

European Commission
Directorate General for Health and Consumers

Evaluation of the EU legislative framework in the field of GM food and feed

Framework Contract for evaluation
and evaluation related services - Lot 3: Food Chain
(awarded through tender n° 2004/S 243-208899)

Inception Report

Submitted by:

Food Chain Evaluation Consortium (FCEC)

Civic Consulting - Agra CEAS Consulting -

Van Dijk Management Consultants - Arcadia International

Project Leader: Agra CEAS Consulting

**European Commission
DG SANCO
Rue de la Loi 200
1049 Brussels**

06.08.2009

Contact for this assignment:

Dr B. Dylan Bradley
Agra CEAS Consulting
Imperial College London
Wye Campus, Wye, Kent, UK
tel: +44 1233 812181
fax: +4 1233 813 309
Dylan.Bradley@ceasc.com
www.ceasc.com

Evaluation of the EU legislative framework in the field of GM food and feed

Inception Report

Prepared by the Food Chain Evaluation Consortium (FCEC)
Civic Consulting – Agra CEAS Consulting –
Van Dijk Management Consultants – Arcadia International

Project Leader: Agra CEAS Consulting

Food Chain Evaluation Consortium
c/o Civic Consulting
Potsdamer Strasse 150
D-10783 Berlin-Germany
Telephone: +49-30-2196-2297
Fax: +49-30-2196-2298
E-mail: alleweldt@civic-consulting.de

Expert Team

Agra CEAS Consulting:

Dr Dylan Bradley
Conrad Caspari
Clifford Biggs
John Nganga
Mariana Ricci

Arcadia International:

Dr Rodolphe de Borchgrave
Daniel Traon

Civic Consulting:

Dr Frank Alleweldt
Dr Sue Williams
Philipp von Gall

fcec

Food Chain Evaluation Consortium
Civic Consulting – Agra CEAS Consulting
Van Dijk Management Consultants – Arcadia International

Contents

1. INTRODUCTION.....	1
2. THE GM FOOD AND FEED SECTOR (TASK 1.2).....	2
2.1. THE LEGISLATIVE FRAMEWORK PRE-2003	2
2.1.1. <i>GM food</i>	2
2.1.2. <i>GM feed</i>	4
2.2. THE LEGISLATIVE FRAMEWORK POST-2003	5
2.2.1. <i>The risk assessment and regulatory approval process</i>	6
2.2.1.1. The scientific evaluation of the risk assessment.....	8
2.2.1.2. Risk management and the regulatory approval process	9
2.2.1.3. Transitional measures for adventitious presence of GM events unauthorised in the EU.....	9
2.2.2. <i>The compulsory labelling of GM food and feed</i>	10
2.3. THE MAIN CHANGES	10
2.4. EVOLUTION OF THE GLOBAL GM SECTOR	10
2.5. CONSUMER PERCEPTIONS OF GM	18
3. INTERVENTION LOGIC (TASK 1.3).....	20
3.1. LEGISLATIVE BACKGROUND TO REGULATION (EC) NO 1829/2003 AND REGULATION (EC) NO 1830/2003	20
3.2. RATIONALE FOR INTERVENTION	22
3.3. REGULATORY OBJECTIVES.....	22
3.4. REGULATORY SCOPE	23
4. EVALUATION QUESTIONS AND EVIDENCE BASE (TASK 1.4)	24
5. INFORMATION SOURCES (TASK 1.5).....	36
6. EVALUATION TOOLS (TASK 1.6)	39
7. WORK PLAN (TASK 1.8)	40
7.1. EVALUATION PROCESS	40
7.1.1. <i>Structuring</i>	41
7.1.2. <i>Observing</i>	41
7.1.3. <i>Analysing</i>	41
7.1.4. <i>Judging</i>	41
7.1.5. <i>Dissemination</i>	42
7.2. PROJECT TIMELINE AND KEY MILESTONES	43
7.3. PRELIMINARY STRUCTURE OF THE DRAFT FINAL REPORT	44
7.4. HUMAN RESOURCES	44
7.4.1. <i>Project management</i>	44
7.4.2. <i>Project team</i>	44

Acronyms

AAF:	Association des Amidonniers et Féculiers (European Union Starch Industry)
ALARA/ALARP:	As low as reasonably achievable / practical
AVEC:	Association of Poultry Processors and Poultry Trade in the European Union
BEUC:	European Consumer's Organisation
BSE:	Bovine spongiform encephalopathy
Bt:	Insect Resistance/resistant
CDG:	Genetic Rights Foundation
CIAA:	Confederation of Food and Drink Industries of the European Union
COCERAL:	Comité du Commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures
DG:	Directorate General
DG AGRI:	Directorate General of the European Commission for Agriculture and Rural Development
DG SANCO:	Directorate General of the European Commission for Health and Consumers
DNA:	Deoxyribonucleic acid
EC:	European Commission
EEC:	European Economic Community
EFSA:	European Food Safety Authority
EQ:	Evaluation Question
EU:	European Union
FCEC:	Food Chain Evaluation Consortium
FEDIOL:	European Union Oil and Proteinmeal Industry
FEFAC:	European Feed Manufacturers' Federation
FEFANA:	European Union Association of Feed Additives and Premixtures Operators
GM:	Genetically Modified
GMO:	Genetically Modified Organism
Ha:	Hectare
HT:	Herbicide Tolerance/tolerant
IP:	Identity Preservation
ISAAA:	International Service for the Acquisition of Agri-biotech Applications
JRC:	Joint Research Centre (of the European Commission)
JRC-IPTS:	The Institute for Prospective Technological Studies of the Joint Research Centre
LLP:	Low level presence
MS:	Member State

EVALUATION OF GM FOOD AND FEED LEGISLATION
DG SANCO Evaluation Framework Contract Lot 3 (Food Chain)

NGO:	Non-Governmental Organisation
OECD:	Organisation for Economic Co-operation and Development
QMV:	Qualified Majority Vote
SCFAH:	Standing Committee on the Food Chain and Animal Health
TC:	Third Country
ToR:	Terms of Reference
UECBV:	The European Livestock and Meat Trading Union
US / USA:	United States of America
VR:	Virus Resistant
WWF:	World Wildlife Fund

1. Introduction

DG SANCO launched this evaluation of the EU legislative framework in the field of genetically modified (GM) food and feed in early June 2009. This refers in particular to Regulation (EC) No 1829/2003 on GM food and feed¹, as complemented by Regulation (EC) No 1830/2003² on GMO traceability and labelling and other relevant accompanying legislation³, which together replace previous legislation⁴.

Both Regulations are now six years old, but the regulatory approach to GM food and feed continues to be high on the European political agenda and the authorisation process has proven difficult; for example, a qualified majority under the Qualified Majority Voting (QMV) system has never been obtained; and the regulatory approach remains highly controversial in the EU. Labelling of GM products is another key issue with the emergence in Member States of a number of national private labelling schemes relating to “GM-free” products and stakeholder discussion over whether the labelling should be extended to include livestock products⁵. As a consequence, few food products labelled as GM are at the present time on the Community market⁶. The situation is completely different for GM feed which is at present predominant on the EU market.

This study is led by Agra CEAS Consulting of the Food Chain Evaluation Consortium (FCEC), with inputs from Arcadia International and Civic Consulting, in the context of the ongoing Evaluation Framework Contract for Lot 3 (Food Chain).

This Report sets out the work undertaken by the contractor during the Inception phase of this project, i.e. the first five weeks of the contract. This has mainly related to the fine-tuning of the methodology and the detailed planning of the assignment. The purpose of this phase is to provide the Steering Group with the opportunity to make a final check on the proposed methodology in relation to the objectives outlined in the ToR.

¹ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

² Regulation (EC) No 1839/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

³ In particular: Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 as regards the application for the authorisation of new MG food and feed, the notification of existing products and adventitious or technically unavoidable presence of GM material which has benefited from a favourable risk evaluation; and Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms.

⁴ Previously GM foods were regulated under the Novel Food Regulation 258/97, whilst GM feeds were partially regulated under Directive 2001/18 on the deliberate release of GMOs into the environment.

⁵ Greenpeace have submitted a petition to the Commission demanding the labelling of foods derived from animals fed with GMOs: <http://www.coextra.eu/news/news804.html>. Accessed 07/07/09.

⁶ Conclusions of the Commission 2006 Report to the European Parliament and to the Council about the implementation of the Regulation (Com (2006)626).

2. The GM food and feed sector (Task 1.2)

2.1. The legislative framework pre-2003

Prior to 2003, GM food was legislated under Regulation (EC) No 258/97⁷. GM feed was partially regulated under Directive 2001/18/EC on the deliberate release of GMOs into the environment. Because GM food and feed were not dealt with together they are discussed separately in the sub-sections below.

2.1.1. GM food

Regulation (EC) No 258/97 identified two categories of GM food:

1. food and food ingredients produced from, but not containing GMOs; and,
2. food and food ingredients containing or consisting of GMOs within the meaning of Directive 90/220/EC⁸.

In general terms, food either containing or produced from GMOs had to fulfil the requirements of all novel foods, that is to say: not present a danger to the consumer; not mislead the consumer; and, not differ from the products they intend to replace to the extent that their normal consumption would be nutritionally disadvantageous.

The authorisation procedure for these two categories of GM food differed. In the case of food produced from, but not containing GMOs, the applicant⁹ had to notify the Commission of the placing on the market of the product. The Commission was then obliged to forward the notification to Member States within 60 days. As noted above, the product had to be substantially equivalent¹⁰ to its traditional counterpart. This equivalence could be established through generally recognised scientific evidence, or on the basis of an opinion delivered by the food assessment body of a Member State.

In the case of foods and food ingredients containing GMOs, the procedure was more complex. The applicant had to submit a request to the Competent Authority in the Member State in which the product was to be placed on the market and forward a copy of this request to the Commission. The request had to contain information which demonstrated that the product fulfilled the general criteria of not:

- presenting a danger to the consumer;
- misleading the consumer; or,
- differing from foods or ingredients it intended to replace to the extent that normal consumption would be nutritionally disadvantageous for the consumer.

A proposal for labelling in line with the labelling rules (see below) also had to be included and a summary of the complete dossier was required.

⁷ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

⁸ According to Directive 90/220/EC, "a 'genetically modified organism (GMO)' means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination".

⁹ Defined as the person placing the product on the EU market.

¹⁰ Equivalence of the novel food in comparison to its traditional counterpart in terms of: composition, nutritional value, metabolism, intended use, level of undesirable substances contained.

On receiving the request, the Member State had to ensure that an initial assessment was carried out either by informing the Commission of the name of its competent food assessment body responsible for the assessment, or by asking the Commission to arrange an assessment by the competent body of another Member State. The Commission provided recommendations for the scientific aspects of information for supporting the application and the preparation of the report¹¹.

The initial assessment report had to be completed within three months, and had to indicate whether or not an additional assessment would be required. The report was then sent through the Commission to other Member States, who had a 60 day period to make comments or objections which were circulated to other Member States within this period.

If no additional assessment was deemed necessary, and no objections were received, the applicant was informed that the product could be placed on the market; otherwise the applicant was informed that an authorisation decision would be necessary. This decision would be taken by the Standing Committee for Foodstuffs, or, in the case that they did not reach an opinion, by the Council. This decision defined the scope of the authorisation, and established:

- the conditions of use of the food or ingredient;
- the designation of the food or ingredient and its specification; and,
- any specific labelling requirements.

The decision also had to respect the environmental safety requirements for GMOs laid down in Article 10 of Directive 90/220/EEC¹². The Commission would then inform the applicant of the decision taken.

The Scientific Committee on Food had to be consulted on any matter likely to have an effect on public health throughout the process.

With regard to labelling, it was necessary to indicate the presence of a GM organism. It was also necessary to indicate any characteristic (such as composition, nutritional value or effects and use of the food) which rendered the product no longer equivalent to an existing product. In the case of such a change in characteristics the modification and methods had to be indicated.

The process is summarised in Figure 2.1.

¹¹ In Recommendation 97/618/EC.

¹² Council Directive of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (90/220/EEC).

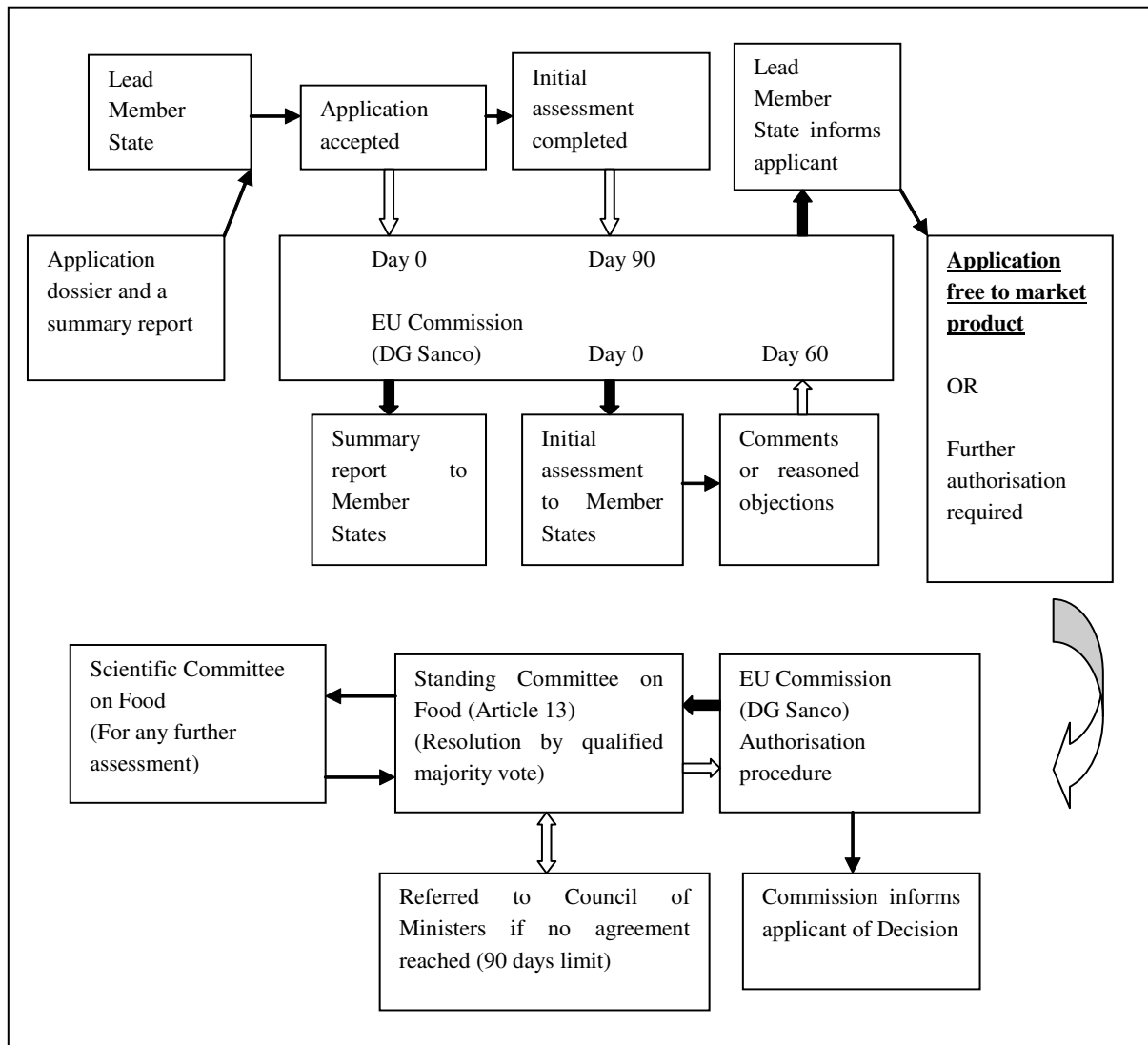


Figure 2.1: The risk assessment and approvals process for GM food pre-2003

Source: O'Mahony, P., Food Safety Authority of Ireland:
<http://www.irishscientist.ie/2001/contents.asp?contentxml=01p62.xml&contentxsl=IS01pages.xsl>. Accessed 07/07/09.

2.1.2. GM feed

GM feed was partially regulated under Directive 2001/18/EC¹³, which had replaced Directive 90/220/EEC. This directive (which remains in force) dealt with the placing onto the market of products derived from or containing GMOs. The directive is applicable to all GM products, and does not contain any specific provisions for GM feed (there was no authorisation procedure specific to GM feed prior to 2003).

Directive 2001/18/EC contains a general notification procedure for GM products being placed on the market. The notification must be submitted to the Member State where the GMO is placed on the market for the first time, and it must be accompanied by:

¹³ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

- information required in Annexes III and IV of the Directive;
- the environmental risk assessment and conclusions;
- conditions for the placing on the market of the product;
- a proposed period for consent, not to exceed 10 years;
- a plan for monitoring;
- a labelling proposal (which must comply with labelling requirements);
- a packaging proposal; and,
- a summary of the dossier

Within 90 days of receipt of the notification, the Competent Authority must prepare an assessment report indicating whether or not the GMOs in question should be placed on the market. The assessment report is circulated to Member States and the Commission, who have 60 days to make comments/present reasoned objections. A total of 105 days are foreseen for resolving outstanding issues.

2.2. The legislative framework post-2003

The system pre-2003 was not perceived to be precise enough to take into account the advances in GM technology. The assessment for novel foods (which included GM foods) was considered to focus more on substantial equivalence than on safety. Furthermore, there was no authorisation procedure for GM feed. As a result of this, and a number of other factors¹⁴, two regulations were introduced in 2003 to deal specifically with GM food and feed. These Regulations superseded the GM provisions laid out in Regulation (EC) No 258/1997. The first of these, Regulation (EC) No 1829/2003 is the main piece of legislation and deals with the general framework for regulating GM food and feed. The second piece of legislation, Regulation (EC) No 1830/2003, regulates traceability and labelling.

The main objectives of the regulations were to:

- ensure high levels of protection of human and animal health;
- encourage the free movement of feed and food; and,
- eliminate differences between authorities in the assessment of GM food which could distort competition.

Regulation (EC) No 1829/2003 identifies two categories of products:

- GM food (defined as GMOs for food use, food containing or consisting of GMOs and food produced from or containing ingredients produced from GMOs); and,
- GM feed (GMOs for feed use, feed containing or consisting of GMOs and feed produced from GMOs).

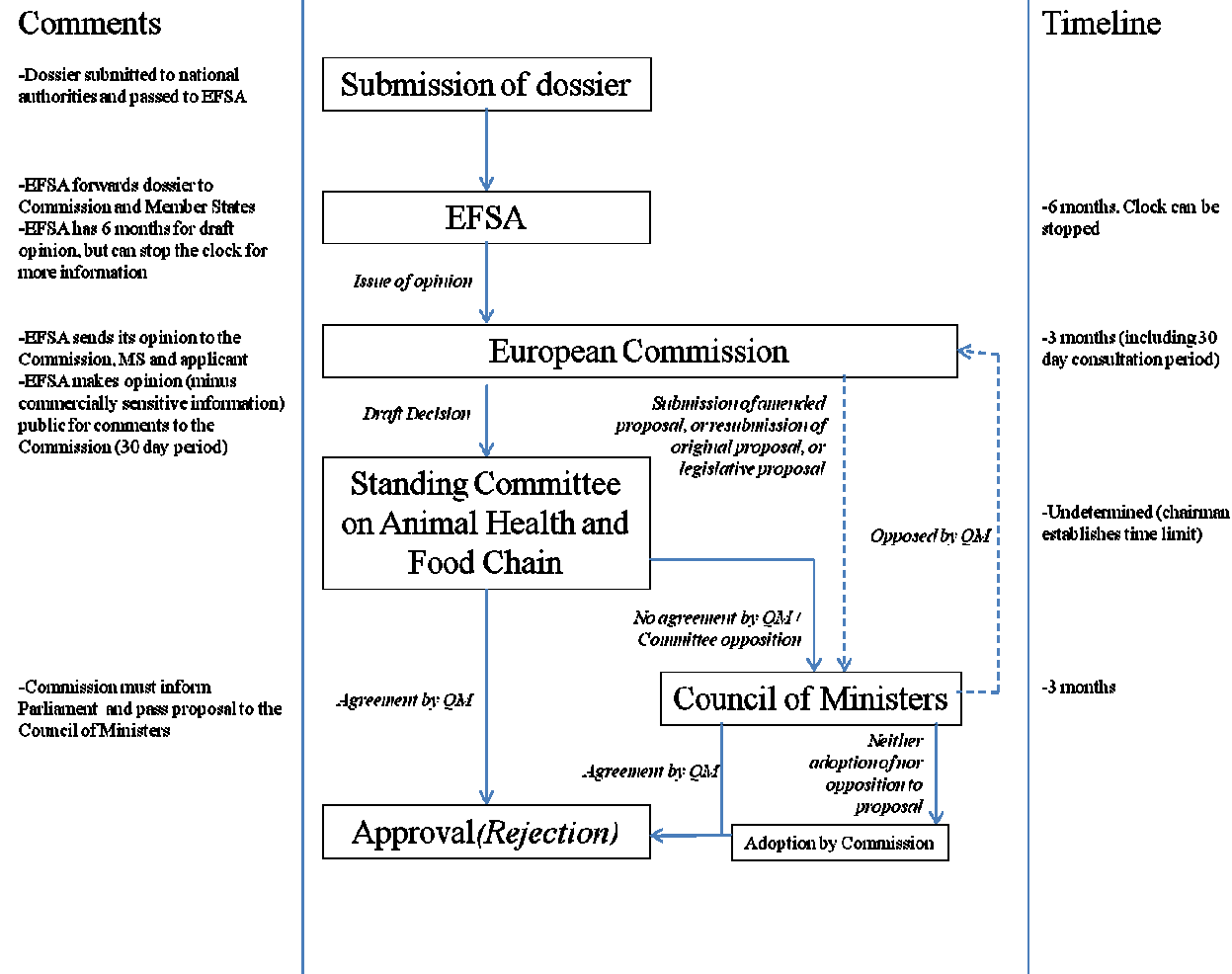
In general terms, as under the previous legislation, GM food has to be safe, not misleading and must not differ from similar, non-GMO, products to the extent that their normal consumption would be disadvantageous to the consumer (it is possible for GM food to offer additional consumer benefits).

¹⁴ Which are set out in the preamble to Regulation (EC) 1829/2003.

2.2.1. The risk assessment and regulatory approval process

The risk assessment and regulatory approvals process for GM food and feed comprises a number of stages. These are set out in Figure 2.2 and are elaborated in the following sub-sections.

Figure 2.2: The risk assessment and approvals process post-2003



Source: Agra CEAS Consulting.

2.2.1.1. The scientific evaluation of the risk assessment

Under Regulation (EC) No 1829/2003, GM food and feed can only be placed on the market if it has been authorised. An application for authorisation must be sent to the national Competent Authority, accompanied by the following documents (the documents listed here relate to food, those for feed are similar):

- the designation of the food and its specification (including events used);
- information to demonstrate compliance with Annex 1 of the Cartagena Protocol (where applicable);
- a detailed description of the method of production and manufacturing (where applicable);
- copies of studies which demonstrate safety and substantial equivalence (where available);
- either analysis supported by data to show that the characteristics of the product are not different from its (non-GM) counterpart, or a proposal for labelling;
- either a reasoned statement that the food does not give rise to any ethical or religious concerns, or a suitable proposal for labelling;
- the conditions for placing the product on the market (where appropriate);
- methods for the detection, sampling and identification of the GM event;
- samples of the food and their control samples, plus information as to where the reference material can be accessed;
- a proposal for post-market monitoring regarding the use of the food for human consumption (where appropriate);
- a summary of the dossier;
- a complete technical dossier related to the release into the environment of GMOs (as outlined in Annexes 3 and 4 of Directive 2001/18) (in the case of GMOs and food or feed containing or consisting of GMOs); and,
- a monitoring plan for environmental effects (as outlined in Annex 7 of Directive 2001/18) (in the case of GMOs and food or feed containing or consisting of GMOs); and.

The Competent Authority must make the application available to EFSA, who must in turn make the application available to the Commission and Member States. EFSA should then give an opinion within six months of the application. However, this time line can be extended where it is necessary to seek supplementary information. This is done by “stopping the clock” while the supplementary information is prepared and submitted.

In preparing its opinion, EFSA:

- should verify if the documents submitted are in accordance with the guidelines, and that the general requirements for GM food are met;
- may ask for a safety assessment by the food assessment body of a Member State;
- may ask for an environmental risk assessment (obligatory for GM seed);
- must send the methods for detection and samples to the relevant Community Reference Laboratories; and,

- must examine the data submitted by the applicant to ensure that the characteristics of the food are not different from a conventional (non-GM) counterpart.

Once ready, the opinion in its entirety must be forwarded to the Commission, Member States and the applicant. The opinion is published on the EFSA website, and the public may make comments to the Commission within 30 days of publication of the opinion. Confidential information (such as DNA sequences and personal information) may be deleted from the publicly available opinion if the Commission considers that disclosure of such data would significantly harm the applicants competitive position. The deletion of this information ensures the applicant's economic interests are not compromised.

2.2.1.2. Risk management and the regulatory approval process

Within three months of receiving EFSA's opinion, the Commission submits a draft decision to the Standing Committee on the Food Chain and Animal Health. This draft decision must take into account the opinion of EFSA, any provisions in Community law, and any other legitimate factors. If the draft decision differs from EFSA's opinion, the Commission must provide an explanation.

The Standing Committee on the Food Chain and Animal Health expresses an opinion on the Commission's draft decision proposing the authorisation or the rejection of the GMOs. If a qualified majority is achieved, the draft decision is adopted. If no qualified majority is attained, the Commission must submit the draft decision to the Council and inform the European Parliament. The Council can act by qualified majority within three months. If the Council opposes the decision by a qualified majority, the Commission must re-examine it. If no qualified majority is attained, then the decision can be adopted by the Commission in accordance with Article 5.6 of the comitology decision process.

Authorisation is valid throughout the Community for a period of 10 years. Authorisations are renewable. An application must be made at least one year before the authorisation expires and must be accompanied by:

- a copy of the original authorisation;
- a report on the results of monitoring (if specified in the original authorisation);
- any other new information relating to the evaluation of safety and risks to the consumer and environment; and,
- a proposal for amending or complementing the conditions of the original authorisation (where appropriate).

The decision procedure and timeline are identical to that for new authorisations (described above); only the submitted documents differ.

2.2.1.3. Transitional measures for adventitious presence of GM events unauthorised in the EU

Authorisation of a GM food or feed granted in a third country before authorisation is granted in the EU is referred to as asynchronous authorisation. Article 47 of Regulation (EC) No 1829/2003 provided for a three year transitional period during which the adventitious and technically unavoidable presence of GM events which had benefited from a favourable risk assessment¹⁵ but had yet to be authorised in the EU (before the entry into force of Regulation (EC) No 1829/2003) could be present below a

¹⁵ From the community scientific committee(s) or EFSA.

tolerance threshold of 0.5%. This transitional period expired in April 2007 and since then, no adventitious presence of any unauthorised (in the EU) GM events has been tolerated.

2.2.2. The compulsory labelling of GM food and feed

Food and feed products containing GM events in proportions in excess of 0.9% must be labelled as GM. This is done by noting GM content in the ingredient list, or if there is no ingredient list the food must be identified as being GM. Food and feeds produced from GMOs must be labelled as GM, or as produced from GM ingredients.

Regulation (EC) No 1830/2003 lays down further requirements for labelling and traceability. At the first stage of placing on the market of a product consisting of or containing GMOs, operators must ensure that the operator receiving the product is informed in writing, that it (1) contains or consists of GMOs; and, (2) the unique identifier assigned to these GMOs. This information must be transferred throughout the food chain to the end user.

2.3. The main changes

The main differences between the pre and post 2003 regulatory frameworks are outlined below.

- **GM feed and food were put into a single regulatory framework.** Prior to 2003, GM food was regulated under the novel foods regulation while feed consisting of or containing GMOs was regulated under Directive 2001/18/EC on the deliberate release of GMOs into the environment. Feed produced from GMOs (such as feed material and additives) was not subject to GM legislation.
- **A single scientific evaluation undertaken by EFSA.** Prior to 2003, the scientific evaluation was carried out by the Competent Authority of one Member State. However, as Member States objected, it had to be completed by the Scientific Committee for Food at a community level. Under the new procedure, scientific evaluations are completed by EFSA.
- **A centralised Community procedure for the authorisation of GM food and feed.** Under the pre-2003 system, the procedure was only partly centralised. Assessments were carried out by national Competent Authorities, and, if the resulting reports indicated that the product could be placed on the market, and no comments were received from the Commission or other Member States within a specified timeframe, the product was approved. Under the new procedure, the Commission must be involved in the process.
- **New, consistent labelling requirements.** All GM food and feed must be labelled above a tolerance threshold of 0.9%. Before 2003, food **containing** GMOs had to be labelled, but there was no such requirement for food **produced from** GMOs, and there were no labelling requirement specific to feed.
- **Transitional measures for adventitious and technically unavoidable presence of GM material.** A 0.5% threshold was set for the presence of GM material which had benefited from a favourable risk assessment but had yet to be authorised in the EU (before the entry into force of Regulation (EC) No 1829/2003). This provision expired in April 2007.

2.4. Evolution of the global GM sector

Table 2.1 presents the evolution of the global area sown to GM crops from 1996 to 2008. The first significant planting of GM crops was in 1996 when 2.8 million hectares were cultivated in six countries (US, China, Canada, Argentina, Australia and Mexico).

EVALUATION OF GM FOOD AND FEED LEGISLATION
DG SANCO Evaluation Framework Contract Lot 3 (Food Chain)

By 2008, some 125 million hectares were sown to GM crop cultivations across 25 countries (Table 2.2), although 80% of total GM area was concentrated in the US, Argentina and Brazil. India, Canada, China, Paraguay and South Africa each had more than one million hectares under GM cultivation.

Maize is the only GM crop cultivated in the EU with 0.1 million hectares sown in Spain in 2008 and less than 50,000 hectares in each of the Czech Republic, Romania, Portugal, Germany, Poland and Slovakia.

Table 2.1: Evolution of global area sown to GM crops 1996-2008

Year	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Million ha	2.8	12	27.8	39.9	44.2	52.6	58.7	67.7	81.0	90.0	102	114.3	125
No of countries	6	6	9	11	15	13	16	18	17	21	22	23	25

Source: ISAAA Annual Reports 1996-2008.

Table 2.2: Global area of biotech crops in 2008

Country	Area (million ha)	Percentage of total	Biotech Crops
USA*	62.5	50.0%	Soybean, maize, cotton, canola, squash, papaya, alfalfa, sugar beet
Argentina*	21	16.8%	Soybean, maize, cotton
Brazil*	15.8	12.6%	Soybean, maize, cotton
India*	7.6	6.1%	Cotton
Canada*	7.6	6.1%	Canola, maize, soybean, sugar beet
China*	3.8	3.0%	Cotton, tomato, poplar, petunia, papaya, sweet pepper
Paraguay*	2.7	2.2%	Soybean
South Africa*	1.8	1.4%	Maize, soybean, cotton
Uruguay*	0.7	0.6%	Soybean, maize
Bolivia*	0.6	0.5%	Soybean
Philippines*	0.4	0.3%	Maize
Australia*	0.2	0.2%	Cotton, canola, carnation
Mexico *	0.1	0.1%	Cotton, soybean
Spain *	0.1	0.1%	Maize
Chile	<0.1	0.0%	Maize, soybean, canola
Colombia	<0.1	0.0%	Cotton, carnation

EVALUATION OF GM FOOD AND FEED LEGISLATION
DG SANCO Evaluation Framework Contract Lot 3 (Food Chain)

Country	Area (million ha)	Percentage of total	Biotech Crops
Honduras	<0.1	0.0%	Maize
Burkina Faso	<0.1	0.0%	Cotton
Czech Republic	<0.1	0.0%	Maize
Romania	<0.1	0.0%	Maize
Portugal	<0.1	0.0%	Maize
Germany	<0.1	0.0%	Maize
Poland	<0.1	0.0%	Maize
Slovakia	<0.1	0.0%	Maize
Egypt	<0.1	0.0%	Maize
TOTAL	125		

* 14 biotech mega-countries growing 50,000 hectares, or more, of biotech crops

Source: ISAAA (2008) [Brief 39: global status of commercialized biotech/GM crops: 2008](#).

There are two basic GM traits: herbicide tolerance (HT) and insect resistance (*Bt*) which can be stacked to provide both herbicide tolerance and insect resistance. The evolution of the area planted with the main GM crops and traits is presented in Table 2.3. Some 51% of total area planted to GM varieties was accounted for by HT soybean in 2007. The next most significant GM crop in terms of area planted is maize, which accounted for 30% of total GM plantings in 2007. Within the GM maize crop the most important event is a stack of herbicide tolerance and insect resistance, which accounts for a little over half of the total GM maize area.

EVALUATION OF GM FOOD AND FEED LEGISLATION
DG SANCO Evaluation Framework Contract Lot 3 (Food Chain)

Table 2.3: Evolution of global area planted with GM events by crop and trait

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2007 % of total
HT soybean	0.5	5.1	15.0	21.6	25.8	33.3	36.5	41.4	48.4	54.4	58.6	58.6	51%
Bt maize	0.3	3.0	7.0	7.5	6.8	5.9	7.7	9.1	11.2	11.3	11.1	9.3	8%
HT maize	0.0	0.2	2.0	1.5	2.1	2.4	2.5	3.2	4.3	3.4	5.0	7.0	6%
Bt/HT maize				2.1	1.4	2.5	2.2	3.2	3.8	6.5	9.0	18.8	16%
Bt cotton	0.8	1.1	1.0	1.3	1.5	2.1	2.4	3.1	4.5	4.9	8.0	10.8	9%
Bt/HT cotton	0.0	<0.1		0.8	1.7	1.9	2.2	2.6	3.0	3.6	4.1	3.2	3%
HT cotton	<0.1	0.4		1.6	2.1	1.8	2.2	1.5	1.5	1.3	1.4	1.1	1%
HT oilseed rape	0.1	1.2	2.0	3.5	2.8	2.7	3.0	3.6	4.3	4.6	4.8	5.5	5%
TOTAL	1.7	11.0	27.0	39.9	44.2	52.6	58.7	67.7	81.0	90.0	102.0	114.3	

Source: JRC-IPTS (2006) Economic Impact of Dominant GM Crops Worldwide: a Review (after various ISAAA reports) and ISAAA (2007) Brief 37: Global Status of Commercialized Biotech/GM Crops: 2007.

The JRC-IPTS report on the economic impact of dominant GM crops worldwide¹⁶ reported that, in 2005:

- **GM soybean** accounted for 60% of the world's soybean harvested area. The main producer was the US where 87% of the national crop was GM. The other major producers of soybean are, based on FAO data, Brazil, Argentina, China and India. The JRC-IPTS report notes that 99% of the Argentinean soybean crop was GM in 2005 and that the adoption rate in Brazil was also high (data from GMO-Compass¹⁷ puts the GM share of Brazilian soybeans at 64% in 2007). It should be noted that the US, Brazil and Argentina account for approximately 90% of world trade in soybeans. China was testing the crop in field trials in 2005, but does not appear to have introduced GM varieties commercial as yet.
- **GM maize** accounted for 14% of the world's maize harvested area. Again, the main producer was the US where approximately half of the maize area was planted to GM varieties. By 2008 GM maize was also being cultivated in Argentina, Brazil, Canada, South Africa, Uruguay, the Philippines and Spain¹⁸. Data from GMO Compass puts the GM share of cultivated maize at 80% in the US in 2008, and 84% in Argentina in 2007. The US and Argentina account for more than 80% of world trade in maize.

¹⁶ JRC-IPTS (2006) Economic Impact of Dominant GM Crops Worldwide: a Review.

¹⁷ <http://www.gmo-compass.org/eng/home/>

¹⁸ Small amounts of GM maize cultivation also took place in a number of other countries, see Table 2.2.

- **GM cotton** accounted for 28% of the world's cotton harvested area. Around 79% of the US national cotton area was GM. Almost two thirds of the Chinese cotton crop was also GM. By 2008 a number of countries were producing GM cotton including Argentina, Brazil, India, South Africa, Australia and Mexico¹⁹.
- **GM oilseed rape (canola)** accounted for 17% of the world's oilseed rape harvested area. In 2005 HT canola was grown exclusively in Canada and the US, but by 2008 areas of GM canola were also cultivated in Australia and Chile.

The OECD Bio Track Product Database recorded 123 GM events authorised in at least one country on 02 July, 2009 (Table 2.4). Of these, almost a quarter, 24%, related to maize, while 16% related to cotton and the same proportion to potatoes. Some 12% related to canola/oilseed rape and 11% to carnations. In terms of traits, 38% are herbicide tolerant, 22% herbicide tolerant and insect resistant while 16% are insect resistant. The main focus is therefore clearly on agronomic traits.

¹⁹ Small amounts of GM maize cultivation also took place in a number of other countries, see Table 2.2.

Table 2.4: GM events authorised in at least one country by crop

	HT	Bt	Ht/Bt	VR	Bt/VR	F	C	E	P	Total
Alfalfa	3									3
Canola/oilseed rape	13					2				15
Carnations							13	1		14
Maize/corn	9	3	18							30
Cotton	9	3	8							20
Flax/linseed	1									1
Papayas				2						2
Potatoes		14		1	5					20
Rice	2									2
Soybeans	8		1			1				10
Sugar Beet	2									2
Tomatoes								1	1	2
Vegetable marrow				2						2
Total	47	20	27	5	5	3	13	2	1	123

Key:

HT: Herbicide tolerant.

Bt: Insect resistant.

VR: Virus resistant.

F: Functionality, in these cases increased oleic acid content.

C: Coloration.

E: Reduced ethylene synthesis.

P: Reduced pectin degradation.

Source: OECD Bio Track Product Database²⁰.

As of 2 July, 2009, 25 GM events were listed on the Community register²¹ for use in GM food and/or feed as follows in Table 2.5 (there were also two GM micro-organisms²²):

²⁰ <http://www2.oecd.org/biotech/default.aspx>. Accessed 02/07/09.

²¹ http://ec.europa.eu/food/dyna/gm_register/index_en.cfm. Accessed 02/07/09.

²² Authorisation of GM microorganisms is regulated under Directive 90/219/EC.

Table 2.5: GM events authorised for food and feed in the EU by crop

	HT	<i>Bt</i>	HT/ <i>Bt</i>	Total
Canola/oilseed rape	3			3
Cotton	2	2	2	6
Maize	3	3	6	12
Soybean	3			3
Sugar beet	1			1
Total	12	5	8	25

Key:

HT: Herbicide tolerant.

Bt: Insect resistant.

Source: Community register of GM food and feed.

The timing of EU authorisations is presented in Figure 2.3. This illustrates the low number of authorisations in the 2000 to 2004 period and also suggests that the introduction of Regulation (EC) 1829/2003 has had some impact in terms of authorisations, given the number of authorisations granted from 2006 onwards.

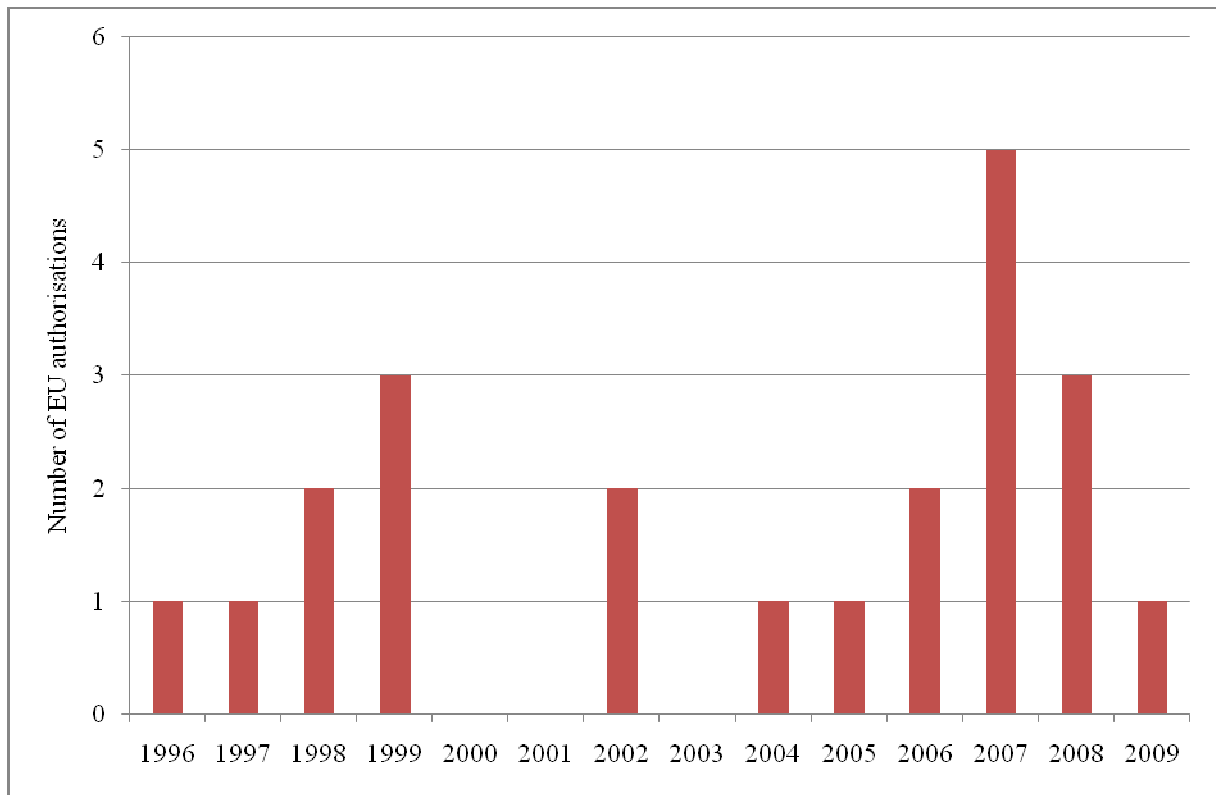


Figure 2.3: GM event authorisations in the EU by year

Note: There are a total of 22 dated authorisations. This differs from the 25 authorisations identified in Table 2.5 because five GM events in the Community register are currently marked as “renewal ongoing”, and are without authorisation dates and two events have expired authorisations which have not been renewed and hence are not in the Community register, but are included in this graph.

Source: OECD Bio Track Product Database and Community register of GM food and feed.

The main socio-economic impacts from GM crops have so far been felt at the farm level and are mostly documented in relation to cultivation. According to the JRC²³ the profitability of GM crops at a farm level depends on a number of factors, including:

- differences in yield;
- reductions in insecticide costs;
- reductions in weed management costs;
- difference in seed prices; and,
- difference in price received for crop.

The exact impact at farm level differs depending on the crops grown and the region. However, a JRC report on GM crops in the EU²⁴ concludes that the adoption of GM crops generally results in net economic gains, though the magnitudes of these gains vary. The size of the farm does not appear to be an obstacle to the adoption of the technology. On aggregate, the welfare created by the use of GM

²³ JRC-IPTS (2006) Economic Impact of Dominant GM Crops Worldwide: a Review.

²⁴ JRC (no date) GM crops in EU agriculture: case study for the BIO4EU project.

crops is mainly shared between the seed developers and the adopting farmers. In some cases, consumers may benefit from lower prices as these are passed through the supply chain, as explained in Agra CEAS's report on the Economics of Identity Preservation for Genetically Modified Crops²⁵.

While the evolution of the GM sector has had economic impacts on the EU markets, it is difficult to quantify these impacts at this early stage of the study. That said, the penetration of GM events in the soybean and maize feed markets is set out in Table 2.6. This shows that the proportion of GM soybeans in the EU is substantially higher than the share of GM maize. Estimations from the same study place the price premium for non-GM soybeans at between 2% and 10% and the price premium for non-GM maize at between 1% and 3%.

Table 2.6: Estimated GM versus non-GM soy and maize use in the EU (2003-04)

Product	Total market size	GM market size	GM share %
	Million tonnes		
Soybeans			
Whole beans	1.50	1.17	78%
Oil	2.12	1.29	61%
Meal	31.15	26.48-27.41	85-88%
<i>Total</i>	<i>34.77</i>	<i>28.94-29.87</i>	<i>83-86%</i>
Maize			
Food and starch	8.97	2.69	30%
Feed	29.25	24.87-26.33	85-90%
Seed	0.78	0.23	30%
<i>Total</i>	<i>39.00</i>	<i>27.79-29.25</i>	<i>71-75%</i>

Source: adapted from Brookes, et al (2005)²⁶.

2.5. Consumer perceptions of GM

Consumer research suggests that the majority of EU citizens have some doubts about the use of GMOs in food. A 2005 Eurobarometer poll showed that little over a quarter (27%) of EU citizens supported GM foods. This was, however, an increase since the 2002 poll in which less than a quarter (21%) of EU citizens supported GM foods. According to the 2005 poll, citizens have slight concerns about the usefulness and moral aspects of GMs, and notable concerns about the perceived risks.

The attitude of EU citizens towards GMs varies between Member States. Eurobarometer identifies two types of support for GM food: (1) outright support²⁷ and (2) risk tolerant support²⁸. The level of

²⁵ <http://www.ceasc.com/Images/Content/Final%20FBCI%20report%201745.pdf>

²⁶ Brookes, G., Craddock, N. and Kniel, B (2005) The Global GM Market Implications for the European Food Chain: an analysis of labelling requirements, market dynamics and cost implications.

²⁷ Where GM is perceived as morally acceptable, useful, non-risky and something that should be encouraged.

total support (outright and risk tolerant) in 2005 varied from 74% in Spain to 12% in Greece (Figure 2.4).

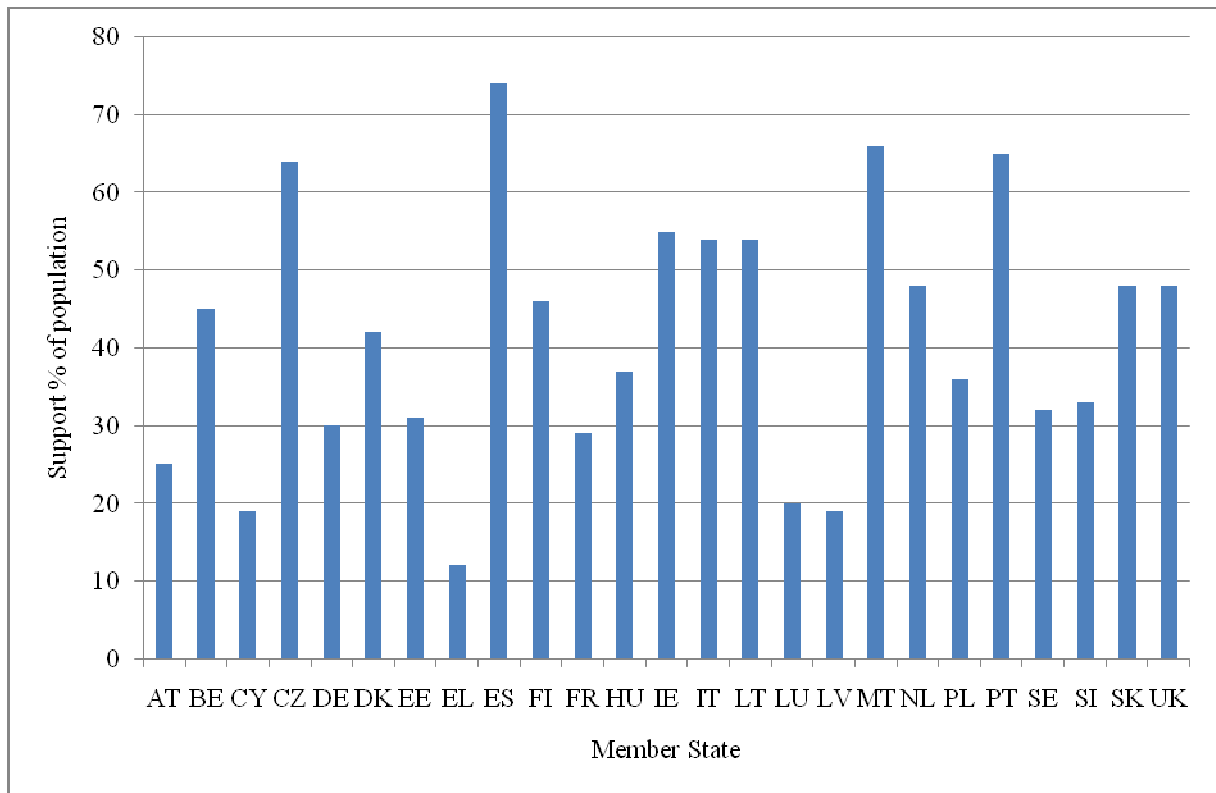


Figure 2.4: Support for GMOs across the EU

Source: Eurobarometer, 2005²⁹.

While citizens are aware of GM technology³⁰, research in the UK suggests that UK consumers feel they have little actual understanding of GM foods³¹. According to an autumn 2008 survey, 49% of consumers rated their understanding of GM as either poor or very poor. A further 34% rated their knowledge as fair, leaving only 17% who claimed a good or very good understanding of GM foods. It is unclear whether this trend is EU-wide, or limited to the UK.

²⁸ Where GM is perceived as morally acceptable, useful, and something that should be encouraged, but risks are perceived.

²⁹ Eurobarometer (2005) Europeans and Biotechnology in 2005: Patterns and Trends. Eurobarometer 64.3. A report to the European Commission's Directorate-General for Research.

³⁰ According to Eurobarometer's 2005 poll, 80% of citizens were familiar with genetic modification.

³¹ Institute of Grocery Distribution (2008) Genetically Modified foods: consumer research. October 2008.

3. Intervention logic (Task 1.3)

The scope of this evaluation covers the following legal instruments:

- **Regulation (EC) No 1829/2003** of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.
- **Regulation (EC) No 1830/2003** of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.
- **Commission Regulation (EC) No 641/2004** of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.
- **Commission Regulation (EC) No 65/2004** of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms.

3.1. Legislative background to Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003

The global objective of EU policy in relation to GM food and feed is to ensure a high level of protection of human life and health, animal health and welfare, environment and consumer interests in GM food and feed whilst ensuring the effective functioning of the internal market.

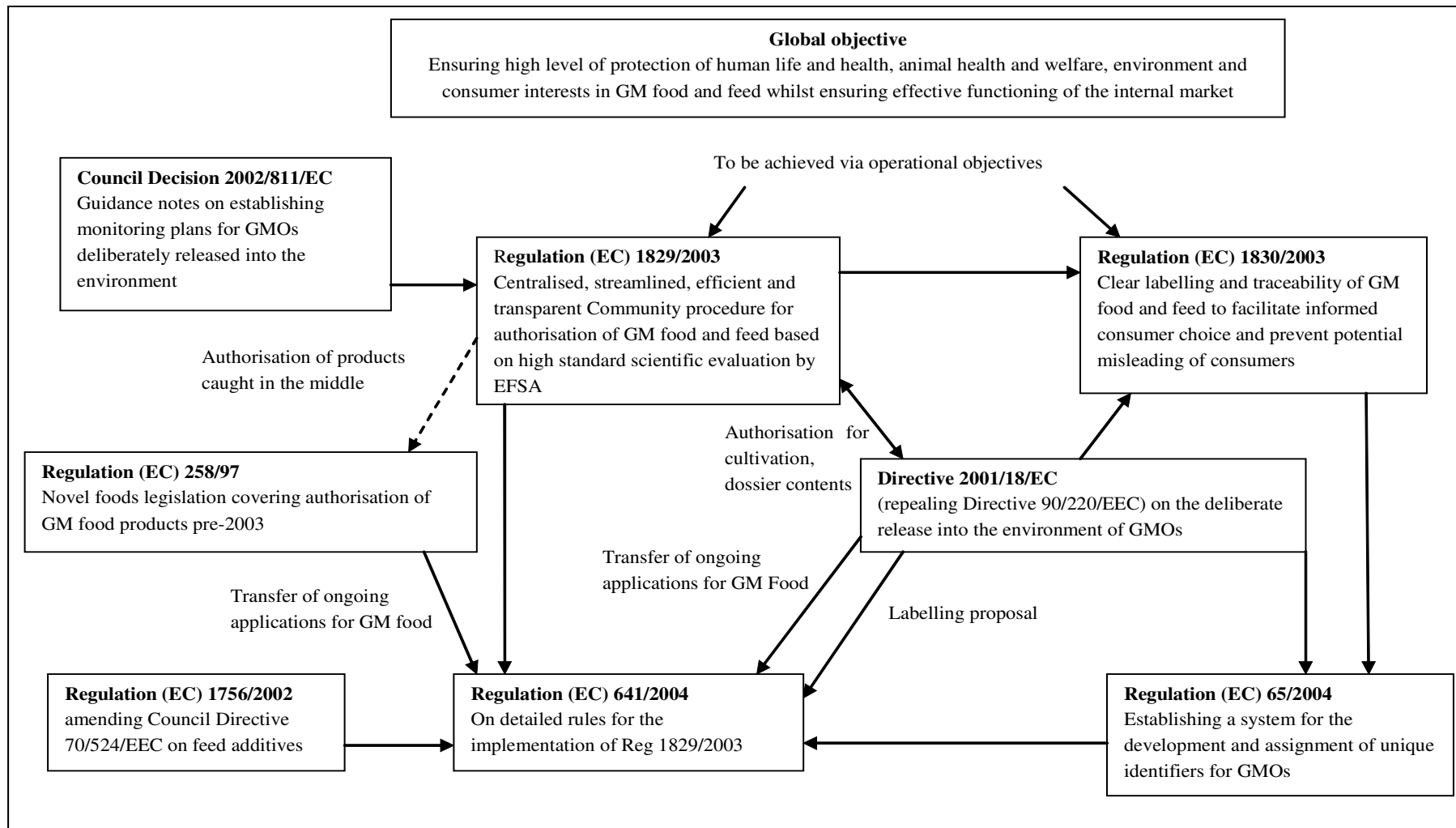
Regulation (EC) No 1829/2003 introduced a centralised assessment procedure for the approval of GM food and feed. This involves a scientific safety assessment carried out by EFSA, rather than individual Member States, as was the case previously. Regulation (EC) No 1829/2003 operates alongside Regulation (EC) No 1830/2003 which deals with the traceability and labelling of products containing GMOs and their derivatives.

A comparison of the legislative framework before and after the introduction of Regulation (EC) No 1829/2003 is set out in section 2.3, above.

Regulation (EC) No 1829/2003 is implemented through Regulation (EC) No 641/2004 with Regulation (EC) No 1830/2003 implemented through Regulation (EC) No 65/2004. Directive 2001/18/EC, on the deliberate release of GMOs into the environment sets out common principles against which any proposed GM product must be assessed and is used in conjunction with Regulation (EC) No 1829/2003

The interrelation of the various relevant pieces of legislation is illustrated in Figure 3.1.

Figure 3.1: Interrelation of legislation related to Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003



3.2. Rationale for intervention

As has been noted by the EPEC consortium in their parallel evaluation of GM legislation in relation to cultivation for DG Environment, EU legislation has been revised and adapted since the early 1990s to keep pace with technical developments in the sector, to respond to demands for greater transparency and to provide more detailed scrutiny of particular products, such as food and feed, to which GM technology might be applied.

The Commission saw a need for further regulation in the GM sector following the adoption of Directive 2001/18/EC in order to address concerns raised by Member States who wished to build public confidence in GM technology by:

- making traceability rules more specific in order to ensure EU-wide harmonisation (not provided for under Directive 2001/18/EC); and,
- extending regulatory requirements to products derived from a GM source, but not containing detectable GM protein or recombinant DNA, i.e. oil products (again not provided for under Directive 2001/18/EC).

Also, in the late 1990s, the US industry decided to not plant GM varieties which had not been authorised in the EU. The US industry subsequently decided that, due to the unpredictability of the EU authorisation process in terms of time to authorisation, they would no longer follow this approach for maize³². This, coupled with the *de facto* moratorium on approvals in place in the EU from 1998 created a disparity between the authorisation of GM food and feed in the EU and the situation in third countries, particularly the US and Canada.

3.3. Regulatory objectives

Regulation (EC) No 1829/2003

The objectives of Regulation (EC) No 1829/2003 are, in accordance with the general principles laid down in Regulation (EC) No 178/2002, to:

- a) provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market;
- b) lay down Community procedures for the authorisation and supervision of genetically modified food and feed; and,
- c) lay down provisions for the labelling of genetically modified food and feed.

Regulation (EC) No 1830/2003

Regulation (EC) No 1830/2003 provides a framework for the traceability of products consisting of or containing genetically modified organisms (GMOs), and food and feed produced from GMOs.

The objectives are to facilitate accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products.

³² The policy was continued for soybean reflecting the fact that the EU is a major export market for US producers.

3.4. Regulatory scope

Regulation (EC) No 1829/2003

The Regulation applies to three types of product:

- a) GMOs for food and feed use;
- b) food and feed containing or consisting of GMOs;
- c) food and feed produced from or containing ingredients produced from GMOs.

Labelling applies to these products where the GM content exceeds 0.9%.

Regulation (EC) No 1830/2003

This Regulation applies, at all stages of the placing on the market, to:

- a) products consisting of, or containing, GMOs, placed on the market in accordance with Community legislation;
- b) food produced from GMOs, placed on the market in accordance with Community legislation;
- c) feed produced from GMOs, placed on the market in accordance with Community legislation.

The Regulation does not apply to medicinal products for human and veterinary use authorised under Regulation (EEC) No 2309/93, nor to GM microorganisms regulated under Directive 90/219/EC.

4. Evaluation questions and evidence base (Task 1.4)

This Chapter presents the Evaluation Questions and sets out the preliminary evidence base on which we intend to draw. This evidence base will be developed as we move through the project. Evaluation questions are considered in turn in Table 4.1.

Table 4.1: Overview of Evaluation Questions (EQs), discussion of issues, identification of indicators and evidence base

	Evaluation Question	Evidence base
A. Overall objectives of the legislation and expected developments in the sector		
EQ1a	On the basis of the evidence collected, to what extent are the established objectives of the Regulation accepted by consumers, stakeholders and Member States as being fully in line with the needs of the EU society?	<ul style="list-style-type: none"> • Desk research encompassing literature on the needs of society in terms of the food sector (including, for example, <u>Food: an analysis of the issues</u> produced by the Strategy Unit of the UK Cabinet Office, <u>JRC Reference report: consequences, opportunities and challenges of modern biotechnology for Europe</u>, etc.. A review of literature on the benefits of GM technology will also be referenced (see EQ2a). Key documents here will be the JRC-IPTS database on <u>the global pipeline of new GM crops</u> and related JRC documents on the current and likely future impacts of GM crops. • Competent Authority survey • Stakeholder survey • Stakeholder interviews • Synthesis of all case studies
EQ1b	To what extent have these objectives been correctly made operational, in particular with respect to the scope of the regulation, the foreseen approval process and the labelling requirements?	<ul style="list-style-type: none"> • Desk research and analysis of the implementation of the legislation. Key documents here are the Commission reports to the Council and the European Parliament on the implementation of Regulation 1829/2003 and 1830/2003. • Stakeholder interviews • Competent Authority survey

	Evaluation Question	Evidence base
		<ul style="list-style-type: none"> • Stakeholder survey • Synthesis of all case studies
EQ2a	<p>What factual developments are to be expected as the consequence of the evolution of the sector (global adoption rates of GM crops, second and third generation GMOs) and how could these developments affect or benefit the EU food industry and livestock sector and the European consumers?</p>	<ul style="list-style-type: none"> • Desk research and analysis of GM events authorised in the EU, currently undergoing the authorisation process, authorised in third countries and those in the pipeline for market release in the near future. There are a number of sources for this information including the <u>JRC-ITPS database on the global pipeline of new GM crops</u>, the <u>JRC-IPTS Review of GMOs under Research and Development and in the pipeline in Europe</u> and the <u>OECD BioTrack product database</u>. There are also a number of industry sources on GM events and their characteristics. • Stakeholder interviews (industry). • Interviews with representatives of a limited number of key third countries.
EQ2b	<p>To what extent are the tools defined by the existing legislation apt to ensure that the EU could make use of these developments in economic, social and environmental terms?</p>	<ul style="list-style-type: none"> • Desk research into GM event applications and their progress through the authorisation process. Comparison to the timelines set out in the legislation. • Desk research into third country authorisation procedures. • Interviews with representatives of a limited number of key third countries. • Stakeholder interviews. • Competent authority survey. • Stakeholder survey.
EQ2c	<p>How could these potential benefits be measured and integrated in the context of the regulatory approval?</p>	<ul style="list-style-type: none"> • Competent authority survey. • Desk research into third country authorisation procedures.

	Evaluation Question	Evidence base
		<ul style="list-style-type: none"> • Desk research into how potential benefits might be measured. • Interviews with representatives of a limited number of key third countries. • Stakeholder interviews. • Stakeholder survey.
B. The risk assessment and regulatory approval process		
EQ3a	To what extent has the EU authorisation procedure and its implementation ensured a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market?	<ul style="list-style-type: none"> • Desk research and textual analysis of the legislation and documents commenting on this. Stakeholder submissions to the Commission in preparation of the reports to the Council and the Parliament may be of use here, as will be the Commission reports themselves on Regulations 1829/2003 and 1830/2003. • Competent authority survey. • Stakeholder interviews. • Stakeholder survey. • Authorisation case study.
EQ3b	To what extent is the current EU approach on stacked events consistent with the objectives of the legislation and what has been its overall impact on the implementation of the regulatory approval process, including the number of pending authorisations and the workload for both EFSA and the Commission?	<ul style="list-style-type: none"> • Interviews with DG SANCO and other relevant Commission services. • Interviews with EFSA. • Desk research on the pipeline for GM events and the importance of stacked events within this. • Desk research on the application dossiers to assess time taken for the authorisation process. • Stakeholder interviews (industry).

	Evaluation Question	Evidence base
		<ul style="list-style-type: none"> • Stakeholder survey. • Competent authority survey. • Authorisation case study.
EQ4a	<p>To what extent are the different steps of the harmonised procedures established by the Regulation for the risk assessment and authorisation of GM food and feed efficient, time-limited and transparent and correspond to demonstrated risks in a proportionate manner?</p>	<ul style="list-style-type: none"> • Desk research on the authorisation process and the time this takes. In this context we note that some of the EU's trading partners may hold detailed information on the progress of dossiers through the EU system. • Stakeholder interviews. • Stakeholder survey. • Competent authority survey. • Interviews with representatives of selected third countries. • Interviews with DG SANCO and other relevant Commission services. • Interviews with EFSA. • Authorisation case study.
EQ4b	<p>What has been their impact on the evolution of the sector and the EU society at large?</p>	<ul style="list-style-type: none"> • Desk research on the development of the biotech industry in the EU. • Interviews with industry. • Interviews with DG Enterprise and DG Research. • Interviews with representatives of selected third countries.
EQ5	<p>To what extent does the procedure foreseen by the Regulation (Article 34, in conjunction with Articles 53 and 54 of Regulation (EC)</p>	<ul style="list-style-type: none"> • Desk research on the procedure of Article 34 and Article 23 of Directive 2001/18. • Interviews with DG SANCO, DG Environment and

	Evaluation Question	Evidence base
	No 178/2002) ensure an appropriate way to deal with "emergency measures" taken by MS?	<ul style="list-style-type: none"> • EFSA. • Stakeholder interviews. • Stakeholder survey. • Competent authority survey. • Authorisation case study.
EQ6a	To what extent is the common and centralised authorisation procedure foreseen by Regulation (EC) No 1829/2003 (one door, one key principle) efficient compared to the situation that was prevailing before the adoption of the Regulation?	<ul style="list-style-type: none"> • Desk research on the applications, authorisations and timelines under both the old and the new system. • Interviews with EFSA. • Stakeholder interviews. • Stakeholder survey. • Competent authority survey.
EQ6b	To what extent is this procedure coherent with other procedures applying to similar sectors of the food safety <i>acquis</i> ?	<ul style="list-style-type: none"> • Desk research on the procedures applying to the pesticide and seed sectors. In this context we note that the FCEC has carried out relevant research on both these regimes. • Interviews with EFSA. • Interviews with SANCO pesticide and seed departments. • Stakeholder interviews. • Stakeholder survey. • Competent authority survey.
EQ7a	What is the foreseeable trend of the GM	<ul style="list-style-type: none"> • Desk research and analysis largely based on evidence gathered in relation to other EQs.

	Evaluation Question	Evidence base
	authorisations in the EU when compared with the authorisations granted in third countries and taking into account the expected worldwide evolution of the GM sector?	<ul style="list-style-type: none"> • Specific questions might need to be added to the stakeholder survey and the Competent Authority survey and to questionnaires for stakeholder interviews.
EQ7b	What would be the consequences of possible differences between the pace of authorisations between the EU and its trading partners?	<ul style="list-style-type: none"> • Desk research on the authorisation process and the instances of asynchronous authorisation. Again, some of the EU's trading partners may hold detailed information of relevance here. There are also databases and other sources setting out the global position with regard to authorisation. • Desk research on the costs of asynchronous authorisation. This will include consideration of the DG Agri report on the <u>Economic impact of unapproved GMOs on EU feed imports and livestock production</u> (taking into account limitations with the quantitative part) . Other sources include, for example, the GBC Ltd report on the <u>Economic impacts of low level presence of not yet approved GMOs on the EU food sector</u> and the Cardy-Brown report on the <u>Impacts of 'unapproved in Europe' GMs on feed and livestock production</u>. • Stakeholder interviews. • Stakeholder survey. • Competent authority survey. • Interviews with representatives of selected third countries. • Interviews with DG Agri. • Authorisation case study. • Synthesis of other case studies.
C. The compulsory labelling of GM food and feed		

	Evaluation Question	Evidence base
EQ8a	To what extent are the current labelling rules for GM food/feed facilitating an informed choice and precluding misleading of consumers?	<ul style="list-style-type: none"> • Desk research on consumer understanding of labelling and comments of consumer organisations. Some research on consumer attitudes to GM has been undertaken in a number of Member States (for example, the UK) and by Eurobarometer (64.3). • Stakeholder interviews. • Stakeholder survey. • Competent authority survey. • Labelling and consumer case studies.
EQ8b	What is the consumers' acceptance of the existing labelling rules?	<ul style="list-style-type: none"> • Desk research on consumer views on acceptance (which may also cover labelling issues). • Desk research on the EU markets for GM food and its evolution. • Stakeholder interviews. • Stakeholder survey. • Competent authority survey. • Labelling and consumer case studies.
EQ9	What impact have the rules on labelling of GM food/feed had on the different actors of the food/feed market?	<ul style="list-style-type: none"> • Desk research on Identity Preservation process and costs. A starting document here will be the <u>Economics of Identity Preservation for GM Crops</u> produced for the Food Biotechnology Communications Initiative. • Stakeholder interviews. • Stakeholder survey. • Competent authority survey.

	Evaluation Question	Evidence base
		<ul style="list-style-type: none"> • Labelling case study. • Feed case study.
EQ10a	To what extent is food on the market labelled as GM?	<ul style="list-style-type: none"> • Desk research is unlikely to reveal comprehensive information on what is in any case an evolving sector, although some information may be of relevance. • Stakeholder interviews. • Stakeholder survey. • Competent authority survey. • Labelling case study.
EQ10b	To what extent is feed on the market labelled as GM?	<ul style="list-style-type: none"> • Desk research on the EU markets for GM feed and food and their evolution. • Stakeholder interviews. • Stakeholder survey. • Competent authority survey. • Labelling case study. • Feed case study.
EQ10c	What are the reasons for this situation?	<ul style="list-style-type: none"> • Desk research on authorisations (under EQ6b) and factors driving uptake. • Stakeholder interviews. • Stakeholder survey. • Competent authority survey.

	Evaluation Question	Evidence base
		<ul style="list-style-type: none"> • Labelling case study.
EQ11	What consequence would an extension of the scope of the labelling rules including the labelling of animal products have?	<ul style="list-style-type: none"> • Desk research on the possible consequences. • Stakeholder interviews. • Stakeholder survey. • Competent authority survey. • Labelling case study. • Consumer case study
EQ12a	What are the approaches currently used in MS in the field of 'GM free' labelling?	<ul style="list-style-type: none"> • Desk research on current “GM-free” schemes. • Stakeholder interviews. • Interviews with administrators of “GM-free” schemes. • Labelling case study.
EQ12b	Do these approaches contribute to improve consumers' informed choice?	<ul style="list-style-type: none"> • Desk analysis of scheme information gathered under EQ12a. • Stakeholder interviews. • Interviews with administrators of “GM-free” schemes. • Labelling case study. • Consumer case study.
EQ12c	What could be the added value (both in terms	<ul style="list-style-type: none"> • Desk analysis of scheme information gathered under EQ12a and EQ12b.

	Evaluation Question	Evidence base
	of information to consumers and market share) of a harmonized "GM free" (or similar) labelling scheme?	<ul style="list-style-type: none"> • Stakeholder interviews. • Stakeholder survey. • Competent Authority survey. • Interviews with administrators of “GM-free” schemes. • Labelling case study. • Consumer case study
D. Acceptance		
EQ13a	The approval process is still subject to controversy amongst stakeholders and the general public. What are the aspects of the authorisation procedure that nourish this controversy?	<ul style="list-style-type: none"> • Desk research on EU citizens’ general attitude towards science (for example, the Eurobarometer report <u>Europeans and Biotechnology in 2005: Patterns and Trends</u>). • Stakeholder interviews. • Stakeholder survey. • Competent Authority survey. • Authorisation case study.
EQ13b	What is the impact/cost of this risk aversion?	<ul style="list-style-type: none"> • Desk research on the authorisation process and the instances of asynchronous authorisation. As noted under EQ7b, some of the EU’s trading partners may hold detailed information of relevance here. There are also databases and other sources setting out the global position with regard to authorisation. • Desk research on the costs of asynchronous authorisation. This will include consideration of the DG Agri report on the <u>Economic impact of unapproved GMOs on EU feed imports</u>

	Evaluation Question	Evidence base
		<p>and livestock production (bearing in mind the quantitative limitations here). Other sources include, for example, the GBC Ltd report on the <u>Economic impacts of low level presence of not yet approved GMOs on the EU food sector</u> and the Cardy-Brown report on the <u>Impacts of ‘unapproved in Europe’ GMs on feed and livestock production</u>.</p> <ul style="list-style-type: none"> • Stakeholder interviews. • Stakeholder survey. • Competent authority survey. • Interviews with representatives of selected third countries. • Interviews with DG Agri, DG Enterprise and DG Research. • Synthesis of case studies.
EQ13c	Are there variations in the sensitivity of EU-wide opinion, as between seed, cultivation, feed and food use?	<ul style="list-style-type: none"> • Desk research on existing studies on consumer attitudes. A report on the GMO Compass website (<u>Opposition decreasing or acceptance increasing? An overview of European consumer polls on attitudes to GMOs</u>) will be a useful starting point here. Consumer research has also been undertaken in a number of Member States. • Stakeholder interviews. • Stakeholder survey. • Competent authority survey. • Case study synthesis.
EQ13d	Can the risk acceptance of EU citizens be measured against the concept of ALARA (as low as reasonably achievable) risk? If so,	<ul style="list-style-type: none"> • Desk research into the use of ALARA in the food industry. • Desk research into consumer attitudes towards risk in science in general, for example the JRC-IPTS report <u>On science and precaution in the management of technological risk</u>.

	Evaluation Question	Evidence base
	how?	<ul style="list-style-type: none"> • Consumer case study.
EQ13e	Can the quality of the EU-wide trust in science based risk assessment be improved in the GM context?	<ul style="list-style-type: none"> • Desk research on problems of trust in science-based risk assessments and possible solutions. • Stakeholder interviews. • Stakeholder survey. • Competent authority survey. • Consumer case study. • Interviews with representatives of selected third countries.
E. Conclusions and recommendations		
EQ14a	What conclusions and recommendations can be drawn on the basis of the evaluation?	Evidence-based conclusions and recommendations drawn from the preceding analysis.
EQ14b	What are the different options (in terms of legislation, procedures, implementation capacities...) for the future to address the identified issues and the new challenges?	Options developed from the preceding analysis and also directly through discussions with stakeholders.
EQ14c	What is the relevance and the social, environmental and economical impact of each proposed option?	Analysis of the options defined under EQ14b.

5. Information sources (Task 1.5)

The main information sources to be used in this research are as follows:

Identified literature. The terms of reference provide a set of base documents and this has been extended substantially through our initial literature search. An evidence database has been constructed. This has also been supplemented by documents made available by those stakeholders whom we have already met whilst undertaking exploratory interviews. Further information has been requested from stakeholders and is currently being collated by them. It is our intention to continually develop our desk research database as the research takes place. Some key sources are set out in Table 4.1.

Exploratory interviews with key EU stakeholders. Interviews have now been undertaken with the following organisations:

- CIAA;
- COCERAL;
- COPA-COGECA;
- EuropaBio;
- FEDIOL;
- FEFAC;
- Friends of the Earth;
- Greenpeace.

BEUC were also contacted, but explained that as they no longer have a position on GMOs they would not be able to contribute to the study. They did, however, note that consumer organisations in some Member States do still have a position and would therefore be able to contribute. We are currently awaiting contact details for these.

The exploratory interviews were used to refine our understanding of the GM sector and to gain a first impression of the likely issues that will arise during the conduct of this research. This process fed into the elaboration of the Evaluation Questions (see Table 4.1) and into the design of the survey questionnaires and semi-structured interview guides.

Competent Authority survey. This survey will cover the Competent Authorities concerned with GM food and feed in each Member State. We note that DG SANCO has a list of relevant Competent Authority contacts and that these will be made available to us at the appropriate point in our research.

Stakeholder survey. This survey will be targeted at the key organisations both at the EU level and at the Member State level. We estimate that around 20 stakeholders will be identified in each Member States providing a sample of approximately 550, to which will be added EU level stakeholders.

Further stakeholder interviews. These will follow the surveys and will follow up areas where further investigations are necessary. We will speak to relevant organisations throughout the food chain and will cover the following organisations:

- **Technology providers:** EuropaBio and selected individual companies. The companies that we interview will be determined according to need and in conjunction with EuropaBio.
- **Users:** COPA-COGECA and selected national farmer associations. The

specific farmer associations that we interview will be determined according to the issues that we will need to examine in more detail.

- **Trade:** COCERAL and selected national members. Again, the national members interviewed will be determined by need. In considering the trade we will ensure that we speak to SMEs as well as larger companies. In this regard we note that DG SANCO will assist with their identification.
- **Processors:** CIAA and selected national members determined by need. We will take account of the SME sector and note that DG SANCO will assist with the identification of suitable contacts.
FEFAC and selected active, observer and associate members according to need.
FEFANA and selected member companies as appropriate.
AAF (EU starch association) and selected members as appropriate.
FEDIOL and selected members as appropriate.
UECBV and selected members as appropriate.
AVEC and selected members as appropriate.
- **Retail sector:** EuroCommerce and selected national association members and company members, again selected according to need.
- **Consumers:** National consumer organisations that have a position on GMOs (to be determined in conjunction with BEUC who no longer have a position).
- **Sampling and quality assessment:** EU associations do not exist. Examples of possible targets: EUROFINS, SGS, GENETIC ID, harbours, etc... + GeneScan.
- **NGOs/interest groups:** Greenpeace.
Friends of the Earth.
WWF.
GMO-free Europe (network of GM free regions).
Genetic Rights Foundation (Consiglio dei Diritti Genetici (CDG)).
- **Others:** EFSA.
the European network European Network of GMO Laboratories (ENGL) (which is co-ordinated by the JRC)
DG SANCO.
DG Trade.
DG Agri.
DG ENV.
DG Research

DG Enterprise

JRC of the European Commission

Any other relevant DGs and Commission services/bodies.

Representatives of selected third countries.

Case studies. The five thematic case studies will allow a more in-depth investigation into some of the issues explored under this evaluation. They will also allow the consultants to capture the range of viewpoints and positions of the various (selected) Member States and their stakeholders.

As already agreed with DG SANCO, the focus will be on a key list of horizontal issues or themes, for each of which a representative sample of Member States (representing the range of positions and viewpoints, e.g. pro and anti-GM), will be proposed.

The suggested themes to cover are as follows:

- Import of commodities.
- Labelling.
- Feed/livestock sector.
- Position of consumers.
- Authorisation procedure.

We have developed some initial thoughts on case study content and Member State coverage and we are awaiting feedback from key stakeholders. However, we would seek discussion and further guidance on the case studies in terms of agreeing the themes, content and coverage.

The FCEC will take a flexible approach to the case studies in that a balance will be sought between themes and Member States. We are able to alter the method of stakeholder consultation by, for example, increasing the use of telephone interviews and decreasing the number of direct interviews as appropriate. This is in line with the approach followed in other FCEC projects with thematic case studies.

6. Evaluation tools (Task 1.6)

It was originally envisaged that the evaluation tools, principally the various questionnaires and interview topic guides would be developed for inclusion in this Inception Report. However, the earlier than envisaged submission of this report has precluded their inclusion here.

The evaluation tools are critical in terms of the successful completion of this assignment and it is important that they are properly thought through. This process has been started, as is evidenced by the considerations presented in respect of the evaluation questions (Chapter 4) and is on-going. Once fully developed the tools will be discussed and further validated with all the relevant parties before data collection starts.

7. Work plan (task 1.8)

This Chapter sets out the work plan for the remainder of the project, a preliminary structure of the draft final report and an overview of the human resources to be used.

7.1. Evaluation process

An overview of the evaluation phases is set out in Figure 7.1.

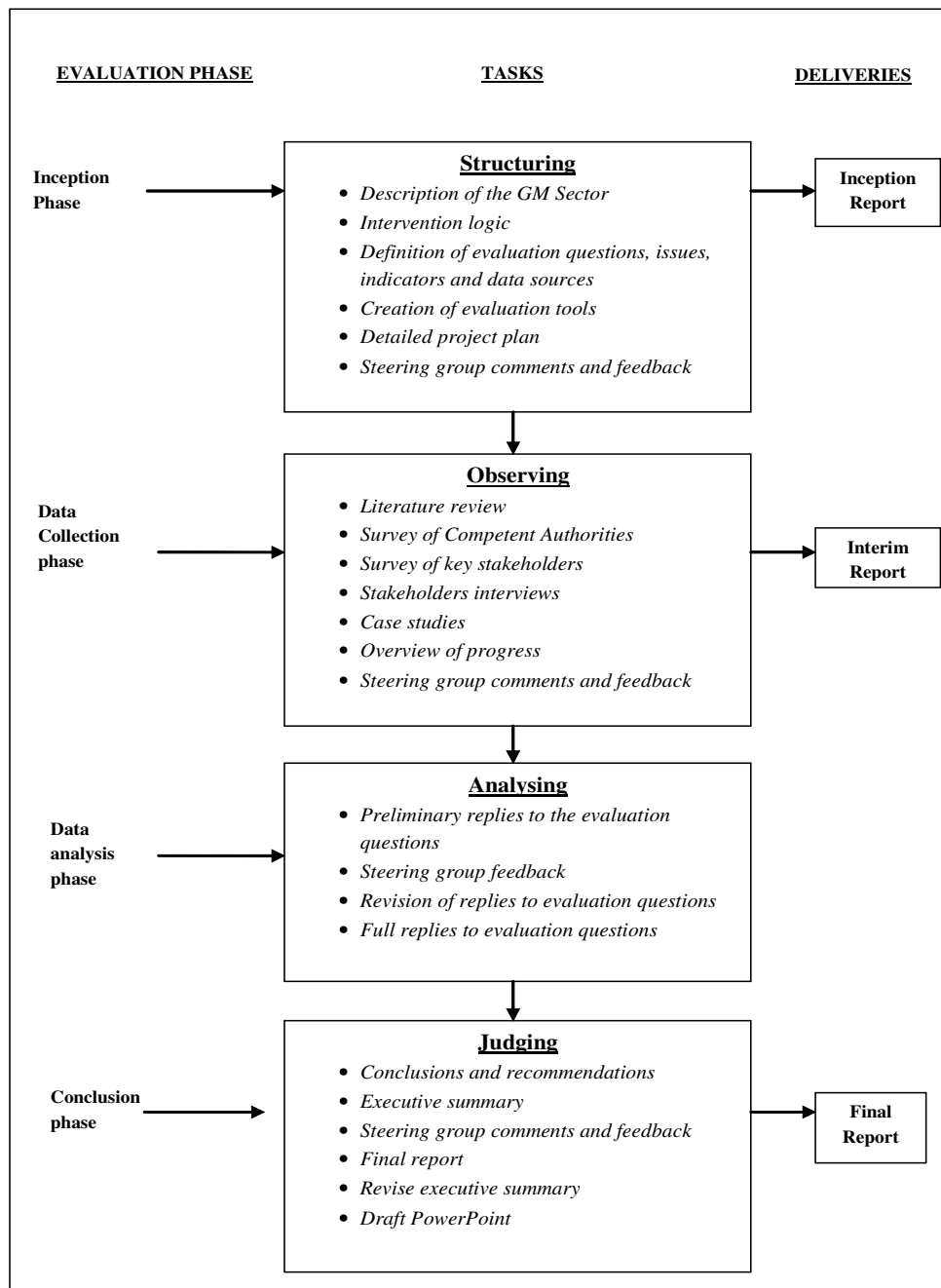


Figure 7.1: Flow chart of evaluation process

7.1.1. Structuring

This initial element of the evaluation involves Tasks 1.1 to 1.8 and the output from this stage is the subject of this Inception Report. This has included:

- drafting a detailed schedule for the evaluation work (Task 1.1, section 1.1 of this report);
- establishing a description of the development of the area of GM food and feed since the entry into force of Regulation 1829/2003 (Task 1.2);
- drafting a model of the intervention logic (Task 1.3, Chapter 3);
- defining the key terms for the evaluation questions (Task 1.4, Chapter 4);
- identifying information sources (Task 1.5, Chapter 5);
- creating the tools needed for the quantitative and qualitative analysis (Task 1.6, Chapter 1)³³;
- compiling the descriptive part (Task 1.7, based on Task 1.2, Chapter 2); and,
- draft a detailed plan for the preliminary draft final deliverable (Task 1.8, section 1.1).

A meeting with the Steering Group will take place on 16 July, 2009 to discuss the Inception Report.

7.1.2. Observing

The observation phase of the evaluation is our information gathering process (Task 2.1). During this phase of the contract we will carry out a full literature review, survey of Competent Authorities, survey of key stakeholders, interviews with key stakeholders and case studies. These information gathering exercises are discussed in Chapter 5.

This phase also includes drafting an overview of the progress of the evaluation (Task 2.2).

Both Tasks 2.1 and 2.2 will be addressed in an Interim Report on the evaluation progress. A meeting with the Steering Group is envisaged in order to receive comments on the report.

7.1.3. Analysing

The analysis phase of the evaluation will contain the draft preliminary replies to the evaluation questions (Task 3.1) which will be based on the output of Task 2.1. In addressing the questions we will comment on the nature of the evidence base and any limits thereof.

These draft preliminary replies will then be modified in the light of comments made by the Steering Group (Task 3.2). These modifications will result in the drafting of full replies to all evaluation questions (Task 3.3).

7.1.4. Judging

The judgement phase of the evaluation will include the drafting of evidence-based conclusions and recommendations (Task 4.1). Limits and validity of the judgement will be specified. A draft executive summary of no more than 25,000 characters (without spacings) will be compiled (Task 4.2). This will focus on the conclusions and recommendations. The preliminary draft final deliverable will be assembled (Task 4.3). This will be based on commonly recognised standards for publication and the core text will not exceed 150 pages. Statistical and technical information will be annexed to the report.

³³ Note that the questionnaires have not been presented in this report because it has been submitted ahead of schedule. Chapter 6 sets out the topic areas that the questionnaires will cover.

A meeting with the Steering Group is envisaged in order to receive comments on the report.

Following comments from the Steering Group, the draft executive summary will be revised (Task 4.4) and presented in both English and French. A synthetic summary of no more than 15,000 characters (without spacings) will be drafted (Task 4.5). A draft PowerPoint presentation will also be produced (in English and French) containing a maximum of 30 slides (Task 4.6). This will highlight the main findings of the evaluation. The final deliverable will then be compiled based on the above submissions and incorporating all changes agreed with the Steering Group (Task 4.7).

7.1.5. Dissemination

Regarding Task 5 (Dissemination of results), following initial discussion with DG SANCO, it is not possible at present to have further precision on the number of dissemination seminars planned, locations, size of the events, as well as exact role and contribution of FCEC (to be able to estimate preparatory work). This issue will be further discussed as appropriate as the project evolves.

7.2. Project timeline and key milestones

The project timetable and key milestones are set out in Table 7.1.

Table 7.1: Timetable and key milestones

Months:	1	2	3	4	5	6	7	8	9	10	11	12
Activities:	2009							2010				
	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
<i>Kick off meeting (w/c 1/06)</i>	■											
Methodology refinement/validation; first round of interviews	■	■										
<i>Inception Report</i>		■										
<i>Inception meeting (6 weeks after project start)</i>		■										
<i>Attendance at the advisory forum for the food chain meeting</i>		■										
<i>Attendance at the SCFAH meeting</i>		■										
Main phase: launch surveys, interviews and case studies			■	■	■	■						
<i>Interim Report (progress report)</i>						■	■					
<i>Interim meeting (6 months after project start)</i>								■				
Main phase: conclude survey and case studies; analysis						■	■	■				
<i>Attendance at stakeholder conference</i>									■			
Draft Final Report (final results and analysis)									■	■		
<i>Final meeting (10 months after project start)</i>										■		
Draft Final Report revision + other Deliverables											■	■
Final Report (approval)												■

7.3. Preliminary structure of the draft final report

The structure of the draft final report will be as set out below. This is a preliminary view and may be revised over the course of the project. It is noted that this structure requires approval from the Steering Group. The draft final report will be accompanied by an executive summary no longer than 25,000 characters (not including spacing).

1. Introduction
2. Methodology
3. The overall objectives of the legislation in the light of the expected developments in the sector
4. The risk assessment and regulatory approval process
5. The compulsory labelling of GM food and feed
6. Acceptance
7. Conclusions and recommendations
8. Annexes

7.4. Human resources

7.4.1. Project management

The study will be managed and co-ordinated by Agra CEAS Consulting. Agra CEAS will thus take overall responsibility for the timely delivery of the contract requirements and will co-ordinate the activities of the consortium for this assignment.

The following sections provide background to the companies in the consortium and pen portraits of the principal consultants involved.

7.4.2. Project team

The evaluation team will be composed of the following experts.

Conrad Caspari is Managing Director of Agra CEAS Consulting. Conrad has more than 25 years experience of assessing EU market and policy developments in EU agri-food sectors and has managed over 500 consultancy projects for a wide range of institutional and private sector clients. He has extensive experience of analysing agri-food related trade, environmental and market issues. Conrad has been involved managed many policy analysis and evaluation studies concerning the EU agri-food sector for the European Commission. Conrad has led a number of assignments under the Food Chain Evaluation Consortium's framework contract including, *inter alia*, an evaluation of the Community Animal Health Policy (CAHP) and an impact assessment of the new pesticides Directive. Conrad is fluent in English, German, French, Spanish and Portuguese.

Dr Dylan Bradley is a Senior Consultant at Agra CEAS Consulting. Dylan joined Agra CEAS in 1997 and has undertaken a number of assignments relating to GM food and feed, most notably a study on the issues and costs of Identity Preservation. Dylan has worked extensively for the European Commission and other Commission services including research for DG Agri, DG Environment, Eurostat and DG SANCO. Dylan has taken part in and managed a number of assignments under the Food Chain Evaluation Consortium's framework contract including a study on stunning/killing practices in slaughterhouses and their economic, social and environmental consequences, a study on fees or charges collected by Member States for official controls, research into setting a maximum amount for vitamin and mineral content in food supplements and fortified food and an assessment of

the legislation relating to dietetic foods. Dylan has also worked on a range of other contracts for international organisations such as the World Organisation for Animal Health, for national governments and for private clients.

Clifford Biggs is a Consultant at Agra CEAS Consulting. Clifford has a BSc in Agricultural Business Management and an MSc in Applied Environmental Economics from Imperial College at Wye, University of London. Clifford worked as an Economist at the secretariat of the International Grains Council in London and has worked for Agra CEAS for some four years. Working mainly on policy monitoring services and economic analysis, Clifford has taken part in the analysis of socio-economic impacts of agricultural policy reforms. He has worked extensively on projects in the EU livestock sectors.

John Nganga is a consultant at Agra CEAS Consulting. John has an MA in International Economic Relations from the University of Konstanz, Germany. Prior to working at Agra CEAS, John completed a Traineeship in DG Development of the European Commission, where he worked primarily on trade issues, and he also worked at the International Trade Centre in Geneva. Since joining Agra CEAS, John has been involved in projects for DG SANCO in the areas of food law, labelling and nutrition; for the European Parliament in the area of agriculture and the environment; and for the World Organisation for Animal Health. John has also worked on a variety of biofuels projects for private clients. He is fluent in English, French and Spanish, has a good working knowledge of German and a basic working knowledge of Polish and Portuguese.

Mariana Ricci is a consultant at Agra CEAS Consulting. Mariana holds an MSc in Politics and Government in the European Union from the London School of Economics and Political Science (LSE). Since joining Agra CEAS in 2008, Mariana has worked on a number of assignments, including a report for the European Parliament on eating habits and the overuse of natural resources. Mariana was responsible for contacting stakeholders and processing data to quantify the impact of policy change for the report on maximum amount for vitamin and mineral content in food supplements and fortified food for the FCEC under the framework contract. Mariana is experienced in collecting data from different sources and conducting policy research, especially within the European Union legislative system.

Dr Rodolphe de Borchgrave is a Partner with Arcadia International, Food Chain consultants. He has previously held senior positions with AT Kearney and Price Waterhouse, where he acquired broad sector and functional experience. Rodolphe's food chain experience includes: supply chain management; technology (biotechnology) management; business intelligence (market analysis, benchmarking, competitive analysis); economic modelling; regulatory monitoring and compliance assessment; project management; policy and programme support; and, evaluation. In relation to GMOs he has carried out a study into the economics and feasibility of various GMO free supply chains (feed (EU), poultry meat (UK), pig meat (UK), beef (UK), dairy products (FR)); an impact assessment of the use of GMOs on the Brazilian economy; economic modelling of dual feed market (GMO/non-GMO) impact on feed/food chains in the EU, including the impact on trade balances; and, a study on the economics of GMO crops in the EU (sugar beet). Rodolphe has also conducted an evaluation of the efficiency and effectiveness of EFSA.

Daniel Traon has degrees in plant health and in information & knowledge management. He is the managing partner of Arcadia International. Daniel worked for the agribusiness and agro-food sector for 15 years before starting a consultancy career in 2004. Over the years, Daniel has gained a deep expertise in agriculture, agribusiness and food sectors at international level. This expertise is today recognised by the European Commission as he is providing evaluation services in the area of agriculture to DG AGRI, agribusiness and food & feed chain to DG SANCO, as part of FCEC. Additionally, Daniel is at home in capacity building and training exercises as demonstrated by the actual support to DG TRADE in organising training seminars in meat traceability, and to DG ENTR in organisation of high level seminars addressing EU food sector competitiveness.

In 2008, Daniel was the project leader of the evaluation of the Community *acquis* on the marketing of seed and plant propagating material. In early 2009, he was responsible for a study on the introduction of electronic identification (EID) as official method to identify bovine animals within the European Union.

Dr Frank Alleweldt is Managing Director of Civic Consulting and the project director of the Food Chain Evaluation Consortium. Civic Consulting is a management consulting company specialising in evaluation and impact assessments related to food chain, animal health and consumer protection. Frank has extensive experience in leading economic studies, evaluations and impact assessments covering food chain and consumer protection issues, including for the European Commission and the European Parliament. He recently led a feasibility study on animal welfare labelling for the European Commission and a study for the OIE on the cost of National Prevention Systems for animal diseases and zoonoses.

Dr Sue Williams is an agricultural biochemist and legal expert with extensive experience in issues related to the agri-food supply chain from plant variety development and protection to crop assurance. She has held a range of posts in research and industry both in the UK and abroad including in developing countries. She has worked in various projects such as the trial formulation of commercial poultry diets for optimum growth, reversal of the breeding season of ewes by manipulating their endocrine system, running drug toxicity trials and developing Elisa assays for measuring pesticide residues in crops. In addition, she managed the commercial plant intellectual property licensing system in the UK arable sector, for both certified and farm saved seed. This included the evaluation of the relevant European legislative frameworks and their implementation by National Governments and practical application throughout the seed chain. She holds a BSc. in Biochemistry and Agriculture, from Bangor University, United Kingdom, a MSc. and Phd in Animal Nutrition from Aberdeen University, United Kingdom that she completed by a Diploma in Law and a Diploma in Legal Practice at Exeter University, United Kingdom.

Philipp von Gall is a researcher at Civic Consulting. Recently, he has worked on a feasibility study on animal welfare labelling carried out by FCEC and a study for the OIE on the cost of National Prevention Systems for animal diseases and zoonoses. Before joining Civic, Philipp has worked, among others, on a research project on the costs of food certification systems for smallholders in developing countries carried out by the German GTZ. Philipp holds a MSc in Agricultural Economics and BSc in Agriculture from the Humboldt University Berlin and studied life and environmental science at the AgroParisTech, Paris.

The proposed role of our experts is indicated in Table 7.2.

Table 7.2: Team of core experts and role in project

Name of consultant	FCEC Member	Cat.	Role in project
Conrad Caspari	Agra CEAS	A	Team leader, overall management; supervision of methodology, analysis and report writing; quality control (overall project).
Dr Dylan Bradley	Agra CEAS	B	Research; analysis; structuring expert input; managing case studies and interviews; drafting reports; quality control (Agra CEAS inputs).
Clifford Biggs	Agra CEAS	D	Research; participation in case studies, surveys and interviews; analysis and report drafting.
John Nganga	Agra CEAS	D	Research; assistance with implementation of expert interviews, surveys and case studies, analysis and

EVALUATION OF GM FOOD AND FEED LEGISLATION
DG SANCO Evaluation Framework Contract Lot 3 (Food Chain)

Name of consultant	FCEC Member	Cat.	Role in project
			report drafting.
Mariana Ricci	Agra CEAS	D	Research; assistance with implementation of expert interviews, surveys and case studies, analysis.
Rodolphe de Borchgrave	Arcadia International E.E.I.G	A	Research; participation in case studies and interviews; analysis and report drafting; quality control (Arcadia inputs).
Daniel Traon	Arcadia International E.E.I.G	B	Research; participation in case studies, surveys and interviews; analysis and report drafting.
Dr Frank Alleweldt	Civic Consulting	A	Research; participation in case studies and interviews, managing surveys; analysis and reporting; quality control (Civic inputs).
Dr Sue Williams	Civic Consulting	B	Research; participation in case studies and interviews, managing surveys; analysis and reporting.
Philipp von Gall	Civic Consulting	D	Research; assistance with implementation of expert interviews, surveys and case studies.