Research project ENV.B.3/ETU/2007/0008

Analysis of field trials management in Member States and prevention of accidental entry into the marketplace

FINAL REPORT

November 2008

Sarah Hugo[1], Jonathan Davey[2], James Blackburn[1] and Belinda Phillipson[1]

[1]Central Science Laboratory
Sand Hutton
York YO41 1LZ, UK

[2]Scottish Agricultural Science Agency
Roddinglaw Road
Edinburgh, EH12 9FJ, UK

CONTENTS

LIST OF APPENDICES

Appendix 1	EU Part B notifications database and instruction manual (MS Excel)
Appendix 2	Questions issued to Member States in the 'Basic survey'
Appendix 3	Screenshots of e-survey
Appendix 4	Questions issued to Competent Authorities in France, Germany, Hungary, The Netherlands, Spain, Sweden and the UK for the detailed survey of MS practices
Appendix 5	Questions issued to EU-wide notifiers that participated in the survey
Appendix 6	Responses to e-survey (MS Excel)
Appendix 7	Responses from Competent Authorities and inspectors in the detailed MS survey
Appendix 8	Responses from MS-based notifiers in the detailed MS survey
Appendix 9	Responses from MS-based field operators in the detailed MS survey
Appendix 10	Responses from EU-wide notifiers
Appendix 11	Literature review
Appendix 12	Data to accompany review "GMO field trials in Europe: assessment of progress against predictions and likely future developments"

ACKNOWLEDGEMENTS

We would like to thank all the individuals in the Member State Competent Authorities of France, Germany, Hungary, The Netherlands, Spain, Sweden and The UK who gave up their time to participate in this study. Similarly, we would like to thank all the GMO inspectors and Member State-based notifiers and their field operators who participated and provided valuable information. We are also very grateful to the notifiers that agreed to take part and provide comments from an EU-wide perspective. Thanks also to the remaining Member State Competent Authorities who participated in the e-survey. We are also grateful to Dr Vasiliki Flari for guidance on expert elicitation and advice on phrasing of questions in the surveys.

CONTACT

If you have any questions about this report please contact:
Sarah Hugo, Central Science Laboratory, Sand Hutton, York, YO41 1LZ, UK.
Tel: + 44 (0) 1904 462223; Fax: + 44 (0) 1904 425250; Email: s.hugo@csl.gov.uk.

EXECUTIVE SUMMARY

1. This project was commissioned to carry out an in-depth analysis of field trials of genetically modified (GM) crops held in the Member States (MS) of the European Union (EU) under Part B of Council Directive 2001/18/EC ('the Directive') on the deliberate release of genetically modified organisms (GMOs), since the Directive came into force in October 2002. The principal aim of this legislation is to protect human health and the environment. Part B of the Directive covers the issuing of consents for the deliberate release of GMOs for any other purpose than placing on the market, for example for research and development. The aim of this research was to verify that the MS are adhering to the provisions of the Directive with respect to Part B releases of GM plants, and that consent holders are meeting their obligations in accordance with the conditions of consents that have been issued.

2. The principal aims of this project were:
   i) To get an overview of concrete measures in place in the EU Member States for the management of field trials, including inspection and control measures by the relevant responsible bodies;
   ii) To assess the effectiveness of these management measures in the prevention of out-crossing from GM crops and other means of GMOs accidentally entering the market place;
   iii) To identify gaps and areas for additional guidance or follow-up work as well as examples of best practice.

3. The report outlines the roles and responsibilities of individuals that are involved in the notification, authorisation and conducting of Part B GMO field trials, and provides detail on how the field trials are executed in practice and where the critical control points lie. Whilst the focus of the project was on field trial management, implementation and authorisation procedures were also examined. Differences in approach towards implementation of the Directive and subsequent handling of authorisations were revealed; these are discussed in the report and where they appear to be having a significant impact on the operation of the Directive, recommendations are made that these should be addressed.

4. The work was broken down into four key modules. One of these was aimed at gathering basic information from all the MS, the second was designed to gather very detailed information from seven selected MS (France, Germany, Hungary, Spain, Sweden, the Netherlands and the UK), and in the third module data was gathered from a number of notifiers that have undertaken field trials in more than one MS. There was also an information-gathering module in which a database of EU Part B notifications was developed, and a review of current and potential future releases of GMOs in Europe was undertaken. Crops of particular interest were maize, oilseed rape, potato, sugar beet and cotton as these have been most widely placed in Part B trials across the EU Member States (although very little information was gathered about trials of cotton). Management practices for these crops in the seven selected MS were reviewed

in detail and attempts were made to make cross-MS comparison where similar field trials have taken place in more than one of these MS. Twenty four of the twenty seven MS responded to the survey and a significant body of information relating to administration and management of Part B field trials was gathered.

5. Analysis of the data held in the GMO notifications database revealed that the number of Part B GMO field trials notified in Europe has gradually increased from a very low level in 2002 when the Directive came into force. Notifications are, however, still below the peak reached in 1997 under Directive 90/220/EC[1] despite the addition of 12 new MS in this time. Since the introduction of Directive 2001/18/EC the number of notifications submitted by large commercial companies has increased fairly dramatically over time, representing around 35% in 2003 to almost 80% of notifications in 2007. Conversely, the number of notifications submitted by research institutes has declined considerably over the same period, from around 50% in 2002 to just 15% in 2007. Likewise, the number of notifications submitted by small/medium-sized enterprises has also decreased, although this number was initially very low. It also emerges that a single crop, maize, now dominates, accounting for almost 58% of GMO field trials. Other prevalent crops in Part B trials are potatoes, at almost 15%, cotton at around 6% and oilseed rape at 3%. The types of crops being placed in trials has also reduced - in the period 1991 to 2001 over 68 different crop types featured in notifications, whereas since 2002 this has fallen to 31. The traits that have been notified are mostly input traits (85%), which provide the plant with an agronomic advantage, such as herbicide tolerance, insect resistance and pathogen resistance. There is also increasing use of stacked events, including multiple herbicide tolerance and multiple insect resistance, providing better protection from insect pests and allowing growers to simplify their crop management practices. Output traits, which enhance the quality of the final GM product, such as modified nutritional status, accounted for just 12% of notifications.

6. This study confirmed that all EU MS have implemented the Directive into national legislation, and have put arrangements in place that appear to be appropriate to manage the notification and authorisation process, and inspection, monitoring and control procedures. We know this to be the case in particular for the seven MS to which detailed visits were undertaken. It was not possible to identify a single MS that could be held up as an example of good practice that other MS could follow. The case-by-case risk assessment principle outlined in the Directive is generally observed, and applications are assessed case-by-case. A number of MS have developed indicative guidelines for management of key crops. Measures adopted by the MS to ensure isolation of the GM crop from sexually compatible crops and/or wild relatives are broadly comparable, as are measures for ensuring the GMO is not dispersed and is disposed of appropriately, but there are differences in detail, in particular for isolation distances. On the whole, measures for prevention of out-crossing from GM crops and other means of accidentally entering the market place, tend to be precautionary. Detailed information on this is provided in the report and in Appendix 7.

[1] Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms.

7. The CAs reported that no GM material from a Part B field trial has entered the market place since the Directive was implemented in 2002. A total of twelve non-compliances were reported, of these 11 were classed as technical breaches of consent (written warnings were issued for two of these), and 1 was a written warning for a more serious non-compliance. We must assume this is an accurate representation of incidents to date. This evidence suggests that the legislation is working effectively. Reflecting on the systems put in place by the CAs and inspectors, and accepting that fairly limited information has been gathered for 17 of the MS, there are no obvious reasons to suggest these systems are not fit for purpose at present or in the future should they have to deal with larger numbers of trials or different types of traits, although it seems unlikely that the MS will see this happening in the short term.

8. A number of countries have a long history of hosting GM trials and therefore have experience that can be called upon. The management practices of Australia, Canada, New Zealand and the USA were reviewed and found to be broadly equivalent to practice that has been adopted in European GMO field trials. They are all designed to address, on a case-by-case basis, risks that have been identified in an environmental risk assessment and are implemented through the terms and conditions of the release with the aim of preventing or minimising dispersal from the release site and ensuring the GMO does not persist in the environment beyond the period of the release.

9. The number and type of breaches of GMO field trial legislation that occurred in Australia, Canada, New Zealand and the USA were also reviewed; two cases were found where GM material that had been authorised for released under experimental field trial conditions entered the marketplace. These cases were LLRICE601 and LLRICE604 in the USA, and Roundup Ready cotton in Australia. In relation to the large number of releases that have been approved in Australia, Canada, New Zealand and the USA, the number of reported incidents has been low, which makes an analysis of susceptible points in the GM trialling cycle difficult to determine. In Australia and to a lesser extent the USA, incidents relating to volunteer management appeared to be more frequent. This might suggest for certain crops which are grown in climates where volunteers can over-winter, or where secondary dormancy of seed is a feature of a plant's lifecycle, vigilance during post-trial monitoring should be a prominent feature of GM research trial management. The seven MS that were interviewed in the detailed survey identified post trial monitoring as a critical control point and make management in this phase a requirement of authorisations.

10. Appointed inspectors in the EU MS follow broadly similar approaches to official control of GMO field trials and ensuring that consent holders manage their trials to ensure compliance with the consents issued. The level of inspection is generally high and is comparable across the MS, although different inspection practices are employed. There is recognition of the importance of good post-trial monitoring and management.

11. In Australia, components of quality assurance systems have been incorporated into deliberate release legislation, for example there is a statutory requirement for notifiers who wish to conduct GMO field trials to be accredited organisations. In the USA, voluntary quality management systems are being promoted by the regulator and by a biotechnology industry representative organisation – these are seen as additional tools to assist notifiers develop sound management practice and ensure compliance with GM field trial regulations and conditions. In the EU it is possible that wider implementation of quality assurance measures by inspectors and notifiers, where they have not already done so, would augment and strengthen the current inspection and control system.

12. The notifiers that contributed to the study were found to have implemented good measures for management of field trials, and to have effective communication systems in place with their nominated field operators. The need for compliance was recognised and well understood by both the notifiers and the field operators. Because of the way the research was conducted, a fairly small sample of notifiers was interviewed. While this is symptomatic of the number and types of field trials currently taking place, the sample is not fully representative of the types of notifiers operating in Europe. We have therefore recommended that the questions should be addressed to a number of universities, research institutes and small and medium sized enterprises (SMEs) to fill this gap in the data.

13. Notifiers reported significant levels of threats and vandalism by protesters at growers' premises: almost 28% of field trials in the seven MS that participated in the detailed study had suffered vandalism that resulted in the termination of some of the trials under those consents. Threats and vandalism by protesters appear to have played a key part in reducing the numbers of trials and possibly the types of organisations that are able to hold trials. The requirement to publish the location of field trials was widely cited as a major contributing factor to the occurrence of these actions. We have recommended that the link between the two should be reviewed in detail with a view to providing guidance to the Member States on this issue.

14. In the course of interviews with notifiers, a number of other issues were identified in connection with implementation and authorisation procedures that can have a significant impact on their ability to execute a GMO field trial. For example, in some Member States time delays can be incurred in assessment of notifications such that the 120 days stipulated in the Directive is, in some cases, not being met. Other examples given were in connection with the amount and level of detail of information that was requested in Part B notifications, and difficulties in obtaining consent to hold a trial when there appeared to be no scientific objections. It was beyond the resources of this project to research and substantiate all of the comments made by the notifiers. In recognition of this, these issues have been referred to the European Commission with the recommendation that they are investigated and addressed.

15. Comparison with a review undertaken for the European Commission (DG Agriculture) by Lheureux *et al*. (2003) suggests that the development of GM crops in Europe is about 5 years behind what was predicted by Lheureux *et al*.

The so-called ‘second’ and ‘third generation’ GM crops that were expected to lead to improved food quality, deliver new medicines, contribute towards preventing disease/reduce health risks, and to improve interactions between the crop and the environment have not moved beyond small scale trials, and many of the predictions made by Lheureux *et al*. such as herbicide tolerant wheat, virus-resistant sugar beet, modified fatty acid in soybeans and oilseed rape, plus many other crop/trait combinations appear to have come to a standstill, at least in terms of EU trials. This is explored in detail in a literature review in Appendix 11, together with longer-term predictions based on current activity outside of Europe.

16. In the USA and Canada, where GM technology has found greater acceptance than Europe, maize, soybean and cotton have been the major focus of GM field trial activity. Herbicide tolerance has been the single most utilised trait, but product quality traits have also accounted for the same number of trials as insect tolerance; product quality traits include, for example, altered amino acid, protein and oil composition. Agronomic properties such as drought resistance and yield increase also featured highly. There have also been noticeable increases in the number of genes that have been inserted (‘stacked’) into GMOs, in particular for maize, soybean and cotton and as a result more stacked genes are being seen in commercial material. A review of the multi-national company’s pipelines suggests stacking will become a common feature of many more transgenic agricultural crops in the future, which will inevitably bring complications for detection and labelling in Europe.

17. In parallel with the expansion of new GM crops and new GM traits there is the ongoing development of new techniques for introducing desired characteristics into plants. These novel plant modification techniques are being developed to speed up the plant breeding process, and to enhance the precision and specificity of the induction or selection of desired properties. Recent novel approaches to the production of plants with modified characteristics include electroporation, targeted mutagenesis techniques, and epigenetic techniques. With the advancement of these techniques the distinction between genetic modification and other plant biotechnology methods is becoming increasingly narrow, and as the technology advances there is the possibility that scientific developments may exceed the legislative frameworks that have been put in place to manage them. In order to bring clarity to these discussions, and to harmonise the approach of Member States, the European Commission has recently established a Working Group to evaluate a list of new techniques for which it is unclear whether they result in genetic modification. It is anticipated that the Working Group will report in 2009.

18. This study provides an overview of the measures in place in the EU Member States for the management of Part B GMO field trials, including implementation and administrative procedures, approaches to risk assessment and inspection and control of deliberate releases. In particular the measures in place in seven key MS have been examined in detail through discussion with all bodies involved in the undertaking of field trials, namely the Competent Authorities and their inspectors, and notifiers and their field operators. Based on the evidence provided, we believe it is reasonable to conclude that the EU Member States

and the notifiers conducting GMO field trials are acting responsibly to ensure that GM material placed in Part B field trials will not accidentally enter the market place. Looking to the future, providing inspection and control and good communications between all parties involved in the field trials are maintained and reviewed regularly, there is no reason to believe that the systems currently in place in the MS should not be sufficiently robust to deal with, for example, increased numbers of releases or more complex GMO traits, and to continue to be fit for purpose.

RECOMMENDATIONS

Based on the findings in this study, and on the gap analysis discussed in section 10 of the report, a number of recommendations have been made. Although the focus of this work was on field trial management, implementation and authorisation procedures were also examined; recommendations are, therefore, divided into these two groups.

a) GM trial management issues

To the European Commission:

1. The relationship between public notification, provision of information on the location of Part B trials and vandalism in research trials throughout the Community should be examined. In the light of legal considerations on site locations, the Commission should consider providing guidance to Member States as to how sufficient information can be provided to the public (and legitimate interested parties) in line with the spirit of Article 9.2 and Annex III B E1, without jeopardising the security of trial operators and to minimise access to sites for unlawful activities (i.e. site vandalism and damage to farm machinery etc.).

2. While recognising that the case-by-case risk assessment principle must be upheld, the European Commission could consider developing science-based indicative guidance for management of trials of GM crops in Europe based on crop biology, published research and previous experience. This guidance could discuss issues that might be expected to arise with specific crops and measures for dealing with these, critical control points in the trial process and options for disposal of GM wastes from trials. In particular this would act as a reference point for newer MS and form the basis of their case-by-case risk assessments. It is envisaged that this could be undertaken as a cross-MS working Group and could build on the work that has already been done by a number of the MS. The aim of the project would be to achieve greater parity across the MS and possibly reduce the bottlenecks that are associated with assessment of notifications. The beneficiaries of this would be CAs and inspectors in MS with limited experience of field trials, also new notifiers that are not part of corporate organisations, in particular universities, research institutes and SMEs.

3. The Commission should consider whether it would be feasible to introduce differentiated procedures for reducing the stringency of management measures placed on a GMO field trial as increasing familiarity with a specific event in a certain crop is gained. This would support the trialling of GM varieties of well-characterised GMOs as they are developed for commercial release, and for which a significant body of data has been generated. This could also take into consideration options for disposal of GMO material that is authorised for food/feed use. The Netherlands adopts these principles.

4. In order to provide a fully representative picture of the management of Part B trials by notifiers, the Commission should undertake a survey of a selection of universities, research institutes and SMEs that currently hold consent(s) to undertake a Part B trial. This gap in the data is symptomatic of the types of

companies undertaking Part B trials at present, however other universities and smaller companies that could be approached to participate are represented in the EU notifications database.

To Competent authorities and inspectors:

1. Inspectors form a critical link between the CA, the notifier and the field operator and are an essential part in ensuring compliance is met, in advising how compliance can be met, and how to deal with potential non-compliance issues that arise. CAs and inspectors should consider implementing quality management systems to underpin and augment the practices of the inspectors to ensure consistency and an analytical, risk-based approach to the work. Similarly, and in order to encourage self-regulation in the notifiers, inspectorates should divide their inspection activities between practices that determine whether the notifier is complying with the practical conditions of a consent (i.e. inspection) and the notifiers' management and/or administrative practice. In particular, inspectors and CAs should ensure that all stages of the GMO field trial process are included in the inspection/audit process, including storage and disposal of GM material.

2. In order to provide a high level of assurance that the GMOs that are being released in field trials are only those that are approved, and that no unauthorised adventitious GMOs are released, CAs and inspectors should review their approach to ensuring notifiers are meeting their duty of care obligations, and consider whether this aspect of their current inspection practice could be reinforced.

3. To promote greater awareness and understanding of the control measures that are undertaken by the MS for Part B GMO releases, CAs and inspectors should review their policy on publication of inspection practices and reports, and consider publishing reports of these activities.

To inspectors and notifiers

1. Vigilance in the post trial monitoring phase of GMO field trials is an essential step in ensuring that material does not enter the food/feed chain. The reviews of field trials for cross-comparison purposes (section 6.4) and of GMO field trial management in third countries (Section 9) highlighted the importance of post trial management, in particular for the control of volunteer populations of the GM plants. In Australia, and to a lesser extent the USA, the majority of non-compliance incidents were reported for this phase of trial management. Notifiers and their field operators should ensure that monitoring and volunteer management continues at all former deliberate release sites until the Competent Authority agrees that, based on monitoring records, the trial can be terminated. Inspectors should ensure that post-trial monitoring inspections are scheduled at appropriate times in the season to ensure notifiers control volunteers and observe subsequent cropping restrictions at their former Part B deliberate release sites.

To notifiers

1. The notifiers interviewed had established procedures in place for running GMO field trials and for meeting the compliance requirements for their consents.

However, specific questions about quality assurance within the companies, and in particular within the management of GMO field trials were not asked. It is likely that many of the large notifiers operate under an overarching quality assurance scheme that is in place across the company. Where this is not the case, we would recommend that all notifiers adopt a suitable quality management system to support self-regulation, transparency and traceability of all GMO-related activities.

2. In order to provide CAs and inspectors with a high level of assurance that the GMOs that are being released in field trials are only those that are approved, and that no adventitious GMOs are released, notifiers should review their approach to meeting their duty of care obligations and ensure they are robust. They should consider what information they would provide to CAs/inspectors to demonstrate this if called upon to do so.

b) Implementation and authorisation issues

To the European Commission:

1. The Commission should explore how national GMO legislation can be amended to ensure it is in line with the Directive, for example, where national legislation automatically excludes the deliberate release of certain crops without a risk assessment, or automatically establishes an exclusion zone around protected sites. Similarly, the Commission should discuss with Member States whether it is permissible under the Directive for national legislation to automatically exclude the transformation and subsequent release of naturally occurring plant species within a Member State's territory, or prohibit hybridisation between GMOs and sexually compatible naturally occurring species.

2. In order to explore in depth the rejection of notifications, the consistency of requests for science-based information made in Part B dossiers in relation to the stage of the development of a GMO, and the appropriateness of isolation distances used in GM field trials across the Community, the Commission should consider setting up an *ad hoc* working group of independent GMO risk assessment experts. As part of its remit, the working group would explore the extent to which the principal reason for refusing a notification to release a GMO is that the risk assessment suggests it would be detrimental to either human health or the environment to proceed with a release, and that risk management measures could not adequately address these risks.

3. In MS where issuing of consents is delayed beyond the 120 days outlined by the Directive, the Commission should enter into dialogue with the CAs and discuss whether there are ways that they can ensure the 120 days deadline can be met. The Commission should also remind all CAs of their responsibility to respond to any notifications that are received and to establish, and maintain, helpful lines of communication with the notifier.

To Competent authorities:

1. Competent Authorities should be aware of their responsibility to respond to any notifications for a Part B GMO release that are received, and to establish and maintain, helpful lines of communication with the notifier.

To the European Commission, Competent Authorities and Notifiers

1. Whilst this project focused on field trial management issues, it also revealed differences in approach towards implementation of the Directive, processing of applications and assessment of applications, which, if confirmed and acknowledged, should be reviewed. There were time and resource constraints to gathering in-depth evidence to substantiate all the comments that were made, particularly by the notifiers, during the course of this project. We recommend, therefore, that MS are invited to comment on this report, particularly those MS that are cited in the report, as a prelude to addressing the issues raised and facilitating a common methodology and application of risk assessment for Part B GMO trials throughout the European Union. One approach might be for the Commission and CAs to explore the possibility of establishing an independent body through which communication could be facilitated between notifiers, CAs and the Commission. This would enable time-sensitive review and resolution of misunderstandings between CAs and notifiers regarding, for example, what one party considers to be unreasonable requests for additional information, or where the reasons for refusal to authorise a Part B release are unclear when the assessment of risks is low and independent scientific evaluation of a notification is positive.

1. INTRODUCTION

1.1 BACKGROUND

1.1.1 Legislative context

Release of genetically modified organisms in the EU

In the Member States (MS) of the European Union (EU) the deliberate release into the environment of all genetically modified organisms (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 of the deliberate release and marketing of GMOs; these are EU Council Directive 2001/18/EC[2] on the deliberate release into the environment of GMOs, and Regulation (EC) No. 1829/2003 on GM food and feed. The principal aims of the legislation are to protect human health and the environment and ensure the free movement of safe and healthy genetically modified products in the EU. Directive 2001/18/EC lays down requirements for the experimental release of GMOs in field trials.

Directive 2001/18/EC: a framework for the deliberate release of GMOs

Directive 2001/18/EC, hereafter referred to as 'the Directive', states that the deliberate release of GMOs at the research stage is in most cases a necessary step in the development of new products derived from or containing GMOs, and that the introduction of a GMO into the environment should be carried out according to a step-by-step principle such that the containment of GMOs is reduced as the scale of release is gradually increased. Each step must be evaluated with respect to risks to human health and the environment, and the absence of adverse risks/effects should be established before moving to the next step. No GMOs intended for commercial release (as the GMO or in products) can be considered for placing on the market without first having been subjected to satisfactory field testing at the research and development phase in ecosystems which could be affected by their use.

The Directive provides a framework within which this controlled assessment of the characteristics of all GMOs must be undertaken. Any person wishing to conduct field trials of a GMO must do so under 'Part B' of the Directive ('Deliberate release of GMOs for any other purpose than for placing on the market'). When seeking authorisation under Part B, detailed information must be provided about the GMO and the trial, in particular with regard to assessment of potential environmental risks and their management. Applications made under Part B do not necessarily need to be in preparation for commercial releases - trials for pure research, development, demonstration and biosafety/risk assessment purposes may also be undertaken.

1.1.2 Deliberate release trials of GMOs across the EU Member States

Any person seeking to release a GMO for commercial cultivation in the EU should conduct a reasonable number of trials in a range of environments across the EU to gather evidence of the potential environmental impacts of that particular GMO. As a prerequisite to market approval, field trials are also intended to provide essential

[2] Which came into force on 17th April 2001, repealing Council Directive 90/220EEC on the deliberate release into the environment of genetically modified organisms (http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32001L0018&model=guichett)

information on the stability of inserted genes and the characteristics of the GM crop relative to the conventional one, for example with respect to growth characteristics.

One of the key requirements of the Directive is for all MS to ensure that material derived from GMOs released under a Part B authorisation is not placed on the market. Member States must, therefore, put arrangements in place to address this. The Directive is implemented across the EU through national legislation and each MS puts in place a regime that is best suited to national government and structures, local environments and agriculture. The same trial may, therefore, take place in a number of different MS and be managed quite differently in each.

Since the Directive repealed Directive 90/220/EEC in October 2002, more than 450 Part B applications ('notifications') have been received by Member States; the crop types and nature of the trials carried out in each MS are published by the European Commission on the website of the Joint Research Centre (JRC)[3]. Tables 1.1 and 1.2 below give a summary of notifications received since October 2002 by crop (table 1.1) and by type of trial (table 1.2). These figures do not give a wholly accurate picture of trials that have taken place because a notification may be for trials to be carried out in multiple locations in any one year, or over a number of years, or the trial may not have gone ahead, or may have been prematurely terminated. In a global context these trials represent a small proportion of the GMO deliberate release trials being conducted worldwide.

Table 1.1: Summary of Part B notifications received under Directive 2001/18/EC (as assessed up to 31 March 2008)

Crop	Number of notifications	% of EU notifications
Maize	264	57.9
Potato	66	14.5
Cotton	24	5.3
Rice	21	4.6
Oilseed rape	14	3.1
Fruit	12	2.6
Wheat	8	1.8
Beet	7	1.5
Vegetables	8	1.8
Legumes (incl. soybean)	6	1.3
Forestry	6	1.3
Solanum spp.	6	1.3
Arabidopsis	4	<1.0
Tobacco	3	<1.0
Linseed/flax	3	<1.0
Barley	2	<1.0
Grass	2	<1.0
Total notifications received	456*	

* Does not include notifications withdrawn by the notifier

[3] http://gmoinfo.jrc.it/

Table 1.2: Summary of types of GMO field trials notified under Directive 2001/18/EC since October 2002 (as assessed up to 31 March 2008)

Type of trial	Number of notifications	% of EU notifications
Types of traits:		
Stacked herbicide tolerance / insect resistance	170	44.0
Herbicide tolerance	101	26.2
Pathogen (fungal or viral or bacterial) resistance	35	9.1
Insect resistance	33	8.5
Altered development (e.g. flowering prevention)	13	3.4
Abiotic stress (drought or salinity) tolerance	9	2.3
Other	8	2.1
Medical/veterinary use (e.g. drug or antibody production)	6	1.6
Modified environmental interactions	5	1.3
Modified consumer properties (e.g. enhanced fruit sweetness)	3	0.8
Industrial/chemical products	3	0.8
Types of trial:		
Agronomic assessment	253	41.9
Pesticide toxicology / efficacy assessment	89	14.7
Variety registration	79	13.1
National listing and variety trials	79	13.1
Ecological/environmental assessment	72	11.9
Analysis of composition	26	4.3
Other	4	0.7
Herbicide/pesticide registration or assessment	2	0.3

The Directive requires all MS to establish a public register providing details of the location in which Part B releases will take place; most Competent Authorities (CAs) for the Directive may provide details on their websites about the authorisation procedures in place, field trials undertaken, and reports of any incidents that arose in connection with the trial.

1.1.3 Potential adverse effects of deliberate release field trials

The Directive requires applicants ('notifiers') to consider the risks associated with the GMO to be released, including the likelihood of gene flow, and present appropriate measures for limiting such events. These measures may include spatial isolation from compatible crops, use of physical barriers to limit gene flow or act as a sink for GM pollen and/or the use of temporal isolation to ensure trial material is not flowering at the same time as commercial plantings. The Competent Authority (CA) will assess these proposals and if consent for the release is given, additional measures to prevent gene flow may also be specified. Consents will also include requirements for management of material removed from the trials, to ensure harvested or waste material does not enter the food or feed chain. Applicants for a Part B release are not required to provide details of an event-specific test for the GMO to be released, but are required to demonstrate how they exercise their duty of care with respect to releasing only the GMO that is covered by the consent, i.e. that they take all steps reasonably practicable to prevent the adventitious presence of an unauthorised GMO in the planting material. It is the responsibility of the CA's nominated regulatory body

to monitor compliance with consent conditions and to request appropriate action where non-compliance is identified.

If the containment measures applied are inadequate for the crop (or trait) in question, or are not applied in accordance with requirements, there may be a risk that nearby seed and/or commodity crops will become contaminated with the Part B GMO. This adventitious GM presence will only be identified if the affected crop/seed/product is GM-tested and the contaminating GMO is present at or above the limit of detection of the analytical test. If these criteria are not met, it is likely that accidental entry into the marketplace will occur. A contamination of this nature can have particularly far-reaching consequences if it enters early breeding material and goes unnoticed through many stages of seed multiplication.

Published incidents

In recent years there have been a small number of high profile reports of contamination of commercial non-GM seeds and/or crops with unauthorised GM events, the most widely publicised of these are the Bt10/Bt11 maize seed mix-up and rice seed containing an unauthorised event LLRice 601[4], both of which occurred in the USA. These incidents have had world wide impacts. In 2006, GM herbicide tolerant *Agrostis stolonifera* (creeping bentgrass) was found to have escaped from an experimental site in Oregon, USA, and the GM trait had been transferred to various grasses up to 3.8 km from the original release site. The GM grass was shown to have spread by pollen-mediated gene flow and by seed movement (Reichman *et al*, 2006).

The cause of the LLRice601 contamination has not been clearly identified, but one explanation is that it occurred as a result of gene flow from a deliberate release field trial to nearby conspecific and/or sexually compatible commercial crop(s). In the case of the Bt10/Bt11 mix-up, tests undertaken in early development stages of the Bt11 crop appear to have been inadequate. To date, incidents of this type have not been reported within the EU suggesting that the 'duty of care' exercised and the management of trials to prevent gene flow and admixture have been successful. Nevertheless, there have been incidents of adventitious GM presence in Part B releases in the EU, for example additional events were found in oilseed rape seed planted in UK farm scale evaluation (FSE) trials in 2002[5], illustrating the fact that failures can occur and robust trials management procedures are essential.

The effective management of deliberate release field trials and careful observation of restrictions imposed to prevent accidental entry into the marketplace by gene flow and/or admixture is clearly of great importance. As the number of GM crops being developed increases worldwide, in particular ones with novel traits coding for example for pharmaceuticals, biologically active proteins or industrial products, it is possible that unauthorised adventitious GM presence will become increasingly more difficult to identify at an early stage, thus increasing the risk of accidental entry into the marketplace.

[4] http://ec.europa.eu/food/dyna/press_rel/press_rel_fs_biotechnology_en.cfm

[5] See 'Supplementary reports' at http://www.gm-inspectorate.gov.uk/reportsPublications/. Note: the FSE trials were authorised under 90/220/EEC.

This research was commissioned to review the approach to management of Part B field trials under the Directive across all the EU Member States. The research was necessary to provide a clear understanding of how each MS manages Part B field trials including receipt of the notification, assessment, issuing of consent, risk management requirements, and monitoring and reporting of compliance with these requirements.

1.2 OBJECTIVES

Key issues

- There have been a number of reports of unauthorised adventitious GM presence in food/feed products entering the market in USA and Japan, with concomitant effects on the European markets. Some of these contaminations are thought to have occurred as a result of deliberate release field trials.
- The number of GM deliberate release field trials is growing worldwide, and increasingly these are likely to include novel traits being developed e.g. for pharmaceuticals, biologically active proteins and industrial markets.
- There are currently 27 Member States within the EU, each of which is free to conduct field trials of GMOs under the regulatory framework and guidelines established by the Directive and as enacted in their territory.
- EU-wide information on best practice, or guidelines on running deliberate release field trials, including post trial monitoring for unanticipated environmental effects is not harmonised and it is likely that approaches to Part B releases differ widely across EU MS.

The objectives of this project are, therefore, to:

1) Carry out an in-depth analysis of ongoing and completed field trials since October 2002, verifying that provisions of the Directive with respect to Part B releases are being adhered to by Member States and that obligations on consent holders are being carried out according to the conditions in the consents:
2) Get an overview of concrete measures in place in the EU Member States for the management of field trials, including inspection and control measures by the relevant responsible bodies;
3) Assess the effectiveness of these management measures in the prevention of out-crossing from GM crops and other means of GMOs accidentally entering the market place;
4) Identify gaps and areas for additional guidance or follow-up work as well as examples of best practice.

The study refers only to trials of genetically modified plants. The main focus of the study was trials of GM maize, oilseed rape, potato, sugar beet and cotton crops.

2. GMO DATABASE

To underpin much of the work in this study a database was developed containing details of all notifications published by the European Commission Joint Research Centre (JRC) at http://gmoinfo.jrc.it/ up to and including 31st March 2008. Whereas the list on the JRC website presents a static snapshot of each notification submitted based on the summary notification information format (SNIF) for each, the database developed for this project is searchable and can be used as an aid to sort the large amount of information contained in the SNIFs.

2.1 Data headings

The data is organised into the following headings, based on the information provided in SNIFS:

- Notification Number
- Project title
- Country
- Species
- Institute / company
- Institute / company consolidated - to take account of different trading names that may be assumed by one company when operating in different countries
- Start date of field trial
- End date of field trial
- Duration of field trial
- Type of modification (generic) for up to four individual traits
- Type of modification (specific) for up to four individual traits
- Marker genes utilised (1 and 2)
- Purpose of release (1 and 2)
- Number of sites specified
- Maximum area of GMO (per site) (m2)
- Number of propagules released (per site per year)
- Risk management measures (up to 6) (additional to the equivalent conventional crop)
- Isolation distance required if appropriate
- Date notification published by JRC

Two headings were added for completion by the Member States participating in the survey, covering actual number of release sites and the status of trials, as listed below:

Number of sites:
1 site
2- 9 sites
10 - 24 sites
25 - 49 sites
50 - 99 sites
100 sites

Status of trial:

- Application withdrawn by notifier
- Consent withdrawn by Competent Authority
- Consent not issued by Competent Authority
- Some/all trials terminated (vandalism)
- Some/all trials terminated (other)
- Trial(s) ongoing or completed (none terminated)
- Other (free text entry)

Each of the data headings have been ordered into appropriate groupings to facilitate searching and identification of trends and other analyses where possible. New notifications published can be added quickly and easily using drop-down menus, which can be easily updated to accommodate new notifications. For example, the types of genetic modification are organised as shown in table 2.1 below. The database (MS Excel) plus instructions for its use can be found at Appendix 1.

Table 2.1: Example of rationalisation of data in the EU Part B notifications database – organisation of types of genetic modification

Generic traits	Specific traits within each category of generic traits
Abiotic stress resistance	drought tolerance salinity tolerance unknown or commercial business information (CBI)
Altered development	modified plant architecture modified flowering earliness flowering prevention lack of photosynthetic proteins ability to self-fertilise altered fruit development unknown (or CBI)
Altered products or enhanced yield	altered carbohydrate composition altered lignin altered oil profile altered starch enhanced functional ingredients (e.g. vitamins, antioxidants) enhanced protein content enhanced yield (general) increased carotenoid content increased oil increased starch industrial/chemical products medical/veterinary use (e.g. drug or antibody production) unknown (or CBI)
Herbicide tolerance	dalapon tolerance glufosinate ammonium (phosphinothricin) tolerance glyphosate (Roundup) tolerance Unknown (or CBI) sulphonylurea tolerance (ALS inhibitor) unknown (or CBI)

Table 2.1 continued

Generic traits	Specific traits within each category of generic traits
Insect resistance	coleopteran resistant Corn borer resistant (*Ostrinia nubilalis; Sesamia* spp) Corn rootworm resistant (Diabrotica spp.) Cry gene/Cry proteins lepidopteran resistant soil phytophagous insect resistance other unknown (or CBI)
Modified consumer properties	altered colour/form (e.g. altered flower colour) unknown (or CBI)
Modified environmental interactions	gene silencing bioremediation (e.g. of soil heavy metals) drought reporter gene unknown (or CBI)
Pathogen resistance	bacteria resistance fungal resistance virus resistance unknown (or CBI)
Unknown or CBI	

The database was used to support project modules as listed below:

1) Data was generated for the literature review to support analysis of the numbers and types of traits that have been put into Part B trials for comparison with those predicted in a review by Lheureux *et al.* 2003 (section 8 and Appendix 11).
2) Individual tables were produced for each Member State listing the trials that have been held in the MS. These were used in the basic and detailed surveys of MS practices (sections 5 and 6).
3) Identification of field trials that have been carried out in more than one Member State, for analysis in detailed MS surveys (section 6).
4) Identification of notifiers that have held trials in more than one Member State, to form the basis for notifier missions (section 7).

Information in the database provided at Appendix 1 is correct up to 31st March 2008, however, the project modules were undertaken prior to this and are therefore based on information held in the database up to 31st December 2007.

3. PART B GMO FIELD TRIALS – PROCESS, ROLES AND RESPONSIBILITIES

3.1 The process of conducting experimental release of GM crops

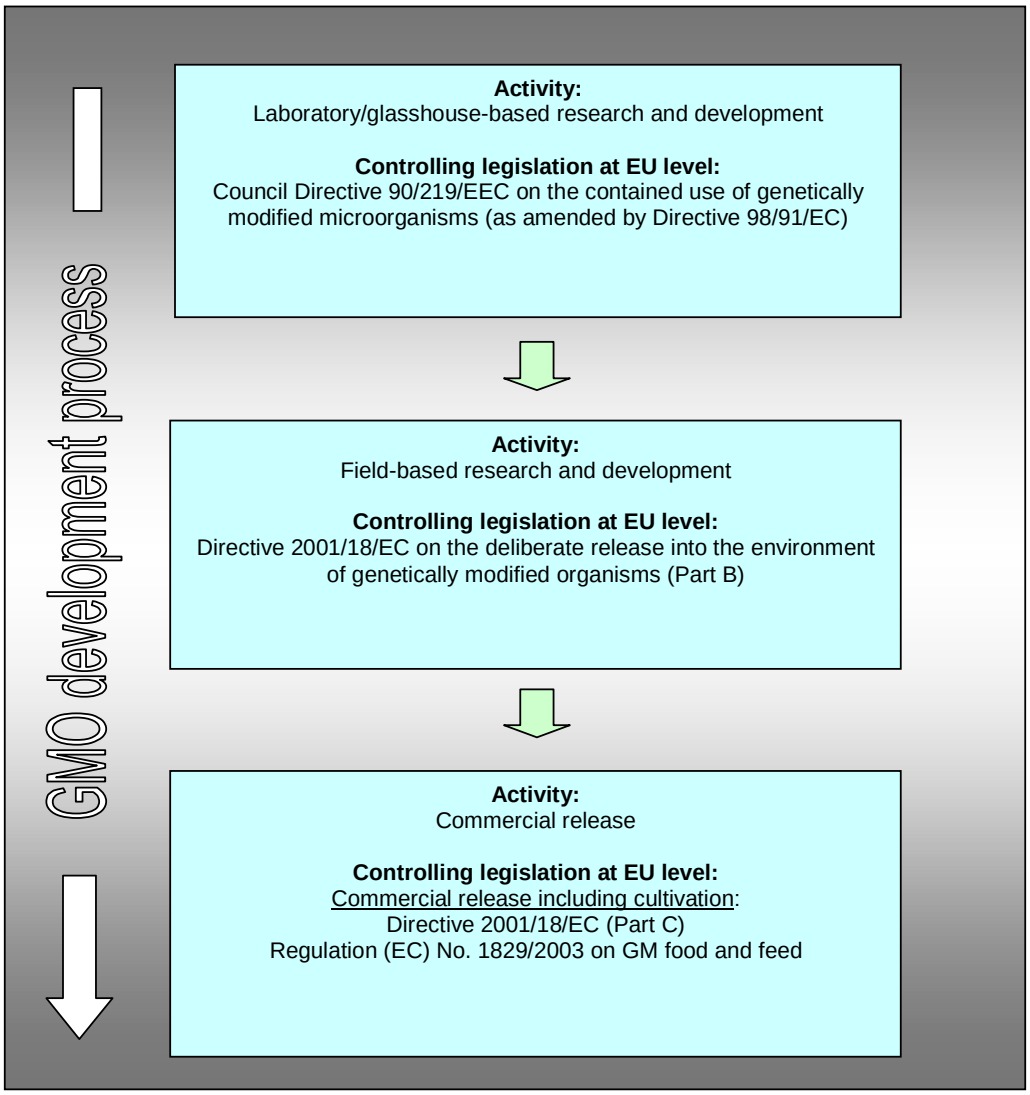
The experimental release of a GM crop is just one step in a multi-stage process that begins with the development of the GMO in the laboratory and aims to finish with a commercially released product, although Part B trials for other purposes such as fundamental research may also be undertaken, as mentioned earlier. Commission Decision 2003/701/EC (of 29/09/2003 on the format for presenting the results of Part B deliberate releases) provides a comprehensive, but not exhaustive, list of the types of deliberate release(s) that may be undertaken under the Directive:

- Research purposes
- Development purposes - e.g. event screening, proof of concept, agronomic performances, altered agronomic properties, altered quantitative properties, stability of expression, multiplication of lines, hybrid vigour study, molecular farming, phyto-remediation, and others;
- Official testing – e.g. variety registration on a national variety catalogue (DUS and/or VCU)[6]
- Herbicide authorisation;
- Demonstration purposes;
- Seeds multiplication;
- Biosafety/risk assessment research – e.g. vertical gene transfer studies, horizontal gene transfer studies, management of volunteers, potential changes in persistence or disposal, potential invasiveness, potential effects on target organisms, potential effects on non-target organisms, observation of resistant relatives, observations of resistant insects, and others.

Figure 3.1 below illustrates the GM crop development process and the legislation controlling each stage.

[6] DUS: distinctness, uniformity and stability; VCU: value for cultivation and use

Figure 3.1: Legislative control of GMOs at EU level



Directive 2001/18/EC enables the controlled deliberate release of GMOs in experimental trials whilst protecting human health and the environment from any adverse effects. It does this by setting out a system by which GMOs have to be approved on safety grounds before they can be released into the environment. It also requires that the national legislation and administrative provisions of all MS are in line with the Directive to ensure that the same safety standards are met across the EU. The requirements of the Directive are:

- The environmental release of a GMO must be authorised under the Directive. Experimental releases are covered by Part B (in accordance with the general provisions of Part A);
- A case-by-case environmental risk assessment must be carried out prior to the release to assess the possibility of any harmful effects on the environment. This risk assessment must consider direct, indirect, immediate and delayed effects of the GMO;

- Safety is assessed by means of a 'step-by-step' progression using data from earlier experiments to inform decisions about the safety of future field trials;
- Trials are monitored by the consent holder to determine the characteristics of the GMO and whether there are any unexpected effects on the environment;
- At each stage in the assessment process any effects are taken into account, thereby allowing decisions to be made on whether a reduced level of containment is justified for future releases of the GMO.

Because the deliberate release of experimental GM crops takes place under a tightly regulated framework, a number of parties are involved in the process. The main parties involved and their roles are shown in Box 1 below. Throughout this report the distinction is made between administrative procedures and management procedures. Administrative procedures are defined as desk-related procedures that are required for complying with the requirements of the Directive (e.g. submission of a notification; acknowledgement, assessment, consultation and communication of a decision concerning a notification; provision of written consent to release where appropriate; consulting and providing information to the public; and reporting by notifiers on releases), whereas management procedures are the practical steps that are required to fulfil the conditions and specifications of a consent issued under Part B of the Directive (e.g. ensuring isolation from related crops, transport and disposal of GM material, monitoring during and after the trial). This project has paid particular attention to risk avoidance measures in consents that are specifically designed to prevent the entry of GM trial material from entering the market place.

Box 1: The four main parties involved in GMO Part B field trials

There are four main parties involved in the operation of deliberate release trials. They are:

- The Competent Authority.
- Enforcement officials e.g. GM Inspectors
- The consent holder (notifier);
- Field operators

These parties work to ensure the release proceeds in accordance with the consent conditions and to help protect human health and the environment.

Competent Authority (CA)

Responsible for the administration and control of the deliberate release of GMOs in each MS. The CA assesses Part B applications, issues consents, appoints inspectors, is responsible for setting up any scientific advisory bodies regarding GM releases, and generally manages the deliberate release process in accordance with national legislation which implements the Directive. Notifier monitoring reports (both growing season and post-trial) must be submitted to the CA.

Enforcement officials/GM Inspectors

Appointed by the Competent Authority, the role of GM Inspectors is to verify that the conditions and limitations attached to the consent for release are being met. It is not the responsibility of Inspectors to monitor the release *per se*, but to ensure that the consent holder is carrying out their duties by means of targeted inspections (see Box 2 'Official control of GMO field trials'). The number of inspections and their timing is related to the environmental risk assessment, the experience of the notifier, and the results of past findings from trials of the same crop/trait and/or notifier. Checks carried out during inspections may include examining the trial site, management procedures and documentation. Inspectors report their findings to the Competent Authority. The powers of inspectors are laid down in national legislation and, depending on the legal system in operation, may include the right to take samples, issue prohibition and enforcement notices, and impose fines. Any infringements of the consent conditions are investigated and brought to the attention of the Competent Authority, and suitable action is taken in accordance with the framework operating in the MS.

The notifier

The notifier submits an application to conduct an experimental trial with the CA in whose territory the release is proposed to take place. The application must contain sufficient information about the GMO to satisfy the CA that its release into the environment will fulfil the conditions of the Directive. Should the CA grant approval to carry out the trial, the notifier is the holder of the authorisation ('consent'). It is the responsibility of the notifier to ensure the trial proceeds and is managed in accordance with the conditions stipulated in the consent. Notifiers must have in place a clearly defined management chain to control how the release proceeds. There must be administrative systems in place to record relevant information, emergency procedures must be defined, and suitable training should be given to those working on the trial site. Conditions in the deliberate release consent stipulate how monitoring is to be performed and reported upon.

Field operators

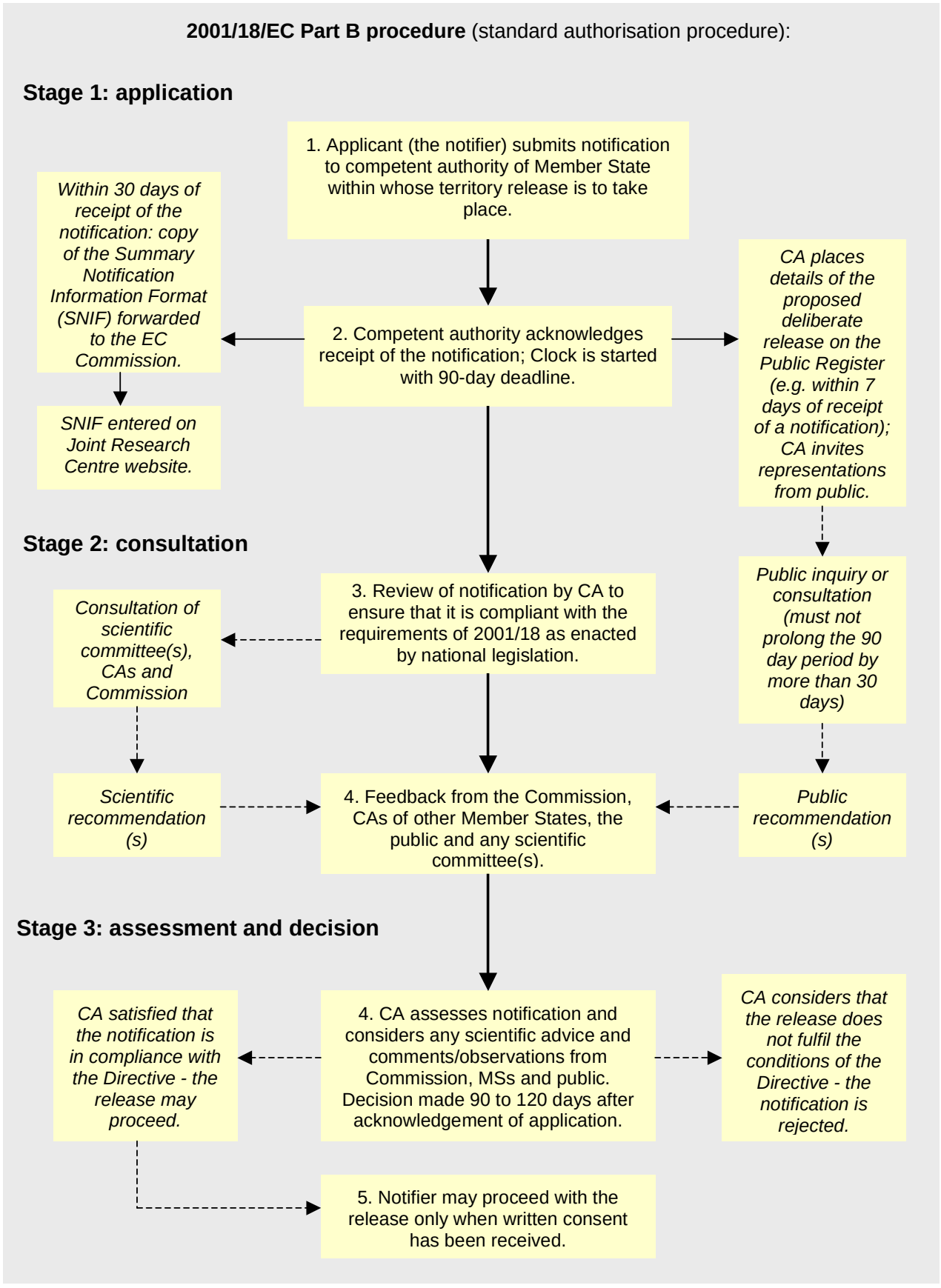
Contracted by the notifier to conduct day-to-day operations in connection with the release. Such work may include crop management (e.g. cultivation, sowing, pest/disease monitoring, applying fertilizers/pesticides, harvesting, etc.), data recording (e.g. plant growth characteristics, efficacy of the trait, environmental impact, etc., depending on the type of trial) and any other day-to-day operational aspects. Field operators may include the farmer on whose land the trial is situated, company or university personnel, or employees of professional trials management companies. Due to the nature of their work these are often the people most frequently on site and are therefore well placed to monitor the release for any problems (actual or potential), infringements or unexpected effects of the GMO. Field operators must work to well defined administrative and trial management procedures, should be conversant with the terms of the consent and clear about their role in helping fulfil them, and there must be clear lines of communication between them and the notifier.

Steps in notifying intention to release a GMO under Part B of the Directive

There are a number of regulatory steps that a deliberate release application must go through before consent may be granted to the notifier. These include an application stage, which involves receipt and publication of the details of the application, a consultation stage whereby the opinions of relevant scientific bodies and the public are requested, and an assessment and decision-making stage. Figure 3.2 shows these steps as per the standard authorisation procedure. A 'simplified procedure' (Commission Decision 94/730/EC[7]) also exists whereby consent can be given either for a single release or for a programme of releases taking place over several years and at several sites. In addition a 'fast track' procedure can be followed for some species where the characteristics of both the inserted gene and the host organism are well known. A single notification can include the release of a combination of GMOs on the same site, or on different sites for the same purpose and within a defined period.

7 Official Journal L 292, 12/11/1994 P. 0031 – 0034 (http://eur-lex.europa.eu/)

Figure 3.2: Flowchart showing the regulatory process for Part B releases under 2001/18/EC

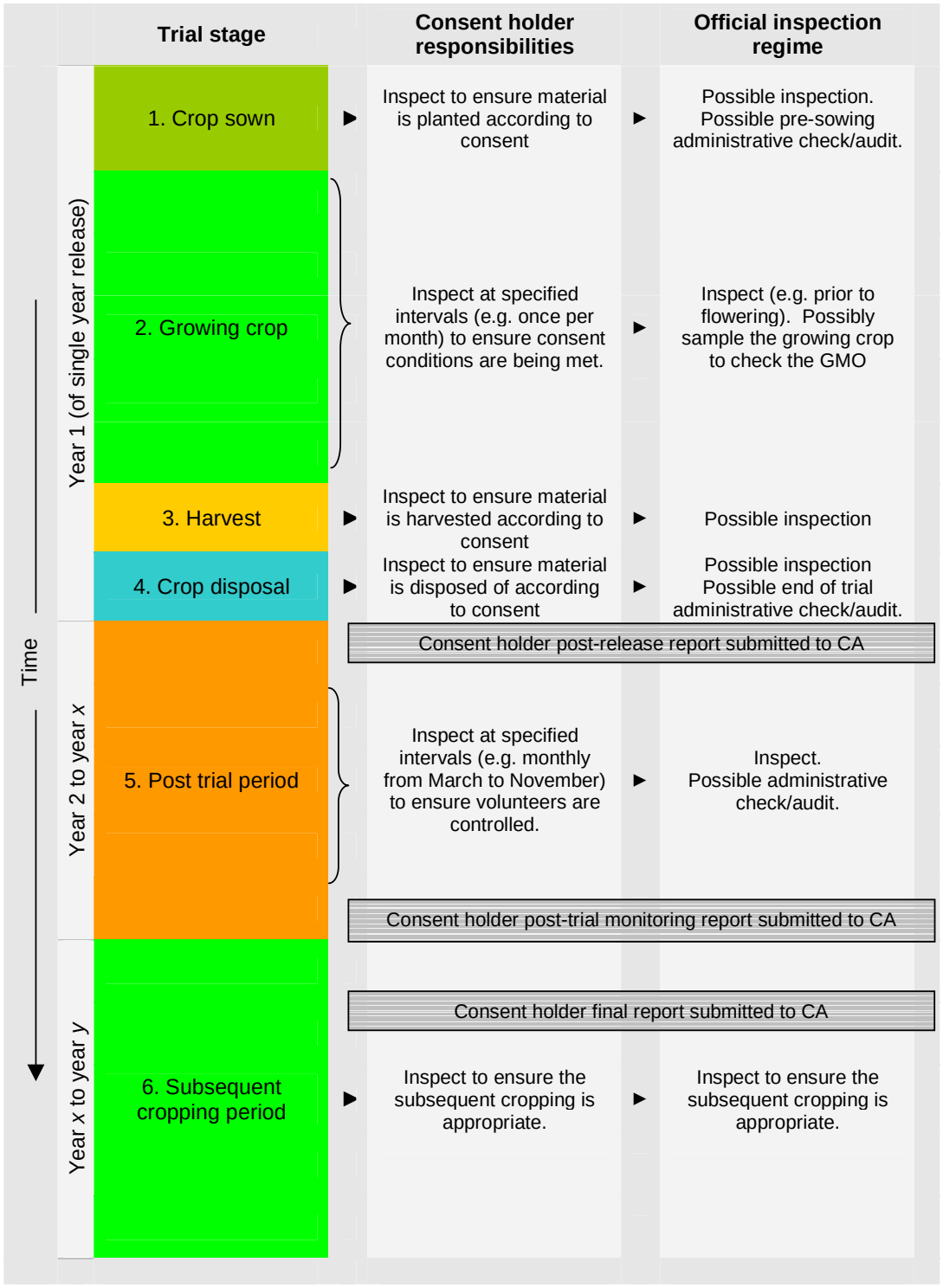


3.2 Roles and responsibilities of notifiers and official inspection bodies

When conducting a deliberate release the Directive requires the notifier to submit a plan for monitoring the release in order to identify any potential effects of the GMO(s) on human health or the environment, and to ensure the limitations and conditions of the consent are being met. The consent holder must carry out routine monitoring at regular intervals during the growing and post-trial periods (as appropriate), and the findings of the monitoring must be reported to the CA. The first monitoring report must be submitted after completion of the release, with any additional reports submitted at intervals specified in the consent, based on the results of the environmental risk assessment.

Competent Authorities are required to organise inspections and other control measures, as appropriate, to ensure the release is in compliance with the Directive. CAs may conduct inspections themselves, or may appoint a separate body to perform this role. The frequency of consent holder monitoring and timing of visits is determined by environmental risk assessment. The number of official inspections is also related to the environmental risk assessment, but other factors may be taken into account such as the level of experience and past record of the notifier, and the experiences of inspectors regarding trials of the same crop or trait. Figure 3.3 illustrates a typical notifier monitoring plan and associated official inspection regime in relation to the different stages of a trial.

Figure 3.3: Consent holder monitoring of Part B releases and the official inspection regime



When submitting a deliberate release application the notifier must specify the type of monitoring that will be undertaken, including its duration and frequency. Notifier monitoring plans may include observations on general plant characteristics and agronomic performance, effects on target and non-target organisms, effects on the rhizosphere and soil organisms and the assessment of general environmental effects. In the years following the release the site will usually be monitored for volunteers (as appropriate, depending on the crop type) and any emerging volunteer plants will be recorded and destroyed. The site may also require checking to ensure subsequent crops are compatible with the consent conditions.

Official inspections are conducted to ensure the notifier is carrying out their duties in accordance with the consent and there is no risk to human health and the environment. Official inspections are most likely to be carried out during the growing stage of the crop, usually before flowering in order to check that isolation distances are satisfactory before any pollen has been released. Additional inspections may be conducted at the sowing/planting stage of the trial, at harvest, and during the disposal of the crop, to check particular management aspects of the release. The type of checks carried out during inspections may include the layout and dimensions of the trial, the number of GM seeds/tubers/plants released, confirmation that the correct GMO has been released, ensuring machinery has been adequately cleaned, checking the isolation distance to related crops, assessing arrangements for the prevention of unauthorised access to the trial, assessing consent holder monitoring records, reviewing arrangements for harvest, storage and disposal of the crop, and ensuring procedures are in place for the implementation of emergency plans. Post trial inspections are conducted (as appropriate) in the years following the release to ensure that the control of volunteers is in accordance with the consent conditions. Subsequent cropping inspections may also be carried out to ensure appropriate follow-on crops have been planted.

4. MANAGEMENT OF GMO FIELD TRIALS IN EU MEMBER STATES - METHODOLOGY

Surveys were undertaken to establish how the Directive has been implemented in each of the Member States, including administrative procedures, practical arrangements for management of GMO field trials, systems for inspection and control, and incidents of non-compliance and how these are dealt with. Surveys were undertaken at a basic level for twenty MS, and at a more detailed level for seven MS that have registered a large number of notifications for GMO field trials namely France, Germany, Hungary, the Netherlands, Spain, Sweden and the United Kingdom (UK)[8].

Basic survey of MS practices ('e-survey')	**Detailed survey (including Competent Authorities, inspectors, notifiers and field operators)**
Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia	France, Germany, Hungary, the Netherlands, Spain, Sweden, the UK.

All questionnaires used in this research were approved by DG Environment before being issued.

4.1 Basic survey of Member States

All MS were asked to answer thirty two questions in the categories listed in table 4.1 below. These questions were designed to provide an overview of the administrative and basic trial management procedures that have been put in place by all the MS. They were not intended to explore in detail practical requirements for management of Part B field trials in each MS, which is covered for selected MS in the detailed MS surveys. The questions cover Article 4 of the Directive, establishing general obligations, and Articles 5 to 11, which make up Part B of the Directive. The questionnaire is provided in Appendix 2.

[8] These countries were specified by DG Environment.

Table 4.1: Survey questions and coverage of Directive 2001/18/EC

Questions	Subject area	Specific articles of Directive 2001/18/EC covered
1	Competent Authority	Article 4 (4) General obligations)
2.1 – 2.4	GMO legislation in the MS	Article 34 (Transposition)
3.1 – 3.3	Summary of Part B GMO deliberate release field trials	Article 6 (Standard authorisation procedure) Article 11 (Exchange of information between competent authorities and the Commission)
4.1 – 4.5	Information and application procedures	Article 5 (General requirements of Part B) Article 6 Annex II (Principles for the environmental risk assessment)
5.1 – 5.5	Assessment of applications	Article 6 Article 28 (Consultation of Scientific Committee(s) Annex II
6.1 – 6.2	The consent	Article 6
7.1 – 7.3	Information provided to the public	Article 9 (Consultation of and information to the public) Article 31 (Exchange of information and reporting)
8.1 – 8.5	Management of authorised GMO deliberate releases	Article 6 Article 10 (Reporting by notifiers on releases)
9.1 – 9.2	Inspection and enforcement	Article 4 (5)
10.1 – 10.3	Non-compliance (breach of consent conditions)	Article 4 (5) Article 8 (Handling of modifications and new information)

The MS that have notified Part B GMO field trials on the JRC website were sent an Excel spreadsheet listing all the field trials notified in their MS; Competent Authorities were asked to confirm that this was an accurate representation of the trials that had actually been held in the MS, and if not, to update the spreadsheet. A summary explanation of the data held in each of the columns was provided to assist Competent Authorities to review their summary spreadsheets. Competent Authorities were also asked to indicate the status of the field trials and the number of sites at which releases took place.

Member States that did not have any field trials notified on the JRC website were asked to confirm that this was the case and to complete the questions on the basis of the administrative systems they have established for Part B field trials, and how they would manage trials in principle.

Questions were issued to individual MS via an on-line 'e-survey'[9]. The e-survey system stores each discrete set of entered data directly into a database and is programmed to enable survey results to be displayed in a graphical format, providing basic analysis of the data received. The e-survey approach offers three key benefits:

[9] The option to complete the survey in a word document was also provided.

- Data is entered into the database directly by the participant in the survey (except in 7 cases where the participant's response was emailed to the project team to enter).
- Data entry errors on the part of the project team are reduced.
- All data provided by the Competent Authorities is saved directly into a database, and can be easily downloaded in an Excel spreadsheet.

The request to participate in the survey was issued individually to each Competent Authority by email in November 2007. The survey was available on-line at http://gmofieldtrials.csl.gov/ and access was provided using the username 'gmofieldtrials' and the password 'access'. Screenshots of the e-survey are provided in Appendix 3. The survey was taken off-line once all responses had been received.

4.2 Detailed Member State survey ('MS missions')

A second series of questions was developed for missions to the seven Member States identified for detailed study. These included the questions developed for the 'basic MS survey' plus additional questions addressed to the Competent Authorities and inspectors of GMO field trials, also MS-based notifiers and their field operators. Each competent authority was asked to nominate a MS-based notifier to participate, and that notifier was asked to nominate one of their field operators[10]. The questions were developed to provide a more detailed picture of the administrative procedures implemented for Part B GMO trials and how these work for the notifiers and field operators, plus a clear understanding of how trials have been managed i) to ensure compliance with the Directive and ii) to prevent the accidental entry of the GM material onto the marketplace by geneflow and other routes. Detailed information on the management practices employed for field trials of GM maize, oilseed rape, potato, beet and cotton was requested, in particular identification and management of critical control points in the trial process. The questionnaires are provided in Appendix 4. The nominated persons in these MS were visited and face-to-face interviews[11] were undertaken in January and February 2008.

Table 4.2: The notifier nominated by the competent authority in each of the 7 key member states to participate in the 'MS missions'

Member State	CA-nominated notifier
France	Pioneer Hi-Bred S.A.R.L. Note: the response was provided by this notifier, but comments had been collated from the key notifiers operating in France.
Germany	Monsanto Agrar Deutschland GmbH. Note: BASF Plant Science GmbH also offered to participate in this part of the study, so responses are provided from two notifiers based in Germany.
Hungary	St. Stephen University, Budapest (see also footnote 11)
The Netherlands	BASF Plant Science GmbH
Spain	Monsanto Agricultura España, S.L.
Sweden	Plant Science Sweden AB
UK	BASF Plant Science GmbH

[10] More detail is provided in the final paragraph of Section 6.2 'Member State-Based Notifiers'.

[11] A total of eight MS-nominated notifiers participated in the project: one from each MS plus one additional notifier in Germany. In Hungary, the seed supplier of the nominated notifier also attended the interview. Detail is provided in section 6.2 and Appendix 8.

Table 4.3 below summarises the number of Part B trials that have been held in each of the MS for the five crops of particular interest in this study, according to notifications listed on the JRC website.

Table 4.3: Part B GMO field trials notified in the 7 key Member States for the five crops of particular interest in this study

Crops	France	Germany	Hungary	Netherlands	Spain	Sweden	UK
Maize	63	11	26	4	104	3	0
OSR	0	2	0	0	0	10	1
Potato	1	23	0	13	7	8	4
Beet	2	1	0	0	1	3	0
Cotton	0	0	0	0	24	0	0

Data for Summary Notifications submitted under Directive 2001/18/EC (i.e. after 17 October 2002) up to 31 March 2008.

4.2.1 Field trials of crops of particular interest

A principal aim of this project was to gather sufficient data to enable comparison of practices across the MS and identify if any gaps and areas of good (or poor) practice exist. The Part B GMO trials database was used to identify where the same field trial had been notified in a number of MS to enable direct comparison of the conditions attached to the release, and management of the trial in different MS. The field trials that were selected for cross-MS comparison are listed in table 4.4 below, for example the BASF trial of potato with a pathogen resistance trait (fungal resistance) has been notified in France, Germany, the Netherlands, Sweden and the UK. Each CA was informed of the trials that were of particular interest and requested to provide specific information on their management. Maize trials dominate this list because there have been significantly more trials of maize notified than other crops.

Table 4.4: Part B GMO field trial notifications identified for cross-MS comparison

No.	Crop	Notifier	Trait(s)	MS
1	Potato	BASF	Pathogen resistance (fungal resistance)	FR, D, NL, SE, UK
2	Potato	BASF	Altered products or enhanced yield (altered starch)	D, NL, SE
3	Sugar beet	Syngenta	Pathogen resistance (viral resistance)	FR, SE
4	Maize	Pioneer	Herbicide tolerance (glyphosate (Roundup) tolerance)	D, ES, FR, HU
5	Maize	Pioneer	Insect resistance (coleopteran resistance + lepidopteran resistance) + Herbicide tolerance (glufosinate ammonium (phosphinothricin) tolerance + glyphosate (Roundup) tolerance)	D, ES, FR
6	Maize	Pioneer	Insect resistance (lepidopteran resistance) + Herbicide tolerance (glufosinate ammonium (phosphinothricin) tolerance)	FR, ES, HU
7	Maize	Pioneer	Insect resistance (lepidopteran/Corn borer resistant) + Herbicide tolerance (glufosinate ammonium (phosphinothricin) tolerance + glyphosate (Roundup) tolerance)	D, FR, ES, HU
8	Maize	Syngenta	Herbicide tolerance (glyphosate (Roundup) tolerance)	FR, ES, HU
9	Maize	Syngenta	Insect resistance (lepidopteran resistant)	FR, ES
10	Maize	Dow AgroSciences	Insect resistance (lepidopteran resistant) + Herbicide tolerance (glyphosate (Roundup) tolerance)	ES, HU
11	Maize	Monsanto	Insect resistance (Corn borer resistant (*Ostrinia nubilalis*; *Sesamia* sp.)	ES, FR
12	Maize	Monsanto	Insect resistance (Corn rootworm resistant (*Diabrotica* sp.)) + Herbicide tolerance (glyphosate (Roundup) tolerance)	FR, ES, HU
13	Maize	Monsanto	Herbicide tolerance (glyphosate (Roundup) tolerance)	D, ES, FR, SE
14	Maize	Monsanto	Herbicide tolerance (glyphosate (Roundup) tolerance) + Insect resistance (lepidopteran resistant)	D, FR, ES

- *Reports from the Member State missions*

For each of the Member State missions, reports recording discussions and responses to each of the questions were drafted following the visits. These were returned to each of the interviewees for their approval and/or amendment before being used in this report. The information used in this report from all parties involved is therefore believed to be an accurate representation of the situation in each of the Member States from the perspective of the Competent Authorities, field inspectors, MS-based notifiers and field operators. For each Member State, the completed and approved package of reports for all of the individuals interviewed was returned to the Competent Authority so they have a complete picture of the information collected on their territory.

4.3 Survey of key EU notifiers ('Notifier missions')

A number of companies have notified field trials in more than one Member State and are therefore in a good position, as end users, to offer a perspective on different practices in place in the MS in which they have notified field trials, and how these

impact on their work. A third series of questions was developed for missions to key European notifiers (Appendix 5). The EU Part B notifications database was used to identify the major notifiers in the seven key MS of interest (table 4.5) and meetings were sought with the relevant persons in four of the six companies that were found to have conducted the largest number of field trials in the widest range of countries. In total three of the key European notifiers agreed to participate in the study; the companies are not specifically named in the report because the comments themselves are relevant rather than the identity of the companies.

Table 4.5: Part B GMO field trials notified by major notifiers in the 7 key MS

Notifier \ MS	BASF	Bayer	Dow	Monsanto	Pioneer	Syngenta
France	1 potato			15 maize	26 maize	4 maize 1 sbeet
Germany	8 potato			4 maize	3 maize	3 wheat
Hungary			3 maize	2 maize	9 maize	1 maize
Spain		20 cotton 1 maize 1 soya	4 cotton; 7 maize	18 maize 1 sbeet	61 maize	11 maize
Sweden	1 osr 8 potato			1 maize		2 sbeet
The Netherlands	6 potato				3 maize	
UK	2 potato	1 osr				1 wheat
Total	18 in 5 countries	23 in 2 countries	14 in 2 countries	41 in 5 countries	102 in 5 countries	23 in 6 countries

- *Reports from the EU-wide notifier missions*

For each of the notifier missions, reports of the discussions held and responses to each of the questions were drafted following the visits. These reports were returned to each of the interviewees for their approval and/or amendment before being used in this report. The information used in this report is therefore believed to be a true and accurate representation of the experiences of each of the notifiers that participated.

4.4 Expert elicitation

Much of the information that was gathered in this study was based on actual management practices and outcomes and was not subject to interpretation. However, questions concerned with the identification of risks of the release of a GMO and management of any potential risks were more subjective and likely to elicit very different responses when aimed for example at a policy maker or regulator in a Competent Authority than when aimed at a notifier in a biotech company or research institute. To ensure that the responses from Competent Authorities, inspectors, notifiers and operators were accurate and without bias, for example because of the phrasing of the questions, advice was sought from a risk analyst with particular knowledge in the field of expert elicitation.

On the basis of this advice, a number of the questions were rephrased. The risk analyst also recommended the use of pre-defined answers where possible for the questions in the basic MS survey to enable structured assessment of the answers

received. This advice prompted use of the ‘e-survey’ software for the basic MS survey because it facilitates the use of pre-determined answers (yes/no, lists and tick boxes), and permitted direct comparison of responses.

5. MANAGEMENT OF GMO FIELD TRIALS IN EU MEMBER STATES – 'BASIC' SURVEY

5.1 RESPONSE TO SURVEYS

Member States participation in the study:

Basic survey of MS practices only:	Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Portugal, Romania, Slovak Republic, Slovenia
Detailed survey, including Competent Authorities, inspectors, notifiers and field operators:	France; Germany; Hungary; the Netherlands; Spain; Sweden; the UK
MS that did not participate:	Malta, Poland, Greece

The data was gathered between November 2007 and March 2008.

5.2 ADMINISTRATION AND BASIC TRIAL MANAGEMENT IN ALL MS

Detailed responses to the 'basic' MS survey are provided in Appendix 6 (MS Excel file). See section 6 for responses to the detailed survey of seven MS.

5.2.1 Implementing Directive 2001/18/EC

Each of the twenty four MS that participated in the study have implemented the Directive, and in all cases provision has been made in the national legislation for holding Part B GMO field trials. The name and outline of the legislation is provided in all cases (Appendix 6).

5.2.2 Database of GMO field trials

Of the twenty four participant MS, eighteen have registered notifications for Part B trials. These MS were each sent a spreadsheet listing only the trials notified in their MS and were asked to confirm whether the spreadsheet was correct. Of the nine MS that have not notified trials (Austria, Bulgaria, Cyprus, Estonia, Greece, Latvia, Luxembourg, Malta and Slovenia), eight confirmed that this was correct (one MS did not respond). Of the eighteen that have notified Part B trials, the spreadsheet was correct for 6 out of 18 MS. A summary is provided in table 5.1.

Where the spreadsheet was incorrect, this was mostly in the areas of management measures applied and the status of the trial. Management measures in the SNIFs listed on the JRC website are those proposed by the applicant and do not reflect actual management measures applied by the CA. In Sweden for example, management measures can vary year on year depending on experience, so it would be very difficult for the CA to ensure that the notifications database reflects management measures for ongoing trials. There is currently no requirement for the CAs to update the list on the JRC website to indicate whether notifications are approved or not, the conditions for release, or reasons for refusal.

Reference to table 5.1 shows that CAs in 11 MS provided updated information regarding the status of notifications they received under the Directive[12]. From this information, we can observe that acceptance and assessment of a notification does not guarantee that consent will be given for a trial to proceed, although the reasons that these consents were not issued by the relevant CAs were not given. As we do not have a complete set of data on the status of notifications in each MS, nor any detailed information regarding the reasons that authorisations were not issued by a CA, it is not possible to draw any conclusions from this information, or on the average levels of approval/rejection of notifications. Although the CAs are not obliged to inform the notifiers of their reasons for rejecting a notification, they are required to inform the Commission of the final decisions taken on notifications received, including reasons for rejecting a notification (Article 11(3)). The Commission should, therefore, be in a position to explore the issues raised by the notifiers.

CAs in three MS indicated that they encourage potential notifiers to enter into discussion with the CA at an early stage to ensure that all submitted notifications meet at least certain minimum criteria.

[12] For some MS, e.g. Spain and Germany it would have been a very lengthy operation to fully update their spreadsheet, so it was anticipated that not every MS would do this.

Table 5.1: Accuracy of information provided on Part B GMO field trials in the MS based on information on the JRC website

MS	Number of notifications[1]	Crops	Spreadsheet correct?	Main reason spreadsheet was incorrect	Trial status
Belgium	1	Apple	Yes	-	No field trials in Belgium since 2002
Czech Republic	11	Potato, Maize	No	Trial start & end dates; No. of sites specified; No. of propagules released per site	All ongoing
Denmark	8	*Arabidopsis thaliana*, maize, ryegrass, fodder beet	No	Not known	Not provided
Finland	2	Birch, potato	Yes	-	All ongoing
France	75	Grape; maize; poplar; potato, sugar beet; tall fescue; tobacco	No	Management conditions vary slightly; Number of release sites	8 not issued by CA 2 consent withdrawn by CA 7 terminated (other) 24 terminated (vandalism) 28 ongoing or completed (none terminated) 6 unknown
Germany	49	Apple; barley; maize; oilseed rape; pea; poplar; potato; *Solanum nigrum*; soybean; wheat	Mostly	Risk management options do not reflect the risk management procedures decided by the risk assessment authority	Not provided (too many trials to update for all)
Hungary	26	Maize	No	Trial start & end dates; purpose of releases; maximum area; number of propagules released per site; isolation distances	2 withdrawn by notifier 17 not issued by CA 7 ongoing or completed (none terminated)
Ireland	1	Potato	Yes	-	(No DR has taken place yet)
Italy	6	Aubergine; lemon; strawberry; tomato; wheat	Yes	-	2 not issued by CA 4 trials terminated (other)
Lithuania	2	Maize	Yes	-	2 not issued by CA
The Netherlands	15	Apple, chicory, maize, potato	Yes	Some consents were authorised but had to be later withdrawn by the Competent Authority following legal challenges and judicial rulings.	
Poland	6	Linseed/flax; maize; potato	N/K	N/K	N/K
Portugal	11	Maize	Yes	-	Not provided
Romania	14	Maize; plum; soybean	No	Trial start & end dates; maximum area of GMO; isolation distance; risk management measures	All ongoing
Slovak Republic	1	Maize	No	N/K	Not provided

Spain	165[2]	Carrizo citrange; cotton; grape/plum; maize; potato; rice; soybean; sugar beet; wheat	No	Purpose of trial	N/K (too many trials to update for all)
Sweden	24	Apple/pear; Arabidopsis thaliana; linseed/flax; maize; oilseed rape; poplar; potato; sugar beet;	No	Management measures may vary for each year of a trial	1 withdrawn by notifier 23 ongoing or completed (none terminated)
The UK	6	Oilseed rape; pea; potato; wheat	No	Management conditions	6 ongoing or completed (none terminated) (3 with no planting)

N/K: means not known

[1] As at 16th November 2007 when the spreadsheet was issued to CAs. For some MS, further notifications have been added since this date.
[2] In Spain consents are issued for 1 year only, so for multi-year programmes notifications must be lodged annually.

5.2.3 Application procedures – information and guidance provided

All respondents stated that they do have notification procedures in place for potential applicants wishing to hold a Part B field trial, and in most cases this is made available on the website of the Competent Authority for the Directive, or through the official Gazette of the government department. In some cases information on how to place a notification is only available in hard copy on request. Some MS also provide guidance to notifiers on the information that should be provided in the notification dossier and/or the general principles that should be considered when developing proposals for practical management of a Part B GMO field trial. Table 5.2 below summarises these responses.

Table 5.2: Guidance provided to applicants

MS	Is guidance provided on:	
	Information required in applications	General principles of management of Part B GMO trials
Austria	No	No
Belgium	Yes	Yes
Bulgaria	No[1]	No
Cyprus	No	No
Czech Republic	Yes	Yes
Denmark	Yes	Yes
Estonia	Yes	No
Finland	Yes	Yes
France	Yes	Yes
Germany	Yes[2]	No
Greece	N/K	N/K
Hungary	Yes[2]	Yes
Ireland	Yes	No
Italy	Yes	Yes
Latvia	No	Yes
Lithuania	Yes	Yes
Luxembourg	No	No
Malta	N/K	N/K
The Netherlands	Yes	Yes
Poland	N/K	N/K
Portugal	Yes[2]	No
Romania	No	Yes
Slovak Republic	No	No
Slovenia	No	No
Spain	No	Yes
Sweden	Yes[2]	No
The UK	Yes[2]	Yes

[1] But will advise potential applicants by telephone &/or a meeting
[2] Will also advise potential applicants by telephone &/or a meeting

5.2.4 Assessment of applications

The Directive establishes a framework for the case-by-case assessment of the risks associated with release of a particular GMO. This underlying principle means that no

plant species should be precluded from release providing the appropriate risk assessment has been undertaken, and that any risks identified can be mitigated by practical management measures. Each MS is, therefore, expected to be open to assessment of all crops, traits and crop/trait combinations providing the risk assessment is in place and suitable risk mitigation measures are identified. This was generally found to be the case, and most MS stated that notifications are undertaken on a case-by-case basis and that the primary criterion for authorisation of a trial is a favourable risk assessment. Some MS will not permit trials of certain crops in regions where local populations of wild relatives are known to exist, for example Spain and Portugal might not permit sugar beet trials in certain regions due to the presence of sexually compatible wild populations of *Beta maritima*. Two MS specified that oilseed rape was unlikely to receive consent due to the presence of sexually compatible wild relatives in the country, while another specified herbicide tolerant oilseed rape for the same reasons. One MS specifically prohibits the release of tobacco, vine, cotton, damask rose, wheat, and all vegetable and orchard crops. It also prohibits any deliberate release into the environment of any GMOs that have been refused consent in the Member States of the European Union (the same applies for placing on the market)[13]; these decisions are written into national legislation. Danish law stipulates that GMOs that transfer genes conferring resistance to antibiotics used in human or veterinary medicine will not be authorised for deliberate release.

Many MS do have administrative requirements that must be fulfilled before an application will be considered. A completeness check is an obvious, but necessary requirement, and ensuring an application is administratively complete makes good sense when one considers the time and cost invested in the assessment that follows. One MS additionally requires the notifier to confirm that the applicant has authority to hold a trial on the particular piece of land that has been notified.

- *Classification of field experiments with GM plants by containment level*[14]

Case-by-case risk assessment is a fundamental principle of the Dutch system and the CA does not have indicative management measures for any crops, traits or crop/ trait combinations. The Dutch operate a tiered system in which GMO field trials are classified into three levels of containment according to the properties of the GMO and stage of breeding/market development. Containment measures are set in proportion to the level of perceived risk that their release could result in adverse effects on human health and the environment. Case-specific mitigation measures are included in the consent conditions. In category 1 ('small-scale field trials') containment measures are applied that ensure that the possible effects of the GMOs do not spread beyond the field plot; a maximum of 5 locations no larger than 1 ha each is permitted. In category 2 ('field trials'), containment measures are only prescribed if they are identified in the risk assessment and are necessary to decrease the risk to a minimum; there is no limit on the number of locations but they cannot annually exceed 10 ha each; in this category dissemination of the GMO need not be avoided.

[13] The release into the environment and the placing on the market of genetically modified animals is also prohibited.

[14] Advice of the Dutch Advisory Committee (COGEM) on Classification of field experiments with genetically modified plants is provided in Appendix 7 pages 69 – 74. This paper was translated into English by the project team with the permission of the Dutch CA and is an unofficial translation of COGEM's advice.

In category 3 ('large-scale non-commercial trials'), there are no restrictions on either the number of locations or their size; containment measures are only required if identified in the risk assessment, and if no environmental risk is perceived, then no mitigation measurements are prescribed to prevent dissemination. A GMO in category three trials would be fully molecularly characterised in accordance with a marketing consent and no harmful environmental impacts will have been demonstrated in category 2 trials (or a similar category trial outside this MS). In category three trials, data would be collected over several seasons e.g. on possible unforeseen environmental impacts, most likely in preparation for market approval.

Progression to higher categories depends on the extent of characterisation of the GMO, a more thorough knowledge of transgenic gene expression and the interaction with the receiving environment (including impacts on non-target organisms), and the conclusions of an up to date risk assessment. Assessment of risks for category 2 and 3 trials also includes assessment of the impact of incidental consumption of the GMOs. Applicants would normally apply for a specific category of field trial, or the CA will determine which is the most appropriate. The CA would advise notifiers undertaking a category three trial to observe national coexistence guidelines for the crop in the trial.

This system marks quite a significant departure from the systems established in the other MS and recognises the fact that different types of trial exist, from small-scale proof-of-concept R&D trials to larger more commercially oriented trials, and that different management measures can be applicable depending on the scale and type of the trial. In most MS, each notification is treated essentially as the equivalent of a category 1 small-scale field trial. Sweden does not operate a tiered system, but for multi-year programmes the CA does reserve the right to alter the conditions of each release. For example, some oilseed rape trials cannot be planted on more than 1ha for the first year of release, but can increase to 3ha afterwards as knowledge increases. The same principle could also, presumably, lead to increased risk management measures if any unexpected effects were identified.

5.2.4.1 Other national legislation that must be observed

The seven MS that participated in the detailed survey were asked if there is any other national legislation that must be observed before consent for deliberate release could be issued (see table 2 in Appendix 7). In Spain and Sweden legislation relating to plant health and seeds must be observed. In Germany national legislation for protection of the environment (the 'Environmental Protection law') requires the CA to undertake an additional risk assessment for all trials that may take place within 1 kilometre of designated protected sites before consent can be issued. If there is evidence that there may be a negative effect on the protected site, the trial cannot proceed. This requirement places a significant extra burden on the CA in particular, but also the notifiers. Nature conservation legislation is also in place in Hungary[15], which prohibits the genetic modification of wild organisms and the spread or transfer of any resulting modified material to other wildlife communities.

In one MS, under the provisions of the GMO Act the deliberate release of any GMOs into areas included in the 'National Ecological Network' (defined in national

[15] Act Nr. LIII. of 1996 on Nature Conservation (1996. évi LIII. Törvény a természet védelméről).

legislation) and adjoining areas within a zone of 30 kilometres around any such areas is prohibited.

Additional requirements such as this can create bottlenecks for the CAs, which can have a significant impact on the time required to process a notification. When the assessment time exceeds the (90 days plus 30 days) timescale outlined in the Directive this will inevitably impact further on the notifier because of the need to submit notifications earlier than would normally be the case.

5.2.5 Scientific Advisory Committees

Most MS have an Advisory Committee established to assess Part B GMO applications. In Denmark, the Danish Forest and Nature Agency receives and assesses applications and the Minister for Environment takes the decision regarding approval or not. In Finland, experts are consulted and they give their opinion to the CA ('Board for Gene Technology'). In Romania the new Biosafety Commission is in the process of being established. Details of the composition of these committees was not provided in all cases, but is summarised below:

'Does the Advisory Committee comprise any of the following':

Government scientists	12 (of the 24 MS)
Non-government scientists	17
Officials	9
Lay persons	4
Other	11

As might be expected, scientists are strongly represented on these committees, particularly in the areas of genetics and plant breeding, microbiology, molecular biology, environmental sciences and veterinary science, making them well suited to assessment of notification dossiers. A range of other bodies may be represented, including NGOs, lawyers, Members of Parliament, agronomists and farming experts and representatives of consumers' bodies. Officials associated with the Committees may be the Secretariat or representatives of regional governments.

5.2.6 Assessment of dossiers

Before a notification for a Part B release can be authorised, the CA must be satisfied that sufficient information has been provided regarding the GMO, the potential risks arising from its release, and how these might be managed (Annex II, Annex IIIB of the Directive). Each CA might have a different view on what is the most critical aspect of a notification with regard to management of risks and ensuring material does not enter the market place. Therefore, each CA was asked to indicate which aspects of the notification they considered to be most important. Table 5.3 below summarises the responses. A simple ranking of the importance of each part of the dossier was obtained by multiplying the number of responses to each ranking by the rank number.

Table 5.3: 'How important do you consider the following information to be when assessing application dossiers':

Level of importance	Number of responses						
	Personnel & training	The GMO	Environmental risk assessment	Risk management measures and rationale	Monitoring during and post-trial	Management of wastes	Emergency response plan
1 (low)	4 (4)	0	1 (1)	0	0	1 (1)	5 (5)
2	4 (8)	0	0	2 (4)	1 (2)	4 (8)	0
3	2 (6)	1 (3)	0	1 (3)	3 (9)	1 (3)	5 (15)
4	4 (16)	1 (4)	1 (4)	2 (8)	4 (16)	5 (20)	5 (20)
5	3 (15)	3 (15)	0	6 (30)	5 (25)	2 (10)	3 (15)
6	3 (18)	3 (18)	4 (24)	4 (24)	1 (6)	2 (12)	1 (6)
7 (high)	4 (28)	16 (112)	18 (126)	9 (63)	9 (63)	9 (63)	5 (35)
TOTAL	**95**	**152**	**155**	**132**	**121**	**117**	**96**

Note: Numbers in columns are the numbers of responses that were received to that particular ranking for that aspect of the dossier. Numbers in brackets are the number of responses multiplied by the ranking. Total is the numbers in brackets totalled.

This very simple ranking indicates that, overall, the environmental risk assessment is considered most important by the CAs when assessing dossiers, closely followed by information about the GMO. In order of decreasing importance are risk management measures and rationale, monitoring during and post-trial, management of wastes, emergency response plan, with information on personnel & training being ranked least important. This is not a fully accurate representation, for example Cyprus, Ireland, Italy and Lithuania place great importance (rank 7) on information about personnel that will be involved and the training they will receive; Belgium, Hungary and Spain also rate this factor quite highly (rank 6). In the Netherlands and Germany there are legislative requirements to nominate responsible persons in the notification document (the Environmental Safety Officer and the Biological Safety Officer respectively), indicating the importance attributed to this aspect of the application. In Sweden less importance is given to the environmental risk assessment because the CA undertakes its own risk assessment, which it considers more important than the applicant's, however increased emphasis is placed on the risk management measures and rationale for these. The emergency response plan was ranked second lowest; discussions with CAs in the MS missions (Appendix 7) indicated that the essential response required in the event of an emergency is that the relevant parties will be informed, the 'incident' will be remedied and the consent holder will ensure all GMO material is fully accounted for. Specific actions to be taken in the event of an emergency are also often described in the consent document. The CAs rely to some extent on their appointed inspectors to ensure that such cases are correctly dealt with. Many CAs commented that in reality each aspect is very important and must at least meet minimum criteria. Should a notifier propose risk management measures that do not meet the CAs requirements, these would be prescribed in the consent document if it were to be issued.

5.2.7 Consent documents

Fourteen MS (58%) have a standard format for the consent document. Where there is not a standard format for the consent, this may be because the notification itself

forms the consent, with a supplementary document specifying the Competent Authority's conditions for the release. Nineteen MS (79%) publish consent documents and this is generally on the Competent Authority website. Five MS stated that the consent document is not published[16].

5.2.8 Information provided to the public, and opportunities for public comment

The Directive places great importance on transparency and making information available to the public, with specific references in Articles 9, 25, 31 and 7. Article 9 lays down requirements for consultation of and providing information to the public on Part B notifications, and Article 31 (3)(a) says that MS shall establish public registers in which the location of the release of the GMOs under Part B is recorded. The Directive does not specify the level at which detail must be provided regarding location – Annex IIIB E1 says the 'location and size of the release site(s) must be provided', but no further detail is given. MS were asked what information is provided to the public, in particular with regard to location, where this information is published and if the public are given an opportunity to comment on applications. Most MS publish the whole consent document without any confidential business information, and most MS confirmed that the public are given opportunity to comment on applications.

Table 5.4: Summary of information in notifications that is made available to the public

MS	What information about location	Where is this published?
Austria	Community or municipality where the trial will take place	CA website
Belgium	The name of the municipality is public, not the precise location	The name of the municipality is included in the notification, and the notification can be consulted at the municipality offices during the public consultation, or at the offices of the public services in charge of the authorisation
Bulgaria	The map of the site wherein transgenic crops are to be grown, including cadastral numbers, the list of owners of adjoining fields and the agricultural practices.	CA website, but this is not yet established
Cyprus	Location of release is published (no detail provided on exact requirements)	Government archive
Czech Republic	The exact location of field trials – the municipality and the land register number (cadastral number). Maps are not provided	CA websites
Denmark	Name of city nearby	Newspapers, websites
Estonia	Intended location by township or city	CA website
Finland	Municipality, but the public decision contains the address of the notifier	Websites at the Official Journal of the Government

[16] If MS had not yet authorised any Part B trials, they were asked to say whether the consent would be published if a trial were to be authorised.

Table 5.4 continued

MS	What information about location	Where is this published?
France	The town must be given, the grid reference is not required	CA website; it must also be advertised in the town hall in which the field trial will take place, also put in the official journal.
Germany	The CA must publish down to the smallest official category of land classification (the parcel of land); the trial normally occupies only a small part of this. The notifier may not know exactly where on this parcel the trial will be over a 4-5 year programme.	Newspapers, websites, also published in the communities in which the trial will take place
Greece	N/K	N/K
Hungary	Site locations are published	Newspapers, CA website, Registrar will provide printed data if requested
Ireland	Townland or townlands	Register of GMO users in Ireland - available in Headquarters of Environmental Protection Agency
Italy	Exact details were not provided. Notification is the responsibility of the regional administration in which the trial will take place. Farmers/ neighbours adjacent to the proposed GMO site must be notified	CA website
Latvia	Location of release is published (no detail provided on exact requirements)	
Lithuania	The region and municipality	Newspapers, website, TV or radio
Luxembourg	The release site is made very visible - town hall of the municipality (local regulatory body) where the GM field trial is planned (very visible)	In the town hall of the municipality (local regulatory body) where the GM field trial is planned (very visible)
Malta	N/K	N/K
The Netherlands	The exact location of GM research trials is not provided - instead a plot 100 times the exact size is made public.	Newspapers, CA website, library of the Ministry of the Environment (Public Register)
Poland	N/K	N/K
Portugal	Detailed identification of the field trial location.	Municipal Councils where the field trials are located
Romania	The locality and the county (or region). Distances to the natural protected areas.	CA websites (Ministry of Agriculture and Ministry of Environment)
Slovak Republic	[No detail provided on exact requirements]	CA website
Slovenia	Exact geographical location and grid reference of the site in the region.	Public GMO register; paper version could be obtained on the request.
Spain	Information of province (municipalities) where field trials are carried out. Exact location of the site is not provided to prevent them from being destroyed, but this would be provided if a specific public request for this information were made to the offices of the relevant CA.	CA websites

Table 5.4 continued

MS	What information about location	Where is this published?
Sweden	Maps showing the detailed location are mailed on request. The consent holder is required to publish locally that a trial will be held and inform the head of the administrative region.	Newspapers in the administrative region where the trial will be held; CA website.
The UK	Four figure grid reference	CA website; public register; applicant must publish in a National newspaper with a 4 figure grid reference.

A wide range of responses were given, with a number of MS making the location of the field trial public at a very fine level of detail. In most cases this is made available on the CA website. Many CAs also require the trial to be notified in the administrative region in which it will take place. Of the eight MS-based notifiers that were interviewed for this part of the study, four stated that they believed the availability of information about the location of a trial to be the major contributing factor to their trials being vandalised by protesters (see tables 5 and 6, Appendix 8).

The requirement for public consultation can also lead to delays in the authorisation process. An example exists in one MS in which two 6-week public consultation periods are established during the approval process for granting a Part B consent. Consent decisions are routinely challenged in court and this can delay a decision. As a consequence of these legal procedures, the Competent Authority cannot guarantee its obligation under Article 6 (6b) of the Directive to issue a decision within 120 days from receipt of a notification, although they strive to do so. In another MS any consent that is issued must contain reasoned responses to any objections that were received to the application; the CA can receive several hundreds up to thousands (>10,000) of objections and it is their role to discuss these objections and present the response in the consent document, which can be extremely time-consuming.

5.2.9 Practical aspects of the management of field trials

Most MS (16 out of 25) have not developed standard practice for management of certain crops or crop/trait combinations and assess each notification on a case-by case basis. Of the nine MS that have developed standard practices, Romania and Spain follow good practice protocols and guidelines established by their Plant Varieties Office; France and Germany have indicative guidelines, but all applications are still assessed on a case-by-case basis, so the procedures may change from notification to notification. In the Netherlands, no practices have been developed because the crops are genetically modified - they are managed according to good agricultural practice in the same way as their non-GM equivalents (while ensuring appropriate containment measures are observed). In Bulgaria isolation distances are specified in the GMO Act for cereals, legumes, oilseed and fibre crops, forage crops and potatoes[17]. Respondents stated that specific management measures are in most cases based on crop biology, also previous experience and published research.

[17] Maize 800m; oilseed rape 400m; soya 20m; potato 200m from tobacco plantings and mass potato plantings; cotton not specified.

Other sources of guidance that may be used as a reference are monitoring reports from other Part B releases, and OECD[18] guidance.

Duty of care

When a GMO is assessed for deliberate release, risks are assessed for the GMO that is described in the notification dossier and consent conditions are applied based on these risks. For reasons of safety and traceability it is therefore important to ensure that the GMO that is released in the field trial(s) is the GMO that has been assessed and authorised for release, also that unauthorised adventitious GMOs are not present. The legal term for this is 'duty of care' and it is the consent holder's responsibility to take all steps reasonably practicable to uphold it. There is also an argument that, providing appropriate risk management measures for the crop are in place and the trial is correctly managed, the GMO itself is less important. This argument is persuasive, but as notifications are issued on a case-by-case basis for a specific GMO that has been risk-assessed, it is important to ensure that only the authorised GMO is released. Should accidental entry to the market place occur, and unauthorised GMOs be traced back to a field trial, this would be a serious breach of the consent conditions, i.e. a non-compliance issue. Competent Authorities were asked what arrangements they have in place to monitor duty of care, responses are summarised in table 5.5 below.

Table 5.5: Requirements to demonstrate presence of the authorised GMO only, and absence of adventitious GM presence

MS	Are consent holders asked to confirm the identity of the GMO released?	What evidence is required?
Austria	Yes	- Provision of sample(s) for official testing - CA takes official sample(s) for testing
Belgium	Yes	- Provision of sample(s) for official testing - CA takes official sample(s) for testing
Bulgaria	No	Not applicable (N/A)
Cyprus	No	N/A
Czech Republic	No	N/A
Denmark	No	N/A
Estonia	No	N/A
Finland	No	N/A
France	No	But – CA may take official samples for testing if resources permit.
Germany	Yes (required by the Federal Länder not the CA)	- GM testing results from the consent holder - Quality assurance documents from the consent holder - Provision of sample(s) for official testing
Greece	Not known (N/K)	N/K
Hungary	Yes	- Production assurance documents from the consent holder - GM testing results from the consent holder

[18] OECD: Organisation for Economic Co-Operation and Development (http://www.oecd.org/)

Table 5.5 continued

MS	Are consent holders asked to confirm the identity of the GMO released?	What evidence is required?
Ireland	Yes	- Production assurance documents from the consent holder - GM testing results from the consent holder - Quality assurance documents from the consent holder - Provision of sample(s) for official testing - CA takes official sample(s) for testing
Italy	No	N/A
Latvia	No	N/A
Lithuania	Yes	- GM testing results from the consent holder - Provision of sample(s) for official testing - CA takes official sample(s) for testing
Luxembourg	No	N/A
Malta	N/K	N/K
The Netherlands	No	N/A
Poland	N/K	N/K
Portugal	No	N/A
Romania	Yes	- GM testing results from the consent holder - Provision of sample(s) for official testing
Slovak Republic	No	N/A
Slovenia	No	N/A
Spain	Yes – for Plant Variety Registration Trials only, except in specific cases where there has been a known seed contamination.	- Production assurance documents from the consent holder - GM testing results from the consent holder - Quality assurance documents from the consent holder - Provision of sample(s) for official testing
Sweden	Not routinely	The CA may take official samples in specific cases if considered necessary
The UK	Yes	- Production assurance documents from the consent holder - GM testing results from the consent holder - Quality assurance documents from the consent holder

Nine of the twenty four MS have arrangements in place to confirm the identity of the GMO that is released, with a further two stating that although specific questions about duty of care are not asked, official samples may be taken if necessary. This could be considered a critical control point in the conducting of a GMO field trial, yet a relatively small number of MS (42%) are seeking assurances from notifiers on this aspect.

Case study:
In Autumn 2002 official tests were undertaken on seeds of oilseed rape as part of a duty of care investigation for GMO field trials scheduled to take place in England and Scotland under consents issued under EC Directive 90/220/EC. The decision to do official tests was taken following a previously reported finding, by the consent holder, of additional GM elements in oilseed rape material sown in spring 2002. The official tests identified the presence of additional GM events that were not authorised for release in GMO field trials scheduled for planting. An investigation confirmed the presence of additional GM sequences nptII, pNOS and p35S. The consent holder

agreed with the conclusions of the official testing, that the detection of nptII and pNOS was accounted for by the presence of Ms1, Rf1 and Rf2 events in the material, and that detection of the p35S promoter was due to the presence of Topas 19/2. Legal advice on this finding concluded that a breach of the consent(s) had occurred[19].

This incident did not result in any unauthorised material entering the market place and no legal proceedings were taken. It serves, however, as a good illustration that errors are possible and that there is benefit in reviewing a notifier's approach to ensuring that only the authorised GMO is released, and that no adventitious GMOs are present in material planted in GMO field trials. Some crops are inherently more disposed to adventitious GMOs than others because of their biological characteristics and this should be taken into account on a crop-by-crop basis. It may not always be appropriate to take samples for testing, for example early stage research trials where material is valuable and in short supply or where a large number of experimental lines are released will not be amenable to this, and sometimes testing may be prohibitively expensive. However, discussion of quality control protocols and review of production assurances can be informative ways of demonstrating whether the notifier has taken all steps reasonably practicable to demonstrate due diligence and ensure, as far as possible, the integrity of trials material. Where an inspector is not satisfied by the information provided in these cases, official testing may be the appropriate next course of action.

5.2.10 Monitoring field trials

All MS place a requirement on the consent holder to provide monitoring reports at the end of each release, or each year of release for multi-year trials. Many CAs require the consent holder reports to be in the EC recommended format as described in Annex VII to the Directive (Commission Decision 2003/701/EC of 8/10/2003). Hungary and the Netherlands stated that continuation of multi-year trials is dependent on submission and acceptance of the end-of-year monitoring report. The CA or the established advisory committee for GMO releases assess these reports, with the exception of Italy and Latvia where the reports are assessed by a different body(ies). Respondents were also asked if they have established procedures for following up observed or unexpected effects at the release site. In this context, an unexpected effect was described as an event that occurred during the course of the trial or the post trial period either in terms of management of the trial, or the crop in the trial, or an effect that was identified in the receiving environment that might have been considered to be due to the GMO itself. The response to this varied: ten MS do not have established procedures in place, but generally it is taken care of by the conditions of consents under which consent holders have a duty to monitor around the trial site and report anything unexpected to the CA. Of the seven CAs that were interviewed, all stated that no unexpected effects had been reported, but that any such reports would be dealt with on a case-by-case basis. Reports of observed or unexpected effects would be followed up by the CA's inspectors, and advice could be sought from the established advisory committee.

[19] Further information on this incident can be found at http://www.gm-inspectorate.gov.uk/reportsPublications.

5.2.11 Arrangements for inspection and enforcement

Recognised procedures for the official control of GMO field trials is summarised in Box 2 below. All MS have arrangements in place for inspection and control of deliberate release field trials. Nineteen of the 25 MS (79%) have inspection and control functions assigned to a dedicated inspectorate (Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Hungary, Ireland, Latvia, Lithuania, the Netherlands, Portugal, Romania, Slovak Republic, Spain, Sweden and the UK). In Germany enforcement is the responsibility of the Federal Länder rather than the CA, and inspectors are appointed within each Länder; in Austria and Italy, inspection and control is the responsibility of the CA and the regional authorities in the territory in which the trial(s) will take place. In Spain where GM field trials can be the responsibility of either Central Government or the Autonomous Regions, there are only dedicated GM Inspectors attached to the Autonomous Regions. In Sweden, until recently the CA was responsible for inspections but this function is now performed by the newly established 'Inspection Division of the Swedish Board of Agriculture', although the CA has retained responsibility for administrative audit of the notifiers. In Slovenia, a number of inspectorates are appointed covering environment and spatial planning, health, agriculture, forestry & food, and veterinary administration and each inspects the trials in accordance with their own competencies. Inspectors were interviewed in the seven MS in the detailed survey, and the findings of these interviews are presented in tables 20 to 23 in Appendix 7 of this report, and are summarised in section 6.

Box 2: Official control of GMO field trials

Under Article 4.5 of the Directive 2001/18, MS are obliged to organise inspection and other control measures as appropriate, to ensure compliance with the Directive. This is achieved by either:

- dedicated **GM Inspectorates** or
- other **enforcement officials**, usually with agricultural and environmental expertise, with delegated authority to inspect GM field trials.

Function

Monitoring of GM field trials, both during and for a prescribed period after a trial, is the responsibility of notifiers. Conditions in a consent will stipulate how monitoring is to be performed and reported upon. The role of the Inspectors is **not** to conduct monitoring but to verify that the conditions and limitations of a consent are being met. Inspectors report their findings to their Competent Authority.

GM Inspectorates (Deliberate Release)

All MS have arrangements in place for inspection and control of GM field trials. Nineteen[20] MS have inspection and control functions assigned to a nominated Inspectorate (see section 5 of the report).

Inspections

Inspections concentrate on assessing GM field trials at key points in the management of a field trial namely sowing or planting, cultivation, harvesting, cleaning of machinery, trial waste disposal, volunteer control and post-trial cropping. Most MS also check labelling, storage conditions prior to release, and secure transport to the site of the release. Inspectorates use standard operating procedures and checklists whilst conducting inspections. Documentation held by the notifier or field operator is checked, especially if a MS encourages or requires notifiers to record all trialling activities and observations in a trial logbook. Inspectorates are usually allied to a diagnostic GM testing service. Samples can be taken to verify the presence of a GM crop or to demonstrate that only the GMO that has been authorised in the consent has been released (duty of care).

Frequency of Inspection

The number of inspections of a trial will vary according to the approach that is taken to control GM field trials in each MS, i.e. field inspection only, inspection plus administrative inspection, or management audits with reduced inspection. For field inspection only approaches, visits can be up to 4 per year, whilst with audit-based approaches only one visit per year may be necessary (see Appendix 7, table 21e).

Reporting

Inspection reports or outcomes of inspections are submitted to Competent Authorities and in some cases are copied to the notifier. Generally, these reports are not published. In some MS inspection activities are summarised and published in an annual report. Only the UK routinely publishes individual inspection reports.

Enforcement powers and serious breaches of consent

These depend on upon the legal system operating in a MS. Where breaches of consent conditions fall under criminal law, Inspectorates report incidents to their Prosecution Services, as in the UK. Where administrative law operates, Inspectorates can issue summary fines without recourse to criminal law. Because each MS has its own legal system, the definition of breach of consent and how these may be dealt with varies between the MS.

Co-ordination between European GM Inspectorates

A network of GM Inspectorates operates throughout the EU via the European Enforcement Group[21]. This promotes harmonisation of inspection procedures and rapid communication of incidents, especially in incidents involving adventitious GM material in agricultural seed.

[20] Nominated Inspectorates operate in Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Hungary, Ireland, Latvia, Lithuania, Netherlands, Portugal, Romania, Slovak Republic, Spain, Sweden and the UK.

[21] The European (GMO) Enforcement Group was established in 1999 to facilitate exchange of knowledge and practical expertise between inspectors of deliberate release field trials (synonymous with the European (GMO) Enforcement Project, EEP).

5.2.12 Non compliances

Under Article 4(5) of the Directive, Member States 'shall ensure that the competent authority organises inspections and other control measures as appropriate, to ensure compliance with this Directive. In the event of a release of GMO(s) or placing on the market as or in products for which no authorisation was given, the Member State concerned shall ensure that necessary measures are taken to terminate the release or placing on the market, to initiate remedial action if necessary, and to inform its public, the Commission and other Member States'.

Dealing with non-compliance will vary a great deal between the MS because each has different legal systems and frameworks, different criteria by which incidents are judged, and different mechanisms for dealing with non-compliance. It is, therefore, difficult to make direct comparisons between the MS. It was beyond the scope of this report to examine in detail the different legal systems available for dealing with incidents associated with the release of GMOs. However, Box 3 below summarises the terms that are mostly encountered in connection with GMO releases, and the types of mechanisms available to deal with these.

Box 3: Compliance with the conditions of consent to release a GMO under Part B of the Directive

Each Member State has its own legal frameworks and administrative mechanisms to enable it to manage non-compliance with national legislation. Punitive measures will be available to CAs depending on the scale and nature of the non-compliance, and the balance of available evidence. Each incident will be considered on a case-by-case basis. An important consideration will be whether the consent holder identified the breach and brought it to the attention of the CA.

The terms listed below are used in the report to describe non-compliance with national legislation.

Breach of consent

When a CA grants consent to a notifier to conduct a deliberate release GMO trial, the conditions under which the trial is allowed to take place will be stipulated. These will include the GMO that may be released, the timescale, location and nature of release, and the requirements for monitoring and reporting. The consent is a legally binding document and the consent holder (= notifier) must meet all the conditions laid down in the consent in order to demonstrate compliance to the CA and nominated inspectors. Should the consent holder fail to meet one of the conditions of the consent, a breach of consent is said to have occurred.

Technical non-compliance

Generally, technical non-compliances occur when the consent conditions are breached but where the outcome of the breach does not cause harm to either human health or the environment. A technical non-compliance may occur during the trial itself, in which case it may be possible to remedy the non-compliance and allow the trial to continue to harvest, or the non-compliance may occur during the post-trial phase. A technical non-compliance may occur due to oversight and would in most cases be unintentional. What constitutes a technical non-compliance is likely to vary between MS, and will be assessed on a case-by-case basis, however a few possible examples are given below:

- Incorrect dimensions of the trial site
- Incorrect isolation distance
- Incorrect crop planted on the former GM trial site in the post trial monitoring phase (e.g. OSR on a former OSR trial site)
- Incorrect GMO inadvertently planted

Mechanisms for dealing with non-compliance

Possible courses of action for dealing with non-compliance, including technical non-compliance if the CA judges it to be appropriate, are listed below. Each MS will have different criteria as to what merits a warning or a fine and what requires legal action.

- Issuing of written **warnings** in connection with the breach
- Issuing of a **fine** proportionate to the scale of the incident
- Issuing of legal **notices**, e.g. prohibiting certain courses of action, or requesting provision of information to assist enquiries
- Formal **investigation** initiated by lawyers, possibly resulting in **prosecution**

Serious non-compliance

There is not a clear distinction between a technical and a serious breach of consent, and each MS will have their own criteria for making this judgement. However, a serious breach would usually have to be intentional acts or demonstrable neglect of procedures. A 'serious' breach would normally initiate a formal response from inspectors and or/the Competent Authority, e.g. a warning letter, a variation to the consent conditions, a fine, or initiation of court proceedings. There will be a legal or political component to decision making in such cases, and/or the potential to cause harm to health or the environment. The case would have to be sufficiently serious and in the public interest to pursue legal proceedings.

Material entered the market place

Under Article 6(9) Member States shall 'ensure that no material derived from GMOs which are deliberately released in accordance with part B is placed on the market, unless in accordance with part C'. Should this be proven to have occurred, it would be a clear breach of the Directive and a serious non-compliance.

The eighteen CAs that have notified GMO field trials were asked to provide details of all non-compliances, including technical non-compliances, that have occurred in their MS since the Directive came into force in 2002. Technical non-compliances were described as in Box 3 above. The notifiers that were interviewed in the seven key MS were also asked to provide information about non-compliances that had occurred under any of their consents – this is provided in tables 5.6, 5.6a and 5.6b below.

Note: In Germany, where enforcement is the responsibility of the Federal Länder, it was not possible to gather information on 'minor' non-compliances from each of the Länder. Inspectors in two of the Länder were interviewed and provided this information for trials that had taken place in their territory. The CA would be notified of any incidents where material had accidentally entered the marketplace or where prosecutions had been pursued. In Spain, which has similar regional organisation, the Regional Autonomous Regions have to inform the Spanish CA of any infringements to the GMO Law, however small.

Table 5.6: Total number of non-compliances in the 18 MS that have notified GMO field trials under Directive 2001/18/EC since 2002

How many non-compliances in the following categories have occurred			
Technical non-compliances	Fines or written warnings issued	Material has accidentally entered the marketplace	Prosecutions pursued
11 (see below for details)	3 (see below for details)	0	0

Table 5.6a: Technical non-compliances

MS	No.	Reason
Denmark	2	Failure in monitoring
France	5	Previously, when the isolation distance for maize was set at 200m, inspectors encountered problems with pollen barriers not being implemented; if the pollen barrier was not in place this had to be treated as a non-compliance and the trial had to be destroyed as a risk management measure. However, the isolation distance for maize is now 400m and this action is no longer necessary.
Germany	1	Contamination of maize seed with authorised MON810 and MON863: the CA for Human Health & Safety (CA for sampling and testing GMOs) identified the contamination. Because these were approved events it was not considered to represent a risk. The applicant was informed of the contamination and the tassels of the male plants were destroyed so that pollen could not be released. There was no other penalty on the company.
Portugal	2	Maize. No details were provided
Spain	1	Maize. A neighbouring farmer cultivated conventional maize within the 200m isolation distance for a GM maize trial. In this case the notifier bought the neighbour's maize crop and it was managed as for the field trial.
TOTAL	**11**	

Table 5.6b: Fines or written warnings issued

MS	No.	Reason
Denmark	2	Failure in monitoring – linked with technical non-compliances above
Spain	1	Maize. One field trial for which the waste material was not incorporated into the soil appropriately. This was determined to be the fault of the notifier, hence the infringement was considered more serious than the non-compliance reported in table 5.6a and a written warning was issued.
TOTAL	**3**	

The CAs reported a total of twelve non-compliances. Of these, 11 were classed as technical breaches of consent, and 1 was a written warning issued in Spain in connection with a maize trial in which the waste management measure had not been properly implemented (tables 5.6, 5.6a and 5.6b). Two of the written warnings that were issued to consent holders in Denmark in connection with the failure to monitor were for technical non-compliances reported in table 5.6a, and these have not been double counted. Four of the twenty-four CAs said they would themselves (as opposed to their legal departments) publish details of non-compliances.

An additional incident was reported in Sweden in 2004 in connection with a consent issued under Directive 90/220/EC. An inspector from the Board of Agriculture observed that a farmer had planted a crop of seed potatoes within the isolation distance stipulated for potatoes in a nearby GMO field trial. The consent holder was informed and responded by correcting the isolation distance and the field trial continued as planned. The Board of Agriculture reported the incident to the authorities and the farmer was prosecuted and fined. The consent holder increased its inspection of trials as a result of this incident.

When the survey was conducted, 431 field trials had been notified under the Directive since it came into force; even if a proportion of these trials did not proceed, the levels of non-compliance that have been reported can, quite reasonably, be said to be low (0.65% per year over a period of five years), with no reports of accidental entry of material onto the market place and no prosecutions pursued. This would appear to be a system that is working well. Interviews with the CAs, inspectors and notifiers in the detailed survey confirmed that the best outcome from any potential non-compliance incidents was gained when notifiers acted quickly and responsibly by declaring any potential breaches to the CA and adopting the required mitigation measures quickly and without recourse to legal proceedings. Most technical breaches are declared and are resolved with Inspectorates without the need to go down the route of formal legal proceedings because corrective action can be applied which returns the trials to a compliant status. This would seem to be a fitting and pragmatic approach where no risks to health or environment have been identified. This explains why there are many more reports of technical non-compliances compared with legal procedures in both third countries and in the EU.

Note: in June 2008 an incident of adventitious GM presence was reported in seeds of non-GM spring oilseed rape sown at a number of small conventional trial sites in Belgium. The source of the adventitious GM presence was investigated by the Belgian authorities, and was thought to be due to human error. However, a full report will be provided to the European Commission in due course.

SUMMARY OF 'BASIC' MS SURVEY

1. This concise survey has shown that the twenty four MS that participated in the study have implemented the Directive. Each Competent Authority has confirmed that information is available to guide and assist in the lodging of a notification to hold a Part B trial under the Directive. The participant MS all have systems in place to assess notifications, consult the public, and to issue consents.

2. Providing the standard procedures are observed (e.g. regarding timelines, interaction with the notifiers and the Commission etc), national governments can implement the Directive at their own discretion, which means there is not parity in systems established in each of the MS. There are differences in the amounts of information and levels of detail required in the notification dossier, and some MS apply more stringent management measures than others. In addition, submission and acceptance of a notification by a CA does not guarantee that an authorisation will be issued, although we do not have sufficient information to draw any conclusions about the reasons for this. The systems themselves mostly appear to meet the requirements of the Directive and to be fit for purpose.

3. The need to observe other national legislation can impact on the Directive and create serious bottlenecks that mean the timelines established under Article 6 (6) of the Directive cannot be met.

4. The participant MS have arrangements in place to ensure that management of Part B trials by the notifiers is subject to inspection and control. A low level of non-compliances since 2002 have been reported, none of which resulted in prosecution. No material has been reported to have accidentally entered the marketplace.

The findings are discussed further in section 6.

6. DETAILED SURVEY OF SEVEN MEMBER STATES

6.1 PARTICIPANT MEMBER STATES – COMPETENT AUTHORITIES AND APPOINTED INSPECTORS

France

The French Competent Authority for Directive 2001/18/EC is the Ministry of Agriculture and Fisheries, Directorate General for Food. The 'Chargée d'étude OGM' is the responsible department within the Ministry.

Note on particular situation in France 2007/08:
A cross-party review on environment-related policy (The 'Grenelle de l'environnement') was undertaken in France between July and October 2007. This included a review of risks and management of GMOs in France[22]. This led to a temporary halt in the notifications procedure while the CA awaited the outcome of the review and the implementation of the recommendations. The CA could not assess new Part B applications until a new law was implemented, which was thought likely to be summer 2008. Trials authorised under the old law could still proceed.

- *GMO field trials held in France*

The notifications database for France was a reasonably accurate representation of Part B field trials held in the country, but because it is a record of notifications, some of the trials did not go ahead. The database has been updated. Further information is available at http://www.ogm.gouv.fr/.

- *Nominated inspection and control body:* the National Inspectorate for Plant Protection, which is part of the Competent Authority. France is divided into 22 regions, within which are principalities. Each region has at least 1 inspector for part B GMO field trials.

Germany

The German Competent Authority for Directive 2001/18/EC is the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) - the Federal Office of Consumer Protection and Food Safety for Germany. BVL has been the leading federal authority responsible for the field of genetic engineering in Germany since 2004. At the BVL, the Department of Genetic Engineering fulfils the mandate as national Competent Authority according to the Genetic Engineering Act (Gentechnikgesetz) and Ordinances of the European Union. The BVL assesses notifications for the experimental use of GMOs and is also involved as the national Competent Authority in the approval of GMOs for food and feed. The BVL gives advice to the Federal Government as well as the Federal States (Bundes-Länder)

[22] The review recommended i) that a single, independent, high authority should be put in place to give an opinion to the government on each GMO, and that this should consider the health and environmental aspects, agronomic and economic interest; and ii) that before summer 2008, a law must be enacted to create the high authority and to set out the principle of coexistence and free choice for consumers and producers. The review also said that knowledge of and public research on genetic manipulation must be increased, notably on health and environmental aspects of each GM crop, and this included Part B releases.

and their bodies on issues of biological safety in genetic engineering. Further information about BVL is available at: http://www.bvl.bund.de/cln_027/nn_496812/EN/06__Genetic__Engineering/genetic__engineering.html__nnn=true.

- *GMO field trials held in Germany*

The notifications database for Germany was a reasonably accurate representation of Part B field trials held in the country. The exception was the risk management measures, which did not reflect the risk management procedures required by the risk assessment authority. All of the trials went ahead but not all of the sites were used. The database was partially updated.

- *Nominated inspection and control body:* in Germany the Federal Bundes-Länder are competent for enforcement and are required to nominate specific authorities. The CA does not have an inspectorate.

Hungary

The Hungarian Competent Authority for Directive 2001/18/EC is the Ministry of Agriculture and Rural Development, based in Budapest. Information can be found at http://biodiv.kvvm.hu/ (some in English).

- *GMO field trials held in Hungary*

The notifications database for Hungary was not an accurate representation of field trials held in the country, but it has been fully updated. Of the 26 field trials notified, 7 went ahead. The main areas of inaccuracy are listed in table 5.1 in section 5. Hungarian GMO legislation establishes that the Ministry of Environment and Water is responsible for exchanging information with the European Commission about notifications for Part B GMO field trials.

- *Nominated inspection and control body:* the Central Agricultural Office, Directorate of Plant Production and Horticulture, Seed Inspectorate.

The Netherlands

The Dutch Competent Authority for Directive 2001/18/EC is the Ministry of Housing, Spatial Planning and the Environment (VROM). The 'GMO Office' supports the VROM in administrative and technical/scientific aspects by handling the applications and supporting policy development. The GMO Office receives all applications for Part B releases (including gene therapy research) and the VROM is responsible for taking decisions on consent applications. Further information is available at http://www.vrom.nl/. Information about biosafety is available in English at http://international.vrom.nl/pagina.html?id=10534.

- *GMO field trials held in The Netherlands*

The notifications database for the Netherlands was a reasonably accurate representation of field trials held in the country. Some consents have been authorised but have had to be later withdrawn by the Competent Authority following legal challenges and judicial rulings. The database was not updated to reflect this.

- *Nominated inspection and control body:* the VROM has its own inspectorate ('The VROM Inspectorate').

Spain

The Spanish Competent Authority for Directive 2001/18/EC is the Ministry of Environment, Department of Quality and Pollution. Spain has two different procedures based on the distribution of competencies between Central Government (Ministry of Environment) and the Autonomous Regions. Applications must be lodged with the National CA and the CA of the autonomous region in which the trial is to take place. All applications are evaluated by the Spanish Commission on Biosafety (CNB), which produces an environmental risk report for the corresponding Competent Authority. Information can be found at http://www.mma.es/portal/secciones/calidad_contaminacion/omg/

- *GMO field trials held in Spain*

The notifications database was mostly correct and was a reasonably accurate representation of field trials held in the country. The database has been partially updated.

- *Nominated inspection and control body:* the National CA does not have a nominated inspectorate; inspectors of Part B field trials are appointed by the Regional Competent Authorities only.

Sweden

The Swedish Board of Agriculture is the Competent Authority for Directive 2001/18/EC. The Crop Production Division of the Crop Production Department is responsible for activities involving genetically modified plants, animals and feeding stuffs. The Board is not responsible for aquatic organisms, or for field trials or the placing on the market of forest trees intended for lumber production, nematodes, spiders or insects. Information about Swedish GMO legislation is available at http://www.gmo.nu/, and is also available in English.

- *GMO field trials held in Sweden*

The notifications database was not correct, mainly regarding management measures for trials because the JRC website contains only the measures proposed by the notifier. In Sweden the CA may request other/additional measures in the consent. Furthermore, for multi-year trials, the Swedish authorities retain the right to modify the conditions of each Decision each year, so as the trial goes ahead year-on-year, the consent may be modified depending on experience in the previous year. The number of release sites and location of release sites does not have to be fixed in the application, so this will also change during the life of the trial.

- *Nominated inspection and control body*: the Inspection Division of the Swedish Board of Agriculture, established 2007. Prior to 2007 the Competent Authority itself was responsible for inspection and control.

The United Kingdom

The Department for Environment, Food and Rural Affairs (Defra) is the national Competent Authority for Directive 2001/18/EC in the UK. Applications to release a GMO (Part B and C) are administered by the 'Northern Ireland, England, Wales and Scotland (NIEWS) GM Unit' based at Defra, which coordinates consultation on all applications. Further information is available at http://www.defra.gov.uk/environment/gm/index.htm.

- *GMO field trials held in the United Kingdom*

The notifications database for the UK was a reasonably accurate representation of field trials held in the country, but one trial that was authorised did not go ahead. The database has been updated.

- *Nominated inspection and control body:* The GM Inspectorate (England), which is based at the Central Science Laboratory, an Executive Agency of Defra. A GM Inspectorate is also nominated for Scotland, and is part of the Scottish Agricultural Science Agency.

The detailed responses provided by the Competent Authorities and their appointed inspectors in the seven Member States are provided in Appendix 7.

6.2 MEMBER STATE-BASED NOTIFIERS

Each Competent Authority was asked to nominate a notifier in their Member State that could provide a representative picture of how the national framework is working for them[23]. Questions were developed to provide an understanding of:

> i) How the national legislation and the procedures that have been established are working for the community that is using it, i.e. the companies, universities and research institutes.
>
> ii) How joined up are the competent authorities, inspectors and notifiers and how effectively do the different players work together; and whether there are any major gaps or problems in the way the CAs, inspectors or notifiers are operating.

The notifiers that were nominated fell into the following categories:
- Multi-national company (USA)
- Multi-national company (European)
- A university

[23] Please refer to table 4.2

Each notifier was asked to identify a field trial operator that they have worked with who would be willing to participate in the study.

The detailed responses provided by the nominated notifiers in the seven Member States are provided in Appendix 8. In Germany the CA nominated one notifier, and a second notifier offered to participate - the responses of both of these notifiers are represented in the tables in Appendix 8. In Hungary the CA nominated a single notifier to participate, in addition the company supplying trials seed to this notifier attended the interview.

6.3 NOMINATED FIELD OPERATORS

The persons interviewed in this part of the study were all operators of GMO field trials for notifiers that were interviewed in section 6.2. These persons were interviewed to provide an impression of:

- The degree to which the notifiers communicate the legal and practical requirements of GMO field trials to their appointed operators, including the arrangements that are put in place to ensure compliance is achieved.

- The practical arrangements that are in place to make sure field trials run as they should do, including arrangements for managing and reporting unexpected events should they arise.

The field operators that were interviewed fell into the following categories:

- Staff directly employed by the notifier, i.e. the company runs its own field trials and has staff dedicated to the task.
- Small companies or research institutes that run field trials on a professional basis for a wide range of customers.

The detailed responses provided by the field trial operators of the nominated notifiers in each of the seven Member States are provided in Appendix 9.

6.4 FIELD TRIALS FOR CROSS-MS COMPARISON

A list of field trials of particular interest for cross-MS comparison purposes was provided to each MS that was visited with a request that information on management measures applied to each would be sought at interviews (see table 4.3, section 4). The Competent Authorities and/or inspectors were not, however, able to provide specific feedback on a notification-by-notification basis (this would have required a lot of research in some cases). Instead, general comments were provided on how the trials proceeded and where there were any issues with a particular trial the CA / inspectors raised these. Tables 6.1 and 6.2 below summarise the management measures that are applied in each MS for trials of GM maize and potato crops, and table 6.3 summarises the responses from each MS regarding how the trials proceeded.

Studying these tables, with the management measures alongside each other, it can be seen that the measures are essentially similar, with the main area of variation being isolation distances. This is particularly so for maize, which ranges from 50m in Sweden (for a Part C authorised maize event) up to 500m in Hungary, with 200m (Germany) and 400m (France) between these. Requirements for monitoring (during and post-trial), disposal of material and inspections do not differ greatly. For the potato trials the isolation distance is 10m or 20m and management measures are focussed on post-trial monitoring to ensure the reduction and removal of potato volunteers. Looking at table 6.3, potato volunteers is one area where CAs have encountered minor problems with populations not declining as was expected; in Sweden and Germany this was due to unusually warm winters which did not succeed in killing off volunteer populations in the way that was anticipated. No information has been provided to suggest that the trait that is placed in the trial influences how the crop is managed.

Apart from the relatively minor problems with potato volunteers, the MS have reported that the trials went ahead as planned and that no unanticipated problems with the GMO arose. The level of compliance is high, with no incidents reported for the trials in question. There were also no incidents of spread of the GMO material outside of the trial area. In one case management measures were reviewed and post trial monitoring for the particular consent was extended, which is also recorded as a lesson learned as a result of the trial. However, in all cases the original risk assessment and risk management plan were considered to have been appropriate for the trial. Most of the trials were said to have contributed data for the notifier for making an application to place a GMO on the market.

Table 6.1: Combined management measures for maize crops in the MS that have held trials of GM maize

MS	Measures to prevent gene flow and/or dispersal of GM material	Cultivation	Sowing	Harvesting	Cleaning machinery	Post trial monitoring	Post-trial cropping	Disposal of wastes	Official inspections	Other crop-specific management requirements
FR	400m. No other measures described	None	None	None GM material is generally destroyed in the field. Maize straw is ploughed back into the field	Not specified	1 year PTM for volunteers but can change on case-by-case basis	1 year no maize but can change on case-by-case basis	GM material is generally destroyed in the field. Maize straw is ploughed back into the field	Growing crop (prior to flowering); Post-trial monitoring period (at least once). No specific requirement to inspect at sowing or harvest (but depends on resources) The notifier is obliged to inspect the trial	No specific requirements for transport or for storage of GM material
DE	200m. Other GM maize, or conventional maize may be allowed within the 200m but all maize within the 200m must be disposed of as GM maize i.e. not for food and feed or placing on the market. Pollen barrier is not required	None	None, except machinery must be cleaned afterwards	None, except machinery must be cleaned afterwards and no GMOs must remain	Must take place at the trial site	1 year with no volunteers, if any GM volunteers are found they must be removed and destroyed before flowering to prevent further volunteers. If this is done, PTM can then cease	Anything can be grown that does not interfere with PTM for volunteers	Any proven destruction method. Maize may be used for biogas. Most maize in Germany is grown for silage, so it does not get ripe & is quite easy to incorporate	Sowing (once); Growing crop (at least once); harvest (once); post trial (at least once)	None

MS	Measures to prevent gene flow and/or dispersal of GM material	Cultivation	Sowing	Harvesting	Cleaning machinery	Post trial monitoring	Post-trial cropping	Disposal of wastes	Official inspections	Other crop-specific management requirements
HU	500m plus additional rows of non-GM varieties, which should be demolished after flowering. Pollen control if necessary	Yes	Yes	Yes	Yes	Yes. Removal and destruction of sexually compatible or related crop found in the isolation zone	Limitation of further use of the field, special requirements for crop rotation for 1 year	Destruction of any material remaining in the field by burning (seeds) or by ploughing in (other materials)	Once each at: - Sowing - Growing crop - Harvest - Post-trial	Removal and destruction of sexually compatible or related crop found in the isolation zone; guarding the trial site
ES	200 m (compulsory), usually plus 4 border rows of non-GM. At least 1 month temporal isolation	None	No. Seed bags labelled. Chemical treatment or burial of unwanted seed waste	Burial of seed and crop waste	Compulsory	1 year	Not the same crop. Specific conditions are set out in each risk evaluation report	After harvest, the plant residues will be chopped and then incorporated into the soil. Incineration of the remains is sometimes allowed	Sowing; Growing crop (once or twice); harvest; post-trial (random)	Secure transport. Chemical treatment or burial of unwanted seed and crop waste
SE	50m (the only maize trial was NK603, which is approved for food and feed & has 0.9% threshold)	None	Cleaning the machinery. Left over seeds for sowing must be destroyed or returned to originator. Consent holders state in end of year reports that they have done this	Maize must be chopped before it is ripe and left in the field with the cobs. It is then ploughed back into the land	Yes	Notifiers have proposed to monitor for 1 year post harvest and the CA has agreed	No maize for 1 year	Any proven destruction method	Growing crop (at least once); post-trial (once). The CA expects the notifier to inspect the crop at appropriate, intervals during the growing season	None

Table 6.2: Combined management measures for potato crop in the MS that have held trials of pathogen resistant potatoes

MS	Isolation	Cultivation	Sowing	Harvesting	Cleaning machinery	Post trial monitoring	Post-trial cropping	Disposal of wastes	Official inspections	Other crop-specific management requirements
DE	10m from a commercial potato crop	No	None, except machinery must be cleaned afterwards and no GMOs must remain	Same as sowing	Must take place at the trial site	Minimum 1 yr PTM. Must be 1 year with no GM volunteers before PTM can stop	Anything can be grown that does not interfere with post-trial monitoring for volunteers	Any proven destruction method. Potato residues may be ploughed under.	Sowing (once); Growing crop (once); Harvest &/ or disposal (once) Post trial (once – twice) CA expects consent holder to inspect	After harvest of GM potatoes the trial site must be cultivated immediately to bring them to the surface and the area checked for tubers left behind. Tubers must be collected and destroyed
SE	20m unless it is a seed production site then seed isolation rules operate	Cleaning the machinery; make sure seeds for sowing are destroyed or returned to originator. Consent holders must state in end of year reports that they have done this.	Machinery must be cleaned. Potatoes must be removed and destroyed, unless they are propagating material	Yes	At least 2 years monitoring until 1 year with no volunteers	No potatoes until 1 year with no volunteers. Trial site must remain fallow for 1 year or in some cases be cultivated with a crop where potato volunteers can be detected and destroyed (e.g. grain)	None	Any proven destruction method. (Note: lots of methods have been approved for potato)	Growing crop (at least once); post-trial (at least once) CA expects consent holder to inspect	Potatoes must be removed and destroyed, unless they are propagating material

MS	Isolation	Cultivation	Sowing	Harvesting	Cleaning machinery	Post trial monitoring	Post-trial cropping	Disposal of wastes	Inspection requirements	Other crop-specific management requirements
UK	20 m isolation from nearest commercial crop.	None	Machinery must be cleaned post sowing and seed must be properly labelled for which the GMI can ask for proof.	Should be harvested according to good agricultural practice.	All machinery must be thoroughly cleaned before leaving the area.	In the 2 years post harvest land must be left fallow and all volunteers must be treated with an application of glyphosate herbicide or hand pulled and removed from the site prior to flowering. The consent holder should inspect the trial area at least once a month from March to November until have 2 consecutive years with no volunteers	No potatoes should be grown until 2 years with no potato volunteers has passed.	All material must be placed in sealed labelled bags and transferred to conditions where GMO (contained use) rules apply or taken to an incinerator or taken for deep burial. Footwear must be washed and machinery must be cleaned.	Sowing (once); Growing crop (once); Harvest &/ or disposal (once); Post-trial (at least once) The consent holder must inspect each GMO area during the period of cultivation of GMOs at least once per month and maintain raw data and reports of inspections of volunteers	During the post-trial monitoring period, no oil seed rape or any other plant species in which volunteers are difficult to identify and control should be grown.

Note: trials of this GM potato have also been held in the Netherlands but no crop-specific management measures were provided for these trials in the Netherlands.

Table 6.3: Management experiences with specific field trials

Questions about the field trials	FR	DE	HU	NL	ES	SE	UK
Did the field trial go according to plan? If not, how did it deviate from the plan?	Yes	Yes	Yes	Yes	Yes	Yes	No. Trial was vandalised
Did any problems arise with the GMO that were not anticipated at the outset?	No	Winter was warm and led to volunteer populations following year	No	No	No	No	No
Were any incidents of non-compliance identified? If yes, what were these and what happened as a result?	No	No	No	No	No	No	No
Was any incident of spread of the GMO outside of the trial area identified?	No	No	No	No	No	No	No
If yes, how was this identified and what measures were taken to remedy the spread?	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Was the origin of the spread of the GMO identified and analysed (e.g. out crossing or/and admixture)?	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Were management procedures reviewed as a result of anything that happened with this release?	No	Yes. PTM was prolonged	No	N/A	No	No	No
Were any lessons learned as a result of this trial?	No	Yes. PTM was prolonged	No	N/A	No	Warm winter did not kill off potato tubers and the site had to be chemically treated	Potential problem with storage of GM material. Was discussed with the consent holder and was corrected.
Were the risk assessment and risk management plan judged to be appropriate for the trial, in particular taking into consideration any incidents of spread of the GMO?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Did data gathered from this trial contribute to an application to place a GMO on the market?	Yes	Not known	Yes	Yes	Yes	Yes	Yes

6.5 DETAILED MS SURVEY: SUMMARY OF RESPONSES

Comments on administrative systems in place are covered in section 5 where the 'basic survey' is discussed. Very little information on management of trials of cotton has been gathered, primarily because Spain was the only MS to have had any releases of cotton. The notifiers that participated in the study did not have any specific comments to make about management of cotton trials.

- *COMPETENT AUTHORITIES AND INSPECTORS (for detailed responses see Appendix 7)*

Role of the CA: control of the deliberate release of GMOs in each MS. Assess Part B applications, issue consents, appoint inspectors, set up scientific advisory bodies regarding GM releases, manage the deliberate release process in accordance with national legislation which implements the Directive. Notifier monitoring reports (growing season and post-trial) must be submitted to the CA.

Specific practices at critical control points:

i) **Trial management**.

Six critical points in the management of a field trial were identified, namely cultivation (of the site prior to sowing), sowing, harvesting, cleaning machinery, post-trial monitoring and post-trial cropping (Appendix 7, tables 10 to 18). Each CA was asked about specific requirements at these different stages for maize, potato, cotton, oilseed rape and sugar beet. The Netherlands and the UK did not specify any measures to be used at any stage in trials because the case-by-case risk assessment principle operates very strongly. The Netherlands stated that no practices have been developed because the crops are genetically modified - they are managed according to good agricultural practice in the same way as their non-GM equivalents. Of the other MS, while each stage in the trial was acknowledged to be important, no special measures were described for cultivation, sowing or harvest, although requirements to clean machinery at each of these stages are in place (the methods for cleaning were not specified). The seven MS require post-trial monitoring to be undertaken to ensure removal of any volunteer plants, and place restrictions on the crops that can be grown subsequently to ensure volunteers can easily be identified. The detail of post-trial monitoring requirements varies slightly between the MS for each crop, but they are broadly comparable; no specific measures are established by the Netherlands or the UK because the case-by-case principle operates (see Appendix 7, tables 12a to 12e). Section 5.2.10 provides further information on monitoring and reporting on field trials. It is the role of inspectors to ensure that any prescribed procedures were carried out.

ii) **Isolation from sexually compatible crops and/or wild relatives**.

Out-crossing between two or more varieties of the same species is one route by which material from a GMO trial might gain entry to the marketplace. Isolation of a GMO trial from conventional commercial crops is the main method employed to minimise out-crossing, possibly in combination with other measures such as pollen barriers and temporal separation of the flowering period. Isolation distances are the minimum separation required to prevent out-crossing, and are employed in seed production where statutory requirements for purity are described. Commercial seed producers have two distinct classes of pure seed: seed for marketing (certified seed) and seed to be used for growing future seed crops (basic seed). For professional

seed growers the consequences of cross-pollination events are far-reaching and could lead to rejection of a commercial seed lot at certification, leading to economic loss, or even the loss of a particular variety.

Isolation distances are affected by pollen weight, wind direction and velocity, field size and shape, and weather conditions (which, for example, influence pollen viability). Statutory minimum isolation distances for seed production for the crops of interest to this study are listed in box 4 below; these have been developed over many decades on the basis of direct experience gained during seed production. The fact that they are based on empirical data rather than on theory or logic means that they are well tested and thus very reliable.

Box 4: Crop isolation - European and internationally accepted standards

Recognised minimum isolation to achieve a specified level of purity

Crop	Isolation distance (minimum distance from sources of contaminating pollen)		Varietal purity (%) (minimum purity at field inspection) (Reference in brackets)	
	Basic seed	*Certified seed*	*Basic seed*	*Certified seed*
Maize (*Zea mays*)	200m	200m	99.5 (1) – 99.9 (2)	99 (1) – 99.8 (2)
Oilseed rape (*Brassica napus*)	500m	300m	98 (3) - 99.9 (4)	98 (3) – 99.7 (4)
Potato (*Solanum tuberosum*)	No statutory isolation distance described for seed production. Very limited dispersal of pollen occurs over distances up to 2.25m (5).		99.9 (6)	99.8 (6)
Cotton (*Gossypium hirsutum*)	800m	200m	99.8 (7, 8)	99.5 (7, 8)
Sugar beet (*Beta vulgaris*)	1000m	300m to 1000m (depending on pollinator ploidy / male sterility)	97 (9, 10)	97 (9, 10)

References:

1: Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31966L0402:EN:HTML)
2: OECD scheme for the varietal certification of maize and sorghum seed moving in international trade 2008 (http://www.oecd.org/dataoecd/30/42/40203633.pdf)
3: EC Council Directive 2002/57/EC (as amended) on the marketing of oil and fibre plant seed (http://eur-lex.europa.eu/LexUriServ/site/en/consleg/2002/L/02002L0057-20050125-en.pdf)
4: *OECD scheme for the varietal certification of crucifer seed and other oil or fibre species seed moving in international trade 2008 (*http://www.oecd.org/dataoecd/30/16/40203167.pdf)
5: Anthony J. Conner, Biosafety evaluation of transgenic potatoes: Gene flow from transgenic potatoes. International Symposium (2006), Ecological and Environmental Biosafety of Transgenic Plants, 127~140 (http://www.tari.gov.tw/GMO/book-1/(P127-140)-Biosafety Evaluation of Transgenic Potatoes.pdf)
6: Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:193:0060:0073:EN:PDF)
7: EC Council Directive 2002/57/EC (as amended) on the marketing of oil and fibre plant seed (http://eur-lex.europa.eu/LexUriServ/site/en/consleg/2002/L/02002L0057-20050125-en.pdf)
8: OECD scheme for the varietal certification of crucifer seed and other oil or fibre species seed moving in international trade 2008 (http://www.oecd.org/dataoecd/30/16/40203167.pdf)
9: OECD scheme for the varietal certification of sugar beet and fodder beet seed moving in international trade 2008 (http://www.oecd.org/dataoecd/30/61/40203417.pdf)
10: Council Directive 2002/54/ECof 13 June 2002on the marketing of beet seed (http://eur-lex.europa.eu/LexUriServ/site/en/consleg/2002/L/02002L0054-20050125-en.pdf)

Isolation distances and GMOs

It is accepted that Part B releases must have some interaction with the environment, and that a very small amount of GM gene flow may occur beyond the isolation

distance (otherwise all experiments would be conducted under contained use conditions). The Directive does not preclude the possibility of cross-pollination between Part B GMO releases and related species, for example Article 4(3) states: "Member States… shall ensure that potential adverse effects on human health and the environment, which may occur directly or indirectly through gene transfer from GMOs to other organisms, are accurately assessed on a case-by-case basis. This assessment shall be conducted in accordance with Annex II taking into account the environmental impact according to the nature of the organism introduced and the receiving environment". In Europe the presence in food, feed or seed of GMOs that have not been legally authorised for commercial release is not tolerated. Reference to Box 4 shows that minimum varietal purity requirements for certified seed are, therefore, less stringent than those for unauthorised GMOs. However, assuming that the conclusion of the risk assessment for a Part B GMO was that gene flow does not pose a risk to the environment or human health, CAs should require the field trial to be undertaken using evidence-based measures to minimize gene flow as far as is reasonably possible while recognising the need to balance risks with what it is practicable to achieve.

Isolation distances in use in the MS

- *Maize*

Reference to Appendix 7 table 13, shows the range of isolation distances in use for the range of crops studied. Isolation for maize (from conventional maize crops) ranged from 200m (Germany and Spain) to 400m (France), with the greatest distance set at 500m (Hungary). In Hungary and Spain a pollen barrier of non-GM maize is also required, and in Spain at least one month temporal isolation from conventional maize crops must be applied. The 500m isolation required in Hungary is based on research that was carried out in Hungary in 2004 on potential gene flow of maize; the results showed that a 500m buffer zone is required to avoid potential gene flow around the trial site[24]. Information provided in the e-survey informed us that in Bulgaria an isolation distance of 800m is required for maize. In Sweden, an isolation distance of 50m was stipulated for a trial of GM maize authorised for food and feed use in EU. In Germany, commercial maize may be planted within the 200m isolation distance, but it must be treated as GMO trial material at harvest and disposal.

- *Potato*

Isolation distances for potato are set at 10m in Germany and Hungary (where a 4m border plus additional rows of non-GM varieties is required), and 20m in Spain and Sweden (the UK also required 20m in a recent potato trial). In Bulgaria 200m isolation from 'tobacco plantings' and 'mass potato plantings' is required.

- *Oilseed rape*

Relatively few oilseed rape notifications have been received in recent years, and these have mostly been in Sweden, where the isolation distance required is 500-800m plus a minimum 6m male sterile OSR border and the removal of wild relatives from 50m around the trial site. In France isolation for oilseed rape is set at 400m from a commercial crop.

[24] The Central Agricultural Office of Hungary published this research in 2004. It formed a chapter in a book entitled "Gene technology and product safety".

- *Sugar beet*

Sugar beet isolation requirements vary significantly, from 10m in Germany where flowering would be strictly prohibited, up to 1000m in France and Spain; in Sweden 50m is required plus at least 1000m from any wild relatives.

- *Cotton*

Only Spain specified an isolation distance for cotton, where 40m is required.

The Netherlands and the UK did not list any specific measures to be used at any stage in a trial because the case-by-case principle operates very strongly. No information on isolation distances was gathered from other member states, but it is probably reasonable to assume that a similar range would be found. In some MS, isolation distances for GMO field trials significantly exceed accepted minimum isolation distances required to meet statutory seed purity requirements. This is particularly true for trials of maize. Of all the MS questioned only Hungary stated that their isolation distance was based on (their own) scientific research. If any of the specified isolation distances were found to be breached, action would be taken on a case-by-case basis in all MS.

iii) **Preventing the dispersal of GM material**.

The underlying requirement of the Directive is that material must not enter the food or feed chain. Out-crossing is not the only route by which the spread of a GMO may occur, physical dispersal of the GM material is possible and should be prevented. France, the Netherlands, Sweden and the UK do not have any specific measures prescribed to achieve this, but it is a condition of the authorisation and will be determined on a case-by-case basis. In Germany specific measures are described for potato and oilseed rape to minimise the time that viable GM material remains at the trial site. For potato this entails cultivating the trial site to ensure any tubers that remain are brought to the surface and are collected and destroyed; for oilseed rape restrictions are placed on cultivation post-harvest plus the seed bank must be encouraged to germinate to deplete GM seeds. In Hungary, in addition to the compulsory crop-specific isolation distances described to prevent the dispersal of GM material, an extensive range of additional measures may be described such as destruction of the remaining material (seeds, stems, roots), cleaning of the machinery, guarding the trial site and other 'safety' requirements such as fencing; in addition further use of the field is limited and crop rotation is required, pollen control may be considered necessary, also removal and destruction of sexually compatible or related crops found in the isolation zone. In Spain, in addition to compulsory isolation distances, secure transport, labelled seed bags, cleaning of machinery, chemical treatment and burial of unwanted seed and crop waste are also specified. Part B of the Directive does not cover the transport and packaging of GMOs intended for release in a Part B field trial[25]. Some of the CAs interviewed stated they expect notifiers to place GM material (seed and harvested material) in secure and appropriately labelled containers when being transported, and that they expect notifers to make suitable arrangements for storage of GMO material where this is necessary. Hungary and Spain have very clear requirements for these aspects of a release, whereas France has no specific requirements for transport or storage of GM material. Checks on arrangements for transport and storage of GMOs are included

[25] The transport of GMOs is regulated by several pieces of legislation e.g. see http://www.agbios.com/docroot/articles/memo00277.pdf.

in official inspections, with the exception of France and Sweden (where only transport is included) (Appendix 7, tables 15 and 23).

iv) **Disposal of GM plant material post-trial**.
These measures are in most cases applied on a case-by-case basis. In France, Hungary and Spain, GM material must generally be destroyed in the field by incorporation including deep burial, or seed may be burned. In Germany, the Netherlands, Sweden and the UK any proven destruction method is permitted – but it must be proven to be effective (and the CA would require proof of this for any new methods). In some cases maize and potato wastes have been permitted to go for biogas production, and in the Netherlands composting has been allowed. In all cases, if GM waste is to be transported from the trial site it must be placed in secure containers and labelled up to the point of safe disposal.

v) **Monitoring for potential gene flow around a trial site**.
No Member States undertake this routinely at present; CAs recognised that to obtain meaningful results from such studies would require a large number of samples to be collected and tested. It is recognised that there will be some gene flow from Part B trials as the level of containment of the GM plants is reduced, however if the conclusion from the risk assessment was that gene flow does not pose a risk to the environment or health, trial management measures including requirements for isolation (spatial and temporal) and disposal of waste material from the trial sites, are specifically designed to minimize gene flow and any unanticipated effects. In Sweden, a notifier is currently undertaking a gene flow study at the request of the CA, which involves monitoring 500m around a trial site for the presence of any wild relatives and feral OSR, and sampling & testing for the gene used in the trial, also testing any OSR plants found in the 500m zone. In Spain, gene flow studies may be undertaken in specific trials for research purposes, and some research trials have been undertaken to test GM thresholds; these trials would be held by the Plant Varieties Office (Oficina Española de Variedades Vegetales, OEVV). In Hungary, exhaustive research was carried out on potential gene flow of maize in 2004. The results verified that the 500m buffer zone is a sufficient requirement for avoiding potential gene flow around the trial site.

- *INSPECTORS ONLY (for detailed responses see Appendix 7, tables 20 - 23)*

  Role of the inspector: appointed by the CA to verify that the conditions and limitations attached to the consent for release are being met. It is not the responsibility of Inspectors to monitor the release *per se*, but to ensure that the consent holder is carrying out their duties by means of targeted inspections.

vi) Inspectors have been nominated in each MS to ensure field trials are monitored for compliance. The different approaches employed to achieve this include inspection only (France, Germany, Spain), inspection plus administrative inspection (Sweden and Hungary), and field inspection with the emphasis placed on management audit (the Netherlands and the UK). With respect to field inspection, the Netherlands occupies the 'lightest' end of the spectrum, with a very audit-focussed approach. At field inspections similar aspects of the trial such as location, crop, dimensions, isolation requirements etc are consistently being checked. Most inspectors check transport and storage arrangements for the GMO, with the exception of France and Sweden. In all MS documents and record keeping are

checked, either at the field inspection visit or at administrative / management audits. In the Netherlands and the UK (and to some extent in Sweden), where audits of the consent holder are undertaken, the inspectors also focus on risk management, monitoring and communication. This type of approach is not dissimilar to quality accreditation and encourages a more self-analytical approach in the consent holder. Inspections are mostly scheduled, but most inspectors would also undertake unscheduled visits if necessary, for example to follow up a reported issue at a field site.

vii) The CAs all expect the notifiers to undertake inspection of the trials at appropriate regular intervals in the growing crop and post trial stages, and expect to see evidence of this in the consent holders' end of year monitoring reports. This aspect may also be checked at administrative audits, in particular in the post-trial management phase. In many cases (Hungary, the Netherlands) submission of end of year reports is a prerequisite for continuation of a multi-year trial (Appendix 7, table 18).

viii) Under German and Dutch legislation the notifier must nominate an individual who will act as the primary responsible person for the trial. In Germany the legislation lays out certain minimum requirements for this person and for the Biological Safety Officer, and this information must be provided in the notification dossier. In the Netherlands there is a statutory requirement for every company wishing to undertake GMO field trials to have a licensed environmental safety officer (MVF), whose role is to ensure compliance with the consent conditions. In the Netherlands the MVF is accountable for management of the trial and is a key focus for all inspections. This approach must serve to reinforce the concept of accountability and encourage self-assessment.

ix) With the exception of Sweden, which has a newly appointed inspectorate, all inspectors have guidelines and/or standard operating procedures (SOPs) developed for inspection. The UK inspectorate operates in an ISO 9001:2000-accredited organisation and SOPs and audits are audited under this. A number of inspectors referred to the checklists developed by the European (GMO) Enforcement Group[26].

x) While all inspectors generate a report for internal purposes, these are not always provided to the Competent Authority. Only the UK officially publishes reports of all growing crop inspections as they are undertaken. Of the seven MS interviewed, three MS publish an annual summary of inspections undertaken each year.

[26] The European (GMO) Enforcement Group was established in 1999 to facilitate exchange of knowledge and practical expertise between inspectors of deliberate release field trials. Synonymous with the European (GMO) Enforcement Project, EEP.

- *MEMBER STATE BASED NOTIFIERS (for detailed responses see Appendix 8)*

Role of the notifier: to ensure the trial proceeds in accordance with the conditions stipulated in the consent. The notifier must have in place a clearly defined management chain to control how the release proceeds. There must be a system in place to record relevant information, emergency procedures must be defined, and suitable training should be given to those working on the trial site. Conditions in the deliberate release consent stipulate how monitoring is to be performed and reported upon.

xi) The notifiers considered the regulatory framework established in the seven key MS to be consistent with the requirements of the Directive, and procedures for submitting a notification to conduct a GMO field trial were said to be clear in all MS. However, the procedures were not always easy to follow; in one MS the notifier reported that difficulties were encountered in successfully meeting all the requirements of the notification process and obtaining consent to carry out a trial. Notifers were generally asked to clarify certain aspects of their notification document, or to provide additional information to the CA, this is often on the GMO itself or environmental interactions, but may be on any aspects of the notification document. The notifiers expect to have to do this, and in general the requests were thought to be reasonable. In another MS, the notifier reported they are required to make a personal representation to the scientific advisory committee when additional information has been requested. Following the representation, the notifier would be required to make adjustments to the dossier as appropriate, and re-submit for further assessment, which further prolongs the assessment period. The notifiers consider it disproportionate to have to attend the scientific advisory committee meeting, but accept that this is the case in this MS.

xii) All of the notifiers interviewed referred to internally developed standard operating procedures and/or notebooks developed to ensure compliance at individual trial sites, and that a compliance notebook is established for each trial site. Training of the staff involved in the operation of field trials was also reported to be a high priority and of great importance to the notifiers that were interviewed, as was achieving compliance.

xiii) The notifiers interviewed considered that they were operating responsibly according to the guidelines established by the respective Member States and complying with the regulatory requirements, yet it seemed to be relatively rare that a notification and the ensuing field trial(s) would proceed as a notifier would expect it to.

xiv) Comments received from notifiers are provided in detail in Appendix 8, but fell broadly into the categories below:

- Requests from the CAs for information about the GMO were considered to be sometimes disproportionate, given the scale and level of containment of a Part B GMO trial. In one MS, the notifiers were requested to provide information that related to the local environmental impact of a widely used herbicide rather than the GMO itself, plus there was an unwillingness to accept internationally accepted test methods as part of the trial protocols.
- Trial management measures further contribute to the high level of control over GMO field trials and the ‘package’ of measures applied by some MS

were felt, by the notifiers, to outweigh the identified risks. These often related to isolation distances that are sometimes considerably in excess of current scientific opinion on isolation distances for pollen transfer (see section 6.5ii), and do not take account, for example, of asynchronous flowering of the GM and conventional crop which effectively limits pollen transfer.

- One notifier commented that the requirements for a GMO trial exceed what is required for the introduction of other new genetic resources, e.g. new garden species or foreign seeds in wild bird feed during winter, yet the risks from the latter are considerably less well characterised than those of a GMO.
- Protracted timelines for reaching a decision on notifications was raised as a real issue for the notifiers, in particular in three MS. .
- Serious practical difficulties of holding trials because of the level of vandalism by protesters, which is strongly linked to the level of information that is made public about location of trial sites. This was said by many of the notifiers to potentially compromise the safety of farmers and their families.
- In most cases there is no relaxation in the management measures required as familiarity with a GMO event increases. There are exceptions where a risk-based, tiered management system operates, also where the permitted area may be allowed to increase as a trial progresses.
- Lack of flexibility regarding the lines that can be released as part of multi-year development programmes where all the lines are based on the same construct.
- One notifier commented on a lack of clarity regarding the role of the inspectors.

- *FIELD TRIAL OPERATORS (for detailed responses refer to Appendix 9)*

Role of the field operator: contracted by the notifier to conduct day-to-day operations in connection with the release, including crop management (e.g. cultivation, sowing, pest/disease monitoring, applying fertilizers/pesticides, harvesting, etc.), data recording (e.g. plant growth characteristics, efficacy of the trait, environmental impact, etc., depending on the type of trial) and any other day-to-day operational aspects. Should be conversant with the terms of the consent and clear about their role in helping fulfil them.

xv) The level of interaction and understanding between the notifiers that were interviewed and their field operators appeared to be effective. Reference to tables 1 to 3 in Appendix 10 provide evidence to support the view that the field operators were all aware of the purpose of the trial, the essential management requirements, the requirements for record keeping and the requirements for reporting. In all cases the notifier provided the field operator with documentation to assist with management of the trial, in some cases this was the form of a notebook in which all operations undertaken at the trial site must be recorded. The operators recognised the need to meet all the requirements and in particular the need to achieve regulatory compliance. Completed documentation recording operations at the trial site were in all cases held by both the field operator and the notifier.

xvi) Field operators confirmed what the inspectors stated regarding the level of inspections and the information that is requested at inspections. Field operators

confirmed that they understood the purpose of the inspection and what the inspector was looking for. The provision of inspection reports varied, in general the notifier received the inspection report and the contents of the report were relayed verbally to the field operator – as compliance is the responsibility of the notifier, this would seem to be the correct sequence of events.

xvii) A few minor unanticipated problems were reported, for example actions by protesters in France and the UK, and in Spain neighbouring farmers planted maize within the 200m isolation zone, but these were remedied. In the UK the affected trial was extensively damaged and the emergency response plan was put into operation. The field trial operator stated there were some practical difficulties with this, but they did not amount to non-compliance. The non-compliances reported by the field operators concurred with those of the notifiers and the competent authorities.

xviii) The main issues raised by the field operators reflected those of the notifiers, namely:

- The requirement to make public the location of field trial sites, which leads to vandalism by protesters. Connected with this is an ongoing problem of finding farmers who are willing to hold a field trial on their land due to threats and vandalism by the protesters. It is often up to the field operators to identify potential sites for a GMO trial, and the threat of vandalism means that a lot more potential trial sites need to be found than will actually be used.
- To generate good data, notifiers ideally need to conduct trials in a region that is suited to production of the crop. Where isolation distances are very large it makes it very difficult to find suitable sites in a region that is suited to grow the crop.
- Extra security is required at field trial sites if protesters are to be prevented from destroying the company's work and material.
- Waiting for annual approval that the field trial can go ahead.
- Flexibility to use grain from a trial of a crop authorised for food and feed use, rather than having to destroy it, or more flexibility in methods of disposal.

xix) One field operator reported that, apart from the increased level of documentation that it is required, it is straightforward to hold a GMO field trial and it presents no challenges.

SUMMARY OF DETAILED MS SURVEY

1. All MS put management measures in place for Part B field trials to mitigate any potential risks to the environment, and to ensure that unauthorised GMOs do not enter the food and/or feed chain. Critical control points[27] are recognised by the CAs when permitting Part B releases, and measures are described to mitigate any risks inherent to these stages of the trial. These may be applied on a strictly case-by-case basis (e.g. the Netherlands and the UK), or indicative guidelines may be developed that are generally applicable to certain crops (e.g. France, Germany, Sweden). There is wide recognition of the importance of the post-trial monitoring phase, and of the need to control dispersal and disposal of the GM material.

2. Isolation distances from sexually compatible crops and/or wild relatives were found to be variable, particularly for maize. Notifiers were of the opinion that isolation distances are much larger than scientific research suggest is necessary to prevent gene flow, and that this is due to external influences, for example to achieve public confidence.

3. The CAs expect notifiers to monitor field trials at appropriate regular intervals during the trial and during the post trial period until the CA determines this can cease. All monitoring reports are assessed by the CAs or a body nominated by the CA, and continuation of a multi-year trial is often dependent on satisfactory monitoring reports. CAs do not routinely require monitoring for gene flow around Part B trial sites because it is considered to be beyond the requirements of a Part B trial.

4. All MS have arrangements in place for inspection of Part B trials to ensure the notifiers are operating in accordance with the requirement of their consent(s) and are managing the process appropriately. While the purpose of inspection is the same in all MS, different approaches are adopted, ranging from checklist-based field inspection only (e.g. France, Hungary, Spain) to largely administrative/audit-based inspection, which encourages a degree of self-regulation in the notifiers (e.g. The Netherlands), and combinations of the two approaches (e.g. the UK and Sweden). It is likely that a combination of the two approaches will achieve the most effective inspection regime. Most inspectors use checklists and standard operating procedures, which ensure consistency of approach.

5. The MS-based notifiers interviewed were each able to successfully notify and later conduct a number of field trials in the MS in which they operate. The notifiers registered a number of concerns regarding the practical workability of the Part B notification system in the MS in which they operate, their main concerns related to the time required to process notifications in some countries, demands for data about the GMOs that were thought to be disproportionate for a small scale, highly managed trial, and problems associated with ongoing threats of, and actual acts of, vandalism. The latter was said to be facilitated by the level of information that is made publicly available about the location of field trials. However, once consent has been given for a trial to proceed, the notifiers reported that the systems work well, and there is good

[27] Cultivation (of the site prior to sowing), sowing, harvesting, cleaning machinery, post-trial monitoring and post-trial cropping.

communication between all parties involved. Any potential non-compliance incidents that arose were dealt with swiftly and in collaboration with inspectors and CAs.

6. Most field operators agreed that that once Part B field trials had been approved, apart from the potential and continual threat of vandalism, the trials ran smoothly and efficiently. Operators saw little need for change and considered the arrangements in place to be fit for purpose. The evidence gathered in Appendix 10 indicates that communication between the notifiers and operators that were interviewed is effective and fit for purpose.

7. NOTIFIER EXPERIENCES EU-WIDE

This part of the study was undertaken to provide the end users' perspective on how comparable the notification and management of Part B releases is in different EU Member States. Notifiers that have placed the same notification in more than one Member State were selected for interview. These notifiers were asked to identify, in the context of the requirements of Directive 2001/18/EC, systems that work well for them, and those that do not work so well.

Responses were provided from three notifiers covering the following situations:

- **Notifications placed and trials held in**: Denmark, France, Germany, Hungary, The Netherlands, Romania, Slovak Republic, Spain, Sweden and the UK.
- **Notifications placed in**: Czech Republic, Hungary, Ireland, Lithuania, Poland and Portugal.
- **Covering trials of crops of**: maize, potato, oilseed rape, soybean and sugar beet.

Each notifier was asked to confirm whether the field trials they have notified according to the JRC website was correct. The database has been updated to reflect the responses.

The three representatives of notifiers that were interviewed were based at their company headquarters and were responsible for coordinating their company's applications for Part B GMO trials in Europe. Each company would, in most cases, appoint an appropriate employee of the company in the Member State in which the trial was to take place (often the local Regulatory Affairs officer) to act as the local agent for management of the application and, later, the actual trial(s). Depending on the company, and the nature of the enquiry, any questions raised by a Competent Authority about a notification that was placed by the company would be answered either by the local representative, or by the company HQ.

7.1 EU-WIDE NOTIFIER RESPONSES

Detailed EU-wide notifier responses are provided in Appendix 10 of the report and a summary of the comments received is given below:

i) **Guidance on submitting an application**: Generally speaking, guidance was thought to be satisfactory in the countries in which notifications have been placed, although the level of detail provided varies between MS. Some MS were said to lack a guidance document outlining exactly what information is required about the GMO and the management of the trial. The importance of good communications between the CA and the notifier was highlighted so that the notifier knows exactly what the CA requires of the notification. Cases were reported where applications were sent to a MS but were not acknowledged by the CA.

ii) **The environmental risk assessment (era)**: notifiers were divided on whether the requirements for the era were proportionate and in accordance with the Directive.

One notifier thought that while some countries ask more questions than others, they are generally proportionate and within requirements. However, the other notifiers thought that the requirements for the era were not always proportionate: some CAs ask for a lot of information about molecular data and gene expression and toxicology data for experimental trials. In one MS specific information was requested for one notification to generate data on specific eco-zone and local economic impacts, which the notifier considered to be beyond the scope of Part B of the Directive. In the same MS, consent was issued with a condition that non-target organism studies be undertaken; again this was considered to be beyond the scope of Part B of the Directive. One notifier thought that it would be difficult for smaller European-based notifiers to gather sufficient data for the dossiers.

iii) **Comparability of assessment of notifications across the MS**: while most notifiers commented that the assessment processes themselves were comparable across the MS, there are significant differences in the timelines taken to assess notifications, also the level of information that is made available to the public in particular with regard to location.

iv) **Rejection of notifications**: all three notifiers had had notifications rejected, with a total of eight notifications having been rejected. The reasons for rejection of a notification were not always given, and in five of the cases the scientific evaluation bodies had delivered a favourable opinion. In these latter cases in particular the notifiers did not consider the reasons for the rejection of their application to be reasonable.

v) **Information regarding duty of care**: generally speaking, notifiers found the requirements for duty of care to be comparable. They commented that in most countries this is about verifying that the event in the trials is the one described in the application, with Germany and the UK being the noted exceptions because they are also interested in confirming the absence of adventitious GMOs. Notifiers are always asked to label seeds and some MS take samples and test. One notifier thought it was reasonable to ask for a sample to provide to the inspector but that this was not a realistic request for new events (which are often only available in limited quantities), only for established events.

vi) **Risk management measures and rationale**: the types of measures adopted to minimise physical dispersal of the GMO and minimise gene flow were said to be comparable across the MS, but the detail is variable, in particular for isolation distances. While the measures themselves were thought to be sensible, the notifiers commented that the rationale behind them was, in many cases, thought not to be wholly based on scientific reasons. One notifier, for example, commented that isolation distances vary between the MS; the same notifier commented that one MS requires two years post trial monitoring for maize in a country where very hard winters will ensure that any viable material is killed off in the year following the trial.

vii) **Inspection and control of Part B field trials**: Notifiers recognised that official inspections were necessary and thought that inspection was broadly comparable across the MS, although being based at HQ these notifiers had limited first-hand experience of the detail of inspections. The requirement for a specific safety officer

was thought by one notifier to indicate a lack of trust, although our understanding is that this is actually aimed at encouraging self-regulation by notifiers. The management audit approach taken by one MS was noted to be unusual, but acceptable.

viii) Documentation requested to demonstrate compliance to inspectors and to the competent authorities was said to be comparable. The timing of the requirements for provision of reports was said to vary, and deadlines could be difficult to meet.

ix) **Achieving compliance**: notifiers were asked to provide details of all non-compliances they had reported to the CA of the Member States in which they had conducted a field trial(s).

Table 7.1: Total number of non-compliances reported by notifiers that have conducted field trials in a number of MS under Directive 2001/18/EC since 2002

How many non-compliances in the following categories have occurred			
Technical non-compliances	Number of fines or written warnings issued	Cases where material accidentally entered the marketplace	Number of prosecutions taken against your company
1*	0	0	0

**Technical non-compliance:*
A trial was destroyed in Spain because the border rows had not germinated & isolation was not correct, which would have become a non-compliance. Similar cases were reported in France, but the border rows were re-planted prior to inspection; the inspector accepted that this was an appropriate course of action, and that there were no non-compliance issues (Appendix 10, table 12).

x) **Unanticipated problems**: the notifiers that participated did not encounter any cases of unanticipated problems with the GMO or the trial. Vandalism was reported to be the only unanticipated event to have occurred (although the notifiers do anticipate this may happen). In all cases where vandalism had occurred it had been reported to the CA.

xi) **Vandalism of field trials**: All notifiers that participated have had trials vandalised. In some cases this had led to termination of the trial (e.g. if acts of vandalism by protesters completely destroy the trial), but it was not always necessary. Where trials were vandalised early, so that no or insufficient data would be generated from the trial, this might also lead to early termination of the trial.

- The notifiers reported vandalism in three MS.
- In one MS 50% of one notifier's trials were vandalised in 2007[28].
- In one MS metal bars were thrown at harvesting machinery and stones were tied to maize cobs.
- The notifiers commented that it is increasingly hard to find farmers who will run trials.

[28] Attempts were made to establish exactly how many trials this represented, but it was not possible to obtain the information.

xii) The EU-wide notifiers were asked what they considered to be the main **challenges of running Part B field trials**: the key issues raised are listed below and detailed responses are in Appendix 10:

- The need for public consultation creates uncertainty about timelines.
- Publishing detailed information on the trials to be performed can lead to pressure on farmers which impacts on their willingness to participate in trials because it impacts on the safety of the farmer and his family, and facilitates trial destruction by protesters. This in turn limits the availability of suitable locations and means that sites have to be found a long way in advance of the planting period (e.g. in the previous summer). In addition, many more farmers/sites have to be found than will actually be needed because some might drop out.

xiii) The EU-wide notifiers were also asked what they **would change about the Part B system**: the key issues raised are listed below and detailed responses are in Appendix 10:

- The information that has to be published should not result in the safety of persons that are conducting the trials for the notifiers being compromised.
- Public consultation should not delay the authorisation process.
- More consistency on requirements for dossier contents.
- Reduction in requirements for stringency of management conditions with increasing familiarity with an event.
- Flexibility on disposal of events authorised for food and feed use when placed in Part B trials.

SUMMARY OF EU-WIDE NOTIFIER RESPONSES

1. While administrative systems for Part B trials are in place in the Member States, notifiers reported that they do not always operate as the notifier would expect them to, i.e. according to the framework laid down by the Directive. In particular the notification process was thought to be subject to external influence, and even if the notification process goes according to plan the field trial itself can still be prevented from going ahead either because of problems from vandalism, or because of conditions that are difficult to meet.

2. The notifiers interviewed in this study have learned to live with the different notification systems once they get to know the requirements, but it would seem to be inconsistent with the Directive that this should be necessary. Such unpredictability was reported to create planning pressures and impact on research. It may also present problems for notifiers less familiar with the delays that may be incurred in the notification process, and for whom time is more critical (e.g. grant-aided university studies).

3. The level of technical detail (e.g. molecular characterisation, gene expression and toxicology data) that is required about the GMO by some CAs was considered by many of the notifiers to be disproportionate considering that the release is taking place under Part B of the Directive. The notifiers consider the focus in a Part B trial should be on finding a good balance of reasonable measures to manage and mitigate risks and prevent dissemination.

4. The notifiers found the refusal of notifications on non-scientific grounds difficult to accept and at odds with the Directive, in particular when the scientific advisory committees had raised no objections to the release.

5. The requirement to provide information about location was thought to be leading to threats and acts of vandalism by protesters in certain countries. This is affecting a large number of trials, and in particular affects the growers and their families. Holding a successful trial was reported to be increasingly difficult.

6. The notifiers would welcome some pragmatic decisions with respect to disposal of GMOs that are authorised in Europe for food/feed/import & processing.

8. GMO FIELD TRIALS IN EUROPE: ASSESSMENT OF PROGRESS AGAINST PREDICTIONS AND LIKELY FUTURE DEVELOPMENTS

1. In future years the EU is likely to witness a host of innovative solutions to crop management, crop protection, yield improvement and many other diverse agricultural and consumer needs. Some of these may be provided by genetic modification, which remains at the cutting-edge of agricultural biotechnology. In the face of these new developments biotechnology regulators need to be confident that the legislative systems in place are satisfactorily robust to protect human health and the environment and inspire public confidence, whilst still remaining supportive of these new technologies. Regulators need to gain insight into future developments in GM crops and traits to enable them to assess whether current legislation is fit for purpose, or whether amendments may be needed, to ensure timely policy responses. In the case of Directive 2001/18/EC, the early identification of any new GM crops and traits that are on the horizon is a useful step in determining the suitability of the legislation for future years.

2. In order to enhance regulatory foresight in this area a review of GMOs under research and development was published by Lheureux *et al.* in 2003, with the aim of identifying and characterising future waves of GMO development. This document, which was commissioned by the European Commission Directorate-General Agriculture (DG AGRI), provides a useful reference source from which to compare predicted developments of GM crops and traits with actual developments, as documented on the JRC website of Part B notifications. Using the database developed for this project (Appendix 1) we have reviewed the actual development of GMOs in Europe as indicated by notifications on the JRC website, and compared these with the developments predicted by Lheureux *et al*. Developments in the USA, Canada and multi-national companies were also reviewed to give a view of what might be entering EU GMO field trials up to 2018. The full review is provided in Appendix 11. The key points are summarised below, with a view to determining whether current arrangements for management of GMO field trials are future-proof.

3. Between 1991 and 1996 there was a steady increase in the number of Part B notifications under Directive 90/220/EC, culminating in a peak of 264 notifications in 1997. After 1998 the number of notifications decreased quite dramatically[29] reaching a low of just 56 notifications in 2002, this was possibly due to the implementation (in 1999) of the *de facto* moratorium on any new authorisations for marketing GM crops. Since the Directive came into force in 2002, there has been a gradual increase in the number of notifications, up to 111 in 2007. It is worth noting that a proportion of this increase is due to the accession of new Member States, such as the Czech Republic, Hungary, Poland, Lithuania and the Slovak Republic in 2004 (accounting for a total of 44 notifications between 2005 and 2007), and Romania in 2007 (accounting for 14 notifications).

[29] A decrease of 76% from 1998 to 2001, as noted by Lheureux *et al*. 2003. Note: 2001 was the last year for which Lheureux *et al* authors had complete data.

4. Since the introduction of the Directive, the number of notifications submitted by large companies has increased fairly dramatically over time, from around 35% in 2003 to almost 80% of notifications in 2007. Conversely, the number of notifications submitted by research institutes has declined considerably over the same period, from around 50% in 2002 to just 15% in 2007. Likewise, the number of notifications submitted by SMEs has also decreased, although this number was initially very low. The possible reasons for this are discussed in Appendix 11.

5. Analysis of Part B notifications under the Directive from 2001 to 2007 shows that maize now dominates, accounting for almost 58% of GMO field trials. Other prevalent crops in Part B trials are potatoes, at almost 15%, cotton at around 6% and oilseed rape at 3%. This situation is something of a shift from that reported by Lheureux *et al*. in 2003, when four main crops of maize (26%), oilseed rape (20%), sugar beet (16%) and potato (11%) dominated. In addition the number of plant species in Part B notifications has also decreased, and there appears to be a tendency to concentrate on the 'major' agricultural crops used for animal feed and for industrial use. This may be symptomatic of the reduction in the number of SMEs and research establishments putting forward notifications. It is also apparent that there is an increasing use of stacked events, including multiple herbicide tolerance and multiple insect resistance in these crops, providing better protection from insect pests, and allowing growers to simplify their crop management practices.

6. During the early years of GM plant development, developers focussed mainly on agronomic input traits (herbicide tolerance, insect resistance, resistance to pathogens, etc.). These so-called "first generation" GMOs were mainly concerned with increasing productivity, simplifying crop management and reducing costs to growers. In 2003, when Lheureux *et al*. published their review, it was expected that there would be a move towards GMOs that would embrace new products and be targeted more towards consumer expectations. These so-called "second-" and "third-generation" GM crops were expected to lead to improved food quality, deliver new medicines, contribute towards preventing disease/reduce health risks, and to improve interactions between the crop and the environment.

7. Lheureux's predictions have been most accurate in the short-term (as might be expected), with the marketing of crops such as herbicide tolerant and insect resistant maize and cotton (both single and stacked events), herbicide tolerant oilseed rape, soya and sugar beet (see table 8.1 below). However, assessment of the notifications submitted under 2001/18/EC (from 2001 to 2007) shows that, overall, GM crops and traits are five or more years behind what was predicted by Lheureux *et al*. in 2003. An example of this is modified starch potato which was predicted to be commercialised in the date range 2003-2007, but is now actually awaiting commercialisation in 2008. In many other cases, however, the developments predicted by Lheureux *et al*. appear to have come to a standstill, at least in terms of EU trials. Examples are herbicide tolerant wheat, virus-resistant sugar beet, modified fatty acid in soybeans and oilseed rape, plus many other crop/trait combinations, all of which appear in Lheureux's 'medium-term' pipeline list (see table 8.2 below) and which we might expect to see in variety registration trials if they are to be commercialised in the next 5 years or so. However, none of these have been present in variety registration trials between 2003 and 2007. Lheureux's 'long-term' list appears to be more accurate, although the fact that certain crops/traits

appear in novel Part B trials does not guarantee they will eventually be commercialised (see table 8.3 below). These developments are discussed in more detail in Appendix 11, and new pipelines are proposed.

Table 8.1: Comparison of Lheureux's predicted short-term 'pipeline products' and actual commercialisation for 2003 – 2007.

Commercialisation predicted 2003 – 2007	**Actual:** products on market 2003 – 2007[a] (crops shown in **bold** indicate where commercialisation has been achieved)
Herbicide tolerant:	
• maize	• **maize – 3 lines** (GA21, T25, NK603)
• oilseed rape	• **oilseed rape - 6 lines** (T45, MS8xRF3, GT73, MS1xRF2, MS1xRF1, Topas 19/2)
• soybean	• **soybean – 1 line** (MON 40-3-2)
• wheat	• wheat - none
• sugar beet	• **sugar beet – 1 line** (H7-1)
• fodder beet	• fodder beet - none
• cotton	• **cotton – 1 line** (Mon 1445)
• chicory	• chicory – none
Insect-resistant:	
• maize	• **maize – 5 lines** (Bt11, Bt176, MON810, MON863, MON863xMON810)
• cotton	• **cotton – 2 lines** (MON 15985, MON 531)
• potatoes	• potatoes – none
Modified starch or fatty acid content in:	
• potatoes	• **potatoes – 1 line** [EH92-527-1 is currently **pending approval**]
• soybean	• soybean - none
• oilseed rape	• oilseed rape – none
Modified colour/form:	
• flowers	• **carnation – 3 lines** (Moonlite, Moonshadow 1, Moondust)
Modified fruit ripening:	
• tomato	• tomato – 1 line
Herbicide tolerant and insect-resistant:	
• maize	• **maize – 6 lines** (1507, 59122, 1507xNK603, GA21xMON810, MON863xNK603, NK603xMON810)
• cotton	• **cotton – 2 lines** (MON15985xMON1445, MON531xMON1445)
Products NOT PREDICTED but PRESENT on the market 2003-2007:	• **carnation – 1 line** (Moonshadow 2 - increased shelf-life) • **rice – 1 line** [herbicide tolerant LL RICE 62 is currently **pending approval**]

[a] marketing includes cultivation, import and processing, and food and feed.
Note: the above table includes lines authorised under 2001/18/EC, those previously authorised under 90/220/EEC, and those authorised under 1829/2003.

Table 8.2: Lheureux's predicted medium-term 'pipeline products' and crops that have appeared in variety registration trials 2003 – 2007.

Commercialisation predicted 2008 - 2012	**Actual:** GM variety registration trials 2003 – 2007 (crops shown in **bold** indicate where variety registration trials have taken place)
Fungi-resistant: • Wheat • Oilseed rape • Sunflower • Fruit trees	*Fungi-resistant:* • Wheat – none [5 agronomic/efficacy notifications] • Oilseed rape – none • Sunflower - none • Fruit trees – none [3 apple agronomic/environmental assessment; 1 lemon agronomic/efficacy/environmental assessment]
Virus-resistant: • Sugar beet • Potato • Tomato • Melon • Fruit trees	*Virus-resistant:* • Sugar beet – none [4 agronomic/efficacy assessment] • Potato – none • Tomato - none • Melon - none • Fruit trees – none
Herbicide-tolerant: • Wheat • Barley • Rice	*Herbicide-tolerant:* • Wheat – none [1 ecological/environmental assessment] • Barley - none • Rice – none [3 ecological/environmental/geneflow assessment]
Modified starch in: • Potatoes • Maize	*Modified starch in:* • **Potatoes – 2 notifications** (Netherlands, 2004; Germany, 2004) • Maize – none
Modified fatty acid in: • Soybean • Oilseed rape	*Modified fatty acid in:* • Soybean - none • Oilseed rape – none [4 notifications (altered oil) for agronomic or production of materials/compounds]
Modified protein in: • Oilseed rape • Maize • Potatoes	*Modified protein in:* • Oilseed rape – none • Maize – none • Potatoes - none
High erucic acid in: • Oilseed rape	*High erucic acid in:* • Oilseed rape – none
Products NOT PREDICTED but PRESENT in variety trials 2003-2007:	• **Oilseed rape - 1 notification -** herbicide tolerant (glufosinate ammonium, incl. pollination control) – (UK, 2003)[a] • **Soybean – 1 notification** - herbicide tolerant (glyphosate)(Romania, 2007) • **Maize – 71 notifications** for herbicide tolerant, insect resistant and combined stacked events.

[a] Note: this release (B/GB/03/R38/1) was authorised but did not go ahead.

Table 8.3: Lheureux's predicted long-term 'pipeline products' for beyond 2012 and novel part B trials notified (years shown in brackets indicate the overall period of release of the trials(s).

Commercialisation predicted beyond 2012	**Actual:** novel Part B GMO trials 2003 – 2007
GM plants resistant against abiotic stress factors (cold, salinity, drought)	• **Maize – 3 notifications** (drought tolerant, France, 2005-2010); • **Maize – 2 notifications** (drought (and herbicide) tolerant, France, 2003-2008); • **Rice – 3 notifications** (salinity and drought tolerant, Spain, 2003). • **Crops/traits not predicted:** • **Linseed/flax – 1 notification** (enhanced accumulation of heavy metals, Czech Republic, 2007-16)
GM plants with enhanced yield (all crops)	• **Maize – 1 notification** (France, 2005-2008); • **Potato – 9 notifications**: ▪ (Germany: 4, 2004-2011); ▪ (Netherlands: 1, 2004-2013); ▪ (Spain: 4 2005-2007); • **Rice – 15 notifications** (Spain, 2003-2003); • **Oilseed rape – 4 notification** (Sweden, 2006-2010);
GM plants for molecular farming (tobacco, maize, potato, tomato)	• **Maize – 3 notifications** (France: 2 notifications for gastric lipase for medical uses; 1 notification for expressing monoclonal antibodies for medical uses in cancerology; 2005-2008); • **Potato – 1 notification** (Germany: pharmaceutical and technical traits, 2006-2008) • **Crops/traits not predicted:** • **Oilseed rape - 1 notification** (Germany: synthesis of health-improving compound resveratrol and/or to reduction the phenylic compound sinapine, 2007-2008). • **Pea – 1 notification** (Germany: antibody production, 2007);
GM plants with an enhanced content of "functional" ingredients (rice, vegetables)	• **Potato – 1 notification** (Poland: higher antioxidant capacity, 2006-2010); • **Tomato – 1 notification** (Italy: accumulation of beta-carotene instead of lycopene, 2004). • **Crops/traits not predicted:** • **Linseed/flax – 1 notification** (Poland: increased antioxidant capacity of flaxseeds, 2006-10); • **Maize – 2 notifications** (France: increased essential amino acid content in the grain, 2003-2006).
GM trees with modified lignin content	• **Poplar – 2 notifications** (France: altered lignin content, 2003-12).
GM hypoallergenic crops	• None
Products NOT PREDICTED but PRESENT as novel Part B trials 2003-2007:	• **Poplar - 1 notification** – bioremediation of soils (Germany, 2003) • **Arabidopsis thaliana – 2 notifications** - change of colour in vicinity of explosives (Denmark, 2006 & 2007) • **Wheat – 1 notification** - enhanced protein content (Germany, 2006-8) • **Pea – 1 notification** - enhanced protein content (Germany, 2005-6) • **Birch – 1 notification** (Finland: flowering prevention, 2005-8) • **Linseed/flax – 1 notification** (Poland: improved properties of flax fibres & increased antioxidant capacity of flaxseeds, 2006-10) • **Potato – 2 notifications** (Germany: production of recombinant spider silk, 2003-5)

8. Looking to the USA and Canada, where GM technology has found greater acceptance than Europe, maize, soybean and cotton have been the major focus of GM field trial activity. Herbicide tolerance has been the single most utilised trait, but product quality traits have also accounted for the same number of trials as insect tolerance. Product quality traits include, for example, altered amino acid, protein and oil composition. Agronomic properties such as drought resistance and yield increase also featured highly. There have also been noticeable increases in the number of genes that have been inserted (stacked) into GMOs, in particular for maize, soybean and cotton. As a result more stacked genes are being seen in commercial material. The review of the multi-national company's pipelines in Appendix 11 suggests we can expect stacking to become a common feature of many more transgenic agricultural crops in the future, which will inevitably bring complications for detection and labelling in Europe (see table 8.4).

Table 8.4: Long-term pipeline for GMOs entering in the European GMO field trials based on activity in USA and Canada

Period 2008- 2012	Period 2013 to 2017	Period after 2018
Product development (within next 5 years) **Agricultural Benefits** Upgrading and extended range of herbicide tolerant maize, soybean and cotton Upgrading and extended range of insect resistant maize and cotton Herbicide tolerance in alfalfa High oil maize[1] Drought resistant maize[1, 2] Insect-resistant traits in soybean[2] Fungal resistance in maize[3] **Food and feed** Modified fatty acid (high oleic[3], stearic, low linolenic) soybean[1, 2]	**Trait development (next 5 to 10 years)** **Agricultural Benefits** High yield maize[1, 2], soybean[2] and oilseed rape[2] Nitrogen utilization maize[2, 4] Drought resistant cotton[2] Nematode resistant soybean[2, 3, 4] Stress tolerant oilseed rape Insect resistant rice Fungal resistance in potato, wheat, barley and oilseed rape Virus resistant sugar beet **Food and feed** Modified fatty acid (stearic) soybean[2, 3] Improved animal feed in maize[4] and soybean[3] Improved oils in oilseed rape	**Gene discovery (more than 10 years)** **Agricultural Benefits** Virus resistance in potato, tomato, tobacco
Renewable resources/biofuels Amylopectin in potato[1] Amylase and Lysine in maize (improved ethanol processing)[2, 4]	**Biopharming** GM plants for molecular pharming (tobacco, maize, barley, rice and safflower)	**Renewable resources** Forestry yield/processing [1]

Sources: [1]Kast (2007), [2]Casale (2008), [3]Pioneer (2008), [4]Syngenta (2007)

9. Reviewing progress in Europe against predictions made by Lheureux *et al*. and the current situation in the USA, the EU is likely to see a continuation of notifications for crops with stacked events. In the long term there is likely to be a greater number of Part B applications for industrial crops producing novel compounds and fibres, etc., as well as crops producing health-related or pharmaceutical compounds. However, a recent desk study on technologies for biological containment of GM and non-GM crops concluded that field crops are unlikely to be the vehicle for any future specialised production of plant-made industrial products and pharmaceuticals, with non-food crop systems in contained

facilities being the method of choice in the future[30]. GM species with special properties, such as soil bioremediation, and indicator species allowing the detection of noxious/harmful substances may also be present in Part B trials, although the number of such notifications will probably remain at a relatively low level. It is also foreseeable that the number of notifications for crops with enhanced yield will continue to increase as more pressure is put on existing crop production due to the demand for food and biofuel.

10. In parallel with the expansion of new GM crops and new GM traits there is the ongoing development of new techniques for introducing desired characteristics into plants. These novel plant modification techniques are being developed to speed up the plant breeding process, and to enhance the precision and specificity of the induction or selection of desired properties. Recent novel approaches to the production of plants with modified characteristics include electroporation, targeted mutagensis techniques and epigenetic techniques. It remains to be seen whether plants derived through any of these novel techniques will be classified as GMOs. In order to bring clarity to these considerations, and to harmonise the approach of Member States, the European Commission has recently established a Working Group to evaluate a list of new techniques for which it is unclear whether they result in genetic modification. It is anticipated that the Working Group will report in 2009. In the future, where a technique is deemed to give rise to a GMO that falls within the scope of the Directive it is conceivable that it will not be taken forward for commercial development because of the costs, time and political uncertainty associated with gaining authorisation to release a GMO. However, the review of the programmes of the major plant breeding / biotechnology companies in Appendix 11 indicates that they have plans to keep developing plants based on GM technology for the foreseeable future.

SUMMARY

1. Notifications for Part B GMO field trials in Europe reached a peak of 264 in 1997, then fell to just 56 notifications in 2002. Since Directive 2001/18/EC came into force there has been a gradual increase in the number of notifications, up to 111 in 2007 but numbers of notifications have still not levelled with the peak reached in 1997.

2. The range of crops being placed in trials has narrowed since 2002, with trials of maize currently accounting for the majority of notifications (58%). There appears to be a tendency to concentrate on the 'major' agricultural crops used for animal feed and for industrial use. Notifications for trials are currently mostly being submitted by large commercial companies; the number of universities submitting notifications is notable for having reduced by about 35% since 2002, and notifications from SMEs remains very small.

3. The GM crops and traits being commercialised are five or more years behind the 'short-term' predictions of Lheureux *et al*. in 2003, while many of the medium term developments predicted by Lheureux *et al*. appear to have come to a standstill, at least in terms of EU trials (e.g. herbicide tolerant wheat, virus-resistant sugar beet,

[30] Research funded by UK Department for Environment, Food and Rural Affairs, see: http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&Completed=0&ProjectID=13020#Description

modified fatty acid in soybeans and oilseed rape). Notifications for novel Part B trials suggest that Lheureux's 'long-term' predictions appear to be more accurate at present.

4. Herbicide tolerant, product quality and agronomic traits are being developed in the USA, mainly in maize, soybean and cotton. Stacked genes are an increasingly common feature of these developments so it is likely that more of these will be seen in Europe. Detection of stacked traits is likely to present complications with respect to ensuring duty of care, but in themselves these should not present any new challenges for achieving compliance with Part B authorisations. It is unclear whether we are likely to see a greater number of crops producing health-related or pharmaceutical compounds for deliberate release in the future, although again trials of these crops need not *per se* present any specific problems for the Part B system, providing appropriate risk mitigation measures can be applied.

5. Plant breeders are developing new techniques for producing plants with desired characteristics. Whether plants derived through these techniques will be classed as GMOs and will have to be authorised under the current legislation or not is currently under review. However, at present the major plant breeding / biotechnology companies appear to have plans to keep developing plants based on GM technology for the foreseeable future.

6. At present, there do not appear to be any developments in the short, medium or long term that would present insurmountable challenges to the current Part B notifications system. It is possible that issues raised in previous sections of the report, for example threats and actions by protesters, may present greater challenges to holding GMO field trials than the GMOs themselves.

9. FIELD TRIAL MANAGEMENT PRACTICES IN THIRD COUNTRIES AND COMPARISON WITH EU PROCEDURES

9.1 Introduction

In order to identify areas of best practice in EU countries it is useful to examine GMO field trial design and approaches in some third countries. To this end, the management practices of the USA, Canada, Australia and New Zealand were studied using information and data published on the websites of the regulators in these countries. Incidents where GMO field trial practice had broken down in these countries were also reviewed so that vulnerable points in the management of these trials could be identified. The countries were chosen because of their long history of hosting GMO field trials (e.g. USA and Canada) or for their distinct approaches in GMO regulation (Australia, Canada and New Zealand). Canada, for example, regulates the introduction of all plants with novel traits irrespective of their breeding method. In New Zealand, GMOs are treated as 'new organisms' and require their introduction to be regulated as non-indigenous organisms. In contrast, the USA, Australia and the European Union have designed their regulatory frameworks specifically for GMOs.

Irrespective of the differing approaches towards classifying GMOs, the four countries follow the biosafety principles set out in OECD guidance for small-scale release trials and scaling-up of experimentation to attain risk assessment data prior to marketing (OECD, 1992; OECD, 1993). They all require prior approval before release, a risk assessment, the implementation of management procedures on a case-by-case basis to prevent dissemination, compliance to terms and conditions, and site monitoring (table 9.1). They also allow the stepwise scaling up of field experimentation following the concept of familiarity[31] and have developed guidance for managing GMO trials.

Some of these approaches, however, have some distinctive features compared with EU procedures that merit highlighting, namely:

- A two-tiered system of confined research trials that is operated in the USA,
- A statutory licensing system for notifiers in Australia, and
- A voluntary introduction of a quality management scheme that is being introduced in the USA.

[31] Familiarity comes from the knowledge and experience available for conducting a risk/safety analysis prior to scale–up of any new plant line or crop cultivar in a particular environment (OECD, 1993)

Table 9.1: Comparison of management frameworks for GMO field trials in the USA, Canada, New Zealand and the European Union

	USA	Canada	Australia	New Zealand	EU
Regulator	Biotechnology Regulatory Service (BRS) within USDA's Animal & Plant Health Inspection Service (APHIS)	Plant Biosafety Office (PBO) of the Canadian Food Inspection Agency	Office of the Gene Technology Regulator (OGTR)	Environmental Risk Management Authority (ERMA)	Lead competent authorities of each Member State.
Prior approval for experimental release	Required. GMOs have to be notified or require a permit for release.	Required. Approval required for any plant with novel traits. It is not restricted to inserted genes from rDNA technologies	Required. A licence is required for release.	Required. A licence is required for release according to conditions.	Required. Part B licence is required under Directive 2001/18.
Environmental Risk Assessment	**Permits**: Prepared by APHIS, which include standard and supplementary conditions.	Environmental review required.	Prepared by OGTR, including a Risk Management Plan	An evaluation review is conducted by ERMA.	Required under Annex II of Directive 2001/18.
Categories of trial set by degree of risk	**Notification** – Low risk **Permit** – Higher risk	No trial categories: scale, scope and location determined on a case-by-case basis.	No trial categories: scale, scope and location determined on a case-by-case basis.	No trial scale, scope categories and location determined on a case-by-case basis	Member States do not have trial categories, except the Netherlands. Whilst the Netherlands places great importance on case-by-case assessment, they also operate 3 categories according to the degree of risk.
Terms and Conditions	**Notification** – Must meet predefined performance standards	Specific to the crop-kind and the nature of the novel trait. Can include, but are not limited to, restrictions on limiting the	Must be a licensed organisation; Adhere to contained transport conditions before release; conditions on a	Conditions can include restrictions on location, containment of the GMO and heritable material, buffer zones,	Trial management requirements are set out in a Part B licenses on a case-by-case basis.

	Permit – Must follow procedures described in applications, specified protocols and permit conditions assigned by the BRS.	size of the trial, reproductive isolation from related species, use of harvested material, and subsequent cropping. Notification and approval required for planting a confined field trial.	case-by-case basis to manage risks; on an annual report, submit an annual report.	planting (and therefore flowering) time, or controls on how the crop is harvested and processed or destroyed. These are set on a risk based approach.	
Reporting adverse or unanticipated effects from the release	**Notification** – Required (unusual occurrences) **Permit** – Required	New information regarding the environmental safety of novel organism, including the risk to human health, that may come to light after authorization, must be reported.	Required. Additional information about risk to human health and the environment and unintended effects from the release.	Reporting of issues likely to be of public interest	Required. Additional information on unintended changes to the GMO that could have consequences to risks for human health and the environment or new information that becomes available that might alter these risks, the notifier must inform the competent authority.
Inspection	**Notification** – Required. Inspected using risk-based criteria. **Permit** Required. Inspected at least once annually. Up to six per site, are required for high risk releases, e.g. plants producing pharmaceutical or industrial compounds	Required. High Inspection rate for trials that are in the ground. Verification of the conditions of the approval.	Required. Verification of the conditions of the approval.	Required. Verification of the conditions of the approval.	Required. Verification of the conditions of the licence. From detailed MS surveys, the level of inspection varied according to the crop and trial activity. As a minimum, trials are inspected annually. Countries that may only inspect a crop or a post-trial site once a year had other control measures in place (NL and UK).
Guidance on managing experimental field trials	**Notification** – Guidance on notification procedures and critical habitat analyses	Conducting confined research field trials, generic and crop specific terms and	Handbook on gene regulation technology. Generic guidance on post harvest crops,	Generic guidance set out on ERMA's website. Specific management guidance set out in	Eleven Member States provide guidance on the general principles that need to be considered for management of

	Permit – Guidance on environmental assessments, pharmaceuticals or industrial compounds, critical habitat analysis and insect permit guidance. Generic Guidance (N&P): on low-level presence of regulated GMOs, Plant incorporated pesticides.	conditions, minimum isolation distances, minimum monitoring guidance.	accreditation of organisations, risk analysis frameworks, good industrial scale practice, transport of GMOs, policy on the transport and supply of GMOs.	proposed controls.	GMO DR trials

Information was interpreted from the websites of the regulatory bodies of
USA: http://www.aphis.usda.gov/
Canada: http://inspection.gc.ca/english/toce.shtml
Australia: http://www.ogtr.gov.au/
New Zealand: http://www.ermanz.govt.nz/

9.2 A two-tiered approach to GMO research trials

Since 1993 the USA has operated a fast track (notification) and a standard approach (permit) to experimental releases[32] that depends on the level of risk to the environment posed by GM organisms.

9.2.1 Notification[33]

Notification is a streamlined procedure which allows the experimental release of GM plants that are considered to present a low risk of harm to the environment and where the regulator, the Biotechnology Regulatory Services (BRS) within the Animal and Plant Health inspection Service (APHIS), has extensive experience and knowledge of the trait in the past. This familiarity gives APHIS confidence that the GMO will not persist in the environment provided the notifier keeps to specified performance standards.

To qualify for notification the applicant must meet a set of eligibility criteria and be prepared to manage the trial according to a set of pre-defined performance standards. The eligibility requirements are related to safety and focus on the novel plant's potential to pose a plant pest risk. The performance standards, on the other hand, are designed to ensure confinement so that the material and its offspring do not persist in the environment. These standards are:

- Containment during transit and storage in a detainment facility before release,
- Prevention of inadvertent mixing of materials during the release,
- Maintaining identity of the GMO whilst in use and contained, or destroyed, after use,
- Elimination of viable vector agents,
- Prevention of the GMO and its off-spring persisting in the environment, and
- Volunteers must be managed to prevent persistence.

Applicants must sign a statement indicating that they will conduct the test in a manner that meets the performance standards listed in the APHIS regulations. As part of the notification process, BRS requires that notifiers provide information about the plant; descriptions of genetic modifications; the source and identity of any genes introduced; and the size, duration, and location of the field test. Notification of sowing and detailed follow-up reports also have to be submitted.

The BRS requires 30 days to review and process notifications for field testing. Releases of GM plants that express pharmaceutical or new industrial compounds, not intended for food and feed, are not eligible for notification. If a plant does not meet the eligibility criteria for a notification, applicants can apply for a permit. If new information becomes available that demonstrates unanticipated effects or plant health risks they must notify APHIS.

[32] See: http://a257.g.akamaitech.net/7/257/2422/11feb20051500/edocket.access.gpo.gov/cfr_2005/janqtr/pdf/7cfr340.4.pdf http://a257.g.akamaitech.net/7/257/2422/11feb20051500/edocket.access.gpo.gov/cfr_2005/janqtr/pdf/7cfr340.3.pdf

[33] See: http://www.aphis.usda.gov/brs/pdf/Notification_Guidance.pdf

9.2.2 Permits

A more rigorous system is applied to GM plants where there is considered to be an elevated risk of harm to the environment, such as those that pose a plant health risk, and plants that produce pharmaceutical or industrial compounds that cannot be used for food and feed purposes. Permit applicants must provide more detailed information about the nature of the GM plant to be introduced and conditions that will be used to prevent the spread and establishment of the plant in the environment. APHIS can also impose additional conditions, for example: reporting unauthorised releases and unintended effects, restricting pollen movement, setting up the perimeter fallow zone, dedicated planting and harvesting machinery, cleaning of equipment, use of dedicated storage facilities, post-harvest monitoring, post-harvest land use restrictions, monitoring reports and notices.

The BRS conducts a comprehensive review of each permit application and has 120 days to approve or reject the application. Permits require notifiers to follow procedures described in their applications, specified protocols (e.g. standard operating procedures) they have submitted, and permit conditions assigned by the BRS.

Since 1987 when GMO field trials first began there have been approximately 14,500 experimental releases (APHIS, 2008). 13,050 of these were notification applications, whilst the remaining 1,450 were permit applications. In view of the large number of GMO research trials that are administered in the USA, there are practical advantages in adopting a two-tier system. It enables all parties, notifiers and regulators, to target their resources towards releases that have the highest potential risks of causing harm to environment. APHIS points out that whilst the two procedures differ; their aim is identical, namely to prevent the unintended release of GMOs.

9.3 Accreditation and Quality Assurance

9.3.1 Accreditation in Australia

Australia has a similar approval system and management practice to EU Part B procedures[34]. A statutory feature of this system is that for licences for release to be approved, the applicant has to be an accredited organisation. An accredited organisation is one that has been accredited by the regulator, the Office of the Gene Technology Regulator (OGTR), after having satisfied certain criteria, including the presence of a properly constituted biosafety committee (IBC) within the organisation. The OGTR expects that the IBC will assist the organisation in meeting the legislated requirements for dealings with GMOs, including the need to provide information back to OGTR.

9.3.2 Quality management in the USA

In September 2007, APHIS announced its intention to introduce a voluntary, audit-based compliance assistance programme known as the Biotechnology Quality Management System (BQMS) (APHIS 2007a). The intention is to complement and not replace APHIS' existing regulatory compliance and inspection process. The aim of the programme, as with any other quality management system, is to assist notifiers (universities, producers and companies) to analyse their operations, identify control

[34] For a full description of the Australia approval system see: http://www.ogtr.gov.au/pdf/handbook/handbook.pdf

points where problems occur, and apply mitigation measures to address these vulnerabilities. The programme was introduced in the spring of 2008 and operates a two-tier system of programmes.

The first level (A) is designed for applicants that do not have formal management systems in place and helps participants to develop good management procedures. It is geared towards small businesses and universities. At this level, the programme is based on industry management practices, Codex Alimentarius' principles and guidelines on the application of the 'Hazards Analysis and Critical Control Point (HACCP)' system.

The second programme (B) is for applicants who already have formal management systems in place and is intended for applicants that grow GM plants at multiple sites, often through the use of operators. It works by ensuring accountability at all levels and by all parties involved. Level B management practices are based on the principles and guidelines of the internationally recognized ISO 9001 standard.

In July 2007 a new American industry initiative, promoted through the Biotechnology Industry Organisation (BIO), was also introduced to address product stewardship and quality management throughout the US biotechnology industry (BIO, 2007). It will include, but will not be limited to, commodity crops, specialty crops, energy crops, perennials, ornamentals, and crops that produce pharmaceutical and industrial products. Its themes are to maintain plant product integrity, publish a Quality Management Programme Guide and to undergo independent third party audits. The biotechnology industry anticipates that the programme will be progressively introduced in the United States up to January 2009 and will subsequently be extended to other interested organisations outside the US by 2012.

9.4 INSPECTION, COMPLIANCE AND INCIDENTS

9.4.1 USA

Inspections and investigations of non-compliance resulting from experimental release trials are undertaken by the APHIS-Compliance and Inspection Branch (CIB). Their aim is to assure compliance with the regulations covering authorisations under the notification and permitting procedures. Current practice, as described on APHIS' website, is that all notification trials are subject to inspection. In practice, they are inspected according to targeted, risk-based criteria. APHIS inspectors use several parameters to select notifications for inspections, such as the GM trait and its characteristics, applicant history, and acreage planted. Each notification receives a total score based on all factors. A computer program generates the scores, and those notifications with the highest scores are assigned for inspection to verify compliance with the performance standards.

All permit trials receive at least one inspection either at or near the beginning of the field test, possibly during the course of the trials, and shortly after the harvest. Plants engineered to produce pharmaceutical or industrial proteins are inspected up to seven times before, during, and after the field trial. These inspections are performed at critical times during field testing, including pre-planting, flowering, harvesting, and after harvest. The BRS maintains a comprehensive database that captures and

tracks inspection-related information to assure that all required inspections are accomplished. Inspections verify compliance with the conditions of the permit.

Non-compliance incidents resulting from experimental release inspections, or potential incidents reported by either notifiers or the public are thoroughly investigated including evaluating facilities, equipment, records of developers, drawing samples and where necessary issuing affidavits.

Between 1995 and 2007 there have been 17 non-compliance incidents recorded involving rice, corn, trees, tomato seeds, creeping bentgrass, soya, tobacco, cotton, papaya and oilseed rape (table 9.2). Three of the incidents were with plant-made pharmaceuticals or industrial compounds. The nature of the incidents varies, however, most incidents were primarily concerned with post trial management of volunteers and incorrect areas being planted, thus breaching permit conditions.

Table 9.2: Incidents of non-compliance of notification and permit conditions occurring in the USA from 1995 to 2007

Number of Incidents	Nature of Incident	Species
1	Accidental release	Creeping Bentgrass
2	Illegal transportation/export	Maize, Tomato,
4	Illegal planting (without permit)	Cotton, Maize, Tree species, Tobacco
2	Planting area breached (wrong site)	Maize, Papaya
1	Buffer zone incorrect size	Maize
1	Cross pollination	Maize
1	Mixing of materials during containment or release.	Rice
5	Volunteer management	Maize (4), Oilseed Rape (1)

A full summary of non-compliance incidents can be viewed at:
http://www.aphis.usda.gov/biotechnology/compliance_history.shtml

For those breaches concerning areas planted without permits or in the wrong area and for the management of volunteers, the offending plants and compatible crops, growing either on the release sites or within the isolation distances, were destroyed. In one post-trial monitoring case, grain from a cover crop of soybean contained GM volunteer maize material, that produced a plant made pharmaceutical product, had reached an elevator, inspectors were able to intervene and 500,000 bushels of grain were destroyed.

In 16 of these incidents, GM produce was thought not to have entered the food and feed chain. Nor have there been any subsequent reports of adverse effects to the environment resulting from these incidents.

One incident involved two field tested lines of GM Rice, LLRICE601 and LLRICE604, that were reported by Bayer Cropscience in 2006 to be present in commercial rice (APHIS, 2007b). The resulting investigations were inconclusive as to the causes of the unauthorised release of this material. Whilst the non-GM varieties that tested positive for these events could be traced to fields on an experimental research station where the GM lines were released under experimental conditions during 1998

and 2001, neither the mechanism of insertion of the GM lines into the conventional varieties or breakdowns in management trial procedures could be identified.
In some circumstances the companies involved with the incidents described in table 9.2 were required to develop management practices, implement staff training programmes and pay fines for breaching federal or civil laws. One company agreed that they would never apply to BRS in the future for a notification or a permit to release a GMO.

9.4.2 Australia

Australia is a model example for reporting and publishing inspection and incident reports. Examination of the non-compliance incidents reported between 2002 and 2007 showed that the majority of incidents occurred during the post-harvest monitoring stage of the license (table 9.3). The nature of incidents reported at this stage varies, however, most are primarily concerned with the management of volunteers or the planting of unauthorised follow-on crops both of which could result in seed with unauthorised adventitious GM presence entering the market place had appropriate remedial action not been taken.

Table 9.3. Incidents of non-compliance of licence conditions in Australia between 2002 and 2007

Number of incidents	Stage incident occurred	Species
2	Sowing	Cotton
19	Growth	Cotton (10); grapevine (1); oilseed rape (2); papaya (2); pineapple (3); sugarcane (1)
4	Site clearance	Cotton
35	Post harvest monitoring	Cotton (25); Indian mustard (3); oilseed rape (3); sugarcane (2); wheat (1); white clover (1)

Incidents are published in Quarterly Reviews of the OGTR;
http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-1

In all cases the risks to human health and the environment were deemed by the OGTR to be negligible. Remedial action involved removing and destroying volunteer plants from the affected sites, and license holders were reminded of their duties during post harvest monitoring. No action was taken to remove any of the unauthorised follow-on crops (as they were all crops listed as suitable follow-on crops in the OGTR Guidelines on Post Harvest Crops). Instead licenses were submitted for amendment and license holders were reminded of the correct procedures to follow when seeking to diversify from the license conditions. In some cases additional monitoring requirements were added to the licenses.

In 2000 a notifier informed GMAC[35] that seed of Roundup Ready cotton had been harvested from a confined release trial and been allowed to be processed commercially (OGTR, 2000). As the GM cotton had been mixed with conventional cotton, there was no possible means of tracking the exact fate (export, animal feed or crushing) of the GM cotton. The GMAC Release Subcommittee considered the biosafety implications of the breach and concluded that there were no risks to the environment or to public health and safety as a result of the breach. This conclusion was based on the risk assessment for Roundup Ready cotton as the variety was

[35] GM Advisory Committee, predecessor of Gene Technology Technical Advisory Committee (GTTAC).

being assessed at the time for general release. The incident resulted in the notifier having to improve their communication processes between all participants involved with GM crop trial to ensure effective dissemination of the licence requirements were known to sub-contractors that handled the release.

9.4.3 Canada

The Canadian Food Inspection Agency is responsible for inspecting confined field trials to ensure compliance with the terms and conditions of the licence for release.

Summaries of Canadian inspections, including compliance rates, are reported annually in the Agency's Departmental Performance Reports[36]. Their current compliance target is for 90% of operators to meet the conditions of their permits. In both 2006-07 and 2005-06 the compliance rate was 94%. The remaining 6% of operators were issued with compliance letters outlining corrective action; follow-up inspections were conducted, where appropriate, to ensure corrective actions had been carried out. During 2001 and 2003, when trial inspection rates were published, the percentage of crop trials that were inspected was on average 97%, and for post-harvest trial sites 39%.

Whilst non-compliance incidents are regularly reported by inspectors, at a level of around 6% per year, none of the incidents raised environmental or human health concerns. Compliance problems that were identified were corrected in such a way that the trials could return to a compliant status. The nature of the incidents, whether they were administrative, technical, accidental or intentional, was not specified (table 9.4).

Table 9.4. Canadian Inspection and Compliance Rates for GMO Field Trials between 2001 and 2003

Year / Trial	Number of sites	Inspected	% Inspected	Non-compliance	% non-compliance
Seeded Trials: Autumn 2000 to Spring 2003	648	621	97%	37	Average 6%
Post-harvest monitoring sites 2001 to 2003	2371	836	39%	46	Average 5%

9.4.4 New Zealand

Any non-compliance incidents for new organisms, including GMOs, are reported on the Environmental Risk Management Authority (ERMA) website[37]. Between 2004 and 2007 no incidents were reported for contained field trials.

9.5 COMPARISON WITH EU PROCEDURES

9.5.1 Management practice

Comparison of the regulatory frameworks of the USA, Canada, Australia and New Zealand showed that the application of management practices to prevent the

[36] http:/www.inspection.gc.ca/english/corpaffr/ar/artoce.shtml
[37] See http://www.ermanz.govt.nz/no/compliance/incidents.html

dissemination and persistence of GM material in the environment and entry into the food and feed supply chains are broadly equivalent. They all adopt the management practices that are used in EU GMO field trials. With the exception of the US notification system, management practice is designed to address any risks of harm to human health and the environment, on a case-by-case basis, that have been identified in an environmental risk assessment and is implemented through the terms and conditions of the release. Progressive scaling up of field trials occurs when new information demonstrates that the potential risks resulting from a release are smaller than those of previous assessments. With the US notification system, trials are managed according to a fixed framework, i.e. a set of pre-determined management standards which rely on the assumption that, if followed, the GMOs will not be dispersed beyond the release site. The American permit system is analogous to the European part B system, where the risks are determined on a case-by-case basis and management practice is implemented to mitigate those risks. Monitoring and inspection are essential features of all the systems.

9.5.2 Accreditation and Quality Management

Member States have an obligation under Article 4 (5) of 2001/18 to "ensure the competent authority organises inspections and other control measures as appropriate, to ensure compliance with the Directive". Whilst accreditation and quality management systems are not a specific requirement of the Directive, they fall into the suite of control measures that Member States can adopt to provide additional assurance that the delivery of a product, in this case conducting experimental field trials to a set of standards, can be competently delivered by an organisation. This may become increasingly more important as the number and scale (land area) of deliberate releases increase and where extensive use of sub-contractors is made or where GMOs have an elevated risk and could cause harm if they entered the food and feed supply chains.

Whilst we are not aware of any Member States that operate a dedicated quality management system for deliberate release trials that is similar to the proposed BQRS system in the USA, various quality control measures are in operation within the Community. These are as follows:

9.5.3 Statutory licensing of an Environmental Safety Officer

In 2004 the Netherlands introduced a statutory requirement for notifiers to appoint a government-approved Environmental Safety Officer (MVF) who has the responsibility for coordinating activities involving GMOs within the organisation and ensuring the approval conditions are met. The function is very similar to the role of the Biological Safety Officer that is appointed under GMO Contained Use legislation. Once a MVF has been appointed the notifier no longer needs to provide details in each application of the responsible scientists (i.e. CVs) associated with the release as required under Annex IIIB of the Directive. This removes duplication of information in subsequent applications and the need to make personnel information public.

This approach would be analogous to the Australian licensing approach, except that in the Netherlands the focal point is placed on a licensed environmental safety officer to ensure that the organisation fulfils the obligations set out in a licence. In the Australian system that role falls to the biological safety committee.

9.5.4 Internationally recognised quality management systems.

Some of the MS Mission field operators that were interviewed in this project held listed assurance management accreditation, e.g. the Dutch operator is listed as being GLP (Good Laboratory Practice) compliant and the UK operator's organisation is certified under ISO 9001:2000. These systems have been designed to produce results from experimental studies that can be relied upon for making risk/safety assessments (GLP) or the organisation works to a generic standard for companies that produce a product or service (ISO 9001:2000).

9.5.5 Management Audits

In the UK the GM Inspectors carry out a management audit on notifiers and their management of experimental trials (see table 22, Appendix 7). The purpose of these audits is to verify that the correct management procedures and protocols are in place to ensure the appropriate planning and operation of GMO field trials. This includes confirming that the conditions laid down in the licenses are known throughout the management chain and are effectively implemented *in situ*, and that all material removed during the trial and post-trial periods is stored and/or disposed of correctly. The notifier is also asked to provide evidence to demonstrate sufficient 'duty of care' so as to ensure that only those GM events covered by the consent are released.

9.5.6 Administrative checks on notifier's records

In Sweden there is a clear distinction between field compliance and administrative compliance. The Competent Authority performs an administrative inspection in which the notifier is required to submit details of managing field trials. This includes instructions to the field operator, a report to the CA on how the field trial performed, and a report to confirm conditions such as the absence of wild relatives have been observed.

9.5.7 Incident findings

With the exception of Canada and Australia, published information from government sources on inspection rates and breaches of GMO trial legislation is limited for third countries. This makes analysis of critical points in the trialling cycles, which may be susceptible to breakdown, difficult to determine. In the USA, from 1995 to 2007 when 11,792 applications were approved for release, the number of incidents on the non-compliance register is 17. Incidents occurred in a variety of crops of which maize was predominant and occurred in all phases of the trialling cycle. There were more incidents with post-harvest (5). In Australia, a higher number of incidents occurred during post-harvest monitoring (35), whilst in Canada, where data was available, there were no apparent differences between non-compliance incidents during and after trialling. This might suggest that in certain crops which are grown in climates where volunteers can over-winter, or where secondary dormancy of seed is a feature of a plant's lifecycle, vigilance during post-trial monitoring should be a prominent feature of GMO research trial management. In Australia, where *Brassica* crops and cotton volunteers can persist, the regulator has published guidance on appropriate cropping during the post-monitoring to facilitate the control of GM volunteers in these crops.

Apart from the two cited cases of LLRICE604 and Roundup Ready cotton there were no incidents from official government sources in these four countries that GM material that has been released from GMO research trials had entered the food and feed chains.

In Europe the number of reports of breaches of national GMO legislations concerning the management of GMO field trials was also found to be very low. The Member States cited three incidents: in Spain an incident involved an isolation distance and a waste disposal incident and in Denmark two failures in monitoring were reported. None of these incidents resulted in GM material entering either the food or feed chains.

SUMMARY

1. The management practices of the four countries reviewed (Australia, Canada, New Zealand and the USA) are broadly equivalent to practice that has been adopted in European GMO field trials. They are all designed, on a case-by-case basis, to address risks that have been identified in an environmental risk assessment and are implemented through the terms and conditions of the release. An exception to this practice is the US notification system, where GMO field trials are managed according to a fixed framework where the applicant has to agree to implement a set of pre-determined management standards which have been designed to ensure dispersal will not occur beyond the release site. However, the aim of all these GMO field trial systems is the same, i.e. to prevent or minimise dispersal from the release site and ensure the GMO does not persist in the environment beyond the period of the release.

2. In Australia, components of quality assurance systems have been incorporated into deliberate release legislation. There is a statutory requirement for notifiers who wish to conduct GMO field trials to be accredited organisations. Notifiers have to be accredited as an organisation by the regulator, the Office of the Gene Technology Regulator (OGTR), and must have a constituted biosafety committee (IBC). The role of IBCs is similar to that in EU Contained Use legislation, where the committee takes on a self-regulatory role to ensure the obligations of their organisation are fulfilled. In the USA, voluntary quality management systems are being promoted by the regulator (APHIS) and by a biotechnology industry representative organisation (BIO). They are seen as additional tools to assist notifiers develop sound management practice and ensure compliance with GMO field trial regulations and conditions.

3. In Europe some Member States and notifiers apply quality management systems, or components of these systems, to GMO field trial management, e.g. licensed Biological Safety Officers, field operators whose organisations are certified under ISO 9001:2000, and management audits of notifier's management practice of GMO field trials. In general, there is no uniformity across the community in terms of their use or application. It is possible that wider implementation of quality assurance measures with the EU GMO field trial system, by both notifiers and inspectors where they have not already done so, would augment and strengthen the current inspection and control system.

4. The number and type of breaches of GMO field trial legislation that occurred in Australia, Canada, New Zealand and the USA were reviewed. In relation to the large number of releases that have been approved in these countries, generally the number of reported incidents have been low, which makes an analysis of susceptible points in the GMO trialling cycle difficult to determine. In Australia and to a lesser extent the USA, incidents relating to volunteer management appeared to be more frequent. This might suggest for certain crops which are grown in climates where volunteers can over-winter, or where secondary dormancy of seed is a feature of a plant's lifecycle, vigilance during post-trial monitoring should be a prominent feature of GMO research trial management. The seven MS that were interviewed in the detailed survey identified post trial monitoring as a critical control point and make management in this phase a requirement of authorisations; we would recommend that inspectors in particular maintain a close watch on this phase of trial management.

5. We see a value in publishing inspection and incident reports as undertaken by the Australian and New Zealand Regulatory Authorities as they promote awareness of the control measures that are undertaken during GMO field trials and should support public confidence.

6. Only two cases were found where GM material that had been authorised for released under experimental field trial conditions entered the marketplace. These cases were (1) LLRICE601 and LLRICE604 in the USA and (2) Roundup Ready cotton in Australia. From replies from Member States to surveys conducted in this project, there were no reported cases of GM material having entered the food and feed supply chain in Europe.

10. ANALYSIS, GAPS AND BEST PRACTICE

A number of key recommendations are made in this section; these are also listed separately in the section entitled 'Recommendations' (pages 7 to 10).

1. The current system for publishing new Part B notifications on the JRC website works effectively for the CAs, but it does not provide an accurate picture of the field trials that have actually taken place in the EU and the management measures that were applied to those trials. It is also a static list that cannot be interrogated. The availability of an up-to-date and searchable database would be of value to Competent Authorities and notifiers and would possibly assist in decision-making when issuing new consents, this may be particularly so for the newer MS. As part of this project a database was developed that contains all the information on the JRC website but which is also searchable and easily updated. However, as the database was developed primarily to support this study and not with broader use in mind, it is possible that further modification would be necessary before it could be made more widely available. Arrangements would also have to be made for updating at appropriate intervals. In its current format, the database is not amenable to publication as an interactive web-based tool because of the software used (MS Excel), but it could be made available as a downloadable file.

2. Relative to 1999, there are now fewer trials being carried out in the Member States of Europe, despite the fact that twelve new countries have joined the Community in this time. The types of traits and the range of crops being notified for trials is less diverse, with maize trials for herbicide tolerance and/or insect resistance being dominant. This trend must partly reflect the complex picture in Europe with respect to attitudes to GMOs rather than any negative influence the Directive itself has had. The survey confirmed that the Directive has been implemented in all MS, and as it's purpose is to enable Part B releases to take place safely, it is reasonable that end users should expect to be able to notify and conduct field trials in all the MS in a manner that is consistent with the basic principles of the Directive. However, evidence gathered in this research suggests that some of the MS appear to be resistant to holding Part B trials, or to create conditions that make it difficult for a trial to proceed. Examples are where a favourable opinion is given on an environmental risk assessment and notification dossier, yet consent is not given for a field trial to take place, or where conditions attached to a trial are so stringent that holding the trial becomes very difficult. It is not possible to say whether this situation arises because an MS is averse to holding field trials on their territory, or does not feel competent to do so.

3. The CAs reported that no GM material from a Part B field trial has entered the market place since the Directive was implemented in 2002 (table 5.6). A total of twelve non-compliances were reported, of these eleven were classed as technical breaches of consent (written warnings were issued for two of these), and one was a written warning for a more serious non-compliance. No prosecutions have been pursued in connection with non-compliances. We must assume this is an accurate representation of incidents to date. This evidence suggests that the legislation is working effectively. Reflecting on the systems put in place by the CAs and inspectors, and accepting that fairly limited information was gathered for 17 of the MS, there are no obvious reasons to suggest they are not fit for purpose at present or

in the future should they have to deal with larger numbers of trials or different types of traits, although it seems unlikely that the MS will see this happening in the short term (see Appendix 11).

4. Whilst this project focused on field trial management issues, it also revealed differences in approach towards implementation of the Directive, processing of applications and assessment of applications, which, if confirmed and acknowledged, should be reviewed. There were time and resource constraints to gathering in-depth evidence to substantiate all the comments that were made, particularly by the notifiers, during the course of this project. We recommend, therefore, that MS are invited to comment on this report as a prelude to addressing the issues raised and facilitating a common methodology and application of risk assessment for Part B GMO trials throughout the European Union. One approach might be for the Commission and CAs to explore the possibility of establishing an independent body through which communication could be facilitated between notifiers, CAs and the Commission. This would enable time-sensitive review and resolution of misunderstandings between CAs and notifiers regarding, for example, what one party considers to be unreasonable or disproportionate requests for additional information, or where the reasons for refusal to authorise a Part B release are unclear when the assessment of risks is low and independent scientific evaluation of a notification is positive.

5. It would undoubtedly be beneficial if there was greater harmonisation with respect to the types of information and level of detail that is requested in notifications, conditions attached to consents, and information that is made available to the public. This would be for the purpose of achieving greater parity rather than to address concerns about risks to human health and the environment posed by the GMOs.

6. From the MS missions to France, Germany, Hungary, the Netherlands, Spain, Sweden and the UK, we do not believe there are any significant gaps in the way that Part B GMO field trials are managed by the CAs and inspectors or by the notifiers. The systems that have been established for management and control follow similar structures and processes and we have not identified any obvious weak points at which breakdown of effective management would be particularly likely to occur and, in doing so, pose risks to human health and the environment, for example by accidental entry to the market place. It is not possible to draw the same conclusions for the systems in place in the remaining MS because we have gained less insight to their detailed arrangements for management and control. However, from the information we have gathered about these countries, and the fact that no entry of material to the market place has been reported from these MS, we have no evidence to suggest the systems would be any less robust. Undoubtedly, some of the earlier-established MS will have experience that would be of value to the newer MS and it may be useful to establish informal mechanisms for sharing knowledge between the two[38].

7. We do not believe that any one Member State can be nominated as an example of best practice because each system has its drawbacks. For example,

[38] The European (GMO) Enforcement Project (EEP) was established in 1999 to facilitate exchange of knowledge and practical expertise between inspectors of deliberate release field trials. The Group is specifically for inspectors, but could provide a model for a similar arrangement between CAs.

three MS operate strictly on the basis of science-based, case-specific risk assessment, but issuing of consents can be seriously delayed by public consultation. Another MS issues consents in a timely and proportionate manner, but there is a risk of vandalism because detailed information about trial location is published. In a different example, the system itself works very well but is necessarily complex because of shared responsibility between regional and central administrations. Similarly with inspection and control practices, each MS has developed its own approach, and they are broadly similar with the same underlying goal. We do believe there are benefits to be gained from inspection that examines the administrative management processes established by the notifiers in addition to practical, checklist-based field inspections, and we would advocate that inspectors consider adopting these approaches if they do not already do so.

8. The e-survey revealed that nine of the twenty four MS have arrangements in place to review duty of care, with a further two stating that official samples may be taken if necessary. Notifiers commented that mostly this is to confirm that the approved GMO is released, rather than to investigate the presence of adventitious GMOs, although Germany and the UK seek assurance on the latter by testing (Germany) or audit (UK). This could be considered a critical control point in conducting a GMO field trial because the CA's assessment of risks is based on the GMO that is described in the notification dossier and the environmental risk assessment, yet a relatively small number of MS are seeking assurances from notifiers on this point. We would recommend that CAs and inspectors should review their approach to ensuring notifiers are taking all reasonably practicable actions to ensure they meet their duty of care obligations, and consider whether this aspect of inspections could be reinforced. In doing so, it should be recognised that there may be practical and economic difficulties attached to testing experimental GMOs for which only a limited amount of material may be available, or for which a large number of experimental lines may be released (or both), and that the steps taken by a notifier can be explored through other means (section 5.2.9).

9. The evidence gathered from the surveys and from interviews with notifiers indicates that most MS take a strongly precautionary approach to releasing Part B GMOs. Part B of the Directive focuses on assessment of potential risks to human health and the environment and measures for containment and mitigation of any risks. A number of the notifiers interviewed expressed the opinion that requests for information about the GMOs were sometimes in excess of what would they would normally expect to provide for a highly managed, often small-scale Part B release. Clearly it is essential that CAs and their advisors are satisfied that there are no risks posed to the environment or health by the release of a GMO; it is also important that perspective is maintained on this aspect of the notification process, and that requests are not made for levels of information that are not appropriate for an experimental field trial. With the high level of containment that is applied to most Part B trials we question, for example, whether it is appropriate that notification for a Part B trial should be expected to contain data about risks that are specific to local environments, for example the fate of a widely used herbicide in the specific environment in which the trial would take place (Appendix 8); such a request is not within the scope of Directive 2001/18/EC as listed in Annex III and should be examined through the Plant Protection Products Directive 91/414/EEC. Annex IIIB (E) specifies that information should be provided relating to the 'proximity to officially

recognised biotopes or protected areas which may be affected', and the 'presence of sexually compatible wild relatives or cultivated plant species'. CAs should also ensure that conditions attached to consents are solely for the purpose of containment and risk mitigation and to ensure that GMOs from Part B trials are not placed on the market, and that where isolation distances are specified, they are based on examination of current scientific evidence.

10. In order to explore the issue of proportionality in requesting information about Part B GMOs, we recommend the Commission should consider setting up an *ad hoc* working group of independent GMO risk assessment experts to explore in depth the consistency of requests for science-based information made in Part B dossiers in relation to the stage of the development of a GMO, and the appropriateness of isolation distances used in GMO field trials across the Community. As part of its remit, the working group would also explore the extent to which the principal reason for refusing a notification to release a GMO is that the risk assessment suggests it would be detrimental to either human health or the environment to proceed with a release, and that risk management measures could not adequately address these risks. Although the CAs are not obliged to inform the notifiers of their reasons for rejecting a notification, under Article 11(3) of the Directive they are required to inform the Commission of the final decisions taken on notifications received, including reasons for rejecting a notification. The Commission should, therefore, be in a position to help explore the issues raised by the notifiers around rejection of notifications.

11. In connection with the above, we believe the Commission should explore how national GMO legislation can be amended to ensure it is in line with the Directive, for example, where national legislation automatically excludes the deliberate release of certain crops without a risk assessment, or automatically establishes an exclusion zone around protected sites. Similarly, the Commission should discuss with Member States whether it is permissible under the Directive for national legislation to automatically exclude the transformation and subsequent release of naturally occurring plant species within a Member State's territory, or prohibit hybridisation between GMOs and sexually compatible naturally occurring species.

12. In accordance with the Directive, the principle of case-by-case risk assessment does underpin the systems that have been established in the MS. Some MS chose to adhere to this more strongly than others, to the extent that they choose not to develop indicative management practices for any crops. Of the seven MS that were interviewed, with the exception of two MS, minimum isolation distances are in place for the crops that are more commonly placed in trials in those countries. These may be altered depending on the trial and according to case-by-case evaluation, but in practice isolation distances will be at least the minimum distance decided by the MS. No evidence was gathered to suggest that the GM trait influences management conditions attached to a trial.

13. The Netherlands has established a tiered system that categorises field trials according to the level of uncertainty about the possible harmful effects of the GMO on the environment[39]. The system is entirely in line with the 'step-by-step' principle

[39] Where harmful is taken to mean unwanted effects that significantly differ from a Dutch reference framework used for current agricultural practice and classical breeding.

established by the Directive, which states: “The introduction of GMOs into the environment should be carried out according to the step by step principle. This means that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken” (recital 24). This tiered system recognises that different scales and types of trial exist, and that that when a GMO is released, knowledge is generated that can be informative for future management of that GMO. No measures to mitigate risk or prevent dissemination are required for a category 3 trial (see section 5.2.4) and as these trials can be large scale, it is not inconceivable that the GMO may accidentally enter the food/feed chain. It is accepted that this could occur but the CA considers that, because of the preceding risk assessment, this would only present an economic risk. To keep any outcrossing and commingling to a minimum the CA would advise notifiers to adopt agreed measures for coexistence (e.g. isolation distances) for category 3 trials. The CA believes that trials at this scale are an important step in the transition from experimental release to full-scale commercial release, which is an entirely logical and pragmatic argument. Whilst we consider this system provides a clear, stepwise framework for fully implementing the underlying principles of the Directive, it must, nonetheless, also remain compliant with Article 6(9) and ensure that no material derived from Part B deliberate release trials is placed on the market. To achieve this, more stringent containment conditions may be needed for category 3 trials over and above the current voluntary co-existence measures, including studies to verify that these additional measures are sufficient. However, we note that no material is reported to have entered the market from the potato trials that have taken place under category 3, and to date only trials of potato have made the transition from category 2 to 3.

14. The Netherlands has adopted the principles of managing the release of a GMO as knowledge about a specific GM event in a particular crop increases. We recommend the Commission considers the feasibility of introducing a differentiated procedure for Part B trials that will facilitate gradual reduction in the stringency of management measures for GMOs that are well characterised and about which a significant body of data has already been generated. This might be, for example, a GM event that is being assessed for commercial release (under Part C of the Directive or Regulation (EC) 1829/2003) for which Part B trials are ongoing in parallel for variety registration purposes, or trials of a GMO that is already authorised for food and feed use. Destruction of an authorised commodity seems wasteful, particularly in the current climate of food/feed shortages and high agricultural input prices. We therefore also recommend that the Commission should consider whether, under these differentiated procedures, material harvested from a trial of a GMO that is authorised for food/feed use could be disposed of into the feed chain, rather than being destroyed.

15. A significant problem raised with the notification processes in some CAs, was the time taken between submission of the notification to the CA and issuing of their decision. In the main this is linked with the commitment to consulting the public, which appears to be contributing to bottlenecks in the application process to the extent that some MS do not fulfil their obligations under Article 6(6b) of the Directive. This is the case in one MS where consents can be tested in Court leading to very lengthy delays which present practical difficulties for the notifiers. Although notifiers

expressed dissatisfaction with this, they can work around the delays once they understand the timelines that can be expected, providing the CA maintains communication. However, situations were described where a notification was submitted to a CA in good time to enable planting in the forthcoming season, but the notification was not acknowledged, or no lines of communication could be established, or the response was delayed to the extent that planting of the proposed crop could not, practically, proceed. To address these points, we recommend the Commission should enter into dialogue with those MS where issuing of consents is often delayed beyond the 120 days outlined by the Directive and discuss whether there are ways that the CAs can ensure the 120 days deadline can be met. The Commission should also remind all CAs of their responsibility to respond to any notifications that are received and to establish, and maintain, helpful lines of communication with the notifier.

16. Competent Authorities require notifiers to exert control at all critical points during the trial, in particular at flowering, harvest and disposal, also storage and transport arrangements. Requirements for management at these points are broadly comparable across the MS and they are, on the whole, precautionary. The CAs expect to see evidence that control has been maintained throughout the trial by the provision of consent holder reports, augmented by official inspections and/or audits. There is good recognition of the need to monitor and control volunteer plants at former trial sites, and the CAs place emphasis on ensuring that compliance is maintained through the post-trial monitoring phase. Reference to the incidents of non-compliance recorded in Australia and USA confirms the importance of vigilance at this stage. It is important that notifiers and their field operators ensure that post trial monitoring and volunteer management continues at all former deliberate release sites until the Competent Authority agrees that, based on monitoring records, the trial can be terminated. In addition, inspectors should ensure that post-trial monitoring inspections are scheduled at appropriate times in the season so as to ensure notifiers are controlling volunteers and observing subsequent cropping restrictions at their former Part B deliberate release sites.

17. The interviews that were undertaken with notifiers and field operators provided good evidence that communication between these two parties is effective and that the need for compliance is understood. The use by notifiers of established documentation for managing and recording all operations at individual trial sites ensures consistency and good practice. Our evidence indicates that the notifiers that were interviewed take a responsible approach to management of the trials and have good internal organisation in this respect. As a result of the limited sample size undertaken in this study, we cannot be certain that the evidence gathered is fully representative of all sectors of the industry. It would be valuable to see what practices are in place in other universities, research institutes and small and medium sized enterprises. This is a gap in the research and we recommend the Commission should address this by undertaking a survey of a selection of other universities, research institutes and SMEs that currently hold a consent to undertake a Part B trial to provide a fully representative picture of the management of Part B trials by notifiers.

18. Member States have an obligation under Article 4(5) of the Directive to “ensure the competent authority organises inspections and other control measures

as appropriate, to ensure compliance with the Directive". All Competent Authorities have set up mechanisms for inspection and control, often through bodies appointed specifically for enforcement purposes, although these are not always dedicated to GMO inspections. The underlying remit of the inspectors is to ensure there are no risks to human health or the environment. Although levels of inspection and/or audit are generally high in the MS, few inspectorates were underpinned by quality assurance systems. Whilst accreditation and quality management systems are not a specific requirement of the Directive, they fall into the suite of control measures that Member States can adopt to provide additional assurance that an organisation can competently deliver a product – in this case conducting or inspecting experimental field trials to a set of standards. In general, there does not appear to be any uniformity across the community in terms of the use or application of quality management systems and we would recommend that notifiers and inspectors should be encouraged to adopt these practices.

19. There are two features of third country practice that deserve further consideration for wider adoption within the EU – adoption of quality assurance systems to complement site inspections, and publishing inspection reports. Quality management systems assist an organisation to self-analyse and self-regulate a product or a service that they are providing for a customer; in the case of a notifier, this would be complying with conditions of a permit, and for GM Inspectorates, delivering an inspection service to a defined standard. Adoption of quality management systems would also help notifiers and inspectors maintain standards in the long term if the numbers of field trials under their supervision were to increase. This would be consistent with developments in Australia and the USA where quality management has increased in importance. In the USA this may be in response to incidents of entry to the marketplace from GMO field trials. Whilst it is too early to assess a dedicated quality management system that is currently being embedded within the USA GMO field trial system, components of such a system have been successfully operating in Australia. Similarly, some European field operators and GM Inspectorates, e.g. in the UK, work according to internationally accepted quality management systems. We consider that adoption of such systems, whether they are a voluntary or a statutory requirement, augment site inspections. Inspectors should also find these systems instructive in terms of evaluating inspection practices and ensuring that inspections are risk-focussed. International Standard ISO/IEC 17020 on 'General criteria for the operation of various types of bodies performing inspections' may provide a good underpinning for inspection bodies.

20. We consider publishing inspection reports promotes greater awareness and understanding of control measures that are undertaken by MS. The Quarterly Reviews of the Australian Office of the Gene Technology Regulator (OGTR) are an example of good practice (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-1). As organisations undertaking GM field trials in Australia have to be accredited and are named on a public register, inspection reports avoid naming individuals. They also publish coded references for field sites and do not publish site locations, thereby reducing potential vandalism issues whilst crops are in the ground. The majority of MS do not currently publish inspection reports, however, we believe there are merits in publishing reports of individual inspections, as in the UK. We would recommend CAs review their policy for reporting GMO field trials; at the very least, an annual

publication of summaries of site inspections would promote greater transparency and understanding of control measures undertaken for GMO field trials.

21. Notifiers reported significant levels of threats and vandalism by protesters at farmers' premises: of the 161 notifications that were updated by MSs, almost 28% had suffered vandalism which resulted in the termination of some or all of the trials under those consents. Threats and vandalism by protesters appear to have played a key part in reducing the numbers of trials and possibly the types of organisations that are able to hold trials. Not only does vandalism (and the threat of vandalism) cost the notifiers valuable resources and have a potentially serious negative impact on research and development and the European biotechnology industry, it also places a burden on Member States' valuable resources. Also, and importantly, there are growers that would like the opportunity to participate in this work but threats from protesters raise concerns about the growers' safety and that of their families, and may lead to them being denied a valuable opportunity to generate income. Vandalism must, in part, be facilitated by the requirement of the Directive to make information available to the public, including the location of the trial. There is marked variation across the MS with respect to transparency and making information available to the public, in particular with respect to location of trial sites. This wide variation in the level of information about trial location that is available to the public could be considered a gap, or inconsistency, in the current system. We recommend that the relationship between public notification, provision of information on the location of Part B trials (table 5.4) and vandalism in research trials throughout the Community should be properly examined. In the light of legal considerations on site locations, the Commission should consider providing guidance to Member States as to how sufficient information can be provided to the public (and legitimate interested parties) in line with the spirit of Article 9.2 and Annex IIIB E1 without jeopardising the security of trial operators and minimising access to sites for unlawful activities (i.e. site vandalism and damage to farm machinery etc.).

22. The literature review in Appendix 11 highlighted that the number of Part B GMO field trials notified in Europe has gradually increased from a very low level in 2002 when the new Directive came into force, but is still below the peak reached in 1997 under Directive 90/22/EC, despite the addition of 12 new MS in this time. Since the introduction of the Directive the number of notifications submitted by large companies has increased fairly dramatically over time, from around 35% in 2003 to almost 80% of notifications in 2007. Conversely, the number of notifications submitted by research institutes has declined considerably over the same period, from around 50% in 2002 to just 15% in 2007. Likewise, the number of notifications submitted by SMEs has also decreased, although this number was very low to start with. There is likely to be a number of reasons for this, but it is possible that it is due to the volume of information required for a notification and in some cases the high costs imposed by some aspects of the legislation, e.g. the time and effort required to prepare consent applications, managing the trials, or fulfilling monitoring requirements. It is also quite conceivable that research institutes and SMEs find it difficult to absorb the cost of acts of vandalism by protesters. As time progresses it may be that notifications will only be placed by those who can afford it, most frequently large commercial companies. This may represent a failure in the system that warrants further investigation. The number of plant species in Part B notifications has decreased, and there appears to be a tendency to concentrate on

the ‘major’ agricultural crops used for animal feed and for industrial use - maize now accounts for almost 58% of GMO field trials. This may be symptomatic of the reduction in the number of SMEs and research establishments putting forward notifications. There is also increasing use of stacked events, including multiple herbicide tolerance and multiple insect resistance in these crops, providing better protection from insect pests, and allowing growers to simplify their crop management practices. The Part B system appears to be utilised by an increasingly narrow sector of industry, and while this may be a reflection of the current research environment, it would be worthwhile examining exactly what has contributed to this and whether actions are needed to redress the balance.

23. In connection with point 21 above, and while recognising that the case-by-case risk assessment principle must be upheld, we can see the benefits of the European Commission developing science-based indicative guidance for management of trials of GM crops in Europe based on crop biology, published research and previous experience. This guidance could discuss issues that might be expected to arise with specific crops and measures for dealing with these, critical control points in the trial process and options for disposal of GM wastes from trials. In particular this could act as a reference point for newer MS and form the basis of their case-by-case risk assessments. It is envisaged that this could be undertaken as a cross-MS working Group and could build on the work that has already been done by a number of the MS. The aim would be to achieve greater parity across the MS and possibly reduce the bottlenecks that are associated with assessment of notifications. In particular the beneficiaries of this would be the CAs and inspectors in MS with little experience of field trials, also new notifiers that are not part of corporate organisations, in particular universities, research institutes and SMEs.

24. The development and commercialisation of GM crops and traits appears to be five or more years behind what was predicted by Lheureux *et al*. in 2003. Lheureux’s predictions have been most accurate in the short-term with the marketing of crops such as herbicide tolerant and insect resistant maize and cotton (both single and stacked events), herbicide tolerant oilseed rape, soya and sugar beet. Other developments predicted by Lheureux *et al*. appear to have come to a standstill, at least in terms of EU trials, for example herbicide tolerant wheat, virus-resistant sugar beet, modified fatty acid in soybeans and oilseed rape, plus many other crop/trait combinations, none of which have been present in variety registration trials between 2003 and 2007. At present the ‘long-term’ list proposed by Lheureux *et al*. appears to be more accurate (e.g. plants resistant to abiotic stress, plants with enhanced yield, functional ingredients and molecular farming), although the fact that certain crops/traits appear in novel Part B trials does not guarantee they will eventually be commercialised.

25. New and diverse techniques are being developed alongside GM technology with the same aims of introducing a range of desired plant characteristics. These novel plant modification techniques are being developed to speed up the plant breeding process, and to enhance the precision and specificity of the induction or selection of desired properties. Given the cost and current political difficulties associated with commercialising a GM crop, the development of a plant breeding technique that has all the benefits of GM technology but without any of the potential risks to human health and the environment and which, therefore, may not fall within

the scope of GM legislation must be a long-term goal for plant breeders. However, at present the major plant breeding / biotechnology companies appear to have plans to keep developing plants based on GM technology for the foreseeable future.

26. In particular, the review of GMO developments in the USA supports Lheureux *et al*.'s prediction that the EU is likely to see a continuation of notifications for GM crops with stacked events in the future. There is no reason to believe that the systems currently in place in the MS should not be sufficiently robust to deal with the types of GMOs that are anticipated, providing inspection and control and good communications between all parties involved in the field trials are maintained and reviewed regularly to ensure they remain fit for purpose.

11. REFERENCES

APHIS (2007a). Biotechnology Quality Management System. (http://www.aphis.usda.gov/publications/biotechnology/content/printable_version/fs_bqms9-2007.pdf).

APHIS (2007b). Report of LibertyLink Rice Incidents. (http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf).

APHIS (2008). Status of Permits, Notifications and Petitions. (http://www.aphis.usda.gov/biotechnology/status.shtml).

BIO (2007). Excellence through Stewardship. (http://www.excellencethroughstewardship.org/facts/).

Casale, C. (2008). Presentation at the Morgan Stanley Conference. (http://www.monsanto.com/pdf/investors/2008/02-21-08.pdf).

Kast, H (2007). Current Developments: The product pipeline for Biotech Crops. Third International Conference on Co-existence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains. Seville, Spain. 20 – 21.09.07. Unpublished communication.

Lheureux, K., Libeau-Dulos, M., Nilsagård, H., Rodriguez Cerezo, E., Menrad, K., Menrad, M., Vorgrimler D. (March 2003). Review of GMOs under Research and Development and in the pipeline in Europe. Published by the Joint Research Centre (DG JRC) Institute for Prospective Technological Studies (http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=1091).

OECD (1992). Good Development Principles (GDP): Guidance for the design of small-scale field research with genetically modified plants and micro-organisms. (http://www.oecd.org/dataoecd/8/3/2375496.pdf).

OECD (1993). Safety Considerations for Biotechnology Scale-Up of Crop Plants. (http://www.oecd.org/dataoecd/26/26/1958527.pdf).

OGTR (2000). Audit of Monsanto Australia Ltd Processes for the conduct of field trials in accordance with GMAC recommendations INFORMATION BULLETIN No. 7 October 2000 (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reportspre2002-3/$FILE/iogtrqrdec00.pdf)

Pioneer Hi-Bred International Inc. (2008). Crop Genetics Pipeline. (http://www.pioneer.com/CMRoot/Pioneer/research/pipeline/Dupont_BG_Pipeline.pdf).

Reichman, J.R., Watrud, L.S., Henry Lee, E., Burdick, C.A., Bollman, M.A., Storm, M.J., King, G.A., Mallory-Smith, C. (2006). Establishment of transgenic herbicide-resistant creeping bentgrass (*Agrostis stolonifera* L.) in nonagronomic habitats. Molecular Ecology **15** (13): 4243 - 4255.

Syngenta. Financial Report (2007).
(http://www.syngenta.com/en/media/pdf/publications/Syngenta_FR2007_english.pdf).