



INTERIM REPORT

*Evaluation of the EU legislative
Framework in the Field of Cultivation
of GMOs under Directive 2001/18/EC
and Regulation(EC) No 1829/2003*

November 2009

Evaluation of the EU legislative Framework in the Field of Cultivation of GMOs under
Directive 2001/18/EC and Regulation(EC) No 1829/2003 and marketing of their
other uses under Directive 2001/18/EC

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INTERIM REPORT

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ABBREVIATIONS

ARM	Antibiotic resistance marker genes
EC	European Commission
JRC	Joint Research Centre
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ERA	Environmental risk assessment
EU	European Union
FVO	Food & Veterinary Office
GM	Genetically modified
GMM	Genetically modified micro-organism
GMHT	Genetically modified herbicide-tolerant
GMO	Genetically modified organism
GS	General surveillance
MS	Member State
NGOs	Non Governmental Organisations
NTs	Notifiers
OGs	Other groups
PMEM	Post market environmental monitoring
RASFF	Rapid Alert System for Food and Feed

EXECUTIVE SUMMARY

I. Introduction and overview

This is an interim report on the evaluation of the EU's legislation framework governing the cultivation of GMOs and marketing for other uses under Directive 2001/18/EC (hereinafter 'the Directive') and Regulation (EC) No 1829/2003 (hereinafter 'the Regulation'). It provides a digest of a pan-EU consultation on issues and experience in the implementation of the legislation framework that engaged Member State authorities, biotechnology companies, NGOs, food chain interests and other stakeholders. The consultation exercise involved a series of in depth interviews with 9 Member State authorities, 7 notifiers, EFSA (the European Food Safety Authority), environmental NGOs, as well as farming and other industry associations. All 27 Member State authorities, EFSA, biotechnology companies, environmental NGOs, farming groups, trade associations and research institutes were asked to respond, in sufficient detail, to a series of detailed questionnaires. 22 Member State authorities, EFSA, 8 notifiers, 5 research institutes, and 4 other types of organisations¹ (i.e. industry associations or environmental NGOs) returned the detailed questionnaire in time to be taken into account in this report. Furthermore, interested organisations across the EU were given the opportunity to register themselves on a project website² to take part in an E-survey. 53 completed E-survey responses were received out of a total of 208 E-survey recipients. The report also benefits from data analysis and research conducted by the project team.

This report distinguishes between Member State authorities (who were interviewed during this consultation exercise), and the positions of national governments of those Member States. The views expressed by the officials in the authorities who were consulted are not necessarily the same as the formal positions of the national governments concerned.

The key message from this research is that, overall, most consultees were generally satisfied with the principles, provisions and requirements specified in the legislative framework but had concerns with its implementation. Views on what aspects had not been adequately implemented, and why, varied across the groups consulted.

Opinions on the implementation of the risk assessment were the most diverse. Notifiers were mostly concerned with procedural aspects, especially those which affect the efficiency of the process. Others, especially environmental NGOs and certain Member State authorities, were most concerned with the actual risk assessment itself and its appraisal by EFSA and the Competent Authorities of Member States.

However, by far the greatest and most consistent concern of MS authorities and other consultees related to the implementation of the authorisation process, especially the inability of Member States, and the reluctance of Commission, to make a decision on whether or not to authorise GMOs for cultivation. Overall there is little appetite amongst consultees for changing the current system; rather, they are looking for improvements within the existing framework.

¹ This group is referred to as "Others" in figures detailing the results of the questionnaire responses throughout the report, and includes surveys returned from some environmental NGOs (Greenpeace and Friends of the Earth), International Federation of Organic Agriculture Movements (IFOAM), the European Seed Association (ESA) and COCERAL.

² <http://gmregister.ghkint.com/>.

II. The legislation's objectives

Most Member State authorities (16 of those who responded) and other consultees were satisfied with the legislation's objectives in principle, but thought that they have not been adequately implemented in practice. The Directive and the Regulation were established for different purposes and have slightly different objectives (such as the explicit reference to effective functioning of the internal market in the objectives of the Regulation). Some environmental NGOs were concerned that decisions taken under the Regulation could see environmental protection traded against market efficiency.

Opinions differed on what constitutes the "needs of society", which in turn affected opinions on whether the objectives were being properly applied in practice. Member State authorities and environmental NGOs believed that society's needs might be better met if socio-economic concerns were included in the objectives of the GMO legislation. On the other hand, notifiers believed that safety should be the prevailing factor – once a product is deemed safe, it should be possible to place it on the market and that if society is being denied the choice of safe products, then society's needs are not being met.

III. The scope of the legislation

Work is being carried out outside this evaluation by a dedicated Working Group consisting of experts appointed by Member States to examine new plant breeding technologies and to consider whether they should be included in the current scope of the legislation. It is clear that characteristics of some new plant breeding techniques create new challenges for regulators, in particular those that use recombinant DNA in the process but have no such DNA in the product that is tested in field trials or placed on the market. Some Member State authorities and other consultees such as environmental NGOs believe all techniques which use recombinant DNA at any stage should fall under the legislation. This could create considerable challenges in terms of the detection and traceability of 'GM' products. Other Member State authorities and consultees such as notifiers want the focus to be on the product not the process, specifically those products where recombinant DNA is in the seeds that are placed on the market.

Consultees did not see the new techniques themselves posing any new issues of significance for the environment or human/animal health, but rather they had concerns with the consequences that might result from the end-traits or end-products produced using these techniques. Most Member State authorities and other consultees focused on the socio-economic impacts of including or excluding new bio-techniques in the GMO legislation. For instance, representatives of the EU biotechnology industry stated that regulation of these new plant breeding techniques as 'GM' would largely preclude their subsequent use and development in Europe.

A key point raised by some Member State authorities was that there is a need for a longer term strategy on handling new techniques in the legislation, given that more novel techniques can be expected in the future as global bioscience innovates and develops.

IV. Risk assessment in the context of the legislative framework for GMO cultivation

Risk assessment is at the core of the legislative framework and central to many of the debates about the framework's efficacy, transparency and efficiency. Most of the activity under the legislation for GMO cultivation, and therefore most of the experience with its implementation, has been limited to the risk assessment phase of the regulatory process. Some consultees - some Member State authorities, notifiers and environmental NGOs - believed there is a general lack of confidence in the risk assessment process amongst some of the actors in, and onlookers of, the system. Many felt that this needs to be addressed, although consultees saw different ways of doing so.

Specific issues were raised by consultees about the process (i.e. transparency and efficiency), and the characteristics of the risk assessment and its appraisal (i.e. the risk

assessment submitted in the dossiers by notifiers, and the appraisal of the dossier by EFSA and Competent Authorities of Member States). Some aspects affect both the process and the characteristics of the risk assessment.

i. Procedural aspects – transparency and efficiency

Most MS authorities and other consultees believed improvements could be made to the transparency, and especially the efficiency, of the risk assessment process. Half of all consultees believed the process was somewhat transparent, with almost a third believing it was not at all transparent. Of the 22 Member State authorities who responded to the questionnaire, 17 believed the risk assessment process was somewhat transparent, and 4 believed it was very transparent. Of all those consulted, almost half believed the process was not at all efficient, with roughly the other half believing it to be only somewhat efficient. The majority of Member State authorities (15) stated it was somewhat efficient, whilst an almost equal number of the remainder believed it was either not at all, or very, efficient.

Consultees highlighted several aspects of the risk assessment procedure and its supporting infrastructure which result in inefficiencies. One of these is the sequential appraisal of the environmental risk assessment (first by the Competent Authority of a nominated Member State and then by EFSA). Instead of the appraisal being conducted entirely by EFSA, the additional appraisal of the environmental risk assessment by a Member State Competent Authority provides Member States with an opportunity to be more closely engaged in the risk assessment process. However, some did note that the current process could be improved. For instance, there could be greater coordination with EFSA, especially on the requests which are sent to notifiers for additional information. Some Member State authorities interviewed who had conducted an appraisal stated that the appraisals do not necessarily have to be sequential – instead a more collaborative, parallel process could be more efficient and potentially more productive.

Although several Member State authorities noted that they would like to use the opportunity to conduct an appraisal of the environmental risk assessment, the lack of necessary resources was highlighted as the greatest obstacle to doing so. Most groups of consultees also raised concerns about the wider adequacy and availability of resources to enable the processing of dossiers by EFSA's GMO Panel, given its extensive workload.

The efficiency of the system is also being affected by the way stacked events are assessed. EFSA is receiving applications for stacked events (which constitute roughly 50% of applications for cultivation which are currently in the pipeline) whose appraisal is contingent on the prior release of an Opinion on the constituent single events. This adds complexity to the system and is exacerbating the application back log.

ii. Characteristics of the risk assessment and its appraisal

Many Member State authorities and other consultees were generally satisfied with the legislative requirements for risk assessment. In survey responses more than 50% of all those consulted were either 'somewhat' or 'very satisfied' with the legislative requirements for an environmental risk assessment. 19 Member State authorities were either 'very' or 'somewhat satisfied'. However, many had concerns with how these principles are being applied in practice, both with regard to the conduct of the risk assessment by notifiers, and its appraisal by EFSA and Member State authorities. Environmental NGOs were consistently dissatisfied, whilst notifiers were the only group who were consistent in their approval of the way the environmental risk assessments (ERAs) were being conducted and appraised. Member State authorities varied significantly in their views on this issue.

Some Member State authorities, environmental NGOs and EFSA, were concerned about the quality of the dossier submitted by notifiers. 16 Member State authorities were somewhat or very satisfied with the environmental risk assessment conducted by notifiers, but 5 were not at all satisfied. EFSA was somewhat satisfied.

Member State authorities and other consultees, with the exception of notifiers, were generally less satisfied with the way EFSA appraised the environmental risk assessment than with the appraisal of the environmental risk assessment by Competent Authorities of nominated Member States. Of the Member State authorities that completed the survey, 20 were 'somewhat' or 'very' satisfied with the appraisal of the environmental risk assessment by other Member State authorities. 14 were 'somewhat dissatisfied' or 'not at all satisfied' with the appraisal of the environmental risk assessment by EFSA. One potential reason for this discrepancy is that certain Member State authorities and environmental NGOs questioned whether EFSA has sufficient experience and expertise to adequately appraise an environmental risk assessment.

Most consultees thought that there was variation in the appraisal of environmental risk assessments by the Competent Authorities of Member States. 13 Member State authorities believed Competent Authorities of Member States are only 'somewhat consistent' in their appraisal of an ERA, whilst a further 3 believed they are 'not at all consistent'. Many Member State authorities and other consultees supported greater harmonisation, although it was unclear what would be the best and most practical means to achieve this.

How best to bring expertise to bear on the appraisal of environmental risk assessments conducted by Member State authorities and EFSA, whilst also widening participation in the process, is a continuing point of debate. Achieving greater participation would increase the knowledge base on which appraisals are made, especially regarding the wide range of ecological and agricultural systems which characterise the European Union. This is especially important given that the majority of Member State authorities (18 of the respondents) and environmental NGOs believed the consideration of regional variability in EFSA opinions, and the subsequent conditions of consent, has been inadequate. In the interviews some consultees, such as environmental NGOs and some Member State authorities also believed that scientific uncertainty needs to be better acknowledged or addressed, although improvements have been made.

There is still considerable uncertainty and disagreement about the way in which the interaction between Directive 2001/18/EC and Directive 91/414/EEC should be managed with regard to the environmental risk assessment of herbicide tolerant GM plants. Many Member State authorities were not entirely satisfied with the way that herbicide tolerance was dealt with in the risk assessment and appraisals of applications for cultivation which involved herbicide tolerant GM plants – only 2 Member State authorities were 'very satisfied', 5 were 'somewhat satisfied', 6 were 'somewhat dissatisfied' and 4 were 'not at all satisfied'..

There is some uncertainty amongst Member State authorities and environmental NGOs about the boundary between risk management and risk assessment. According to the legislative requirements for an environmental risk assessment, practical risk management strategies play a role in the determination of overall risk. None of the Member State authorities who responded were entirely satisfied with the way risk management strategies were being addressed in the formal risk assessment. Opinions varied between consultees on whether there was a need to improve this, and in what way it should be done.

iii. Aspects which affect both the process and characteristics of the risk assessment

Member State authorities and other consultees identified four additional aspects of the risk assessment that are having significant impacts on both the process and the characteristics of the risk assessment:

- the process, quantity and content of additional information requests;
- the quantity and quality of communication and cooperation within and between MS authorities, EFSA and notifiers;
- the fact that notifiers are choosing to use the Regulation for cultivation applications, rather than the Directive; and,

- EFSA guidelines.

These are seen as impacting on the efficiency of the process and its transparency, and on the quality of the dossier that is submitted. For instance, the process by which additional information requests are dealt with impacts on the efficiency of the risk assessment. EFSA has 6 months in which to complete the appraisal of an application, however the appraisal is put on hold every time additional information is requested. Most significantly, the 'clock' remains stopped even after the additional information is received, and only restarts once the information has been assessed and deemed satisfactory. Although notifiers do sometimes take a significant amount of time to submit the additional information (depending on the type of information that is requested), analysis of available data seems to indicate that the greater source of delay is the time taken to appraise the additional information once it has been provided. All applications to date have been stalled by requests for additional information. Some Member State authorities and environmental NGOs also believed that the number and subject of additional information requests reflect the quality of the dossiers that are submitted.

The appraisal of the risk assessment by EFSA and the Competent Authorities of nominated Member States are affected by some of the same factors. The level of communication and cooperation between EFSA, Member State authorities and notifiers emerged as a particular issue and a priority area where improvements could and should be made. Communication between EFSA and Member State authorities is well established but could be improved, both in terms of communication with all Member State authorities, as well as specifically with the Member State authority that assesses the ERA. Half of Member State authorities who responded stated that the 3 month window for consultation specified in the legislation is insufficient. Most Member State authorities who responded stated that EFSA's response to comments from Member State authorities could be improved (only 3 Member State authorities were very satisfied with the way comments are dealt with by EFSA). The vast majority of Member State authorities (18 of those who responded), stated that more opportunities for bilateral engagement with EFSA, such as bilateral meetings under Article 30 of the General Food Law (Regulation 178/2002) would be beneficial. Notifiers also thought that increased communication with EFSA and more direct communication with the Competent Authorities conducting the appraisals of the environmental risk assessment would be beneficial.

12 Member State authorities and most other consultees, including EFSA and especially notifiers, stated that the procedure under the Regulation is an improvement on that of the Directive. 10 Member State authorities believed that use of this approval 'channel' has an impact on the environmental risk assessment by, for instance, changing who is involved in its appraisal, and how. Many of the Member State authorities that were interviewed thought their scope to engage with the assessment's appraisal was greater under the Directive. EFSA has a more active role under the Regulation and so its capacity and expertise has a greater impact on the conduct of the ERA appraisal.

Several Member State authorities and some notifiers called for better guidance on the preparation of a risk assessment and its appraisal in order to address some of these issues. However, the benefits of clarifying guidance need to be balanced with the potential consequences of 'changing the rules' and pressure for retroactive application of new standards.

V. Implementation of the Part B of Directive 2001/18/EC governing field trials of GMOs

Since 2006 the number of notifications for field trials in Europe has declined. Field trials are also increasingly concentrated in a few Member States. Some notifiers believed these trends are due to increasing difficulties in both obtaining approvals and in completing field trials. Field trial destruction was raised as a consistent and increasing concern by the industry. Other consultees, such as environmental NGOs and some Member State

authorities, called for more independent research on the impacts of GMOs, especially on the environment, and for notifiers to make their research material more widely available to independent institutes. 17 Member State authorities agreed that there is a need to harmonise the design, conduct and analysis of field trials, especially those held for regulatory purposes.

There are important links between field trials and cultivation which have potential consequences for the future of cultivation of GMOs in the EU. The quantity and quality of field trials being conducted can impact on the quantity and quality of applications for cultivation, in that applications for cultivation depend on the evidence which is collected from field trials. A lack of authorisations for cultivation can also reduce the incentive to invest in research, and thus the demand for further field trials. The overwhelming majority of notifiers agreed that declining field trial numbers in some countries were affecting applications for cultivation. Member State authorities were divided on the issue; whilst 6 agreed with the notifiers, 10 others did not agree that the situation with field trials was affecting applications for cultivation. In contrast to other consultees, there was a degree of scepticism among Member States that field trials were providing sufficient evidence to support applications for cultivation – 11 of the Member State authorities who responded noted that field trials only sometimes provide sufficient evidence to support applications for cultivation, whilst a further 6 believed the evidence from field trials either rarely or never provided adequate evidence. There was more agreement among consultees that the uncertainty of the political context and a lack of market authorisations have had a negative impact on the biotechnology industry and, in some Member States, also on the number of actual field trials being conducted.

VI. Risk management in the context of the legislative framework

Risk management here encompasses both (a) the ‘institutional’ decision-making processes of Member States and the European Commission relating to the authorisation of GMOs for cultivation; and (b) the ‘practical’ management measures applied to GMOs authorised for deliberate release (for example, monitoring and mitigation measures).

i. ‘Institutional’ decision-making process

The ‘institutional’ decision-making processes of Member State authorities and the European Commission relating to the authorisation of GMOs for cultivation are not functioning as envisaged. The inability, to date, of Member State authorities to reach a qualified majority and the reluctance of the Commission to make a decision in the absence of a qualified majority have combined to create a stalemate.

Stakeholder views, Member State voting patterns, and the polarised nature of the current debate on GMO cultivation indicate that it is unlikely that the Member State authorities will reach a qualified majority under present conditions. Most consultees agreed that indecision, particularly on the part of the Commission, is a significant concern.

The different groups of consultees expected very different outcomes if the Commission was to adopt a final decision. Notifiers expected the Commission to vote in favour, given that EFSA repeatedly issues favourable Opinions. However, environmental NGOs thought that the Commission would not approve the authorisation of these GMOs for cultivation on the basis of the precautionary principle and in the context of a significant number of Member State authorities still having unresolved concerns about GMOs being released into the environment on a commercial scale.

There was general agreement among consultees that the current indecision and unpredictability which characterises the authorisation process for GMOs is unsustainable. A number of Member State authorities have made suggestions for reform. These range from proposals that Member State authorities should provide explanations for all their votes and objections in meetings of the Regulatory Committee and the Council of Ministers, to

change of procedure that would take regional variability into account more explicitly in the ERA process.

Other, more far-reaching, suggestions were to allow Member States to determine for themselves whether to cultivate GMOs or not, and to include socio-economic criteria in the decision making process. These two suggestions, although discrete, can also be combined. Of the 22 Member State authorities who responded, 16 were positive about the 'opt-out' proposal. In contrast, five of the seven main notifiers said that the 'opt-out' proposal was not at all appropriate. Notifiers and environmental NGOs were concerned that an 'opt-out' clause could unnecessarily open up the legislation and could create a significant amount of unpredictability, both in terms of its use and its possible effects. The majority of Member State authorities (16 out of 22 either strongly agreed or agreed), along with environmental NGOs, agreed that socio-economic concerns should be taken into account when making decisions on the authorisation of GMOs for cultivation. Five notifiers disagreed or strongly disagreed, citing concerns about the practical difficulties with an *ex ante* assessment of individual GM products. The NGOs and some of the 'other' consultees also agreed that socio-economic concerns must be considered in the GMO authorisation process, as it would highlight both positive and negative social and economic impacts. All consultees agreed that there are a number of legal, logistical and practical challenges of including socio-economic concerns in the authorisation process.

Due to the slight differences in provisions, the choice of Regulation versus Directive could have an impact on the authorisation outcomes and on use of safeguard measures, though the scarcity of votes and decisions makes this a theoretical concern at present.

Most Member State authorities (13 of those who responded) said that the national safeguard and emergency measures were not operating efficiently.

ii. Practical management and mitigation measures

More than half of all those consulted agreed that the 'practical' risk management (for example, monitoring and mitigation measures) requirements and provisions under the current GMO legislation are an improvement over the old legislation. However, two Member State authorities had concerns regarding its predictability and adequacy. Twelve of the Member State authorities who responded said that current post market environmental monitoring (PMEM) plans were not in line with the objectives of the legislation in term of protecting the environment and human health objectives.

The definition and assembly of data on baselines is a challenge for notifiers and Member State authorities. Both groups stated that good quality and reliable data for defining baselines are scarce. Most Member State authorities and notifiers found it difficult to give accurate answers regarding the definition of baselines due to the limited experience with GM cultivation. Member State authorities are looking for clearer demarcation of the borderline between case specific monitoring and general surveillance. The type of monitoring methods that should be used on farms where GMOs are cultivated and the adequacy of networks that could be co-opted for general surveillance are both debated. Both Member State authorities and notifiers acknowledged that surveillance has been curtailed in some instances by the lack of, or refusal of, publicly funded networks to contribute to the general surveillance programmes. Member State authorities recognised the need for a review of present programmes of general surveillance in EU Member States including both agricultural and environmental institutions and agencies.

Most Member State authorities (17 of those who responded) and notifiers (4 of those who responded) believed that the existing Commission guidelines, though still inadequate, have led to more consistency among Member States in the design, scope and application of PMEM plans. Several Member State authorities and notifiers called for more specific guidelines on general surveillance from EFSA under the revised guidelines with regards to the environmental risk assessment.

Member State authorities stated that monitoring reports are too general and there is a need to improve the quality of reporting and to harmonize monitoring practices across the EU. All Member States have arrangements in place for inspection and control of GM field trials. A number of them stated that more work is needed to deal with the risk of adventitious presence of GMOs. Some Member States have national systems designed to ensure that variability in ecosystems/environments and/or geographic areas is recognised in risk management measures.

VII. Risk communication with the public

The risk communication provisions of the legislation continue to have support but many consultees believe their implementation in practice could be improved. There is variation in risk communication practice at the national level, especially in the context of field trials. This variation extends to the type and amount of information provided to the public, the channels of communication and the consultation timeframe on field trials. The overwhelming majority of all those who were consulted (88% of those who responded), including all Member State authorities, believed the variations in the provision of information to the public are either somewhat significant or very significant. Experience of risk communication on cultivation is limited given the absence of market authorisations.

Member State authorities and notifiers both communicate details of field trials to the public, although the methods and level of engagement vary. Some Member State authorities release more information on field trial applications and locations than others. At an EU level, the role of actors and their levels of activity are different; Member State authorities for instance, have a limited role in public consultation at the EU level with most adopting a reactive rather than proactive approach to the provision of information. Furthermore, at the EU level EFSA has a key role in 'official' risk communication.

Satisfaction with the way risk communication is implemented at the EU level varies. Many consultees commented that while the availability of information is generally good, its accessibility could be improved. The highly technical nature of information and opinions provided by risk assessors (including the Competent Authorities of Member State and EFSA) means that it is incomprehensible to those who lack technical expertise.

The response to, and participation in, public consultations varies across Member States and between different groups. Some Member State authorities believed that few people engage with the consultations and most of the comments received are statements of opposition to GM technology or the biotechnology industry rather than a specific response to the consultation in question. It is difficult to establish whether the comments that have been made have an impact on the risk assessment's appraisal or risk management decisions. 14 of the Member State authorities who responded to the questionnaire stated that the results of the public consultation only 'somewhat' feed into risk assessment opinions and authorisation decisions on GMO releases. A further 3 Member States stated the results do not have any impact. Member State authorities did note that the nature of the public feedback determines the extent to which the comments are taken into account. Comments of a scientific nature are given the most consideration, although views on socio-economic or ethical concerns are somewhat taken into account by at least a third of Member State authorities who responded. Of the e-survey respondents, 40% believed that comments did not have any impact, whilst 26% believed results of the public consultation had a great deal of impact.

VIII. Other issues

i. Confidentiality

The consultees who did have an opinion on the matter were split roughly 50:50 on whether the Regulation is clearer and more rigorous in its approach to confidentiality than the Directive. Some Member State authorities pointed out that the GMO legislation does not

directly impact on disclosure because there are national rules on freedom of information and access to environmental information.

Part B confidentiality provisions vary by country and, with the exception of disclosure of field trial locations, are broadly accepted by the industry, though NGOs would like to see more transparency. Member State authorities pointed out that there are few confidentiality issues in Part C applications.

Proposals for change made by those consulted illustrate the difficulty of balancing transparency and commercial confidentiality. Most requests for confidential information have come from NGOs.

ii. Zero-tolerance policy

The seed industry, notifiers and 12 Member State authorities agreed that the zero tolerance policy on unauthorised GMOs in seeds has a negative effect on trade and the EU seed sector, and will become more difficult to sustain over time. Member State authorities and notifiers both stated that the absence of a proportionate, evidence-based tolerance threshold for the presence of unauthorised GMOs in conventional and GM seed lots continues to hold back the development of cohesive co-existence arrangements with the food, feed and organic sectors and is having an adverse effect on EU plant breeding and seed production companies.

Consultees in favour of the ZTP noted that if the tolerance for unauthorised GMOs in seed were to be increased from zero then there will be implications for coexistence, especially for consumer confidence in organic food and crops. One MS authority pointed out that the zero tolerance policy is beneficial for its agricultural economy since buyers in its export markets have demanded that the crops are certified that they have been cultivated in GM-free regions. ZTP for unauthorised GMOs in seeds also avoids the risk of any adverse environmental impact under the precautionary principle.

iii. Other national legislation impacting on the cultivation of GMOs

Half of the Member State authorities surveyed said that they have national or sub-national legislation in place that must be observed when a GMO is placed on the market. Some Member State authorities mentioned the existence of good environmental practices and codes that support the main objectives of their national GM legislation. Besides GM risk management and coexistence rules, Member States also have environmental legislation in place at national and regional level, specifically for the protection of nature reserves and unique geographical areas. These laws take into account potential environmental and ecological effects of GMOs by imposing special cultivation conditions in order to ensure compliance with EC legislation on the conservation of natural habitats, of wild fauna and flora, of wild birds and also with the rules included in national legislation on designation of protected areas and on environmentally sensitive areas.

1 INTRODUCTION

This is the interim report of the Evaluation of the EU legislative Framework in the Field of Cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) No 1829/2003 and marketing of their other uses under Directive 2001/18/EC, a project commissioned by DG Environment of the European Commission from the EPEC consortium. The consulting team is led by GHK Consulting Ltd which is working with co-consultants Technopolis and a number of individual experts in biotechnology, risk and communication from across the EU.

The core purpose of this report is to present the results of a comprehensive consultation undertaken for the project during the summer of 2009. A detailed description of the stakeholder consultation methodology is provided in Annex A of this report. The EPEC team would like to thank the many individuals and organisations who contributed generously to the consultation in time, effort and information.

The consultation exercise involved:

- In-depth interviews with 9 Member State authorities, 7 notifiers, EFSA (the European Food Safety Authority), environmental NGOs³, as well as farming and other industry associations⁴;
- Detailed questionnaires sent to authorities in all 27 EU Member State, EFSA, biotechnology companies, environmental NGOs, farming groups, trade associations⁵, and research institutes;
- An online 'E-survey' which was open to all interested organisations in Europe⁶.

This report distinguishes between Member State authorities (who were interviewed during this consultation exercise⁷), and the positions of national governments of those Member States. The views expressed by the authorities and officials who were consulted are not necessarily the same as the formal positions of the national governments concerned.

The questionnaires invited scaled responses to a number of questions (e.g. 'very satisfied' through to 'not at all satisfied'). The figures and charts throughout the report are based on the scaled responses of all consultees for the key questions. Many consultees qualified their responses to these questions by providing additional explanatory text. That information has been used as evidence here, supplementing face-to-face interviews. The text also draws upon research and analysis conducted by the project team based on previous studies, industry data and information provided by consultees over the last few months.

This report is organised according to the major elements of the research 'problem' as defined in the inception report and represented in Figure 1.1. These elements relate to specific parts of the current EU legislative framework for GMOs. They are:

- The **objectives** of the legislation (Chapter 2);

³ The environmental NGOs interviewed were Greenpeace, Friends of the Earth, the European Centre for Nature Conservation (ECNC) and the European Environmental Bureau (EEB).

⁴ The industry associations interviewed were EuropaBio, COPA-COGECA, COCERAL, and European Seed Association (ESA).

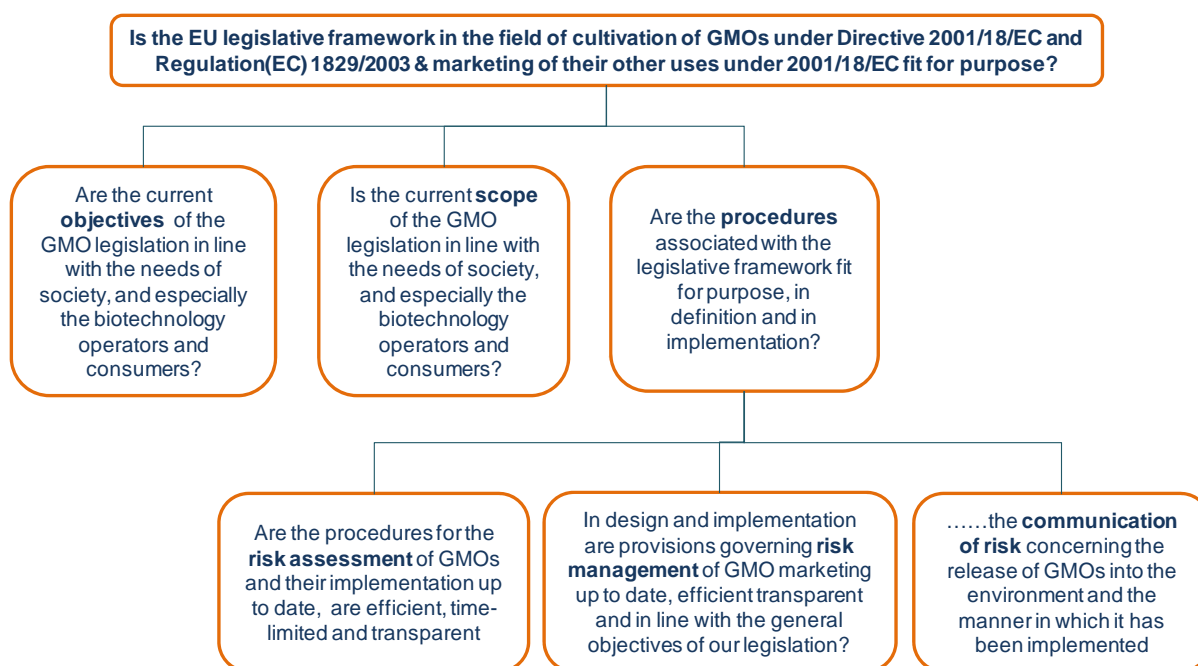
⁵ Surveys were returned from some environmental NGOs (Greenpeace and Friends of the Earth), International Federation of Organic Agriculture Movements (IFOAM) European Seed Association (ESA) and COCERAL, this group is represented in figures of survey responses as "Others".

⁶ See Annex A for a breakdown of respondents' affiliations and countries of origin.

⁷ Member State authorities include the National Competent Authority, other relevant national ministries, scientific advisory committees and national inspectorates.

- The **scope** of the legislation (Chapter 3);
- **Risk assessment** as defined and practised in the legislative framework (Chapter 4);
- The **implementation of Part B of the Directive** governing field trials (Chapter 5);
- **Risk management**, covering both the authorisation ‘decision’ and the measures deployed to monitor and mitigate the risks of an authorised deliberate release (Chapter 6); European Centre for Nature Conservation;
- **Risk communication** covering both the communication activities of risk assessors and risk managers to and from the public (Chapter 7); and
- **Other discrete issues** which covers confidentiality, the zero tolerance policy on the presence of unauthorised GMO seeds, and other relevant national legislation which impacts on the cultivation of GMOs (Chapter 8).

Figure 1.1 High level structure of the evaluation



Source: GHK Consulting Ltd.

Within each of these areas a number of research questions were defined by the project terms of reference and in the preparatory analysis as presented by EPEC in the inception report (see Annex B for the project terms of reference). These questions formed the basis of the consultation, which included some very detailed questionnaires that ‘drilled down’ deep into the relevant aspects of what is a complex system.

This report provides a digest of the responses of consultees to those questions. The responses provide insights into the current situation in each part of the system and, collectively, to a picture of the functioning of the legislative framework as whole. This report thus provides interim answers to the core evaluation questions identified in the project terms of reference.

But this is not the ‘final word’ on the consultation: there is further work to be done on survey results and interviews to extract all the information that they have to offer. A small number of survey responses from Member State authorities have not yet been returned and there is

some further information to be provided by other consultees. There are some additional actors, such as DGs of the European Commission that are yet to be consulted. This additional material will be available for the draft final report, which is the project's next formal deliverable.

This report does not provide definitive conclusions or suggestions on the way ahead in any specific area. However, wherever available, proposals for improvement suggested by the consultees are summarised at the end of each chapter.

For the avoidance of doubt, the scope of this project is restricted to cultivation of GMOs (under Directive 2001/18/EC and the Regulation (EC) No 1829/2003) and their marketing for other uses under the Directive 2001/18/EC (hereinafter referred to as 'the Directive' and 'the Regulation'). The EU's legislative framework for use of GMOs in food and feed is out of scope, and is the subject of a separate study that has been commissioned by DG SANCO.

2 OBJECTIVES OF THE LEGISLATION

This chapter⁸ examines whether implementation has been consistent with the stated objectives of the Directive and the Regulation, and whether those objectives are consistent with the needs of society. The objectives are, broadly, to protect human and animal health, the environment and consumer interest, while ensuring the effective functioning of the internal market.

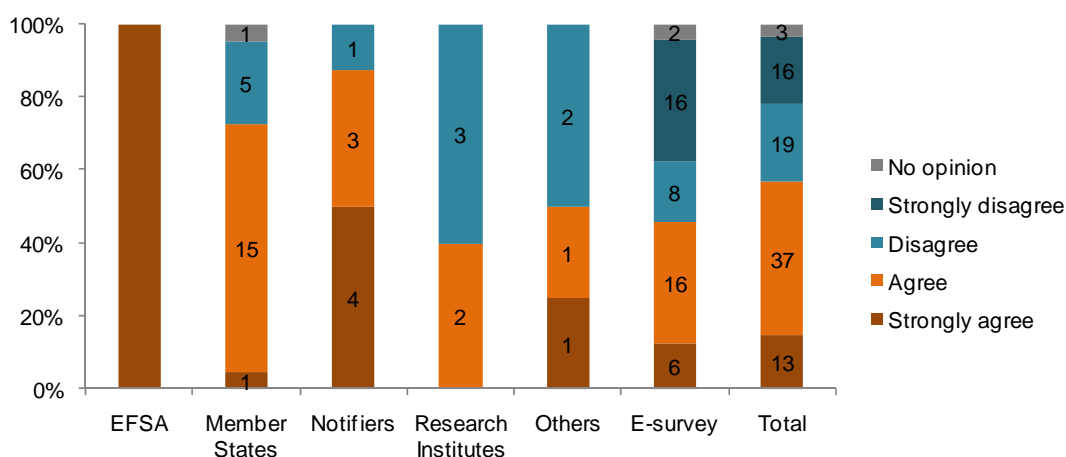
2.1 Most consultees were satisfied with the legislation’s objectives in principle, but thought that they have not been adequately implemented in practice

The majority of those interviewed were satisfied with the stated objectives of the legislative framework (see Figure 2.1). However most consultees stated that the implementation of the legislation (or rather, the lack thereof) meant these objectives were not being adequately met in practice. The survey found that most consultees agreed that the current objectives with regard to cultivation of GMOs are generally in line with the needs of society. Several consultees expressed a view that the ability of the legislation to meet the needs of society could be improved if socio-economic considerations were to be included in the objectives (see section 2.3 below).

All consultees interviewed seemed to agree that ensuring the safety of GMOs should be the over-riding priority of the legislative framework. However, some environmental NGOs and certain MS authorities believed that safety considerations were not being adequately addressed in the current framework, and saw shortcomings in the risk assessment process (see section 4). A few MS authorities were also concerned that the protection of the environment was being compromised in the interest of ensuring the efficient operation of the internal market.

Figure 2.1⁹ Most consultees agreed that the objectives of the legislation, as it relates to cultivation, are in line with the needs of society

“To what extent do you agree that the current objectives of the EU legislation as it relates to cultivation of GMOs are in line with the needs of society?”



⁸ This chapter on the objectives of the legislation addresses Question 1 of the project terms of reference

⁹ “Others” refers to surveys returned from some environmental NGOs (Greenpeace and Friends of the Earth), International Federation of Organic Agriculture Movements (IFOAM) European Seed Association (ESA) and COCERAL

Notifiers consistently noted that whilst the legislative framework is meant to firstly ensure that the products are safe, it is also meant to serve as a mechanism by which these products can be delivered to the market. As such, they see a failure to enable the latter (see section 6.2) which means that the needs of society are currently not being met: farmers are not being given the option to cultivate GMOs, and consumers are not being given the option of buying GMOs that are grown in the EU. Other consultees however, including one MS authority, stated in the interviews that providing the option of GMOs would restrict the ability of farmers and consumers to use or buy other types of products. Thus they felt that in some cases it is not possible to have the option of choosing between both GMOs and non-GMOs plants simultaneously, in that the latter is only possible without the former.

2.2 The Directive and the Regulation were established for different purposes and have slightly different objectives, which a few those consulted believe creates potential conflicts

The Directive was introduced specifically to ensure the safety of the deliberate release of GMOs into the environment. The Regulation was established to ensure the safety of GMO food or feed products being placed on the market.

The differences in objectives between the Directive and Regulation reflect their different origins. Whilst both refer to the protection of animal and human health and the environment with regards to the placing of a GMO on the market as or in products, the Regulation also considers the effective functioning of the internal market, the protection of consumer interest, and putting in place harmonised Community procedures for the authorisation and supervision of genetically modified food and feed. Although the effective functioning of the internal market is not explicitly mentioned in the legislative text, the Directive was adopted under Article 95 of the Treaty, which does explicitly refer to the internal market.

Some environmental NGOs believed it was inappropriate for the Regulation to be used as a mechanism for dealing with applications for the deliberate release of GMOs, given that its provisions are determined by a different purpose. For instance, since the effective functioning of the internal market is an objective of the Regulation but not the Directive, there was a concern that this could be considered equal to ensuring the protection of the environment (see above). The fact that the Directive explicitly mentions the precautionary principle in the legislative text, whereas the Regulation does not, was highlighted. Nonetheless, one MS authority noted that the Regulation is coupled with the General Food Law (Regulation 178/2002), which does mention the precautionary principle. Overall, other consultees did not believe that there was an obvious conflict created by the slight differences in objectives between the two legal instruments. However, there are other differences in the provisions between the Directive and the Regulation that could potentially affect both the outcome of the risk assessment¹⁰ and the political decisions themselves (see sections 4.7 and 6.2.6 respectively).

2.3 Many consultees would like to see socio-economic concerns included in the objectives of the GMO legislation, although notifiers are concerned about the potential consequences

As mentioned in section 2.1 some consultees, particularly MS authorities, questioned whether society's needs would be better met if the regulatory regime on GMOs also took

¹⁰ Although the requirements of the environmental risk assessment stipulated in the Directive apply equally regardless of whether an application for cultivation is submitted under the Regulation or the Directive, there are other aspects which consultees noted could affect the ERA (see section 4.5 for more details).

explicit account of factors other than safety, i.e. 'socio-economic concerns'. Notifiers, on the other hand, did not see many benefits from doing so. The interest in taking into account socio-economic concerns stems from a number of underlying issues with cultivation of GMOs and the GMO legislation, as pointed out by the consultees:

- Many of the influencing factors that MS authorities face when deciding on the authorisation of GMOs are of a political nature rather than based exclusively on scientific risk. Public concerns go beyond strict definitions of safety;
- No authorisations for GM crops for cultivation have been granted under the new legislation. The Regulatory Committee of Directive 2001/18/EC and the Council of Ministers have yet to reach a qualified majority for the approval of a new GMO for cultivation under the new legislation. Political and popular views on GM crops remain polarised across Europe;
- There is an increasing need to consider sustainability principles and current societal challenges such as climate change and sustainable development;
- The benefits of cultivating GMOs should be assessed alongside the risks; and,
- Consideration of socio-economic factors will allow MS authorities to better consider the special circumstances of the area where cultivation might take place, such as specific environmental, agronomic, ecological and social and economic factors.

Some MS authorities saw many benefits from explicitly including socio-economic concerns within the objectives of the GMO legislation. For instance, it could allow MS authorities to address some of the political issues associated with authorisation of GM crops for cultivation and potentially break the stalemate in voting patterns by providing more comprehensive and transparent information on the risks and benefits of GMOs. On the other hand, MS authorities and other key consultees have also acknowledged that explicitly including socio-economic concerns in decisions on whether to authorize a GMO for cultivation can have some negative consequences and present significant challenges that need to be dealt with in advance.

In recognition of these issues, the Council of European Ministers of Environment concluded in December 2008 that the Commission would submit a specific report on the implementation of the Directive 2001/18/EC, including an assessment, *inter alia*, of the socio-economic implications of deliberate releases and placing on the market of GMOs. Accordingly, most MS authorities have tentatively started looking into implications of socio-economic implications of deliberate releases and placing on the market of GMOs.

The opinions of consultees, and the implications of taking socio-economic concerns into account when making a decision on whether to authorise GMOs for cultivation, are discussed in more detail in section 6.2.4.

3 SCOPE OF THE GMO LEGISLATION

3.1 This chapter¹¹ considers issues relating to the scope of legislation

There are new plant breeding techniques, (hereinafter 'new techniques'), that might already be in use or in the pipeline for commercial use, in the EU or elsewhere. In its report "New Techniques in Plant Biotechnology", the Netherlands' Commission on Genetic Modification (COGEM) has argued that it is unclear whether the prevailing GMO legislation covers:

- reverse breeding;
- agroinoculation;
- gene silencing (by DNA methylation or RNA degradation)
- grafting on GM rootstock;
- site-directed mutation using oligonucleotides;

There are a number of issues to be considered:

- that the inclusion of these techniques in the legislation might blur the boundary between GM and non-GM products, because in some cases there is no recombinant DNA in the final product that would be placed on the market, or;
- the risk that use of these techniques might pose to human health and the environment, and how that risk should be managed; and,
- the inclusion in or exclusion from the legislation of these new techniques might have socio-economic implications.

The issue of whether these techniques should be included in the present scope of European legislation is currently being considered by a Working Group set up by DG Environment and consisting of experts appointed by Member States. It is due to report in 2010.

This section of the interim report relays the content of discussions about the issue of the scope of the legislation held by the EPEC team in the context of this current project.

3.2 The approach to the regulation of new techniques that are emerging from bioscience will have implications for developments in MSs and the industry

3.2.1 *The characteristics of some new techniques create new challenges for regulators*

The increasing sophistication of genetic science and engineering means that determination of what is genetically modified, at least in terms of the characteristics of the products that may become available to be put on the market, is becoming increasingly blurred.

At the moment, the legislative framework defines a, '*genetically modified organism (GMO) as an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*' (Article 2(2), Directive 2001/18/EC). Given that this definition is quite broad, it is not always clear whether "new" techniques of genetic modification fall within the current scope of the legislation or not.

There is a particular challenge arising from the fact that in the case of some techniques, such as reverse breeding, recombinant DNA is in the production process¹² but the products

¹¹ This chapter on the scope of the legislation addresses the second part of Question 1 of the project terms of reference

that ultimately result (i.e. those which would be placed on the market) do not contain any novel characteristics, added sequences, mutations or other changes (see Table 3.1). Other products, such as those generated by the application of mutagenesis coupled with oligonucleotides, may feature mutations in the genome in a similar way to the genome of products developed by conventional techniques, i.e. techniques listed in Annex IB that are excluded from regulatory oversight under the Directive.

Table 3.1 A number of new techniques may employ recombinant DNA during processing to produce organisms that do not contain recombinant DNA

New technique	Definition
Zinc finger nuclease technology	Utilising proteins that bind to specific DNA sequence in a plant and creates a DNA breakpoint at the binding site ¹³ .
Oligonucleotide directed gene mutation	Oligonucleotides bind to the target homologous DNA. Following the binding of the oligonucleotides to the DNA, DNA breakage can take place when the target DNA is subjected to radiation ¹⁴ .
Cisgenesis	A plant is modified with coding DNA sequences from the species itself or by using DNA from crossable species ¹⁵
RNA dependent DNA methylation via RNAi/siRNA	Requiring an insertion of double-stranded RNA whose sequence is similar to the DNA sequence of promoters naturally occurring in plants. Targeted promoters are methylated, genes under the control of these promoters are "switched off", resulting in gene silencing ¹² .
Grafting	Concerning molecules such as RNAi being produced by transgenes in the rootstock and transported to the graft where they cause the desired effect ¹² .
Reverse breeding	Creating heterozygous hybrids from homozygous parents. Recombination during meiosis is suppressed in the desired heterozygous hybrid lines by a foreign gene, which is subsequently selected against prior to crossing ¹² .
Agro-infiltration	Using <i>Agrobacterium tumefaciens</i> to integrate genetic material into certain tissues, such as the leaf, where the expression of a transgene occurs in the infected tissue. The transgene does not integrate in the genome and regeneration of transgenic plants is not the objective ¹² .
Synthetic biology	DNA sequences can be designed using computers and chemically synthesised in the laboratory: from a single gene to an entire genome. Natural genetic components may also be used to design novel genetic sequences, biological pathways, parts and devices ¹⁶ .

¹² In a report by the Netherlands' Commission on Genetic Modification (COGEM) on "New Techniques in Plant Biotechnology", it was unclear whether these new techniques listed were covered by the prevailing GMO legislation. <http://www.cogem.net/ContentFiles/CGM061024-02%20New%20techniques%20in%20plantbiotechnology.pdf>

¹³ <http://www.sigmaaldrich.com/life-science/functional-genomics-and-rnai/zinc-finger-nuclease-technology.html>

¹⁴ COGEM report on new techniques in plant biotechnology

¹⁵ <http://www.cogem.net/ContentFiles/CGM060706-03%20Ethical%20and%20societal%20aspects%20of%20cisgenesis%20En%E2%80%A61.pdf>

¹⁶ <http://www.parliament.uk/documents/upload/postpn298.pdf>

New technique	Definition
Double haploid	Doubled haploids are genetically pure plants developed through a special cross-breeding and chemical process ¹⁷ .
Gene shuffling	Generating large number of chimeras ¹⁸

3.2.2 **New techniques are being developed and applied elsewhere in the world**

New techniques are being developed worldwide. Companies such as Dupont and Cibus have been active in developing and fine-tuning these methods outside Europe (see Table 3.2). Some MS authorities and notifiers see the decision on whether to regulate these new techniques as 'GM' as an important contributing factor in determining their future development and use within Europe.

Table 3.2 North and South America are seeing increasing use of these novel techniques in development of new agricultural crops

New technique	Organisation	Crop/organism	Country	Progress	Year (of press release)
Double haploid*	Dupont	Corn	Argentina	In the pipeline	2009 ¹⁹
Gene shuffling*	Dupont	Corn, soybean	USA, Canada	Approved	2009 ²⁰
Reverse breeding	Dupont	Soybean	Brazil	In the pipeline	2007 ²¹
Directed mutagenesis using oligonucleotides	Cibus	Sorghum	USA	In the pipeline	2006 ²²
Zinc finger nuclease	University of Minnesota	Tobacco	USA	In the pipeline	2009 ²³
Zinc finger nuclease	Dow AgroSciences	Canola	USA	In the pipeline	2008 ²⁴

¹⁷ <http://www.pioneer.com/CMRoot/Pioneer/research/pipeline/brochures/DbIHapBrch17.pdf>

¹⁸ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC102241/>

¹⁹ <http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9MjE3MTkyNHx0aGlsZEIEMzNjI0NnxUeXBIPtI=&t=1>

²⁰ <http://www.pioneer.com/web/site/portal/menuitem.917ffb4c5c0ae4574a624a62d10093a0/>

²¹

http://vocuspr.vocus.com/VocusPR30/Newsroom/Query.aspx?SiteName=DupontNew&Entity=PRAsset&SF_PRAsset_PRAssetID_EQ=106524&XSL=PressRelease&Cache=False

²² <http://www.cibus.com/press/press111606.php> Cibus considers the technique to be non-transgenic

²³ http://www1.umn.edu/news/news-releases/2009/UR_CONTENT_107428.html

²⁴ <http://www.dowagro.com/newsroom/corporatenews/2008/20080212b.htm>

New technique	Organisation	Crop/organism	Country	Progress	Year (of press release)
Cisgenesis	Wageningen University	Potato	The Netherlands	In the pipeline	2008 ²⁵
Grafting	INRA	Grape	France	In the pipeline	2004 ²⁶
Synthetic biology	Dupont	E.coli	USA	In the pipeline	2007 ²⁷

* Not being considered by the Working Group on New Techniques

3.3 Consultees highlighted the socio-economic impacts of including or excluding new techniques in the GMO legislation

3.3.1 *The industry states that regulation of these new techniques as ‘GM’ would largely preclude their subsequent use and development in Europe*

The output of the Working Group on new techniques is awaited with anticipation within the industry. Notifiers stated that the regulation of some of these new techniques as ‘GM’:

- would effectively result in the curtailment of their use and development in the EU;
- might create a serious barrier to the commercialisation of products developed using these techniques; and
- would result in resources being diverted to those technologies which are not included in the legislation.

Some notifiers believe RNA methods are likely to be included in the legislation. However, given the current uncertainty, they are hesitant to invest R&D efforts in new techniques in Europe.

Notifiers further believed that the effective removal of these techniques from the “available toolbox” if they were to be included in the GMO legislation would put the EU at a competitive disadvantage with the rest of the world, assuming that the current stalemate in GMO authorisations continues. Consequently, some notifiers and MS authorities believed that excluding any of the above new techniques listed in the COGEM report from the legislation would have a positive impact on plant breeders and biotechnology companies in the EU.

Environmental NGOs did not highlight any specific socio-economic impacts from either including or excluding new techniques in the GMO legislation. Their concern was mainly that research effort should be directed towards techniques that they thought were more “sustainable” than genetic modification, such as marker-assisted breeding.

3.3.2 *Consultees did not see the new techniques themselves posing new issues for the environment or human/animal health*

During the interviews, there was a general agreement across all consultees that the emergence of new techniques did not raise new issues for the environment or human/animal health. Instead, some consultees, especially MS authorities, had concerns

²⁵<http://www.durph.wur.nl/NR/rdonlyres/A03C74F6-7B5E-42A0-85B0-3919AD0BB3BE/65165/DuRPhbrochureENlagersolutie.pdf>

²⁶ <http://cat.inist.fr/?aModele=afficheN&cpsid=15728008>

²⁷ <http://www3.interscience.wiley.com/cgi-bin/fulltext/121398192/HTMLSTART>

not with the actual techniques themselves, but rather with the safety issues that might result from the end-traits or end-products that will be produced using these techniques. However, one MS authority did point out that should these techniques change enzymes or proteins in a way that could be harmful, it is important that a risk assessment is performed to ensure safety to the environment and human/animal health.

3.3.3 Inclusion of some of new techniques would create fresh challenges with regard to detection and traceability

Some of the new techniques result in end products that do not necessarily contain novel characteristics or recombinant DNA (i.e. DNA that does not occur naturally). Many consultees highlighted that if these techniques were included in the scope of the legislation then problems would arise with their detection, traceability and labelling.

Any type of labelling that is not based on chemically or physically detectable traits is open to abuse. In this instance, enforcement and traceability would be solely reliant on an administrative paper trail. The determination of 'GM' status by testing products for whether they contain a genetic modification would not be available.

The success of the audit trail rests on all parties in the supply chain participating, which is not easily ensured. Nonetheless, labelling based on documentary control is applied in several existing cases, such as labelling on origins and organic production methods. Moreover, documentary control has become a necessity for food producers for general safety and liability reasons, so it is arguable that the required systems could already be in place.

3.3.4 The impact of any change of scope on EFSA's workload is determined by whether new techniques, once regulated, are actually used by the industry

In principle, the inclusion of new techniques within the scope of the legislation might have an effect on EFSA's workload, by increasing the number of events requiring authorisation. However, as EFSA noted in consultation, its workload will only be affected if these techniques are actually used and notifications are submitted for a significant amount of products developed using these techniques. If the notifiers' contention - that including these techniques within the scope of the legislation would result in use of them being discontinued - is correct, then EFSA's workload is unlikely to be increased with the regulation of these techniques.

3.4 Some consultees stated that the legislative scope should exclude techniques which only use recombinant DNA in the process and which do not result in recombinant DNA being present in the end-product

As illustrated above, certain techniques use recombinant DNA but there is no recombinant DNA in the end product which would be brought to market. Some consultees, notifiers and certain MS authorities, stated that the legislation's scope be limited to those techniques resulting in end products that contained recombinant DNA. Others, particularly environmental NGOs, felt that if recombinant DNA was used at any stage of the process, the product should be regulated as a GM, regardless of the characteristics of the end-product.

3.5 More novel techniques can be expected in the future as global bioscience innovates and develops so there is a case for a longer term strategy on handling new techniques in the legislation

One Member State authority suggested that policy-makers should be willing to exclude techniques from the scope of the legislation, rather than start from the position of inclusiveness which is fostered by the current broad definition of a GMO in the legislation. This would require the clarification of formal exclusion processes and criteria (that are not too prescriptive or inclusive). An agreement on the interpretation of Article 2 which defines a GMO is fundamental.

Given the likely increase in the development of novel breeding techniques, it is likely that the issue of which techniques should be included in the legislation will arise again. One MS authority highlighted that finding a sustainable means of doing so that is efficient, predictable and proportionate is key. Officials suggested that an approach which is less inclusive and informed by a more developed sense of what is meaningful in terms of novelty might be one way forward.

For instance, some MS authorities suggested that the focus of regulation should be shifted to the **end traits** of the products, rather than the techniques on which the products are based (i.e. to regulate on the basis of phenotype, rather than technique). Some MS authorities noted that it seems illogical that a herbicide tolerant plant produced using genetic modification is assessed more rigorously than a herbicide tolerant plant produced through mutagenesis (where genetic mutations are induced by use of chemicals or radiation), given that the environmental impact will be much the same. This trait-based approach could potentially accommodate any product produced by a novel technique, either now or in the future.

3.6 Summary: consultees suggestions on future scope

- Some consultees (notifiers and certain MS authorities) stated that the legislation's scope should be limited to those techniques resulting in end products that contained recombinant DNA.
- Others consultees (particularly environmental NGOs, but also some MS authorities) stated that the legislation's scope should include all techniques that use recombinant DNA at any stage of the process, regardless of the characteristics of the end-product.
- Some MS authorities suggested that the focus of regulation be shifted to the end traits of the products, rather than the techniques on which the products are based (i.e. to regulate on the basis of phenotype, rather than technique).

4 RISK ASSESSMENT

4.1 This chapter provides an interim report on the evaluation of the risk assessment components of the current legislation framework, including the process and its characteristics

This part of the report comments on:

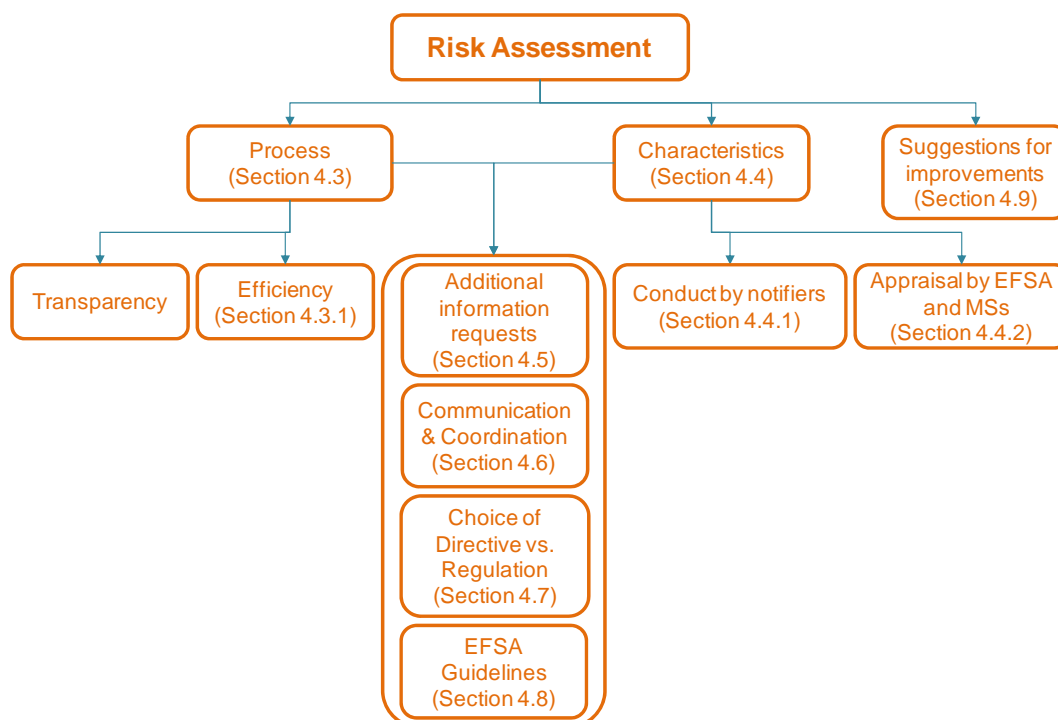
- the transparency and efficiency of the risk assessment (RA) process (section 4.3); and,
- the characteristics of the actual risk assessments conducted by notifiers, and its appraisal by EFSA and by the Competent Authorities of MSs (in the case of the environmental risk assessment) (section 4.4).

Some specific aspects (additional information requests, communication, guidelines, and the choice of using the Regulation over the Directive) impact on both the RA procedure and the characteristics of the RA. These are considered in dedicated sections (sections 4.5 – 4.8) as shown in Figure 4.1. Finally, some key suggestions from consultees for improving the current RA are presented (section 4.9).

Since 2005 risk assessment experience under the legislation has been limited to the Regulation, given that, since then, there have been no cultivation applications submitted under the Directive. Consequently, the discussion below focuses on the process and characteristics of the RA under Regulation, as opposed to that under the Directive. However, the implications of the choice that notifiers make between the Directive and the Regulation when choosing to submit an application for cultivation is discussed in section 4.7.

Figure 4.1 This chapter on risk assessment addresses three of the thirteen core questions in the project terms of references (Q. 2, 3 and 4)

Diagrammatic representation of the issues covered in this chapter

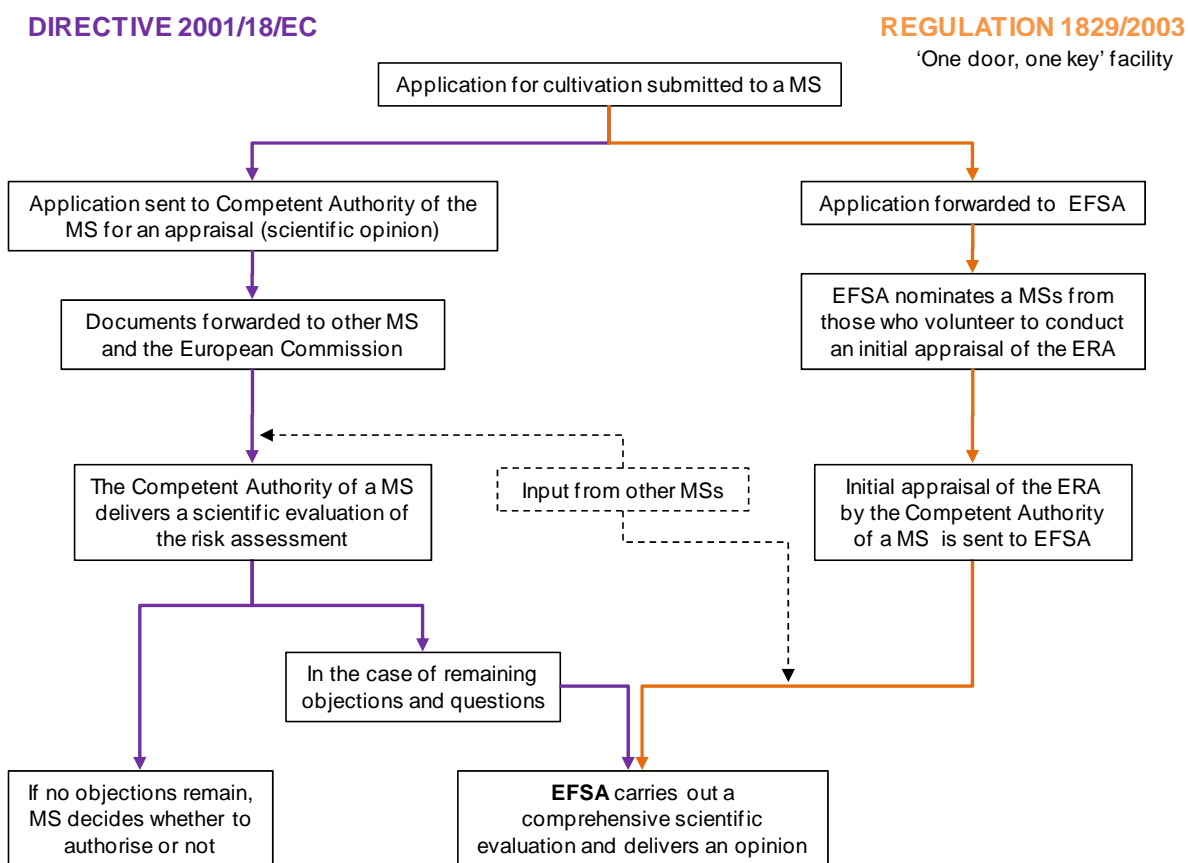


Source: GHK Consulting Ltd.

4.2 Risk assessment is at the core of the legislative framework and central to many of the debates about its efficacy, transparency and efficiency

Most of the activity under the legislation for GMO cultivation, and therefore most of the experience with its implementation, has been limited to the RA phase of the regulatory process (see Figure 4.2). 15 applications have been submitted under the Regulation's 'one door, one key' facility since 2005 (an additional two were submitted but subsequently withdrawn) (Figure 4.3). Three applications (the Amflora potato and maize Bt11 and 1507) were submitted under the Directive before the Regulation came into force. All have received favourable assessments from the rapporteur MSs. Some MS authorities did raise objections for health or environment reasons. EFSA was consulted on these objections and gave a favourable opinion in all cases. However, no final decision has yet been made on their market approval. No applications for cultivation have been submitted under the Directive 2001/18/EC since 2005.

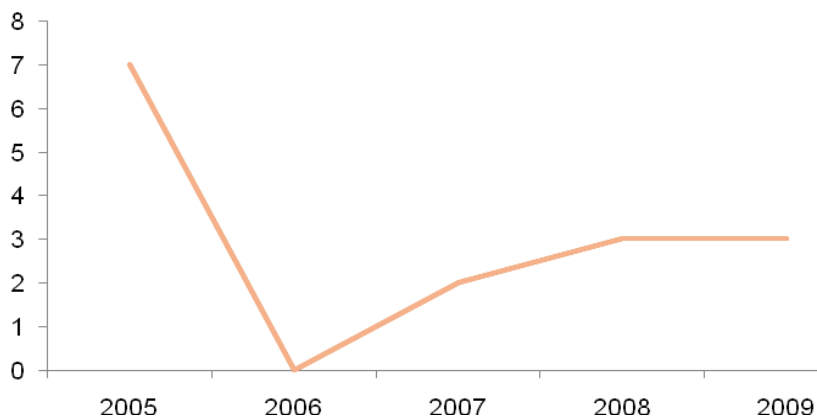
Figure 4.2 Diagrammatic representation of the risk assessment processes under Directive 2001/18/EC and Regulation EC 1829/2003



Source: GHK Consulting Ltd.

Figure 4.3 A consistent, albeit small, number of cultivation applications have been submitted under the Regulation since a steep decline in 2006

Number of applications for cultivation submitted per year since 2005



Source: EFSA GMO Register of Questions

(<http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO&questiontype=2>)

No EU authorisation for the cultivation of a GMO has been given since 1998. Many consultees - some MS authorities, notifiers and environmental NGOs - noted that a general lack of confidence in the risk assessment process may be playing a role in preventing Member State authorities from reaching a qualified majority when coming together to vote on a Commission draft decision for authorisation. Consequently, finding ways in which to build this confidence is seen as a key priority. In order to do so, a good understanding is needed of the problems that consultees have with the RA process.

The consultation and analysis undertaken for this project has shown that different groups who were consulted are concerned about different aspects of the RA process:

- Notifiers, as well as some MS authorities and some other stakeholder groups, are generally satisfied with the conduct and appraisal of the environmental risk assessment (ERA), but are much more concerned about the procedural aspects of the system – particularly its transparency and efficiency (see section 4.3);
- Other MS authorities, and the environmental NGOs, are much more concerned about the characteristics of the conduct and appraisal of the RA, i.e. the specifications in terms of the scope, framing and outputs from the risk assessments.

4.3 Most consultees believed improvements could be made to the transparency, and especially the efficiency, of the risk assessment procedures

Although it is widely recognised that some improvements have been made to both the transparency and the efficiency of the RA process, there are still areas of some concern for certain consultees.

With regard to transparency for the public, a few Member State authorities expressed concern about the accessibility of the information (i.e. the ability of lay persons to understand it, rather than its physical availability). The technical nature of the subject precludes some stakeholders from being able to fully understand and appreciate the content and process of the RA. Risk communication therefore becomes important (and is discussed further in section 7). Interviews with some consultees also revealed some misconceptions about the RA process, indicating that more detailed information on the actual proceedings could be beneficial.

The study survey found that the majority of MS authorities (17 of those who responded) and notifiers believe the RA process is ‘somewhat transparent’ (i.e. there is scope for improvement) (see Figure 4.4). For notifiers, there could be more transparency in the processing of the dossiers, for instance, the determination of when the ‘clock’ managed by EFSA should restart (see section 4.5). Most changes that could improve transparency for MS authorities related to better communication and cooperation with EFSA (see section 4.6.2).

Better communication and cooperation overall, between Member State authorities, EFSA and notifiers would also greatly benefit the efficiency of the RA process (see section 4.6). Views on the efficiency of the RA process are more diverse than those on transparency, especially between MS authorities and notifiers, although the majority of both (15 of the Member State authorities and 5 of the notifiers) are ‘somewhat’ satisfied (see Figure 4.5). Table 4.1 below shows how long it has taken for the appraisal of the five applications which thus far have received an Opinion from EFSA.

Whilst notifiers expressed the view that the efficiency of the process is not entirely satisfactory, the unpredictability and current indecision of the institutional decision-making process is of far greater concern to them (see section 6.2).

Figure 4.4 Most consultees were generally satisfied with the level of transparency of the risk assessment process, but that there could be some improvements

“To what extent are the current procedures for risk assessment transparent (i.e. the process, and the basis of the decision, are clear to those outside it)?”

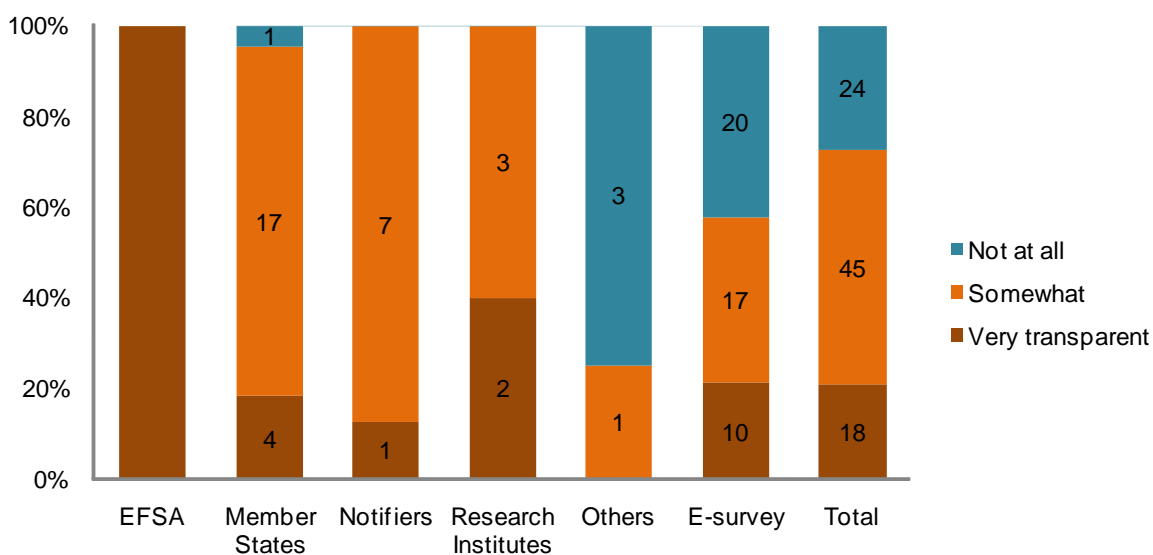


Figure 4.5 Many consultees, especially MS authorities and notifiers, thought that the efficiency of the risk assessment procedure is only somewhat efficient

“To what extent are the current procedures for risk assessment efficient?”

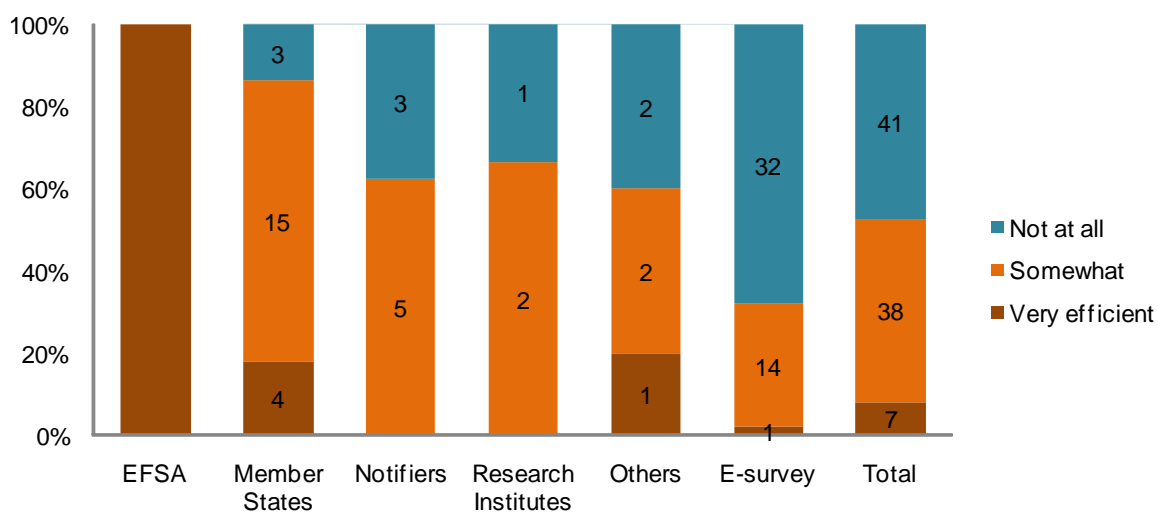


Table 4.1 The end-to-end processing time for the appraisal of cultivation applications which have received an Opinion from EFSA ranges from 21 to 46 months

Time from initial submission of dossier to EFSA Opinion

Application	Legislation	Time taken for appraisal (months)	Notes
NK603 maize	Regulation	46	
MON810 maize	Regulation	25	Renewal
1507 maize	Directive	43 in total (8 - EFSA arbitration*)	Originally submitted under 90/220 in 1998
Bt11 maize	Directive	21 in total (13 - EFSA arbitration*)	Originally submitted under 90/220 in 1996
EH92-527-1 potato	Directive	35 in total (10 – EFSA arbitration*)	Submitted under Directive 2001/18 in 2003

* Under the Directive, the risk assessment for a cultivation application is appraised in full by a Member State authority. Other Member States are able to comment or make objections on this appraisal. If within 3 months any objections remain unresolved, the objections and the application is sent to EFSA. Consequently, under the Directive EFSA only plays an arbitration role in the case of unresolved objections.

Source:Correspondence between EFSA, notifiers, and MS authorities on cultivation applications submitted since 2005 under the Regulation 1829/2003 (up until July 2009); EFSA GMO Register of Questions (<http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO&questiontype=2>); GMO compass (www.gmo-compass.org)

4.3.1 Consultees highlighted several aspects of the risk assessment procedure which result in inefficiencies

Figure 4.6 shows the current functioning of the RA process under the Regulation once an application is forwarded to EFSA (based on the small sample of 13 applications currently in the pipeline). A third of the total elapsed time is spent on validating an application. In an effort to reduce this, EFSA has implemented an internal deadline of 6 weeks for the initial completeness check with an outcome in a first clarification request, or within which to issue a Statement of Validity.

Results from the consultation suggest that the six issues (discussed further below), which have the greatest effect on the efficiency of the RA process under the Regulation are:

- EU-level resourcing of the RA system;
- The sequential appraisal of the ERA first by a Competent Authority of a nominated MS and then by EFSA;
- Stacked events;
- Additional information requests (discussed separately under section 4.5);
- Communication (discussed separately under section 4.6);
- EFSA guidelines (discussed separately under section 4.7).

Some consultees voiced concern about the resources available to support EU level appraisal of the risk assessment

Several consultees, including some Member States, environmental NGOs and notifiers, had concerns about the EU's resourcing of the systems being used to conduct the European level appraisal of environmental risk assessments. This concern was centred on the resourcing and composition of the GMO Panel and its supporting infrastructure.

The core GMO Panel comprises 21 scientific experts, of whom seven have an environmental or ecological background. The Panel can draw on a further pool of more than 40 scientific experts. However, the majority of these external experts have full time jobs elsewhere (like most members on other Panels). The few who do not are mostly retired.

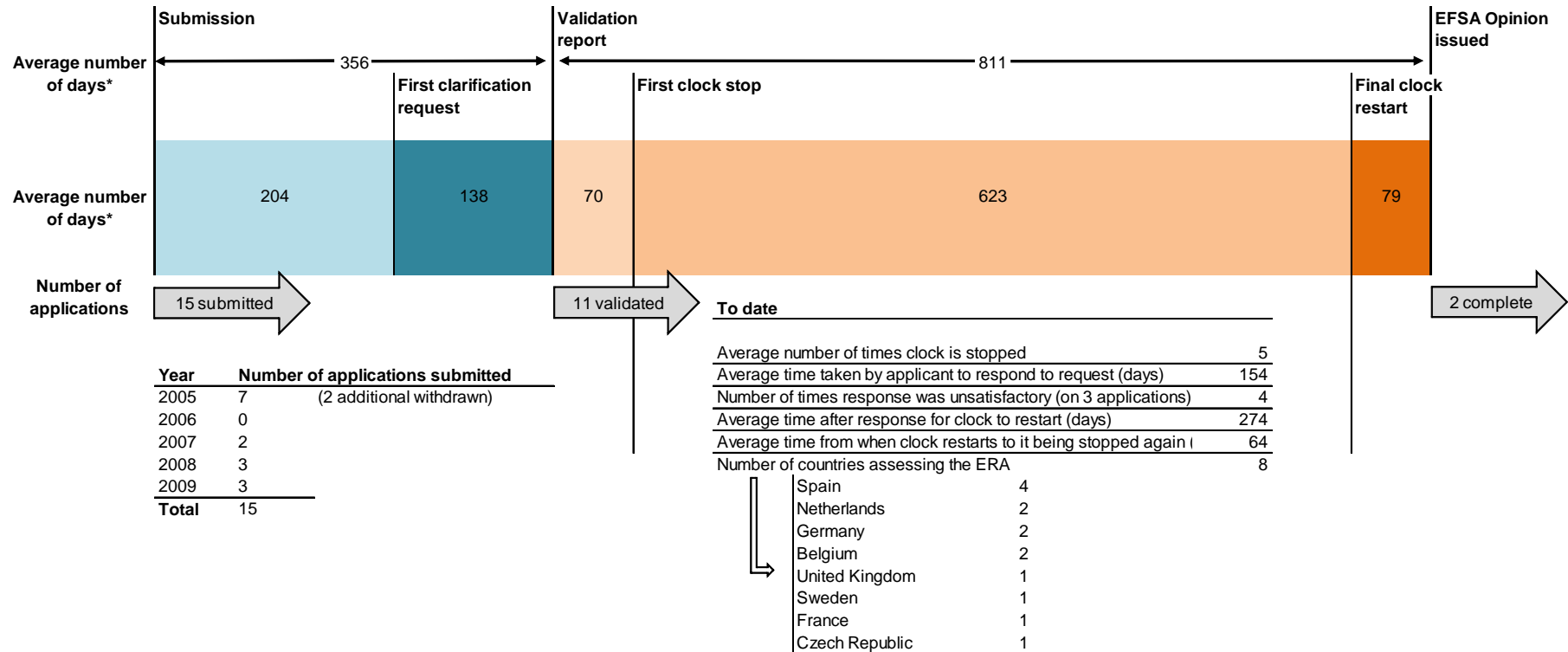
In addition to assessing authorisation dossiers, EFSA's GMO Panel also:

- undertakes 'Self-Tasking Activities', particularly in fields such as emerging risks where scientific knowledge and approaches are continually evolving (such as the use of animal feeding trials for the safety evaluation of whole GM Food and Feed);
- accepts mandates from the European Commission (e.g. EFSA was given a mandate to re-assess the safety of the antibiotic resistance marker gene in the EH92-527-1 potato in 2008);
- assesses the scientific evidence submitted by Member State authorities in support of a national safeguard measure; and,
- prepares and periodically updates guidance documents.

There was general recognition among consultees that these resourcing/capacity issues were impacting negatively on the system's efficiency. EFSA has been making strong efforts to address these concerns, but is managing a large and expanding GMO workload. Additional tasks are not accompanied by additional funding to EFSA.

Figure 4.6 13 of the 15 applications submitted since 2005 are still being processed, with most of the delays being caused by additional information requests

Timeline of applications submitted under the Regulation



* Average for each step taken from the total of applications which have completed that stage

Source: Correspondence between EFSA, notifiers, and MS authorities on cultivation applications submitted since 2005 under the Regulation 1829/2003 (up until July 2009); EFSA GMO Register of Questions (<http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO&questiontype=2>); GMO compass (www.gmo-compass.org)

Under the Regulation the sequential appraisal of the ERA by a Member State Competent Authority and then EFSA potentially increases the overall processing time

Under the Directive, the risk assessment for a cultivation application is appraised only once, in full, by a Member State Competent Authority. EFSA only plays an arbitration role in the case of unresolved objections. Whilst in practice this has been the case for every application so far, in principle the legislation allows the RA to be appraised only once by the Competent Authority of a MS.

Conversely, if an application is submitted whose scope includes cultivation under the Regulation:

- One Member State is nominated from those who volunteer; its Competent Authority then conducts the initial appraisal of the ERA;
- Once that appraisal is produced, EFSA conducts its own appraisal of the ERA by building on the work of the MS authority. Besides the ERA, EFSA also assesses the food and feed safety²⁸, and the molecular characterisation²⁹.

The time needed to complete the exercise is potentially increased due to the need for two appraisals and because they are done sequentially, rather than in parallel. However, in principle the timeline foreseen under the Directive is slightly longer than the six months provided for by the Regulation; if MS authorities maintain their objections under the Directive, the overall time taken for the appraisal of a risk assessment can reach 195 days³⁰. Nonetheless, in practice, an application for cultivation has never been completed within the six month time limit under the Regulation partly due to additional information requests which cause the clock to be 'stopped' (see section 4.5 for further discussion).

Instead of the appraisal being conducted entirely by EFSA, the additional appraisal of the ERA by a Competent Authority of MS provides MSs with an opportunity to be more closely engaged in the risk assessment process. However, some did note that the current process could be improved. For instance, there could be greater coordination with EFSA, especially on the requests which are sent to notifiers for additional information. Some MS authorities interviewed who had conducted an appraisal stated that the appraisals do not necessarily have to be sequential – instead a more collaborative, parallel process could be more efficient and potentially more productive. Although several MS authorities noted that they would like to use the opportunity to conduct an appraisal of the ERA, the lack of necessary resources was highlighted as the greatest obstacle to doing so.

EFSA is receiving applications for stacked events whose appraisal is contingent on the prior release of an Opinion on the constituent single events - adding complexity to the system and exacerbating the application back-log

In the EU, stacked events are required to undergo a separate (albeit simplified) authorisation procedure even if the single events have been given a favourable appraisal of the risk assessment. If an application for a stacked event is submitted while the single event is still being assessed, the application for the stacked event is put on hold until the appraisal of the single event is complete (i.e. an Opinion is issued). Each dossier for the stacked event must contain the full assessment for the single events. Currently there is a backlog of 13 applications for cultivation awaiting an Opinion. Over 50% of these applications in the pipeline are stacked events (7 of the 13), and all of these were submitted before the

²⁸ Including the compositional, nutritional, and agronomic characteristics, as well as the potential toxicity and allergenicity of the GM product.

²⁹ The molecular characterisation of the GM product takes account of the characteristics of the donor and recipient organism

³⁰ The Directive allows 60 days for the appraisal of the risk assessment by the rapporteur MS, 45 days to resolve any outstanding issues. If these remain unresolved, EFSA has 60 days to address these issues in its appraisal of the risk assessment

appraisal for the relevant singles were complete. The way that stacked events are assessed, and the impacts this has on the process of the risk assessment also has implications for food and feed applications, not just for applications whose scope includes cultivation.

With the exception of most notifiers, other consultees (including 19 of the Member State authorities) believed stacked events should be assessed in addition to the singles. However, the requirement for a separate appraisal increases the load put on the system and seems to be a key cause of the backlog of applications because stacked events are put 'on hold' pending the results for the single events.

Three suggestions for improvements were made by consultees:

- **Notifiers should submit applications for stacks only after the appraisals for the singles are complete:** By the time the stacked event is appraised, the information on the single event provided within the stacked event dossier will be out of date because it will not contain all the additional information supplied during the single event's appraisal. The re-submission of all the information for the single event once the appraisal for the stacked event begins can cause delays. This suggestion would significantly reduce the number of applications 'on hold' at EFSA, though the rate of output of Opinions would not be affected. Pending applications would be held with notifiers, rather than with EFSA.
- **The appraisals should be done in parallel (as far as possible):** Some notifiers suggested that the evaluation of the stacked event should be done in parallel with that of the single. However, other consultees, such as EFSA and some Member State authorities who were interviewed, raised concerns about the logistical difficulties of doing so, especially given the coordination that would be necessary. For instance, it is possible that Competent Authorities from two different Member States would be completing the appraisals of the risk assessments for the single and the stacked event. Belgium, for instance, is appraising the ERA for a triple stack (59122 x 1507 x NK603), whose single events were appraised by Spain and the Netherlands. This would be more difficult were single and stacked events to be run in parallel. Some consultees did note however that while a completely parallel appraisal might be too difficult, there might be some parts of the assessment that could be done while the single event is being appraised, so that the stacked event is not put completely on hold.
- **Ensure, as far as possible, that the Competent Authority from the same Member State appraises the single and stacked events:** If a MS authority was familiar with the single event as a result of having conducted its appraisal, this might increase the efficiency of the appraisal of the stacked event. The stacked event procedure is a simplified assessment which considers the potential interactions between single events.

4.4 **Whilst many consultees were satisfied with the RA requirements, many had concerns with the characteristics of their application in practice**

The majority of consultees were largely satisfied with the requirements of an ERA as specified in the legislation (see Figure 4.7). For instance, 9 Member State authorities were 'very satisfied', and a further 10 'somewhat satisfied'. Satisfaction with the actual implementation of the legislative requirements varied considerably. Notifiers were the only group who were consistent in their approval of the way the ERAs were being conducted and appraised, while environmental NGOs were consistently dissatisfied. MS authorities varied significantly in their viewpoints on this issue (see Figures 4.8 and 4.9).

12 Member State authorities were 'somewhat satisfied', 4 'very satisfied', but 5 were 'not at all satisfied' with the environmental risk assessment conducted by notifiers. EFSA was 'somewhat satisfied'. Member State authorities and other consultees, with the exception of

notifiers, were generally less satisfied with the way EFSA appraised the ERA than with the appraisal of the ERA by Competent Authorities of nominated Member States. Of the Member State authorities consulted, 14 were ‘somewhat satisfied’ and 6 ‘very satisfied’ with the appraisal of the environmental risk assessment by other Member State authorities, whilst 11 were ‘somewhat dissatisfied’ and 3 ‘not at all satisfied’ with the appraisal of the environmental risk assessment by EFSA.

Figure 4.7 Many consultees were generally satisfied with the legislative requirements of the ERA

“In general, how satisfied are you with the ERA requirements as specified in the legislative framework?”

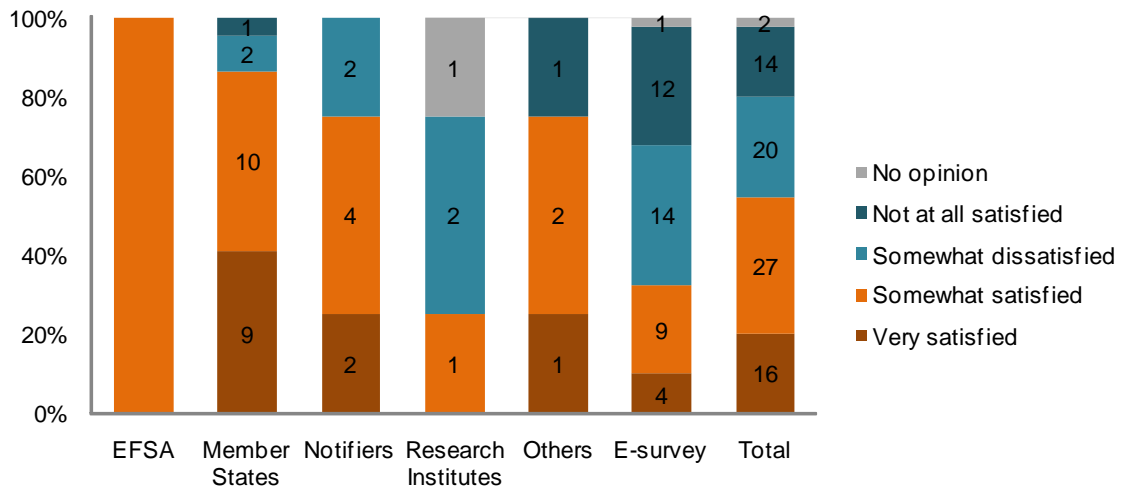


Figure 4.8 Satisfaction levels with the way notifiers are conducting the ERA varied considerably

“Overall, how satisfied are you with the way in which ERAs for GMOs are being conducted by notifiers?”

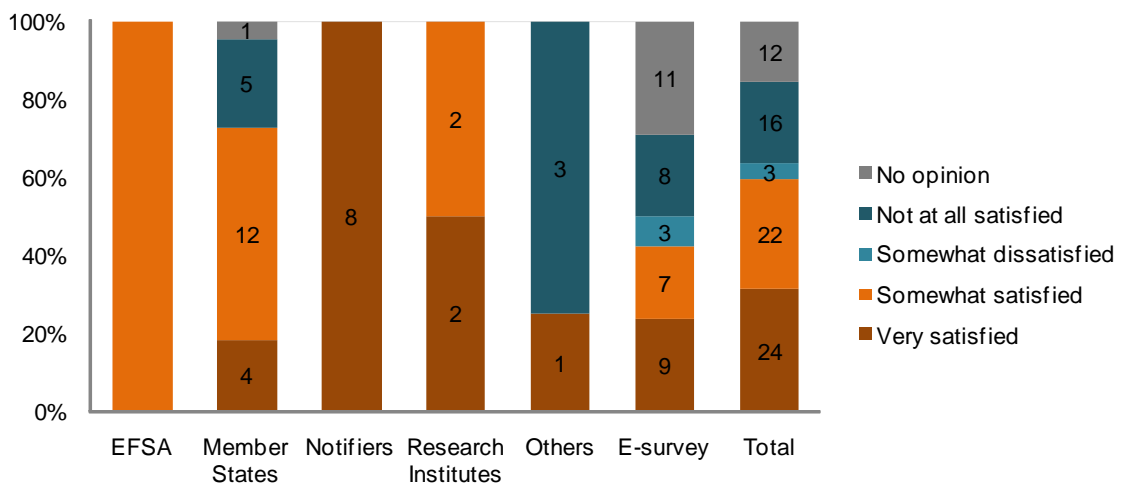
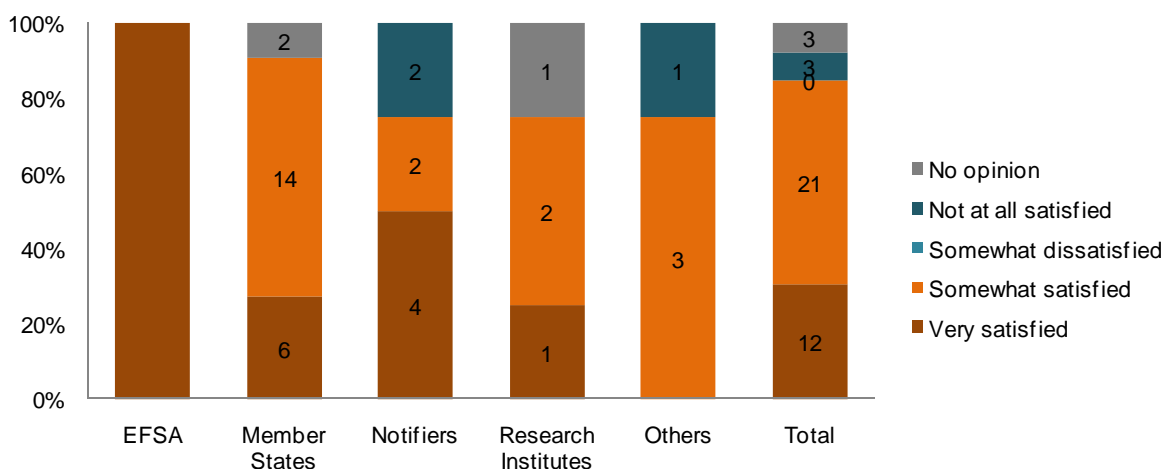
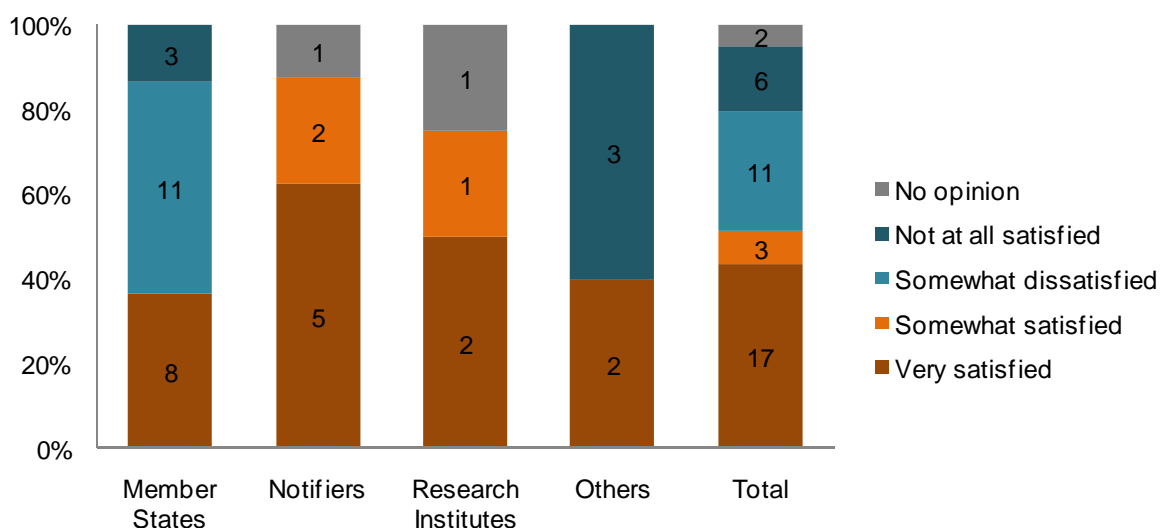


Figure 4.9 Although satisfaction levels varied, consultees were generally less satisfied with the way EFSA appraised the ERA than MS Competent Authorities.

“Overall, how satisfied are you with the way in which ERAs for GMOs are being assessed by MSs?”



“Overall, how satisfied are you with the way in which ERAs for GMOs are being assessed by EFSA?”



4.4.1 The quality of the dossier submitted by notifiers was raised as a concern by several consultees

Although some MS authorities who were interviewed did see that there has been progress up a learning curve, others stated that there has been no obvious improvement as experience has increased. They saw the quality of the dossiers as varying considerably. Key areas where consultees thought quality could be improved are:

- evidence on the environmental and ecological aspects, such as the effects on non-target organisms and the effect of changes in agricultural management techniques (e.g. herbicide use);
- the justification for, and clarity of the evidence that is submitted, i.e. the reasons for submitting particular pieces of evidence and an explanation of why that evidence supports certain conclusions;

- the principle of comparative analysis could be better applied, given that some characteristics of a GMO in question are not always compared to those of a non-modified organism and its use;
- the details provided on the post-market environmental monitoring plan; and
- administrative aspects, e.g. layout.

The perceived lack of improvement might be due to the fact that there have been few opportunities to gain experience. Most applications were submitted in 2005, and the rate of submission of new applications is now much lower. More than 80% of applications submitted are still in the process of being appraised. Furthermore, there is a general consensus amongst most consultees, including MS authorities and notifiers, that MS authorities are not entirely consistent in their appraisal of the ERA, which can make it difficult for notifiers to know what is expected of them (see Figure 4.10 in section 4.4.2 below on the consistency and harmonisation of RA approaches by Competent Authorities of MS). The updating of EFSA's guidelines also contributes to a problem of "moving targets" (see section 4.8).

Some consultees - environmental NGOs and some MS authorities - saw the consistent need for additional information as a reflection of the poor quality of the applications. EFSA believes that the need for additional information requests reflects the situation that notifiers are not conducting risk assessments sufficiently in line with EFSA's guidelines. On the other hand, some notifiers suggested that requests for clarification and additional information are a natural characteristic of a scientific process, and are thus to be expected - regardless of the quality of the submission.

Virtually all consultees interviewed commented that better communication, both in terms of quantity and quality, would significantly improve the quality of the dossiers that are submitted. Better guidance, in terms of content and clarity, was also suggested by several consultees as a possible means of improvement.

Issues concerning additional information requests, communication and guidance are further discussed in sections 4.5, 4.6 and 4.8 respectively.

4.4.2 *How best to bring expertise to bear on the ERA appraisal by Member State authorities and EFSA, whilst also widening participation in the process, is a continuing point of debate*

In the applications for cultivation the assessment and management of environmental risks is a key concern. Some consultees, including some Member State authorities and environmental NGOs, raised concerns that the quantity of environmental expertise available to support the processes that EFSA administers is not adequate given the scale and complexity of the ERA workload that the system is being called upon to process. These processes are heavily dependent on the seven members of the GMO Panel that have a background in environmental biology and ecology (plus the supporting additional external experts), though they mostly have full time jobs elsewhere.

A further stated concern of environmental NGOs was that EFSA's appraisals are based exclusively on data submitted by the applicant, which some (including environmental NGOs and certain MS authorities) thought were biased and of poor quality. However, EFSA, as well as the Competent Authorities of nominated MSs, stated that they do take into account all available information, not just that which is submitted by the notifier. On the basis of the other available evidence, they approach the notifier if needed to further clarify or consider additional aspects.

For the initial appraisal of the ERA, EFSA sends a letter to MSs asking them to submit an expression of interest. Of those who volunteer, EFSA then selects the most appropriate MS

on the basis of certain criteria³¹. Not all MS authorities we interviewed were aware of the criteria. Many thought the criteria were too demanding, and would discourage them from volunteering.

Currently, only a modest number of MSs (eight in total) have volunteered, with Spain alone being responsible for reviewing four applications. Some applications have had no MS volunteer. EFSA approached the European Commission on what action to take in these situations. The Commission suggested that the Competent Authority of the MS in which the application was submitted should then be nominated. EFSA, having recognised the lack of volunteers as a concern, is now taking a much more active approach and contacting MS Competent Authorities directly in order to encourage participation. This has seen some success, with the Competent Authorities of two MSs - the Czech Republic and Sweden - recently being nominated to do an ERA appraisal for the first time.

In the interviews conducted for this project, by far the most significant reason given by MS authorities for not volunteering was the lack of the necessary human and financial resources. The limited number of MS Competent Authorities appraising the ERA affects the conduct of the ERA in two ways, discussed further below. Firstly, the identity of the MS is seen to affect the ERA as MS authorities are not consistent in their appraisals (see below). Secondly, some consultees, including environmental NGOs and some MS authorities, questioned whether one MS authority is able to assess the environmental impact of a GMO for the entire EU, given the regional variability that exists in environmental and agro-economic conditions. Having the same MS authorities assess the ERA time and again limits the knowledge base on which the appraisals are made.

Most consultees saw variation in the appraisal by Competent Authorities of Member States and many supported greater harmonisation

Most consultees, including Member State authorities, felt that Member State authorities are not entirely consistent when assessing the ERA (see Figure 4.10). Specifically, 13 Member State authorities believed Member State authorities are only somewhat consistent in their appraisal of an ERA, whilst a further 3 believed they are not at all consistent.

Differences among MS authorities were noted in:

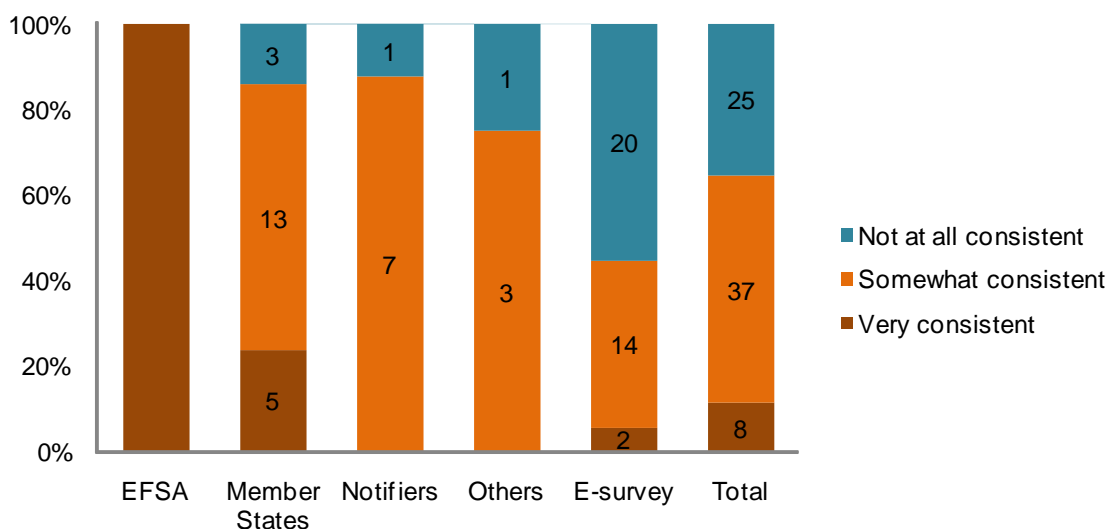
- the level of information required to assess the management effects associated with cultivating a GMHT crop;
- the extent to which MS authorities compare the risks of a GM plant to that of conventional agricultural practices;
- the application of the precautionary principle;
- the consideration of specific agricultural or environmental conditions; and,
- the conclusions for monitoring requirements (including the distinction between case-specific monitoring and general surveillance).

All MS authorities either wanted full harmonisation, or at the very least more harmonisation of risk assessment practices than is currently the case. It was highlighted that this lack of consistency negatively impacts on the transparency and efficiency of the risk assessment and its appraisal, creates confusion for notifiers, and, perhaps most importantly, affects the voting behaviour of MS authorities and impedes the ability of MS authorities to reach a qualified majority.

³¹ The criteria include general GMO experience (e.g. with ERA, national evaluation reports, professional experience in a multidisciplinary environment, etc.); specific experience of the GMO product (e.g. in ERAs specific to these types of products, e.g. herbicide tolerant, insect resistant); certain skills (e.g. English language skills, capacity, flexibility, availability, etc.)

Figure 4.10 Very few consultees felt that MS authorities were very consistent in their appraisal of an ERA

“How consistent are Member States in assessing ERAs for applications whose scope includes cultivation?”



EFSA has established a Working Group on Scientific Cooperation (ESCO), after the harmonisation of methodologies for RA was identified as a main priority area in EFSA’s ‘Strategy for Cooperation and Networking’ between Member States and EFSA. The aim of this harmonisation is to increase transparency and confidence in the appraisals of the RAs by Member State Competent Authorities through simply identifying possible discrepancies, not by actually standardising RA methodology.

A report has been released by ESCO on the harmonisation of RA approaches³², however it focuses exclusively on identifying discrepancies in procedural, not scientific, aspects. Furthermore, the report did not cover the RA of GMOs, as a report based on a similar questionnaire was completed in 2007.³³ That questionnaire revealed differences:

- among Member States in the practical organisation of an RA appraisal; and,
- within Member States between an RA appraisal under the Regulation and the Directive.

A guidance document is being worked on to describe differences in scientific aspects. Whether this will include the RA of GMOs is unclear. In the meantime, ESCO has made four recommendations for harmonising the way RAs are appraised between MS authorities:

- EFSA and Member States develop ‘country profiles’ for a better understanding of the role and competencies of national risk assessment institutions in the different countries;
- Risk assessment outputs of national organisations should be made publicly available;
- Quality management tools should be implemented in the risk assessment process; and,
- Risk assessment approaches need to be further harmonised within the specific scientific areas.

³² http://www.efsa.europa.eu/cs/BlobServer/DocumentSet/ESCO_HARM_RA_final_report_03-12-2008.0.pdf?ssbinary=true

³³ http://www.efsa.europa.eu/cs/BlobServer/DocumentSet/report_gmo_af_meeting.pdf?ssbinary=true

7 MS authorities consulted believed that these actions were somewhat important, and most (14 of those who responded) thought that they were very important. However, most MS authorities (15 of those who responded) only felt that these suggestions were somewhat realistic. A few Member State authorities in the interviews suggested that there is a need to develop guidance specifically for MS authorities on the actual appraisal of the ERA, in addition to guidance for the notifiers on the conduct of an ERA.

It appears then that there is work to be done to harmonise risk appraisal methodologies among MS authorities, however it is unclear what would be the best and most practical means to do so. However, consultees seem to generally agree that the benefits of managing to do so would be far-reaching.

Several reasons were proposed for what MS authorities and environmental NGOs saw as an inadequate consideration of regional variability in EFSA Opinions and subsequent conditions of consent

The majority of MS authorities surveyed (18 out of 22) stated that more account should be taken of regional variability in EFSA Opinions and the subsequent conditions of consent. Interviews with certain MS authorities confirmed that this was a key concern for some. Furthermore, a few pointed out that consideration of regional variation should be applied not only to ecological conditions, but also to the variability in agricultural systems.

A few consultees, including one Member State authority and most notifiers, stated that regional variability is sufficiently taken into account. They stated that the opportunity is there for MS authorities to raise concerns about regional variability in the 3 month consultation period, but that few have done so. However, in our interviews some MS authorities stated that they have raised these concerns in their comments, but that their concerns have not been sufficiently addressed by EFSA in its final Opinion. Others stated that they have not raised their concerns because they saw little point in doing so given that the way EFSA deals with the comments is not always satisfactory. EFSA has not however received any official complaints from MS authorities regarding the way they deal with comments. So although it is the case that the mechanism for MS authorities to raise regional issues is there, some see the mechanism as inadequate and it is therefore not being fully utilised (communication is discussed further in section 4.6).

Those consultees who do not believe that greater weight should be given to regional and ecological variability stated that thus far there has been no need to do so. They observe that those products which are currently undergoing authorisation do not require conditions of consent which are specifically tailored to certain regions (e.g. one MS authority noted that neither maize nor potatoes have the ability to hybridize with wild flora in the EU).

On the other hand, however, a few MS authorities suggested in the interviews that it is not the characteristics of the products, but instead the lack of available data that prevents specific conditions of consent from being included. The information on what measures might be necessary to take regional variability into account, and what are the best means by which to do so, is lacking.

Furthermore, several consultees, including environmental NGOs and some MS authorities, were also concerned that the GMO appraisal system as it is currently configured cannot properly assess the potential impact of a GMO on the environments across the entire EU. The Competent Authority of the nominated Member State should have the expertise to assess the environmental impact on its own region, but it is not realistic to expect it to be able to do so for the regions of all the other relevant Member States. These consultees also suggested it was unrealistic to expect the seven experts of the GMO Panel that have an environmental or ecological background to be able to properly evaluate the significance of the impacts across all regions where the crop might be planted. As such, a few MS authorities felt that the principle of subsidiarity should be more strongly applied - it not being possible to properly consider regional variability within Europe in a single decision made on an EU level.

EFSA is currently working on updating its RA guidelines on the basis of a mandate sent by the Commission in March 2008. It is foreseen that regional variability will be elaborated on in more detail (see section 4.8 for further discussion). EFSA is due to deliver its updated guidelines by March 2010. Balancing the need for a harmonised approach, whilst providing space for region-specific conditions of consent, is inherently difficult.

Although improvements have been made, several consultees still think that scientific uncertainty needs to be better acknowledged or addressed

Some consultees, including environmental NGOs and certain MS authorities, stated that confidence in the RA process could be improved by clearer identification and acknowledgement of scientific uncertainty. Decision makers are only able to make informed decisions if they are aware of the key uncertainties.

Some believed that notifiers and EFSA avoid using the terms 'risk' and 'uncertainty' for fear that these terms would be misinterpreted and misused. This was evident in the way some notifiers wanted to avoid applying the term 'case-specific monitoring' to some monitoring aspects, given the associated presumption that a potential risk had been identified and despite the recommended monitoring being hypothesis-driven (both of which are characteristics of case-specific monitoring, see section 6.3.2).

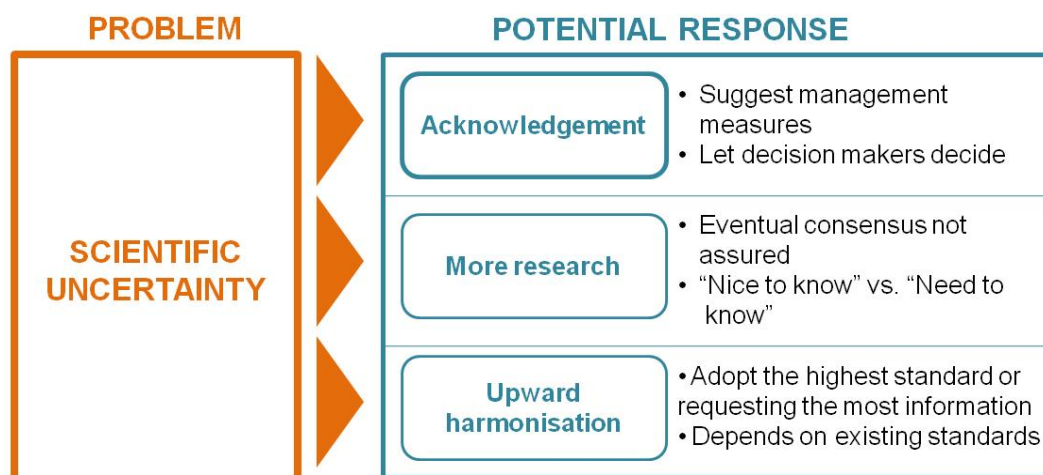
However, statements from, for example, environmental NGOs, demonstrated that a failure to acknowledge risk and uncertainty can have potential impacts on the confidence in the RA process. Notifiers also noted that GMOs seem to be expected to meet a criterion of 'zero risk'. Many notifiers and a few MS authorities noted that this was unrealistic, given that uncertainty is an inherent characteristic of decision making. Some MS authorities and environmental NGOs in the interviews did express the view that EFSA is becoming better at acknowledging scientific uncertainty, but that more still needs to be done.

If uncertainty is not adequately identified, and decision makers feel they are unable to make an informed decision, two further options remain; more research and upward harmonisation (see Figure 4.11). Evidence of both can be seen in the context of GMOs and are explained in more detail below.

Several consultees, including some MS authorities and environmental NGOs, called for more research to properly support a risk assessment of GMOs. With this, many notifiers felt there is an increasing tendency away from risk assessment, towards risk research. Notifiers believed that conducting continual risk research is not necessary to perform a risk assessment; there is an unlimited amount of research that could be done but not all research is needed to complete a risk assessment. Other consultees, including certain MS authorities and environmental NGOs, noted that a risk assessment is based on risk research, and one cannot separate one from the other. Most importantly, having more research on which to base a risk assessment does not necessarily lead to less uncertainty, and does not necessarily mean a decision should be deferred until such time as a consensus can be reached.

Figure 4.11 The stakeholder consultation revealed that different consultees believe there are different ways of dealing with scientific uncertainty

Three proposed means of addressing scientific uncertainty



Source: GHK Consulting Ltd.

In the cases where there are conflicting views on what standards to adopt or how much information to request, and it is not possible to reach an agreement, a few MS authorities argued that the highest standards should be adopted or more information requested. EFSA, for instance, adopts a case-by-case approach towards the need to conduct a 90-day feeding trial³⁴, whereas other consultees (including certain MS authorities), maintain that this should be part of every assessment. Adopting the most demanding of the potential options (i.e. requiring such a feeding trial for every application) would constitute upward harmonisation but always applying this principle could lead to excessive and rigid requirements, which some consultees might see as ‘unnecessary’. Additionally, upward harmonisation is not possible for some concerns where standards do not exist, or for cases where it is not possible to have clear standards to compare.

There is still considerable uncertainty and disagreement in the way consultees believe the interaction between Directive 2001/18/EC and Directive 91/414/EEC should be managed with regard to the ERA of herbicide tolerant GM plants

Under Directive 91/414/EEC, a herbicide must undergo an appraisal before being placed on the market. The ERA must include an assessment of its impacts on certain non-target organisms and studies of its residual activities in soil and water, but does not include assessment of its indirect impacts on biodiversity within crops and changes in agro-ecosystems.

Assessment of these latter impacts (biodiversity and agro-ecosystem effects) is required in relation to GM plants. As such, a herbicide used on a herbicide-tolerant GM (GMHT) plant requires an assessment that is different to that required for the same herbicide when used on non-GMHT plants and conventional plants.

³⁴ The whole GM product must be tested in order to consider the potential effects on human and animal health. This necessitates a minimum 90-day toxicity study in rodents “if the composition of the GM is modified substantially, if there is no appropriate conventional comparator, or if there are any indications for the potential occurrence of unintended effects, based on the preceding molecular, compositional or phenotypic analysis”. From: EFSA’s guidance document on the risk assessment of GMOs (EFSA 2006b) http://www.efsa.europa.eu/cs/BlobServer/Guidance_of_Panel/comm_Guidance_gmo_en.0.pdf?ssbin ary=true

Many consultees, including environmental NGOs, MS authorities and notifiers, saw this asymmetric approach as illogical. However, some did believe that an assessment of the indirect impacts of the herbicide and its management on biodiversity is necessary. Some MS authorities stated that indirect effects on biodiversity should be assessed under Directive 2001/18/EC since they are not considered by Directive 91/414. Many were of the view that the same criteria should be applied in the evaluation of the environmental impacts of an application for a non-GMHT and a GMHT plant. It is hoped that the amendments to the Plant Protection Products legislation will harmonise the two pieces of legislation, at least with respect to the way biodiversity is considered. Nonetheless, one MS authority highlighted that there also needs to be an alignment of what the assessment endpoints are, in terms of what constitutes harm.

Despite the alterations being made to the Plant Protection Products legislation, changes in herbicide management would still need to be considered when assessing a GMHT plant under Directive 2001/18 as a potential indirect effect of a GMO; Annex II notes that the ERA should consider changes in management techniques, including, where applicable, in agricultural practices.

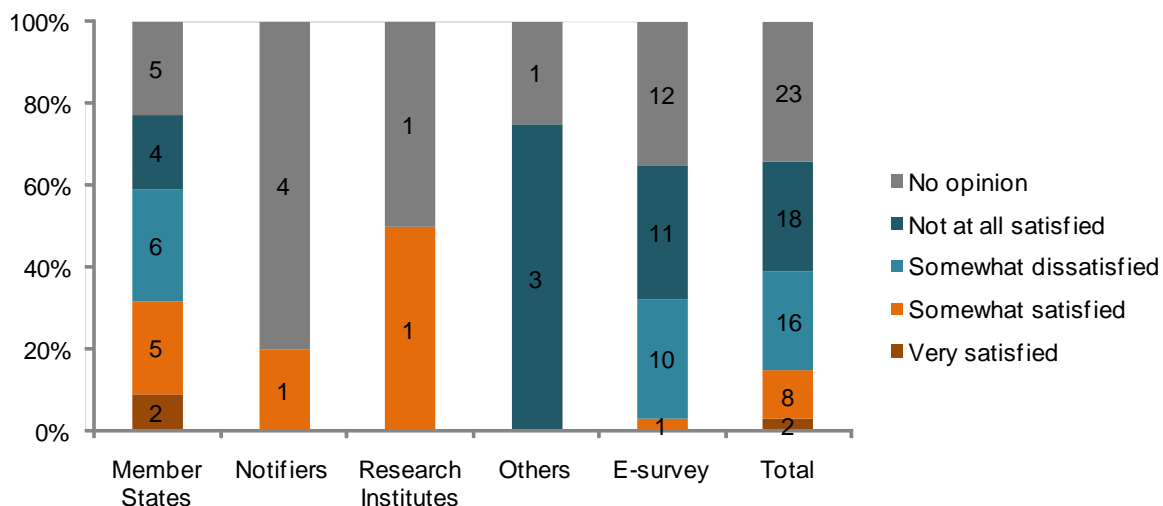
In December 2008, the Environment Council concluded that there is a need to ensure coherence between risk assessments of GM plants using plant protection products which produce active substances covered by Directive 91/414. The Commission stated that the environmental impact should be assessed according to the Directive 2001/18/EC. However, in its working document on the interplay between Directive 2001/18/EC and Directive 91/414/EEC, EFSA concluded that it is not feasible to carry out a meaningful environmental impact assessment of the herbicides used on GMHT crop. Instead appropriate herbicide management systems for GMHT crops should be implemented to avoid adverse impacts on the environment, since it is primarily the function of the herbicide management programme that determines the environmental impact, not the herbicide itself.

Overall, there is no common approach as yet, for the risk assessment of GMHT plants. In the meantime, the indirect environmental impact of the herbicides used with GMHT crops, especially with regards to biodiversity and non-target organisms (NTOs), is a persistent concern, and is one often voiced by MS authorities in the comments made to EFSA (see Figure 4.19 in section 4.6.2).

Thus far only one product that is to be cultivated as herbicide tolerant, NK603 maize, has been given an Opinion by EFSA. MS authorities vary in their levels of satisfaction with the way herbicide tolerance was treated in the assessment and its appraisal (see Figure 4.12) - only 2 Member State authorities were very satisfied, whilst 6 were somewhat dissatisfied and 4 were not at all satisfied. 5 were somewhat satisfied. Whilst some MS authorities thought EFSA provided a well-argued discussion, others argued that the impact of the altered and increased use of the herbicide was not thoroughly assessed. Some MS authorities also commented that the information provided by applicants on the issue has been variable, and that often biodiversity and the impacts on NTOs had not been sufficiently dealt with in the applications. Thus the lack of consensus on how a GMHT should be assessed is especially apparent between notifiers and certain MS authorities, and is reflected in the additional information requests that are submitted that relate to the herbicides and their management (see Figure 4.14 in section 4.5).

Figure 4.12 Although a few consultees had no opinion, many others, including MS authorities, were not entirely satisfied with how well herbicide tolerance was dealt with in the risk assessment and its appraisal.

“How satisfied are you with the way that herbicide tolerance, and its impact on the environment was treated in the ERA for the applications including cultivation, such as the application for NK603, Bt11 and 1507 maize, as well as soybean 40-3-2?”



Notifiers reported that they considered that some MS authorities are going beyond the requirements in the ERA and are making requests for information that are more appropriately addressed under Directive 91/414/EC. However, several MS authorities have noted that the issue should be addressed under Directive 2001/18 since it is primarily the management of the programmes, and not the herbicide itself, that determines the environmental impact. Given that the management techniques do change when a herbicide is used with a GMHT compared to a conventional crop, assessing these effects is important. Furthermore, a comparison with agricultural practices for cultivation of non-modified crops should be applied, which requires adequate data on conventional herbicide treatment to be included in the notification for GMHT plants.

Conversely, one MS authority noted that the environmental impacts of a herbicide associated with GMHT plants should be assessed under Directive 91/414. Another MS authority highlighted that in their view, the effects of the herbicide management techniques, and the development of resistance is an agricultural issue, not an environmental one.

The majority of MS authorities highlighted the need for more systematic coordination to deal with the interplay between the Plant Protection Products legislation and the Directive 2001/18. One highlighted that the decisions taken under Directive 91/414 should take into consideration, and be interlinked with, those decisions made under Directive 2001/18. The most effective means of cooperation between authorities should be identified to ensure that sufficient data are available to address the assessment of GMHT plants, while avoiding the duplication of work. Monitoring was highlighted as an area where cooperation could be especially useful, for instance, by setting up a clear information exchange between the responsible institutions to monitor resistance development to plant protection products associated with GMHT plants.

The call for more coordination extended not only to the different Competent Authorities under the two legislative frameworks, but also to the work of the GMO and Plant Protection Products and their Residues (PPR) Panel of EFSA. The EC is addressing this issue in its regular meetings with the Competent Authorities of the Member States.

Views of the consultees varied on whether and in what way risk management strategies should be given more consideration during the formal risk assessment

The stakeholder consultation revealed some uncertainty over the extent to which risk management should be considered within the context of risk assessment. The confusion is potentially a result of the term being used to encompass two very different concepts:

- the identification of 'practical' measures for managing potential risks (for example, monitoring and mitigation measures, see section 6.3), as well as
- 'institutional' decision-making by Member State authorities and the European Commission (see section 6.2).

The latter is clearly not within the remit of risk assessors. EFSA is very clear on the fact that it is not a political decision making body, but that its role is strictly limited to giving scientific advice by making recommendations and issuing Opinions³⁵. These then inform the decisions taken by risk managers on whether to actually authorise a GMO or not. A clear distinction is thus made between science and politics.

Nonetheless, the practical aspects of risk management are relevant to the risk assessment, in that risk management strategies contribute to the determination of overall risk. Step 5 and 6 of the guidance notes on environmental risk assessment (detailed both in Annex II of Directive 2001/18/EC and Decision 2002/623/EC) state that the ERA may identify risks and measures to manage them and a risk management strategy should be defined. It states that *'an evaluation of the overall risk of the GMOs should be made taking into account any risk management strategies which are proposed'*. As such, it is understood that the level of hazard associated with an identified risk is determined by whether there are appropriate management measures to address that risk. Both aspects need to be included in the risk assessment which informs risk managers, as they can only determine the significance of a risk if they know both what the risk is, and whether it can be dealt with.

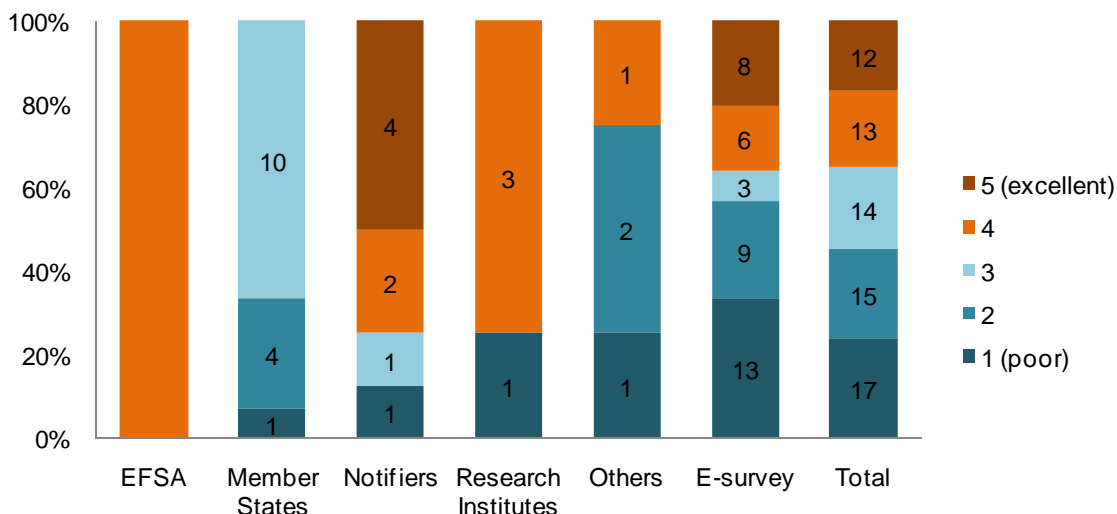
Some consultees, especially MS authorities, raised concerns that the practical side of risk management is not being adequately addressed during the conduct and appraisal of the ERA (see Figure 4.13). Practical risk management includes both monitoring and other mitigation measures in response to potential risks. Some MS authorities highlighted that they would like to see more details on monitoring, whilst others thought that monitoring requirements are well-addressed. Meanwhile other MS authorities would like to see other types of mitigation measures also play a bigger role in the ERA. One MS authority thought that risk management measures should play a more prominent role, whether or not a concrete risk has ultimately been defined.

There was some uncertainty over who should ensure that risk management measures are better considered in relation to the risks that are identified. It is the remit of the notifiers to conduct the initial risk assessment, identify any risks, and submit an appropriate risk management strategy. However, if notifiers do not identify any risks, risk management measures will be limited to general surveillance, which has generally been the case to date. Indeed, one MS authority highlighted that risk management has not usually been addressed because the RA has not often identified a risk that requires risk management measures. However, some MS authorities said that EFSA should be doing more to ensure that mitigation measures are considered in the ERA.

³⁵ See "EFSA's role and activities" - http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178621456978.htm

Figure 4.13 Most MS authorities were not entirely satisfied with how well risk management strategies were being addressed in the ERA, whilst opinions amongst other consultees varied

“On a scale of 1 to 5 (where one is poor and five is excellent), to what extent do you think the way ERAs are currently conducted and assessed is achieving the objectives of an ERA to identify if there is a need for risk management and if so, the most appropriate methods to be used?”



EFSA, or the Competent Authority of the MS nominated to initially appraise the ERA, might identify a risk that was not identified by notifiers during its appraisal. Certain MS authorities would like EFSA to consider the options for managing such risks in more detail. EFSA however noted that there is a practical limit to the amount of detail that it can include, given the different ecological and agricultural structures throughout the EU. It believes that the general recommendations currently proposed are sufficient, and that MS authorities have the relevant expertise to better understand how best to specifically address the risks that have been identified within their borders.

4.5 The process, quantity and content of additional information requests have significant consequences for the efficiency and perceived characteristics of the risk assessment and its appraisal

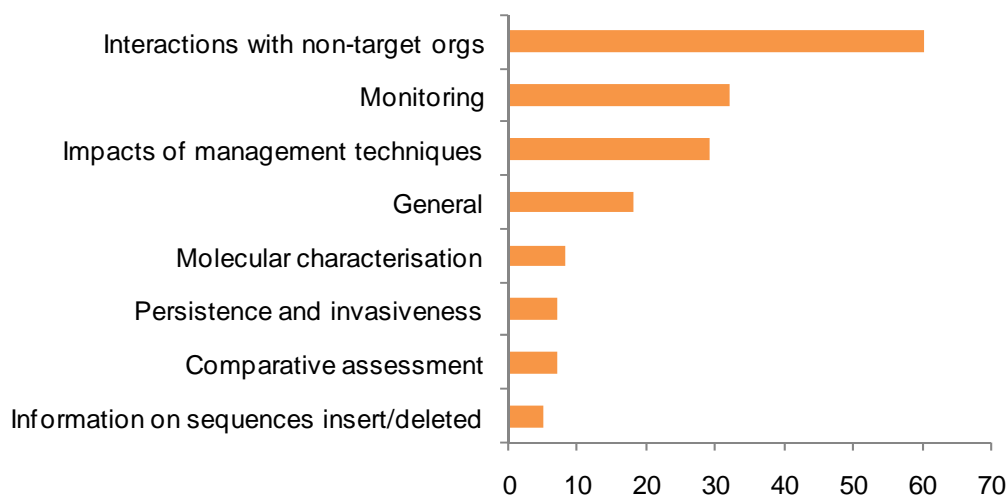
Requests for additional information reflect both on the process and the quality of the assessment. Some aspects have been touched upon already (section 4.3 and 4.4 above). There are issues with the number of requests, their content, and the process by which they are dealt with. These issues are also particularly relevant for applications whose uses only include food and feed under the Regulation³⁶. The following comments by consultees and data analysis however, apply specifically to applications for cultivation only.

EFSA has 6 months within which to conduct the appraisal of an application, however the clock is stopped when additional information is requested (either by EFSA or the Competent Authority of the MS conducting the initial appraisal). All applications to date have been stalled by requests for additional information. There is a current backlog of 13 applications, 9 of which are currently on hold due to requests for additional information. On average, an application receives 5 calls for additional information, each call containing several requests.

³⁶ A study has been commissioned by DG SANCO which is to look solely at the Regulation (EC) No 1829/2003 as it relates to food and feed

Figure 4.14 Requests for additional information are most often related to interactions with non-target organisms, monitoring and management techniques (i.e. herbicide treatment).

The main areas for which requests for additional information are made.



Source: Correspondence between EFSA, notifiers, and MS authorities on cultivation applications submitted since 2005 under the Regulation 1829/2003 (up until July 2009)

Some consultees, including a few MS authorities and environmental NGOs thought that the number of additional information requests reflects the poor quality of the applications. On the other hand, some notifiers believed that requests are to be expected regardless of the quality of the submission, due to the scientific nature of the process. The content varies somewhat in terms of the amount of further information required and what the information pertains to (see Figure 4.14), which reflects where the quality of dossiers is perhaps lacking the most. Notably, this relates to the interactions with non-target organisms, monitoring and the impacts of changes in agricultural management techniques (i.e. herbicide treatments).

Whilst some requests only require improvements to the structure of the dossier or a clearer presentation of reasoning, other requests require the notifier to submit additional data, and sometimes to conduct further studies, which can cause significant delays. However, such requests are often qualified with a statement that additional data are only required if notifiers cannot clarify why the data that have already been submitted are representative of, or comparable to, the situation in the EU. Substantiating the reasons for submitting certain evidence, and better explaining the basis for the conclusions that are reached are two areas where notifiers could improve which would have immediate effect. Thus, some MS authorities thought that sometimes it is not the actual evidence, but the clarification supporting the evidence, that is lacking.

A further MS authority highlighted that they sometimes have to request data from field trials that they know have been completed in the EU but whose data were not submitted. It was noted, however, that this was more a reflection of the inefficiency of the process than a reflection of the quality of the submission as the field trials were completed while the appraisal of the dossier was ongoing. There is perhaps scope here for notifiers to make better use of their ability to submit information spontaneously, rather than wait for a request to be made. If relevant field trials are completed in the EU whilst the appraisal is ongoing, delays would be reduced if notifiers submitted the data on their own initiative. So far, such unprompted information has only been submitted once on one application for cultivation under the Regulation.

EFSA and some MS authorities saw the quality of notifiers' responses as a key problem which led to further delays due to requests having to be reiterated. However, an analysis shows that, thus far, responses to only four of the requests have been judged unsatisfactory (on three applications), and led to a reiteration of the request. When discussing this further with EFSA, it was noted that this problem was perhaps more relevant for food and feed applications, and did not play as important a role with applications for cultivation.

Some consultees, including EFSA and some MS authorities, not only raised concerns with the quality of the notifiers' responses, but also the time taken for notifiers to reply. However, an analysis of the data showed that, whilst notifiers take on average 154 days to respond to a request, the average time taken for the clock to be restarted once a response was submitted was much greater, namely 274 days (see Figure 4.6 in section 4.3). Thus it seems the appraisal of the additional information, rather than its submission, is the greater source of delay.

This was reflected in the fact that many notifiers had more concerns with the process by which additional information requests were dealt with, rather than their number or their content. Part of the problem is the ambiguity about when the clock should restart. It was unclear to many, including some MS authorities, why the clock only restarts after the additional information has been assessed and deemed satisfactory, rather than immediately on receipt of the additional information. Given that the 6 month deadline is for the appraisal of the dossier, many notifiers and some MS authorities interviewed felt the deadline should also apply to the appraisal of the additional information which completes the dossier. EFSA highlighted that capacity constraints and procedures make this difficult, as the relevant Working Groups do not meet often enough, and the quantity of information submitted is generally too large to assess within the given time span.

Without a firm timeline, notifiers noted that the incentive to process the information quickly might not be sufficient. Options might include setting a more realistic overall time limit (i.e. longer than 6 months) but requiring that this include the appraisal of the additional information, or, alternatively, to have a separate timeline which would apply exclusively to the appraisal of the additional information.

A new concern has arisen for some MS authorities and notifiers, in that, in the interest of efficiency, EFSA has decided that a request for additional information will only be sent once. If the response from the notifier does not entirely satisfy the request, the appraisal will continue on the basis of the available information only. Thus notifiers are no longer able to request clarification, or submit further information following a reiteration of the request. Notifiers noted that it is not always clear exactly what information is required, or what the reasoning for the request is, and that this affects the information that is submitted. For its part, EFSA has undertaken to make requests much clearer, and ensure they are accompanied by a much better explanatory rationale, moves that EFSA hopes will address this concern.

Some MS authorities have also raised concerns about this new approach, saying that the quality of the ERA could be compromised in the interest of efficiency. Instead, they would rather ensure they have the information necessary to come to a reasoned opinion, even if this results in reiterations and delays.

4.6 The quality and quantity of the dialogue among consultees has far-reaching impacts, and has been identified as an area where improvements could and should be made.

Current shortcomings in the level of communication and cooperation are affecting both the process and the quality of the RA, as well as the confidence in the eventual outputs.

4.6.1 Communication between EFSA and MS authorities is well established but could be much improved, both in terms of communication with all MS authorities, as well as specifically with the Competent Authority of the MS which appraises the ERA.

For some, the 3 month window for consultation with MS authorities is not long enough and comments from MS authorities could be better managed

Once an application is validated, MS authorities have three months within which to comment on the dossier. The extent to which Member State authorities use this opportunity varies (see Figure 4.15). The inadequacy of this consultation period, both in terms of its length and its outputs, was raised as a key concern by some MS authorities.

Half of MS authorities who responded argued that the 3 months stipulated in the Regulation was too short a time period in which to sufficiently assess the dossier and submit their concerns. Several highlighted that the 3 month limit did not give them enough time to assess and comment on the additional information that is submitted by the applicant. On average, 70 days pass before the first request for additional information is made. By the time the applicant responds to that request, the deadline for MS authorities to submit their comments is usually over, without even considering the further additional information requests that so far have inevitably followed the first. A few MS authorities also believed that it would be helpful if they were able to officially comment on the final Opinion that is issued by EFSA. This could perhaps be achieved by EFSA issuing a draft which MS authorities could comment on before EFSA submits its final Opinion to the Commission.

The outputs of the consultation period, although improving, are also seen as inadequate by some MS authorities. EFSA now includes an Annex with every Opinion which shows the comments made by MS authorities and how EFSA addressed the concerns. Nonetheless, many Member State authorities still feel that EFSA is still not doing enough to deal with the concerns they raise; the majority of MS authorities were either somewhat dissatisfied or only somewhat satisfied. Only 3 were very satisfied. (see Figure 4.16). Although they are addressed in a transparent way, some MS authorities thought that EFSA’s responses were not detailed enough, and that they were sometimes addressed perfunctorily.

Figure 4.15 Opinion was almost evenly split between MS authorities who felt the 3 month window was sufficient, and those who thought it was not

“Member States are only consulted once by EFSA during the risk assessment procedure under Regulation 1829/2003, whereby national competent authorities have three months after the date of receiving the request within which to make their opinion known (Article 6(4), Article 18(4)). Does this arrangement provide sufficient opportunity to engage in and provide input to the assessment?”

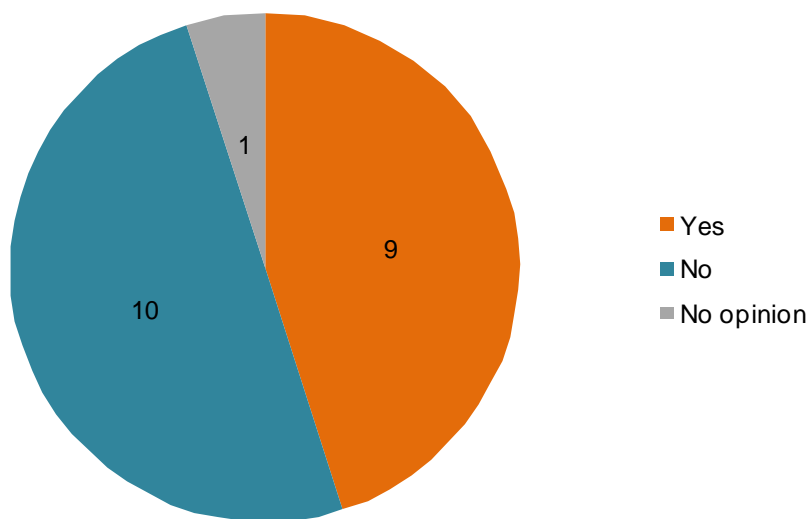
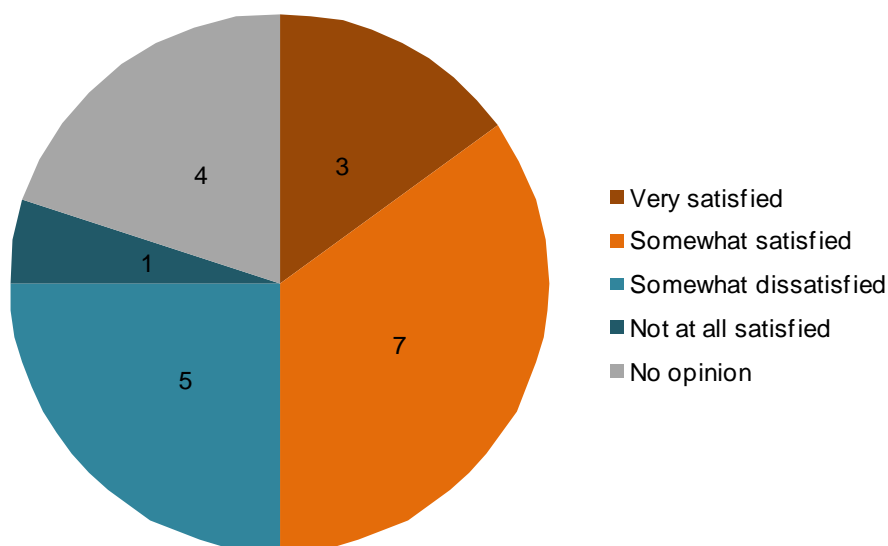


Figure 4.16 Opinion between MS authorities varied widely on whether their comments are adequately dealt with by EFSA

“How satisfied are you with the way your comments are dealt with by EFSA (the process by which they are received, examined, and responded to, as well as the responses)?”



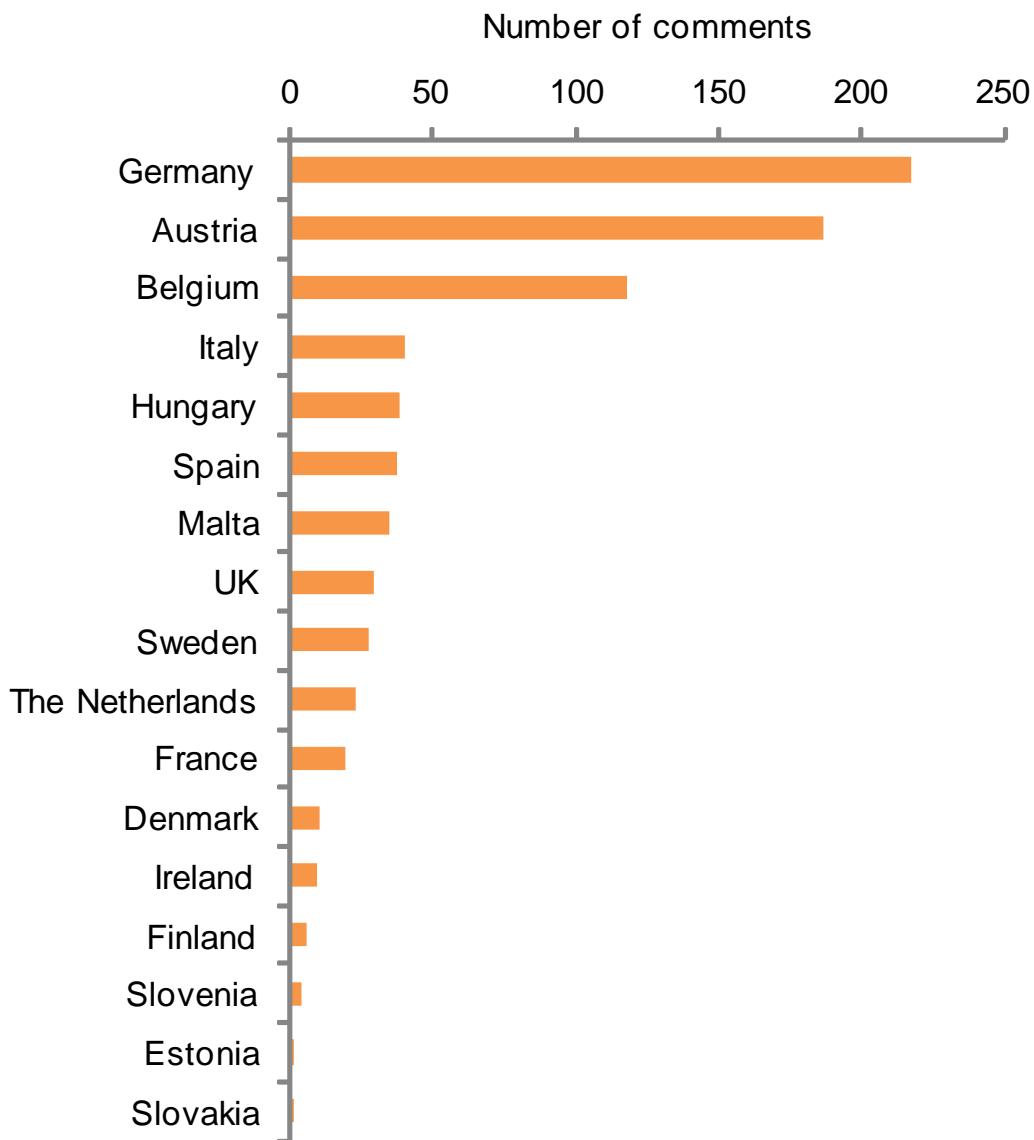
A total of 53 comments were made on the application for maize NK603, of which 34% led, or were related to, additional information requests. However, 11% of the comments were considered outside EFSA’s remit. As no other opinions for a novel product have been issued for cultivation, it is as yet unclear what EFSA’s response will be to the comments that have been made on applications currently in the pipeline. Nonetheless, it is clear that the similar comments are made time and again, with some aspects being of greater concern than others (see Figure 4.18). When we asked some MS authorities why they continue to make the same comments on different applications, we were told that EFSA had not sufficiently addressed their concerns the first time they made the comment, and so they concluded that they have to submit the comments again.

This reiteration is inefficient. One way of avoiding it could be to have more bilateral meetings between EFSA and Member State authorities. The overwhelming majority of MS authorities (18 of those who responded) thought more of these would be beneficial, though some highlighted that they need to be very focused and well-planned in advance in order to be useful. So far, few bilateral meetings to discuss substantive scientific divergences have been held under Article 30 of Regulation 178/2002. Bilateral meetings have been held with the relevant authorities of every MS that has implemented a national safeguard measure. Of the MS authorities we were able to speak to about these meetings, many felt that the outcomes were not entirely satisfactory. Some thought that the lack of sufficient time and inadequate preparation affected the productivity and usefulness of the meeting. Others also noted that in some cases it might just not be possible to reach an agreement, and that participants had to ‘agree to disagree’.

Many MS authorities argued that both EFSA and MS authorities should take more responsibility for identifying when there is a need to hold a bilateral meeting, and for ensuring that the meetings are well planned and beneficial to the participants.

Figure 4.17 There is a significant variation between MS authorities in the number of comments submitted on applications for cultivation, with Germany and Austria submitted the most comments on average

Number of comments submitted by MS authorities on applications for cultivation under the Regulation since 2005



Source: Correspondence between EFSA, notifiers, and MS authorities on cultivation applications submitted since 2005 under the Regulation 1829/2003 (up until July 2009)

Figure 4.18 Although a significant number of comments submitted by MS authorities are of a general nature, most focus on monitoring. Comments on interactions with non-target organisms also play a prominent role.

The subject of comments submitted by MS authorities on applications for cultivation under the Regulation since 2005



Source: Correspondence between EFSA, notifiers, and MS authorities on cultivation applications submitted since 2005 under the Regulation 1829/2003 (up until July 2009)

Communication between EFSA and the Competent Authority of the MS nominated to assess the ERA is good but MS authorities see some areas for further improvement

EFSA has three meetings with the Competent Authority of every MS that is nominated to assess an ERA. Many MS authorities were satisfied with the outcomes of these meetings and the support that they receive from EFSA during the ERA. However, some noted there is scope for improvement in the way that the additional information requests from MS authorities are dealt with by EFSA. At the moment, in order to best respect the competence and expertise of the MS authorities, EFSA acts only as a 'post-box', passing along the additional information requests from the MS authority to the notifier.

Some MS authorities have noted that some feedback and coordination with EFSA on additional information requests would be useful and make the process more efficient. If MS authorities and EFSA could work together, and coordinate additional information requests better, notifiers could receive fewer sets of requests. EFSA highlighted that this cooperative approach was attempted on a few initial applications, and the process did not work very well as some MS authorities felt that EFSA was interfering with their requests. Nonetheless, given the right approach, there is an opportunity here to improve the dialogue between MS authorities and EFSA, build on previous experience, and increase the efficiency of the RA process.

Some MS authorities also noted that more dialogue and coordination would be useful between MS authorities who have assessed ERAs in the past, and those who are in the process of assessing ERAs for cultivation applications. Others judged that the support they get from EFSA was sufficient. Nonetheless the sharing of experience might be useful in increasing the consistency and confidence of MS authorities in the RA process.

4.6.2 Notifiers thought communication with EFSA and MS authorities could be much improved

Notifiers suggested that the current arms-length approach adopted by EFSA, although understandable, could be replaced by a more interactive approach without compromising EFSA's independence and objectivity. Notifiers are able to discuss their application with the secretarial GMO Unit and EFSA's scientific officers are available for direct phone contact. However, notifiers have no direct contact with the experts on the GMO Panel who assess the scientific aspects of their applications. Given the complex nature of the applications, notifiers thought that significant efficiency gains could be achieved through occasional direct contact rather than a laborious process of waiting months for written responses on aspects that could very easily and very quickly be clarified over the phone. Nonetheless, they understood the need for traceability and accountability.

EFSA noted that the GMO Unit holds annual meetings which bring together notifiers and the GMO Panel, and which provide notifiers with an opportunity to sit down in the afternoon with the relevant experts and discuss their applications. Notifiers commented that this process is not regular enough, and that the time available within which to discuss the applications is insufficient.

Both the notifiers and some MS authorities stated that occasional direct contact between the Competent Authority of the nominated MS and the notifier could be beneficial. Currently all correspondence goes through EFSA. MS authorities did note that the initiative should come from the risk assessors, and not from the notifiers.

The majority of notifiers also suggested that pre-application discussions would be very helpful. These would be similar to those which used to take place under Directive 2001/18/EC with rapporteur MSs. EFSA raised concerns that these might duplicate the current process whereby an application is validated. Some notifiers suggested that the pre-application discussion could be held as soon as the decision was made to apply for cultivation approval. Given the strict case-by-case approach, they suggested it would be useful to be able to discuss what risk assessors considered might be applicable given the characteristics of the product, so that the appropriate studies could be planned and the

necessary evidence collected. EFSA was concerned with the additional burden this would place on already limited resources, for something that would not necessarily be beneficial.

Overall, greater communication between notifiers and assessors could potentially improve the quality of the dossiers that are submitted, as notifiers would understand better what is expected of them and could plan ahead accordingly rather than having to retroactively address concerns that are raised. More dialogue, which would reduce the scope for ambiguities and misunderstandings, could also increase the efficiency of the appraisal if some concerns were clarified or resolved directly. Nonetheless there is a balance to be struck between these gains, and the effect that more direct dialogue could have on the independence and objectivity of the ERA (perceived or otherwise).

4.7 Notifiers consistently choosing to use the Regulation instead of the Directive has potential impacts on the process and characteristics of the risk assessment

Since the Regulation came into force, notifiers have chosen to use its 'one door, one key' facility instead of the Directive for cultivation applications. The views of consultees vary on what impact this choice has. There are potential impacts on efficiency, communication, and the ERA. A key difference is the role of EFSA.

4.7.1 Most consultees, especially notifiers, believe the Regulation is an improvement on the process under Directive

Notifiers prefer to use the Regulation because it is simpler and more efficient to submit one application which covers all uses rather than to submit two dossiers separately. Other attractions are that the process under the Regulation is centralised and that an independent body, EFSA, plays a pivotal role - which should allow for the appraisals to be more standardised.

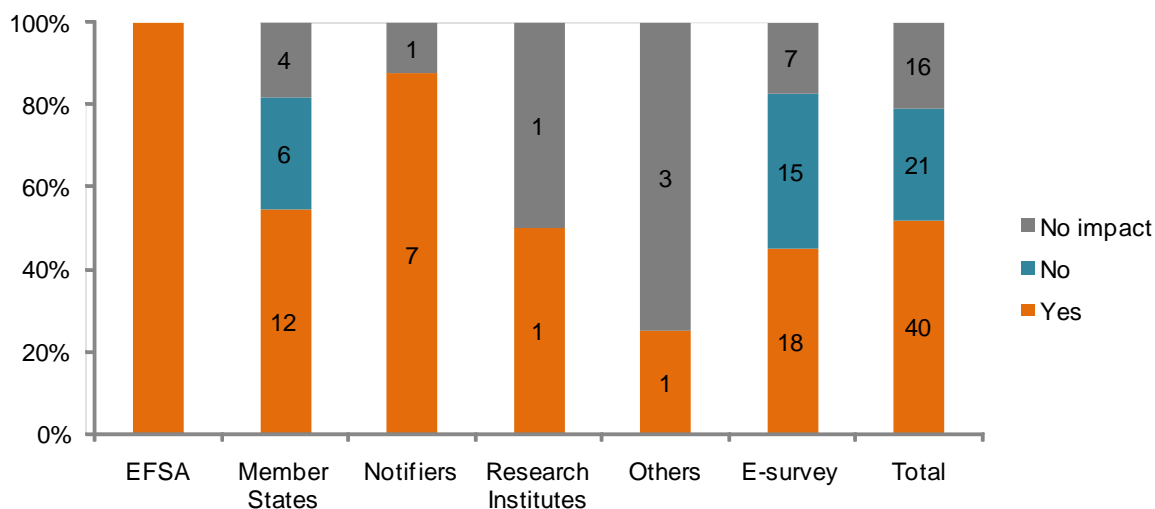
The only aspect that notifiers thought to be better under the Directive was the quality of the dialogue with the rapporteur MS. The ability to communicate directly with the MS authority on the scientific and the administrative aspects of the application was thought to be very beneficial. Nonetheless, the overwhelming majority of notifiers suggested that the procedure under the Regulation improves on the process under the Directive, in that the efficiency gains of a centralised process outweighed the benefits of having better communication during the assessment and its appraisal. Some notifiers therefore suggested that the process under the Directive (but not its requirements) has become somewhat redundant.

Several MS authorities (12 of those who responded) and EFSA also thought that the Regulation improves on the Directive but others did not (see Figure 4.19). Most significantly, MS authorities raised the same issue as notifiers, i.e. that the ability to comment on the assessment was much better under the Directive. The different provisions for engagement significantly affected their ability to contribute to the appraisal. Contrary to the notifiers, this did lead some MS authorities to question whether the Regulation's process did in fact improve on the Directive's. Besides the different timelines for consultation on the appraisal³⁷, many MS authorities were also not entirely satisfied with the way their comments were dealt with by EFSA (see section 4.6.2 above).

³⁷ Under the Regulation, MSs have a three month window within which to submit comments on a dossier once it has been validated. Under the Directive's Article 15, MSs also have three months within which to submit comments or reasoned objections from the date of circulation of the report. In total however, MSs and the Commission have 105 days from the date of circulation in which to discuss any outstanding issues

Figure 4.19 Most consultees felt that using the Regulation is an improvement on the Directive

“Does the “one door, one key” option available under Regulation 1829/2003 improve on the process available under Directive 2001/18EC?”



4.7.2 The choice between the Regulation and the Directive has theoretical implications for the role of the JRC in the validation of detection methods

There is a discrepancy between the Regulation and the Directive concerning appointment of the Joint Research Centre (JRC) as the Community Reference Laboratory for the validation of detection methods in the appraisal of a GMO. Whilst the JRC is mentioned in the Regulation (e.g. Article 32), there are no such provisions in the Directive. Consequently the JRC has no legal basis under the Directive to receive payment by the notifiers, and has to carry the costs itself for applications submitted under the Directive. The JRC is also unable to request additional information from the notifiers if they feel information in the dossier is insufficient. The JRC’s role thus far on products both pending authorisation and having been authorised under the Directive has been ad hoc and a ‘good-will’ basis. One MS authorities commented that the process under the Regulation, by formalising the role of the JRC and the validation of detection methods, improves on the Directive’s process.

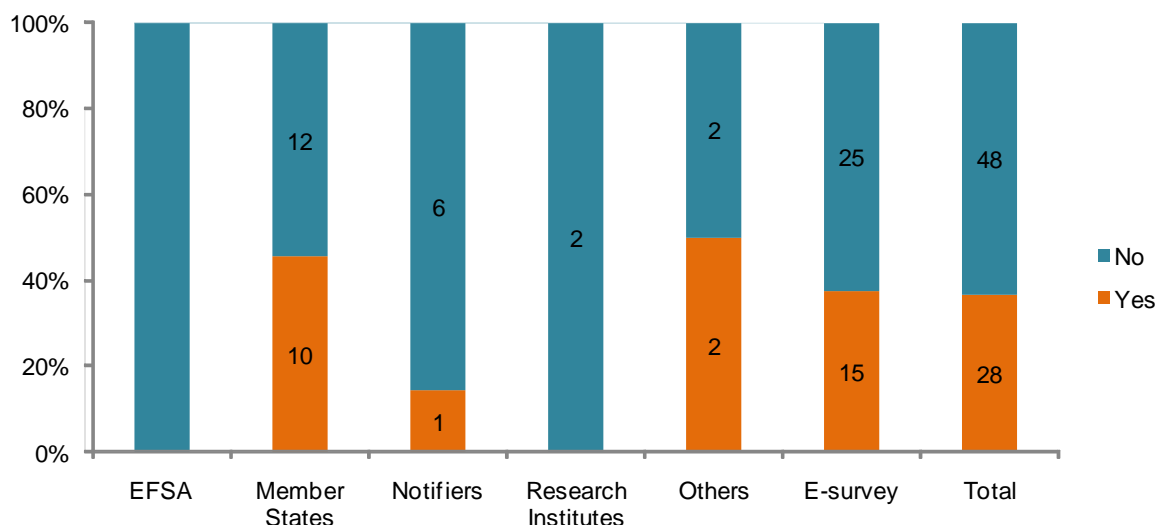
In practice, this inconsistency is likely to become less significant over time as all applications for cultivation have been submitted under the Regulation since 2005. Notifiers who did comment on this inconsistency especially believed the point was largely moot, given that there is a food or feed component to nearly all GM plant approvals, which requires approval under the Regulation. Nonetheless, products for import whose scope do not cover food and feed are still being submitted under the Directive (e.g. applications for the import of carnations Moonlite and Moonaqua were submitted respectively in December 2005, and as recently as October 2007).

4.7.3 The choice between Regulation and Directive has potential impacts on the characteristics of the ERA through its influence on who is involved in its appraisal, and how

When an application for cultivation is submitted under the Regulation’s ‘one door, one key’ facility, the ERA requirements of the Directive must be applied, so in principle the choice of authorisation channel should have no impact on the ERA. All notifiers agreed that in practice this is indeed the case. However, other consultees, including many Member State authorities (10 of 22), did feel the choice impacted on the ERA (see Figure 4.20).

Figure 4.20 Although most consultees did not believe that the using the Regulation’s ‘one door, one key’ facility has an impact on the ERA, almost half of MS authorities did believe there was an impact

“Does the “one door, one key” option available under Regulation 1829/200 impact on the quality or the outcome of the ERA assessment?”



The choice of the Regulation over the Directive can potentially affect the quality and outcome of the ERA through that decision’s impact on:

- the extent to which Member State authorities are able to engage with the process;
- the identity of the Member State Competent Authority assessing the dossier; and
- the extent to which EFSA is engaged in the process.

Many of the MS authorities who were interviewed think their scope to engage with the assessment’s appraisal was greater under the Directive

As mentioned in the previous section, many of the MS authorities who were interviewed are concerned that their ability to engage with the appraisal has been somewhat curtailed under the Regulation. If MS authorities are not able to sufficiently comment on the dossiers, and if their comments are not adequately taken into account, then an opportunity is missed to share knowledge and improve the ERA.

Under the Regulation the notifier does not have control over which MS conducts the appraisal, but the MSs who appraised the assessment under the Directive and those which appraise the ERA under the Regulation are similar

Under the Directive, the appraisal of a risk assessment is completed by the MS authority in which the notifier chooses to submit the application. The notifier therefore has control over who assesses their application. Under the Regulation, however, EFSA selects a MS authority from those which volunteer (one of the Competent Authorities designated under Directive 2001/18/EC). Given that MS authorities are not necessarily consistent in their appraisals of the ERAs (see section 4.4.2), and that their expertise varies, these differences could, in principle, impact the ERA. In practice however, the MS which appraised applications under the Directive are similar to those under the Regulation, so the impact here is, so far, limited. If more MS authorities were to volunteer however, it is possible that a wider sample of MSs would be able to assess the applications which might increase the collective knowledge base on which the ERAs are assessed. Alternatively, it might increase the diversity in their judgements.

EFSA has a more active role under the Regulation

EFSA plays a much more important role under the Regulation than under the Directive. The capacity and expertise of EFSA (see section 4.3.1), could thus impact on the conduct of the ERA. As mentioned in section 4.4.2, some have questioned whether EFSA (and indeed the Competent Authority of any individual Member State), can sufficiently take particular regional aspects into account given the different environmental conditions in different MSs.

4.8 The benefits of clarifying guidance need to be balanced with the practical consequences of ‘changing the rules’ and pressure for retroactive application of new standards

EFSA has produced a guidance document for the risk assessment of GMOs. This was originally adopted in 2004, updated in 2006 and then again updated in 2008 for Food and Feed. EFSA’s guidance has an effect both on the efficiency of the process and on the conduct of the ERA. If the guidance is clear and comprehensive, then this should positively impact on the quality of the dossier. If the quality of the dossier is high, then there is less need to request additional information, which means the clock will not be stopped and the appraisal will be completed in a timely manner. The Commission also has a legal basis for developing guidance, in that it can complement technical Annexes through guidance.

As such the quality of the guidance plays a significant role in affecting the RA. Throughout the consultation process, improving and expanding the guidance was seen as a key means for addressing many of the administrative and scientific shortcomings which consultees saw in the RA. Indeed, in March 2008, EFSA received a mandate from the Commission to further develop and update its guidelines as regards the ERA of GMOs, to consider in detail:

- the potential effects on non-target organisms;
- the development of criteria for field trials to assess the potential ecological effects;
- the identification of EU geographic areas where GM plants may be released;
- the selection of techniques to assess potential long term effects, including experimental and theoretical methodologies, and recommendations for establishing relevant baseline information.

Although many of those consulted saw merit in EFSA accepting the mandate, they highlighted several auxiliary risks which need to be considered. Most importantly perhaps are the mixed messages and misinterpretations resulting from this mandate.

All the aspects which the mandate is meant to address are already covered in the legal requirements and current guidance. Thus EFSA’s purpose for accepting the mandate is merely to further elaborate on the existing guidance, in order to improve transparency and clarify certain aspects so as to make it clearer to applicants what is expected of them and therefore to improve both the quality and efficiency of the RA.

Notifiers also indicated that the clarity of the guidance was not entirely satisfactory, and some expressed the concern that ambiguity in the guidance meant that the requirements were interpreted differently by different MS authorities. This creates a problem of “moving targets” which makes the appraisal of the risk assessment unpredictable. Thus all parties seem to think the aspiration of clarifying the guidance is worthwhile in principle.

In practice however, by accepting this mandate which addresses requirements stipulated in the existing legal framework and guidance, some environmental NGOs have interpreted this as evidence that EFSA is currently not meeting its legal requirements. They are thus calling for all opinions to be put on hold until the updated guidance has been completed.

Under the legislative framework, EFSA is authorised to continue its appraisals of dossiers and adopt Opinions on these regardless of whether the guidance is in the process of being updated.

There is a fine line then between what EFSA is aiming to do, and what some consultees perceive. On the one hand, EFSA is hoping to enable notifiers to improve what they are already doing, which is submitting dossiers which meet the requirements of the legislation and the guidance. At the moment the dossiers are entirely satisfactory only after requests for clarification, structural improvements or additional information are made, but eventually they are considered satisfactory. Conversely, some consultees such as environmental NGOs perceive that the need to change the guidance means that the dossiers that have been submitted are not satisfactory, neither at the point of submission, nor at the point of the final Opinion.

As a result of this latter perception, many notifiers are concerned that the updated guidance will have retroactive effects on applications which have already been and are currently being assessed. Although EFSA have said that they will not require past applications to be re-assessed, this does not preclude certain MS authorities from voting against the products in the decision making phase on the basis of them having been assessed under the old guidance. Thus in practice, some notifiers are concerned that the products might require re-assessment to be authorised.

Similarly, updating the guidance might negatively impact on the confidence in the RA. Already consultees feel that confidence is lacking and that this is one of the potential reasons for the current stalemate. Given the mixed messages involved with updating the guidance, there is a concern from a few MS authorities and notifiers that updating the guidance might contribute to that situation.

All of the above concerns mean that although there are benefits in improving the guidance in principle, there are also costs. Some MS authorities and notifiers agreed that there might be other, less controversial, means through which to clarify expectations and improve the dossiers submitted by notifiers. One possibility would be to simply improve communication and cooperation between the assessors and the notifiers. One MS authority said that giving positive feedback on dossiers which were of a high quality or sharing examples of best practice might be beneficial.

Nonetheless, some MS authorities, pointed out that some actors will always attempt to find reasons to criticise the RA process and that there are other reasons besides concerns with the guidance for the voting behaviour of some MS authorities. Consequently, this should not preclude the improvement of the guidance, which many felt was necessary.

Many MS authorities did however note that there was a balance to be struck between clarity and flexibility. Some were concerned that there was a danger that by clarifying some aspects, the guidance might become too prescriptive. Others noted that the guidance is already not sufficiently flexible, being too tailored towards herbicide tolerant and insect resistant traits, and does not provide enough flexibility to deal with other traits such as the altered composition in the two potatoes (EH92-527-1 and AV43-6-G7). Indeed, one MS authority suggested that the guidance should be legalised rather than continue being merely 'recommendations', which could decrease potential flexibility.

4.9 Summary: consultees' suggestions for improvement

Suggestions have been made by consultees to address some of the concerns raised above on the process and quality of ERA (i.e. that Competent Authorities of very few Member States are involved with ERA, the issue of regional variability, the lack of communication between Member State authorities and between Member State authorities and EFSA, and the slow speed of the process given the need for two appraisals of the ERA).

- **The possibility of a parallel rather than sequential appraisal of the ERA under the Regulation should be considered:** Notifiers suggested that in order to improve the process, the ERA could be appraised by the MS Competent Authority and EFSA in parallel, rather than sequentially. This would be predicated on good quality dialogue between EFSA and the Competent Authority of the nominated MS, in order to ensure the coordination of additional information requests (see section 4.5). Many MS authorities were open to this suggestion, as long as EFSA constructively engaged, rather than interfered, with MS authorities.
- **The way the risk assessments of stacked events are appraised could be improved to increase efficiency:** several suggestions were made by which this could be achieved, including - notifiers should submit applications for stacks only after the appraisals for the single events are complete; the risk assessments for the stacked events and the single events should be appraised in parallel as far as possible; and, to ensure as far as possible that the same MS authority appraises the single and the stacked events
- **EFSA should collaborate with organisations that have EU-wide environmental expertise during the appraisal of the ERA:** Some consultees suggested that EFSA should work more closely with European organisations that have explicit environmental expertise, such as the European Environmental Agency (EEA) or the European Centre for Nature Conservation (ECNC) as a means of reinforcing its capacity to assess environmental impacts. This could also allow for regional variability in environmental conditions to be better taken into account. In discussion EFSA expressed a willingness to cooperate more with such organisations, and the ECNC also expressed the view that it would be open to working with EFSA on certain aspects.
- **MS authorities should be financial compensated for the appraisal of an ERA:** Many MS authorities and some environmental NGOs argued that there should be a mechanism for compensating MS authorities for the cost of conducting the appraisal of the ERA, which was seen as highly resource intensive. It was suggested that the lack of such support could be seen as discriminating against those MS authorities who may wish to assess an ERA but are unable to do so because of resource constraints. Having more MS authorities involved would increase the knowledge base and allow regional variability to be better addressed.
- **The general resourcing of the system should be examined:** Resourcing emerged as a significant issue for consultees in two areas: lack of resources at Member State level as an obstacle to volunteering to conduct an appraisal of the ERA, and resourcing of the GMO panel at EFSA having an impact on the speed with which material could be processed.
- **MS authorities should be encouraged to co-lead on ERA appraisals:** Relevant prior experience is a criterion of EFSA's for being able to assess an ERA under the Regulation. One way of involving more MSs in appraisals, which would address this aspect (albeit not the lack of capacity) would be to encourage the Competent Authority of one MS to lead on an appraisal, but with other MS authorities supporting and learning from the appraisal. This would build experience and expertise and allow other MS authorities to become sufficiently confident enough to volunteer to assess future ERAs. Again, having more MS authorities involved would increase the knowledge base and allow regional variability to be better addressed.
- **Communication and coordination between all relevant parties needs to be improved:** Throughout the consultation, better communication and coordination between all parties (e.g. EFSA, Member State authorities, notifiers, environmental NGOs) was seen as a key means through which to improve both the process and the quality of the ERA.

- **Better account should be taken of regional variability in EFSA Opinions and conditions of consent:** several MS authorities and some environmental NGOs believed that the consideration of regional variability to date has not been adequate. A few MS authorities also pointed out that consideration of regional variation should be applied not only to ecological conditions, but also to the variability in agricultural systems.
- **Guidance could be improved, both in terms of content and clarity:** Several consultees (including some MS authorities, notifiers and environmental NGOs) highlighted the need for the guidance to be improved. MS authorities also suggested that guidance specifically aimed at how to appraise an environmental risk assessment, rather than just the current guidance on how to conduct an environmental risk assessment would be helpful for them. However, the benefit of improving the guidance needs to be weighed against the practical consequences of doing so (see section 4.8).

The above suggestions are meant to improve the existing system. However, other propositions were developed during the stakeholder consultations which were aimed at changing the system more significantly to better accommodate the concerns raised. These propositions centred around three options. A brief description of each of three options is given below, followed by a table (Table 4.2) of some potential advantages and disadvantages of each option. It should be noted that these options are speculative in nature and are not 'feasibility-tested'.

- **Option 1 – More MS authorities cooperate to assess the ERA**

- The Competent Authority of one Member State would take the main responsibility of conducting the ERA, supported by Competent Authorities of a number of other Member States either affected or likely to grow the GMO under application.
- EFSA would only undertake the scientific RA related to food / feed safety and molecular characterisation, and would no longer deal with the ERA.

This option takes the existing suggestion of several MS authorities cooperating on the ERA appraisal in the current system one step further, by removing EFSA from the ERA appraisal process. As such, the appraisal of the ERA would be somewhat similar to the old system under the Directive 2001/18, which many suggested had better opportunities for engagement and communication between MS authorities. EFSA could still issue an overall Opinion, based on its work and the ERA it receives from the combined effort of Member State Competent Authorities.

- **Option 2 – EFSA assesses the ERA**

- EFSA would be entirely responsible for the overall RA, including the ERA.
- Member State Competent Authorities would support EFSA during the appraisal of the ERA.
- The Competent Authority of one MS is no longer nominated to do the initial appraisal, but instead affected and interested MS authorities actively coordinate and support EFSA in its appraisal.

This option would require some form of obligation (instead of MS authorities just volunteering) for MS authorities to support EFSA.

- **Option 3 – MS authorities individually assess the ERA.**

This option presumes that there is national determination for decisions concerning the cultivation of GMOs.

- EFSA would provide an overall opinion on the RA (as now) but each MS would have the option to do its own appraisal of the ERA, tailored to its national and regional characteristics and concerns and use it for deciding whether to cultivate the GMO in their own border.
- MS authorities who do not have the capacity to do their own ERA could either collaborate with neighbouring MSs, or choose to use EFSA's opinion for their final decision.

Table 4.2 A selection of advantages and disadvantages for each option

Options	Potential advantages	Potential disadvantages
Option 1	<ul style="list-style-type: none"> • Better account of regional variability • More MS participation in RA could increase dialogue and confidence • Potentially more efficient • Difficulty in deciding how many and which MSs should be involved 	<ul style="list-style-type: none"> • Capacity of MS authorities could still be an issue • Depends on good quality communication and coordination between MS authorities • Could lead to substantial divergence
Option 2	<ul style="list-style-type: none"> • Better account of regional variability • Standardised appraisal of the risk assessment • Potentially more efficient 	<ul style="list-style-type: none"> • Burden on EFSA will increase • Depends on good quality dialogue between MS authorities and EFSA • Risk of concerns raised by MS authorities that their views are not sufficiently taken into account could still remain
Option 3	<ul style="list-style-type: none"> • Better account of regional variability • Might avoid the issues of divergences in opinion 	<ul style="list-style-type: none"> • Lack of capacity in smaller MSs • Could affect effective functioning of the single market • Ecological/environmental impacts do not respect political boundaries, which could lead to cross-border issues due to divergent views

5 IMPLEMENTATION OF THE PART B OF DIRECTIVE 2001/18/EC GOVERNING FIELD TRIALS OF GMOS

This chapter³⁸ examines the extent to which the Part B provisions and their implementation by the Member State authorities have affected the risk assessment and authorisation procedure of GMOs for later commercial use, and whether they have fulfilled the objectives of the legislation.

5.1 **Since 2006 the number of notifications for field trials in Europe has declined and trials are increasingly concentrated in a few MSs**

Publicly available information on GM field trials is effectively limited to the number of notifications submitted³⁹. Furthermore, the terms of a notification and the subsequent permit can differ significantly, from a one-year, small scale field trial at one location, to multi-year, large scale field trials at several locations. Field trials can also be held for a variety of purposes (e.g. to investigate agronomic parameters, assess the environmental, ecological or toxicological impacts, etc.) Not all field trials are therefore conducted for regulatory purposes, i.e. to support applications for later use. Little information is available on how many notifications actually lead to authorisations, how many authorisations actually lead to field trials which are completed, and how many of these are used to support later applications for cultivation. Although notifications therefore provide a very imprecise indication of actual field trial numbers, the information on which conclusions can be based is largely limited to the number of notifications.

The number of notifications for GM field trials rose throughout the 1990s to a peak in 1997 and then went into steep decline (see Figure 5.1). Numbers increased again slightly in 2002, and started to increase further in 2006. The increases seem to correspond to the Directive and the Regulation coming into force. However, the numbers remain far off the heights experienced in the mid to late 1990s, and have declined again since 2006. There are far fewer GM field trials in Europe than in the US (see Figure 5.2).

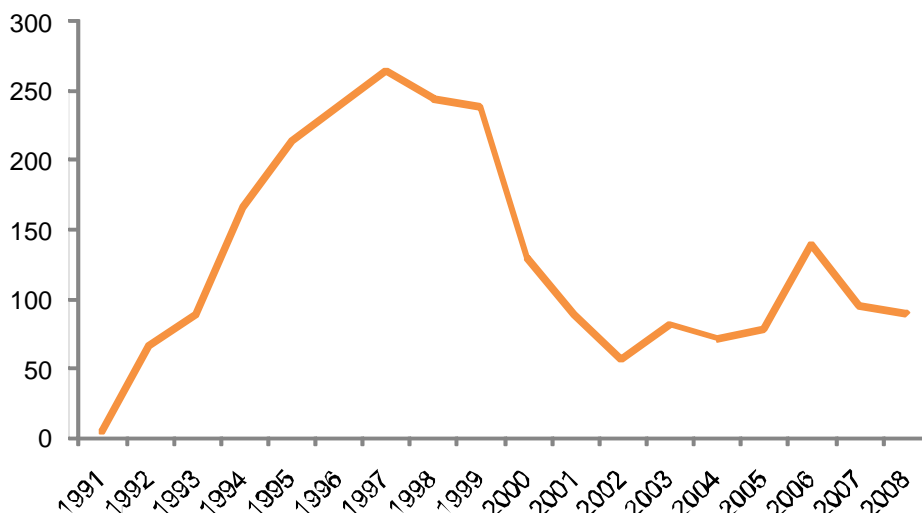
36% of all field trials notifications have been registered in Spain. France and Spain together account for 50% of field trial notifications to date (see Figure 5.3). Germany follows third, with 10%. However, the number of notifications in Germany and France has significantly declined following the implementation of national safeguard measures in both countries.

The consultation found that notifiers and some other consultees such as MS authorities and certain industry associations thought that difficulties in both obtaining approval for field trials (due to strict data requirements and conditions of consent) and in completing the field trials (due to a high level of field trial destruction) have had a negative impact on the biotechnology industry and the number of field trial notifications that are submitted in some MSs (see section 5.2 and 5.3 respectively). Given that field trial data from a range of regional conditions are required in support of applications for cultivation, many notifiers suggested that these difficulties will make it increasingly difficult to apply for authorisation to cultivate a GMO (see section 5.4.1). Some MS authorities disagreed with this premise. Many consultees however, including MS authorities, indicated that the uncertainty of the political context caused by a lack of cultivation authorisations creates a disincentive to invest in the research and development of new types in and for Europe (see section 5.4.2).

³⁸ This chapter on the implementation of Part B of Directive 2001/18 addresses Question 5 of the project terms of reference

³⁹ <http://gmoinfo.jrc.ec.europa.eu/>

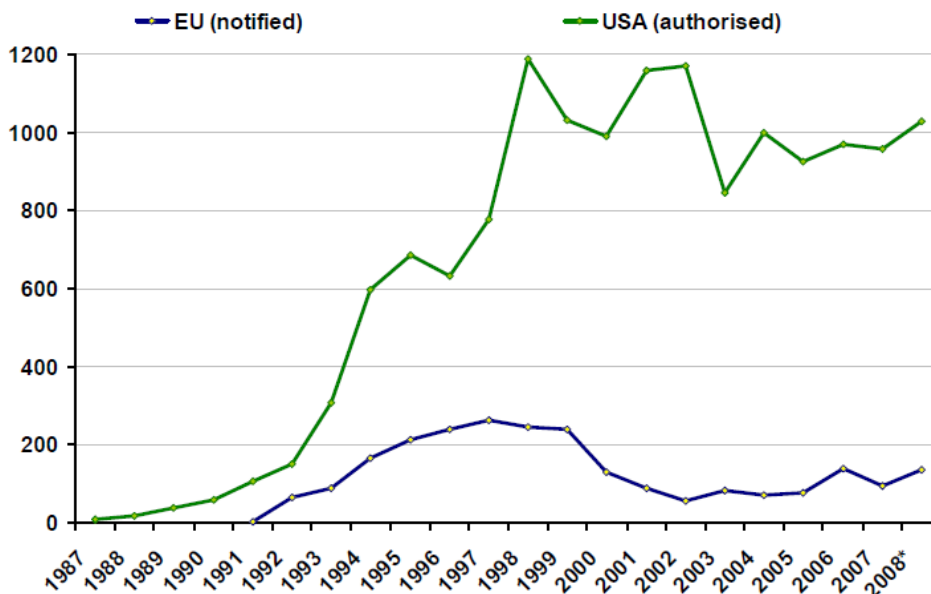
Figure 5.1 After a steep decline in 1998, the number of field trial notifications slightly increased after 2002 and increased further in 2006, but have declined since
Total number of annual field trial notifications submitted since 1991



Source: GHK analysis based on data at <http://mbg.jrc.ec.europa.eu/deliberate/dbcountries.asp> (up until September 2009). For Austria, Finland and Sweden data is not available before 1995 because the state did not yet belong to the EU

Figure 5.2 The number of field trials authorised in the US significantly exceeds the number of notifications submitted for field trials in the EU

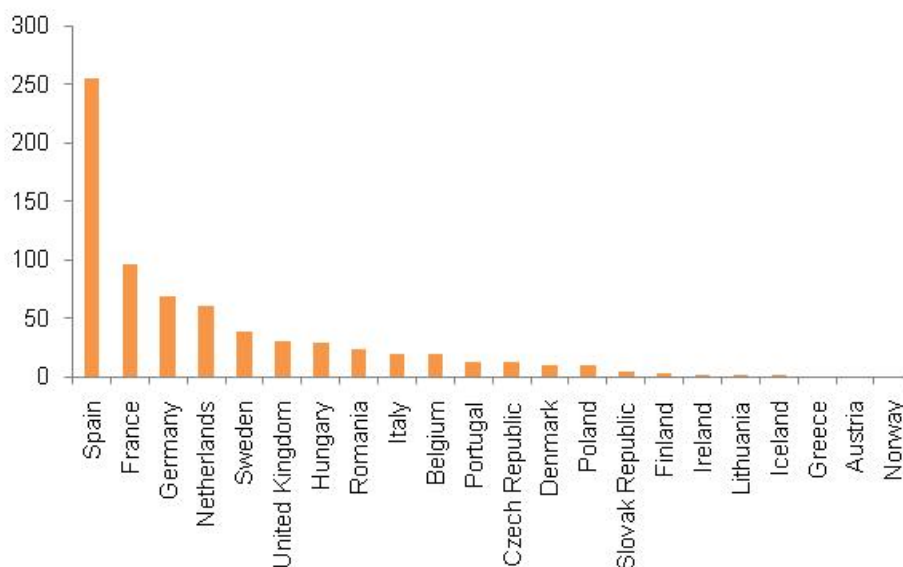
A comparison of the number of field trials authorised in the USA and the number of field trial notifications submitted in European countries



Source: APHIS data (ISB 2008) and JRC data (JRC 2008).
 Note: * Estimate for 2008 based on data for first term plus 50 percent.

Figure 5.3 Most field trial notifications in Europe are submitted in Spain.

Number of field trial notifications submitted in European countries between 2001 and 2008



Source: GHK analysis based on data at <http://mbg.jrc.ec.europa.eu/deliberate/dbcountries.asp> (up until September 2009). For Austria, Finland and Sweden data is not available before 1995 because the state did not yet belong to the EU

A report was recently prepared for the DG Environment of the European Commission on the management of field trials⁴⁰. Many issues raised by consultees on field trials during this consultation reflected similar issues to those found in that report, especially those issues covered in section 5.2, and the issue of field trial destruction covered in section 5.3. In the interest of limiting overlap, discussion on these aspects is kept to a minimum. Instead, this consultation attempted to build on the results of the previous report, especially with regard to the links between field trials and cultivation, which is discussed in section 5.4.

5.2 Notifiers believe that obtaining approvals of field trials is becoming increasingly difficult due to a combination of four factors

As in the report on the management of field trials, notifiers identified four factors during the consultation that were impacting on field trial authorisations– the timeliness of approvals; data requirement; conditions of consent; and, the use of non-scientific criteria.

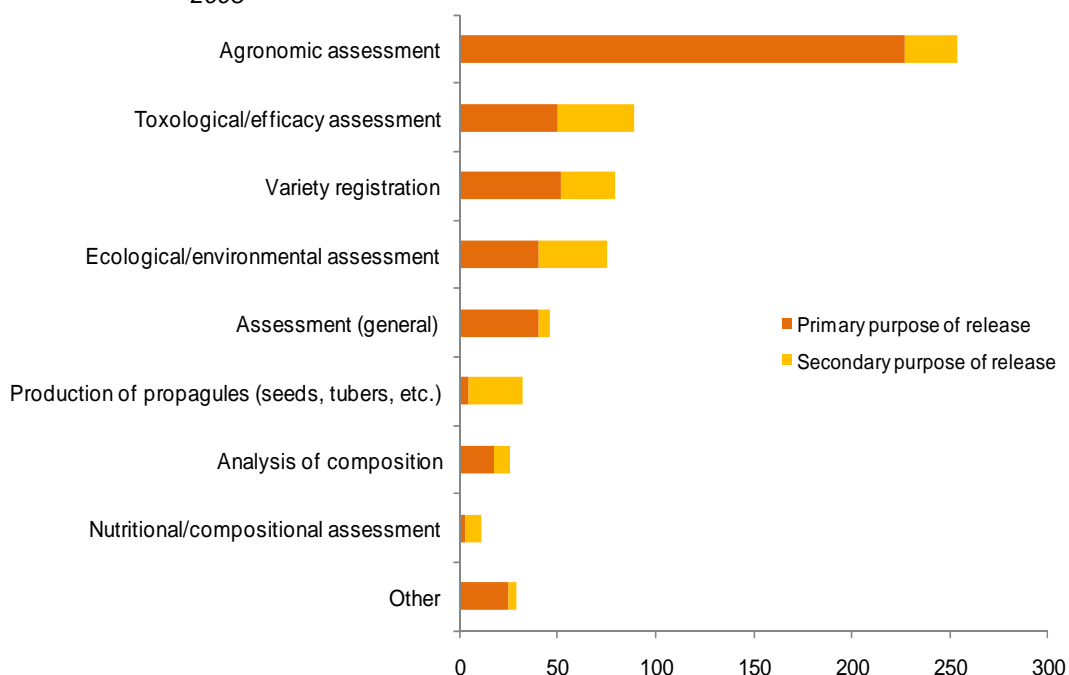
- **Timeliness of approvals:** In certain MSs, the growing season is missed because approvals are given too late.
- **Data requirements:** Notifiers are concerned that some MS authorities require an excessive amount of data to be included in applications for field trials.
- **Conditions of consent:** Conditions of consent vary between MSs, and can potentially place burdens on notifiers which can render field trials impractical. Some notifiers believed there were cases of excessive risk management measures that were not proportionate to the risk. On the other hand, if the field trial is intended to contribute to the risk assessment, then the putative risks would not be known prior to the conduct of the trial.

⁴⁰ CSL / SASA (2008). Analysis of field trial management in Member States and prevention of accidental entry into the marketplace. Available from: http://ec.europa.eu/environment/biotechnology/reports_com_stud.htm

Risk management measures are not the only conditions of consent. Hungary, for instance, is in the process of changing its legal framework for field trials to impose a compulsory condition of consent requiring that environmental effects are investigated at some point during the consent period. This is based on a view that data on the direct and indirect effects of GM plants on the environment is lacking. Many other MS authorities and other consultees also raised the dearth of environmental data as a concern. Some consultees, including other Member State authorities, expressed approval of a MS authority addressing this issue rather than leaving it up to notifiers. The evidence certainly supports the contention that notifiers submit far more notifications for agronomic purposes than for any other reason (see Figure 5.4).

Figure 5.4 The primary purpose of most field trials is agronomic assessment

Number of field trial notifications submitted in European countries between 2001 and 2008



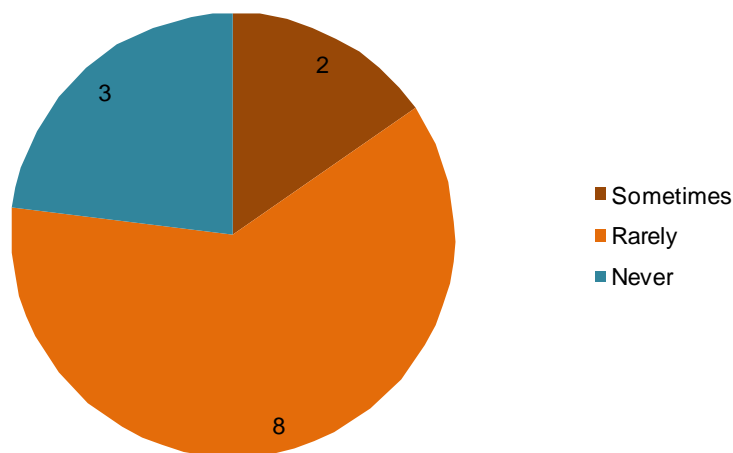
Source: GHK analysis based on data from Appendix 1 of the Report (2008) commissioned by DG Environment on the "Analysis of field trial management in Member States and prevention of accidental entry into the marketplace". Available from: http://ec.europa.eu/environment/biotechnology/reports_com_stud.htm

- **Use of non-scientific criteria:** A key issue raised in the previous report was the rejection of field trials by some MS authorities despite a favourable appraisal of the risk assessment. Although some MS authorities did note the potential use of non-scientific criteria when rejecting a field trial, this practice is seemingly not widespread.

Of the MS authorities who have received 10 or more notifications for field trials since the Directive came into force, the majority (about 60%) state that they rarely reject field trials (see Figure 5.5). An almost equal number of the remainder say they either sometimes or never reject field trials. The overwhelming reason given by MS authorities for rejecting a field trial is because the notification was incomplete and the notifier failed to provide the required additional information. MS authorities noted that notifiers are given the opportunity to improve their applications, hence rejections are unusual. In one MS, an applicant is usually informed at an early stage if the field trial is unlikely to meet safety requirements, so in most cases unsatisfactory notifications lead to withdrawals rather than rejections

Figure 5.5 Most MS authorities who have received more than 10 notifications under Part B of the Directive only rarely reject field trials

“How often have you rejected applications for a field trial?”



Although very few MS authorities indicated that rejections were made when the appraisal of the risk assessment was favourable, some reasons beside safety were given as a potential basis for a rejection. One MS authority noted that trial applications were rejected for political reasons in certain regions. Another noted that strong local opposition or economic reasons could also result in a rejection. One MS authority stated that it would reject a field trial with oilseed rape because of the economic implications of potential contamination. Overall, although this shows that rejections on the basis of non-scientific criteria can occur, results from the consultation indicate that the rejection of applications for reasons beyond science is not common practice.

5.3 Concerns about the conduct and completion of field trials focused on field trial destruction, the independence of the research, and the need for harmonisation

5.3.1 *Field trial destruction was raised as a consistent and increasing concern*

Vandalism was raised as a key issue in the previous report on field trials. Our research confirms that this is a significant concern for notifiers. This consultation attempted to build on the previous report by exploring the potential effects and extent of the problem, and what could be done to address it. Notifiers stated that the risk of vandalism is causing them to avoid holding field trials in certain countries, which potentially reduces the amount of regional variation in the data. Notifiers reported that the risk of vandalism was especially acute in countries where details of the specific location of field trials were published. They were concerned that the ruling in the European Court of Justice (ECJ)⁴¹ that details of the location of field trials must be made available, will mean that field trial destruction is likely to increase further. Some MS authorities also thought that the ECJ ruling would result in an increased occurrence of vandalism in their borders.

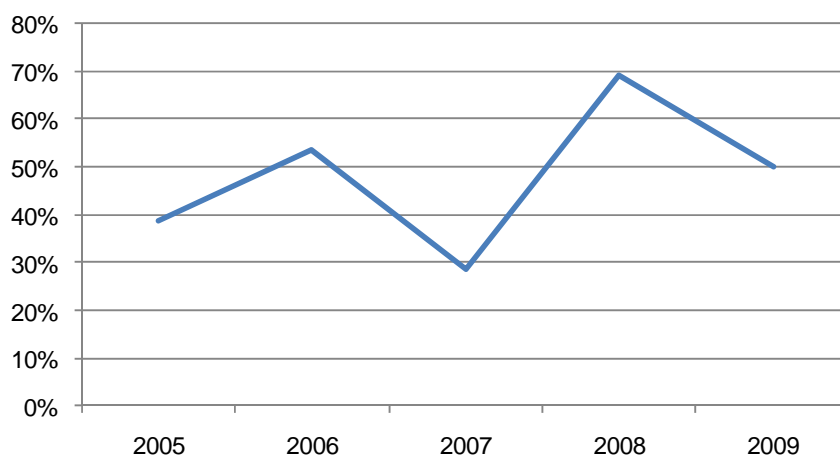
Other consultees, such as certain MS authorities and environmental NGOs, thought that field trial destruction was not as widespread as was being claimed. Data on the destruction

⁴¹ Preliminary ruling in Case C-552/07 on the 17th February, 2009: The 'location of release within the meaning of Article 25(4) of Directive 2001/18 is determined by all the information relating to the location of the release submitted by the notifier to the competent authorities of the Member State on whose territory that release is to take place in the context of the procedures referred to in Articles 6, 7, 8, 13, 17, 20 or 23 of that directive. The Court also said that an exception relating to the protection of public order or other interests protected by law cannot be relied on to oppose the disclosure of the information set out in Article 25(4) of Directive 2001/18.

of field trials were requested data from relevant MS authorities to resolve this issue but have so far been provided by only two MS authorities. Annually, the level of vandalism in France since 2009 has varied between 29% and 69% of sites (see Figure 5.6). The number of notifications submitted for field trials remained low but stable in France between 2005 and 2007 until the national safeguard measure was implemented in 2008. The number of actual field trials being conducted however has been steadily declining since 2005 (see Figure 5.7).

Figure 5.6 Annual vandalism of field trials in France has been between 29% and 69%

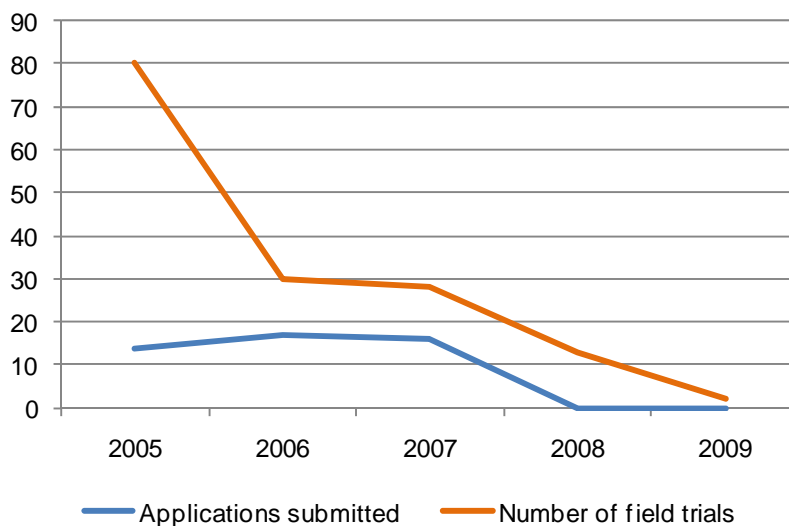
Annual percentage of field trials which are destroyed due to vandalism in France between 2005 and 2009



Source: GHK analysis based on data provided from the French Competent Authorities

Figure 5.7 Field trials notifications and numbers in France have been decreasing

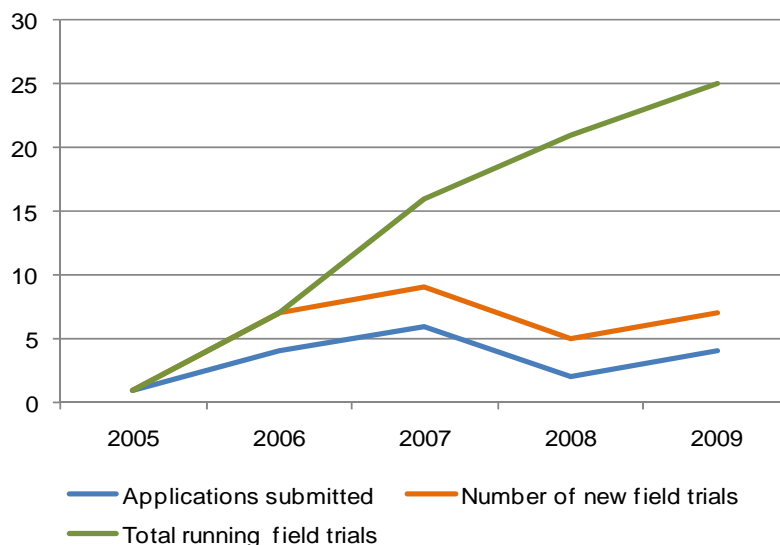
Field trials notifications and numbers of field trials being conducted in France between 2005 and 2009



Source: GHK analysis based on data provided from the French Competent Authorities

Figure 5.8 In Czech Republic, the number of field trials notifications has remained steady whilst the running total of field trials being conducted is steadily increasing

Field trials notifications and numbers of field trials being conducted in Czech Republic between 2005 and 2009



Source: GHK analysis based on data provided from the Czech Republic Competent Authorities

In the Czech Republic, a steady number of applications are being submitted each year and the number of running field trials is actually increasing (see Figure 5.8). There have been no cases where a complete field trial has been vandalised, although in 2007 and 2009 there was a case where a small part of a field trial was destroyed. Hungary has also not experienced any vandalism of field trials. Sweden has only experienced one case of vandalism since 1989.

Viewpoints varied between MS authorities, notifiers, and other consultees on what could and should be done to address the issue, and where the responsibility for doing so lies. The underlying issue is the need to balance transparency and with the freedom for approved research to be conducted without interference. Some MS authorities argued that the right to information was the most important consideration, and that limiting public access was not an acceptable way of counteracting vandalism. Other MS authorities suggested that detailed information should only be given to affected parties. Two MS authorities reported that exact location details are only released upon request, and in one of those a record is kept of those who requested the information. Some MS authorities felt that only general information is necessary, whilst another noted that the location of field trials should not be public at all in certain instances. Most MS authorities however judged that a balance was necessary, although some were unsure of how best to achieve this.

Notifiers called for better enforcement and prosecution when field trials are destroyed. Some MS authorities agreed with this, and noted that it should be made clear that field trial destruction is not an ‘act of self defence’. A few MS authorities suggested that the issue of field trial security should be a matter dealt with by the notifier, and that proper planning of the trial will prevent destruction. Some other MS authorities however did think that the Competent Authority can and should also play a role.

Several MS authorities highlighted that the solution lies in dealing with the underlying problem, namely the hostile attitude to GM research in some stakeholder groups. They noted that the ultimate goal should be to engage with, and improve communication to, the public.

5.3.2 Many consultees would like to see more independent research being conducted

During the interviews, some consultees including MS authorities and environmental NGOs raised the concern that independent research on the impacts of GMOs, especially on the environment, is lacking and that existing research is heavily biased towards that done by the notifiers themselves. Some thought independent research was partly being impeded by the unwillingness of companies to allow access to research material.

Notifiers highlighted two difficulties in increasing access to their research material. Firstly, given that some of the material has not been commercialised, commercial confidentiality could be compromised. Secondly, requests for access are sometimes not granted because of concerns about liability. Some notifiers noted that in the past, risk management measures were not properly followed by some organisations, for which the notifiers themselves were liable. To address these concerns of the notifiers, and simultaneously address the perceived need for more objectivity in the research that is conducted, some research is done in cooperation with other independent institutes. For instance, every field trial in the Czech Republic is conducted in association with other institutes.

Nonetheless, some MS authorities suggested that the two difficulties raised by notifiers could be overcome with the appropriate legal contracts, and that these reasons should not prevent research material being made more available to independent and reputable institutes.

5.3.3 Most MS authorities would like to see some harmonisation of the design, conduct and analysis of field trials, especially those held for regulatory purposes

An overwhelming majority of MS authorities argued that there is a need to better harmonise the way that field trials are designed, conducted and analysed (17 of those who responded agreed or strongly agreed that there is a need for more harmonisation). Most notifiers disagreed that further harmonisation is necessary (see Figure 5.9).

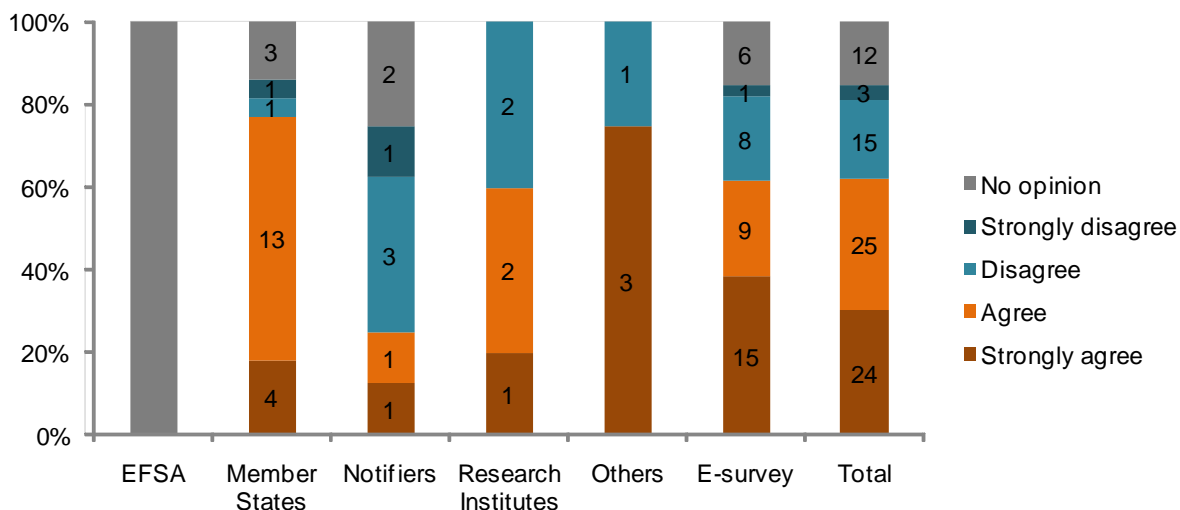
The main rationale put forward by MS authorities for further harmonisation was the need to standardise tests to produce statistically comparable results in different ecological conditions. Some MS authorities further suggested that currently the problem formulation and execution of some field trials are not statistically sound. MS authorities suggested that harmonisation is needed on aspects that include, *inter alia*, the confinement methods used, experimental design, statistical analysis, surveillance methods, reporting format and methodology for the results, problem formulation and which environments should be studied.

Several MS authorities noted that increased consistency could facilitate the ERA for subsequent market approvals, by making it easier to compare results from different MSs and to apply coherent risk management measures. However, some MS authorities highlighted that the objectives of field trials vary - some being conducted purely for research purposes with no other further agenda. Thus it seems that the focus of harmonisation efforts, as a MS priority, might be limited to field trials which are conducted to support an application for market release.

Interestingly, while some MS authorities argued that harmonisation was needed because of the variations in regional conditions, other MS authorities highlighted that harmonisation is not entirely feasible precisely because there are differences in ecological conditions across the EU.

Figure 5.9 Most MS authorities believed there is a need to harmonise the way field trials are designed, conducted and analysed, whilst most notifiers did not

“To what extent do you agree that there is a need to further harmonise the way in which field trials are designed, conducted and analysed across Member States?”



One MS authority noted that it should not be the obligation or prerogative of MS authorities to harmonise field trials, given that a case-by-case approach should be followed and that MS authorities are unlikely to come to an agreement on what data are necessary in a field trial notification. Nonetheless, many other MS authorities did make recommendations on how best to achieve greater consistency in field trials. These recommendations focused on:

- **Guidance:** the most common suggestion was to achieve consistency through the means of establishing EU guidance on the subject. One MS authority noted that the ongoing work on harmonising field trials for seed variety approvals provided an example of how consistency could be achieved. Despite many MS authorities highlighting the need for guidance, there was no clarification on how this guidance should be established. EFSA was unsure about whether it was appropriate for them to be involved in developing this guidance given that field trials are applied for, conducted and approved on a national basis, and are not always conducted for regulatory purposes. Nonetheless, some MS authorities did feel that EFSA would be the best body to develop appropriate guidance, especially if the harmonisation of field trials was restricted to those which were conducted in support of an application for market approval. For instance, EFSA has recently published an Opinion on the statistical considerations for the safety evaluation of GMOs, which details statistical guidelines and approaches for the analysis of compositional, agronomic and phenotypic data from field trials for the RA of GM plans and derived foods/feeds in order to ensure sufficient statistical power and estimation of natural variability.⁴²
- **Encourage MS authorities to implement existing principles:** Some MS authorities said the existing framework is sufficient, and that harmonisation could be achieved simply by encouraging MS authorities to implement the Directive and existing best practices as they stand. One MS authority noted that trials are already meant to be designed according to recommendations from European level scientific bodies/authorities (e.g. EFSA), and are conducted according to specific company/institute standard operating procedure and by observing good laboratory practices.

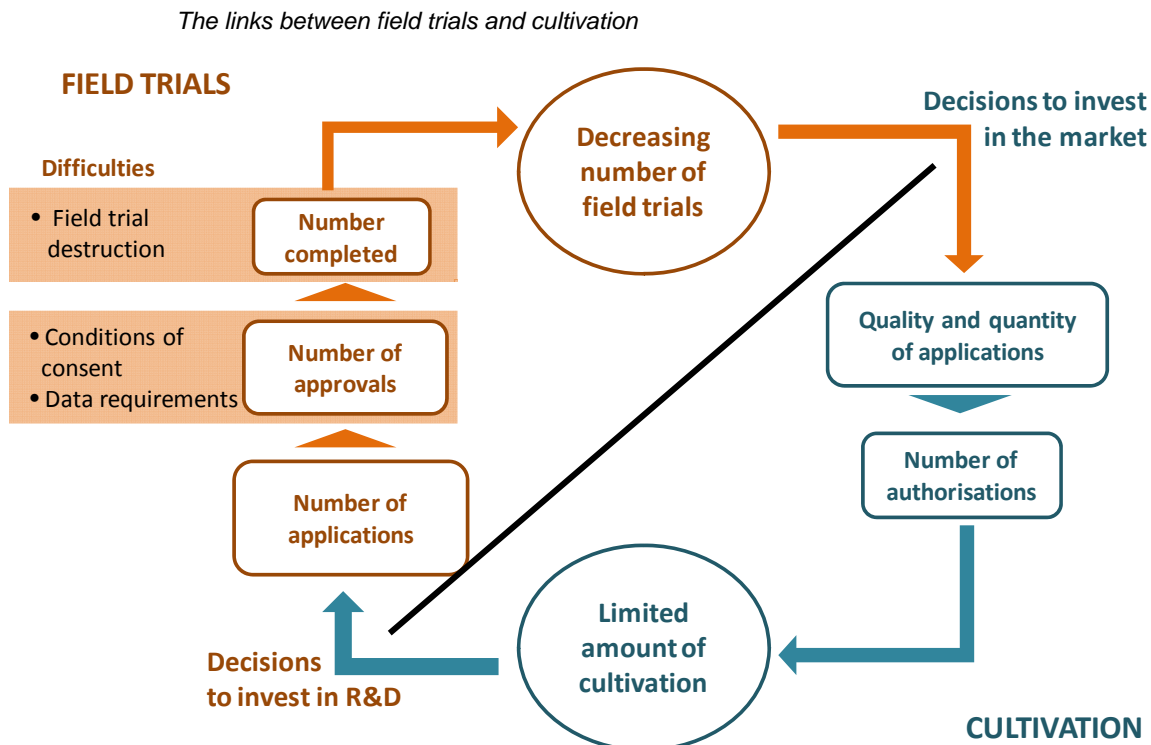
⁴² http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902768517.htm

- **Clarification of terms in the legislation:** Although it is the case that the Directive does detail some aspects of the requirements for field trials, some MS authorities highlighted that ambiguity in the semantics of the legislation are leading to inconsistencies. For instance, clarifying the meaning of “place of deliberate release”, given its importance for decision making and public participation, would be helpful. Furthermore, Recital 25 of the Directive states that before a GMO can be authorised for placing on the market, it must be subject to “satisfactory field testing at the research and development stage in ecosystems which could be affected by their use”. There is ambiguity in the interpretation of both “satisfactory” and “ecosystems which could be affected by their use”, e.g. whether the latter means all potential ecosystems or only a representative sample of the type of ecosystems that might be affected.
- **Better exchange of views:** Some MS authorities stated that there is no case for formal harmonisation but instead views and information could be exchanged between MS authorities in order to improve consistency and, potentially, to set best practice standards.

5.4 The links between field trials and cultivation have potential consequences for the future of GMOs in the EU

There is a feedback loop between field trials and cultivation (see Figure 5.10). The quantity and quality of field trials can potentially impact on the number of applications submitted for cultivation, whilst a lack of authorisations for cultivation could potentially reduce the incentive to invest in field trials to complete the necessary research in, and development of, new products for market authorisation.

Figure 5.10 There is a feedback loop between field trials and cultivation



Source: GHK Consulting Ltd

5.4.1 The quantity and quality of field trials being conducted has potential impacts on the quantity and quality of applications for cultivation

Both the quantity and the quality of field trials can impact on cultivation applications. Field trial numbers are declining (see Figure 5.1 above). The overwhelming majority of notifiers agreed that the difficulties they have with GM field trials are affecting the number of downstream marketing applications. MS authorities however were divided on the issue; whilst some agreed with the position of notifiers, most others did not see that the situation with field trials was affecting later applications (see Figure 5.11). Very few MS authorities thought that difficulties in obtaining approval in some MSs are having much impact on future applications, given that field trial data needs only to be representative, and is not required from every MS. Nonetheless, several MS authorities did agree that the threat of vandalism does have an impact on the product pipeline.

It was recognised however that getting approval and completing a successful field trial is costly and whilst it may not have a significant impact on the number of future applications submitted, the cost does impact on the type of companies which are able to submit an application. Thus the potential role for small or medium sized companies (SMEs) is curtailed, given that they do not have the requisite amount of resources. Nonetheless, the cost associated with conducting field trials is merely one of several factors which are impacting on the ability of SMEs to participate in the GMO arena, not least of which are the broader regulatory costs and uncertainty of the political context (discussed further below).

It might also be expected that the quality of the field trials will affect the quality of the marketing application dossier that is eventually submitted. If the quality of the evidence is unsatisfactory, it is less likely that EFSA will give a favourable opinion, or that MS authorities will vote in favour of the product being authorised. However, one MS authority did note that decisions on cultivation in EU are made only partially on the evidence from relevant field trials. Whilst EFSA took the view that quality of the data gathered from field trials is very often sufficient to support market authorisation, only 3 MS authorities agreed. Indeed, most of the MS authorities (11 of 20 those who responded) judged that field trials only sometimes provide adequate evidence for subsequent authorisations for cultivation (see Figure 5.12) – there being inconsistencies and a lack of information on the ecological effects across the biogeographical regions of the EU.

Figure 5.11 Opinions within MS authorities vary on whether the number of field trials being conducted affects the number of applications submitted for cultivation, whilst most notifiers think there is an impact

“To what extent do you agree that the current operation of Part B of Directive 2001/18 is affecting the number of applications submitted for placing a GMO on the market (given possible difficulties in obtaining approval, or obstacles to successfully completing a field trial)?”

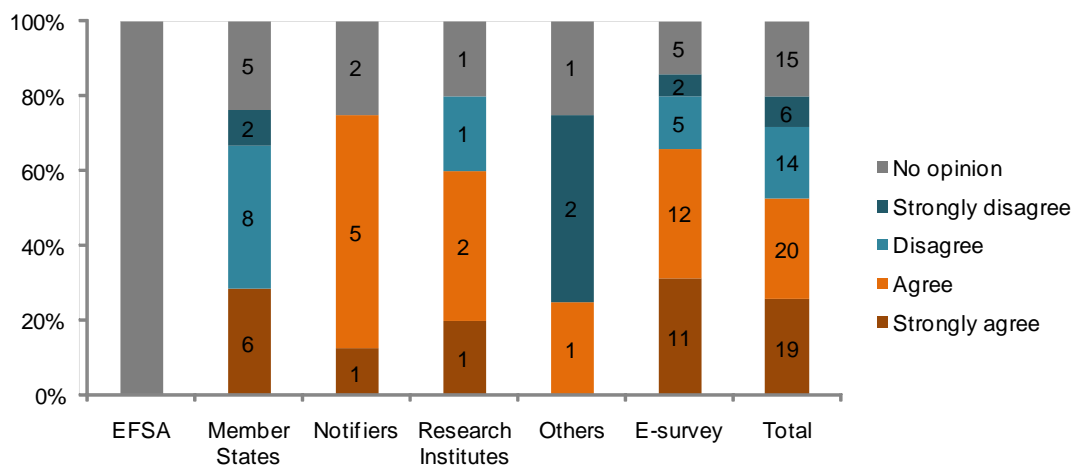
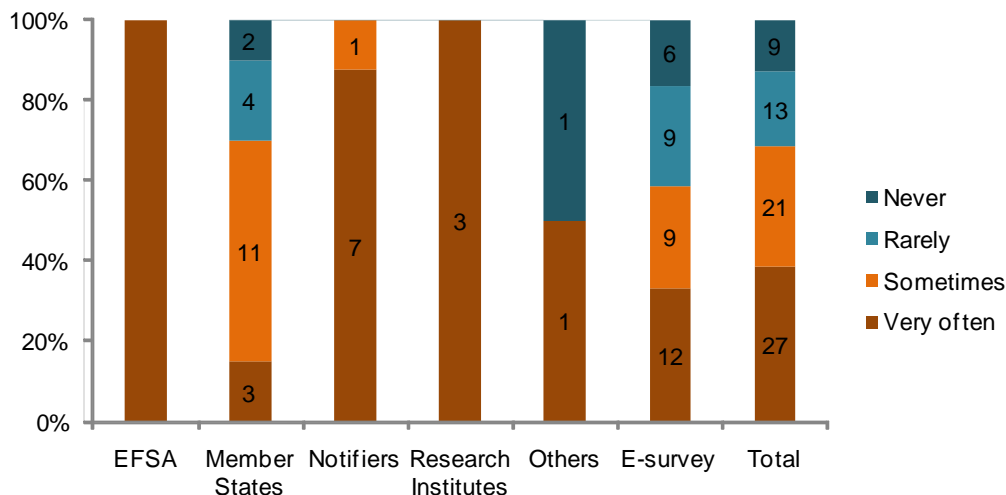


Figure 5.12 In contrast to most other consultees, most MS authorities believe that field trials only sometimes provide sufficient evidence to support applications for cultivation

“Does the design, conduct and analysis of Part B field trials provide adequate evidence (in terms of quality and quantity) for subsequent authorisations for cultivation?”



5.4.2 A lack of authorisations for cultivation can potentially reduce the incentive to invest in further field trials

Views are mixed on the degree to which the political context affects field trials and the biotechnology industry. Several MS authorities took the view that it was not the difficulties surrounding the actual field trials, but rather the current political context and lack of market authorisations for the cultivation of GMOs that was having the greatest impact on the declining number of field trials. Eight MS authorities commented that they thought the political context had a significant impact on the biotechnology industry and/or the number of field trials. Nonetheless other MS authorities did not agree that there was a much of an impact, at least not on the biotechnology industry or field trial numbers within their specific MS.

Many MS authorities agreed that the lack of market authorisations was having an effect on investment and research in the biotechnology industry. One MS authority commented that two companies had halted further investment in planned products due to the unpredictability of the authorisation procedure. Concerns were raised during some interviews on the increasing tendency for investment to leave the EU because of the unreceptive political environment. Some MS authorities noted that the development of GM varieties for the European market has declined considerably; instead biotechnology companies are focusing their efforts on developing varieties for other markets outside the EU. One MS authority felt that while their biotechnology industry had decreased substantially, they were unsure whether there was a causal connection with the political context.

Whilst some commented on both the negative impact on the industry as well as the impact on the number of field trials, other MS authorities felt that whilst there had been an effect on the biotechnology industry, that effect was not necessarily reflected in a decreasing number of field trials.

Some MS authorities also highlighted that the negative perception of the authorisation procedure discourages companies, and particularly smaller companies, from seeking product authorisation in the EU.

5.5 The consultation revealed some further points of interest

- **Contradictions between demands and actions:** some consultees, including certain MS authorities, highlight the lack of relevant research in the EU whilst simultaneously opposing that research from being conducted. The contradiction in terms was not missed by these consultees, including some environmental NGOs. This contradiction could exacerbate the inertia which is potentially already created by the problems outlined above; uncertainties lead to calls for more research, whilst the ability and incentive to conduct that research declines.
- **Encouraging more research:** The ability to influence the amount of research that is conducted is shared across different actors, including MS authorities and notifiers. A suggestion from the recent report on the management of field trials, for instance, suggested that MS authorities could implement differentiated procedures as familiarity with the product increases. Thus the data requirements and the conditions of consent could be less demanding, for instance, for products which have already been authorised for placing on the market. Viewpoints were divided on the issue. Notifiers felt this would be beneficial, although some MS authorities and other consultees did not feel that this was a reasonable suggestion. Notifiers on their part could make their research material more available to reputable independent institutes. MS authorities could also do more to engage with the public, which might increase acceptance.
- **Field trials and public acceptance:** Although communicating better with the public could increase the acceptance of field trials in order to encourage more field trials, ironically, having more experience with field trials and cultivation might itself increase public acceptance. In this case, some consultees suggested that more familiarity with the deliberate release of GMOs could increase acceptance, which would then allow more research to be conducted. Field trials themselves then can be seen as a risk communication tool. However, overcoming the existing public scepticism and turning the current vicious circle into a virtuous one is difficult.

5.6 Summary: consultees' suggestions for improvement

- The timeliness of approvals could be improved;
- MS authorities and notifiers should, as far as possible, discourage field trial destruction;
- The conduct, design and analysis of field trials, especially those conducted for regulatory purposes, should be better harmonised; and,
- More research should be encouraged.

6 RISK MANAGEMENT

6.1 This chapter provides an interim report on the evaluation of the risk management components of the legislative framework

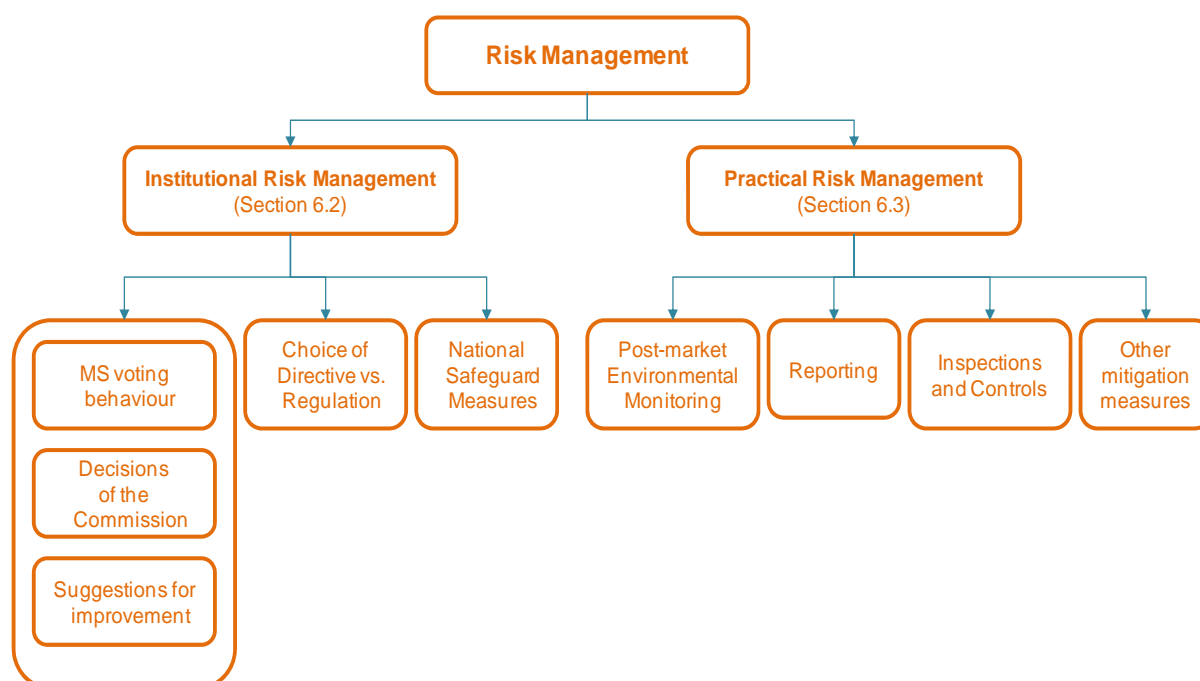
Risk management (RM) involves the consideration of policy alternatives and the selection and application of appropriate risk prevention and control options. Under the legislation this involves the evaluation of the current provisions in terms of inspections, controls, monitoring, reporting and special protection of eco-systems, environments and geographical areas for the risk management of GMO marketing and their implementation to date.

This evaluation is asked to consider the current provisions for the risk management of GMO marketing and their implementation to date. It is required to analyse whether the respective provisions, as well as their implementation, are efficient, transparent and in line with the general objectives of the legislation.

The scope of this element of the evaluation is shown graphically in Figure 6.1. The terms of reference require that special emphasis is placed on the applicable provisions for inspections, controls, monitoring and special protection of eco-systems, environments and geographical areas.

Figure 6.1 This chapter on risk management addresses three of the thirteen core questions in the project terms of reference (Questions 7, 8 and 10)

Diagrammatic representation of the issues covered in this chapter



Source: GHK Consulting Ltd

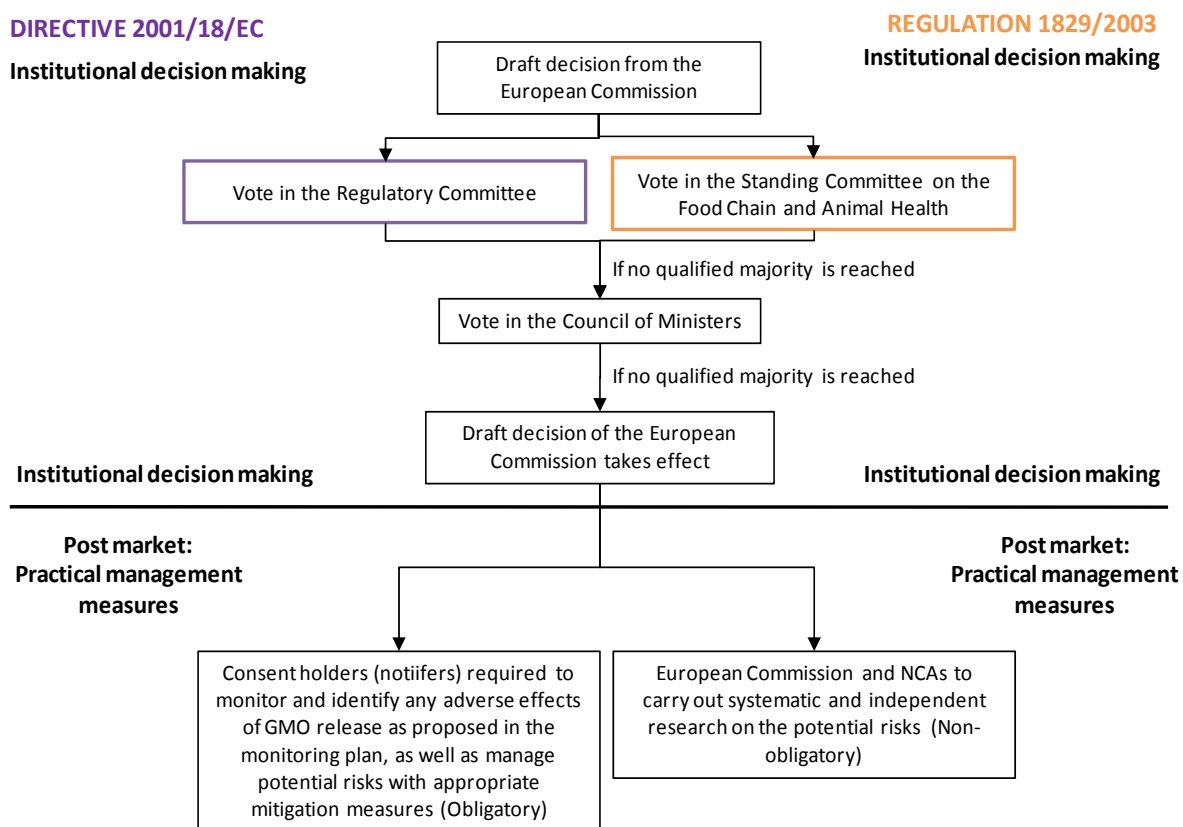
In the specific context of the evaluation of the legislative framework being considered here it encompasses both:

- the ‘institutional’ decision-making processes of Member State authorities and the European Commission about the authorisation of GMOs for cultivation; and
- the ‘practical’ management measures applied to GMOs authorised for deliberate release (for example, monitoring and mitigation measures such as isolation distances or “buffer zones”, and use of border rows of non-transgenic plants to catch pollen).

The relationship between these two closely related sets of activities - (i) the institutional decision-making and (ii) the specification and application of practical management measures - is shown in Figure 6.2.

During our consultation exercise, we found that for some consultees the use of the term ‘risk management’ to cover the decision-making step and the post-authorisation mitigation and management of risk is confusing. For these reasons, the two aspects of risk management - ‘*institutional decision making*’ and ‘*practical management measures*’ – are considered separately in the following sections.

Figure 6.2 Risk management as discussed here spans both institutional decision-making and practical management measures put in place when GMOs are placed on the market



Source: GHK Consulting Ltd

Under 'institutional decision making' (section 6.2), we:

- look at the reasons for MS authorities not being able to reach a qualified majority;
- provide a discussion on the deferral of decisions by the Commission in the absence of a qualified majority;
- discuss the implications of the 'opt-out' proposal and taking socio-economic concerns into account in decision making on authorisation of GMOs for cultivation;
- consider the impact of choosing the Regulation or the Directive on Risk Management; and
- evaluate the procedures on national safeguard and emergency measures under the GMO legislation.

Under 'practical risk management measures' (sections 6.3), we:

- evaluate the provisions and requirements for a post market environmental monitoring (PMEM) plan, including case specific and general surveillance;
- discuss reporting requirements for consent holders; and
- review inspection and control measures.

An important point of context for this chapter is that the practical experience with risk management of GM cultivation under the current legislation, beyond field trials, has been very limited since no GMOs have been approved for cultivation. The institutional decision-making, by contrast, has proven difficult and is not functioning as anticipated by the legislation. The discussion therefore begins with the decision-making process and explores the issues there in some depth.

6.2 The process of institutional decision-making on GMO cultivation is not functioning as envisaged

After EFSA carries out a scientific appraisal of the risk assessment of the GMO application, the authorisation process follows the Comitology procedure, in that a decision is drafted by the European Commission and MSs are asked to vote on the draft decision in the Regulatory Committee (under the Directive) and the Standing Committee on the Food Chain and Animal Health (under the Regulation), and again in the Council of Ministers if no qualified majority is reached in the Committee. If MSs are still unable to reach a qualified majority then the decision reverts back to the European Commission.

No qualified majority has been achieved in recent years for the authorisation of GMOs for cultivation under EU legislation. In accordance with Council Decision 1999/468/EC on Committee Procedures, in the absence of a qualified majority the European Commission has adopted decisions for the authorisation of some GMOs for imports and processing. To date, the Commission has not adopted any decision on GMOs for cultivation, despite five GMOs having received favourable Opinions for cultivation from EFSA⁴³. The vote on BASF's potato EH92-527-1 (hereinafter 'Amflora potato') was taken two years ago and the Commission has yet to issue a final decision.

⁴³ 1507 maize, Bt11 maize, EH92-527-1 potato, NK603 maize and MON810 maize

While the Comitology procedure seems to work very well for most other policy areas⁴⁴, it is not functioning well in respect of GMO authorizations. Decision-making has ground to a halt as a result of:

- the inability, to date, of MSs to reach a qualified majority; together with
- the reluctance, to date, of the Commission to make a decision in the absence of a qualified majority⁴⁵.

Consultees were in general agreement that the current indecision and unpredictability which characterises the authorisation process for GMOs is unsustainable. Consultees, including MS authorities, environmental NGOs, industry associations and notifiers, have a variety of reasons for wanting MSs to overcome the deadlock, and envisage different outcomes (see section 6.2.2 below) if they do.

Understanding why MSs are unable to reach a qualified majority in the case of GMOs, and what would be required for this situation to change, is key.

6.2.1 Member States have been unable to reach a qualified majority

It can be argued that there are two reasons for MSs being unable to reach a qualified majority:

- views within and among MSs are polarised, which manifests itself as a significant number of votes both for and against authorisation; and
- a significant number of MSs do not have a view either way or are not making their viewpoints known, which results in a significant number of abstentions.

If the latter reflected the current situation, then one way of breaking the existing stalemate could be quite simply for more MSs to take a stand one way or another on the authorisation of GMOs for cultivation. Several consultees, including certain environmental NGOs and some notifiers, did highlight during the consultation for this study that it might be that indecision on the part of individual MSs begets indecision on the overall authorisation of a GMO, and that it might be helpful if more MSs did not 'sit on their hands'.

Since the Directive came into force, votes⁴⁶ have been taken on just three applications for GM cultivation (1507 maize, Bt11 maize, and the Amflora potato). The voting patterns on these applications were such that a qualified majority (which requires 72% of all votes) would not be possible even if every MS that abstained voted instead either for or against the authorisation of the GMO in question (see Figure 6.3 and 6.4). If these cases are indicative of future voting on GMO cultivation, then the current stalemate can only be broken if a significant number of the MSs who consistently oppose authorisation in cases where there is a positive EFSA Opinion and Commission draft decision, changed their votes in favour, or vice versa⁴⁷. The number of abstentions might also need to decline in order for a qualified majority to be reached.

⁴⁴ The Commission is able to adopt more than 99% of the implementing measures submitted to different Committees. Very few cases are referred to the Council under the management and regulatory procedures. (EIPASCOPE 2009/1; "Comitology between Political Decision-making and Technocratic Governance Regulating GMOs in the European Union", available from: http://www.eipa.eu/files/repository/eipascope/20090709110450_Art1_Eipascoop2009_01.pdf)

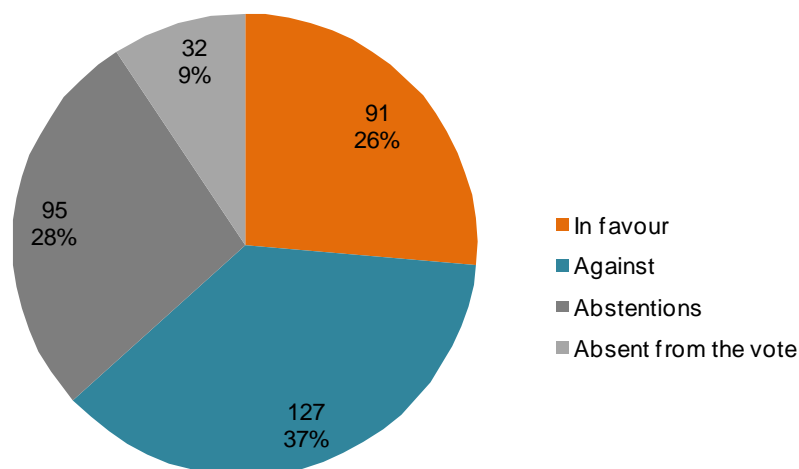
⁴⁵ In other policy areas the Commission is, for the most part, able to implement its draft decision with the endorsement of a qualified majority of Member States.

⁴⁶ Voting in the Council of Ministers is not public and thus not 'transparent'.

⁴⁷ The basis and merits of these general perspectives on GMO cultivation are, for the most part, outside the scope of this study.

Figure 6.3 Votes by Member States on 1507 and Bt11 maize for cultivation are split roughly in thirds for those who are in favour, against and who abstain

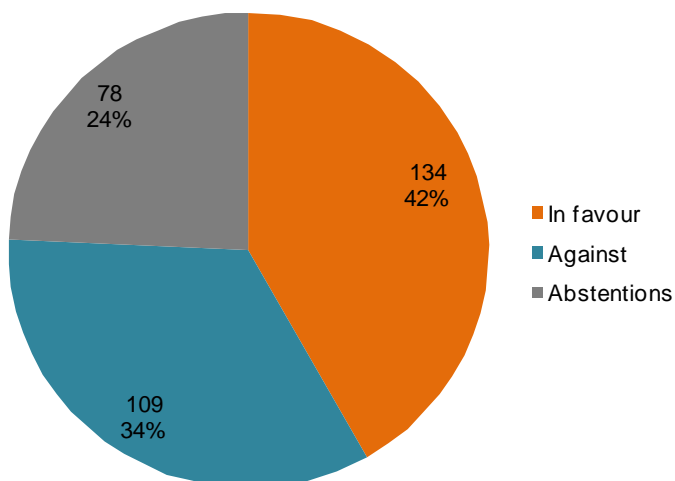
Member states' voting patterns on 1507 and Bt11 maize for cultivation (% of qualified votes cast)



Source: DG Environment, European Commission

Figure 6.4 Votes of Member States are polarised, with roughly two-thirds each voting either for or against the authorisation of Amflora potato for cultivation

Member states' voting patterns on Amflora potato for cultivation (% of qualified votes cast)



Source: DG Environment, European Commission

6.2.2 The Commission has been reluctant, thus far, to make a decision in cases where a qualified majority has not been achieved

In 2005, EFSA issued a favourable opinion on cultivation applications for 1507 maize, Bt11 maize, and the Amflora potato. Votes on the potato in the Regulatory Committee and the Council (on December 4, 2006 and July 16, 2007 respectively) were inconclusive. The College of Commissions held an orientation debate on GMOs on May 7, 2008. In the

conclusions of its College debate on GMOs⁴⁸, the Commission deferred a decision on the Amflora potato until EFSA re-examined the safety of the marker gene (*nptII*) used in the potato. Accordingly, EFSA's issued a joint opinion of the GMO and Biological Hazards Panel (BIOHAZ) in June 11, 2009, concluding that "adverse effects on human health and the environment" as a result of the use of the market genes in GM plants "are unlikely based on the current state of knowledge"⁴⁹, thereby reconfirming the safety of the Amflora potato.

After votes in the Regulatory Committee and the Council of Ministers also failed to achieve a qualified majority on 1507 and Bt11 maize, on the same day the Commission also deferred a decision and urged further review by EFSA of the scientific studies related to the impact on the environment of the cultivation of these two products. EFSA found no reason to invalidate the former risk assessment on either 1507 or Bt11 maize. Consequently, another vote was taken on both maize products in the Regulatory Committee on February 25, 2009 which again resulted in no qualified majority. A vote in the Council is now pending.

Many consultees expressed their frustration with the continual deferral of a Commission decision. In the interviews, consultees across all groups seemed to agree that indecision is the greatest problem with the system overall. The majority of those interviewed said that, in the current system, it is unlikely that the MSs will reach a qualified majority given the polarised nature of the views, and thus it is the responsibility of the Commission to make a decision.

Although most consultees agreed that they wanted the Commission to adopt a final decision, the expected outcomes were very different for different groups:

- Notifiers expected the Commission to vote in favour, given that EFSA repeatedly issues favourable Opinions;
- Environmental NGOs thought that the Commission would not approve the authorisation of these GMOs for cultivation on the basis of the precautionary principle, given that a significant number of MS authorities still have unresolved concerns about GMOs being released into the environment on a commercial scale.

Several issues were raised in discussion:

- **The predominant position:** One environmental NGO suggested that the Commission should act in accordance with the 'predominant position'. In 1999, the Commission pledged "*to act in such a way as to avoid going against any predominant position which might emerge within the Council against the appropriateness of an implementing measure*"⁵⁰. However the point at which a position can be considered predominant is unclear (e.g. is it to be determined as a majority of MSs, majority of votes, population criterion, or a combination of some or all of these).
- **Confidence in the risk assessment and its appraisal:** Some consultees, especially notifiers and some MS authorities, stated that, besides the actual deferral of a decision, the means being used by the Commission to defer a decision is also having a detrimental effect. They thought that asking EFSA to re-examine risk assessments that had already been completed undermines

⁴⁸ www.endseurope.com/docs/80507a.doc

⁴⁹ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902604575.htm

⁵⁰ European Commission Declarations on Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (1999/C 203/01).

confidence in EFSA and the science that underpins the risk assessment and its appraisal, at a time when such confidence is sorely needed (see Chapters 4 and 7 for further discussion). Their concern was that this could reinforce public scepticism of GMOs.

- **The importance of timelines:** Notifiers noted that the timelines currently stipulated in the approval framework are not being correctly applied. For instance, under the Regulation and upon receipt of EFSA's Opinion, the Commission has three months within which to draft and submit a decision to the Regulatory Committee (under the Directive) or the Standing Committee (under the Regulation). EFSA's Opinion on the Amflora potato was issued in December 2005, but the draft decision was not submitted to the Regulatory Committee until November 2006. Notifiers and some environmental NGOs also highlighted that, in the absence of strictly defined timelines, the process can stall without any legal implications. Currently, the Commission is only required to move dossiers through the process "without undue delay".
- **The role of MSs:** Although indecision on the part of the Commission was seen as a key problem, several consultees (some MS authorities, environmental NGOs and notifiers) thought MSs were also responsible for delaying decisions. Some highlighted that the concerns raised by MSs after the RA phase is complete prompt the Commission to repeatedly request that EFSA re-examine its initial appraisal. As such, the RA phase of the regulatory process is never actually complete. It was argued that MS authorities should instead use the existing opportunities – in particular the three month consultation period within the RA appraisal under the Regulation - to raise their concerns. However, many MS authorities said that this period is insufficient, and the outputs are not entirely satisfactory (see section 4.6.2). It should be noted that under the Directive's Article 15 MS authorities have the opportunity to submit reasoned objections, comments, etc within 60 days of receiving the application.

The point was also made that the delays in the system breed further inefficiencies, in that new scientific evidence or issues can arise in the time that elapses between an Opinion being issued by EFSA, and the point at which a decision is required. If the system worked within the timeframe intended, these issues would be addressed by the mechanisms built into the existing system - the facility to implement a national safeguard measure, and the fact that consents are only issued for a 10 year period, after which they must be renewed.

Potential reasons for the deferral of decisions by the Commission

Interviewees speculated on the reasons behind the continual deferral of cultivation authorisation decisions, noting that decisions have been made on the import of some of the same GMOs, such as 1507 and Bt11 maize.

Certain notifiers, MS authorities, and environmental NGOs, stated that there is more pressure for decisions on the import of GMOs, both externally from the WTO and major trading companies, as well as internally from industry groups, given the EU's reliance on animal feed imports (such as soy)⁵¹. On the other hand, certain MS authorities, notifiers and environmental NGOs highlighted that the external pressures for a positive decision on cultivation are weaker whilst, at the same time, the intra-EU pressures against a decision are stronger, given the concerns of various MSs and consultees about safety and environmental risks.

Although the Comitology procedure is generally an effective mechanism, it does not seem able to effectively and efficiently deliver decisions in the case of GMO authorisations for

⁵¹ http://greenbio.checkbiotech.org/news/industry_calls_rapid_eu_decision_gmo_import

cultivation. It is possible that this is because views on the subject are polarised, politically charged, and entrenched.

In practice, it is difficult for the Commission to deviate from EFSA's Opinion with regards to the risk assessment and its appraisal. Although the legislative framework allows the Commission to draft a decision which contradicts EFSA's Opinion, it must justify its reasons for doing so. However, according to a judgement by the ECJ⁵², this justification "*must be of a scientific level at least commensurate with that of the opinion in question*". This legal opinion means that the Commission, an administrative institution, would need to assemble a scientific argument that trumps that of EFSA, a purely scientific body. However, if the Commission were to make a decision to authorise Bt11 maize, 1507 maize and the Amflora potato for cultivation, it would be doing so without the endorsement of a significant number of MSs.

This raises issues about the efficiency and accountability of the Comitology procedure as it relates to the GMO authorisations, given that the Commission would have to take a decision on the *de facto* basis of an opinion from a scientific body⁵³. Certain consultees thus saw it as understandable that the Commission has instead chosen to defer decisions on the matter.

Member State authorities have made suggestions for reform, with the aim of breaking the current deadlock

Given the current situation and differences of opinion on the risk and benefits of cultivating GMOs in Member States, some Member State authorities have argued for a new approach to deal with the authorisation and use of GMOs in agriculture. They have variously suggested that:

- MSs should give reasons and explanations for all votes and objections in meetings of the Regulatory Committee of the Directive, the Standing Committee of the Regulation and the Council of Ministers;
- MS authorities should have greater possibility to influence the draft decisions. The period between despatch of the draft to MS authorities and the vote should be extended. Consultation could be done through written procedures;
- The draft final decision on the authorisation of GMOs should take into consideration the possibility of excluding certain geographical areas (i.e. GMO Free Areas);
- Regional variability should be taken into account more explicitly in the ERA process (see section 4.4.2) and conditions of consent which specifically address the protection of particular ecosystems/environments and/or geographical areas, should be more readily included in the Commission's draft decisions;
- There is a need for a more collaborative and harmonised approach between MS authorities and EFSA at the risk evaluation stage to increase confidence in the RA appraisal (see sections 4.4.2 and 4.6) (initiatives to achieve this have already begun).

Two further suggestions have been made by some MSs, which could potentially require significantly greater changes and could have more extensive impacts than those above:

⁵² Case T-13/99 Pfizer Animal Health SA v Council of the European Union, Judgement of the Court of First Instance, 11 September 2002 [2002] ECR II-03305.

⁵³ EIPASCOPE 2009/1; "Comitology between Political Decision-making and Technocratic Governance Regulating GMOs in the European Union", available from: http://www.eipa.eu/files/repository/eipascope/20090709110450_Art1_Eipascoop2009_01.pdf

- That once a GMO has been given a favourable Opinion by EFSA on its safety, and if a decision is drafted by the Commission to authorise its cultivation, MSs should be able to decide on a national level whether or not to cultivate it;
- That MSs should be able to explicitly consider socio-economic concerns as well as safety issues when making a decision on whether to allow a GMO to be authorised for cultivation at an EU level;

Although these are two separate suggestions, they are not mutually exclusive, as illustrated by a proposal earlier this year from the Netherlands that suggested that, once a GMO has been given a favourable Opinion on its safety at the EU level, MSs should be able to decide on a national level whether to cultivate a GMO or not on the basis of socio-economic criteria.

National self-determination on GMO cultivation and the pros and cons of taking into account socio-economic concerns in the authorisation of GMOs for cultivation are discussed in the next two sections.

6.2.3 Member State authorities were more positive about national self-determination on cultivation than other consultees

On 25 June, 2009, Austria⁵⁴ submitted a paper to the Environment Council concerning the right of Member States to opt-out of growing GMOs on their territory which have been approved by the EU. Previously, the Netherlands submitted a similar declaration to the Environment Council on 2 March 2009 and to the Agriculture Council on 23 March 2009.

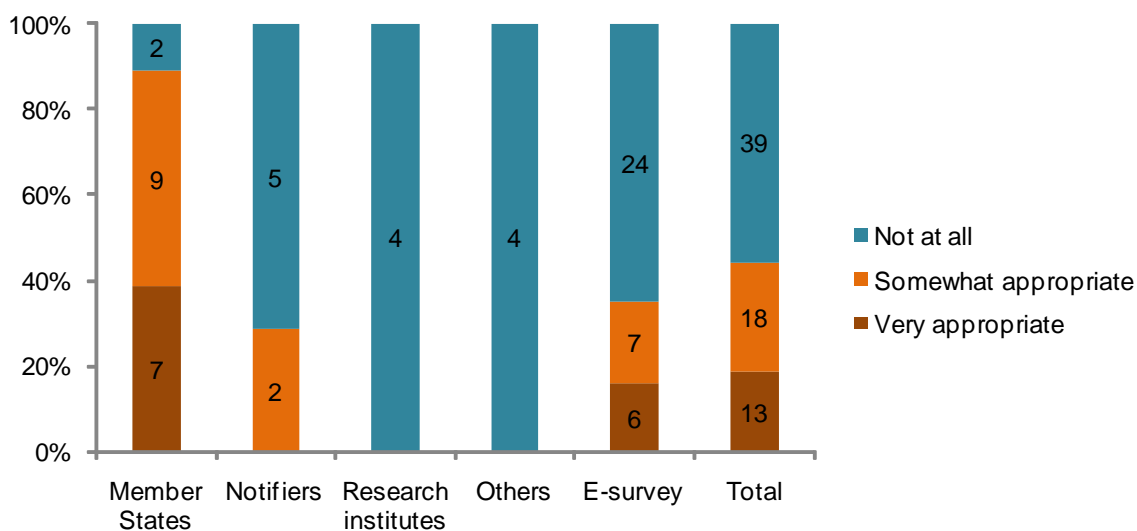
Providing the MSs with the right to opt-out would lead to the EU legislative framework focusing on providing authorisation on an EU level for placing a GMO on the European market (instead of authorisation for 'use'), leaving MSs with the option of choosing to cultivate or not. The proposal would allow each country to consider the impact of GMO cultivation within its own territory. The idea is that MSs who oppose the cultivation of GMOs in their own territory could protect their interest without having to, in effect, veto the rights of others within the EU to do so.

In the consultations undertaken for this project, views on the merits of the 'opt-out' clause as a solution to the qualified majority problem varied widely among the groups of those consulted. MS authorities generally thought it was an appropriate suggestion, whilst most other groups who were consulted were less optimistic (see Figure 6.5). Of all MS authorities consulted, 16 classified an 'opt-out' clause as a 'somewhat appropriate' solution in the project's written survey. Most of these suggested that allowing national self-determination could encourage MSs to take responsibility for decisions on cultivation of GMOs, especially if those decisions could affect its local or regional environment. In the absence of a qualified majority, each MS should be able to decide on the cultivation of the specific GMO in accordance with the precautionary principle taking into account the environmental and socio-economic conditions of the specific state. One MS authority suggested that allowing Member States to decide for themselves whether to grow GMO on their territory could mitigate tensions and lower the temperature of the political debate. Some MS authorities pointed that the political nature of the issue cannot be ignored and believed that the 'opt-out' clause could contribute to more acceptable scientific opinions and increase ability to achieve a qualified majority. This is because the opportunity to take into account national measures after the EU authorisation could help find support for the EU authorisations from some MSs now opposing or abstaining for political reasons.

⁵⁴ The proposal has been signed by Bulgaria, Ireland, Greece, Cyprus, Latvia, Lithuania, Hungary, Malta, Slovenia and the Netherlands, and is backed by France, Poland, Portugal and parts of the German government

Figure 6.5 The majority of MS authorities agree with the ‘opt-out’ proposal but notifiers are concerned

To what extent is the ‘opt-out’ proposal an appropriate solution to the problems represented by Member States’ inability to achieve a qualified majority?



Some MS authorities and some other consultees from the E-survey believed that in principle, it could help MSs with a science-based position on the authorisation process to adopt the GM technology and cultivate the crop within its borders. They also noted that it could address the problem of national bans being imposed by some MSs on non-scientific grounds.

The basis of the scepticism about the ‘opt-out’ option varied among the different groups of consultees.

- **Notifiers** were concerned that implementing an ‘opt-out’ clause would require that the legislation be re-opened. Five of the seven notifiers consulted said that they did not consider the ‘opt-out’ clause an appropriate solution to the problems represented by Member States’ inability to achieve a qualified majority. Given that their concerns focus on the implementation of the legislation, rather than the text itself, they thought this would be a case of fixing something which is not broken. They also suggested that changing the legislation would not guarantee that the new system would work any better. Indeed, changes could lead to greater problems, and it would be virtually impossible to revert back to the existing system. Notifiers suggested that MSs already have options under the current legislation which allow some opt-out from GMO cultivation, such as varietal registration requirements, safeguard clauses and coexistence legislation. In that context the benefits of opt-out looked questionable, especially given the potential costs and risks.
- One **MS** authority suggested that options within the current framework should be better explored before the EU embarked on a change as significant as implementing an ‘opt-out’ clause. For instance, it was noted that substantial progress has already been made by the Environment Council in improving certain aspects of the legislative process, as evidenced by the Council Conclusions of December 2008. National self-determination represents a substantial shift from the current legislative framework and any changes should only be made after proper examination by MSs and the Commission of the existing scope in the current legislation. A thorough understanding of the nature of the options, their implications and timescales is needed *before* launching any process of change.

Another MS authority thought that GMO-free regions should be given a clearer legal status. These already exist in several MSs⁵⁵ and are an informal mechanism for a region to decide against the cultivation of GMOs. However, given their voluntary basis, enforceability is problematic, especially if a minority do not wish to be GMO-free. The potential role of GMO-free zones was highlighted in the Council Conclusions which noted that GMO-free zones “*can be created on the basis of voluntary agreement which, in line with relevant national law, could be tacit between the economic operators concerned in the area in question and that in order to ensure freedom of choice all concerned operators must be properly informed about an intention to create the GMO-free zone*”.

- **Environmental NGOs** did not expect national self-determination to resolve the current stalemate. They believed that the concerns that MS authorities have raised regarding the risk assessments and their appraisal by EFSA would still remain and these MSs could still vote against authorising the cultivation of GMOs. Environmental NGOs were also concerned about the impacts of opening the legislation. As with notifiers, their concerns rest with the implementation of the legislation, not with the legislative framework itself.

Some environmental NGOs had concerns about the potential impacts of the ‘opt-out’ clause itself, even if the legislation was not opened up. Given that they believe there are still unresolved safety concerns they were concerned that the ‘opt-out’ clause would enable the cultivation of GMOs in some MSs, with potentially detrimental, possibly irreversible, consequences on the environment. Furthermore, it was noted that natural boundaries do not necessarily correspond to political ones, and that allowing cultivation in one MS could have cross-border environmental impacts which would not respect a MS’s decision not to cultivate a GMO. There may also be issues of liability and enforcement to be explored, if (for instance) GMOs which are authorised at the EU level are (inadvertently) cultivated in areas where they are prohibited at a national level.

Overall, consultees were concerned that an ‘opt-out’ clause would create a significant amount of unpredictability, both in terms of its use and its possible effects. For instance, self-determination could lead to further regionalisation in those Member States with federal systems. This could make the situation for all bio-tech industries more risky and speculative. One MS authority suggested that regionalisation of GMO products for cultivation would require biotech companies to re-locate production in each country to minimise costs, and could lead to an increase in the price of consumer products.

Furthermore, although the suggestion was generally supported by MS authorities, some did highlight that the logistics of its implementation could prove difficult. Labelling and enforcement might be problematic. Tensions could be created if producers were required to label products as being banned for the purpose of cultivation in certain MSs, not least with the WTO. However, MSs could implement the restrictions purely through legal documentation on their part without the need for specific labelling requirements. MS authorities called for the Commission Legal Service to explore the feasibility and desirability of the policy change in the context of the single market.

Preventing farmers from growing the seeds concerned could be difficult given that their sale would still be legal. Cross-border enforcement will also be an issue and would rely on strict testing at borders and further responsibilities for inspection authorities. Nonetheless, certain MS authorities did note that national bans under Article 23 of the Directive are already in place and this is not seen as a serious problem in practice. Consultees identified two further possible effects of the ‘opt-out’ clause:

⁵⁵ <http://www.gmo-free-regions.org/gmo-free-regions/maps.html>

- tensions among Europe's farmers might increase and the concept of a common approach to agriculture eroded. This would need to be weighed against the additional freedom provided to those who believe lack of access to GM products will ultimately harm parts of the European farming sector;
- the current stalemate between MSs places the onus for making a decision on whether to authorise a GMO for cultivation with the Commission. Shifting this responsibility onto MSs could provide interest groups with a more local focus for their objections as it would then become more apparent who was responsible for either allowing or prohibiting the cultivation of GMOs.

Overall, most MS authorities, some notifiers and some E-survey participants agreed on similar but few points on the opt-out proposal. On the other hand, a number of different points were made against the opt-out clause by different consultees.

6.2.4 *There is a divergence of views on whether a separate socio-economic assessment on cultivation applications is desirable or practical*

There was no consensus between consultees on the merits of more explicit consideration of socio-economic factors (Figure 6.6). The majority of Member State authorities (16 out of 22 either strongly agreed or agreed) believed that socio-economic concerns should be taken into account when making decisions on the authorisation of GMOs for cultivation. The common suggestion was that if a decision could take account of both the potential risks and the potential benefits, then the current stalemate could be overcome by allowing MSs to base their decisions on more comprehensive and more transparent information. Some MS authorities also suggested that explicit, and separate, consideration of socio-economic factors could increase confidence in EFSA and the risk assessment procedure by allowing some MSs to openly base their decisions on reasons other than safety, rather than using safety concerns as a 'front' for a political position that is based on socio-economic and ethical considerations. As a result, MSs will be likely to take more responsibility for taking decisions to cultivation GMOs in their own territory

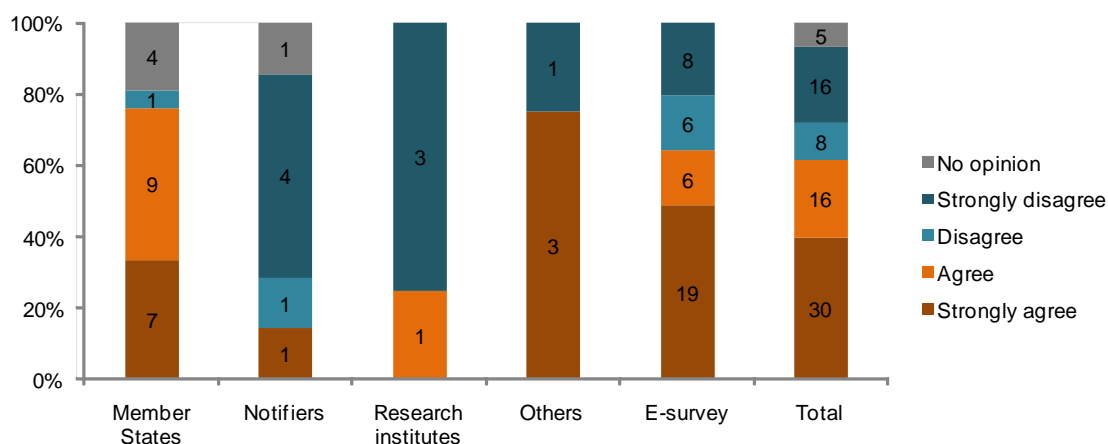
One MS authority noted that socio-economic concerns are an important factor for rejection of GMOs by the general public and governments in some MSs. Currently such concerns are not taken into account for decisions on authorisation of GMOs. The proposed framework would thus help in addressing this important issue. Most E-survey participants did not elaborate on their answers. However, a few E-survey participants said that considering socio-economic concerns follows sustainability principles to address societal challenges such as climate change and sustainable development. One of the E-survey participants supported the inclusion of socio-economic concerns on the grounds that it will take into consideration any agricultural or economic advantages or disadvantages.

NGOs and some other consultees also agreed that socio-economic concerns must be considered in the authorisation process. GMO cultivation in some countries (e.g. Spain, US, South America) has shown that GM cultivation can have both positive and negative social and economic impacts⁵⁶. Approving a GMO for cultivation not only affects the farmer growing it but can also impact on the entire food production, supply and consumption chain.

⁵⁶ Evidence from industry and NGOs/others on the social and economic impact from GMO cultivation is not conclusive.

Figure 6.6 MS authorities and notifiers have split views on including socio-economic concerns for GMO authorisation for cultivation

“Do you agree that socio-economic concerns should be taken into account when making decisions on the authorisation of GMOs for cultivation?”



MS authorities, though recognising the need for including socio-economic concerns, did acknowledge that including socio-economic concerns could:

- require new legal frameworks to provide a firm basis for national decisions; and
- violate EU internal market principles;

On the other hand 5 notifiers disagreed or strongly disagreed that socio-economic concerns should be taken into account when making decisions on the authorisation of GMOs for cultivation. A key concern was that *ex ante* assessment of individual GM products would be very difficult in practice. Estimates on yields, costs of production and farm profitability can only be reliable if they are available. Given that only one maize product is currently authorized for cultivation in the EU, and is only grown in significant amounts in one MS, this is a problem⁵⁷.

Furthermore, notifiers argued that explicit consideration of socio-economic criteria would result in a high degree of subjectivity and risk decisions becoming arbitrary. Without proper guidelines, including socio-economic concerns could further complicate the authorisation process. It is much more difficult to have a consensus on a socio-economic evaluation than a scientific risk evaluation. Several notifiers also argued that, should problems arise in practice, it would be virtually impossible to revert back to a system where socio-economic criteria were no longer explicitly taken into account.

Notifiers stated that safety should be the overriding priority and that if a product is safe, it should be placed on the market in order to allow consumers to make their own decisions. Their view was that, beyond determination of safety, it is not up to the Commission and MSs to decide whether or not society should be offered the choice of products which have been deemed safe. Notifiers and EuropaBio also suggested that the inclusion of socio-economic criteria could further politicise what should be a science-based, rational, approval process and thereby fail to meet the requirement of legal certainty required under the Lisbon Treaty and the Treaty establishing a Constitution for Europe (TCE). Furthermore, basing product approvals on socio-economic criteria could potentially create conflicts with international trade obligations which require that restrictions in international trade must have a scientific (as opposed to a socio-economic) justification. However, both WTO rules and European legislation accept that policy decisions can and will involve both scientific and non-scientific considerations; what they preclude is basing such decisions on non-scientific

⁵⁷ The validity of socio-economic data obtained from outside the EU is a further area of debate

considerations alone. The expert assessments of risk must be taken into account, and not discounted or ignored.

A concern voiced by one of the notifiers was that the inclusion of a socio-economic evaluation into the EU approval process for GMOs for cultivation is without precedent, given that all other new technologies which have been introduced into EU agriculture have been (officially) assessed against strict scientific criteria, without a separate and explicit socio-economic appraisal. Applying a different approach to GMOs for cultivation would be inconsistent with legislative approaches for other agricultural technologies or products. This outcome would either send the message that GMOs for cultivation are, for some reason, unique and require a more comprehensive assessment than other types of agricultural products, or it could lead to fundamental changes in other legislative acts. Additionally, it could raise questions about the sustainability of certain conventional crops and cultivation methods which, at present, are not subject to any such assessment. Equally, it is unclear, even within the GMO policy area whether socio-economic criteria should be limited to cultivation, or be extended to food, feed and imports.

The practicalities of explicitly including socio-economic criteria raises new challenges

All consultees agreed that the justification for and the means of using socio-economic criteria must be clear. Some MS authorities suggested that the criteria that could be used in such an assessment of GMO applications, and the way in which they might be included, should be examined at EU level.

Given that MS authorities have only just begun to consider the practical logistics of explicitly including socio-economic concerns, the concept of 'socio-economic' criteria is being interpreted very broadly at present, ranging from measures of public opinion on GM through to the economic impact on farmers of a new GMO being made available for cultivation.

Discussions suggest that in practical terms there are two dimensions to be considered:

- the extent to which socio-economic factors are considered (and quantified) on a case-by-case basis or as a matter of strategic policy choice;
- the extent to which socio-economic factors will be harmonised at EU level or whether Member States will be able to devise their own decision-making structures.

Obtaining a common understanding amongst MS authorities and other consultees of what factors to include, and how these will be considered, will not be easy. Consequently, it is necessary to firstly collect and analyse the spectrum of socio-economic concerns (adverse or beneficial effects) in the EU as background information for further discussion in this issue.

For national governments there will be challenges in defining and managing the process through which decisions are made. Some MSs have existing systems or structures that might be used for this purpose; others do not. In April 2009, the French Minister for Ecology announced the formation of the new High Council for Biotechnology (HCB), which has a unique dual assessment structure; one committee is to assess the scientific elements of an application, whilst a second committee will focus on the economic, social and ethical issues⁵⁸. The system would also need to accommodate sub-national views where devolved administrations may take different views on GM cultivation than the national government.

There are also issues to be resolved regarding the data, its availability, quality and reliability. For instance, notifiers might be expected to include the necessary information in the dossiers they submit (similar to what is required now for the safety assessment). Alternatively, public and independent research institutes might be tasked with supplying the information. If the responsibility fell to notifiers, there could be significant challenges (and

⁵⁸ USDA GAIN Report (2009). EU-27 Agricultural Biotechnology Annual

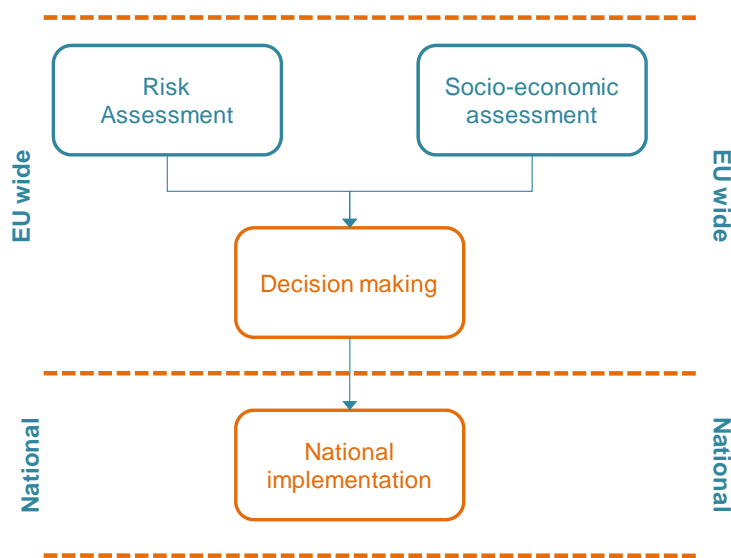
costs) associated with assembling the socio-economic ‘dossiers’ in support of national decisions – both because of the need to do this for a large number of different MSs that might have different requirements and because anticipating socio-economic (market) outcomes, *ex ante*, of crop marketing would be very difficult.

It has been noted that, given some clarification, socio-economic concerns could be accommodated more explicitly by the existing framework. Provisions for ethical considerations are already included in the legislation as it stands, however not as factors to be considered while deciding on authorisations⁵⁹; MSs are allowed to take into account the ethical implications of biotechnology, whilst the Commission should consult with the European Group on Ethics in Science and New Technologies. Furthermore, the Regulation 1829/2003 already provides that, under certain conditions and as part of a case by case examination, ‘legitimate factors’ specific to the GMO being assessed can be taken into account in the risk management process which follows the risk assessment⁶⁰. In order for this existing provision to be used, clear recommendations or guidelines would have to be produced.

Most consultees we spoke to during the interviews indicated that, if socio-economic criteria were to be included, they would foresee a socio-economic evaluation being conducted in parallel with the current technical risk assessment, both of which would then feed into the decision-making phase (see Figure 6.7 below).

Alternatively, as mentioned above in section 6.2.2, national self-determination and the inclusion of socio-economic criteria could be combined, so that the technical risk assessment continue to be conducted at the EU level, whilst a socio-economic assessment would be allowed to be conducted on a national basis which MSs could take into consideration when deciding whether or not to permit cultivation of a GMO. This will be discussed in the next section.

Figure 6.7 One option is to include an evaluation of the socio-economic impacts of cultivating a GMO at the EU level



Source: GHK Consulting Ltd.

⁵⁹ See Directive 2001/18/EC, Recitals 9,56,57,58 and Article 29 under Part D. Also the Regulation 1829/2003, Recital 45 and Article 33.

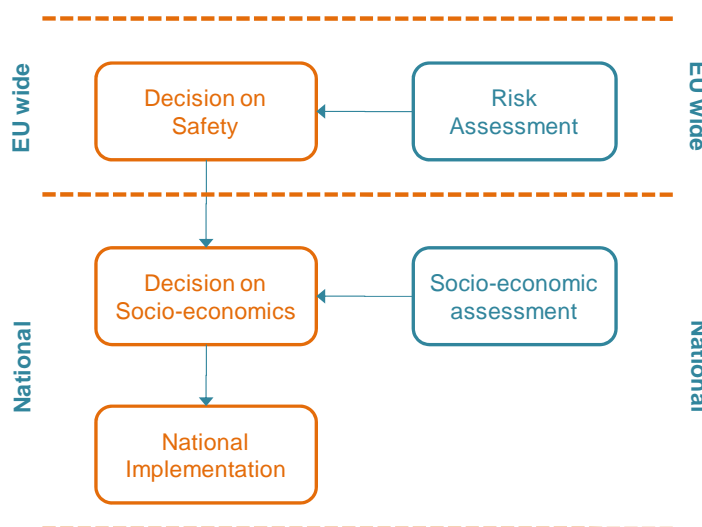
⁶⁰ As highlighted in the conclusions of the Environment Council in December 2008. A report on the implementation of the Directive 2001/18/EC, including an assessment, inter alia, of the socio-economic implications of deliberate releases and placing on the market of GMOs, will be submitted by the Commission in 2010.

6.2.5 The Dutch proposal to Council combines national self-determination with socio-economic criteria

Combining national self-determination with socio-economic criteria has been suggested by the Netherlands. The proposal is still very much in its infancy and its legal and practical considerations have yet to be explored in detail.

A diagrammatic representation of how it might work is shown in Figure 6.8. The technical scientific assessment would remain at the EU level and be separated from the socio-economic assessment, which would be done on a national basis. This could allow MSs, in principle, to vote in favour of authorising a GMO for cultivation on a safety basis at the EU level, and yet still vote against authorising a GMO for cultivation on a socio-economic basis at a national level. Compatibility of this option with obligations under international agreements, and especially WTO, should be subject to further examination.

Figure 6.8 An alternative model would see the socio-economic evaluation conducted at national level



Source: GHK Consulting Ltd.

6.2.6 The choice of the Regulation versus The Directive could have an impact on the authorisation outcomes and on use of safeguard measures, though the scarcity of votes and decisions makes this a theoretical concern at present

Since the Regulation came into force, notifiers have chosen to use its ‘one door, one key’ facility for cultivation applications, rather than the Directive. Given that the underlying purpose of the Directive and the Regulation differ (see section 2.2), it is understandable that certain provisions between the two also differ.

If an application for cultivation is submitted under the Regulation instead of the Directive, the provisions under Part D of the Directive must be applied together with the requirements specified in Annex II on the ERA, Annex III on the content of notifications and Annex VII on the monitoring plans. Nonetheless, some consultees, including environmental NGOs and certain MS authorities, did highlight that potentially significant differences in some provisions still remain. The impact of these differences on the process and characteristics of the risk assessment (both its conduct by notifiers, and its appraisal by EFSA and the Competent Authorities of MSs) are discussed in section 4.7 above. However, there are also potential impacts on the risk management provisions, which are discussed in this section.

The difference mentioned most frequently in the interviews related to safeguard measures. The safeguard clause under the Directive (Article 23) is much more detailed than that under

the Regulation (Article 34) (see section 6.2.7 for further discussion). The current situation with MON810 provides an example of the potential conflicts. MON810 maize, authorised under Directive 2001/18, is the only GM product whose cultivation is currently allowed in the EU. France has implemented a national safeguard measure against MON810 under the Directive's Article 23 and the Regulation's Article 34 but five other MSs have implemented national safeguard measures against its cultivation only under the Directive. MON810 is currently undergoing renewal under Regulation 1829/2003. If MON810's authorisation is renewed, it is unclear, especially for certain MS authorities, whether the safeguard measures MSs currently have in place might still be valid given that they have been implemented under the Directive. However, even if the legal basis for national safeguard measures under Article 23 of the Directive expired fully, they would still be valid under national legislation and the prohibitions would remain in place.

This would merely be a logistical concern, if not for the fact that the safeguard clauses under the two pieces of legislation differ. One MS authority believed that the Directive's safeguard clause allows a ban to be implemented if there is evidence of potential harm, whilst a safeguard measure under the Regulation might only be implemented if it can be shown that harm has occurred. As such, the option under the Directive is based much more clearly on the precautionary principle than the Regulation's (and the Directive explicitly mentions the precautionary principle whilst the Regulation does not).

In principle, the choice of a notifier to use the Regulation over the Directive could also have an impact on the voting patterns. The Environment Council of Ministers votes on authorisations for cultivation made under the Directive, the Agriculture Council of Ministers votes if an application was submitted under the Regulation. Some consultees suggested that this could have an impact on the outcome. In practice, neither Council has been able to reach a qualified majority on the authorisation of a GMO for any use.

In summary, there are potentially significant differences in the provisions under the Directive and the Regulation. The Directive was introduced specifically to ensure the safety of the deliberate release of GMOs into the environment, whilst the Regulation was established to ensure the safety of GMO food or feed products being placed on the market. Some consultees are sceptical of whether the Regulation is an appropriate mechanism for dealing with applications for the deliberate release of GMOs, given that its provisions are determined by a different purpose.

So far, the only products that have been voted on are those which were originally submitted under the Directive (1507 maize, Bt11 maize, Amflora potato). However, all products now in the pipeline awaiting authorisation for cultivation were submitted under the Regulation. This includes two products which have recently been given a favourable Opinion by EFSA and which are awaiting a vote in the Standing Committee (MON810 and NK603 maize). Consequently, although the concerns raised so far on this issue have been largely theoretical, it is likely that they will become more significant in the future as the differences between the Regulation and the Directive become clearer in practice.

6.2.7 MS authorities are divided over the implementation of national safeguard and emergency measures for addressing the objectives of the legislation

Article 23 of Directive 2001/18/EC provides for a safeguard clause. Where a Member State identifies that a GMO is liable to 'constitute a risk to human health or the environment' it may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory. Under Article 34 of the Regulation 1829/2003 (in conjunction with Articles 53 and 54 of the Regulation 178/2002 on General Food Law), a Member State can implement an emergency procedure "*where it is evident that products authorised by or in accordance with [the] Regulation are likely to constitute a serious risk*". A similar procedure follows, where the Commission also presents a proposal under the Comitology procedure. Consultation with EFSA however is not obligatory under emergency measures for Regulation 1829/2003.

Currently, six safeguard measures are in place under Directive 2001/18/EC⁶¹. One emergency measure has been implemented, by France, under Regulation 1829/2003 (same prohibition, notified also under Directive 2001/18). Since the entry into force of the Directive, a total of seven Member States have introduced provisional bans on five authorised GMOs.

EFSA found no reason to believe that there is a risk of adverse effects on the provisional bans on MON810 under the provisions of Article 23 of the Directive. Thus, the Commission, in accordance with its obligation under the EC Treaty, is in the process of requesting the MSs concerned to withdraw their national measures prohibiting the sale of these products. But in February 2009 the Standing Committee of the Regulation failed to reach agreement on lifting the French and Greek national bans on GM crop cultivation of MON810, leaving the decision to the Council of Ministers. On 2 March 2009, with a qualified majority of 282 votes⁶², 22 of 27 Member State authorities rejected the Commission's proposal to force the waiving of the bans in Austria and Hungary of Monsanto's MON810.

Some MS authorities noted that the main issue with national safeguard and emergency measures is that they are implemented on the basis of, at least partially, political motives rather than scientific motives. MSs with existing bans have justified their actions on the grounds that regional specific circumstances and conditions regarding environment, health and long term effects are not sufficiently acknowledged by EFSA. In our consultation MS authorities stressed the need for more detailed and more rigorous environmental risk assessment methodology and criteria, which should be used by notifiers to carry out concrete scientific research (see section 4.4). One MS authority even suggested that a national appraisal of the risk assessment should be undertaken for particular release and this appraisal should form the basis for a decision on cultivation.

Some MS authorities have said that the lack of bilateral consultations between EFSA and relevant MSs and 'inadequate' consideration of MS views on EFSA's opinion could be a factor in the bans. MS authorities with existing bans called for more robust dialogue and coordination between EFSA and MS experts. A number of MS authorities said that it is important that comments from MS authorities be taken into account from the beginning of the evaluation procedure and dealt with appropriately by EFSA (see section 4.6 for further discussion). The examination procedures need to be more transparent, and involve other member-states as well and other stakeholders that are interested.

Some MS authorities suggested that the fact that some national safeguards have not been repealed, despite EFSA opinions, was an indicator of the system's inefficiency. Some MS authorities believed that the current process, based on MSs having to justify their safeguard measures with quantified evidence and this evidence being subsequently appraised by EFSA, provides for an open and transparent system. However, one MS authority noted that because only scientific justifications can be given in support of national safeguard measures, the political reasons which are potentially behind some safeguard measures (and the support for them from other MSs) are not immediately transparent. Allowing non-scientific justifications for an 'opt-out' clause could lead to more transparency, by allowing MSs to indicate the 'real' reasons for their decisions. It could also reduce the inefficient and repetitive discussions on safeguard clauses and, in turn, reduce some of EFSA's workload. In terms of protection, most MS authorities said that there was no evidence of harm to ecosystems, environments or geographical areas as a result of crops against which safeguards have been taken.

⁶¹ Hungary, Austria, France, Luxembourg, Germany and Greece.

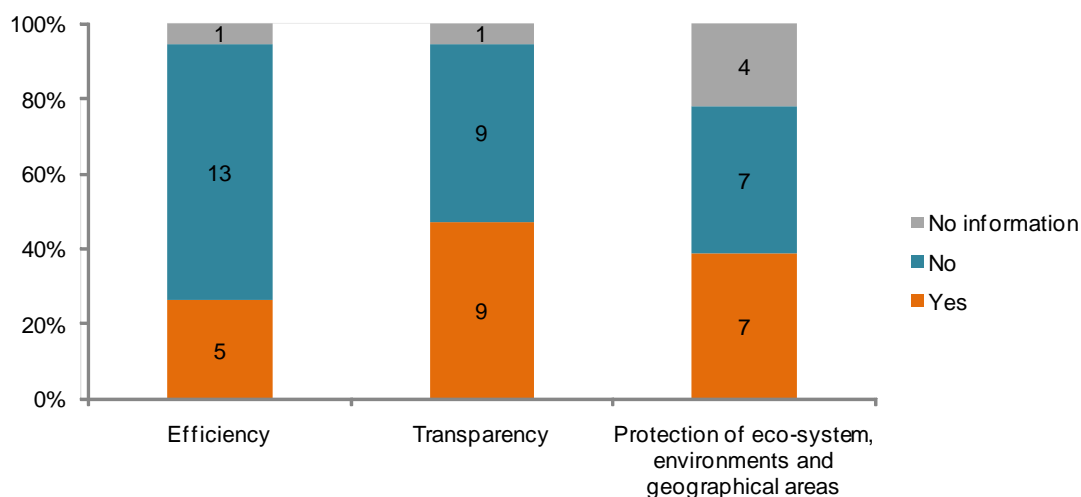
⁶² The number of votes allocated to each EU country roughly reflects the size of its population. For example, Germany, France, Italy and the UK each have 29 votes out of a total 345. Malta, in contrast, has just 3 votes. A minimum of 255 votes out of 345 (73.9 %) is required to reach a qualified majority.

When asked during the consultation exercise whether the implementation of the current system of national safeguard and emergency measures addresses the objectives of the legislation, in terms of: efficiency, transparency and protection of eco-systems, environments and geographical areas, most MS authorities (13 of those who responded) said 'No' in terms of efficiency and were more or less split in half on transparency and protection of eco-systems, environment and geographic areas (Figure 6.9).

Of the notifiers, only Monsanto has been directly affected by the bans, as its product (maize MON810) is the only GMO currently authorised and actively cultivated in the EU. The size of the market at stake prompted the company to take legal action in Germany and France. This has been unsuccessful to date. In the past the company has worked to avert a ban without recourse to legal action – in 2008 Monsanto negotiated with Germany to implement stricter post-market environmental monitoring measures, which allowed a ban to be avoided.

Figure 6.9 Most MS authorities said that the national safeguard and emergency measures do not address the objectives of the legislation in terms of efficiency and were divided equally in terms of transparency and protection of eco-systems, environments and geographical areas

Does the implementation of the current system of national safeguard and emergency measures address the objectives of the legislation, in terms of: efficiency, transparency and protection of eco-systems, environments and geographical areas? Views of MS authorities given in figure below.



6.3 Consultees highlighted some key suggestions for improvements

The key suggestions highlighted by consultees for improving the 'institutional' decision-making processes of MSs and the European Commission about the authorisation of GMOs for cultivation are given below:

- most consultees agreed that it is unlikely that the MSs will reach a qualified majority given the polarised nature of the views, and thus it is the responsibility of the Commission to make a decision;
- some Member State authorities have argued for a new approach to deal with the authorisation and use of GMOs in agriculture. They have variously suggested that:
 - MSs should give reasons and explanations for all votes and objections in meetings of the Regulatory Committee of Directive 2001/18/EC and the Council of Ministers;

- regional variability should be taken into account more explicitly in the ERA process (see section 4.4.2) and specific conditions of consent should be more readily included in the Commission's draft decisions; and
- there is a need for a more collaborative and harmonised approach between the Competent Authorities of MSs and EFSA at the risk evaluation stage to increase confidence in the RA appraisal (see sections 4.4.2 and 4.6) (initiatives to achieve this have already begun).
- MS authorities generally supported the 'opt-out' clause, but called for the Commission Legal Service to explore the feasibility and desirability of the policy change in the context of the single market;
- most MS authorities agreed on including socio-economic concerns for the authorisation of GMOs for cultivation and suggested the way in which they might be included, should be examined at EU level;
- most consultees agreed that it was necessary to first collect and analyse the spectrum of socio-economic concerns (adverse or beneficial effects) in the EU as background information for further discussion on this issue;
- most of the consultees foresee a socio-economic evaluation being conducted in parallel with the current technical risk assessment, both of which would then feed into the decision-making phase;
- MS authorities noted that the main issue with national safeguard and emergency measures is that they are implemented on the basis of, at least partially, political motives rather than scientific motives, and suggested:
 - the need for more detailed and more rigorous environmental risk assessment methodology and criteria, which should be used by notifiers to carry out concrete scientific research; and
 - more robust dialogue and coordination between EFSA and MS experts specially involving MSs with existing bans.

6.4 The practical risk management measures in the GMO legislation though an improvement over the previous legislation can be improved further

The post-market environmental monitoring (PMEM) prescribed in both the Directive and Regulation begins with the cultivation approval for a genetically modified plant.

Under the Directive, a PMEM plan for genetically modified plants is a mandatory requirement for applicants and is required to identify possible adverse effects on human health or the environment. Annex VII, supplemented with Guidance notes of Commission Decision 2002/811/EC, provides principles and objectives of the environmental monitoring plan *but* does not clearly indicate approaches and methods that should be used. Currently, there is no European consensus on how monitoring plans shall be designed⁶³.

The EFSA GMO Panel assesses the scientific quality of the PMEM plans presented in notifications submitted under Directive 2001/18/EC (if transmitted to EFSA) and in all applications for food/feed and import and processing, containing or consisting of GMOs submitted under Regulation (EC) 1829/2003 (EC, 2003). PMEM is only one subset of practical RM measures but is the topic that has received the most attention.

⁶³ Sanvido et al., 2005

6.4.1 RM requirements and provisions under the GMO legislation are an improvement over the previous legislation with some concerns regarding its predictability and adequacy for protecting human health and the environment

Most consultees noted that in the absence of any authorisations under the existing legislation, analysis of risk management requirements and provisions relating to cultivation are essentially academic, or at best reflect experience with Part B field trials. More than half of all consultees agreed that the 'practical' risk management (for example, monitoring and mitigation measures) requirements and provisions under the GMO legislation are an improvement on those of Directive 90/220/EEC and the Novel Foods Regulation (258/97/EC) to provide more a transparent and predictable EU regime (Figure 6.10).

MS authorities noted that the current legislation, compared to the previous one, improved the transparency of RM measures as well as the clarity of data for RM measures from applicants. However, MS authorities thought that the predictability of the authorisation process has suffered from the ongoing political discussions in the EU on the cultivation of GM crops. Predictability has been affected due to the lack of implementation of the GMO legislation and the variety of risk management measures taken by the different Competent Authorities. One MS authority (which disagreed) said that the RM decisions include "other legitimate factors", which makes the EU regime less predictable. Furthermore, they stated that the RM measures linked to the GMO decisions are not communicated to the public in an accessible way, making the measures less transparent.

Some of the E-survey participants (13 of those who responded) disagreed or strongly disagreed that the current legislation is an improvement on the grounds that there is no comprehensive EU-wide structure or system in place for RM. Three E-survey participants said that the current RM requirements and separation of RM from RA still does not prevent MSs from taking "populist" political decisions.

Most MS authorities (14 of those who responded) and notifiers noted that the provisions in the Directive and the Regulation are fit for purpose but are too general in practice (Figure 6.11). For example, the required 'quality' of the monitoring plan is unspecified - in terms of types and depth of studies and over what time period the monitoring activity should be carried out. MS authorities were split over the adequacy of the provisions under the new legislation. Some MS authorities thought that the provisions of the new legislative framework provide adequate measures to protect human health and the environment but acknowledged facing issues in terms of implementation. Other MS authorities thought that the provisions under the new legislation are not adequate to take into consideration the specific circumstances of each ecosystem, geographical regions or specific environments. They argued that the special circumstances of each area should play a significant role in the risk management requirements. As such, there is scope for further improvement. MS authorities noted that inspection and controls are regulated by national legislation and specific protection measures are not specified in any detail in the EU legislative framework.

Some MS authorities also found that the provisions of the Directive and the Regulation for monitoring and special protection of eco-systems, environments and geographical areas are not easily applicable as they require substantial resources in terms of personnel, organisational structures and procedures which eventually translates into considerable costs. Some MS authorities thought that these provisions can increase the burden on MSs to convince EFSA and other MS authorities of the need for defining specific management measures for the protection of special eco-systems and geographical areas in the final consent.

Overall, most MS authorities thought that risk management measures need to be made more simple and predictable, and the guidance improved.

Figure 6.10 Most consultees agreed that RM requirements under the new legislation are an improvement

Do you agree that the risk management requirements introduced in Directive 2001/18/EC and Regulation 1829/2003 provide more transparent and predictable EU regime compared to that under the Directive 90/220/EEC and the Novel Foods Regulation (258/97/EC)?

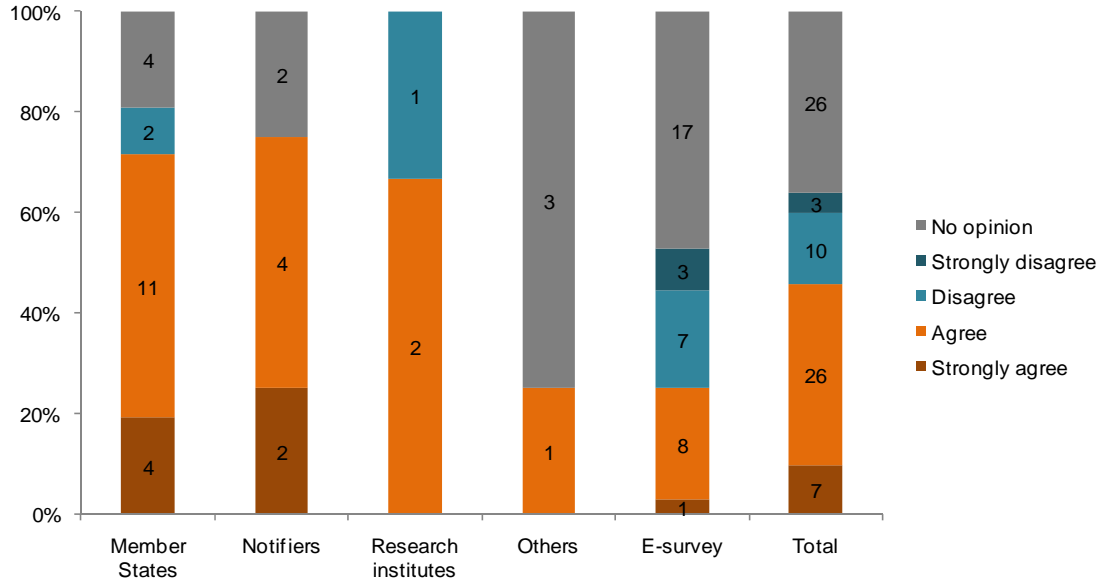
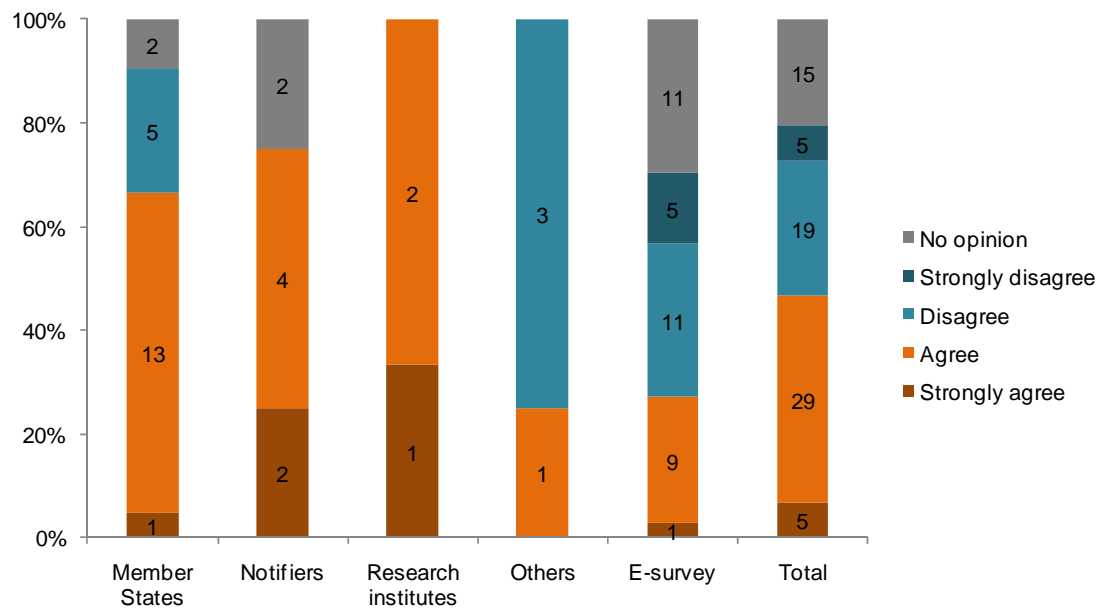


Figure 6.11 Most consultees agreed that the provision in the new legislation is fit for purpose

Are the provisions in Directive 2001/18/EC and Regulation 1829/2003 for monitoring and special protection of eco-systems, environments and geographical areas, fit for purpose?



Notifiers are implementing post-market monitoring programmes for products authorised under Directive 90/220/EEC under the principles of Directive 2001/18/EC, as well as comprehensive programmes for insect resistance management (IRM). IRM maximises the likelihood of insect-resistant crops remaining effective in the long term. Notifiers thought the RM requirements are transparent in principle, but not in detail. They were concerned that detailed risk management requirements can be proposed by the Commission and Member State authorities for inclusion in product authorisation decisions without consultation with applicants as to the appropriateness, proportionality or cost of implementation. One notifier noted that it was difficult to provide a conclusive response on the transparency and predictability of the RM requirements since no events have been approved for cultivation under this system as yet.

Although notifiers make recommendations in the dossier on what kind of PMEM measures are appropriate, they do not know what measures will eventually be included in the final decision. Sometimes, they are able to see the decision before it is voted upon, although they have no formal rights to do so.

Notifiers also noted that, since there have been no approvals for GM cultivation under Directive 2001/18/EC or Regulation EC No 1829/2003, there is no requirement for MSs to implement the provisions of the new legislation for products approved for cultivation under the old framework (Directive 90/220/EEC). However, according to one notifier, they have designed and implemented post-market monitoring programmes which are consistent with the requirements of Directive 2001/18/EC and certain MS authorities have engaged with the implementation of these programmes.

6.4.2 *Post-market environmental monitoring (PMEM) is not in line with the objectives of the legislation in terms of protecting the environment and human health objectives and needs substantial improvement*

There are two types of post market environmental monitoring of GM crops:

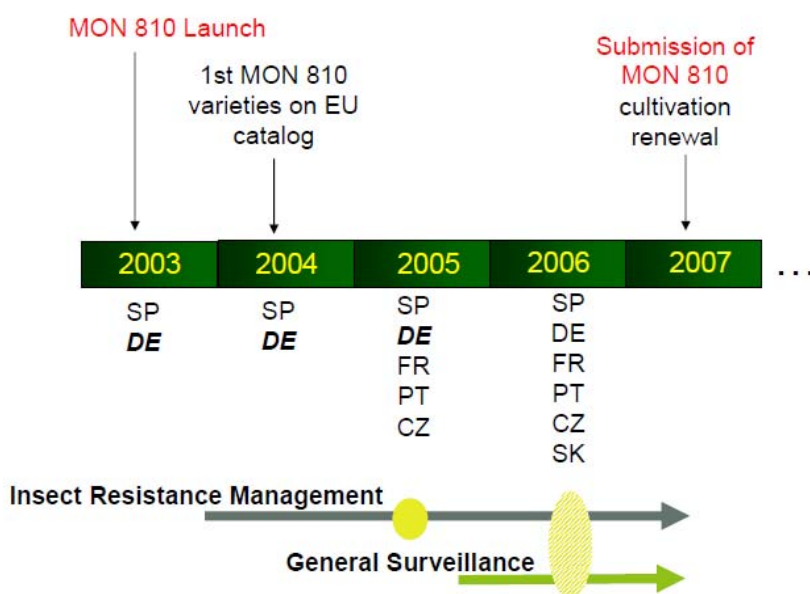
- **General surveillance (GS)** to identify unexpected long-term effects. GS is prescribed for all GM plants, and is not hypothesis-driven. Notifiers are responsible for GS, but MSs can also carry out their own GS if they choose to.
- **Case-specific monitoring (CSM)**, which is prescribed for certain GM crops to investigate effects that were identified as a potential risk during the risk assessment. CSM is hypothesis driven. An example is monitoring of resistance in European corn borers in Bt maize.

Where there is scientific evidence of a potential adverse effect linked to the genetic modification, then case-specific monitoring should be carried out after placing on the market. General surveillance is mandatory for cultivated GMOs.

Current experience with implementing PMEM plans is limited to MON810

Currently only MON810, originally approved under the old Directive 90/220/EEC, is actively being cultivated in Europe. MON810 was approved before the new PMEM provisions under Directive 2001/18 were active. No practical risk management measures were introduced by the Decision 98/294/EC in its normative parts (Art. 1 and 2). Monitoring and practical risk management measures have been implemented on a voluntary basis by Monsanto.

Figure 6.12 Monitoring since commercialisation of MON810



Source: Monsanto, Workshop on Post Marketing Environmental Monitoring of Genetically Modified Plants: Harmonization and Standardization – a Practical Approach, Berlin, April 26th 2007

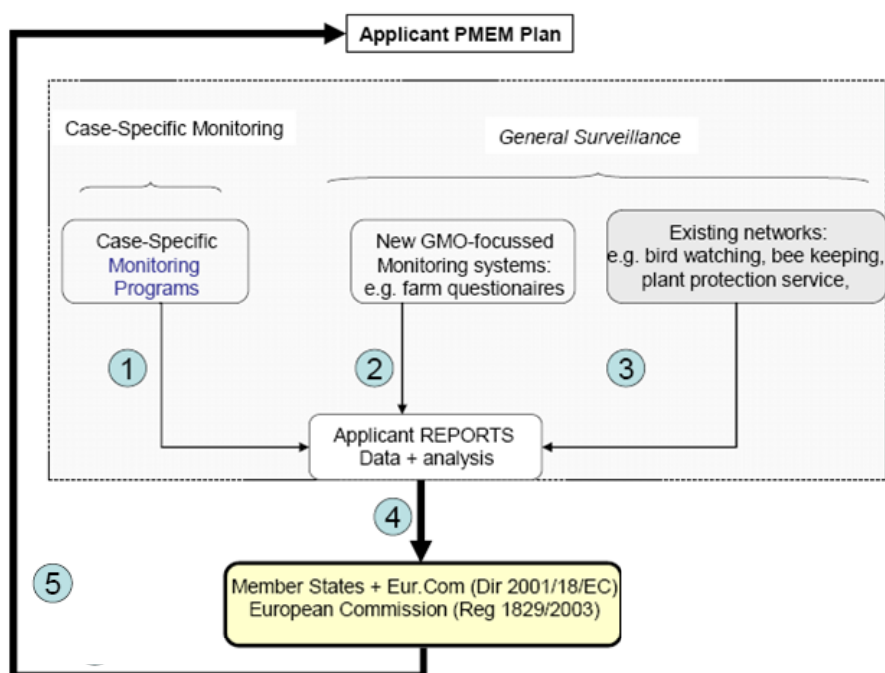
Since 2005, Monsanto has implemented a General Surveillance programme in 6 MSs (Figure 6.12 above) on a voluntary basis to satisfy the requirements of Directive 2001/18/EC. MON810's authorisation recently expired. Consequently, an application for renewal of an "existing product" was submitted according to Regulation 1829/2003 in April 2007. With respect to the renewal procedure of MON810's authorization, Monsanto submitted a PMEM plan according to the requirements of Directive 2001/18/EC to the Commission in May 2007. However, the conditions of consent in the original authorisation for MON810 in 1998 (without the PMEM plan) are still valid until such time as a decision for its renewal is made. In April 2007, the responsible German Competent Authority (Federal Office for Consumer Protection and Food Safety – BVL) took action to guarantee the implementation of the newly submitted PMEM plan, independent of the duration of the renewal process. Subsequently, Monsanto submitted a proposal for national implementation of the new PMEM plan in Germany (BVL, 2007).

Developing a PMEM plan involves notifiers, MS authorities and the Commission

Applicants (notifiers), risk assessors and risk managers each have a role in developing a PMEM plan. The various tasks of data generation, reporting and analysis at different stages of a PMEM plan is given in figure 6.13 below.

1. Collection of data from case specific monitoring (CSM), if applicable;
2. Collection and analysis of data from GMO-focussed general surveillance (GS) networks as suggested or set up by applicants;
3. Where appropriate, additional data from existing national networks (e.g. bird watching, plant protection services) should be collected as well;
4. PMEM reports are sent to risk managers in the European Commission who forward it risk managers in MSs; and
5. The lead Competent Authority may adapt the PMEM plan based on the monitoring results.

Figure 6.13 Main stages of PMEM plan



Source: Adapted by GHK from Bartsch D et. al (2006), *The EFSA opinion on post market environmental monitoring of GM plants*, Ninth International Symposium on Biosafety of Genetically Modified Organisms, Korea

The issues raised during the stakeholder consultation focused on the following six aspects of the PMEM plans:

- The content of the PMEM plans;
- The need for better guidelines;
- Defining baselines;
- The borderline between case-specific and general surveillance;
- The methods on which general surveillance is based; and
- The need for efforts of notifiers to be complemented by those of MS authorities.

Content of the PMEM plans are not adequate to meet the legislation’s objectives

Only 11 MSs have had experience either with GMO cultivation or field trials under Part B and were able to evaluate PMEM plans under Part C⁶⁴ and monitoring plans under Part B⁶⁵ of the Directive. When consulted about the design of the PMEM plans submitted by applicants under Part C, 12 MS authorities disagreed or strongly disagreed that PMEM plans were in line with the objectives of the legislation in terms of protecting the environment and human health objectives, whereas EFSA felt that the legislation’s objectives were met (Figure 6.14). The PMEM plans need to provide more detail on how they are to be implemented at MS level using existing monitoring systems. A number of MS authorities agreed that the PMEM plans in general need substantial improvement, as a consequence of the lack of detail in the monitoring reports provided so far by applicants. The monitoring plans usually do not foresee any scientific studies, but focus on very

⁶⁴ Requirements for a monitoring plan under Part C are set out under Annex VII of the Directive and Guidance notes 2002/811/EC

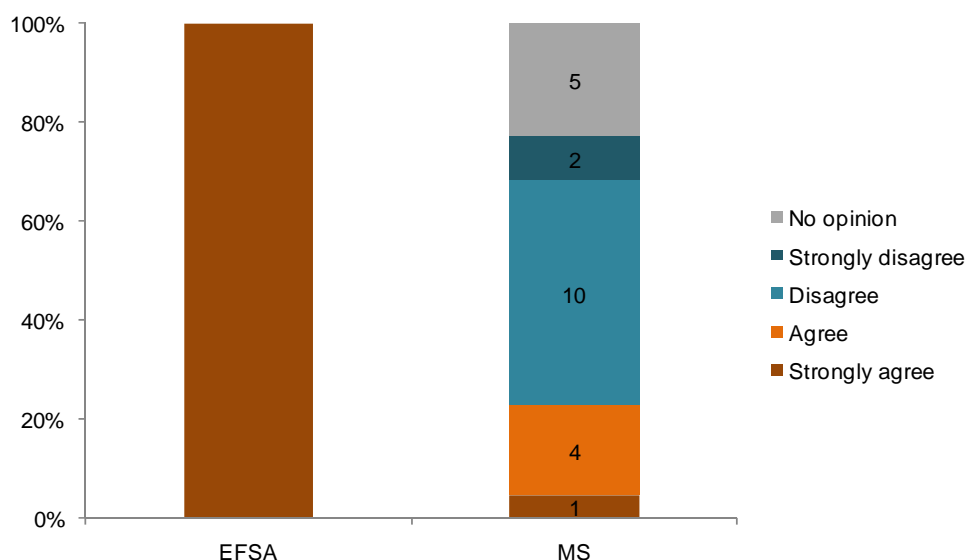
⁶⁵ Requirements for monitoring plan under Part B are set in accordance with relevant parts of Annex III, of the Directive.

general questionnaires issued to farmers cultivating GMOs. This was considered inadequate. MS authorities were looking for sound PMEM plans that would address complex environmental issues. This can only be achieved by scientific experts, using appropriate methods.

The consultation exercise also highlighted the differences between monitoring requirements of MS authorities and EFSA. Some MS authorities want more specific details on the monitoring plans to be implemented in their MS but EFSA opinions state that the specific details and method do not have to be included in the original PMEM plan submitted by the notifier. Case specific monitoring is rarely proposed. Some MS authorities thought that CS monitoring was necessary to monitor the effects on non-target organisms.

Figure 6.14 Majority of MS authorities thought that the PMEM plans in general do not meet the legislation’s objectives

Do you agree that the design of the PMEM plans that are submitted by applicants under Part C and Part B generally meet the legislation’s objectives (Annex VII of the Directive 2001/18/EC)?⁶⁶



In general, most consultees highlighted the lack of clear definition of protection goals (ecological systems and biodiversity, soil function, sustainable agriculture, plant health and human and animal health) and a definition of ‘base-lines’ (discussed further below). Notifiers stated that their monitoring should be fairly consistent across MSs. EuropaBio⁶⁷ are working to develop well defined processes and questionnaires to ensure consistency and harmonisation of PMEM across all MSs.

There is a need for better guidelines from the Commission and EFSA

As mentioned in section 6.3.1, MS authorities are finding it difficult to develop strategies for risk management from existing guidelines. Several MS authorities stated that the guidelines developed by the EC under Annex VII of the Directive and Decision 2002/811/EC are not sufficient to ensure harmonized surveillance measures are implemented at Community level (Figure 6.15). Some MS authorities wanted more detail in that Decision to address areas where the wording is unspecific and gives too much room for interpretation. MS authorities have called for more details on the separation between case specific monitoring and general surveillance, definition of relevant protection goals, the choice of indicators and

⁶⁶ The question was only proposed to EFSA and MSs.

⁶⁷ European biotech industry sector association

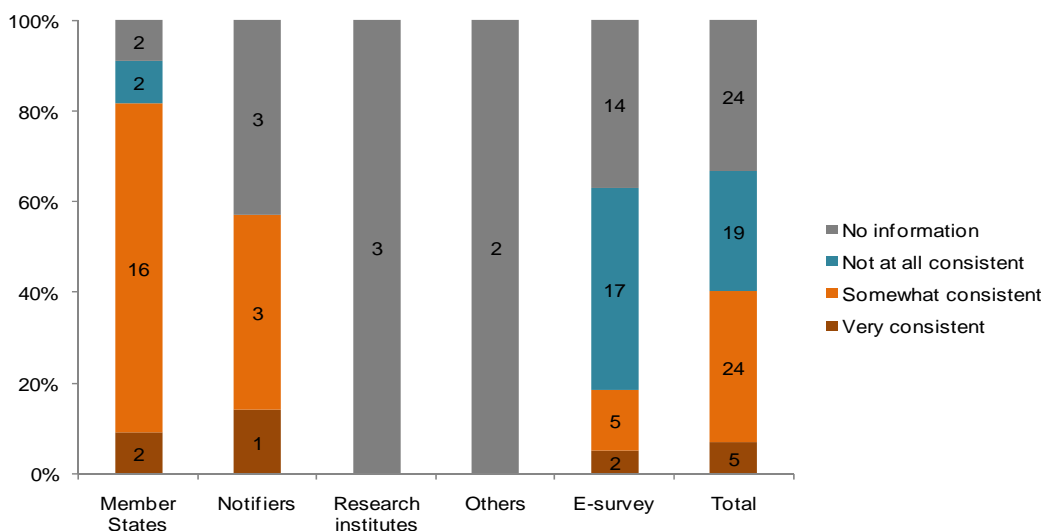
test species and the definition of minimum requirements on test systems (indicators, measurements and endpoints). MS authorities acknowledged that more experience is probably needed to improve the guidance.

Most MS authorities (18 of those who responded) and four of the notifiers thought that the existing Commission guidelines, though inadequate, have led to more consistency among MSs in the design, scope and application of the PMEM (Figure 6.15) plan. However, the use of existing monitoring systems is likely to vary, depending on what is available. Expectations on the design and scope of the PMEM plan also differ by MSs. Some consider monitoring hazards (e.g. pollen flow) as well as adverse effects appropriate as a risk while others do not. Interpretation of what is considered to be cost-effective and proportionate also differs. There are differences in interpretation among MS authorities about what constitutes case-specific monitoring and general surveillance (discussed further below) and given this, what can be achieved through general surveillance.

Two MS authorities suggested that the results of the EC Monitoring Working Group under Directive 2001/18/EC should be taken into account in improving the guidance. One MS authority specially pointed to the benefits of the three checklists that have been prepared by the Monitoring Working Group (MWG)⁶⁸, having found the checklists useful for applicants when designing post market monitoring plans. These checklists identify the potential harmful effects to be considered by applicants during the environmental monitoring plan according to Annex VII of Directive 2001/18/EC and Commission Decision 2002/811/EC⁶⁹. The checklists include a list of research studies, recommendations for CS monitoring and GS, which could be undertaken after the GM crop has been placed on the market.

Figure 6.15 Majority of MS authorities and Notifiers agreed that the Commission’s guidance (Decision 2002/811/EC adopted on the basis of Annex VII of Directive 2001/18/EC) have led to more consistency among MSs in the design, scope and application of the PMEM

Given the guidance that has been developed by the Commission, to what extent do you believe that the types of post-market monitoring that will be required will be consistent in terms of design, scope and application across all Member States?

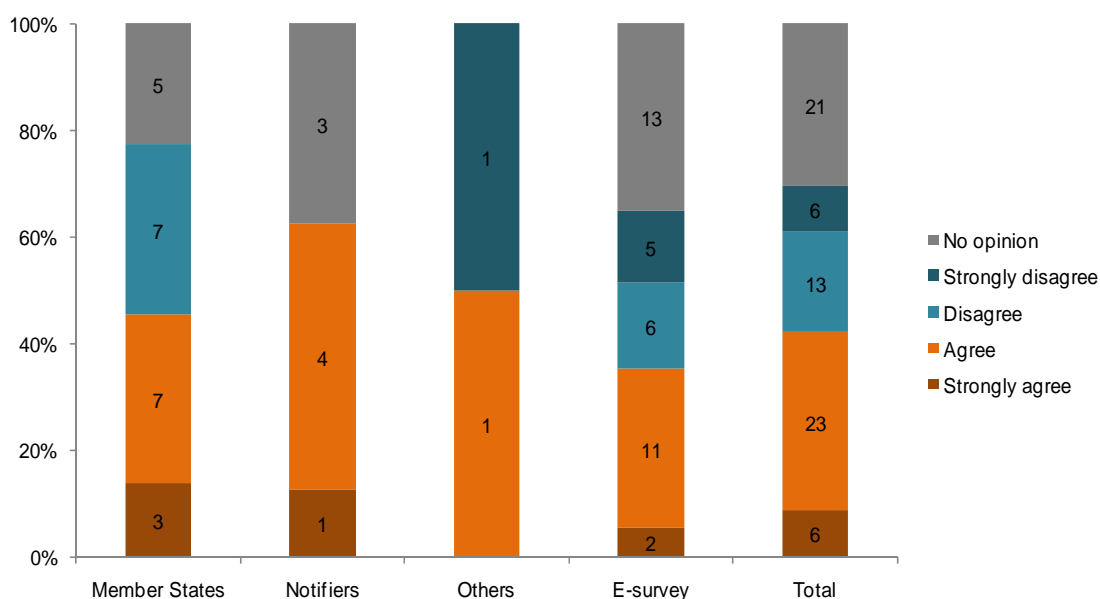


⁶⁸ Bt maize specific checklist, HT oilseed rape (OSR) checklist and Starch Potato checklist.

⁶⁹ Establishing guidance notes supplementing Annex VII to Directive 2001/18/EC on the deliberate release into the environment of GMOs

Figure 6.16 Most MS authorities and notifiers agree that EFSA’s GMO Panel’s recommendations for PMEM measures are clear and practical.

Do you agree that the EFSA GMO Panel’s recommendations for the management and conduct of PMEM by both applicants and risk managers are clear and practical?



Most consultees, especially MS authorities (10 of those who responded) and notifiers agreed that EFSA GMO Panel’s recommendations for the management and conduct of PMEM by both applicants and risk managers are clear and practical (Figure 6.16). However, some MS authorities said there was scope for improvement and called for more specific guidelines on general surveillance from EFSA under the revised guidelines with regards to the ERA.

The definition and assembly of data on baselines is a challenge for notifiers and Member State authorities

Most consultees agreed that defining the baseline against which the impact of GMOs is to be compared is difficult. The baseline is the current status quo, e.g. current conventional cropping or historical agricultural or environmental status. In practice direct comparison with non-GM plant reference areas is used if available⁷⁰, but reference can also be made to the “historical knowledge” and experiences of the “observer” (e.g. farmers, inspectors, wildlife surveyors, etc.) in relation to the situation prior to the introduction of the GM plant.

In discussion, notifiers stated that they do not have adequate guidance on whether to use current conventional cropping or historical agricultural or environmental data for the baseline, and that good quality and reliable data for defining baselines are scarce. Most MS authorities also acknowledged the problem of defining baselines. There is variation in the baselines used by MS authorities, with instances of some making reference to organic agriculture, others to conventional cultivation.

Most MS authorities and notifiers found it difficult to give accurate answers regarding the definition of baselines due to the limited experience with GM cultivation.

⁷⁰ Bartsch D et. al (2006)

Member State authorities are looking for clearer demarcation of the borderline between case specific monitoring and general surveillance

Some consultees highlighted problems in defining the borderline between risk assessment and risk management measures under PMEM (including CSM and GS)⁷¹. In the consultation, 14 out of 22 MS authorities agreed that there were issues concerning the boundary between case-specific monitoring and general surveillance monitoring which they would like to see addressed. MS authorities indicated that the limitations of the available data create uncertainties around the conclusions of GM risk assessments. Such issues should be subject to case specific monitoring, but are currently addressed only under general surveillance, and the approaches adopted for that are not adequate. One MS authority noted that the definition of the boundary matters because responsibilities for carrying out the case specific monitoring and/or general surveillance have to be defined. Member State authorities were looking for better guidance from EFSA and the Commission or more information on identification and quantification of risk from the applicants.

The GS/CSM borderline issue was highlighted in the recent EFSA Opinion on the cultivation of the herbicide tolerant maize NK603⁷². In its appraisal of the ERA, the Spanish Competent Authority recommended CS monitoring under the Directive to identify potential indirect effects on non-target organisms due to weed management, the development of weed resistance, and the evolution of flora associated with management of NK603 maize cultivation, including potential impacts on biodiversity. As an alternative option, EFSA suggested the use of management and mitigation measures to reduce the adverse environmental effects of the herbicide, alongside monitoring for weed resistance evolution under Directive 91/414/EEC and general surveillance monitoring under Directive 2001/18/EC to determine unanticipated adverse environmental effects.

MS authorities have recognised that RA should evaluate RM measures proportionate for the risk and that EFSA should play a greater role in terms of guidance on what should be provided for management measures associated with cultivation of GMOs (as an element of the overall appraisal of the ERA). EFSA could better address potential RM strategies or scenarios, perhaps through making more comprehensive recommendations on possible mitigation measures. This can be adapted by MS authorities taking into consideration regional characteristics.

The type of monitoring methods that should be used on farms where GMOs are cultivated and the adequacy of networks that could be co-opted for general surveillance are both debated

To date, general surveillance has been based on farmer questionnaires, and the use of existing monitoring networks. Concerns have been raised on the adequacy of these methods.

Some MS authorities did not think that the current use of farmer questionnaires was acceptable as they have an inadequate scientific basis. Additionally, they believed most farmers do not have the necessary expertise to collect the kinds of data that are required. Notifiers' counter-argument was that farmers know their fields better than any other group or monitoring network. Other consultees, such as MS authorities and some environmental NGOs, did not generally believe that farmers have the expertise to monitor ecological and biological interactions around their fields; although farmers' knowledge of pests, yields, crops and weeds might be exceptional, the majority do not know enough about biodiversity to be able to identify expected, let alone unexpected, effects on the wider environment.

⁷¹ EFSA, 2006

⁷²

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/gmo_op_ej1137_maizeNK603_en.3.pdf?ssbinary=true

Concerns were also raised about the adequacy of both the quantity and quality of monitoring networks. Both MS authorities and notifiers acknowledged that surveillance has been curtailed in some instances by the lack, or refusal of, publicly funded networks to contribute to the GS programme.

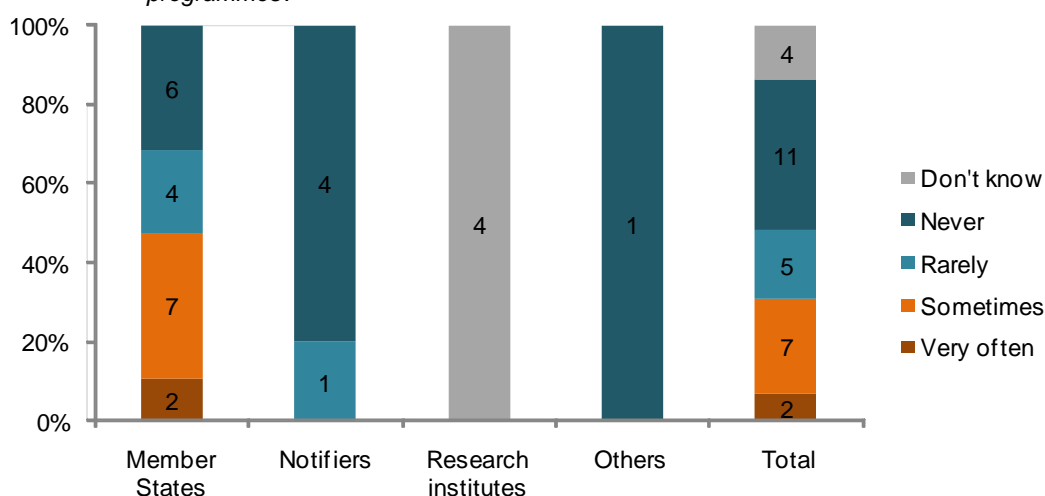
Notifiers must ensure that the data from these networks are adequate to address the monitoring requirements. However, both MS authorities (10 of those who responded) and notifiers (5 of those who responded) highlighted the small number of existing networks and systems that exist for monitoring GM cultivation (Figure 6.17). Most networks are not suited to monitoring the environmental and ecological impact of GM crops. Notifiers also said that most networks are reluctant to participate or cooperate due to negative public perception, lack of capacity, financial issues and other reasons. There may be a need for additional environmental surveys and for amendments to the monitoring objectives of existing monitoring systems⁷³. In most cases EFSA opinions have accepted the monitoring systems and surveys proposed by the notifier.

Consultees have made suggestions of how the current problems with the general surveillance system could be addressed. EFSA's opinion on NK603 maize said that the general surveillance plan should not only rely on farm questionnaires, but also use other sources of data, such as stewardship programs and literature. One MS authority has also suggested that some phytosanitary systems are suitable and biodiversity data are collected by relevant institutions (e.g. RSPB and Natural England in the UK).

In order to improve GS, some MS authorities suggested that MSs should first define the role of Competent Authorities in surveillance, which should be complementary to that of notifiers and meet their responsibilities. The procedures and methods, e.g. any quantitative measures must be improved in order to get meaningful monitoring from GS. MS authorities recognised the need for a review of present programmes of general surveillance in EU Member States including both agricultural and environmental institutions and agencies. MS authorities should also ensure that GS is establishing data systems which are of adequate quality for scientific and environmental analysis related to GM cultivation.

Figure 6.17 MS authorities and notifiers were split on whether the provision in the legislation for monitoring encourages MS authorities to coordinate more with each other

“Do the provisions in Directive 2001/18/EC and Regulation 1829/2003 for monitoring and special protection of eco-systems, environments and geographical areas, encourage relevant authorities in your Member State to establish links with applicants in order to coordinate data collection and analysis from different monitoring programmes?”



⁷³ Sanvido et al., 2005

Notifier PMEM plan requirements can be complemented by efforts of MS authorities

The interviews with consultees and our research suggest that notifiers' PMEM plans (CSM and/or GS) requirements and its efficacy could be improved if they were complemented by national or regional initiatives by Member State authorities. Member State authorities are themselves not sure about the distinction between CSM and GS and the division of responsibility for surveillance between Competent Authorities and notifiers. The conclusions of the Environment Council on 4 December, 2008, also require that MS authorities concerned with the cultivation of GMOs establish their own monitoring activities, without any prejudice to the obligations of applicants.

MS authorities are responsible for investigations beyond the monitoring plan that concern those (open) questions where no exclusive link to the GMO can be made in advance (e.g., large-scale dynamics of pests). The notifier delivers comparable data for the GMO as required within the case-specific monitoring or general surveillance. MS institutions, contracted by the notifier, may participate in the monitoring⁷⁴.

A number of MS authorities recognise the need for improving or creating new surveillance networks where no existing network can meet the requirements (Table 6.1). One MS authority for example, recognised the limit to which notifiers can carry out post-market monitoring and have initiated a taskforce to build on existing networks/resources and outline new requirements.

GS within the cultivation area is the responsibility of the notifier. The responsibility for GS outside the cultivation areas differs by MS. One MS authority, for instance, holds the view that GS beyond the cultivation area, and in addition to the 10 years time limit of the consent set out in the legislation, should not be the responsibility of the notifier. Guidelines from the European Commission are not clear on this point.

Furthermore, since monitoring methods are not standardised, comprehensive and effective monitoring strongly depends on the cooperation between MS authorities and notifiers on the exact scope, design and application of the monitoring plan. MS authorities also felt that they should work towards harmonization of national surveillance, exchange of protocols and systems implemented in Member States if necessary. Harmonization of monitoring plans could occur through a clear definition of the objectives for the protection of the environment. Each Member State must however be able to adapt the surveillance based on the characteristics of its environment and its priorities for ecosystem protection. In addition to the notifiers, MS authorities should also inform other MS authorities and the Commission the results of the monitoring and the protocols and systems implemented.

Table 6.1 Examples in Europe where General Surveillance can make use of existing and on-going monitoring studies for relevant data

Switzerland	The Swiss Biodiversity Monitoring Programme (BDM) has carried out measurements of biological diversity since 2001 using evenly-spread random plots all over the country which are sampled to draw conclusions about Switzerland as a whole (Bühler, 2006). A central coordination office compiles data collection, analysis and publication. Vascular plants, breeding birds and butterflies are assessed. From a conceptual point of view, the sampling strategy of BDM meets the basic principles of general surveillance (EFSA, 2006b). The BDM provides baseline information that can be used to detect unanticipated consequences of the cultivation of GM plants (Bühler, 2006). The BDM uses no predictions about the changes that might happen to infer a specific sampling design and so is not hypothesis-driven. Both BDM and General Surveillance search for unanticipated adverse effects.
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⁷⁴ Wilhelm, et. al, 2003, http://www.biosicherheit.de/pdf/dokumente/bba_monitoring.pdf

France	The biological survey of the national territory of France, consists of monitoring the evolution of crop pests and other bio-indicators linked to agricultural productions (Delos et al., 2006). The annual assessments of a large number of indicators enable the detection of significant time trends which may be linked to agricultural practices, new plant protection products, changes in farming practices or plant cultivars. The early detection survey of any significant modification was developed in accordance with the French Agricultural Orientation Law of 1999 implementing biovigilance activity (Loi n 99-574 d'orientation agricole, 1999). Since 1998, this surveillance has been aimed at a number of pests and other animal organisms of maize crops. It was extended to other environment parameters: weed flora on nearly 900 fields of different crops in rotation since 2002, spread on the main crops areas of the territory, fungi of corn kernel and mycotoxins since 2004, soil pests and birds since 2005. In 2006, the programme continued including all plant diseases and pests of crops involved in a rotation on a nine hundred fields-network.
Austria	Austria has 24,300 baseline data-records to compare any future changes at a landscape level. Within the 215 species of butterflies occurring in Austria, 152 appear in agricultural landscapes and therefore are in potential contact with GM crops (e.g. pollen of Bt maize). Maps were already designed for parameters "pollination time from maize" and "larval development of butterflies". These baseline data could be a starting point for post-market surveillance of Bt maize cultivation in Austria.

Source: Bartsch SourSource: Bartsch D, et. al (2007)⁷⁵

6.4.3 MS authorities stated that monitoring reports are too general and there is a need to improve the quality of reporting and to harmonize monitoring practices across MSs

Most consultees were not able to comment on the monitoring reports since there have been no approvals for GM cultivation under Directive 2001/18/EC or Regulation 1829/2003. Thus, their views mainly reflect monitoring of field trials via reports supplied by consent-holders or monitoring reports from 'inspection & control' authorities.

Most MSs have designated authorities that assess the monitoring reports submitted by consent-holders. These authorities are either represented by the Ministries of Environment or Ministries of Agriculture/Forestry or Food.

A number of MS authorities stated that monitoring reports are too general and a harmonised approach would be beneficial in order to give real insights into the effects of GMOs on the environment. The current guidelines are quite general and MS authorities find it difficult to consistently derive concrete RM implementation strategies from the monitoring reports. Data from general surveillance vary in type, quality and scope. The standard reporting formats adopted by the Regulatory Committee in May 2009 should help to improve the quality of reporting and help to harmonize monitoring practices. MON810 cultivation reports, GMOs Import and Processing reports and Food and Feed reports were assessed to draft the standard reporting format for monitoring GM cultivation. The standard reporting format only relates to post market monitoring. It is not designed for reporting on field trials.

⁷⁵ Bartsch D, et. al (2007), First EFSA experiences with monitoring plans. J. Verbr. Lebensm. 2 (2007) Supplement 1: 33 – 36, Journal of Consumer Protection and Food Safety

MS authorities also consult on the monitoring reports and the reporting data. However, not enough mechanisms are put in place by MS authorities for scientific analysis of the reporting data. A number of MS authorities have suggested the need for better cooperation between Competent Authorities (under Directive and Regulation) and cooperation with the consent holders.

Some MS authorities raised concerns that the data obtained from monitoring and reporting in different MSs could not be compared in terms of scientific data analysis due to differences in monitoring requirements and networks. However, 10 out of 22 MS authorities agreed or strongly agreed that risk monitoring and reporting provide good quality data for scientific analysis at Member State and EU level (Figure 6.18).

One MS authority stated that monitoring reports are circulated among MS authorities each year. Some MS authorities considered these reports to be sufficient to learn and increase their experience with monitoring reports. 9 out of 21 MS authorities agreed that adequate arrangements are in place (at EU and Member State level) for learning from monitoring and reporting data (Figure 6.19).

One MS authority noted that with the increase in the number of GM crops and/or events and of the number of countries growing GM crops, the harmonisation and monitoring and reporting data will become more important.

Figure 6.18 More MS authorities (9) agreed than those who disagreed (5) that risk monitoring and reporting were providing good quality data for scientific analysis at Member State and EU level

Do you agree that risk management measures (e.g. monitoring and reporting) are providing good quality data for scientific analysis at Member State and EU level? Member State authorities' responses to questionnaire

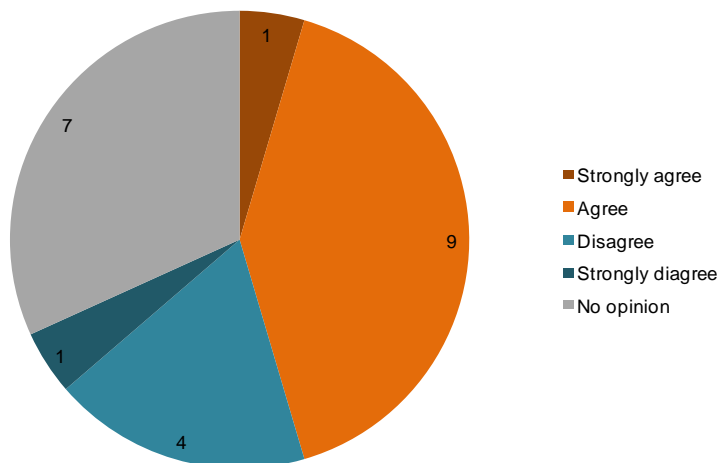
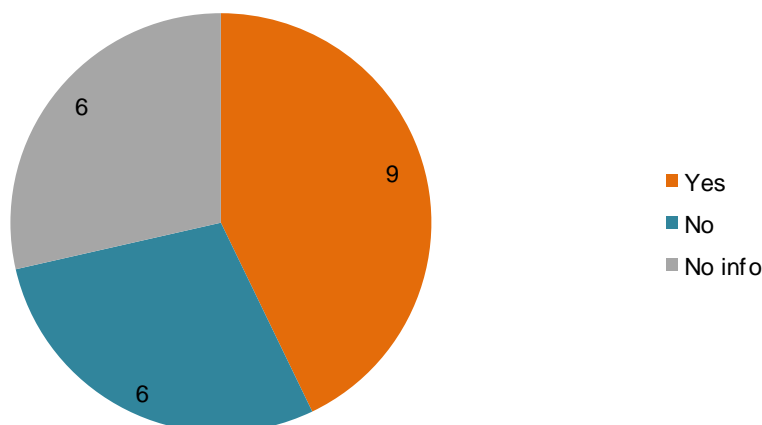


Figure 6.19 More MS authorities (9) said that they have adequate arrangements in place for learning from monitoring and reporting data

Are adequate arrangements in place (at EU and Member State level) for learning from monitoring and reporting data? Member State authorities' responses to questionnaire



6.4.4 Most MSs have inspection and control measures in place for enforcement of the legislation but more work is needed to deal with the risk of Adventitious Presence of GMOs

Inspection and control experience is mostly limited to field trials. Under Article 4.5 of Directive 2001/18, MSs are obliged to organise inspection and other control measures as appropriate. This is carried out either by dedicated GM Inspectorates or other enforcement officials, usually with agricultural and environmental expertise, with delegated authority to inspect GM field trials.

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. In the Netherlands and the UK, where audits of the consent holder are undertaken, the inspectors also focus on risk management, monitoring and communication

All MSs have arrangements in place for inspection and control of GM field trials

Nineteen⁷⁶ MSs have assigned inspection and control functions to a nominated Inspectorate. With the exception of Sweden, which has a newly appointed inspectorate, all inspectors have developed guidelines and/or standard operating procedures (SOPs) for inspection. A number of inspectors referred to the checklists developed by the European (GMO) Enforcement Group⁷⁷.

Inspectors' powers can include: full access to research sites, authority to request samples for further investigation, tests, investigating accidents (with field trials and cultivation), imposing fines in cases of small offences, taking any necessary action (such as serving a prohibition notice or instituting proceedings), remedying harm, investigating public complaints and referring offenders to the public prosecutor.

⁷⁶ 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.

⁷⁷ 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.

Most MSs have arrangements in place for notifiers to demonstrate that they have acted in accordance with their duty of care

For reasons of safety and traceability, it is important to ensure that the GMO released is the same GMO that has been assessed and authorised for release, and also that unauthorised presence of adventitious GMOs are not present. Most MSs have a penalty and liability system for the non-compliance.

Most MSs (17 out of 22 responding) have arrangements in place for notifiers to demonstrate that they have acted in accordance with their duty of care. These arrangements are enforced by national law and thus differ by MS. National policy may affect the level of stringency with which GM legislation is enforced. For example, while some MSs may adopt a zero tolerance approach for adventitious presence (AP), levels of 0.1%, 0.5%, 0.7% and 0.9% are reported.

Nine of the twenty four MSs responding 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. Confirming the identity of the GMO to be released is considered as a critical control point in a GMO release or field trial⁷⁸.

Sampling differs by MS, ranging from 100% of all different types of seeds, to no sampling and testing at all. Testing is reasonably comparable across MSs, and most operate according to established, recognised standards. Some MS authorities check whether field releases are in line with the consent by examining documents and from time to time also analysing samples taken from the field trials in order to confirm the identity of the GMOs for which the deliberate release has been authorised.

A number of MS authorities stated that more work is needed to deal with the risk of Adventitious Presence of GMOs in conventional seeds

However almost all MS authorities (20 of those who responded) and 4 notifiers agreed or strongly agreed that further regulation at EU and national level is needed to deal with the risk of adventitious presence of GMOs (Figure 6.20) in conventional. MS authorities also recognised that there is still a need to ensure that such regulations are enforced properly in each Member State.

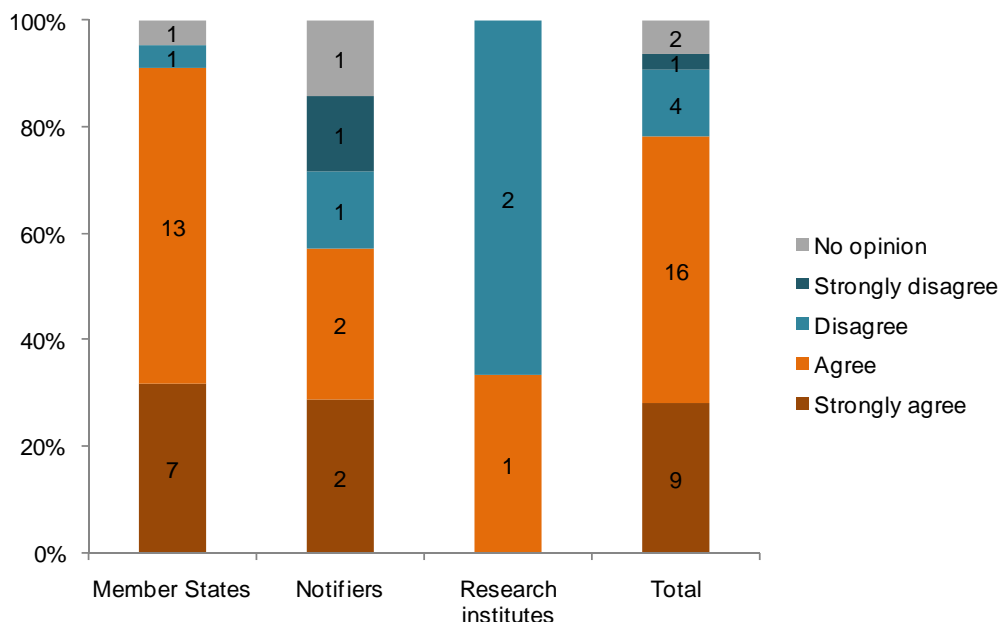
Most MS authorities agreed that there is a need for a legal instrument establishing seeds thresholds, at EU level. Some MS authorities wanted more flexibility to define their own level of safety for adventitious presence of GMOs. A number of MS authorities said that the implementation of labelling and traceability legislation of conventional seed lots without such thresholds for adventitious presence is extremely difficult.

However, some MS authorities pointed out that accessing reference material from non authorised GMOs is a problem for the laboratories concerned. Most MS authorities said that authorised reference material and validated detection methods are needed if adventitious presence is to be controlled. MS authorities also called for further action or further regulation at EU level since national reports on risk of adventitious presence of GMOs in conventional seed lots differ among EU Member States.

⁷⁸ Analysis of field trials management in Member States and prevention of accidental entry into the marketplace (November, 2008), Research project ENV.B.3/ETU/2007/0008. Central Science Laboratory and SASA.

Figure 6.20 Most consultees agreed, especially a majority of MS authorities, that more work is needed to deal with the risk of AP of GMOs

Do you agree that further action or further regulation is needed at EU level to deal with the risk of adventitious presence of GMOs (e.g. guidance, harmonised evaluation criteria, validated detection methods, authorised reference material)?



6.5 Other practical risk management mitigation measures have been either developed through national systems or on a case by case basis

Most risk management measures in place have been developed for field trials because there has been limited GMO cultivation. Some MS authorities are developing recommendations for standard risk management practices but these are not yet finalized.

One MS has developed a general management strategy to assist its regions in case the MS authority would authorize an application for GMO cultivation. But it cannot be finalised until thresholds for adventitious presence of GMOs in other conventional seed lots are adopted. Another MS authority noted that past experience with field trials has helped to define some "best practice measures" but not all of these practices have been clearly documented as a reference guide. For most MSs, only field trial data are available to validate the isolation distances that are required to prevent spread of GMOs to non-GMO fields in the interest of co-existence.

Some MSs have developed several protocols for field releases of transgenic plants. These protocols contain management measures such as isolation distance (and/or isolation borders) and after-harvest measures (such as the destruction of harvest and deciding on crops to be grown the following years). These isolation distances or buffer zones vary from MS to MS and have been described in detail in the EC Working document SEC(2009) 408 final⁷⁹. Coexistence rules for commercial cultivation of GMOs have also been established on a regional level in some MSs.

Some MS authorities said that the assessment of what is necessary as a precautionary RM measure is made on case-by-case basis. As long as the Competent Authority considers the

⁷⁹ Commission of the European Communities, Commission Staff Working Document accompanying Report from the Commission to the Council and the European Parliament on the coexistence of genetically modified crops with conventional and organic farming, Implementation of national measures on the coexistence of GM crops with conventional and organic crops, Brussels, 2.4.2009, SEC(2009) 408 final

suggestions to be sufficient they will be accepted. However, notifiers tend to suggest more or less similar RM practices across all MS authorities. This means that in practice, crop specific management measures are similar even though field trials may differ.

6.5.1 Some Member States have systems designed to ensure that variability in ecosystems/environments and/or geographic areas is recognised in RM measures

Most MS authorities take into consideration the variability of the ecosystems / environments and / or geographical areas when defining RM measures. However, some MS authorities felt that consideration for regional variability was inadequate either because the ERA did not take these specific characteristics into proper consideration, or the provisions were not adequate. A number of MSs have not dealt with RM measures as no GMO cultivation has taken place.

One MS authority noted that it seeks advice on the hazards/risks that may vary depending on regional bio-geographic areas and agronomic practice. However, this has not resulted in any specific conditions being attached to consents under Directive 2001/18 or a refusal to issue a consent.

One MS authority said that its nature conservation authority can impose special cultivation conditions in order to ensure compliance with EC legislation on the conservation of natural habitats, of wild fauna and flora, of wild birds and also with the rules included in national legislation on designation of protected areas and on environmentally sensitive areas.

6.5.2 Field trial risk management is generally handled on a case by case basis

In most MS authorities, risk management measures for field trials are set on a case-by-case basis by an individual authorisation decision that takes into account the location of the site and any variability in ecosystems/environments and/or geographic areas. One MS requires that the regional authority in the area where the field trial is to take place is also consulted on the dossier. The region has a right of veto on the trial.

Some MS authorities pointed out that most field trial ERAs have been valid for their entire territory, which meant that no specific risk management measures were required. In some MSs the variability of ecosystems is not so great that it needs to be taken into consideration during field trials.

6.6 Summary: consultees' suggestions for improvement

Suggestions made by consultees for improving the 'practical' risk management measures applied to GMOs authorised for deliberate release are summarised below:

- most MS authorities thought that risk management measures need to be made more simple and predictable, and the guidance improved;
- most consultees highlighted the lack of clear definition of protection goals (ecological systems and biodiversity, soil function, sustainable agriculture, plant health and human and animal health) and a definition of 'base-lines';
- MS authorities were looking for better guidance from EFSA and the Commission or more information on identification and quantification of risk from the applicants for a clearer demarcation of the borderline between case specific monitoring and general surveillance;
- MS authorities recognised that RA should evaluate RM measures proportionate to the risk and that EFSA should play a greater role in terms of guidance on what should be provided for management measures associated with cultivation of GMOs (as an element of the overall appraisal of the ERA). EFSA could better address potential RM strategies or scenarios, perhaps through making more comprehensive recommendations on possible mitigation measures, given that

they are evaluating the risk in the first place. This can be adapted by MS authorities taking into consideration regional characteristics;

- a number of MS authorities recognised the need for improving or creating new surveillance networks where no existing network can meet the requirements. MS authorities also felt that they should work towards greater harmonization of national surveillance and exchange of protocols and systems implemented in Member States;
- notifiers and the Commission are required to ensure cooperation of these national networks and ensure that the data from these networks are adequate to address monitoring requirements;
- MS authorities stated that monitoring reports are too general and there is a need to improve the quality of reporting and to harmonize monitoring practices across the EU; and
- a number of MS authorities stated that more work is needed to deal with the risk of Adventitious Presence of GMOs in conventional seed lots.

7 RISK COMMUNICATION WITH THE PUBLIC

7.1 This chapter⁸⁰ examines the communication between risk managers/assessors and the public on the risks of GMO cultivation

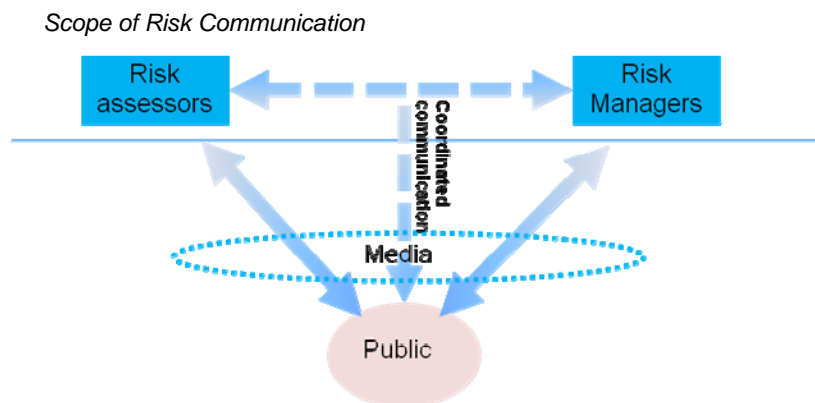
This evaluation has been asked to examine the communication of risk concerning the release of GMOs into the environment and the manner in which it has been implemented so far by the Commission, EFSA, national Competent Authorities, the industry and other stakeholders.

Risk communication (RC) encompasses a wide range of communication links, all of which are essentially two-way processes (see Figure 7.1). Communication between risk assessors and risk managers can have significant impacts on both the process and substance of the regulatory process.

Risk assessors in this context include notifiers (who conduct the risk assessment), and the Competent Authorities of MSs and EFSA (who appraise the risk assessment). Risk managers are decision makers, such as MS authorities and the European Commission. The links between risk assessors and risk managers have been considered in detail in section 4.6. This section focuses on communication to and from the public both from risk assessors and risk managers.

Although this communication is potentially moderated by the media, this aspect will not be considered in depth.

Figure 7.1 The risk communication covered in this chapter is limited to that which occurs between risk assessors/risk managers and the public



Source: GHK Consulting Ltd

7.2 The provisions of the legislation continue to have support but many consultees believe the practice of risk communication could be improved

Articles 9 and 24 of the Directive 2001/18/EC contain provisions for public information and public participation. MSs are expected to “consult the public and, where appropriate, groups on the proposed deliberate release”. Member States are required to define arrangements for this consultation, including a reasonable time-period, in order to give them the opportunity to express an opinion.

There is broad agreement amongst consultees that the risk communication (RC) provisions of the EU’s GMO legislation and their objectives remain relevant (see Figure 7.2). Sixteen MS authorities and 53% of all those consulted were either very satisfied or somewhat

⁸⁰ This chapter on the implementation of Part B of Directive 2001/18 addresses Question 9 of the project terms of reference

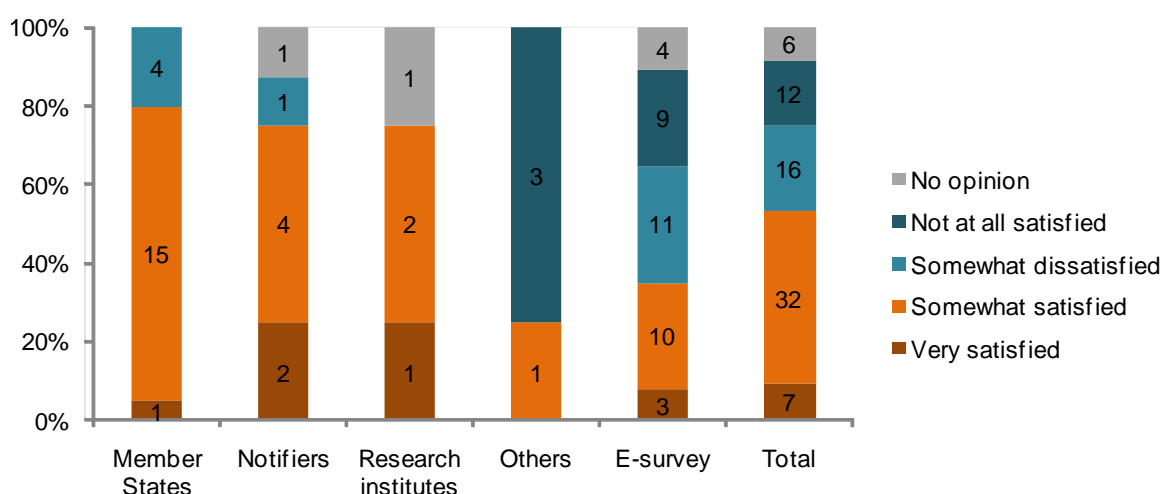
satisfied with the current arrangements for public consultation and engagement regarding authorised GMO releases under the Directive and the Regulation.

However, for notifiers and interest groups – particularly those groups having links with biotechnology companies – the main issue is whether the RC provisions are implemented properly and how well RC works, rather than the provisions of the legislation per se. Several notifiers and industry groups disagreed with the use of the term ‘risk communication’ as, in their view, no risk has been proven to date. A number of consultees, including some MS authorities, notifiers and other groups, are somewhat dissatisfied with the way DG Environment has handled RC questions regarding GMOs.

Opinions on what the objectives of risk communication activities are vary within and across the groups of those who were consulted. Some objectives are considered more relevant than others. Our consultation with the MS authorities revealed that, for some authorities, RC activities are important for providing the public with information, while, for others, these activities are also intended to provide the authorities with public feedback on risk assessors’ opinions and risk managers’ draft decisions. Several MS authorities also consider public consultation to be a means of promoting public participation and transparency in decision-making, as do notifiers and other consultees. As such, risk communication at the EU level is both a one-way education and a two-way dialogue between the public, and risk assessors and managers.

Figure 7.2 Stated satisfaction with the current arrangements for public consultation and engagement on authorised GMO releases under the Directive (Parts B and C) and the Regulation are highest amongst Member State authorities

“How satisfied are you with the current arrangements for public consultation and engagement regarding authorised GMO releases under the Directive (Parts B and C) and the Regulation?”



7.3 The implementation of risk communication provisions varies

This section presents the views of consultees on the risk communication process in the context of public consultation on GMO releases authorised under the Directive and the Regulation. It discusses, in passing, broader GM-related risk communication activities carried out by consultees (national authorities, EFSA, notifiers and environmental NGOs). These awareness-raising and opinion-shaping activities are outside the scope of our evaluation. They are, however, part of the context within which RC on GM releases takes place.

7.3.1 There is variation in risk communication practice at the national level, especially in the context of field trials

Arrangements and opinions relating to national communication activities vary within and between the groups of those consulted. The overwhelming majority of all those who were consulted (88% of those who responded), including all Member State authorities, believed the variations in the provision of information to the public are either somewhat significant or very significant. There is variation in terms of:

- The type and amount of information provided to the public;
- The channels of communication of information; and
- The consultation timeframe on field trials.

Some Member State authorities release more information on field trial applications and locations than others; the role of disclosure in field trial destruction is contested

According to the Directive (Article 9), MSs are required to “make available to the public information on all Part B releases in their territory”. Information on the general description of the GMO, the name and address of the notifier, the purpose of the release, the location of its release and its intended uses must not be kept confidential (Article 25(4)).

Nonetheless, MSs have considerable flexibility in implementing Article 9; there being some ambiguity on the level of detail that should be provided. This flexibility is reflected in the variation seen across the EU in the information provided to the public. Most MSs only publish the Summary Notifications (SNIFs) but some release the full application dossier (excluding confidential information) online or upon request.

Recently, there has also been a trend towards providing more detailed information on the location of field trials. In consultations, notifiers did think that the practice of certain MS authorities to release very detailed information on the location of field trials does have an important role in facilitating field trial destruction (see section 5.3.1 for more detail). As a result, several feel there is an imbalance between transparency and commercial interest considerations, and those specific RC arrangements in those countries are not appropriate.

The differences in public consultation arrangements between MSs are not the determining factor in notifiers' choice of where to submit a notification for a field trial. Some notifiers consulted, for instance, reported that despite the openness and transparency in the German consultation arrangements under Part B and problems with field trial destructions, they prefer to submit their application in Germany (rather than in the Netherlands) for a number of reasons. These include the importance of the country for individual companies, particularly companies of a German origin, the suitability of the conditions for research and development regarding the performance of a particular GMO in these countries and the fact that notifiers will eventually obtain a permit. Overall, the notifiers consulted appeared to prefer the relative ‘certainty’ of the German consultation arrangements over the ‘uncertainty’ of obtaining a permit in the Netherlands where a permit issued is usually challenged in administrative court, the Council of State, and is often revised on legal procedural grounds.

Getting the right balance between transparency and protection of trial/commercial interest, and the specific issue of releasing details of the location of field trials, was reported as a key issue by a few Member State authorities (also see section 5.3.1). But most MS authorities interviewed did not consider these issues burdensome. Some MS authorities attributed this to the more ‘open and participatory’ risk assessment system in certain MSs and national policies/strategies on GMOs that are based on broad political consensus.

Member State authorities and notifiers both communicate to the public on field trials, although the methods and level of engagement vary

Most MS authorities use official means of risk communication, such as the public register, their own website and the Official Journal. A few advertise through mass media. Several

have not introduced arrangements to inform 'special interest' groups about field trials. Thus, farmers, for instance, are sometimes only informed about a trial in their vicinity through their farmer's organisation, neighbours or even notifiers.

Notifiers play an active role in informing stakeholders locally about field trials and progress/results through the national press and meetings at the local level. Personal meetings with stakeholders who are directly involved are considered the most effective means of communication. Several notifiers, however, stated they have not been very actively involved in general communication activities over recent years - there is still considerable public resistance to risk communication by the biotechnology industry and communication campaigns can be costly.

It was difficult for most MS authorities to judge the effectiveness of the methods they employ to inform and consult the public. Several favour a multi-pronged approach to consultation that involves provision of information at local/regional and national levels through official and private channels of communication. The use of mass media would be most effective as these can reach, and attract the attention of, the general public.

The consultation timeframe on field trials ranges from 21 to 60 days

According to Article 9 of the Directive, MSs are required to lay down arrangements, including a reasonable time-period, within which to express their opinions. This flexibility again leads to considerable variation; the consultation timeframe ranges between MSs from 3 weeks in Slovenia to 60 days in Finland. Most Member States allow 30 days.

7.3.2 *Satisfaction with the way Risk communication at the EU level is being implemented varies*

Whilst several of those consulted are active in risk communication at the EU level, EFSA has a key role in 'official' risk communication

EFSA plays a key role in GM risk communication. Its remit is not only to assess all risks associated with the food chain, but also to communicate these risks to all stakeholders and the public at large, in order to raise awareness and further explain the implications of its scientific work. EFSA staff emphasised the importance of public information and consultation on aspects related to GMOs and opportunities provided in the context of the EU regulation and related to EFSA's remit. Indeed some consultees thought that EFSA was perhaps the most active EU body in communicating risks, including GM-related risks, to the public.

In consultation Member State authorities stated that they have a limited, even non-existent, role in public consultation on decisions being made at the EU level (i.e. cultivation authorisations). During the interviews, some MS authorities noted they adopt a reactive rather than proactive approach to provision of information. A few reported publishing some information on Part C notifications.

Environmental NGOs, by contrast, are very active in communication campaigns at the national level but also seek to raise awareness about GM issues at the EU level. As part of their role, they are in contact with, and monitor the activities of, DG SANCO and EFSA as well as DG ENV. The NGOs consulted for this project operate specifically at the EU level and found it difficult to comment on RC issues at the national level. They did note however that efforts are also being made by some national organisations to shape public consultation and influence decisions on GMOs through the preparation of 'opposition' letters submitted by members of the public.

Whilst information on authorisations is available to the public, some consultees believed improvements could be made on both the amount and the technical nature of the information that is provided

Most MS authorities interviewed consider the amount of information provided to the public under the Directive sufficient, though less comprehensive than that provided under the

Regulation. Information provided under the latter (including, for instance, EFSA's overall opinion, the scientific opinion of EFSA's GMO Panel, CRL validation documents and information exchanges between EFSA and the Competent Authorities) can contribute to the formulation of a well-informed opinion by members of the public who have the relevant scientific knowledge.

However this information is not accessible to a large proportion of the EU-27 public as:

- it is published only in English; and,
- the highly technical nature of information and opinions means that it is incomprehensible to anyone lacking technical expertise.

Some MS authorities favour introducing a version drafted in more accessible language, though they are aware of the obstacles, most notably the cost. Notifiers also suggested that the abundant and rather scientific/technical information provided to the general public is not appropriate as public communication material.

Most consultees gave a high rating to the quality of information that is provided through channels at the EU level, such as the websites of DG SANCO, EFSA and GM Compass. Several consultees commented positively on EFSA's communication initiatives targeting the public, including its newsletter, and the up-to-date information on the 'status' of GM products provided by GM Compass.

On the other hand, EFSA staff view the public as being generally well informed on the Opinions of the Authority and the Panel on applications submitted under the Directive and the Regulation. EFSA staff noted that the public can comment on EFSA's Guidance Documents, and comment on the opinions of the Authority and the Panel on applications submitted under the Directive and the Regulation. Groups of citizens can engage with EFSA through its Stakeholder Consultative Platform and ad hoc meetings.

EFSA staff emphasised the need for risk managers to better inform the public on the roles and responsibilities of different actors in the process in order to avoid confusion on what the various remits are for EFSA, MSs, the Commission and notifiers.

Several consultees, including notifiers, thought the European Commission could do more to enhance public understanding of the legislative and decision-making framework for GMOs, and to increase understanding of the benefits of the technology for the environment, sustainable agriculture and the EU economy. Some consultees voiced concern that the Commission's approach does not demonstrate sufficient confidence in the risk assessment, and leads to an 'erosion of trust' in EFSA, its Opinion and, ultimately, to the overall system (see section 6.2.2).

Environmental NGOs acknowledged EFSA's efforts, but would appreciate more substantial and frequent engagement which resulted in tangible outcomes. One NGO stated that the provision of information at the EU level is fragmented in a way that is not helpful for public interest groups, let alone individual citizens who are unfamiliar with EU processes.

It was not within the remit of this evaluation to consult with the wider public on whether they believe the risks are sufficiently communicated either by MS authorities, environmental NGOs or EFSA.

7.4 Few people engage with the consultations and most of the comments received are statements of opposition to GM technology or the biotechnology industry rather than a specific response to the consultation in question

This section discusses how consultees view the public's response to consultation. It draws, almost exclusively, on discussions with the MS authorities, EFSA and notifiers as other types of consultees found it difficult to comment on these issues.

Overall, public participation on GMO issues is rather low across the EU Members although it varies by country. Some MS authorities receive more public comments (on average, 100-150) than others. One MS, for instance, has never received any comments on risk assessment opinions and draft decisions. Several authorities reported receiving thousands, or tens of thousands, of virtually identical similar opinions, presumably prepared by environmental NGOs. The level of participation varies depending on where consultation takes place and under which regulatory framework – at the national level for field trials notifications under the Directive, or at the EU level for applications for placing a GMO on the market. Our discussions with selected MS authorities suggest that, in general, the public is more responsive to consultation on the former rather than the latter. The public, according to several interviews, is more interested in ‘developments’ ‘closer to home’ and also has, in general, easier access to information – particularly less complex/technical information. It should be noted however, that opportunities to comment on developments at the EU level have been rather limited, given the small number of submissions and authorisations for the cultivation of GMOs (see sections 4.2 and 6.2).

Notifiers’ comments were similar to those of the MS authorities. The overall view is that the process is largely driven by, and relies on, a very small proportion of the population. Several pointed out the levels of public participation have been at consistently low levels over the last 5 years despite the opportunities created by the Regulation.

Interviews with the MS authorities and EFSA suggest that the majority of public comments are unrelated to the subject matter of consultation. They mostly express opposition to the technology, while several raise general concerns about the interests of specific economic operators (e.g., organic farmers) and the environment. Very few science-based public comments and even fewer comments in support of GMOs are submitted. As most consultees, including one environmental NGO, pointed out, the general public lacks training/expertise to make an informed decision and make the contribution envisaged by the EU rules.

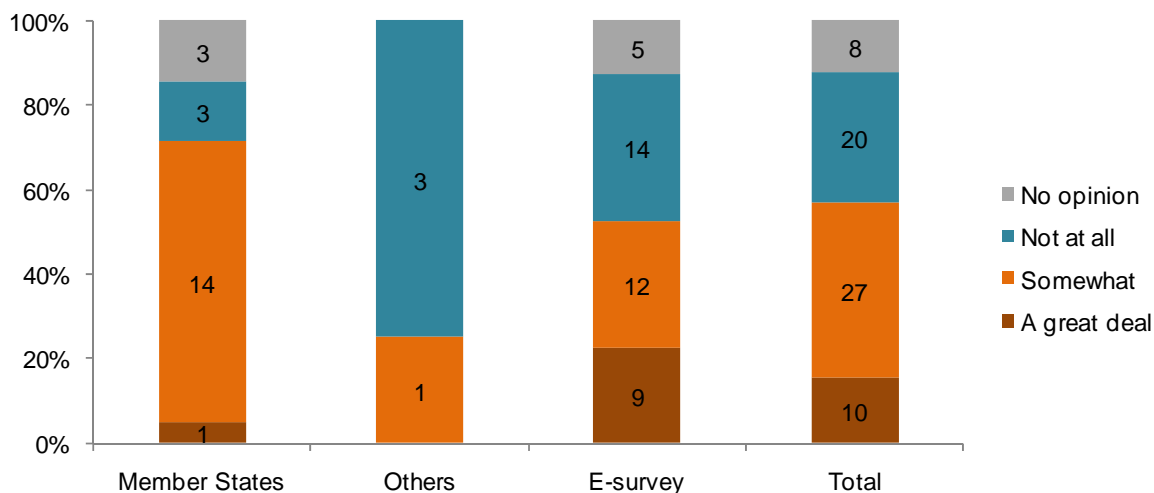
7.5 Comments resulting from public consultation are most likely to impact on risk management decisions if they are of a scientific nature

This section addresses issues related to communication of messages from the public to risk managers and how these shape RM decisions.

Our discussions with consultees suggest that it is rather difficult to establish the overall impact of public consultation on risk managers’ final decisions. MS authorities pointed out that this varies, depending on individual cases and the nature of the public feedback. Most Member State authorities (14 of those who responded) believed that the results of the public consultation only somewhat feed into risk assessment opinions and authorisation decisions on GMO releases. A further 3 believed the results do not have any impact. Of the e-survey respondents, 40% believed that comments did not have any impact, whilst 26% believed results of the public consultation had a great deal of impact (see Figure 7.3).

Figure 7.3 Most MS authorities believed that the results of a public consultation have some impact, although opinions amongst respondents to the E-survey varied more widely.

“To what extent do the results of public consultation feed into risk assessment opinions and authorisation decisions on GMO releases?”



All MS authorities interviewed said that public opinions based on scientific evidence and related to the risk assessment did have an impact, either by being taken into account in the actual risk assessment, or by being incorporated into decisions made by risk managers. The remaining public comments (of, for instance, a political, socio-economic or ethical nature) are incorporated in documents on Part B risk management decisions but they don't necessarily shape them. Socio-economic concerns, reportedly, have shaped decisions made by risk managers on field trials because they were supported by relevant scientific evidence. A scientific basis makes it difficult for notifiers to challenge the decision.

At the EU level, public comments do not feed directly into EFSA's Opinion. Public comments on dossiers submitted under the Regulation are forwarded to EFSA by the Commission. Such comments, according to discussions with EFSA, usually inform subsequent EFSA work, most notably new guidelines developed by the Authority (although they, reportedly, have not shaped, or modified, EFSA's overall Opinion to date).

However, some environmental NGOs were particularly dissatisfied with the way the public is able to comment on the risk assessment and its appraisal. Unlike MS authorities, the public does not have immediate access to the dossiers (which must be requested under Decision 2005/370/EC regarding access to information), and are not able to comment on the appraisal of the risk assessment while it is ongoing. The public are only able to comment on EFSA's final Opinion in a one month window that opens once the Opinion is published. That timeframe is regarded by these NGOs as insufficient. Furthermore, the public's ability to have any impact on the assessment process is limited given that comments are only allowed after the Opinion has been issued, which was thought to be too late to have any real influence.

Notifiers, in general, were unable to provide specific examples or attribute 'unfavourable' decisions to specific public input or to the overall political climate. Several, however, suggested that the potential destruction of field trials is affected by the level of detail which is provided on field trial locations, whilst obtaining a cultivation approval in time for the growing season is sometimes hindered by the time it takes in some MS authorities to consult with the public. Thus certain characteristics of the consultation process do affect their activities.

7.6 Summary: consultees' suggestions for improvement

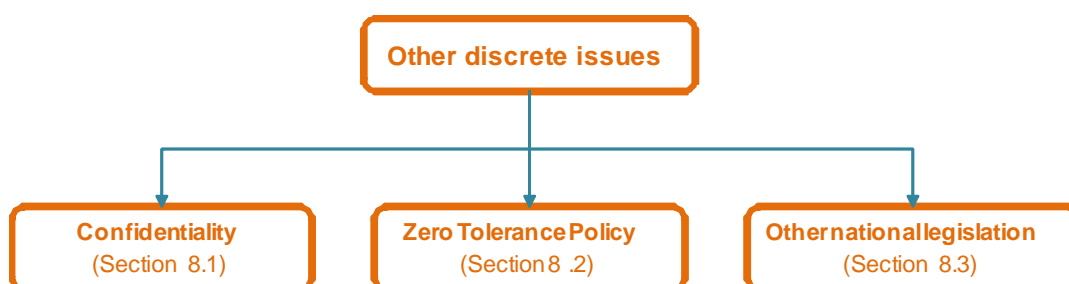
- Several consultees, including notifiers and some MS authorities, suggested that the Commission and MS authorities should consider providing the public with information on GM technology which includes not only the potential risks but also the potential benefits.
- Consultees such as MS authorities and EFSA suggested that the Commission and national risk managers should do more to explain the roles and responsibilities of risk assessors and risk managers. There has been little attention paid to this to date. Lack of understanding about these issues causes confusion to the public and renders the risk management and risk assessment process less transparent.
- Notifiers suggested that national authorities should consider providing detailed information on trial location only upon request as a means of reducing the risk of trial destruction (see section 5.3.2 for further discussion).
- Some representatives from the industry and environmental organisations suggested that the Commission should consider establishing a European web portal to collect, and facilitate the dissemination of, information on biotechnology, including GM technology to reduce the fragmentation of information on risk communication related to GMOs.
- Some MS authorities suggested that MS authorities could consider implementing measures to facilitate public access to information in the contexts of applications for placing GMOs on the market under the Directive and the Regulation.
- MS authorities with limited human resources would appreciate some guidance from the Commission on evaluating public feedback – in particular, which types of public comments, could be taken into account in decisions on applications under Part B, and how.

8 OTHER ISSUES

This chapter addresses issues that are distinct from risk assessment, risk management and risk communication (see Figure 8.1). These include confidentiality, the zero-tolerance policy on unauthorised GMOs in conventional seed lots and other national measures that impact on GMO cultivation (apart from co-existence).

Figure 8.1 This chapter on other issues addresses three of the thirteen core questions in the project terms of references (Q. 12, 13 and 6)

Diagrammatic representation of the issues covered in this chapter



8.1 Confidentiality

This section discusses the issue of confidentiality, examining in particular:

- Whether the rules on confidentiality of the Directive are consistent with those Regulation (EC) 1829/2003 and their potential links to Regulation (EC) 1049/2001 (considering differences in scope and categories);
- Whether the rules are efficient enough so as to protect confidential information and intellectual property rights, while ensuring transparency with regard to the deliberate release of GMOs into the environment and in particular the associated risk assessment.

8.1.1 **Most consultees are generally satisfied with the current provisions for confidentiality**

EFSA and 17 MS authorities were generally satisfied with the provisions on confidentiality in the Directive and the Regulation. These provisions are seen by most as reasonable and sufficiently clear. A few MS authorities, however, were not entirely satisfied with:

- the way they are implemented;
- the ambiguity caused by the differences between the two legislative frameworks; and,
- the balance between confidentiality and transparency.

Most notifiers and industry representative bodies were also comfortable with existing arrangements, as they strike an adequate balance between transparency and the protection of commercial interests. As several consultees pointed out, 'sharing data' is now acceptable to most companies, as the companies are confident that commercially sensitive details are well protected. However, notifiers did have concerns about the level of detail released to the public on the location of field trials and about the data protection period. A few were uncomfortable with the demands for higher levels of transparency in the EU.

By contrast, other consultees, most notably environmental NGOs, considered the current provisions for public access to information rather restrictive. In addition, some were dissatisfied with the different practices prevailing in the EU Members.

8.1.2 *Consultees that have a view tend to see the Regulation as clearer and more rigorous in its approach to confidentiality than the Directive*

Most consultees, including the Member State authorities that participated in the e-survey, found it difficult to comment on this issue. The following discussion draws on our discussions with, primarily, MS authorities and a few notifiers and industry bodies.

There was agreement amongst the consultees interviewed that the Regulation is clearer and more rigorous than the Directive. The Regulation provides a comprehensive list of what should be made public, although the list does not cover the monitoring reports and plans that are listed in the Directive.

It was also pointed out that the Directive does not clearly state the level of confidentiality that would be acceptable with regards to information on field trial locations. The Directive does not clarify the competencies of EFSA. These differences can cause confusion. Several consultees suggest that these differences should be clarified. In addition, the involvement of different actors, according to a few MS authorities, renders the risk assessment process somewhat less transparent. This can be confusing for notifiers and the public. It can also affect the credibility of the EU rules and procedures.

Some stakeholders also indicated that the Directive does not clarify the roles and responsibilities of EFSA, which is due to the fact that the Directive was adopted before the establishment of this Authority. In this respect it should be noted that the EFSA founding Regulation (EC) 178/2002 outlines what should be treated as confidential by the Authority (Art. 39) and this provision has taken into account the provision of the Directive (Art. 25).

8.1.3 *The implementation of the provisions vary*

This section draws on the views of the Member State authorities, notifiers and industry representative bodies. Other consultees, including environmental NGOs, made very few, or no, comments, on this issue, being unfamiliar with the details of implementation.

8.1.4 *Part B confidentiality provisions vary by country and, with the exception of disclosure of field trial locations, are broadly accepted by the industry though NGOs would like to see more transparency*

Implementation of Part B confidentiality provisions varies by country, with the exception of personal data, which are considered confidential across the EU. The Member State authorities consulted generally respect companies' confidentiality markings, but look for satisfactory justification. Business information and intellectual property data are protected. Detailed information on field trial locations is kept confidential in some countries, but it can be revealed upon request. Risk assessment is not subject to confidentiality provisions although supporting data may be.

Notifiers and their representative organisation, EuropaBio, were satisfied, in general, with the MS authorities' handling of information marked as confidential, but called for detailed information on field trial locations to be treated as confidential across the EU. Notifiers and business organisations pointed out that in some countries disclosure of field trial locations facilitates trial destruction. This, in their opinion, contradicts the objective of research and assessment that the legislation is intended to promote (see section 5.3.1 for further discussion). They also said that proprietary information (e.g. information on sequences and 'raw data'), submitted as confidential business information (CBI), should be treated as confidential if not related to human and environmental health. This is to avoid it being used unfairly by competitors in third countries. This concern was reported by a few as a reason why companies would prefer not to submit applications under the Directive.

Other consultees, including environmental organisations, expressed dissatisfaction with confidentiality practices. They suggested that no documents or information should be kept secret from the public or 'special interest' groups, e.g., the GM-free food sector.

8.1.5 *There are few confidentiality issues in Part C applications*

Lead authorities' decisions on confidentiality are based on the provisions of the Directive and the national legislation – which, in some cases, ensures higher levels of transparency. Some lead authorities pointed out that most Part C applications do not contain any confidential information. They found it difficult to identify any type of information whose disclosure could harm commercial interests. This explains one authority's opinion that 'public interest' should be the primary determinant of confidentiality for documents and aspects of information related to Part C applications.

Most authorities consulted were unable to discuss this issue as they have no experience as the lead authority. They simply comply with the confidentiality decision of the lead authority and the Commission.

8.1.6 *Procedures for proposing and evaluating the case for confidentiality are now well established in notifiers and competent authorities*

Discussions with notifiers suggest that companies have developed standard procedures to identify confidential information and provide justification sufficiently robust to stand legal scrutiny. This 'two-stage' process involves legal staff, technical experts and scientists who discuss and formulate a sound argument to protect commercial confidentiality and interest. To do that, they take into account what information could be claimed as confidential and past experience – what has been acceptable to date and what kind of information could impact on the company's interests.

The Directive requires notifiers to indicate information they wish to be treated as confidential and provide justification. Following consultation with the applicant, the MS authority decides which information remains confidential and notifies the applicant and the relevant authority/authorities. MS authorities' assessments are made on a case-by-case basis, taking into account the requirements of the Directive and national rules, if any. A few MS authorities also mentioned that confidentiality decisions are also shaped by the provisions of Reg. (EC) 1049/2001. No MS authority reported the use of formal, or standard, criteria.

8.1.7 *Most requests for confidential information come from NGOs*

Information marked as confidential is mostly requested by, and disclosed to, NGOs but also members of the public, consultants and competitors of the notifier⁸¹. Information requested includes the exact location of field trials, exchanges between the MS authorities and notifiers, raw data, and impact studies by notifiers. One NGO, for example, requested a study of the health impact of GM maize on rats. Another NGO obtained confidential information from a MS following a court appeal. Requests for access to confidential information are also submitted to EFSA (71 since 2002).

8.1.8 *Proposals from consultees for change illustrate the difficulty of balancing transparency and protection of commercial interests*

- Consultees struggled to suggest how to achieve a greater degree of openness without upsetting the delicate balance between transparency and commercial confidentiality. This was evidenced in the following views of stakeholders on how to balance these 'conflicting' objectives and the impacts of enhanced or reduced confidentiality;

⁸¹ This section draws on our consultation with the MSs and input from EFSA staff.

- Several MS authorities stated that a sufficient degree of openness has been achieved – there are few grounds to refuse public access to information. What is needed, in practice, is a common sense approach aimed at ensuring high levels of openness but realising the obligation to protect commercial interests;
- Some MS authorities stated that a shift in the current balance in favour of commercial confidentiality might increase GM field trial activity but also increase public opposition to the technology, whilst greater openness would discourage notifiers but not result in elimination of trials altogether;
- Notifiers have accepted transparency as a route toward obtaining approvals and building public confidence. Most, however, took the view that further increases in transparency would have implications for commercial confidentiality. Other consultees from industry also share this position, as stated by one interviewee, “it is difficult to improve the current ‘balance’ because of the deeply rooted differences between those favouring and those opposing the technology”;
- The NGOs consulted were supportive of even higher levels of transparency and openness. Some, for instance, advocated full access to information on the GM event and the related research material to enable independent testing and research while a few viewed that considerations of ‘special interests’ should be clearly given priority over notifiers’ interests (see section 5.3.2 for further discussion).
- Consultees interviewed agreed on the need for uniform rules on disclosure across the EU. Achieving that, without compromising the position in the more open countries, would mean harmonisation of procedures, drawing on the example of MSs that have well established legal traditions ensuring both openness and protection of business interests.
- Some MS authorities would appreciate guidance from the Commission on the development of criteria to facilitate public access to information under the Directive.
- Notifiers and their representative associations are looking for a ‘moratorium’ on public access to information on the exact location of trials in the hope that this would reduce the frequency of field trial destruction. Information should, however, be disclosed to the relevant regional and local authorities.
- Some notifiers would prefer for the data protection period provided for in the Regulation under Article 31 to be longer. A parallel harmonisation of the EU’s requirements with the existing international arrangements would be helpful, as the level of transparency within the EU is higher than in other EU partner countries.
- EFSA believes there is a need to align the provisions on confidentiality of the Directive with those of the Regulation and to acknowledge EFSA’s role in the relevant processes. In addition, there is a need to clarify the interaction between the provisions on confidentiality in the GMO legislation and those on public access in Regulation 1049/2001/EC.

8.2 The seed industry, notifiers and many Member State authorities believe that the zero tolerance policy on unauthorised GMOs in seeds has a negative effect on trade and the EU seed sector, and will become more difficult to sustain over time

Under EU legislation the presence of unauthorised GMOs in any product, such as seeds, is not tolerated. The zero tolerance policy (ZTP) creates practical challenges, not least in the context of asynchronous authorisations (when GMOs are fully approved in other countries but not in the EU). Most consultees, including 12 MS authorities and all notifiers agreed or strongly agreed that the ‘zero-tolerance’ policy for unauthorised GM material in seeds is having a negative impact on trade (Figure 8.2).

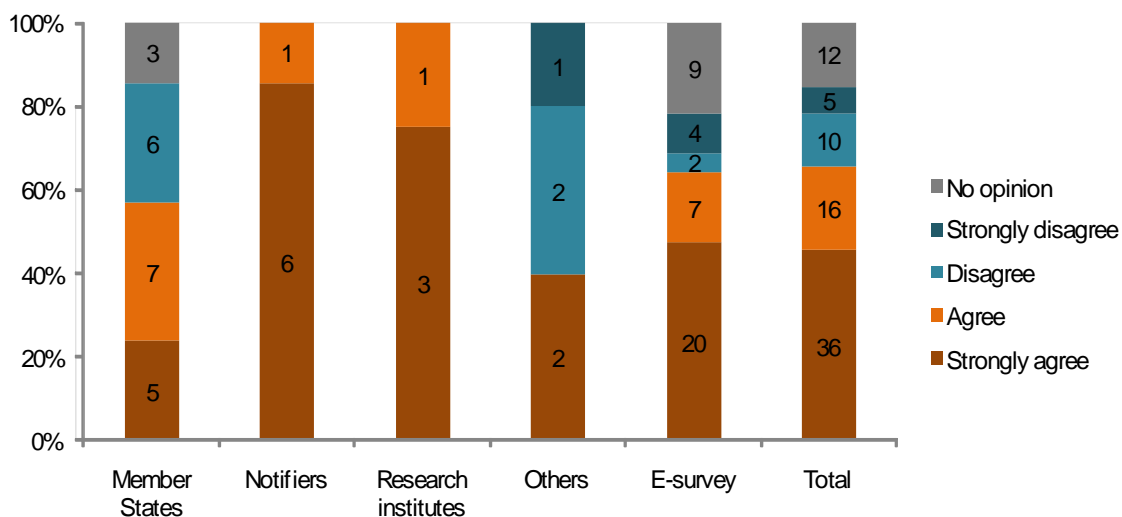
A study by the Institute for Prospective Technological Studies (IPTS) suggests that the problem could intensify because the number of GM crops approved outside the EU will quadruple to 120 by 2015⁸². GM crops are increasingly being grown in all parts of the world. In 2007, 12 million farmers in 23 countries cultivated genetically modified crops on 114 million hectares⁸³. Most of these GM crops are commodity crops that are traded internationally throughout the world. Trade can be disrupted if these crops are not authorised in all countries trading in these crops.

MS authorities and notifiers both noted that the absence of a proportionate, evidence-based tolerance threshold for the presence of unauthorised GMOs in GM or conventional seed lots continues to hold back the development of cohesive co-existence arrangements with the food, feed and organic sectors and is having an adverse effect on community plant breeding and seed production companies. This in turn has an adverse effect on seed production, trading and seed prices (See box 8.1).

According to notifiers, ZTP causes disruption of international seeds trade. EU MSs imported agriculture and vegetable seeds worth nearly \$3 billion (€2 billion) in 2007 (Figure 8.3). Trade flows in seeds and crops to and from the EU is increasing the risk of adventitious presence (AP) of events not approved in the EU, especially those from and to countries with commercial production of biotech seeds and crops (e.g. Argentina, Canada, United States, Chile and increasingly China, India and other countries).

Figure 8.2 Consultees agree that ZTP is negatively affecting trade and pushing up seed prices

Do you agree that the 'zero-tolerance' policy for unauthorised GM material in seeds is having a negative impact on trade (e.g. on imports of seeds and related seed prices)?



⁸² <http://ipts.jrc.ec.europa.eu/publications/pub.cfm>

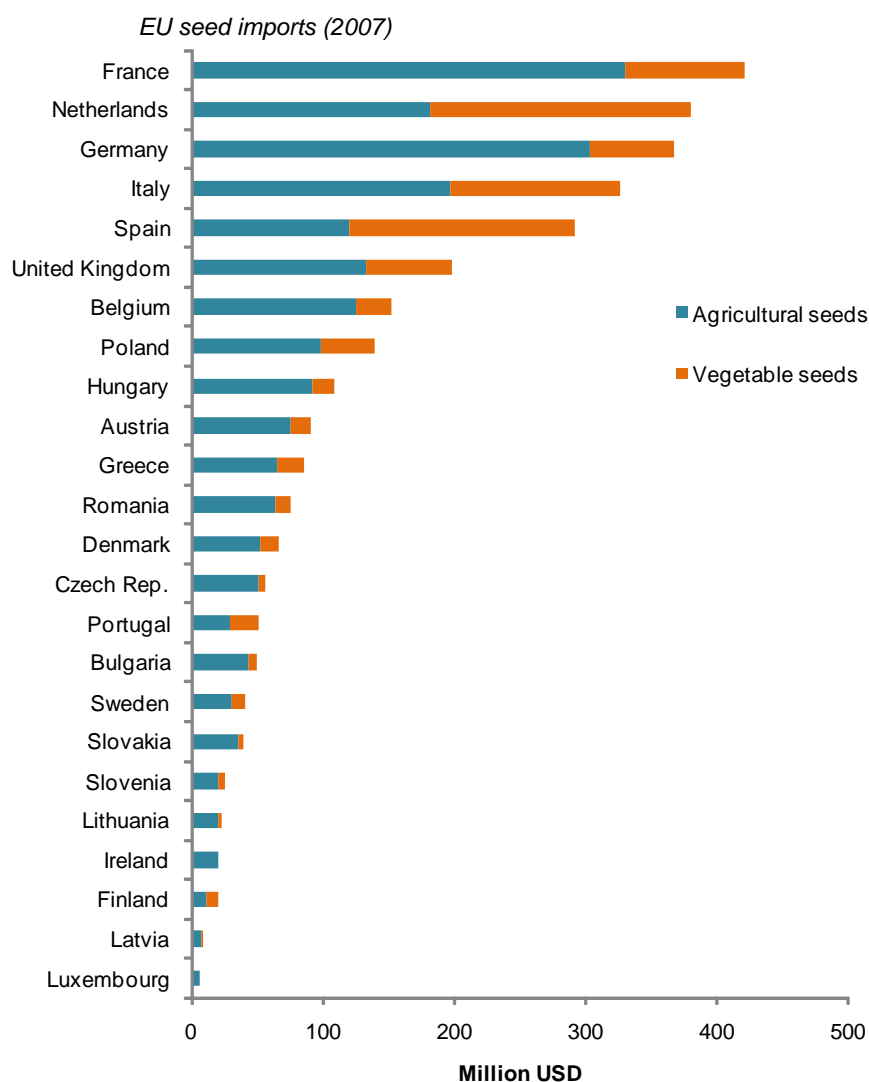
⁸³ Source: <http://www.gmo-compass.org/eng/news/333.docu.html>

Box 8.1 Trade and cost impacts of zero tolerance policy for unauthorised GMOs in seeds

The zero tolerance policy has resulted in the termination of seed imports from countries cultivating GM varieties of the crop concerned. For example, Canadian exports to Europe of oil seed rape, as seeds to be marketed or as seeds to be crushed, have stopped. (Source: Statement of one MS authority)

The zero tolerance policy could result in higher production costs due to segregation needs (separate storage, processing and transportation, storage and processing equipment and the extra administration necessary for the documentation). (Source: Statement of one MS authority). Additional costs for seed companies arise from the need for extensive GMO testing, cases where seed lots are rejected due to the presence of unauthorised GM seeds, and compensation of farmers who have already grown plants derived from contaminated lots. (Source: Statement of one MS authority)

Figure 8.3 France, Netherlands, Germany and Italy are Europe’s biggest importers of agriculture and vegetable seeds



Source: International Seed Federation⁸⁴

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http://www.worldseed.org/cms/medias/file/ResourceCenter/SeedStatistics/SeedImports/Seed_Imports_2007.pdf

In practice, ZTP is very hard to comply with and to enforce. The European Seed Association (ESA) stated that adventitious presence of GMOs in seed is technically unavoidable and will be increasing prevalent as the use of biotech crops worldwide increases. They suggest this cannot be ignored by a “simplistic and legalistic” demand of 100% purity which is unachievable in any seed production. Most biotech companies have systems in place to ensure that there is no adventitious presence of non-EU authorised GM seeds in lots of GM and non-GM seeds.

Notifiers and ESA argue that tolerance levels are important elements for trade in seeds (whether internationally or locally) and to provide consumers and farmers with genuine choice. They say tolerance thresholds are required for Europe’s conventional seed industry and its continued development of more competitive varieties which form the “base of the EU’s competitive agro-food chain”. The lower the threshold levels that are imposed, the higher the cost of EU production, with a consequent negative impact on the competitiveness of EU seed domestically and on world markets. A study⁸⁵ and data on costs of ZTP has recently been presented to the European Commission. The study found that compliance costs increase exponentially as AP thresholds are lowered, e.g. from 6.8% per seed bag for AP levels of 1.0% to 68.0% for AP levels of 0.1%. AP includes both authorised and unauthorised GMOs in conventional seed lots. However, these ratios give an idea of the cost of complying with ZTP for unauthorised GMOs in conventional seed lots for cultivation. Most MS authorities have called for the introduction of an evidence-based, tolerance threshold for the presence of unauthorised GMOs in conventional and authorised GM seed lots as recommended by the EU’s Scientific Committee on Plants. ESA also noted that smaller companies face relatively higher compliance costs than larger companies. Most of Europe’s conventional seed companies are small and medium sized enterprises. Their compliance costs are generally proportionately higher than those of larger, non-EU seed companies.

Consultees from industry associations (EuropaBio and ESA) also noted that ZTP can lead to costs which are not easy to quantify in monetary terms. They pointed out that plant breeding and seed production are globalised activities. European plant breeding companies work in a wide range of locations within and outside the EU, making use of counter-seasonal breeding and seed production and accessing non-EU markets. Consultees from industry stated that the current zero tolerance level for unauthorised GMOs in seeds is threatening this well-established practice with fewer geographic areas available for breeding. It is also affecting European biotech industry and research institutions access to germplasm and the benefits it receives from worldwide research.

One MS authority noted that if the tolerance for unauthorised GMOs in seed is increased from zero there will be implications for coexistence, especially for consumer confidence in organic food and crops. A threshold may erode this confidence as the purity of organic produce will not be guaranteed. One MS authority pointed out that the zero tolerance policy is beneficial for its agricultural economy since buyers in its export markets have demanded that the crops are certified that they have been cultivated in GM-free regions. Another MS authority highlighted the positive environmental and social impacts of the ZTP in terms of society’s reluctance to accept any other limit other than zero. ZTP for unauthorised GMOs in seeds also avoids the risk of any adverse environmental impact under the precautionary principle

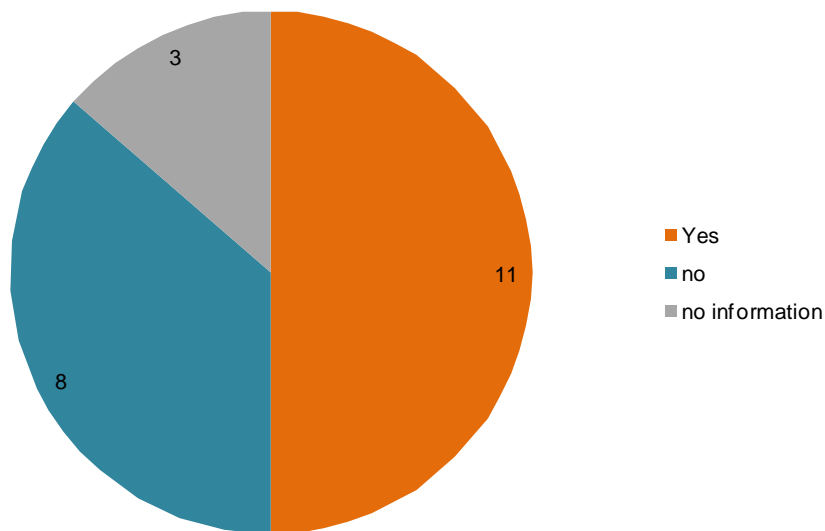
⁸⁵ Prof. N. Kalaitzandonakes, in 2007/8, ‘The Economics of Adventitious Presence Thresholds in the EU Seed Market’. EMAC working paper series; available on www.euroseeds.org).

8.3 Other national legislation impacting on the cultivation of GMOs

Half of MS authorities surveyed said that they have national or sub-national legislation in place that must be observed when a GMO is placed on the market (see Figure 8.4).

Figure 8.4 Half of all MS authorities surveyed have national/sub-national legislation governing GMOs for cultivation

Is there any other national or sub-national legislation in your country that must be observed when a GMO is placed on the market (excluding rules governing co-existence)? (No. of MSs)



In some MSs, GM plants with ARM-genes are not allowed. MSs also have national legislation governing production of seeds and planting material, legislation on state supervision, phytosanitary rules, etc. One MS authority said that a GM variety must be approved under their national seed legislation if it does not comply with the Community seeds legislation.

Some Member State authorities mentioned the existence of good environmental practices and codes which support the main objectives of their national GM legislation. Besides GM risk management and coexistence rules, MSs also have environmental legislation in place at national and regional level, specifically for the protection of nature reserves and unique geographical areas. These laws take into account potential environmental and ecological effects of GMOs by imposing special cultivation conditions in order to ensure compliance with EC legislation on the conservation of natural habitats, of wild fauna and flora, of wild birds and also with the rules included in national legislation on designation of protected areas and on environmentally sensitive areas. Most MSs also have penalties for non-compliance cases and for inspection and control authorities.

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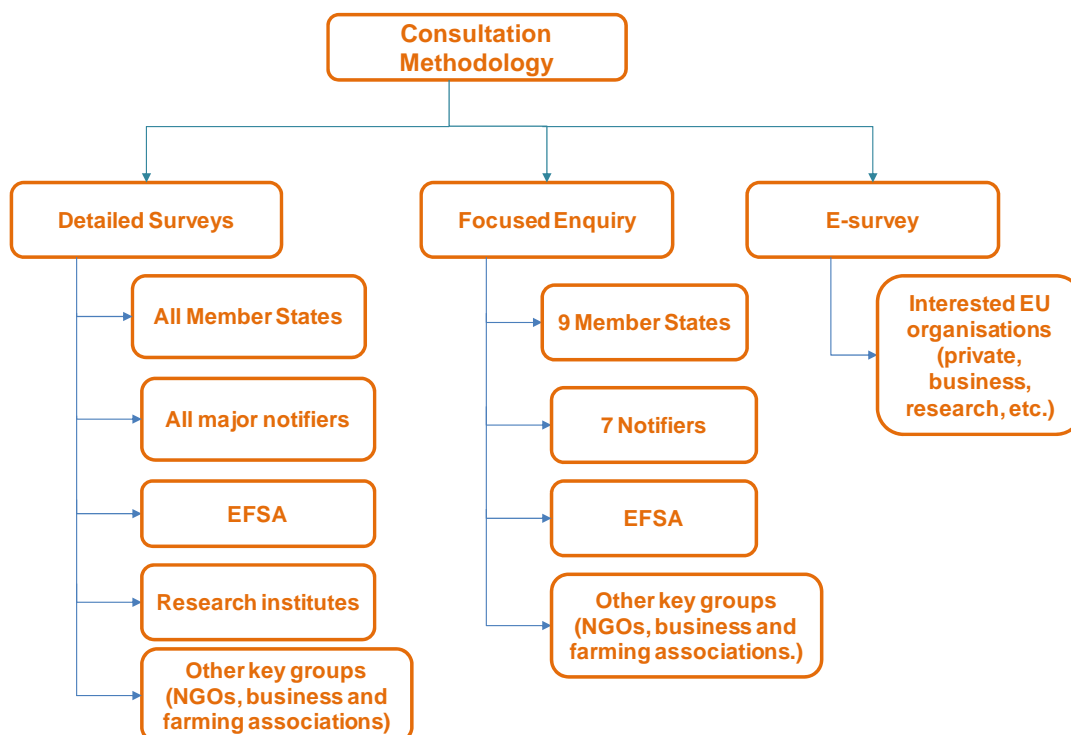
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ANNEX A: CONSULTATION METHODOLOGY

The EPEC consulted Member State authorities and other key actors, including industry, farmers' groups, NGOs, EFSA and research organisations for the evaluation of the EU legislative framework in the field of cultivation of GMOs. The breakdown for each group of consultees is given in Table A1. Figure A1 provides an overview of the consultation methodology.

Figure A1 Overview of the consultation methodology



Source: GHK Consulting Ltd.

Our consultation was organised in three parts, as follows:

1. **Detailed survey** - a standard set of 'core' questions was addressed to all Member State authorities, notifiers, research institutes and other organisations. The universal survey contained scaled responses for the 'core' questions which were used to create the main response figures from consultees throughout the report.
2. **Focused enquiry** – we also proposed some additional, more detailed questions to particular Member State authorities, EFSA, notifiers and other key groups. These questions were discussed through interviews, conducted by telephone or face-to-face and through written questions provided as annexes to the universal survey.
3. **E-survey** – interested organisations were given the opportunity to register themselves on a database for this survey by entering their details on the GHK website at <http://gmregister.ghkint.com/>. This website was publicised via various news services as well as suggestions of organisations by notifiers and Member State authorities. All those who registered received a universal electronic survey through a web-based survey tool called 'SNAP'.

The universal survey and the focused enquiry were divided in five parts that together covered the activity within the scope of the EU legislative framework for GMOs. These parts were:

1. Objectives of the legislation;
2. Scope of the legislation;
3. Risk Assessment;
4. Risk Management;
5. Risk Communication; and,
6. Confidentiality issues.

Table A1 Main groups of consultees and the means of consultation

- ✓ - Interviewed (Focused enquiry)
- ◆ - Returned survey (in time for inclusion in the interim report)

Member State authorities		Other key consultees		Notifiers	
Austria	◆✓	European Food Safety Authority (EFSA)	◆✓	AVEBE	◆✓
Belgium	◆✓				
Bulgaria		EuropaBio	✓	BASF	◆✓
Cyprus	◆	COCERAL	◆✓	Bayer	◆✓
Czech Republic	◆✓	COPA-COGECA	✓	Dow	◆✓
Denmark	◆	European Centre for Nature Conservation (ECNC)	✓	Monsanto	◆✓
Estonia	◆				
Finland	◆	European Environmental Bureau (EEB)	✓	Pioneer	◆✓
France	◆✓				
Germany	◆✓	European Seed Association (ESA)	◆✓	Syngenta	◆✓
Greece		Friends of the Earth (FOE)	◆✓	KWS	◆
Hungary	◆✓	Greenpeace	◆✓		
Ireland	◆	International Federation of Organic Agriculture Movements (IFOAM)	◆		
Italy	◆				
Latvia	◆				
Lithuania	◆				
Luxembourg					
Malta					
Netherlands	◆✓				
Poland	◆				

Portugal	
Romania	◆
Slovak Republic	◆
Slovenia	◆
Spain	◆✓
Sweden	◆
UK	◆✓

The nine Member State authorities were selected on the following basis:

- Member States whose Competent Authorities have appraised ERAs under the Regulation;
- Member States whose Competent Authorities have dealt with applications for cultivation (under the Directive and/or the Regulation);
- Member States having had field trials;
- Member States with GMO cultivation; and
- Member States with safeguard measures.

The universal questionnaires were very detailed covering around 70 to 90 questions. In addition to this the key 9 MS authorities and 7 notifiers (Table A1) were asked a further 40 to 50 questions. The written responses from the consultees were sufficiently detailed and covered all questions. The interviews were very productive in terms of the information required and key suggestions made. The team undertook 25 interviews in total and have transcribed 46 hours worth of interview discussions with key consultees. On average each interview lasted for around 2.5 hours.

E-Survey

We surveyed the opinions of interested EU industry, farming groups, research organisation non-governmental organisations and other stakeholders who registered on the GHK website. We received 53 completed E-survey responses out of a total of 208 E-survey recipients. NGOs and business representatives accounted for 34% and 26% of all responses respectively (Figure A.1). Most of the responses came from Member State authorities in whose Member State there has been GMO cultivation or GMO field trials. Stakeholders from Germany, UK and Spain accounted for bulk of the E-survey responses (Figure A.2).

Figure A.1 There was a total of 53 responses to the E-survey; most respondents were affiliated to NGOs and business representative groups

Respondents' affiliation

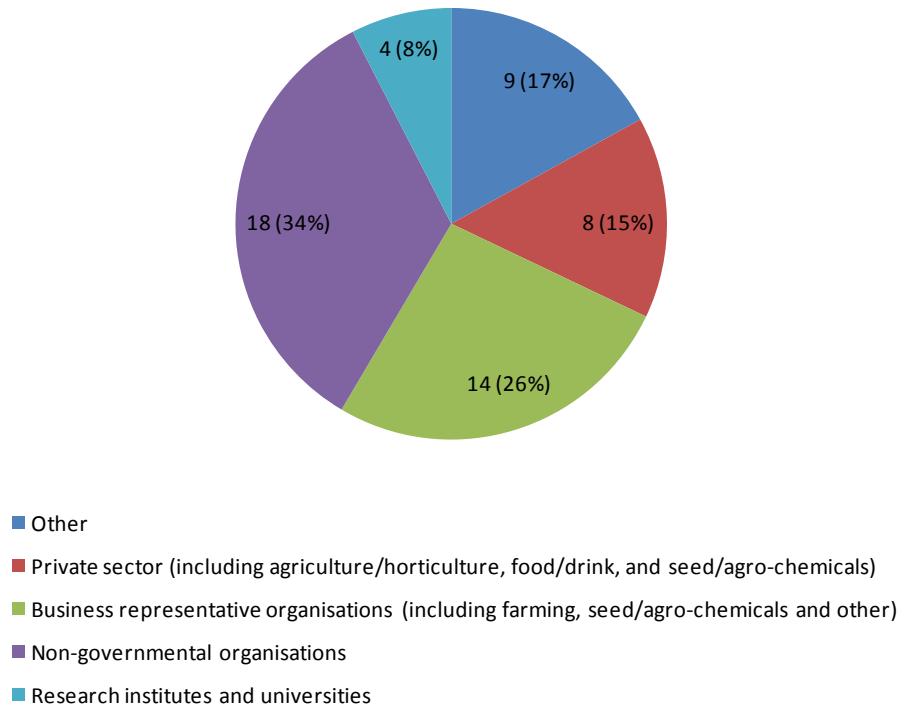
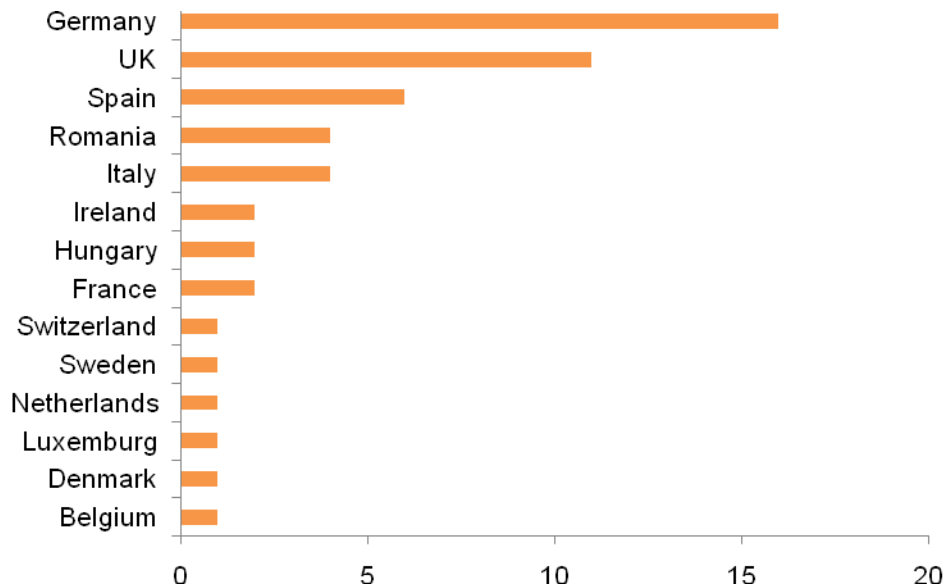


Figure A.2 Most respondents were from Germany and the UK

Respondents' country of origin



ANNEX B: TERMS OF REFERENCE

Background – A description of the activity to be evaluated

The regulatory framework that will be evaluated

The present exercise aims at the evaluation of the regulatory framework of the cultivation of GMOs under Directive 2001/18/EC on the deliberate release into the environment of GMOs (hereinafter: the Directive)⁸⁶ and Regulation (EC) No 1829/2003 on GM food and feed (hereinafter: the Regulation)⁸⁷ and the marketing of their other uses under the Directive.

The aim of the evaluation is to assess to what extent the legislative framework on the cultivation and marketing of GMOs and its up to date implementation have achieved its objective of protecting human and animal health, the environment and consumers' interest, while ensuring the effective and efficient functioning of the internal market.

The evaluation will cover the provisions concerning risk assessment, authorisation procedures, post-marketing management, risk communication, national safeguard measures, confidentiality rules and zero-tolerance of unauthorised GM material in seeds.

Annex 3 offers an extended description of the provisions of the regulatory framework that will be evaluated.

The present evaluation does not cover the EU legislative framework in the field of GM food and feed as this is covered by a parallel evaluation launched by the Commission. The medicinal uses of GMOs are regulated under a different regime⁸⁸ which falls outside the scope of this evaluation.

Implementation aspects: Authorised products, national safeguard measures and national transposition acts up to date

Under the procedure of the Directive, the European Community authorised two GM oilseed rapes for import and processing, one GM carnation for import and four varieties of GM maize for import and feed uses⁸⁹.

No GMO has been authorised for cultivation under the current regulatory regime. The only GMO authorised under the old regime (Directive 90/220/EEC) and still actively cultivated in the EU is MON810. Three notifications for cultivation are pending under the Directive and ten under the Regulation. Two applications for renewal of authorisations (MON810 and T25) are also pending under the Regulation.

Three Member States (Austria, Hungary and Greece) have invoked the safeguard clause of the Directive and one Member State (France) has adopted an emergency measure under the Regulation against the cultivation of MON810. Austria has also invoked the safeguard clause of the Directive against the cultivation of T25, the feed uses of MON863 and the import and processing of two oilseed rapes (Ms8Rf3 and GT73).

None of the Commission proposals for the authorisation of a GMO for any use has received a favourable qualified majority at the Regulatory Committee or the Council under the applicable Committee procedure. This constitutes an exceptional case compared to the thousands of proposals submitted by the Commission every year in other policy areas and which receive favourable votes at the level of Regulatory Committees.

⁸⁶ Directive 2001/18/EC on the deliberate release into the environment of GMOs, entered into force on 17 October 2002

⁸⁷ Regulation(EC) No 1829/2003 on genetically modified food and feed, entered into force on 7 November 2003

⁸⁸ Regulation(EC) No 726/2004

⁸⁹ Notifications on feed uses have been submitted before the Regulation on GM food and feed entered into force

The Commission proposals for the repeal of national safeguard measures have also received no opinion at the Regulatory Committee and most of them have been rejected by qualified majority at the Council. A significant number of Member States usually abstain during the voting.

Finally it should be noted that all Member States have transposed the Directive into their national legislation. Member States have also adopted complementary decrees regulating further the cultivation and marketing of GMOs. All these national acts are not always in conformity with the Directive and the overall EU legislation and may introduce different approaches to the cultivation of GMOs.

Reporting activities, meetings and studies

Experimental releases of GMOs into the environment are subject to the provisions of Part B of the Directive. Decision making on "Part B releases" takes place at the level of Member States. An analysis of field trials management in Member States and prevention of accidental entry of GMOs on the market has recently been carried out by CSL upon Commission's request⁹⁰ and is going to be published soon.

A specific study on the operation of the Directive was undertaken in 2004, identifying means to improve the consistency and efficiency of the legislative framework in the field of biotechnology⁹¹. The outcome of this study was incorporated in the 2004 Report from the Commission to the Council and the European Parliament on the experience of Member States with GMOs placed on the market under Directive 2001/18/EC⁹². The second implementation report from the Commission was published in 2007⁹³. In 2006 the Commission also adopted the respective report about the implementation of the Regulation according to Article 46 of the Regulation itself.

As provided by the Directive and the Regulation, Member States and the Commission meet regularly to vote on Commission proposals and to exchange information on the experience acquired with regard to the release and marketing of GMOs. Ad hoc working groups have also elaborated issues such as the monitoring of the effects of GMO into the environment.

In view of the above it can be concluded that, a few years after the new regulatory framework entered fully into force, a significant amount of information is already available for evaluation by the contractor. A full list of the available material can be found in Chapter 5 and Annex 5. On the other hand, there is still limited practical experience in this area, since no GMO has been authorised for cultivation under the new regulatory regime.

Objective and scope of the evaluation

The objective of the evaluation is to assess, on the basis of data and factual evidence, to what extent the legislative framework on marketing and cultivation of GMO and its implementation have proven capable to accomplish the objective of protecting human and animal health, the environment and consumers' interest, whilst ensuring the effective functioning of the internal market. The evaluation shall provide the Commission with key findings and lessons of experience from past and current implementation of EU legislation and will introduce prospective options for the future.

The report will be in particular designed to:

⁹⁰ Report expected to be published before the end of 2008.

⁹¹ http://ec.europa.eu/environment/biotechnology/pdf/background_study.pdf

⁹² http://ec.europa.eu/environment/biotechnology/pdf/com_575_final.pdf

⁹³ http://ec.europa.eu/environment/biotechnology/pdf/com_2007_81.pdf

- provide the Commission's policymakers and managers with information on the implementation of the current legislation,
- identify problems in the design and implementation of the current legislation,
- recommend options for potential future action,
- identify, where available, the potential social, economic and environmental impacts of the current implementation and of recommended options for action,
- create the basis for the conduct of a possible impact assessment concerning the review of broader aspects of the GMO legislation.

The evaluation will not cover all aspects of the legislation concerning cultivation and marketing of GMOs and will solely focus on selected key areas of the regulatory framework. An overall assessment of the entire scope of the respective legislation would follow, if deemed necessary, after the conclusion of this evaluation and within the framework of a potential impact assessment.

In this view the evaluation will focus on following topics:

- The risk assessment and risk management of GMOs under the Directive, and specifically for cultivation under the Regulation, including authorisation procedures;
- Risk communication;
- The national safeguard measures under Directive 2001/18/EC and emergency measures under the Regulation on the cultivation of GMOs;
- The applicable rules on confidentiality and data protection
- The zero-tolerance of unauthorised GM material in seeds;

The contractor should collect the available data and information in a form that could later on feed into a possible impact assessment⁹⁴. These data should be analysed in order to identify impacts of different policy options to possibly revise the existing legislation. The study shall also include an analysis of the limitations of available data, comparison against varied baselines and statistical significance of time series, which should allow assessing the conclusiveness of results. Areas requiring follow-up should be identified as well.

The evaluation shall encompass the timeframe since the entry into force of the Directive and the Regulation. The contractor shall analyse with a special regard to the focus areas as outlined above. He/she will also follow the most updated developments during the conduct of the evaluation (e.g. future submissions of proposals for authorisations or safeguard measures, EFSA Opinions, Committee and Council votes, etc).

Main identified challenges

The regulatory framework has been subject to controversy between Member States, stakeholders and the general public. Its implementation has faced difficulties as well. More specifically:

- (a) New techniques.

Member States increasingly deal with questions from stakeholders whether newly applied techniques result in a GMO. In order to harmonise the approach of Member States in this issue, a Working Group has been established to address whether these techniques lead to GMOs as defined under Directive 2001/18/EC and also GMMs under Directive

⁹⁴ Details on Impact Assessments can be found at http://ec.europa.eu/governance/impact/index_en.htm

90/219/EEC⁹⁵. The terms of reference of this working group will be finalised after the meeting of Competent Authorities of 17 November 2008 and its works will commence on 15 December 2008. A document outlining the state of play of the work will be presented to the Competent Authorities as early as possible in 2009.

The scientific/technical aspects of these new techniques, including their environmental, health and socio-economic variables, will be examined by a separate expert study that will be requested by the Commission.

Taking into account the above, an evaluation is needed on the regulatory aspects concerning the available plant breeding techniques. Companies and other operators partly determine their strategy on the development and use of particular techniques on the basis of whether they are subject to the GMO legislation or not. It would be thus useful to understand to what extent the compatibility of these techniques with the current definition of GMOs has influenced the development of the biotechnology sector and has generated potential costs or benefits for the involved companies, plant breeders, other operators and consumers. In this view the socio-economic, environmental and health impacts of the inclusion or non-inclusion of these techniques under the GMO legislation should be examined.

(b) Evaluation of environmental risk assessment.

Under both applicable procedures, national Competent Authorities are called to carry out the evaluation of environmental risk assessments. In the case of the Regulation, EFSA has to delegate the environmental risk assessment to a national Competent Authority. EFSA shall thereafter adopt overall opinions on which the Commission proposals are based. Under the Directive, EFSA is only involved after a Member State's or Commission's objection on the environmental risk assessment is maintained after a consultation period of a total of 105 days. Concerns have been expressed by Member States, EFSA and other stakeholders about the involvement of each side in the environmental risk assessment. Same concerns have been voiced during the assessment of scientific justifications of national safeguard measures. While the work of EFSA is subject to a different legislation and evaluation, the regulatory provisions about the role of each side in the environmental risk assessment of GMOs remains an important topic of debating. Moreover, the environmental risk assessment of herbicide tolerant GMOs raises issues about the interplay with the legislation on plant protection products⁹⁶, since the risk assessment and authorisation of the concerned herbicides take place under the latter legislation.

(c) Interplay of the two pieces of legislations on cultivation.

As outlined above, notifications for the cultivation of GMOs can also be submitted under the Regulation, together with the food/feed uses, under the "one-door-one-key" principle. This leads to the application of different procedures not only in terms of risk assessment, risk management and national safeguard measures for the same use of GMOs, but also in the responsibility of the Community Reference Laboratory (CRL) in its role as validator of the event specific methods to be supplied by the notifier. Indeed, whereas method validation by the CRL is mandatory under 1829/03 (and the notifier contributes to the costs incurred) this is not foreseen in the Directive, but has been done *de facto* for the most recent applications, without any financial contribution made by the notifier. In this view it is important to evaluate the appropriateness and implementation of this principle.

(d) Centralised authorisation at Community level.

⁹⁵ Working Group on the Establishment of a List of Techniques Falling under the Scope of Directive 2001/18/EC on the Deliberate Release of GMOs into the Environment and Directive 90/219/EEC on the Contained Use of GM Micro-organisms

⁹⁶ Directive 91/414/EEC

As outlined in Annex 2, Member States have no margin to deviate, on grounds of environmental and health protection, from the terms of the consent or authorisation adopted at Community level. In case new scientific information or re-assessment of existing information becomes available that give detailed grounds for considering that a GMO constitutes a risk for human health or the environment, a Member State can adopt a safeguard measure or initiate the procedure for the termination or amendment of the consent. Up to date Member States have only adopted safeguard measures and have not asked for amendments of consents. Under the special procedure of the EC Treaty⁹⁷ the Commission has rejected the draft measures of Austria (Upper Austria) and Poland thus denying the possibility of regional bans. Member States have sought several different ways to regulate cultivation of GMOs through the transposition acts of the Directive, additional acts, or safeguard measures. These measures provide a wide array of manners to regulate cultivation, such as:

- additional authorisation procedures at national or regional level;
- regional or general prohibitions of GMO cultivation;
- establishment of GM-free zones, either through administrative acts or through the voluntary agreements of concerned farmers;
- isolation distances from ecologically sensitive areas; ,
- monitoring of environmental effects of GMO cultivation, even if this is not foreseen by the Community consent (case of MON810)

Therefore it is important that the Commission obtains a comprehensive overview of the legislative methods applied by Member States to regulate the cultivation of GMOs and their potential social, economic and environmental effects.

(e) "Zero-tolerance" for unauthorised GM material in seeds.

Under both pieces of legislation the presence of unauthorised GMOs in any product, such as seeds, cannot be tolerated. A recent report by DG AGRI⁹⁸ analysed the question how severely imports of animal feed could be affected by the presence of non-approved GMOs in maize and soybean products. Such a study does not exist for the presence of traces of unauthorised GM material in seeds, thus it would be useful to receive an input by the concerned shareholders on the matter.

(f) Inspections and controls of seeds.

Article 4(5) of the Directive allows Member States to carry out their inspections and controls without specifying further the manner and the scope of these inspections. The FVO reports have indicated that the controls of the presence of unauthorised GMOs in seeds have been uneven per Member State. It remains therefore questionable whether further harmonisation, through the introduction of more specific provisions for controls and inspections, would be appropriate to ensure the same level of environmental protection and functioning of the internal market throughout the EU.

(g) Safeguard and emergency measures.

As outlined with more details in Annex 3, several Member States have used safeguard measures to prohibit the cultivation and marketing of certain GMOs. Some of these prohibitions have lasted for many years and the Commission proposals to repeal them have never received any favourable opinion under the Comitology procedure. It remains also questionable whether the application of the emergency procedures of the Regulation is suitable for the examination of national measures on the cultivation of GMOs.

⁹⁷ Art. 95(5) EC Treaty

⁹⁸ "Economic impact of un approved GMOs on EU feed imports and livestock production", http://ec.europa.eu/agriculture/envir/gmo/economic_impactGMOs_en.pdf

(h) Confidentiality and data protection.

Given the up to date experience, it is deemed important to assess several aspects concerning the clauses on confidentiality and data protection, and their consistency with other pieces of legislation, such as Regulation (EC) No 1049/2001 on access to documents.

The evaluation questions

The evaluation questions are intended to steer and facilitate the work of the contractors. Replying to these questions on the basis of factual evidence and founded analysis is considered the core activity of the evaluator and the basis for the recommendations required.

The answer to each question shall include the following elements:

- interpretation and comprehension of the key terms of the question;
- indication of the judgement criteria allowing to answer the question;
- indication of the quantitative and qualitative information needed/collected/used
- description of the evaluation methods used (including their possible limitations)
- detailed description of the reasoning followed in the analysis
- conclusions directly drawn from the analysis, founded on the data and referred to the judgement criteria

1. whether the current objectives and scope of the GMO legislation are in line with the needs of society, and especially the biotechnology operators and consumers. The contractor must evaluate in particular:

- Which plant breeding techniques are already applicable or in the pipeline for commercial uses, in the EU and elsewhere;
- The socio-economic, environmental and health effects that the exclusion or inclusion of each technique into the GMO legislation may have on the biotechnology sector and other segments of the society;
- Options for future policies with regard to these techniques and the potential health, environmental and socio-economic impacts of each option.

This evaluation must take into account the scientific/technical aspects that will be addressed by the Working Group and the commissioned study (see chapter 3 a.), whose work the contractor should take into account as background information together with other relevant information.

2. whether the procedures for the risk assessment of GMOs and their implementation up to date, are efficient, time-limited and transparent The contractor will also analyse whether the procedures are capable to accomplish the objective of the existing legislation, namely to protect human and animal health, the environment and consumers' interest, whilst ensuring the effective functioning of the internal market

3. more specifically, and in the context of the above:

- the co-operation between national Competent Authorities and EFSA, as well as the role of each of them in the environmental risk assessment; the contractor should analyse *inter alia* the comments of MS, their inclusion in the EFSA opinions, the co-operation between EFSA, Competent Authorities and notifiers, the completeness and quality of the application dossiers and the possible need for additional information during the risk assessment , and the applicable timelines;

- the existence of two separate procedures for the authorisation of GMOs for cultivation as well as the application of the "one-door-one-key" principle under the Regulation for cultivation files. The contractor must compare the two procedures (under the Directive and the Regulation), analyse their impact on the environmental risk assessment and on the assessment of the validity of the detection methods to be provided for traceability and labelling, and evaluate whether the "one-door-one-key" principle for cultivation properly fulfils the objectives of the legislation;
4. the interplay between the environmental risk assessment of herbicide tolerant GMOs under Directive 2001/18/EC and the environmental risk assessment for the use of the respective herbicides under Directive 91/414/EC (Directive on Plant Protection Products); the evaluation should in particular consider whether there are any loopholes, overlaps or lack of co-ordination in the system as it has been applied so far.
 5. on the basis of the upcoming study on field trials (shortly to be published by DG ENV), the way in which MS implement the provisions of Part B of Directive 2001/18/EC. In particular, the contractor will analyse the extent to which the Part B provisions and their implementation by the Member States have affected the risk assessment and authorisation procedure of GMOs for later commercial use, and whether they have fulfilled the objectives of the legislation.
 6. the effect that national measures on GMO cultivation (apart from co-existence measures) have on the internal market, environmental and health protection, and possible options for future action. This evaluation has to be kept separate from the socio-economic aspects of the cultivation of GM crops, which are dealt with by national co-existence rules. The Commission is going to produce a Communication in 2009 on this issue and the contractor should take it into account as background information.
 7. the current provisions for the risk management of GMO marketing and their implementation up to date. The contractor must analyse whether the respective provisions, as well as their implementation, are efficient transparent and in line with the general objectives of our legislation; special emphasis to be placed on the applicable provisions for inspections, controls, monitoring and special protection of eco-systems, environments and geographical areas.
 8. the inspections and controls of the presence of unauthorised GM material in seeds as carried out by the Member States. The contractor must review *inter alia* the respective FVO reports, their findings and their recommendations, evaluate the current legislation and its implementation and present options, if necessary, for potential improvements.
 9. the communication of risk concerning the release of GMOs into the environment and the manner in which it has been implemented so far by the Commission, EFSA, national Competent Authorities, the industry and other stakeholders. The contractor will analyse *inter alia* press releases, publications, scientific events and websites of the above authorities, as well as opinion polls related to the perception of risk by the public and involved stakeholders. The evaluation will not cover communications on GM feed and food which fall outside the scope of the current evaluation.
 10. whether the procedures on national safeguard / emergency measures on cultivation under the Directive and the Regulation are efficient, effective, time-limited and transparent, the role of the Commission, Member States and EFSA in the procedure and whether there are any loopholes in the system;
 11. whether the provisions related to national safeguard measures under the Directive and the Regulation are coherent (e.g. consideration of safeguard measures on cultivation under the emergency procedures of the general food law);
 12. whether the applicable rules on confidentiality and data protection of the Directive are consistent with those of the Regulation and Regulation(EC) No 1049/2001(e.g. whether the

scope and the categories of protected information are different between the two legislative tools), whilst the different concepts of data protection and confidentiality shall at all times be kept separate; it should also be assessed whether they are efficient enough so as to sufficiently protect confidential information and intellectual property rights, while ensuring the maximum possible transparency with regards to the deliberate release of GMOs into the environment and in particular the associated risk assessment;

13. the effect of zero – tolerance policy on unauthorised seeds in the EU, with specific reference to the impact of this policy on imports of seeds and on related seed prices.

14. Where available, the answer to the above questions must also indicate social, economic and environmental impacts of the current implementation and of the suggested future options. The contractor is also invited to identify any other issues not addressed by the above questions; this could include conclusions as to whether the current legal framework has contributed to achieve its key objectives.