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ADVENTITIOUS TRACES OF GENETICALLY MODIFIED SEEDS IN CONVENTIONAL SEED LOTS: CURRENT SITUATION IN MEMBER STATES

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CONTENTS

Executive summary	Page 1
1. Introduction	2
2. Inspection and control programmes for adventitious GM presence in seeds	8
Questionnaire to member states	
Information gathering and management	
Accessing results and development of a user interface	
Limitations of the user interface	
3. Member State responses	19
4. Qualitative assessment of MS responses	21
Inspection and control programmes	23
Sampling seeds for GMOs	29
Incidents of adventitious GM presence	35
Sampling and incidents of adventitious GM presence combined	38
Analytical testing	51
Enforcement	59
5. MS seed production, import and import / re-export data	63
6. Statistical analysis of results	65
7. Discussion	97
8. References	101
Acknowledgements	102
Appendices	
Appendix A: Questionnaire	
Appendix B: Data integrity and security	
Appendix C: Letter from DG Environment to accompany the survey	
Appendix D: EU MS e-survey response	
Appendix E: MS seed stats	

EXECUTIVE SUMMARY

1. A survey has been conducted of programmes operated by the Member States (MS) of the European Union (EU) to monitor and control adventitious presence (AP) of genetically modified organisms (GMOs) in conventional seed lots. To our knowledge this is the first time a comprehensive survey of MS practice in this area has been conducted. A substantial amount of information has been gathered.
2. Data was collected directly from respondents using electronic survey software developed by CSL. The requested information was provided by 23 out of 27 MS, which we consider to be an excellent response. The level of detail in the provided data was variable and significant gaps exist for some aspects, in general though MS have provided as much information as they reasonably could. Seventeen (17) MS provided sufficient data to support statistical analyses, which we also consider to be a very positive outcome.
3. The electronic approach to gathering data achieved the goal of reducing administrative inputs by the project team, and was generally well received by respondents. Data collected was made available via a web-enabled user interface. The web-link will be available to DG Environment, hosted on the CSL servers for as long as is required and agreed. Raw data is collected in Excel spreadsheets, and is provided in Appendices to this report (and on CD). Findings are summarised in tables in the body of this report.
4. The majority of MS include maize, oilseed rape and soya in their monitoring and control programmes. The level of sampling varies very widely between MS, and should be considered in the context of whether it is based on prior risk assessment or not. Sampling ranges from 100% of all seeds, to no sampling and testing at all. Testing is reasonably comparable across the MS, and most operate according to established, recognised standards. A total of 280 incidents of AP of authorised GMO were reported between 2001 and 2006, plus a total of 43 incidents of unauthorised GMO, which equates to an average of 61 incidents per year. The level of AP of GMO at which lots are rejected or labelling is requested is not consistent across the MS; while most operate a policy of zero tolerance or 0.1%, levels of 0.5%, 0.7% and 0.9% are reported.
5. The effectiveness of a control programme is not simply a function of the level of sampling and testing undertaken, but is described by a combination of the sources of uncertainty introduced by sampling (primary sample through to laboratory working sample), the number of samples taken, the limit of detection of analytical tests, and decisions taken with respect to labelling and enforcement. MS can adjust each component of the control programme to increase or decrease the stringency of control.

6. An illustration has been produced of the likely levels of adventitious GMO in accepted seed lots of maize imported from 3rd countries. This uses an estimate of the performance of an MS control plan and an estimate of the concentration of adventitious GMO in the whole population of seed lots.
7. The approach followed in this study provides a structured framework within which rational decision-making about the requirements of a control programme can be supported, based upon knowledge of the components of the control programme and potential risks associated with seed lots. Recommendations are made for working towards an EU-wide approach to gathering data and monitoring AP of GMO in non-GM seeds.

1. INTRODUCTION

1.1 Background to the study

Legislative context

Release of genetically modified organisms in the EU

In the MS of the EU deliberate release into the environment and marketing of GMOs is strictly controlled. Two key pieces of legislation collectively provide a harmonised approach to the assessment of risks to the environment and human health; these are EU Council Directive 2001/18/EC¹ on the deliberate release into the environment of GMOs, and Regulation 1829/2003 on GM food and feed². The principal aim of the legislation is to protect human health and the environment, ensure the free movement of safe and healthy genetically modified products in the EU and ensure consumer choice.

Directive 2001/18/EC provided for the possibility of establishing thresholds for the adventitious presence of traces of GMO in other products, and Regulation 1829/2003 established legal requirements for thresholds for the adventitious presence of authorised GMOs (AP of GMO) in non-GMO food, feed and products when they came into force September 2003 (0.9% for authorised GMOs).

Seeds for cultivation

EU legislation on seeds³ 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 inscribed in a national catalogue, the Commission is required to inscribe the variety in the 'common catalogue' and the seed of that variety can then be marketed throughout the EU.

GMOs and seeds

Seeds legislation also requires that all GM seed varieties must be authorised in accordance with EU Directive 2001/18/EC before they are included in the common catalogue and marketed in the EU⁴. Currently, 31 varieties of genetically modified maize MON 810 are registered in the European common catalogue and three more are pending. There is zero tolerance of unauthorised GMOs in any seeds.

¹ Which came into force on 17th April 2001, repealing Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms.

² 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 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.

⁴ 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.

Seeds legislation recognises that 100% purity is not possible, and thresholds have been set which take account of the fact that plants are grown in an open field, that cross-pollination is a natural phenomenon and that wind and insects which contribute to this cannot be controlled. Marketing regulations establish purity levels for the tolerance of seeds of other species within a certified seed lot, but they do not at present prescribe tolerance for the adventitious presence of GMOs that have been authorised through the EU regulatory system.

The legislative EU framework requires the labelling of conventional seed lots that contain any detectable traces of authorised GM seeds. This legal requirement has been in place since labelling provisions were introduced under Directive 90/220/EEC and maintained under Directive 2001/18/EC (repealing Directive 90/220/EEC). Any seeds found to contain unauthorised GMOs cannot, of course, be placed on the market.

Approaches to monitoring for adventitious GM presence

In most EU Member States, legislation on the AP of GM seeds in conventional seeds is enforced under appropriate national legislation. Thus, there are a number of different approaches to monitoring for AP of GMO across the MS; in addition national policy may affect the level of stringency with which this legislation is enforced, for example while some MS may adopt a zero tolerance approach for AP, others may adopt a labelling threshold of 0.3%. A small survey carried out by the European Enforcement Project⁵ [1] exploring project members' approaches to monitoring for AP found that across the MS there is a broad range of approaches, including sampling and testing at the point of import, sampling and testing pre-defined seed lots, and audits aimed at developing company awareness and best practice. Similarly, monitoring programmes may be established to ensure that sufficient seed samples are tested to provide assurance that seeds being placed on the market do not contain GMOs, or perhaps just to target a number of random samples within a defined budget to induce seed companies to comply with national legislation. One of the key aims of this project was to try to establish exactly the monitoring and enforcement programmes that have been implemented in the EU MS to date, and gather information on how these are operated.

Issues associated with testing for GMOs in seed

The regulation of AP of GMOs in seeds, crops and foodstuffs necessitates sampling and testing processes that can provide a predictable minimum level of confidence in their results. This is essential if test results are to be used to inform decisions on labelling and/or rejection of commodities (including seeds) due to their GMO content, and to maintain public confidence [2]. Impurity testing in seeds has traditionally been done using either single or sequential seed-pool tests. From an analytical seed sample (e.g. 3000 seeds) equal seed pools are made and analysed individually for the trait of interest; using binomial statistics, the number of seed pools positive for the trait can be used to estimate the total number of positive seeds in the analytical sample. These semi-quantitative tests work well because given a known (and low) false positive and negative rate the binomial statistics give well-defined risks for the seed lot being falsely accepted (consumer's risk) or falsely rejected (producer's risk).

⁵ European Enforcement Project on contained use and deliberate release of GMOs.

Testing plans can be designed to conform to a specified threshold and consumer and producer risk. However, these tests only work when the threshold is the seed itself. When the tested unit is a variable fraction of one seed, such as when looking for AP of GM DNA, then the associated statistics and results are no longer valid. EC guidance for testing of GM presence in food specifies the use of units as % GM DNA. It is therefore possible that in the interests of consistency, any future EU thresholds for AP of GMO in seeds will also be specified in terms of % GM DNA.

Testing of seed for GMOs is currently carried out using protein-based assays or DNA-based PCR assays, these may be qualitative, testing for the presence or absence of GMOs, or may attempt to quantify the level of GMO present. Each of these approaches has differing sensitivities in terms of limits of detection and quantification, such that different testing methods can give slightly different results for the same sample. These discrepancies are due to the complex genotype of some seeds, copy number of GM events, and whether qualitative or quantitative methods are used [3].

Within the European Community, GMO legislation requires that quantification of GMOs is calibrated using certified reference materials (CRMs). These are prepared from certified seeds of the GM line and the (near isogenic) non-GM parental variety used for the transformation; a range of reference materials are produced with a range of concentrations of GMO content. Genomic DNA can then be extracted from these to calibrate quantitative PCR tests. Again, the complex genotype of some plants (e.g. variation in the ratio of a GM genome to the number of genomes contained in a plant species, intraspecies variation in nuclear DNA content, ploidy levels of the tissue and zygosity of the parent) can mean that the CRMs might not always be fully representative of the sample being analysed [4].

Seed testing for GMOs may be funded by the national government, in which case a reasonably consistent approach should be assured, or evidence of testing may be a requirement for import and/or marketing, in which case testing may have been done by one of any number of commercial or in-house laboratories, each presenting a slightly different approach to testing, presentation and interpretation of results. Furthermore, there are also many different standards or accreditation schemes that testing can be performed to, for example AFNOR⁶, UKAS⁷ and ISO standards⁸ to name just three. Analytical testing for any enforcement purpose is inevitably subject to such complications and the relatively new area of GMO analysis is no exception.

1.2 AIMS OF THE PROJECT

This project was commissioned to provide baseline data required by the European Commission to enable accurate assessment of the possible impact of establishing thresholds for AP of GMO in conventional seeds, at a range of levels and in different crops. Specific tasks were undertaken to establish the following for maize, oilseed rape and soya:

⁶ Association française de normalisation (<http://www.afnor.fr/portail.asp?Lang=English>)

⁷ The United Kingdom Accreditation Service (<http://www.ukas.com/>)

⁸ ISO, International Organization for Standardization

- The frequency and levels of adventitious traces of GMOs in conventional seed lots that are currently being detected by Member States and what levels of detection are being employed in terms of enforcement.
- The statistical significance of the results taking account of the amount of seed produced (i) regionally/nationally and (ii) imported following production in third countries.

1.3 METHODOLOGY

To meet the aims of the study, the customer specified a list of tasks (table 1.1 below). To facilitate delivery of these the work was broken down into the modules listed below. Table 1.1 links the tasks with project modules. The modules were largely dependent upon each other for completion, i.e. module four could not commence until all data identified for collection in modules two and three had been collected. In addition, the statistical techniques suitable for analyses to be undertaken in module four were determined by the quantity and quality of the data obtained in modules two and three. These aspects are discussed in more detail in the report.

- **Module 1**, testing seeds for GMOs: a review of current practices and key problems - to set the scientific context of the work. At the outset of the project, emphasis was placed on the survey and the review was not required. It was agreed that it might be necessary in the latter part of the project when a clearer view of practices in MS has been collated. When this stage had been reached, we reached the opinion that a review would not add to the report. Key influences over the performance of a control programme, such as analytical tests and sampling are reasonably consistent across MS and conducted according to widely recognised standards; issues such as improving analytical test performance by minimising measurement uncertainty are already being considered by other groups within the Community. Efforts and resources have, therefore, focussed on survey data.
- **Module 2**, questionnaire and database - to establish the framework for collection of necessary data and create a mechanism for capturing, storing and management of data. Establish contact with relevant persons in competent authorities and seek the required data from them.
- **Module 3**, seed import and production statistics on a country by country basis – to gather basic data on conventional seed production to enable evaluation of each competent authority's monitoring activities for AP of GMO.
- **Module 4**, data analysis (general analysis plus detailed analysis of different approaches) – assessment of data gathered in modules 2 and 3 to give a measure of the levels of AP of GMO that are being enforced in the different countries examined and the ease with which any possibly future thresholds may be enforced.

Table 1.1 Tasks specified to meet the aims of the project, together with project modules for delivery

TASK	Project module	Report section
A description of the inspection and control programmes being employed in Member States for conventional seed lots, importantly including maize, oilseed rape and soybean, to determine any adventitious presence of GMOs	2	2, 3, 4 Appendices A & D
The frequency and number of tests employed to determine whether adventitious traces of GMOs are present and their approval status	2	
The 'tests' employed to determine or not whether adventitious traces of GMOs are present, namely sampling and detection methodology or other means	2	
The frequency with which adventitious traces are being detected and to what level and their approval status	2	
The 'level of detection' value used to determine adventitious presence and the level used to enforce the legislation	2	
The legal basis under which inspection and control and enforcement is carried out	2	
A description of the statistical figures available concerning seed production in MS and third countries. This should include (by species) the total of lots/amount (weight/bags) produced domestically (as well as the number of seed producing companies involved) and total lots/amount (weight/bags)imported by the MS (and from which third countries) as well as total lots/amount (weight/bags) produced/imported by the MS and re-exported to other MS and other countries	3, 4	3, 5, 6 Appendix E

2. INSPECTION AND CONTROL PROGRAMMES FOR ADVENTITIOUS GM PRESENCE IN SEEDS

Introduction

One of the key aims of the project was to establish a standard body of information from the competent authority (CA) for Directive 2001/18/EC of each EU MS with respect to their approach to the management of AP of GMO in conventional seeds both produced in their countries and imported. Collection of this data was achieved with the use of a questionnaire distributed to all MS electronically for completion as an on-line survey ('e-survey'). Responding via this interface facilitated direct storage of data into a database, thus reducing time spent on administrative input by the project team, also reducing the likelihood of errors in data entry. The survey and database into which responses are stored is hosted on CSL servers and accessed via a web-enabled user-interface. Data is retrieved via a second web-enabled user interface using Adobe ColdFusion MX technology, to pass requests for data searches to the database and deliver formatted output to the user.

The steps adopted by CSL to ensure maintenance of data integrity and security are given in Appendix B.

2.1 Questionnaire to Member States

The underlying principle in designing the questionnaire was that it should elicit accurate, numerical data from member states that would be suitable for statistical analysis.

The **objective** of the questionnaire was to obtain the following information specifically for maize, oilseed rape and soya:

- 1) A description of the inspection and control programmes being employed in Member States for conventional seed lots, in particular maize, oilseed rape and soybean, to determine any presence of GMOs.
- 2) The frequency and number of tests employed to determine or not whether adventitious traces of GMOs are present and their approval status.
- 3) Sampling and detection methodology employed to determine whether adventitious traces of GMOs are present.
- 4) The frequency with which adventitious traces of GMOs are being detected, to what level, and their approval status.
- 5) The level of detection value used to determine adventitious presence and the level used to enforce the legislation.
- 6) The legal basis under which inspection, control and enforcement is carried out.
- 7) What have been the outcomes when AP of GMO has been identified?
- 8) The degree to which competent authorities are prescriptive about testing seeds for AP of GMO (for example by identifying accredited or approved testing

laboratories that must be used, or offering guidance given to seed companies in commissioning testing).

- 9) The frequency of occurrence of ambiguous results from analytical tests, for example positive/negative results very close to threshold values, and the occurrence of single GM elements.

2.1.1 Structure of the questionnaire

The questionnaire was divided into seven main sections seeking information about the following for each MS of the EU:

The respondent: basic information to establish identity and contact details, and to establish whether an inspection and control programme is in place in the MS and which crops are covered.

The inspection and control programmes for AP of GMO: to establish the nature of the monitoring programme with respect to practical arrangements in place, whether the programme is regular/repetitive in nature, or is responsive to any number of specified risk factors.

Sampling seeds for GMO presence: to establish what seed lots are sampled (imported and/or home grown seeds, certified and/or as-grown seed lots), and the proportion of these that are tested for AP of GMO.

Testing seeds for GMO presence: to explore MS approach to GMO testing for the seeds that they do sample, including the type/s of tests employed and quality standards required.

Results of GMO testing: to gather results of GMO testing that has been done under the inspection and enforcement regime, and the approach taken to enforcement in the event that AP of GMO is identified.

Seed production statistics: to gain information on the seed production and import statistics, and seed companies active in each MS. A spreadsheet (MS Excel) was developed for distribution with the questionnaire to gather basic details on seeds being marketed, imported and imported then re-exported in each of the Member States for 2005 and 2006, for maize, oilseed rape and soya and any other major crops.

A total of 129 questions were asked, of which 91 were mandatory (the on-line system will not accept e-survey responses unless all mandatory questions are answered). The questionnaire is reproduced from the e-survey format in Appendix A of this report. Note that in the questionnaire, the abbreviation 'AGMP' was used when referring to adventitious presence of GMOs.

2.2 Information gathering and management

To gather data sets from individual MS an on-line survey (questionnaire) system was utilised in an effort to minimise administrative input and reduce the possibility of operator error on the part of the project team. The questionnaire was accessed at: <http://euseeds.csl.gov.uk/survey.cfm> via a dedicated secure website hosted on CSL servers.

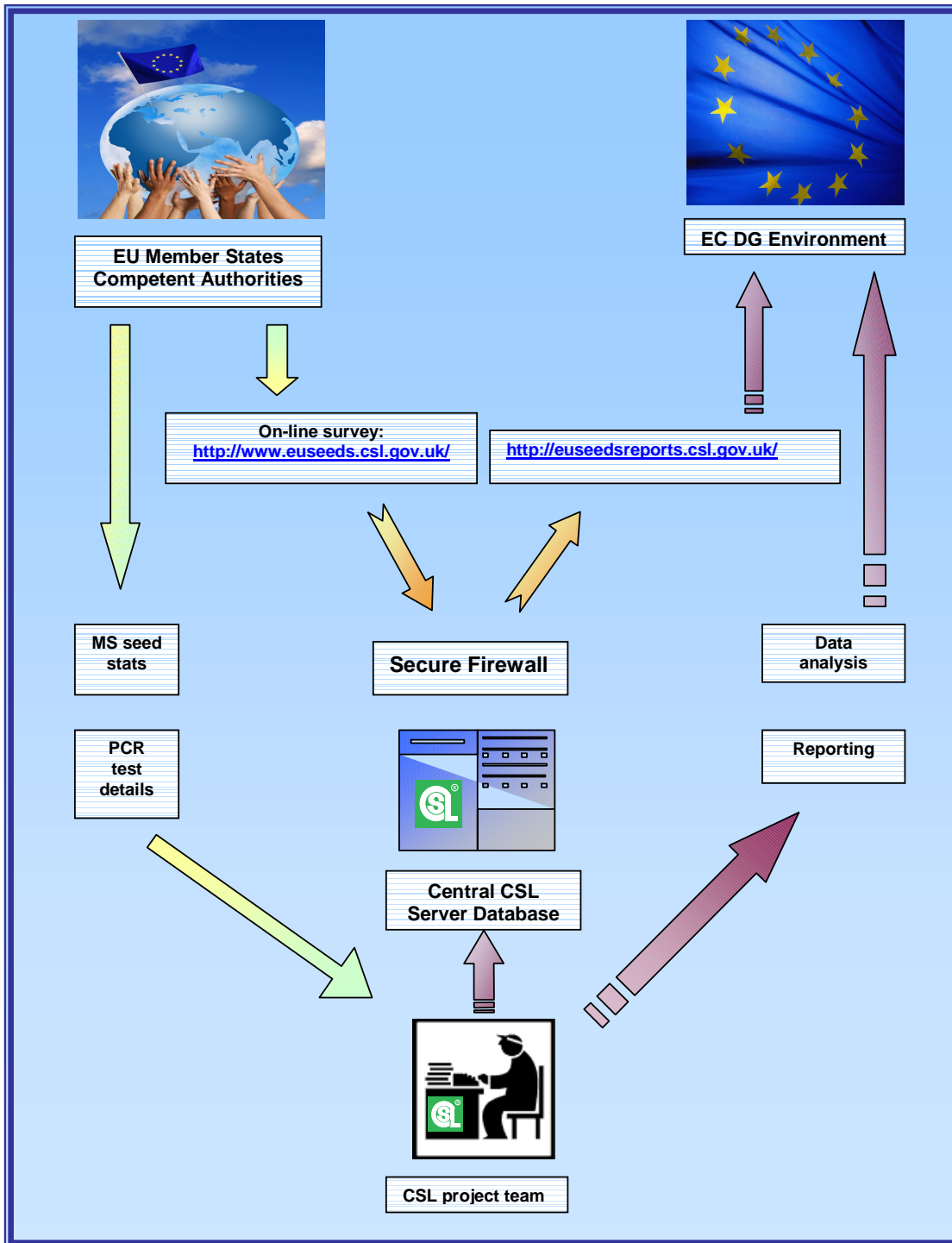
The software used to create the 'e-survey' was developed in-house by the CSL Information Services Team and is nominally called "Survey O'Matic". It has been used successfully to support a number of e-surveys for both internal (e.g. annual occupational health surveys) and external use (e.g. the UK government's Countryside Survey 'Countryside Information System'⁹).

The 'Survey O'Matic' system stores each discreet set of data directly into a database sitting behind the e-survey, which is programmed to display survey results in graphical format, providing a basic level of analysis. To facilitate detailed management and analysis of the results all data can be downloaded from the database directly into an Excel spreadsheet. In addition, to enable the survey owner (DG Environment) to view and interrogate the collected data more intuitively using a visually accessible format, a dedicated web-based user interface was developed for access by the secure weblink: <http://euseedsreports.csl.gov.uk/>. An overview of the on-line survey information gathering and data management system is provided in figure 2.1 below.

(Note added after the survey was completed: a drawback of the survey, which was commented upon by a few respondents was that it could not be partially completed and answers added as they were gathered. We acknowledge that this was inconvenient for some, and have fed this comment back to the software development team).

⁹ <http://cis.csl.gov.uk/survey.cfm>

Figure 2.1: Overview of electronic management of survey and data gathered

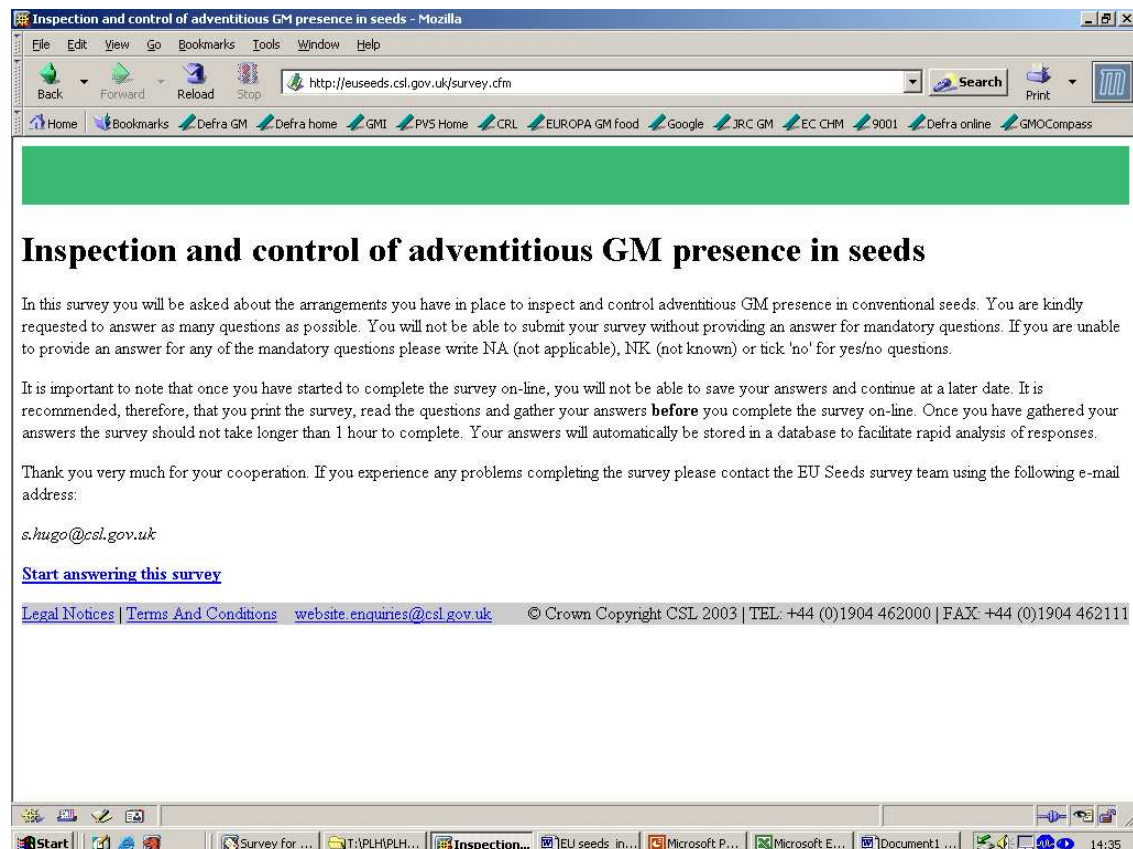


2.2.1 Issuing the survey

The link to the e-survey hosted on the CSL website at <http://euseeds.csl.gov.uk/survey.cfm> plus the spreadsheet for gathering MS seed statistics was issued by email to all MS on Monday 19th February 2007. The e-survey questions were agreed with DG Environment before the survey was issued. Access was username and password protected. Figure 2 below gives a screenshot of the e-survey home page. To encourage MS to participate in this information gathering exercise (and in doing so provide CSL with the data requested) the email also contained a letter from DG Environment (Appendix C of this report).

Primary recipients of the email were nominated contacts in each of the MS competent authorities (CA); the email was also copied to all other named personnel in each of the MS CAs and to MS representatives on the EC Standing Committee for Seeds. MS were given four weeks to complete the survey, with telephone calls and email reminders commencing in the third week after issuing (Monday 12th March 2007). Not all MS were able to complete the survey on-line and an alternative Microsoft Word version of the survey was provided upon request to facilitate data collection. In such cases, the project team manually submitted the response into the database. The survey was closed on Friday 29th June 2007, when all responses had been submitted.

Figure 2.2: Screenshot of e-survey

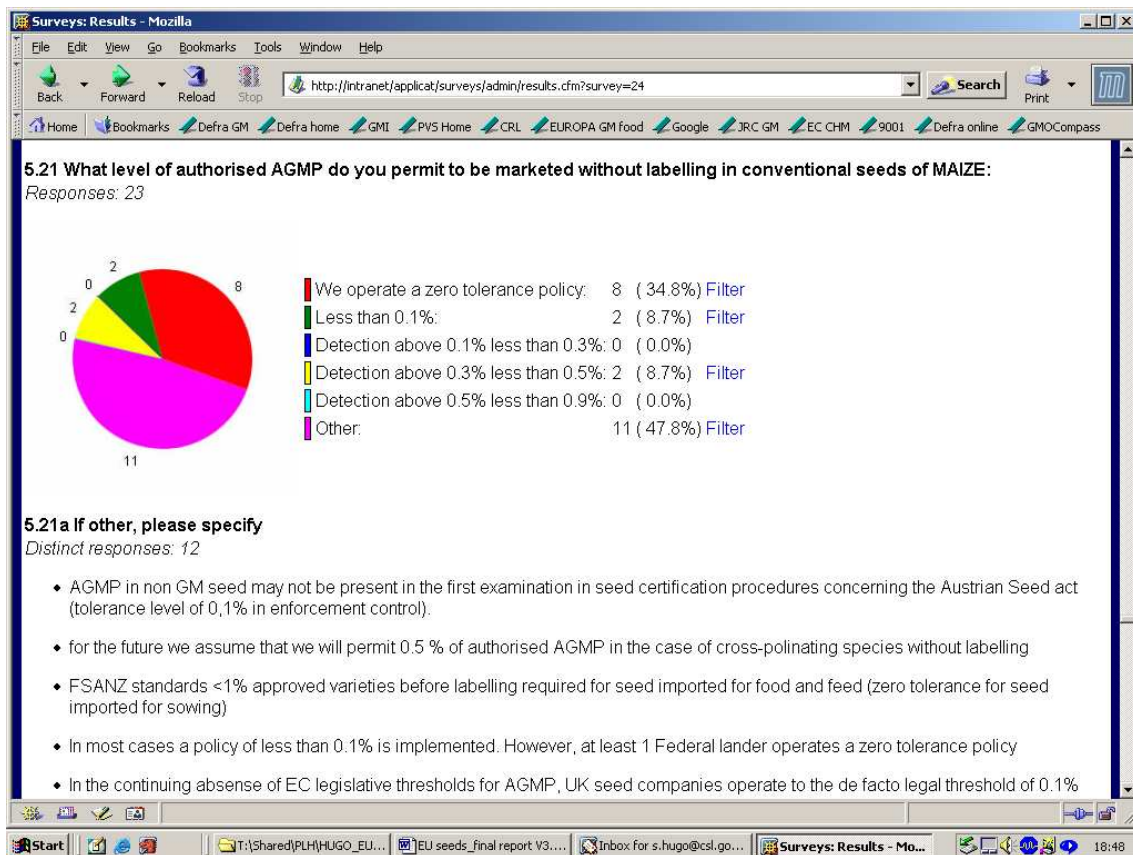


2.2.2 Utility of the e-survey user interface

The e-survey facility enables the 'owner' of the survey¹⁰ to view the data that has been collated in three formats – graphical representation, download into an Excel spreadsheet, and presentation as a table.

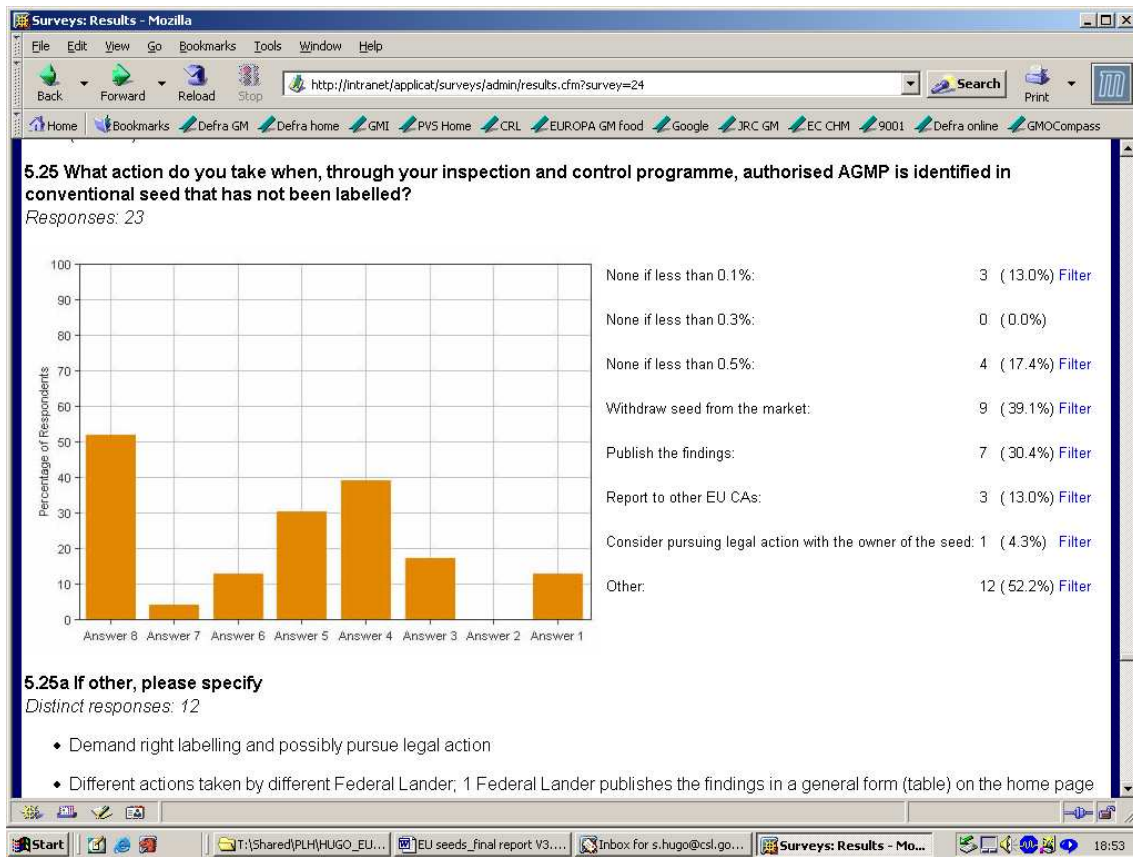
The graphical representation facility provides visual representation of very basic analysis of the collated data. This tool gives a useful first impression of the responses received; for this project it has, however, been of limited value due to the complex nature of the questions and the range of answers provided by the participants. Results can be displayed visually as a pie chart, for example see figure 2.3 below where answers to questions 5.21 (What level of authorised AGMP do you permit to be marketed without labelling in conventional seeds of maize?), and graphically as in figure 2.4, which shows answers provided to question 5.25 (What action do you take when, through your inspection and control programme, authorised AGMP is identified in conventional seed that has not been labelled?). It is the Excel download facility that is most useful, as it provides an automatically populated spreadsheet, on which analysis of data can be based.

Figure 2.3: E-survey analysis of answers collated to question 5.21



¹⁰ CSL as the contractor and DG Environment as the customer

Figure 2.4: e-survey representation of answers provided to question 5.25

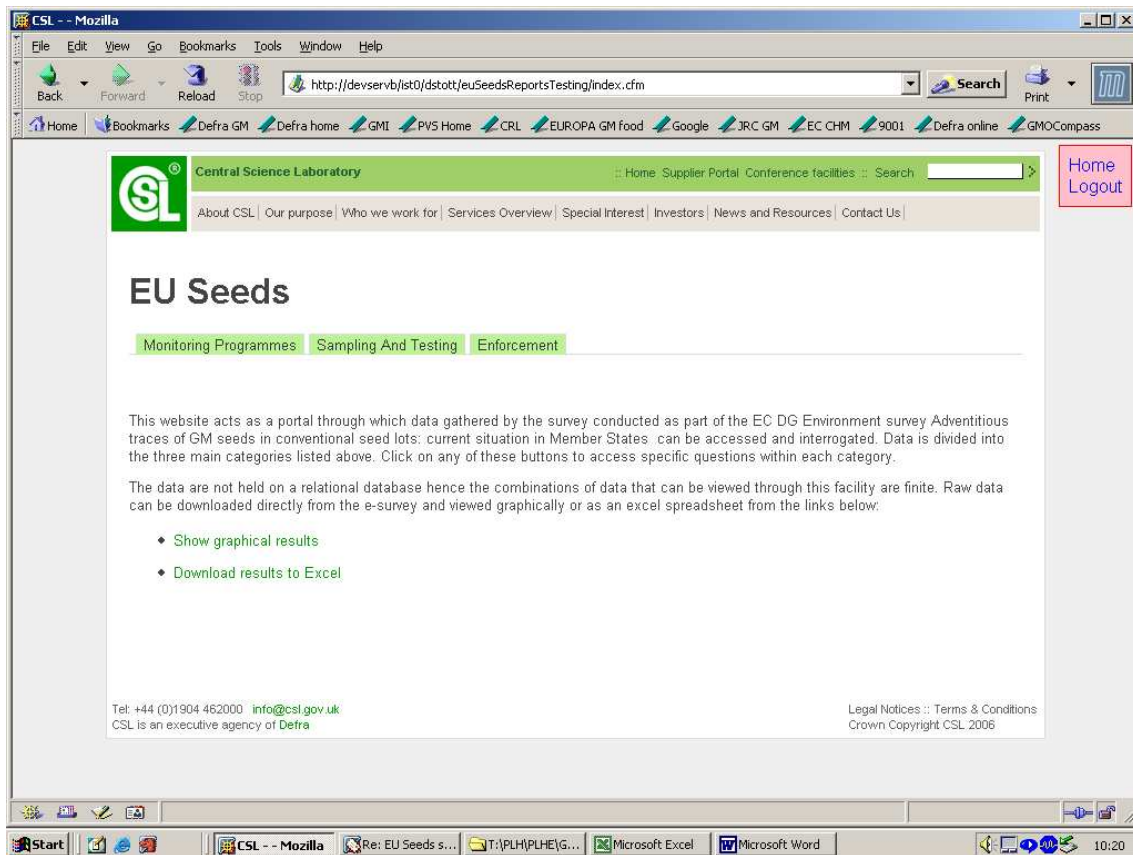


2.3 Accessing results and development of a user interface

The user interface was developed to provide a link to the raw data via which the information collected in the survey can be viewed and manipulated. It also provides a link to the graphical representation of e-survey data and a link to permit the download of the raw data as an excel spreadsheet. The user interface also allows data to be viewed on an MS by MS basis.

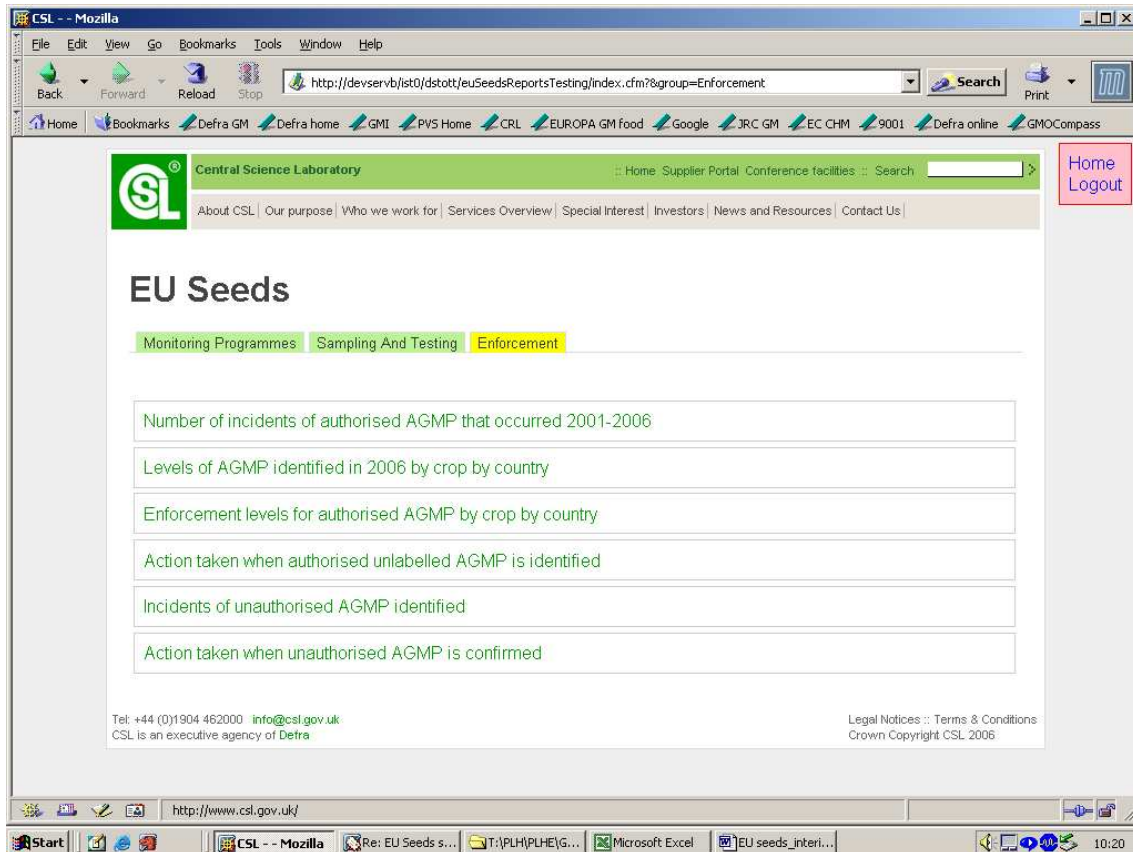
The homepage of the e-survey user interface was made available on 15th March 2007 (see screenshot in figure 2.5 below). It is accessed at <http://euseedsreports.csl.gov.uk> using the username 'dgenv' and the password 'aefgyujid' (this was randomly generated; more usernames and passwords can be issued if necessary). This resource will be available for as long as is required after completion of the project.

Figure 2.5: E-survey user interface homepage



The home page of the user interface offers three main sections: 'monitoring programmes', 'sampling and testing' and 'enforcement', which are based on the e-survey questionnaire. Survey data is displayed by selecting parameters of choice from drop-down menus. In each section a list of options is available that will select and display data collected in the e-survey. For example figure 2.6 below illustrates the options available under the Enforcement section heading.

Figure 2.6: Options available under the Enforcement section of the user interface



Selecting certain options will display additional filters, which allow the user to select information according to more specific criteria such as a particular year, a group of countries, a single country or a crop type. For example, if a user selects the option to display the number of incidents of authorised AP of GMO that occurred 2001-2006 under the enforcement section, an additional filter is displayed that permits the user to select the information based on either a group of countries or an individual country.

Figure 2.7 below illustrates the user has selected to display the information relating to the number of incidents of authorised AP of GMO that occurred 2001-2006 for the EU countries pre-May 2004. The result of this query is displayed in figure 2.8 below.

Figure 2.7: Additional filter for the number of incidents of authorised AP of GMO that occurred 2001-2006

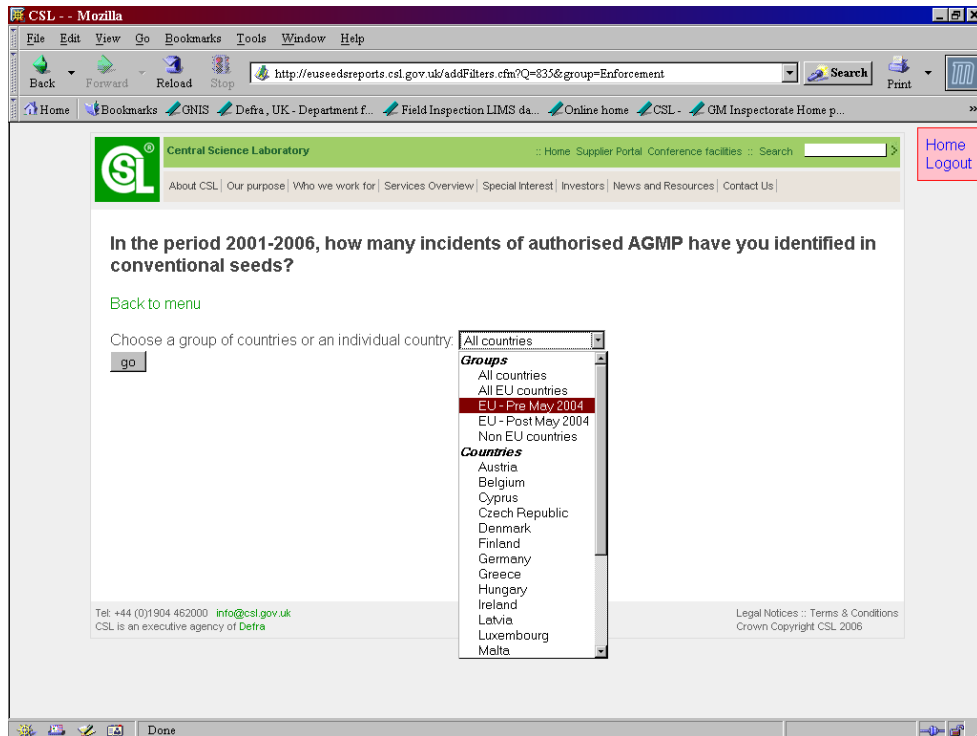


Figure 2.8: Table of results for the number of incidents of authorised AP of GMO that occurred 2001-2006

	In the period 2001-2006, how many incidents of authorised AGMP have you identified in conventional seeds of MAIZE	In the period 2001-2006, how many incidents of authorised AGMP have you identified in conventional seeds of OILSEED RAPE	In the period 2001-2006, how many incidents of authorised AGMP have you identified in conventional seeds of SOYA	In the period 2001-2006, how many incidents of authorised AGMP have you identified in conventional seeds of other crops?
Austria	0	0	0	
Belgium	Walloon region: 0, Flemish region: 2	0	0	
Denmark	0	0	0	
Finland	NONE	NONE	NONE	
Germany	10	2	0	
Greece	NA	0	0	
Ireland	2	n/a	n/a	
Luxembourg	None	None	None	
Netherlands	3	0	not applicable	
Spain	90	N/A	N/A	
Sweden	NA	0	NA	
United Kingdom	1	1	NA	

2.4 Limitations of the user interface

The user interface is a useful tool for improving accessibility to the results of the e-survey, but there are limitations to the amount and combinations of data that can be accessed using this approach. The data collected in the survey is not stored in a relational database so the information that can be viewed through the user interface is finite and can only be searched according to the pre-determined filters.

2.5 Preparation for analysis of data

For analysis of the information provided, all data was downloaded directly from the e-survey into an Excel spreadsheet and saved as separate worksheets corresponding to distinct sections of the e-survey. These are provided at Appendix D of this report, and formed the basis for analysis of the data described in section 6.

3. MEMBER STATE RESPONSES

3.1 E-survey and seed production and import data

Table 1: Responses received

MS		E-survey	Seed Stats
AT	Austria	✓	✓
BE	Belgium	✓	x
BG	Bulgaria	x	x
CY	Cyprus	✓	✓
CZ	Czech Republic	✓	✓
DE	Germany	✓	✓
DK	Denmark	✓	✓
EE	Estonia	x	x
EL	Greece	✓	✓
ES	Spain	✓	✓
FI	Finland	✓	✓
FR	France	✓	✓
HU	Hungary	✓	✓
IE	Eire	✓	✓
IT	Italy	x	✓
LT	Lithuania	x	✓
LU	Luxembourg	✓	✓
LV	Latvia	✓	✓
MT	Malta	✓	✓
NL	The Netherlands	✓	✓
PL	Poland	✓	✓
PT	Portugal	x	x
RO	Romania	✓	✓
SE	Sweden	✓	x
SI	Slovenia	✓	✓
SK	Slovak Republic	✓	✓
UK	United Kingdom	✓	✓

Of the 27 MS, a total of 20 full responses, 2 partial responses (e-survey only), 2 partial responses (MS seed stats only), and 3 nil responses were collected. Twenty three responses were entered into the database.

Comments on data collection

Collecting the data presented problems for a number of the MS, particularly those with very large administrations. Regulatory responsibility for seeds and for GMOs often lies within different departments and in some cases it has been difficult to establish exactly who should take responsibility for completion of the e-survey, however once this has been resolved, a response has been provided. For MS that operate on a strongly regional basis (for example Spain and Germany), gathering the requested data was a fairly substantial undertaking for them, nevertheless both countries provided comprehensive responses. Further detail on this is provided in section 4 (qualitative assessment of responses).

All data is provided in Excel spreadsheets in Appendix D (EU MS e-survey response) of this report; each workbook consists of six sheets, each corresponding to one of the

six sections of the e-survey. EU Member States seeds stats data is provided in Appendix E (MS seed stats).

[Note: MS were also invited to provide very detailed information about the analytical sampling, sub-sampling and testing strategies in use and link these with quantitative PCR test results obtained for seeds in the MS control programme. Information about this would have enabled additional assessment of the combined performance of the sampling and testing regime, which is of particular interest to the project team. It was, however, additional to the primary aims of the project. A very small amount of this data was collected. This was probably because the survey was addressed to competent authorities rather than testing laboratories. The lack of collected data here did not compromise the project.]

4. QUALITATIVE ASSESSMENT OF MS RESPONSES

Detailed statistical analysis of responses is provided in section 6 of this report, in this section the responses received are summarised and presented in a series of tables, and qualitative observations are made. A small number of very basic statistical assessments are given, which have been taken directly from the e-survey results.

In the tables that follow we have brought together essential basic data collected about MS approach to inspection and control of AP of GMO, and combined data that is held in separate worksheets of the data tables in Appendix D. For example information about sampling seeds and test results are held in separate worksheets but they are intrinsically linked and it is useful to be able to view them together.

Notes about data collected

As already described, the purpose of utilising the e-survey approach was to standardise responses to questions and facilitate subsequent analysis of data. On the whole this strategy proved to be effective and key data has been provided in a consistent, comparable format (this is particularly true for questions that were obligatory). Data on seed sampling was provided by some MS in percentage figures and by others in total numbers of lots sampled, which made direct comparison difficult. Optional questions and those where pre-determined answers were not provided inevitably led to a range of responses; we have tried, where possible, to standardise these where answers clearly mean the same thing but are worded differently (for example “countries out of EU” and “only third countries”).

Note about French data

In France, inspection and control of adventitious GM presence in conventional seeds is implemented by two bodies – La direction générale de l'alimentation (DGAL) (Ministry of Agriculture), and La direction générale de la concurrence, de la consommation et de la répression des fraudes (DGCCRF) (Directorate-general for competition, consumers and repression of fraud). DGAL is responsible for ensuring conformity with labelling in seed imported from third countries, while DGCCRF is responsible for ensuring conformity in marketed seeds that are home-produced and those imported from EC Member States. Sampling of imported seed lots is carried out by the regional plant protection services of DGAL at the point of import. Data for the survey were provided jointly by DGAL and DGCCRF and are maintained separately in the spreadsheets in Appendix D and the tables below.

Note about German Federal Länder

In Germany, inspection and control of AP of GMO in conventional seed is the responsibility of the Federal Länder. Answers were received from 7 out of 16 Federal Länder (2 Länder do not inspect and control seeds because of very limited agricultural production). The response in the tables below and spreadsheets in Appendix D represent the combined response of the Federal Länder as collated and provided by the German CA.

Note about non-participants

Only four MS did not participate in the e-survey. A limited amount of information about programmes for inspection and control of AP in GMO in two of these countries

was obtained from information provided by DG Environment via DG Sanco. Of the non-participant countries, only one is known to be cultivating a small amount of GM maize and it would have been useful to obtain a full response from this MS.

Country codes used

AT	Austria	IT	Italy
BE	Belgium	LT	Lithuania
BG	Bulgaria	LU	Luxemburg
CY	Cyprus	LV	Latvia
CZ	Czech Republic	MT	Malta
DE	Germany	NL	Netherlands
DK	Denmark	PL	Poland
EL	Greece	PT	Portugal
ES	Spain	RO	Romania
FI	Finland	SE	Sweden
FR	France	SI	Slovenia
HU	Hungary	SK	Slovak Republic
IE	Ireland	UK	United Kingdom

Symbols used

[Blank cell]	participant did not provide information
-	Non- participant (some information may have been provided by DG Environment)
n/a	Not applicable
n/k	Not known
DGAL	La direction générale de l'alimentation – Ministry of Agriculture, France
DGCCRF	La Direction générale de la concurrence, de la consommation et de la répression des fraudes - Directorate-general for competition, consumption and the repression of fraud, France
FL	German Federal Länder

Notes about tables 4.1 to 4.12

The data provided in these tables has been brought together from responses entered into the e-survey database. Responses have been summarised where necessary for the purposes of saving space, consistency of wording and to facilitate comparison across the tables. The original wording provided is in the excel spreadsheets in Appendix D.

4.1 Summary of MS approaches to inspection and control of adventitious GM presence in conventional seeds

Summary

1. Of the responses that were received:
 - 19 Member States have a formal programme in place for inspection and control of AP of GMO in conventional seeds.
 - Belgium and the UK do not have a formal programme but AP of GMO is monitored by other means (discussed below).
 - Estonia, Lithuania, Latvia and Malta do not have an inspection and control programme in place. Latvia was able to provide data on *ad hoc* checks undertaken for AP of GMO. Malta does not have a programme in place because it does not have any large-scale arable cultivation.

MS	Formal inspection & control programme?	Crops included in the programme	Other crops	Purpose of the programme		Programme commenced
				EU legislation	National legislation	
AT	Yes	Maize, oilseed rape, soya		EC Directive 2001/18/EC, Regulation 1829/2003	Austrian seed act	25/07/2000
BE	No, but AP of GMO is monitored by another route	Maize, oilseed rape	Sugar beet, <i>Raphanus raphanistrum</i> , <i>Brassica nigra</i> , <i>Brassica juncea</i> , <i>Hirchfeldia incana</i> , <i>Brassica rapa</i> (Walloon Region); sugar beet (Flemish Region)	Other	Controls are done in the context of seed legislation (taking into account Directive 2001/18)	2001
BG	-	-	-	-	-	-
CY	Yes	Maize				
CZ	Yes	Maize, oilseed rape, soya		EC Directive 2001/18/EC, Regulation 1829/2003		01/01/2006
DE	Yes	Maize, oilseed rape, soya	Sugar beet, potatoes, zucchini, tomatoes (single Federal Länder)	EC Directive 2001/18/EC, Regulation 1829/2003	German Seed Law	01/01/2001
DK	Yes	Maize, oilseed rape		EC Directive 2001/18/EC		24/01/2001
EE	No	-	-	-	-	-
EL	Yes	Maize, oilseed rape, soya	Cotton, beets, tomato for processing		Common Ministerial Decision 332657/16-2-2001, OGF 176B/21-2-2001	21/02/2001
ES	Yes	Maize		EC Directive 2001/18/EC, Regulation 1829/2003		

MS	Formal inspection & control programme?	Crops included in the programme	Other crops	Purpose of the programme		Programme commenced
				EU legislation	National legislation	
FI	Yes	Oilseed rape		EC Directive 2001/18/EC	Seed trade law	
FR	Yes	Maize, soya, oil seed rape (DGCCRF). Maize (DGAL).		EC Directive 2001/18/EC, Reg'ns 1829/2003 & 1830/2003		01/01/1999 (DGCCRF), 01/01/2002 (DGAL)
HU	Yes	Maize		EC Directive 2001/18/EC, Regulation 1829/2003	Compliance with national legislation	2002
IE	Yes	Maize		EC Directive 2001/18/EC		01/01/2001
IT	Yes	Maize, soya	-			
LT	No	-	-	-	-	-
LU	Yes	Maize				01/09/2000
LV	No	Maize, oilseed rape				
MT	No	No inspection and control programme	n/a	N/a	n/a	n/a
NL	Yes	Maize		EC Directive 2001/18/EC, Regulation 1829/2003		01/04/2001
PL	Yes	Maize, oilseed rape		Compliance with EC authorisation system and labelling requirements	Compliance with national seed legislation	00/00/2005
PT	[Yes]	-	-	-	-	-
RO	Yes	Soya		EC Directive 2001/18/EC, Regulation 1829/2003	2002/54/EC 66/401/EEC 66/402/EEC 2002/57/EC 78/458/EEC	Dec-06
SE	Yes (AP of GMO is also monitored by another route)	Maize, oilseed rape	<i>Brassica rapa</i> (turnip rape)	EC Directive 2001/18/EC	"Gentlemen's agreement" from the Standing Committee on Seeds of July 2000	2000
SI	Yes	Maize, oilseed rape		EC Directive 2001/18/EC		23/03/2004
SK	Yes	Maize, oilseed rape, soya		EC Directive 2001/18/EC, Regulation 1829/2003		1999
UK	No, but AP of GMO is monitored by another route	Maize, oilseed rape, soya	<i>Brassica rapa</i> (turnip rape)	Other	To assist seed producers, importers and suppliers in meeting their legal duty to minimise the risk of AP of GMO in conventional	01/05/2000

					seeds	
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Additional information about countries that do not have a formal programme for inspection and control of AP of GMO, but monitor AP of GMO by a different route.

Belgium

At present testing Belgium does not have a nationally coordinated programme for monitoring and control of AP of GMO. Control is currently undertaken at the regional level, under the control of the authorities of the Walloon region and Flemish region. It is anticipated that monitoring and control will be coordinated by the Belgian competent authority for Directive 2001/18/EC when agreement is reached at EU level on permitted levels of AP of authorised GMO in conventional seeds.

Latvia

This country is a relatively new member of the European Union, and does not yet have a formal policy for monitoring and control of AP of GMO. The country imports seeds of maize and oilseed rape and has undertaken some *ad hoc* testing of these. The competent authority has provided information where they were able.

Sweden

In Sweden the monitoring and control programme consists of checks on all seed imported directly from third countries. In addition, producers must perform checks on home-produced "breeder's seed" of oilseed rape and turnip rape (regardless of where that seed will be marketed). Sugar beet is the responsibility of the breeder.

United Kingdom

The UK has had a voluntary programme of monitoring for AP of GMO since 2001. UK legislation does not permit proactive sampling and testing of seeds for the presence of AP of GMO unless there is evidence to suggest that seeds may contain a GMO. Under the voluntary programme companies marketing seeds of crops included in the programme are, therefore, invited to participate in an audit of their procedures for managing the risks of AP of GMO in the seed they market. The crops included in the audit programme are identified using models of quantitative risk analysis. Guidance is issued to seed companies as to where the main risks lie in the seed production process and approaches to managing these risks. It is not a requirement to provide evidence of analytical testing of seeds for the presence of GMOs. A report is provided to companies that are audited. The UK competent authority for seeds (Plant Variety Rights Office and Seeds Division of the Department for Environment, Food and Rural Affairs) runs the seed audit programme. GM Inspectorates for England and Wales and for Scotland undertake the audits. Where concerns are identified that AP of GMO may be present, the GM Inspectorates have powers to allow sampling and testing of seeds. The current approach will be reviewed when agreement is reached on permitted levels of authorised AP of GMO in conventional seeds at EU level.

4.2 Summary of crops that are monitored by MS

This table gives an overview of the crops that are currently being monitored. These generally reflect the prevailing agricultural activity in each MS, but may also give an impression of the attitude to GMOs and the 'risk appetite' of the MS.

Crops	Included in MS inspection and control programme
Maize	7 (Cyprus, Eire, France (DGAL), Hungary, Luxembourg, The Netherlands, Portugal)
Maize + OSR	4 (Denmark, Latvia, Slovenia, Poland)
Maize + OSR + other crops	2 (Belgium, Sweden)
Maize + OSR + soya	4 (Austria, Czech Republic, France (DGCCRF), Slovak Republic)
Maize + OSR + soya + other crops	3 (Germany, Greece, UK)
Maize + soya	1 (Italy)
Maize + other crops	1 (Spain, crop not specified)
OSR	1 (Finland)
OSR + soya	0
Soya	1 (Romania)
No inspection and control programme	3 (Estonia, Lithuania, Malta)
Other crops monitored	Belgium (Walloon): sugar beet, <i>Raphanus raphanistrum</i> , <i>Brassica nigra</i> , <i>Brassica juncea</i> , <i>Hirchfeldia incana</i> , <i>Brassica rapa</i>
	Belgium (Flemish): sugar beet
	Germany : sugar beet, potatoes, zucchini, tomatoes (single Federal Länder)
	Greece : cotton, beets, tomato for processing
	Sweden, UK : <i>Brassica rapa</i> (turnip rape)

Note 4.2 (1): the crops that are monitored partly reflect the decision of the Standing Committee on Agricultural, Horticultural and Forestry Seeds and Plants dated 10th July 2000¹¹ following findings of adventitious presence of GMO seed in non-GMO varieties, in which MS agreed to organise testing of selected seed lots of conventional varieties to determine the presence of GMO impurities, until the coming into force of related new legislative measures. It was agreed that testing would apply in particular to seeds of species grown in large scale in whole or part of the Community, and for which the presence of GMOs was suspected. Seeds of all categories (pre-basic seed, basic seed, certified seed of the different generations, commercial seed and standard seed) were included. The species concerned in this original decision were beet, maize, oilseed rape, soya bean, cotton and tomato, for processing purposes.

¹¹http://ec.europa.eu/food/fs/rc/scsp/rap15_en.html

4.3 MS approaches to inspection and control:

There are a number of ways in which MS may obtain information about AP of GMO in seeds – they may take responsibility for the sampling and testing of seeds themselves, or may require seed companies to participate more proactively in the programme by providing (a greater or lesser) amount of the information to the appropriate CA. The range of practices currently in use is summarised in table 4.3 below.

Table 4.3: Approaches to sampling and testing in MS inspection and control programmes. See also notes 4.3 (1) and (2) below.

Type of programme		MS adopting this approach
1	Sample seed lots themselves and test them (or commission tests) for AP of GMO	BE, CY, CZ, DK, EL, FI, FR, HU, IT, LU, LV, PL, RO, SI, SK
1.1	1 plus: other	NL (If positive results are found companies are requested to provide evidence of how they manage the risks of AP of GMO in the seed lots they market in NL)
1.2	1 plus: request companies to provide evidence of how they manage the risks of AP of GMO in the seed lots they market in your country	SE
1.3	1 plus: require seed companies to sample and test the seed lots they are marketing in the respective country and provide the CA with the results	IE
1.4	1 plus: require seed companies to sample and test the seed lots they are marketing in the respective country and provide the CA with the results, and other	DE (if consent is given for placing on the market of a new genetically modified plant, this transformation event will be considered in the inspection and control programme as appropriate)
1.5	1 plus: require seed companies to sample and test the seed lots they are marketing in the respective country and provide the CA with the results, and request companies to provide evidence of how they manage the risks of AP of GMO in the seed lots they market in the respective country	AT
2	Request seed companies to provide samples of seed lots they are marketing in the respective country and then test these samples (or commission tests) for the AP of GMO	ES
3	No inspection and control programme	EE, LT, MT
4	Inspection and control is undertaken but details are unknown	PT

Note 4.3 (1): Question 3.28 asked respondents “Do you require seeds to be sampled in accordance with internationally recognised standards (for example ISTA rules)”. Twenty out of 23 respondents said that they did, and of the 18 that specified their recognised sampling standards, all of these specified ISTA rules for sampling seeds. Additional standards quoted were:

- AOSA (American Association of Official Seed Analysts) (2 MS)

- Commission Recommendation 2004/787/EC of 4th October 2004 on technical guidance for sampling and detection of genetically modified organisms (1 MS)¹²
- National guidelines for sampling of seeds to be certified (2 MS)

Note 4.3 (2): Where CAs permit seed companies to test seed themselves, 21.7% (5 out of 23 respondents) of CAs carry out testing to confirm seed companies' results (question 4.8). Only two CAs answered the subsequent question ("Do your results always agree with the company"), both answered no. One of these stated that discordant results were rare, and that action was only taken if the results were within the 0.5% threshold for AP of GMO permitted within that particular MS.

¹² http://ec.europa.eu/environment/biotechnology/pdf/recom2004_787.pdf

4.4i Sampling seeds in preparation for GMO testing: all samples, 2006

Each MS will have considered the strategy behind their monitoring and control programme; while a major influence on this is likely to be their national agricultural profile, the perception of (and possibly the appetite for) risk of AP of GMO may also be taken into consideration when deciding which seeds (and the proportion) to sample and test. Resource availability will also influence decisions on sampling and testing, questions on this were not specifically included in the survey but see note 4.4 (5) below.

MS	Sampling and & testing			Maize seed				OSR seed				Soya seed			
	Home-produced seeds?	Imported seeds?	Risk-based? ^a	Home-produced		Imported		Home-produced		Imported		Home-produced		Imported	
				Certified lots	As-grown	Certified lots	As-grown	Certified lots	As-grown	Certified lots	As-grown	Certified lots	As-grown	Certified lots	As-grown
AT	Yes	Yes	All (& HR)	5-10 %	0	10-25 %	0	5-10 %	0	10-25 %	0	5-10%	0	10-25 %	0
BE	No	Yes	HR	0	0	0 (100%)	0	0	0	0 (100%)	0	0	0	0	0
BG	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CY	No	Yes	All	n/a	n/a	100%	n/a	n/a	n/a	n/a	n/a	n/a	N/a	n/a	n/a
CZ	Yes	Yes	All (& HR)	0	0	1.8	0	0	0	0.6	0	0	0	21	0
DE	Yes	Yes	All (& HR)	10% (1 FL); 2 lots (% n/k; 1 FL)	N/k	88% (1 FL); 100 % (1 FL); 63 samples (3 FL)	n/k	26 lots/6% (1 FL); app. 10% of the presented lots (1 FL)	n/k	5 samples (% n/k 2 FL); 4.6% (4 lots, 1 FL); 5.8 % (5 samples, 1 FL)	n/k	n/k	N/k	n/k	n/k
DK	No	Yes	HR	0	0	0	0	0	0	0	0	0	0	0	0
EE	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
EL	Yes	Yes	All	100% (203)	100	46.1	0	0	0	0	0	0	0	100	0
ES	Yes	Yes	All	0.9	0.1	0.9	n/a	n/a	n/a	n/a	n/a	n/a	N/a	n/a	n/a
FI	No	Yes	All	n/a	n/a	n/a	n/a	n/a	n/a	None	none	n/a	N/a	n/a	n/a
FR	Yes (DGCCRF) No (DGAL)	Yes (DGAL)	HR	n/k	n/k	n/k	n/k	n/k	n/k	n/k	n/k	n/k	N/k	n/k	n/k
HU	No	Yes	HR	n/a	n/a	36 tests	0	n/a	n/a	0	0	n/a	N/a	0	0

MS	Sampling and & testing			Maize seed				OSR seed				Soya seed			
	Home-produced seeds?	Imported seeds?	Risk-based?	Home-produced		Imported		Home-produced		Imported		Home-produced		Imported	
				Certified lots	As-grown	Certified lots	As-grown	Certified lots	As-grown	Certified lots	As-grown	Certified lots	As-grown	Certified lots	As-grown
IE	No	Yes	All (& HR)	n/a	n/a	15%	n/a	n/a	n/a	None	n/a	n/a	n/a	n/a	n/a
IT	n/k	Yes	n/k	n/k	n/k	n/k	n/k					n/k	n/k	n/k	n/k
LT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
LU	No	Yes	All	n/k	n/k	1%	0%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
LV	No	Yes	HR	n/a	n/a	n/k	n/k	n/a	n/a	n/k	n/k	n/a	n/a	0	0
MT	No	No	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
NL	No	Yes	HR	n/a	n/a	5%	n/a	n/a	n/a	0%	0%	n/a	n/a	0%	0%
PL	Yes	Yes	All	0	n/s	0	n/s	0	n/s	0	n/s	n/a	n/s	n/a	n/s
PT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
RO	Yes	No	n/a			0	0			0	0	34%	66%	0	n/a
SE	Yes	Yes	HR	n/a	n/a	100% of imports directly from 3rd countries	n/a	100% of breeder's seed and 100 % of exported seed lots	Breeder's responsibility % n/k	100% of imports directly from 3rd countries	n/a	n/a	n/a	n/a	n/a
SI	No	Yes	All	n/s	n/s	80% (imported from 3rd country)	n/s	n/s	n/s	5 samples from the EU market	n/s	n/s	n/s	n/s	n/s
SK	Yes	Yes	HR	2.6	n/a	100	n/a	1.2	n/a	n/a	n/a	4.1	n/a	100	n/a
UK	No	No	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

^aKey to risk-based sampling and testing for imported seeds:

All = seeds imported from all countries including those within EU are sampled and tested

HR = seeds imported from countries considered to be high risk of AP of GMO are sampled and tested

See also notes below

Note 4.4 (1): there appears to be very little sampling and testing of as-grown seeds (harvested seeds before they are formed into lots) for AP of GMO, except in Greece and Spain where 100% and 10% respectively of as-grown maize seeds were sampled and tested. Table 4.4ii below therefore focuses on certified seed lots only, in 2005 and 2006.

4.4ii Summary of sampling in preparation for GMO testing: details about certified seed lots (2005, 2006)

MS	% Certified seed lots sampled & tested for GMOs											
	Maize				OSR				Soya			
	Home-produced		Imported		Home-produced		Imported		Home-produced		Imported	
	2005	2006	2005	2006	2005	2006	2005	2006	2005	2006	2005	2006
AT	5-10 %	5-10 %	10-25 %	10-25 %	5-10 %	5-10 %	10-25 %	10-25 %	5-10 %	5-10%	10-25 %	10-25 %
BE	0	0	100% of imported lots from "risky" countries, 10% of imported lots from FR and SP (= 1 lot)	0	0	0	Walloon region: 100% of imported lots from "risky" countries (0 lots)	0	0	0	0	0
BG	-	-	-	-	-	-	-	-	-	-	-	-
CY	n/a	n/a	100%	100%	N/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
CZ	0	0	0	1.8 (= 10 lots; 9 imported from EU countries, 1 from Romania)	0	0	0	0.6	0	0	0	21
DE	12 % (1 FL); 2 lots (% not known, 1 FL)	10 % (1 FL); 2 lots (% not known, 1 FL)	87 % (1 FL); 69 samples (% NK, 5 FL)	88 % (1 FL); 100 % (1 FL); 63 samples (3 FL)	26 lots/ 5% (1 FL); 14 samples from 450 lots (app. 3 %; 1 FL)	26 lots/6% (1 FL); app. 10 % of presented lots (1 FL)	3.6% (1 FL); 8.4% (7 lots, 1 FL); 21 samples (%n/k 2 FL)	5 samples (%n/k, 2 FL); 4.6% (4 lots, 1 FL); 5.8% (5 samples, 1 FL)	n/k	n/k	n/k	n/k
DK	0	0	0	0	0	0	0	0	0	0	0	0
EE	-	-	-	-	-	-	-	-	-	-	-	-
EL	0	0	43.3	46.1 (aim = 100%)	0	0	100	0	0	0	0	100
ES	0.9 (90%)	0.9 (90%)	0.9 (90%)	0.9 (90%)	N/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

MS	% Certified seed lots sampled & tested for GMOs											
	Maize				OSR				Soya			
	Home-produced		Imported		Home-produced		Imported		Home-produced		Imported	
	2005	2006	2005	2006	2005	2006	2005	2006	2005	2006	2005	2006
FI	n/a	n/a	n/a	n/a	n/a	n/a	0	0	n/a	n/a	n/a	n/a
FR	n/k	n/k	n/k	n/k	n/k	n/k	n/k	n/k	n/k	n/k	n/k	n/k
HU			33 tests ^a	36 tests ^a			0	0			0	0
IE	n/a	n/a	15%	15%	N/a	N/a	None	none	n/a	n/a	n/a	n/a
IT	-	-	-	-	-	-	-	-	-	-	-	-
LT												
LU	0	0	1% (15 lots)	1% (2 lots)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
LV	n/a	n/a	n/k	n/k	n/a	n/a	n/k	n/k	n/a	n/a	non	non
MT	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
NL	n/a	n/a	5% (30 lots, 20 from EU, 10 from 3rd countries (7 Chile, 1 USA, 1 Turkey, 1 Romania))	5%	n/a	n/a	0%	0%	n/a	n/a	0%	0%
PL	0	0	No data	0	62%	No data yet	No data	No data	n/a	n/a	n/a	n/a
PT												
RO	0	0	0	0	0	0	0	0	0	34%	0	0
SE	n/a	n/a	100% of imports from 3rd countries	100% of imports from 3rd countries	100% of "breeder's seed" & 100% of exported seed lots	100% of "breeder's seed" & 100% of exported seed lots	100% of imports from 3rd countries	100% of imports from 3rd countries	n/a	n/a	n/a	n/a
SI	0	0	No data	80% (15 samples, 3 from EU; 12 from 3rd country)	0	0	0	5 samples from EU market	0	0	0	0
SK	2.9 (10 lots)	2.6 (10 lots)	100 (1 lot)	100 (4 lots)	1.2	1.2 (1 lot)	n/a	n/a	66.7	4.1 (4 lots)	100	100 (7 lots)
UK	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

^aFigures on kgs of maize imports were not available

Note 4.4 (2): In most cases, where seed is sampled specifically in connection with the programme for inspection and control of AP of GMO, all seed is actually tested for the presence of GMOs (in 73.9% of cases, out of 23 respondents). Where seed is not all tested, laboratory capacity was quoted as one reason (75% of seed is tested), in another case 90% is tested and the remaining 10% is subject to documentary checks, in another case sampled seed was said to be randomly tested.

Note 4.4 (3): If sampling is risk-based it can be expected to have a significant influence on the results of seed testing; seeds that are sampled only from countries that have been identified to be at higher risk of containing GMO than other countries would be expected to show higher levels of AP of GMO than seeds sampled across all countries. Targeted, risk-based sampling strategies would also be expected to sample a smaller proportion of total seeds than a strategy in which all seeds are assumed to contain GMO.

Information on MS sampling strategies was collected through questions 3.1 ('do you sample and test seeds produced in your country') and 3.14 ('do you sample and test seeds imported into your country'). In addition, question 3.27 focussed on sampling & testing strategies for imported seeds and asked 'do you sample and test seeds imported from all countries including those within EU, or seeds imported from countries considered to be high risk of AGMP'. A very GMO risk averse MS might be expected to be one in which there is no commercial GM crop cultivation yet both home-produced and all imported seeds are sampled and tested, with additional effort focussed on countries considered to be high risk. Conversely, the most targeted risk-based strategy would be one in which only seeds imported from countries considered to be at high risk of adventitious GM presence are sampled and tested. Answers to these questions are summarised below. Questions were not asked about the basis of MS risk assessments, i.e. the strategy and methodologies of risk assessment.

Do you sample and test seeds produced in/imported into your country (Qs 3.1 and 3.14):

Do you sample and test seeds that are produced in your country (Q3.1)?		Do you sample and test seeds that are imported into your country (Q3.14)?	
Yes	No	No	Yes
AT; CZ*; DE* EL; ES* FR* PL; RO; SE; SK	BE; CY; DK; FI; HU; IE; LU; LV; NL; SI	RO	AT; BE; CY; CZ*; DE*; DK; EL; ES*; FI; FR*; HU; IE; IT; LU; LV; NL; PL; SE; SI; SK

Countries marked with an asterisk (*) are known to be currently cultivating GM maize

What imported seeds do you sample and test (Q 3.27)²:

Seeds imported from all countries including those within EU	CY; EL; ES*; FI; LU; PL; SI
Or seeds imported from countries considered to be high risk of AP of GMO	BE; DK ¹ ; FR*; HU; LV; NL; SE; SK
Seeds imported from all countries including those within EU and seeds imported from countries considered to be high risk of AP of GMO	AT; CZ*; DE*; IE
No sampling and testing programme	EE; LT, MT; UK

Countries marked with an asterisk (*) are known to be currently cultivating GM maize

¹Seeds from within EU are not tested – testing is targeted to perceived risk

²In December 2006 Romania implemented a programme for control of home-grown soya seeds only. This is presumed to be a risk-based decision related to soya seeds that were grown prior to accession to the EC.

Note 4.4 (4): Question 3.27a asked respondents to list the top 5 countries identified as being high risk for AP of GMO, 12 responses were given, with the following results:

Countries considered, by some MS, to be high risk source of AP of GMO (number of MS), in rank order
USA (7)
Argentina (4); Canada (4); Chile (4); France (4)
Turkey (3)
'All countries outside the EU' (2); Australia (2); Hungary (2); India (2); South Africa (2)
Brazil (1); China (1); Colombia (1); Germany (1); Honduras (1); Indonesia (1); Mexico (1); Philippines (1); Romania (1); Spain (1); Uruguay (1)

One respondent stated that all countries are considered 'without prejudice', which was taken to mean that all countries are assumed to represent the same level of risk

Note 4.4 (5): Response to question 2.2 "Is your inspection and control programme the same each year?" 21 respondents answered this question, 12 of which stated that their inspection and control programme is the same each year. Of the 9 MS for which the programme varies each year, answers to question 2.3 "If no, what determines what you will monitor?" were as follows (note that none of these identified cost as a determining factor):

Determining factor	Number of MS
Cost	0
Crop areas	1
Risk assessment	2
Previous findings of AP of GMO	2
Other	3
<p>These answers were also given:</p> <p>Previous results and changing risks (1)</p> <p>Previous findings of AP of GMO, crop areas and costs (1)</p> <p>Risk assessment and results of routine audits (1)</p> <p>New marketing consent being issued in EU would lead to review of programme (1)</p> <p>National law / arrangements (2)</p>	

4.5. Results of testing: incidents of AP of GMO identified in conventional seeds of maize, oilseed rape and soya in MS

AP of authorised GMO means identification of GM events that have been authorised through the EU approvals process for cultivation in EU. AP of unauthorised GMO refers to the presence of any GMO not authorised for cultivation in the EU. In most cases answers are provided as numbers of incidents.

Member State	Conventional maize seed lots					Conventional OSR seed lots				Conventional soya seed lots				Other crops	
	Auth' d AGMP	Incidents of unauthorised AGMP				Auth' d AGMP	Incidents of unauthorised AGMP			Auth' d AGMP	Incidents of unauthorised AGMP			Auth' d AGMP	Unauth' d AGMP
	2001-2006	2004	2005	2006	In GM maize seeds	2001-2006	2004	2005	2006	2001-2006	2004	2005	2006	2001-2006	2001- 2006
AT	0	0	4	5	0	0	0	0	0	0	1	2	0	No	
BE	2 Flemish region)	0	0	0	0	0	0	0	0	0	0	0	0	No	0
BG	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CY	1	N/a	0	0		n/a	N/a	n/a	n/a	n/a	n/a	n/a	N/a	No	
CZ	0	0	0	0	0	0	0	0	0	0	0	0	0	No	
DE	10	0	0	4	<0.1% of GA21, MON863, NK603 T25	2	6	0	1	0	0	0	NK	No	0
DK	0	0	0	0	0	0	0	0	0	0	0	0	0	No	0
EE	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
EL	25	8	1	0	n/a	0	0	0	0	0	0	0	0	No	Cotton: 90
ES	90	0	0	0	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Yes	Cotton: 0
FI	0	0	0	0	0	0	0	0	0	0	0	0	0	No	0

Member State	Conventional maize seed lots					Conventional OSR seed lots				Conventional soya seed lots				Other crops	
	Auth'd AGMP	Incidents of unauthorised AGMP				Auth'd AGMP	Incidents of unauthorised AGMP			Auth'd AGMP	Incidents of unauthorised AGMP			Auth'd AGMP	Unauth'd AGMP
	2001-2006	2004	2005	2006	In GM maize seeds	2001-2006	2004	2005	2006	2001-2006	2004	2005	2006	2001-2006	2001- 2006
FR (DGCCRF/DGAL)	14 / 20% (37 in 2005) ²	0 / 4	0 / 2	0 / 3	-	0 / No imports	0 / No control	0 / No control	0 / No control	0 / No imports	0 / No control	1 / No control	1 / No control	-	-
HU	0	0	0	0	0	-	-	-	-	-	-	-	-	No	n/a
IE	2	0	0	0	0	n/a	No testing	n/a	n/a	n/a	n/a	n/a	N/a	No	n/a
IT	116 ¹									27 ¹					
LT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
LU	None	None	None	None		None	n/k	n/k	n/k	n/k	n/k	n/k	N/k	No	
LV	0	0	0	0	0	0	0	0	0	0	0	0	0	No	0
MT	N/a	N/a	n/a	n/a		n/a	n/a	n/a	n/a	n/a	n/a	n/a	N/a	No	n/a
NL	3	0	0	0	0	0	0	0	0	n/a	0	0	0	No	0
PL	4 (MON 810)	N/a	1	n/a	<0.1%	n/a	n/a	5	No results yet	n/a	n/a	n/a	N/a	No	
PT	5	-	-	1	-	-	-	-	-	-	-	-	-	-	-
RO	Pre-accession	0	0	0	No	Pre-accession	0	0	0	Pre-accession	No reports	No reports	12%	No	No
SE	N/a	N/a	n/a	n/a	0	0	0	1	0	n/a	n/a	n/a	N/a	No	1
SI	1	1	0	1	T25 and Bt11	0	No samples	n/s	0	0	n/s	n/s	N/s	No	
SK	30	0	0	0	No	2	0	0	0	1	0	0	0	No	
UK	1	0	0	0		1	0	0	0	n/a	0	0	0	No	

¹This figure seems high, and it was considered if it might refer to tests also conducted on grain maize imported for food &/or feed use, but it was not possible to confirm or refute this

² According to the published document "Bilan du plan de contrôle 2005 des semences importées de pays tiers".

Note 4.5 (1): Summary of total numbers of incidents of AP of GMO (authorised and unauthorised) in maize, OSR and soya

Number of reported incidents of AP of authorised GMO 2001–2006:

Crop	Total incidents 2001-2006 inclusive	Incidents p/a averaged over 6 years
Maize	274 ^a (390 if figures from Italy are included)	46 (65)
OSR	5	<1
Soya	1 (28)	<1 (5)
Total	280 (396)	47 (66)

^aFrance reported 37 incidents of authorised AP of GMO in 2005, as a rough approximation we have assumed similar levels in 2004 and 2006 to give 111 incidents for France (maize imports in 2006 were less than in 2005, but imports in 2004 were more than 2005, so this should balance out)

Numbers of reported incidents of unauthorised AP of GMO 2004-2006

Crop	2004	2005	2006	2001-2006	TOTAL
Maize	5	7	14		26
OSR	6	6	1		13
Soya	1	3			4
Other crops				90 cotton 1 <i>B. rapa</i>	91
Total	12	16	15	91	43 (134 if other crops are included) Equates to 14 incidents per year (27 if other crops are included)

**Based on the figures reported in this survey, the average number of incidents (authorised and unauthorised) per year for maize, OSR and soya is 61 across all of the MS.

Note 4.5 (2): we do not know the exact number of tests undertaken in a year, however based on answers provided to question 4.19 ('how many GMO test results do you examine each year?'), we estimate in the region of 1901 tests may be undertaken per year for GMO analysis of seed samples. (This is likely to be an underestimation, as 7 MS stated that they examine >200 test results per year, but we have taken this to mean 200 tests). With an average of 61 incidents of AP of GMO per year, this suggests that 3.2% of lots tested are giving a positive result per year, which is slightly higher than calculations in table 4.8 below, which was done for maize only.

4.6i Sampling and incidents of adventitious GM presence

In the next three tables, the approach to sampling for presence of AP of GMO has been combined with findings of AP of GMO on a crop-by-crop basis for i) maize (below), ii) oilseed rape and iii) soya plus other crops

i) Maize

MS	Sampling & testing scheme			Level of sampling for GMOs				No. of GMO tests per year*	Incidents of AGMP identified				
	Home-produced seeds?	Imported seeds?	Risk-based?	Home-produced		Imported			Authorised	Unauthorised			
				Certified lots	As-grown	Certified lots	As-grown		2001-2006	2004	2005	2006	In GM maize seeds
AT	Yes	Yes	All (& HR)	5-10%	0	10-25%	0	> 200	0	0	4	5	0
BE	No	Yes	HR	0	0	0 (100%)		1-10	2 Flemish region)	0	0	0	0
BG	-	-	-	-	-	-	-	-	-	-	-	-	-
CY	No	Yes	All	n/a	n/a	100%	n/a	11-50	1	n/a	0	0	
CZ	Yes	Yes	All (& HR)	0	0	1.8	0	51-100	0	0	0	0	0
DE	Yes	Yes	All (& HR)	10 % (1 FL); 2 lots (% not known, 1 FL)	n/k	88 % (1 FL); 100 % (1 FL); 63 samples (3 FL)	n/k	> 200	10	0	0	4	<0.1% of GA21, MON863, NK603 T25
DK	No	Yes	HR	0	0	0 (100% of at-risk)	0	1-10	0	0	0	0	0
EE	-	-	-	-	-	-	-						
EL	Yes	Yes	All	203 (100%)	100	46.1 (aim = 100%)	0	>200	25	8	1	0	n/a
ES	Yes	Yes	All	0.9	0.1	0.9	n/a	> 200	90	0	0	0	0
FI	No	Yes	All	n/a	n/a	N/a	n/a	0	0	0	0	0	0
FR (DGCCRF / DGAL)	Yes / No	Yes (DGAL)	HR	n/k	n/k	n/k	n/k	101-150 / >200	14 / 20% (37 in 2005)	0 / 4	0 / 2	0 / 3	
HU	No	Yes	HR	n/a	n/a	36 tests	0	11-50	0	0	0	0	0
IE	No	Yes	All (& HR)	n/a	n/a	15%	n/a	11-50	2	0	0	0	0

MS	Sampling & testing scheme			Level of sampling for GMOs				No. of GMO tests per year*	Incidents of AGMP identified				
	Home-produced seeds?	Imported seeds?	Risk-based?	Home-produced		Imported			Authorised	Unauthorised			
				Certified lots	As-grown	Certified lots	As-grown		2001-2006	2004	2005	2006	In GM maize seeds
IT								>200	116 ¹				
LT	-	-	-	-	-	-	-	-	-	-	-	-	-
LU	No	Yes	All	n/k	n/k	1%	0%	11-50	None	None	None	None	
LV	No	Yes	HR	n/a	n/a	N/k	n/k	51-100	0	0	0	0	0
MT	No	No	n/a	n/a	n/a	N/a	n/a	0	n/a	n/a	n/a	n/a	
NL	No	Yes	HR	n/a	n/a	5%	n/a	11-50	3	0	0	0	0
PL	Yes	Yes	All	0	n/s	0	n/s	> 200	4 (MON 810)	n/a	1	n/a	<0.1%
PT	-	-	-	-	-	-	-	-	5	-	-	1	-
RO	Yes	No	n/a	-	-	0	0	> 200	Pre-accession	0	0	0	No
SE	Yes	Yes	HR	n/a	n/a	100% of imports directly from 3rd countries	n/a	11-50	n/a	n/a	n/a	n/a	0
SI	No	Yes	All	n/s	n/s	80% (imported from 3rd country)	n/s	11-50	1	1	0	1	T25 and Bt11
SK	Yes	Yes	HR	2.6	n/a	100	n/a	> 200	30	0	0	0	No
UK	No	No	n/a	n/a	n/a	N/a	n/a	0	1	0	0	0	

All = seeds imported from all countries including those within EU are sampled and tested; HR = seeds imported from countries considered to be high risk of AP of GMO are sampled and tested

*Note: this is the total number of GM tests performed in one year for all crops – the distinction was not made between maize, OSR, soya and other crops in the question that was asked (Q 4.19).

¹This figure seems high, and it was considered if it might refer to tests also conducted on grain maize imported for food &/or feed use, but it was not possible to confirm or refute this.

4.6ii: Sampling and incidents of adventitious GM presence combined: oilseed rape

MS	Sampling & testing scheme			Level of sampling for GMOs				Incidents of AGMP identified			
	Home-produced seeds?	Imported seeds?	Risk-based?	Home-produced		Imported		Authorised	Unauthorised		
				Certified lots	As-grown	Certified lots	As-grown	2001-2006	2004	2005	2006
AT	Yes	Yes	All (& HR)	5-10 %	0	10-25 %	0	0	0	0	0
BE	No	Yes	HR	0	0	0 (100%)	0	0	0	0	0
BG	-	-	-	-	-	-	-	-	-	-	-
CY	No	Yes	All	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
CZ	Yes	Yes	All (& HR)	0	0	0.6	0	0	0	0	0
DE	Yes	Yes	All (& HR)	26 lots/6% (1 FL); app. 10 % of the presented lots (1 FL)	n/k	5 samples (% NK, 2 FL); 4,6 % (4 lots, 1 FL); 5,8 % (5 samples, 1 FL)	n/k	2	6	0	1
DK	No	Yes	HR	0	0	0	0	0	0	0	0
EE	-	-	-	-	-	-	-	-	-	-	-
EL	Yes	Yes	All	0	0	0 (100%)	0	0	0	0	0
ES	Yes	Yes	All	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
FI	No	Yes	All	n/a	n/a	none	none	0	0	0	0
FR (DGCCRF / DGAL)	Yes / No	Yes (DGAL)	HR	n/k	n/k	n/k	n/k	0 / No imports	0 / No control	0 / No control	0 / No control
HU	No	Yes	HR	n/a	n/a	0	0				
IE	No	Yes	All (& HR)	n/a	n/a	none	N/a	n/a	No testing	n/a	n/a
IT											
LT	-	-	-	-	-	-	-	-	-	-	-
LU	No	Yes	All	n/a	n/a	n/a	n/a	None	N/K	N/K	N/K
LV	No	Yes	HR	n/a	n/a	n/k	n/k	0	0	0	0
MT	No	No	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

MS	Sampling & testing scheme			Level of sampling for GMOs				Incidents of AGMP identified			
	Home-produced seeds?	Imported seeds?	Risk-based?	Home-produced		Imported		Authorised	Unauthorised		
				Certified lots	As-grown	Certified lots	As-grown	2001-2006	2004	2005	2006
NL	No	Yes	HR	n/a	n/a	0%	0%	0	0	0	0
PL	Yes	Yes	All	0	n/s	0	n/s	n/a	n/a	5	No results yet
PT	-	-	-	-	-	-	-	-	-	-	-
RO	Yes	No	N/a			0	0	Pre-accession	0	0	0
SE	Yes	Yes	HR	100% of breeder's seed and 100 % of exported seed lots	Breeder's responsibility % n/k	100% of imports directly from 3rd countries	n/a	0	0	1	0
SI	No	Yes	All	N/s	n/s	5 samples from the EU market	n/s	0	Not sampled	Not sampled	0
SK	Yes	Yes	HR	1.2	n/a	N/a	n/a	2	0	0	0
UK	No	No	N/a	n/a	n/a	N/a	n/a	1	0	0	0

All = seeds imported from all countries including those within EU are sampled and tested; HR = seeds imported from countries considered to be high risk of AP of GMO are sampled and tested

4.6iii: Sampling and incidents of adventitious GM presence combined: soya and other crops

MS	Sampling & testing scheme			Level of sampling for GMOs				Incidents of AGMP identified				Other crops	
	Home-produced seeds?	Imported seeds?	Risk-based?	Home-produced		Imported		Authorised	Unauthorised			Auth'd	Unauth'd
				Certified lots	As-grown	Certified lots	As-grown	2001-2006	2004	2005	2006	2001-2006	2001-2006
AT	Yes	Yes	All (& HR)	5-10%	0	10-25 %	0	0	1	2	0	No	
BE	No	Yes	HR	0	0	0	0	0	0	0	0	No	0
BG	-	-	-	-	-	-	-	-	-	-	-	-	-
CY	No	Yes	All	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	No	
CZ	Yes	Yes	All (& HR)	0	0	21	0	0	0	0	0	No	
DE	Yes	Yes	All (& HR)	n/k	n/k	n/k	n/k	0	0	0	NK	No	0
DK	No	Yes	HR	0	0	0	0	0	0	0	0	No	0
EE	-	-	-	-	-	-	-	-	-	-	-	-	-
EL	Yes	Yes	All	2	0	100	0	0	0	0	0	No	Cotton: 90
ES	Yes	Yes	All	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	Yes	Cotton: 0
FI	No	Yes	All	n/a	n/a	n/a	n/a	0	0	0	0	No	0
FR (DGCCRF / DGAL)	Yes / No	Yes (DGAL)	HR	n/k	n/k	n/k	n/k	0 / No imports	0 / No control	1 / No control	1 / No control	-	-
HU	No	Yes	HR	n/a	n/a	0	0	-	-	-	-	No	n/a
IE	No	Yes	All (& HR)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	No	n/a
IT				-				27 ¹					
LT	-	-	-	-	-	-	-	-	-	-	-	-	-
LU	No	Yes	All	n/a	n/a	n/a	n/a	n/k	n/k	n/k	n/k	No	
LV	No	Yes	HR	n/a	n/a	0	0	0	0	0	0	No	0
MT	No	No	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	No	n/a
NL	No	Yes	HR	n/a	n/a	0%	0%	n/a	0	0	0	No	0
PL	Yes	Yes	All	n/a	n/s	n/a	n/s	n/a	n/a	n/a	n/a	No	
PT									-	-	-	-	-

MS	Sampling & testing scheme			Level of sampling for GMOs				Incidents of AGMP identified				Other crops	
	Home-produced seeds?	Imported seeds?	Risk-based?	Home-produced		Imported		Authorised	Unauthorised			Auth'd	Unauth'd
				Certified lots	As-grown	Certified lots	As-grown	2001-2006	2004	2005	2006	2001-2006	2001-2006
RO	Yes	No	n/a	34%	66%	0	n/a	Pre-accession	No reports	No reports	12%	No	No
SE	Yes	Yes	HR	n/a	n/a	N/a	n/a	n/a	n/a	n/a	n/a	No	1
SI	No	Yes	All	n/s	n/s	N/s	n/s	0	NS	NS	NS	No	
SK	Yes	Yes	HR	4.1	n/a	100	n/a	1	0	0	0	No	
UK	No	No	N/a	n/a	n/a	N/a	n/a	n/a	0	0	0	No	

All = seeds imported from all countries including those within EU are sampled and tested; HR = seeds imported from countries considered to be high risk of AP of GMO are sampled and tested

¹This figure seems high, and it was considered if it might refer to tests also conducted on soya grain imported for food &/or feed use, but it was not possible to confirm or refute this.

4.7: Summary of incidents of AP of authorised GMO identified in seeds of maize, OSR and soya in 2006, and the levels identified

MS	Level of AP of authorised GMO in incidents identified in 2006														
	Maize seeds					OSR seeds					Soya seeds				
	<0.1%	>0.1% <0.3%	>0.3% <0.5%	>0.5% <0.9%	>0.9%	<0.1%	>0.1% <0.3%	>0.3% <0.5%	>0.5% <0.9%	>0.9%	<0.1%	>0.1% <0.3%	>0.3% <0.5%	>0.5% <0.9%	>0.9%
AT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BE	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
CY	0	0	0	0	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
CZ	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DE	9	1	0	0	0	2	0	0	0	0	n/a	n/a	n/a	n/a	n/a
DK	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EE	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
EL	0 /203 seed lots tested	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
ES	23	15	6	5	3	n/a	n/a	N/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
FI	None	None	None	None	None	None	None	None	None	None	None	None	None	None	None
FR (DGCCRF/ DGAL)	5 / 17%	0.6% (DGAL)	0	0	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
HU	0	0	0	0	0	-	-	-	-	-	-	-	-	-	-
IE	0	1	0	0	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
IT															
LT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
LU	None	None	None	None	None	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
LV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MT	n/a	n/a	n/a	n/a	n/a	n/a	n/a	N/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
NL	0	0	0	0	0	n/a	n/a	N/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

MS	Level of AP of authorised GMO in incidents identified in 2006														
	Maize seeds					OSR seeds					Soya seeds				
	<0.1%	>0.1% <0.3%	>0.3% <0.5%	>0.5% <0.9%	>0.9%	<0.1%	>0.1% <0.3%	>0.3% <0.5%	>0.5% <0.9%	>0.9%	<0.1%	>0.1% <0.3%	>0.3% <0.5%	>0.5% <0.9%	>0.9%
PL	Not monitored 2006	Not monitored 2006	Not monitored 2006	Not monitored 2006	Not monitored 2006	No results yet	No results yet	No results yet	No results yet	No results yet	n/a	n/a	n/a	n/a	n/a
PT	6														
RO ^a	None	None	None	None	None	None	None	None	None	None	62.5%	18.7%	2.1%	4.7%	12.0 %
SE	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
SI	2 (EU seed = Bt11; 3rd country seed = MON 810)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SK	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UK	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

^aNote: in 2006 Romania was not a member of the European Union and was not, therefore, working within the EU legislative framework

Note 4.7 (1): The limited information that has been provided on the levels of AP of authorised GMO identified can be summarised thus (see also additional data about Greece, Spain and France below, which has been incorporated into the tables of data in Appendix D):

Levels of authorised AP of GMO identified in seed lots in 2006 (number of incidents):

Crop	<0.1%	>0.1% <0.3%	>0.3% <0.5%	>0.5% <0.9%	>0.9%
Maize	16	18	6	5	3
OSR	2	0	0	0	0
Soya	62.5% ^a	18.7% ^a	2.1% ^a	4.7% ^a	12.0% ^a

^aWe do not have information on the total number of incidents these figures equate to.

Additional data provided by Greece

In accordance with Common Ministerial decision 332657/16-2-2001, OGF 176B/2001 of 2001, Greece samples and tests every seedlot produced in or imported into Greece for cotton, maize, tomato for processing, beets, soya and oilseed rape (but note, data entered directly into the survey do not reflect this). Where a number of seedlots are accompanied by a 'GMO-free' declaration, 10% of these are sampled. Any seedlot found to have AP of GMO are destroyed or re-exported.

Results of sampling and testing 2001-2006

	2001		2002		2003		2004		2005		2006	
	Total	+ve	Total	+ve	Total	+ve	Total	+ve	Total	+ve	Total	+ve
Cotton	554	8	640	2	346	12	197	35	246	21	253	12
Maize	489	2	475	1	314	5	245 ⁽¹⁾	8 ⁽²⁾	251 ⁽³⁾	1	203	0
Tomato for processing	102	0	115	0	70	0	124	0	145	0	105	0
Beets	4	0	19	0	4	0	16	0	57	0	38	0
Soya	-	-	-	-	7	0	-	-	-	-	2	0
Oilseed rape	-	-	-	-	-	-	-	-	1	0	-	-
Total	1149	10	1249	3	741	17	582	43	700	22	601	12

- (1) Seedlots in which the percentage of GMOs was lower than 0,5% but the GMOs are authorized for cultivation by EU, are included in these seedlots (22 out of 245).
- (2) In five out of the eight seedlots the percentage of GMO presence was higher than 0,5%. In the other seedlots the percentage was lower than 0,5% but presence of non-authorized for cultivation GMOs (Bt-11) was found.
- (3) In three out of the 251 seedlots the percentage of GMOs was lower than 0,5%, but the GMOs were authorized for cultivation by EU.

Additional data provided by Spain (via DG Environment)

Number of samples tested from certified seeds lots of non-GM varieties: 843

Origin of seed	No lots containing AP of GMO	Av. % AP of GMO in those lots	N° of lots which contain GMO in a proportion higher than:					
			>0.9	>0.7	>0.5	>0.3	>0.1	<0.1
EU	16	0.180	0	0	0	4	11	5
3rd countries	26	0.418	3	3	5	7	14	12

Additional information provide by France

In the French report "Bilan du plan de contrôle 2005 des semences importées de pays tiers", published in 2006, the French authorities stated that 'adventitious rates were low, and were generally below the limit of quantification of 0.1%'. The rates of AP of GMO observed were less than or equal to 0.1% in 89.7% of cases (35 samples) and lower than 0.25% in the other cases. They also stated that in the majority of cases, the GMOs were not quantifiable individually but were present in the various batches of seed around the limit of detection (0.01%). Most of the findings in this report related to the AP of authorised GMO (only 2 samples out of 39 positive samples were unauthorised).

4.8 Summary of incidents reported in maize (countries in **bold** are those for which most detailed data was provided)

MS	Total number of incidents of AP of authorised GMO 2001-2006	In 2006, in how many of these were GMO present at:					Total number of incidents of presence of unauthorised GMO 2004-2006	GMO tests per year ^a	No. of years' data
		<0.1%	>0.1% but <0.3%	>0.3% but <0.5%	>0.5% but <0.9%	>0.9%			
FR (3rd country)	20%	17%	0.6%	0	0	0	9	>200	6
FR (domestic)	14	5	0	0	0	0	0	101 - 150	6
DE	10	9	1	0	0	0	4	> 200	6
ES (3rd country)	26 (2006 only)	12	14	7	8	3	0	843 ^b	1
ES (EU)	16 (2006 only)	5	11	4	0	0	0		
EL	25	0	0	25	0	0	17	1977	6
AT	0	0	0	0	0	0	9	> 200	6
BE	2	0	0	2	0	0	0	1 – 10	6
BG	-	-	-	-	-	-	-	-	-
CY	1	0	0	0	0	0	0	11 - 50	6
CZ	0	0	0	0	0	0	0	51 - 100	1
DK	0	0	0	0	0	0	0	1-10	6
EE	-	-	-	-	-	-	-	-	-
FI	0	0	0	0	0	0	0	0	6
HU	0	0	0	0	0	0	0	11 - 50	5
IE	2	0	1	0	0	0	0	11 - 50	6
IT	116							1645 ^c	3
LT	-	-	-	-	-	-	-	-	-
LU	0	0	0	0	0	0	0	11 - 50	6
LV	0	0	0	0	0	0	0	51 - 100	1
MT	0	0	0	0	0	0	0	0	
NL	3	0	0	0	0	0	0	11 - 50	6
PL	6	6					1	> 200	1
PT	4	0	0	0	0	0	0	?	N/a
RO	0	0	0	0	0	0	0	> 200	1

MS	Total number of incidents of AP of authorised GMO 2001-2006	In 2006, in how many of these were GMO present at:					Total number of incidents of presence of unauthorised GMO 2004-2006	GMO tests per year ^a	No. of years' data
		<0.1%	>0.1% but <0.3%	>0.3% but <0.5%	>0.5% but <0.9%	>0.9%			
SE	0	0	0	0	0	0	0	11 - 50	6
SI	2	2	0	0	0	0	2	11 - 50	3
SK	30	0	0	0	0	0	0	> 200	6
UK	1	0	0	0	0	0	0	0	6

^aFigures represent GMO tests undertaken per year for all crops, distinction between separate crops was not made in the questions

^bWe do not know the split of tests between seeds imported from EU and seeds imported from 3rd countries.

^cThis figure is averaged over 3 years (total tests in 3 years was 4931). The figure seems very high for seeds and it was considered if it might refer to tests also conducted on maize grain imported for food &/or feed use, but it was not possible to confirm or refute this.

4.8.1 Rough estimation of the number of positive reports for AP of GMO by MS

The figures provided for number of incidents of AP of GMO identified and the number of GM tests conducted per annum, together with figures provided by Spain with respect to distribution of levels of AP of GMO, were used to derive an approximate (best available but uncertain) estimate of the number of positive results that could be expected to occur in maize seeds being marketed in Europe. It was not possible to do this for oilseed rape or soya seeds as there was insufficient data.

The figures in table 4.8.1 below give an indication of the rate at which positive GMO tests results can expect to be found in maize seeds in Europe. For AP of authorised GMO only, this is estimated to be 1.90% of tests giving a positive result, when unauthorised incidents are combined with this the figure rises to 2.18% of tests giving a positive result. Spanish data reports average levels of AP of GMO in maize (imported and sourced from within EU) at 0.299% (section 4.7 above), so this has been used as the best available indicator of the average amounts of AP of GMO that might be expected in maize.

These figures should be viewed with some caution; reference to table 4.4 shows that most MS are taking a risk-based approach to testing, which is more likely to produce positive test results, hence the rate of positive tests may be an overestimation of the total amount of GMO in EC. However, this is a general problem when samples are taken from a proportion of commodities to be checked and could only be solved by sampling every seed lot produced and imported. A source of further complication is that figures provided for the number of GM tests undertaken in a year represents the total number of tests, and is not specific for maize, which may lead to slight underestimation. The units of measurement also vary between MS - where %mass and %seed units of measurement are employed the actual levels of GMO in maize seeds will be less than reported due to the zygoty of maize.

Table 4.8.1: Rough assessment of the level of AP of GMO in maize seeds

MS	Average % of positive results (i.e. positive results / number of tests p/a)			
	Authorised GMO only		Including reports of unauthorised GMO (if different)	
France DGAL 3rd	20	10.93 average for France	20	10.93 average for France
France DGCCRF (domestic)	1.86		1.86	
Germany	0.555		0.777	
Spain 3rd ^a	6.18	4.99 average for Spain	6.18	4.99 average for Spain
Spain EU ^a	3.8		3.8	
EL	1.26		2.12	
AT	0		1.5	
BE	6.06		6.06	
CY	0.546		0.546	
CZ	0		0	
DK	0 (no maize sampled 2005 & 06)		0 (no maize sampled 2005 & 06)	
EE				
FI	Maize not monitored		Maize not monitored	

MS	Average % of positive results (i.e. positive results / number of tests p/a)	
	Authorised GMO only	Including reports of unauthorised GMO (if different)
HU	0	0
IE	1.093	1.093
IT	2.35	2.35
LT		
LU	0	0
LV	0	0
MT		
NL	1.64	1.64
PL	2	2.5
PT		
RO	Maize not monitored	Maize not monitored
SE	0	0
SI	2.19	4.37
SK	2.5	2.5
UK		
Total reports	36.114	41.376
Average	1.719714286 (19 MS)	1.970285714 (19 MS)
Average number of positive test results	1.901	2.178

^aWe do not know how tests were split between seeds imported from EU and seeds imported from 3rd countries; for the purposes of this calculation, we assumed a 50:50 split of tests i.e. 421 tests each.

Note : There is very large variation in the average numbers of positive results being reported by the MS; analysis in section 6 of this report shows that there is not a large amount of variation in performance of analytical tests between MS, and the majority of MS follow ISTA rules for sampling. The variation must, therefore, be explained by variation in the proportion of lots sampled, and the underlying strategy for sampling, i.e. the seed lots to which sampling and testing efforts are targeted.

4.10: Summary of testing methodology employed for detection of adventitious GM presence in conventional seeds across EU MS

MS	Testing lab	Standards required	Type of test		UOM	LOD	LOQ	No. of tests p/a	Essential elements in tests			Event-specific tests
			Molecular required?	Protein-based accepted?					Maize	OSR	Soya	
AT	CA	No	Yes	No	1 seed	1 GM seed in 3000 seed	1 GM seed in 3000 seed	> 200	CaMV P35S, NOS	EPSPS, PAT, tNos	CaMV P35S, NOS	Maize: Bt11, Bt10, MON 810, MON 863, NK 603, Bt176, TC 1507, GA21, T25 Soybean: RR-Soy Rape: GT73 (RT73) Rice: LL601, LL62, Bt63
BE	Nominated (Belgian reference laboratory for GMOs)	European accepted standards	Yes	No	Haploid genome equivalents (HGE) or copy numbers (cp)	20 HGE/cp or < 0.1%	100 HGE/cp or 0.1%	1-10	CaMV P35S, NOS, Additional elements	Additional elements	CaMV P35S, NOS, Additional elements	
BG	-	-	-	-	-	-	-	-	-	-	-	-
CY	Nominated	No	Yes	n/a		N/a	n/a	11-50	n/a	n/a	n/a	
CZ	Nominated	No	Yes	No		0.10%		51-100	CaMV P35S, Cry, EPSPS, PAT, BAR	CaMV P35S, PAT, BAR, tNos	CaMV P35S, EPSPS, BAR, NOS	Bt11, Bt176, T25, MON810, GA21, NK603, CBH351, Bt10
DE	CA & Nominated	Depends on Federal Länder. See note 1 below	Yes	No	Depends on Federal Länder. See note 2 below	Depends on Federal Länder. See note 3 below	0.10%	> 200	CaMV P35S, Cry, PAT, BAR, NOS, Additional elements	FMV P35S, CaMV P35S, SsuAra, NptII, EPSPS, PAT, BAR, tNos, additional elements	CaMV P35S, EPSPS, NOS, Additional elements	Community Reference Laboratory tests

UOM = Unit of measurement; LOD = Limit of detection; LOQ = Limit of quantification

HGE is equivalent to %GM DNA

MS	Testing lab	Standards required	Type of test		UOM	LOD	LOQ	No. of tests p/a	Essential elements in tests			Event-specific tests
			Molecular required?	Protein-based accepted?					Maize	OSR	Soya	
DK	CA	Methods validated in multilab studies (ENGL)	Yes	No	% weight or haploid genome equivalents (HGE).	As low as possible	0.10%	1-10	CaMV P35S, NOS	FMV P35S, CaMV P35S	CaMV P35S	
EE	-	-	-	-	-	-	-	-	-	-	-	-
EL	Nominated	Laboratory accredited by the Hellenic Accreditation Council (IEC 17025:2005)	Yes	n/a	% genome basis	0.0	0.10%	>200	CaMV P35S, NOS	CaMV P35S, tNos	CaMV P35S, NOS	
ES	Nominated (Instituto de Biologia Molecular, C.S.I.C. Ministry of Science & Technologie)	Yes (but not specified)	No	No	% mass	0.01% related to certified standard	0.01% (related to certified standard)	> 200	CaMV P35S, Cry, T35S, NOS	N/a	n/a	Bt11, T25, GA21
FI	Nominated (Finnish Customs Laboratory)	ISTA, EU/JRC	Yes	n/a	% of GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes	0.01%	0.10%	0	Not applicable	N/a	n/a	

MS	Testing lab	Standards required	Type of test		UOM	LOD	LOQ	No. of tests p/a	Essential elements in tests			Event-specific tests
			Molecular required?	Protein-based accepted?					Maize	OSR	Soya	
FR	CA	ISO 21569, 21570, 21571, 21572, 24276	Yes	No	Haploid genome copy numbers (DGCCRF); %GM seeds (based on analyses made in haploid genome copy numbers) (DGAL)	0.01%	0.10%	101-150 (DGCCRF); >200 (DGAL)	CaMV35S, PAT, NOS (DGCCRF); CaMV35S, NOS (DGAL)	CaMV35S, PAT, BAR	CaMV35S (DGCCRF); CaMV35S, EPSPS, NOS (DGAL)	Maize: Bt11, Bt10, MON 810, MON 863, NK 603, Bt176, TC 1507, GA21, T25, CBH351 and those validated by the CRL. OSR: GT73 (RT73), Topas 19/2, RF1, RF2, RF3, MS8, T44. Soybean: Round-up Ready
HU	CA (labs are determined & designated by the national legislation)	ISTA, but no standard method in ISTA Rules, the method is chosen by the lab	No	Yes	DNA copies or % (if we apply QPCR)	0.10%	0.10%	11-50	CaMV P35S, NOS	n/a	n/a	MON810
IE	Nominated (State Lab, Youngs Cross, Co Kildare (Patricia Bonner))	No	No	n/a	% / seed unit	N/a	n/a	11-50	T35S, NOS	n/a	n/a	n/a
IT	CA							>200				
LT	-	-	-	-	-	-	-	-	-	-	-	-

MS	Testing lab	Standards required	Type of test		UOM	LOD	LOQ	No. of tests p/a	Essential elements in tests			Event-specific tests
			Molecular required?	Protein-based accepted?					Maize	OSR	Soya	
LU	Nominated (Laboratory of National Health Ministry)	Yes – ISO	Yes	No	Weight/weight. Recently HGE is used	0.10% for qualitative PCR; LOD of RT-PCR = 0.02%	0.1%	11-50	CaMV P35S, Cry, PAT, BAR, NOS	n/a	CaMV P35S	
LV	CA	Yes (but not specified)	Yes	Yes		N/k	n/k	51-100	CaMV P35S, Cry, EPSPS, PAT, NOS	FMV P35S, CaMV P35S, pNos, barnase, barstar, EPSPS, PAT, CaMV T35S, tNos	CaMV P35S, EPSPS, PAT, NOS	
MT	N/a	No	No	n/a		N/a	n/a	0	n/a	n/a	n/a	
NL	Nominated (Specialised seed testing lab (NAK), 2 locations depending on crop)	No	Yes	n/a	% of seeds GM	Prescribed test procedure from which detection limit can be derived. In practice able to detect < 0.1% GM contamination	Prescribed test procedure from which detection limit can be derived. In practice able to detect < 0.1% GM contamination	11-50	CaMV P35S	CaMV P35S	n/a	If positive results are found we test event specific

MS	Testing lab	Standards required	Type of test		UOM	LOD	LOQ	No. of tests p/a	Essential elements in tests			Event-specific tests
			Molecular required?	Protein-based accepted?					Maize	OSR	Soya	
PL	CA	EN-ISO 21571:2005, 21570:2005, 24276:2006, 21569:2005. Samples are taken according to ISTA rules	Yes	n/a	Percentage of copy number	<0.1%	0.10%	> 200	CaMV P35S, T35S, NOS, Additional elements	CaMV P35S, barnase, EPSPS, GOX, PAT, BAR, tNos, Additional elements	n/a	Maize: MON 810, NK 603, TC 1507, MON 863, T25
PT	-	-	-	-	-	-	-	-	-	-	-	-
RO	Nominated (National Institute for food bio-resources specialised in GMO analyses in agricultural products and food (IBA))	ISO CEI 17025 for accreditation. ISO 21572/2004 for analytical guidelines	No	Yes		0.14%	0.14%	> 200	n/a	n/a	EPSPS	
SE	Nominated (Accredited by SWEDAC & Participates in the ISTA proficiency test on GMO analysis)	Yes (but not specified)	Yes	n/a	Ratio of copies of the analysed gene:total copies plant DNA	0.01%	n/k	11-50	n/a	NptII, GOX, PAT, BAR, tNos	n/a	n/a so far, but would accept the event specific methods validated by CRL
SI	Nominated (National Institute of Biology Accredited According to ISO17025)	Methods validated according to ISO 17025 and CEN GMO standards	Yes	No	% of GMO (based on copy number)	25 copies of DNA (although some methods used are more sensitive)	50 copies of DNA (although some methods used are more sensitive)	11-50	CaMV P35S, NOS	CaMV P35S, tNos, Additional elements	CaMV P35S	Only after screening: RR Soya, Bt176, MON810, Bt11, T25, GA21, MON863, NK603, TC 1507, RT73

MS	Testing lab	Standards required	Type of test		UOM	LOD	LOQ	No. of tests p/a	Essential elements in tests			Event-specific tests
			Molecular required?	Protein-based accepted?					Maize	OSR	Soya	
SK	CA	EN ISO 21570, ISO 21569, CRL JRC EC validated methods	Yes	n/a	mass %	0.10%	0.10%	> 200	CaMV P35S, Amp, EPSPS, PAT, BAR, T35S, NOS	CaMV P35S, NptII, PAT, CaMV T35S, tNos	CaMV P35S, EPSPS, T35S, NOS	
UK	N/a	No	No	n/a	N/a	n/a	n/a	0	n/a	n/a	n/a	n/a

UOM = Unit of measurement; LOD = Limit of detection; LOQ = Limit of quantification; He = haploid genome equivalent (= %GM DNA)

DE Note 1. Analytical testing standards in use in German Federal Länder: prEN ISO 24276:2005 DIN EN ISO 21569:2005 DIN EN ISO 21570:2005 DIN EN ISO 21571:2005; CRL methods according to notification procedures under regulation (EC) No 1829/2003; AOCS; ISTA; official national methods according to German food law and gene technology working groups

DE Note 2. Units of measurement in use in German Federal Länder: Qualitative: detectable / not detectable. Qualitative (depends on Fed. Land): % GMO (compared with IRMM reference material); seed number and seed weight; % transgenic DNA copy number relative to total DNA (measured by the copy number of a taxon-specific gene); % transgenic DNA copy number in relation to target taxon specific copy numbers calculated in terms of haploid genomes

DE Note 3. Limits of detection in use in German Federal Länder: Generally 0,1 % and below. Maize screening: CaMV 35S-promotor 0.03%, nos terminator 0.03%. OSR: 0.1 %. Analysis of at least 3000 kernels to find 1 GMO kernel in 3000 non-GMO kernels

Note 4.10 (1): Question 4.17 asked participants if they “require evidence of the operating parameters of analytical tests (e.g. standard error)”; of the 17 responses to this question, 76.5% (13 out of 17) said that they did require evidence of this. The evidence required was variable, but many referred to percent standard deviation and measurement uncertainty. For further details refer to the response tables in Appendix D.

4.11 Additional information about testing undertaken,

4.11.1 Elements employed in analytical tests (questions 4.20 – 4.25a).

	Essential elements in analytical tests (ranked most used to least used, out of 23 responses) ¹	Cry elements used (5 responses)	Event-specific tests used (three responses received, listed in no order) ²
Maize	CaMV p35s (69.6%) NOS (65.2%) PAT (26.1%) Cry proteins (21.7%) BAR (17.4%) CaMV t35s (17.4%) EPSPS (13.0%) Amp (4.3%) [Plus additional elements – 13%]	Cry1(A); Cry1(B); Cry3Bb; Cry9C	Bt10 Bt11 Bt176 CBH351 GA21 MON810 MON863 NK603 T14 T25 TC1507
Oilseed rape	CaMV p35s (43.5%) tNOS (43.5%) PAT (39.1%) BAR (26.1%) EPSPS (21.7%) FMV p35s (17.4%) NptII (17.4%) Barnase (8.7%) GOX (8.7%) CaMV t35s (8.7%) pNOS (4.3%) SsuAra (4.3%) Barstar (4.3%) [Plus additional elements – 21.7%]	N/A	BXN gene CaMV p35s-nptII CaMV p35s-PAT CMoVb pFMV-EPSPS pSSU-Ara-bar RT73 (=GT73)
Soya	CaMV p35s (52.2%) tNOS (34.8%) EPSPS (21.7%) PAT (4.3%) BAR (4.3%) CaMV t35s (4.3%) [Plus additional events – 8.7%]	N/A	CaMVP35s-Petunia hybrida CTPS RR Soya
Other crops	<ul style="list-style-type: none"> • Cotton, beets, tomato for processing: CaMV p35s, NOS • Cotton: RR Cotton, Bolgard I, Bolgard II, LL Cotton • Horticultural vegetable seeds (cucumber, cabbage, lettuce, courgette, melon, chicory, endive, sweetcorn (2003, 60 samples): CaMV p35s, tNOS, nptII • Rice: CaMV p35s, tNOS • Potato: nptII, CaMV p35s, tNOS • Sugar beet: EPSPS, PAT, CaMV p35s, FMV p35s • Tomato: CaMV p35s • Turnip rape (<i>Brassica rapa</i>): as for oilseed rape 		

¹92.3% (12 out of 13) respondents will not accept analytical test results if elements they consider essential are not included in tests

²93.8% (15 out of 16) respondents accept results of event-specific tests as evidence of freedom from AP of GMO.

4.11.2 Units of measurement and limits of detection and quantification

Of the MS that provided this information, the most common responses were as follows:

Units of measurement in use:

- Haploid genome equivalents (= %GM DNA): 10 MS
- % seed 2 MS
- % mass 2 MS
- (Note the different Federal Länder in Germany use different UOMs – all of the above are used)

Limits of detection in use:

- 0.1% 8 MS (plus 1 MS stated 0.14%)
- 0.01% 4 MS
- 0.03% 1 MS
- 25 copies of DNA 1 MS
- (Note the different Federal Länder in Germany use different UOMs, but in general 0.1% and 0.03% are used)

Limits of quantification in use:

- 0.1% 10 MS (1 MS stated 0.14%)
- 0.01% 1 MS
- 0.02% 1 MS

There is a reasonably high degree of consistency of approach to GM testing, which perhaps illustrates the influence of EC guidance documents that have been issued, and the Community Reference Laboratory (CRL) and European Network of GMO Laboratories (ENGL). The certified standards produced by the CRL and multi-lab evaluation studies run by the ENGL were also referred to in responses, again illustrating their usefulness in developing a standardised approach to GM testing. However, as these standards are only available for GMOs that are authorised in Europe, they provide no support for strategies for testing for unauthorised GMOs.

4.12 Approaches to enforcement in cases of authorised adventitious GM presence

Member State	What level of authorised AGMP do you permit to be marketed without labelling in non-GM seeds of:				Action taken when authorised AGMP is identified in conventional seed	Action taken if unauthorised AGMP is confirmed
	Maize	OSR	Soya	Other crops		
AT	AGMP may not be present in the 1st examination in seed certification procedures (tolerance level of 0.1% in enforcement control). National measures: bans on MON810, BT176, T25 and GT73.				Withdraw seed from the market; publish the findings	Withdraw seed from the market; publish the findings
BE	Zero tolerance policy				Withdraw seed from the market; inform other EU member states	Withdraw seed from the market; inform other EU member states
BG	-	-	-	-	-	-
CY	Zero tolerance policy				Withdraw seed from the market	Withdraw seed from the market
CZ	In future, we assume we will permit 0.5% authorised AGMP in the case of cross-pollinating species without labelling	In future, we assume we will permit 0.5% authorised AGMP in the case of cross-pollinating species without labelling	In future, we assume we will permit 0.7% authorised AGMP in the case of soya without labelling		Draw owner's attention to the fact that the seed must be labelled	Consider pursuing legal action with the owner of the seed
DE	Mostly <0.1%, but at least 1 FL operates a zero tolerance policy			2 Federal Länder: sugar beet, less than 0.1 %	None if less than 0.1%; publish the findings; consider pursuing legal action with the owner of the seed. Different actions taken by different Federal Länder, e.g. 1 Federal Land publishes the findings in a general form (table) on the homepage of the responsible institution	None if less than 0.1%; withdraw seed from the market; publish the findings; consider pursuing legal action with the owner of the seed (note, not all Federal Länder take the same actions). Will inform EU CAs in case the seeds have already been on the market, & seeds will be confiscated and inactivated

Member State	What level of authorised AGMP do you permit to be marketed without labelling in non-GM seeds of:				Action taken when authorised AGMP is identified in conventional seed	Action taken if unauthorised AGMP is confirmed
	Maize	OSR	Soya	Other crops		
DK	Less than 0.1%			< 0.1%	None if < 0.1%, publish the findings, report to other EU CAs, other	Withdraw seed from the market; publish the findings; consider pursuing legal action with the owner of the seed
EE	-	-	-	-	-	-
EL	Less than 0.5% of authorised AGMP for cultivation			Cotton, beets & processing tomatoes; <0.5% of authorised AGMP	None if < 0.5%	Withdraw seed from the market
ES	Detection >0.3% but <0.5%	n/a	n/a	Zero tolerance policy	None if less than 0.5%; withdraw seed from the market; publish the findings	None if less than 0.1%; withdraw seed from the market; consider pursuing legal action with the owner of the seed
FI	Zero tolerance policy			Zero tolerance policy	Withdraw seed from the market; publish the findings; report to other EU CAs	Withdraw seed from the market; publish the findings
FR	Zero tolerance policy				Demand correct labelling and possibly pursue legal action	Withdraw seed from the market; consider pursuing legal action with the owner of the seed (DGCCRF); refusal of importation (DGAL)
HU	Currently a legal ban in HU for GM production and marketing of MON810	Only maize seeds are tested	Only maize seeds are tested	Not relevant	Other (not specified)	Withdraw seed from the market; consider pursuing legal action with the owner of the seed
IE	Detection >0.3% but <0.5%			n/a	None if less than 0.5%	Withdraw seed from the market
IT	-	-	-	-	-	-
LT	-	-	-	-	-	-

Member State	What level of authorised AGMP do you permit to be marketed without labelling in non-GM seeds of:				Action taken when authorised AGMP is identified in conventional seed	Action taken if unauthorised AGMP is confirmed
	Maize	OSR	Soya	Other crops		
LU	Zero tolerance policy			Zero tolerance policy	Other (not specified)	Withdraw seed from the market
LV	Policy not yet established				Policy not yet established	Policy not yet established
MT	Zero tolerance policy			N/A	Withdraw seed from the market, request the owner to re-label and market as GM or destroy seed lot	Withdraw seed from the market; publish the findings; consider pursuing legal action with the owner of the seed; inform EU commission and other EU MS
NL	In all crops we would aim at <0.5% but there is only a legal basis to require <0.9%				If >0.5% ask compliance if >0.9 demand compliance (i.e. labelling)	Withdraw seed from the market; consider pursuing legal action with the owner of the seed; where appropriate (i.e. art 23.1 2001/18/EC), inform the public. Report to other EU CAs
PL	Zero tolerance policy				Report to national CAs (Minister of Environment)	Inform CAs and take action relevant to CAs instruction
PT	-	-	-	-	-	-
RO	Not yet decided	Not yet decided	Detection >0.5% but <0.9%	Not yet decided	Withdraw seed from the market	Withdraw seed from the market
SE	<0.5%				None if less than 0.5%	Withdraw seed from the market; consider pursuing legal action with the owner of the seed
SI	Zero tolerance policy				Withdraw seed from the market; publish the findings; report to other EU CAs	Withdraw seed from the market; publish the findings; consider pursuing legal action with the owner of the seed
SK	<0.1%				None if less than 0.1%	None if less than 0.1%
UK	Seed companies operate to the <i>de facto</i> legal threshold of 0.1% (the level of detection) and would not knowingly market seed with any detectable level of GM				Withdraw seed from the market, publish the findings	Withdraw seed from the market; publish the findings

Note 4.12 (1): Summary of approach to enforcement: Answering questions 5.21, 5.22 and 5.23 ('what level of AP of authorised GMO do you permit to be marketed without labelling in conventional seeds of maize/oilseed rape/soya') was mandatory. The majority of MS operate a zero tolerance policy (i.e. below the limit of detection of analytical tests), but other tolerances are in operation. Responses are summarised as follows:

MS	Level of AP of authorised GMO permitted without labelling (number of MS)					
	Zero tolerance	<0.1%	>0.1<0.3%	>0.3<0.5%	<0.5%	>0.5%<0.9%
Maize	9 ^a (BE, CY, FI, FR, HU, LU, MT, PL, SI)	5 (AT, DE, DK, SK, UK)		2 (ES, IE)	3 (CZ, EL, SE)	1 (NL ^b)
OSR	8 ^a (BE, CY, FI, FR, LU, MT, PL, SI)	5 (AT, DE, DK, SK, UK)	1 (IE)		3 (CZ, EL, SE)	1(NL ^b)
Soya	8(BE, CY, FI, FR, LU, MT, PL, SI)	5 (AT, DE, DK, SK, UK)		1 (IE)	2 (EL, SE)	3 (CZ (0.7%), RO (0.7%), NL ^b)
Other crops	4 (BE, ES, FI, LU)	3 (DE (sugar beet), DK, UK)			1 (EL (cotton, beets, tomato for processing))	1 (NL ^b)

^aPlus at least one German Federal Länder

^bOperates legal tolerance of 0.9%, but would aim for <0.5%

Response to incidents of AP of GMO: A range of actions are described where AP of authorised GMO is identified, nonetheless where unauthorised GMO are identified 87% of respondents would act by withdrawing the seed from the market and 43.5% of MS would consider pursuing legal action with the owner of the seed, illustrating the seriousness with which this is viewed.

5. MS SEED PRODUCTION, IMPORT AND EXPORT / RE-EXPORT DATA

MS provided data on seed production, import and import/re-export. The collated data is provided in Appendix E of this report.

5.1 Analysis of MS seeds stats data

It was envisaged that the efficacy of MS control programmes to control AP of GMO in non-GM seeds, and the statistical significance of the results they achieve would be analysed using data collated on:

- i) Seed production and import data for each MS (Appendix E)
- ii) Proportion of seed lots sampled and tested for control programmes (Appendix D), and
- iii) MS findings of adventitious GM presence – numbers of incidents and levels of AGMP identified (Appendix D).

It has not been possible to do the analysis as envisaged for all MS for the following reasons:

- No full data sets were collected for any MS.
- There are key data gaps for many MS in the proportion of lots that are sampled.
- Little information was available on the actual levels of AP of GMO identified in control programmes. This was needed to determine the true (observed) distribution of AP of GMO in seeds within the Community.
- In connection with this, it was not possible to link incidents of AP of GMO with seed source (i.e. whether in home-produced seeds or imported seeds). This was needed to establish probable levels and distribution of AP of GMO in seeds produced within the community and in imported seeds. Some sampling programmes are risk-based and targeted, while others sample a broader selection of seeds, to assess performance it is, therefore, important to establish the level of AP of GMO that is likely to be in the pool/s that they sample from.
- The performance of a control programme is also dependent upon the performance of analytical tests and the threshold applied by the MS. These factors therefore also need to be taken into account when assessing the overall performance of an MS control programme.

Revised approach to analysis

The collated data is analysed in section 6 of the report. Analysis has focussed on assessing individual components of MS control programmes and the contribution each makes to the overall performance of a programme, and considering how the components can be managed to improve the stringency of a control programme.

A scenario based on (additional) data provided by one MS is presented at the end of section 6. In this scenario, the performance of the MS control programme for maize imported from a third country is presented in terms of the probable levels of GMO that will be in accepted seed lots, given a known likely distribution of AP of GMO, when different proportions of lots are sampled for a range of labelling thresholds.

6. STATISTICAL ANALYSIS OF RESULTS

6.1 Introduction

The aim of this part of the study was to assess monitoring systems in place across the MS of the EU to control the AP of GMO in conventional seed lots. There are many contributing factors to the analysis and reporting of the presence of GMOs in seeds, which means that the effectiveness of a MS control system cannot effectively be assessed by a straightforward calculation of the amount of sampling and testing of seeds as a proportion of the total level of production and/or import. To gain a more accurate picture we have assessed MS monitoring systems by considering the following questions:

1. How accurate are test results when considered as an estimate of the true mean GMO concentration in a lot?
2. Which parts of the control process contribute most to the variation associated with test results?
3. How can the accuracy of tests results be improved most easily?
4. To what extent will different legal thresholds affect the quantity of AP of GMO in lots?
5. What is the impact of testing different proportions of lots on the potential concentration of GMO in seed in the EU?

To answer these questions, this part of the study considers the control plans used by MS for GMO in seed lots, their differences and similarities, and the range of performance associated with the control plans. Seventeen MS provided sufficient information for an assessment to be undertaken. Three products are examined (in order): soya, oilseed rape and maize. The findings are not presented on an individual MS basis, but are grouped on the basis of similar performances, or scenarios.

6.2 Characteristics of control plans for GMO

MS control plans for GMO consist of the following components:

Programme

- Testing of lots for the presence of GMO can be applied in two ways. Where testing is intended to directly control the level of GMO in lots from a particular source, all lots are tested. Where testing is intended to give assurance that previously applied control has been effective, or that direct control is unnecessary because GMO are absent in lots from a particular source only a proportion of lots is tested.

Sampling

- Primary sampling: a number of small portions (primary samples) are taken from different locations in a lot.

- Formation of the composite sample: primary samples are combined and mixed to form a homogenous composite sample.
- Formation of the submitted sample: A portion of the composite sample is submitted to a laboratory for testing.

Analysis

- Formation of the working sample: a portion of working sample is taken from the submitted sample, ground to flour, and homogenised.
- DNA extraction: DNA is extracted from a portion of the working sample.
- Measurement of target event: target event genes are amplified by PCR and their quantity measured.

Action

- Comparison with a threshold: measurement results above a threshold lead to a decision that the lot contains a high concentration of GMO and some action is taken.

6.3 Control plans employed by MS

6.3.1 Programme

The proportion of lots selected for testing from the target population, and the target population of lots from which lots were selected for testing varies widely among MS. Many MS have no testing programme for home produced lots. However, those MS that produce GM products do test home produced lots. The proportion of lots tested ranges from 0% to 100%. The proportion of maize lots tested tends to be higher compared to other products. Table 6.1 shows the proportion of home produced lots tested in 2005 and 2006. Table 6.2 shows the target population of lots selected for testing from imported lots and the proportion of lots tested in 2005 and 2006.

Table 6.1: Proportion of home produced lots tested

Member State	Maize				OSR				Soya			
	Certified seed lots		As grown		Certified seed lots		As grown		Certified seed lots		As grown	
	2005	2006	2005	2006	2005	2006	2005	2006	2005	2006	2005	2006
Austria	5-10 %	5-10 %	0 %	0 %	5-10 %	5-10 %	0 %	0 %	5-10 %	5-10%	0 %	0 %
Belgium						No testing						
Bulgaria	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Cyprus						No testing						
Czech R	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %
Denmark						No testing						
Eire						No testing						
Estonia						No testing						
Finland						No testing						
France	NK	NK	NK	NK	NK	NK	NK	NK	NK	NK	NK	NK
Germany	12 %	10 %	NK	NK	3 – 9%	6 – 10 %	NK	NK	NK	NK	NK	NK
Greece	0 %	0 %	75	100 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %
Hungary						No testing						
Italy	NK	NK	NK	NK	NA	NA	NA	NA	NK	NK	NK	NK
Latvia						No testing						
Lithuania	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

6.3.2 Sampling

Eighteen out of 25 MS base their sampling on ISTA Rules [5]. The 18 included all of the 17 MS who gave sufficient information on which to base an assessment. If the composite sample is properly homogenised then the two parameters that affect the performance of sampling are the number of primary samples and the mass of the working sample (expressed as a number of seeds). For large seed lots 40 primary samples are required [5], and the working sample should be a mass equivalent to at least 3000 seeds [5]. Hence control plans examined in this study are based on 40 primary samples and a working sample of 3000 seeds.

6.3.3 Analysis

Eighteen out of 25 MS require either 'molecular based testing' or the 'quantification of GM DNA'. The 18 included all of the 17 MS who gave sufficient information on which to base an assessment. Eleven of the 17 MS used the quantity of GM DNA as the unit of measurement, but 3 of these also used %mass or %seed as measurement units.

Most member states required replicate analysis. This could be replicate DNA extracts or replicate analysis of DNA extracts. It was not clear in all cases which type of replication was required. Where the type of replication was not stated it was assumed to be replicate analysis of individual DNA extracts.

Most MS required that analytical tests be conducted in accordance with some international standard (ISO or ENGL/CRL/JRC). In general the use of international standards can assure the users of results that methods of analysis are under proper control, but the uncertainty associated with measurement results can be more reliably estimated from other sources of information such as results in proficiency tests (see Analytical variability (reproducibility), section 6.4.3).

Sixteen MS reported a required limit of quantification/detection for tests. Required limits of quantification/detection lay between 0.1% and 0.01%.

Table 6.3 shows units of measurement, replication and limits of quantification/detection required by member states.

Table 6.3: Summary of analysis undertaken by MS

Member State	Measurement units	Limit of quantification	Replicates	Replicate DNA extracts	Replicate PCR tests per extract
Austria	% seed	1 in 3000 seeds ($\approx 0.033\%$)	2	not reported	not reported
Belgium	%DNA	0.1%	4	2	2
Czech Republic	not reported	0.1 %	2	not reported	not reported
Denmark	%mass. or %DNA	0.1%	4	not reported	not reported
Eire	%seed	not reported	4	not reported	not reported
Finland	%DNA	0.1 %	2	not reported	not reported
France	%DNA or %seed	0.1%	6	2	3

Member State	Measurement units	Limit of quantification	Replicates	Replicate DNA extracts	Replicate PCR tests per extract
Germany	%DNA or %seed, or %mass	0.1 %	2 to 6	not reported	not reported
Greece	% DNA	0.1%	4	not reported	not reported
Hungary	%DNA	0.1 %	3	not reported	not reported
Luxembourg	%DNA	0.02%	2	not reported	not reported
Poland	%DNA	0.1%	4 to 6	2 to 3	2
Slovak Republic	%mass	0.1%	2 to 3	not reported	not reported
Slovenia	%DNA	50 copies of DNA ($\approx 0.1\%$)	4	2	2
Spain	%mass	0.01%	at least 2	not reported	not reported
Sweden	%DNA	0.01%	not reported	not reported	not reported
Netherlands	%seed	0.1%	2	not reported	not reported

6.3.4 Action

Thirteen out of 21 MS operate a test result threshold between 'zero tolerance' to 0.1% for all products (11 out of the 17 MS that provided sufficient information on which to base an assessment of control plans). One out of 17 MS operates a threshold of 0.9% for all products (while requesting action at 0.5%). Four out of 17 MS operate a threshold of 0.5% for all products. One MS operates a threshold of 0.5% for maize and oilseed rape and a threshold of 0.7% for soya.

The unit of measurement employed by MS has an effect on the effective threshold. Where measurement results are expressed as %GM DNA then measurement results can be compared directly to the threshold. However, where measurement results are expressed as %seed or %mass measurements of %GM DNA must be converted by the 'zygosity' of the GM event. The zygosity is the average number of modified genomes per haploid genome in a GM seed. Authorised GM events in soya have a zygosity of 1 (the maximum possible zygosity), authorised events in oilseed rape commonly have a zygosity of 1 but may have a zygosity of 0.5. Authorised GM events in maize commonly have a zygosity of 0.58. Hence multiplying thresholds expressed in %seed or %mass multiplied by zygosity gives the equivalent threshold expressed as %GM DNA. An exception to this arises for 'zero tolerance' to 0.1% thresholds because in practice 0.1% GM DNA is frequently used as a 'reporting limit' for measurement results. Table 6.4 shows the thresholds reported by MS, and the equivalent threshold expressed as %GM DNA where this differs from the reported value.

Table 6.4: Thresholds for AP of GMO as reported by MS (effective thresholds in %GM DNA in brackets where this is different)

Member State	Maize (%)	Oilseed Rape (%)	Soya (%)
Austria	0.1	0.1	0.1
Belgium	0	0	0
Cyprus	0	0	0
Czech Republic	0.5	0.5	0.7
Denmark	0.1	0.1	0.1
Eire	0.5 (0.29)	0.5 (0.5, 0.25)	0.5
Estonia	not reported	not reported	not reported
Finland	0	0	0
France	0	0	0

Member State	Maize (%)	Oilseed Rape (%)	Soya (%)
Germany	0.1	0.1	0.1
Greece	0.5	0.5	0.5
Hungary	0	not tested	not tested
Italy	not reported	not reported	not reported
Latvia	not reported	not reported	not reported
Lithuania	not reported	not reported	not reported
Luxembourg	0	0	0
Malta	0	0	0
Poland	0	0	0
Portugal	not reported	not reported	not reported
Romania	not reported	not reported	0.9
Slovak Republic	0.1	0.1	0.1
Slovenia	0	0	0
Spain	0.5 (0.29)	not applicable	not applicable
Sweden	0.5	0.5	0.5
The Netherlands	0.9 (0.52)	0.9 (0.9, 0.45)	0.9
United Kingdom	0.1	0.1	0.1

6.4 Framework for the assessment of control plans

Control plans used by MS were assessed by estimating the contribution made by each part of the control plan to overall uncertainty, the size of overall uncertainty, and the effect of overall uncertainty on the probability of deciding that a lot selected for testing contains GMO above a threshold.

6.4.1 Uncertainty associated with primary sampling (lot heterogeneity)

In general, it is assumed that 'there is no non-tolerable variation among different parts of the seed lot'. Tests for detecting heterogeneity are specified by ISTA [6]. According to ISTA rules, an attribute of a lot with mean value \bar{X} % is sufficiently homogenous if

$$\frac{V}{W} - f = H_{crit}$$

Where V is the observed variance between samples, W is the acceptable variance and f is a factor that describes the level of 'heterogeneity that is achievable in good seed production practices'.

20 samples of 1000 seeds each are tested. For purity testing of non-chaffy seeds $f=1.1$ and $H_{crit}=0.99$.

Hence for GMO with mean concentration \bar{X} % GM DNA and zygosity z

$$W = \frac{\frac{\bar{X}}{z} \times \left(100 - \frac{\bar{X}}{z}\right)}{1000} \times f$$

Hence for a 'just sufficiently homogenous lot'

$$V = \frac{(H_{crit} + f) \times \frac{\bar{X}}{z} \times \left(100 - \frac{\bar{X}}{z}\right)}{1000} \times f$$

The estimate of V includes a contribution made by within sample variance, hence variance due entirely to lot heterogeneity S is given by

$$S = \frac{(f \times (H_{crit} + f) - 1) \times \frac{\bar{X}}{z} \times \left(100 - \frac{\bar{X}}{z}\right)}{1000}$$

Hence lot heterogeneity relative standard deviation RSD_S is given by

$$RSD_S = \sqrt{\frac{1.299 \times z \times \left(100 - \frac{\bar{X}}{z}\right)}{1000 \times \bar{X}}} \quad \text{Equation 1}$$

6.4.2 Uncertainty associated with formation of the working sample

For the purposes of this study, it is assumed that working samples are representative of the bulk sample from which they are drawn (i.e. unbiased). Hence variation associated with the working sample depends only on the number of seeds in the working sample n , the concentration of \bar{X} % GM DNA and the zygosity z of the GM event. Variance (W) is given by

$$R = \frac{\frac{\bar{X}}{z} \times \left(100 - \frac{\bar{X}}{z}\right)}{n}$$

Hence working sample relative standard deviation RSD_W is given by

$$RSD_W = \sqrt{\frac{z \times \left(100 - \frac{\bar{X}}{z}\right)}{\bar{X} \times n}} \quad \text{Equation 2}$$

6.4.3 Analytical variability (reproducibility)

The variability associated with the measurement of GM DNA was estimated using results of rounds 5¹³ [7] and 6¹⁴ [8] of the ISTA proficiency test scheme for GM seeds (soya and maize), the only two rounds for which suitable results are available.

Measurement reproducibility relative standard deviation RSD_R was estimated to be equal to 0.496.

$$RSD_R = 0.496 \quad \text{Equation 3}$$

Figure 6.1 shows standard deviation and assigned concentration (%GM DNA) reported by the ISTA proficiency test scheme. Standard deviation and assigned concentration reported by the GEMMA (genetically modified material analysis scheme) proficiency test scheme¹⁵ (personal communication) for the measurement of

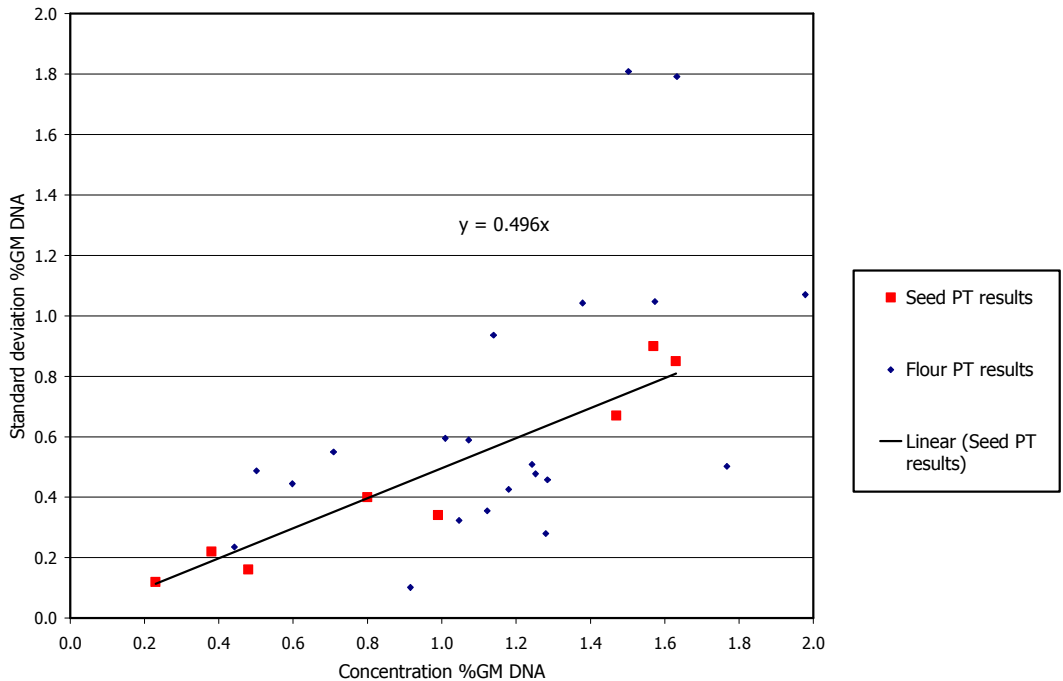
¹³ https://www.seedtest.org/upload/cms/user/131_p221.pdf

¹⁴ https://www.seedtest.org/upload/cms/user/Pages33-35fromST1132_Oct06.pdf

¹⁵ <http://www.fapas.com/gemma.cfm>

GM flour (wheat, maize and soya) in 19 rounds is consistent with the performance observed in the ISTA proficiency test scheme.

Figure 6.1: Estimates of reproducibility standard deviation from proficiency test results



6.4.4 Analytical variability (repeatability)

It is assumed that laboratories just meet the ENGL method validation criterion that analytical repeatability relative standard deviation RSD_r is no greater than 0.25^{16} .

$$RSD_R = 0.25 \quad \text{Equation 4}$$

6.4.5 Effect of limit of detection on analytical variation

The value of limit of detection given in the survey was used to provide information on the additional variation (in addition to RSD_R) associated with the analysis of samples containing low concentrations of GMO. In practice the value of the limit of detection is often estimated as a multiple of the standard deviation displayed by the results of replicate analyses of samples containing low concentrations of analyte. A value of 3 is often used as the multiplying factor. Hence, an estimate of the standard deviation associated with the measurement of low concentrations of analyte is given by

$$s_{LOD} = \frac{LOD}{3}$$

¹⁶ Available at <http://gmo-crl.jrc.it/doc/Method%20requirements.pdf>

The value of the additional relative standard uncertainty associated with the analysis of samples containing low concentrations of GMO RSD_{LOD} is given by

$$RSD_{LOD} = \frac{LOD}{3 \times \bar{X}} \quad \text{Equation 5}$$

Where LOD is the value of the (target) LOD reported in the survey

6.4.6 Uncertainty associated with complete sampling and analysis scheme

Estimates of the variation associated with the complete sampling and analysis scheme $RSD_{control}$ were calculated by combining the relative standard deviations associated with lot heterogeneity, formation of the working sample, analytical variation and limit of detection.

For a control plan based on N primary samples, a working sample of n seeds from which a mean measurement result from M independent sub-samples analysed m times each is reported, $RSD_{control}$ is given by

$$RSD_{control} = \sqrt{\frac{RSD_s^2}{N} + RSD_w^2 + \frac{RSD_R^2 - \frac{m-1}{m} \times RSD_r^2}{M} + \frac{RSD_{LOD}^2}{m \times M}}$$

Hence combining Equations 1 to 5, gives Equation 6:

$$RSD_{control} = \sqrt{\frac{1.299 \times z \times \left(100 - \frac{\bar{X}}{z}\right)}{N \times 1000 \times \bar{X}} + \frac{z \times \left(100 - \frac{\bar{X}}{z}\right)}{3000 \times \bar{X}} + \frac{0.496^2 - \frac{m-1}{m} \times 0.25^2}{M} + \frac{LOD^2}{9 \times \bar{X}^2 \times m \times M}}$$

Equation 6

6.4.7 Measurement uncertainty associated with test results

In order to assess the effect of the uncertainty expressed by $RSD_{control}$ it is necessary to express the uncertainty as a confidence interval calculated using an associated statistical distribution. The variation displayed by the measurement of GM components of foodstuffs in proficiency tests has been shown to be consistent with a log-normal distribution [9]. Hence, the log-normal distribution is assumed when interpreting the effect of $RSD_{control}$ (Equation 6) on the interpretation of results. Hence, for a lot containing \bar{X} % GM DNA, approximately 95% of measurement results can be expected to lie between $e^{\mu-2 \times \sigma}$ and $e^{\mu+2 \times \sigma}$ [10] where

$$\sigma = \sqrt{\ln(RSD_{control}^2 + 1)} \quad \text{Equation 7}$$

$$\mu = \ln(\bar{X}) - \frac{1}{2} \sigma^2 \quad \text{Equation 8}$$

6.4.8 Probability of accepting a lot that contains GMO

For the production of Operating Characteristic Curves the probability p_{accept} that a measurement yields a result below a threshold T is required. This is given by the value of the cumulative normal distribution (mean= μ , standard deviation= σ) at $\text{Ln}(T)$.

$$p_{accept} = N^{-1}(\text{Ln}(T), \mu, \sigma) \quad \text{Equation 9}$$

where μ and σ are defined in Equations 7 and 8.

6.4.9 Effect of testing only a proportion of lots

Where it is believed that lots from a particular source contain no GMO only a proportion of lots may be tested. The relation between GMO concentration and the maximum (with 95% confidence) number of lots that may be accepted n_{accept} before a single measurement result above a threshold is observed (demonstrating that lots from the source do contain GMO) can be derived from p_{accept} (Equation 9) using

$$n_{accept} = \frac{\log(0.05)}{\log(p_{accept}) \times p_{test}}$$

where p_{test} is the proportion of lots tested.

6.5 Control of GM seed in soya

6.5.1 Sources of variation

Figure 6.2 shows the relationship between measurement variation (using Equation 7) and GM DNA concentration for the measurement of a homozygous GM event employing duplicate analysis of a single DNA extract. The limit of detection of the analytical method is 0.033%. Replicate analysis of a single DNA extract is used. The relationship between the size of different sources of measurement variation, shown in figure 6.2, is broadly representative of all of the control plans examined in this study for all commodities.

- For lots containing high concentrations of GMO overall variation is dominated by the variation associated with analysis.
- For lots containing low concentration of GMO overall variation is dominated by the variation associated with forming the working sample.
- Primary sampling is not an important source of variation.
- If a reduction in measurement uncertainty is required it can be achieved by reducing the uncertainty associated with those components that dominate overall uncertainty by increasing the total number of seeds in the working sample from which DNA is extracted, and the number of replicate DNA extractions.

Figure 6.2: Components of measurement variation (soya)

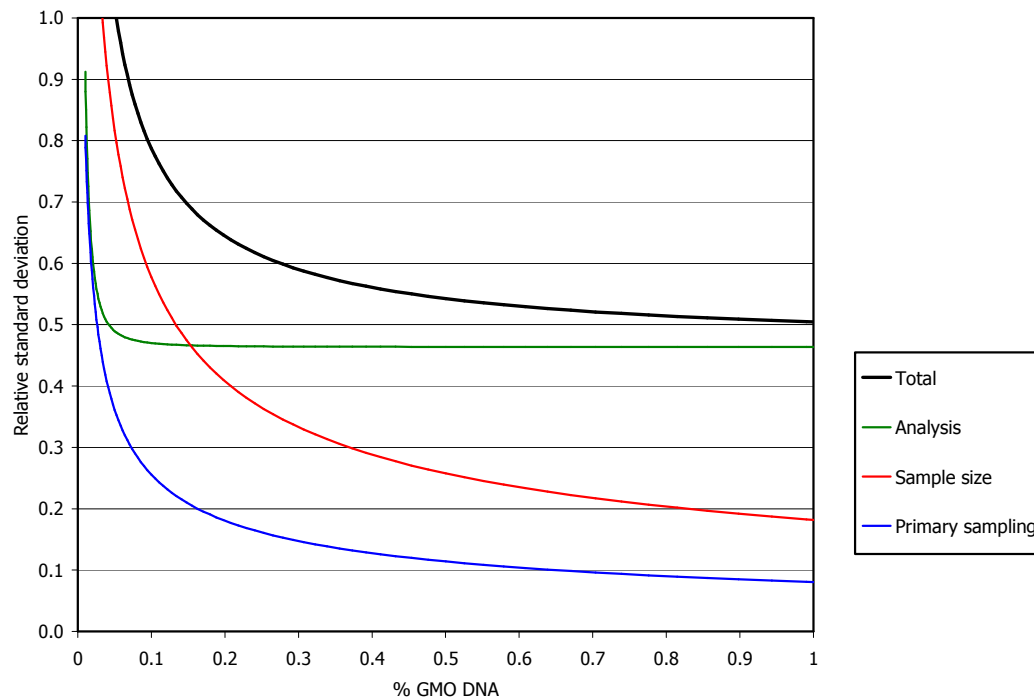
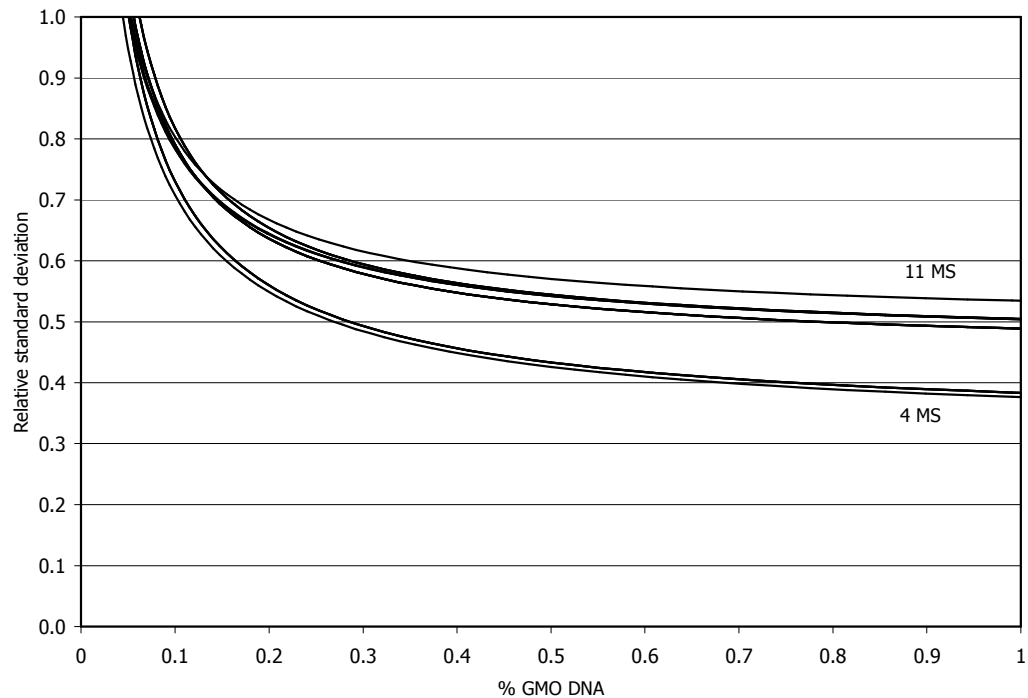


Figure 6.3 shows the relationship between the variation associated with measurement results and concentration of AP of GMO in lots. Control plans fall into two groups:

- For 4 MS, who reported the use of replicate independent DNA extracts, the relative standard deviation associated with measurement results tends towards a value of 0.4 as the concentration of GMO DNA increases.
- For 11 MS, who did not report the use of replicate independent DNA extracts, the relative standard deviation associated with measurement results tends towards a value of 0.5 as the concentration of GMO DNA increases.

Figure 6.3: Variation associated with measurement results

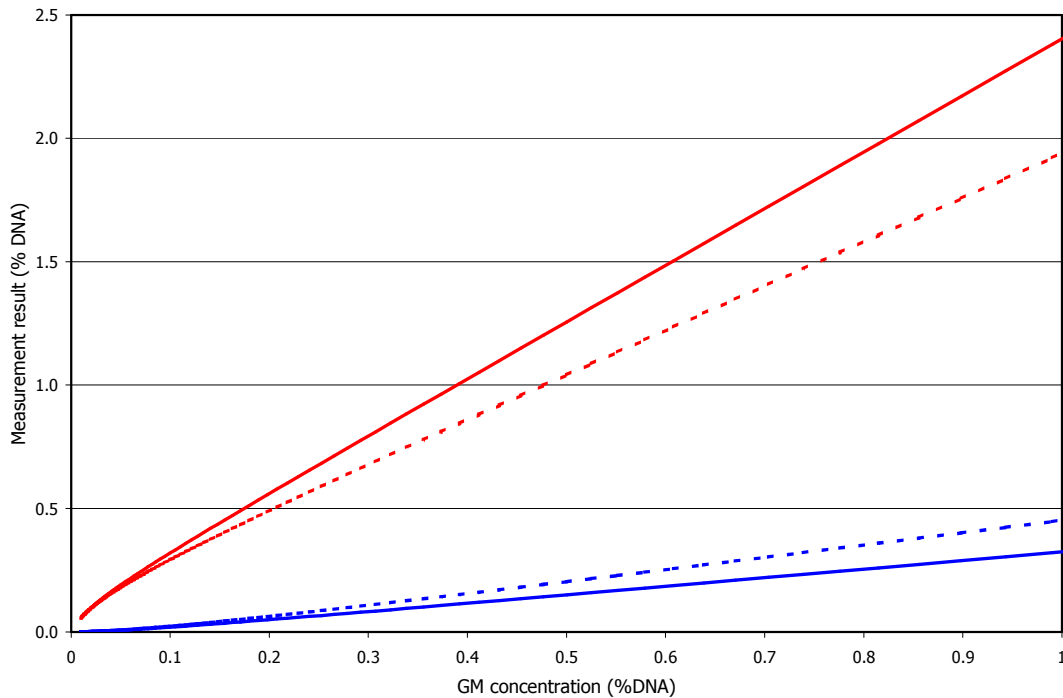


6.5.2 Measurement uncertainty

Figure 6.4 shows the relationship between the range within which measurement results can be expected to lie (with approximately 95 % confidence) and the concentration of GMO in lots.

- The widest range for a true GMO concentration of 0.3 % is between 0.082 % and 0.79%
- The narrowest range for a true AP of GMO concentration of 0.3% is between 0.11% and 0.68%

Figure 6.4: Maximum and minimum measurement uncertainty associated with control plans

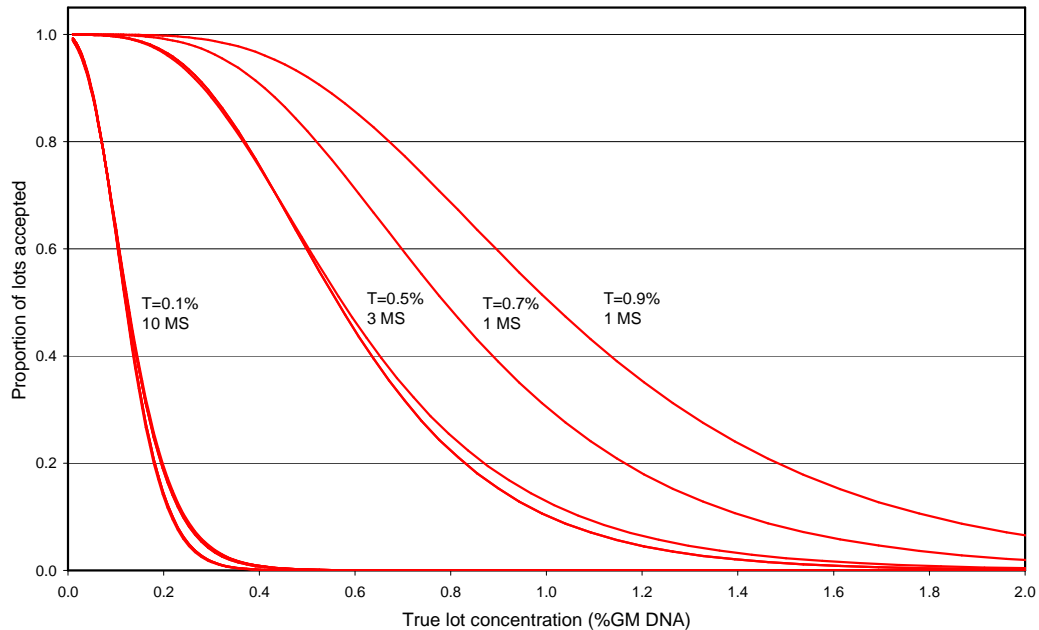


6.5.3 Operating characteristics of MS control plans

Figure 6.5 shows the relationship between the probability that a lot is accepted as containing a sufficiently low concentration of GMO and the concentration of GMO in lots. Curves fall into 3 groups: ten MS use thresholds of 'zero tolerance' to 0.1%, three MS use a threshold of 0.5% and two MS use higher thresholds. For homozygous events (zygosity=1) the different units of measure (%GM DNA, %mass, %seed) are equivalent. The small variation within the zero tolerance to 0.1% group and within the 0.5% group shows the relatively small effect that differences in measurement uncertainty between MS has on the outcome of control plans.

- Differences between the outcomes of applying MS control plans are driven entirely by differences between thresholds applied by MS.
- MS employing thresholds of 'zero tolerance' to 0.1% will accept approximately 3% of lots containing 0.3% GMO.
- MS employing a threshold of 0.5% will accept approximately 90% of lots containing 0.3% GMO.
- MS employing a threshold of 0.9% will accept approximately 98% of lots containing 0.3% GMO.

Figure 6.5: Relationship between the probability that a lot is accepted as containing a sufficiently low concentration of AP of GMO and concentration of AP of GMO in lots

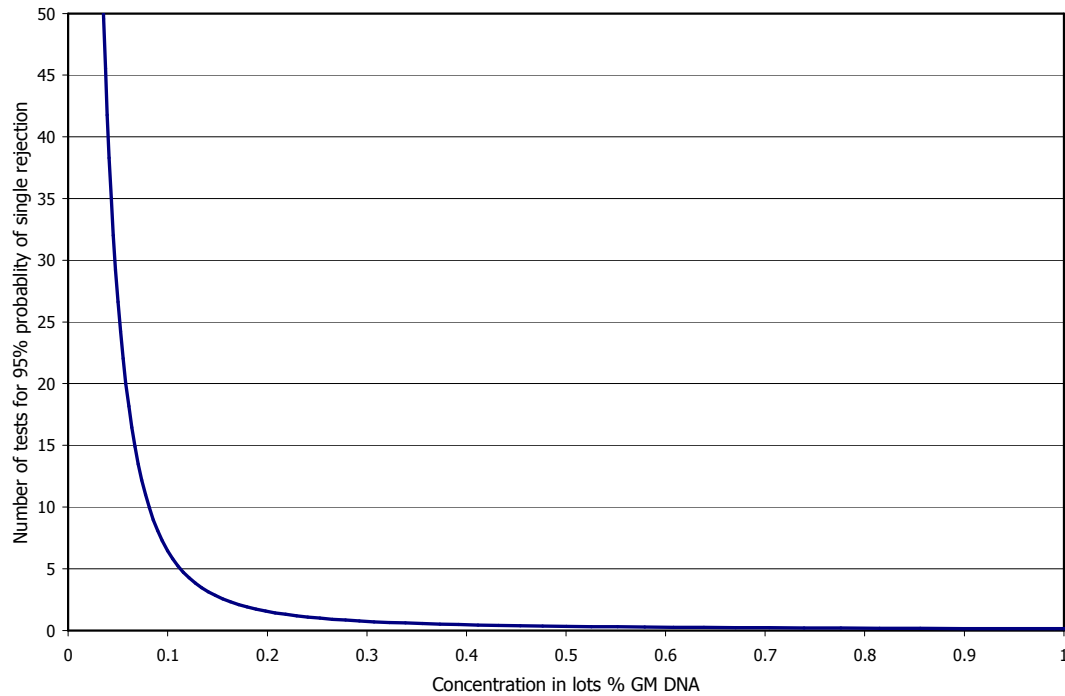


6.5.4 Effect of testing only a proportion of lots

Figure 6.6 shows the relationship between the number of tests required for a high probability of observing a single positive (above a threshold of 0.1%) result, and the concentration of GMO in lots. Where no positive results are observed within a much larger number of tests than that predicted, and there is reason to believe that there is a low risk of GMO associated with a particular source, then control based upon the testing of a proportion of lots is reasonable.

- A positive result can be expected (with 95% confidence) within 7 tests if lots contain at least 0.1% GM DNA.
- For programmes based on testing 100% of lots, 7 lots containing at least 0.1% GMO may be accepted before a single positive result is observed.
- For programmes based on testing 5% of lots, 140 lots containing at least 0.1% GMO may be accepted before a single positive result is observed.
- For programmes based on testing 10% of lots, 70 lots containing at least 0.1% GMO may be accepted before a single positive result is observed.
- For programmes based on testing 20% of lots, 35 lots containing at least 0.1% GMO may be accepted before a single positive result is observed.

Figure 6.6: Relation between the number of tests required for a high (95%) probability of observing a single positive result and concentration of GMO in lots



6.6 Control of GM seed in oilseed rape (OSR)

6.6.1 Sources of variation

GM events in oilseed rape may be heterozygous (zygosity=0.5). Where events have a zygosity of 0.5 and GMO is expressed as %DNA, GM events at a particular concentration are present in twice as many seeds compared to homozygous events. Figure 6.7 shows the relationship between measurement variation (using Equation 7) and GM DNA concentration for the measurement of a GM event in OSR with a zygosity equal to 0.5 employing the same plan used to illustrate the control of soya.

- The association of a larger number of seeds with a particular GMO concentration (expressed as %GM DNA) leads to a reduction in potential variation associated with primary sampling and the variation associated with the production of the working sample compared to GM events in soya. This leads to a small reduction in overall variation for the measurement of GMO. The reduction is greatest for low concentrations of GMO.

Figure 6.7: Components of measurement variation (OSR)

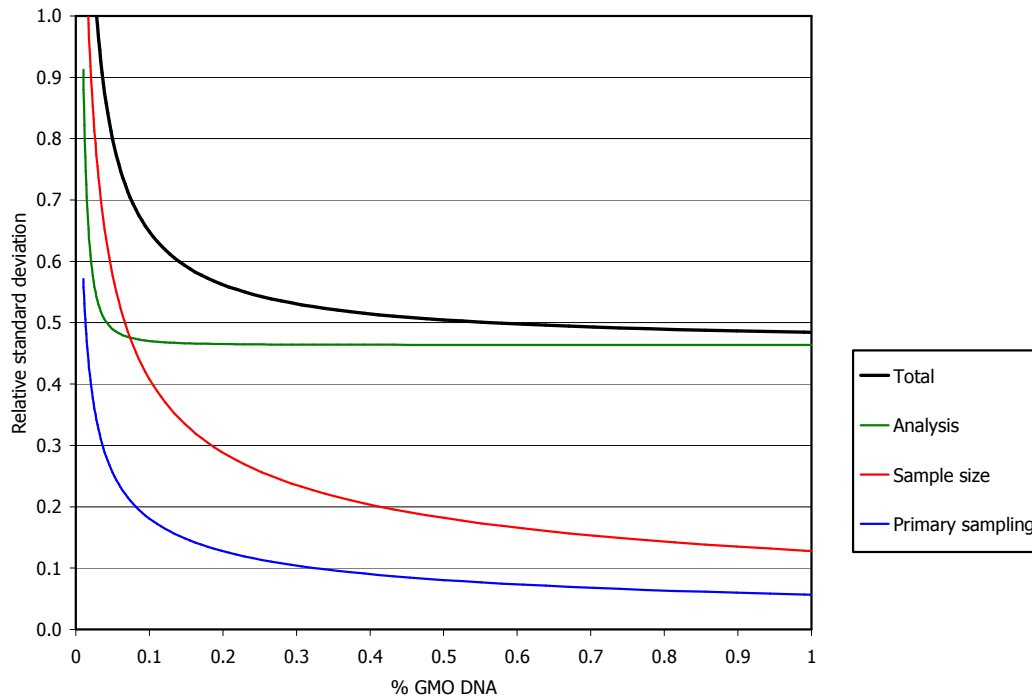
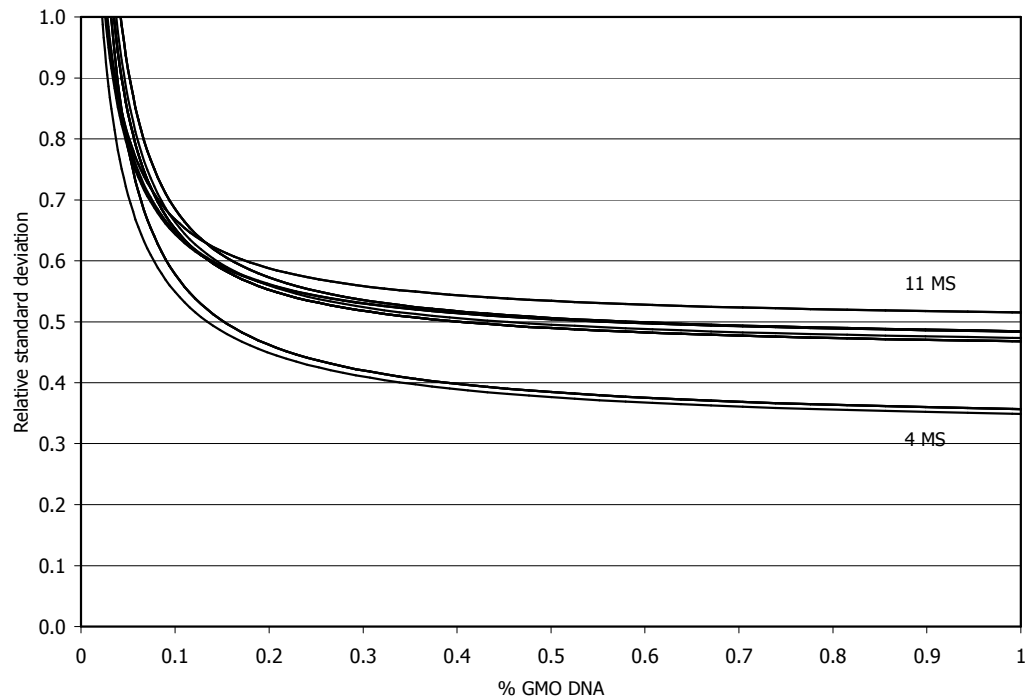


Figure 6.8 shows the relationship between the variation associated with measurement results and concentration of GMO in lots. Control plans fall into the same two groups seen for the measurement of GMO in soya. The variation associated with measurement results is slightly reduced compared to the measurement of GMO in soya.

- For 4 MS, who reported the use of replicate independent DNA extracts, the relative standard deviation associated with measurement results tends towards a value of 0.35 as the concentration of GMO DNA increases.
- For 11 MS, who did not report the use of replicate independent DNA extracts, the relative standard deviation associated with measurement results tends towards a value of 0.5 as the concentration of GMO DNA increases.

Figure 6.8: Variation associated with measurement results

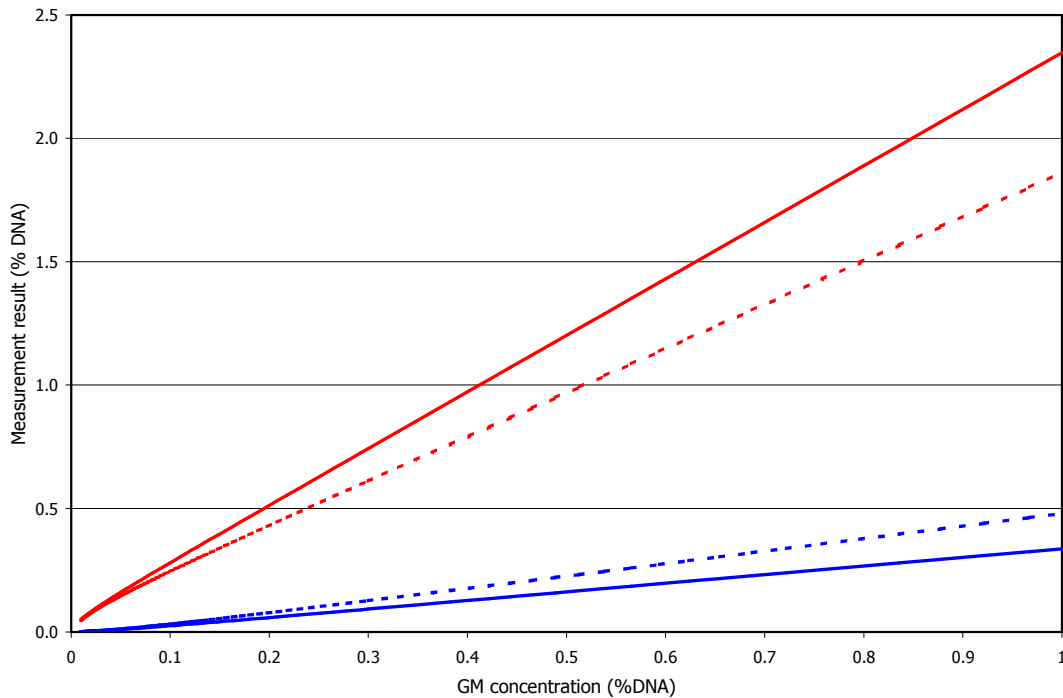


6.6.2 Measurement uncertainty

Figure 6.9 shows the relationship between the range within which measurement results can be expected to lie (with approximately 95 % confidence) and the concentration of GMO in lots.

- The widest range for a true GMO concentration of 0.3 % is between 0.093% and 0.74%.
- The narrowest range for a true GMO concentration of 0.3% is between 0.12% and 0.61%.

Figure 6.9: Maximum and minimum measurement uncertainty associated with control plans

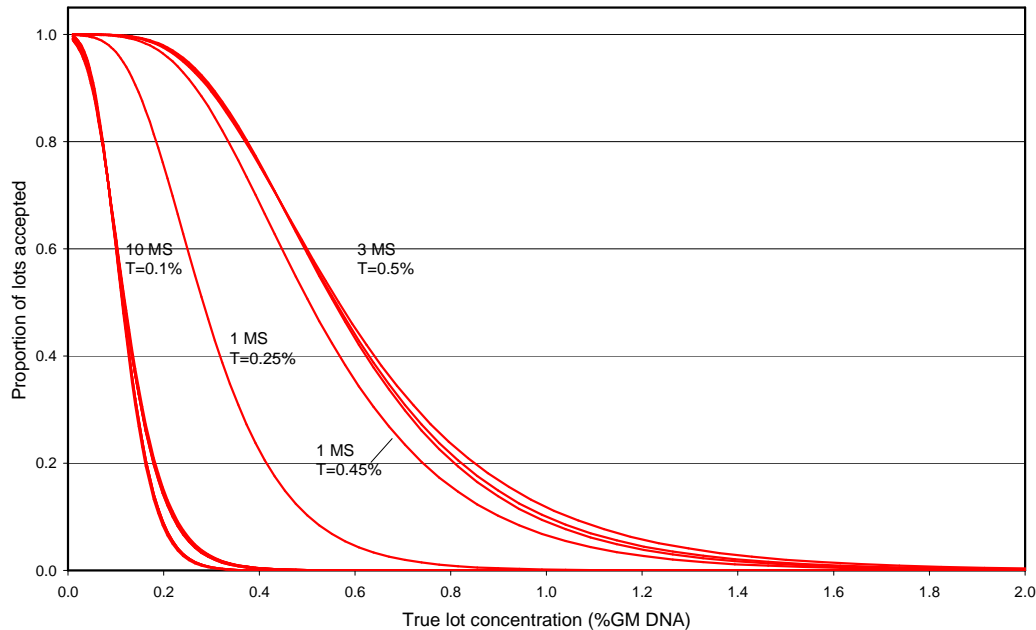


6.6.3 Operating characteristics of MS control plans

Figure 6.10 shows the relationship between the probability that a lot is accepted as containing a sufficiently low concentration of GMO and the concentration of GMO in lots. 10 MS use thresholds of ‘zero tolerance’ to 0.1%, 3 MS use a threshold of 0.5%, 1 MS uses a threshold of 0.5% seed which is equivalent to a threshold of 0.25% GM DNA and 1 MS uses a threshold of 0.9% seed which is equivalent to 0.45% GM DNA. In common with the measurement of GM DNA in soya, the small variation within the zero tolerance to 0.1% group and within the 0.5% group shows the relatively small effect that differences in measurement uncertainty between MS has on the outcome of control plans. The slightly reduced measurement uncertainty (compared to soya) leads to slightly better performance of the control measures.

- Differences between the outcomes of applying MS control plans are driven entirely by differences between thresholds applied by MS. This includes the effect of applying thresholds in different units of measurement.
- MS employing thresholds of ‘zero tolerance’ to 0.1% will accept approximately 1% of lots containing 0.3% GMO.
- MS Employing a threshold of 0.5% seed (0.25% GM DNA) will accept approximately 45% of lots containing 0.3% GMO
- MS employing a threshold of 0.9% seed (0.45% GM DNA) will accept approximately 85% of lots containing 0.3% GMO.
- MS employing a threshold of 0.5% GM DNA will accept approximately 90% of lots containing 0.3% GMO.

Figure 6.10: Relationship between the probability that a lot is accepted as containing a sufficiently low concentration of GMO and concentration of GMO in lots

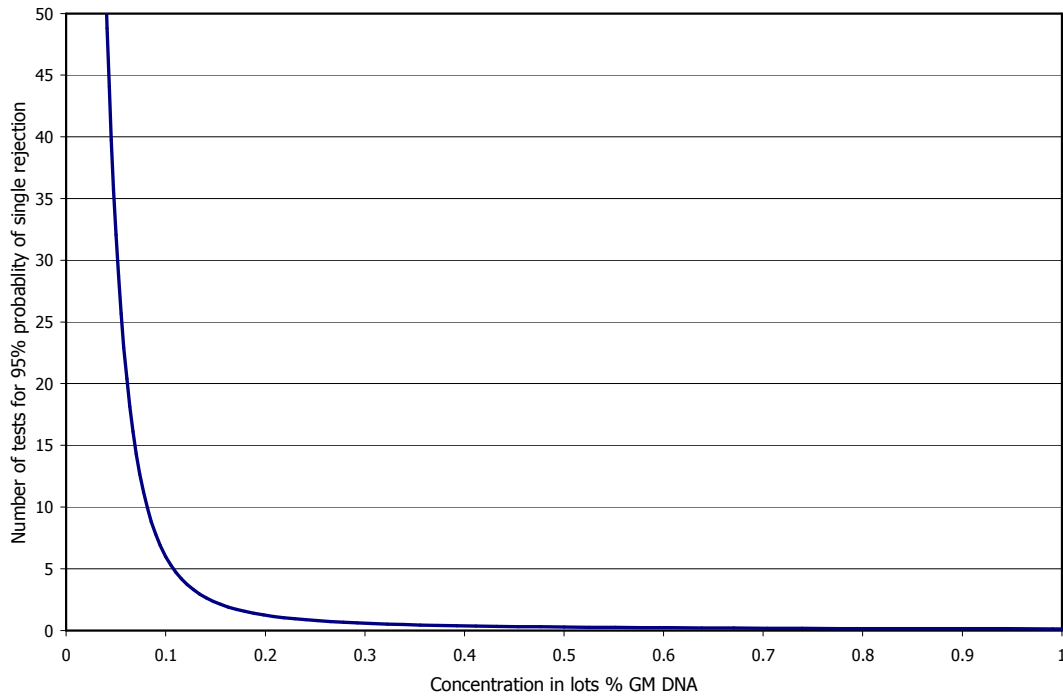


6.6.4 Effect of testing only a proportion of lots

Figure 6.11 shows the relationship between the number of tests required for a high probability of observing a single positive (above a threshold of 0.1%) result, and the concentration of GMO in lots. Where no positive results are observed within a much larger number of tests than that predicted, and there is reason to believe that there is a low risk of GMO associated with a particular source, then control based upon a the testing of a proportion of lots is reasonable.

- A positive result can be expected (with 95% confidence) within 6 tests if lots contain at least 0.1% GM DNA
- For programmes based on testing 100% of lots, 6 lots containing at least 0.1% GMO may be accepted before a single positive result is observed.
- For programmes based on testing 5% of lots, 120 lots containing at least 0.1% GMO may be accepted before a single positive result is observed.
- For programmes based on testing 10% of lots, 60 lots containing at least 0.1% GMO may be accepted before a single positive result is observed.
- For programmes based on testing 20% of lots, 30 lots containing at least 0.1% GMO may be accepted before a single positive result is observed.

Figure 6.11: Relationship between the numbers of tests required for a high (95%) probability of observing a single positive result and concentration of GMO in lots



6.7 Control of GM seed in maize

6.7.1 Sources of variation

GM events in maize commonly have a zygosity of 0.58. Hence the performance of control plans is very similar to the performance for OSR (zygosity=0.5). Figure 6.12 shows the relationship between measurement variation (using Equation 7) and GM DNA concentration for the measurement of a GM event in maize employing the same plan used to illustrate the control of soya and OSR.

- Measurement variation is dominated by contributions from the variation associated with analysis and variation associated with formation of the working sample.
- Measurement variation is close to that calculated for the measurement of GMO with zygosity=0.5.

Figure 6.12 Components of measurement variation (maize)

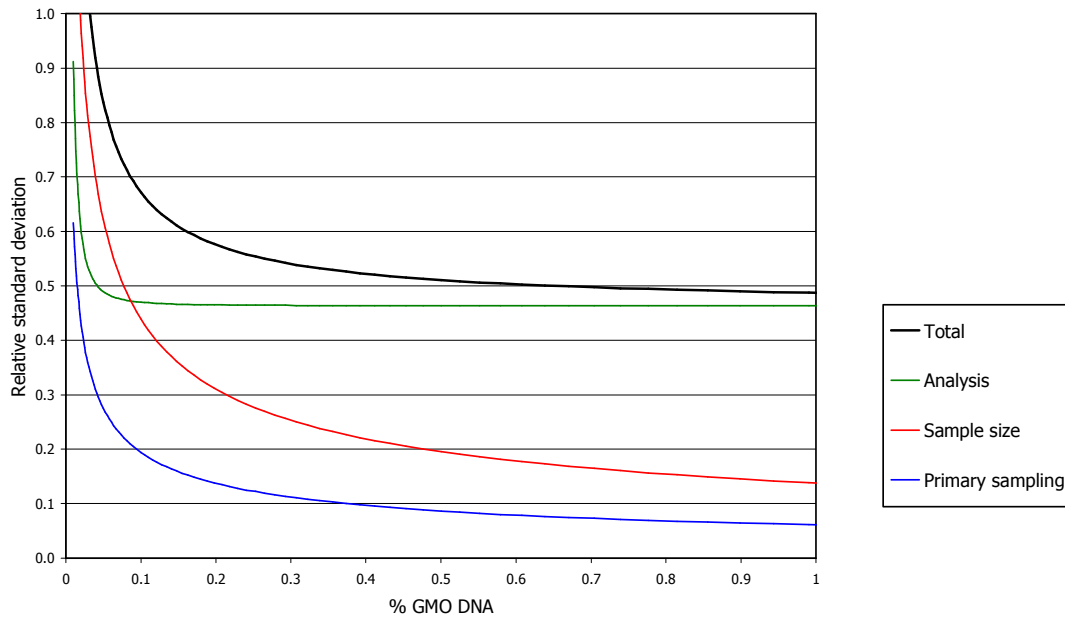
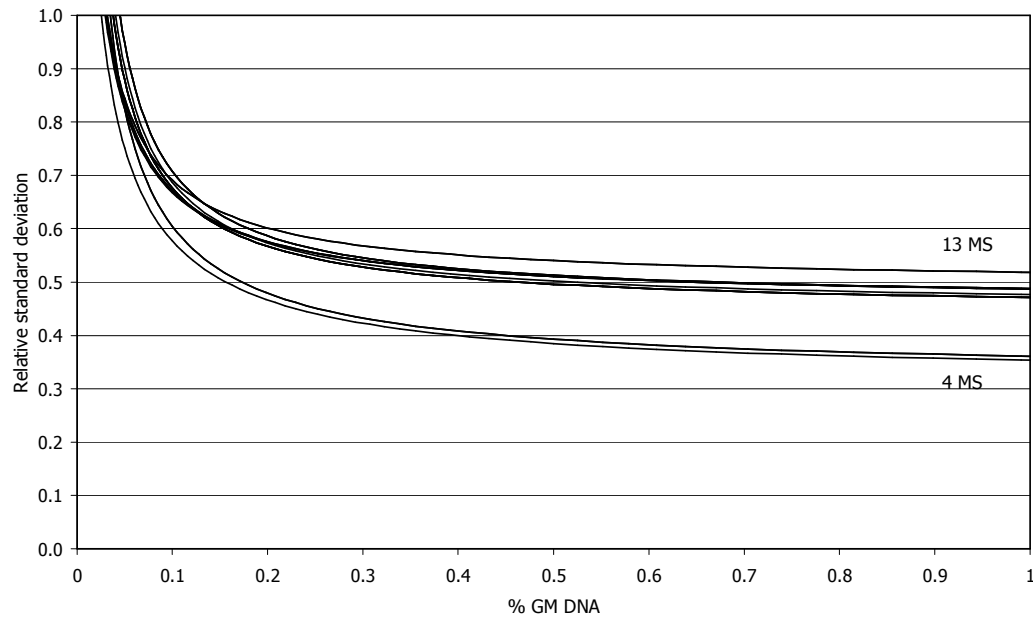


Figure 6.13 shows the relationship between the variation associated with measurement results and concentration of GMO in lots. Control plans fall into the same two groups seen for the measurement of GMO in soya and OSR. The variation associated with measurement results is slightly reduced compared to the measurement of GMO in soya.

- For 4 MS, who reported the use of replicate independent DNA extracts, the relative standard deviation associated with measurement results tends towards a value of 0.35 as the concentration of GMO DNA increases.
- For 11 MS, who did not report the use of replicate independent DNA extracts, the relative standard deviation associated with measurement results tends towards a value of 0.5 as the concentration of GMO DNA increases.

Figure 6.13: Variation associated with measurement results

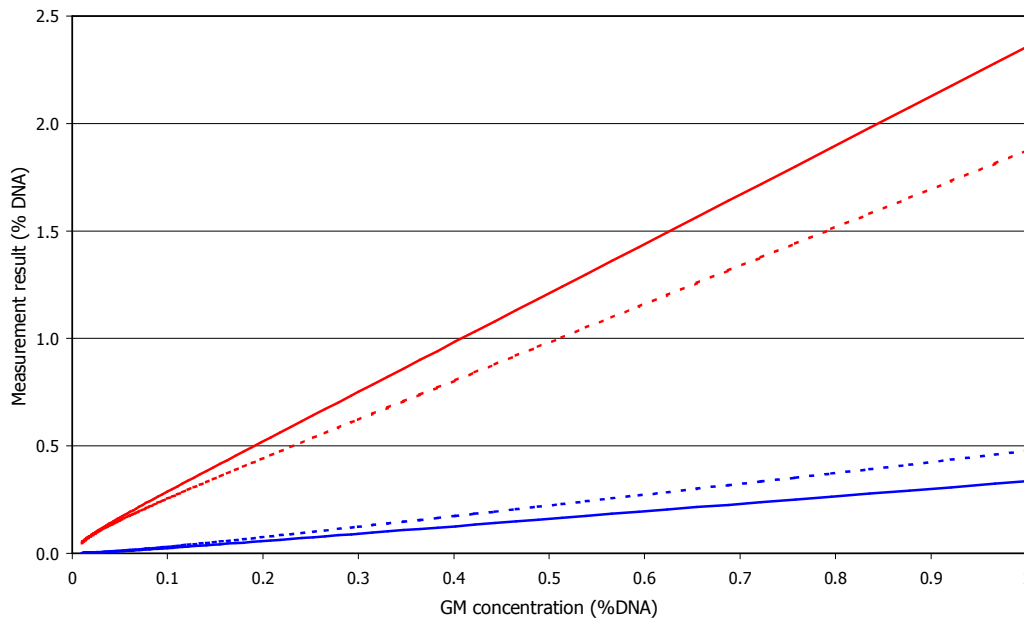


6.7.2 Measurement uncertainty

Figure 6.14 shows the relationship between the range within which measurement results can be expected to lie (with approximately 95% confidence) and the concentration of GMO in lots.

- The widest range for a true GMO concentration of 0.3 % is between 0.091% and 0.75%.
- The narrowest range for a true GMO concentration of 0.3% is between 0.12% and 0.62%.

Figure 6.14: Maximum and minimum measurement uncertainty associated with control plans

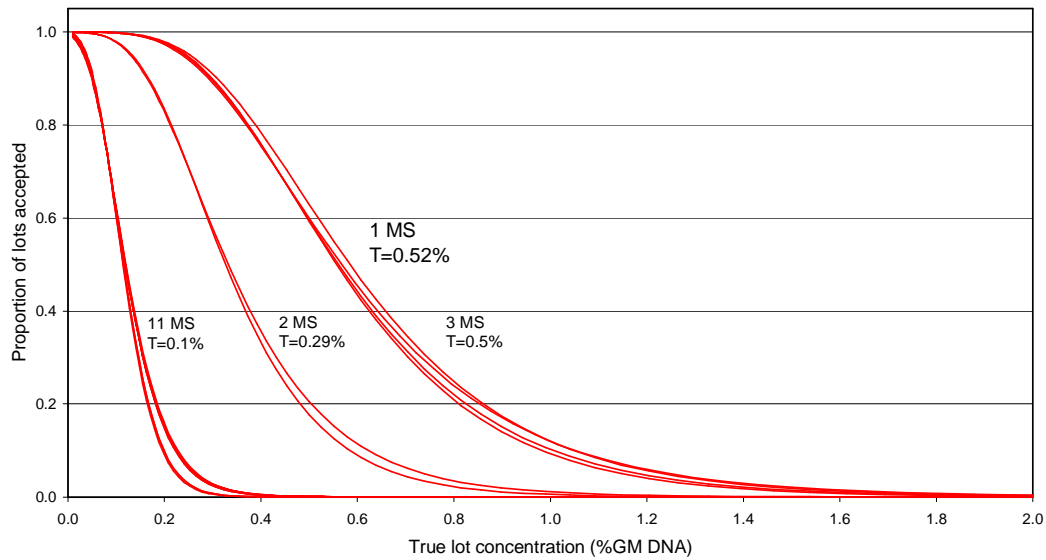


6.7.3 Operating characteristics of MS control plans

Figure 6.15 shows the relationship between the probability that a lot is accepted as containing a sufficiently low concentration of GMO and the concentration of GMO in lots. 11 MS use thresholds of ‘zero tolerance’ to 0.1%, 3 MS use a threshold of 0.5%, 2 MS use a threshold of 0.5% seed (which is equivalent to a threshold of 0.29% GM DNA) and 1 MS uses a threshold of 0.9% seed (which is equivalent to 0.52% GM DNA). In common with the measurement of GM DNA in soya and OSR, the small variation within the zero tolerance to 0.1% group and within the 0.5% group shows the relatively small effect that differences in measurement uncertainty between MS has on the outcome of control plans.

- Differences between the outcomes of applying MS control plans are driven entirely by differences between thresholds applied by MS. This includes the effect of applying thresholds in different units of measurement.
- MS employing thresholds of ‘zero tolerance’ to 0.1% will accept approximately 1% of lots containing 0.3% GMO.
- MS employing a threshold of 0.5% GM DNA will accept approximately 90% of lots containing 0.3% GMO.
- MS Employing a threshold of 0.5% seed (0.29% GM DNA) will accept approximately 55% of lots containing 0.3 GMO
- MS employing a threshold of 0.9% seed (0.52% GM DNA) will accept approximately 90% of lots containing 0.3% GMO.

Figure 6.15: Relation between the probability that a lot is accepted as containing a sufficiently low concentration of GMO and concentration of GMO in lots

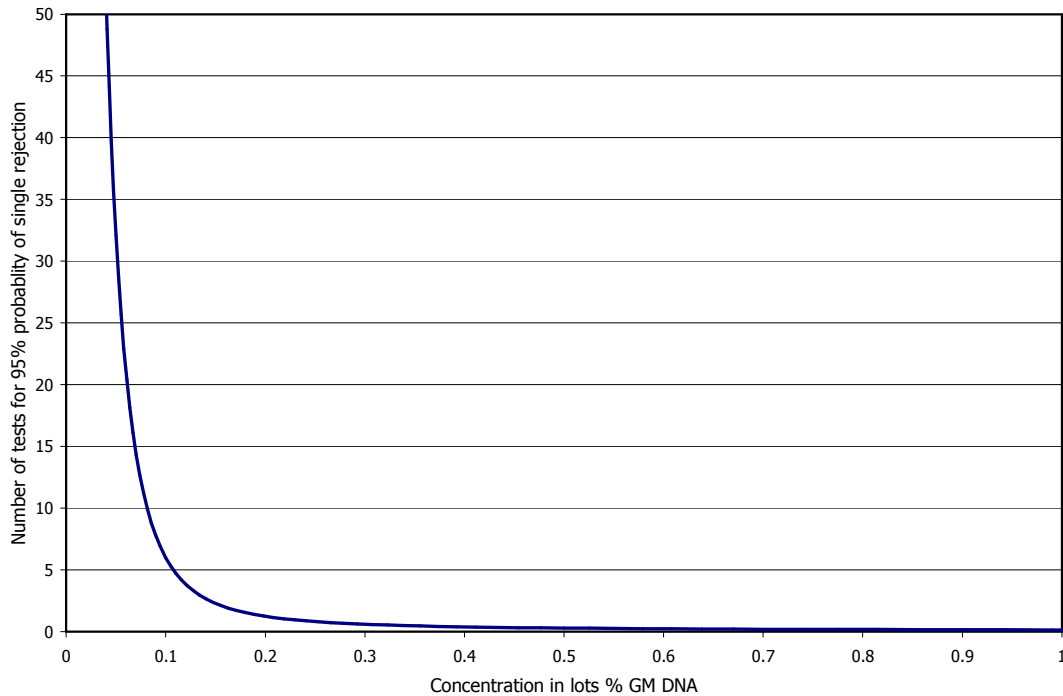


6.7.4 Effect of testing only a proportion of lots

Figure 6.16 shows the relationship between the number of tests required for a high probability of observing a single positive (above a threshold of 0.1%) result, and the concentration of GMO in lots. A positive result may be expected (with better than 95% confidence) after 7 tests. Where no positive results are observed within a much larger number of tests than that predicted, and there is reason to believe that there is a low risk of GMO associated with a particular source, then control based upon a the testing of a proportion of lots is reasonable.

- A positive result can be expected (with 95% confidence) within 7 tests if lots contain at least 0.1% GM DNA.
- For programmes based on testing 100% of lots, 7 lots containing at least 0.1% GMO may be accepted before a single positive result is observed.
- For programmes based on testing 5% of lots, 140 lots containing at least 0.1% GMO may be accepted before a single positive result is observed.
- For programmes based on testing 10% of lots, 70 lots containing at least 0.1% GMO may be accepted before a single positive result is observed.
- For programmes based on testing 20% of lots, 35 lots containing at least 0.1% GMO may be accepted before a single positive result is observed.

Figure 6.16: Relationship between the number of tests required for a high (95%) probability of observing a single positive result and concentration of GMO in lots



6.8 Summary of the effect of different thresholds on the probability of a lot being accepted

The OC curves produced in this study showed that the variation between MS in thresholds applied to measurement results had the largest effect on the probability of a tested lot with certain concentration of AP of GMO being accepted. The variation between MS consisted of differences in the 'headline figure': between 'zero – tolerance' to 0.9%, and variation in the unit used to express the threshold: '% GM DNA', 'mass' or 'seed'. Tables 6.5, 6.6 and 6.7 show the effect of different thresholds on the probability of seed lots containing 0.1%, 0.3% and 0.5% GMO DNA being accepted.

For a homozygous (zygosity=1) GM event, such as those commonly found in soya, (Table 5.5):

- The different measurement units are equivalent.
- The measurement result from lots containing 0.3% AGMP will be under a threshold of 0.1% for 5% of tests.
- The measurement result from lots containing 0.3% AGMP will be under a threshold of 0.3% for 61% of tests.

Table 6.5: Effect of control plan threshold on the probability of a lots being accepted (zygosity =1)

True concentration	Threshold			
	0.1% GMO DNA	0.3% GMO DNA	0.5% GMO DNA	0.9% GMO DNA
0.1% GMO DNA	65%	96%	99%	100%
0.3% GMO DNA	5%	61%	88%	99%
0.5% GMO DNA	0%	23%	60%	91%

For a heterozygous (zygosity=0.5) GM event, such as those commonly found in OSR, (Table 6.6 and 6.7):

- The different measurement units are not equivalent.
- The measurement result from lots containing 0.3% AP of GMO will be under a threshold of 0.1% GMO DNA for 3% of tests.
- The measurement result from lots containing 0.3% AP of GMO will be under a threshold of 0.3% GMO DNA for 60% of tests.
- The measurement result from lots containing 0.3% AP of GMO will be under a threshold of 0.1% seed for less than 1% of tests.
- The measurement result from lots containing 0.3% AP of GMO will be under a threshold of 0.3% seed for 13% of tests.

Table 6.6: Effect of control plan threshold on the probability of a lots being accepted (zygosity =0.5, threshold expressed as % GMO DNA)

True concentration	Threshold			
	0.1% GMO DNA	0.3% GMO DNA	0.5% GMO DNA	0.9% GMO DNA
0.1% GMO DNA	64%	97%	100%	100%
0.3% GMO DNA	3%	60%	89%	99%
0.5% GMO DNA	0%	21%	60%	93%

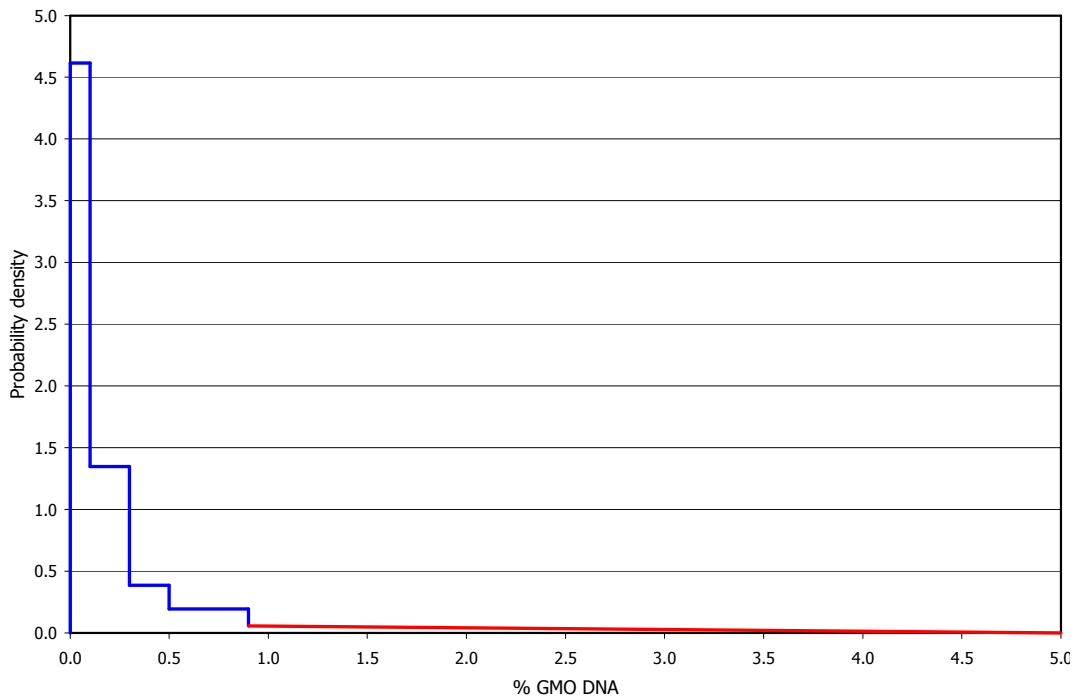
Table 6.7: Effect of control plan threshold on the probability of a lots being accepted (zygosity =0.5, threshold expressed as % seed)

True concentration	Threshold			
	0.1% seed	0.3% seed	0.5% seed	0.9% seed
0.1% GMO DNA	26%	82%	95%	99%
0.3% GMO DNA	0%	13%	46%	85%
0.5% GMO DNA	0%	1%	12%	51%

6.9 Illustration of the assessment of the effect of control plans on AP of GMO in imported seeds

Given estimates of the relation between the concentration of AP of GMO in a lot and the probability that a lot is accepted as containing a sufficiently low concentration of AP of GMO described by an OC curve, the effect of control on AP of GMO in the population of accepted lots, can be estimated if the distribution of AP of GMO in the population of 'all lots' can be estimated. As an illustration, the "the additional data provided by Spain" (Note 4.7 (1)), was used to estimate a probability density function (pdf) for the concentration of AP of GMO in imported lots. In order to produce the pdf an estimate of how the upper tail (above 0.9%) of the distribution behaved was required. Hence it was assumed that no lots contained more than 5% AGMP, and that the pdf between 0.9% GMO DNA and 5% GMO DNA was linear. Figure 6.1.7 shows the pdf. The pdf applies to the proportion of lots that contain GMO AP (26/843).

Figure 6.17: Probability density function for GMO AP in maize imported from 3rd countries (derived from additional data provided by Spain)



In order to assess the effect of different control plans the pdf was used as an estimate of the population of lots to which control plans would be applied. A simulation of the application of control plans (by randomly selecting 'lots' from the pdf and using OC curves to simulate testing and decision making) was undertaken. The simulation used thresholds at 0.1, 0.3, 0.5 and 0.9 % GMO DNA, and testing 0, 20, 50, 80, 90 and 100% of lots.

Estimates of the mean concentration of GMO DNA that could be expected in unlabelled lots (including 97% not containing AP of GMO) were gained (table 6.8). The expected mean concentration of AP of GMO where no testing was undertaken was 0.013%, reducing to 0.0009% where a threshold of 0.1% was applied and all 'lots' were tested.

Table 6.8: Effect of control plan threshold and proportion of lots tested on estimates average GMO DNA concentration in unlabelled lots

Threshold	Proportion of lots tested					
	100%	90%	80%	50%	20%	0%
0.1%GMO DNA	0.0009%	0.0022%	0.0033%	0.0071%	0.0103%	0.0132%
0.3% GMO DNA	0.0026%	0.0035%	0.0046%	0.0079%	0.0108%	0.0132%
0.5% GMO DNA	0.0037%	0.0046%	0.0056%	0.0085%	0.0109%	0.0132%
0.9% GMO DNA	0.0053%	0.0060%	0.0068%	0.0091%	0.0117%	0.0132%

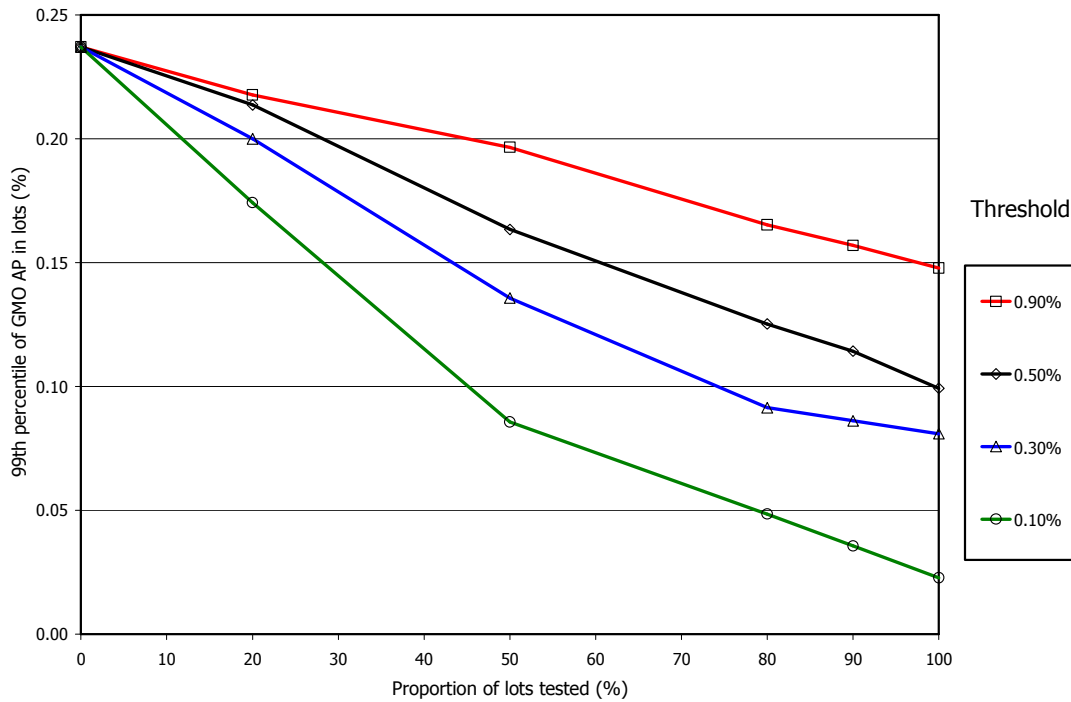
Possibly a more important estimate of the effect of control on AP of GMO is the concentration of AP in an upper percentile of accepted lots. Table 6.9 and Figure 6.18 show estimates of the concentration of AP of GMO in the 99th percentile of lots. That is, we estimate that 99% of lots will contain AP Of GMO at a lower concentration than the figure given in Table 6.9.

- If no control is undertaken then the 99th percentile of lots contains 0.24% GMO DNA
- If 100% of lots are tested with a threshold of 0.1% then the 99th percentile of lots contains 0.02% GMO DNA

Table 6.9: Effect of control plan threshold and proportion of lots tested on estimates of the concentration of GMO DNA concentration in the 99th percentile of unlabelled lots

Threshold	Proportion of lots tested					
	100%	90%	80%	50%	20%	0%
0.1% GMO DNA	0.02%	0.04%	0.05%	0.09%	0.17%	0.24%
0.3% GMO DNA	0.08%	0.09%	0.09%	0.14%	0.20%	0.24%
0.5% GMO DNA	0.10%	0.11%	0.13%	0.16%	0.21%	0.24%
0.9% GMO DNA	0.15%	0.16%	0.17%	0.20%	0.22%	0.24%

Figure 6.18: Effect of control plan threshold and proportion of lots tested on estimates of the concentration of GMO DNA concentration in the 99th percentile of unlabelled lots



6.10 Conclusions about control programmes for GMO in conventional seeds

Information about systems to control GMO in seed lots (individually of soya, oilseed rape and maize) has been combined with information on the performance of analytical tests, ISTA sampling guidelines and statistical theory to gain estimates of the uncertainty associated with each component of the control system, the uncertainty associated with the measurement of GMO in seed lots, and the relationship between the concentration of GMO in seed lots and the probability that a test result exceeds a threshold value.

Based on these estimates, the following observations can be made:

1. Analytical test results can be expected to lie within a factor of approximately $\times 2$ to $\div 3$ (depending on the degree of analytical replication) of the true lot mean GMO concentration for concentrations well above the limit of detection of an analytical method. For example a test on a sample taken from a lot containing 0.5% GMO can be expected to generate a result between 0.15% and 1.3% (single analysis).
2. The uncertainty associated with analysis by quantitative PCR makes the largest contribution to overall uncertainty for lots containing high concentrations of GMO (above 0.15% to 0.4% depending on the GM event and degree of analytical replication). The uncertainty associated with forming

the working sample from the laboratory sample makes the largest contribution for lots that contain lower concentrations of GMO.

3. The uncertainty associated with test results can be reduced most easily by the analysis of independent replicate working samples.
4. Variation between MS in the test result threshold (including the units in which the threshold is expressed) for the labelling/rejection of lots has a much larger effect on the control of GMO in individual lots than variation in analytical limit of detection and replication.
5. The analysis of samples taken from seed lots can be used to directly control the concentration of GMO in individual seed lots from a particular source if all seed lots are tested. If only a proportion of seed lots from sources believed to give low risk of GMO are tested, then a sequence of 'negative' test results can assure MS that the risk of GMO from particular sources is sufficiently low. The degree of risk associated with testing only a proportion of lots depends on the proportion of lots tested. For example if the concentration of GMO in lots is at least 0.1%, an MS operating a 'zero tolerance to 0.1% threshold' and testing 20% of lots can expect to accept 35 lots before a result above the threshold is observed; If 10% of lots are tested then 70 lots may be accepted before a positive result is observed.

6.11 Implications for control of GMO in seeds in the EU

- MS control programmes for GMO in conventional seeds are dependent on a combination of components; the efficacy of a control programme has to be assessed by looking at it as a whole. If the underlying principles of the programme are the same for each crop, the effectiveness of an MS control programme does not vary greatly between crops.
- The two most influential factors controlling true levels of AP of GMO placed on the market is the level at which MS set their enforcement threshold and the proportion of lots they test. At present this is not consistent across all MS.
- The true concentration of AP of GMO in a seed lot may be a factor 3x higher or lower than the measurement result. This should be an important part of considerations aimed at ensuring that the 0.9% permitted levels in food and feed can be met. MS should be encouraged to minimise measurement uncertainty associated with their tests - the CRL and ENGL have working groups focussing on these issues. In all cases examined, there is opportunity to reduce uncertainty associated with test results by increasing the number of replicate working samples from which DNA is extracted (there would be resource implications associated with this). The opportunity to improve in this area is finite, because improvements in uncertainty associated with test results will eventually mean that uncertainty associated with primary sampling becomes important, and these standards are set on a global scale (e.g. by ISTA).

- The proportion of lots that is tested is a result of underlying decisions regarding risk assessment and the risk appetite of the MS. If 100% of lots are tested, as Greece has chosen to do, true control can be exerted using the control plans in this study. This is necessary if there is a high risk associated with seeds. The underlying assumption to such a strategy must be that all seed lots are at risk of containing GMOs, and therefore must all be tested (there must be significant resource implications for such an approach). If the number of positive test results is consistently very low, this would provide evidence to suggest that the underlying assumption was inaccurate, and that control may be in excess of what is needed (the Greek example would suggest that this is the case for tomato for processing, beets and soya).
- A risk-based strategy would target control to where positive test results are most expected to arise (e.g. specific crop types, crops with a certain type of biology, seeds imported from certain countries). Testing 100% of these targeted lots (e.g. as Cyprus does for lots of imported maize seed: only 1 incident of authorised GMO was identified 2001-2006) would effectively exert control where risks are perceived to be high. Again, the results of such a control programme would inform whether the underlying assumptions are correct. The decision to sample only a proportion of lots from within a high-risk group increases the number of lots above a certain threshold that may be accepted before a positive result is observed.
- The Greek authorities currently test 100% of maize seed lots (home-produced and imported) and reported 17 out of 1977 positives (a proportion of 0.0086, or 0.86%) in a 6-year period. Based on the effect of testing only a proportion of lots and providing the source of the lots remained unchanged, testing 20% of lots per annum would have achieved a similar result. Spanish authorities test 90% of all maize seed lots, and in 2005 reported 42 positive lots out of 843 imported lots (EU and 3rd countries), a proportion of 0.05, or 4.98%. Assuming testing is comparable, the much higher incidence of positives suggests that Spain may be importing maize from 'riskier' sources, and that the high rate of testing employed is appropriate for them. It should be considered that seed companies might direct different seed lots to an MS that has a policy of testing 100% of lots than to an MS that has a policy of randomly testing a smaller proportion of lots, hence the underlying strategy for an MS control programme may have a direct influence on seeds that are sent to that MS.
- The countries with GM production within their borders have identified higher levels of GMO in conventional seeds. However, it is difficult to establish whether this is because they have more finely targeted sampling and testing programmes that would be expected to identify a greater proportion of positive results. If similar data are collected again in the future, it would be useful to ask questions that would clearly establish the link between incidents of GMO in conventional seeds and the source of the seed.
- Given a scenario in which thresholds for authorised GMO are standardised across all MS to produce similar operating characteristic curves. The issue of what proportion of seeds should be sampled to provide 95% probability that

seeds on the market are accurately labelled, will still depend on testing either 100% of all seeds lots, which would be a very costly exercise, or basing sampling regimes on accurate risk assessment that takes into account country of origin, level of GM cultivation in the country of origin, level of control in operation in the country of origin and biological characteristics of the crop, etc. Data to feed into such risk assessments could be sourced from the data currently being collected by the MS in their control programmes, in particular those testing high proportions of imported seed lots. This approach could be used to provide a source of generic advice on risk assessment and built into a decision support tool for MS in deciding which seed lots should be targeted for testing.

8. DISCUSSION

1. This has been the first comprehensive, EU-wide survey of practices in place in MS to monitor and control adventitious GM presence in conventional seeds. Data has been gathered from 23 of 27 MS covering the nature of their control programme, the crops included, sampling and testing undertaken, and the levels of enforcement applied to prevent GMO entering the market place as adventitious presence.
2. Data were collected directly from participants using 'e-survey' software developed by CSL¹⁷. This approach was chosen because it provided a way to ensure that responses were provided in a pre-determined format that is entered directly, by the respondent, into a database. This methodology has been successful and has achieved the goal of reduced administrative input on the part of CSL (and therefore reduced input error). The data collection phase of the project took significantly longer and required significantly more input from the project team than was originally anticipated. With the benefit of hindsight, we can appreciate that data often had to be collected from a number of different bodies, and required administrative clearance.
3. Most respondents were able to gain access to the survey, but six responses were sent by fax to CSL and entered by CSL. All collected data are available via a bespoke web-enabled e-survey user interface (security protected) that was developed as part of this project¹⁸. The user interface provides access to all the collected data directly via a searchable database and as downloaded excel spreadsheets of raw data, it also displays basic graphical analysis of data, which is useful to give an initial impression of the distribution of responses to individual questions.
4. Most MS have an inspection and control programme of some description in place where it is necessary. The exception that we have knowledge about is Malta, which does not have a programme because it does not have any large-scale arable agriculture. We know nothing about the control programmes of Bulgaria (which was a new MS in 2007), Estonia and Lithuania, and very little about Portugal. The main driver for the inspection and control programmes is European Council Directive 2001/18; some MS also have national legislation in place to control GMOs in seeds. For long-standing MS, programmes have generally been in place since 2000/2001.
5. Of the crops included in control programmes, maize is sampled and tested by all MS with the exception of Romania (which was a new MS in 2007 and as the survey focussed on activities in 2006, this may explain their slightly different approach). Oilseed rape and soya are also widely tested. Other crops included in MS control programmes include cotton, sugar beet, tomatoes (processing), *Brassica rapa* and zucchini.

¹⁷ <http://euseeds.csl.gov.uk/survey.cfm>

¹⁸ <http://euseedsreports.csl.gov.uk>

6. Most MS sample the seeds in their programmes themselves, and test (or commission tests) themselves. The level of sampling that is undertaken varies very widely between MS, but is almost entirely aimed at certified seed lots, the exceptions being Greece and Spain, which have undertaken some sampling of as-grown seeds (home-produced seeds before being formed into lots). Some MS operate a risk-based regime, whereby only imported seeds are tested, and in some cases only seeds imported from third countries. These countries operate on the assumption that the majority of seeds do not contain adventitious GMOs, but they will target the ones they believe to be at risk. Countries operating on this basis demonstrate a range of activities with respect to the level of 'targeted' seed lots that are sampled – some sample 100% (which might be expected given the seeds are assumed to be at high risk of containing GMO), while others sample anything between 1% and 100%. Countries that have GM maize production within their borders generally also undertake testing of their home-produced maize seeds (DE, ES, FR), which presumably is a decision related to risk-assessment.
7. Other countries operate on the assumption that all seeds of certain crops may contain GMOs, and therefore sample all seed lots of those crops. The most extreme example of this is Greece, which aims to sample and test 100% of home produced and imported lots of maize, OSR and soya (also cotton, beets and tomato for processing). The UK is alone in having a programme based entirely on audit and the production of evidence attesting to the non-GM status of seeds. A number of countries were not able to provide information about the level of sampling undertaken for their testing programmes.
8. Testing for GMOs is undertaken according to broadly similar practices, although the detail of which elements are employed varies between MS. The unit of measurement used by most MS is %GM DNA, others used (to a lesser extent) are %mass and %seed. The limit of detection most commonly recognised is 0.1%, although a few work to 0.01%, and the limit of quantification is generally set at 0.1%. Many respondents reported that they accept the use of junction-spanning and event-specific primers in analytical tests as proof of absence of AP of GMO. While these tests confirm the presence of authorised and known GMO events, they do not provide a screen for unauthorised or unknown GMOs.
9. A total of 280 incidents of authorised GMO were reported between 2001 and 2006, plus a total of 43 incidents of unauthorised GMO, which equates to an average of 61 incidents per year. Based on figures provided for numbers of test results examined each year, we estimate that these results are reported from 1901 tests per year, which equates to an estimated rate of 3.2% of tests per annum being positive. Incidents of authorised GMO were reported almost entirely for maize with a very small number from oilseed rape. In maize seeds 33.3% had less than 0.1% reported levels of authorised GMO, 37.5% had >0.1% but < 0.3% (= 70.8% with less than 0.3% AP of GMO), although 6.25% of reported findings were above 0.9%. AP of unauthorised GMO was also highest in maize. Of the other crops monitored, 90 incidents of AP of unauthorised GMO were reported in cotton over a six-year period (Greece).

10. It might be expected that the approach to enforcement by MS was consistent, but this is not the case. While most MS operate at zero tolerance, or 0.1% (limit of detection), 5 MS will allow maize containing up to 0.5% for the AP of authorised GMO to be marketed unlabelled. Similar patterns can be seen for oilseed rape and maize. One MS will tolerate lots with test results up to 0.9% for the AP of authorised GMO without the need to label, but 'would aim for 0.5%'. All MS operate zero tolerance (or 0.1% limit of detection) for the AP of unauthorised GMO and affected seed would be removed from the market.
11. Statistical analysis of data on MS inspection and control programmes was not straightforward. No complete data sets were collected for any MS. This meant it was not possible to assess the performance of MS control programmes based on seed production and import data, sampling undertaken and levels of reported incidents of AP of GMO. Analysis of results therefore focussed on assessing individual components of control programmes and the contribution made by each to overall performance of the control programme.
12. The effectiveness of a control programme is not simply a function of the level of sampling and testing undertaken, but is described by a combination of the sources of uncertainty introduced by sampling (primary sample through to laboratory working sample), the number of samples taken, the limit of detection of analytical tests, and decisions taken with respect to labelling and enforcement (which currently varies across MS). MS can adjust each component of the control programme to increase or decrease the stringency of control.
13. The proportion of seeds sampled should be placed in the context of the underlying strategy for the sampling programme, i.e. whether it is risk-based or not. Only programmes in which 100% of seeds are tested exert complete control, even in the absence of other information on which to base risk assessments. However, measurement uncertainty exerts an influence such that the true level of GMO in a sample may be higher than the test result, which may sometimes lead to incorrect labelling decisions. Within a risk-based programme, the overall operating characteristics of a control programme will depend on the MS responding appropriately to risk, i.e. by increasing the level of sampling from 'risky' sources. As the proportion of lots sampled becomes smaller, the number of results that must be examined before a positive result is observed increases, and the likelihood that incorrect decisions will be made also increases.
14. At present, the difference in the acceptance of levels of GMO and the proportion of lots tested is contributing most to differences in how their programmes perform in controlling the AP of GMO in conventional seed lots being placed on the market.
15. An assessment was made of the distribution of AP of GMO in imported maize seeds using additional data provided by an MS. Results of this analysis estimate that if no control is undertaken, 99% of lots will contain less than 0.24% GMO DNA, whereas if 100% of lots are tested with a threshold of 0.1% applied, then 99% of lots will contain less than 0.02% GMO DNA.

16. This survey has provided the first framework for collating key data on MS programmes for monitoring and control of AP of GMO in conventional seeds, and a substantial amount of data have been gathered. Examining the data has enabled us to identify the key elements that contribute to the performance of control programmes, and to recognise that MS can manipulate the performance of their control programme by changing these elements. We have good information on how control plans perform, but to get a reliable estimate of how much AP of GMO is in accepted seed lots on an MS basis, more detailed information is needed on observations of AP of GMO in seed lots that have been tested.
17. This data creates the opportunity for an ongoing data-informed and more collaborative EU-wide approach to monitoring AP of GMO. Currently each MS develops their own strategy for monitoring AP of GMO and this is appropriate to ensure their national requirements are met. But, having access to EU-wide data must be of value to individual MS to assist decision-making, for example whether more / less testing should be undertaken to meet national requirements.
18. GM testing of seeds is a relatively new area within which MS are operating. Understanding of issues surrounding sampling and testing for GMOs is increasing rapidly within the community; this is particularly so for new MS. The framework developed can be used to provide the basis for rational decision-making with regard to ensuring control programmes are fit for purpose. It can also be utilised at the EU-level to assess how MS control programmes have developed in response to changes in scientific knowledge and changing risks, and to ensure that they remain fit for purpose.
19. Based on our findings through the survey of MS CAs and our modelling, we suggest the following package of potential actions for an interim period (e.g. 3 years) to work towards sharing the burden of sampling and testing across MS, reduce remaining uncertainties and assist implementation of EU policy on GMOs in seed:
 - Agreeing data requirements and format based on the modelling and evaluation identified in this report
 - Seeking a consensus on a risk-based approach to sampling of lots and designing an EU-wide sampling programme to achieve this
 - Exchanging data from the sampling and testing programme on a timely basis through a secure web-enabled central information system
 - At the end of the interim period, undertaking further analysis and modelling to provide an evidence-based rationale for future measures.

Taken together, we believe these actions would continue to provide protection against AP of GMO in seed lots imported into and traded in the EU, maintain public confidence, protect against future risk (e.g. any increase in AP of GM in imported or EU-grown seed lots) and reduce the burden of sampling and testing on individual member states.

July 27th 2007

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APPENDIX A: QUESTIONNAIRE

SECTION 1: Introductory questions

1.1 Name:

1.2 Department/organisation:

1.3 Role within department/organisation:

Answering this question is optional.

1.4 Contact telephone no:

1.5 E-mail address:

1.6 Are you a competent authority (CA) or the CA's nominated agent/ representative?

Competent authority

CA's nominated agent

1.7 If you are CA's nominated agent/representative, what is your status:

Government agency within same department as CA

Government agency within different department as CA

Private company

University

Other

Answering this question is optional.

1.8 Does your country have a programme to inspect and control adventitious GM presence (AGMP) in conventional seeds?

Yes

No

No, but AGMP is monitored by another route

1.8a Please provide details of this activity if possible. Answering this question is optional.

1.9 If **no**, have you ever conducted any sampling and testing of seeds on an ad hoc basis?

Yes

No

Answering this question is optional.

1.9a Would you be prepared to make the data gathered available for this survey?

Yes

No

If **yes**, you will be contacted shortly, please state your preferred method of contact and confirm the correct telephone number or email address

1.10 Which crops are included in the programme?

Maize

Oilseed rape

Soya

Other crops (please provide further information)

No inspection and control programme

1.10a Other crops included in your programme. Answering this question is optional.

1.11 Is your inspection and control programme carried out specifically to ensure compliance with:

EU Directive 2001/18/EC

Regulation 1829/2003

Other (please specify)

Answering this question is optional.

1.11a Other - please state why your inspection and control programme is carried out.

Answering this question is optional.

1.12 When did the inspection and control programme begin (dd/mm/yyyy)?

Answering this question is optional.

SECTION 2: Inspection and control programmes for AGMP

2.1 In your inspection and control programme, do you:

- Sample seed lots yourselves and test them (or commission tests) for the presence of AGMP?
- Request seed companies to provide samples of seed lots they are marketing in your country and then test these samples (or commission tests) for the presence of AGMP?
- Require seed companies to sample and test the seed lots they are marketing in your country and provide the CA with the results?
- No sampling and/or testing is performed
- Request companies to provide evidence of how they manage the risks of AGMP in the seed lots they market in your country?
- Other
- No inspection and control programme

If other, please provide details

2.2 Is your inspection and control programme the same each year?

2.3 If **no**, what determines what you will monitor? Answering this question is optional.

2.3a Other (please specify). Answering this question is optional.

SECTION 3: Sampling and testing seeds for GMO inspection and control

3.1 Do you sample and test seeds that are PRODUCED in your country?

- Yes
- No
-

No sampling and testing programme

- 3.2 If your answer to 3.1 is **yes**, for MAIZE what % of the home-produced certified seed lots were sampled and tested for the presence of GMOs in 2005?
- 3.3 If your answer to 3.1 is **yes**, for MAIZE what % of the home-produced certified seed lots, were sampled and tested for the presence of GMOs in 2006?
- 3.4 And what % of home-produced 'as-grown' (i.e. harvested seeds prior to forming into lots) MAIZE seeds were sampled and tested for the presence of GMOs in 2005?
- 3.5 And what % of home-produced 'as-grown' (i.e. harvested seeds prior to forming into lots) MAIZE seeds were sampled and tested for the presence of GMOs in 2006?
- 3.6 If your answer to 3.1 is **yes**, for OILSEED RAPE what % of the home-produced certified seed lots were sampled and tested for the presence of GMOs in 2005?
- 3.7 If your answer to 3.1 is **yes**, for OILSEED RAPE what % of the home-produced certified seed lots were sampled and tested for the presence of GMOs in 2006?
- 3.8 And what % of home-produced 'as-grown' (i.e. harvested seeds prior to forming into lots) OILSEED RAPE seeds were sampled and tested for the presence of GMOs in 2005?
- 3.9 And what % of home-produced 'as-grown' (i.e. harvested seeds prior to forming into lots) OILSEED RAPE seeds were sampled and tested for the presence of GMOs in 2006?
- 3.10 If your answer to 3.1 is **yes**, for SOYA what % of the home-produced certified seed lots were sampled and tested for the presence of GMOs in 2005?
- 3.11 If your answer to 3.1 is **yes**, for SOYA what % of the home-produced certified seed lots were sampled and tested for the presence of GMOs in 2006?
- 3.12 And what % of home-produced 'as-grown' (i.e. harvested seeds prior to forming into lots) SOYA seeds were sampled and tested for the presence of GMOs in 2005?
- 3.13 And what % of home-produced 'as-grown' (i.e. harvested seeds prior to forming into lots) SOYA seeds were sampled and tested for the presence of GMOs in 2006?

3.14 Do you sample and test seeds that are IMPORTED into your country?

- Yes
- No
- No sampling and testing programme

3.15 If your answer to 3.14 is **yes**, for MAIZE what % of imported certified seed lots were sampled and tested for the presence of GMOs in 2005?

3.16 If your answer to 3.14 is **yes**, for MAIZE what % of imported certified seed lots were sampled and tested for the presence of GMOs in 2006?

3.17 And what % of imported 'as-grown' (i.e. harvested seeds prior to forming into lots) MAIZE seeds were sampled and tested for the presence of GMOs in 2005?

3.18 And what % of imported 'as-grown' (i.e. harvested seeds prior to forming into lots) MAIZE seeds were sampled and tested for the presence of GMOs in 2006?

3.19 If your answer to 3.14 is **yes**, for OILSEED RAPE what % of imported certified seed lots were sampled and tested for the presence of GMOs in 2005?

3.20 If your answer to 3.14 is **yes**, for OILSEED RAPE what % of imported certified seed lots were sampled and tested for the presence of GMOs in 2006?

3.21 And what % of imported 'as-grown' (i.e. harvested seeds prior to forming into lots) OILSEED RAPE seeds were sampled and tested for the presence of GMOs in 2005?

3.22 And what % of imported 'as-grown' (i.e. harvested seeds prior to forming into lots) OILSEED RAPE seeds were sampled and tested for the presence of GMOs in 2006?

3.23 If your answer to 3.14 is **yes**, for SOYA what % of imported certified seed lots were sampled and tested for the presence of GMOs in 2005?

3.24 If your answer to 3.14 is **yes**, for SOYA what % of imported certified seed lots were sampled and tested for the presence of GMOs in 2006?

3.25 And what % of imported 'as-grown' (i.e. harvested seeds prior to forming into lots) SOYA seeds were sampled and tested for the presence of GMOs in 2005?

3.26 And what % of imported 'as-grown' (i.e. harvested seeds prior to forming into lots) SOYA seeds were sampled and tested for the presence of GMOs in 2006?

3.27 Do you sample and test:

- seeds imported from all countries including those within EU?
- seeds imported from countries considered to be high risk of AGMP
- No sampling and testing programme

3.27a Please list the top 5 countries you have identified as being high risk for AGMP.

Answering this question is optional.

3.28 Do you require seed to be sampled in accordance with internationally recognised standards? (for example ISTA)

- Yes
- No
- No sampling and testing programme

3.28a If yes, please list your accepted sampling standards:

SECTION 4: TESTING FOR THE PRESENCE OF GMOS

4.1 Is all seed that is sampled for the GMO inspection programme actually tested for the presence of GMOs?

- Yes
- No
- No inspection and control programme

4.2 If no, what % of sampled seed is tested and why? Answering this question is optional.

4.3 Do you specify the type of testing that should be carried out?

Yes

No

4.3a If so, do you provide guidance on your requirements? Answering this question is optional.

Yes

No

4.4 Do your testing requirements vary between crops? Answering this question is optional.

Yes

No

4.4a If **yes**, please provide details. Answering this question is optional.

4.5 Analytical testing, do you:

Carry out the testing yourself

Use a nominated laboratory

Not applicable

4.6 If you use a nominated laboratory/ies, please provide details if you are able to. Answering this question is optional.

4.7 Do you allow seed companies to select their own testing laboratory? Answering this question is optional.

Yes

No

4.7a If no, do you provide a list of approved laboratories. Answering this question is optional.

Yes

No

4.7b Please provide details of these laboratories if you are able to. Answering this question is optional.

4.8 Do you carry out any testing to confirm the seed companies' results?

Yes

No

4.8a If **yes**, do your results always agree with the companies'? Answering this question is optional.

Yes

No

4.8b If **no**, how often does this happen and what action do you take? Answering this question is optional.

4.9 Do you require analytical tests to be conducted according to any international standards, e.g. AFNOR, ISTA?

Yes

No

4.9a If **yes**, please state which standard/s you will accept

4.10 Do you require molecular-based testing?

Yes

No

4.11 Will you accept results from protein-based tests (e.g. Elisa)?

Yes

- No
- Not applicable

4.12 Do you accept results of junction-spanning PCR tests as evidence of freedom from AGMP?

- Yes
- No
- Not applicable

4.13 Do you require quantification of the levels of GM DNA present?

- Yes
- No

4.14 What unit of measurement do you require?

4.15 What limit of detection do you require for qualitative tests?

4.16 What limit of quantification do you require for quantitative tests?

4.17 How many replicates do you require to be included in tests?

4.18 Do you require evidence of the operating parameters of analytical tests (e.g. standard error)? *Answering this question is optional.*

- Yes
- No

4.18a If yes, please list these and your minimum standards. *Answering this question is optional.*

4.19 How many test results do you examine each year?

- 0

- 1 - 10
- 11 - 50
- 51 - 100
- 101 - 150
- 151 - 200
- > 200

4.20 If you test (or commission tests) yourself, from the list of genetic elements opposite, please tick all that apply as 'essential' in tests for MAIZE:

- CaMV P35S
- Amp
- NptII
- Cry (4.20a)
- EPSPS
- GOX
- PAT
- BAR
- dam
- barnase
- T35S
- NOS
- Additional elements (please specify - 4.20b)
- Not applicable

4.20a Cry variant/s: Answering this question is optional.

4.20b Additional elements: Answering this question is optional.

4.21 If you test/commission tests yourself, from the list of genetic elements opposite, please tick all that apply as 'essential' in tests for OILSEED RAPE:

- FMV P35S
- CaMV P35S
- pNos
- E9 3'
- SsuAra
- TA29
- Amp
- NptII
- barnase
- barstar
- EPSPS
- GOX
- PAT
- BAR
- CaMV T35S
- tNos
- Ocs
- 3'g7
- Additional elements (please specify- 4.21a)
- Not applicable

4.21a Additional elements: Answering this question is optional.

4.22 Please tick all that apply as 'essential' in tests for SOYA:

- CaMV P35S
- GUS
- Amp
- NptII
- EPSPS
- GOX
- PAT
- BAR
- T35S
- NOS
- Additional elements (please specify- 4.22a)
- Not applicable

4.22a Additional elements: Answering this question is optional.

4.23 If you test/commission tests for crops other than maize, OSR and soya, please specify the crops and list the elements that must be tested for each. Answering this question is optional.

4.24 Where seed companies provide test results themselves, do you accept results if any of these 'essential' elements are not included? Answering this question is optional.

- Yes
- No

4.25 Do you conduct (or accept results from) event-specific tests (e.g. Topas 19/2, Hyola, Laurical, T25, Bt11 etc)?

- Yes
- No

Answering this question is optional.

4.25a If yes, please list the specific element tests you conduct (or will accept).

Answering this question is optional.

SECTION 5: Results of GMO testing

5.1 In the period 2001-2006, how many incidents of authorised AGMP have you identified in conventional seeds of MAIZE

5.2 In 2006, in how many of these was AGMP present at <0.1%

5.3 In 2006, in how many of these was AGMP present at >0.1% but <0.3%

5.4 In 2006, in how many of these was AGMP present at >0.3% but <0.5%

5.5 In 2006, in how many of these was AGMP present at >0.5% but <0.9%

5.6 In 2006, in how many of these was AGMP present at >0.9%

5.7 In the period 2001-2006, how many incidents of authorised AGMP have you identified in conventional seeds of OILSEED RAPE

5.8 In 2006, in how many of these was AGMP present at <0.1%

5.9 In 2006, in how many of these was AGMP present at >0.1% but <0.3%

5.10 In 2006, in how many of these was AGMP present at >0.3% but <0.5%

5.11 In 2006, in how many of these was AGMP present at >0.5% but <0.9%

5.12 In 2006, in how many of these was AGMP present at >0.9%

5.13 In the period 2001-2006, how many incidents of authorised AGMP have you identified in conventional seeds of SOYA

5.14 In 2006, in how many of these was AGMP present at <0.1%

5.15 In 2006, in how many of these was AGMP present at >0.1% but <0.3%

5.16 In 2006, in how many of these was AGMP present at >0.3% but <0.5%

5.17 In 2006, in how many of these was AGMP present at >0.5% but <0.9%

5.18 In 2006, in how many of these was AGMP present at >0.9%

5.19 In the period 2001-2006, have you identified authorised AGMP in conventional seeds of other crops?

- Yes
- No

5.20 If yes, for 2006, please list the crops and specify the levels of AGMP identified

5.21 What level of authorised AGMP do you permit to be marketed without labelling in conventional seeds of MAIZE:

- We operate a zero tolerance policy
- Less than 0.1%
- Detection above 0.1% less than 0.3%
- Detection above 0.3% less than 0.5%
- Detection above 0.5% less than 0.9%
- Other

5.21a If other, please specify. Answering this question is optional.

5.22 What level of authorised AGMP do you permit to be marketed without labelling in conventional seeds of OILSEED RAPE:

- We operate a zero tolerance policy
- Less than 0.1%
- Detection above 0.1% less than 0.3%
- Detection above 0.3% less than 0.5%
- Detection above 0.5% less than 0.9%
- Other

5.22a If other, please specify. Answering this question is optional.

5.23 What level of authorised AGMP do you permit to be marketed without labelling in conventional seeds of SOYA:

- We operate a zero tolerance policy
- Less than 0.1%
- Detection above 0.1% less than 0.3%
- Detection above 0.3% less than 0.5%
- Detection above 0.5% less than 0.9%
- Other

5.23a If other, please specify. Answering this question is optional.

5.24 What level of AGMP do you permit to be marketed without labelling in conventional seeds of other crops? Please specify on a crop-by-crop basis.

Answering this question is optional.

5.25 What action do you take when, through your inspection and control programme, authorised AGMP is identified in conventional seed that has not been labelled?

- None if less than 0.1%
- None if less than 0.3%
- None if less than 0.5%
- Withdraw seed from the market
- Publish the findings
- Report to other EU CAs
- Consider pursuing legal action with the owner of the seed
- Other

5.25a If other, please specify. Answering this question is optional.

5.26 In 2004, how many incidents of unauthorised AGMP were identified in seeds of maize?

5.27 In 2005, how many incidents of unauthorised AGMP were identified in seeds of maize?

5.28 In 2006, how many incidents of unauthorised AGMP were identified in seeds of maize?

5.29 Have you ever identified unauthorised AGMP in GM seeds of maize?

Answering this question is optional.

Yes

No

5.29a If yes, please provide details. Answering this question is optional.

5.30 In 2004, how many incidents of unauthorised AGMP were identified in seeds of OILSEED RAPE?

5.31 In 2005, how many incidents of unauthorised AGMP were identified in seeds of OILSEED RAPE?

5.32 In 2006, how many incidents of unauthorised AGMP were identified in seeds of OILSEED RAPE?

5.33 In 2004, how many incidents of unauthorised AGMP were identified in seeds of SOYA?

5.34 In 2005, how many incidents of unauthorised AGMP were identified in seeds of SOYA?

5.35 In 2006, how many incidents of unauthorised AGMP were identified in seeds of SOYA?

5.36 In the period 2001-2006 how many incidents of unauthorised AGMP have been confirmed in seeds of other crops (please list). Answering this question is optional.

5.37 What action do you take if unauthorised AGMP is confirmed? Please tick all that apply

None if less than 0.1%

- None if less than 0.3%
- None if less than 0.5%
- Withdraw seed from the market
- Publish the findings
- Report to other EU CAs
- Consider pursuing legal action with the owner of the seed
- Other

5.37a If other, please specify. Answering this question is optional.

5.38 Do you ever see 'false positive' results? Answering this question is optional.

- Yes
- No

5.39 If yes, how many false positive results were identified in 2006? Answering this question is optional.

5.40 When you get a false positive result do you:

- Re-test
- Ignore if 2 negatives obtained
- Other

Answering this question is optional.

5.40a If other, what action do you take when false positive results are obtained?

Answering this question is optional.

SECTION 6: Seed production

A simple Excel spreadsheet has been emailed to you in which you are asked to provide figures on the amount of seed produced in your country and the amount of seed imported. It is important that you provide as much information as possible for seeds of maize, oilseed rape and soya and return to s.hugo@csf.gov.uk.

If you do not wish to complete the Excel spreadsheet, but can provide the data in an alternative format, we would be pleased to receive this also.

6.1 Will you be returning the completed Excel spreadsheet providing seed production and import figures for your country?

- Yes
- No

6.1a If no, please state why

6.2 Please list the 10 major MAIZE seed producing companies active in your country.

Answering this question is optional.

6.3 Please list the 10 major OILSEED RAPE seed producing companies active in your country. Answering this question is optional.

6.4 Please list the 10 major SOYA seed producing companies active in your country.

Answering this question is optional.

SECTION 7: Additional information

As part of this project we are keen to establish contact with any CA or CA representative who would be able to provide detailed data about the seed testing regime they employ.

This would include providing laboratory sampling details such as number of analytical samples (seed pools), mass of each seed pool ground for analytical testing, mass of ground seed (sub-sample) used for DNA extraction and number of such sub-samples.

If you think you may be able to provide such information please contact Sarah Hugo (s.hugo@csf.gov.uk); Tel: + 44 (0) 1904 462223.

Do you consider it likely that you would be able to provide such information?

Yes

No

Please provide any other information that you think may be relevant. This may be submitted by email if preferred to s.hugo@csl.gov.uk. Answering this question is optional

APPENDIX B: CSL POLICY FOR MAINTAINING DATA INTEGRITY AND SECURITY

Data integrity and security are an essential aspect of database design and management. CSL adopts the following steps as routine:

i) Backup and server policy:

- All servers are backed up every night and the tapes stored in a fireproof safe.
- All servers are subject to a once monthly backup, which is securely stored off site, and a separate once monthly backup, which is stored on site but in a different part of the building, remote from the first on site copy.
- This back-up policy, which is already in place, offers a substantial benefit over many commercial data centres, which will only back up hosted web sites/databases at extra cost.
- All servers operate in an environmentally controlled machine room, complete with automatic fire protection. Entry is proximity card protected and controlled by a central computer remote from the machine room, with access only allowed to key IT personnel.
- All servers and software are covered by maintenance contracts.
- The CSL internet connection now has a built in backup such that if the main service fails, there is now a 30 second automatic dial up on a separate ISDN line. This backup line is connected to a different part of the ISP's network in case of failure at one connection point.
- The database is replicated to a second server such that should the main server fail, the second will take over.

ii) Data security:

- All data will be stored in a secure database, access to which will be limited to designated scheme members and nominated staff at CSL only; all CSL staff will be subject to a confidentiality agreement.