



**INCEPTION REPORT  
(Revised)**

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

**June 2009**



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other uses under Directive 2001/18/EC

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INCEPTION REPORT

(Revised)

DG ENVIRONMENT

A report submitted by EPEC

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**ABBREVIATIONS**

ARM	Antibiotic resistance marker genes
CA	National competent authority
EC	European Commission
EC JRC	European Commission Joint Research Centre
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ERA	Environmental risk assessment
EU	European Union
FVO	Food & Veterinary Office
GM	Genetically modified
GMM	Genetically modified micro-organism
GMHT	Genetically modified herbicide-tolerant
GMO	Genetically modified organism
GS	General Surveillance
MS	Member States
PMEM	Post market environmental monitoring
RASFF	Rapid Alert System for Food and Feed

# 1 PURPOSE

This is the inception report for the *Evaluation of the EU legislative Framework in the Field of Cultivation of GMOs under Directive 2001/18/EC and Regulation(EC) No 1829/2003 and marketing of their other uses under Directive 2001/18/EC* (hereafter, the 'Project'). The report is submitted by EPEC, the consultants appointed to conduct this evaluation. For this project the lead firm from within the EPEC consortium is GHK Consulting Ltd.

The purpose of this report is to:

- Explain in detail the consultants' understanding of the requirements of the project, including each of the evaluation questions;
- Set out in detail the proposed approach to addressing those questions and the overall objectives;
- Describe the proposed programme, team structure and responsibilities, and risk management strategy.

The contractual requirements of this report as specified in the terms of reference for the Project are set out Box 1.1. According to the method set out in the EPEC proposal the stakeholder questionnaires will be prepared for the interim report rather than offered in final form in this report.

## **Box 1.1 The contractual requirements**

"This report will describe the intervention, providing the current intervention logic. It will describe the evaluators' understanding of the evaluation objectives, issues and questions. This document will present in detail the evaluators' methodology, how it is going to be implemented and in particular how the method will provide an answer to each evaluation question. The inception report will describe the way the evaluators intend to structure their activities, the number of human resources involved in the exercise, their background and the number of meetings they propose to have with the steering group. It will include the draft questionnaires which the evaluators will use to obtain information from the different stakeholders, for approval by the steering group. This document will provide the steering group with the opportunity to make a final check of the feasibility of the methodology proposed and the extent to which it corresponds with the information needs outlined in the terms of reference".

The inception report is the first of three formal deliverables due under this project, the others being:

- An interim report, due within 5.5 months after project start;
- A final report, of which the draft is due 9 months after project start.

This report is structured as follows:

- Chapter 2 provides intervention logics for the Directive and Regulation;
- Chapter 3 explains how the evaluation is structured, the consultants' interpretation of the evaluation questions provided in the terms of reference and how this will in turn impact on the research method;
- Chapter 4 describes the project plan and programme;
- Chapter 5 sets out the project organisation.

## 2 INTERVENTION LOGICS

### 2.1 Purpose of this chapter

This chapter provides intervention logics for Directive 2001/18/EC and for EC Regulation 1829/2003 (as it relates to the terms of reference of this evaluation). These set out the 'logic models' that underpin each piece of legislation and include summaries of the:

- Legislative background;
- Problem that the Directive and Regulation were designed to address;
- Objectives
- Legal basis and purpose;
- Scope;
- Transposition (for Directive only);
- Management arrangements;
- Provisions for the deliberate experimental release and placing on the market of GMOs;
- Harmonised standards;
- Conformity assessment procedures;
- Enforcement;
- Complementarity with other EU instruments.

Section 2.1 and 2.2 cover the Directive and the Regulation respectively. There are some issues common to both the Directive and the Regulation. These are discussed in section 2.3.

### 2.2 Intervention logic for Directive 2001/18/EC

#### 2.2.1 *The legislative background to Directive 2001/18/EC*

Directive 2001/18/EC updates European Union (EU) law on the deliberate release into the environment of genetically modified organisms (GMOs). It replaced Directive 90/220/EEC, which underpins the current Member States (MS) regulations on the release of GMOs for either research or commercial purposes. The Directive entered fully into force on 17<sup>th</sup> October 2002.

Since 1990, the European Community has had a legislative framework governing the release of GMOs. This consists of a number of specific sectoral measures and a series of horizontal Directives, including:

- Directive 90/219/EEC on the contained use of genetically modified micro-organisms in research and industrial facilities, most recently amended by Directive 98/81/EC (the "Contained Use Directive");
- Directive 90/220/EEC on the deliberate release into the environment of GMOs, later repealed by Directive 2001/18/EC (the "Deliberate Release Directive"); and
- A range of EU-wide guidance and additional regulations to address specific issues beyond cultivation, including Regulation (EC) No 1829/2003 on genetically modified

food and feed and Regulation (EC) No 1831/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products produced.

### **2.2.2 The problem that the Directive was designed to address**

The main purpose of Directive 2001/18/EC was to introduce a harmonised and generic framework for the deliberate release into the environment of GMOs within the EU. It provides for the approval (or not) of GM products for the EU internal market, and includes mechanisms to allow agreement to be reached between MS and the Commission.

The problem was clear – there was a need to develop an internal market in GMOs, and to increase the protection of environmental, animal and human health whilst simultaneously ensuring the effective functioning of the internal market.

The precautionary principle (UN Global Compact principle<sup>1</sup>) informed the drafting of this Directive and must be taken into account when implementing it. The main reason for introducing the Directive in accordance with the 'precautionary principle' was to raise environmental protection standards (human, animal and plants), improve risk assessment methods, remove trade barriers, remove inconsistencies with national regulations, aid competition and create a level playing field. Safety, freedom of choice, and case-by-case evaluations are key principles underpinning the rationale behind the Directive.

Directive 90/220/EEC had a number of perceived shortcomings, *viz*:

- Its case-by-case approach did not include an assessment of cumulative, indirect and long term impacts;
- The problem of cross-pollination of organic and conventional crops and its effect on farming system was not considered;
- Small-scale trials were not addressing the complexity of the natural environment;
- Experimental trials for risk assessment contained minimal research into environmental/ecological effects.

Provisions within Directive 2001/18/EC were intended to address these problems by:

- Increasing scientific scrutiny of applications by clarifying and extending the scope of risk assessments for Part B and Part C applications to cover indirect, cumulative and long-term effects and wider impacts on biodiversity; potentially negative effects should not be discounted on the basis that they are unlikely to occur;
- phasing out of antibiotic resistance marker genes (ARMs) that may have adverse effects on human health and the environment from the end of 2004 for Part C releases and 2008 for Part B releases;
- mandatory post-market monitoring plans (Annex VII) for Part C releases to confirm that the assumptions made in the risk assessment are valid and to identify any unanticipated effects on the environment;
- new annexes on techniques for genetic modifications (Annex I), principles for risk assessment (Annex II), guidelines for notification (Annex III A&B), general principles for the monitoring plan (Annex VII);
- more thorough management provisions, in addition to monitoring, taking into consideration conditions for the protection of particular ecosystems/environments and/or geographical areas (Article 19 (3)(c));

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<sup>1</sup> <http://www.unglobalcompact.org/AboutTheGC/TheTenPrinciples/principle7.html>

- the potential for restrictions on geographical areas where GMOs are grown or areas of applications;
- consideration of the impacts of the farming practices associated with the use of a GMO;
- measures to ensure traceability at all stages of Part C releases and labelling of GMO products; and
- time limits of ten years or less on all Part C consents, after which they have to be renewed.

### **2.2.3 Objectives of the Directive**

In accordance with the precautionary principle, the main objective of the Directive 2001/18/EC is to:

- protect the environment, human and animal health when carrying out deliberate release into the environment of GMOs for any other purposes than for placing on the market within the Community;
- ensure effective functioning of the internal market with regards to placing on the market GMOs as or in products with the European Community.

### **2.2.4 Legal basis and purpose**

The Directive was introduced on the basis of Article 95 of the Treaty which sets out the principles for the establishment of the internal market. The principal goal of the Directive, therefore, is to ensure the free movement of GMO products within the EU, though by establishing a set of essential product requirements the Directive also has strong environment, animal and human health and safety objectives.

### **2.2.5 Scope**

The Directive covers all types of GMOs, including plants, animals and micro-organisms. The only GMOs that are not within the scope of the Directive are genetically modified novel foods and medicinal products, as these are covered by specific legislation providing an equivalent level of protection to human health and the environment. Human beings are also excluded by the scope of the legislation.

The Directive covers two distinct types of GMO release: commercial releases (referred to as Part C releases); and releases for any other purposes, including research (referred to as Part B releases).

Applications for Part C releases are made to a Member State, but the decision on whether or not to approve a release is made by all Member States and the Commission acting jointly. As a result, national legislation only covers certain aspects of the Part C approvals process. In contrast, decision-making on Part B releases is at the Member State level, fully implemented through national legislation.

### **2.2.6 Transposition**

MS had until 17 October 2002 to transpose the Directive into their national laws. As with all EU Directives, Member States were free to choose the form and means by which the Directive was transposed into national law, provided that the intended objectives and results were achieved. The transposition process required Member States to notify the Commission as regards the national provisions (laws) that implement the Directive. Commission guidance also stipulates that Member States should provide the Commission

with a table showing the relationship between their national law(s) and the provisions of the Directive (often referred to as a concordance or correlation table<sup>2</sup>).

As at the end of February 2009, all 27 Member States had notified the Commission as regards their national provisions that implement the Directive<sup>3</sup>. It should be noted however, that the presence of national execution measures does not necessarily result in the measures being either comprehensive or in conformity.

### 2.2.7 **Provisions for the deliberate experimental release and placing on the market of GMOs**

The Deliberate Release Directive contains a number of provisions that industry, operators and MSs are required to meet in order to place products falling within the scope of the legislation on EU market<sup>4</sup>. It sets out common approval, safety, fair competition and public information standards for any GM product marketed in the EU. It also provides for mandatory traceability and labelling of GMOs as or in any product. The fundamental requirement of the Directive is that no product that consists of or contains GMOs may be placed on the Community market without a specific consent based on a thorough assessment of any possible risks to human health and the environment.

In addition to the provisions in the Directive 2001/18/EC as an improvement over the old Directive (as given in Section 2.2.2), Article 23 of the Directive states two key provisions:

- 1) Article 23 of the Deliberate Release Directive stipulates that Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive.
- 2) Article 23 further provides for **a safeguard clause**, where a Member State that identifies that a GMO is liable to 'constitute a risk to human health or the environment' it may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory. The Member State must inform the Commission immediately, citing the reason (including review of the environmental risk assessment indicating whether and how the conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based) for the invocation of the safeguard clause. The Commission then considers whether the measures taken were justified within 60 days. Up until November 2008, the safeguard clause was invoked 5 times under the Directive 2001/18/EC, by Hungary, Austria and Greece (and 5 times under the Directive 90/220/EC Article 16)<sup>5</sup>.

### 2.2.8 **Harmonised standards**

Harmonised technical standards play an important role within the operation of the Directive. The principles for the environmental risk assessment (ERA) procedure are specified in Annex III of the Directive. EFSA has produced guidelines to assist Member States in carrying out the ERA<sup>6</sup> but these leave room for flexibility. Standards on labelling and traceability are binding, but most other standards are not. The standards are intended to

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<sup>2</sup> Whilst the provision of a concordance table is a requirement of the Directive, across the body of EU legislation as a whole there is an agreement between the Commission and the Member States that the concordance table is not mandatory.

<sup>3</sup> [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:72001L0018:EN:NOT#FIELD\\_BE](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:72001L0018:EN:NOT#FIELD_BE)

The fact that there is a reference to national execution measures does not necessarily mean that these measures are either comprehensive or in conformity.

<sup>4</sup> 'Placing on the market' means making available to third parties, whether in return for payment or free of charge.

<sup>5</sup> <http://ec.europa.eu/environment/biotechnology/pdf/table2.pdf>

<sup>6</sup> EFSA risk assessment guidelines [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620775747.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775747.htm)

help industry, operators and Member States ensure and demonstrate compliance by, in effect, providing detailed information as to what they need to do in order to ensure that their product can be placed on the market.

The Directive outlines standardised methods for:

- The authorisation procedure (Article 6 and 13): the applicant (notifier) is required to submit a notification (notification procedure, Article 13) to the competent authority of the Member State within whose territory the release is to take place. The notification shall include:
  - A technical dossier, with information specified in Annex III A and B for carrying out an ERA;
  - An ERA and the conclusions required in Annex II, section D, together with any bibliographic reference and indications of the methods used.
- Detecting the GMO – An organism is "genetically modified" if its genetic material has been changed in a way that does not occur under natural conditions through cross-breeding or natural recombination (ref Article 2 of the Directive (2001/18/EC)). In individual cases it can be difficult to determine if an organism has been genetically modified in a way that does not occur "naturally"<sup>7</sup>. The Directive names several techniques (Annex I B) that lead to GMOs:
  - Transfer of recombinant DNA that was created outside the organism by laboratory techniques;
  - Certain procedures used for cell fusion.
- Monitoring – under the Directive monitoring is a two-fold exercise (Part C, Annex VII): 1) General surveillance to identify unforeseen effects of large-scale GMO production on the environment 2) Case specific monitoring focussing on adverse effects identified in the ERA. Case-specific monitoring should be carried out for a sufficient time period to detect immediate and direct as well as, where appropriate, delayed or indirect effects which have been identified in the ERA. On the other hand surveillance could, if appropriate, make use of already established routine surveillance practices such as the monitoring of agricultural cultivars, plant protection, or veterinary and medical products. For Part B, a plan for monitoring in accordance with the relevant parts of Annex III has to be submitted to identify the effects of the GMO(s) on human health or the environment.
- Post market environmental monitoring (PMEM) is used for determining if potential negative effects noticed during safety assessments actually cause problems. Under the terms of Directive 2001/18/EC (Annex IIIB), a post-release monitoring plan must accompany applications for cultivating GM plants. Authorisation is contingent upon a parallel, general monitoring plan, which in some cases can include special stipulations addressing crop-specific areas of concern.
- Labelling - The Directive 2001/18/EC also introduces standardised rules on mandatory labelling and traceability at all steps of market placement (Annex IV).

### **2.2.9 Conformity assessment procedures**

GMOs may only be deliberately released or placed on the market in conformity with Part B or Part C respectively.

Under Part B, procedures ensuring conformity of the specific ERA and equivalence with the provisions of this Directive must be provided for by the said legislation, which must refer to

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<sup>7</sup> [http://www.gmo-compass.org/eng/glossary/115.genetically\\_modified\\_organism\\_gmo.html](http://www.gmo-compass.org/eng/glossary/115.genetically_modified_organism_gmo.html)

the Directive. Under Part B, the notifier may proceed with the placing on the market only when he has received the written consent of the competent authority in accordance with Articles 15, 17 and 18, and in conformity with any conditions required in that consent.

Under Part C a more stringent procedure is required for ERA (principles set out in Annex II), notification (information in Annex III and IV), labelling (Annex IV) and monitoring (Annex VII). Part B notifications for field trials also have to comply with the ERA and notification principles mentioned above.

### **2.2.10 Complementarity with other EU instruments**

The Deliberate Release Directive interacts with a number of other EU policy instruments:

- Directive 91/414/EC concerning the placing of plant-protection products on the market;
- Directive 90/219/EC (amended by Directive 98/81/EC) on the contained use of genetically modified microorganisms (GMMs) in research and industrial facilities<sup>8</sup>;
- Directive 2004/35/EC on environmental liability and the prevention/remedying of environmental damage;
- Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species;
- European Council decision on Comitology 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission;
- Regulation 178/2002 on the general principles and requirements of food law;
- Regulation 1049/2001 on public access to European Parliament, Council and Commission documents;
- Regulation 1946/2003 on the international movement of GMOs;
- Regulation 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare;
- Regulation 65/2004 on systems for development/assignment of unique identifiers for GMOs;
- Regulation 641/2005 on detailed rules for the implementation of 1829/2003;
- Recommendation 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming;
- Recommendation 2004/787/EC providing technical guidance on sampling / detection of GMOs.

### **2.3 Fit between Directive 2001/18/EC and Regulation 1829/2003**

Directive 2001/18/EC interacts with the more recent Regulation 1829/2003 for placing of GMOs as and in products in the European Community in several ways.

Regulation (EC) 1829/2003 provides a single unified approval process for GMOs intended for food and feed uses, which will not then require separate approval under Part C of Directive 2001/18/EC. Regulation 1829/2003 provides a 'one door one key' facility whereby a single application for authorisation can cover environmental release and clearance for use

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<sup>8</sup> MS differ in their approach to clinical trials of gene therapy, some classifying them as a deliberate release under Part C of the Directive 2001/18/EEC, others classifying them under the Directive 90/219/EC as a contained use.

as a food and feed. For notifiers looking for authorisation for cultivation, 'defined as a GMO that may be used as a food or as a source material for production of food and feed (Article 2(8)(9))', an ERA in keeping with the requirements of 2001/18/EC is required. The initial application is made through the competent authority of a Member State but the lead responsibility for processing the applications and safety assessment rests with the European Food Safety Authority (EFSA). Table 2.1 below outlines the key similarities and differences for authorisation for cultivation under the Directive and the Regulation.

Table 2.1 Directive 2001/18/EC and Regulation 1829/2003 (for cultivation only)<sup>9</sup>

	Directive 2001/18/EC	Regulation 1829/2003
Environmental and health standards	No harmful effects on human or animal health or on the environment  Regulation also mentions not to mislead the consumer	
Requirements for authorisation	Environmental Risk Assessment in accordance with Dir 2001/18/EC Annex II principles. EFSA is obliged to consult the CAs under both instruments concerning environmental risk assessments for cultivation.  Monitoring plan in accordance with Dir 2001/18/EC Annex VII.  A proposal for labelling complying with requirements of Directive 2001/18/EC Annex IV  Standardised method for detecting the GMO.  Post-market monitoring mandatory	
Approval process	Submit application to CAs  Initial assessment (scientific opinion) by national agencies  Documents forwarded to the national authorities of the Member States and to the European Commission  In the case of objections and open questions:  Safety assessments at the EU level (EFSA)  MSs can block and raise objections regarding the authorisation procedure	Application submitted to EFSA  Scientific evaluation from EFSA expert committee  Recommendation made by EFSA  In the case of objections and open questions:  Member States and stakeholders can submit comments and opinions
Decision for authorisation	Draft for decision from the European Commission  Vote in the "Standing Committee for the Food Chain and Food Safety" (Member States): The European Commission's draft may be accepted or rejected with a qualified majority.  If no qualified majority can be reached, the European Commission submits its draft to the Council of Ministers.  Vote in the Council of Ministers: Approval or rejection by	

<sup>9</sup> Adapted from: [http://www.gmo-compass.org/eng/regulation/regulatory\\_process/158.two\\_laws\\_governing\\_genetically\\_modified\\_plants.html](http://www.gmo-compass.org/eng/regulation/regulatory_process/158.two_laws_governing_genetically_modified_plants.html)

	qualified majority - without qualified majority the Commission's draft takes effect.	
Authorisation expires after:	10 Years	10 Years

## 2.4 Intervention logic for Regulation (EC) 1829/2003

**This evaluation is concerned with cultivation issues.** Regulation (EC) 1829/2003 covers is primarily concerned with food and feed applications, which are outside the scope of this study. But the applications for cultivation can be made through the Regulation, under circumstances explained below. To fully explain the context for such activity and the background to the legislative, a detailed explanation of the purpose and function of the Regulation is provided here – including issues (pertaining to food and feed) that go beyond the terms of reference of this evaluation.

### 2.4.1 The legislative background to Regulation (EC) 1829/2003

Regulation (EC) 1829/2003 –defines specific Community procedures and provisions for the assessment, authorisation, supervision and labelling of genetically modified (GM) food and feed. Its objective is to provide the basis for ensuring a high level of protection of human, animal and environmental health, and consumers' interests, whilst ensuring the effective functioning of the internal market.

The Regulation introduced the option to use a centralised assessment procedure for the approval of GM food and feed. Since 18 April 2004, such assessment has been carried out through the European Food Safety Authority (EFSA) rather than (as previously) by individual MSs.

Alongside Regulation (EC) 1829/2003, the European Commission (EC) put forward a second Regulation (1830/2003) which deals with the traceability and labelling of products containing GMOs and their derivatives. Traceability is required throughout the supply chain and is recognised as critical for informing consumers. The two Regulations are complementary and should be applied jointly.

Regulation (EC) 1829/2003 harmonises the legislation on the labelling of GMOs by amending or repealing the legislation in force.

Regulation (EC) 1829/2003 is closely associated with Directive 2001/18/EC. The Directive sets out the basic common principles against which any proposed GM product must be assessed. However, more specific and detailed factors, going beyond these common principles, may be relevant to particular products, such as food ingredients. The Directive allows such products to be considered under separate sectoral legislation which covers these wider factors whilst at the same time ensuring that requirements reflecting, for example ERA, are at least equivalent to those in the Directive. The detailed terms of any product exemption or derogation must be set out in a separate Regulation. The Regulation 1829/2003 is one such measure.

### 2.4.2 The problem that the Regulation was designed to address

The EU legislative framework described above has been revised and adapted since 1990 to keep pace with technical developments, to respond to demands for greater transparency, openness and to provide more detailed scrutiny of particular products, such as food and feed, to which GM technology may be applied.

Following the adoption of Directive 2001/18/EC in 2001, the Commission saw a need for further GM regulation, mainly because of pressures from Member States who were looking to build public confidence by:

- Making traceability rules more specific in a way that would ensure harmonised requirements throughout the EC, something not addressed in the Directive 2001/18/EC;
- Extending regulatory requirements to products derived from a GM source but not containing detectable protein (Directive 2001/18/EC only applies to products containing detectable GM protein or DNA).

Member States demanding further legislation formed a blocking minority, arguing that the decision-making process under Directive 90/220/EEC should be suspended until further legislation meeting their concerns had been adopted. This created trade tensions, particularly with the US.

The scarcity of new EU approvals has created a disparity with the situation in other countries, such as the US, Argentina and Canada, where several GM varieties have been approved for commercial use since 1998. Some of these GMOs have received a positive risk assessment from the relevant European authorities but have not received final authorisation. The major agricultural exporting countries that have approved GMOs on which the EU has not yet taken a decision, claim that the failure by the EU to take decisions amounts to a trade restraint. This is illustrated particularly in the case of maize, where some 18 GM varieties have been approved in the US, but only 6 have been approved in the EU (MON810 for all uses, 1507, Bt11, NK604, MON863, Herculex and their stacked events).

### **2.4.3 Objectives of the Regulation**

The objectives of the Regulation, in accordance with the general principles laid down in Regulation (EC) No 178/2002, are:

1. To ensure a high level of protection of animal and human health and the environmental - any possible risks to animal, human health and the environment from GMOs must be properly assessed, managed and communicated to the public. Products that do not meet the relevant safety criteria are not allowed to be sold. Most countries in the world that produce or import GM products have similar systems of safety assessment. International agreements, such as the Cartagena Protocol on Biosafety, lay down common minimum standards of assessment and information. EFSA has also produced extensive guidelines in this area, which are currently being updated. In addition, the assessment of GMOs for cultivation need to adhere to the principles set out in Annex II of the Directive 2001/18/EC (supplemented by Decision 2002/623/EC);
2. To protect the consumer interest - consumers should have appropriate and reliable information about the GM content of products, for instance through labelling, and supported by traceability. Regulation (EC) 1829/2003 lays down provisions for the labelling of genetically modified food and feed. Labelling, or other clearly displayed information, is intended mainly to inform the person who buys or consumes a particular product ("the final consumer") about particular characteristics that may affect his or her individual choice of what to buy;
3. To support the effective function of the internal market (fair competition) – under the principles of the Regulation (EC) 1829/2003, GM products should be able to be sold and used anywhere in the EU provided they meet, and continue to meet, approval and safety criteria thus ensuring the effective functioning of the internal market. Member States may not restrict the sale and use of an approved product without being able to bring forward and sustain evidence of a significant adverse risk to human health or the environment;

4. To lay down Community procedures for the authorisation and supervision of genetically modified food and feed.

#### **2.4.4 Legal basis and purpose**

The Regulation was introduced on the basis of Article 37, 95 and 152 to the Treaty. The purpose of the Regulation is to put in place a centralised, uniform and transparent EU procedure for all applications for placing on the market, whether the GMO itself or the food and feed products derived from it.

The objectives of the Regulation are to ensure a high level of protection of human and animal health, the environment, and consumer interest.

#### **2.4.5 Scope**

The scope of the Regulation encompasses the marketing of any GMO whose produce, or derived products, is intended for food or feed, including the cultivation of crop plants that are intended for these uses.

The Regulation applies to three types of product, Article (1)(a)(b)(c) :

1. GMOs for food and feed use;
2. food and feed containing GMOs; and
3. food and feed produced from or containing ingredients produced from GMOs.

The cultivation of GMOs enters the scope of the Regulation through Article (2)(8)(9): *'genetically modified organisms for food/feed use' means a GMO that maybe used as food/feed or as a source material for the production of food/feed.*

The labelling requirement does not apply to foods containing GMOs in a proportion no higher than 0.9 per cent of the food ingredients considered individually, provided that this presence is adventitious or technically unavoidable. Also excluded from the scope of the Regulation are products obtained using a genetically modified processing aid.

In this study we will examine the impact of the Regulation (EC) 1829/2003 on cultivation only, as defined above, even though the Regulation mainly relates to food and feed.

#### **2.4.6 Provisions for placing GMOs on the market**

The Regulation contains a number of provisions that industry, operators and Member States are required to meet in order to place products falling within the scope of the legislation on the EU market<sup>10</sup>. Regulation 1829/2003 introduced some important changes to the pre-existing system:

- In the case of GMOs or food/feed containing or consisting of GMOs, the risk assessment is conducted by Member States in accordance with the principles set out in Annex II to the Directive. A monitoring plan for environmental effects confirming with Annex VII to the Directive;
- The possibility of consumers inadvertently consuming GM products is addressed by extending the range of products requiring traceability, labelling and other controls - including products with ingredients derived from a GM source that is not identifiable by analysis ("derived products") as well as products consisting of or containing GMOs;

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<sup>10</sup> 'Placing on the market' means making available to third parties, whether in return for payment or free of charge.

- The need to build public confidence is addressed by centralising the consideration and co-ordination of risk assessment issues under the independent European Food Safety Authority (EFSA); and
- Trade issues are now tackled by providing a framework to support the proper functioning of international trade by firstly requiring that detectable GMOs as, or in, products, and entering the market as commodities or other goods, should be traceable and identifiable via a system of unique identification codes reflecting international standards.

#### **2.4.7 Harmonised standards**

Harmonised technical guidelines play an important role within the operation of the Regulation. They are intended to help industry, operators and Member States ensure and demonstrate compliance by, in effect, providing detailed information as to what they need to do in order to ensure that their product can be placed on the market. The Regulation calls for:

- Harmonised procedures for risk assessment and authorisation that are efficient, time limited and transparent, and criteria for evaluation of the potential risks arising from genetically modified foods and feed. The authorisation requires a scientific safety assessment to ascertain that a GMO is just as safe as a comparable conventional product. This ERA (Article 5 and 17, (5)) should be carried out in accordance with the principles set out in Annex II to the Directive 2001/18/EC. Articles 6(5e) and 18(5e) of Regulation 1829/2003 specify that an opinion from EFSA which favours the authorisation of a GMO should include, if appropriate, any conditions or restrictions which are necessary for the protection of particular ecosystems, environmental or geographical areas.
- Methods for detecting the GMO – applicants for authorisation should propose appropriate methods for sampling, identification and detection, and deposit samples of the genetically modified food and feed with the Authority; methods of sampling and detection should be validated, where appropriate, by the Community reference laboratory.
- Traceability - the traceability rules make it mandatory on the operators concerned, i.e. all persons who place a product on the market or receive a product placed on the market within the Community, to be able to identify their supplier and the companies to which the products have been supplied. The traceability requirement varies depending on whether the product consists of or contains GMOs (Article 4 of Regulation (EC) No 1830/2003) or has been produced from GMOs (Article 5 of Regulation (EC) No 1830/2003).
- Labelling - products consisting of or containing GMOs and food products produced from GMOs which are authorised under the procedure set out in Directive 2001/18/EC (Part C) or under Regulation (EC) No 1829/2003 are subject to the labelling requirements laid down in Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003. Harmonised labelling requirements are laid down for genetically modified feed to provide final users, in particular livestock farmers, with accurate information on the composition and properties of feed, thereby enabling the user to make an informed choice.
- Monitoring – the purpose of monitoring is to identify unforeseen effects of large-scale GMO production on the environment. It can also be useful for determining if potential negative effects noticed during safety assessments actually cause problems. In the case of GMOs or feed containing or consisting of GMOs, a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent. Products authorised shall be entered into a

public register of GM food and feed<sup>11</sup>. Authorisations will be granted for a period of 10 years, subject where appropriate to a post-market monitoring plan). Authorisations are renewable for 10-year periods.

#### **2.4.8 Complementarity with other EU instruments**

The Regulation interacts with a number of other EU policy instruments:

- Directive 2001/18/EC: after the Regulation 1829/2003 came into force, notifications submitted under the Directive which included feed use and for which an assessment report had not yet been provided were transferred to the authorisation procedure under the Regulation. The traceability and labelling requirements of the Directive were also partially amended and replaced by the new requirements;
- Directive 91/414/EC: Interplay with ERA of herbicide tolerant GMOs;
- Regulation (EC) No 1946/2003 on Transboundary Movements of Genetically Modified Organisms, with the exception of intentional movements within the Community regulates intentional and unintentional movements of GMOs between Member States of the EU and third countries;
- Regulation (EC) No 178/2002, which establishes the European Food Safety Authority and lays down general procedures in matters of food safety, including the requirement for traceability at all stages of production, processing and distribution of food, feed, food-producing animals and any other substance intended, or expected to be, incorporated into food or feed;
- Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species;
- European Council decision on Comitology 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission;
- Directive 89/107/EEC on food additives in foodstuffs;
- Directive 88/388/EEC on flavourings in foodstuffs;
- Directive 82/471/EEC on animal nutrition products;
- Directive 70/524/EEC on additives in feeding stuffs.

### **2.5 Issues common to both Directive and Regulation**

#### **2.5.1 Management arrangements**

The management arrangements and responsibilities for risk assessment, management and communication are shared between EU executive and political institutions and Member States. Details of institutional roles and responsibilities are shown in Table 2.2, whilst the process for proceedings and decision making for authorisation of GMO for cultivation under the Directive and the Regulation are shown in Figure 2.1. An applicant can either submit an application for deliberate release under both the Directive 2001/18/EC and the Regulation 1829/2003, or submit an application under either the Directive or the Regulation. The former however only permits the cultivation of GMOs, while the latter also permits the use in food and feed. Thus if a GMO is to be used for food and/or feed use, an applicant must obtain authorisation under the Regulation regardless. However, if an application for a GMO or food and feed containing or consisting of GMOs is submitted under the Regulation, the authorisation must be in accordance with the criteria laid down by the Directive 2001/18/EC (such as an ERA, in accordance with the principles set out in Annex II, and the inclusion of a unique identifier in order to help identify and detect the GMO). A single application can

<sup>11</sup> [http://europa.eu.int/comm/food/dyna/gm\\_register/index\\_en.cfm](http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm)

therefore be submitted which covers the environmental requirements of the Deliberate Release Directive as well as the food safety requirements under the Regulation 1829/2003.

The 'one door one key' approach provided by the Regulation 1829/2003 (which allows for a single application to be submitted for food and feed use as well as cultivation) does not fundamentally change the principles of risk assessment. It is intended to increase the efficiency and effectiveness of the delivery of scientific and technical support to ensure these principles are adhered to in the increasingly complex area of the safety of food and feed. Its purpose was to increase the certainty and predictability of the safety regime for companies submitting applications for authorisation for the approval of GMOs or food/feed containing or consisting of GMOs.

### **2.5.2 Enforcement**

Responsibility for the enforcement of the Directive and Regulation rests with the Member States. They are responsible for ensuring that GMO products placed on the market on their territory comply with the provisions of the legislation.

Compliance with the Directive is established by official inspection carried out by GM inspectorates in the Member States to ensure that releases are being conducted in accordance with the conditions of consents. Non-compliance with consent conditions can lead to enforcement action including, where necessary, the prosecution of consent holders.

GM inspection bodies from Member States participate in a European Enforcement Project concerned with inspection and enforcement issues of GMOs in contained use and deliberate release. This group consists of GM inspectorates from EU (members and applicants), EEA and EFTA states. Whilst funding for the project was formally stopped in June 2003, some of the work of the group has continued and includes notification of GM incidents in other Member States and publication of scientific papers. The EC Food and Veterinary Office (FVO) reports also often present figures on breaches and the responses of national authorities.

Member States are obliged to implement a monitoring plan in order to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs as or in products after they have been placed on the market. In accordance with the Treaty, Member States are obliged to take further measures for monitoring and inspection, for example by official services, of the GMOs as or in products placed on the market.

Non-compliance typically includes, for Part C, traces of non-authorised GMOs in food/feed products, imports of GM plants or seed not authorised in the EU and illegal deliberate releases<sup>12</sup>. Once non-compliance is detected it is addressed through the Rapid Alert System for Food and Feed (RASFF) under Regulation 178/2002<sup>13</sup>. The rapid alert system is a network of Member State authorities managed by the Commission<sup>14</sup>. Alert notifications are sent when a food or feed presenting a serious risk is on the market and when immediate action is required. Alerts are triggered by the Member State that detects the problem and has initiated the relevant measures, such as withdrawal/recall. The notification aims at giving all the members of the network the information to verify whether the concerned product is on their market, so that they also can take the necessary measures.

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<sup>12</sup> Examples of such cases are described in <http://www.gmcontaminationregister.org/>

<sup>13</sup> [http://ec.europa.eu/food/food/rapidalert/index\\_en.htm](http://ec.europa.eu/food/food/rapidalert/index_en.htm)

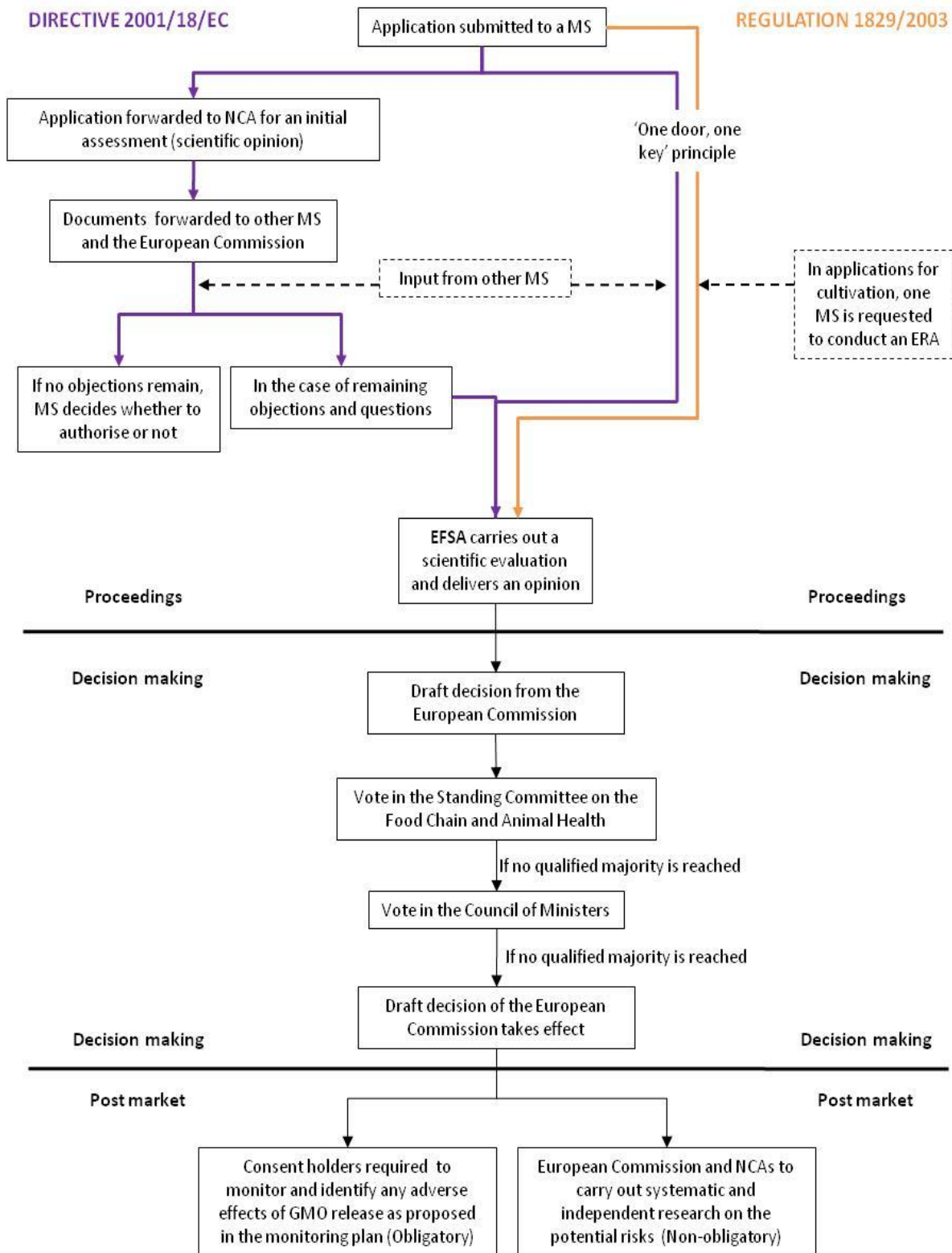
<sup>14</sup> Members - [http://ec.europa.eu/food/food/rapidalert/members\\_en.htm](http://ec.europa.eu/food/food/rapidalert/members_en.htm)

MS are obliged to impose penalties in the event of release or placing on the market contrary to the provisions of this Directive, particularly as a result of negligence. Penalties can be different depending on the national law.

**Table 2.2: Institutional roles and responsibilities**

	<b>Institution</b>	<b>Role</b>
External to the immediate management structure	European Parliament	Adopts Community legislation
Part of the immediate management structure	European Commission	<p>Proposes legislation, ensures implementation and uniform application, as well as mandating harmonised standards</p> <p>The European Commission plays a more central role within the Regulation's authorisation procedure than under the Directive's. Under the latter, the CA which carried out the original assessment may reject or authorise a GMO product for placing on the market. The Commission is only involved if objections from other Member States remain unresolved after the conciliation phase. Under the Regulation however, it is the Commission who must draft a decision, and grant or reject authorisation if the representatives of Member States cannot reach a qualified majority. Nonetheless, to date the Commission has by default played an equally important under the Directive, as all authorisation decisions under the Directive so far have been drafted and adopted by the Commission due to objections remaining unresolved.</p>
	Standing Committee on the Food Chain and Animal Health	Consists of representatives from all Member States and may approve or reject the Commission's draft with a qualified majority
	Council of Ministers	Considers proposals and has authority to make decisions to commit governments to new policies through qualified majority voting
	EFSA	<p>EFSA is the central authority for the scientific evaluation of food and feed safety in the EU, dealing with risk assessment and risk communication. EFSA is supported by eight scientific panels, including the GMO Panel. Further specific Working Groups discuss practical applications of the Directive and the Regulation, and develop draft scientific opinions on specific issues</p> <p>EFSA plays a central and immediate role in the Regulation's authorisation procedure, whereas its involvement within the Directive's authorisation procedure is tentative, and subject to being unable to resolve any objections. However, applicants submitting an application under the Directive also have the choice to submit an application directly to EFSA under the 'one door one key principle', after which proceedings continue according to the Regulation 1829/2003.</p>
	Member States	Implement the legislation and appoint CAs, inspection and enforcement bodies

**Figure 2.1: The authorisation process under the Directive 2001/18/EC and Regulation 1829/2003**



Other than this, however, the Directive does not specify the extent of market monitoring and enforcement, nor the resources that Member States should commit to such activity. Non-binding guidelines published by the Commission (2002/811/EC)<sup>15</sup> provide further information as to how national market monitoring systems might operate.

If new information is made available with regards to the risks of a GMO on human health or the environment then the notifier should take immediate steps to prevent the risks and inform the competent authority and the Commission.

### **2.5.3 Expected impacts of the intervention process**

The Directive and Regulation were adopted with the expectation and hope of achieving:

- An increase in trade, with the removal of potential barriers to cross-border trade (varying safety and labelling requirements between Member States);
- Health and environmental requirements;
- Harmonised and enhanced supervision of the industry leading to improved security;
- Greater public confidence in (or reduced opposition to) GMO releases from the more robust and open regulatory system;
- Fewer breaches and refusals.

However, it is now generally acknowledged that there have been problems with implementation of the legislation:

- Decisions are not being made;
- There is variation in practice;
- There is dissatisfaction with the system and the decision-making process;

With cultivation the issues being addressed are often local and national in character and context. The evaluation will have to take into account the socio-political context for the legislation, and the different views, interpretations and implementation of MS, e.g. in terms of risk assessments (RA) and monitoring.

Many of the issues explored in the 2004 report for the Commission remain 'live'. Although they might now be more clearly defined, they still haven't been resolved. For example, questions remain specifically about the definition and content of the risk assessment, what constitutes an 'adverse effect', what is considered an acceptable risk as well as how and what type of monitoring should be done.

It is the purpose of this evaluation to map out and seek to understand these issues, using analysis, research models and stakeholder consultation.

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<sup>15</sup> [http://www.esgct.net/downloads/2002\\_76404.pdf](http://www.esgct.net/downloads/2002_76404.pdf)

### 3 DEFINITION OF THE SCOPE AND ‘THE PROBLEM’, AND THE IMPLICATIONS FOR THE EVALUATION STRATEGY

#### 3.1 Purpose of this chapter

This chapter sets our understanding of the purpose and scope of this technical evaluation, and our intervention of the evaluation questions detailed in the terms of reference.

#### 3.2 General scope

This technical evaluation considers the EU legislative framework in the field of cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) 1829/2003 & marketing of their other uses under Directive 2001/18/EC. The evaluation covers all 27 Member States of the EU.

The majority of the activity (together with most of the difficulties experienced) under the above legislative framework has concerned agricultural crops. Although crops are expected to be prominent in the evaluation, the scope includes all GMOs covered by the framework. However, the legislative framework as it applies to food and feed applications is **out of scope** for the purposes of this evaluation.

The assignment is a technical evaluation that assumes and implies no new policy initiative in this area, but which is intended to draw together information on experience and opinions in the implementation of the legislative framework. The consultants will seek to engage with stakeholders from across the EU and from across the full range of interested stakeholders.

The period of this evaluation coincides with a number of processes relating to the legislative framework and involving the same stakeholders. This evaluation will seek to draw upon and coordinate with these complementary initiatives as far as possible. These initiatives include:

- Activity managed by DG ENV relating to the preparation of a three year implementation report on Dir 2001/18/EC, including the submission of a questionnaire to CAs;
- EFSA’s review of its risk assessment guidelines;
- The 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; and
- An initiative to better document the socio economic implications of the placing of GMOs on the market, with Member States supplying information and the Commission working towards a report on the issue in June 2010.

The management of these linkages and dependencies is discussed further in section 4.6 of this report.

#### 3.3 Understanding of the problem

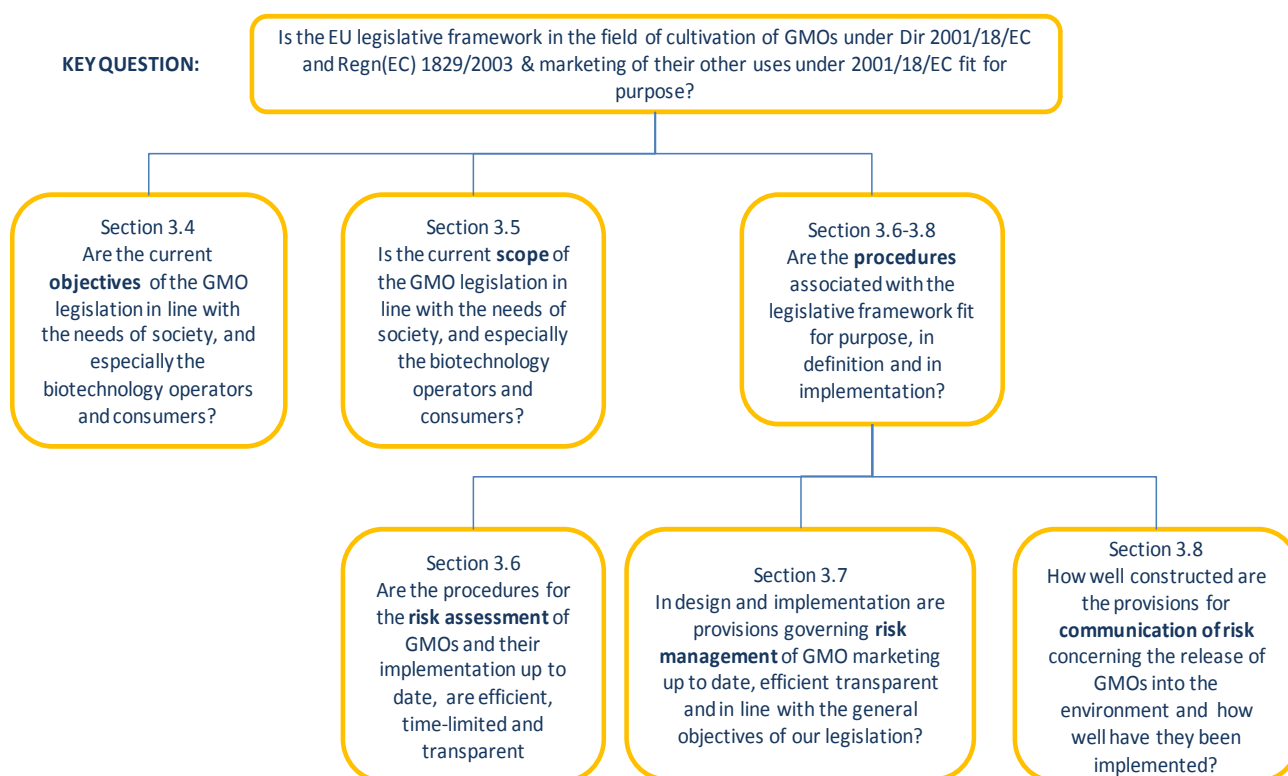
##### 3.3.1 *The high level structure*

The following sections of this chapter explain:

- how we propose to structure the evaluation;
- our interpretation of the evaluation questions in the term of reference;
- the implications for approach to the research, given the context, available information and interpretation of the questions (a description of the overall method, task-by-task, is provided in chapter 4).

Figure 3.1 shows how the main analytical question is addressed by deconstructing the operation of legislative framework into a series of component parts – objectives, scope and requirements - and evaluating each in turn. Each of the main components are themselves then deconstructed, as explained in the remainder of this chapter.

**Figure 3.1 High level structure of the evaluation**



### 3.3.2 Context and framing

Preliminary scanning of the evidence and expert discussions within the team both strongly suggest that the evaluation is unlikely to provide the best insight if it looks only at the ‘anatomy’ and internal functions of the legislative framework, without regard to its ‘environment’ or socio-political context.

It is readily apparent that some of the problems that have been experienced with the implementation of the legislative framework arise from interactions between the framework and the social, political and economic environment within which it is operating. These interactions could occur, and may be observable, in a number of locations, for example:

- In the implicit or explicit framing assumptions used by risk assessors in the risk assessment process;

- At the risk management stage, when stakeholders and MS are unable to agree because they bring different values, priorities or perceptions; and are looking at GMOs in the context of different farming systems, ecological contexts, etc.

The legislation is predicated on there being a consensus about core propositions – e.g. a ‘high’ level of protection, an ‘adverse’ effect. In practice these are often subjective concepts to which MS bring different assumptions.

So although this is a technical evaluation of the legislative framework, it needs to (i) be alert to, (ii) try to reveal and (iii) seek to understand:

- The nature of the linkages between the legislative and the socio-economic and political context;
- How these vary across Europe for different issues; and
- How they impact on the (possible) performance of the legislative framework.

These insights may then help to signpost options for change.

### **3.4 The objectives of the legislation**

#### **3.4.1 Context**

The stated objectives of legislative framework are:

- Protection of animal/human health and the environment (both Directive and Regulation);
- Promotion of consumer interest (only for the Regulation);
- Ensuring effective functioning of the internal market (both Directive and Regulation).

The evaluation needs to consider, how well the legislation has met the objectives (protecting human/animal health, the environment, consumers’ interest and ensuring the effective and efficient functioning of the internal market), given the potential costs that have been avoided but also the benefits that have been foregone. The implementation of the legislation so far has resulted in some approvals for field trials, but no approvals for cultivation.

We will consider this question of objectives within this part of the evaluation, taking into account not only the direct (observable) impacts on health, the environment, etc., but also the possibility of impacts (both positive and negative) avoided. Also, Question 2 on the procedures for risk assessment, and question 7, on the provisions for risk management, ask whether these are capable of meeting the objectives of the legislation

As discussed in Chapter 2, the functions of the legislation include:

- Providing a means of identifying, preventing and managing the risk of possible damage to human health and the environment arising from the release of GMOs;
- Providing a WTO-compliant mechanism for managing the deliberate release of GMOs in the EU;
- A channel through which GMOs can, subject to process, reach the European market;
- A harmonised and generic EU-wide framework for regulating releases of GMOs to avoid the problems that would arise without one;

- Protecting the interests of the consumers and increased consumer/public confidence.

### ***Protecting health and the environment***

The protection of animal/human health and of the environment is provided by the requirement to apply given procedures that assess and manage the risks that GMOs might pose to these 'receptors'. Beneath these broadly stated objectives is a layer of complexity that is addressed in the framing of the risk assessment and subsequent processes – e.g. exactly what the receiving 'environment' is assumed to be. That complexity is mainly considered in the section of the evaluation dealing with risk assessment.

### ***Consumer interest***

For the purposes of this evaluation we assume a 'consumer' to mean any natural person who, in contracts covered by the Directive or Regulation, is acting for purposes which are outside his trade, business, craft or profession (Article 2 of the Directive).

Consumer interest underpins the requirements for traceability and labelling in the Directive and Regulation - the labelling facilitates a choice between GM and GM-free products. But, beyond labelling, the boundaries of consumer interest are less clear - 'consumer interest' is not defined explicitly in the text of the Directive 2001/18/EC or Regulation (EC) 1829/2003. Some have argued for consideration of particular aspects or outcomes of GMOs as matters of consumer interest, including the price of food and the role of GM technology in facilitating, whether directly or indirectly, an extension of the market power and control exercised over the food production system by large, multinational companies. The lack of a harmonised definition of 'consumer interest' is a recognised issue.

### ***Effective functioning of the internal market***

The effective functioning of the internal market is a clear economic objective. As discussed further on in this chapter, the legislation controls the right to sale and to use of regulated GM products within the EU. The Articles providing for prohibition of specified GMOs and GM products do not distinguish between 'use' and 'cultivation'.

## **3.4.2 Approach to the research**

The consultants are asked to consider whether these objectives are in line with the needs of society. Figure 3.2 shows how this question can be deconstructed. Embedded within it, and in the subsidiary ideas shown in the diagram are a series of challenging propositions:

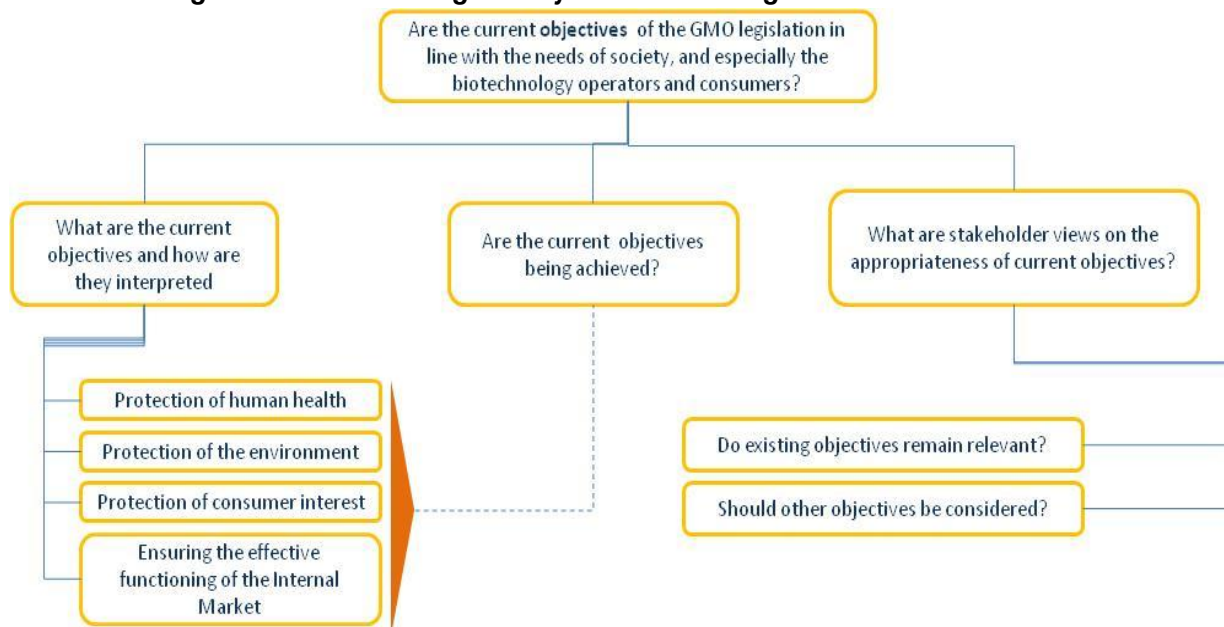
- The determination of society's 'needs' as distinct from its 'wants';
- Who claims to be representing 'society' in these discussions? How do minority views get heard? What weight should they have?;
- That the identified groups - consumers, biotechnology operators, etc. – themselves contain divergent interests, and groups with variable capacity to give 'voice' to their views and protect their interests (e.g. large companies/small firms; healthy adults/babies/the elderly/wealthy/poor).

Through its research the team will examine:

- How current objectives are understood and interpreted;
- Stakeholder views on the appropriateness of the current objectives;

- View on whether objectives should be changed, seeking to understand:
  - the source of any differences of views among stakeholders;
  - the magnitude of these differences.

**Figure 3.2 Evaluating the objectives of the legislation**



### 3.5 The scope of the legislation

#### 3.5.1 Context

##### *New Techniques*

Directive 2001/18/EC and Regulation 1829/2003 apply to GMOs as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC.

The legislative framework results in additional procedures and costs when bringing to market products developed using techniques that are within scope, and uncertainty about whether the product will be approved for release and ultimately for cultivation. Products that provide the same functionality by use of other technique are not affected. Potential outcomes include changes to research investment patterns (less overall, or a redistribution), and stimulation of interest in new techniques that provide efficiency but are beyond the scope of the legislation.

At the same time global scientific knowledge moves on and there is the potential for legislation to lag behind – i.e. fail to cover techniques that also have the potential of posing a risk to human health and the environment.

Member States increasingly deal with questions from stakeholders on whether newly applied techniques result in a GMO. A working group has been convened by the Commission to consider this issue.

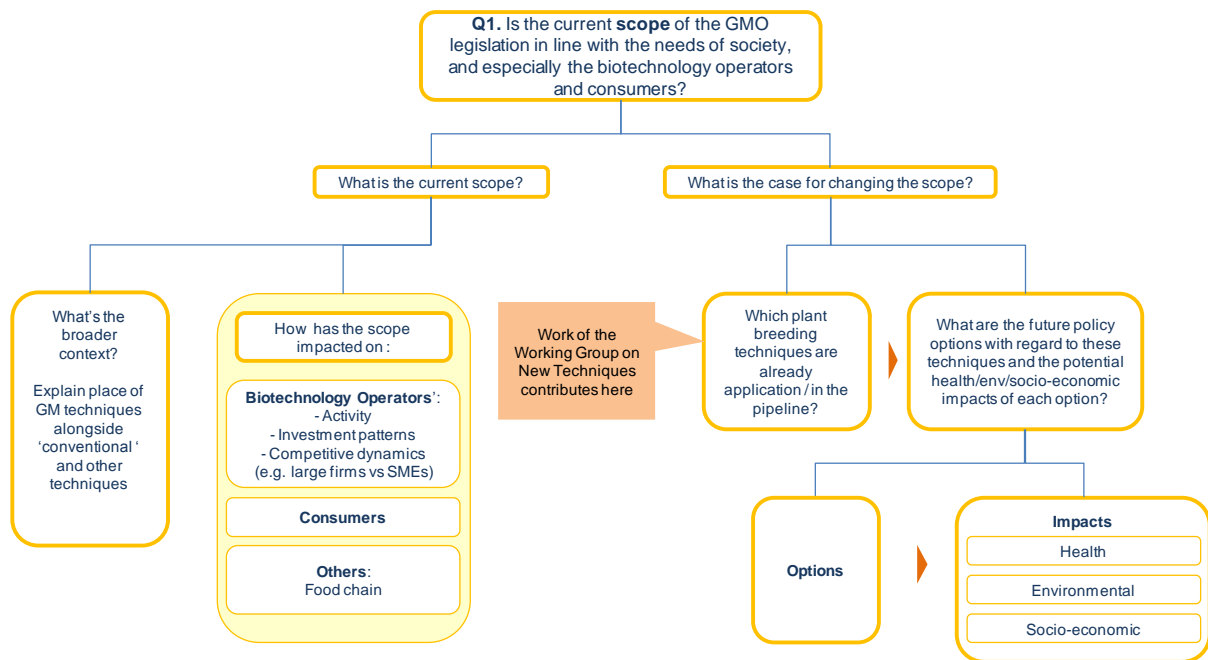
#### 3.5.2 Implications for the research

An overview of the scope evaluation is provided in Figure 3.3. We will examine:

- How the current scope has impacted upon stakeholders: This will draw upon the preceding analysis of how, based on experience to date, inclusion of techniques in scope impacts on stakeholders, including the biotechnology industry and consumers. Effects on industry may include:
  - Impacts on the overall quantity of research conducted in the EU;
  - Impacts on the composition of the research portfolio;
  - Differential impacts on large and small firms;
  - Impacts on the cost and time to bring products to market.
- The case for changing the scope of the legislative framework, in particular by inclusion of additional biotechnology techniques.

This question involves highly complex issues. The exploration of the merits of extending the scope of the Directive will draw, as far as possible, upon the outputs of the Working Group on New Techniques and stakeholder reactions to the proposition of changing scope. **This evaluation will not investigate the technical and scientific issues associated with these techniques**, but will explore the socio-economic dimension of their inclusion in the legislative framework.

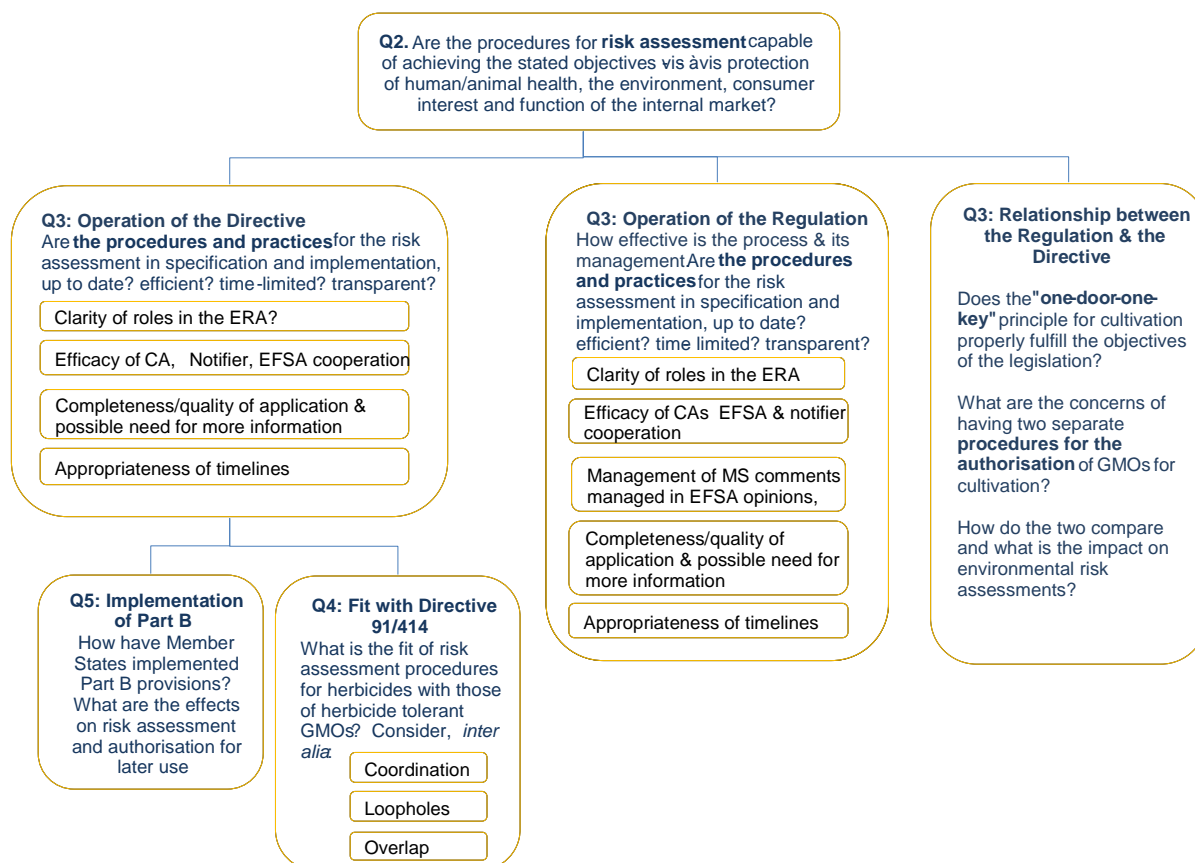
**Figure 3.3 Evaluating the scope of the legislation**



### 3.6 Risk assessment aspects of the legislative framework

Obtaining a robust appraisal of the risk assessment aspects of the legislative framework is perhaps the most important and challenging part of the overall evaluation. The suggested hierarchy of questions is shown in Figure 3.4. In practice there are numerous linkages between the structural and operational questions and an integrated approach will need to be taken. The procedures, including the responsibility for risk assessment, set out under the two items of legislation, are shown in Figure 3.5.

**Figure 3.4 Structure of the evaluation of the risk assessment aspects of the legislative framework**



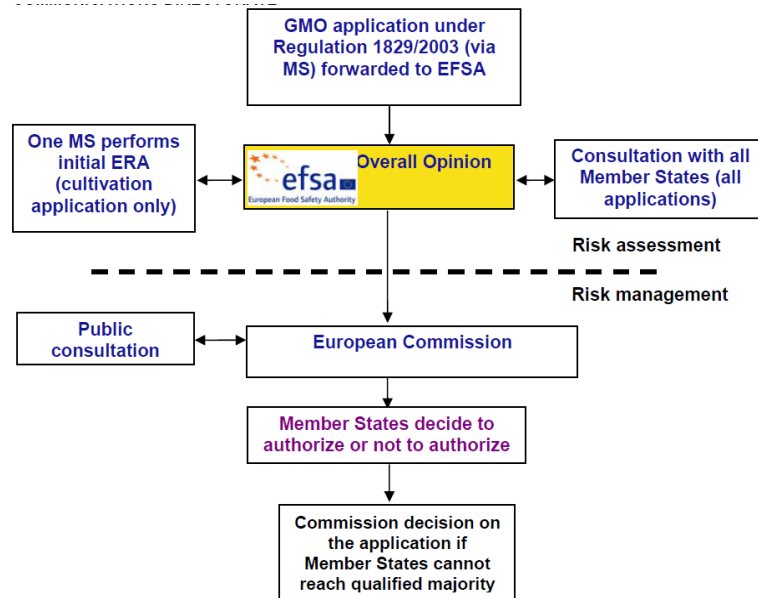
#### 3.6.1 Risk assessment in the context of the Directive 2001/18/EC

##### Context

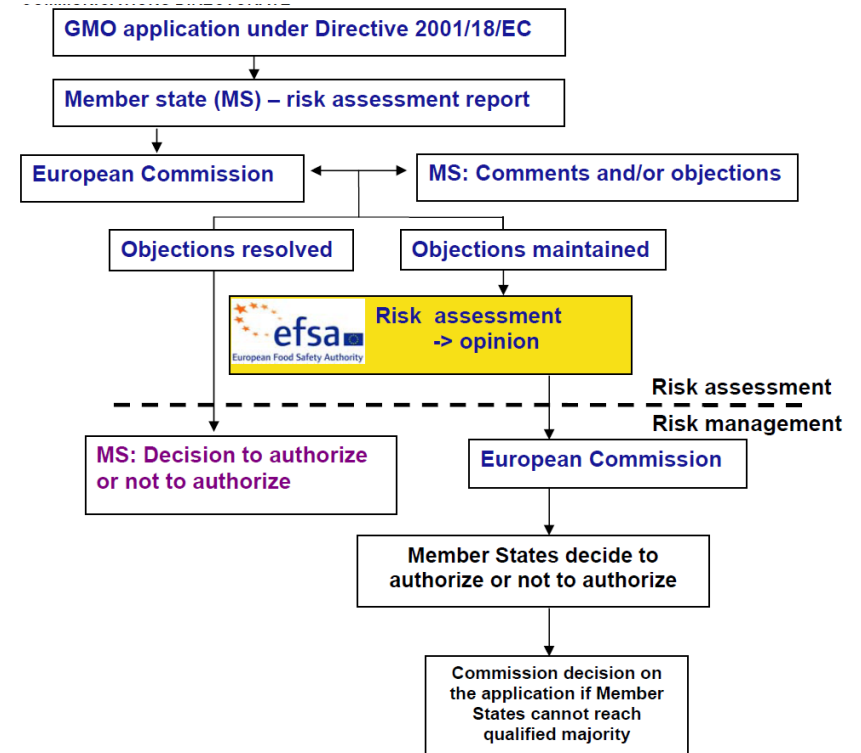
Risk assessment is central to the authorisation procedure under the Directive. Issues of interest include who does the risk assessment, how it is done, as well as how the public is consulted and informed. There are differences of process within the Directive itself, depending on whether a GMO is deliberately released for experimental purposes (Part B), or whether it is placed on the market (Part C).

**Figure 3.5** In many instances organisations wishing to get authorisation for a deliberate release of GMOs can choose between two equivalent regulatory processes which are, in effect, in competition. The Regulation is proving to be the more popular option

Authorisation procedure under Reg (EC) No 1829/2003  
 (centralised procedure via EFSA)



Authorisation procedure under Directive 2001/18/EC



Source: EFSA Factsheet - EFSA's role in the GMO regulatory framework for authorisations under Regulation 1829/2003 and Part C of Directive 2001/18/EC

For the experimental release of GMOs, authorisation is a purely national procedure, in that the decision to authorise or reject the release of the GMO lies fully with the CA which has received the notification (although other MS and the EC may make observations). Conversely, all MS are actively involved in authorising a GMO for placing on the market<sup>16</sup>. For both purposes under the Directive, the notifier must submit an evaluation of the environmental risks as part of the application, from which the CA must issue an opinion in the form of an assessment report.

### **Implications for research**

The evaluation of procedures and practice will be built around the given metrics of efficiency, timeliness, transparency and by reference to aspects of accepted best practice (to examine whether procedures etc. are 'up to date'). Indicators that we expect to give insights into these issues are shown in Table 3.1. Although performance metrics and documentary evidence should provide some insights, we expect to rely on engagement with EFSA, CAs and the stakeholder community for the detailed investigation of the issues.

**Table 3.1 The evaluation attributes provided in the terms of reference suggest research questions, lines of enquiry and indicators**

<b>Attribute</b>	<b>Research focus / Stakeholder insights &amp; perceptions</b>
“Up to date”	<i>Cross reference to accepted best practice in risk assessment;</i> <i>Stakeholder perceptions of process improvements/learning &amp; responsiveness</i>
“Efficient”	<i>Predictability;</i> <i>Cost;</i> <i>Processing time from initial application to final decision;</i> <i>Clarity of information requirements;</i> <i>Number of times the clock is stopped</i>
“Time-limited”	<i>Risk assessment process operating to defined timetables</i>
“Transparent”	<i>Basis of decisions and progress of applications is clear to stakeholders;</i> <i>Evidence on which decisions are made is available for scrutiny;</i> <i>Process for considering comments is clear to stakeholders;</i>

The team will engage in particular with:

- MS that have had experience of risk assessments under Part B applications;
- MS that have managed Part C applications under the Directive;
- MS that have registered comments with EFSA/the Commission in relation to Part C applications;

Some commentators have observed that risk assessment and risk management regimes of GM crops differ among EU Member States not because risk assessors are interpreting shared bodies of data in contrasting ways, but:

- Because they are asking and answering slightly different questions, and
- They are asking those different questions because they are making different risk assessment policy assumptions.

<sup>16</sup> Questions and Answers on the Regulation of GMOs in the European Union. Available from: <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/06/58>

This part of the evaluation needs to explore not only the risk assessment process but also how that process is 'framed' in different MS. For instance, are the 'framing assumptions' to be used by the risk assessors clearly stated by those tasking them? Are they provided but not transparent to other stakeholders? Or are the framing assumptions determined by the risk assessors? Framing assumptions cover issues such as:

- The environment/agricultural system against which the comparison is made; and
- Whether the organism or also the agricultural system of which it is a component is assessed.

The implementation of Directive 2001/18/EC introduced more stringent requirements for risk assessment, extending the scope to cover cumulative and long term effects. The effect of these developments will need to be closely examined. In particular, the evaluation needs to explore the extent to which the principles established by Annex II of the Directive, and supplemented by Decision 2002/623/EC have been upheld by risk assessors. This applies equally to applications for cultivation submitted under Regulation 1829/2003, as dossiers are required to include information and conclusions about the risk assessment in accordance with the principles set out in Annex II of the Directive 2001/18/EC (Article 5(5)). EFSA has to ensure that the environmental safety requirements specified in Directive 2001/18/EC have been applied (Article 6(4)) and that the product complied with the criteria in Article 4(1), which includes no adverse effects on human health, animal health or the environment. EFSA may also ask CAs to carry out an ERA.

EFSA has produced a guidance document for the risk assessment of GMOs<sup>17</sup>. This was originally adopted in 2004, and then updated in 2008. In March 2008, EFSA received a mandate from the Commission to further develop and update its guidelines as regards the ERA of GMOs<sup>18</sup>, to consider in detail

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

The effect of these guidelines, and how they have been used, especially in relation to assessing long term and cumulative effects, including the effects on biodiversity and the ecosystem will need to be evaluated. One risk to the legislative framework is that significant differences in national risk assessment policies will emerge and solidify as Member States define risk assessment policies more explicitly and accountably. This could create conditions for enduring conflict that would be very difficult to resolve.

### **Part B activity and implementation**

Since 1992, there have been around 2,400 field trials involving GMOs in the EU. These trials have involved 66 species in the following order of significance (in terms of number of field trials): maize, rapeseed, beet, potato, tomato, cotton, chicory, tobacco, rice, wheat. 47% of field trials concerned herbicide tolerance, 17% altered composition/ new substances, 16% insecticide resistance, 7% male sterility, 5% resistance to viral disease, 4% resistance to fungal disease. Field trials have occurred in 20 Member States. The

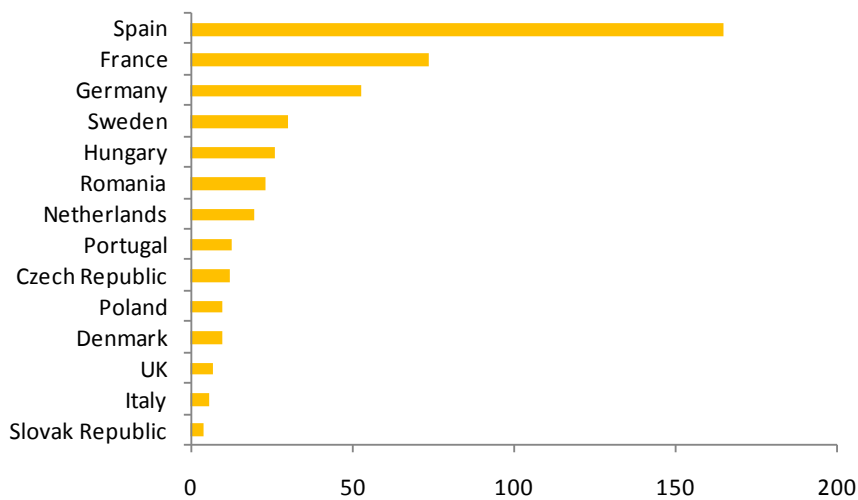
<sup>17</sup> Available from: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620775747.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775747.htm)

<sup>18</sup> General Mandate: Aspects of Environmental Risk Assessment (ERA) and the ERA guidance. Information available at: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionDetailsRO.jsf>

largest number has occurred in Spain and France, followed by Germany and Sweden<sup>19</sup>. The number of non-plant notifications is much smaller and the geographical distribution of these releases is quite different (compare Figure 3.6 with Figure 3.7). The decision to authorise or reject the experimental release of a GMO under Part B of the Directive is exclusively determined by the national CA which has received the notification.

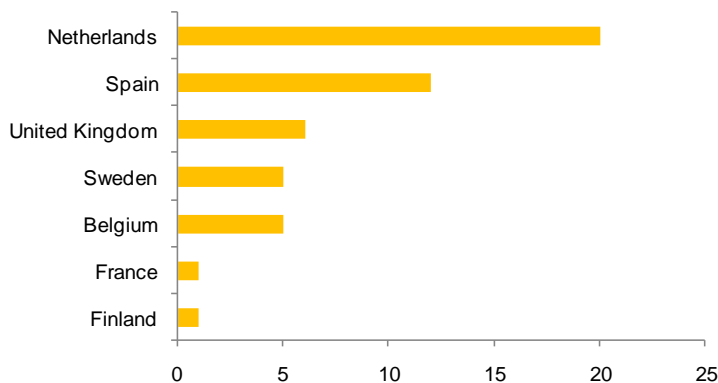
Activity under the Directive is of most interest in respect of authorisations for experimental release. Applications for cultivation are now tending to be made using the procedures of Regulation 1829/2003 rather than the Directive (see later section), though the Directive's risk assessment procedures are applied.

**Figure 3.6** *Two thirds of summary notifications submitted under Part B of Directive 2001/18/EC<sup>20</sup> for plant GMO field trials have occurred in just three member states – in part because of the dominance of maize in the trial population. Countries having received less than four notifications for field trials are not shown.*



Source: GHK analysis based on data at [http://gmoinfo.jrc.ec.europa.eu/gmp\\_browse.aspx](http://gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx)

**Figure 3.7** *Far fewer non-plant notifications have been submitted under Part B of Directive 2001/18/EC; they show a very different geographical pattern and have come from a much larger range of sponsoring organisations*



Source: GHK analysis based on data at [http://gmoinfo.jrc.ec.europa.eu/gmp\\_browse.aspx](http://gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx)

<sup>19</sup> [http://www.gmo-compass.org/eng/agri\\_biotechnology/field\\_trials/](http://www.gmo-compass.org/eng/agri_biotechnology/field_trials/)

<sup>20</sup> Up until the end of March 2008

Member States have some discretion on how they implement the Directive, especially Part B e.g. data requirements, timelines and information to the public). This has given rise to some concern about a lack of consistency among Member States. For example, Article 9 of the Directive sets a broad requirement for Member States to make provision to consult the public for a “reasonable” period of time before decisions are taken on Part B applications. The Member States thus decide details of the consultation system for themselves. Most provide a minimum of 30 days for public comments. There are also differences in the way Member States deal with clinical trials on gene therapy and whether applicants use the opportunity for pre-application discussions with CAs. The Directive neither provides for nor explicitly prohibits these opportunities for discussion. Whether a MS offers this opportunity has implications for the time taken to make a decision and the consequent administrative burden. A full discussion could reduce requests for further information during the formal notification period, thus reducing time and resources required. Indeed, requests by CAs for additional information have been cited as the biggest cause of delays. Whether a notifier engages in a pre-application discussion (if the option is available) may reflect the clarity of the guidance.

Member States also have different systems for appeals (Article 9). For instance, whilst any public interest organisation or citizen can appeal against an authorisation of a field trial in the Netherlands and France, only citizens whose interests may be affected can appeal in Germany. No appeal system exists in the UK.

The way Member States deal with the risk evaluation of field trials also differ. Most CAs indicate that, after the end of a field trial with GM crops, consent holders have to send a report to the CA on observations of any risk for human health or the environment. However, only some CAs make these reports accessible to the public. Additionally, whilst national enforcement bodies in most countries regularly monitor whether consent holders comply with the risk management measures that are sometimes required following the risk evaluation of a field trial, only a few of them make their findings publicly available.

There is scope for variation among Member States in the standards required of Part B applications in terms of, for example, the scale (number of fields, etc.) and duration (years) of field trials. This has the potential to create problems if the evidence collected in crop trials according to domestic practice in one Member State under a Part B application is then used to support a Part C application that attracts greater scrutiny from across the EU. Other Member States may find that, when compared to their own guidelines, those same crop trial data are inadequate as the basis for a decision to approve. Different cultures and data requirements (i.e. technical and political differences) can later collide and conflict at the EU level and thereby affect the potential for Part C authorisation.

Further differences that could have important consequences include the use of simplified and differentiated procedures, and the use of antibiotic resistance markers (ARMs). Commission Decision 93/584/EEC established the criteria for simplified procedures regarding the deliberate release of GMOs. Article 7 of the Directive 2001/18/EC allows (but does not obligate) MS to use differentiated and simplified procedures for the release of certain GMOs into specific ecosystems when sufficient experience has been obtained, thus allowing for shorter timetables for the approval of releases for GMOs under these circumstances. However, there are significant differences among MS in their use of, or preferences for, simplified and differentiated procedures. Most CAs have allowed for both under national legislation. Simplified procedures have also been suggested for ‘stacks’ of previously authorised GM products. Industry has supported the use of simplified procedures, highlighting the benefits of reduced time, resources and costs required.

Although there is still limited experience with differentiated procedures, there have been concerns that simplified procedures compromise the ability for the public to be sufficiently informed. In particular, the 15 day period of notice of intention to plant a GMO is not regarded as sufficient by some stakeholders. However, the Directive allows the use of

differentiated and simplified procedures only after due consideration has been given to how the interests of the public can be best protected.

The use of ARMs in GM plants (needed to find or select transformed cells amongst untransformed ones) is strictly controlled. Under Directive 2001/18/EC, ARMs in GMOs which may have adverse effects were to be phased out by 31 December 2004 for Part C applications and 31 December 2008 for Part B applications. In 2004, EFSA released a report on the use of ARMs, concluding that a general ban on all ARMs is not justified. Instead, ARMs have been separated into three groups:

- Unlimited use: can be used without restrictions, e.g. *nptII* marker gene.
- Not for use in commercial GM plants: can be used in field trials, but not to be used for agriculture.
- Not allowed: are no longer to be used as they confer resistance to antibiotics of high value.

However, divergent national policies on Part B releases remain. Some CAs have allowed certain ARMs to be allowed in Part B releases, as long as they do not endanger the use of corresponding antibiotics. Other CAs do not allow any ARMs in Part B releases. There is a possibility that further development of non-plant GMOs may increase the use of ARMs, especially as they are often needed to fulfil monitoring requirements for field trials. Although new marker systems are being and have been developed, these can be prohibitively expensive and may not offer similar safety advantages. However, future GM plants should contain fewer ARMs given that GM plants which do not contain ARMs are likely to require simplified safety assessments. In January 2006, the first application for a marker-free GMO (LY 038) was submitted in the EU. Nonetheless, the use of ARMs in non-EU countries is continuing.

### **3.6.2 Interface with the Plant Protection Products Directive (Question 4)**

#### **Context**

There seem to be three main areas which need to be evaluated in order to explore the interplay between the Directive 91/414/EEC on Plant Protection Products and the Directive 2001/18/EC:

- The coherence of risk assessment practices used under both Directives (considering that the Directive 91/414/EEC is to be replaced through a Regulation to be published in July 2009 and which is due to enter into force at the end of 2010);
- The impact of changes in management practices, and therefore the effectiveness of herbicide management systems implemented by MS to specifically prevent adverse impacts of genetically modified herbicide-tolerant (GMHT) crops;
- The extent of coordination between competent authorities under both Directives, and the coordination between the GMO panel and the pesticides panel when assessing GMHT plants.

There is a requirement under Decision 2002/623/EC, supplementing Annex II of Directive 2001/18/EC, to assess the environmental impact of changes in management, including agricultural practices of GM crops. There is therefore a need to evaluate the environmental impact of the herbicides used on GMHT crops in addition to the environmental impacts directly associated with the GM plant/crop itself.

Under the Directive on Plant Protection Products (Directive 91/414/EEC) a herbicide used on a GMHT crop is assessed differently from the same herbicide used on a non-GMHT crop. Under 91/414/EEC, the ERA of herbicides includes an assessment of impacts on certain non-target organisms and studies of residual activities in soil and water, but does not include assessment of impacts on biodiversity within crops and changes in agro-

ecosystems, which are required in relation to GM crops. As such, a herbicide used on a GMHT crops requires a different assessment compared to the same herbicide used on non-GMHT crops and conventional crops. In December 2008, the European Council concluded that there is a need ensure coherence between risk assessments of GM plants which produce active substances covered by Directive 91/414 and the corresponding plant protection products.

To date no agreement has been found regarding a common approach for the risk assessment of GMHT crops, although EFSA has given some guidance for the ERA of GMHT crops. Research shows that the environmental impact of herbicides on GMHT crops depends on a wide range of baselines and on agronomic and environmental factors, which vary from region to region and from season to season<sup>21</sup>. Effects thus depend on the type of herbicide used and the management of the herbicides in the crop production system. The environmental impacts of conventional herbicides applied to conventional crops are also subject to the same factors, making it difficult to establish detailed baselines for comparison of GMHT systems. EFSA therefore concluded that it is not feasible to carry out a meaningful environmental impact assessment of the herbicides used on GMHT crops<sup>22</sup>.

Instead, EFSA proposed that applicants and the appropriate CAs in MS establish and implement herbicide management systems for GMHT crops to avoid adverse impacts on the environment, since it is primarily the herbicide management programme that determines the environmental impact. Several measures have been developed to mitigate environmental effects of herbicide, such as controlling when and where herbicides are applied. These management measures should be reviewed and updated, and be in line with the provisions under Directive 91/414/EEC and national regulations concerning weed resistance management strategies. EFSA also recommends that monitoring of herbicides be conducted by the agrochemical companies, under the auspices of the pesticide regulatory systems in MS. It has been suggested that monitoring be carried out especially for the most common ecosystems and farming practices. General surveillance however, is only adequate to address unanticipated effects. Therefore case-specific monitoring, especially in the initial years of cultivation, is key to monitor specific identified effects, as has been requested in Spain in the risk assessment of NK 603.

The Commission responded to EFSA's proposal, in September 2008, by pointing out that the provisions of Directive 2001/18/EC were explicit and clear in its ability to undertake an ERA which takes into consideration the impact of cultivation of GM crops on biodiversity and the changes in the use of pesticides. Since the creation of a GMHT modifies the use pattern of the respective herbicide, the resulting impact on the environment, both quantitative and qualitative, have to be evaluated according to the requirements under Directive 2001/18/EC<sup>23</sup>. However, as regards the herbicides, their use in a given Member State is subject to an authorisation under Directive 91/414/EC by the concerned Member State (as opposed to the actual active substance involved). These requirements under Directive 91/414/EEC will have to be taken in to account in addition to the possible conditions set out in the authorisation of GMHT plants under Directive 2001/18/EC. Specifically, according to Annex VI of Directive 91/414, Member States have to perform a risk assessment for the plant protection product under the conditions of use in the GM crop, to assess the possibility of long term effects on the abundance and diversity of non-target species. This means that competent authorities under the Directive 2001/18/EC and Directive 91/414/EEC need to coordinate their action as far as possible. This is explicitly

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<sup>21</sup><sup>21</sup> The GM Crop Farm Scale Evaluations, Section 3. In: GM Science Review, Second Report. Available from: <http://www.gmsciencedebate.org.uk/report/pdf/gmsci-report2-full.pdf>

<sup>22</sup> Working Document from the EFSA GMO Panel 2008. Environmental risk assessment of genetically modified herbicide tolerant plants and the interplay between Directive 2001/18/EC and Directive 91/414/EEC.

<sup>23</sup> Available from: [http://www.efsa.europa.eu/cs/BlobServer/DocumentSet/gmo\\_response\\_european\\_commission\\_en.pdf](http://www.efsa.europa.eu/cs/BlobServer/DocumentSet/gmo_response_european_commission_en.pdf)

made clear in the text of the Directive 2001/18/EC itself (Recital 26). The GMO panel should also be coordinating closely with the pesticides panel when assessing GMHT plants.

Under the Thematic Strategy on Pesticides, Directive 91/414/EEC is scheduled to be replaced by an Authorisation Regulation<sup>24</sup>.

### **Implications for the research**

The above analysis suggests the following lines of enquiry:

- How does the risk assessment procedure under the Directive 91/414 compare with the risk assessment for the Directive / Regulation? What are the areas of overlap and what are the implications of these? Which of the two do stakeholders think is more appropriate for assessing GMHT crops and why? What are baselines being established, and what baselines are being used?
- To what extent have MSs implemented herbicide management systems for GMHT crops? What provisions are there in MSs for post market environmental monitoring of herbicides and how has it been implemented?
- To what extent do the relevant competent authorities at the national level coordinate and communicate? Have any explicit provisions for this been made? How are they functionally and institutionally separated, and how does this impact on the level of coordination?
- To what extent has the GMO panel and the pesticides panel coordinated their activities? What has the role of the Commission been to promote coordination at the EU level?

### **3.6.3 Risk assessment in the context of Regulation 1829/2003**

#### **Context**

The Directive and the Regulation have different approval procedures, involving institutions in different ways. The role and obligations of EFSA differs in each, with a knock-on effect on the roles of relevant CAs. Under the Regulation, EFSA is responsible for the scientific risk assessment, which should cover the environmental risks, and a safety assessment for human and animal health. In order to prepare its opinion, EFSA may request that food assessment bodies of MS carry out a food assessment (in accordance with Article 36 of Regulation 178/2002). If a product requires approval according to Directive 2001/18/EC, EFSA may also ask a CA to carry out an environmental risk assessment (but must ask a CA if the GMO is to be used as seeds or other plant-propagating material).

Although EFSA has a more prominent role under the Regulation's authorisation procedure, its remit is strictly limited to giving scientific advice to the EU institutions and MS, by making an assessment of all possible risk factors of the intended uses of the GMO. These assessments are carried out by EFSA's GMO Panel of scientific experts who are supported by a number of highly specialised working group experts that are selected according to the scientific topic to be investigated. EFSA has also produced a guidance document for the risk assessment of GMOs<sup>25</sup>, which was originally adopted in 2004 and updated in 2008. In March 2008, EFSA received a mandate from the Commission to further develop and update its guidelines as regards the ERA of GMOs<sup>26</sup>.

EFSA has initiated Focal Points in the MS which act as an interface between EFSA and the different national food safety authorities, research institutes, consumers and other EFSA-

<sup>24</sup> <http://ec.europa.eu/environment/ppps/strategy.htm>

<sup>25</sup> Available from: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620775747.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775747.htm)

<sup>26</sup> General Mandate: Aspects of Environmental Risk Assessment (ERA) and the ERA guidance. Information available at: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionDetailsRO.jsf>

related stakeholders. The key objective for Focal Points is to support their Advisory Forum members.

### **Implications for research**

The research requires an examination of the risk assessment procedures as outlined in the terms of reference and the EPEC proposal. Metrics will be used (as in Table 3.1) to establish aspects of performance. The survey and interviews with EFSA, Member States and industry will provide insights to particular areas where there are difficulties with implication. For example, issues to explore include:

- How far the EFSA involves CAs and how they cooperate: how and to what extent EFSA engages, acknowledges and acts on the input of CAs;
- How effective are have the procedures introduced to make all comments public and to increase transparency.

### **3.6.4 The relationship between the Regulation and the Directive**

#### **Context**

For a food/feed product containing GMOs or consisting of such organisms where authorisation for cultivation is required, the applicant has a choice:

- the application in its entirety is subject to Regulation (EC) No 1829/2003 under the "one door, one key" principle with authorisation for the deliberate release of GMOs into the environment managed in accordance with the criteria laid down by Directive 2001/18/EC, and the authorisation to use the GMO in food or feed managed in accordance with the criteria laid down by Regulation (EC) No 1829/2003; or
- the application — or part of the application — is submitted both under Directive 2001/18/EC and Regulation (EC) No 1829/2003.

Depending on whether the application is submitted under the Directive or the Regulation, the authorisation follows different routes up until EFSA gives its opinion. From then on the authorisation process follows the same procedure (as shown in Figure 2.1). Under the Directive, the authorisation is first forwarded to the relevant CA in a Member State where the application is submitted, and then forwarded to other Member States and the Commission, who can make comments and issue objections. Only if these remain unresolved is the application forwarded to EFSA. Under the Regulation's one door one key process, the application is automatically forwarded to EFSA from the original Member State's CA.

The one door, one key facility thus leads to the application of different procedures in terms of risk assessment, risk management, and national safeguard measures for the same use of GMOs. The initial application is made through the competent authority of a Member State but the lead responsibility for processing the applications and safety assessment rests with a central body, the European Food Safety Authority (EFSA). The responsibility of the Community Reference Laboratory in its role as validator of the event specific methods supplied by the notifier is also different. CRL method validation is mandatory under 1829/2003 but this is not foreseen in the Directive. It has been done *de facto* in most recent applications, but without any financial contribution from the notifier.

In theory, the 'one door one key' approach provided by the Regulation 1829/2003, allowing for a single application to be submitted for food and feed use as well as cultivation, does not fundamentally change the principles of risk assessment - the applicant has to adhere to the principles established under Annex II of the Directive 2001/18/EC, regardless. Instead, the 'one door one key' approach is intended to increase the efficiency and effectiveness of the delivery of scientific and technical support to ensure these principles are adhered to, and thereby increase the certainty and predictability of the safety regime for companies submitting applications for authorisation for the approval of GMOs or food/feed containing

or consisting of GMOs. Whether this has in fact happened in practice will need to be evaluated. There are some aspects of the process which have caused some confusion, rather than certainty, such as the role of CAs and the obligation of EFSA, given that EFSA only has an ambiguous obligation to consult advisory bodies and CAs under Regulation 1829/2003. How such choices made by EFSA have affected risk assessments is of key importance. Despite efforts at clarification, issues have also remained over the information needed for an application given that additional information is often requested, causing the procedural clock to be suspended in the process. The reasons for this (on the part of the applicant and in terms of the clarity of the guidance which is given), and the extent of the effects of this will also need to be considered.

The appropriateness of the one door one key principle will need to be examined in terms of whether the Regulation improves on the Directive, and whether it meets the objectives of the legislation better. In order for this to be established, differences will need to be identified in terms of:

- **Processes:** before, during and after an application is submitted.
- **Requirements for authorisation:** what inputs are needed from the notifier in order for an application to be accepted?
- **Responsibilities:** how do the responsibilities of the different institutions and actors vary under both the Regulation and the Directive?

For instance, in terms of the requirements, an authorisation under Regulation 1829/2003 for cultivation (Article 5(5)) needs to adhere to the complete technical dossier required by Annexes III and IV of the Directive 2001/18/EC, including the principles for risk assessment laid out in Annex II, as well as a monitoring plan as specified in Annex VII. Having established differences across all three aspects listed above, their effect on risk assessment, risk management, and ultimately on the objectives of the legislation will need to be evaluated

Overall, applicants seem to currently prefer to seek authorisation through the Regulation and to make use of the “one door, one key” principle (where a single application and a single risk assessment is submitted to gain a single authorisation for a GMO and all its uses). Nonetheless, applicants often choose to split an application which covers food, feed and cultivation between the Regulation and the Directive, where authorisation for food and feed is considered under the Regulation, but authorisation for cultivation under the Directive. This has occurred with the recent application for Bt11 maize<sup>27</sup>. When an applicant only seeks authorisation for cultivation, they have also sometimes chosen to submit the application entirely under the Directive, as in the case of 1507 maize (authorisation for food and feed had already been given under Regulation 1829/2003)<sup>28</sup>. Why applicants prefer authorisation under the Regulation, why some choose to split their application, and the opinion of other actors and institutions will provide key insights into how the Regulation and the Directive work in practice.

### **Implications for research**

The stakeholder consultations will seek to establish whether and why notifiers have a preference for the Regulation, why and whether that is consistent across the EU and within particular stakeholder groups. Issues to explore include:

- Why do applicants tend to prefer one instrument to the other? Why do some applicants still choose to split their application and use both the Regulation and the Directive?

<sup>27</sup> EFSA Opinion: [gmo-compass.org/pdf/regulation/maize/Bt11\\_mais\\_cultivation\\_opinion\\_efs.pdf](http://gmo-compass.org/pdf/regulation/maize/Bt11_mais_cultivation_opinion_efs.pdf). GMO Compass details: <http://www.gmo-compass.org/eng/gmo/db/68.docu.html>

<sup>28</sup> <http://www.gmo-compass.org/eng/gmo/db/>

- Which legal instrument is more appropriate for certain application and why?
- Whether 'one door one key' is appropriate instrument, to what extent and has it served its purpose and achieved its objectives under ERA (and for RM)?

### 3.7 Risk management aspects of the legislative framework

#### 3.7.1 Context

Risk management involves the consideration of policy alternatives and the selection of appropriate prevention and control options. Risk management is thus distinct from risk assessment<sup>29</sup>. Within the context of the GMO legislative framework, the responsibilities for each generally lie with different institutions. Whilst EFSA offers scientific evidence for making informed decisions (risk assessment), the decisions themselves (risk management) are the responsibility of policy making bodies<sup>30</sup> such as the Commission and governments of the Member States (see Figure 3.8).

At the EU level, decisions regarding risk management are made on the basis of the results of a risk assessment, as well as other factors. The legislation requires the Commission to take into consideration the views of experts such as EFSA, but also national authorities, the European Group of Ethics in Science and New Technologies, as well as other stakeholders. On receiving EFSA's opinion, the Commission has three months in which to draft a decision and submit it to the Standing Committee on the Food Chain and Animal Health. At the Committee representatives of Member States may approve or reject the Commission's draft on the basis of a qualified majority. If there is no agreement, or a decision cannot be reached, the Commission's draft decision is submitted to the Council of Ministers. The Council has 90 days to approve or reject the decision, also with a qualified majority. In the event of a rejection, the Commission must revise its draft. Without approval, or without a qualified majority, the Commission's draft decision comes into effect.

As of November 2008, seven GMO products<sup>31</sup> have been authorised under the Directive 2001/18/EC for import and processing, and in some cases also for use in feed<sup>31</sup>. Under Regulation 1829/2003, 27 genetically modified products have been authorised for food and feed use<sup>32</sup>. However, since 1998 only two genetically modified products have been authorised for cultivation under the GMO legislation (maize T25 and maize MON810), with only MON810 being actively cultivated. No GMO has been authorised for cultivation since the adoption of the new regulatory framework (Directive 2001/18/EC and Regulation (EC) 1829/2003<sup>33</sup>. However, two GM maize types (1507 and Bt-11) are currently considered for cultivation, but on the 25th of February 2009, members of the Standing Committee on the Food Chain and Animal Health were unable to come to a decision<sup>34</sup>. The next step will be a submission to the Council of Ministers for consideration under the Comitology procedure (Council Decision 1999/468 Article (5)(6). As yet, the Council of Ministers has not given a majority backing to a GMO for marketing or cultivation. If they fail to agree, the application returns to the Commission.

<sup>29</sup> EFSA, 2004. Guidance document for the risk assessment of genetically modified plants and derived food and feed, prepared by the Scientific Panel on Genetically Modified Organisms of the European Food Safety Authority, September 2004. Available from: [http://www.efsa.eu.int/science/gmo/gmo\\_guidance/660/guidance\\_docfinal1.pdf](http://www.efsa.eu.int/science/gmo/gmo_guidance/660/guidance_docfinal1.pdf)

<sup>30</sup> From EFSA's website: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_AboutEfsa.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_AboutEfsa.htm)

<sup>31</sup> European Commission, DG Environment. EU Policy on Biotechnology. Available from: [http://ec.europa.eu/environment/biotechnology/pdf/eu\\_policy\\_biotechnology.pdf](http://ec.europa.eu/environment/biotechnology/pdf/eu_policy_biotechnology.pdf)

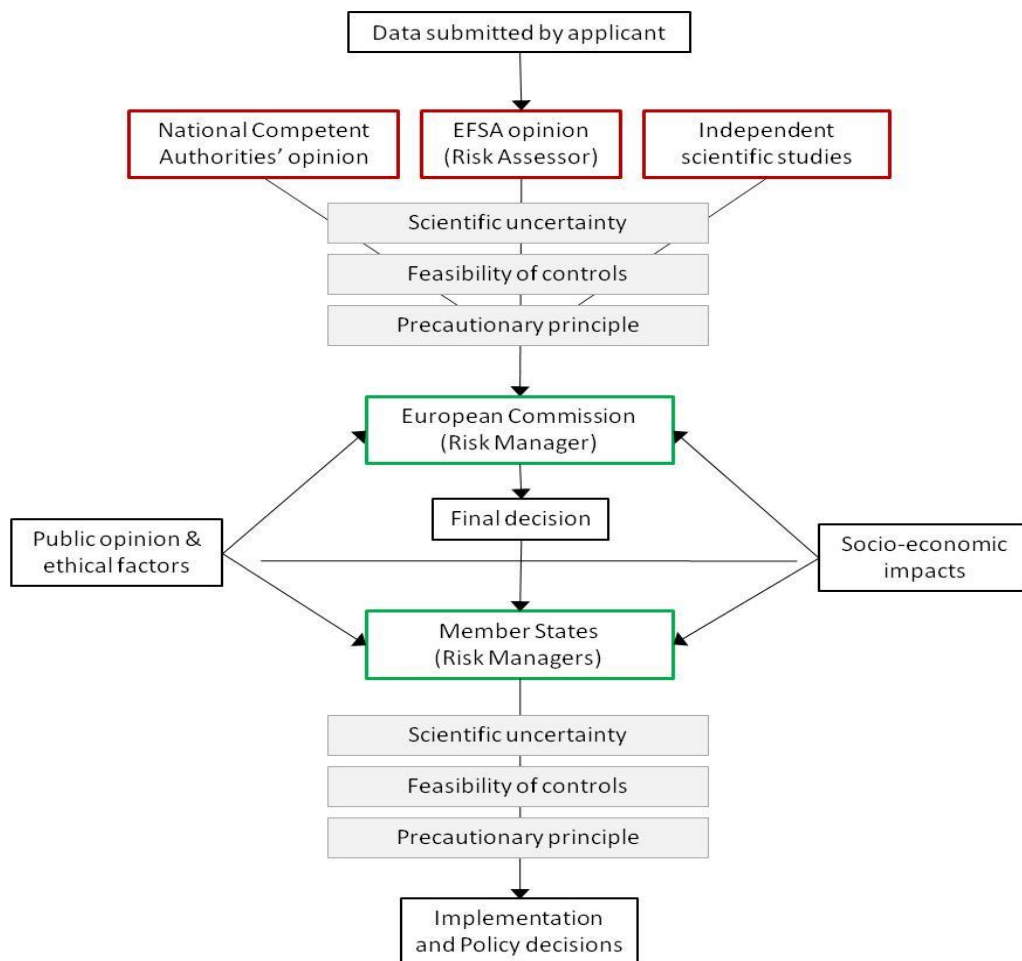
<sup>32</sup> Community register of genetically modified food and feed, [http://ec.europa.eu/food/dyna/gm\\_register/index\\_en.cfm](http://ec.europa.eu/food/dyna/gm_register/index_en.cfm)

<sup>33</sup> GMO Compass, [www.gmo-compass.org/](http://www.gmo-compass.org/)

<sup>34</sup> Euractiv, February 2009. EU meeting on GM maize ends in deadlock. Available from: <http://www.euractiv.com/en/sustainability/eu-meeting-gm-maize-ends-deadlock/article-179795>

Given the decisions made at the EU level, Member States themselves have to then make risk management decisions. There is scope for differences in national risk management measures. Provisions considered in this evaluation under risk management include monitoring, traceability and labelling, and national safeguard and emergency measures. More specific management measures that are taken following authorisation or the risk evaluation of field trials will also be considered. Member States have more scope for flexibility on some decisions than others. For instance most traceability and labelling decisions have already been established at the EU level, whereas the decision to use safeguard measures is a purely national concern. **Although co-existence measures also fall under the remit of (national) risk management provisions mainly on economic grounds, these will not be explicitly evaluated in this project as these are already in the process of being examined by the Commission.**

**Figure 3.8 Diagrammatic representation of the separation between risk assessment and risk management on both the EU and MS level<sup>35</sup>.**



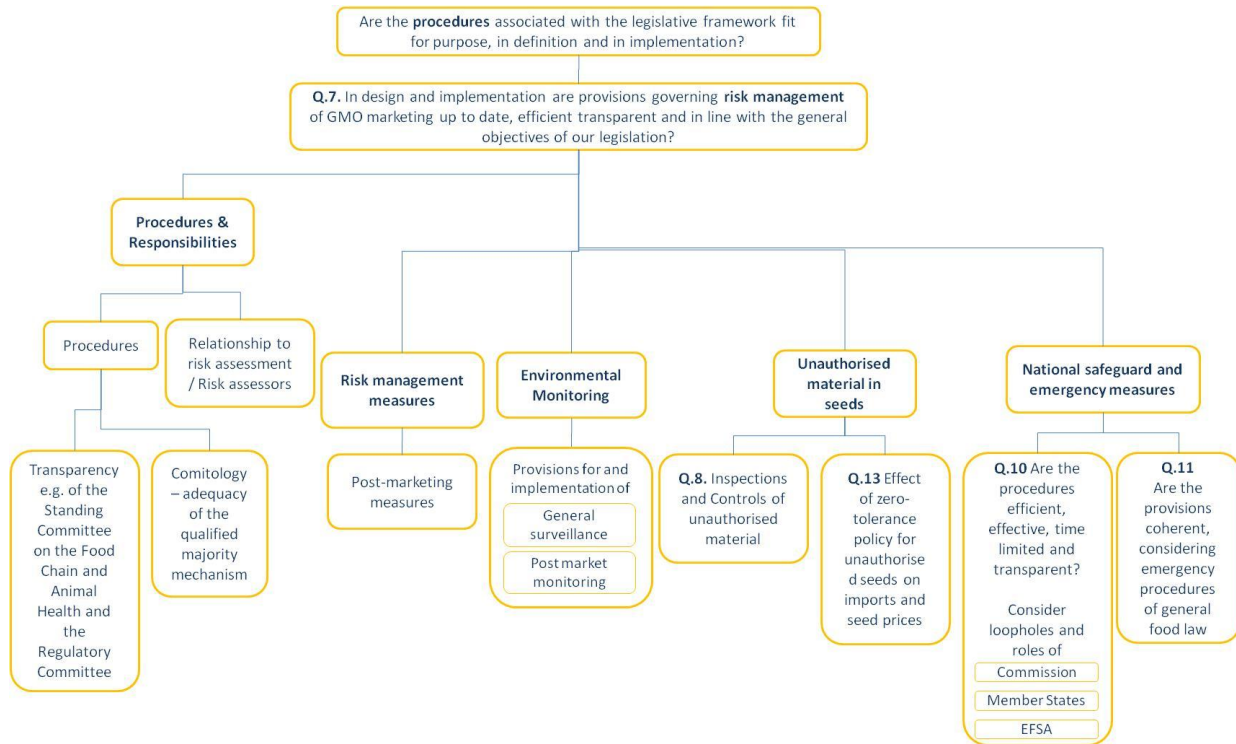
*Note: The factors that are taken into account when making risk management decisions (including the results from the risk assessment) are incorporated. The decision making process is also 'filtered' by various the framings and interpretations of certain aspects, some of which are represented.*

<sup>35</sup> Adapted from: <http://www.greenpeace.org/raw/content/eu-unit/press-centre/policy-papers-briefings/flaws-in-the-EU-authorisation.pdf>

### 3.7.2 Approach to the research

In the terms of reference, questions 7, 8, 10, 11 and 13 address the legislative, procedural and practical aspects of the risk management activity. A mapping of the hierarchy of questions is shown in Figure 3.9.

**Figure 3.9 Structure of the evaluation of the risk management aspects of the legislative framework**



### 3.7.3 Evaluating procedures and responsibilities

The research will seek to provide insights into difficulties that stakeholders are experiencing with the risk management process.

The interaction and relationship between risk assessment and risk management will also be considered, as it is the line between the two can be unclear. This will perhaps be more obvious at the level of the Member State rather than the EU level, where the allocation of responsibility to separate institutions has been clearly made and codified in Regulation 178/2002. Member States have varied in their approach to allocating these roles, including whether they are vested with separate institutions. Functional and institutional separation of risk assessment and risk management will therefore need to be examined.

The focus of this evaluation is on cultivation and how the requirements and guidelines associated with the GMO legislative framework are being applied. There is potential, however, for policy decisions on the handling of risk assessment and risk management further down the food chain to influence (directly or indirectly) the design and delivery of decisions relating to cultivation, by changing organisational ‘norms’ and institutional arrangements.

In 2007 all Member States agreed that, with respect to food products (which lie *outside* this evaluation),<sup>36</sup> that all risk assessments must be framed by a set of prior non-scientific judgements covering, for instance:

- What counts as a relevant ‘risk’; and
- How much of which kinds of evidence are necessary and/or sufficient to sustain advance to permit, restrict or forbid products to be marketed.

These judgements constitute ‘risk assessment policy’. Consequently:

- Determination of risk assessment policy should be included as a specific component of risk management;
- Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties;
- This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent. The mandate given by risk managers to risk assessors should be as clear as possible; and
- Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

The evaluators need to be aware of these other driving forces and influences. The evaluation will look at the extent to which EFSA is considering the risk assessment policy in its review of risk assessment guidelines.

To understand the way risk management has been implemented the theoretical distinction between risk assessment and risk management will need to be examined, including how it has worked in practice, and what impact it has. In this context any conflict between risk managers and risk assessors will also be examined.

The evaluation of procedures and practice will be built around the given metrics of efficiency, transparency and fit with the general objectives. Metrics, questions and line of enquiry that we expect to give insights into these issues are shown in Table 3.2.

**Table 3.2** *The evaluation attributes provided in the terms of reference suggest research questions, lines of enquiry and indicators*

<i>Attribute</i>	<i>Research focus / Stakeholder insights &amp; perceptions</i>
<i>“Efficient”</i>	<i>Predictability, Cost, Time taken</i>
<i>“Transparent”</i>	<i>Evidence on which decisions are made is available for scrutiny</i> <i>Process is clear to stakeholders</i>
<i>“Fit with objectives”</i>	<i>Protection of human and animal health, the environment and consumer interest</i> <i>The effective and efficient functioning of the Internal market</i>

Consultations with stakeholders will be used to explore the transparency, efficiency and performance of the risk management process as it operates both under the Directive and under the Regulation. The research will seek to establish whether the difficulties arise from deficiencies in the risk management structures and where they are actually due to upstream or downstream factors – such as the way in which the risk assessments are prepared.

<sup>36</sup> Codex Alimentarius Commission. The Working Principles for Risk Analysis for Food Safety for Application by Governments. Available from: <http://www.fao.org/docrep/010/a1550t/a1550t00.htm>. See also: [http://ec.europa.eu/food/fs/ifsi/eupositions/ccgp/ccgp\\_ec-comments\\_cl-2005-17\\_en.pdf](http://ec.europa.eu/food/fs/ifsi/eupositions/ccgp/ccgp_ec-comments_cl-2005-17_en.pdf).

Interviews with EFSA and other stakeholders on risk management issues will be integrated with those covering risk assessment and risk communication.

### **3.7.4 Risk management measures**

#### ***Post-marketing risk management measures following authorisation***

Articles 6(5e) and 18(5e) of Regulation 1829/2003 specify that an opinion from EFSA which favours the authorisation of a GMO should include, if appropriate, any conditions or restrictions necessary for the protection of particular ecosystems, environmental or geographical areas. The Directive, under Article 19(3)(c) also requires the consent to specify the conditions for placing a GMO on the market, including the conditions are also required to be specified, including those which are meant to protect certain ecosystems, environments or geographical areas. Thus under the Directive 2001/18/EC risk management measures (regarding the precautions taken to minimise or prevent dispersal of any reproductive organ of a GMO during and after the release) are indicated in the notification and in the consent of the CA within whose territory the research is to take place. Risk management measures are identified, and a risk management strategy defined as a result of the environmental risk assessment procedure (as specified in Commission Decision 2002/623/EC). These measures can include isolation distances, at every relevant stage of the handling and use of GMOs. In the cultivation of herbicide-resistance plants, the focus is on changed cultivation conditions and the effect on the environment and its ecosystems. Regarding insect-resistance, the focus is on the extent to which the GMO can affect non-target organisms and food chains.

National enforcement bodies are supposed to regularly monitor whether consent holders comply with the risk management measures that have been imposed. So far there have only been a select few cases where consent holders have violated the risk management conditions attached to the consent. None of these cases have been reported to have resulted in harm to the environment<sup>37</sup>.

However, the efficacy of the risk management measures has rarely been routinely monitored (e.g. the efficacy of measures to limit pollen flow has not been systematically evaluated and in many cases field trials have been conducted with few isolation measures).

### **3.7.5 Environmental monitoring: post market monitoring and general surveillance**

#### ***Context***

The risk evaluation of field trials before GMOs are placed on the market is considered under the risk assessment section part of the evaluation (see Section 3.6), specifically in the response to question 5 on the implementation of Part B of the Directive.

Under the Regulation, post market monitoring in the case of GMOs or food/feed containing or consisting of GMOs for cultivation (Article 5(5b)) is obligatory, and must be in accordance with the principles given in Annex VII of the Directive. Under Directive 2001/18 a post-release monitoring plan must be submitted with an application for authorisation to cultivate GM plants (in accordance with the principles outlined in Annex VII as supplemented by Decision 2002/811/EC) and for authorisation under Part B (in accordance with the relevant parts of Annex III). According to Annex VII, the plan must incorporate provisions for general surveillance for unanticipated adverse effects, however, case-specific monitoring is only required if it is deemed necessary, focusing on adverse effects identified in the ERA.

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<sup>37</sup> COM(2004) 575 - Commission Staff Working Paper SEC(2004) 1063. Annex to the 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 and incorporating a specific report on the operation of parts B and C of the Directive.

EFSA has released guidelines on post-market environmental monitoring (PMEM), making a number of recommendations for the management and conduct of PMEM by both applicants and risk managers. EFSA is responsible for assessing the scientific quality of post market monitoring plans submitted with each application<sup>38</sup>.

There are two main components to PMEM – general surveillance and case-specific monitoring:

- A commitment to general surveillance is a necessary condition of authorisation and involves a general monitoring plan which can include specific stipulations addressing areas of concern. The objective of general surveillance is to identify unanticipated adverse effects that are not accounted for in the environmental risk assessment. General surveillance is thus not hypothesis driven and so it is not primarily conducted using directed experimental approaches<sup>39</sup>.
- Case-specific monitoring is used to verify the environmental risk assessment and is not obligatory. When the degree of uncertainty is negligible, then case-specific monitoring is not required. The main objective of case-specific monitoring is to determine the significance of any adverse effects identified in the risk assessment; case-specific monitoring should also apply to confirm that there is no, or only a negligible risk<sup>40</sup>.
- Adverse effects fall into three categories:
  - *Anticipated effects*: Potential risks identified in the ERA as worthy of investigation via case-specific monitoring as well as those assessed as being extremely unlikely to occur and to cause harm;
  - *Interactive or cumulative effects*: Potential effects which are difficult to predict or assess fully in a single dossier and its risk assessment. e.g. effects that might arise as a result of an increase in the scale of cultivation and potential effects arising as a result of interactions between the GM crop and future varieties (GM and non-GM) that are released;
  - *Unanticipated effects*: Complete unknowns, i.e. potential effects not identified in the ERA, which can only be addressed by general surveillance.

There is variation both:

- In the provisions for monitoring set out under the Directive and the Regulation; and
- The implementation of monitoring provisions across Member States;

According to a Commission Working Document<sup>41</sup>, approaches to post-market monitoring vary depending on individual countries' climatic and environmental conditions. The document highlights the need for a coordinated approach to supplement individual approaches depending on the specificities of each country. There is agreement that

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<sup>38</sup> Opinion of the Scientific Panel on Genetically Modified Organisms on the Post Market Environmental monitoring (PMEM) of genetically modified plants (adopted January 2006). Available from: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620769727.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620769727.htm)

<sup>39</sup> (2007) Second 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. Accompanying document. Available from: [http://ec.europa.eu/environment/biotechnology/pdf/sec2007\\_274\\_en.pdf](http://ec.europa.eu/environment/biotechnology/pdf/sec2007_274_en.pdf)

<sup>40</sup> [http://www.efsa.europa.eu/cs/BlobServer/Scientific\\_Opinion/gmo\\_op\\_ej319\\_pmем\\_en,0.pdf](http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/gmo_op_ej319_pmем_en,0.pdf)

<sup>41</sup> COM (2007) 81 final

monitoring plans submitted to the national CAs are not entirely appropriate. They need to provide more details and a clear allocation of responsibilities<sup>42</sup>.

### **Approach to the research**

The above analysis suggests the following lines of enquiry:

- How are notifiers carrying out monitoring, given that the responsibility lies with the person or the company that has marketed the GMOs (Article 20(1) of the Directive 2001/18/EC)?
- Are the submissions in line with the GMO Regulatory Framework, specifically considering the principles established under Annex VII of Directive 2001/18/EC and supplemented by Decision 2002/811/EC? Have the time periods specified in the monitoring plan been upheld?
- What effect has the guidance document produced by EFSA had, and how has it been used?
- Are EFSA's recommendations regarding case specific monitoring and general surveillance in line with its own guidelines?
- How are MS implementing post-market monitoring provisions? Are they going beyond what is required, given that the Directive has ensured that MS have retained their right to take additional measures for post-market monitoring and inspection of GMOs? (not obliged)?
- What is being monitored, and are the results leading to any outcomes or outputs? What are the CAs in the MS and the Commission doing with the report once it is received? Has the information been fed into policy, given the regular meetings between the Commission and the MS (provided for under Article 31(1) of the Directive 2001/18/EC)?
- Are the results of the monitoring being made publically available (Article 20(4) of the Directive 2001/18/EC)? If so, how?
- What requirements have EFSA and CAs made of notifiers to carry out monitoring and reporting, and how have these compared to the monitoring plans that were submitted? Have CAs modified any monitoring plans after the first monitoring period, and if so, why and how?
- Have the differences between the provisions in the Directive and the Regulation been affected by the preferred authorisation procedure under the Regulation? (For example, given that reports do not have to be submitted to CAs under the Regulation, and that the Regulation does not provide for additional post-market monitoring measures and inspections as the Directive does).

### **3.7.6 Unauthorised GM material in seeds**

#### **Context**

To date, no tolerance thresholds for unauthorised seeds have been set. It is therefore illegal to place on the market conventional seeds lots which contain GMOs not approved for cultivation in the EU and that have not benefited from a favourable risk evaluation. These 'non-EU authorised GMOs' could be (i) authorised in non-EU countries, and/or (ii) authorised only in some Member States for field trials under Part B of Directive 2001/18/EC.

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<sup>42</sup> (2007) Second 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. Available from: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0081:FIN:EN:PDF>

The purpose of this zero-tolerance policy on unauthorised seeds is to protect animal and human health, and the environment.

The zero tolerance policy creates a situation of “asynchronous authorisations”, where GMOs are fully approved in other countries but not in the EU<sup>43</sup> means the potential for trade disruptions is steadily increasing. There is a risk that these disruptions will become more frequent, more severe and affect more products<sup>44</sup>.

The acreage of non-EU authorised GM crops and GM seed multiplication in commercial cultivation in other continents is rapidly growing<sup>45</sup>. Global seed companies consequently face increasing difficulties in avoiding the presence of ‘non-EU-authorised’ GM seeds in conventional seed lots. Thus the issue of unauthorised GM material in seeds mainly concerns imports of actual conventional seed lots, not imports of GM material itself. The situation is especially acute given that the EU is heavily dependent on imports of conventional seeds from third countries where GM cultivation is present. About 30% of maize seeds, 50% of soya bean seeds and 80% of cotton seeds are imported<sup>46</sup>. Sales of conventional seeds of certain crop species and conventional breeding programs have already come to a stop in Europe due to liability considerations<sup>47</sup>.

The extent of these effects and the likelihood of there being severe economic impacts depend on several factors, including<sup>48</sup>:

- the rate at which new GMOs are developed and authorised elsewhere;
- the systems which segregate varieties in the producing countries;
- the extent of unwanted mixing from illegal or experimental cultivation; and
- the response of the EU, and the policies in producing countries for authorisation (some third countries are making authorisation dependent on the impact on their exports).

There is also a risk of an impact, even to ‘clean’ imports, because of the contingent risk to importers that trace contamination with unauthorised material might be found, and that they might therefore have to bear the cost of a lost cargo.

#### **Key issues and implications for the research:**

##### *i. Responsibility is fragmented*

National legislation specifies the authorities charged with enforcing the GMO legislation. Some aspects can also be delegated from federal level to provincial or regional/state authorities<sup>49</sup>.

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<sup>43</sup> e.g. when the commercial cultivation of DAS-59122 maize was authorised in the US but not in the EU

<sup>44</sup> (2007) Economic impact of Unapproved GMOs on EU feed imports and livestock production. Available from: [http://ec.europa.eu/agriculture/envir/gmo/economic\\_impactGMOs\\_en.pdf](http://ec.europa.eu/agriculture/envir/gmo/economic_impactGMOs_en.pdf)

<sup>45</sup> For instance, in 2005, the EU’s seed trade deficit had decreased to US\$82 million from US\$162 million in 2002 due largely to a reduction in imports of maize seeds by France, mostly because of the adventitious presence of unapproved GM material.

<sup>46</sup> Questions and Answers about GMOs in seeds. Available from: <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/03/186&format=HTML&aged=0&language=EN&guiLanguage=en>. NB: these figures may no longer be correct following enlargement. Hungary in particular is a major maize importer.

<sup>47</sup> Schenkelaars Biotechnology Consultancy (2004) Study: Means to improve the consistency and efficiency of the legislative framework in the field of biotechnology Article 31 (7a, 7b and 7d) of Directive 2001/18/EC. Available from: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2004:0575:FIN:EN:DOC>

<sup>48</sup> (2007) Economic impact of Unapproved GMOs on EU feed imports and livestock production. Available from: [http://ec.europa.eu/agriculture/envir/gmo/economic\\_impactGMOs\\_en.pdf](http://ec.europa.eu/agriculture/envir/gmo/economic_impactGMOs_en.pdf)

ii. *Rigour of enforcement varies*

Previous reports have indicated that the level and scope of enforcement across the EU varies and that analytical activities, if carried out, can be impeded by a lack of quantitative GMO detection methods and certified reference materials. The most comprehensive report, which considered survey practices in 23 of the 27 Member States, found that the level of sampling varied widely, ranging from 100% of all seeds to no sampling or testing at all. 43 incidents of unauthorised GMO were reported between 2001 and 2006<sup>50</sup>.

National policies can affect stringency with which the legislation is enforced. For instance, monitoring programmes may be established to ensure that sufficient samples are tested to give high confidence that seeds being placed on the market do not contain GMOs, whilst others just take a number of random samples within a defined budget to induce seed companies to comply with national legislation.

Technical guidance (Recommendation 2004/787/EC) for sampling and detection has been criticised by some for being overly complex, and not proportionate to the time and expense involved. There have been calls for protocols to be harmonised with international testing methods<sup>51</sup>.

The judgement criteria specified in the terms of reference are the following:

- Effectiveness of inspections and controls, which is function of the level of sampling and testing undertaken, the sources of uncertainty introduced by sampling, the number of samples taken and the limit of detection of analytical tests<sup>52</sup>.
- Impact of the zero-tolerance policy on imports and seed prices.

This analysis suggests the following lines of enquiry:

- Are the Recommendations 2004/787/EC for sampling and detection being taken into account? Have the national procedures for sampling been changed/updated accordingly?
- At what level are the decisions made? Are regions aware of any guidance documents?
- What are the provisions in national monitoring / control plans? How many controls are provided for? Are the controls limited to any particular commodities?
- How often and at what level are the reports / results collated?

### **3.7.7 National safeguard and emergency measures: procedures and coherence**

#### **Context**

Under Article 23 of the Directive 2001/18/EC, a Member State may, as a result of new or additional scientific evidence, determine that an authorised GMO poses a risk, and invoke a

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<sup>49</sup> (2007) Adventitious traces of genetically modified seeds in conventional seed lots: Current situation in Member States. Central Science Laboratory. Available from: [http://ec.europa.eu/environment/biotechnology/pdf/seeds\\_study\\_2007.pdf](http://ec.europa.eu/environment/biotechnology/pdf/seeds_study_2007.pdf)

<sup>50</sup> (2007) Adventitious traces of genetically modified seeds in conventional seed lots: Current situation in Member States. Central Science Laboratory. Available from: [http://ec.europa.eu/environment/biotechnology/pdf/seeds\\_study\\_2007.pdf](http://ec.europa.eu/environment/biotechnology/pdf/seeds_study_2007.pdf)

<sup>51</sup> (2007) Second 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. Accompanying document. Available from: [http://ec.europa.eu/environment/biotechnology/pdf/sec2007\\_274\\_en.pdf](http://ec.europa.eu/environment/biotechnology/pdf/sec2007_274_en.pdf)

<sup>52</sup> (2007) Adventitious traces of genetically modified seeds in conventional seed lots: Current situation in Member States. Central Science Laboratory. Available from: [http://ec.europa.eu/environment/biotechnology/pdf/seeds\\_study\\_2007.pdf](http://ec.europa.eu/environment/biotechnology/pdf/seeds_study_2007.pdf)

**national safeguard measure** - provisionally restricting or prohibiting the sale and use of this GMO on its territory. It must inform the EC and other Member States, and provide a review of the environmental risk assessment and the scientific evidence on which its decision is based. EFSA then gives its opinion on receiving this evidence from the Commission, upon which the Commission prepares a proposal on whether the Member State should repeal, maintain or amend its decision. The proposal is either accepted or rejected by qualified majority vote.

Similarly, under Article 34 of the Regulation 1829/2003 (in conjunction with Articles 53 and 54 of the Regulation 178/2002 on General Food Law), a Member State can implement **an emergency procedure** based on evidence that an authorised GMO is likely to constitute a risk. A similar procedure follows, where the Commission also presents a proposal under the Comitology procedure. Consultation with EFSA however is not obligatory under emergency measures for Regulation 1829/2003.

Currently, five safeguard measures are in place under Directive 2001/18/EC (by Hungary, Austria and Greece). One emergency measure has been implemented, by France, under Regulation 1829/2003<sup>53</sup>. Since the entry into force of the Directive, a total of 7 MS have maintained provisional bans on five authorised GMOs. EFSA has found no reason to believe that there is a risk of adverse effects<sup>54</sup>.

The Member States concerned have been consistently requested to withdraw their national measures but in February 2009 the EC expert committee failed to reach agreement on lifting the French and Greek national bans on GM crop cultivation of MON810, leaving to the decision to the Council of Ministers<sup>55</sup>. The Council has 2 months to react before the final decision is automatically referred back to the Commission. Ministers have neither managed to find a qualified majority for nor against the national bans introduced by Hungary and Austria, leaving the final decision to the Commission, which ordered MS to lift them. A vote was taken on the plans to force Hungary and Austria to lift their bans on the 2 March, where environment ministers from 22 MS found a qualified majority against the repeal of the bans<sup>56</sup>.

The Commission has made several attempts to lift bans in the Standing Committee and in the Council of Ministers but has so far failed to reach support by a qualified majority of Member States. Therefore some bans are still in force although they were invoked more than 10 years ago (under Directive 90/220/EEC). These provisions have therefore effectively worked to block cultivation of GM crops in some Member States.

Although there are arguments that national safeguard measures have been invoked in order to 'dress policy up as science', it may be that the use of national safeguard measures stems from the inherently different interpretations and applications of precaution. Thus, despite efforts to accommodate these diverse views through EU-level expert advice, regulatory conflicts persist because the differences in interpretations remain<sup>57</sup>. National

<sup>53</sup> <http://ec.europa.eu/environment/biotechnology/pdf/table2.pdf>;  
<http://ec.europa.eu/environment/biotechnology/pdf/table3.pdf>

<sup>54</sup> (2007) Second 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. Available from: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0081:FIN:EN:PDF>

<sup>55</sup> Euractiv, February 2009. EU fails to lift French, Greek GM crop bans. Available from: <http://www.euractiv.com/en/environment/eu-fails-lift-french-greek-gm-crop-bans/article-179478>

<sup>56</sup> Euractiv, March 2009. Ministers back right to refuse GM crop cultivation. <http://www.euractiv.com/en/sustainability/ministers-back-right-refuse-gm-crop-cultivation/article-179882>

<sup>57</sup> (2007) A general framework for the precautionary and inclusive governance of food safety: Accounting for risks, uncertainties and ambiguities in the assessment and management of food safety threats. Available from: <http://www.dialogik-expert.de/en/forschung/A%20General%20Framework%20for%20the%20Precautionary%20and%20Inclusive%20Governance%20of%20Food%20Safety.pdf>

safeguard and emergency measures are therefore a means through which this conflict can be eased.

### ***Approach to the research***

The research will need to examine the handling of national safeguard measures and stakeholder views on the performance of the system (Q10). The analysis suggests the following lines of enquiry:

- What lessons have been learnt by countries who have maintained their measures, and those who have removed (or changed) them?
- How does the interaction between the Regulation and the Directive impact on the use of these measures? Do MS favour one over the other? How does the Regulation 178/2002 affect the use of these measures under both the Directive and the Regulation?
- Are there any cases where the matter is resolved bilaterally between the MS and the manufacturer in question, without recourse to the safeguard/emergency clause?
- In providing a facility in EU law to ban the sale and use of GMOs at national level, a ban on the sale of a produce clearly has an impact on the functioning of the internal market. It is less obvious that a ban on cultivation need do so, i.e. does the function of the internal market require that purchasers not only have access to a product (the right to buy) but also the right to use (i.e. to cultivate)?
- How are local/regional authorities involved?

In so doing the research will also explore stakeholder views on the emergency provisions and their fit to food law (Q11).

## **3.8 Risk communication aspects of the legislative framework**

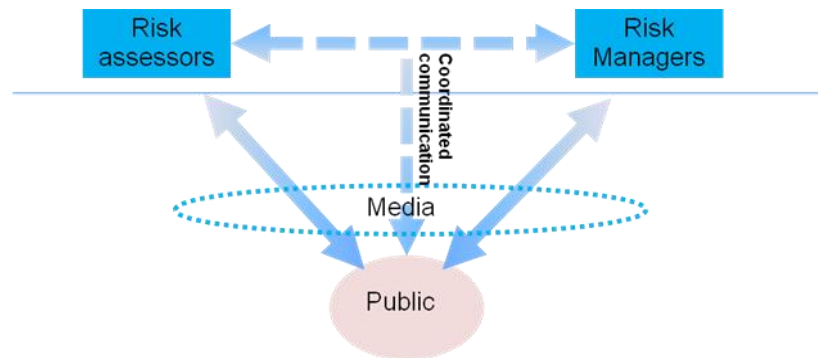
### **3.8.1 *Understanding of the context***

Risk communication is one of the three elements of risk analysis in the GMO regulatory debate, alongside risk assessment and risk management. Risk communication has received less attention than the other two.

Risk communication is a fundamental aspect of several key multilateral legal instruments that govern multilateral trade in genetically modified products, including the Biosafety Protocol of the Convention on Biological Diversity primarily regarding threats to biodiversity, and the 'Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters' regarding public information and participation in the domain of GMOs.

Risk communications, and public understanding of risk in the context of GMOs, are broad topics. Focus – in particular a focus on the risk communication requirements of the legislative framework - is essential. Although the specified question within the project brief is quite limited, and suggests communication only to the public, the communication is a two way process. Thus, there is communication to and from the public both from risk assessors and risk managers, which in turn can be moderated by the media (see Figure 3.10 below). Communication between risk assessors and risk managers, which ideally should lead to agreement on the communication that is made to the public, is considered here as a risk management issue.

**Figure 3.10 Scope of Risk Communication**



Conceptually, risk communication can be categorized into three aspects: (1) public information; (2) risk notification among governments; (3) consultations among governments regarding preventive and precautionary measures that limit the risk as much as possible.

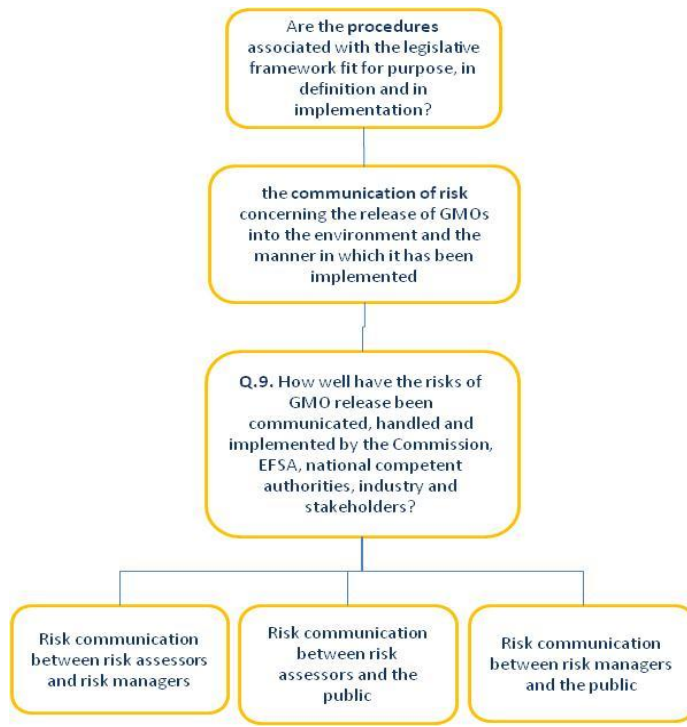
At EU level, risk communication is a one-way education and two-way dialogue between the public and risk assessors and managers. The two-way dialogue is mainly to improve the one-way education. At Member State level risk communication also takes place between risk assessors and managers.

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

### **3.8.2 Approach to the research**

In the terms of reference, questions 9 and 12 address the legislative, procedural and practical aspects of the risk communication activity. A mapping of the hierarchy of questions is shown in Figure 3.11. The evaluation of the risk communication process needs to consider how the risks of GMO release been communicated, handled and implemented by the Commission, EFSA, CAs, industry and stakeholders.

**Figure 3.11 Structure of the evaluation of the risk communication aspects of the legislative framework**



### 3.8.3 How well have the risks been communicated?

#### Context

The scope of communication in the risk cycle is very broad and covers communicating activities under risk assessment and risk assessment as shown in Figure 3.12.

Official representations of EU food safety regulators increasingly express commitment to a more systematic recognition and communication of the scientific uncertainties involved in the assessment of risks. At the centre of a more systematic approach to dealing with the challenge of scientific uncertainty lies the application of the precautionary principle, formally established as a general principle of EU food law. Communication between various authorities in charge of risk assessment and risk management would include the issue of dealing with uncertainty. The study should explore the provisions in place for dealing with uncertainty.

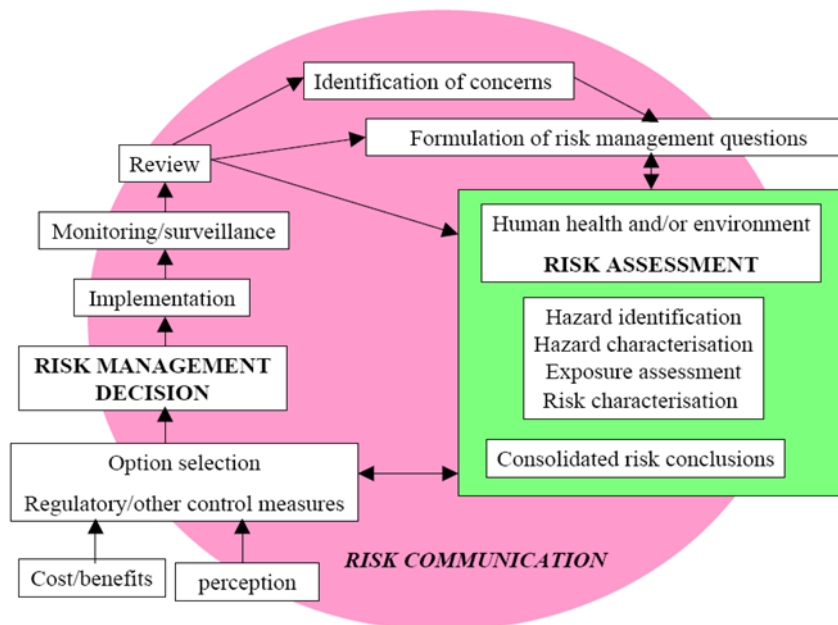
In order for risk communication to be evaluated, the goal of the communication should be identified. Once this has been established, it can then be assessed whether the communication has been successful. Communication needs to be evaluated in two ways:

- **Availability:** to what extent is the information readily available? Where is it? Can it be easily located?
- **Accessibility:** to what extent is the information understandable? In what format is it presented? What type of language is being used?

In this context both general communication and specific technical communication will be examined. The evaluators will examine whether this communication has been predominantly passive or active, and which actors prefer which methods. In this project, there is a need not only to understand the information itself, but also the channels through which it is communicated. As such, and as shown in Figure 3.10 above, there are 3 ways in which risk communication can take place:

- risk communication between risk assessors and risk managers;
- risk communication between the public and risk assessors; and
- risk communication between the public and risk managers.

**Figure 3.12 Scope of communication in the risk cycle**



Source: CSL, UK

### ***Risk communication between risk assessors and risk managers***

Risk assessors include EFSA and certain CAs. Risk managers include the European Commission and the decision making bodies within Member States. In some cases, there is considerable overlap between CAs and Member States' decision-making bodies, making the distinction between risk assessors and risk managers more difficult to establish (e.g. in Austria). There are four main ways by which risk communication takes place between risk assessors and risk managers:

- EFSA communicates with partners in the Member States through its network of National Focal Points, or with scientific organisations in the Member States able to support EFSA in developing its opinions. EFSA also co-ordinates several European Scientific Cooperation (ESCO) projects involving experts from EFSA and the Member States. MSs can also request opinions from EFSA.
- EFSA communicates with other EU bodies such as the Joint Research Centre (JRC), European Medicines Agency (EMA) and European Centre for Disease Prevention and Control (ECDC). EFSA receives requests for opinions mainly from the Commission and occasionally from the European Parliament. The EFSA Register of Questions<sup>58</sup> contains information on questions asked to EFSA by the EU regulatory authorities on food and feed safety issues within EFSA's remit.
- Under Article 11 of Directive 2001/18/EC, MS are required to send the Commission a list of GMOs referred to in Article 7 which have been released on their territory and a

<sup>58</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf?nocache=1237477966637>

list of notifications which were rejected. These are then forwarded to the CAs of other Member States.

- Member States communicate with the Commission in the case of non-compliance through the Rapid Alert System for Food and Feed (RASFF) under Regulation 178/2002<sup>59,60</sup>. If new information is made available with regards to the risks of GMO on human health or the environment then the notifier or the CA should take immediate steps to prevent the risks and inform the competent authority and the Commission.

### ***Risk communication between the public and risk assessors***

Risk is communicated between the public and risk assessors by, in particular, CAs and EFSA.

### **National Competent Authorities (CAs)**

Public information in the context of the Directive and the Regulation is provided by either GMO-specific legislation or general administrative legislation. For example a 2002 report found<sup>61</sup>:

- Legal provisions for public information on a proposed Part B release were implemented by national GMO-specific legislation in Belgium, France, Germany, and Ireland;
- In Denmark, Finland, The Netherlands, Slovak Republic, Sweden and the United Kingdom, legal provisions for public information were foreseen by general, administrative legislation;
- In Austria, Estonia and Poland legal provisions for public information were foreseen by a combination of GMO-specific legislation and general, administrative legislation; and
- In Italy, Portugal and Spain there were at that time no legal provisions for public information.

CAs inform the public about a proposed Part B release through placing a notice in a government gazette, local and regional newspapers, website, town hall of municipality in proximity of location(s) of site(s) or via distribution of the application to interested parties. CA advisory committees in MS also engage with the public. In some Member States advisory committees of the CAs only include scientific experts (UK / Netherlands), whereas others include representatives of public interest groups.

There are differences in what is made available to the public by CAs. Most CAs require that consent holders have to send a report to the CA on observations of any risk for human health or the environment at the end of a GM field trial. Some CAs make these reports accessible to the public. In most countries, national enforcement bodies monitor whether consent holders comply with the imposed risk management measures, but only in a few Member States do the enforcement bodies make their findings publicly available.

### **EFSA**

Risk communication is a core part of EFSA's mandate. To explain the implications of its assessments, EFSA identifies a number of its opinions which require more in-depth communication. EFSA develops a suitable communications approach e.g. media activities,

<sup>59</sup> [http://ec.europa.eu/food/food/rapidalert/index\\_en.htm](http://ec.europa.eu/food/food/rapidalert/index_en.htm)

<sup>60</sup> Members - [http://ec.europa.eu/food/food/rapidalert/members\\_en.htm](http://ec.europa.eu/food/food/rapidalert/members_en.htm)

<sup>61</sup> [http://files.efbpublic.org/downloads/Public\\_Information\\_and\\_Participation\\_1.pdf](http://files.efbpublic.org/downloads/Public_Information_and_Participation_1.pdf)

profiling the issue on the EFSA website or in EFSA publications, or discussion at scientific events. It also co-ordinates its activities with national authorities to help ensure consumers receive coherent messages on issues that concern them in a form they understand.

#### ***Risk communication between risk managers and the public***

Directive 90/220/EEC contained optional provisions for consultation with members of the public on releases of GMOs under Part B provisions. Directive 2001/18/EC introduced a mandatory requirement for Member States to consult the public or groups on proposed Part B releases. The precise form of consultation is a matter for Member States. Directive 2001/18/EC also contains specific requirements for seeking views from the public and requires the Commission to make certain information centrally available.

#### **3.8.4 Implications for the research**

Based on our understanding of risk communication in the context of the Directive and Regulation, the team will examine through the course of the study:

- The scope of the public information and participation procedure;
- The prerequisite for forming an informed opinion? E.g. full application file on a proposed Part B or Part C release, including the data submitted, the full risk assessment and advice by advisory bodies;
- The legal opportunities for public participation in decision-making;
- Whether the time period of 30 days for submitting concerns and questions about (a decision on) a proposed Part C release in particular adequate for a meaningful public participation?
- Are the right methods being used to reach and engage the public?
- Is the Register of genetically modified food and feed publicly accessible, both in language and physical terms?
- Does the decision on a Part B release give account of how public comments have been taken into account?
- Do CAs contact local communities nearby the release sites and persons, which might be affected by the release?
- What is meant by ethical consideration? What is the role of ethics committee? Does the risk assessment under the Directive take into consideration ethical aspects when GMOs are deliberately released or placed on the market? Are environmental and health issues also ethical issues?

Key questions regarding uncertainty in risk communication to be addressed by this study:

- To what extent does communication explicitly address issues of uncertainty, ambiguity and ignorance as well as risk?
- How far and in what manner it is acknowledged that quantitative levels of safety may remain indeterminate?
- To what extent are divergent expert or disciplinary judgements or perspectives represented in communication?
- How much and what kind of attention is given to the possibility of persistent gaps in knowledge and areas where further research is required?

### 3.9 Discrete issues

#### 3.9.1 Confidentiality and data protection

The evaluation shall consider the issue of confidentiality and data protection, examining in particular:

- Whether the rules on confidentiality and data protection of the Directive consistent with those Regulation (EC) 1829/2003 and Regulation (EC) 1049/2001? (considering differences in scope and categories);
- Whether the rules are efficient enough so as to protect confidential information and intellectual property rights, while ensuring transparency with regards to the deliberate release of GMOs into the environment and in particular the associated risk assessment.

#### **Context**

Provisions for confidentiality, as it pertains to this project, are contained in several pieces of legislation. Although confidentiality is a necessary device for protecting commercial interests, care needs to be taken to ensure it is not used as a pretext for withholding information of legitimate public interest<sup>62</sup>.

Regulation 1049/2001 stipulates the principles, conditions and limits on grounds of public or private interests that govern the right of public access to European Parliament, Council and Commission documents. The exception that is relevant here regards Article 4(2), where access may be refused where disclosure would undermine the protection of commercial interests, including intellectual property.

In Directive 2001/18/EC s confidentiality is addressed in Article 25, which states a notifier can request that information submitted in a notification which might harm his competitive position be kept confidential. If verifiable justification is given, and following consultation with the notifier, the CA decides what information will be kept confidential. Some information cannot be kept confidential:

- General description of the GMO, details of the notifier, purpose, location and intended use of the release;
- The details of the monitoring plan and emergency response;
- The environmental risk assessment.

Similar conditions are provided for under the Regulation 1829/2003, where the applicant may also indicate information which might significantly harm its competitive position and therefore which should be kept confidential. Verifiable justification must also be provided in this case. Under the Regulation it is the Commission, rather than the relevant CA, which makes the decision. The Regulation is more comprehensive in the types of information that may not be kept confidential (especially as regards the characteristics of the GMO) which, besides the above, includes:

- The composition, physio-chemical and biological characteristics of the GMO;
- The effects of the GMO on human, animal health and the environment, and on the characteristics of animal products and its nutritional properties; and
- The methods for detection and information on waste treatment.

The Regulation, coming into force after EFSA was established, also designates a role for EFSA (which the Directive does not). Regulation 178/2002 (Article 39) further designates confidentiality rules for EFSA, whereby the public may request access to the full

<sup>62</sup> EFSA 2003. Openness, transparency and confidentiality. [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620791409.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620791409.htm)

documentation submitted by applicants and third parties. However, EFSA shall refuse access to documents to commercially sensitive information in accordance with Article 4 of Regulation 1049/2001 mentioned above, where confidentiality has been requested and justified. Under some circumstances such information must be made public in order to protect public health. EFSA treats transparency as the rule, and confidentiality as the exception, the balance between the two being determined by the maximum information that can be disclosed, so that only the essential minimum is kept confidential which needs to be duly justified<sup>63</sup>. EFSA aims to discuss openly with companies how to interpret the concept of commercially sensitive information “in a proportionate and balanced manner”. In the cases where the Commission makes decisions regarding confidentiality claims of third parties, EFSA is bound by the outcome of these decisions.

### **Implications for the research**

Because of the many provisions under Regulation 1049/2001, Directive 2001/18/EC, Regulation 1829/2003 and Regulation 178/2002, there is scope for confusion, complication and conflict. One example pertains to MON863, where in 2005 a report from *The Independent*, a newspaper in the UK, revealed that research conducted by Monsanto as part of the risk assessment of MON863 showed significant variations in rats fed with conventional maize and those fed with GM maize. Monsanto refused to reveal the documents on the grounds of that they contained confidential business information. Subsequently the German government ruled that Monsanto had to make the documents publically available under Directive 2003/4/EC regarding public access to environmental information.

The case highlights the confusion over what exact sections of the dossiers are covered by claims of ‘confidential business information’, and what information cannot be considered confidential as stated in Articles 25(4) and 30(3) of the Directive 2001/18/EC and Regulation 1829/2003, respectively. The case also underlines the confusion over how documents can be obtained under other EU or national legislation concerning freedom of information. The interaction between Regulation 1049/2001 and the provisions in the GMO is also unclear, given that the Regulation 1049/2001 is meant to cover documents relating to the European Parliament, the Council and the Commission rather than documents submitted by applicants for GM consents. There is also confusion regarding who makes the decisions concerning whether claims are justified, and the role of EFSA in these decisions and in upholding them, given the provisions in EFSA’s mandate mentioned above.

The above analysis suggests the following lines of enquiry:

- Who is entitled to make decisions regarding whether information can be considered confidential? On what basis are these decisions made?
- Under what conditions are requests for information being kept confidential verifiably justified? Are there differences among competent authorities in MS as to what counts verifiable justification?
- What is the role of EFSA in making decisions about confidentiality? What role does EFSA play under the Directive 2001/18/EC?
- Under what circumstances can the relevant information be obtained regardless?
- How many times has information been made confidential? How many times has the claim to confidentiality been invoked? Of these, have there been any cases where the request has been denied? Typically, what kinds of information, pertaining to what area of the dossier, have been claimed as being confidential?

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<sup>63</sup> EFSA Working Group on Transparency in Risk Assessment. Available from:  
[http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620769466.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620769466.htm)

### **3.9.2 National Measures**

In evaluating the legislative framework for GMOs, the effect that national measures have on all aspects of the project, including risk assessment, risk management, and risk communication will need to be considered.

Consideration will need to be given especially to the way in which these measures affect the objectives on the legislation, including the functioning of the internal market, and the protection of the environment, and human and animal health. Given this, coexistence measures and the socio-economic aspects of the cultivation of GM crops, will not be considered.

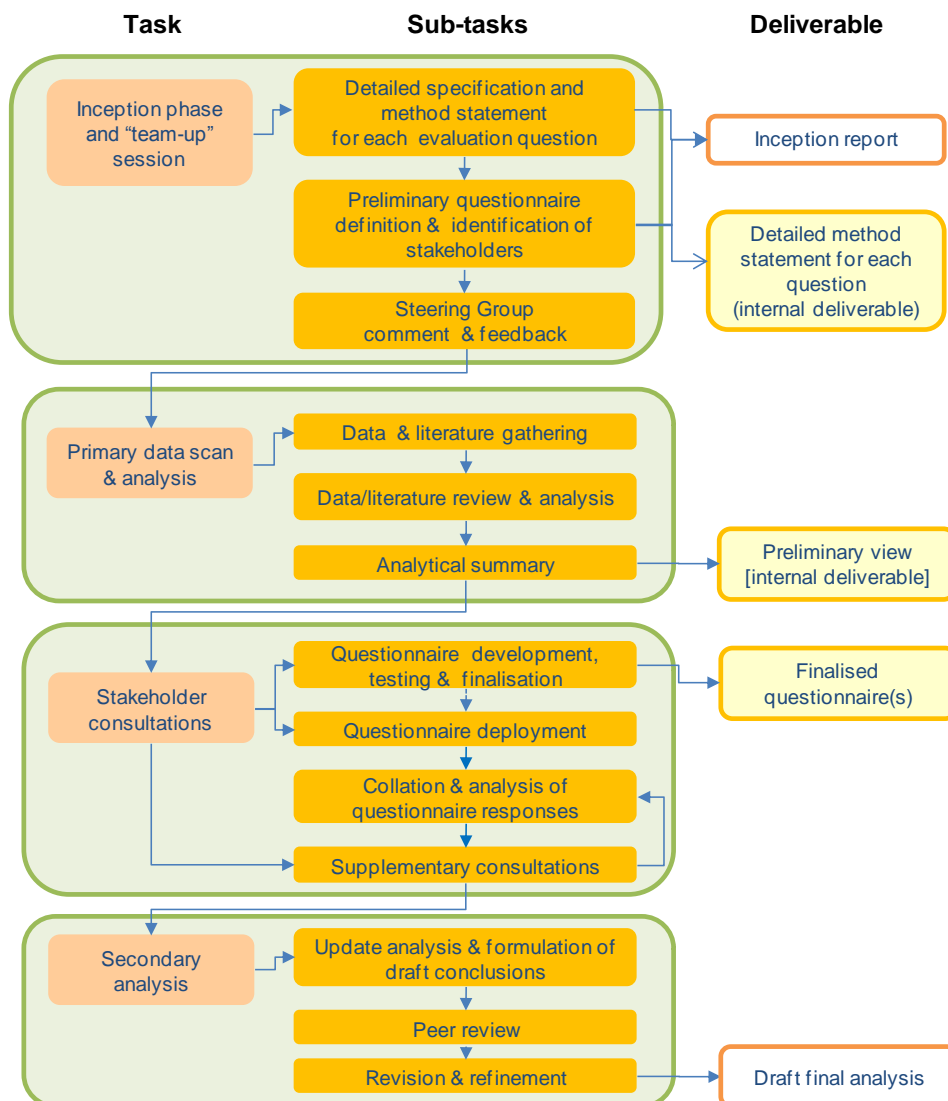
## 4 PROJECT PLAN

### 4.1 Purpose of this chapter

This chapter describes the proposed approach to delivery of the project and achievement of its objectives, including a detailed specification of the tasks.

The overall project workflow is shown in Figure 4.1. This report is one deliverable from the inception phase task. The project then moves through a phase of desk research into a stakeholder consultation exercise. The results of that stakeholder consultation process are used to iterate the 'Preliminary Views' on the questions that were determined in the initial research and, where appropriate, explore possible policy options. Findings are presented in a draft final report and then, following Commission review, a final report.

**Figure 4.1 Outline of project process**



## 4.2 Detailed task descriptions

### 4.2.1 Task 1 – Inception

The acceptance of this report will bring the inception phase to a conclusion. Activities that have taken place within the inception phase include:

- A start-up meeting with Commission services;
- Development of method statements and scoping of stakeholder questionnaires;
- A 2-day ‘team-up’ exercise involving the research team and experts to discuss the approach to the project and its evaluation questions in detail;
- Assembly of background documents, registration for news scanning and other preparatory work for the research phase that follows;
- Preparation of this report.

### 4.2.2 Task 2 – Primary data scan and analysis

**Objective:** *To assemble the relevant data required to support analysis, including the development of an intervention logic for the two pieces of legislation*

**Deliverables:** *A ‘Preliminary View’ document for each question; Project interim report*

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The purpose of this task is to assemble and examine as much as possible of the written evidence required to support the evaluation, in order to:

- Refine intervention logics articulating the internal logic underpinning the two pieces of legislation, on the basis of which research instruments can be developed;
- Ensure that the stakeholder engagement phase is conducted from a ‘position of strength’ – i.e. that the team is fully appraised of all the key issues and emerging problems;
- Help focus the stakeholder engagement on issues that matter – potentially influencing the selection of stakeholders, informing design of questionnaires and the structuring of follow-up interviews.

Figure 3.4 provides an illustration of the specific data requirements for individual evaluation questions. This list will be developed and expanded in the inception phase.

We note and welcome the commitment by Commission services to provide access to key documents relating to the operation of the Directive and Regulation as per section 5 and Annex 5 of the terms of reference – this will be critical to several parts of the overall process.

Preliminary contact will be made with a number of the stakeholders identified in the inception phase to request relevant documentation and discuss arrangements for the consultation that will follow.

This ‘discovery and examination’ phase will:

- Include the preparation of Preliminary View documents that set out the first stage analysis and any emerging findings, including early identification of possible policy options (where possible/appropriate);
- Inform the refinement of approach and detail of the stakeholder engagement process in the next task (including questionnaire design).

#### 4.2.3 **Task 3 – Questionnaire & supplementary stakeholder consultations**

**Objective:** To ensure that the evaluation accesses views and evidence from a broad range of stakeholders in the operation of the Directive and Regulation from across the EU

**Deliverables:** Completion of survey and supplementary stakeholder engagement / case studies

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Stakeholder consultation is at the heart of the evaluation. We propose a comprehensive questionnaire of key stakeholders, supplemented by:

- Telephone and face-to-face interviews to improve response rates and to supplement questionnaire responses;
- In-depth consultations and case studies on particular issues.

Our past experience of similar projects suggests that compiling and refining the questionnaire can be a time-consuming exercise. The survey will need to cover the full set of evaluation questions, be tested for clarity and subject to comment by the Steering Group. The study method programme has been designed with this in mind.

The design process will begin in inception phase when a ‘first cut’ of questions will be compiled. This will be supplied with the inception report for consideration by the Steering Group.

The question set will then be refined, drawing on:

- Steering Group comment, and
- Issues highlighted by the preliminary analytical phase (Task 2).

The structured list of questions will be integrated into a functional questionnaire. It may be appropriate to construct a number of different questionnaires (or questionnaire sections) for different stakeholder groups (on the basis that we will be seeking to ask different questions of, for example, GMO developers and companies in the agri-food chain). We propose to use of an online survey tool to provide added flexibility and accelerated information management.

As outlined in section 2, we propose to distribute questionnaires to, and otherwise engage:

- CAs in all 27 MS,
- EU institutions involved in application of GM legislation (e.g. DGs of the EC, EFSA, FVO);
- Companies and research organisations with an interest in the application of GM technology to plants (including seed specialists), animals and microorganisms (drawing on the list of organisations that have put forward notifications);
- Companies in the supply chain of the sectors involved (such as grain traders, food and feed processors and retailers in the agri-food chain);
- National and EU representative organisations for the farming sector;
- Other (e.g. medical, bioenergy) biotech companies and research institutes in MSs (e.g. IPTS);
- Non-governmental organisations with a specialist interest in GM issues;
- Other consumer representative bodies – e.g. BEUC at EU-level, and associated/other national consumer groups;
- Other interested research bodies (e.g. in Member States).

The relevant individuals within organisations will be identified from sources such as:

- Registry of CAs supplemented by Commission/EFSA advice and telephone contact where necessary;
- Trade associations and representative bodies;
- Online research and email/telephone contact;
- Databases of GMO notifications.

The team also has a large number of relevant contacts from previous studies in this area, including:

- The 2004 study for the Commission on Directive 2001/18/EC (RPA/Schenkelaars);
- Membership of expert networks dealing with GMO and risk assessment issues.

In section 4.3 below we put forward a proposal for a facility by which interested stakeholders can register online to be included in the consultation exercise. This will provide increased transparency and open the exercise to a wider pool of interested parties than would otherwise be possible. A sample of stakeholders will be taken from among those registered.

In line with practice on other recent evaluations for other DGs of the EC we propose operating the questionnaire in English, but providing all respondents with the option of translation into a preferred alternative language if required.

### **Survey**

The draft questionnaire prepared at inception will be developed based on the understanding set out in the Preliminary Views, and taking into account feedback from the Steering Group. The revised draft questionnaire will be submitted to Commission services. A pre-testing phase is recommended in which the questionnaire is shared with a small number of respondents and their response evaluated to ensure that the questions, and the form of answer required, are expressed clearly enough. Once the online survey is constructed and pre-tested, information about the survey will be distributed to all target stakeholders. A supporting letter from the Commission may be appropriate.

Completion rates will be monitored. Missing responses will be followed up by email and telephone after a suitable period of time has elapsed. Responses that are unclear will be followed up and clarified by email or telephone.

### **Interviews**

The responses will be used as the basis of more detailed consultations focused on the 'hot-spot' areas (issues, MS) identified at the inception phase and confirmed in Task 2. These additional consultations will generally be conducted by telephone or video-conference in order to minimise travel time/expense and carbon impact. The team will also be alert to opportunities to meet large numbers of stakeholders together – such as at industry or NGO meetings in Brussels.

The consultants will maintain records of who has responded to the survey and those involved in one-to-one interviews to demonstrate coverage of the 27 Member States and of the various stakeholder interests.

Detailed consultations will be needed with some parties, e.g. with EFSA in relation to aspects of the risk assessment process and management of stakeholder comments. These points of more focused research will be highly in the interim report issued before this task begins.

The questionnaire and consultations will need to ensure that, particularly where highlighted in the terms of reference, stakeholders are engaged on policy options and their impacts – not just their experience of current arrangements.

#### 4.2.4 **Task 4 – Secondary analysis, including case study research**

**Objective:** To prepare final analysis, formulate conclusions and policy options

**Interim milestone:** Conclusions & Options meeting

**Deliverables:** Input to draft final report

---

This task will see the strands of work directed to addressing the 13 evaluation questions brought together. The Preliminary View documents will be updated with the results of the stakeholder engagement process. Additional documentary analysis will be conducted as required to:

- Achieve a clear and evidenced answer to each of the evaluation questions;
- Provide the overview and technical content needed for the draft final report;
- Ensure that any additional work required to explore policy impacts and their potential impacts is identified

The full evaluation team will come together for a joint ‘Conclusions and Options’ meeting to:

- discuss and test the findings, to ensure that conclusions are robust under challenge;
- explore policy options and their implications;
- agree the detailed approach to the DFR.

#### 4.2.5 **Task 5 – Policy options & impacts**

**Objective:** To ensure full analysis of policy options where required and that groundwork is in place for impact assessment

**Deliverables:** Input to draft final report

---

The purpose of this task is to ensure that information on policy impacts and their impacts is organised in a way suitable for a full Impact Assessment.

The EPEC team will engage with Commission services about option specification in order to ‘sense-check’ the options under development. Gaps in evidence bases or uncertainties arising from the evaluation process will have been highlighted in advance.

Provision has been made in the programme for additional input to this task between DFR and FR stage to ensure that Steering Group comments can be addressed.

#### 4.2.6 **Task 6 – Final reporting**

**Objective:** To prepare draft final and final deliverables, taking into account Steering Group comment

**Deliverables:** Suite of draft final and final deliverables as defined in the terms of reference

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##### **Draft final report**

The draft final report (DFR) will be delivered within 9 months of the contract signature. It will be written in English in clear language, and present well-structured responses to the evaluation questions.

The analysis will be well established and clearly linked to recognised evaluation methods and clearly reasoned. Uncertainties and assumptions will be clearly stated. Limits to the

judgement will be specified. Appraisal will be unbiased and realistic. The structure will respect the structure set up by common Evaluation Standards. The EPEC team will provide:

- an executive summary (of no more than 25,000 characters), including a brief presentation of the evaluation work, methods used, conclusion and recommendations;
- a main report of not more than 150 pages, structured as per agreement with the Steering Group, and presented in a clear and digestible format;
- technical annexes, and a draft one-page summary on the key messages of the evaluation.

The DFR will be presented to the Steering Group.

#### **Final report**

On receipt of comments from the Steering Group and input from the quality assessment, the team will revise the draft final report and the executive (synthetic) summary into the form of a final report. In addition the EPEC team will supply:

- A French edition of the executive summary;
- A final edition of the one-page summary;
- A PowerPoint presentation in English and French, of not more than 30 slides.

Final deliverables will be submitted within 12 months of contract signature.

#### **4.2.7 Task 7 - Dissemination**

The EPEC team will support the Commission in dissemination of results by attendance at two post-publication meetings at locations to be determined.

#### **4.3 Communication & transparency**

Obtaining stakeholder buy-in and support for the project process is an important supporting objective. The extent to which the project process and consultations will be opened to full public access was discussed at the start-up meeting.

It is proposed that GHK:

- Registers a domain name for the evaluation, e.g. <http://www.gmo-cultivation-evaluation.eu/>
- Creates a simple website at that location on which is posted:
  - Text provided by the Commission about the strategic purpose and positioning of the evaluation;
  - The terms of reference for the project;
  - An outline of the project process;
  - A facility through which stakeholders can register interest in being consulted during the project.

The registration facility will collect the following data: name (individual / institution); organisation type (company/NGO/research institution/individual/other); address; and contact details (telephone / email).

The list of individuals/organisations that register will be used to supplement the list prepared in consultation with the Commission and MS. The text on the website, posted in a number

of EU languages, will make clear that registration does not guarantee that the stakeholder will be consulted. Details of the stakeholders that are included in the e-survey and subsequent consultations will be posted on the website later in the project.

This registration mechanism provides a means of:

- (a) Soliciting interest from stakeholders that have something to contribute to the project;
- (b) Increasing the openness of the project whilst providing a “buffer” against the possibility of the project being swamped by tens of thousands of ‘protest’ messages or individual responses (e.g. as a consequence of local campaigns).

#### **Public meeting**

The option of a public meeting at a later stage of the project was discussed at the start-up meeting, as a means of increasing openness and stakeholder buy-in. Arrangement of a major public meeting in Brussels was not included or costed in the original proposal.

A provision has been made in the resource plan for preparation and delivery of presentations at such a meeting. If EPEC was asked to organise and arrange the event this would be negotiated as an additional cost.

A decision on whether to hold such a meeting does not need to be taken until after submission of the interim report.

## **4.4 Programme**

### **4.4.1 Work programme**

The project programme is provided at Figure 4.2.

### **4.4.2 Deliverables schedule**

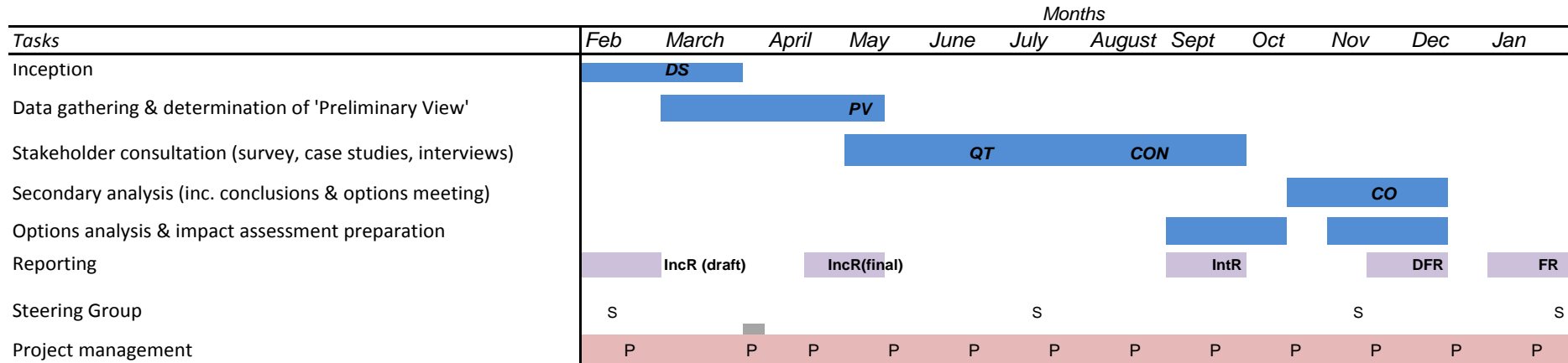
Drawing on discussions with the Commission we propose a modification to the schedule of deliverables, namely placing the interim report a little later in the study programme so that it can be used to present the results of the stakeholder consultations rather than simply desk analysis. The revised schedule is shown in Table 4.1 below.

In addition to technical reports EPEC will supply monthly progress reports to the Commission reporting.

**Table 4.1 Schedule of deliverables**

<i>Deliverable</i>	<i>Timing</i>
Inception report	6-8 weeks
Interim report	8 months
Draft final report	10.5 months
Final report	12 months
Progress reports	Monthly throughout the project

**Figure 4.2 Project programme**



**Client deliverables**

- IncR - Inception Report
- IntR - Interim Report
- DFR - Draft Final Report
- FR - Final Report
- P - Monthly project progress report
- S - Meetings with Steering Committee

**Internal deliverables/milestones**

- DS - Detailed specifications (document)
- PV - Preliminary View (document)
- QT - Stakeholder Questionnaire
- CON - Stakeholder Consultation
- CO - Conclusions & Options (meeting)

#### **4.4.3 Interim report**

According to the revised project programme (Figure 4.2), we now propose that the interim report will be delivered at the end of September. It will have two sections:

- A technical section that reports the results of the stakeholder consultation programme, highlighting key issues, and signposting 'emerging thinking' on the evaluation questions;
- A process section that describes progress against programme, management of risks and any project management or delivery issues arising that need to be brought to the attention of the Steering Group.

The interim report will be prepared in English and will be addressed to the Steering Group. It will be presented by the EPEC team at a Steering Group meeting. Commission comments and feedback will be incorporated in subsequent phases of work.

#### **4.4.4 Project progress reports**

Progress reports will be issued on a monthly basis and document activity by tasks, any risk management issues arising and points for discussion. These progress reports will support monthly project management telephone meetings with DG Environment.

#### **4.5 Steering Group meetings**

Steering Group meetings will be convened to consider the inception report, interim report, draft final report and final report. The Steering Group comprises officials from DG ENV, DG SANCO and EFSA, together with senior representatives of the project team.

#### **4.6 Contingencies, linkages and critical path**

The project plan and programme assume and require good coordination with a number of parallel policy, research and consulting processes relevant to the terms of reference. These include:

- Activity managed by DG ENV relating to the preparation of a three year implementation report on Directive 2003/18/EC, including the submission of a questionnaire to CAs;
- EFSA's review of its risk assessment guidelines;
- 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.
- Forthcoming completion of Commission impact studies on the establishment of seed thresholds for the adventitious presence of unauthorised material
- Socio-economic implications: MS to collect and exchange relevant information by January 2010, after which Commission is to submit to the Parliament and Council a report based on the information by June 2010.

#### **4.7 Risks and risk management**

A risk register has been compiled and is provided at Annex 4. This will be managed and updated during the project, and included in the monthly progress reports.

## 5 PROJECT ORGANISATION

### 5.1 Accountabilities

The client is DG Environment (DG ENV) of the EC. The Steering Group, which will meet to consider project deliverables, comprises DG ENV and DG SANCO. The party contracted to DG Environment is EPEC (the European Policy Evaluation Consortium) which is a consortium of GHK Consulting, Technopolis and the Tavistock Institute.

GHK Consulting Ltd. is the lead partner for this project. GHK has responsibility to EPEC and so the Commission for the proper delivery of the project.

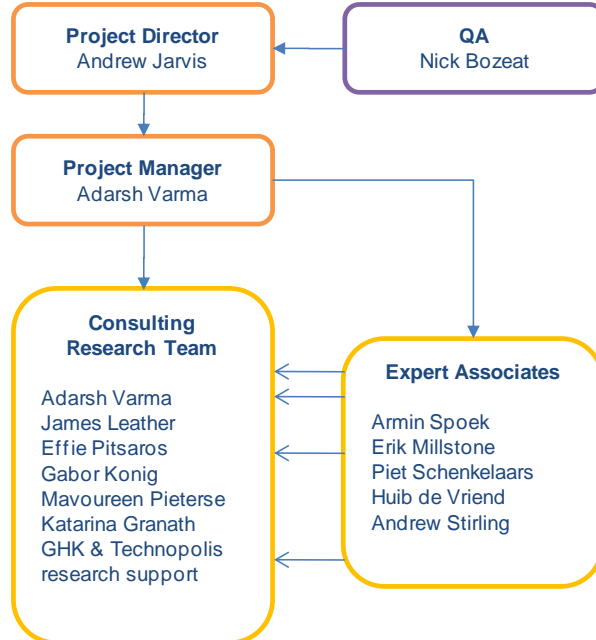
GHK's partners in the delivery of the project are:

- Technopolis (UK);
- Professor Erik Millstone and Professor Andy Stirling of the University of Sussex (UK);
- Piet Schenkelaars (Netherlands);
- Dr Armin Spoek (Austria);
- Huib de Vries (Netherlands).

### 5.2 Consulting team structure and project management arrangements

The team structure is shown in Figure 5.1 below.

**Figure 5.1 Team structure**



#### **Project management team**

The project management team will steer the evaluation through to conclusion, ensuring delivery that meets the Commission's requirements for clarity, content and quality. The project director and project manager will both be heavily involved in the technical conduct of the study as well as providing a project management function.

- **Andrew Jarvis**, as project director, will take primary responsibility for delivery of the project deliverables and reporting to the Steering Group.
- **Nick Bozeat**, the GHK Director with lead responsibility for the company's services to the Commission, will provide high level quality assurance (QA), project advisory and client liaison services to the project. Through regular meetings with the project management team he will ensure that the project is on track and being delivered in accordance with GHK's QA system.
- **Adarsh Varma**, as project manager, is responsible day-to-day contact with Commission services and is responsible for planning, managing and delivering the consultancy to the satisfaction of the client. He will manage the team inputs and prepares the overall work plan, staffing schedule and individual job descriptions. As project manager, he will also establish project filing systems, communications protocols, email addresses, etc. He will be heavily involved in the research work as well as discharging his responsibilities as project manager.

### ***Research team and expert associates***

Profiles of the research team and expert associates are provided at Annex 3. The expert associates will take oversight roles on particular aspects of the evaluation.

## **5.3 Confidentiality & data protection**

### **5.3.1 Confidentiality**

The contract is bound by the following confidentiality provisions under the EPEC framework contract. These form part of the subcontracts and apply to all parties engaged on the project.

#### **ARTICLE II.9 – CONFIDENTIALITY**

- II.9.1 The Contractor undertakes to treat in the strictest confidence and not make use of or divulge to third parties any information or documents which are linked to performance of the Contract. The Contractor shall continue to be bound by this undertaking after completion of the tasks.
- II.9.2 The Contractor shall obtain from each member of his staff, board and directors an undertaking that they will respect the confidentiality of any information which is linked, directly or indirectly, to execution of the tasks and that they will not divulge to third parties or use for their own benefit or that of any third party any document or information not available publicly, even after completion of the tasks.

## **5.4 Data Protection**

The project will be managed in accordance with GHK's data protection policies. Subcontractors have been directed to contact the GHK project in the event of any queries about data protection.

## **ANNEXES**

## ANNEX 1 INPUT INTO STAKEHOLDER QUESTIONNAIRE

This annex continues initial thoughts of issues relevant to discussions with stakeholders and the associated survey instruments.

It identifies *potential* issues for inclusion in the stakeholder questionnaires and consultation. It is not final nor is it intended to be fully inclusive.

As described in the original EPEC proposal, and above in this inception report, further work is required to finalise the schedule of questions. During the course of the initial analytical task, and in conjunction with the parallel survey undertaken by the Commission, survey questionnaires will be developed for approval, testing and deployment.

### On risk assessment:

- What are the institutions are doing the risk assessment in MS?
- Where is the location of decision making? What is the relationship of risk assessors to risk managers?
- Are risk assessment bodies complying with time limits? How many times is the clock stopped?
- How do the risk assessments being performed by MS compare to the EFSA guidelines (indication of the quality of the guidance and the quality of the dossiers) and the principles established in Annex II of Directive 2001/18/EC and supplemented by Decision 2002/623/EC?
- What is the scope of the risk assessment? What are the possible outcomes that are considered a possible hazard?
- What is the ecological context – does the risk assessment cover the crop itself and the context?
- What amount and what type of data is considered necessary and/or sufficient?
- What are the benchmarks that are used for comparison?
- What is the chosen level of protection?
- What position is taken on key aspects of the constituting of proof? For each relevant stage in the risk assessment process:
  - on which side of the argument lies the onus of persuasion (ie: in support of a null hypothesis of safety or of harm)?
  - how does the process characterise the 'weight of evidence' or 'level of proof' required to sustain such persuasive argument?
  - on which parties are placed the financial and resource burdens necessary to produce the requisite evidence and analysis?
- Regarding test requirements / methodologies:
  - What is considered, only crop, crop management, or environment-crop interaction?
  - How many environment-crop interactions are considered?
  - What are the range of crop-management options that are considered?
  - Who collects the data?
  - What is the duration of the studies?

- What is the frequency of data collection?
- What are the different parameters that are considered?

To MS and EU regulators and innovators:

- Do you view EFSA guidance adequate for conducting ERAs? If not, why not?
- What are your experiences, if any, with applications for renewal of consent?
- Are there in your view differences between market approval procedures for GM crops in the US and EU? What are these differences, and what do they imply for your operations?

To MS regulators:

- If there is a biosafety advisory committee in your country, what is its composition? Scientific expertise only? Or also inclusion of stakeholder groups? If so, why? If not, why not?

To MS and EU regulators and innovators:

- How are clinical gene therapy trials regulated? In case of a regulatory interface with Directive 2001/18, are there (still) any specific issues that urgent need attention?

#### **On the implementation of Part B provisions:**

To MS regulators and notifiers:

- Is there a (legally permissible) possibility to have a pre-application discussion in your country? If not, why not?
- Are there, compared to 2004, new national provisions for Part B releases? If so, what are they?
- Have they facilitated regulatory oversight? If so, why? If not, why not? Have they facilitated innovators applying for Part B releases? If so, why? If not, why not?
- Is current working of Part C of Directive 2001/18 still dampening the number of Part C applications for field trials with GM crops?
- What was the total number of field trial applications during the last five years? How many field trials were rejected? What was the reasoning behind the rejection?
- How do you explain the relatively low (or high) number of field trials with GM crops in your country during the last five years?
- Why do notifiers choose particular member states for their applications? Is it possible to identify particular trends or patterns during the last five years?
- How has the Directive for environmental liability, with a view to Part B releases of GMOs, been implemented in your country? Has this facilitated innovators applying for field trials with GM crops? If not, why not?
- How are the provisions for public disclosure of field trial locations of Directive 2001/18 implemented in your country? In case there has been sabotage of field trials in your country, has this encouraged or discouraged sabotage of field trials? And has this encouraged or discouraged innovators applying for field trials with GM crops?

To MS regulators

- Have there been court cases in your country concerning public disclosure of field trial locations? If so, what were the results?
- Do you find final reports of field trials useful for the ERA in case of a Part B application for next step, a scaled-up, less or not confined field trial? If not, why not?
- Are in your view final reports of Part B trials useful for the ERA of a Part C application, including cultivation? If not, why not?
- What are the levies or administrative costs of a Part B application, if any?
- What are the levies or administrative costs of a Part C application, if any?

To innovators:

- Do you consider EFSA's position on ARMs useful? If not, why not?
- Has EFSA's position on ARMs had an impact on your R&D? If so, what impact?
- Has the EU legislation had an impact on your use of ARM genes in R&D?
- Has research on GMOs advanced as a result of the Directive and Regulation?

#### **On the fit of risk assessment procedures for herbicides under Directive 91/414/EC:**

- Do measures to mitigate environmental effects of herbicides in conventional systems work for GMHT? What are GMHT specific measures?
- How do the risk assessment submitted under the Directive 91/414 compare to the risk assessment under the Deliberate Release Directive and the Food and Feed Regulation?
- Which risk assessment procedure do stakeholders think is more appropriate for assessing GMHT crops? Why?
- What is the relationship between competent authorities involved in the implementation of Directive 2001/18/EC and Directive 91/414/EEC?

#### **On the process evaluation of risk assessment procedures and responsibilities**

For EFSA:

- How are risk assessments to CAs allocated? On what basis? What are the trends?

For MS:

- Are they satisfied with the way EFSA allocated RAs to CAs?

For CAs

- Are they satisfied with the way EFSA allocated RAs to CAs?
- Are they satisfied with their relationship with EFSA?
- To what extent has their role and their input changed since the implementation of Regulation 1829/2003?
- How is the risk assessment done? (see questions above on risk assessment requirements / methodology)

For notifiers:

- Do you have a preference for submission of application for market approval, including cultivation, under Directive 2001/18 or Regulation 1829/2003? If so, why? If not, why not?
- Does, it make a difference? If not, why not? Or under what conditions would it make a difference?

To MS regulators, EFSA, EMEA and innovators:

- According to the 2004-study some GMO releases were regulated under different legislation (e.g. gene therapy trials) in different MS with an unclear interface with EMEA procedures. Is this still so? Or have adjustments been implemented to reduce regulatory uncertainties for innovators? Are they adequate? Workable? If not, why not?

To EFSA and MS regulators:

- What are the experiences so far?

### **On environmental monitoring and management measures:**

To regulators:

- Does post-market monitoring of cultivation of GM crops that could in the nearby future approved under Regulation 1829/2003 require a different interaction between institutions in your country and at the EU-level than in the case of cultivation-approval under Directive 2001/18? If so, why?
- Has the Directive / Regulation led to new types of monitoring?
- Has the guidance developed by the Commission been helpful?
- How consistent do you think the types of PMEM are across the EU?
- Have you got any comments on the monitoring and /or general surveillance plan that is planned by applicants?
- Do you have any concerns about the development and implementation of general surveillance monitoring?
- What are the investigative routines and the associated records?
- What are the sanctions for noncompliance?
- What are the levels of resourcing?
- Do you find post-market case-specific monitoring requirements for EU-approved (and EU-grown) adequate? Workable? If not, why not?
- Is in your view the distinction between case-specific monitoring and general surveillance clear? Workable? If not, why not? What do you have to contribute to general surveillance; what are the annual costs?
- What kinds of management measures have been adopted? Have the effect of these been evaluated?
- How often are management measures adopted following the risk evaluation of field trials?

To innovators:

- Are the provisions for post-marketing monitoring and traceability in Directive 2001/18 and Regulations 1829/2003 workable? If not, why not?

### **On inspections and controls of unauthorised GM material in seeds:**

To regulators:

- How do you control compliance with provisions for adventitious presence of non-EU authorised GM seeds in lots of GM and non-GM seeds? What are the institutions, methods and frequencies involved? What have been the results so far? In case of non-compliance, what has been decided on what basis?

To CAs:

- What measures have you developed or implemented within your MS for the purpose of verification?
- Do you have any comments to make about the Recommendation 2004/787/EC on technical guidance for sampling and detection of GMOs and material produced from GMOs?
- Are they still considered too expensive / time consuming? If so, what are MS doing as a result? Are they still using the guidance, or are they using something else instead?
- Is any further action or further regulation needed in relation to adventitious presence of GMOs? E.g. further guidance / harmonised evaluation criteria / validated detection methods / authorised reference material
- How do you control compliance with provisions for adventitious presence of GM material above 0,9 % in non-GM food/feed? What are the institutions, methods and frequencies involved? What have been the results so far? In case of non-compliance, what has been decided on what basis?

To innovators and operators in seed supply chains:

- Has the absence of thresholds for the adventitious presence of non-EU authorised GM seeds in lots of GM and non-GM seeds impacted your operations? If so, how?

### **On the effect of the zero-tolerance policy on unauthorised GM material in seeds:**

To CAs:

- What are your views on the workability of the system set out in the Directive and the Regulation concerning traceability and labelling?
- Have any specific issues arisen with regard to import of GMOs?
- Is there still a gap in knowledge of how to detect the adventitious presence of materials that are unauthorised in the EU?
- Do you have any comments to make about the Recommendation 2004/787/EC on technical guidance for sampling and detection of GMOs and material produced from GMOs?
- Are they still considered too expensive / time consuming? If so, what are MS doing as a result? Are they still using the guidance, or are they using something else instead?
- Is any further action or further regulation needed in relation to adventitious presence of GMOs? E.g. further guidance / harmonised evaluation criteria / validated detection methods / authorised reference material
- Do you have any comments about thresholds concerning the adventitious presence of un-authorised GM seeds in seed lots of non-GM varieties or authorised GM varieties?

**On national safeguard and emergency measures:**

- What are the definitions of harm?
- What constitutes proof?
- What are the provisions in respect of third party liability in the event of such emergencies?

**On risk communication:**

- To what extent does communication explicitly address issues of uncertainty, ambiguity and ignorance as well as risk? In other words: How far and in what manner is it acknowledged that quantitative levels of safety may remain indeterminate?
- To what extent are divergent expert or disciplinary judgements or perspectives represented in communication?
- How much and what kind of attention is given to the possibility of persistent gaps in knowledge and areas where further research is required?
- Is uncertainty perceived?
- What is communicated to the public?
- What is the reason / purpose for informing the public?
- What methods are being used? What type of communication is most effective?
- What are the outcomes of public communication? i.e. is the public using the information, is the public acting on the information?
- To what extent does publication of risk assessment procedures and results allow independent reconstruction of the assumptions adopted and the particular reasoning underlying the conclusions reached?
- Is the underlying data itself published in full, or simply in aggregated form?
- To what extent might residual confidentiality constraints be addressed through anonymisation procedures or independent confidential third party peer review, with publication of generic findings?
- Is there explicit attention to uncertainties and data gaps?
- Is any kind of sensitivity analysis performed, under which conclusions are tested against potentially reasonable variations in parameter values or other contrasting assumptions?
- Is there disclosure of dissenting individual or minority expert opinions on the part of advisory bodies involved in the risk assessment process? Does such disclosure take the form simply of noting divergent views, or stating the reasons for the differences of judgement?

To farmers, operators in the agro-food chain and public interest NGOs:

- Do you find the way your national authority implements provisions for public information and participation of Directive 2001/18 in case of Part B applications adequate? If not, why not?

- Did you ever make use of these provisions? What were the results? Were they to your satisfaction? If not, why not?
- Do you find the way the European Commission and your national authority implement provisions for public information and participation of Directive 2001/18 in case of Part C applications adequate? If not, why not?
- Do you find the way the European Commission and EFSA communicate with the public adequate?
- In case of membership of a biosafety advisory body; what are your experiences? Are you satisfied the way your input is considered in advice to regulators? If not, why not?

## ANNEX 2 INITIAL SCHEDULE OF STAKEHOLDERS

The schedule of stakeholders to be consulted will be developed during the initial analytical phase, including through the website registration process discussed above. It is expected to include:

- EU institutions involved in application of GM legislation (e.g. DGs of the European Commission, EFSA, FVO);
- National Competent Authorities;
- Companies and research organisations with an interest in the application of GM technology to plants (including seed specialists), animals and micro-organisms;
- Companies in the supply chain of the sectors involved (such as grain traders, food and feed processors and retailers in the agri-food chain);
- National and EU representative organisations for the farming sector;
- Other (e.g. medical) biotech companies and research organisations;
- Non-governmental organisations with a specialist interest in GM issues;
- Other consumer representative bodies – e.g. BEUC at EU-level, and associated/other national consumer groups.

The relevant individuals within organisations will be identified from sources such as:

- Registry of national competent authorities supplemented by
- Commission/EFSA advice and telephone contact where necessary;
- Trade associations and representative bodies;
- Online research and email/telephone contact;
- Databases of GMO notifications

**Scan of stakeholder involvement according to particular evaluation questions**

Evaluation Question	Stakeholders and interest groups to be consulted							
	EFSA, Other EU institutions	MS national Competent Authorities	Corporate interests and representatives	Research base	Supply chain (e.g. agric-food)	Consumer Groups	NGOs	Other
Q.1. Suitability of objectives	✓	✓	✓	✓	✓	✓	✓	
Q.1.a New techniques	✓	✓	✓	✓	✓	✓	✓	
Q.2. Risk assessment procedures	✓	✓	✓	✓		✓	✓	
Q.3. Roles and responsibilities for risk assessments	✓	✓	✓	✓			✓	
Q.4. Fit of risk assessment procedures with those for Directive 91/414/EC	✓	✓	✓	✓	✓		✓	Herbicide manufacturers
Q.5. Implementation of Part B provisions by MS	✓	✓	✓	✓	✓			
Q.6. The effect of national measures	✓	✓	✓	✓	✓	✓	✓	
Q.7 Provisions for risk management of GMO marketing	✓	✓	✓	✓	✓	✓	✓	
Q.8. Inspections and controls of unauthorised GM material	✓	✓	✓	✓	✓		✓	FVO, seed distributors, farming representative groups, national cereal authorities, GM inspectorates in MS

Q.9 Risk communication of GMO release	✓	✓	✓	✓	✓	✓	✓	
Q.10 Procedures on national safeguard and emergency measures	✓	✓	✓	✓	✓	✓	✓	National FSAs, MS CAs which have invoked the safeguard clause
Q.11 Coherence of national safeguard measures	✓	✓	✓	✓	✓	✓	✓	National FSAs, MS CAs which have invoked the safeguard clause
Q.12. Confidentiality and data protection	✓	✓	✓	✓		✓	✓	
Q.13. Effect of the zero-tolerance policy on unauthorised seeds	✓	✓	✓	✓	✓		✓	Farm operators, feed and food companies, including importers

## ANNEX 3 STAFF PROFILES

**The named GHK and Technopolis consultants will, together with the project manager and director, provide the core ‘delivery capacity’ for the evaluation.**

### **Andrew Jarvis, Principal, GHK**

Andrew Jarvis is an experienced policy analyst with a background in applied biology and environmental economics. He has 15 years experience in consultancy and government, and has worked principally in the UK, Brussels and Hong Kong. He now leads GHK’s consultancy work on food, environment and related areas.

He has recently returned to GHK after 2½ years as the lead policy adviser for environment and energy in the Prime Minister’s Strategy Unit in the UK Cabinet Office. In that capacity he managed a major review for the UK Prime Minister of food and food policy. This included a scan of GM issues in the food and feed supply chain and commissioning of further evidence. This food policy review was one of a series of high level strategic policy development projects that Andrew led while in the Cabinet Office. These all required:

- Rapid appraisal of evidence
- Evaluation of success/failure of existing policies and legislation
- Development and appraisal of new policy options
- Preparation of clear, coherent and well-evidenced reports for high level decision-makers

His previous consultancy experience, including 10 years with GHK, encompasses evaluations, regulatory impact assessments, market studies, and policy research for various Directorates-General of the European Commission and for government clients in the UK, Hong Kong, Taiwan and elsewhere. He is familiar with a wide range of evaluation methods and approaches to stakeholder engagement.

Andrew will be the project director for this evaluation. He will take primary responsibility for delivery of the project deliverables and reporting to the Steering Group. Andrew is based in GHK’s London office.

### **Adarsh Varma, Senior Consultant, GHK**

Adarsh Varma is an economist with over 6 years experience working on environmental-economic issues in the UK. In particular he has expertise on environment-economic models and environmental policies on climate change, waste and energy. He is currently finishing a Phd on UK’s Climate Change levy and emission trading scheme and its impact on competitiveness of efficiency of firms. His Phd research has been independently published in 2 journals and one book. Adarsh has worked with the Mayor of London as an economist for nearly 4 years before joining GHK. At the GLA he has worked on housing, transport and environmental issues. He was responsible for analysing the environmental-economy linkages of the Mayoral strategies. He has worked closely with RDAs and the Environment Agency as regional coordinator for London as part of the SCPnet project. He has also worked with ODPM and HM Treasury as a member of their research advisory board for the Barker Review on increasing housing output in the UK.

### **James Leather, Senior Consultant, GHK**

James Leather is a Senior Consultant at GHK with eight years of experience of public policy research. James specialises in ex ante, interim, and ex post evaluations and impact

assessments of legislation, programmes and projects. His particular areas of expertise include enterprise and entrepreneurship, innovation and research, and learning and skills. James has managed a number of studies for the European Commission, most recently two assignments for DG Enterprise and Industry on the application of the principles of Think Small First in EU legislation and programmes, and an ex post evaluation of innovation activities funded through the Sixth Framework Programme. James has also managed a study for DG Enterprise and Industry evaluating the Cosmetics and Explosives Industry, and a study for DG Education and Culture providing support services in the preparation of an impact assessment for the European Institute of Technology. James has extensive experience of research techniques including national case studies, the design and analysis of questionnaire surveys, policy review, legislative review, and stakeholder consultation. James holds a Master and a Bachelor degree in economic geography, both from the University of Birmingham in the UK. His mother tongue is English.

### **Effie Pitsaros, Technopolis**

Effie has considerable experience in research, analysis and evaluation in several policy areas, including agriculture and food and relevant environmental and trade issues, gained through involvement in a range of projects, mostly international in scope, commissioned by clients such as the European Commission, FAO, WTO, IAEA plus Greek and UK Governments. She has recently contributed to the evaluations of the GMES Bureau and FP6 Space activities and an evaluation of the effectiveness and efficiency of the European Environment Agency. Effie holds a MA in International Relations from San Francisco State University and a BA in Political Science from Panteion University, Athens, Greece. She has also carried out PhD research on the European Union's enlargement to the East in the areas of agriculture, environment and food safety at the University of Sussex.

### **Mavourneen Pieterse**

Mavourneen Pieterse joined GHK in 2009 as a Research Assistant. Prior to joining GHK, she completed a research internship at Chatham House in the Energy, Environment and Development Programme, working on projects related to energy security, pro-poor business procurement, and illegal logging. She recently completed an MSc in Environment and Development at the London School of Economics, where she graduated with Distinction. Previously she completed a BSc in Ecology, with Honours in Conservation and Ecological Management at the University of Edinburgh, where she graduated top of her year.

### **Gabor Konig**

Gabor Konig is an agricultural economist. Since 2001 he has worked as a senior economist at the Hungarian Ministry of Agriculture's Agricultural Economics Research Institute (AKI) and he has been responsible for researching and publishing policy oriented reports and studies that assist decision makers in the Government to implement policy. He specialized in agricultural trade, marketing, food industry, agro-business mainly in Central Europe, dairy, beef production and sales; market competition regulation, EU enlargement, and how food aid, customs, subsidies, and agreements affect trade, and policy. In 2007-2008 he worked in Washington DC at the US Department of Agriculture's Economic Research Service (ERS). In 2003 and 2005 he assisted with WTO and FAO negotiations and has since presented papers at several conferences in Europe and the US. In 2005, he gained experience in the finance and investment sectors at French bank called Crédit Agricole in Nantes. He has a PhD in management and organizational science, 2 MBAs from Hungary and France, and a Master degree in agricultural economics. He speaks Hungarian, English and French. He joined GHK's London office in 2009.

### **Supplementary research support**

The project will receive additional support from GHK and Technopolis teams as required to ensure the proper conduct of the study. This will include input to stakeholder consultations where additional language expertise is required (see Figure 5.3)

### **The expert associates will take oversight roles on particular aspects of the evaluation**

#### **Erik Millstone**

For 34 years, Erik Millstone has been conducting comparative studies of structures and processes for assessing and management the risks arising from agricultural and food technologies. His work has covered, for example, the risks arising from food additives and contaminant, pesticides, Bovine Spongiform Encephalopathy and GM crops, not just in Europe, but in other OECD countries and developing countries, as well as at the global Codex level. He has participated in at least 9 such projects over the past 20 years, two funded by the UK's Economic and Social Research Council, with the remaining 7 by the European Commission, of which he was the principal researcher in the most recent 3. He has worked with the governments or Parliaments of 7 EU Member States, with the European Commission and European Parliament, and with the World Health Organisation.

#### **Armin Spoek**

Armin Spoek is a senior researcher and head of the Biotechnology Research Unit at the IFZ-Interuniversity Research Centre for Technology, Work and Culture in Graz, Austria. He has more than 14 years of experience in research and advisory work on scientific, regulatory and wider policy aspects of biotechnology, including genetically modified plants and microorganisms as well as food, feed, pharmaceuticals, chemicals, cosmetics and other products derived from them. A particular focus is the assessment and management of environmental and health risks. In these contexts he has participated as principal researcher in more than 20 projects frequently including cross-country comparisons and authored more than 50 publications. Armin Spök is a member of the EFSA Advisory Group on Risk Communication and of the OECD Task Force on the Safety of Novel Foods and Feeds; he is also working as occasional advisor in various national and international contexts (e.g. FAO, Cartagena Protocol on Biosafety, EU Framework projects).

#### **Andy Stirling**

A social scientist with a background in natural science, Andy Stirling has worked for eighteen years at SPRU, University of Sussex, on the governance of risk, science and innovation. He co-ordinated a project on 'Science and Precaution in the Management of Technological Risk' for the European Science and Technology Observatory in 1999, which was cited in the 2000 EC White Paper. He was a lead member of the editorial team producing the 2001 European Environment Agency study of precaution in environmental regulation 'Late Lessons from Early Warnings' and of the subsequent European Framework projects 'PrecauPri' and 'Safe Foods', which developed specific proposals for more precautionary risk governance in the fields of chemicals and food safety, respectively. He has served on a number of policy advisory bodies including the EU Energy Policy Consultative Committee, Science in Society Advisory Group and Expert Group on Science and Governance and the UK Advisory Committee on Toxic Substances, GM Science Review Panel and Defra Science Advisory Council.

### **Piet Schenkelaars**

Piet Schenkelaars has been active in the field of biotechnology for more than twenty years. Since the formulation of his consultancy Schenkelaars Biotechnology Consultancy (SBC) in 1998, he has undertaken a range of various studies, produced reports on workshops on risks, benefits, regulations and other policy issues related to GMOs, with this work commissioned by the Netherlands Government, the European Commission, the United Nations, biotechnology companies, food firms, scientific institutions, and Dutch and European environmental and consumer organisations. His work on GMO regulations for the European Commission DG Environment includes a study in co-operation with Risk & Policy Analysts Ltd (UK) on “Means to improve the consistency and efficiency of the legislative framework in the field of biotechnology Article 31 (7a, 7b and 7d) of Directive 2001/18/EC (April 2004)”. Moreover, his review of the EU legislation for Healthcare biotechnology, Agro-food Biotechnology and Industrial Biotechnology, commissioned by the Netherlands Ministry of Economic Affairs, served as input for a European Round Table in 2004. In 2007 the GMO Office, the executive office of the Dutch competent authority, commissioned him a study to investigate which novel aspects have to be taken into account in the risk assessment of two novel GM plants, i.e. drought tolerant GM maize and omega-3 fatty acid GM soybean, that are currently in the mainstream of research and development efforts, in order to study whether their environmental risk assessment involves novel aspects compared to that of current generations of GM plants. In addition, in 2008 he completed a study on the regulatory costs of the market approval of a GM crop in the US and the EU, which was commissioned by the Committee on Genetic Modification (COGEM), the national biosafety advisory committee to the Dutch competent authority.

### **Huib de Vriend**

Huib de Vriend is an expert in public attitudes, consumer behaviour and communication strategies concerning genetically modification, and is very well informed about the regulatory framework addressed in this evaluation. Between 1991 and 2005 he worked for the Consumer & Biotechnology Foundation, an expert centre for consumer related issues in biotechnology. He has been is an independent consultant on societal issues in life sciences and innovation since January 2005. He is highly experienced in balanced analysis of technological developments, societal impacts and policy options for innovation strategies and stakeholder involvement. He has conducted several studies on technological and regulatory developments, the socio-economic impacts and public attitudes and public perceptions of biotechnology and genomics and has been involved in several initiatives aiming at debate and constructive dialogue between scientists, public authorities, industry representatives and NGOs.

## ANNEX 4 STRUCTURE OF THE FINAL REPORT

A revised proposed structure for the final report will be provided in the interim report for Commission review and comment. The results will broadly follow the structure of the evaluation as set out in the figures included in this report.

*Title page:*

- \_ title and nature of evaluation (e.g. ex post)
- \_ title of programme, generation, duration
- \_ identification of author, date of submission, commissioning department

*Table of contents:*

- \_ main headings and sub-headings
- \_ index of tables of figures and graphs

*Executive summary:*

- \_ an overview of the entire report in no more than five pages
- \_ a discussion of the strengths and weaknesses of the chosen evaluation design

*Introduction:*

- \_ description of the programme in terms of needs, objectives, delivery systems etc.
- \_ the context in which the programme operates
- \_ purpose of the evaluation in terms of scope and main evaluation questions.
- \_ description of other similar studies which have been done

*Research methodology:*

- \_ design of research
- \_ implementation of research and collection of data
- \_ analysis of data

*Evaluation results:*

- \_ findings, with specific elaboration of the questions asked in chapter 4;
- \_ conclusions, following up to the questions asked in chapter 4;
- \_ recommendations

*Annexes:*

- \_ terms of reference
- \_ additional tables
- \_ references and source
- \_ glossary of terms

## ANNEX 5 RISK REGISTER

This draft risk register is provided here for discussion. The risk register will be kept updated throughout the project.

<b>Ref</b>	<b>Issue</b>	<b>Risk management strategy</b>	<b>Owner</b>
1	Maintenance of client-consultant communication	Monthly progress reports and telephone 'meetings' to review progress and discuss issues. Mobile phone numbers for Project Director and Project Manager provided to Commission.	GHK/DG Env
2	Project is targeted by anti-GM campaigners intending to swamp the consultative process	Project website to provide registration facility for stakeholders and e-survey to require reference/registration number	GHK
3	Project timetable delayed by linkages to parallel to Commission survey	Active communication with EC	GHK (DG ENV support)
4	Delays associated with approval of survey questionnaires	Timely delivery of project interim report	GHK
5	Survey questionnaires yield insufficient data to support analysis	Increased resource allocation to telephone interviews	GHK/Technopolis
6	Report criticised by stakeholders for lack of balance / omission of stakeholder viewpoints	Registration mechanism for stakeholders + discussion with Member States to ensure good coverage of stakeholders. Accurate write-up of interviews. Transparency of process.	GHK/Technopolis
7	Lack of project fit to appraisal and performance assessment criteria	GHK to review all deliverables against Commission's performance review criteria	GHK(AJ)
8	Breadth, depth and complexity of evaluation challenges team capabilities	Weekly internal project management meetings. Peer review of deliverables and process by expert associates.	Project team