine casework, whether specific releases, or the risk management practices associated with them, require a higher frequency of inspections.

Scottish Ministers have considered the report and have accepted the recommendations in full. The GM Inspectorate will implement ACRE's recommendations in two ways. During the assessment of an application for deliberate release the GM Inspectorate advise NIEWS on inspection and enforcement issues that may be relevant to the application. The GM Inspectorate will take account of the recommendations during their consideration of the application. If Scottish Ministers approve a release, the GM Inspectorate will apply specific inspection procedures for verifying compliance with the conditions set out in the consent.

9. PARTICIPATION IN THE EUROPEAN ENFORCEMENT GROUP

The GM Inspectorate belongs to a European Enforcement Group concerned with inspection and enforcement issues relating to the Directive 2001/18/EC. This group consists of GM Inspectorates from 15 EU Member States, as well as those from Iceland, Norway and Switzerland. A network has been formed for debate and exchange on GM deliberate releases inspection issues and has concentrated on developing sampling techniques, especially those that support the implementation of monitoring plans.

A member of the Inspectorate attended the annual meeting in May 2003 held in Thun, Switzerland. Discussion related to monitoring and sampling of GMOs, in particular issues concerned with GM animal feed, biodiversity monitoring, and co-existence of GM crops with conventional and organic agriculture.

The GM Inspectorate was also represented at a joint monitoring and sampling visit to Hamburg in June 2003 with colleagues from the CSL GM Inspectorate. The Ministry of Environment and Health, Hamburg hosted the visit. The visit was structured around one of Hamburg's largest grain importers with the intention of gaining experience in techniques used for sampling bulk grain and assessing GM detection techniques used for oilseed rape, maize and soya grain samples.

⁴ ACRE's report 'Review of the GM Inspection and Enforcement Regime covering the Deliberate Release of Genetically Modified Plants under Part B of Directive 2001/18/EC' is available at http://www.defra.gov.uk/environment/acre/advice/pdf/acre_advice37.pdf

10. GM DETECTION AT SASA

The 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. A Sequence Detection System (real-time PCR) is also available for quantitative PCR analyses.

During the reporting year a sampling and test method for detecting adventitious GM material (elements) in growing GM crops was deployed. The method was used on winter oilseed rape carrying the GM modification Ms8xRf3. 5000 plants were sampled using a zigzag walk across the entire crop. Each plant was sampled by removing a disk of leaf tissue. Work carried out prior to the sampling had shown that the assays used were capable of detecting one GM leaf disk (carrying the element to be tested) when present at 1 leaf disk in 1000 leaf disks. The tests carried out were for the detection of *nptII*, *Pnos*, *Pnos::nptII* hybrid, *bar*, *Tnos*, P35S and LibertyLink[®]. Although these tests were shown to work at 1/1000, the 5000-leaf disk sample was divided into 500 disk subsamples to give a two-fold margin of error for detection. DNA from each sample was prepared in duplicate, and the quality of the DNA was determined by spectrophotometry, and by the use of a PCR assay for chloroplast-specific sequences. No unauthorised GM presence was found in the samples analysed.

DMB section participated in the 2nd ISTA GMO proficiency test and, as in the 1st round, the GM-containing samples were correctly identified, with no false-positives or –negatives. A member of DMB attended a workshop held at ISTA headquarters to discuss the results of the 2nd proficiency test, and to formulate advice for those participating in future rounds of the test.

The 3rd ISTA GMO proficiency test is currently underway, and the results of the submitted data are as yet unknown. The 3rd proficiency test entailed the use of several maize event-specific PCR assays which had not previously been used at SASA – these were Bt11, Bt176, LibertyLink[®] T25 and MON810.

SASA is a full member of the European Network of GMO laboratories (ENGL). ENGL is an enforcement network of GMO laboratories. The network provides up to date and detailed information on GMOs, particularly in the sampling, detection and identification and quantification of GMOs in the environment, food, feed and seeds. Through this group, GM Inspectorate and DMB staff are participating in the KeLDA (Kernel Lot Distribution Assessment) project (see Section 4).

For the KeLDA project a soybean bulk shipment was sampled at a dockside in 2003. One hundred samples were taken sequentially through the discharging of hold. The samples were ground (in Belgium) and extracted in duplicate, and tested for the presence of GM material at SASA. Data has been submitted to the project co-ordinators and will contribute to the final report. A further shipment is being sampled and tested in 2004.

Finally, the section continues to expand its portfolio of GM detection assays, particularly with regards PCR based assays. These assays are vital in the detection of authorised and unauthorised events. To meet the new EU requirements on traceability and labelling of GM

food and animal feed, SASA is developing quantitative PCR based methods for seed and grain to check compliance with the thresholds set out in this legislation.

11. TRAINING

During March 2003 two members of the GM Inspectorate attended a training course on giving evidence in court as expert witnesses.

Members of the Inspectorate attended the following conferences and courses during the year:

- The First European Conference on the Co-existence of Genetically Modified crops with Conventional and Organic Crops. 13-14 November 2003, Slagelse, Denmark.
- A European Science Foundation Workshop, Scientific Programme on Assessment of the Impacts of Genetically Modified Plants (AIGM) on 'Measuring and Monitoring the Impacts of GMOs. 30 March – 1 April 2004, Cambridge.

SASA GM Inspectorate

1 July 2004

WORK PLAN: 1 APRIL 2003 - 31 MARCH 2004

1. All active GMO deliberate release sites in Scotland will be inspected. Post trial monitoring inspections will be conducted on all sites covering the time period for which the consent holders are responsible for post-release monitoring. Priority will be given to consents and sites perceived to have any potential risk, i.e. new applications and selected consent holders and growers. Provision will be made for emergency inspections. At least two non-routine inspections will be conducted, one harvest inspection and one unannounced inspection. Monitoring reports in an agreed format will be provided as soon as possible after an inspection. The number of planned inspections for the forthcoming year will be reviewed in the annual workplan.

Inspections will be conducted on all GMO deliberate release sites in Scotland where there is a requirement for consent holders to conduct for post-release 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. The number of planned inspections for the forthcoming year will be reviewed in the annual workplan.

2. Conduct management audits on Scottish consent holders. Conduct joint management audits with the CSL GM Inspectorate on consent holders where consents are relevant to both England & Wales and Scotland.
3. Audit marketing consents, including inspection, sampling and testing of shipments.
4. Audit Scottish seed importers where there is suspicion of seed containing genetically modified products.
5. Audit Scottish seed merchants to confirm that marketed non-GM seed conforms to the thresholds of the EU interim measures for adventitious presence of GM events in conventional seed.
6. Develop sampling and testing procedures for GM presence in line with the European Commission's recommendations of the European Commission's Working Party on sampling and detection of GM seeds in seed lots and GM grain in bulk commodities. This work will be done in liaison with SASA's Diagnostic and Molecular Biology Section (DMB), European Enforcement Group-Deliberate Release (EEG-DR), European Network of GM Laboratories (ENGL) and the International Seed Testing Association (ISTA).
7. Attendance as required at ACRE meetings. Implement the recommendations of ACRE's Review of the GM Inspection and enforcement regime covering of the deliberate release of genetically modified plants under Part B of the Directive 2001/18/EC.
8. Liaison with the Scottish Executive and the NIEWS GM unit in Defra in the development of standards, technical guidance and publications in connection with inspection and enforcement functions.
9. Institute appropriate actions where breaches of consent have occurred, to remedy the breach and prevent realisation of harm.



10. Participate in the EEG-DR and liase between this group and the ENGL via DMB.
11. Explore accreditation with an appropriate quality assurance scheme.



SASA 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

The Scottish Agricultural Science Agency (SASA) audited eight Scottish seed merchants in 2003 in order to verify that:

- that the merchants were able to demonstrate due diligence in making sure all reasonable steps had been taken by them to ensure that the seed marketed was free from the presence of adventitious GM material in compliance with the European Directive 2001/18/EC.

The audit programme covered spring sown seed (four audits during May and July 2002/2003) and winter sown seed (four audits during November 2003).

SASA conducted the seed audit procedure in liaison with the CSL GM Inspectorate who were able to provide confirmation that seed lots imported via, and produced in, England had been covered by their audit programme. As a result of 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 eight companies. Therefore all seed encountered in the 2003 audit programme was found to be in compliance with the European Directive 2001/18/EC.

As with the 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, however through close liaison with CSL, the SASA GM Inspectorate know that these suppliers do in fact provide satisfactory assurance, with regard to GM adventitious presence during seed production, to the CSL GM Inspectorate. During the 2004 audit programme the SASA Inspectorate will continue to stress that, whilst GM presence is not covered by the seeds legislation, there is 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 European Directive 2001/18/EC.

GM INSPECTORATE
15 March 2004