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 THE PLACING ON THE MARKET OF GMOS AS OR IN PRODUCTS UNDER DIRECTIVE 2001/18/EC

Final Report

EPEC

For DG SANCO, European Commission

Main Report

March 2011

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Final Report

An EPEC report to DG SANCO

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Explanatory note

This report has been prepared under a contract awarded to the EPEC consortium (www.epec.info) by DG Environment of the European Commission (the file was subsequently transferred to DG SANCO). The team was led by GHK Consulting Ltd (www.ghkint.com) working with the support of Technopolis (www.technopolis-group.com).

The core team members were:

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The core team benefitted from expert advice and research input from Professors Erik Millstone and Andy Stirling of the University of Sussex, Huib de Vriend of LISConsult, Dr. Armin Spoek of IFZ-Interuniversity Research Centre for Technology, Work and Culture, and Piet Schenkelaars of Schenkelaars Biotechnology Consultancy

The main text of the document reports events as of 15 March 2010. Appendix B provides a commentary on institutional decision-making issues set in the context of the European Commission's proposals of July 2010, and was drafted after the main text.

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1 INTRODUCTION

This is the final 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 the placing on the market of GMOs as or in products under Directive 2001/18/EC*, a project commissioned by DG Environment of the European Commission from the EPEC consortium. The consulting team has been led by GHK Consulting Ltd. GHK has worked with co-consultants Technopolis (our partner in EPEC) and a number of individual experts in biotechnology, risk and communication from across the EU[1].

This final report presents the conclusions of the evaluation. It comprises:

- a short introduction to the strategic purpose and specific objectives of the project (section 2);
- a summary of the approach taken to the work (section 3);
- conclusions and suggested options for change, on each of the main components of the legislative framework, i.e.
    - The **scope and objectives** of the legislation (section 4);
    - **Risk assessment** as defined and practised in the legislative framework (section 5);
    - The implementation of Part B of the Directive governing **field trials** (section 6);
    - **Risk management**, covering both the authorisation 'decision' and the measures deployed to monitor and mitigate the risks of an authorised deliberate release (section 7);
    - **Risk communication** covering both the communication activities of risk assessors and risk managers to and from the public (section 8); 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 (section 9).
- a summary section that draws together the overall conclusions.

A detailed analysis of the results of the consultation that was conducted for this study has been published in the project interim report and is not repeated here. An update of those results is available in a supplementary paper submitted alongside this final report as a separately bound appendix (Appendix A). The intervention logics and other 'framing' analysis that form the foundation of the evaluation are provided in the inception report. The inception and interim reports are available to download on the DG SANCO website[2].

At the time of drafting the main text of this document the Commission was working on the adoption of a legislative proposal and a Recommendation on co-existence. Those options,

[1] Professors Erik Millstone and Andy Stirling of the University of Sussex, Huib de Vriend of LISConsult, Dr. Armin Spoek of IFZ-Interuniversity Research Centre for Technology, Work and Culture, and Piet Schenkelaars of Schenkelaars Biotechnology Consultancy

[2] Both reports are available to download at http://ec.europa.eu/food/food/biotechnology/index_en.htm

together with consideration of self-restriction of the scope of applications by notifiers and other options, were addressed by some stakeholders during the consultation period.

The Commission made proposals for changes to certain aspects of the system covered by this evaluation in July 2010, and issued a Recommendation on co-existence. In order to factor those proposals into this evaluation some additional work was undertaken in late 2010. The results are presented in Appendix B which identifies and evaluates options for change in relation to parts of the risk management component of the evaluation, taking into account the Commission's proposals.

2 THE PURPOSE AND FOCUS OF THE EVALUATION

2.1 This evaluation examines the issues that have arisen in the implementation of the EU's legislative framework governing cultivation of genetically modified organisms

The European Commission initiated this technical evaluation to:

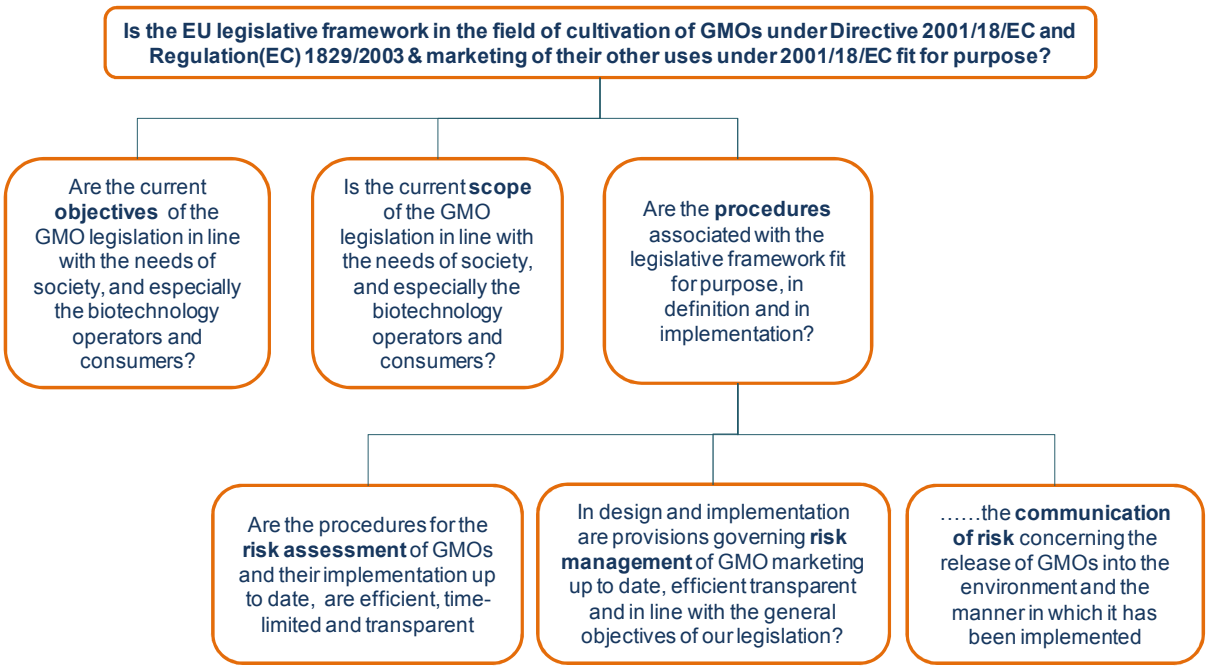
- gather information on the issues faced by those involved in the operation of the EU's legislative framework on the cultivation of genetically modified organisms (GMOs) and the marketing of their other uses;
- generate options and ideas on how any problems that are identified might be addressed.

The project is technical in nature and does not imply any intent on the part of the Commission to instigate proposals for reform. This project is focused on cultivation. A separate, parallel evaluation is considering the issues arising in relation to the regulation of GMOs in food and feed within the EU.

2.2 The research effort has concentrated on the specific questions posed by the terms of reference

The strategic goal of the evaluation is to examine the performance of the European Union's legislative framework for GMO cultivation, drawing on the available data and on consultations with those that work in and with it – from Member State officials through biotechnology companies to farmers' groups and non-governmental organisations. The answer to the question of whether the framework is, overall, 'fit for purpose' has been considered through examination of each of the main constituent parts of the framework and of the system that it defines. This high level structure is shown in Figure 2.1.

Figure 2.1 High level structure of the evaluation



Source: GHK Consulting Ltd.

Within each component the evaluation has consider subsidiary questions on performance, looking in particular at efficacy, efficiency and transparency. The work has been guided by, and focused, the core questions set out by the European Commission in the project terms of reference. These are:

- 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, considering the socio-economic, environmental and health effects that the exclusion or inclusion of each technique into the GMO legislation may have;
- Whether the procedures for the ***risk assessment*** of GMOs and their implementation up to date, are efficient, time-limited and transparent;
- The ***co-operation*** between national Competent Authorities and EFSA, as well as the role of each of them in the environmental risk assessment;
- 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 interplay between the environmental risk assessment (ERA) of herbicide tolerant GMOs under Directive 2001/18/EC and the ERA for the use of the respective herbicides under Directive 91/414/EC[3] (Directive on Plant Protection Products);
- 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;
- 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;
- The current provisions for the ***risk management*** of GMO marketing and their implementation up to date, including whether the respective provisions, as well as their implementation, are efficient transparent and in line with the general objectives of the legislation;
- The ***inspections and controls*** of the presence of unauthorised GM material in seeds as carried out by the Member States;
- 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;
- 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, whether there are any loopholes in the system, and whether the provisions related to national safeguard measures under the Directive and the Regulation are coherent;
- 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; and
- 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.

[3] Recently replaced with Regulation 1107/2009 on plant protection products

The following chapters provide our conclusions on the situation in each of these components of the system, building up to the summary analysis provided in the concluding chapter. As directed by the Commission, the research and this report put more emphasis on some issues (e.g. operation of risk assessment procedures) than on others (e.g. inspection and controls). Cross-reference is made to the inception and interim report, and to Appendix A of this report (which is separately bound), as appropriate.

3 APPROACH AND METHOD

The evaluation has involved:

- A phase of desk research that provided a definition of the legislative framework, an outline of the current situation and a detailed schedule of issues to be explored
- A large scale consultative exercise that engaged with governments, industry, NGOs and other interests across the EU;
- The gathering of additional data and evidence to support the analysis;
- The formulation of conclusions to the principal evaluation questions;
- The development of options that might be considered to address the problems that have been identified.

The overall project workflow is shown in Figure 3.1.

Figure 3.1 Outline of the project process

The consultation phase absorbed the largest share of the project time and resources[4]. It involved:

- In-depth interviews with 9 Member State authorities, 7 key notifiers[5], EFSA (the European Food Safety Authority), environmental NGOs[6], as well as farming and other industry associations[7];
- Detailed questionnaires sent to authorities in all 27 EU Member State, EFSA, biotechnology companies, environmental NGOs, farming groups, trade associations[8], and research institutes;
- An online 'E-survey' which was open to all interested organisations in Europe[9]. This resulted in 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. 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.

The nine Member State authorities chosen for an in-depth interview were Austria, Belgium, the Czech Republic, France, Germany, Hungary, the Netherlands, Spain and the United Kingdom. These were selected on the basis of the following activities:

- 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.

It is important to note that the project analysis 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 authorities and officials who were consulted are not necessarily the same as the formal positions of the national governments concerned.

The interim report of this study reports and explains the consultation results. Detailed information is also available in Appendix A to this final report.

[4] See Annex A of the Interim Report for more details on the methodology of the consultation

[5] The notifiers interviewed were AVEBE, BASF, Bayer, Dow AgroSciences, Monsanto, Pioneer and Syngenta.

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

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

[8] 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".

[9] 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'.

4 THE SCOPE AND OBJECTIVES OF THE LEGISLATION

4.1 The objectives of the legislation

The issues

The existing objectives remain necessary but there is some disagreement about whether they are sufficient

The core objectives of the legislation are to protect human and animal health, the environment and consumer interest, while ensuring the effective functioning of the internal market. These remain necessary, relevant and appropriate. They have the broad support of consultees[10], though different interests groups put different weight on the importance of, for instance, environmental protection versus internal market considerations.

There is less agreement on whether they are sufficient. There are, for instance, no explicit references in the existing objectives to the issues around which many of the GMO debates in Europe revolve – the socio-economic benefits, potential impacts on social cohesion or the ethical issues. Those debates therefore take place outside the regulatory process, impinging upon it but never squarely addressed. Their exclusion reflect an explicit choice made in the development of the legislative framework – i.e. that the duty of the regulator is to ensure that the environment and public health are protected, leaving it to individuals to choose whether or not to make use of the product once it is has been judged safe and made available. On this model, perceptions of value and benefit, to the economy and society, are deliberately excluded from the regulatory screening process and left instead to the market, in this instance (for the most part) to farmers and end consumers.

Proposals put to the Council in 2009 by certain Member States mark a step away from that essential principle by suggesting (i) explicit inclusion of socio-economic factors in the decision-making process and (ii) providing Member States with the right to declare areas within which approved GMOs could not be cultivated (a choice that might, presumably, be based in part on ethical considerations). Adoption of such proposals would presumably imply some modification of the objectives. This issue is addressed further below and in section 7.

These proposals reflect the situation that, in some parts of the EU, opposition to GM technology has become codified in social choices, in so far as there are countries where it is a common position of all major political parties and/or parliaments have adopted measures that signal opposition to GMO cultivation. *De facto*, individual choice (of, for instance, the individual farmer) has been supplanted by collective opinion. This in turn impacts on risk managers acting with the current framework.

The objectives are not being met in the way intended by the legislation

Although there may be a general consensus that the legislation's core objectives are still relevant, it is harder to argue that they are being met in the way that was originally envisaged. The regulatory framework is not functioning as had been anticipated and certain objectives are being met 'by default' rather than through due process. For example, the environment and human health are being protected from potential adverse risks of GMO cultivation not by the screening out of 'unsafe' products, but instead by the absence of decisions one way or another on cultivation applications.

[10] Discussion of stakeholders' responses to questions about the objectives are detailed in Section 2 of the Interim Report.

Our interviews with major biotechnology companies, as well as other evidence, indicates that GM-related research effort has been directed to other parts of the world where there is greater prospect of the resulting products being brought to market[11], and most EU farmers have not had the opportunity to exercise a choice between GM and non-GM crop varieties (except for MON810 maize which was approved under previous legislation and whose authorisation is currently undergoing review under the Regulation).

Whether these outcomes can be said to be meeting the 'needs of society' (including consumers and biotechnology operators) is, inevitably, contested – among sector interest groups and among Member States. The biotechnology industry's view is that once a product is deemed 'safe' by the defined process, 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.

Others disagree, with calls for consideration of other factors (as discussed later in this report). Current discussions about whether there should be more explicit inclusion of socio-economic aspects of GMO cultivation in the decision-making process are, in part, a reaction to this situation. In the consultations carried out for this study, several Member State authorities stated that explicit consideration of socio-economic considerations would help to ensure that society's needs are better met. Such debates are set within the context of an ongoing debate within the EU about the potential benefits of GMOs to farmers, consumers and society at large.

Consultees are, understandably, more concerned about resolution of the implementation issues than changes to the objectives of the legislation[12]. Those implementation issues go to the heart of the processes of risk assessment, management and communication which are discussed in more detail in subsequent sections of this report.

Options

The processes of risk assessment, management and communication that the legislative framework defines are instruments for implementing the stated objectives. The core objectives remain necessary but the operation of the associated processes is deficient. The key issue therefore is whether (i) the implementation problems can be resolved through changes to existing processes alone, (ii) additional objectives (and associated new processes) should be adopted, or (iii) both types of change are required.

The proposals that emerged in 2009 for national self-determination on cultivation (within the framework of a common EU system for scrutinising product safety) and more explicit consideration of socio-economic factors by Member States (described in more detail in section 7 of this report) arise from a belief that a pan-EU consensus cannot be reached on the ethical and economic arguments. Evidence and experience suggest that changes to the legislation which would try to force common views on such issues are unlikely to succeed.

Discussion of the case for changing (or, more likely) expanding the list of objectives into the economic and ethical realms cannot sensibly be separated from the analysis of the way the

[11] See Section 5.4.2 of the Interim Report, as well as, for instance: *What shapes the research agenda in agricultural biotechnology – Plant Breeding Case Study*, a report by the Agriculture and Environment Biotechnology Commission (AEBC). April2005, also Last biotech moves GM research to US, report in Times Higher Education Supplement, April 2004 http://www.timeshighereducation.co.uk/story.asp?sectioncode=26&storycode=189783 , and Meldolesi, A. (2010). Pea trials flea to US. Nature Biotechnology 28(8). Available from: http://www.nature.com/nbt/journal/v28/n1/full/nbt0110-8b.html

[12] See Section 2 of the Interim Report

political decision-making process has operated. So, rather than explore options for modification to stated objectives here, we discuss the issues further in the risk management section of this report, and again in the concluding remarks.

4.2 The scope of the legislation

For the purposes of this evaluation the 'scope' of the legislation is set by the definition of a 'genetically-modified organism'. Adjustment to the scope of the legislation was considered in the analytical work for this evaluation and in discussions with consultees. The team that conducted this evaluation is not technically qualified to comment on the relative risk to health or the environment associated with the new techniques being considered, and we make no attempt to do so. We focus instead on the consultees' general perspectives on the scope of the legislation, and on the potential practical implications of modifications to it.

Some more detailed issues of the interpretation of the legislation's existing scope, i.e. the alignment of Member State expectations of the scope of the environmental risk assessment with the central European process are discussed in the following chapter.

The issues

The legislation defines GMOs by reference to fixed schedules of techniques

The legislative framework defines a GMO as an organism "*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). This definition is further qualified in the legislation, in that genetic modification is stated to occur at least through the use of techniques listed in Annex 1A, part 1, whilst part 2 references a set of examples of biotechnology techniques which fall outside the definition. The current approach in effect defines a GMO through the process by which the product is engineered, rather than from the genetic characteristics of the product itself.

Scientific knowledge is increasing over time and the use of techniques by researchers and industry is changing. The scope of the legislation therefore warrants periodic review to ensure that it remains relevant and to examine whether the new techniques are covered by the scope of the existing legislation. Such a review is underway, to be informed by the output of a Working Group set up by DG Environment which is due to report in 2010.

The biotech industry is against expansion of the legislation's scope but some consultees are concerned about the potential impacts of the products derived from new techniques

The consultations carried out for this evaluation suggest that consultees do not regard the new techniques in the immediate pipeline as posing any new issues of significance for the environment or human/animal health. It is the potential consequences of traits or products produced using these techniques, and not the techniques themselves, which some (i.e. certain Member States and the environmental NGOs) believed raised potential concerns for environmental safety and health.

There is, however, interest in the socio-economic impacts of including or excluding new bio-techniques in the GMO legislation. In particular, representatives of the biotechnology industry state that regulation of these new plant breeding techniques as 'GM' would largely preclude their subsequent use and development in Europe. It could certainly be argued that products based on such techniques would by definition be excluded from the market if covered by GMO cultivation approval processes that did not yield decisions, whether positive or negative. Other consultees did not offer detailed views on the economic impacts of including new techniques. Debate about these areas seems likely to increase when the findings of the Working Group are released.

How far a change in scope would change industry practice and product pipelines if the legislation was operating more efficiently and effectively is difficult to determine. Neither research nor the consultations yielded data that would support estimates of the socio-economic consequences of inclusion or exclusion of individual techniques.

Some contemporary plant breeding techniques create new challenges for regulators

The characteristics of some of the plant breeding techniques now being used do create new challenges for regulators. This is particularly true of techniques 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. Since it is not possible to determine the 'GM' status of such products by direct assessment of their DNA, inclusion of such techniques within the scope of the legislation would require a different approach to that currently in use for monitoring and traceability of the products concerned. Systems based on administrative audit trails, of the kind used for labelling on origins and organic production methods would be required. This would enable a chronological record of events to be kept, so that events and transactions can be tracked if need be at a later date in order to verify the origin, and identity of the GMO in question. Regulation 1829/2003 already relies to some extent on administrative audit trails, for instance in the case of oil produced from genetically modified soy beans.

The pan-EU environmental NGOs consulted want to see all techniques which use recombinant DNA during the plant breeding process fall under the legislation governing GMO cultivation[13]. This would include, for instance, reverse breeding and grafting. The biotechnology industry wants the focus to be on the resulting organism not on the technique. Nonetheless, some did expect the legislation's scope to be extended to include techniques which do, for instance, contain foreign DNA in the product, although not in the offspring (e.g. RNA degradation and agroinoculation). Member States consulted are divided on the issue.

The continuing innovation in bioscience means that keeping legislation in step with research and industry practice will be on on-going task

More novel techniques can be expected in the future as global bioscience innovates and develops. This will present ongoing challenges to regulators.

Options

In the early stages of the use of GM technologies many of the products that were advanced to market were demonstrably 'different', in terms of their DNA and the traits they exhibited, from the conventional plants they displaced. An example is transgenic products in which a plant contained DNA from a different species or different class of organism (e.g. a bacterium). Assessment procedures were developed to appraise the risks that might arise – such as this 'foreign' DNA and the traits it coded for migrating to other species of plant.

Today, as the discussion above shows, innovations in bioscience are, in some cases, weakening the link between the use of a genetic techniques in the product development pipeline, the characteristics (genetic and phenotypic) of the final product and thus, many would argue, the differential risk that the final product might pose to the environment or human health. In principle, for example, a plant that had been propagated using reverse breeding could well be indistinguishable (in its DNA and physical characteristics) from another plant propagated from the same (distant) parent through conventional techniques. So as the science moves forward, there is a manifest challenge to regulators to determine

[13] This excludes screening techniques developed with recombinant DNA and applied in conventional breeding, including for instance the use of Marker Assisted Selection or Marker Assisted Breeding, which is supported.

the potential for risk (to the environment, health, etc.) and to keep regulatory controls effective and proportionate.

There is also a challenge to ensure that management of the environmental and health risks posed by all crops is balanced, proportionate and consistent. Plants can be brought to market with traits equivalent to those delivered by GM techniques (as currently recognised) but through other methods. An example is crops displaying herbicide tolerance that have been developed through conventional breeding. Plant breeders have previously induced mutations in plants by bombarding them with radiation.

Looking ahead, it is clear that keeping the legislative framework 'congruent' with the technologies and techniques being used in bioscience is going to be an ongoing challenge. If the framework is going to remain coherent then the principles by which the scope is defined need to be clear.

The options identified are as follows;

- **Conduct a strategic appraisal of the principles by which scope will be determined in the future**

  Based on the above analysis there is a case for the Commission launching a process to establish the principles on which the scope of the risk assessment (and thus, within present rules, the legislative framework) should be set in the future. This would provide guidance that would help with the definition of a longer term strategy for the EU as it looks to keep pace with innovation in bioscience.

  This assessment would be tasked with identifying a set of working principles to guide regulators. It could consider the case for retaining a focus on techniques in the definition of scope (where if a technique of genetic modification is used, then the resulting organism is a GMO) or, alternatively, putting more emphasis on the organism placed on the market. Putting more emphasis on the organism could exclude from the scope of the legislation techniques of genetic modification that result in organisms that are indistinguishable from an organism developed using traditional breeding techniques.

  The review might also consider, again in the context of the evolution of bioscience, how to ensure that vigilance applied to crops developed with bioscience is not only proportionate to the potential for risk but also consistent with that applied to crop development via other techniques. Regulatory controls ought to be proportionate to risk. EU consumers and farmers might reasonably expect that products placed on the market are assessed on the basis of the potential for risk, irrespective of the technique used in their development. A system that regulates GM innovations very highly, but neglects products that exhibit the same characteristics or traits which have been developed through conventional means, may not meet that test.

  The determination of the principles by which scope is determined should be informed by technical analysis such as that of the current Working Group, and expert appraisal of risks. As noted above, this report does not comment on the relative risk to health or the environment associated with the individual techniques that might be considered.

  The review should also include a consultative process that seeks inputs from interested parties and the wider public. It may well be, for instance, that public opinion would support a continued focus on the technique used.

  Even if a strategic review of the kind set out above (whose results may require a full legislative amendment) is not adopted, many of the choices will be

implicit in any short term review of scope following the work of the current Working Group[14]. This short term review may see:

- **Extension of scope taking into account the genetic characteristics of the resulting organism**: compared to extension on the basis of the technique used, an approach that puts the emphasis on the resulting organism would result in fewer products falling within the scope of the legislation and thus, all else being equal, one would expect more products to reach the market over time and/or more research and development in the related areas of bioscience within the EU. A case-by-case approach to defining scope would still be required. In cases where recombinant DNA was absent from the organism placed on the market expert appraisal would be needed to confirm that 'upstream' use of excluded GM techniques did not pose additional 'downstream' risks in terms of health or environmental impacts.
- **Extension of scope taking into account the technique used:** this option, compared to the above, would be expected to cover a larger number of products. It would mean that authorisation is needed for products where 'GM' techniques are used in upstream process even if there was no recombinant DNA in the product placed on the market. One likely scenario would be that most of the examined techniques could be considered to fall at present under the scope of the legislation.

[14] The Working Group is not expected to formally conclude on its findings. It is currently preparing a report that will be presented as advice to the Competent Authorities of Directive 2001/18/EC. The Competent Authorities will then discuss the report and the Commission will take into consideration the outcome of this informal discussion to decide on the way forward.

5 RISK ASSESSMENT

5.1 Introduction

Risk assessment is at the core of the legislative framework. Most of the activity under the EU 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. In the consultations conducted for this evaluation the views on risk assessment component of the framework were the most diverse. The indecision of the institutional decision-making process was of greater concern but the effective functioning of the institutional decision-making phase of the legislative process critically depends on confidence in the risk assessment.

The principles for risk assessment of GMOs in the EU are defined in considerable detail. Guidance on principles and procedures has been regularly updated. In consultations, the majority of consultees were generally satisfied with the legislative requirements for risk assessment, seeing them as being in line with the objectives of the legislation.

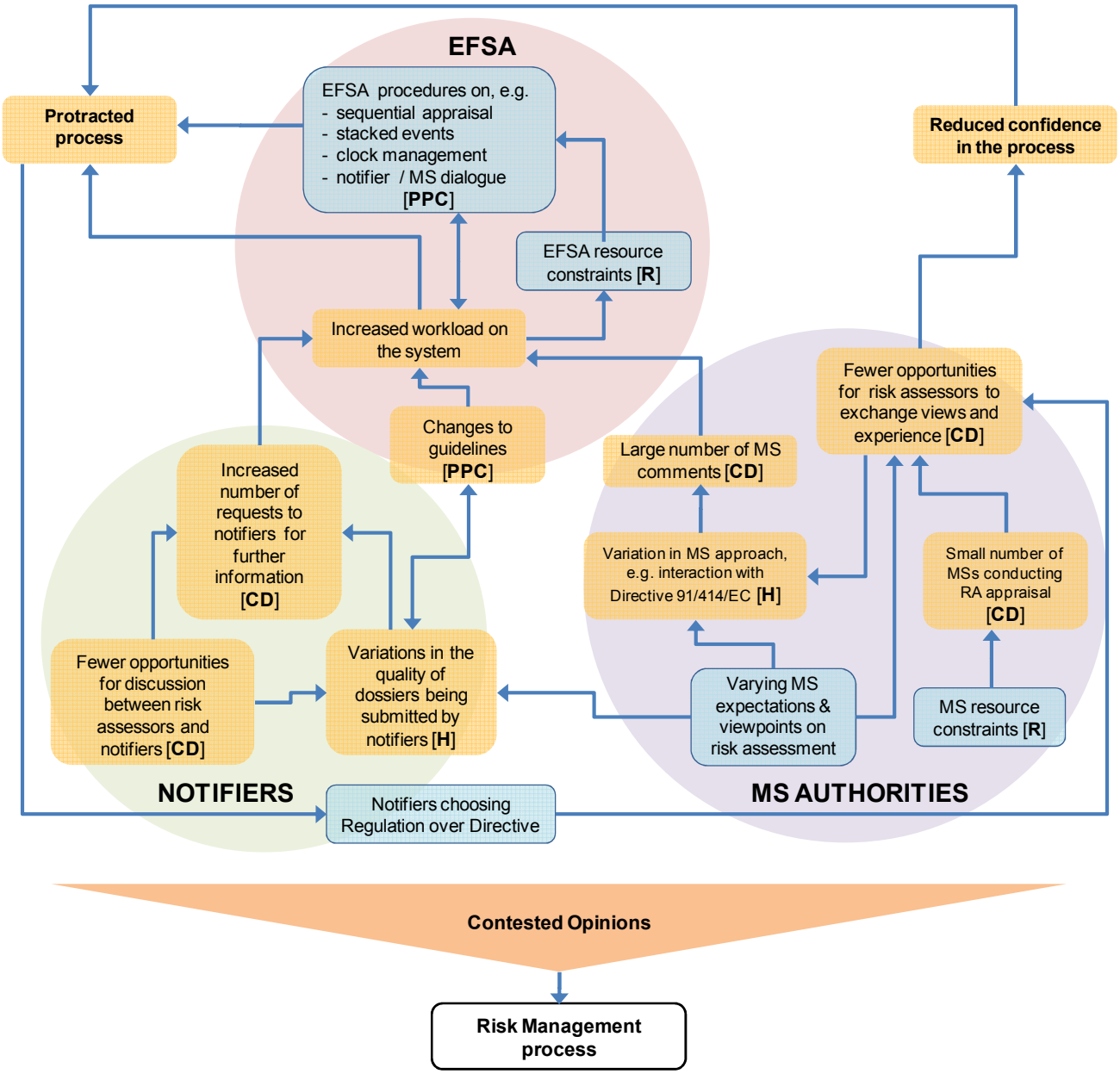
But the comments made in consultations and the data gathered suggest that there are opportunities to improve the efficiency, transparency, timeliness and adequacy of the risk assessment process. Figure 5.1 provides a representation of the various pressures, responses and feedback loops that influence the observed performance of this component of the legislative framework. This kind of analysis can be used to inform analysis of options for change, as described in the section that follows. The relative significance of different factors can be debated, but the mapping helps to emphasise that a 'system'-based approach is needed.

The diagnosis of the risk assessment process suggests potential for improvement through actions on:

- **Communication and dialogue**: so as to increase the rate of learning in the system, improve confidence in the assessment process and thereby reduce the number of comments and responses circulating in the system;
- **Procedures, process and capacity**: to streamline the process and provide more opportunities for engagement;
- **Resourcing**: as a means of facilitating wider participation in the risk assessment appraisal and accelerating elements of the process; and
- **Harmonisation**: to increase consistency of practice among Member States and notifiers, and therefore predictability and efficiency throughout the process.

Conclusions and associated options for change are considered below under those headings. Certain options would require legal changes. Achieving improvements within the current legal framework ought to be the priority.

Figure 5.1 A system view of the pressures, challenges and constraints on the risk assessment process



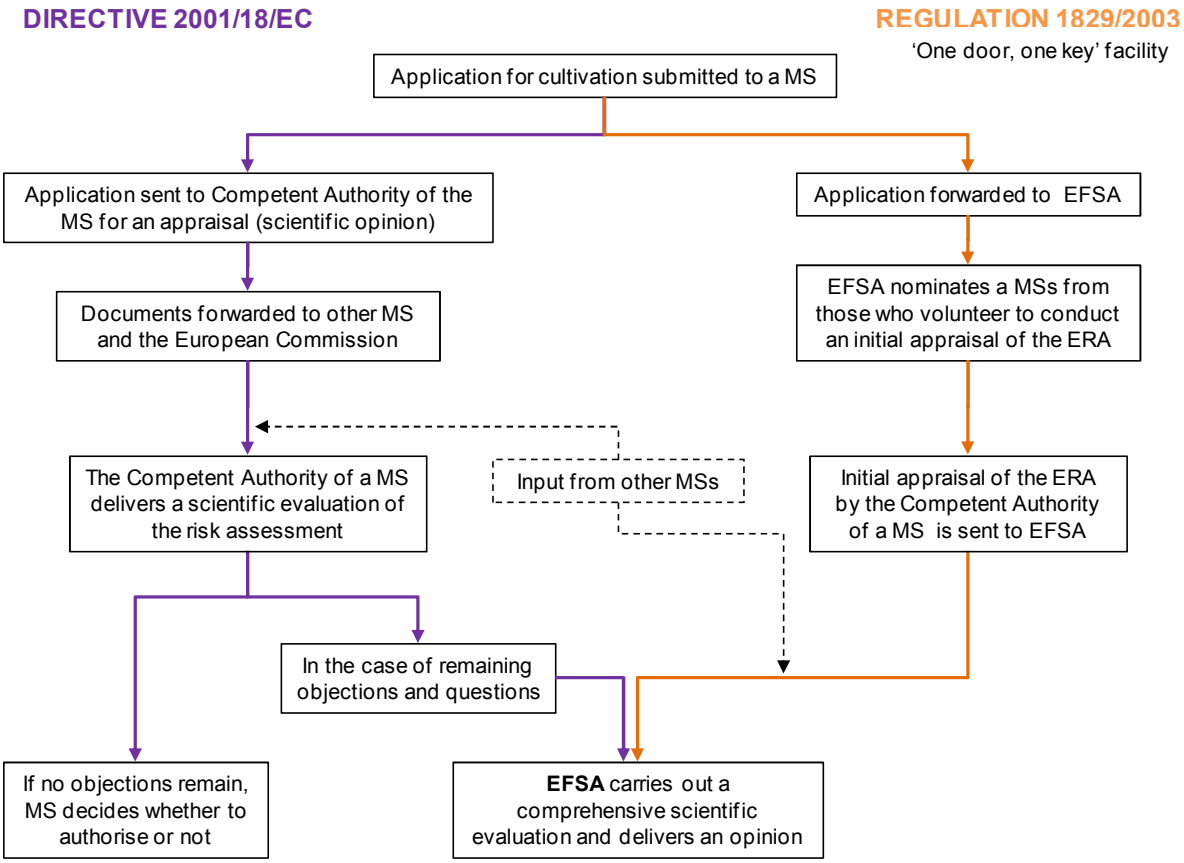
Source: GHK Consulting Ltd.

The discussion below is generally set in the context of the process and characteristics of the risk assessment under Regulation, as opposed to that under the Directive (Figure 3.2 shows the procedural differences of the risk assessment process under the Directive and the Regulation). This is because since 2005 risk assessment experience under the legislation has been limited to the Regulation because after that date there have been no

cultivation applications submitted under the Directive[15]. Nonetheless, several of the options will be applicable whether or not notifiers chose to use the Directive again in the future (use of the Directive might resume if GMOs are developed which have purely industrial uses and do not have the food or feed application required to qualify for application under the Regulation).

However, regardless of the use of the Directive's procedures in practice, the principles established in the legislative text, and especially in its Annexes are still very much relevant. Indeed in many respects they form the cornerstone of the legislative framework for GMO cultivation[16]. As such, the development of any option below should complement and build upon the principles set out in the Directive to avoid any future conflicts or discrepancies.

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



Source: GHK Consulting Ltd.

[15] 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. This choice has potential impacts on the risk assessment process given the procedural differences. See Section 4.7 of the Interim Report for further details.

[16] 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.

5.2 Communication and dialogue

The evaluation's consultation and analysis suggest that there is scope to improve the efficiency of the current system through promoting greater communication amongst the relevant actors with the aim of:

- Encouraging the preparation of application dossiers that are closer to being 'right first time', and which thus trigger fewer requests for additional information; and
- Addressing Member State concerns further 'upstream' in the authorisation process, rather than after EFSA has issued a final Opinion.

Improving communication and dialogue would simultaneously address several of the key issues which currently afflict the risk assessment process. Firstly, discussions and exchanges of views that help to address persistent concerns to the satisfaction of all parties should increase confidence in the risk assessment process, particularly as more comprehensive Opinions could then be delivered if these persistent issues were more explicitly addressed. For instance, during the consultation process it became clear that a key concern for some Member States was the treatment of (i) regional variability, and (ii) risk management strategies in the appraisal process and in EFSA's final Opinions.

Secondly, most applications for cultivation are now being submitting via the Regulation's 'one door one key' facility. A key difference between Directive 2001/18/EC and Regulation (EC) No 1829/2003, from Member States' point of view, is that the Regulation provides fewer opportunities to engage in the risk assessment process. This adds to the demand for Member State authorities to be provided with better opportunities to comment, and to pressure for comments that are raised to be adequately addressed.

Lastly, providing more opportunities for discussion and the exchange of views could help to reduce inconsistencies in the way that Member State authorities appraise environmental risk assessments. Specifically, 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 for the first time. A key area where there are inconsistencies is the way Member States deal with the interplay with Directive 91/414 (recently replaced by Regulation 1107/2009 on plant protection products) in the case of GM herbicide tolerant (GMHT) plants. A clarification of the interplay between the two directives would require clarifications from regulators with respect to the overlap and gap in the environmental risk assessments. Improving the consistency with which Member State authorities appraise environmental risk assessment is important as the current variation in views and subsequent approach 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.

There is therefore a powerful case to be made for improving the level of communication and coordination between all parties in the system. Options discussed below therefore target the following areas:

- Communication between risk assessors and notifiers; and
- Communication with risk assessors, both amongst Member States themselves, and between EFSA and Member States.

Changes to communication and coordination processes need to be considered together with the resourcing and capacity issues discussed further on in this section.

5.2.1 Improved communication between risk assessors and the notifiers

The issue

The consultations suggest scope to improve communication between risk assessors and notifiers.

Notifiers are currently able to discuss their application with scientific officers of the EFSA GMO Unit, e.g. by direct phone contact[17]. Notifiers have no direct contact with the experts on the GMO Panel who assess the scientific aspects of their applications. This is pivotal to ensure the independence of the Panel, thus all correspondence goes through EFSA. Enquiries are dealt with through a system of written enquiry and response, mediated by the secretariat. This takes time. Efficiency gains are potentially available if points of clarification could be handled through use of other technologies (e.g. by telephone, or online) whilst retaining the integrity and transparency of the system.

Both the notifiers and some MS authorities also stated that occasional direct contact between the Competent Authority of the nominated MS and the notifier could be beneficial. Some MS authorities have held a meeting or have contacted notifiers directly to clarify certain issues without explicitly involving EFSA. EFSA reports that it is usually informed about these meetings but is not actually present. In all cases the purpose and outcomes of these meetings should be shared with EFSA to ensure traceability and transparency, as is already being done with all written correspondence between notifiers and MS authorities (which is sent through EFSA).

Options

- **Pre-application discussions**

  Pre-application discussions could be similar to those which used to take place under Directive 2001/18/EC with rapporteur Member States. In discussion of this option EFSA raised concerns that such discussions might duplicate the current process whereby an application is validated. However, 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, it would be useful for notifiers 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. The added value would be greatest where applications related to new traits or new crops.

  A danger here is that by the time the dossier is submitted following a prior pre-application discussion, the requirements might have changed as the guidance is updated. A possible solution would be for EFSA to keep applicants informed when they become aware of any forthcoming changes that might require the applicant to potentially submit additional evidence. With sufficient notice, the applicant could still make the necessary changes, facilitating the process further downstream when it comes to the appraisal of the dossier without the need to request additional information at that later stage.

  Another danger is that pre-application discussions between EFSA and notifiers can be perceived as an opportunity for notifiers to exert undue influence on the process, which might lead to doubts over EFSA's independence and objectivity. Such caveats are discussed further below, along with possible measures to address these issues.

[17] EFSA's position is that its staff are available for procedural questions or clarifications and will also assist on scientific issues once the panel has addressed them.

Given that this kind of initiative would place an additional administrative burden on already limited EFSA resources, this option would need to be considered in conjunction with a consideration of system resourcing.

- **More direct communication between notifiers and EFSA / Competent Authorities of nominated MSs during the appraisal process**

  The efficiency and speed of the process could be improved by opening up more direct, interactive communication channels between notifiers and risk assessors. This needs to be done in such a way that it does not compromise the independence and objectivity of the assessors. MS authorities might, for instance, be encouraged to take the initiative to directly contact notifiers where issues could be more easily and quickly resolved. As mentioned above, some MS authorities have already done so and have found the process to be worthwhile. Others have not done so, and would like to officially be given the option to do so. In order to maintain traceability and avoid duplication, EFSA would need to be kept informed of any such communication, and be at liberty to contribute to the exchanges.

Options such as these are likely to become more important in the future given that EFSA has recently 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[18]. Notifiers are no longer able to request clarification, or submit further information following a reiteration of the request. Some MS authorities have raised concerns that this approach might compromise the quality of the ERA 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.

In consultation, notifiers stated 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, in an effort to address this concern. It also encourages notifiers to contact EFSA if they feel clarification is needed before they prepare their response.

Caveats

Although these options would go some way in improving the efficiency and effectiveness of the process, they could also result in potential tensions and conflicts if appropriate counter measures are not taken. Any changes would need to be mindful of the need to ensure;

- **Objectivity:** it would be necessary to ensure that accountability and regulatory independence was maintained. Concerns about the potential for 'regulatory capture'[19] could be addressed by, for instance, the recording of all such conversations and their storage with other dossier information on EFSA data systems.
- **Transparency and that duplication is avoided:** any direct communication with the risk assessors and the notifiers should be traceable and all parties involved should

[18] When EFSA asks a particular question it does so once, providing a rationale for the question. The notifier is expected to answer the question. If there is uncertainty as to the meaning of the question the notifier is encouraged to contact EFSA to discuss it before proceeding to answer the question. The data in the provided answer, or other issues linked to the dossier might generate other questions or follow up questions. EFSA has no limit on the number of rounds of questions but expects asked questions to be answered and will not reiterate a specific question.

[19] Where industry has undue influence over regulatory agencies and/or processes

be made aware of the communication that took place and the outcomes that resulted from it. The sharing of this information would also avoid repeated and therefore unnecessary conversations.

- **The length of the process is not unduly extended:** there is a risk that by opening up more channels of communication the efficiency of the process could be affected through there was excessive and unnecessary use. However, if the initiative for these kinds of direct conversations is placed in the hand of risk assessors, this could be minimised. Moreover, it is in the interest of all parties to have an efficient process, and the purpose of opening these channels is indeed to avoid the more cumbersome and timely process that is currently in place.

5.2.2 Improved communication and coordination between Member States and between EFSA and Member States

Increasing communication and coordination among Member States authorities and between Member States and EFSA is a means of building those authorities' confidence in the risk assessment process. The consultations conducted for this project suggest that many Member States believe the three month window for consultation specified in the legislation is insufficient. Many were also unhappy with EFSA's response to their comments. These issues in part reflect different expectations of specification of the risk assessment process, and general views on GM techniques.

Issues and options are discussed to enhance engagement communication and coordination within the following aspects of the appraisal process:

- The participation of Member States in the ERA appraisal;
- The handling of requests for additional information;
- Consultation on the dossier and its appraisal; and,
- The management of Member States' comments.

Widening Member State participation in the environmental risk assessment appraisal

The issue

There is broad acceptance that it would be helpful to widen participation in the risk assessment process and to bring greater expertise to bear on the appraisal of environmental risk assessments conducted by Member State authorities and EFSA.

Relatively few Member States (eight in total) have been involved in appraisal of risk assessments. 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 and environmental NGOs believed the consideration of regional variability in EFSA opinions, and the subsequent conditions of consent, have been inadequate.

Options

- **Provide financial support to Member State authorities that participate in the ERA appraisal**

  At present Member States that volunteer to carry out the ERA appraisal must fund this work from their own internal resources. In consultation several Member State authorities noted that they would like to use the opportunity to conduct an appraisal of the environmental risk assessment under the Regulation, but cited the lack of necessary resources as the greatest obstacle to them doing so (although in principle, under the Directive, they should all have the capacity to carry out or review an ERA).

Options for mobilising resources to support such a change are discussed further on in this section.

- **Allow several Member States to cooperate in the ERA appraisal**

  This could be done either by the Competent Authority of one Member State having primary responsibility for conduct of the environmental risk assessment, whilst being supported by Competent Authorities of a number of other Member States that were likely to see cultivation of the GMO concerned. Alternatively, a couple of Member State authorities could co-lead. Either option would allow Member State authorities without the necessary resources to learn about the appraisal process and be more closely engaged than would be possible if they were only to submit comments during the three month consultation window.

  The criteria[20] used by EFSA to decide which MS authority to nominate creates a "barrier to entry" into the appraisal of GMO applications for Member States in that the criteria themselves are quite demanding, and require, *inter alia*, prior appraisal experience. This option might therefore enable Member State authorities to build up the necessary expertise which might give them the confidence to later volunteer to be the lead MS authority in an appraisal. EFSA does now inform Member States of the possibility of cooperative approaches, and encourages Member State authorities to cooperate on the appraisal of dossiers.

Handling requests for additional information

The issue

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 feedback and coordination with EFSA on additional information requests would be useful and would make the process more efficient.

There are also opportunities to improve some procedural aspects of the system. EFSA has six months within which to conduct the appraisal of an application. But the 'clock' is stopped when additional information is requested (either by EFSA or the Competent Authority of the MS conducting the initial appraisal). It does not restart immediately upon receipt of the additional information – but only after that only information has been assessed and deemed satisfactory.

This distinction matters as for the average cultivation application the greatest amount of time elapses while the additional information is being assessed, rather than in the collating of the additional information by the notifier (as some consultees believed). Notifiers take

[20] The criteria are sent as an Annexe in the letter EFSA sends to Member State authorities inviting them to volunteer for the appraisal of an ERA. They include general experience in GMO risk assessment (including "experience in GMO environmental risk assessment"; "experience in writing national evaluation reports under Directive 2001/18/EC"; "number of years of experience in GMO risk assessment"; and, "professional experience in a multidisciplinary environment"); specific experience of the GMO product in question (e.g. in ERAs specific to these types of products, e.g. herbicide tolerant, insect resistant, crop); and certain skills (e.g. English language skills, capacity, flexibility, availability)

on average 154 days to respond to a request[21]. On average it has taken 274 days for the clock to be restarted once a response was submitted.[22]

Given that the six month deadline is for the appraisal of the whole dossier, the deadline should arguably 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.[23]

Options

- ***Improve coordination of additional information requests between EFSA and the Competent Authority of the nominated MS***

  If MS authorities and EFSA could work together, and coordinate additional information requests better, notifiers would receive fewer sets of requests. In consultation 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, perhaps by exploring past experiences and learning from them, a new improved approach could be adopted. There is therefore an available opportunity here to improve the dialogue between MS authorities and EFSA, build on previous experience, and minimise delays in the RA process.

- **Review the application of timelines to the assessment of additional information**

  A more realistic overall time limit could be set (i.e. longer than six months), allied to a requirement that this should include the appraisal of the additional information, within which an 'assessment' clock would still operate. This would be stopped while a notifier assembles the requested additional information, but would then restart as soon as the information has been submitted, rather than only restarting once the information has been processed and deemed satisfactory. Alternatively a separate timeline could be set that applied exclusively to the appraisal of the additional information. Any changes to timelines should be discussed and agreed upon by EFSA and MS authorities as well as notifiers to ensure their applicability in practice, and that the quality of the comprehensive safety assessment is not compromised. These changes would usefully be considered in conjunction with system resourcing.

[21] Figure calculated on the basis of each request and its subsequent response (not just those that led to the clock restarting).

[22] Figure calculated on the basis of only those requests which then directly led to the clock subsequently restarting, i.e. only the last information submitted before the clock restarts (and therefore not including the different 'rounds' of clarification / additional submission of information). Accordingly the sample size is quite small (6 accounts of the clock restarting on 4 separate applications: maizes 1507xNK603; 59122; MON810 and soybean 40-3-2). The average has been significantly skewed due to one stacked event application (1507xNK603) which alone took 932 days for the clock to restart upon receipt of the additional information that had been requested. The time taken for MS to process information and request the clock to restart has not been included in the calculation, as MS can only request for the clock to restart. However, for completeness - it takes MS authorities an average of 168 days to request that the clock be restarted following the submission of the relevant information (regardless of whether the clock actually restarts or not). Again this number is slightly skewed due to the one application 1507xNK603.

[23] The assessment of some field trial data, especially for feeding trials, can be time consuming, sometimes needing several months of work according to EFSA. This is exacerbated by the fact that EFSA's panels are not directly employed by EFSA, thus there is a limit to the time EFSA can ask them to invest.

Consultation on the dossier and its appraisal

The issue

Member States have a three month window within which they can submit comments to EFSA on the dossier and its appraisal. Many regard this as insufficient. The reasoning behind this is apparent considering the number of requests for additional information and the time taken for these to be processed. 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 tend to follow the first. Consequently, the three month limit does not provide Member States with sufficient time to assess and comment on the additional information that is submitted by the applicant and so Member States have only been able, as of yet, to submit comments on an incomplete dossier.

Options

There are potentially two ways to improve the opportunities for Member States' to submit comments on the dossier and its appraisal:

- **The three month window could be extended**. Given the number of delays, particularly due to additional information requests, there is a case for allowing a longer period for consultation. This need not further extend the duration of the overall process if introduced in conjunction with other system reforms that aim to improve efficiency (as outlined elsewhere in this report). Currently, the average application for cultivation is 36 months (albeit based on a very small sample of two completed applications)[24]. However, this will require changes to the legislative text, which is difficult. Furthermore, an extended time frame would not necessarily ensure that MS authorities would be able to comment on all the additional information that is submitted, as some requests might still be made after the timeline had expired.
- **Member State authorities could comment on a draft of the ERA appraisal conducted by the Competent Authority of a nominated Member State.** This would give Member States opportunities to directly input into the appraisal conducted by the nominated Member State authority, once all the additional information requested by the Competent Authority has been received and assessed. This might reduce further the differences in opportunities for engagement noted by Member States between the Directive and the Regulation – under the Directive Member States had more opportunities to directly communicate with the rapporteur Member State. Over the long term a better understanding and appreciation might also develop about the different approaches between different Member States in their appraisals.
- **Member State authorities could instead comment on a draft Opinion** issued by EFSA before the final Opinion is released. This could, for instance, enable Member State authorities to consider the whole dossier in addition to the draft text of EFSA's Opinion, including any additional information that was submitted in response to any previous requests. This process is already established to allow the public to comment on Opinions which are issued for some of the other Panels under EFSA's jurisdiction. The legal basis for such a change in the context of GMOs would need to be explored. Though this approach might reduce the number of Member State comments at later stages of the authorisation process, and thus the delays involved in dossiers being sent back to EFSA for reconsideration, a potential disadvantage of this option is the

[24] NK603 and MON810 (renewal)

delay to the publication of a final EFSA Opinion. Examination of MSs' comments and consultation with them would inevitably take some time.

The management of Member States' comments

The issue

Some Member State authorities stated during the consultations that their comments are not properly dealt with. The risk is that inadequacies in the 'upstream' consultation process result in Member States raising comments and concerns further on in the approval process line, after EFSA has issued its final Opinion. This can either result in the European Commission asking EFSA to do a reassessment (as was the case for the Amflora potato, and 1507 and Bt11 maize[25]) or it could further contribute to problems in achieving a qualified majority at the subsequent vote in the Standing Committee or Council.

Furthermore, some Member State authorities noted that they have submitted the same comments on several applications because their concerns were not sufficiently addressed the first time. Resolution of Member States' concerns early on could lead to fewer comments on future applications, and fewer delays during the authorisation process.

Options

- **More detailed response to comments made by MS authorities.** EFSA has already made considerable improvements to the way in which it addresses the comments made by MS authorities. Alongside the final Opinion, EFSA now publishes a table of each comment made by MS authorities, along with the way in which these comment has been addressed. Thus EFSA notes whether the comment relates to issues outside its remit, whether the comment led to or related to requests for additional information, what the relevant recommendation was in the final Opinion.

  Some MS authorities would still like to see more detailed consideration of the comments that they raise. Given the need to improve the efficiency of, and build confidence in, the risk assessment process, the benefits of ensuring that as many concerns are resolved early on should make the additional effort worthwhile.

- **More use of bilateral meetings between MS authorities and EFSA.** More bilateral meetings could be held to discuss issues that have not been resolved through the comment and response mechanism, especially where issues are persistent and are seen as critical by the relevant MS authority. So far, a few bilateral meetings to discuss substantive scientific divergences have been held under Article 30 of Regulation 178/2002 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.

  If these shortcomings were addressed, bilateral meetings held under Article 30 of Regulation 178/2002 could offer significant opportunities for discussing technical and scientific differences in opinion. Where it is not possible to reach a consensus, such meetings do at least provide a means to share these differences in a transparent way by recording any scientific divergences in the form of a subsequent report. To date the differences have not been thought 'substantive' enough to qualify under Article

[25] In 2008 the Commission deferred a decision on the Amflora potato until EFSA re-examined the safety of the marker gene (*nptII*) used in the potato. In the same year, the Commission also deferred a decision on maize 1507 and Bt11 and urged further review by EFSA of the scientific studies related to the impact on the environment of the cultivation of these two products

30(3) and Article 30(4) as needing further action such as this, which was surprising to some consultees. It would be useful if EFSA and MS authorities were to be more ready to use the provisions under Articles 30(3) and 30(4), in order to make any unresolved differences (however substantive) clear. If these divergences are clearly stated and acknowledged the potential benefits include improved transparency, increased awareness of possible differences and therefore, potentially, increased confidence in the process. Any documents produced could be included as Annexes to the relevant Opinions of EFSA.

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

Where differences are persistent and pervasive, bilateral meetings might not be sufficient. In this case, more substantial and systematic action might be needed to increase consistency, which would need to involve several MS simultaneously (see section 5.5).

5.3 Other points of procedure, process and capacity

Some points of procedure that can be improved (and potential options for doing so) have already been discussed:

- The consultation window within which Member States can submit comments;
- The direct channels of communication with notifiers;
- The current handling of additional information requests.

The issues that remain to be discussed here are:

- Differences among Member States, and between some Member States and EFSA, on the scope and specification of the risk assessment process;
- The process by which stacked events are assessed; and
- The sequential assessment of the ERA by a MS and then by EFSA.

Differences among Member States, and between some Member States and EFSA, on the scope and specification of the risk assessment process

The issue

There are differences among Member States in the scope, approaches, methods and interpretation of the risk assessment of GM crops, occasionally resulting in expectations not being met. Furthermore, Member States institutions, by virtue of acting as both risk managers and risk assessors, can have concerns which are not necessarily covered by EFSA's remit (EFSA only being a risk assessor and not a risk manager) but which they expect to see addressed by the EU approval process.

For example, monitoring is the topic most commonly raised in comments made by Member State authorities to EFSA during the appraisal process. MS authorities often request more detail than is presented in the monitoring plans that are submitted with products whose scope includes cultivation. In the case of NK603 for example[26], Italy commented that, "*the monitoring plan presented by the notifier is not adequate and scarcely detailed....The data supplied by the notifier refers to specific pedoclimatic environment that may not correspond to those in the Member States; hence, the studies should be contextualized to the receiving*

[26] http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO&questiontype=2

environment". EFSA's response to these requests is based on its understanding of its mandate to focus on risk assessment. It highlights that guidance on PMEM plans states that "*details of the specific plans and methods of monitoring in each country should not be included in the original application... detailed local arrangements will be developed by the applicant after the application has been accepted*[27].

Options:

- **Future guidelines should be developed with the extensive involvement of risk managers and experts from Member States.** EFSA already works closely with many other partners and networks, including risk managers, national food safety authorities, international organisations, third countries, stakeholder organisations and research institutes. Nonetheless, more extensive involvement specifically with the experts of Member States, and the relevant authorities during the development of new guidance documents would potentially be useful. By way of example, a few MS authorities noted that they would have preferred to see a draft of the recently published updated guidance document for the risk assessment of GM plants and derived food and feed sooner, and that a clearer timetable for their involvement would have been useful.
- **Future guidelines on risk assessment should be formally approved by the Commission after consultation with the Member States (Comitology procedure), providing collective agreement** on the scope and specification of the process. Currently, detailed guidelines on the risk assessment process are developed in a process led by EFSA. Although the input from MS authorities is sought, the guidance documents are never formally approved by the Commission. This option is already being pursued in the case of EFSA's 2008 updated guidance document for the risk assessment of GM plants, and derived food and feed. Once adopted by EFSA, the updated guidance was presented to the European Commission and Member States and has been used by the Commission to draft a Commission Regulation, on implementing rules concerning applications for authorisation of GM food and feed.[28]. Those guidelines would complement the existing ones outlined in Annex II of the Directive and in Decision 2002/623/EC.

  This option would most successfully be implemented in conjunction with the option detailed above, given that this option only seeks the official approval of risk managers once the guidance document has already been formally adopted by EFSA. Having extensive and clearly defined input from MS authorities and associated experts earlier on in the process would make this latter option much more effective. This option is also indicated in the mandate that the Commission sent to EFSA on 19 March 2008 for the guidelines on environmental risk assessment, mentioning the objective to assign regulatory status to the guidance document.

[27] Section 5.2 of EFSA's Opinion on PMEM: "Details of the specific plans and methods of monitoring in each country should not be included in the original application. The GMO Panel advises that the application should describe the general approaches and methods that the applicant would apply in different commercialisation sites, including the type of dialogue that would be established with risk managers in each Member State. Thus detailed local arrangements will be developed by the applicant after the application has been accepted (…)." Available from: http://www.efsa.europa.eu/en/scdocs/doc/gmo_summary_op_ej319_pmem_en1,0.pdf

[28] http://www.efsa.europa.eu/en/gmotopics/topic/gmo.htm

The process by which stacked events are assessed

The issue

In the EU, stacked events[29] 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[30]. 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, or a reference where the information can be found in single event applications".. **[**

Currently 13 applications for cultivation are being reviewed by EFSA. Over 50% of these applications in the pipeline - 7 of the 13 - are stacked events. All were submitted before the appraisal for the relevant single events were complete. 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.

Options

- **The appraisals could be done in parallel (as far as possible).** The evaluation of the stacked event could be done in parallel with that of the single. However, this presents some logistical difficulties 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. Coordination would be challenging if single and stacked events were to be run in parallel. Currently EFSA is responsible for circulating the relevant information between the relevant Member State authorities. Further difficulties arise if additional information is requested on the single event, information then needs to be extended to other stacked event applications. Nonetheless, 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 (such as the period during which the content, layout and structure of the dossier is checked and during requests for clarification are made on in order to for the dossier to be validated before the actual content is processed).
- **Ensure, as far as possible, that the Competent Authority from the same Member State appraises the single and stacked events.** The stacked event procedure is a simplified assessment which considers the potential interactions between single events. If a MS authority was familiar with one of the single events as a result of having conducted its appraisal, having that same MS appraise the stacked event might increase the efficiency of the process. However, a potential objection is that this option would place too great a burden on a single MS. Given the increasing trend towards stacked events, a few MSs might become 'locked in' to appraising a stream of applications. Since MSs have different approaches, any measure which limits the number of MSs conducting the appraisal risks reproducing any perceived 'limitations' in their approach. Increasing the number of MSs conducting these appraisals may also identify new issues. A balance will need to be sought between

[29] 'Stacked events' refers to the presence of more than one GM 'event' within a single product.

[30] The legislation is silent on the interpretation of the status of stacked events but the Commission has considered that a product with stacked events is a 'new' GMO and thus subject to its own approval procedure.

gains in efficiency, strains on the resources of a particular MS, and achieving a balance of views.

Where it is not possible for the Member State that appraised the single events to also appraise the stacked event, a cooperative, collaborative approach could be encouraged between the relevant Member State authorities (i.e. the one(s) which assessed the single events, and the authority which then assesses the stacked event), along the lines of the option laid down in Section 5.2.2.

Sequential appraisal of the applications by Member States and then EFSA

The issue

Under Directive 2001/18/EC, 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 risk assessment to be appraised only once by the Competent Authority of a MS.

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

- 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 safety[31], and the molecular characterisation[32].

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.

Options

- **A more collaborative, parallel process could be adopted.** Significant gains might be made by synchronising and improving the levels of collaboration in the current process (whereby the initial appraisal of the ERA by the Competent Authority of a nominated Member State is followed by a comprehensive appraisal of the entire risk assessment). Allowing the risk assessment by EFSA and the Competent Authority of the nominated Member State to be conducted in parallel could be more efficient than the current sequential process operated under the Regulation. For instance, as mentioned above, there could be greater coordination with EFSA, especially on the requests which are sent to notifiers for additional information. For this option to work there would need to be a good quality dialogue between EFSA and the Competent Authority of the nominated MS. Under this system, one MS authority would still conduct an appraisal of the ERA, working closely and collaboratively with EFSA. EFSA would still be in charge of the entire risk assessment appraisal, including the ERA. Essentially, EFSA and a MS authority would work together to complete an appraisal of the ERA, whilst EFSA would still be solely responsible for the other parts

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

[32] The molecular characterisation of the GM product takes account of the characteristics of the donor and recipient organism

of the risk assessment (namely the food and feed safety[33], and molecular characterisation[34]).

Many MS authorities were open to this suggestion, as long as EFSA constructively engaged, rather than 'interfered', with MS authorities. In order to ensure that dialogue is constructive and leads to collaborative outcomes, it would perhaps be useful to clarify the different remits of MS authorities (who act both as risk managers and risk assessors) and EFSA (who acts solely as a risk assessor) in order to manage expectations (see section 5.3).

- **EFSA is made responsible for the whole appraisal.** EFSA could be entirely responsible for the appraisal of the entire risk assessment, including the ERA. Consequently, 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. All Member State Competent Authorities would continue to support EFSA during the appraisal of the ERA, and comment on the dossier as previously.

  This option might require some form of obligation (instead of MS authorities just volunteering) for MS authorities to support EFSA. Additionally, this option would be highly dependent on a good close working relationship with relevant MS authorities to ensure the knowledge base on which the appraisal is based is as wide as possible. This option has the benefit of centralising the process further. This would make improving system resourcing much simpler as efforts could be concentrated on increasing the resources available to EFSA.

5.4 Resourcing

The issue

The financial resources applied to the operation of the GMO legislative framework do not follow the activities within it. Applications for GMO cultivation are managed by EFSA and Member States with resources funded by their respective institutional budgets. Institutions handle applications and specific mandates without receiving funding to cover the marginal cost of their administration.

There is some evidence that the financial environment shapes the way in which the system is operating. For example:

- Resource constraints have been cited as a barrier to participation by some Member States in the environmental risk assessment appraisal;
- There is some evidence of delays in the processing of applications as a consequence of the necessary prioritisation of activities when workload exceeds that which can be delivered within the fixed resources available.

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);

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

[34] The molecular characterisation of the GM product takes account of the characteristics of the donor and recipient organism

- 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 resourcing/capacity issues were impacting negatively on the system's efficiency. This extensive workload mentioned above falls upon the GMO Unit and its Panel of experts. The initial appraisal of the ERA in the case of applications whose scope includes cultivation is the responsibility of the Competent Authority of the nominated MS. Member State authorities who volunteer to conduct the appraisal are not given any compensation for doing so. Furthermore, additional tasks outside of the usual assessment of dossiers resulting from, for instance, mandates from the Commission are not accompanied by additional funding to EFSA.

Concerns about the resourcing of EFSA also partly related to the breadth of expertise, particularly on environmental issues, and partly to fit between resourcing of the GMO Panel and its workload. The core GMO Panel that assesses dossiers for cultivation 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. The Panel receives secretarial support from EFSA staff.

EFSA is making inroads to address these issues, and has significantly increased the capacity of its GMO Unit which provides secretarial and administrative support. As part of this effort, many of these additional staff members have significant scientific expertise which should alleviate some of the burden resting on the GMO Panel.

Several of the means to improve the efficiency of the system critically depend on the availability of the necessary resources. The processing of additional information requests, for instance, absorbs a large share of the time taken to appraise a dossier. The main reason given for why the assessment of this additional information is not subject to the six month deadline was the lack of resources – sometimes extensive information is submitted which could not reasonably be assessed within the time allowed unless the clock remains stopped. Increasing resources therefore would enable this bottle-neck to be addressed.

With improved resourcing, communication with notifiers could also be improved and increased, which might lead to better quality dossiers if notifiers could anticipate and more clearly understand what is needed from them on a case-by-case basis. At the moment there is little direct communication, most of which is limited to administrative aspects rather than scientific content. This could minimise the need to actually request additional information, which would mean less information would actually need to be processed later on in the assessment stage.

As mentioned above in section 1, better resourcing would also be needed to improve communication with Member State authorities, which might avoid later delays if their concerns could be appropriately addressed from the outset. This would likely require bilateral meetings. Currently, the potential to make best use of these is curtailed partly due to the strain they put on the limited resources. Improved resourcing might therefore allow more attention to be directed towards persistent concerns. Critically, if these outstanding issues were to be better addressed, confidence in the risk assessment process might be increased.

Moreover, the 'dysfunction' in the system as it is currently operating increases the workload on the Panel by increasing the number of times a given GMO has to be considered, as a result of:

- Requests for EFSA to re-assess information relevant to past Opinion on individual cultivation applications, e.g. in the light of new information;
- Requests to examine national safeguard measures on GMOs already approved for cultivation.

The proposals elsewhere in this section could help to reduce that additional workload. Changes to the current financial arrangements should also be considered in order to help:

- Broaden Member States' participation in the process, with potential 'downstream' benefits in terms of the number of comments at consultation and after the EFSA Opinion has been issued;
- Facilitate a better match of skills and capacity to demand;
- Accelerate the application process.

Options

- **An application fee for cultivation applications could be introduced.** Perhaps the simplest way of increasing available resources would be to charge applicants a fee for submitting an application. This was already the case under the Directive in most Member States. There is some variability in the way that MSs chose to charge notifiers for the assessment. Some MSs charged a set fee which did not change, others charged a fee for each stage of the assessment, whilst a few charged a fee depending on the size of the dossier, and effort required. Under those systems a notifier could be charged up to €150,000 in exceptional circumstances.

  It has been estimated that, accounting for time and cash costs, it costs between €200-400 million to bring a new genetic trait to market[35]. Of those, the regulatory costs of obtaining market approval in the EU for a GM plant with one trait have been estimated to amount to €6.8 million[36]. Set alongside these costs of bringing a product to market, and opportunity cost of the time taken for authorisation processes to complete under current arrangements (in sales foregone during the years the applications are held within the system), it seems unlikely a reasonable application fee would discourage applications if, in return, it helped to make the process more predictable and robust.

  Greater resourcing would provide EFSA with greater freedom to respond to the pressure it is under to increase the bank of environmental skills that it has access to. For instance, improved resourcing might make it more feasible to collaborate with EU-wide environmental organisations such as European Environment Agency (EEA) or the European Centre for Nature Conservation (ECNC), which would also increase the environmental expertise on which the appraisals are based, especially with regard to making recommendations on appropriate risk management strategies where risks are identified.

- **Financial contribution for MS authorities conducting the ERA appraisal.** Offering a financial contribution towards the cost of conducting the environmental risk assessment appraisal would address one of the key barriers to more MS authorities volunteering[37]. This option could be combined with the application fee approach described above, where a portion of the fee charged to the notifier is allocated to the Competent Authority of the nominated MS.

[35] http://www.minlnv.nl/portal/page?_pageid=116,1640360&_dad=portal&_schema=PORTAL&p_file_id=47648
[36] http://www.cogem.net/ContentFiles/CGM%202008-05%20Dossierkosten%20markttoelating%20gg-gewas%20VS%20en%20EU5.pdf
[37] Under Article 36(2) of the General Food Law (Regulation (EC)178/2002) for instance, competent organisations designated by the Member States which assist EFSA are "eligible for financial support".

- **Specific mandates given to EFSA could be accompanied by a financial contribution towards the cost of that work.** Given the number of tasks EFSA's GMO Panel is responsible for, these is a case for additional funding to be provided when outputs are required of the Panel beyond its core tasks. For instance, the authority which requests the additional work could offer EFSA some compensation. In the case of mandates from the Commission, such as the request to further review scientific studies related to the impact on the environment of the cultivation of 1507 and Bt11 maize, the Commission might consider offering additional funding commensurate with the effort required to process these additional requests Such an arrangement would change the nature of the financial relationship between the Commission and EFSA and would require some further discussion. Similarly, in the case of MSs who chose to implement a national safeguard measure, they might be required to pay a fee to EFSA for assessing the scientific evidence submitted by the Member State authorities in support of a national safeguard measure. One potential disadvantage is that in the case of national safeguard measures, MS authorities might see this financial contribution as an indirect 'fine' on the adoption of such a measure. Nonetheless, if such a financial contribution was introduced across the entire spectrum of additional mandates given to EFSA, and depending on the required size of the contribution, MS might be willing to agree to such a measure, especially if it meant the rest of the process would improve as a result.
- **Explore options and incentives to increase collaboration with external scientific officers.** Currently, the GMO Panel's work depends on external experts have full time jobs elsewhere (like most members on other Panels), whilst the few who do not are mostly retired. Furthermore, the experts are based outside of Parma (where EFSA's offices are located), who therefore have to make lengthy trips on a regular basis to attend the relevant meetings. Some comments were received about the modest level of fees offered to experts[38]. All these factors contribute to a protracted process, and create disincentives for experts to participate. In order to counteract these, incentives should be explored. For instance, experts could be seconded from their faculties to work on the Panel, with the relevant organisation being paid for their time[39]. Some use is now being made of technologies such as video conferencing and live-share documents to facilitate processes - such innovations should be fully exploited.

5.5 Improving the consistency of dossiers submitted by notifiers and the way in which MSs appraise the ERA

The issue

Evidence from the consultation and the literature[40] indicates that there is variability in the outcomes of appraisals conducted by MSs of the ERA and the quality of the dossier

[38] An increase is expected from July 2010 onwards.

[39] Such an option would need to ensure that the independence of advisors was maintained.

[40] See for instance Dolezel, M.; Miklau, M.; Eckerstorfer, M., Hilbeck, A.; Heissenberger, A.; Gaugitsch, H. (2009). Standardising the environmental risk assessment of genetically modified plants in the EU. BfN-Skripten 259. Available from: http://www.bfn.de/fileadmin/MDB/documents/service/Skript259.pdf;
Levidow, L., Carr, S., Wield, D. (2005) 'EU regulation of agri-biotechnology: precautionary links between science, expertise and policy', *Science & Public Policy* 32(4): 261-76;
Millstone, E., van Zwanenberg, P, Levidow, L., Spök, A., Hirakawa, H. (2008). Risk Assessment Policy – Differences between jurisdictions. JRC Scientific and Technical Reports 23259 EN, Seville: IPTS. Available from: http://ftp.jrc.es/JRC37719.pdf;
Spök A, Hofer H, Lehner P, Valenta R, Stirn S, Gaugitsch H (2004): Risk Assessment of GMO Products in the European Union. Toxicity assessment, allergenicity assessment and substantial equivalence in practice and proposals for improvement and standardisation. Series of the Federal Ministry of Health and Women Vol. 7-04. Vienna: BMGF. Available from:
http://www.bmgf.gv.at/cms/site/attachments/6/8/7/CH0255/CMS1090828056047/risk_assessment_of_gmo_products-bmgf-layout.pdf

submitted by notifiers. According to the responses received, the treatment of the following areas differed significantly among applicants:

- 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 application of the principle of comparative analysis, 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.

Differences in Member States' appraisals of the ERA 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).

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, potentially affects the voting behaviour of MS authorities and impedes the ability of MS authorities to reach a qualified majority. All MS authorities either wanted full harmonisation, or at the very least more harmonisation of risk assessment practices, than is currently the case[41]. Investing in these efforts to build a consensus on the way appraisals of the ERA should be conducted by MS and EFSA is arguably a necessary (albeit not necessarily a sufficient) condition for breaking the deadlock in the decision-making phase of the process (discussed in Section 7). By addressing some of the technical and scientific differences in approach which concern some of the MS authorities, (especially with respect to post-market environmental monitoring, effects on non-target organisms, and toxicology), the difficulties encountered further downstream in the process will likely be reduced.

In order for them to be sustainable, two general operating principles should be considered in all efforts to harmonise risk assessment practices:

- Experts from MSs should be involved extensively in the process of harmonisation in order to best accommodate and take into account the differences in views;
- Outputs resulting from any of the below options (e.g. guidelines) should be officially endorsed by Member States' risk managers (i.e. through a vote of Member States).

[41] During 2010 EFSA will launch risk assessment networks between EFSA and MS authorities in several areas, including GMOs. One of the objectives is to stimulate the 'harmonisation of risk assessment practices'.

Options

Clear and comprehensive guidance should positively impact on the quality of dossiers. 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. Improving and expanding the guidance is therefore a key means for addressing many of the administrative and scientific shortcomings which consultees identified in the risk assessment.

EFSA originally adopted its guidance on the risk assessment of GMOs in 2004. This was subsequently updated in 2006 and then again updated in 2008 for food and feed applications. In March 2008, EFSA received a mandate from the Commission to further develop and update its guidelines on the ERA of GMOs. The delivery of this work by EFSA is still pending, and expected later in 2010.

EFSA should continue to update its guidance on the risk assessment of GMOs as needs arise. 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.

Specific options identified in this area are:

- **EFSA could work with MSs to ensure there is sufficient clarity on how they should appraisal the ERA.** Some of the Member States consulted suggested that a document which is tailored towards MSs and their appraisal of the ERA would be helpful, especially given that EFSA is taking a more pro-active approach, with some success, to widening participation amongst Member States (some whom might not have much prior experience with appraising risk assessments). EFSA's guidance document on the risk assessment of GMOs is intended to aid the conduct of the risk assessment itself (i.e. what should or should not be included in the dossier). While helpful, this does not directly address the concerns raised by Member States in the consultation for this evaluation, namely on how to best appraise the dossier (and specifically the environmental risk assessment contained therein) once it has been submitted. The EFSA-MS risk assessment network, being launched later in 2010, could be used to clarify such issues.
- **EFSA's Working Group on Scientific Cooperation (ESCO) could support EFSA with harmonising the scientific aspects of appraisal of the ERA by MSs.** ESCO has produced a report on the harmonisation of RA approaches[42] but this focused exclusively on identifying discrepancies in procedural, rather than scientific, aspects. It also did not cover the risk assessment of GMOs, as an earlier report, based on a similar questionnaire, had already been completed on procedural differences in the risk assessment of GMOs in 2007[43] . EFSA could task ESCO to extend its work to the scientific aspects of the risk assessment of GMOs to provide a more complete picture of the discrepancies in the ways MSs appraise the ERA. By doing so, ESCO would support EFSA in developing the risk assessment methodologies.
- **Improved communication with notifiers.** Given the auxiliary risks associated with updating EFSA's guidance, alternatives means of bringing the quality of dossiers in line with the expectations of assessors could be considered. Greater communication between notifiers and assessors could potentially improve the quality of the dossiers, as notifiers would understand better what is expected of them and could plan ahead rather than having to retroactively address concerns that are raised. More dialogue, if

42 http://www.efsa.europa.eu/en/esco/escoharmonised.htm

43 http://www.efsa.europa.eu/efsa/efsa_locale-1178620753812_1178656904823.htm

it reduced the scope for ambiguities and misunderstandings, could also increase the efficiency of the appraisal if concerns were clarified or resolved directly. 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). More activity of this kind would have resource implications for EFSA.

- **Strengthen coordination to deal with the interplay of plant protection products ("PPP") legislation (Regulation 1107/2009 replacing Directive 91/414/EC) and GMO legislation (Directive 2001/18/EC and Regulation 1829/2003).** One of the key areas of inconsistency noted during the consultation was the interplay between the PPP and GMO legislation, and the resulting various ways in which risk assessors appraise herbicide tolerant plants.

  Currently, "a herbicide used on a GMHT crop is assessed differently from the same herbicide on non-GMHT crops (e.g. imidazolinone- and atrazine-tolerant crops) and conventional crops"[44]. This creates a level of confusion and introduces uncertainties into the risk assessment of GMHT plants[45].

  Accordingly, the Environment Council concluded in December 2008 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 (now Regulation 1107/2009). 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, due to the numerous agricultural practices varying from a region to region, and even from field to field[46]. 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 has been no agreement to date on a common approach in order to address these differences in the risk assessment of GMHT plants. Consequently there are currently considerable inconsistencies in the way MSs have dealt with applications for GMHT plants, especially with regard to the indirect environmental impact of the herbicides used.

  Better coordination therefore is needed between the relevant bodies under PPP and GMO legislation. 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. Furthermore, decisions taken under PPP legislation should take into consideration, and be interlinked with, those decisions made under Directive 2001/18/EC.

  Improved coordination on this aspect should extend 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. More coordination is also needed between Member States which appraise environmental risk assessments GMHT plants, which should improve the

[44] The Environmental Risk Assessment of genetically modified herbicide tolerant plants and the interplay between Directive 2001/18/EC and Directive 91/414/EEC. Working Document from the EFSA GMO Panel. Available from: http://www.efsa.europa.eu/EFSA/DocumentSet/gmo_working_document_en.pdf?ssbinary=true

[45] For further details see Section 4.4.2 of the Interim Report

[46] The Environmental Risk Assessment of genetically modified herbicide tolerant plants and the interplay between Directive 2001/18/EC and Directive 91/414/EEC. Working Document from the EFSA GMO Panel. Available from: http://www.efsa.europa.eu/EFSA/DocumentSet/gmo_working_document_en.pdf?ssbinary=true

inconsistency currently evident in the various approaches. Progress is already being made in this area, with the Commission addressing this issue in its regular meetings with the Competent Authorities of the Member States.

6 FIELD TRIALS

6.1 Introduction

The evaluation was asked to consider the extent to which Part B provisions of the legislative framework (governing GMO field trials) 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.

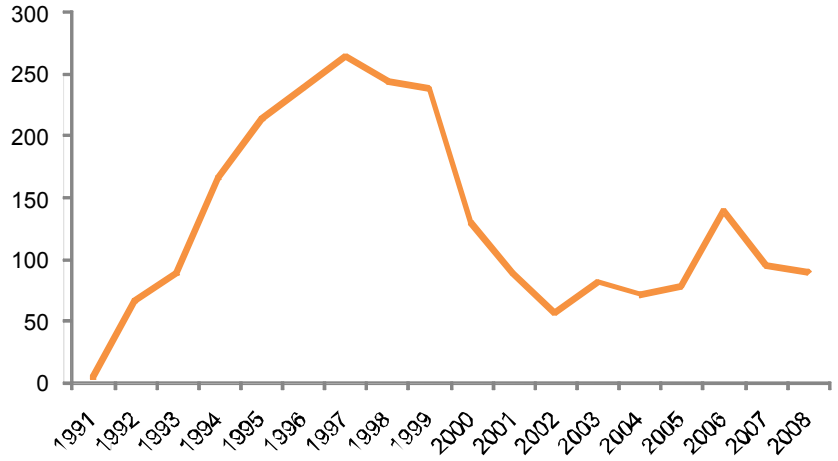
A report was recently prepared for the DG Environment of the European Commission on the management of field trials[47]. Many issues raised by consultees on field trials during this consultation reflected similar issues to those found in that report, especially regarding difficulties in obtaining approval, and field trial destruction. In the interest of limiting overlap, this consultation attempted to build on the results of the previous report, especially with regard to the links between field trials and cultivation. The report made several recommendations for the management of field trials, as well as the suggesting ways to improve the implementation and authorisation procedures. Consequently, the options laid out here, and those detailed in the earlier report complement, and should be considered alongside, one another.

6.2 The issues

Since 2006 the number of notifications for field trials in Europe has declined[48] . 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. In consultations the industry raised field trial destruction as a consistent and increasing concern.

Figure 6.1 After a steep decline after 1998, the number of field trial notifications increased after 2002, peaked in 2006, and has since declined again

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

[47] 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

[48] See Section 5.1 of the Interim Report, specifically Figures 5.1 and 5.2. Also http://www.gmo-compass.org/eng/agri_biotechnology/field_trials/228.summary_gmo_field_trials_eu_year_crop_trait.html

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; and
- A lack of authorisations for cultivation can also reduce the incentive to invest in research, and thus the demand for further field trials.

There was broad 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. 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, although most did not agree that the situation with field trials was affecting applications for cultivation.

There was a degree of scepticism among Member States that field trials were providing evidence that was robust enough to support applications for cultivation. Half of the Member State authorities who responded noted that field trial evidence was only sometimes sufficient to support applications for cultivation, whilst several more believed the field trial evidence was either rarely or never adequate. The majority of 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 to support applications for commercialisation. Any requirements or guidelines should be careful not to adversely affect or place any additional burdens on research conducted for non-commercial purposes.

6.3 The options

The political context for GMO cultivation in Europe, and its expression in the specification and operation of the legislative framework for GMO cultivation is the largest single factor affecting the flow of field trial applications. These 'demand side' issues are addressed elsewhere in this report.

There are certain actions that could be taken to address issues on the supply side. These potential remedies mostly lie outside the direct legislative framework for GMOs and are, strictly, thus beyond the scope of the evaluation. However the options that emerged from analysis and consultations are reported here for completeness.

These are:

- To facilitate more information on the effects of cultivation of GMOs through:
  - Encouraging more independent research, particularly on GMOs' environmental impacts;
  - Efforts to avoid field trial destruction.
- To reduce the scope for evidence presented in dossiers to be rejected as inadequate or inconsistent by promoting the development of guidelines on the design and delivery of field trials that are conducted to produce evidence for cultivation applications in the EU; and
- To gather better data on trends in EU field trial activity.

6.3.1 Facilitate research

The need for more research on GMOs, especially on the environmental impacts of GMO plants in an EU context, was a key point raised by several groups consulted for this study.

Notifiers in turn highlighted that when such research is conducted, it should not be unduly obstructed. Several consultees specifically called for more public research from 'independent'[49] institutes and institutional support to complement private sector efforts. A potential obstacle to this, however, is access to the relevant research material (i.e. of the GMO in question), which generally would require the cooperation of the relevant private sector company or companies.

Biotechnology companies highlighted two difficulties that they had in increasing access to the relevant research material of the GMO:

- A concern to avoid compromising commercial confidentiality in respect of intellectual property;
- Concerns about potential liabilities. Some notifiers noted that in the past, some third party organisations had not properly followed risk management measures, for which the notifiers themselves were liable.

The extent to which intellectual property rights are a constraint to research on GMOs deserves further examination. Different types of research (e.g. research on the technology or the product; research on the environmental or health effects) have different needs in terms of the types of genetic material required. Some might only require the relevant seed material (which, if the product is commercialised, can be purchased); however, other types of research might also require access to the isogenic comparator which constitutes the reference material, for which special access is likely to be needed.

It is possible that these difficulties could be tackled with appropriate contracts. Some research is already being done by the large biotechnology companies in cooperation with independent institutes. For instance, every field trial in the Czech Republic is conducted in association with other institutes. However, even in this case these institutes would be subject to contractual obligations of the relevant companies with whom the research is being conducted.

Member States can also influence research through the conditions of consent attached to GMO field trials. Evidence shows that notifiers submit far more notifications for agronomic purposes than for any other reason. Hungary is in the process of using conditions of consent to encourage more research on the environmental impacts of GMO plants. It is 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 in order to increase the availability of data on the direct and indirect effects of GM plants on the environment.

6.3.2 Enhancing protection of field trials

Rates of field trial destruction appear to vary widely across the EU. Notifiers have variously responded by reducing field trial investments and/or increasing security provided. Member States have the option to take a more robust approach to the protection of field trials through public communication strategies, cooperation with field trial promoters on security and appropriate application of the law. EU interest in such actions might be founded on the established freedom to conduct scientific research (Article 13 of the European Charter of Fundamental Rights)[50].

[49] In this case 'independent' is taken to mean that the research conducted and its results are free from any undue influence from any vested interests of the industry.

[50] http://www.europarl.europa.eu/charter/pdf/text_en.pdf

The management of information about field trial locations, and the release of that information as a trigger for field trial destruction, is the matter of some debate. In consultations some Member States and notifiers stated that the ease of access and level of detail of the information about field trials released could influence rates of vandalism. Member States have had considerable flexibility to determine the level of detail on field trials to release, and how to do so. This resulted in significant variability among MSs in terms of what kind of information was made publically available.

However, a ruling by the European Court of Justice[51] has determined that 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 relevant Member State. Furthermore, 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. The ECJ ruling has meant that Member States' flexibility to determine what level of detail should be released on the location of field trials has been reduced.

Viewpoints varied between consultees on what could and should be done to address the issue, and where the responsibility for doing so lies[52]. The underlying issue is the need to balance transparency with the freedom for approved research to be conducted without interference. It is likely that solutions will need to be tailored to the conditions of each Member State. Further progress on risk communication is likely to assist if it improves engagement and communication with the public on issues of GMO-related risk (see Section 8).

6.3.3 Improving the consistency of research conducted for regulatory purposes

Evidence from field trials is a very important component of GMO cultivation applications and thus ensuring that they these are of good quality and consistent is critical. The majority of MS authorities consulted for this evaluation complained of great variability in the quality and quantity of evidence submitted by notifiers to support applications for cultivation. In particular they highlighted what they saw as inconsistencies and a general lack of information on the ecological effects across the bio-geographical regions of the EU.

Addressing these Member State concerns would require further harmonisation of specifications of field trials that are conducted for regulatory purposes with the aim of producing statistically comparable results from different ecological conditions.

Specific areas the consultees identified were:

- confinement methods used;
- experimental design;
- statistical analysis;
- surveillance methods;
- reporting format and methodology for the results;
- problem formulation; and
- the environments that should be studied.

Field trials are already meant to be designed according to recommendations from European level scientific bodies/authorities (e.g. EFSA), and conducted according to specific

[51] Preliminary ruling in Case C-552/07 on the 17th February, 2009

[52] See section 5.3.1 of the Interim Report

company/institute standard operating procedure, observing good laboratory practices. EFSA has recently published an Opinion on statistical considerations in the safety evaluation of GMOs. This details statistical guidelines and approaches for the analysis of compositional, agronomic and phenotypic data from field trials for the risk assessment of GM plants and derived foods/feeds in order to ensure sufficient statistical power and estimation of natural variability.[53] This may help notifiers to design field trials in such way that they yield better data on GM plant's agronomic relevance and its potential risks in the field.

Specific options for further development, to respond to Member State concerns, are:

- **For an initiative to be launched to promote a more harmonised approach to field trials**, either through voluntary standards or official guidance. These options are discussed below:
    - **Voluntary standards and protocols**: Further harmonisation could be achieved through the development of voluntary best practice principles that brought together already existing operating procedures and other existing guidelines.
    - **Official guidance:** Both EFSA and the European Commission are empowered to develop guidance to aid the implementation of the legislation, but in this instance (given its scientific nature), EFSA is the natural lead. Development of any future guidance on field trials would have to be supported, and should be endorsed collectively by EU risk managers. Experts from Member States, and other interested parties should be involved in the process to account for the various purposes, needs and conditions that characterise research being conducted across the EU.

  There are advantage and disadvantages to either of these options which deserve further consideration. For instance, voluntary standards and protocols are more flexible than official guidelines but could potentially undermine public (and political) trust in the outcomes of the research due to the dependence on industry's self-regulation. Independent oversight might therefore be necessary to increase confidence in their application. A benefit however, is that industry is perhaps better placed to design and implement relevant standards given it has the relevant technical knowledge, experience and capacities. If official guidance were to be developed instead, other issues would need to be considered. For instance, guidelines would need to be targeted to the harmonisation of research conducted in support of applications for commercialisation, in order to avoid adversely affecting or burdening research conducted for non-commercial purposes.
- **In support of that effort, official interpretations should be provided of technical terms in the legislation**. Some of the inconsistencies in the way field trials are being conducted could be due to ambiguity in the legislation's text. For instance, 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 scope for differences in 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.
- **There should be an exchange of views and information** among MS authorities on the way in which field trials are being conducted in their territories in order to establish examples of best practice, as part of any of the above initiatives.

[53] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902768517.htm

6.3.4 Gather better data on EU field trial activity

Robust analysis of the GMO field trials at EU level is hindered by a lack of data on, for instance:

- 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.

Centrally collated information is effectively limited to the number of notifications submitted[54], which is an imprecise guide to the actual level of field trials. More information is required if EU decision makers are to have a clear picture of trends in field trial activity and the extent to which the issues highlighted by notifiers, such as difficulties in obtaining approvals and rates of field trial destruction, are supported by the data.

Member State authorities are, for instance, obliged under Article 11(3) of the Directive to inform the Commission of the final decisions taken on notifications, including reasons for rejecting a notification, but this information has not yet been made available by all Member States. Moreover, Member States are also obliged to submit the results of these releases. The Commission should pursue this issue with Member States and ensure the gathering of data on which field trials are satisfactorily completed, as required by the legislation..

Furthermore, notifiers are required to submit a report on the results of field trials once these are concluded, and at any intervals during the release as specified in the conditions of consent. However, only 27% of those notifications currently listed on the GMO register of plant field trials also include a final report[55]. The application in practice of reporting requirements of notifiers and Member States should therefore be explored as existing means to gather better data on field trial activity.

Options

- **Gather information on field trials conducted for non-commercial purposes by institutes and organisations.** This evaluation and the recent report prepared for the DG Environment on the management of field trials[56] both focused on the activity of the major notifiers. Little is known about the extent and type of research that is conducted by organisations that are not involved in applying for GMOs to be placed on the market. For the Commission to have a complete picture, it would be helpful to explore whether the concerns and difficulties encountered by the major notifiers are echoed in the experience of these institutes and organisations, who may face different obstacles and offer different opportunities[57].

[54] http://gmoinfo.jrc.ec.europa.eu/

[55] http://gmoinfo.jrc.ec.europa.eu/. Information up to date as of 22 January 2010. Includes notifications submitted between 19/12/2002 - 19/01/2010, and excludes any which were withdrawn.

[56] 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

[57] A publication is currently under preparation under the FP6 project SCIENCE 4 BIOREG, addressing obstacles public researchers faced over the last couple of years in terms of field trial applications

7 RISK MANAGEMENT

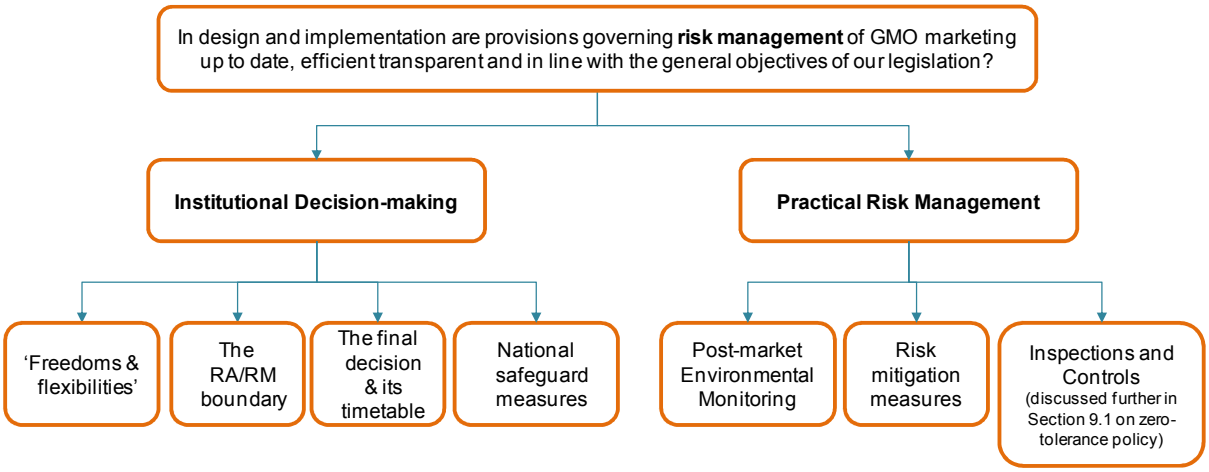
7.1 Introduction

This chapter examines the risk management aspects of the legislative framework. This section of the evaluation covers the issues shown in Figure 7.1, specifically:

- Institutional decision-making, covering the timing, flexibility and the factors taken into account (section 7.2); and
- The management of risks during the deliberate release of GMOs through mitigation measures, including provisions for inspections, controls, monitoring and special protection of eco-systems, environments and geographical areas (section 7.3);

The scope of the discussion here reaches 'up' into the work of EFSA and 'down' into the risk management and monitoring measures applied by Member States.

Figure 7.1 Structure of the evaluation of the risk management aspects of the legislative framework



Source: GHK Consulting Ltd.

Within this framework 'risk management' means different things in different contexts, which can be confusing

During the consultation, we found some confusion around the use of the term 'risk management'. This is because it is used in relation to two different but related concepts – (i) the institutional decision making phase of the process, and (ii) the post-authorisation mitigation and management of the risks associated with cultivation. These two phases, although separate, do overlap in some respects in that the decision making phase includes the consideration of the practical options for managing the risks that have been identified. Decision makers can choose to include general mitigation measures in the conditions of consent, in this case acting as risk managers in both senses of the word. However, distinguishing between the two different aspects of the term is useful. Consequently, this report separates the two aspects of risk management, considering:

- **'institutional decision making'**, which concerns the decisions taken on authorisation made by the Standing Committee, Council or European Commission and the activities associated with those decisions; as distinct from

- **'practical management measures'**, i.e. the specification and implementation of post-approval risk management measures on the basis of the risk assessment when the approved product is cultivated.

The allocation of res**ponsibilities, and particularly** the explicit separation of risk assessment and risk management roles, reflects experience in 1990s with, for instance, the control of bovine spongiform encephalopathy[58]. EU law confers responsibility for authorisation decisions on the Member States and the European Commission. EFSA and notifiers, with the support of Member States, provide the scientific evidence to inform those decisions (the risk assessment).

Member States have responsibility for the implementation of risk management and monitoring measures in association with cultivation of approved GMOs. Experience with such measures is, however, limited because – up until the announcement by the Commission of authorisation for the Amflora potato in March 2010 - no decisions, positive or negative, on cultivation authorisations had been made under the current legislative framework for the deliberate release of GMOs[59]. The potato is the first GMO to be authorised since for cultivation in the EU since MON810 maize in 1998.

Some actors and institutions (e.g. government ministries, scientific advisory committees, inspectorates) are involved in both of the above aspects of risk management. Some are also involved in the upstream risk assessment process. The types of actors and institutions and their roles and responsibility also differ by Member States. There can be a mismatch between the scope of what these organisations are required to consider at a Member State level, and the scope of the assessment conducted at EU level. For instance, France's High Council for Biotechnology must take economic, social and ethical issues into account when assessing a GMO, aspects which are not explicitly taken into account during EFSA's risk assessment. This situation can lead to differences in interpretation of issues and sometimes confusion about what is being addressed at each stage.

Feedback loops connect the two aspects of risk management, as illustrated in Figure 7.2. For instance, it may be that decisions would be aided by (i) clearer specification of risk management options by risk assessors and (ii) greater confidence among Member States in the effectiveness of the practical post-authorisation risk management measures. But experience in developing and implementing practical risk management measures is limited as a consequence of the lack of cultivation approvals.

Frustration with the implementation of the framework is concentrated on the risk management stage, and in particular on the absence of decisions

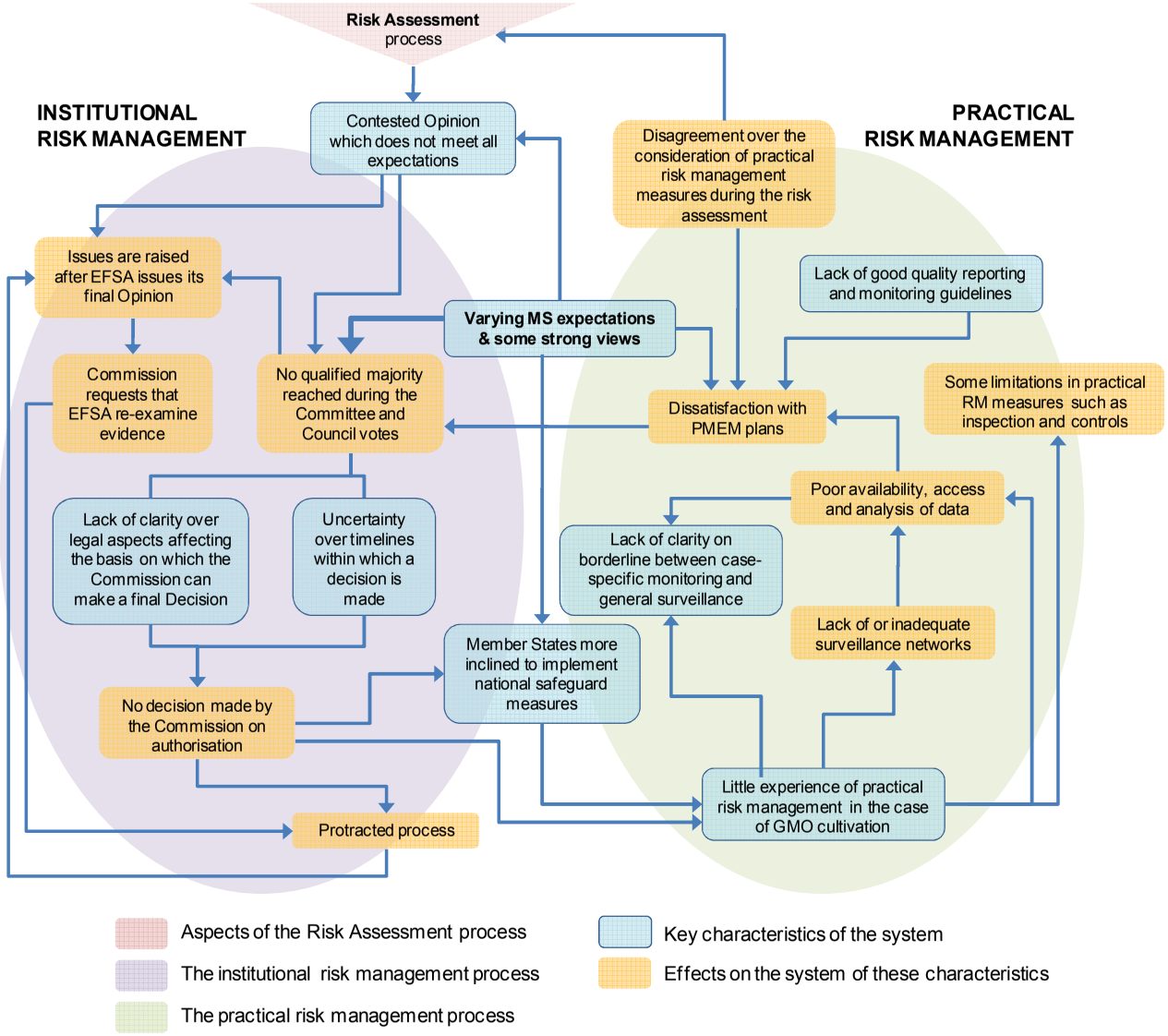
As discussed earlier in the report, the risk assessment process is the cause of some unhappiness among Member States and other consultees (Chapter 5 discusses options that would fine-tune the process and bring more resources into the system to increase its capacity). Nonetheless, consultees' frustration with the risk assessment phase is modest compared to that caused by the risk management stage. The research conducted for this study suggests that it is the lack of decisions, whether positive or negative, that is of particular concern[60].

[58] This history is explored in the literature in sources as such as: Millstone E, 2009. *Science, risk and governance: Radical rhetorics and the realities of reform in food safety governance*. Research Policy 38 (2009) 624–636; also Chapter 2 of Zwanenberg P & Millstone E, 2005. *BSE: risk, science and governance.* Oxford University Press.

[59] Directive 2001/18/EC was adopted in April 2001; Regulation 1829/2003 adopted in November 2003.

[60] A discussion of stakeholders views on this is provided in Section 6.2 of the project Interim Report.

Figure 7.2 System map of the principal issues, challenges and feedback loops in the risk management component of the legislation



Source: GHK Consulting Ltd

The system for making decisions on whether or not to authorise cultivation has demonstrated a form of regulatory paralysis:

- Firstly, when the Commission has put forward a draft Decision on cultivation to a vote, Member States have been unable to reach a qualified majority (the same situation applies for all other uses, although there have been slightly more votes in favour in those cases). The lack of qualified majority is mainly attributed to the polarised views within and among Member States and a significant number of abstentions;
- Secondly, the Commission has chosen not to issue a final Decision itself (though a decision on the Amflora potato was issued in March 2010) or not proceed with proposals to the Council where the votes were inconclusive (in the case of maizes 1507 and Bt-11[61]). Five GMOs have received favourable Opinions for cultivation from EFSA[62], on which only the potato has progressed to EU authorisation.

This situation gives rise to comments, heard repeated in consultations, that the legislative framework is not being implemented as intended. Empirically, the risk management aspects of the framework as implemented are not efficient, transparent or, in aggregate, fit for purpose. Consultees agreed that the current situation with GMO authorisations in Europe is not sustainable[63].

There is scope to improve the risk management process

The situation is, in some part, a consequence of differences of perspective not being resolved by the 'upstream' processes and then becoming manifest at the point of final decision. But there are also aspects of the specification and organisation of the risk management stage which exacerbate an already difficult situation.

The efficiency and transparency of the risk management process could be improved – both by addressing 'upstream' risk assessment issues and through changes to the risk management stage.

Appendix B to this report identifies and evaluates a number of options for 'unblocking' the decision making through changes to the way the risk management is approached under the legislative framework, including the freedoms and flexibilities that Member States to exercise choice about cultivation. This issue is now an area of active policy development by the European Commission together with the Member States and the European Parliament. Appendix B was prepared after the rest of this final report text was finalised and after the Commission's proposals had been released.

The remainder of this section considers the other aspects of the decision-making process, in particular:

- The boundary between risk assessment and risk management;
- The timetable for the decision; and
- The use of national safeguard measures and emergency measures.

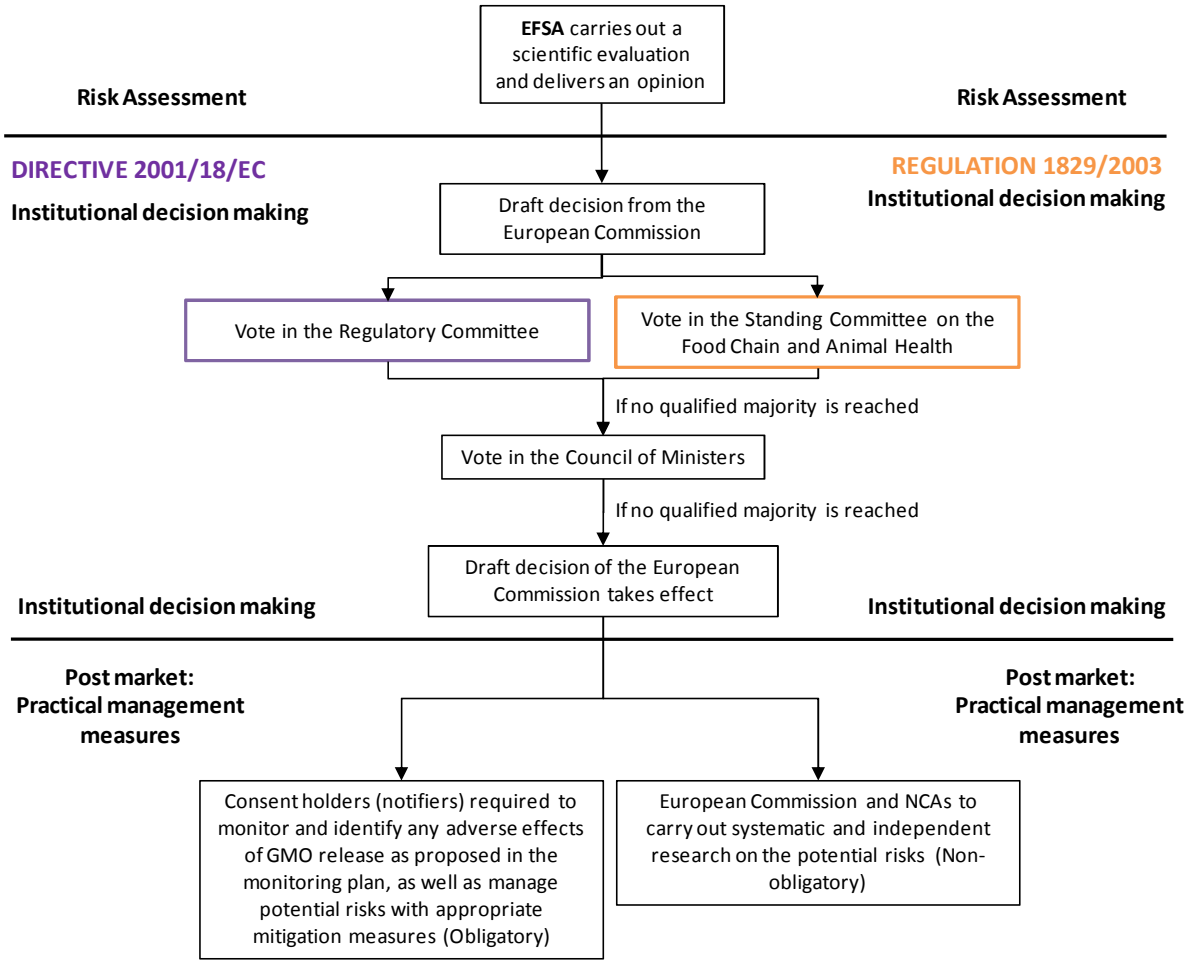
Figure 7.3 shows the structure of this part of the system as defined by the legislation.

[61] This report text reflects the situation as of 15 March 2010.

[62] 1507 maize, Bt11 maize, Amflora (EH92-527-1) potato, NK603 maize and MON810 maize

[63] For more detailed information on the current implementation of the institutional decision-making process, see Section 6.2 of the Interim Report.

Figure 7.3 The risk management stage as defined by the legislation



Source: GHK Consulting Ltd.

7.1.1 The risk assessment / risk management boundary

There is some lack of clarity on the boundary between risk assessment and risk management and, in particular, the extent to which the EFSA's Opinions should detail options for risk mitigation and management

The issue

The consultation showed that Member States were looking for the central risk assessment process to identify and evaluate risks, and provide options for risk managers to consider on how such risks should be mitigated and managed[64]. EFSA was reluctant to do so, fearing that if it did so it would be stepping beyond its remit as a risk assessor[65].

[64] Discussion of stakeholders' views on this are detailed in Section 4.4, page 41-42 of the interim report

[65] Article 3(11) and (12) of the General Food Law (Regulation (EC) 178/2002) defines 'risk assessment' and 'risk management'. The latter is defined as a process which is "distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and if need be, selecting appropriate prevention and control options". Risk Assessment meanwhile is defined as "a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation". However, 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

Currently, EFSA requires that applicants provide information on their proposed risk management strategies/measures in response to any identified risks, and, as the final step of the ERA, an assessment of the overall risk taking into account the efficacy of the risk management measures. EFSA then considers this assessment. Therefore, the ERA includes a step which allows the risk management strategies proposed by the applicant to be assessed. However, applicants are often reluctant to identify a risk, and therefore do not necessarily propose a corresponding risk management strategy. If EFSA identifies a risk not identified by the applicant[66], it can (and sometimes does) comment on potential management measures. If EFSA identifies a risk that the applicant did not, but then does not put forward options for a matching risk management strategy, then risk managers may not have all the information they are looking for.

Research for this study found that consultees are not clear on the way in which EFSA determines whether Case Specific Monitoring (CSM) is needed once a risk has been identified. CSM is based on the principle that, if a risk is identified, specific hypothesis-led measures should be put in place to monitor it. When EFSA has identified risks in past Opinions, it has occasionally argued that CSM is not required as long as appropriate risk management measures are applied to reduce the risk to a negligible level.

The issue is further complicated by the suggestion in the Council Decision 2002/811/EC that CSM can be avoided if it would not be cost effective, regardless of the risk. The judgement on cost-effectiveness lies with the risk manager, not EFSA. There is also a need to ensure that management measures are being enforced.

Although there have been some developments in the specification of risk management options in EFSA's Opinions, overall the consultation showed a gap between current process and expectations of certain Member States.

Option

- **Ask Member States to agree on a specification of the advice that EFSA Opinions provide to risk managers on options for mitigation and management of the risks that have been identified in the assessment**, thereby removing the current uncertainty about roles and responsibilities. Agreement by EU risk managers (e.g. through agreement in Council) on a structure that EFSA should work to in handling risk management options within its Opinions on cultivation applications would help to prompt the information that some Member States are expecting. For instance, a condition could be introduced that requires EFSA to comment on, or suggest, potential management measures, regardless of whether an applicant does so in the first instance.

  Determining a format that prompts responses from the risk assessors but is flexible enough to cope with the range of risks and management issues that might be posed by different products is not straightforward. One option is for a checklist of practical RM measures to be prepared, drawing on the advice of expert and scientific advisory committees in Member States. EFSA Opinions would then include a completed checklist. This would show the risk management options to be considered, their specification in the context of the product in question, any additional issues to be considered, and any important uncertainties not resolved by the appraisal.

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that '*an evaluation of the overall risk of the GMOs should be made taking into account any risk management strategies which are proposed*'. The level of risk associated with an identified hazard 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, who can then appraise and select the appropriate options.

[66] This can either be because the applicant did not identify the aspect in question, or identified the relevant aspect, but merely did not believe it was a risk as such.

The checklist of practical measures should consider the suggestions made by consultees for improving practical risk management, for example, providing clearer definition of protection goals, 'baselines' and borderline between case-specific monitoring (CSM) and general surveillance (GS). A thorough update of the monitoring chapter in the ERA guidelines could help. The checklist of RM measures as part of the ERA should identify the effects of GMO cultivation that may affect indicators for protection goals, which would then help in identifying appropriate indicators for baselines, such as, ecological functions and soil-specific key species.

Practical RM measures such as PMEM plans and risk management strategies influence each other. Risk management strategies (whose efficacy still needs to be assessed) affect the quality of the PMEM plans. The requirements/findings from case-specific monitoring and general surveillance provide risk managers with the information for decision making and developing risk management strategies post-authorisation (see section 7.5.1 below for more discussion on issues with PMEM plans, and the links between quality of PMEM plans and decision making by risk managers).

7.1.2 The final decision and its timetable

Issues raised after the final Opinion is published can result in the Commission inviting EFSA to review new or existing evidence, delaying the decision making process, and adding to the workload of the GMO panel

The issue

A feature of the system as it currently operates is that new scientific evidence sometimes emerges after EFSA issues its final Opinion and before the decision-making is concluded. This leads the Commission to repeatedly request that EFSA re-examine its initial appraisal. For instance, following inconclusive votes in the Regulatory Committee and Council of Ministers, the Commission has invited EFSA to re-examine evidence on Opinions it has issued for the Amflora potato (and other already authorised products) with regards to the safety of the antibiotic resistance marker gene that they all contain. The Commission also invited EFSA to examine new scientific studies related to the impact on the environment of the cultivation of maizes 1507 and Bt11 after the delivery of the respective opinions.[67]

This tendency results in:

- Further delay to the progress of an application through the process to a decision;
- Additional burden of work on the EFSA GMO Panel and the Commission.

Options

One possibility is to improve the 'upstream' risk assessment process, in order to ensure that concerns are sufficiently dealt with early on in the overall process. Indeed, Member States have cited the insufficiency of the three month duration of the consultation phase as one reason why comments are displaced to this final stage. Another reason may be dissatisfaction with the way issues of concern have been handled by the central process, and different perceptions of risks. Alongside adjustment to the consultation window and the risk assessment guidelines, an additional option that could be considered is for Member States to be invited to comment on the draft (as opposed to final) Opinion. These issues are discussed further in section 5.2.2 above.

[67] It remains to be seen whether the same will apply to NK603, on which a vote (at time of writing) is pending in the Standing Committee on the Food Chain and Animal Health following a favourable Opinion by EFSA.

Another consideration is the current protracted nature of the institutional decision-making phase. At present, the delays in the process mean that new scientific evidence or issues can arise between an Opinion being issued by EFSA, and the point at which a decision is required.[68] By making the system more efficient as a whole, there would be fewer opportunities for new concerns to arise before a decision is taken. Mechanisms built into the existing system allow issues raised by new scientific evidence to be examined if so required – specifically, the facility to implement a national safeguard measure, and the fact that consents are only issued for a 10 year period, after which the product must be re-assessed before authorisation can be renewed.

Nonetheless, even if the system worked within the timeframe intended, new scientific evidence may still emerge and require assessment in the window between Opinion and decision. In order to minimise delays if this continues to occur, a time limit could be set within which EFSA must issue an Opinion on the new evidence, similarly to that which currently applies to scientific evidence submitted to EFSA in support of a national safeguard measure. A procedure could therefore perhaps be established which emulates that of Article 23(2) of the Directive, where a decision on the matter must be taken within 60 days (notwithstanding the 60 days within which the Commission awaits the opinion of EFSA). However, it should be noted that merely setting a timeline does not inevitably improve the efficiency or effectiveness of a process. Once set, the timelines need to be adhered to in order for there to be improvements in practice. This point, and the issue of timelines more broadly, is discussed further in the following option.

There is a lack of clarity on the timetable on which a final decision is made and voting patterns are not published

The issue

The risk assessment process is time-limited (though the procedure does allow for the 'clock' to be stopped when additional data has been requested). Limits apply to some aspects of the risk management process too, but again the implementation has seen matters move far more slowly than might have been anticipated by those who drafted the legislation.

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). Under the current Comitology legislation, if no qualified majority is reached in the relevant Committee, the Council of Ministers has a maximum of three months upon referral of the decision from the Commission in which to reach a qualified majority. Beyond these specifications, there are no explicit timelines covering the rest of the process, for instance:

- In the case of no qualified majority being found in the Regulatory or Standing Committee, on the time in which the decision should then be submitted in turn to the Council of Ministers for another vote;
- In the case of no qualified majority being found in the Council of Ministers, on the time in which the Commission then has to adopt a final decision.

Instead, the Commission is only required to move dossier through the process 'without delay'[69]. Applications' progress through this stage of process has in practice been very

[68] Options that would improve the efficiency of the risk assessment process are discussed above in section 5. Options for improving the efficiency of the decision-making process are discussed further in this section. For more information on the cause of efficiencies and detailed suggestions made by consultees, see the Interim Report, e.g. Section 4.3 and Section 6.2

[69] Article 5 of Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission

slow. For instance, despite EFSA's Opinions on the maizes 1507 and Bt11 being issued in 2005, no final decision has yet been made. Although a final decision has now been made to authorise the cultivation of the Amflora potato, it has taken 5 years for a decision to be taken since EFSA published its final Opinion, also in 2005. Notifiers and some environmental NGOs highlighted that, in the absence of strictly defined timelines, the process has been able to stall without any legal implications.

Moreover, even where timelines have been specified (as detailed above), these have not necessarily been complied with. For instance, 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 (Article 18 of the Directive sets a maximum of 120 days for the whole procedure to be completed). Such delays introduce additional uncertainty into the process.

Member State voting is currently one of the less transparent aspects of the authorisation system. Vote of individual Member States and the reasons for their decisions are not published.

Options

- **Explore options for setting time limits within the GMO legislation where these currently do not exist, independently of the existing or future Comitology procedure,** to underpin the reforms suggested further 'upstream'.

  One potential option would be to set a time limit within which a final decision must be made. Article 18 of the Directive for instance already provides for a 120-day period within which to reach a decision, allowing for the clock to be stopped if new evidence emerges. The Regulation however introduces no such limit and relies on the general Comitology procedure instead. This option could be complemented by a time-limited period within which new evidence must be considered, as mentioned above.

- **Member States explain their votes**. The Commission could invite Member States to publish explanations of the reasoning for their vote (whether whether positive, negative or an abstention) at the Standing / Regulatory Committee and at Council. This would give the Commission a better understanding of the basis on which MSs vote, providing helpful context to the drafting of a final Decision. This requirement cannot be legally established.

7.1.3 National safeguard / emergency measures on cultivation under the Directive and the Regulation

The issue

The legislation provides a facility for a Member State to introduce a national safeguard or emergency measure where it identifies that a GMO is liable to, 'constitute a risk to human health or the environment'. In such circumstances it may restrict or prohibit the use and/or sale of that GMO as, or in, a product on its territory. The Member State must inform the Commission immediately, providing reasons for its action. The Commission then considers whether the measures taken were justified, and may refer the evidence provided to EFSA for evaluation.

Currently, seven safeguard measures on cultivation are in place[70]. One of them was also notified by France as an emergency measure under Regulation 1829/2003. Any measures notified after April 2007 are handled under Article 34 of the Regulation (the time since the renewal of MON810 is also dealt with under Regulation 1829/2003). Moreover, and since

[70] Hungary, Austria, France, Luxembourg, Germany and Greece on MON810 (and Austria on T25, which is not commercialised)

the entry into force of the Directive, Austria has introduced bans on three products authorised for import, feed and industrial uses only[71]. Altogether, six Member States currently have in place provisional bans on five authorised GMOs.

After the examination of national bans of MON810, EFSA found no reason to believe that there is a risk of adverse effects under the provisions of Article 23 of the Directive. But a Council vote in March 2009 yielded a qualified majority against a Commission proposal to force the repeal of the bans in Austria and Hungary of Monsanto's MON810. It was the third time that the Council delivered such a vote for the Austrian measure and second time for the Hungarian one.

The consultations conducted for this evaluation suggest that there is a general understanding amongst most Member States and consultees that the use of national safeguard measures, while presented as having a scientific justification, is sometimes an expression of frustrations with the current risk assessment practice, of non-scientific objections to GMO cultivation and of political circumstances. Member States with 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 consultation Member State 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 scientific research.

The activation of national safeguard measures adds to the administrative and evaluation burden of work in the system, from the tasking of the GMO panel, to votes in Council. The choice of implementing safeguard measures under the Directive or Regulation can also lead to conflicting outcomes. It is unclear, especially for certain MS authorities, whether the safeguard measures MSs currently have in place for MON810 will still be valid given that they were implemented under the Directive although MON810's renewal is being processed under the Regulation[72]. 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.[73]

These concerns provide the context within which, for instance, France has chosen to notify both a safeguard and emergency measure for MON810 under the Directive and the Regulation, respectively. The provisions and purpose of the two measures are quite different. The safeguard clause under the Directive (Article 23) is much more detailed than that under the Regulation (Article 34)[74] and is based much more clearly on the precautionary principle[75]. The Regulation only provides for an authorisation to be suspended or modified when the need is urgent, and where the products are likely to constitute a "serious risk to human health, animal health or the environment", i.e. in an *emergency*. In this context it, the Regulation refers to the special provisions of Regulation (EC) No 178/2002 (Art. 53 and 54) which rather reflect the needs arising from the food/health crisis of the late 1990s.

The Directive, in contrast, allows a product to be *provisionally* restricted or prohibited if new or additional information provides "detailed grounds for considering that a GMO...constitutes a risk to human health of the environment". Only in the event of a

[71] Maize MON863 and oilseed rapes GT73 and Ms8Rf3.
[72] 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.
[73] Of further relevance here are Articles 53 and 54 of the General Food Law (Regulation (EC)178/2002) on Emergency Measures
[74] See section 6.2.7 of the Interim Report for further discussion
[75] Indeed, the Directive explicitly mentions the precautionary principle whilst the Regulation does not.

"severe risk", does the Directive allow a MS to resort to emergency measures such as suspension or termination of placing on the market. Moreover, the Directive makes consultation with EFSA on the national scientific evidence obligatory, while no such obligation is established under the Regulation.

It is arguable therefore, that the use of the Regulation's emergency measure as a safeguard against cultivation is inappropriate, even if the use for cultivation is authorised under the Regulation. Given the potentially significant differences in the provisions under the Directive and the Regulation, the above concerns would still remain for GMO products now in the pipeline awaiting authorisation for cultivation submitted under the Regulation.

Options

Our core conclusion is that, although there is evidence that national safeguard measures are not being used as intended, it would be practically difficult to outright reject them as politically – and not scientifically - motivated. All national measures up to date have been notified to the Commission together with a dossier containing scientific evidence for analysis. Therefore the solution to this problem does not lie in amendment to the safeguard measures but instead in changes to the way in which the rest of the authorisation process is specified and operates.

Some suggested options are:

- **Change to the authorisation process that result in more efficient and transparent institutional decision-making could also prevent the misuse of national safeguard and emergency measures**

  Most MS authorities noted that the main issue with national safeguard and emergency measures is that they are invoked on both scientific and political grounds. This could include procedural options (e.g. providing Member States with an opt-out from the collective authorisation, and explicit inclusion of socio-economic concerns in the authorisation process) that would allow MSs to be more transparent with their decisions and separate their scientific concerns from political.

- **Special effort should be made to resolve and explain the differences of EFSA/MS interpretation of the science being used to justify existing bans**

  EFSA should consider attaching a special status to the consultation between MSs with bans, as some MSs have scientific concerns which are currently not adequately being addressed by EFSA's standard procedures. 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[76].

  MS authorities with existing bans also called for more robust dialogue and coordination between EFSA and MS experts. EFSA has already organised technical meetings with countries who have adopted a national ban (e.g. with Austria, France, Greece and Hungary). These meetings are organised and managed according to *ad hoc* rules, which differ on a case-by-case basis. This variation, and the lack of agreement between EFSA and MS on a consistent and coherent protocol, can lead to the meetings being less effective. Instead, it might be useful therefore for EFSA to develop and consolidate a transparent, consistent model of bilateral cooperation in the case of technical matters such as the adoption of a safeguard measure by a MS.

[76] See Section 4.6 of the Interim Report for further discussion

- **The differences, especially in application, between the Regulation's emergency measure and the Directive's safeguard clause should be made clearer**

  The Commission should stipulate clearer guidelines on the application of the Regulation's emergency measure and the Directive's safeguard clause to ease the current scepticism of notifiers and Member States regarding the Regulation being an appropriate mechanism for dealing with applications for the deliberate release of GMOs, given that its provisions was established to ensure the safety of GMO food or feed products being placed on the market[77]. 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 in legal implications of bans under the Regulation and the Directive become more prominent if the number of approvals for cultivation, especially if products are authorised under the Regulation, begin to increase.

7.2 Current provisions for the risk management of GMO marketing and their implementation, including provisions for inspections, controls, monitoring and special protection of eco-systems, environments and geographical areas

This section considers current provisions for 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.

Overall, more than half of all the groups consulted agreed that the practical risk management measures introduced in the new legislation provide a more transparent and predictable regime than the previous legislation. Most consultees (Member States and notifiers) also agreed that the provisions in the new legislation provide adequate measures to protect human health and the environment but acknowledged that they faced issues in implementation. There is still scope for improvement, especially for taking into consideration specific circumstances of each ecosystem, geographical region and specific environment.

The lack of any GMO authorisation under the new legislation means that there has been little experience with the practical risk management measures and makes it difficult to develop concrete recommendations for improvement. For example improvement in monitoring guidance has been hampered by the lack of experience with GMO approvals. However, some MS authorities have made a number of suggestions to improve RM requirements and provisions based on their limited experience with cultivation and/or field trials.

This section considers issues and options relating to:

- Post-market environmental monitoring (PMEM); and
- Inspections and controls.

7.2.1 Post-market environmental monitoring (PMEM)

Both the Directive and Regulation prescribe post-market environmental monitoring (PMEM) following cultivation approval. The PMEM plans are the main cause for concern amongst consultees in the area of practical risk management.

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

[77] Of further relevance here are Articles 53 and 54 of the General Food Law (Regulation (EC)178/2002) on Emergency Measures

plan *but* does not clearly indicate approaches and methods that should be used. The EFSA GMO Panel assesses the scientific quality of the PMEM plans presented in notifications submitted under the Directive (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). EFSA has also published an Opinion laying down guidelines on the PMEM of GM plants[78]. However, there is no European consensus to date on how monitoring plans shall be designed.

PMEM plans provide risk managers with the information for decision making and developing risk management strategies post-authorisation. If a flow of new GMO approvals was seen, pressure for improvement in the quality and content of PMEM plans would rapidly develop. Currently the main issue with the monitoring of GMO cultivation, according to the majority of Member States, is that PMEM plans do not meet the objectives of the legislation. Member States highlighted deficiencies in the content, guidelines, definition of baselines and borderline between case specific and general surveillance (GS). General surveillance is mandatory for cultivated GMOs in order to help identify unanticipated adverse effects. Case specific monitoring is required after placing on the market where there is scientific evidence of a potential adverse effect linked to the genetic modification.

The methods used for general surveillance and quality and availability of networks are also judged inadequate by consultees There is a risk that existing general surveillance networks will be unable to cope if approvals for GM cultivation increase in the future. Inadequate general surveillance networks will also affect the availability of good quality data for PMEM plans for future GM cultivation approvals.

Thus, the main challenge for improving GMO post market environmental monitoring in Europe is to better coordinate and manage data access, data analysis and knowledge transfer/sharing for the dual (and interrelated) purposes of improving PMEM plans and post-authorisation monitoring and surveillance. This can be done by:

i. improving the content of PMEM plans;

ii. promoting greater harmonisation and standardisation of data access and analysis;

iii. providing better guidelines; and

iv. improving or creating new surveillance networks.

The content of PMEM plans, including definitions and data

The issue

The content of PMEM plan depends on the quality of and availability of data from field trial monitoring of the GMO. There is a large number of monitoring sites across Europe but considerable differences in the type, quality, storage systems and availability of data generated. The tools and methods used for collecting the data also differ across Member States. The data obtained from field trial monitoring and reporting in different MSs are not comparable due to differences in monitoring requirements and general surveillance networks. Hence, it is a considerable challenge to analyse the GMO specific information and to identify possible adverse effects of GMO cultivation.

Under Directive 2001/18/EC and Regulation (EC) No 1829/2003, a report on the results of the monitoring shall be submitted by the applicant as part of an application for renewal of the consent. It is very important for EFSA, and MSs that the data collected during the PMEM forms a sound basis for scientific assessment of the renewal applications. Within the

[78] Available from: http://www.efsa.europa.eu/en/scdocs/scdoc/319.htm

current legislation EFSA has no power to enforce the recommendations it makes in its opinions regarding the PMEM (e.g. regarding harmonizing the data collected over several different MSs during the 10 year cultivation permit) even though EFSA will rely on these data during assessment of renewal applications.

Member States and notifiers 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 'baselines'. The baseline is the current *status quo*, e.g. current conventional cropping or historical agricultural or environmental status. 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. There is variation in the baselines used by MS authorities, with instances of some making reference to organic agriculture, others to conventional cultivation.

Options

- **Better define baselines to underpin a scientifically sound monitoring approach**. The selection of the baselines used for monitoring the release of GM plants into the environment should reflect current trends in cultivation of plants and management of land, and should evolve over time. However "historical knowledge" of crop cultivation can provide a useful baseline for reference;
- **Explore potential indicators for baseline data**. Collaborate and develop inventory(ies) and biodiversity assessment in agro-ecosystems and neighbouring natural habitats to provide indicators for baseline data. Current farming trends coupled with new ways of comparing different agricultural practices and patterns and distribution of crops can also assist in determining potential indicators. Given the variation in the use of baselines and protection goals by MSs, existing monitoring programmes (e.g. countryside surveys) should be used as baselines for comparison purposes as much as possible. The quality of these data could vary by MS. Rather than try to match the quality of the available baseline data; notifiers, scientists and risk managers should try to extract as much information as possible from these kinds of surveys in a way that improves their ability to detect any large-scale and long-term changes in the farm environment. Any significant gaps and shortcomings should be acknowledged for future reference;
- **Encourage the scientific community to engage in research, development and education associated with the data required for the effective implementation of post market environmental monitoring programmes.** Critical and innovative thinking is essential to develop new and appropriate methodologies. Identify and mobilise relevant expertise, especially cultivation and traditional expertise, as well from biotechnologists, biologists, ecologists and environmental scientists. Include expertise from other fields, like social sciences and better engage scientific societies;
- **Determine trigger values for the selected indicators for protection goals that lead to management action**. Define the amount of change in any recommended indicator for protection goals that would trigger concern. It will also be beneficial to understand what aspects of the environment and cropping/soil management practice might affect (increase or decrease) these trigger values[79]. The ERA should identify the effects of GMO cultivation that may affect indicators for protection goals which would then help in identifying appropriate indicators i.e. baselines, ecological systems, soil-specific keystone species, etc.

[79] FAO Expert Consultation, Genetically Modified Organisms in Crop Production and their Effects on the Environment: Methodologies for Monitoring and the Way Ahead, 18–20 January 2005

Working groups with experts from different Member States could be convened to work on such options.

Harmonisation and standardisation of data access and analysis

The issue

A cross section of different organisations, institutions and programmes across Europe are involved in GM monitoring related data access and analysis. Monitoring programmes and data are organized at different levels, have different functions and differ across Member States. For example: cropping related data are provided by farmers, scientific institutions carry out investigations on biosafety and research, notifiers/consent holders are responsible for data on the performance of monitoring and fulfilment of monitoring conditions, competent authority evaluate monitoring plans, results, and data, identify research demand and are responsible for country and EU-wide coordination, public institutions (central and regional) are responsible for partial aspects of the monitoring pan and delivery of data for GMO monitoring and/or for the assessment of the monitoring results.

Access to the environmental monitoring data that are required for monitoring plans is not easily achievable for all stakeholders. A variety of institutions are involved and there are differences in their scope, functions and legal responsibilities. The consultation exercise also highlighted differences between monitoring data requirements of MS authorities and EFSA. Thus there is a need for greater harmonisation and standardisation of data access and analysis[80].

Options

- **Develop a common exchange format for environmental data**. A common exchange format would support a standardised data acquisition system for environmental surveys and other GM monitoring related data access. It could help in harmonising GM monitoring data access and analysis in Europe given the different legal status, scopes of use and responsibility for handling monitoring data in different institutions across Europe;
- **The Commission and Member States should use information gained from monitoring data to come up with methods and systems for harmonising data access and analysis.** Methods to integrate heterogeneous data and gaps, methods to present and share large scale correlations of observed changes (to GM crops) should be explored. A geographical information system (GIS) and a geo-statistical framework can be considered for harmonising data access, exchange and analysis;
- **Member states should consider novel ways to enable better access to non-documented knowledge (e.g. farmer experience).** New ways should be explored to target the person or group with the best routine experience of the ecology and farming landscape. Examples might include encouraging the sharing of knowledge and experience in local environmental newsletters, and provide monetary incentives for reporting to the nearest environment agency or biodiversity institution.
- **Explore the benefits of undertaking measures for greater harmonisation and standardisation of data access and analysis**. Systematic and standardised data collection and analysis from different data systems for a specific purpose is one of the most complicated things to undertake. It requires a significant amount of resources for coordination and interface technology. Exploring the benefits of such undertakings will help in identifying cost-effective measures before investing in any data exchange and analysis system. This option of course should be examined

[80] There can also be problems of rights to data.

without prejudice to the potential legal restrictions with regards to the disclosure of those data.

Guidance on monitoring and reporting for MS authorities and notifiers

The issue

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 EU level. Some MS authorities wanted more detail than is given 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 test species and the definition of minimum requirements on test systems (indicators, measurements and endpoints). Moreover, it is not clear who is responsible for general surveillance where the GMO is being cultivated and who is responsible for it outside the cultivation area. MS authorities acknowledged that more experience is probably needed to improve the guidance. MS authorities also 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.

Options

- **Risk managers should consider strategies to manage uncertainties as a result of biases from field trial monitoring data and from existing ERAs**. Currently field trial monitoring data is reliant on large scale and integrated risk assessments which can be influenced by numerous factors and non-fixed references. The key factors determining whether a parameter needs to be monitored are the same as those in risk assessment: is there a potential adverse effect, how likely is it that the effect will occur; what are the consequences if it does occur? This creates a 'Catch-22' situation affecting the quality of monitoring: the limitations of the availability of data create uncertainties around the conclusions of GM risk assessments and the parameters identified in the GM risk assessment determine what should be monitored. Thus, as mentioned above the indicator for protection goals that would trigger concern should be identified in the ERA, in order to establish risk management strategies including PMEM and GS;
- **EFSA's revised guidelines on the environmental risk assessment, should be more specific and less subject to interpretation with regards to monitoring.** This is particularly important for the borderline between case specific and general surveillance, definition of relevant protection goals and the choice of indicators and test species. For example, there should be guidelines for testing farmer questionnaires, as used in general surveillance. These can now take into the several years worth of accumulated knowledge and experience;
- **Guidelines are needed to cover general surveillance beyond the cultivation area and beyond the 10 years time limit of the consent** as set out in the legislation, as this is not the responsibility of the notifier; and
- **The Commission and MS authorities should put in more resources into, and create new mechanisms for, scientific analysis of reporting data.** This is important for developing new guidelines given that reporting data are already quite scarce. The standard reporting format adopted by the Regulatory Committee for post

market monitoring in May 2009[81], though still to be adopted by notifiers for their reports, should help to improve the quality of reporting and harmonize monitoring practices.

Surveillance networks

Issue

Surveillance networks are important for post-authorisation general surveillance purposes specially for identifying occurrence of adverse effects which were not anticipated in the environmental risk assessment. Surveillance networks are also important for providing evidence for PMEM plans for future GM cultivation applications. Surveillance networks comprise the institutions and people involved in the monitoring, studying and surveying of ecological systems and biodiversity, soil function, agriculture, plant health and human and animal health. These monitoring activities are important for developing indicators for protection goals. If the protection goals were clear, then it might be easier to expand or adjust existing surveillance networks in such a way that they are able to pick up unanticipated adverse effects/risks for these protection goals.

A majority of MS authorities and notifiers highlighted that there are only a small number of networks and systems exist for monitoring GM cultivation. Most networks are not suited to monitoring the environmental and ecological impact of GM crops. Notifiers said that most networks are reluctant to participate or cooperate in such activity due to negative public perception, lack of capacity, financial issues and other reasons. There may be a need for additional environmental surveys and new forms of surveillance systems given the excessive reliance on farm questionnaires. Notifiers also said that amendments to the monitoring objectives of existing monitoring systems should also be explored.

A number of MS authorities recognised the need to improve or create new surveillance networks where no existing network can meet the requirements for GMO monitoring. Notifiers are responsible for case specific PMEM and could be made responsible for general surveillance inside the agricultural setting of GMO cultivation. However, the responsibility for funding and organisation of general surveillance outside the cultivation area is not clear.

A few MS authorities with GM cultivation experience also felt that they should work towards greater harmonization of national surveillance and exchange of protocols and systems implemented in Member States. EuropaBio[82] is working to develop well defined processes and questionnaires (for GS) to ensure consistency and harmonisation of PMEM across all MSs.

Options

- **Reasons for the limited number of GM-related surveillance networks should be explored in more detail.** Cost-effective solutions for improving or creating new networks should be identified. These solutions can be identified by stakeholder surveys, cost-benefit analysis of measures to address the barriers for improving/creating networks and prioritising efforts in networks with greater scope and high levels of transparency.
- **MSs with experience of GMO cultivation should be encouraged to play a greater role in improving or creating new networks.** The Commission, with

[81] The Regulatory Committee adopted a new format for reporting of monitoring results under Decision 2009/770/EC.

[82] European biotech industry sector association

support from MSs, could conduct a review of relevant organisations, ecological inventory data and potential partners in key Member States. MS authorities, with the support of the Commission, could set up a taskforce to identify existing opportunities, learn from other MSs with better networks and outline requirements for new networks. Resources will be required for improving existing networks and creating new networks. Funding may be sourced through partnerships between the public sector, biotechnology industry and other private sectors, and various stakeholder groups. The benefits of any new investments should always be considered with a view to making cost-effective choices;

- **Notifiers and the Commission should cooperate with these national networks and to help ensure that the data from these networks are adequate to address monitoring requirements.** This can be achieved by supporting existing initiatives, such as the ongoing work by EuropaBio for harmonising monitoring systems for GMO cultivation as part of general surveillance. Their key tasks include developing a harmonised farmer questionnaire and a harmonised approach for the use of existing environmental surveillance networks. Another, albeit more challenging, option is to create a central EU reporting office which could help assess observations from existing (environmental/biodiversity) networks for general surveillance and causes of adverse effects. However, this would require significant resources and further consultation with related legislative processes, such as health and biodiversity. A high degree of standardisation and harmonisation will help to optimise the whole monitoring process;
- **More creative approaches should be used for general surveillance.** General surveillance currently relies mainly on farm questionnaires. Other sources of data, such as stewardship programmes, peer-reviewed publications, scientific experts and institutes and better use of issue alerts[83] should also be considered more widely. Experience from other established surveillance and monitoring systems (e.g. the approach used for consumer and pharmaceutical surveillance systems) could also be used for considering new survey techniques and in designing the questionnaires;
- **Knowledge/know-how transfer should be improved.** Knowledge transfer could be improved by informal working groups, alliances and initiatives to bridge transparency gaps and improve GMO post-authorisation monitoring and risk management. Informal working groups can comprise of plant breeders, plant protection services, resistance management networks, scientists, researchers and local/regional authorities. These groups can promote communication and information dissemination; and

The outcome of the monitoring programme in the future should inform decision making by risk managers

Issue

Since there have been no approvals for GM cultivation under the new legislation, there is no requirement for MSs or notifiers to implement the provisions, including PMEM plans, of the new legislation for products approved for cultivation under the old framework (Directive 90/220/EEC). However, Monsanto has implemented a general surveillance programme in 6 Member States on a voluntary basis to satisfy the requirements of Directive 2001/18/EC[84].

[83] Issue alerts are notifications by authorities, existing networks, press, etc. of potential adverse effects associated with regard to a product.

[84] MON810's authorisation recently expired and an application for renewal of an "existing product" was submitted according to Regulation 1829/2003 in April 2007.

Thus, currently there is very limited information coming out of monitoring programmes for risk managers to use in making decisions and developing appropriate risk strategies. Risk managers identify the actions required in response to information from monitoring programmes. If it is unclear for what purpose monitoring data will be used, the monitoring programme will be ineffective and irrelevant.

Options

- **Outcomes of the monitoring programme should provide feedback to the regulatory processes and policies that support the development and implementation of sustainable RM agro-environmental practices and risk strategies.** Monitoring results should be linked to decision making through clarity, transparency, effective policy development and capacity building. This can be achieved by establishing chains of multi-way communication that extend from local government to farmer, to researcher, notifier, regulator and policy developer.
- **The Commission and Member States should ensure that monitoring networks are up and running in good time if and when positive decisions on cultivation emerge.** Even imperfect monitoring network can be helpful. There is no need to wait for perfect systems to be in place.
- **Dialogue between all relevant actors and scientists/notifiers should be improved.** This can be achieved by focusing stakeholder inputs towards specific questions to be addressed for managing monitoring programmes. The process should be transparent, comprehensive and include an education and information dissemination programme for stakeholders.

7.2.2 Inspection and controls

Inspection and control experience is mostly limited to field trials due to the lack of GM cultivation authorised under the new legislation. However, inspection and controls are regulated by national legislation and particular control/inspection activities are not specified in any detail in the EU legislative framework. Specific protection measures are established by the individual authorisations of GMOs. All Member States have arrangements in place for inspection and control with adequate powers for investigation, tests and penalties. Some of the key issues and options are discussed below.

One of the missions of FVO is to check on compliance with the requirements of EU food safety and quality, veterinary and plant health legislation within the European Union and in third countries exporting to the EU. FVO inspections will therefore be needed for the marketing and use of GM seeds to be used as source material for the production of food.

Issue

All GM inspectors generate inspection reports for internal purposes, but these are not always provided to the Competent Authority. Only the UK officially publishes reports of all growing crop inspections as they are undertaken. Three MS (Netherlands, France and Hungary) publish an annual summary of inspections undertaken each year. 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.

Option

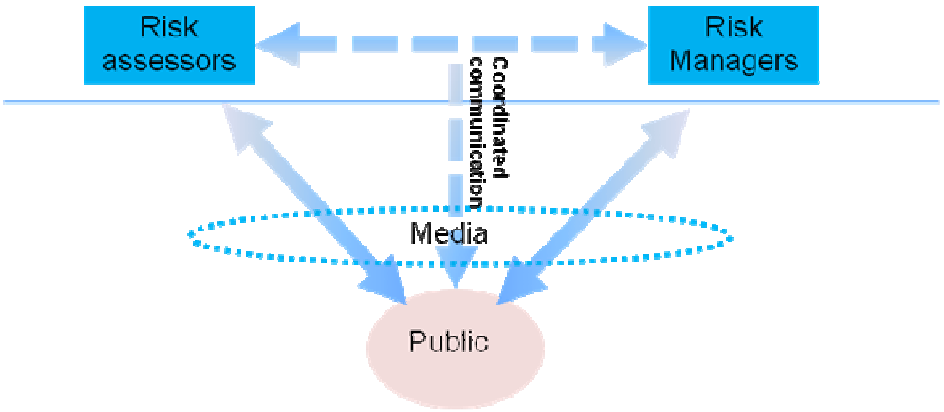
Member States could increase the transparency of the system by making inspection reports more widely available to competent authorities across all Member States and the general public.

The issue of adventitious presence of GMOs in conventional seed lots is discussed in more detail in section 9.1.

8 RISK COMMUNICATION

This evaluation has been requested 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, for example, the Commission, EFSA, national Competent Authorities and the industry. This chapter presents our conclusions, and the principal findings of the evaluation underpinning them, followed by suggested options for change concerning the communication of risks regarding GMO cultivation between risk managers/assessors and the public. In this context, risk managers are decision makers, most notably the national authorities and the European Commission, while risk assessors include MSs, EFSA and notifiers. This chapter does not cover communication of risk between risk assessors and risk managers as this has been considered in Section 5.2 above (see Figure 8.1). An overview of the main challenges and linkages within the context of risk communication with the public are shown in Figure 8.2.

Figure 8.1 The risk communication covered in this chapter is limited to that which occurs between risk assessors/risk managers and the public



8.1 Relevance of the risk communication provisions of the legislation and their objectives

The issue

The provisions for risk communication with the public are detailed in Article 9 and 24 of the Directive. Article 9 address the consultation of and information to the public in the case of deliberate releases of GMOs for experimental purposes, stating that MSs shall lay down arrangements for consulting the public, including a "reasonable time-period" in order for the public to respond. Specifically, MSs are required to provide the public with information on "all part B releases of GMOs in their territory", whilst the Commission shall provide the public with information contained in the Summary Notifications. The latter is achieved through the GMO Register (http://gmoinfo.jrc.ec.europa.eu/), led by the Joint Research Centre (JRC).

For the placing of GMOs on the market, Article 24 of the Directive notes that the Commission shall immediately, upon receipt of a notification, make available to the public a summary of the dossier and, eventually, the Opinions of the Competent Authority and EFSA following the appraisal of the dossier, indicating whether the GMO should be placed on the market. Article 24 also allows the public 30 days within which to submit their comments to the Commission in response to these documents, which are then forwarded to the relevant Competent Authority.

The key provisions in Regulation 1829/2003 for risk communication to the public are detailed under Article 29 on public access to information. The Regulation requires that, (excluding confidential information) the dossier, supplementary information from the applicant, Opinions from Competent Authorities and EFSA, monitoring reports and information from the authorisation be made available to the public. Article 28 of the Regulation also calls for the Commission to establish and maintain a publicly available register for GM food and Feed.

The General Food Law (Regulation (EC) 178/2002) defines EFSA's responsibilities for communication with the public. One of its tasks is to "ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information"[85]. Articles 9[86] and 10[87] lay down further provisions on public consultation and public information.

Overall the provisions of the EU's GMO legislation on public information and participation and their objectives certainly remain relevant. All groups consulted agree on the need for public consultation and engagement regarding GMO releases under the EU's legislation and consider the current arrangements satisfactory. Many consultees, however, believe there is scope to improve the implementation of risk communication provisions.

Similarly, the objectives of the risk communication provisions of the EU's GMO legislation remain relevant and have the broad support of consultees. These objectives are provision of information to the public and promotion of public participation in decision-making regarding GMO releases with the view to further enhancing the transparency and legitimacy of processes and decisions.

Some objectives are more relevant than others. Consultees, including notifiers, consider promotion of public participation and transparency in decision-making most critical. In addition, some objectives are less fully achieved than others. The findings of our work suggest, for instance, low levels of public engagement in processes regarding GMO releases to the environment and a rather limited impact on relevant decisions[88]. Arguably, this situation hast the potential to undermine somewhat the legitimacy of decisions on GMOs.

Options

The objectives of risk communication concern, essentially, crucial elements of democratic processes and decisions of the EU and its Members. Several of these elements are also spelt out in additional EU rules concerning general, or sector-specific, decision-making processes. Finally, these objectives and concepts are the subject-matter of international and regional regulation on decision-making in the environmental domain, binding for the EU and its Members. Therefore, changes in the current objectives of the risk communication provisions of the EU regulation on GMOs would be difficult, if not impossible.

The relevance and salience of the provisions and objectives of the Regulation could be enhanced via improvements in the implementation of individual components of the

[85] Article 23.

[86] Article 9 of the General Food Law on public consultation requires that there be "open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it".

[87] Article 10 of the General Food Law on public information requires that authorities take appropriate steps to inform the general public of the nature of the risk to health, the risk that food or feed may present, and the measures which are taken to prevent, reduce or eliminate that risk.

[88] For more information, see Sections 7.4 and 7.5 of the Interim Report

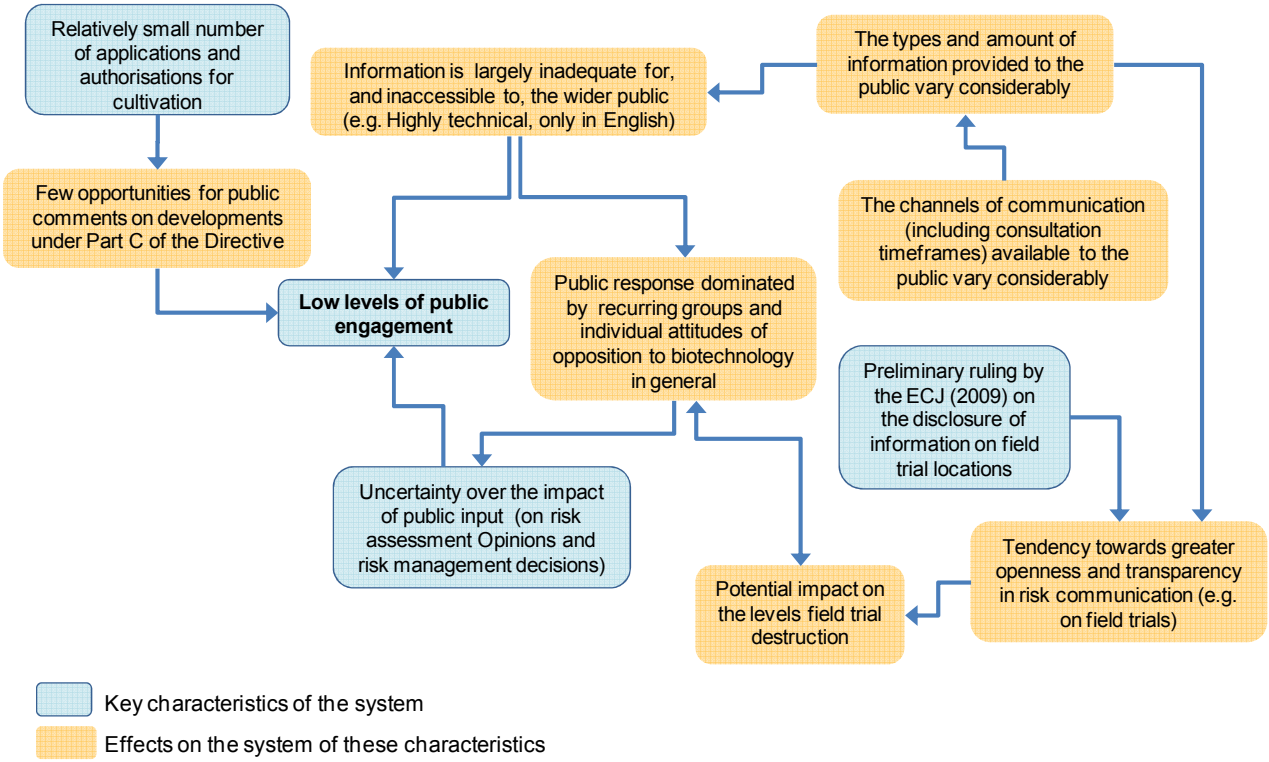
legislation and initiatives aimed at the general public. The suggested options are presented in Sections 8.2 and 8.3 below.

8.2 Implementation of risk communication provisions

The issue

Risk communication practices in the context of consultation on field trials vary considerably across the MSs and amongst notifiers, in terms of the type and amount of information provided to the public; the channels of communication of information; and, in the case of MSs, the consultation timeframe on field trials.

Figure 8.2 Main issues, challenges and feedback loops concerning the risk communication with the public in the context of the EU's GMO legislation



Our research findings suggest that, in the case of risk communication concerning field trials, most MSs publish the Summary Notifications while some make available to the public the full application dossier (excluding confidential information) mainly via official channels of risk communication. In addition, notifiers tend to play a proactive role in informing local stakeholders about field trials, despite their almost minimal engagement in general communication activities. Thus, some national public, and particular stakeholder groups, are provided with sufficient information and better opportunities for participation in consultations and contribution to risk assessment opinions and authorisation decisions.

Openness and transparency in risk communication and public consultation arrangements have gained salience in some MSs that have opted for disclosing more detailed information on the location of field trials. The preliminary ruling by the European Court of Justice of

2009 on disclosure of information on field trial locations is expected to further enhance openness and transparency in risk communication.[89]

It was impossible to gauge the impact of the trend toward enhanced openness and transparency in risk communication and consultation arrangements. Arguments that field trial destruction has increased[90] suggest that this trend might have upset the balance between transparency and commercial interest considerations. However, increased transparency and differences in public consultation arrangements between MSs are not the only factor determining the selection of the notification location by notifiers.

The implementation of the risk communication provisions at the EU level has been smooth overall but there is scope for improvement. The information provided to the public by risk assessors, including EFSA and the lead NCA, though abundant, is arguably inadequate for, and inaccessible to, the general public in the EU MSs because of the highly technical nature of the information provided and as it is generally published only in English. In addition, some consultees noted that the provision of information is fragmented. Therefore, the effectiveness and impact of the information is somewhat limited as it tends to only reach members of the public who have the necessary technical expertise and familiarity with EU processes.

Overall, more effort can be made to facilitate the supply of adequate information to, and enhance the understanding of, the general public about the EU's GMO legislation and decision-making process and of the technology. With regards to communication of risk assessment, notifiers, lead Competent Authorities and EFSA are considered as key partners .

Options

The recent trend towards, and increasing demands for, transparency in risk communication as well as risk assessment and management processes and decisions require more coherent and consistent implementation of the risk communication provisions across the EU. This, in turn, involves adjustments in the current risk communication practices. Such adjustments could be introduced gradually in the MSs. The blueprint could be encouraging the gradual introduction of risk communication practices characterised by high levels of openness and transparency.

MSs, for instance, could consider following a multi-targeted approach to information and consultation at the national, regional and local levels and with the use of public and private means of communication.

Striking the right balance between transparency and commercial interest is closely related to confidentiality provisions. Suggested options are outlined in the section on confidentiality below.

The main issue of risk communication at the EU level concerns the nature of information provided to the public in the context of consultation. This also emerged as a major issue of public response to consultation and, therefore, it is addressed in our subsequent discussion.

[89] Preliminary ruling in Case C-552/07 on the 17th February, 2009

[90] See section 5.3 of the Interim Report for more information and evidence on field trial destruction

8.3 Public response to consultation

The issues

Communication of the risks relating to GMO releases needs to be more effective at engaging the EU public at large. Our consultations suggest that the public, in general, tends to be more responsive to consultations taking place on field (Part B of the Directive) than on commercial releases (under the Regulation and Part C of the Directive). This difference in public response was attributed, by several MS authorities consulted, to a number of reasons, including easier access to information (and particularly to less complex technical information), interest in 'local' developments and lack of familiarity with EU-level processes and procedures[91]. Opportunities for public comments on developments under Part C of the Directive have been rather limited due to the relatively small number of applications and authorisations for cultivation.

Discussions with consultees and a review of public comments submitted in the context of consultation under the Directive and the Regulation (including the recent consultation on MON810) showed that most comments are unrelated to the subject matter of the consultation. Public responses are largely driven by individual attitudes of opposition to GM technology and the biotechnology industry and are often shaped by environmental NGOs.

It was difficult to establish the extent to which public comments have had an impact on risk assessment opinions or risk management decisions. The findings of our work suggest this impact varies depending primarily on the nature of the comment. Not all comments received provide well-founded arguments or evidence.

Public comments related to risk assessment and based on scientific evidence have been taken into account by risk assessors and risk managers, while comments of socio-economic nature have shaped risk management decisions. Public comments on dossiers submitted under the Regulation do not directly feed into Opinions by EFSA at the EU level although they usually shape subsequent EFSA work (e.g., guidelines developed by the Authority). Recent examples include comments on EFSA's Opinions on the renewal of the authorisation of GM maize MON810 for cultivation and food and feed and on an application for the authorisation of GM Maize NK603 for cultivation as well as food and feed. These public comments (some of which fell outside the scope of the Opinions) were considered by the Authority but did not result in Opinion change.

Options

- **Communication strategy**. The Commission and MS authorities could consider launching communication campaigns to enhance public engagement. This campaign would complement EFSA's communication activities. It should aim at the clarification of the most important issues and avoid taking positive or negative sides with a technology that has raised strong emotions. .
- **Explain the process.** The Commission and the national authorities should seek to explain the process of risk assessment and risk management and clarify roles and responsibilities of those involved in these processes, as well as the role of different types of comments received during the consultation process. Enhanced understanding of these issues on the part of the public can arguably increase confidence in the processes, manage expectations and encourage public engagement in consultation.
- **Facilitate easier access to information**. The national authorities could consider using different channels to disseminate information about applications under the

[91] see discussion in Section 7.4 of the interim report

Directive and the Regulation. Mass media – the internet, television and radio - are likely to be more accessible and therefore effective channels of communication than the national GMO register or the Government Gazette and possibly contribute to encouraging public response to consultations.

- **Consolidate information for a clearer message.** The Commission, in cooperation with other actors involved in risk communication regarding GMOs at the European level, could consider measures to reduce the existing fragmentation of information (and the confusion stemming from this), thereby facilitating the dissemination of information to the broader public and encouraging participation in consultation. One possibility would be establish a common, central EU portal (for instance under the Cartagena Protocol) where relevant information can be stored. Alternatively the Commission could give a more comprehensive presentation of EU-wide and MS specific information on their relevant websites.
- **Exchange of experience on risk communication and public consultation.** Risk assessors and risk managers should consider exchanging experiences and lessons learned from risk communication and public consultation. They might also consider developing some guidelines on evaluating the impact of public feedback on RA and RM outcomes. These activities might be particularly useful to the newer EU members.

9 OTHER DISCRETE ISSUES

This section considers two issues which were part of the terms of reference for this study and which do not fall neatly under any of the other parts of the analysis. These are:

- The management of confidentiality; and
- Policy towards unauthorised GMO seeds in the EU.

9.1 Confidentiality

The evaluation has been requested to examine the following issues:

- Whether the rules are efficient enough so as to protect confidential information and intellectual property rights, while ensuring transparency with regards to the deliberate release of GMOs into the environment and, in particular, the associated risk assessment;
- Whether the applicable rules on confidentiality and data protection of the Directive are consistent with those of Regulation (EC) 1829/2003 and potential links to Regulation (EC) No 1049/2001 (taking into account differences in scope and categories).

9.1.1 The confidentiality and data protection provisions of the EU legislation on GMOs

The issues

Provisions for confidentiality are laid down in Articles 25 and 30 of the Directive and the Regulation, respectively. Furthermore, Article 31 of the Regulation lays down details on data protection. One of the significant reasons for differences in practice between the implementation of the Directive and the Regulation in terms of confidentiality is the fact that the Directive is implemented through national regulation. These national provisions vary across MSs in their requirements for transparency.

One example (albeit regarding food and feed, not cultivation) where differences between MS and wider EU provisions led to a dispute is the case of Monsanto's application for MON863, specifically regarding details of the 90 day feeding study. Monsanto had refused to reveal documents containing information on the feeding trial on the grounds that "it contains confidential business information which could be of commercial use to our competitors." This was followed by a campaign by groups such as Greenpeace. The German state ordered Monsanto to make available to the public the relevant documents on the basis of the Directive 2003/4/EC on public access to environmental information. The company appealed against the decision to disclose the document, but this was overruled by the German court and Monsanto was subsequently ordered to disclose the suppressed report[92].

Overall, the confidentiality provisions remain relevant to the needs they were intended to address. The provisions of the Directive (under Parts B and C) have helped to ensure

[92] http://www.greenpeace.org/raw/content/international/press/reports/mon863_chronicle_of_deception.pdf

transparency while safeguarding commercial interest and intellectual property and, are acceptable to most MSs authorities and notifiers consulted. This view, however, is not shared by a few consultees from environmental organisations having some familiarity with the details of the provisions and their implementation.

The confidentiality provisions regarding Part B applications have not resulted in consistent outcomes across the EU as, in some countries, national rules on freedom of information and public access to environmental information prevail over the provisions of the Directive, and result in higher levels of transparency. Similarly, confidentiality decisions on Part C applications by the lead authority are determined by national rules rather than by the Directive. The general trend has been towards higher levels of openness, as illustrated by the ECJ ruling of 2009 on the disclosure of detailed information on field trial location. This may have an impact on the activities of biotechnology companies. It is difficult, however, to argue that increased openness and transparency may result in the elimination of trials within the EU altogether.

There are considerable differences between the confidentiality provisions of the Directive and Regulation (EC) 1829/2003. The latter can address confidentiality issues more efficiently and effectively given the clarity, comprehensiveness and rigour of its approach. The Regulation, for instance, provides a comprehensive list of what should be made public. This list was also pointed out by several MS authorities consulted[93].

Options

- **The Commission and the MSs authorities should seek to redress the imbalance between transparency and the real, or potential, impacts of enhanced, or reduced confidentiality**. This could be done, for instance, via the adoption of uniform rules on disclosure of confidential information across the EU, drawing on the experience of MSs having most worked on the confidentiality assessment of GMO files and practices ensuring openness and protection of commercial interest.

- **The gap between the Directive and Regulation on confidentiality could be addressed.** The Commission and MSs should consider addressing the different confidentiality arrangements of the two EU regulatory frameworks on GMOs. In the short term, it might be useful to clarify these differences – the Commission, for instance, could develop guidelines to facilitate the work of the NCAs. The Commission and the EU Members should also consider aligning the provisions of the Directive with those of the Regulation in the longer term. Alignment can be expected to enhance the effectiveness and efficiency of the Directive.

9.2 Zero tolerance policy

The effect of zero tolerance policy on unauthorised GMO seeds in the EU

In the EU a principle of zero tolerance is applied to the presence in conventional or GMO seed for all GMOs that are not authorised for cultivation. This includes GMOs authorised in the EU for food and feed, and those pending authorisation (so-called asynchronous authorisations). When a GMO for which the EU authorisation procedure is pending is cultivated in third countries there is a risk that it will be present at low levels in seed imported into the EU. Seed consignments identified as containing EU unauthorised GMOs - even at extremely low/trace levels – would have to be sent back, relocated, or destroyed.

[93] For more information see Section 8.1 of the Interim Report

Enforcing 100% purity is already recognised as being impossible given the technical and feasibility constraints of current sampling and testing methods. EU seed legislation and the OECD seed certification schemes acknowledge that 100% pure seed of one variety is impossible to achieve and allow for a certain varietal impurity in conventional seed production (including organic seeds). For cereal seed production, levels vary from 0.1 to 10%[94].

The seed industry, notifiers and many Member States believe that the zero tolerance policy (ZTP) for unauthorised GMO seeds has a negative effect on trade and the EU seed sector, and will become more difficult to sustain over time. Some MS authorities and notifiers have requested that the Commission address the technical constraints which currently exist concerning the low level presence (LLP) of non authorised GMOs in seed. They have argued it is important for domestic and international trade and will alleviate the monetary and non-monetary costs otherwise imposed on seed breeding, production and research activities.

Hard evidence substantiating claims of additional costs is not readily available. Seed imports are smaller than food and feed imports in Europe, and seed imports have not, thus far, seen major disruption. There is, however, an increasing risk of trade disruptions as more GM crops are approved outside of Europe.

The equivalent problem in food and feed imports has been observed concerning the low level presence (LLP) of unauthorised GM products, particularly in feed products. This has caused considerable trade disruption and led to legal uncertainties for operators in the EU.

To address this issue the Commission presented a proposal which lays down rules for sampling and testing non authorised GMOs to the Genetically modified Food and Feed and Environmental Risk section of the Standing Committee on the Food Chain and Animal Health section. On 22 February 2011 the Regulatory Committee gave a qualified majority. The proposal is subject to the scrutiny of Parliament and Council before final adoption.

Existing Member State inspection programmes to monitor and control adventitious presence (AP) of EU-authorised and non-EU-authorised GMOs in seed lots

Directive 2001/18/EC establishes labelling provisions for GMO seed placed on the market. Article 21.2 provides for the possibility of setting a labelling threshold for the technically unavoidable or so-called adventitious presence (AP) of authorised GMOs in conventional seeds below which GMO presence should not be labelled. In the absence of this harmonised EU threshold, any AP of authorised GMOs in conventional seeds must be labelled.

According to the 2007 FVO report[95],two MSs had adopted threshold values above the limit of detection for GMOs that have been authorised in the EU. Member States setting their own thresholds is not in line with the existing EU legislation. A 2007 study on the Member States' practice regarding the AP of GMOs (whether authorised in the EU or not) in conventional seeds[96] showed that neither the legal requirement to label any presence of

[94] Depending on the species, the generation of the seed and whether hybrid seeds are concerned (Council Directive 66/402/EEC, OJ P 125, 11/7/1966, p. 2309).

[95] The Food and Veterinary Office (FVO) carry out yearly inspection programmes. The findings of each inspection carried out under the programme are set out in an inspection report, together with conclusions and recommendations. The FVO also produces general overview reports that summarise the results of a series of inspections to a number of Member States. See: http://ec.europa.eu/food/fvo/index_en.cfm

[96] See also Article 4(5) of Directive 2001/18/EC, according to which MS shall ensure that the competent authorities organise inspections and other control measures as appropriate to ensure compliance with this Directive. In the event of a release of GMO for which no authorisation was given, the MS concerned shall ensure

authorised GMOs in seeds nor the current zero tolerance towards non-authorised GMOs in seeds are enforced in an harmonised manner. National policy may affect the stringency with which this legislation is enforced. In fact, several Member States have proceeded to implement their own criteria to label GM presence ranging in values from limit of detection to 0.9%. Practice is not harmonised regarding the sampling and testing of non-authorised GMs.

Two hundred and eight incidents of EU-authorised GMOs and 43 incidents of non-EU-authorised GMOs in seed lots were reported between 2001 and 2006. It has been estimated that this equates to a rate of 3.2% of tests per annum being positive[97].

Legislative differences between Regulation 1829/2003 and Directive 2001/18/EC are apparent as far as provisions on detection methods and validation are concerned. The Regulation is more detailed than the Directive with respect to detection methods and validation (see Article 32 and the Annex)[98]. However, in practice these are being implemented in a consistent manner in line with the "one door one key" principle, and some provisions are being applied *de facto* to GMOs authorised under both pieces of legislation.

Event-specific polymerase chain reaction (PCR) methods are made available by the biotech companies as part of the notification process to facilitate the detection of GMOs to be authorised later.

More discussions are needed at the EU level on equivalent harmonised rules for the presence of non-EU authorised GMOs in seed lots given the current fragmented nature of controls across the EU.

Options

- **No change** at this time, given the higher level priorities for reform in the system and limited economic impact to date;
- Harmonisation of controls based on adoption of **common protocols for sampling, testing and reporting** of results for unauthorised GMOs in seed lots (similar to the technical solution proposed for LLP- low level presence in feed).

A further consideration is the potential for interaction between legislative requirements set for seeds and those set for food and feed. This would need to be taken into account. The harmonisation of controls on seeds suggested above, if aligned to that under consideration for feed, would avoid that potential problem.

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that necessary measures are taken to terminate the release or placing on the market, to initiate remedial action if necessary and to inform its public, the Commission and other MS.

[97] Hugo Sarah *et.al.* (2007), Adventitious Traces of Genetically Modified Seeds in Conventional Seed Lots: Current Situation in Member States, Central Science Laboratory Sand Hutton, Final Report, 27th July 2007, http://www.gm-inspectorate.gov.uk/reportsPublications/documents/EUseeds_final_081007.pdf

[98] See Section 4.7.2 of the Interim Report for more information.

10 FINAL REMARKS & SUMMARY CONCLUSIONS

This chapter provides some remarks on the overall conclusions of the evaluation. It considers first the extent to which the system as a whole is meeting its objectives. It then goes on to report the conclusions reached on the individual questions that this study was asked to consider. A summary of the options identified as ways of improving the performance of the system is provided in Table 10.1.

10.1 The legislative framework as it operates today is not meeting needs or expectations, or its own objectives

At time of adoption the Directive and Regulation constituted an attempt at a new and improved legislative framework governing what had proven to be a difficult area of EU policy. Yet, from the time they came into force until March 2010 the EU did not adopt a single decision, positive or negative, on an application to cultivate a GMO. The Amflora potato is the first cultivation approval in Europe since 1998. Applications cycle within the system are stalled, inch forward and then cycle again at the next stage of the process. Dissatisfaction and frustration is widespread in all quarters.

This evaluation was asked to consider whether the legislative framework in the field of cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) 1829/2003 and marketing of their other uses under 2001/18/EC is fit for purpose. The empirical evidence is clear – as currently implemented, it is not. Despite the best effort of many hard-working individuals and ongoing efforts to improve it, the system is not working as envisaged and is not, in aggregate, meeting its objectives. As the analysis in this report and earlier outputs from this evaluation have suggested, the 'dysfunction' arises as a consequence of a complex set of factors, both external and internal to the authorisation process.

The external socio-political environment undoubtedly affects the way actors engage with and use the authorisation process. The EU is attempting to operate an approval system based on a science-based safety assessment for products that many in Europe, including Member State governments, object to on socio-economic and ethical grounds.

And while extensive efforts have been made to ensure that the appraisal systems are rigorous, they struggle to accommodate the particular assumptions, perceptions of risk and local concerns of different actors The resulting frustration triggers objections, which result in requests for further analysis, which increases the workload on the system, which in a world of finite resource leads to more delays, which further increases frustration.

The evaluation has identified a number of options that could help to fine-tune (through changes in procedure and process) and lubricate (through greater resources) the authorisation machinery. These changes are worthwhile: each could make a small contribution towards creating a system that is more efficient, time-limited and transparent.

None of these modifications, however, directly address the gap between the scope of some actors' concerns with GMO products and the scope of the EU's authorisation process as set out in the legislation. The Commission's initiative to bring forward options that allow more choice to Member States in deciding whether to cultivate GMOs does, however, reach into this more difficult territory.

Consideration of these more fundamental reforms should not delay or substitute for efforts to improve the authorisation system as it exists today – improving the specification of processes where needed and looking at whether injection of more resources would help those processes work faster and better.

10.2 Summary conclusions on the specific questions from the terms of reference

10.2.1 The objectives

The legislation's stated objectives are still consistent with the needs of society but there is some disagreement about whether they are sufficient. There is a view amongst some Member States that socio-economic factors should have a more prominent place in the framework. A more pressing issue is that the objectives are not being met in the way intended by the legislation. The environment and human health are being protected from potential adverse risks of GMO cultivation not by a timely, efficient process that screens out of 'unsafe' products, but instead by the absence of any decisions on cultivation applications.

10.2.2 The scope

Pressure to update the scope of the legislation arises as innovations in biotechnology lead researchers and industry to adopt new techniques. Some of the new techniques available create new challenges for the regulatory system because there is no recombinant DNA in the product placed on the market. The biotech industry is against expansion of the legislation's scope. Certainly, expansion of the system's scope to new techniques without improvements to its efficiency would, in effect, automatically bar any products produced with those techniques from the EU market. But some consultees are concerned about the potential impacts of the products derived from new techniques. The rate of innovation in the global biotechnology sector is unlikely to slow down and ensuring that legislation remains relevant is likely to be an ongoing challenge, especially if the focus is on the techniques used rather than the characteristics of the final products and the traits they express. There is a case for considering the principles that should define the scope of the legislation in the future.

10.2.3 The procedures for risk assessment

The procedures for the risk assessment of GMOs as implemented are not efficient, time-limited or fully transparent.

A key aspect of the current situation is the mismatch between some consultees' expectations of the risk assessment and the current process, in particular disagreement over its:

- 'resolution' – i.e. the extent to which the risk assessment considers the diversity of agro-ecological environments and non-target species within Europe and thus addresses the specific concerns of particular Member State or region; and
- coverage of management and mitigation options – i.e. how far EFSA risk assessors go in identifying risk mitigation and management measures for risk managers to consider at a later stage of the process.

There is also the issue that some Member States are looking to have a more explicit consideration of socio-economic factors, which is not provided for in the current EU framework.

Involving risk managers from Member States in the determination of these boundaries and assumptions, and asking them to formally recognise and accept the guidance that emerges is one means of ensuring alignment of otherwise diverse Member States concerns and the

EFSA-mediated process under the Regulation (which is the currently the most popular cultivation authorisation channel for notifiers).

The problems experienced in implementation could be addressed through measures that:

- Increase the rate of learning in the system through promotion of communication and dialogue amongst the principal actors in the system (notifiers, Member States, EFSA);
- Streamline the process and promote engagement through reforms to system procedures, process and capacity;
- Address the scale and flow of financial resources in the system;
- Improve predictability and efficiency through greater harmonisation of practice among Member States and notifiers.

If adopted, these measures should help to improve the co-operation between national Competent Authorities and EFSA, and clarify their role of each of them in the environmental risk assessment.

10.2.4 The existence of two separate procedures for GMO cultivation authorisations and the application of the "one-door-one-key" principle under the Regulation files

The existence of two separate procedures by which GMOs can be authorised for cultivation has caused comparatively few problems. Notifiers have switched over to use of the Regulation; there has been no application via the Directive since 2005. However, regardless of the use of the Directive's procedures in practice the principles established in the legislative text, and especially in its Annexes are integral to the legislative framework for GMO cultivation. Where use of the alternative channels has emerged as an issue it has mainly been in the context of procedural aspects such as:

- Dialogue – with the Directive providing more opportunities for direct discussion between notifiers and those conducting the appraisal of the risk assessment; and
- Emergency and safeguard measures – with some differences in the conditions attached to use of the national safeguard measure provided for under the Directive and the emergency measure provision of the Regulation[99].

In the context of the challenges facing the system as a whole these issues are comparatively modest.

10.2.5 The interplay between the environmental risk assessment (ERA) of herbicide tolerant GMOs under Directive 2001/18/EC and the ERA for the use of the respective herbicides under Directive 91/414/EC[100]

Currently, "a herbicide used on a GMHT crop is assessed differently from the same herbicide on non-GMHT crops (e.g. imidazolinone- and atrazine-tolerant crops) and conventional crops"[101]. This creates a level of confusion and introduces uncertainties into the risk assessment of GMHT plants[102]. This issue is exacerbated by the fact that, to date,

[99] Of further relevance here are Articles 53 and 54 of the General Food Law (Regulation (EC)178/2002) on Emergency Measures

[100] Recently replaced by Regulation 1107/2009 on plant protection products

[101] The Environmental Risk Assessment of genetically modified herbicide tolerant plants and the interplay between Directive 2001/18/EC and Directive 91/414/EEC. Working Document from the EFSA GMO Panel. Available from: http://www.efsa.europa.eu/EFSA/DocumentSet/gmo_working_document_en.pdf?ssbinary=true

[102] For further details see Section 4.4.2 of the Interim Report

there has been no agreement on a common approach in order to address these differences. Consequently there are currently considerable inconsistencies in the way MSs have dealt with applications for GMHT plants, especially with regard to the indirect environmental impact of the herbicides used.

Given the prevalence of herbicide tolerance as a GM trait, there is therefore a need to introduce a more coherent approach to the risk assessment of GMHT plants in order to manage expectations and create a more predictable and transparent risk assessment process. Better coordination is necessary between the applicable legislative frameworks, namely the Plant Protection Products legislation (Directives 91/414/EC, replaced by Regulation 1107/2009) and 2001/18/EC, as well as between the authorities managing the processes. This activity should extend to the work of the GMO and Plant Protection Products and the Residues Panel of EFSA, and between Member States which that appraise the environmental risk assessment of GMHT plants.

10.2.6 Have Part B provisions fulfilled the legislation's objectives and has their implementation affected the risk assessment and authorisation procedure of GMOs

Field trial applications are becoming more concentrated in fewer Member States and the total number has declined since 2006. Some notifiers believed these trends are due to increasing difficulties in obtaining approvals and in completing field trials.

There is some frustration among Member States about the quantity and quality of evidence generated by field trials that is presented in cultivation applications, and an interest in further harmonisation of the design, conduct and analysis of field trials conducted with GMOs for eventual commercial use. There are links between field trials and cultivation in that the quantity and quality of field trials being conducted impacts on the quantity and quality of applications for cultivation (by determining the field trial evidence available) and a lack of authorisations for cultivation also reduces the incentive to invest in research, and thus the demand for further field trials.

The remedies lie mostly outside the GMO legislative framework but there is potential to tackle the issues through facilitating more information on the effects of cultivation of GMOs by encouraging more independent research, promoting efforts to avoid field trial destruction, promoting the development of guidelines on the design and delivery of field trials. Better data on trends in EU field trial activity would also be helpful.

10.2.7 Are the current provisions for the risk management of GMO marketing and their implementation up to date

The evaluation has considered both the institutional decision-making (culminating in the decision whether or not to authorise) and the practical risk management issues associated with GMO cultivation. Frustrations among consultees with the legislative framework are concentrated at this stage of the process. Member States have proven unable to reach a qualified majority on any of the draft Decisions put forward, and the Commission has itself has only recently issued a final Decision on an application active for 13 years where the choice was not resolved by the Council, namely the Amflora potato. Views amongst Member States are polarised and voting patterns suggest little prospect of a qualified majority emerging under current rules.

There are some process and procedural remedies available that could address current concerns about aspect of the defined process, such as the extent to which EFSA's Opinions should detail options for risk mitigation and management. But many of the causal factors behind the blockages in decision-making lie 'upstream' in the risk assessment process or 'beyond' the scope of the authorisation procedure as currently defined. Member State voting is believed to reflect in part objections to the technology that have a socio-

economic or ethical basis and which thus have no voice in a science-based assessment of safety.

The consultations found support among Member State consultees for looking at options that would provide Member States with more flexibility and freedom within the framework of a common science-based safety assessment. These options are considered separately in Appendix B.

Experience with practical risk management measures is limited given the lack of cultivation approvals within the last decade. However, consultees regard them as an improvement on the previous legislation. The evidence suggests that the infrastructure which is needed to support the legislation's requirements for monitoring and surveillance will have to be strengthened. There is a demand for clearer specification of what is required of post market environmental monitoring plans. Investment in these systems and protocols has the potential to create positive feedback loops into the risk assessment process by providing most robust evidence on impacts. If cultivation approvals did begin to emerge from the decision-making process then the need to reinforce surveillance arrangements would increase.

10.2.8 The communication of risk concerning the release of GMOs into the environment and the manner in which it has been implemented

The legislation's provisions on risk communication remain relevant. The degree to which they are being fulfilled varies; research suggests low levels of public engagement and limited impact of public feedback on decisions.

There is considerable variation in practice among Member States and among notifiers in the communication activities linked to field trials. There appears to be a general trend towards more openness among Member States, reinforced by an ECJ ruling on disclosure of field trial locations.

There seems to be less public engagement with cultivation applications than with Part B field trial applications - a consequence perhaps of the former being a more 'distant' and more complicated process with uncertain local impacts (recall the lack of authorisations over the past decade). The accessibility of information, which is often highly technical, is a recognised issue. There is a case for more effort to be made to upgrade and extend communication activities, something that should certainly be prioritised if the authorisation process was 'unblocked' in the future.

10.2.9 The procedures on national safeguard / emergency measures on cultivation under the Directive and the Regulation

The national safeguard measures and emergency measures are not functioning as intended and are not, at this time, efficient, time-limited or transparent. There is a general understanding amongst most Member States and other consultees that the use of national safeguard measures, while presented as having a scientific justification, is sometimes an expression of frustrations with the current risk assessment practice, of non-scientific objections to GMO cultivation and of political circumstances. Member States have not adopted Commission proposals calling for such measures to be revoked where EFSA has found them to be unsubstantiated.

There is a lack of clarity on the appropriateness and applicability of safeguard measures under the Directive compared to the emergency measures under the Regulation, given differences in the provisions of the legislative texts and the tendency for notifiers to submit cultivation applications under the Regulation.

The solution to this problem does not lie in amendment to the safeguard measures but instead in changes to the way in which the rest of the authorisation process is specified and operates. Changes to the authorisation process that result in more efficient and transparent institutional decision-making could help to prevent the misuse of national safeguard and emergency measures. Special effort should be made to resolve and explain the differences of EFSA/MS interpretation of the science being used to justify existing bans. Differences, especially in application, between the Regulation's emergency measure and the Directive's safeguard clause should be made clearer.

10.2.10 Consistency of rules on confidentiality and data protection in the Directive with those of the Regulation and Regulation (EC) No 1049/2001

The confidentiality provisions of the legislation remain relevant. The balance struck between transparency and protection of intellectual property has the support of most MS authorities and notifiers consulted.

There are considerable differences between the confidentiality provisions of the Directive and Regulation 1829/2003. The latter can address confidentiality issues more efficiently and effectively. As an example it provides a list of what should be made public. Aligning the Directive with the Regulation is something to consider for the future.

10.2.11 Other issues

The effect that national measures on GMO cultivation have on the internal market, environmental and health protection

No information emerged from the research and consultations on specific national measures that had a direct impact on the system under evaluation. However, 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, including the existence of good environmental practices and codes that support the main objectives of their national GM legislation, and more specific measures that impose specific conditions on cultivation in order to protect environmentally sensitive areas such as nature reserves or unique geographical areas.

There is also a range of GM-related activity at Member State level which defines the wider 'environment' within which the legislative framework works. This includes national level bodies created to advise governments on GMO issues (including consideration of socio-economic factors), and the creation of GM-free regions.

The effect of zero tolerance policy on unauthorised GMO seeds in the EU

In the EU a principle of zero tolerance is applied to the presence in conventional or GMO seed for all GMOs that are not authorised for cultivation. This includes GMOs authorised in the EU for food and feed, and those pending authorisation (so-called asynchronous authorisations). Seed consignments identified as containing EU unauthorised GMOs - even at extremely low / trace levels – have to be sent back, relocated, or destroyed.

The seed industry, notifiers and many Member States believe that the zero tolerance policy (ZTP) for unauthorised GMO seeds has a negative effect on trade and the EU seed sector, and will become more difficult to sustain over time, though hard evidence substantiating claims of additional costs is not readily available. To address the issue the Commission presented a proposal which lays down rules for sampling and testing non authorised GMOs.

Existing Member State inspection programmes to monitor and control adventitious presence (AP) of EU-authorised and non-EU-authorised GMOs in seed lots

Article 21.2 of the Directive provides for the possibility of setting a labelling threshold for the technically unavoidable or so-called adventitious presence (AP) of authorised GMOs in conventional seeds below which GMO presence should not be labelled. In the absence of this harmonised EU threshold, any AP of authorised GMOs in conventional seeds must be labelled. Evidence suggests that neither the legal requirement to label any presence of authorised GMOs in seeds nor the current zero tolerance towards non-authorised GMOs in seeds are enforced in an harmonised manner.

More discussions are needed at the EU level on equivalent harmonised rules for the presence of non-EU authorised GMOs in seed lots given the current fragmented nature of controls across the EU. Harmonisation of controls based on adoption of common protocols for sampling, testing and reporting of results for unauthorised GMOs in seed lots, is one option to be considered. The potential for interaction between legislative requirements set for seeds and those set for food and feed would need to be taken into account. Harmonisation of controls on seeds, if aligned to that under consideration for feed, would avoid that potential problem.

Table 10.1 Summary of options

Stage	*Issue*	*Option*	*Lead*			
			EC	*EFSA*	*MS*	*N*
OBJECTIVES						
	Objectives in principle are satisfactory, but are not being met as originally intended	Explore options for improving the legislation's implementation (detailed below)	✓		✓	
SCOPE						
	Varying views on how the scope of the legislative should evolve Continuing innovation in bioscience will present new challenges in the future	Establish the principles by which the scope will be determined in the future to lay the foundations for a long term strategy for handling future bio-techniques	✓			
		Extend the scope of the legislation either on: – a process basis; or, – a product basis	✓			
RISK ASSESSMENT						
Communication and dialogue	A lack of sufficient communication between risk assessors and notifiers leads to inconsistencies and delays to the RA process	Pre-application discussions		✓		
		Increase direct communication during the appraisal process		✓	✓	
	A lack of sufficient communication between risk assessors themselves leads to recurring concerns, inconsistencies and delays	Widen participation of MSs in the ERA appraisal through: – financial support; – allowing several to cooperate simultaneously on the appraisal	✓	✓		
		Improve handling of requests for additional information by: – improving coordination between EFSA and MS authorities; and, – reviewing timelines	✓	✓		

Stage	*Issue*	*Option*	*Lead*			
			EC	*EFSA*	*MS*	*N*
		Improve consultation on the dossier and its appraisal by: – extending the three month window; and, – allowing MS authorities to comment on a draft versions of the ERA appraisal by a MS and/or EFSA's Opinion	✓	✓		
		Improve the management of MS comments through: – more detailed response; and, – more use of bilateral meetings		✓		
Procedures, process and capacity	Differences on the scope and specification of the risk assessment mean expectations are not met	Develop future guidelines with extensive involvement of risk managers and MS experts		✓		
		Formally approve future guidelines by ministers in Council	✓			
	The process by which stacked events are assessed increases the duration of the RA process	Appraisals to be done in parallel, as far as possible		✓		
		Ensure, as far as possible, that the same MS appraises the single and stacked events		✓		
	The sequential assessment of the ERA by a MS and then by EFSA increases the duration of the RA process	Adopt a more collaborative, parallel process		✓	✓	
		Make EFSA responsible for the whole appraisal		✓		
Resourcing	EFSA resource constraints affects the duration and characteristics of the RA process	Introduce an application fee for cultivation applications	✓	✓		
		Specific mandates to EFSA to be accompanied by a financial contribution	✓			
		Explore options and incentives to increase collaboration with scientific officers		✓		
	MS resource constraints prevent widespread participation	Provide MS authorities conducting an ERA appraisal with a financial contribution	✓	✓		

Stage	*Issue*	*Option*	*Lead*			
			EC	*EFSA*	*MS*	*N*
A lack of consistency...	...in the dossiers submitted by notifiers increases the duration of the RA process and means expectations are not met	Update guidance on risk assessment as needs arise		✓		
		Improve communication with notifiers		✓	✓	
		Improve consistency of MS appraisals (see below)		✓	✓	
	...in MSs' appraisals of the ERA impedes the transparency and predictability of the RA process	Develop guidance for MSs on the appraisal of the ERA		✓		
		ESCO Working Group to support EFSA in harmonising scientific aspects of MS appraisals		✓		
		Improve coordination to deal with the interplay of the plant protection products legislation (the Plant Protection Products legislation (Directive 91/414/EC, replaced by Regulation 1107/2009) and Directive 2001/18/EC		✓	✓	
FIELD TRIALS						
	Declining field trial numbers	Facilitate research			✓	
	High rates of field trial destruction in some MS	Enhance the protection of field trials			✓	
	The quality of evidence from field trials in the EU in support of applications for later use varies	Improve consistency of field trial data collected for commercial / regulatory purposes through: – voluntary standards or official guidance; – clarification of technical terms in the legislation; – exchanging views and information among MSs	✓	✓		✓
	Public data on GMO field trial activity are not complete enough to support policy-makers	Gather better data on trends in EU field trial activity through: – enforcing existing legal obligations for reporting; – gathering information of field trials conducted for non-commercial purposes	✓		✓	

RISK MANAGEMENT						
Institutional decision-making	***Providing flexibilities and freedoms to Member States***					
	See Appendix B					
	Issues and options for improving institutional decision-making within the existing framework					
	Lack of clarity on the boundary between risk assessment and risk management	Agreement by Member States on a specification of the advice that EFSA Opinions provides to risk managers on options for mitigation and management of the risks that have been identified in the assessment	✓			
	Delays in the decision making process from new evidence or issues emerging after EFSA issues its final Opinion	Improve the 'upstream' risk assessment process to ensure that concerns are sufficiently dealt with early on in the overall process	✓			
		Explore the options for setting a time limit within which EFSA must issue an Opinion as a result of any additional requests	✓	✓		
	There is uncertainty over the timetable within which a final decision is made	Explore options for setting time limits within the GMO legislation where these currently do not exist, independently of the existing or future Comitology procedure	✓			
		Member States to explain their reasoning behind their votes in the relevant Committee or Council	✓		✓	
	MSs have justified national safeguard measures on political motives in addition to scientific reasons.	Improve the efficiency and transparency of the upstream authorisation process to reduce the need of MSs to resort to national safeguard and emergency measures	✓	✓		
		Special effort should be made to resolve and explain the differences of EFSA/MS interpretation of the science being used to justify existing bans		✓	✓	

	Lack of clarity on the appropriateness and applicability of safeguard measures under the Directive and emergency measures under the Regulation	Clearer guidance on the application of the Regulation's emergency measure and the Directive's safeguard clause, specifically the contexts within which each is appropriate, and how their application is affected if a product is notified either under the Regulation or Directive	✓			
Practical risk management	Content of PMEM plans suffers from poor quality and availability of data. Lack of clear definition of protection goals and baselines.	Better define baselines to underpin a scientifically sound monitoring approach	✓		✓	
		Explore potential indicators for baseline data.		✓		
		Encourage the scientific community to engage in research, development and education associated with the data required for PMEM plans	✓			
		Determine trigger values for the selected indicators for protection goals that lead to management action.		✓	✓	
	Data access and availability is not harmonised or standardised across MSs. Need for greater harmonisation and standardisation of data access and analysis	Develop a common exchange format for environmental data.		✓		
		Identify methods and systems for harmonising data access and analysis.	✓		✓	
		Explore the benefits of undertaking measures for greater harmonisation and standardisation of data access and analysis.	✓		✓	
		Consider novel ways to enable better access to non-documented knowledge (e.g. farmer experience)			✓	
	Need for better guidelines for monitoring and reporting for MS authorities and notifiers. Current monitoring guidelines are unspecific and gives 'too much' room for interpretation, e.g. between CS and GS	Risk managers should consider strategies to manage uncertainties arising from field trial monitoring data and from existing ERAs	✓		✓	
		The new monitoring guidelines, issued as part of EFSA's revised ERA guidelines, should be more specific and less subject to interpretation.		✓		
		Guidelines covering general surveillance beyond the cultivation area and beyond the 10 years time limit of the		✓		

		consent				
		More resources for mechanisms for scientific analysis of reporting data.	✓		✓	
	Availability and quality of existing surveillance networks is inadequate for the purposes for general surveillance. Need for new forms of surveillance systems given the excessive reliance on farm questionnaires. Lack harmonization of national surveillance and data exchange systems	Reasons for the limited number of GM-related surveillance networks should be explored in more detail	✓			
		MSs with experience of GMO cultivation should be encouraged to play a greater role in improving or creating new networks			✓	
		Notifiers and the Commission should cooperate with these national networks and to help ensure that the data from these networks are adequate to address monitoring requirements	✓			✓
		More creative approaches should be used for general surveillance			✓	✓
		Knowledge/know-how transfer should be improved	✓		✓	✓
	Lack of information from monitoring programmes for risk managers to use in making decisions and developing appropriate risk strategies.	Outcomes of the monitoring programme should provide feedback to the regulatory processes and policies that support the development and implementation of sustainable RM agro-environmental practices and risk strategies	✓		✓	
		Dialogue between all actors and scientists/notifiers should be improved	✓			✓
		The Commission and Member States should ensure that monitoring networks are up and running in good time if and when positive decisions on cultivation emerge	✓		✓	
	Inspectorates do not always provide the inspection reports to the Competent Authority	Member States should encourage inspectorates to make the reports more widely available			✓	
RISK COMMUNICATION						
	Variation in information provided to the public	Promote risk communication practices in all MSs characterised by high levels of openness and transparency	✓		✓	

	Low levels of public engagement	Launch a communication campaign	✓			
		Better explain the processes on which the legislative framework is based	✓			
		Facilitate easier access to information	✓	✓	✓	
		Consolidate information for a clearer message	✓	✓	✓	
	Uncertainty over the impact of public engagement	Exchange of experience on risk communication and public consultation		✓	✓	
OTHER ISSUES						
Confidentiality	A lack of consistent outcomes in the application of existing confidentiality provisions	Adopt uniform rules of disclosure to improve balance between the need for transparency and confidentiality	✓		✓	
	Differences between the provisions for confidentiality in the Directive and the Regulation	Address the differences between the Directive and the Regulation on confidentiality	✓		✓	
Zero-tolerance policy	Lack of harmonisation of controls relating to the presence of non-EU authorised GMOs in seed lots	No change at this time, given the higher level priorities for reform in the system and limited economic impact to date				
		Harmonisation of controls based on adoption of common protocols for sampling, testing and reporting of results for unauthorised GMOs in seed lots (similar to the technical solution proposed for LLP- low level presence in feed).	✓		✓	

Note: EC = European Commission, EFSA = European Food Safety Authority, MS = Member States, N = Notifiers.

APPENDIX A

This appendix is bound as a separate document.

APPENDIX B INSTITUTIONAL DECISION-MAKING

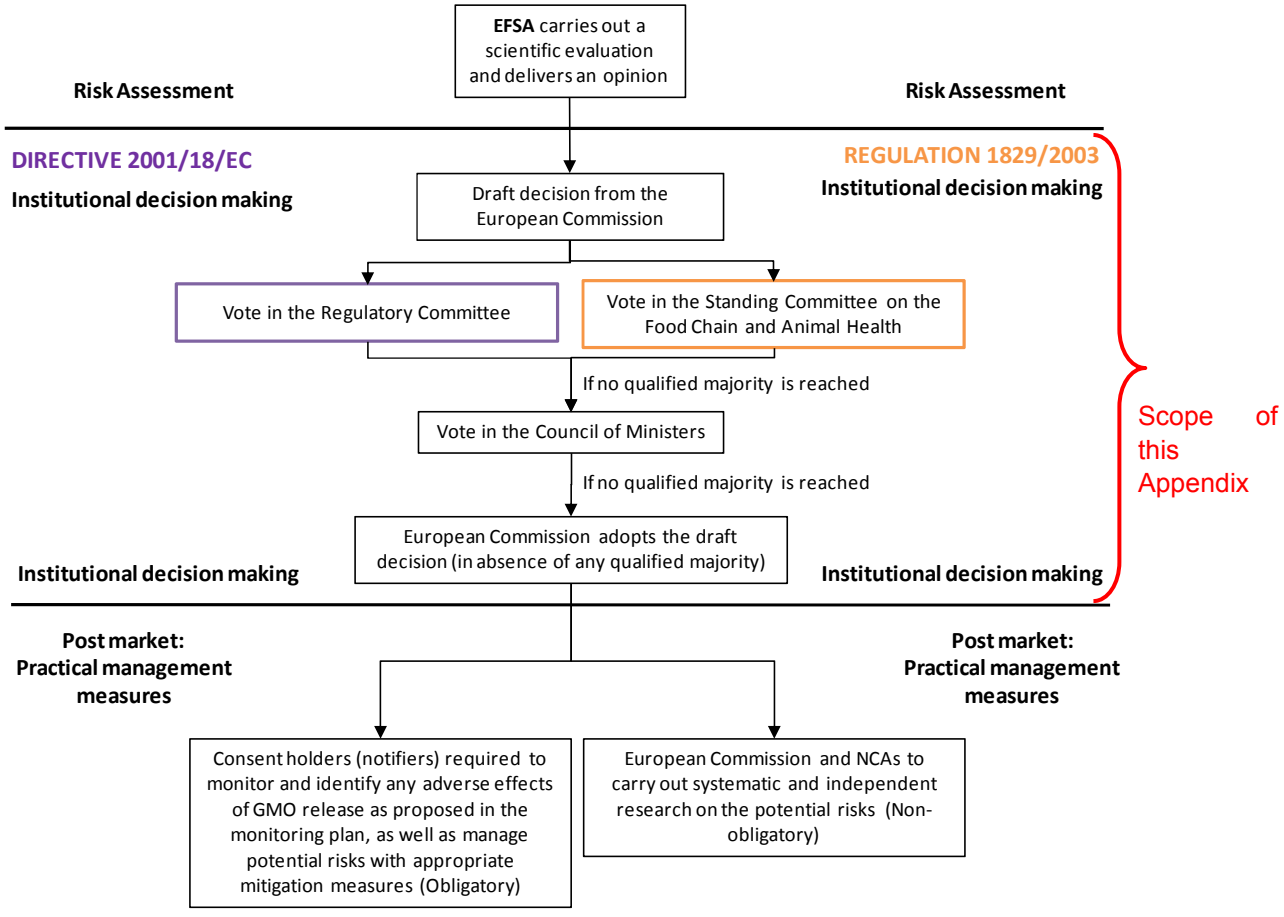
B1 Introduction

B1.1 This appendix focuses on the institutional decision-making component of the risk management procedures

The purpose of this appendix to the final report is to consider options for changing the procedures governing institutional decision-making arrangements on authorisations of GMOs for cultivation. It supplements the discussion in chapter 7 which covers other aspects of the procedures that follow the risk assessment, and the interface between risk assessment and risk management. The scope of this Appendix in the context of the authorisation process is shown graphically in Figure B.1.

The final report on the evaluation was finalised in May 2010. This appendix was drafted in November 2010. This places it some months after the release (in July 2010) by the Commission of proposals for changes to the legislative framework in areas within its scope. The drafting of this text precedes the release by the Commission of a report on socio-economic aspects of GMOs. Whilst the conclusions of that report are not directly linked to the institutional decision-making aspect of the risk management process, the information therein (which will draw on submissions made by Member States to the Commission during 2010) might nonetheless prove useful.

Figure B.1 This appendix considers the decision-making 'machinery' that sits between the release of EFSA's final Opinion and the post-approval activation of risk management measures



Source: GHK Consulting Ltd.

B1.2 Evidence shows that the institutional decision-making aspects of the legislative framework are not functioning as had been anticipated when it was adopted

This evaluation was asked to consider whether the risk management aspects of the framework as implemented are efficient, transparent or, in aggregate, fit for purpose. On current evidence, the conclusion must be that the institutional decision-making aspects of the framework are not.

When the Commission has put forward a draft Decision on cultivation to a vote, Member States have been unable to reach a qualified majority (the same situation applies for all other uses, although there have been slightly more votes in favour in those cases). The lack of qualified majority is mainly attributed to the polarised views within and among Member States and a significant number of abstentions. For instance, in the case of 1507 and Bt11 maize, Member States' votes on cultivation were split roughly equally between those who were in favour, those against and those who abstained. Similar patterns applied for the Amflora potato,.

Also, the Commission has chosen not to issue a final Decision itself (though a decision on the Amflora potato was issued in March 2010) or to proceed with proposals to the Council where the votes were inconclusive (in the case of maize varieties 1507 and Bt-11[103]). Under the current legislative framework there have been five GMOs for which the scientific Opinion from the rapporteur Member State, and then EFSA, has contained a favourable assessment and a proposal for authorisation for cultivation then made[104]. Yet only the potato has progressed to EU authorisation. Applications are lodged in the system for long periods without a final decision being made. There is uncertainty and a lack of clarity over timetables.

Also, and despite favourable risk assessment opinions being delivered by the lead national authorities carrying out the initial risk assessment and by EFSA, seven Member States have chosen to prohibit or restrict the cultivation of individual authorised GMOs on their territories through safeguard measures[105] or through general prohibitions of GM seeds[106]. In all cases, EFSA has concluded through a scientific assessment that these measures were not based on new or additional scientific information that has arisen since authorisations were granted and therefore such measures were not legally justified. Nonetheless, the Council has consistently rejected by qualified majority all Commission proposals to repeal these national safeguard measures[107].

The analysis of the use of national safeguard measures provided in section 7.1.3 of the main report concluded that there is evidence that national safeguard measures are not being used as intended. The analysis found that it would be practically difficult to outright reject national safeguard measures as politically - and not scientifically – motivated

[103] This report text reflects the situation as of 15 March 2010.

[104] 1507 maize, Bt11 maize, Amflora (EH92-527-1) potato, NK603 maize and MON810 maize

[105] Maize MON 810 has been prohibited by AT, HU and LU on the basis of Article 23 of Directive 2001/18/EC, EL on the basis of Article 23 of Directive 2001/18/EC and Article 18 of Directive 2002/53/EC, FR and DE on the basis of Article 23 of Directive 2001/18/EC and Article 34 of Regulation (EC) No1829/2003. Maize T 25 has been prohibited by AT on the basis of Article 23 of Directive 2001/18/EC. Amflora Potato has been banned by AT, HU and LU on the basis of Article 23 of Directive 2001/18/EC.

[106] PL has also adopted a legislation prohibiting in general the marketing of GM seeds which was not based on the safeguard clauses set out in EU legislation. On 16 July 2009 the Court of Justice of the EU issued a judgement whereby it considered that legislation contrary to EU law and condemned Poland for failure to fulfil its obligations (case C-165/08).

[107] Namely in June 2005, December 2006, February 2007 and March 2009

(dossiers containing scientific evidence should be provided with each of the national measures notified to the Commission). The main report concludes that the solution to this problem does not lie in amendment to the safeguard measures but instead in changes to the way in which the rest of the authorisation process is specified and operates.

It is clear that there would be a benefit to resolving the underlying issues that are causing the problems observed in the implementation of the legislation framework, both before and after an authorisation decision is made. The challenge is to find ways to improve the efficiency and transparency of the risk management process through changes that will be supported by Member States, and other partners and stakeholders. This appendix considers the strengths and weaknesses of various possible elements of that way forward. It draws on the consultations carried out for the evaluation, documents, data and analysis by GHK and the rest of the evaluation team.

B1.3 Reform of 'upstream' processes could be helpful, but is unlikely to be sufficient to remove the blockages in the decision-making process

The current situation is, in some part, a consequence of differences of perspective not being resolved by the 'upstream' processes and then becoming manifest at the point of final decision. Addressing those upstream risk assessment issues (as discussed in chapter 5 of the main report) ought to help improve the system, but is unlikely to be sufficient to remove all the blockages which impede the smooth operation of the decision-making process.

The potential for more radical changes to the scope, basis and location of decisions on cultivation to resolve the problem should be considered

Consultees agreed that the current situation with GMO authorisations in Europe is not sustainable[108]. Industry consultees, frustrated by the applications being stalled for long periods, called for the law governing authorisation decisions to be implemented in full. The system was designed so that a decision would be taken by Member States, either at the Committee or Council level. The law provides for a final Decision to be made by the Commission each time a qualified majority vote is not achieved but it was not foreseen that this would be a regular occurrence. In that context, the routine use of such Decisions by the Commission to keep the authorisation machinery moving is not a desirable or sustainable long term solution.

Yet analysis of voting patterns suggests that, unless well-entrenched attitudes in many Member States were to change quite substantially (and there are no indications that they will do so), it is unlikely that a qualified majority will be achieved, whether for or against, in a vote on the authorisation of a GMO that has received a final scientific Opinion from EFSA considering it to be safe. In addition, experience suggests that some Member States might trigger the safeguard clause to ban the cultivation of EU-authorised GMOs and that these safeguard clauses, although temporary in principle, would become permanent due to the rejection by the Council of the Commission's proposals to repeal the measures.

With no end to the deadlock in sight, there is reason to look to options for reforming the decision making process. Within this particular stage of the overall legislative framework there is, in principle, scope for flexibility in two aspects of the process:

- The decisions that are made at (i) EU level and (ii) Member State level; and
- The criteria that can be used in making those decisions, and their relative weight.

[108] For more detailed information on the current implementation of the institutional decision-making process, see Section 6.2 of the Interim Report.

The remainder of this appendix considers options that address one or both of those dimensions of the decision. It discusses the proposals made by certain Member States in 2009 and the European Commission in July 2010, and the ideas within them. It then examines other possible options for change.

B2.1 Some Member States and the Commission have suggested that the system would be improved if greater freedom and flexibility was given to Member States on GMO cultivation decisions, within the framework of a common EU assessment of safety

In 2009 certain Member States made proposals intended to address current problems in the approval processes for cultivation of GMOs within the EU by changing the existing approval system. The proposals only relate to the cultivation of GMOs, and not to their use for food or feed. Specifically they have proposed giving greater freedom to individual Member States to exercise choice about cultivation, within a common EU framework defined by a science-based safety assessment.

A proposal submitted by the Netherlands in March 2009 to the Environment Council and Agriculture Council suggested that, once a GMO has been given a favourable scientific Opinion on its safety at the EU level (first by the lead national Competent Authority and subsequently by EFSA) and as a consequence authorised at EU level, MSs should be able to decide on a national level whether or not to cultivate a GMO on the basis of socio-economic criteria.

In June 2009, Austria, supported by other Member States[109], submitted a paper[110] 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. The proposals suggested that once a GMO has been given a favourable scientific Opinion by EFSA on its safety, and if a decision is proposed by the Commission to authorise its cultivation as a result, MSs should be able to decide on a national level whether or not to cultivate it. MSs who oppose the cultivation of GMOs in their own territory could thereby protect their interest without having to, in effect, veto the rights of others within the EU to do so. If the analysis elsewhere in this report is correct, such a change is likely to reduce the use of safeguard or emergency measures.

According to the Austrian proposals the EU-wide safety assessment would continue to be based on a scientific appraisal of risk. Providing the MSs with the right to opt-out would focus the EU legislative framework on authorising the placing of GMOs on the market on an EU level, leaving MSs with the option of choosing to cultivate or not on a national level.

Their strategic objective – of accommodating Member States' different concerns more explicitly in the authorisation process and thus 'unblocking' the decision-making process - received high level endorsement within the Commission. Using GMOs as an example in his political guidelines for the new Commission[111], Commission President, José Manuel Barroso highlighted the need for subsidiarity to be applied more effectively in order to adequately account for the diversity in an EU with 27 Member States. He noted that "*it should be possible to combine a Community authorisation system, based on science, with*

[109] 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 (as noted in the proposal: http://register.consilium.europa.eu/pdf/en/09/st11/st11226-re02.en09.pdf)

[110] http://register.consilium.europa.eu/pdf/en/09/st11/st11226-re02.en09.pdf

[111] Available from: http://ec.europa.eu/commission_barroso/president/pdf/press_20090903_EN.pdf

freedom for Member States to decide whether or not they wish to cultivate GM crops on their territory"[112].

In March 2010 it was announced that, Health and Consumer Policy Commissioner John Dalli had been, "*asked to come forward with a proposal by summer 2010 setting out how a Community authorisation system, based on science, can be combined with freedom for Member States to decide whether or not they wish to cultivate GM crops on their territory*"[113].

In July 2010 the Commission released a package of proposals which responded to that request, with measures which would provide Member States with the right to opt out of cultivation of a centrally approved GMO and also greater freedom in the definition of national co-existence measures.

Specifically, the proposals provide Member States with a legal basis for prohibiting the cultivation of any and all GMOs authorised for cultivation under the Directive 2001/18/EC or the Regulation (EC) 1829/2003 in their territory. The proposals relate only to cultivation and do not, for instance, give Member States freedom to adopt measures prohibiting the import and/or the marketing in the EU of authorised GM seeds.

The package does not propose a new common assessment of factors other than the health and environmental risk assessment to be undertaken at EU level, or by all Member States, on individual GMOs as part of the authorisation process. Instead, individual Member States would be given the freedom to elect to opt out (on a general or specific basis) if they are able to provide legitimate grounds for doing so. Exactly what those grounds might be is currently the subject of discussion through the co-decision process. The grounds on which an individual Member State might decide to exercise an opt-out are not specified.

The Commission's July package did not comment on the potential place of socio-economic criteria (however defined) as grounds for an opt-out. However, during the stakeholder consultation conducted for this evaluation in 2009, consultees commented on the potential use of socio-economic criteria in the process for assessing whether a GMO should be authorised for cultivation, and the merits and drawbacks of doing so. Section B3.2 of this appendix discusses the use of socio-economic factors in some detail, considering both issues of principle and practicality.

What would not be legitimate grounds for an opt-out is clearer. According to the proposals, Member States that wish to exercise an opt-out would need to base the decision on grounds other than those covered by the health and environmental risk assessment conducted at the EU level during the authorisation process. A number of additional constraints are imposed by the wider legal framework. The Member States' decision must, for instance, be consistent with the general principles of the Treaties and the Single Market, as well as the international obligations of the EU.

A more detailed summary of the Commission's proposals is provided below in Box B.1.

[112] *Political guidelines for the next Commission*. José Manuel Barroso. September 2009.

[113] European Commission press release IP/10/222, , available online at http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/222

Box B.1 - The Commission's July 2010 Package

On 13 July, 2010, the Commission proposed a new, amended approach to the current system by which GMOs are authorised for cultivation. Whilst the current scientific risk assessment at the EU level will be maintained, this will be supplemented with greater flexibility for Member States to decide on the cultivation of GMOs at the national level. The proposals do not allow Member States to adopt measures prohibiting the import and/or the marketing in the EU of authorised GM seeds.

The new approach attempts to address the request of 13 Member States made in June 2009, asking the Commission to prepare a more flexible approach to GMO cultivation. It recognises the need for Member States to be able to take into account their local, regional and national conditions on GMO cultivation.

The proposal has three parts:

- A Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on the freedom for Member States to decide on the cultivation of genetically modified crops[114]: Introduces and explains the more flexible approach and the proposed amendment.

- A proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory[115]: The proposal maintains the current EU-level authorisation system. It proposes the inclusion of a new Article (26b). The introduced Article 26b would establish a new legal basis for Member States to prohibit the cultivation of any and all GMOs authorised for cultivation under the Directive 2001/18/EC or the Regulation(EC)1829/2003 in their territory. Member States may use any grounds to do so, other than those covered by the health and environmental risk assessment during the EU level authorisation process. Thus Member States will no longer need to use the safeguard clauses under the two legislative frameworks to restrict the cultivation of GMOs on their territory. Their decision will not need to be authorised by the Commission, but other Member States and the Commission will have to be informed one month prior to adoption of any measures. Measures adopted by Member States have to respect the general principles of the Treaties and the Single Market, and be consistent with the international obligations of the EU.

- A Commission Recommendation on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops[116]: Replaces the previous Recommendation of 2003 and better reflects the possibility provided in the existing legislation (Article 26a of Directive 2001/18/EC) for Member States to adopt measures to avoid the unintended presence of GMOs in conventional and organic crops. It gives Member States more flexibility for defining co-existence measures. In particular, it provides for measures to be introduced which aim at levels of unintended GMO presence that are lower than the 0.9% labelling threshold of the EU legislation. The previous Recommendation directly linked the use of coexistence measures to the 0.9% labelling

[114] European Commission (July, 2010). Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on the freedom for Member States to decide on the cultivation of genetically modified crops. COM(2010) 380 final. Available from: http://ec.europa.eu/food/food/biotechnology/docs/communication_en.pdf

[115] European Commission (July, 2010). Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory. COM(2010) 375 final. Available from: http://ec.europa.eu/food/food/biotechnology/docs/proposal_en.pdf

[116] European Commission (July, 2010). Recommendation on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops. Official Journal of the European Union C 200/1. Available from: http://ecob.jrc.ec.europa.eu/documents/CoexRecommendation.pdf

threshold; Member States were advised to limit their measures to compliance with that threshold. When such measures are not sufficient to prevent the unintended presence of GMOs in conventional or organic crops, Member States can now explicitly also restrict GMO cultivation in large areas of their territory, by creating 'GM-free areas'. The recommendation is based on the recognition that the unintended presence of GMOs in other crops has specific implications for some producers, such as organic farmers, and potentially the final consumer.

The new Recommendation on co-existence is non-binding and immediately came into effect, replacing the previous recommendation. The proposal for revising Directive 2001/18/EC is subject to co-decision, and will need to be approved by both the European Parliament and the Council before entering into force.

The new approach essentially places responsibility for the cultivation of GMOs within the exclusive competence of Member States.

Sources:

Europa Press Release (2010) Questions and Answers on the EU's new approach to the cultivation of GMOs. Available from: http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/10/325

Europa Press Release (2010) GMOs: Member States to be given full responsibility on cultivation in their territories.
Available from: http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/921

Reuters (2010). EU move to break GM deadlock could sow discord.
Available from: http://in.reuters.com/article/idINIndia-49750020100629

B2.2 These proposals offer a more flexible but also more complex system for cultivation approvals

The Dutch, Austrian and Commission proposals:

- Do not touch the current centralised process for assessing safety (but leave it open to further improvement, as suggested elsewhere in this report);
- Imply that a GMO with central authorisation could be placed on the European market and thus sold, traded and transported anywhere within the EU, but the authorisation of that final step of planting it, and so triggering the impacts of cultivation, may be withheld on a Member State-by-Member State basis (on grounds other than those covered by the health and environmental risk assessment).
- Mean that Member States can vote on the collective choice (i.e. the authorisation decision under the EU legislative framework) in the knowledge that if they have concerns related to aspects other than those covered by the health and environmental risk assessment related to all or parts of their territory, they have the option of managing them through unilateral action and not just by voting against its authorisation for the EU as a whole;
- Create a more complex regulatory environment for notifiers and for those who oppose GMOs to navigate by introducing the possibility of a set of new decisions relevant to cultivation authorisation taking place within Member States in addition to Member States' collective decision at EU level.

There are significant differences in the detail of the proposals. The various components – Member State opt-outs, more explicit consideration of socio-economic criteria, etc. - are explored in more detail below, with discussion of the impacts of alternative strategies.

B2.3 Providing for Member State opt-outs would be a significant departure from the current model

At present the key decisions on GMO cultivation are taken collectively by EU Member States. Under the law, Member States have flexibility, within limits, to set national measures on co-existence and through varietal registration requirements, but the authorisation process is centralised and one Decision provides authorisation for cultivation across the whole of the EU. In practice, the use of national safeguard measures has introduced variation within the EU in farmers' freedom to plant GM crops that have been authorised at EU level.

Providing for Member State opt-outs within the EU legislative framework would radically change the model. The opt-out is a facility which enables a Member State to exclude itself from an EU cultivation authorisation providing it can supply legitimate grounds to do so on a basis other than the health and environmental risk assessment – either for the country as a whole or by designating areas or regions to be excluded.

At present the Directive and Regulation do not explicitly exclude such regional qualifications but nor do they explicitly provide for them. The Commission may submit decisions under general Comitology rules to restrict the scope of decisions. Austria proposed that the amendments could be based on the subsidiarity principle (Article 5 TUE) and the principle of unanimity for decisions on land use (Article 192 TFUE), meaning that the opt out clause could "easily" be integrated into the existing legislation. The Lisbon Treaty "puts in place new procedures to allow national parliaments to intervene if they have concerns about subsidiarity".[117]

Feedback from consultees on providing Member States with national self-determination on cultivation (within a framework of shared safety assessment) is discussed at length in the interim report to this evaluation[118]. On the specific issue of self-determination proposals, the Member State authorities consulted for this study were, overall, more positive than other consultees. Most MSs were positive and believed that the 'opt-out' proposal could, with accompanying measures, potentially alleviate the current indecision and unpredictability of the GMO framework. Neither industry nor environmental NGOs were particularly enthusiastic about the idea of MS-specific cultivation approvals, albeit for different reasons (industry being concerned about additional cost and complexity, and new barriers to the Single Market; the NGOs being concerned about the direct and indirect effects of 'opening the door' to GMO cultivation in some Member States). For instance, there was a perception amongst notifiers that costs would arise from a need to expend additional time and resources tracking national decision-making processes and also (possibly) assembling and providing additional information that might be required by those processes. These non-MS consultees expressed some scepticism that the reforms, if realised, would achieve the intended aims.

Implications at Member State level

For Member States the practical considerations of the opt-out include:

- The decision-making model to be adopted;
- The legal basis for any decisions on national opt-out;

[117] Political Guidelines for the next Commission, J.M. Barroso. Available from: http://ec.europa.eu/commission_barroso/president/pdf/press_20090903_EN.pdf

[118] See Section 6.2.3 – 6.2.5 of the Interim Report

On the former, there would seem to be two alternative options for each Member State:

- Codifying **a general presumption against GMO cultivation** – at a national or sub-national level – in a decision that could, for instance, recognise GMO-free regions or zones;
- Adopting **a case-by-case approach** in which the merits of individual GMOs were determined individually

A priori, one would expect countries with a strong domestic consensus against cultivation of GMOs to adopt the former strategy. Member States that wanted to retain the right to exercise an opt-out selectively where necessary would be expected to adopt the second strategy. The former is likely to be less administratively burdensome, the latter to provide more flexibility.

The scale of the implementation issues at Member State level would depend on the means by which the 'national choice' was made and given a legal basis. For example, if a new law was required to codify the system by which the national government would conduct its case-by-case assessment, then there could be a significant delay while that system was researched, developed, drafted, consulted upon, subjected to due parliamentary process and ultimately brought into effect.

Where a case-by-case approach is adopted, the basis of choice, and associated evidence, would need to be considered. This issue is discussed below.

If Member States have freedom to opt-out of cultivation of centrally authorised GMOs one can anticipate some of the debate on the issues, and some of the associated pressure, move from comparatively 'remote' procedures in Brussels into Member States' domestic political arenas, with impacts for governments, industry and others .

Implications at EU level

The Member State opt-out is of interest in this evaluation to the extent that it facilitates a more efficient, transparent and effective EU decision-making machinery. An opt-out design that obstructs that EU level process has little value.

Mechanisms for recognising opt-outs in the EU decision-making process could potentially include:

i. Member States voting on a draft decision by the Commission for authorisation of use, as now, but for this authorisation to explicitly allow the exclusion of certain MSs (or their regions), where these have given prior notification of the desire to opt-out from cultivation in part (i.e. some regions) or in full;

ii. Retrospective qualification of the EU Decision by Member State opt-outs, presumably recorded by the European Commission on a central register recognised in the legislation.

iii. A fully flexible approach in which a Member State could notify the Commission of its decision to opt out at any time in the progress of the GMO through the authorisation process (and post-approval).

A potential problem with option (i) is that a final EU Decision would need to be delayed until 27 Member State processes had been completed, and notified to Brussels. As noted in an independent discussion paper produced on this topic[119], it is reasonable to expect that

[119] A Way Forward for GMOs in Europe? Chatham House, 2009. Energy, Environment and Development Programme Paper: 09/03. www.chathamhouse.org.uk/files/15278_1109gm_europe.pdf

Member States would vary in the speed of their response. Those Member States that have made strategic choices not to accept GMO cultivation without reservation, might be expected to respond more quickly than Member States that wanted to review each GMO on a case-by-case basis. In the latter cases the complexity and timescale of the national process would determine the rate at which opt-out decisions could be notified.

The issue with option (ii) is that a new means of retrospective recognition of Member State decisions, once notified, would need to be devised and incorporated into the legislation. And, without the pressure of an EU decision to force the pace, it could be imagined that the pan-EU process could be drawn out, prolonging the uncertainty for notifiers.

Option (iii) provides the most flexibility. The Commission's July 2010 proposals are closest to option (iii).

If they are to work as intended any such provisions made in EU law need to be robust enough to withstand potential challenge – whether from individual companies or from third countries. The Commission's July 2010 proposals suggested new text for amendment to Article 26 of the Directive. In consultations, other implementing options mentioned included making more detailed use of specific parts of the Directive 2001/18/EC and Regulation 1829/2003[120] and potentially also Directive 2002/53/EC (the 'Seeds Legislation')[121].

B2.4 Another option is to give greater freedom for such factors to be taken into account in other national measures governing GMO cultivation

Under the current EU authorisation system, it is possible in principle to differentiate between regions in the risk assessment, on the basis of scientific arguments.[122] If the cultivation of a GMO raises particular regional concerns during the scientific risk assessment, these concerns must be addressed in the EU authorisation through specific conditions or risk management measures. Such measures may include restriction or prohibition measures. They must, however, be scientifically justified.

A further option for reform of present arrangements would be for the EU to allow Member States greater freedom to use non-scientific factors in setting national rules and regulations that affect GMO cultivation. Examples might include:

- The adoption of co-existence measures that provide more flexibility than those introduced under the previous guidelines (Recommendation 2003/556/EC) as a result of a Member State deciding to protect other production chains;
- Making more use of opportunities provided by the legislation to define 'GMO-free' areas.

Proposals of this kind are included in the Commission's July 2010 package, as explained in Box B.1. In the new Recommendation on co-existence, for instance, relaxes some of the previous constraints on the conditions under which GM-free areas can be established.

In line with Article 26a of the Directive, Member States are able to take appropriate measures to avoid the unintended presence of GMOs in other products. Such national

[120] Specifically Article 19, sub-para 3 sub-para c of the Directive and the corresponding provision 6 of the Regulation, which allow for authorisations to include measures for protection of ecosystems, geographical areas and different environments.

[121] Specially, Article 16 which provides grounds to exclude cultivation on the basis of agronomic reasons, climatic conditions, health or environmental factors.

[122] In line with Article 19(3)(c) and Annex II of Directive 2001/18/EC and Article 6 and Article 18 of Regulation (EC) No 1829/2003.

measures are meant to avoid the potential economic impact of the admixture of GM and non-GM crops (conventional and organic). The new guidelines for the development of national co-existence measures better reflects the possibilities provided in the existing legislation (Article 26a of Directive 2001/18/EC) for adopting such national measures.

The new Recommendation replaces the Commission adopted guidelines under Recommendation 2003/556/EC[123], which highlighted that co-existence management measures should be efficient and cost-effective, without going beyond what is necessary to comply with EU threshold levels for GMO labelling (e.g. 0.9% for the presence of GMOs in food/feed). The new Recommendation recognises that Member States can introduce measures which aim at levels of unintended GMO presence that are lower than the 0.9% labelling threshold of the EU legislation.

Furthermore, if it can be demonstrated that these measures cannot prevent the unintended presence of GMOs in conventional or organic crops, Member States can now explicitly restrict GMO cultivation in large areas of their territory, by creating 'GM-free areas'. However, such measures need to be "proportionate to the objective pursued" (namely the protection of conventional or organic farming needs) and Member States must demonstrate that "other measures are not sufficient to prevent the unintended presence of GMOs in conventional or organic crops" in the areas in question.[124]

The previous guidelines had been quite demanding and their implementation has been narrow. The majority of Member States have adopted up-to-date measures to regulate the co-existence of GM with non-GM crops. The Commission has issued 22 opinions on the draft measures notified under the special procedure of Directive 98/34/EC. Those opinions have in several occasions requested Member States to refrain from disproportional, discriminatory or other types of measures in breach of the GMO and EU legislation in general.

Now Member States are explicitly able to extend co-existence measures or establish GM-free areas beyond the restrictions of the previous guidelines. For instance they are allowed to adopt measures ensuring the relative absence of GMOs from other products (and not just to respect the 0.9% labelling threshold).

An advantage of the strategy taken in the new Recommendation is that Member States can use an existing notion (subsidiarity, to avoid the unintended presence of GMOs in other products, as introduced by Article 26a of the Directive) to regulate cultivation as they wish on their territories. Depending on their local economic priorities, they can restrict or prohibit cultivation of GMOs in order to protect the other crops.

The disadvantage of this option could be seen in the possible abolition of the overall notion of "co-existence". With Member States free to establish GM-free areas or adopt very large isolation distances, the very existence of GMOs in several regions (or even in entire MS) might lapse. In those cases there would be no issue of "co-existence" at all, but simply of a GMO ban. However, the requirement that such measures be proportionate and necessary to prevent the unintended presence of GMOs in conventional or organic crops should go some way to limit the risks of this occurring.

[123] Guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming.

[124] European Commission (July, 2010). Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on the freedom for Member States to decide on the cultivation of genetically modified crops. COM(2010) 380 final. Available from: http://ec.europa.eu/food/food/biotechnology/docs/communication_en.pdf

B3 Looking beyond the ideas developed in the July 2010 Package, there are alternative options which could also be considered

The discussion in section 1.2 focused on options and issues which relate reasonably closely to those proposed in the Commission's July 2010 package. This section considers the other options that have been identified through consultations and research. Specifically, it looks at:

- Expanding the scope of the information that can legitimately be used to inform the authorisation decision through more explicit consideration of socio-economic factors, both at Member State and at EU level;
- Alternatives to the elective opt-out suggested by the Commission's July 2010 proposals, i.e.
    - Qualification of the geographic scope of an application by the notifier; and
    - Qualification of geographic scope by the notifier based on Member States' declaration of intent to opt out.

B3.1 There are some provisions in the existing legislation for consideration of 'other legitimate factors' in the decision-making process but they are limited in scope and utility

There are already existing mechanisms in place for socio-economic and ethical concerns, for instance, to be better taken into account at the EU level. However it seems unlikely that the full potential of these mechanisms to address the strategic issues facing the authorisation system will be realised without some effort being invested in the development of information on where and how they could be used.

The provisions for ethical considerations already included in the legislation however, are not meant as factors to be considered while deciding on authorisations[125]; Recital 9 for instance, states that "Member States may take into consideration ethical aspects when GMOs are deliberately released or placed on the market as or in products" whilst Article 29 notes that the Commission should consult with the European Group on Ethics in Science and New Technologies. 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 assessment. Crucially, these restrictions however can only be used in certain cases and cannot be used in a systematic manner as justifications for such restrictions must be specific to each GMO and can only be taken into account at the moment of the adoption of the decision of authorisation of the GMO in question. In addition this possibility does not exist under Directive 2001/18/EC and would thus not be applicable to GMOs authorised under this Directive. In order for such provisions to be regularly or more comprehensively used (rather on a case-by-case approach), the legislative framework would have to be amended.

These existing provisions as they stand therefore do not provide the necessary freedom for Member States to decide whether or not they wish to cultivate GMOs in their territory on the basis of their specific conditions.[126]

[125] 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.

[126] European Commission (July, 2010). Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on the freedom for Member States to decide on the cultivation of genetically modified crops. COM(2010) 380 final. Available from: http://ec.europa.eu/food/food/biotechnology/docs/communication_en.pdf

B3.2 The consultations showed widespread interest among non-industry consultees in the more explicit use of information on socio-economic factors in the decision-making process, though analysis suggests there would be some practical challenges

In consultations carried out for this study there was a general consensus among non-industry consultees on the merits of more explicit consideration of socio-economic factors, not just in terms of the considering the potential drawbacks associated with the cultivation of GMOs, but also to provide a better appreciation of the potential benefits[127]. Some consultees suggested that taking into account not just the risks, but also the benefits, might lead to a more balanced consideration of the potential outcomes of GMO cultivation. The majority of Member State authorities believed that socio-economic concerns should be taken into account when making decisions on the authorisation of GMOs for cultivation.

The Commission's July 2010 proposals would require Member States to base opt-outs on grounds other than those covered by the health and environmental risk assessment but did not explicitly mention socio-economic criteria. The earlier Dutch proposal did suggest the use of socio-economic criteria but did not define 'socio-economic' factors in detail.

The discussion that follows explores the practicalities of a more systematic (and EU-wide) use of socio-economic criteria but many of the points would apply equally well to an elective system in which only a group of self-selected Member States were considering additional factors. It considers issues of:

- Scope/content (i.e. what are considered legitimate socio-economic factors) and
- The level of harmonisation of scope/content:
    - The development of a common EU basket of factors; or
    - Member States' being free to develop their own baskets;
- Procedure and practicality, i.e.
    - Access to data and use of results;
    - The use in devolved or centralised appraisal systems.

In exploring how a socio-economic assessment could be implemented in the EU, existing systems which have already incorporated aspects of these considerations could be examined. Lessons can for instance potentially be learnt from international agreements and other EU and non-EU national legislation which have already established mechanisms for considering socio-economic concerns in the decision making process.

Scope and its harmonisation

Discussions undertaken for this study and elsewhere show that countries could interpret the term 'socio-economic' very broadly, and differently. The basket of socio-economic factors could potentially contain a wide range of issues and impacts[128], including:

- The economic benefit of the GMO to farmers;
- The economic impact on society more generally;
- Public attitudes to GMOs in general, or the GMO in question;
- Ethical considerations;
- 'Sustainability', howsoever defined.

[127] See Section 6.2.4 of the Interim Report

[128] A Way Forward for GMOs in Europe? Chatham House, 2009.

In a scenario in which socio-economic criteria were to be considered by all Member States, agreeing on a common basket (e.g. through Commission guidelines) is unlikely to be straightforward or speedy, but may be preferable to a situation in which each Member State developed its own basket on the basis of national priorities and public opinion. It would take a significant period of time for 27 countries to develop such systems and, where necessary, codify them into national law so that governments' decisions had a legal basis.

In a scenario in which there was consideration of socio-economic factors in an additional exercise that individual Member States could choose to carry out if they wished (and only a small number did so), the additional complexity would be less. Nonetheless, consistency across their 'baskets' could reduce the total additional demand for information on the socio-economic aspects of an individual GMO (whether that information was supplied by the public research base, notifiers or other sources).

At the beginning of 2011 the Commission will submit a report to the European Parliament and to the Council containing an assessment of socio-economic implications of deliberate releases and placing on the market of GMOs. The Commission's information-gathering exercise on socio-economic factors could shed light on Member States' views, although it is not directly related to the suggested reform of the institutional decision making process.

Practicality

Practical issues to be considered include[129]:

- ***Robustness*****:** The future success of a new product in the market, in terms of uptake by farmers, is uncertain. The net economic impact on the farming sector of a given product is generally hard to determine retrospectively and very difficult to project in advance – the assumptions used *in ex ante* projections would be open to legitimate challenge. The industry prefers the current legislation's focus on a science-based risk assessment and authorisation of products deemed safe.
- ***Stability***: There may be issues of the stability of socio-economic evidence over time if, for instance, measures of public opinion were incorporated into the basket as some have suggested. If measures on key indicators change (shifting the composition of the basket), would Member States seek to (or be allowed to) review their opt-out decision?
- ***Reach***: A decision would be needed on whether evidence gathered outside the EU would be admissible as evidence in the socio-economic dossier (e.g. economic impact on farm enterprises cultivating the GMO in North America), and on what terms.

A further practical question is whether:

- the factors are each evaluated on a ***case-by-case basis*** for each GMO as it is presented for authorisation, or
- ***strategic policy guidance*** is set for some, or all, of the factors, such that a case-by-case appraisal is not always required.

There is a risk that the assessments would be characterised by a higher degree of subjectivity than the current science-based appraisals and result in decisions becoming arbitrary, it being more difficult to have a consensus on a socio-economic evaluation than the current risk evaluation.

[129] See Chatham House, ibid.

Procedures

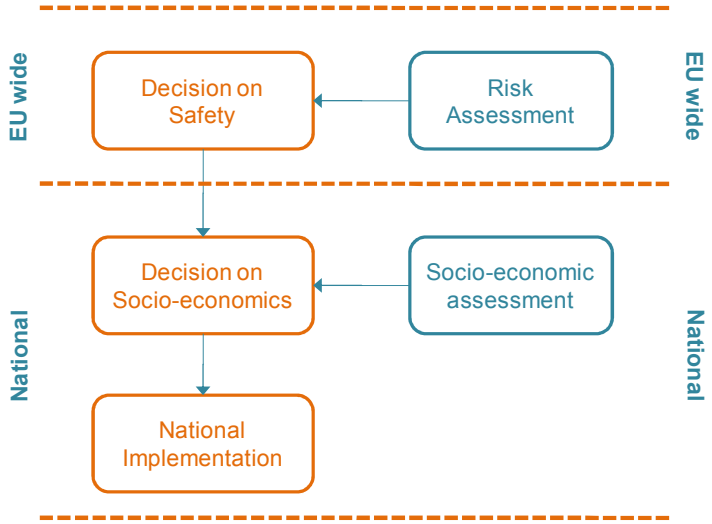
A socio-economic assessment could be done:

- either at the national level or at EU level; and
- once a GMO has been authorised for cultivation on the basis of the safety risk assessment or while a GMO is being authorised for cultivation on the basis of the safety risk assessment.

National level consideration of socio-economic factors

In principle, a socio-economic assessment could be done at the MS level, once a GMO has been authorised at the EU level on the basis of a safety risk assessment. A simplified illustration of this system is shown in Figure B.2.

Figure B.2 Diagrammatic representation of a socio-economic evaluation being conducted at national level



Source: GHK Consulting Ltd.

This option mirrors the proposal which was submitted by the Netherlands, which suggested that the opt-out and socio-economic proposals could be combined but would take place at different levels, such that when a MS decides whether to allow the cultivation of a GMO or not, they can explicitly and officially consider socio-economic concerns as well as safety issues when making the decision. Thus, the technical scientific assessment would remain at the EU level and would not be explicitly framed by socio-economic considerations, which would be managed 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 have a national position against authorising a GMO for cultivation on a socio-economic basis at a national level.

Some examples of the inclusion of socio-economic considerations in decision-making at the national level include:

- Under the Norwegian Gene Technology Act (GTA), release of GMOs is only allowed when there is no risk or adverse effect on health and environment[130]. The possible benefit to society and likeliness that it promotes sustainable development are also given considerable weight. When the GTA procedure was applied to a genetically

[130] For more information, see for example: http://www.utviklingsfondet.no/filestore/Casper_Linnestad.pdf

modified carnation it became clear that this broad and dual assessment approach was a very complex process. The working group looking at this policy framework concluded that there was insufficient documentation to assess the full scope of the criteria and that additional research and data was needed.

- The High Council for Biotechnology (HCB) in France, established in April 2009, has a unique dual assessment structure; one committee is tasked with assessing the scientific elements of an application, whilst a second committee focuses on the economic, social and ethical issues[131]. The system will also need to accommodate sub-national views where devolved administrations may take different views on GM cultivation than the national government. The system has not yet been used very often, having only been established in April 2009. However, it did recently deliver an opinion on Bt11 maize in April of 2010, following a request by the French food safety agency (the AFSSA). The HCB found that the cultivation of Bt11 is acceptable so long as monitoring plans on the impact of human health and the environment are rigorously established.[132] As experience with the HCB grows, it could prove a useful, intra-European testbed for exploring the practical implications of formally accommodating non-scientific factors.
- The Committee on Genetic Modification (COGEM) of the Netherlands has a committee that examines the ethical and societal aspects of genetic modification. However, papers delivered by this committee lack any advisory status in the same legal manner as the advice of the technical committees. Nonetheless, the outputs of this committee are used by the Competent Authority for further policy development. An example is the paper on socio economic aspects of GM crops that was released in October 2009.[133]

It is unclear whether introducing elements of any of the above examples into the EU authorisation system would be possible under the existing legislative framework, or whether they would require amendments to be made to the legislation.

EU level consideration of socio-economic factors

Some consultees suggested that more 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.

Several consultees who were interviewed 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 B.3 below).

In practical terms a single system would be more workable than the operation of a number of different decision-making systems around the EU, each with its own data requirements and administrative processes. The latter could potentially create a significant and costly

[131] USDA GAIN Report (2009). EU-27 Agricultural Biotechnology Annual

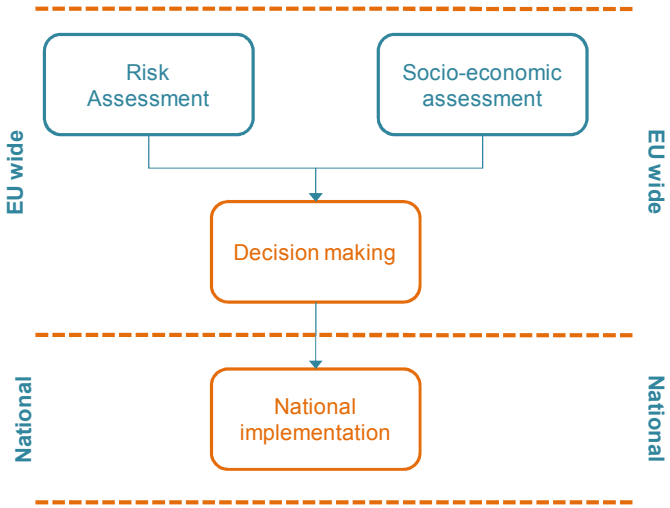
[132] Haut Conseil Des Biotechnologies. Comite Scientifique. Paris, le 16 avril 2010. Avis en réponse à la saisine1 100118-saisine HCB- dossier Bt11 culture concernant la partie « culture » du dossier C/F/96/05.10; Haut Conseil Des Biotechnologies. Comite Economique, Ethique et Social. Paris, le 16 avril 2010. Recommandation en réponse à la saisine 100118 - saisine HCB - dossier Bt11 culture concernant la partie « culture » du dossier n°C/F/96/05.10

[133] Available from: http://www.cogem.net/main-adviesdetail-signaleringEN.aspx?pageid=54&loc=2&version=&mode=&id=517

new barrier to GMO authorisation. It is not difficult to imagine that companies, if it was notifiers who were responsible for compiling the socio-economic analysis, would not develop dossiers for smaller countries – potentially impacting on the Single Market, and leaving countries unable to activate their decision-making systems. The scale of such impacts would also depend on various other factors, such as if and how the socio-economic assessment interfaced with Member State opt-outs.

Examples of the practical issues associated with using socio-economic evidence to inform such decisions has been discussed above, and would apply equally to EU-level deliberations as well as those by Member States.

Figure B.3 One option is to include an evaluation of the socio-economic impacts of cultivating a GMO at the EU level



Source: GHK Consulting Ltd.

B3.2 In principle, a system which allowed notifiers to qualify the geographical scope of their applications for cultivation authorisations might mimic some of the effects of a system of Member State opt-outs

Selective applications by the notifier

In this option the notifier would restrict its application for authorisation of a GMO for cultivation to named Member States. The scope of the environmental risk assessment would be more focused on the environmental context of those Member States. The final decision would be restricted to authorisation of cultivation in the named Member States.

Currently, the EU GMO legislation on cultivation provides approval for cultivation across Europe. However, even with full approval, a notifier might expect to seek cultivation in only a subset of Member States because of market, environmental and agricultural conditions. A potential alternative to the Member State opt-out would be to allow notifiers to apply for cultivation authorisation only in named Member States.

The food and feed safety assessment and the environmental risk assessment would remain at the EU level in order to ensure the free movement of such goods between the Member States (this distinction is also reflected the proposals made by the Commission in July). As noted above, the Directive and Regulation do not exclude qualifications of geographical scope but nor do they explicitly provide for them. The Commission may submit decisions under general Comitology rules to restrict the scope of decisions in line with the application.

This option could simplify the ERA process – currently EFSA's risk assessment must consider the regional variability of agro-ecosystems across the whole of the EU. This has been a key issue of contention with MSs, with the majority believing that the consideration to date of regional variability in the risk assessment process has been inadequate[134]. By providing for a more selective process, it is possible that this option could improve the transparency and efficiency of the current system.

Implicit in this option is the proposition that notifiers could anticipate which Member States would accept cultivation (subject, of course, to due process and a positive Opinion from the safety assessment). There is, clearly, a risk for the notifier that the *a priori* view of a Member State government might change for non-scientific reasons between its pre-application discussions with the notifier and the final decision. Even in the event of a positive Opinion from the risk assessment appraisal this could result in a negative vote from the Member State concerned.

If this system was taken forward for further consideration there are points about the rules and logic of voting on applications that are restricted in scope which would warrant more detailed discussion as application of 'standard' voting rules might create some 'difficult' situations. For instance, would Member States want voting to be restricted to those countries that fell within the scope of the application (perhaps with others abstaining)? Would authorisation for each of the Member States named in the application be contingent upon a positive vote by each of the corresponding Member State governments? If so, this would result in what would be, *de facto,* a national authorisation decision being made by the national government but within the context of a vote of EU Member States. If not, a vote could (theoretically) see a Member State voting in favour of cultivation in another Member State, when that second Member State votes against authorisation for cultivation within its own territory.

The system would also (presumably) have to be open to review of the authorisation decision to accommodate:

- extensions of the authorisation to new countries (e.g. because of changes in market conditions, or if another country joins the EU);
- reductions of the scope of authorisations (e.g. because of Member State governments reversing an acceptance of the GMO)

Such additional requests might eventually place a significant burden on the system. Extensions of scope would presumably require a review process to determine what additional information would be required to provide an adequate environmental risk assessment for the 'new' Member State, and then the development and appraisal of that assessment.

Additional issues to consider in relation to this option are:

- Its implicit rejection of the presumption of a common EU approach and a pan-EU authorisation being the normal position;
- The use of a centralised EU process (engaging EFSA and all Member States) for a product that will only be available to plant in selected countries;
- The latent potential for neglect of smaller countries and thus under-served markets (e.g. if there were expectations of data from each country that could not be met, or for which the benefit-cost ratio was unfavourable);

[134] See section 4.4.2 of the Interim Report for more information

- As ecological/environmental impacts do not respect political boundaries, the possibility for cross-border issues arising due to divergent views between the countries where the product is authorised and those where it is not. Although every GMO undergoes a safety risk assessment at the EU level prior to authorisation (meaning that no GMO is placed on the market unless it has received a scientific Opinion from EFSA which contains a favourable assessment and is subsequently authorised) this issue was nonetheless brought up by consultees during the stakeholder consultation as a point of concern given the regional variations in ecological conditions across Member States in the EU.

Qualification of geographic scope by the notifier based on Member States' declaration of intent to opt out

There is an alternative 'hybrid' option which combines elements of the Member State opt-out and the selective application. This would see applications processed in the same way as under the current system up until the point where the Commission receives a final scientific Opinion from EFSA that contains a favourable assessment. At this stage Member States would be able to inform the Commission of any reservations they might have, of any nature, about the cultivation of the GMO on their territory. The Commission would relay these statements (in effect, requests to opt out) to the notifier. The notifier would then propose a qualification of the geographical scope of its application, excluding those Member States which had registered reservations. These geographical restrictions would be specified in the draft Decision prepared by the Commission. By including restrictions in the geographic scope of a product's authorisation for cultivation in the conditions of use, notifiers would not be able to seek marketing authorisation in those Member States which had raised reservations about the GMO in question.

This option has some advantages over the selective application option above. For instance:

- The notifier is responding to an explicit statement of intent from the Member State rather than having to anticipate *ex ante* which Member States might accept or reject the GMO even if a positive Opinion is issued, thereby increasing transparency;
- Responsibility for restricting the scope of the authorisation is, in effect, shared among the key actors, with recognition by notifiers of Member State reservations;
- The appraisal of the risk assessment continues, as at present, to look at potential impacts on an EU-wide basis and should therefore be still fit-for-purpose should the conditions of use be altered at a later date, or concerns arise over 'spill-over' environmental effects from Member States where the GMO is cultivated and those where it is not;

However the hybrid option shares several of the challenges facing other options. For instance:

- If Member States take a case by case approach to determine whether to opt out from cultivation of a GMO, and that decision draws on evidence in the Opinion or evidence that will only be prepared once a positive Opinion is in place, then the decision is likely to take some time. This means that either (1) if a long period is provided for that decision then a new source of delay will be introduced into the authorisation process, or (2) if the notice period is short some Member States may not be able to make a decision within the window, with impacts on the subsequent votes if the principle of presumed consent is applied. The extent to which this sequencing issue poses a problem is likely to be influenced by other factors, such as the availability to Member States of generic opt-outs (as discussed in section B2.3).
- The qualifications could get complex if, as is likely to be the case, regional autonomy and differences of view mean that Member States seek to restrict authorisation on a

region-by-region basis. The need for some Member State governments to consult with devolved administrations would also add to the time taken to deliver a decision.

- If governments and Member State preferences change there are questions about whether and how the geographical scope specified in the authorisation could be changed (either to permit a Member State to opt in at a later date, or to opt out) before the review of the authorisation after 10 years.

In the event that no qualified majority was reached in the Standing Committee and Council, the Commission would have additional information on which to base its own Decision.

B4 A thorough debate on the options and their implications would be needed to ensure the implications had been fully explored

All of the above options would see the collective decision on a science-based risk assessment of product safety remain in place. What they add is space for consideration of other factors and the facility to partially or completely 'opt out' from cultivation. They have some appeal because they directly address the non-scientific aspects of attitudes to GMO cultivation which are not explicit in the EU authorisation process but which are present in Member States decisions and actions.

The preliminary analysis discussed above suggests that there are potentially significant challenges, of principle and of practicality, to be taken into account when developing these proposals. These include:

- On principle,
  - the precedent it would set of departure from an ostensibly science-based decision-making framework;
  - the compatibility of such measures with the principle of strengthening the EU Internal Market;
  - consistency of the EU's and MS's obligations under the rules of the WTO, though as a recent report noted:

    "The WTO allows more regulatory measures by national governments than is generally perceived... Examples showed that restrictions based on concern for "public morale" are sometimes allowed under the WTO." Nonetheless, "any measure should be rationally motivated, that is, related to a legitimate objective and based on scientific or other evidence. In developing their line of argumentation countries need to define socioeconomic aspects as risk-, health- or trade-related to make them subject to either of three WTO Agreements, each of which represents a specific 'box' of arguments."[135]
- On practicality,
  - the means by which they would be introduced (within the EU framework and, where necessary, national law) and
  - how they would operate (e.g. whether socio-economic factors are considered (and quantified) on a case-by-case basis or as a matter of strategic policy choice, whether they are harmonised at EU level or set individually by Member States), who would prepare the assessment and

[135] GMOs in European Agriculture and Food Production (2009). Conference Report: The Hague, The Netherlands,. Available from: http://www.minlnv.nl/portal/page?_pageid=116,1640393&_dad=portal&_schema=PORTAL&p_document_id=111104&p_node_id=2100602&p_mode=BROWSE

with whose data/assumptions, and whether 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).

The mandating of new kinds of assessment on a case-by-case basis in all Member States would be more burdensome than options which provided greater freedom for notification of GMO free areas or nations, selective opt-outs and selective use of socio-economic assessment. Yet there are balances to be struck between, for instance, the benefits of giving greater for individual Member State choice over cultivation and the benefits of having clear, transparent, shared systems that provide a consistency of approach, help to reduce the total administrative burdens of the authorisation process across Europe and maintain the integrity of the Single Market.

A further, and significant, factor is the constraints imposed by the existing legal framework which, although it does not explicitly exclude these options, also does not, for the most part, anticipate them. Such constraints could, in principle, be addressed by changing the law. A straightforward legal solution that did not risk unravelling the current legal framework would need to be found. The kinds of options listed above could be designed from first principles and incorporated into the appropriate part of the legislation.

Though many consultees were in favour of the kind of proposals outlined above in principle, few were enthusiastic about the idea of having to open up Directive 2001/18/EC or Regulation 1829/2003 in order to implement them. The consultations showed a general preference among non-MS consultees for the **existing** law to be better implemented, not for the law to be changed.

They highlighted the following concerns about a further attempt at legislative reform:

- It could lead to unintended consequences– because, even if the intent was to make small 'targeted' changes, the legislative process was such that the entire text could be opened up for review; and thus it:
- Would introduce new uncertainty into the regulatory process;
- Would be likely to slow down the progress of current applications even further;
- Would absorb significant time and resources; and
- Would lead to regulatory lock in with no option of going back to the old system.

These concerns would be mitigated if proposals for changes to the EU law were introduced in a focused, limited and controlled manner, and in way that eliminated the risk of the entire text being opened up for review.

A thorough debate on the options, their implications (including the national, EU and international legal issues) and timescales would be needed. Any such efforts should not distract effort and attention from efforts to improve the efficiency and transparency of other aspects of the existing framework which, as recommendations elsewhere in this report suggest, can be improved.

ANNEX 1 TERMS OF REFERENCE

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)[136] and Regulation (EC) No 1829/2003 on GM food and feed (hereinafter: the Regulation)[137] 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 regime[138] 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 uses[139].

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.

[136] Directive 2001/18/EC on the deliberate release into the environment of GMOs, entered into force on 17 October 2002

[137] Regulation(EC) No 1829/2003 on genetically modified food and feed, entered into force on 7 November 2003

[138] Regulation(EC) No 726/2004

[139] 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 approached 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 request[140] 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 biotechnology[141]. 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/EC[142]. The second implementation report from the Commission was published in 2007[143]. 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:

- provide the Commission's policymakers and managers with information on the implementation of the current legislation,

[140] Report expected to be published before the end of 2008.

[141] http://ec.europa.eu/environment/biotechnology/pdf/background_study.pdf

[142] http://ec.europa.eu/environment/biotechnology/pdf/com_575_final.pdf

[143] http://ec.europa.eu/environment/biotechnology/pdf/com_2007_81.pdf

- 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 assessment[144]. These data should be analysed in order to identify impacts of different policy options to possible 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 90/219/EEC[145]. 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

[144] Details on Impact Assessments can be found at http://ec.europa.eu/governance/impact/index_en.htm

[145] 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

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 products[146], 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.

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

[146] Directive 91/414/EEC

special procedure of the EC Treaty[147] 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:

(i) additional authorisation procedures at national or regional level;

(ii) regional or general prohibitions of GMO cultivation;

(iii) establishment of GM-free zones, either through administrative acts or through the voluntary agreements of concerned farmers;

(iv) isolation distances from ecologically sensitive areas; ,

v) 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 AGRI[148] 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.

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.

[147] Art. 95(5) EC Treaty

[148] "Economic impact of un approved GMOs on EU feed imports and livestock production", http://ec.europa.eu/agriculture/envir/gmo/economic_impactGMOs_en.pdf

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:

a. interpretation and comprehension of the key terms of the question;

b. indication of the judgement criteria allowing to answer the question;

c. indication of the quantitative and qualitative information needed/collected/used

d. description of the evaluation methods used (including their possible limitations)

e. detailed description of the reasoning followed in the analysis

f. 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.

Geographical scope

The evaluation shall cover the 27 Member States of the European Union. To the limit of the data collection/creation, the evaluator could make reference to the situation of the specific Member States. In this case the consultant will collect a robust and representative sample of stakeholders' assessments of the issues in scope of this evaluation across all the 27 Member States. By doing so, the regional specifics resulting from cultural, traditional or organisational differences should be considered in order to reach the important actors in all the Member States.

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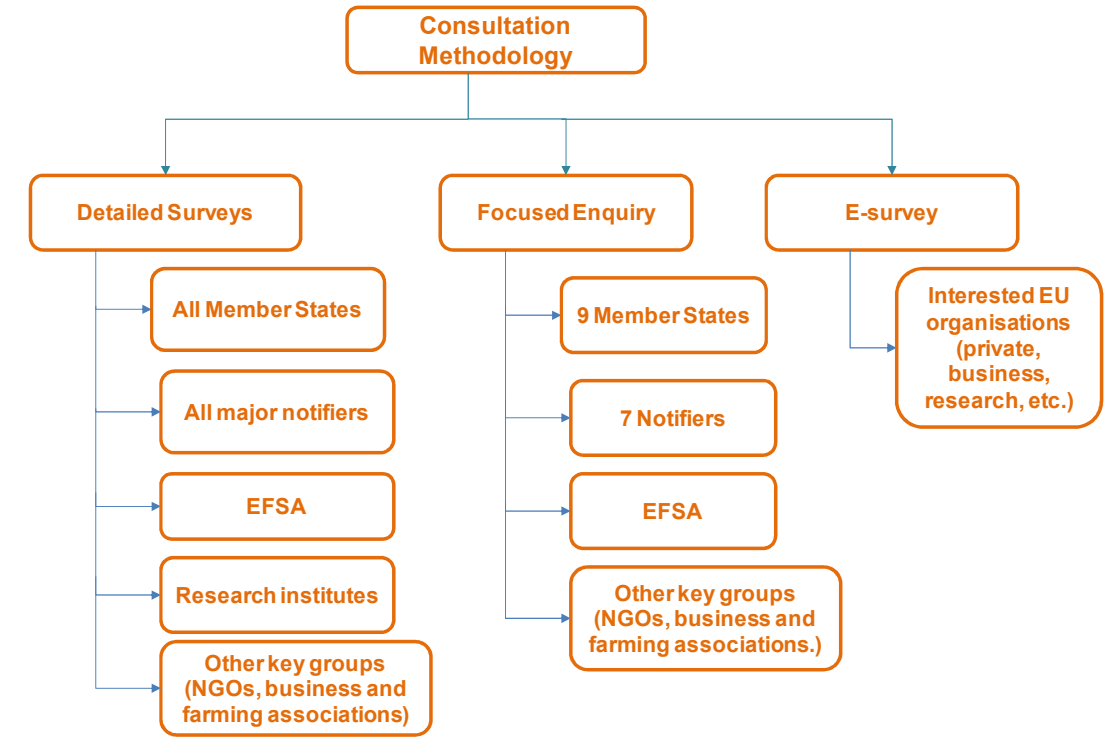
ANNEX 3 CONSULTATION METHODOLOGY AND CONSULTEES

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**		**Research Institutes**	
Austria	◆✓	European Food Safety Authority (EFSA)	◆✓	AVEBE	◆✓	ISTIS (The Romanian State Institute for Variety Testing and Registration)	◆
Belgium	◆✓	EuropaBio	✓	BASF	◆✓	Max Planck Institute for Chemical Ecology	◆
Bulgaria		COCERAL	◆✓	Bayer	◆✓	Max Planck Institute of Molecular Plant Physiology	◆
Cyprus	◆	COPA-COGECA	✓	Dow AgroSciences	◆✓	SW Seed	◆
Czech Republic	◆✓	European Centre for Nature Conservation (ECNC)	✓	Monsanto	◆✓	VIB (Flanders Institute for Biotechnology)	◆
Denmark	◆	European Environmental Bureau (EEB)	✓	Pioneer Hi-Bred International	◆✓		
Estonia	◆	European Seed Association (ESA)	◆✓	Syngenta AG	◆✓		
Finland	◆	Friends of the Earth (FOE)	◆✓	KWS SAAT AG	◆		
France	◆✓	International Federation of Organic Agriculture Movements (IFOAM)	◆				
Germany	◆✓						

Greece	◆
Hungary	◆✓
Ireland	◆
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 A2). 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 A3). A full list of the 53 organisations who responded is given below in Table A2.

Figure A2 There was a total of 53 responses to the E-survey; most respondents were affiliated to NGOs and business representative groups

Respondents' affiliation

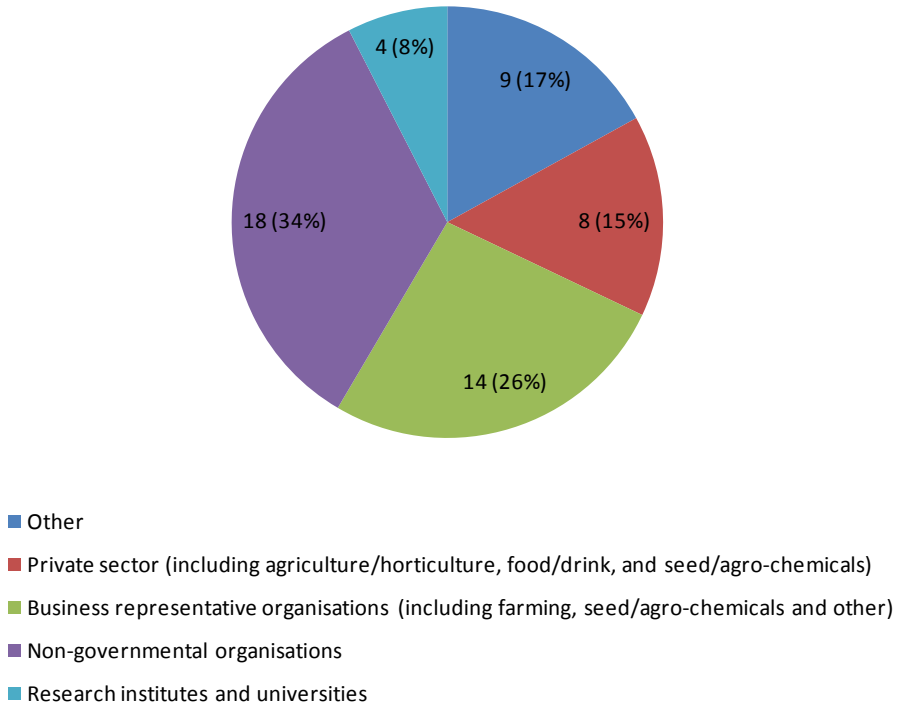


Figure A3 Most respondents were from Germany and the UK

Respondents' country of origin

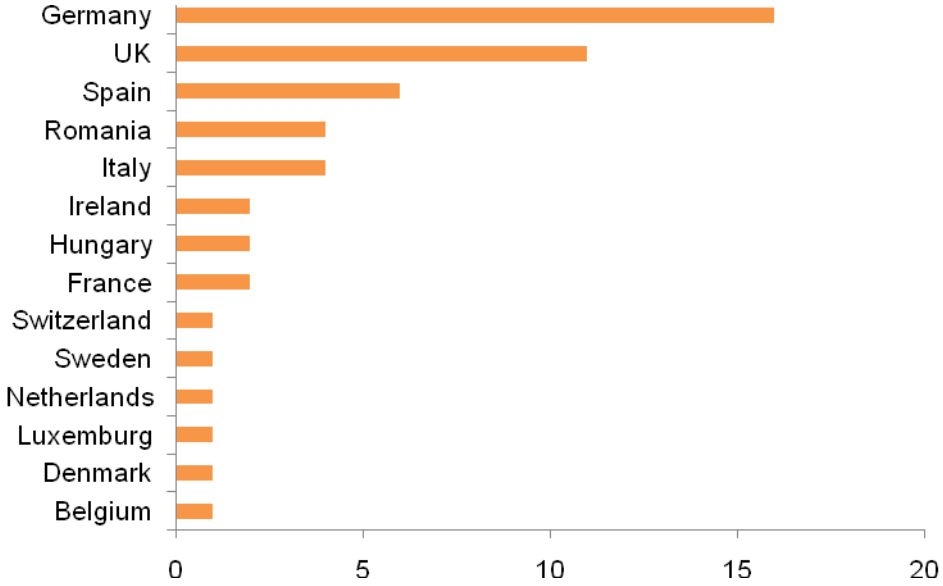


Table A2 List of organisations that completed the E-survey

Name of organisation	Country	Type of organisation	Website
Africando	Spain	Non-governmental organisation	www.africando.org
Agent Green	Romania	Non-governmental organisation	www.agentgreen.ro
AgroBiotechRom (ABR)	Romania	Business representative organisation - seed / agro-chemicals	www.agrobiotechrom.ro
Amigos de la Tierra	Spain	Non-governmental organisation	www.tierra.org
Aoel e.V. Assoziation Ãkologischer Lebensmittelhersteller	Germany	Business representative organisation - other	www.aoel.org
AsoproVac (The Spanish Association of Beef Cattle Producers)	Spain	Business representative organisation - other	www.asoprovac.com
BioPlant (Biotechnologisches Forschungslabor GmbH)	Germany	Private sector - Seed/agro-chemicals business	www.bioplant.de
Biotechnology and Biological Scienes Research Council (BBSRC)	United Kingdom	Research institute/university	www.bbsrc.ac.uk
BÖLW (Bund Ökologische Lebensmittelwirtschaft)	Germany	Business representative organisation - other	www.boelw.de

Name of organisation	Country	Type of organisation	Website
BSPB Ltd.	United Kingdom	Business representative organisation - seed / agro-chemicals	www.bspb.co.uk
Bundesverband Deutscher Pflanzenzüchter e.V. BDP	Germany	Business representative organisation - seed / agro-chemicals	www.bdp-online.de
Bundesverband Naturkost Naturwaren (BNN) Herstellung und Handel	Germany	Business representative organisation - other	www.n-bnn.de
Danish Seed Council	Denmark	Other	www.seedcouncil.dk
Deutsche Saatveredelung AG (DSV)	Germany	Private sector - Seed/agro-chemicals business	www.dsv-saaten.de
Deutschen Industrievereinigung Biotechnologie (DIB)	Germany	Business representative organisation - other	www.dib.org
Dublin Institute of Technology	Ireland	Research institute/university	www.dit.ie
Egyetemes Létezés Természetvédelmi Egyesület - ETK	Hungary	Non-governmental organisation	www.etk.hu
European Professional Beekeepers Association	Germany	Business representative organisation - farming	www.professional-beekeepers.eu
European Technology Platform	Belgium	Non-governmental organisation	www.plantetp.org

Name of organisation	Country	Type of organisation	Website
FARM UK	United Kingdom	Non-governmental organisation	www.farm.org.uk
Federal Agency for Nature Conservation	Germany	Public - Other public sector	www.bfn.de
Fondazione dei Diritti Genetici	Italy	Non-governmental organisation	www.fondazionedirittigenetici.org
Food and Water Europe	United Kingdom	Non-governmental organisation	www.fweurope.org
Food Control	United Kingdom	Other	www.foodcontrol.co.uk
Genetic ID (Europe) AG	Germany	Other	www.genetic-id.de
GM Freeze	United Kingdom	Non-governmental organisation	www.gmfreeze.org
GM-free Ireland Network	Ireland	Non-governmental organisation	www.gmfreeireland.org
GMO Information Centre	Romania	Non-governmental organisation	www.infomg.ro
HZPC Holland B.V.	Netherlands	Private sector - Seed/agro-chemicals business	www.hzpc.com

Name of organisation	Country	Type of organisation	Website
Initiative Luxembourg sans OGM	Luxembourg	Non-governmental organisation	www.ounigentechnik.lu
Institute of Biochemistry, Romanian Academy	Romania	Research institute/university	www.biochim.ro
Institute of Plant Genetics, University of Hannover	Germany	Research institute/university	www.genetik.uni-hannover.de
International Seed Federation (ISF)	Switzerland	Business representative organisation - seed / agro-chemicals	www.worldseed.org
Irish Apple Growers Association	Ireland	Business representative organisation - farming	www.theapplefarm.com
Irish Doctors Environmental Association [IDEA]	Ireland	Non-governmental organisation	www.ideaireland.org
Italian Seed Association	Italy	Business representative organisation - seed / agro-chemicals	www.sementi.it
KAMPFFMEYER Food Innovation GmbH	Germany	Private sector - Food & drink business	www.kampffmeyer.de
LECICO GmbH	Germany	Private sector - Food & drink business	www.lecico.de
Life Food GmbH / Taifun-Tofuprodukte	Germany	Private sector - Food & drink	www.taifun-tofu.de

Name of organisation	Country	Type of organisation	Website
		business	
Limagrain Group	France	Private sector - Seed/agro-chemicals business	www.limagrain.com
MaizEurop	France	Business representative organisation - farming	www.agpm.com
Mundivia	Spain	Business representative organisation - farming	www.mundivia.es
National Association of Italian biotechnology (ANBI)	Italy	Non-governmental organisation	www.biotecnologi.org
Office of the Parliamentary Commissioner for Future Generations	Hungary	Public - Other public sector	http://jno.hu/en/
PG Economics	United Kingdom	Other	www.pgeconomics.co.uk
Swedish Seed Trade Association (Svenska Utädesföretagens Förening)	Sweden	Business representative organisation - seed / agro-chemicals	www.svuf.se
The Liaison Centre for the Meat Processing Industry in the European Union (CLITRAVI)	Belgium	Business representative organisation - other	www.clitravi.eu
The University of Milan	Italy	Research institute/university	www.unimi.it

Name of organisation	Country	Type of organisation	Website
The University of Warwick	United Kingdom	Research institute/university	www.warwick.ac.uk
UK National Farmers Union	United Kingdom	Business representative organisation - farming	www.nfuonline.com
Veterinarians Without Borders (VSF)	Spain	Non-governmental organisation	www.veterinariossinfronteras.org
Zukunftstiftung Landwirtschaft der GLS Treuhand	Germany	Other	www.zs-l.de