



## GM INSPECTORATE SEED AUDIT PROGRAMME

### Why has the seed audit programme been reviewed and what will it mean to me?

#### Q1. Why is the seed audit programme necessary?

Genetically modified crops are not currently commercially cultivated in the UK. However, 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. There is, therefore, potential for seed to acquire adventitious GM presence (AGMP) at many stages in the seed production process from early breeding through to processing, either by cross-pollination or admixture. While certified seed production methods employ measures to ensure the purity of certified seeds, these are not specifically geared towards ensuring seed is free of AGMP. At present there are no thresholds established in the seed marketing regulations for the adventitious presence of GMOs in conventional seed, however, under EU Directive 2001/18/EC and Regulation 1830/2003, seed containing an authorised GMO must be labelled. It is illegal to market seed containing a GMO that has not been authorised for commercial cultivation. The seed audit programme has been in place since 2000 to assist seed importers and producers in ensuring that the seed they market in England is free of AGMP.

#### Q2. Why is it necessary to change the current programme?

The inclusion of crops included in the audit programme to date has been based on qualitative assessments of risk, and the underlying aim of the programme has been to audit all seed of these crops marketed in any one year, hence audits have been conducted twice yearly to cover spring- and winter-sown crops. There is recognition within government of the need to focus regulatory enforcement where it will be most effective, i.e. where the risks are greatest. Plant Variety Rights Office and Seeds Division (PVS) therefore commissioned a quantitative assessment of the risks of AGMP in seeds to establish where seed monitoring efforts should be focussed.

#### Q3. What are the changes?

On the basis of identified risks of AGMP, the crops that will be audited are *Brassica napus* (spring and winter oilseed rape, swede and swede forage rape), *Brassica rapa* (turnip, turnip fodder rape, stubble turnips, pak choi, Chinese cabbage, etc.), *Zea mays* (maize and sweetcorn) and *Glycine max* (soya). The risks of AGMP in seeds will be reassessed on an annual basis and species may, therefore, be added or removed from the scope of the audit programme.

All seed companies marketing seed of interest that agree to participate in the audit programme will be asked each year to submit basic information about relevant seed they have marketed, in particular variety, seed lot reference numbers and country of origin. As with the previous system, each company will first receive a letter, which will be followed up by a phone call to discuss what has been marketed and/or grown in private trials. These basic data can be submitted electronically via the GM Inspectorate's secure extranet (<http://www.gm-inspectorate.gov.uk> and select "Extranet" from the menu on the top right of the page) or as a simple Excel spreadsheet (a template will be made available); alternatively we will visit you to gather the information if you prefer. The information will be entered into our seed audit database and will enable us to monitor what seed is being marketed and ensure we can track seed rapidly should an incident of AGMP occur.

Audits will be undertaken in a rolling programme, whereby each company marketing seed of interest will be visited once every three years for a detailed audit. These will focus on awareness and management of the risks of AGMP rather than the current approach of gathering details of every seedlot marketed; we will also discuss analytical testing to ensure you are clear about what tests would be best for your company. In addition, targeted audits will be undertaken on an *ad hoc* basis where a seedlot is considered to be higher risk, e.g. where seed has been imported from a country known to cultivate a high proportion of GMOs, or a company has changed its approach to analytical testing, etc.

Under the new system all audited companies undergoing a detailed routine or targeted audit will receive a report from their audit. The report will provide details of what was discussed and identify any areas that would benefit from improvement. This report will be identical to the report sent to Defra and will be intended to assist your management of the risks of AGMP. Follow-up audits may be requested to



determine whether audit recommendations have been implemented. Tables summarising the audit findings will continue to be published on the GM Inspectorate website for all companies that are audited.

#### **Q4. Does this mean I do not need to worry about AGMP in my seed any more?**

No – it is essential that you continue to be aware of the risks of AGMP in your seed and your legal obligation to manage these risks. This is why the GM Inspectorate will remain in contact with you to offer support and advice where necessary.

#### **Q5. What is the quantitative risk assessment (QRA)?**

The GM Inspectorate at CSL has developed a computer-based model for quantitative assessment of the risks of AGMP in conventional seeds. The model generates probability distributions of relative GM presence based on worldwide GMO activity, crop biology and seed production processes and produces a ranked list of relative risks for the major crop species. The QRA has been designed as a decision support tool for monitoring activities and to identify points in each crop's production where risk mitigation should be focussed. The QRA will be updated annually and form the basis for decisions on which crops should be audited each year. The summary results of the QRA exercise will be published on the GM Inspectorate website in due course.

#### **Q6. If I participate in the programme, how will the changes affect me?**

- 1) You will continue to receive our annual letter and seed audit guidance documents. The audit programme will run from April to March each year.
- 2) The GM Inspectorate will no longer audit your company twice every year; instead you will be routinely visited every three years.
- 3) In the intervening years we will maintain contact with you and ask you for some basic information about the seed that you are marketing (for example, if you have started to market new crops, imported from a new supplier, or changed your approach to analytical testing).
- 4) In the 3-years between routine scheduled audits you *may* be asked to participate in a targeted audit if you have changed your activities.
- 5) The new approach is intended to reduce the administrative burden on your company while continuing to assure adequate management of the risk of AGMP.
- 6) You will receive a detailed report following the audit visit, which will also include recommendations for improvements where these are identified.
- 7) You will receive an annual newsletter updating you on risks of AGMP in conventional seeds.
- 8) The audits remain voluntary.
- 9) **You must continue to be aware of the risk of AGMP in the seeds you are marketing, and that participation in the audit programme does not relieve companies of their obligations, nor should it be seen as an assurance that the GM Inspectorate will not exercise its powers in appropriate cases under Part VI of the Environmental Protection Act 1990.**