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

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Final Report

Submitted by:

Food Chain Evaluation Consortium (FCEC)

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Contents

Acronyms

AAF:	Association des Amidonniers et Féculiers (European Union Starch Industry)
AFSSA:	Agence française de sécurité sanitaire des aliments (*French Food Safety Agency*)
AIDS:	Acquired immune deficiency syndrome
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
CA:	Competent Authority
CAP:	Common Agricultural Policy
CDG:	Genetic Rights Foundation
CFIA:	Canadian Food Inspection Agency
CIAA:	Confederation of Food and Drink Industries of the European Union
CJD:	Creutzfeldt–Jakob Disease
CNTBio :	Comissão Técnica Nacional de Biossegurança (*The Brazilian National Biosafety Commission*)
CO2 :	Carbon Dioxide
COCERAL:	Comité du Commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures
CO-EXTRA:	Project on Coexistence and Traceability in GM and non-GM Supply Chains
COGEM:	Commissie Genetische Modificatie
CPB:	Cartegena Protocol on Biosafety
CRIIGEN:	Comité de Recherche et d'Information Indépendantes sur le génie Genétique. *English : Commitee of Research and Indepedant Information on Genetic Engineering.*
DDGS:	Dried Distillers Grains with Solubles
DG:	Directorate General
DG AGRI:	Directorate General of the European Commission for Agriculture and Rural Development

DG ENV:	Directorate General of the European Commission for E*nvironment*, Nuclear Safety and Civil Protection.
DG ENTR:	Directorate General of the European Commission for Enterprise and Industry
DG RTD:	Directorate General of the European Commission for Research
DG SANCO:	Directorate General of the European Commission for Health and Consumers
DG TRADE:	Directorate General of the European Commission for Trade
DGAL:	Direction générale de l'alimentation (*French DG for food*)
DGCCRF:	Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (*French DG of Competition, Consumers and Fraud Repression*)
DNA:	Deoxyribonucleic acid
DTI:	Department of Trade and Industry (of the UK)
EC:	European Community
EEC:	European Economic Community
EFSA:	European Food Safety Authority
EGGenTDurchfG :	(German) Gesetz zur Durchführung der Verordnungen der Europäischen Gemeinschaft auf dem Gebiet der Gentechnik und über die Kennzeichnung ohne Anwendung gentechnischer Verfahren hergestellter Lebensmittel. *English: German Law for Implementation of EU GM Labelling Provisions.*
EP :	European Parliament
EPA :	Environmental Protection Agency (of the US)
EQ:	Evaluation Question
ESA :	European Seeds Association
EU:	European Union
FAIR:	Agro-industrial Research Programme under the Framework Programme of the European Commission
FAO:	Food and Agriculture Organisation
FCEC:	Food Chain Evaluation Consortium
FDA:	Food and Drug Administration (of the US)
FEDIOL:	European Union Oil and Protein meal Industry
FEFAC:	European Feed Manufacturers' Federation
FEFANA:	European Union Association of Feed Additives and Premixtures Operators

FERM:	Federation of European Rice Millers
FNSEA:	Fédération nationale des syndicats d'exploitants agricoles (French National Farmers' Syndicate)
FoE:	Friends of the Earth
FoEE:	Friends of the Earth Europe
FP5 (FP6, FP7):	Framework Programme 5 (6, 7) of the European Commission
FSA:	Food Standards Agency of the UK
GDP:	Gross Domestic Product
GM:	Genetically Modified
GMO:	Genetically Modified Organism
Ha:	Hectare
HCB:	Haute Conseil des Biotechnologies
HT:	Herbicide Tolerance/tolerant
IFA:	Isolated Foreign Approval
INRAN:	Italian National Institute of Research on Food and Nutrition
IP:	Identity Preservation
ISAAA:	International Service for the Acquisition of Agri-biotech Applications
JRC:	Joint Research Centre (of the European Commission)
JRC-IHCP:	The Institute for Health and Consumer Protection of the Joint Research Centre
JRC-IPTS:	The Institute for Prospective Technological Studies of the Joint Research Centre
LLC:	Limited Liability Company
LLP:	Low level presence
LMO:	Living Modified Organism
MAPA / MARM:	Spanish Ministry of the Environment, Rural and Marine Affairs
MIPAF:	Italian Ministry of Agricultural and Forestry Policies
MRL:	Maximum Residue Level
MS:	Member State
NAS:	National Academy of Sciences (of the US)

NGO:	Non-Governmental Organisation
NPV:	Net Present Value
OECD:	Organisation for Economic Co-operation and Development
OGM:	(French) Organisme Génétiquement Modifié. *English: GMO.*
OSR:	Oilseed Rape
PNT:	Plant with Novel Trait
PP:	Precautionary Principle
PPP:	Plant Protection Product
PR:	Public Relations
PRRI:	Public Research and Regulation Initiative
QM:	Qualified Majority
QMV:	Qualified Majority Voting system
QS:	Qualitäts- und Sicherungssystem (*German Quality and Safety System for the Meat and Feed Production Chains*)
RA:	Risk Assessment
RASFF:	Rapid Alert System for Food and Feed
R&D:	Research and Development
RR:	Roundup Ready
SBM:	Soybean Meal
SCFCAH/ SCoFCAH:	Standing Committee on the Food Chain and Animal Health
SE:	Substantial Equivalence
SFAIRP:	So far as is reasonably possible
SG:	Secretariat General of the European Commission
SH:	Stakeholder
SIGMEA:	Sustainable Introduction of GMOs into European Agriculture of the sixth Framework Programme of the European Commission
SKU:	Stock Keeping Unit
SMEs:	Small and Medium sized Enterprises
S&PM:	Seed and Propagating Material

TC:	Third Country
ToR:	Terms of Reference
UECBV:	The European Livestock and Meat Trading Union
US/USA:	United States of America
USDA:	United States Department of Agriculture
USDA FAS:	United States Department of Agriculture Foreign Agricultural Service
VR:	Virus Resistant
vzbv:	Verbracherzentrale Bundesverband (*German Consumer Organisation*)
WHO:	World Health Organisation
WTO:	World Trade Organisation
WWF:	World Wildlife Fund

S1. Executive summary

DG SANCO launched this evaluation of the EU legislative framework in the field of genetically modified (GM) food and feed in June 2009 and the final report was submitted in June 2010. The evaluation covers Regulations (EC) No 1829/2003 on genetically modified food and feed and (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

This evaluation is not intended to be a scientific assessment; rather its main goal is to collect opinions and perceptions of the examined issues particularly from stakeholders and Competent Authorities (CAs). This broad evidence base allows an assessment of the effectiveness and efficiency of the current legislative processes and results in the formulation of options for the improvement/adjustment of the system to make it more relevant and sustainable moving forward.

The evaluation therefore forms part of a wider evidence base for the European Commission alongside other studies on behalf of the Commission Services.

This study was led by Agra CEAS Consulting of the Food Chain Evaluation Consortium (FCEC).

The evaluation followed the classical evaluation steps of structuring, observing, analysing and judging. This included in particular a survey and semi-structured interviews with stakeholders, CAs, Commission Services and Third Country (TC) representatives.

S1.1. Overall objectives of the legislation and expected developments in the sector

The evaluation found that there is broad support for the stated objectives of the legislation. In general, the legislation is seen as responding to EU society's needs for safe food and feed; however, stakeholders in particular do not believe the legislation contributes to the objectives of securing a secure all-year-round supply of feed for livestock, or a fair standard of living for EU food producers.

The majority view is that the current legislative system represents an improvement on that which prevailed up to 2003. CAs generally believe that the implementation of the legislation allows its objectives to be achieved, although stakeholders were less confident about this. The implementation of the legislation was considered weakest in terms of enabling the effective functioning of the internal market.

Almost all interviewees considered that while the legislation had been made correctly operational for the risk assessment phase, the risk management stage is not fully operational, mainly because of the time taken to reach decisions.

CAs generally feel that the implementation of the legislation provides a high level of protection of consumer interests and that consumers understand the labelling provisions, although many stakeholders did not agree.

The factual developments expected in the sector include an increase in the number of countries growing GM crops, as well as increases in the number of GM crops specifically designed for non-EU domestic markets and of stacked events. These developments are likely to result in an increasing number of applications to the EU as a result of which asynchronous authorisations and more frequent incidents of low level presence of unauthorised GMOs between the EU and Third Countries are likely to occur.

Benefits from future developments in the sector may encompass those arising from the traits themselves and those arising from supply-chain management systems. Other potential benefits may include a contribution to food security and quality, global reductions in pesticide use and contribution to meeting the challenges of climate change and environmental damage. Crops for the production of compounds destined for industry (and not for the food/feed chain) may become important and

developments in drought tolerant crops and GM wheat are expected by the industry in the medium-term.

There are concerns that the current legislative framework is not suited to ensuring that the EU can take advantage of new developments, but these concerns are not universally accepted and it may be too early to come to a clear conclusion on this given the uncertainty in terms of the timing of new developments and what these might actually entail.

The European Commission has been preparing a report on the use of socio-economic criteria within the GMO authorisation process whilst this evaluation has been conducted. Although the main focus of this is cultivation, there are potential implications for GM food and feed.

There is no consensus in terms of whether the explicit and systematic use of socio-economic criteria could and should be used in connection with GM food and feed. Stakeholders with a known anti-GMO stance tend to be in favour of the use of such criteria and *vice versa*. The consideration of "other legitimate factors" is already allowed for under Articles 7(1) and 19(1) of Regulation (EC) No 1829/2003, although there is concern that considering non-science based issues overtly in the authorisation process might be perceived as going beyond the regulatory role.

There is no consensus on whether risk assessments carried out by Third Countries should be accepted as a way of enabling better access to the potential benefits of GM crop developments for food and feed.

S1.2. The risk assessment and regulatory approval process

The EU authorisation procedure is generally considered to achieve the objectives of the protection of human and animal health through the use of science-based risk assessment. It should also be noted that there have been no cases of animal or human health problems resulting from GMOs to date. The authorisation procedure is also seen as contributing to the protection of the environment. There are some concerns that the authorisation procedure may not facilitate the effective functioning of the internal market as well as it could, partly as a result of the potential for different interpretations of the tolerance level for adventitious and technically unavoidable presence.

The EU approach to the authorisation of stacked events differs from that in the USA and Canada where stacked events are automatically authorised if the single events have already been authorised. The EU is by no means alone in its approach which is a step towards minimising the uncertainty about potential risk associated with GMOs. The approach thereby assures a high level of protection of human life and health and environmental protection, although it increases the workload of EFSA and the Commission. Finally, because of the different approaches, the gap between authorisation in the USA and Canada and authorisation in the EU is likely to be more significant with respect to stacked events than single events. This means that in future as the number of these types of event rises the EU approach is likely to result in a larger application backlog with current resource and, as a result, more asynchronous authorisations with consequential impacts in terms of LLP incidents.

The risk assessment conducted by EFSA is considered efficient, although the risk management procedure is not considered to be efficient and a backlog of EFSA opinions is building up, largely because the Standing Committee and the Council do not deliver a qualified majority opinion. This backlog is likely to grow if current rates of authorisation are not increased. That said, the centralised authorisation process is considered more efficient than the system in place prior to the 2003 legislation. The cost to applicants is around 25% higher in the EU compared to the USA.

The actual time to authorisation exceeds that envisaged in the legislation by a substantial margin, partly due to the submission of incomplete dossiers by applicants. EFSA has improved its performance in administrative terms and this has brought the actual timings closer to those anticipated.

The authorisation process is considered to be fairly transparent, although this is not to say this aspect could not be further improved. Finally, and on balance, the EU authorisation process is considered to be proportionate to the potential risks. It is noted that the risk assessment system should be re-examined as necessary in the light of future developments in the biotech sector which might have implications in terms of nature and magnitude of risk.

The EU's agricultural biotechnology sector could, in the mid-term, generate benefits to EU society in excess of the current benefits. The legislation has been designed to meet public concern relating to the technology and this has had an impact on the development of the sector in that the EU is no longer a world leader in this field. The EU's biotechnology strategy (European Commission, 2002b) notes that more attention is needed in terms of how legislation can help foster the development of research and innovation, assist in developing consumer acceptance and to ensure the functioning of the internal market. The main issue is for the EU to decide an appropriate balance between potential economic risk and economic potential benefits, which include those to EU society from a well developed agricultural biotechnology sector.

Article 34 of Regulation (EC) No 1829/2003, setting out the EU response to the use of "emergency measures" by Member States, has only been invoked twice and the procedure took one year. On balance, the history and timescale of the use of Article 34 suggests that this may not be the most appropriate instrument to use with respect to cultivation, and this is probably also a valid conclusion with respect to GM food and feed, although it should be reiterated that so far it has not been applied in these sectors.

The best measure of the efficiency of the regulatory process for GM food and feed pre and post-2003 is in terms of the number of authorisations processed and on this basis the post-2003 "one door, one key" approach is considered more efficient with an average of four authorisations a year since 2004 compared to just one per year between 1996 and 2003.

While it can be said that the approval procedures are judged to be consistent overall, there still remain, across food safety regulations for different categories of products, some points of inconsistency. An example of this is the requirement for labelling of some products of GMO origin (for example, oil or lecithin) while others (for example, the use of enzymes) are not labelled. There is also an inconsistency in the use of zero tolerance levels for unauthorised GM material and non-zero maximum residue limits for harmful substances such as food contaminants. The lack of interaction in the risk assessment for products yielding complementary risks, such as herbicide and herbicide tolerant GMOs is also a point of inconsistency.

There are three distinct causes of LLP: asynchronous authorisations, asymmetric authorisations and escaped research approvals. LLP incidents can result in potentially significant administrative and legal costs, damage to supplier and/or customer relationships, potential long-term loss of customers and potentially lengthy litigation with suppliers/customers for individual operators in the food and feed chains. The actual costs resulting from LLP incidents to date range from €0.8 million to €3.5 million for individual operators. Estimates of the potential future impact of LLP are considerable. Under the growing global trend of new GMO authorisations in TCs, the current EU authorisation regime, specifically given the pace at which it operates and its use of zero tolerance, is likely to generate severe economic problems for the food and feed sectors.

S1.3. The compulsory labelling of GM food and feed

Although there is a consensus in favour of compulsory positive labelling, there are some concerns with the current labelling system.

The labelling provisions provide the consumer with the possiblity to make an informed choice, although there are some doubts as to whether consumers have the necessary knowledge to make an

informed choice. Consumers that are concerned about GM content are certainly able to find information, however, a significant minority of Competent Authorities and stakeholders do not believe that consumers understand and accept the labelling provisions and, if this is the case, the provisions may not be entirely facilitating an informed choice.

The introduction of the current labelling provisions coincided with a general withdrawal of products which would have had to be labelled and this has not facilitated choice, informed or otherwise. Finally, there are elements of the labelling provision which might be considered misleading, at least for some consumers, in terms of the threshold for adventitious and technically unavoidable presence, the inclusion of oil products within the labelling scope and the exclusion of livestock products.

At least one million EU citizens would like to see GM labelling extended to encompass livestock products, which implies a lack of acceptance of the current scope of labelling, if not its current application, by this group of citizens.

The history of GM food products reveals that operators made changes to their supply chains before the introduction of the 2003 legislation. This means that the introduction of labelling provisions under Regulation (EC) No 1830/2003 had limited direct impact on the actors in the food sector. While the cost of segregation and Identity Preservation has increased for food products, the impact is diluted in final consumer prices. This process has been exacerbated by reductions in the availability of non-GM supply and this has resulted in high segregation and Identity Preservation costs for this market segment, although these costs will be diluted to some extent in the value chain depending on the use of IP feed and feed conversion ratios for different species. That said, Identity Preservation costs have increased substantially and the impact on consumer prices cannot be seen as negligible any more.

The availability of GM labelled food products in the EU is extremely limited. The range of GM labelled products consists primarily of soybean oil for cooking and some imported products; there are no retailer own-brand labelled GM products.

The vast majority, 85%-90% of compound feed is labelled as GM, up to 95% of soybean imports are labelled as GM and these proportions have been increasing as planting of GM events increases. There is a relatively small niche market of non-GM feed for the "organic" segment and non-GM supply chains.

Food markets have evolved towards the dominant use of non-GM supply chains and the conventional feed sector (more slowly) towards the dominant use of GM supply chains. The labelling regulations played only a limited role in these evolutions. Mandatory labelling requirements were introduced after market forces had determined the direction and pace of market evolution in the late 1990s and early 2000s. In the case of food products, these factors were mostly internal to the EU consumer market. In the case of feed, they were largely external.

Any extension of labelling scope to include livestock products would result in the vast majority of products being labelled, providing consumers with information, but also potentially restricting consumer choice in the absence of far reaching/in-depth reorganisation of the supply chain. However, in theory it may be possible to increase the proportion of non-GM livestock feed in some Member States. Evidence suggests that there is a market for non-GM fed livestock, and that consumers are willing to pay a premium for it, although the size of the market and premium are not clear.

There may also be some issues with segregation and enforcement. Segregation of livestock production is generally seen as more problematic than segregation of feed. Enforcement is generally seen as complicated, open to fraud and costly. Furthermore there may be some difficulty in defining "GM-free" for livestock products.

It is not clear if any extension to labelling could be imposed on and controlled in terms of imports from Third Countries. An extension to labelling scope which included processed products would

considerably increase the scope of labelling, and would be more complicated, but may also be more logical from a consumer point of view.

Currently there are only national provisions for "GM-free" labelling in three Member States and a number of operator-specific "GM-free" labelled schemes in several other Member States. Further national provisions are expected to be implemented in several Member States in the near future.

Evidence suggests that consumers may not fully understand the meaning of "GM-free" labelling on livestock products. Nonetheless, there is evidence to suggest that some consumers want to be able to purchase livestock products labelled as "GM-free". There is some consumer confusion due to differences between schemes and concerns that confusion will increase with the proliferation of schemes. Despite their best intentions, it is questionable whether existing "GM-free" schemes provide consumers with an informed choice.

There are several potential benefits from a harmonised approach to "GM-free" labelling, however, there may be some problems with the fundamental concept. Such labelling could be considered as misleading if a tolerance level is used to allow for adventitious and technically unavoidable presence of GM material; it may negatively affect consumer perceptions of GM; it may confuse consumers if operated in tandem with positive labelling; and, it could be costly to implement. Furthermore, there may be difficulties in agreeing criteria and scope of such a scheme at EU level.

On the other hand, a harmonised scheme would allow fairer competition between EU operators, minimise operational expenses and make it easier to build market share in the "GM-free" sector.

S1.4. Public acceptance

While EU citizens do not appear particularly concerned about the use of GMOs in farming, there is nevertheless both relatively little support for their use, and a specific group concerned by their use. However, it should be noted that there is little correlation between consumer behaviour and the stated preference of citizens. The implication of this is that it is not really possible to assess public acceptance given the lack of availability of GM labelled products in European stores.

Public awareness of the risk assessment process is considered be generally low and the public acceptance (or otherwise) of GMOs results from general perceptions of the technology rather than specific aspects of the authorisation process.

The impact of risk aversion on the EU agricultural biotechnology sector has mainly had an impact in terms of commercial development of crops for cultivation and is therefore outside the scope of this evaluation. A JRC-IPTS report comprehensively reviews the impact of GM crops globally and concludes that there are some benefits where these crops are cultivated. Most GM crops are not suitable for widespread growth in the EU and this may result, at least in part, from the general lack of acceptance of agricultural biotechnology in the downstream food chain and more widely; in other words, risk aversion.

The overall economic benefits of GM crops that might be realised at the cultivation stage may be reduced in the EU as a result of the lack of GM food products in the EU and, more significantly, the use of non-GM food chains and feed supply chains for livestock products which implies a cost for segregation and Identity Preservation which will limit any overall net benefits to society. Another reason that the EU may not benefit from GM crops is asynchronous authorisation which results in EU producers being denied access to GM events pending their authorisation in the EU. Additionally, asynchronous authorisation and the risk of low level presence incidents can deny access to usual sources of feed material. In all cases the root cause of the costs/denial of benefit can be traced back to a lack of perception of benefit and a lack of public acceptance, i.e. risk aversion.

Whilst it is clear that there is least some public sensitivity with regard to the use of GM feed, probably at least partly due to the exclusion of livestock products from the scope of labelling, the relative public

sensitivity in terms of GM cultivation and GM food is more nuanced. CAs believe that there is more sensitivity with regard to cultivation whereas stakeholders feel that sensitivity is more similar between this and GM use in food.

There is a fundamental concern with the use of As Low As Reasonably Achievable (ALARA) risk in relation to GMOs in that the concept deals with known risks and authorised GMOs do not pose a known risk by definition. That said, the use of ALARA can be envisaged in conjunction with a defined threshold in relation to the labelling of GM products and also in relation to the LLP of GM material not authorised in the EU. In both cases there are also concerns that the term "reasonable" is open to interpretation which could have consequences in terms of the operation of the single market. Depending on its application, the use of ALARA would also not permit consumers to avoid the use of GM technology if they so wish which might negatively affect public acceptance. On the other hand, if the use of ALARA prevented LLP incidents, then this might improve public acceptance.

The relative absence of public authority communication has left it up to stakeholders to communicate to the public and many have done so, generally promoting their own views. Finland has demonstrated that it is possible to generate greater public interest in science-based risk assessment and further attempts to communicate more effectively are planned here and also in the UK.

There are three main factors which should be taken into account in general communication strategies on GM: increased engagement of industry and government organisations; better definition of the target audience; and, a need to contextualise potential risks against potential benefits.

The key to improving public trust in relation to GMOs is seen as being more and better communication, although a number of challenges will need to be overcome. These are: belief in the messenger; appropriate communication channels; public ability to understand the issues; and, public desire to understand the issues rather than come to judgements based on preconceived ideas.

S1.5. Recommendations

Authorisation process

- The majority of stakeholders and Competent Authorities were in favour of leaving the responsibility for the risk assessment with EFSA (*status quo*).
- Stakeholder views were united on the need to allow for some form of public comment during the risk assessment process, but were divided on the exact form this should take.
- There is majority support for an approach to stacked events which uses a fast-track risk assessment combined with the current risk management procedure; such a system could be considered akin to the *status quo*.
- Efforts should continue to ensure that applicants submit the correct information in the correct format to EFSA to facilitate the authorisation process. The soon to be released new guidelines are therefore welcomed.
- Half of stakeholders and the majority of Competent Authorities were also in favour of maintaining the status quo with regard to risk management (i.e. the Commission takes a decision after consulting Member States).
- The constraints of the comitology procedure notwithstanding, continuing efforts should be made by the European Commission to table Draft Decisions in a timely fashion. As the number of applications received increases it will be necessary to ensure that the risk management process does not become a bottleneck.

- The majority of Competent Authorities and stakeholders believe that some kind of solution for the adventitious and technically unavoidable presence of unauthorised GM material is required other than zero tolerance.
- Maintaining the zero tolerance policy for adventitious and technically unavoidable presence of unauthorised GM material is likely to result in an increased number of Low Level Presence (LLP) incidents as the global use of GM crops increases. The fact that these are alerted under the Rapid Alert System for Food and Feed (RASFF), which is concerned with safety issues, is seen as inappropriate by some stakeholders. It is clear that a way has to be found to reduce the number of LLP incidents.
- While the impact of asynchronous authorisations can at least be addressed, partly by closing the gap between EU and Third Country authorisations, asymmetric authorisations pose a different challenge because there is no intention here (or motivation) for developers of events to seek authorisation in the EU because there is no intent to export to the EU. International co-operation will therefore be required to address this issue.
- The majority of Competent Authorities and stakeholders are in favour of the use of independently generated data in risk assessments where this is possible and where it can be used to supplement data generated by the applicant (this is allowed for under the current system).
- The overall risk assessment system should be re-examined as necessary in the light of future developments in the biotech sector to ensure the continued protection of consumers, animal welfare and the environment.
- Competent Authorities were split over the explicit and systematic inclusion of socio-economic criteria in relation to GM food and feed. Stakeholders on the other hand were generally against their inclusion.
- The EU and Member States should actively consider what an appropriate balance is between economic risk and potential benefits of adopting plant biotechnology or not.

Labelling

- The majority of Competent Authorities were in favour of maintaining the status quo with respect to the use and scope of positive labelling, although stakeholder opinion was more divided.
- A majority of Competent Authorities support the use of some form of negative labelling (i.e. "GM-free"), although this view is not shared by the majority of stakeholders. Within this there is majority support for voluntary rather than mandatory labelling and for harmonisation at EU level.
- There was a clear majority in relation to both food and feed in support of maintaining the labelling threshold status quo, i.e. 0.9%.
- While to some extent consumer understanding of labelling provisions is related to the lack of experience with labelled products, additional communication efforts may become necessary if more GM labelled products appear on the market.
- Consideration needs to be given to how the concerns of those who wish to see the labelling of livestock products can be addressed and whether this would be proportionate given the potential extent of labelling, complexity and likely economic/administrative burden for the food chain.
- If labelling scope is extended to include livestock products, the wording of any labelling will have to be carefully formulated to make clear to consumers that the feed, rather than the livestock product, contained GM material; failure to make this clear would mislead the consumer.

- Any review of an extension to labelling scope will have to carefully consider the cost implications arising from traceability requirements and the potential consumer reaction; a shift from consumption of domestic (labelled) livestock products to imported (unlabelled) livestock products which may have been fed on GM material not even authorised in the EU could not be considered to enhance consumer protection and there might also be wider, potentially adverse, implications for the EU livestock sector.
- It would appear disproportionate and potentially confusing to simultaneously use a positive and negative approach to labelling; consideration should be given as to which approach better protects consumer interest.
- There is an expansion of (unharmonised) "GM-free" schemes at national level with different requirements, but relatively consistent labelling which may imply a comparability that does not exist. These may currently compromise the smooth functioning of the single market and consideration should be given to introducing an approach harmonised at EU level if "GM-free" labelling is to be used.
- Given the use of thresholds for adventitious presence of GM material, whether "GM-free" schemes really allow consumers to make an informed choice should be carefully considered.

Public acceptance

- It is not the responsibility of public authorities to actively seek to increase acceptance of GMOs and clearly it is the right of citizens to arrive at their own judgement. However, in changing and implementing policy, the impacts on acceptance should be considered, particularly given that aspects of the legislative framework may have an impact on the existing low level of acceptance and general risk aversion.
- Public trust in science-based risk assessments in the context of GMOs is currently low and better communication may be needed. In changing and implementing policy, the impacts on public trust in a science-based risk assessment should be considered.

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 with the final report submitted in June 2010. The scope of the evaluation covers the following legislation:

- 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.

This legislative framework replaced the previous system under which GM foods were regulated under the Novel Food Regulation 258/97, whilst GMOs were partially regulated under Directive 2001/18 on the deliberate release of GMOs into the environment. There was no specific legislation covering GM feed.

Both main Regulations are now seven 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, according to the terms of reference, a qualified majority for authorisation 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 products[1]. As a consequence, few food products labelled as GM are at the present time on the market in the EU[2]. The situation is completely different for GM feed which is at present predominant on the EU market as a result of the importance of soybean as a raw material.

This evaluation is not intended to be a scientific assessment, rather its main goal is to collect opinions and perceptions of the examined issues from stakeholders, Competent Authorities and more widely where this is possible. This broad evidence base allows an assessment of the effectiveness and efficiency of the current legislative processes and results in the formulation of options for the improvement/adjustment of the system to make it more relevant and sustainable moving forward.

In doing this the evaluation will form part of a wider evidence base for the European Commission alongside other studies which have been completed or are currently being undertaken on behalf of Commission Services including an evaluation of the legislation relating specifically to cultivation[3]

[1] 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.

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

[3] Evaluation of the EU legislative Framework in the Field of Cultivation of GMOs under Directive 2001/18/EC and

(launched by DG Environment, now with DG SANCO), an assessment of the economic performance of GM crops worldwide[4] (launched by DG Environment, now with DG SANCO) and an assessment of the implications of asynchronous GMO approvals for EU imports of animal feed products[5] (DG Agriculture).

This wider evidence base also includes work carried out directly by Commission Services such as European Commission reports on the implementation of Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003 to the European Parliament and Council and a study into the impact of asynchronous GMO approvals carried out by DG Agriculture. A number of other reports have been produced under the auspices of the JRC Institute for Prospective Technological Studies (IPTS).

The construction and use of this evidence base will allow the European Commission to make informed choices as part of its wider GMO strategy.

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

This Report is structured as follows: the methodology used to complete the study is outlined in Chapter 2. In Chapter 1, the legislative framework pre- and post-2003 and highlights the main changes that occurred. The evolution of the global GM sector is briefly considered, as, again briefly, are consumer perceptions of GM technology. Chapter 4 presents the intervention logic behind EU legislation on GM food and feed. The 14 EQs are covered in Chapters 5-9. Chapter 5 covers the set of EQs on overall objectives of the legislation and expected developments in the sector; Chapter 6 the risk assessment and regulatory procedure; Chapter 1 the compulsory labelling of GM food and feed; Chapter 8 public acceptance; and Chapter 9 conclusion and options for the future, based on the four preceding chapters. Chapter 1 contains the bibliography, and finally Chapter 1 contains a list of interviewed organisations. There are also three appendixes in a separate file which include the survey results, thematic case studies, and Third Country case studies.

Regulation(EC) No 1829/2003 and marketing of their other uses under Directive 2001/18/EC.

[4] Tender ENV.B.3/ETU/2009/0010.

[5] TENDER N° AGRI / 2008-EVAL-09.

2. Methodology

The evaluation was completed in four phases:

Structuring. This included: exploratory interviews with EU stakeholders, the development of an initial literature database; the development of the intervention logic; definition of the evaluation questions, issues and indicators; and the development of a detailed project plan.

Observing (the data collection phase). This included: a survey of Competent Authorities and stakeholders; semi-structured interviews with EU level stakeholders and Commission services; thematic case studies based on semi-structured interviews and data collection in Member States; Third Country analysis following interviews with Third Country representatives and desk research; conference attendance; and a review of relevant literature.

Analysis. This phase consisted of brainstorming, followed by the development of replies to the evaluation questions based upon the evidence base assembled during the observing stage.

Judgement. This phase consisted of drafting conclusions and recommendations based on the replies to evaluation questions.

2.1. Literature review

An initial literature list was developed during the structuring phase, and considerably more literature was both searched for and received during the course of the project. A brief description of each piece of evidence was included in the database and each entry was flagged according to relevance to the four groups of Evaluation Questions. The flagging acted as a filter; there is a huge body of literature on GMOs, however not all of this is relevant to the specific Evaluation Questions. A bibliography based on the literature database comprising nearly 400 references can be found at the end of this report.

2.2. Surveys

A survey of Competent Authorities and the survey of stakeholders was led by Agra CEAS, and completed during September and October 2009. The evidence gathered from the survey can be found in Section 1 of the appendices. This formed part of the evidence base for the drafting of the Evaluation Questions.

2.3. Semi-structured stakeholder interviews

A programme of semi-structured interviews with key EU stakeholders was completed during October and November 2009 by Agra CEAS and Arcadia. Some 24 organisations were spoken to, the vast majority face-to-face. A number of other organisations were approached, but declined to be interviewed. A list of organisations interviewed is presented in Section 1. Interviewees were given the opportunity to review the notes of the interview, and in the majority of cases, interviewees did review and verify these. The notes from these interviews formed part of the evidence base from which the Evaluation Questions were drafted.

2.4. Semi-structured interviews with EFSA and Commission services

Semi-structured interviews with Commission Services (DGs SANCO, ENV, AGRI, TRADE, RTD, ENTR and SG) were completed in early February, 2010. A semi-structured interview was held with the EFSA GMO unit in Parma on 21 January, 2010; a semi-structured interview was held with DG JRC-IPTS in Seville on 22 January, 2010; and a semi-structured interview was completed with JRC-

IHCP on 1st March 2010. Interviewees were given the opportunity to review the notes of the interview, and in the majority of cases, interviewees did review and verify them. The notes from these interviews formed part of the evidence base from which the Evaluation Questions were drafted.

2.5. Conference attendance

Six relevant conferences were attended by evaluation team members:

- EFSA and GMO risk assessment for human and animal health and the environment, 14-15 September, 2009, Brussels;
- EPC Policy Dialogue: Risk or opportunity? Has Europe got the balance right on GMOs? Thursday 15th October 2009.
- GMO-free food and feed: an economic opportunity for European producers. Lunchtime meeting 5 November, 2009 at the European Parliament;
- GMOs in European Agriculture and Food Production, 25-26 November 2009, The Hague;
- The impact of EU GMO-regulations on biotechnology research for the public good, 25 February 2010, European Parliament, Brussels; and,
- GMO asynchronous and asymmetric approvals: bringing lasting solutions to identified problems, March 18-19, 2010, Brussels.

The notes and papers from these conferences formed part of the evidence base from which the Evaluation Questions were drafted.

2.6. Case studies

Case study visits were completed between November 2009 and January 2010. The list of organisations spoken to is included in section 11.2. Interviewees were given the opportunity to review the notes of the interview, and in the majority of cases, interviewees did review and verify them. Based on the interview notes and literature supplied by interviewees, five thematic case studies were completed:

- **Risk assessment and the regulatory approvals process:** Austria, Belgium, France
- **Consequences of EU lagging behind Third Countries in authorisations:** Italy, Netherlands, Poland, Spain and the UK.
- **The current labelling regime:** France, Germany, Poland, Spain and the UK.
- **Extensions to the labelling regime to include livestock products and GM-free labelling:** Finland, France, Germany, Poland and Spain.
- **Public acceptance:** Czech Republic, Greece, Italy and the UK.

These thematic case studies can be found in section 2 of the appendices.

2.7. Third country analysis

An analysis of the regulatory treatment of GMOs within key Third Countries was completed, based on interviews with representatives of Third Countries and desk research. The evidence gathered is presented in section 3 of the appendices, and has been used in the drawing up of answers to the Evaluation Questions.

2.8. Brainstorming sessions

Various project team brainstorming sessions were held during the project. There were two key brainstorming meetings. The first was held during the structuring phase on 22nd June 2009. The objectives of this meeting were to:

- develop the intervention logic;
- define evaluation questions and indicators, and identify issues;
- share initial knowledge and findings; and,
- construct a roadmap for the observing phase.

Prior to the analysing phase a second key project team brainstorming session was held on 18/19 January, 2010. The objectives of this meeting were to:

- ensure that all research materials were disseminated to all partners;
- present and share experiences from the conduct of interviews and case studies;
- discuss the project next steps; and,
- construct a "roadmap" for the answering of each Evaluation Question.

2.9. Drafting of Evaluation Question responses and judgements

Following the dissemination of the evidence base and the final brainstorming, responses to the Evaluation Questions were drafted. In drafting the Evaluation Question responses, the evidence was presented and discussed with respect to the indicators set out and agreed in the Inception Report.

In order to ensure consistency, evidence was presented in a specific order where appropriate and as far as possible. This order is as follows: literature; quantitative survey findings; evidence from our semi-structured interview notes (from discussions with key EU stakeholders, the Commission Services and EFSA); evidence from our Third Country review; and finally, from the thematic case studies. This approach provided each EQ with a conceptual frame and the order of evidence used became more detailed and specific while moving through answers.

Based on the evidence presented, a judgement was formed in respect of each EQ. This judgement comments on the strength (or otherwise) of the evidence. From these judgments, the conclusions and options for the future were developed.

3. Description of the GM food and feed sector

3.1. The legislative framework pre-2003

Prior to 2003, GM food was legislated under Regulation (EC) No 258/97[6]. GM feed was partially regulated under Directive 2001/18/EC on the deliberate release of GMOs into the environment (and by Directive 90/220/EEC which was later repealed and fully succeeded by Directive 2001/18/EC). Because GM food and feed were not dealt with together they are discussed separately in the sub-sections below.

3.1.1. 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/EC[7].

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, two approaches were possible.

- First, where the product was substantially equivalent[8], the applicant[9] could notify the European Commission of the placing on the market of the product under Regulation (EC) No 258/97. The European Commission was then obliged to forward the notification to Member States within 60 days. As noted above, the product had to be substantially equivalent to its traditional counterpart. Substantial 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.
- Second, and this was also the system with respect to foods and food ingredients containing GMOs, 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 European 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.

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

[7] 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".

[8] 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.

[9] Defined as the company placing the product on the EU market.

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.

On receiving the request, the Member State had to ensure that an initial assessment was carried out either by informing the European Commission of the name of its competent food assessment body responsible for the assessment, or by asking the European Commission to arrange an assessment by the competent body of another Member State. The European Commission provided recommendations for the scientific aspects of information for supporting the application and the preparation of the report[10].

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 European 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/EEC[11]. The European 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.

In the case of *Glycine Max L.* genetically modified soybeans (covered by Decision 96/281/EC) and *Zeya May L.* genetically modified maize (covered by Decision 97/98/EC), special labelling requirements were laid out in Council Regulation (EC) 1139/98. Food produced in whole or in part from these GM crops, and containing their DNA, had to be labelled as "produced from genetically modified soya/maize" (the precise requirements varied based on the final product, and were specified in Article 2 of this Regulation).

Regulation (EC) No 49/2000 (concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms) added a labelling threshold of 1% for adventitious presence, while Regulation (EC) No 50/2000 (on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms) extended the labelling scope to include additives and flavourings containing GMOs.

[10] In Recommendation 97/618/EC.

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

The process is summarised in Figure 3.1.

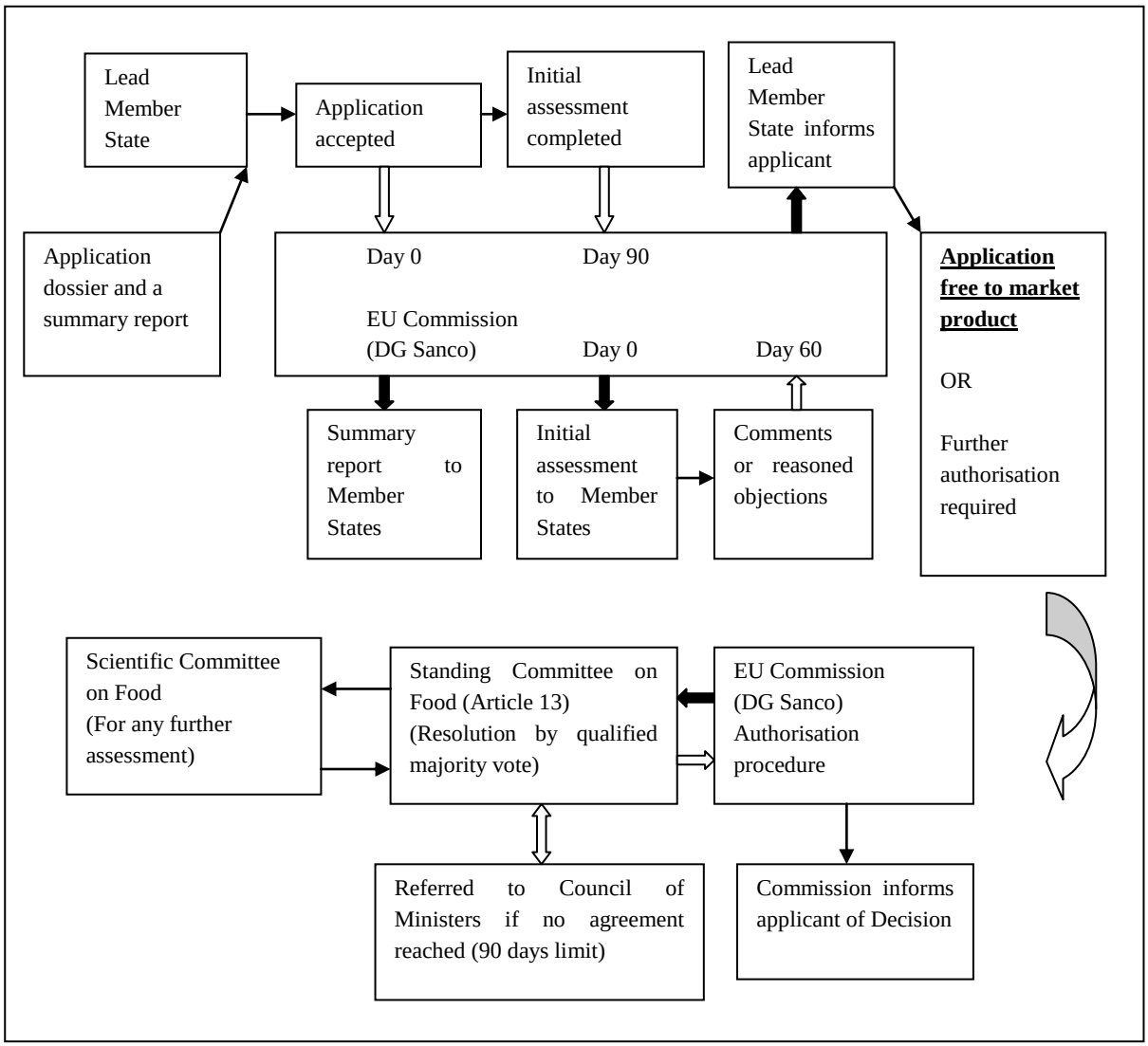

Figure 3.1: The risk assessment and approvals process for GM food pre-2003

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.

3.1.2. GM feed

GM feed was partially regulated under Directive 2001/18/EC[12], which had replaced Directive 90/220/EEC. This Directive (which remains in force) dealt with the placing onto the market of products containing or consisting of GMOs. The Directive is applicable to all GMOs, and does not contain any specific provisions for GM feed; therefore GMOs used directly as feed were covered by Directive 2001/18/EC, but processed feed was not. There was no authorisation procedure specific to GM feed prior to 2003.

[12] 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.

Directive 2001/18/EC contains a general notification procedure for GMOs 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:

- 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 GMO;
- 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 European Commission, who have 60 days to make comments or present reasoned objections. A total of 105 days are foreseen for resolving outstanding issues.

3.2. The legislative framework post-2003

Prior to 2003, GM food products were authorised as novel foods under Regulation (EC) No 258/97. There was no specific authorisation procedure for GM feed and, as a result, only GM feed containing or consisting of GMOs had to be authorised under Directive 2001/18/EC (feed produced from GMOs did not require authorisation). As a result of this, and a number of other factors[13], 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 and feed which could distort competition.

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

- GM food and GMOs that are expected to enter the food chain (defined as food containing or consisting of GMOs, food produced from or containing ingredients produced from GMOs and GMOs for food use); and,
- GM feed and GMOs that are expected to enter the feed chain (GMOs for feed use, feed containing or consisting of GMOs, feed produced from GMOs and GMOs for feed use).

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

[13] Which are set out in the preamble to Regulation (EC) No 1829/2003.

disadvantageous to the consumer (it is possible for GM food to offer additional consumer benefits). The same principles apply to GM feed. With respect to environmental safety, products containing or consisting of GMOs have to comply with the requirements of Directive 2001/18/EC.

3.2.1. The risk assessment and regulatory approval process

The risk assessment and regulatory approvals process for GM food and feed comprise a number of steps. These are set out in Figure 3.2 and are elaborated in the following sub-sections.

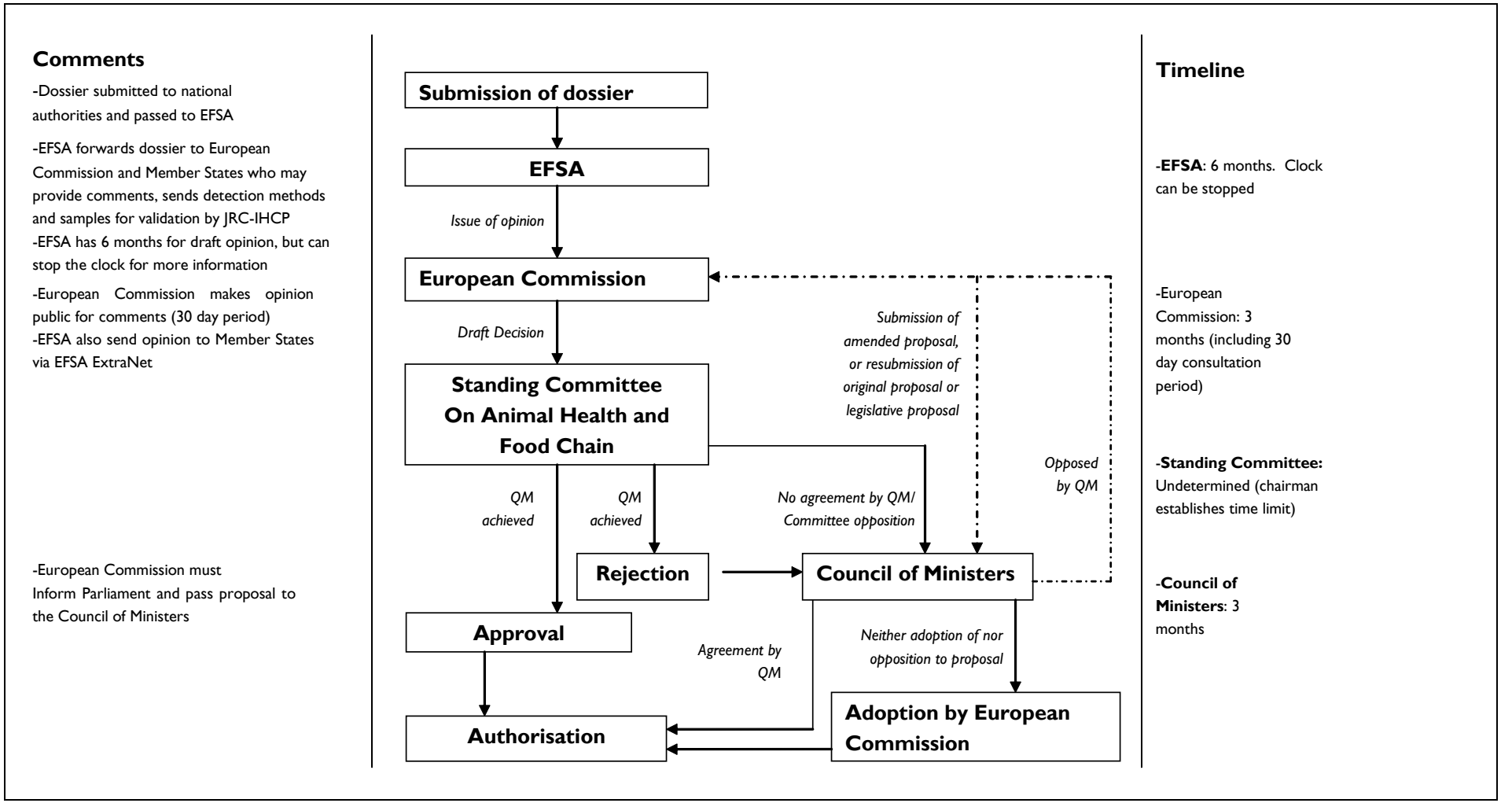

Figure 3.2: The risk assessment and approvals process post-2003

Source: Agra CEAS Consulting.

3.2.1.1. 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 a national Competent Authority of the applicant's choosing, accompanied by the following documents (the documents listed here relate to food, those for feed are similar):

- name and address of the applicant;
- 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, that the product does not mislead the consumer and does not differ from food it is intended to replace (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[14];
- positive and negative control samples of the food to be used for control purposes, 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/EC) (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/EC) (in the case of GMOs and food or feed containing or consisting of GMOs).

The Competent Authority must make the application available to EFSA, who must in turn make the application available to the European Commission and Member States. The dossier is assessed for its completeness and, if deemed valid, EFSA should give an opinion within six months of the application. However, this time line can be extended where it is necessary to seek supplementary information from the applicant. This is done by "stopping the clock" while the supplementary information is prepared and submitted by the applicant and subsequently assessed for completeness by EFSA.

In preparing its opinion, EFSA:

[14] Applicants seeking authorisation are required to provide a detection method. The method is validated by the JRC-European Community Reference Laboratory prior to authorisation in accordance with Regulation (EC) No 641/2004 and Regulation (EC) No 1981/2006.

- should verify if the documents submitted are in accordance with the EFSA guidance document for the risk assessment of GM plants and derived food and feed, and that the general requirements for GM food are met;
- offers Member States the opportunity to provide voluntary comments on the dossier during a three month period;
- may ask for a safety assessment by the food assessment body of a Member State;
- may ask for an environmental risk assessment by a Member State Competent Authority (obligatory for applications for cultivation);
- must send the methods for detection and samples to the relevant Community Reference Laboratories who assess these; 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 European Commission, Member States and the applicant. This opinion comprises an overall opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 and a number of annexes as follows:

Annex A:	Scientific opinion of the GMO Panel (EFSA)
Annex B:	Cartagena Protocol (Applicant)
Annex C:	Labelling (Applicant)
Annex D1:	Validation report (CRL)
Annex D2:	Validation detection method (CRL)
Annex E:	Certified reference materials (CRL)
Annex F:	Monitoring plan (Applicant)
Annex G:	Member State comments (Member States and EFSA)

The opinion is published on the EFSA website, and the European Commission (DG SANCO) provides on its website specific arrangements for the public to submit comments with a 30 day window for responses. Confidential information (such as part of the DNA sequences representing the companies intellectual property and information pertaining to personal data) may be deleted from the publicly available opinion if the European Commission considers, following consultation with the applicant and appropriate justification on their part according to Regulation (EC) No 1829/2003, that disclosure of such data would significantly harm the applicant's competitive position.

3.2.1.2. Risk management and the regulatory approval process

Within three months of receiving EFSA's complete opinion, the European 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 EU law, and any other legitimate factors. If the draft decision differs from EFSA's opinion, the European Commission must provide an explanation.

The Standing Committee on the Food Chain and Animal Health expresses an opinion on the European Commission's draft decision proposing the authorisation or the rejection of the application. If a qualified majority in favour is achieved, the draft decision is to be adopted by the Commission. If a qualified majority against or no opinion is delivered, the European Commission must submit the draft decision to the Council and inform the European Parliament. The Council may act by qualified majority within three months. If the Council opposes the decision by a qualified majority, the European Commission must either resubmit the original draft decision, submit an amended version or bring forward a legislative proposal. If no qualified majority in favour or against is attained (including the case where the Council has not acted within the three-month period), the decision must be adopted by the European Commission in accordance with Article 5.6 of the comitology decision process[15].

Authorisation is valid throughout the Union for a period of 10 years. Authorisations are renewable. An application for renewal 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 those for new authorisations (described above); only the submitted documents differ.

3.2.1.3. 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 assessment from the community scientific committee(s) or EFSA, 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 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.

3.2.2. The compulsory labelling of GM food and feed

Food and feed products containing GM events in proportions no higher than 0.9% and which result from adventitious and technically unavoidable presence do not have to be labelled as GM. Products containing GM material in proportions higher than this have to be labelled. This is done by noting GM content in the ingredient list, or if there is no ingredients list the food and/or feed must be identified as being GM. Food and feed produced from GMOs must be labelled as GM, or as produced from GMOs.

The application of the labelling rules established under Regulation (EC) No 1829/2003 is supported by Regulation (EC) No 1830/2003 which lays down further requirements for labelling and traceability. At the first stage of placing on the market of a product containing or consisting of GMOs, operators

[15] The comitology procedure is a horizontal decision making tool set out in Council Decision 1999/468/EC as amended by Council Decision 2006/512/EC.

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 and feed chain to the end user. These rules apply to all products (including food and feed) containing or consisting of GMOs. In addition, food and feed produced from GMOs are also subject to traceability rules to ensure that this information is transmitted and retained along the supply chain.

3.3. The main changes

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

- **GM feed and GM 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, if Member States objections remained, it had to be completed by the Scientific Committee for Food at the EU level. Under the new procedure, scientific evaluations are completed by EFSA in a single step.
- **A centralised EU 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 European Commission or other Member States within a specified timeframe, the product was approved. Under the new procedure, the European Commission must be involved in the process in all cases.
- **Systematic labelling requirements.** All GM food and feed must be labelled above a tolerance threshold of 0.9% which allows for adventitious and technically unavoidable presence. Before 2003, labelling of food products was in accordance with Regulation (EC) No 1139/98[16] and Regulation (EC) No 49/2000[17], but there were no labelling requirement for GM feed or for food/feed produced from GMOs. It should be noted that products derived from livestock, i.e. meat, milk or eggs, are not subject to labelling.
- **Submission of GMO detection methods and control samples.** The Community Reference Laboratory must validate the detection method prior to authorisation. Applications for authorisation should include, *inter alia*, methods for detection and identification of the transformation event and samples of the food/feed and their control samples. Further details on the requirements were provided in Regulation (EC) No 641/2004[18] and Regulation (EC) No

[16] Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC.

[17] Commission Regulation (EC) No 49/2000 of 10 January 2000 amending Council Regulation (EC) No 1139/98 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC.

[18] 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.

1981/2006[19]. Prior to 2003 there was no legal EU requirement for the submission and validation of GMO detection methods.

- **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 in the EU, 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.

3.4. Evolution of the global GM sector

Figure 3.3 presents the evolution of the global area sown to GM crops from 1996 to 2009. 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).

By 2009, some 134 million hectares were sown to GM crop cultivations across 25 countries (Table 3.1), 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 up to100,000 hectares sown in Spain in 2008 and up to 50,000 hectares in each of the Czech Republic, Romania, Portugal, Poland and Slovakia.

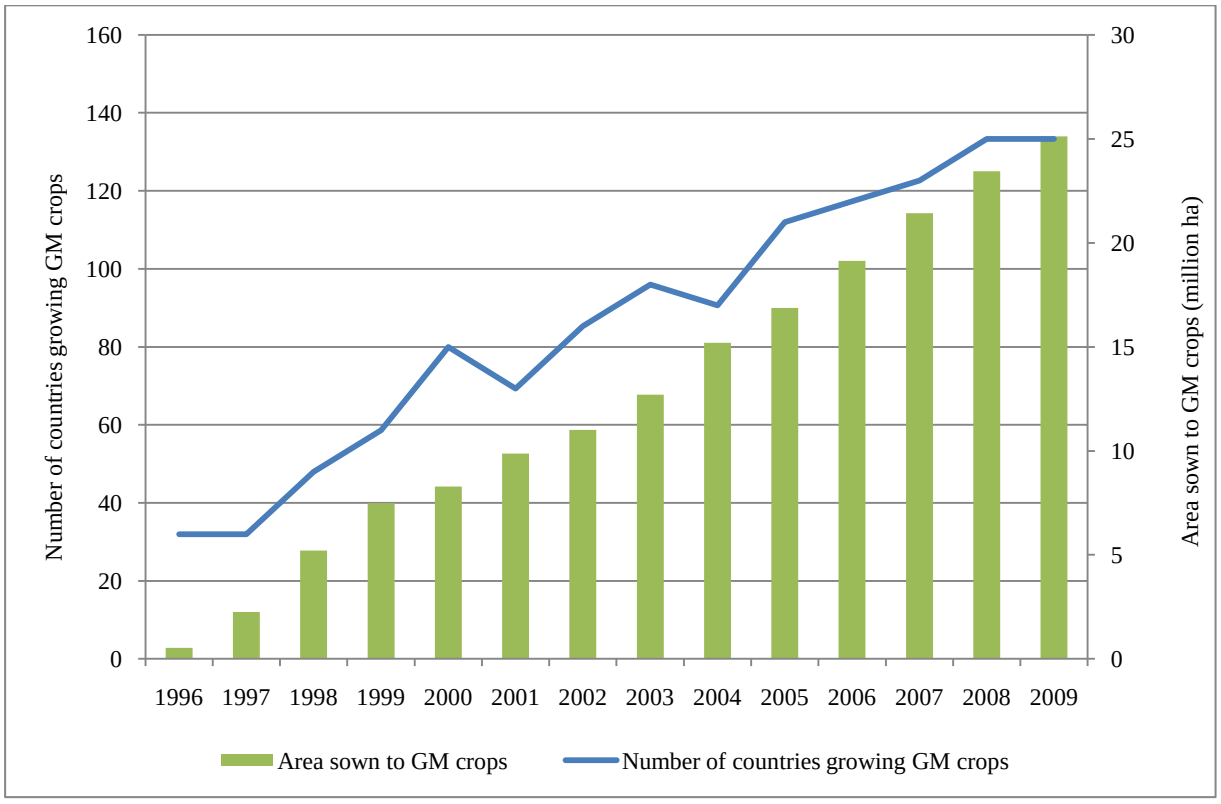

Figure 3.3: Evolution of global area sown to GM crops 1996-2009

Source: James 1996-2009.

[19] Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms.

Table 3.1: Global area of biotech crops in 2009

Country	Area (million ha)	Percentage of total	Biotech Crops
USA*	64.0	47.8%	Soybean, maize, cotton, canola, squash, papaya, alfalfa, sugar beet, potato
Brazil *	21.4	16.0%	Soybean, maize, cotton
Argentina *	21.3	15.9%	Soybean, maize, cotton
India	8.4	6.3%	Cotton
Canada	8.2	6.1%	Canola, maize, soybean, sugar beet
China	3.7	2.8%	Cotton, tomato, poplar, petunia, papaya, sweet pepper
Paraguay	2.2	1.6%	Soybean
South Africa	2.1	1.6%	Maize, soybean, cotton
Uruguay	0.8	0.6%	Soybean, maize
Bolivia	0.8	0.6%	Soybean
Philippines	0.5	0.4%	Maize
Australia	0.2	0.1%	Cotton, canola
Burkina Faso	0.1	0.0%	Cotton
Spain	0.1	0.0%	Maize (75,000 ha in 2007 according to European Commission (2008i)
Mexico	0.1	0.0%	Cotton, soybean
Chile	<0.1	0.0%	Maize, soybean, canola
Colombia	<0.1	0.0%	Cotton
Honduras	<0.1	0.0%	Maize
Czech Republic	<0.1	0.0%	Maize (5,000 ha in 2007 according to European Commission (2008i)
Romania	<0.1	0.0%	Maize (400 ha in 2007 according to European Commission (2008i)
Portugal	<0.1	0.0%	Maize (4,200 ha in 2007 according to European Commission (2008i)
Costa Rica	<0.1	0.0%	Cotton, soybean
Poland	<0.1	0.0%	Maize (300 ha in 2007 according to European Commission (2008i)
Slovakia	<0.1	0.0%	Maize (900 ha in 2007 according to European Commission (2008i)
Egypt	<0.1	0.0%	Maize
TOTAL	**125**		

Source: James (2009) and European Commission (2008i).

There are two basic GM traits: herbicide tolerance (HT) and insect resistance (*Bt*) which can be associated, commonly referred to as "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 3.2. Some 52% of total area planted to GM varieties was accounted for by HT soybean in 2009. The next most significant GM crop in terms of area planted is maize, which accounted for 31% of total GM plantings in 2009. Within the GM maize crop the most important type is an association of herbicide tolerance and insect resistance, which accounts for almost two-third (63%) of the total GM maize area.

Table 3.2: Evolution of global area planted with GM events by crop and trait (million hectares)

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2009 % of total GM area
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	65.8	69.2	52%
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	7.1	9.2	7%
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	5.7	6.4	5%
Bt/HT maize	-	-	-	2.1	1.4	2.5	2.2	3.2	3.8	6.5	9.0	18.8	24.5	26.1	19%
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	11.9	12.4	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	2.6	2.6	2%
HT cotton	<0.1	0.4	-	1.6	2.1	1.8	2.2	1.5	1.5	1.3	1.4	1.1	1.0	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	5.9	6.4	5%
HT sugar beet	-	-	-	-	-	-	-	-	-	-	-	-	0.3	0.5	<1%
HT alfalfa	-	-	-	-	-	-	-	-	-	-	-	0.1	0.1	0.1	<1%
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**	**125.0**	**134.0**	

Source: Gómez-Barbero and Rodríguez-Cerezo (2006a) (after various ISAAA reports) and ISAAA (2007), ISAAA (2008) and ISAAA (2009).

Gómez-Barbero and Rodríguez-Cerezo (2006a) reported that:

- GM **soybean** accounted for 60% of the world's soybean harvested area in 2005. The main producer was the US where 87% of the national soybean crop was GM. The other major producers of soybean are, based on FAO data, Brazil, Argentina, China and India. Gómez-Barbero and Rodríguez-Cerezo (2006a) note that 99% of the Argentinean soybean crop was GM in 2005 and that the adoption rate in Brazil was also high (data from GMO-Compass[20] 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 in 2005. 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 Spain[21]. Data from GMO Compass puts the GM share of cultivated maize at 80% in the US in 2008 (up from 50% in 2005), and 84% in Argentina in 2007. The US and Argentina account for more than 80% of world trade in maize.
- GM **cotton** accounted for 28% of the world's cotton harvested area in 2005. 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 Mexico[22].
- GM **oilseed rape (canola)** accounted for 17% of the world's oilseed rape harvested area in 2005. While in 2005 HT canola was grown exclusively in Canada and the US, by 2008 areas of GM canola were also cultivated in Australia and Chile.

The OECD Bio Track Product Database recorded 130 GM events authorised in at least one country on 11 February, 2010 (Table 3.3)[23]. Of these, more than a quarter, 28%, related to maize, while 15% related to cotton and the same proportion to potatoes. Some 12% related to canola/oilseed rape and 11% to carnations. In terms of traits, 36% are herbicide tolerant, 23% herbicide tolerant and insect resistant while 17% are insect resistant. The main focus is therefore clearly on agronomic traits.

[20] http://www.gmo-compass.org/eng/home/

[21] Small amounts of GM maize cultivation also took place in a number of other countries, see Table 3.1.

[22] Small amounts of GM maize cultivation also took place in a number of other countries, see Table 3.1.

[23] Commission Services report that OECD have explained that this database is no longer up to date since some countries have stopped reporting new GMO authorisations to the OECD.

Table 3.3: 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	10	4	21			1				36
Cotton	8	4	8							20
Flax/linseed	1									1
Papayas				2						2
Potatoes		14			6					20
Rice	2									2
Rose							1			1
Soybeans	8		1			1				10
Sugar Beet	2									2
Tomatoes								1	1	2
Vegetable marrow				2						2
Total	**47**	**22**	**30**	**4**	**6**	**4**	**14**	**2**	**1**	**130**

Key:

HT: Herbicide tolerant.

Bt: Insect resistant.

VR: Virus resistant.

F: Functionality, increased oleic acid content for soybeans and increased lysine content for maize/corn.

C: Coloration.

E: Reduced ethylene synthesis.

P: Reduced pectin degradation.

Source: OECD Bio Track Product Database[24].

As of 09 June, 2010, 31 GM events were listed on the EU register[25] for use in GM food and/or feed, including products undergoing renewal of authorisation, as follows in Table 3.4 (there were also two GM micro-organisms[26]):

[24] http://www2.oecd.org/biotech/default.aspx. Accessed 11/02/10.

[25] http://ec.europa.eu/food/dyna/gm_register/index_en.cfm. Accessed 09/06/10.

[26] Authorisation of GM microorganisms is regulated under Directive 90/219/EC.

Table 3.4: GM events authorised for food and feed in the EU by crop

	HT	***Bt***	**HT/Bt**	**F**	**Total**
Canola/oilseed rape	3				3
Cotton	2	2	2		6
Maize	3	5	9		17
Potato				1	1
Soybean	3				3
Sugar beet	1				1
Total	12	7	11		31

Key:

HT: Herbicide tolerant.

Bt: Insect resistant.

F: Functionality. In this case the potato contains an inhibited gbss gene responsible for amylase biosynthesis. As a result, the starch produced has little or no amylase and consists of amylopectin.

Source: EU register of GM food and feed.

The timing of EU authorisations is presented in Figure 3.4. 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.

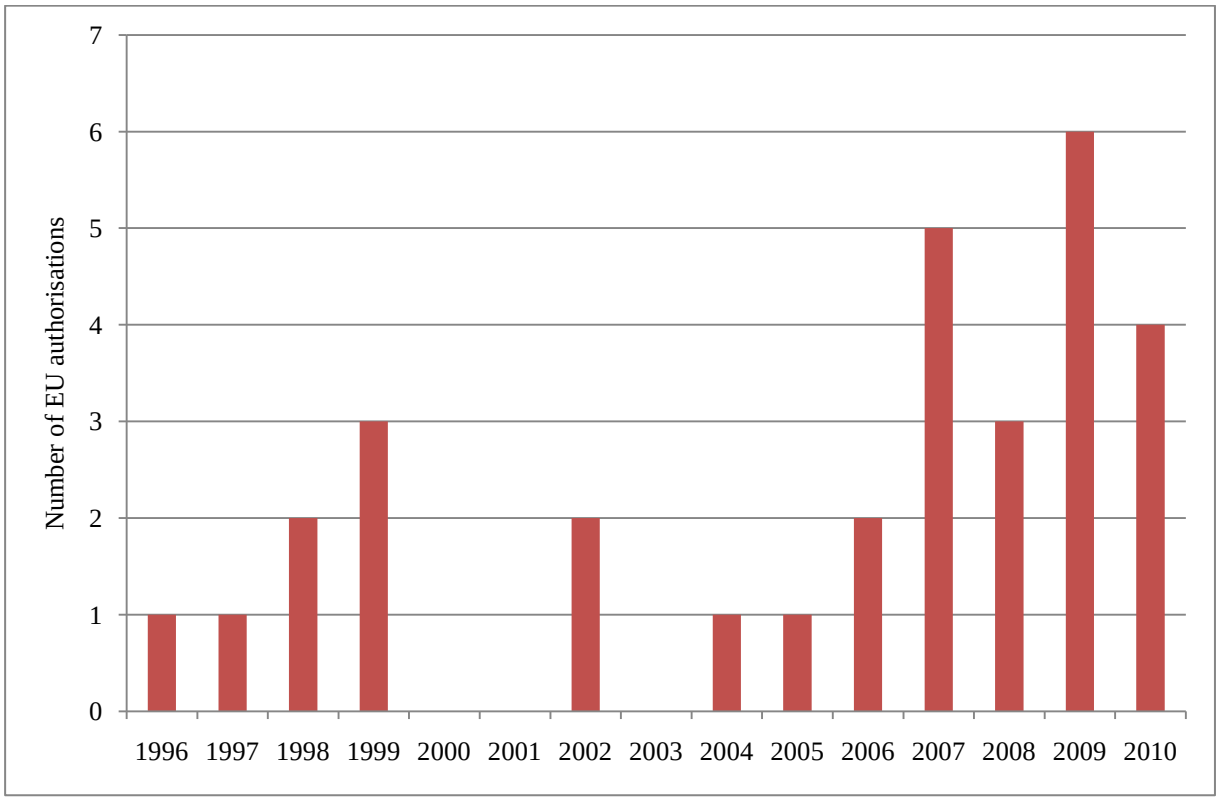

Figure 3.4: GM event authorisations in the EU by year

Source: OECD Bio Track Product Database and EU register of GM food and feed[27].

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. A study is currently underway under the auspices of DG Environment to examine the socio-economic impacts in more detail[28]. According to Gómez-Barbero and Rodríguez-Cerezo (2006a) 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, Gómez-Barbero and Rodríguez-Cerezo (2006b) conclude that the adoption of GM crops (both HT and *Bt*) generally results in net economic gains where they are cultivated, 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 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 by Buckwell, *et al* (1998).

[27] Commission Services report that OECD have explained that this database is no longer up to date since some countries have stopped reporting new GMO authorisations to the OECD.

[28] Tender ENV.B.3/ETU/2009/0010: Assessment of the economic performance of GM crops worldwide.

The penetration of GM events in the soybean and maize feed markets is set out in Table 3.5 for the year 2003/04. This Table has been adapted from the original source where the percentages given were actually for certified non-GM. This is important because the estimates of GM penetration which result are therefore over-estimations as some supply which is not certified as non-GM will be non-GM in any case.

That said, the situation for soybeans is consistent with industry views on GM market penetration where imports account for the majority of the EU market. This is not the case with respect to maize where the majority of the EU market is supplied domestically and, because GM maize is only grown in a limited number of EU countries, non-GM status will often not be specified in contracts.

For this reason, the source has been updated by the original authors to estimate the actual market penetration of GM maize (Brookes, 2010, pers. comm.). The Table shows that the proportion of GM soybeans in the EU is substantially higher than the share of GM maize. Estimations from Brookes, *et al* (2005) 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 3.5: Estimated use of GM soybean and maize in the EU (2003/04)

Product	**Total market size**	**GM market sizes (market size not required to be certified as non-GM)**	**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%
Total	*34.77*	*28.94-29.87*	*83-86%*
Maize			
Food and starch	8.97	0.45	5%
Feed	29.25	1.46	5%
Seed (for planting)	0.78	0.04	5%
Total	*39.00*	*1.95*	*5%*

Source: adapted from Brookes, *et al* (2005) which is based on PG Economics, American Soybean Association, Oil World sources and updated by the authors via personal communication with Brookes, G. (2010).

3.5. Consumer perceptions of GM

Consumer research suggests that EU citizens have differing attitudes towards different biotechnology applications. A 2005 Eurobarometer poll indicated that there is more support for pharmaceutical ("red") and industrial ("white") than for agricultural ("green") biotechnology. 55% of respondents supported nanotechnology, 52% pharmacogenetics and 50% gene therapy (all primarily "red" biotech). Significant support was also demonstrated for "white" biotech applications such as biofuels. In comparison, only 27% of EU citizens supported GM foods (Gaskell, *et al*, 2006). This was,

however, an increase since the 2002 poll in which 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. Gaskell *et al* (2006) identified two types of support for GM food: (1) outright support[29] and (2) risk tolerant support[30]. The level of total support (outright and risk tolerant) in 2005 varied from 74% in Spain to 12% in Greece (Figure 3.5).

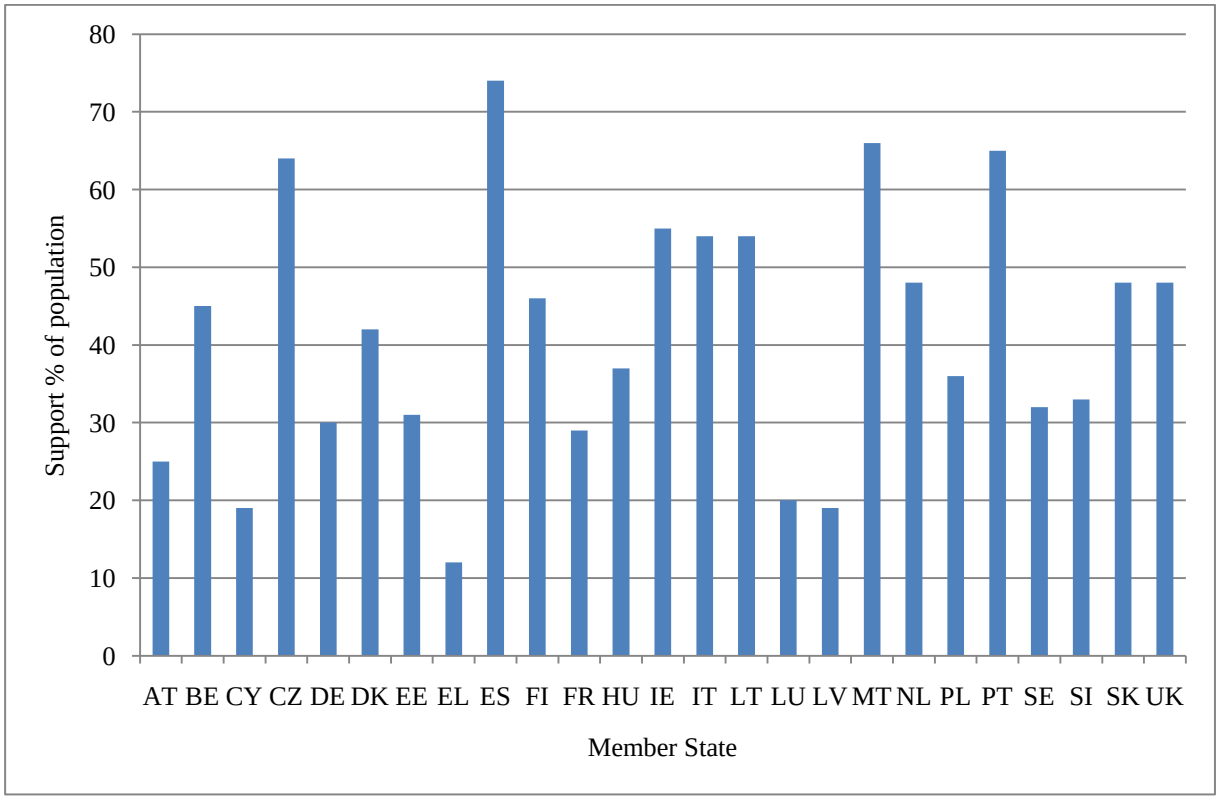

Figure 3.5: Support for GMOs across the EU

Source: Gaskell *et al* (2006).

While citizens are aware of GM technology[31], research in the UK suggests that UK consumers feel they have little actual understanding of GM foods (IGD, 2008). 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. To add to this lack of understanding, Kearton (2009) found in a 2009 survey that less than two-thirds (62%) of Welsh consumers knew that foods containing GM ingredients were on sale in the UK. This author also found that 34% of Welsh consumers are against the idea of buying GM food, whilst 24% think GM foods should be banned from sale in the UK. It is unclear whether this trend is EU-wide, or limited to the UK.

The issue of acceptance and controversy is explored further in EQ13, notably in EQ13A (section 8.1).

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

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

[31] According to Gaskell *et al* (2006), 80% of citizens were familiar with genetic modification.

4. Intervention logic

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.

4.1. 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 3.3, 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 4.1.

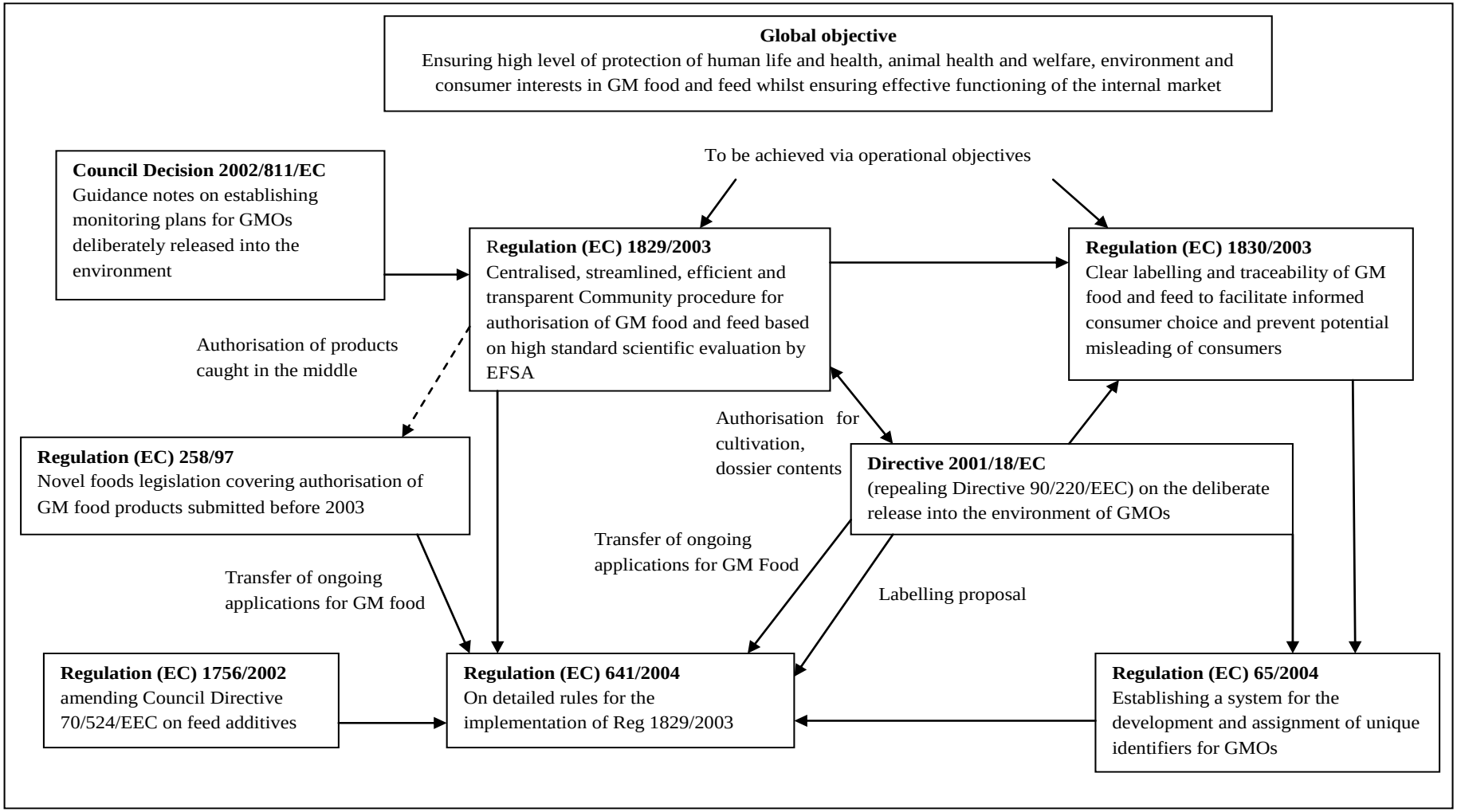

Figure 4.1: Interrelation of legislation related to Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003

4.2. 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 European Commission saw a need for further regulation in the GM food and feed 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).

4.3. 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 Union 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.

4.4. 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 products containing, consisting of or produced from GMOs with a tolerance of 0.9% provided that the GM presence is adventitious and technically unavoidable.

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 EU legislation;

b) food produced from GMOs, placed on the market in accordance with EU legislation;

c) feed produced from GMOs, placed on the market in accordance with EU legislation.

The Regulation does not apply to medicinal products for human and veterinary use authorised under Regulation (EEC) No 2309/93, nor to GM micro-organisms under contained use regulated under Directive 2009/41/ EC.

5. Overall objectives of the legislation and expected developments in the sector

This theme comprises five Evaluation Questions which are answered in the following sub-sections.

5.1. Acceptance of the objectives of the Regulation

The full title of this Evaluation Question is: *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?*

This answer is structured as follows:

- The needs of EU society.
- The extent to which the objectives of GM food and feed legislation are consistent with these needs.
- Acceptance of the objectives of Regulation (EC) No 1829/2003.

5.1.1. The needs of EU society

Our survey asked respondents to identify the importance of a range of societal needs (see 1.3.1 in the appendix). There was unanimous agreement amongst Competent Authorities and stakeholders that the provision of safe food is important or very important, and almost complete agreement that secure all-year-round food and feed supply are important or very important.

Affordable plant products for human consumption, food produced to high environmental standards and sustainable standards of production were also placed by both respondent groups in the top seven needs of EU society with respect to food and feed.

Over four-fifths of Competent Authorities and almost all stakeholders stated that fair standards of living for EU food producers, including SMEs, were important or very important needs of EU society.

Stakeholders held somewhat more negative views of the importance of food with improved functionality and the maintenance of food traditions compared with Competent Authority respondents.

5.1.2. The extent to which the objectives of GM food and feed legislation are consistent with these needs

Respondents were then asked the extent to which EU GM food and feed legislation is consistent with these identified needs. The vast majority of Competent Authorities believed that the legislation is consistent or very consistent with the aim of securing safe food (one Competent Authority did not agree) and just over three-quarters of stakeholders also agreed with this. In general, stakeholders believed the legislation was more inconsistent with meeting the food needs of EU society than did Competent Authorities. A majority of stakeholders stated that it was inconsistent or very inconsistent with providing secure all-year-round livestock feed supplies, mainly due to problems with asynchronous/asymmetric authorisation and LLP difficulties. A majority of stakeholders also saw the legislation as inconsistent or very inconsistent with a strong EU-based research and development sector, a fair standard of living for EU food producers, sustainable standards of production and food with improved functionality.

Table 5.1 shows where Competent Authorities and stakeholders diverge in their views and where they are in closer agreement (the "CA:S" difference), and their general ranking of legislation and its consistency with needs. In almost all cases, there was a disparity in percentage of consistent or very consistent responses, and the Competent Authorities consistently viewed the legislation more

positively than did stakeholders. The greatest differences between the groups were seen in responses to the question of whether the legislation was consistent with the need to secure all-year-round feed supply and the provision of a fair standard of living for EU food producers. Three-quarters of the Competent Authorities believed the legislation was consistent or very consistent with the former, compared with only just over a third of stakeholders. A quarter of Competent Authorities felt the legislation was inconsistent with the provision of a fair standard of living for EU food producers, although none found it very inconsistent, compared with just under two-thirds of stakeholders (of whom over half found it very inconsistent).

Stakeholders did not agree as much with Competent Authorities that the legislation was consistent with a strong EU research and development sector, sustainable standards of production or a secure all-year-round food supply. The only response for which there was a slightly more marked disparity in favour of stakeholders was in their views on how well the legislation was consistent with food production to high animal welfare standards; half of Competent Authorities, just under two-thirds of stakeholders.

Table 5.1: Views of respondents on consistency of legislation with EU society needs and comparison of Competent Authority and stakeholder responses

Need of EU society with respect to food and feed	Responses of "consistent" or "very consistent"		
	Competent Authorities	Stakeholders	CA:S
Secure all-year-round feed supply	75%	36%	+39
A strong [EU-based] research & development sector	63%	40%	+23
Sustainable standards of production	63%	41%	+22
Secure all-year-round food supply	72%	51%	+21
Food with improved functionality	60%	44%	+16
Affordable animal products	66%	53%	+13
Safe food	88%	76%	+12
Food produced to high environmental standards	72%	67%	+5
Affordable plant products for human consumption	60%	56%	+4
Fair standard of living for food producers inc. SMEs	37%	36%	+1
Maintaining local food traditions/food production	46%	49%	-3

Source: FCEC survey.

Interviews with Competent Authorities indicated different degrees of agreement on the question of whether the legislation's objectives are consistent with EU societal needs. One Competent Authority noted that ensuring safe food and feed and environment protection has been achieved, but that ensuring free movement of goods and an all-year-round secure feed supply has not been. In the case of all-year round feed supply, consistency was questioned due to problems of LLP and asynchronous/asymmetric authorisations (see section 6.9 in particular). Another Competent Authority stated that the need to conduct a risk assessment prior to issuing an authorisation could achieve a high

level of protection of health and the environment, but added that the assessment criteria needed to be improved.

One Competent Authority noted that the labelling provisions allow a good level of protection of consumers' interests, but in order to meet the expectations of a greater number of consumers, EU legislation should define the conditions under which statements such as "GM-free" may be used for plant and livestock products (see section 7.1). This harmonisation would also avoid problems of distorted competition and/or barriers to trade between Member States (see sections 7.8, 7.9 and 7.10).

Interviewed Commission Services agreed that the overall objectives for GM food and feed legislation remain relevant and that, in their opinion, implementation is sufficient to allow these objectives to be met (see section 5.2). Some problems with the implementation of the legislation were acknowledged, but these were not considered significant in terms of the ability to meet the legislative objectives.

5.1.3. Acceptance of the objectives of Regulation (EC) No 1829/2003

The objectives as set out in Regulation (EC) No 1829/2003 are to:

- provide a high level of protection of human life and health
- provide a high level of protection of animal health and welfare
- provide a high level of protection of the environmental
- provide a high level of protection of consumer interests
- ensure effective functioning of the internal market.

Our survey showed broad agreement with the stated objectives of the legislation, generally more so with regard to the Competent Authority sample than was the case among stakeholders (section 1.3.2 of the appendix). There was widespread agreement among the Competent Authorities with the first four stated objectives, although support for the effective functioning of the single market was weaker with more than 40% of Competent Authorities slightly agreeing with this objective rather than strongly agreeing.

Although at least 70% of stakeholders strongly agreed with all the stated objectives (and there was consensus amongst different types of stakeholders), a small proportion (less than 5%) did not agree with each of the first four objectives. The area of least agreement again related to the effective functioning of the single market with 13%, more frequently NGOs, not agreeing with this stated legislative aim.

Judgement

There is general agreement amongst Competent Authorities and stakeholders with the stated objectives of the legislation, although agreement is weaker in terms of the objective of effective functioning of the internal market, especially among stakeholders. In terms of consistency between the objectives of the legislation and EU societal needs, opinions were much more divergent between the groups. In general, the legislation is seen as answering EU society's needs for safe food and feed; however, stakeholders in particular do not believe the legislation offers a secure all-year-round supply of feed for livestock, or that it offers a fair standard of living for EU food producers. There are strong disparities between the agreement by Competent Authorities compared to that of stakeholders with regard to consistency of the legislation with a secure all-year-round supply of feed, a strong agriculture and food biotech R&D sector in the EU and sustainable standards of production; this in part reflects strong views on these issues by different types of stakeholder.

5.2. Implementation of the Regulation

The full title of this Evaluation Question is: *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?*

This answer is structured as follows:

- The extent to which implementation allows the objectives to be achieved.
- The approvals process.
- The labelling requirements.

5.2.1. The extent to which implementation allows the objectives to be achieved

Respondents to our survey were asked to compare the suitability of the current GM food and feed legislation against the previous system (see section 1.4.1 in the appendix). Two-thirds of Competent Authorities and 61% of stakeholders (disproportionately feed processors) felt that the current system represents an improvement. Eight Competent Authorities stated that the centralised procedure for authorisation was an improvement. Eight also explained that covering both GM food and feed within the same Regulation is more suitable. Other advantages of the current legislation compared with that before 2003 included the higher priority given to the protection of the environment, the obligation for manufacturers to provide detection methods and reference material and greater consumer choice through more consistent labelling. However, all types of stakeholders reported that the actual implementation of the legislation, and the fact that aspects of the risk management process are politicised, are problems with the current system.

Respondents were also asked about the extent to which the implementation of the legislation allows the legislative objectives to be met (see section 1.3.2 in the appendix). Fourteen Competent Authorities (56%) noted that the legislation fully enables a high level of protection for the environment and a high level of protection for human life and health. However, there was generally much less confidence in the implementation of the legislation to enable objectives to be met amongst the stakeholders. For example, technology providers and the food and feed industries commented on how the risk management part of the authorisation process, asynchronous authorisations and LLP problems hindered the realisation of some objectives, most notably the competitiveness of EU industries (livestock in particular) and trade. NGOs commented that the protection of human life and health is hindered as potential long-term health effects are not assessed and the risk assessment relies on the applicant's data.

Both Competent Authorities and stakeholders agreed that the implementation of the legislation was weakest in terms of enabling the effective functioning of the internal market with around a fifth of Competent Authorities and a quarter of stakeholder noting that implementation slightly hinders this and just over a fifth of stakeholders (but no Competent Authorities) claiming that implementation actively hinders the effective functioning of the internal market (however, no specific qualitative comments on the functioning of the internal market were provided). Interestingly, NGOs and consumer organisations in particular thought the current implementation hinders all objectives except the functioning of the internal market.

Examining responses at the most negative and positive ends of the survey, it can be seen from Table 5.2 that no Competent Authorities felt that the implementation of the GM legislation greatly hinders the achievement of the objectives; a small majority (just over half) believed that the legislation has fully enabled objectives of the protection of human life and health and animal health and welfare, as did slightly more than a third of stakeholders. A reasonable minority, about one third, of both types of respondents believed that the legislation fully enabled protection of the environment. Although almost

half of Competent Authorities said that the legislation also enabled protection of consumer interests, only a small minority of stakeholders (less than a fifth) agreed with this. The functioning of the internal market was not regarded as being fully enabled by most respondents.

Table 5.2: Comparison of responses on implementation

	Responses by type of respondent			
	Hinders greatly		Fully enables	
	Competent Authorities	stakeholders	Competent Authorities	stakeholders
A high level of protection of human life and health	0%	13%	56%	44%
A high level of protection of animal health and welfare	0%	10%	56%	35%
A high level of protection of the environment	0%	12%	36%	35%
A high level of protection of consumer interests	0%	20%	45%	16%
The effective functioning of the internal market	0%	21%	20%	14%

Source: FCEC survey.

Stakeholders from the food, feed and technology provision industries identified some legislative barriers in some Member States (section 1.3.2 in the appendix). The most commonly cited was the existence of national labelling provisions and "GM-free" labelling schemes, such as those in Germany. National bans, such as the Polish ban on feed imports in 2008 (effective from 2012) and co-existence measures were also cited as barriers by some respondents, although it should be noted that these related to cultivation and not food or feed. While not legislative barriers per se, several stakeholders identified Member State behaviour during the voting process and their overall political stance as obstacles in some cases.

Consumer organisations and NGOs believe that the legislation is fundamentally appropriate in theory, although it is considered that it has not been made operational in areas of long-term human or animal safety testing, long-term environmental testing or in labelling as a result of the omission of livestock products from the scope.

For industry, the main concerns with the legislation as a whole are slowness and uncertainty in the authorisation process and the effects of the zero tolerance policy for unauthorised GM material which results in LLP incidents. The implication of this is that the legislation is not fully operational in terms of providing access to secure year-round feed supplies. The legislation is seen by a Czech industry interviewee as dealing with two unconnected issues, health risk assessment and the pro/anti GMO debate, which are being artificially linked in the implementation. Zero tolerance and LLP for unauthorised GM events were noted by a technology provider as having an impact on consumer interests in terms of the pricing of EU produced livestock products. A European food and feed industry organisation said they had hoped that the "one door, one key" policy would have speeded up the authorisation process, stating that there is a blockage at the political level with the Standing Committee, Council and the Commission all needing to express their (not necessarily science-based) views.

5.2.2. The approval process

Survey respondents were also asked to comment on the extent to which specific elements of the authorisation process for GM food and feed are efficient (section 1.4.5 of the appendix). Although this is dealt with fully under section 6.3, this is relevant here because a lack of efficiency would compromise the achievement of the legislative objectives. This first point to note is that Competent Authorities generally find elements of the process more efficient than do stakeholders. The only exception to this is the use of the comitology procedure, although neither group finds this especially efficient in any case. Generally, elements of the process relating to EFSA are considered to be relatively more efficient than elements post-risk assessment. The only exception here is that stakeholders find Member State comments on risk assessment to be relatively less efficient, even though this forms part of the risk assessment rather than the risk management process.

Almost all interviewees believed the legislation had been made correctly operational for the risk assessment phase, with some constructive criticism. However, NGOs uniformly stated that the EFSA GMO Panel is not functioning properly, with comments such as "it is not independent" and "it does not listen to Member States". A Third Country interviewee believed that the major factors causing perceived ineffectiveness of the legislation lay with the risk assessment stage and EFSA, noting a lack of transparency, lack of support to the applicants and no possible dialogue as well as undue delays in regard to completeness checks, validations and the release of opinions, and a lack of communication from EFSA at scientific or political level with the country concerned.

Some of the perceptions presented above do not appear to accurately reflects the facts. Commission Services pointed out that EFSA is not forbidden from entering into a dialogue with applicants to clarify questions, but is reluctant to do this in case it is seen as being too close to the industry. EFSA added that staff are available for procedural questions or clarifications and that they can also assist on scientific issues once these have been addressed by the panel. Applicants can therefore discuss their application with scientific officers within EFSA's GMO unit. Applicants can not, however, have direct contact with experts on the GMO Panel. This is considered by EFSA to be pivotal in ensuring the independence of the Panel.

Competent Authorities generally regard EFSA's work in the risk assessment stage as very professional and scientific. However, one Competent Authority stated that the phrasing in EFSA opinions such as "a high probability that this GMO is safe for human health", i.e. without full certainty, ensures that elected politicians will always be against authorisation; such statements at the end of the risk assessment phase also provide arguments to NGO opposition.

Commission Services drew attention to some inefficiencies in the process, notably delays in the risk assessment stage resulting from applicant failure to provide sufficient data. It was, however, accepted that EFSA could sometimes do more to make its needs clear. They also highlighted some occasional difficulties in terms of following the arguments behind EFSA's conclusions. Commission Services noted the good and useful comments provided by Member States and acknowledged that it takes some time for EFSA to address these. The fact that further scientific points are raised for discussion at Standing Committee level arises because it is not possible for Member States to comment on draft EFSA opinions.

One Competent Authority commented on the clock-stopping during risk assessment necessitated because data from applicants is not precise enough, and suggested improved guidelines on data requirements and field trials. EFSA and Commission Services agreed with this point and noted that new guidelines are being prepared to address this. EFSA itself noted that it currently receives 12 to 15 applications per year and it is expected to be increasingly difficult to stick to the six month timeline for risk assessment in future because of the increased complexity and diversity of future applications; the time period for risk assessments may therefore need to be extended or additional resource provided.

Most industry respondents across all case study countries commented that overall EFSA performs well. The risk assessment stage of the approval process is thus regarded as operational by industry; a Competent Authority respondent noted that, in their view, EFSA is one of the best EU Agencies. A technology provider commented extensively on the operation of the process; in their view, EFSA could increase its speed of provision of opinions (this interviewee also felt that DG SANCO should reduce the time taken to draw up draft decisions for the Standing Committee). In order to speed up the risk assessment, EFSA could ask applicants questions in one batch at the start of the process instead of sequentially, since each round of questions posed by EFSA requires around three months by the time the applicant company has dealt with the response and EFSA has processed the new material (this presupposes that applicants provide satisfactory answers). Another suggestion to increase operational efficiency was for EFSA to have enough full-time risk assessors based in Parma.

Industry respondents from Greece regarded EFSA as being insufficiently transparent or satisfactory in terms of consumer protection; in their view the GMO Panel is seen as insufficiently transparent in terms of the selection of members and there is a view that too much regard is paid to industry-generated data. It was also mentioned that there are conflicts of interest because Panel members also work for the industry. However, in this context it should be noted that candidates for the GMO Panel are subjected to a vetting procedure which would not allow the appointment of scientists with vested interests (EFSA, 2007g). To make the system more fully operational, Greek respondents believe that Member States should be more involved in the choice of Panel scientists and EFSA should perhaps have the mandate to request and co-ordinate independent trial work.

In terms of the risk management stage, nearly all respondents, whether Competent Authorities or stakeholders, believed this was not fully operational. NGOs particularly stated that the European Commission is not fulfilling its role as risk manager, as it effectively takes all EFSA opinions as decisions through the use of the comitology procedure. Most adverse opinions and comments concerned the time taken for decisions to be made. Others referred to the difficulties of the comitology process. One Competent Authority stated that there is no need to shorten the procedure because a long approval procedure fits with this Member State's position vis-à-vis GMOs. Another Competent Authority stated that discussions within the Standing Committee are very democratic, but lead nowhere and are not conducive to decision making; there are too many national positions which are not based on science and too many questions that are unrelated to the case under discussion and are raised after EFSA's analysis in order to simply slow the process down (although see the Commission Service comment above on Member State opportunities to raise questions). Similar comments were made by another Competent Authority and by a Third Country interviewee, who added that the time taken to final publication of an authorisation was too long.

A couple of Competent Authorities highlighted the inability to deliver a qualified majority either in favour or against Draft Decisions and noted that this was one of the causes of asynchronous approvals. Commission Services explained that the comitology procedure works perfectly well in other areas and that the failure to reach a qualified majority is unique to the GM field. This may be because Member States do not want to take responsibility for what might be contentious decisions.

Asynchronous approvals are seen as a problem throughout the EU, even where the prevailing political view is against GMOs. Most interviewees agreed that this issue will get worse unless the authorisation process is accelerated. The use of a non-zero tolerance level for adventitious and technically unavoidable presence would facilitate the achievement of the objective of ensuring adequate year round supplies of feed. There is general agreement that the use of a non-zero tolerance level should only be for events which have either been risk assessed in the EU, or for events authorised in Third Countries for which the EU has accredited the risk assessment process. It was pointed out that there is no other area of legislation where there is absolute zero tolerance in terms of adventitious presence.

It was noted that many Member States hold a position on GMOs and always vote the same way, i.e. they do not treat each application on its merits. The voting position is now quite defined with typically 12-14 votes in favour and 12-14 against with a few switches and abstentions on a case-by-case basis; most Member States voting against will probably never vote in favour and vice versa.

On a practical note, one Competent Authority believes that the risk management process could be improved if documents could be received in advance of Standing Committee sessions and if more events could be discussed at each meeting.

There was support for the inclusion of socio-economic criteria during the risk management phase on two grounds: first, that it is useful to have a full debate for each approval; and second, that this will allow Member States to set out their positions more clearly. It was pointed out that GMOs authorised to date are not intended to provide a benefit to the consumer, or for the protection of the environment, and the balancing of these interests against the risks should be taken into account during the risk management phase. NGOs noted that the legislation does allow for the consideration of "other legitimate factors" under Articles 7(1) and 19(1) of Regulation (EC) No 1829/2003, although this opportunity has not been used in the authorisation process.

5.2.3. The labelling requirements

The survey asked whether respondents thought the legislation had supported the objective of protecting consumer interests, by which we understand the right to make informed purchasing decisions from a choice of food products, access to reasonably priced food and, of course, food safety.

In general terms 70% of Competent Authorities felt that the implementation of the legislation either fully or slightly enables the legislative objective of providing a high level of protection of consumer interests to be met, just under a fifth felt that the implementation of the legislation slightly hinders the achievement of this objective (section 1.3.2 of the appendix). Stakeholders were less positive with just over a quarter noting that the implementation of the legislation either fully or slightly enables the legislative objective to be met while just under a quarter felt that implementation slightly hinders the achievement of the objective and a fifth felt that the achievement of this objective is greatly hindered. It was noted by a number of Competent Authorities that consumer interests would be better protected if there was either "GM-free" labelling or if labelling scope were extended to cover livestock products (see section 7.7 for consideration of the consequences of such an extension).

In more specific terms, sixteen Competent Authorities (64%) and just over a fifth of stakeholders felt that the legislation had been positive or very positive in terms of providing consumer choice (but see section 7.4 and section 7.6), although the Danish Competent Authority pointed out that it is difficult to comment on the impact without more products on the shelves (section 1.4.7 of the appendix). Stakeholders were generally negative about the effect that legislation has had on consumer prices. Just over half of Competent Authorities felt that the legislation had been positive in terms of its impact on consumer awareness of GMOs; however, this view was shared by only a fifth of stakeholders. The impact of the implementation of the legislation in terms of consumer safety was considered positive or very positive by four-fifths of Competent Authorities and just over half of stakeholders, although NGOs and consumer organisations did not share this view, mostly regarding the impact as negative or very negative.

With respect to the labelling requirements of Regulation (EC) No 1830/2003 and their impact on protection of consumer interests, respondents were asked a series of questions on their perception of consumer understanding of labelling and the scope of the provisions (section 1.5.1 of the appendix). Three-quarters of Competent Authorities saw the current labelling provisions as easy for consumers to understand and almost all believed that the current labelling provisions facilitate an informed consumer choice. By contrast, only just over a quarter of stakeholders believed that the current labelling provisions were easy to understand and only slightly over half of stakeholders thought they

facilitated consumer choice. Slightly less than half of all respondents felt that consumers do not understand or accept the current labelling provisions. There is clearly a gap here between Competent Authorities and stakeholders in their views on some aspects of the labelling provisions, and potentially some work to do in communicating the meaning of the provisions to the consumer.

Some Competent Authorities, for example, those in France and Denmark, commented on the omission of livestock products from the positive labelling scheme. However, the Danish Competent Authority noted that although the Danish position when negotiating Regulation (EC) No 1829/2003 had been that livestock products should be labelled, the lack of labelling has not in fact raised questions. Responses by specific stakeholder group were roughly as expected. Generally speaking, consumer organisations and NGOs were more negative about the current labelling provisions, pointing to the lack of livestock product labelling as a loophole, and the 0.9% threshold for adventitious and technically unavoidable presence as a weakness.

Food industry and feed processor stakeholders were more positive, particularly with regard to facilitating choice and being easy to understand (feed processors), and avoiding the misleading of consumers and appropriate scope (food industry). Several food and feed industry respondents were against labelling where the presence of GM events cannot be detected (and also the extension of labelling to animal products). They also questioned whether consumers could make an informed choice given the small number of products on the market, a view shared by technology providers, who otherwise generally replied "don't know", reflecting their position in the supply chain.

One of the Competent Authority interviewees noted that one of the biggest challenges with the EU labelling legislation is that it applies to EU products only and does not need to be followed in the Third Countries that produce GM raw materials. This means that there is less incentive than there might be to maintain adequate segregation and identity preservation systems; further communication of EU legislative requirements to Third Countries may be needed.

Consumer and organic organisations from Austria, Germany and the Czech Republic believe that the labelling legislation has not been made properly operational because livestock products are omitted from the scope. In their view this issue should be addressed at the EU level to ensure harmonisation. NGOs also support the labelling of livestock products. A German NGO commented that labelling should be process-based to allow consumers to choose between products produced with and without GM technology and therefore it is appropriate that oil products fall within the labelling scope and inappropriate that livestock products do not. One Competent Authority explained that the scope of compulsory labelling should not be broadened beyond its current range since its enforcement would be very challenging.

The labelling regulations are mainly seen as operational by industry, with some important criticisms. One feed industry grouping noted that there is a perception problem with GM technology as a result of the application of the labelling requirements. Austrian, Belgian, German and Finnish industry respondents from the food and feed sectors were very concerned that the requirement for labelling food products derived from GMOs (for example, oil products) causes problems because it is not possible to test and there is therefore a potential for fraud and failure to protect consumer interests.

Finally, a German organisation involved in "GM-free" certification noted that the threshold for adventitious presence means that consumers will be under the impression that unlabelled products are free from GM material when this is not necessarily the case. A major food retailer would prefer negative rather than positive labelling in order to provide a clearer choice to consumers.

Judgement

The majority view is that the current legislative system represents an improvement on the previous situation, mainly as a result of the centralised procedure for authorisation and the coverage of food and feed under the same Regulation. Competent Authorities generally believe that the implementation of the legislation does allow its objectives to be achieved, although stakeholders were less confident about this. Both Competent Authorities and stakeholders agreed that the implementation of the legislation was weakest in terms of enabling the effective functioning of the internal market (however, no specific qualitative comments on the functioning of the internal market were provided), although NGOs and consumer organisations did not agree. Different stakeholders hold different concerns with consumer organisations and NGOs believing that the legislation has not been made operational in areas of long-term human or animal safety testing, long-term environmental testing or in labelling as a result of the omission of livestock products from the scope. The main concerns for industry relate to the slow pace of authorisation and the effects of the zero tolerance policy for unauthorised GM material, which results in LLP incidents that hinder secure access to year-round feed supplies.

Almost all interviewees believed the legislation had been made correctly operational for the risk assessment phase, with some constructive criticism. However, in terms of the risk management stage, nearly all respondents, whether Competent Authorities or stakeholders, believed this was not fully operational, mainly because of the time taken to reach decisions.

Competent Authorities generally feel that the implementation of the legislation provides a high level of protection of consumer interests, although stakeholders were less positive. It was noted that consumer interests may be better protected if the labelling scope encompassed livestock products (see section 7.7 for further detail). While Competent Authorities think that consumers understand the labelling provisions, stakeholders are not so sure and there may be a need for more communication on this issue.

5.3. The future development of the sector

The full title of this Evaluation Question is: *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?*

This answer is structured as follows:

- The expected factual developments in the sector.
- Consequences of expected developments for the EU.
- Benefits of expected developments for the EU.

5.3.1. The expected factual developments in the sector

The main factual developments expected as a consequence of the evolution of the sector are set out in the report produced by the Institute for Prospective Technological Studies of the JRC, which concerns the period 2008-2015 (Stein and Rodríguez-Cerezo, 2009). This anticipates:

- an increase in the number of Third Countries growing GM crops;
- an increase in the number of GM crops containing events that are designed for domestic markets and are therefore of regional, but not necessarily EU relevance. About half of new events by 2015 are expected to come from Asia and South America, referred to by the authors as Isolated

Foreign Approvals (IFAs); more recently these have become known as asymmetric approvals, reflecting the fact that these approvals may not be isolated; and,

- a greater number of stacked events in the major crops of interest to the EU (Stein and Rodríguez-Cerezo (2010) anticipate an exponential increase in the number of stacked events).

Stein and Rodríguez-Cerezo (2009) expect impacts to be of greater or lesser significance depending on crop, but overall to include:

- an increase in stacked events requiring authorisation, leading to a significant increase in workload in those parts of the world that regulate stacked events as new GM crops; this is likely to result in more asynchronous approvals;
- an increase in the likelihood of LLP as a result;
- an increase in problems caused by LLP arising from asymmetric authorisation, particularly of crops such as rice and cotton;
- an increase in rejections of imports as a result of LLP due to the existence of the zero tolerance policy;
- an increase in the economic risks of rejection of imported shipments as a result; and,
- a possible scenario in which exports are directed to countries with a less rigorous GM policy in terms of authorisation and approach to LLP, i.e. a non-zero threshold.

Clearly the prevalence of GM events in agriculture and consequently in world trade is increasing. The global area planted with GM crops increased to 134 million hectares in 2009 (James, 2009), an increase of 7.2% from 2008 (see Table 5.3 below and section 3.4) while the number of countries growing GM crops has increased to 25 (see Table 5.3 below and section 3.4). James (2009) expects to see at least 15 new countries to be planting GM crops by 2015 and a total global area planted of 200 million hectares, with GM rice, potatoes, sugarcane, cassava and pulses as well as the current GM commodity crops.

It should be recognised that James (2009) is an industry source rather than official data. However, it is clear from other sources including Stein and Rodríguez-Cerezo (2009) that stacked events are forming a greater percentage of total traits with each passing year: GM events with 4 stacked traits are currently entering the EFSA approval process (USDA FAS, 2009) and a GM maize with 8 stacked events, Monsanto and Dow's SmartStax™, which combines tolerance of two herbicides with multiple insect resistance genes, is expected to be commercialised in the USA in 2010 (Monsanto, 2009). In the near future, the major traits will remain herbicide tolerance, insect resistance and combinations of these, as Table 5.3 suggests. However, abiotic stress traits are close to commercialisation, and the joint BASF-Monsanto development of drought-resistant maize is expected to be commercialised in the USA by 2012, according to BASF (2009). It should, however, be noted that NGOs do not accept the industry's estimations of developments in the pipeline believing that there has been a track record of undelivered developments to date; in their view future GM events will largely comprise additional agronomic traits.

Table 5.3: Summary of evolution of GM crops worldwide 2005-2008

	2005	2006	2007	2008	2009
Area under GM crops (million hectares), of which:	90	102	114	125	134
HT	71%	68%	63%	63%	62%
Bt	18%	19%	18%	15%	16%
HT+*Bt*	11%	13%	19%	22%	21%
GM area by crop					
Soybean	6%	57%	51%	53%	52%
Maize	24%	25%	31%	30%	31%
Cotton	11%	13%	13%	12%	12%
Canola/OSR	5%	5%	5%	5%	5%
Regions and number of countries growing GM crops, of which:	21	22	23	25	25
N America	2	2	2	2	2
C&S America	7	7	8	9	10
Australia & Asia	5	5	4	4	4
Europe	6	7	8	7	5
Africa	1	1	1	3	3

Sources: After James (2009); James (2007); James (2006).

By June 2010, there were 26 single gene events undergoing the approval process in the EU (including renewals) and 22 authorisations for single events (including notification as existing products). In contrast, there were 24 stacked events undergoing the approval process (including renewals) and 9 authorisations (including notification as existing products) (Table 5.4). This clearly shows a trend to stacked events, and also reveals the workload that the EFSA GMO Panel faces that will at some point require treatment in the risk management phase to achieve authorisation (50 submissions within EFSA versus 15 available for discussion and decision in the Risk Management stage).

Table 5.4: Progress of applications through EU approval process (June, 2010)

GM crop submission	Stage of authorisation process								
	Application submitted / Renewal submitted / TOTAL			Risk Assessment report / Renewal of authorisation report / TOTAL			Valid authorisation / Notified as existing product / TOTAL		
Single events:									
Cotton	4	3	7	1	-	1	1	3	4
Maize	6	1	7	3	-	3	9	4	11*
Oilseed rape	2	-	2	-	-	-	2	-	2
Potato	1	-	1	-	-	-	1	-	1
Rice	-	-	-	1	-	1	-	-	-
Soybean	8	1	9	-	-	-	2	1	3
Sugar beet	2	-	2				1	-	1
Sub-total	***21***	***5***	***26***	***5***	***-***	***5***	***16***	***8***	***22***
Stacked events:									
Cotton	6	2	8	-	-	-	-	2	2
Maize	12	1	13	10	-	10	6	1	6**
Oilseed rape	1	-	1	-	-	-	1	-	1
Soybean	2	-	2	-	-	-	-	-	-
Sub-total	***21***	***3***	***24***	***10***	***-***	***10***	***7***	***3***	***9***
TOTAL	**42**	**8**	**50**	**15**	**-**	**15**	**23**	**11**	**31**

Note:

* two events are listed as having both valid authorisation and are notified as existing products.

** one event is listed as having both valid authorisation and is notified as an existing product.

Source: GMO-Compass, March 2010.

Stein and Rodríguez-Cerezo (2009) reported 33 **traits** approved and in commercial use worldwide in 2008 and predicted that there would be 122 by 2015. However, the OECD's Bio Track Product Database reported 130 **events** in February 2010[32] (see section 3.4 for a breakdown of these events by crop and trait) which suggests that the number of events will be considerably higher by 2015.

Cardy Brown & Co Ltd (2008), in a presentation to the European Sherpa Group on 10 October 2008, presented an outline of expected developments in soybean GM traits which indicates 24 new traits from 2009 over the following 10 years. Of these, 12 relate to composition, feed-nutritional and

[32] Commission Services report that OECD have explained that this database is no longer up to date since some countries have stopped reporting new GMO authorisations to the OECD.

processing characteristics, such as high oleic acid content, enhanced beta-conglycinin content, increased omega-3 fatty acid content or increased protein content. A major agrochemical and plant biotechnology company, BASF, sees yield and stress traits overtaking herbicide tolerance and insect resistance as the dominant traits by 2025, with feed-related characteristics almost as important in value terms as herbicide tolerance (BASF, 2009). Agronomic traits such as larger seeds, more seeds, more biomass and increased root biomass provide the basis for greater production efficiency. BASF is also developing GM plants with improved amino-acid profiles and omega-3 fatty acids, currently in proof of concept or early development stages. The company is at an earlier stage of development of high-oil GM crops for industrial use.

5.3.2. Consequences of expected developments for the EU

As a consequence of such developments and authorisations outside the EU, JRC-IPTS sees very strong short-term possibilities for LLP problems (Stein and Rodríguez-Cerezo, 2009). This is illustrated in Table 5.5.

Table 5.5: EU asynchronous and asymmetric approvals as sources of LLP

Crop	Asynchronous approvals	Asymmetric approvals	Total sources of LLP
Maize	6	5	11
Rice	1	4	5
Soybean	2	1	3
OSR/canola	0	1	1
Cotton	3	9	12

Source: After Stein and Rodríguez-Cerezo (2009).

What is particularly clear is that, of the events entering the regulatory process worldwide, according to Stein and Rodríguez-Cerezo (2009), a minority are fully approved or are undergoing approval in the EU (Table 5.6). Stein and Rodríguez-Cerezo (2009) note that there are well over 100 possible sources of asynchronicity and, as a consequence, many potential sources of LLP in the five main crops (soybean, maize, rice, OSR/canola and cotton).

Table 5.6: Events worldwide by crop, showing regulatory status in the EU (2008)

	Maize	Cotton	OSR/canola	Soybean	Rice
Global total, of which:	40	33	24	23	21
Approved or in renewal in EU	8	4	4	3	0
New events under assessment in EU	5	3	0	4	0
Pending a decision in EU	1	1	0	0	1
Planning to submit in EU	0	0	0	2	0
Not planning to submit in EU therefore potential sources of asynchronicity/LLP	26	25	20	14	20

Source: After European Commission (2009g).

EuroBiotechNews (2010) reports that the Chinese Agriculture Ministry's biosafety panel has now authorised field trials of GM rice containing the *Bt*63 event and commercialisation is expected in the next 2-3 years; four other types of GM rice and GM wheat are under development or in tests of productivity or field performance. According to the article, some commentators believe that up to 25% of the world's rice supplies could be GM in the relatively near future and that *Bt63* and similar insect and blight-resistant rice strains could bring an economic benefit of €3 billion per year. *Bt63* rice has already caused problems in the EU during its field testing in China, with LLP of this unapproved event resulting in food withdrawals in several EU Member States.

In 2006 and 2007, Dow AgriScience & Pioneer Hi-Bred's Herculex® maize and Bayer-Syngenta's GA21 maize caused disruptions to imports of maize to the EU from the USA and Argentina respectively; the maize events were authorised in the US but not the EU, leading to several LLP incidents. The result was a fall in maize and DDGS imports from the USA and additional costs for the EU's feed and livestock industries estimated at €1.575 billion in the 2007-2008 season (Cardy Brown & Co Ltd, 2008). This estimate includes the extra costs of sourcing substitutes for maize and maize by-products and costs of disruption and feed import restrictions. Another industry-funded study (van Wagenberg, 2009) concluded that the possible direct and indirect costs of an LLP incident in soybeans, such as that produced by presence of traces of unapproved maize events in soybean shipments in June 2009, could amount to between €1.1 and €8.4 billion in the six month period to March 2010, for the food and feed industry, depending on how much of the supply chain is affected. Assumptions include that a technical solution to zero tolerance is not found, that soybean crushing may have to stop in the EU and that all potential costs may or may not be transferred to the final food and feed prices; in addition, only time will have told whether these estimates are in reality too high or indeed whether the problem actually occurred.

5.3.3. Benefits of expected developments for the EU

Information provided in Stein and Rodríguez-Cerezo (2009) suggests that the benefits from the expected developments may encompass:

- those arising from the traits themselves such as access of EU food and feed chains and consumers to crops and crop products of enhanced nutritional composition, including fatty acid and oil profiles and amino-acid and protein content; and,
- those arising from supply-chain management systems, such as development of appropriate identification tests and institution of testing at ports of loading rather than ports of destination, which would reduce the risks of LLP in imports.

Backus, *et al* (2008) presents some possible benefits of GM crops, mainly in the context of cultivation, but including some comments on GM food and feed. The report suggests that GMOs can contribute to the production of food with better nutritional value or other health-giving traits, or by indirect routes, such as insect-resistant crops also being less affected by fungi associated with mycotoxin production. The production of food from crops with abiotic stress tolerance is also seen as contributing to food security and quality.

In relation to potential benefits, the Danish Ministry of Food, Agriculture and Fisheries recently issued a report supporting the use of GM crops for reduction of pesticide use, noting that GM crops have the potential to contribute to meeting the challenges of climate change and environmental damage as well as maintenance of food supply (Danish Ministry of Food, Agriculture and Fisheries, 2009a).

One topic not covered in the above analysis is the development of GM technologies for use in crops for the production of compounds destined for industry (and not for the food/feed chain). BASF's Amflora potato was mentioned in Stein and Rodríguez-Cerezo (2009) and has now been authorised.

This issue was brought up by respondents in relation to the aptness of the legislation to deal with such industrial and biofuels-orientated developments and is covered in more detail in section 5.4.

Interviews with Commission Services revealed that beyond 2015, there is an expectation that there will be GM wheat and considered that this will be a key development for the western world, in particular for Europe due to its regional importance as a crop. On a global level, rice is not a heavily traded crop, but it is important for certain countries, which is the reason for public sector research into GM rice in China, for example. Europe is reliant on rice imports (although not from China), which complicates the situation for the EU in terms of the potential for LLP arising from asymmetric authorisations.

Drought tolerance in cereals has been researched for a long time; Commission Services reported that, according to Monsanto, the current trait is first generation but it will be followed by second generation traits in 2-3 years and drought tolerance is likely to be combined with HT and/or *Bt* traits. Commission Services also noted the emergence of techniques of genetic engineering which cannot be detected in products. Field trials have been carried out on this material, for example resulting from cis-genesis techniques, or from the use of biotechnological techniques such as "reverse-breeding" that cannot be detected in the final plants. As COGEM (2009a) notes, the regulatory status of plants produced using these techniques is uncertain. Commission Services explain that this issue is currently subject to an exchange of views between the European Commission and Member State Competent Authorities under Directive 2001/18/EC in the framework of an *ad hoc* working group.

Judgement

The factual developments expected in the sector include an increase in the number of Third Countries growing GM crops, and an increase in the number of GM crops designed for their domestic markets (especially in Asia and South America) which are not likely to be for export. In the case of GM crops designed for Third Country domestic markets, it is unlikely that applications will be submitted to the EU. A greater number of stacked events in the major crops of interest to the EU is, however, also expected. These developments are likely to result in an increasing number of applications to the EU which is likely to result in asynchronous (and in some cases, asymmetric) authorisations and more frequent LLP incidents between the EU and Third Countries. This may result in the diversion of export crops to markets with less onerous GM legislation.

Benefits from future developments in the sector may encompass those arising from the traits themselves, for example, crop products of enhanced nutritional composition and those arising from supply-chain management systems. Other potential benefits may include a contribution to food security and quality, global reductions in pesticide use and contribution to meeting the challenges of climate change and environmental damage. Crops for the production of compounds destined for industry (and not for the food/feed chain), such as the Amflora potato (starch potato, EH92-527-1) that was recently authorised in the EU may become important and developments in drought tolerant crops and GM wheat are expected in the medium-term. The latter could potentially be of great interest in the EU where wheat is a major crop.

5.4. The extent to which the EU can access these developments

The full title of this Evaluation Question is: *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?*

This answer examines:

- Experience of the application of the legislation and related management tools such as tolerance thresholds to existing GM events, leading to expectations surrounding assessment and management of future GM events.
- Consideration of the relationship between the legislation and the biotechnology R&D sector that is producing GM events that might be of benefit to the EU.
- Relations between the EU and Third Countries in terms of regulatory management and trading.
- The relevance of the legislation to the possible economic, social and environmental effects of the authorisation of GM events.

5.4.1. Experience of implementation

Concerns about the aptness of the legislation to ensure that the EU can make use of the beneficial aspects of current and future GM developments tend to revolve around current and past experience of the impacts of asynchronous authorisations and rejection of imported seed and grain cargoes containing LLP of unauthorised GM events. The economic impacts have been estimated in both independent and industry-funded reports as being extremely substantial (see section 6.9). In addition, it is pointed out by Backus, *et al* (2008) that impurities or contaminations in traded commodities are difficult to avoid, and other food safety legislation allows certain unwanted materials to be present below a defined threshold (e.g. dirt, weeds or mycotoxins).

The Advisory Group "Cereals, Oilseeds and Protein Crops" presented a motion to the European Commission in September 2008 requesting urgent action on the application of zero tolerance to LLP of events "duly authorised" in Third Countries, specifically MON89788 soybeans, which the Group pointed out might be found at low levels in shipments of soybeans to the EU from autumn 2008 onwards (Advisory Group "COPC", 2008). Ultimately this event was authorised in the EU in December 2008, 10 months after EFSA had issued a positive opinion on it and some 33 months after the dossier had been submitted by the applicant (European Commission, 2010).

The European industry organisation COCERAL and Member State industry organisations such as the Swedish Food Federation and Swedish Meat Industry Association made a similar approach to the EU in 2009 as a result of the finding of unauthorised maize MON88017 and MIR604 in soybean cargoes, noting that the LLP was of events that had been positively risk-assessed by EFSA (FEDIOL, FEFAC, COCERAL and COPA-COGECA, 2009; Swedish Food Federation, 2009). Again, a rapid response was possible under the existing legislation and MON88017 and MIR604 were authorised in the EU in October and November 2009 respectively, 6 and 4 months respectively after the issue of the individual positive opinions by EFSA and 47 and 58 months respectively after original dossier submission.

The US authorisation approach, if it remains in place, will continue to pose problems compared with the current EU approach. The US definition of a stacked event is broader than the EU's and is described succinctly by Stein and Rodríguez-Cerezo (2009) as including plants with multiple-trait constructs in addition to plants hybridised conventionally from transgenic parents. In addition, stacked-gene crops are not regarded by the US FDA as requiring fresh regulatory oversight if the component events have previously been authorised, unless there is a specific reason to believe that the combination has some new characteristics in terms of the safety, nutritional status or other regulatory status of the resulting food. In such a case, the developer is encouraged (but not obliged) to consult the FDA (see section 3 of the appendix). In the EU, each stacked event crop is treated as a new submission for authorisation.

There are, however some signs that the USA is also recognising that its own legislation may not adequately cater for developments in Third Countries, either in identifying trends in development or coming to terms with how to handle LLP in imports. The main recommendations put forward by the US Government Accountability Office concern better linkage between the three agencies involved in

regulating GM crops, food and feed, USDA, FDA and EPA, in particular noting that FDA had proposed to require GM food developers to notify the agency before marketing products but at the time of the report had not finalised the proposed rule (US Government Accountability Office, 2008).

Respondents to our survey were asked for their views in terms of the aptness and adequacy of the current legislation to allow the potential benefits of future GMO traits to be realised in the EU. Table 5.7 summarises the results of the survey.

The future traits most often mentioned were those of nutritional composition (e.g. fatty acid, oils, or protein profiles) or abiotic stress (e.g. drought or salt tolerance). Nineteen Competent Authorities from the 25 which responded (76%) responded that the legislation is adequate or entirely adequate; in contrast, only 41% of stakeholders support this view. Four Competent Authorities (16%) believe that the legislation is inadequate; 38% of stakeholders agreed with this verdict, and a further 12% believe the legislation is entirely inadequate, i.e. 50% in total. Stakeholders clearly hold a more polarised position than Competent Authorities.

Table 5.7: The extent to which legislation is adequate with regard to food and feed to allow the potential benefits of future GMO traits to be realised in the EU

	Competent Authorities	**Stakeholders**
Entirely adequate	1 (4%)	8%
Adequate	19 (76%)	33%
Don't know	1 (4%)	8%
Inadequate	4 (16%)	38%
Entirely inadequate	0 (0%)	12%

Source: FCEC survey.

Different stakeholder groups had different attitudes towards the overall aptness and adequacy of the legislation. The vast majority of technology providers considered it adequate, commenting that the legislative framework in itself is suitable, but it needs to be correctly applied (see section 5.2 for a discussion on the implementation of the legislation). On the other hand, the majority of feed and food industry respondents considered the legislation inadequate in terms of allowing the benefits of future traits to be realised. The reasons given for this were: the long, unpredictable and burdensome authorisation process; national provisions and bans; and a lack of general provisions to encourage innovation. Finally, several NGOs considered the adequacy of the legislation to be irrelevant as, based on past experience, they believe it unlikely that radically new traits will be developed by the industry (the industry and the JRC-IPTS do expect such developments).

5.4.2. The relationship between the legislation and the biotechnology R&D sector

A small number of survey respondents (two Competent Authorities and 8% of stakeholders) did not agree that a strong research and development sector is an important need of EU society. The vast majority, approximately four-fifths, of both the Competent Authorities and stakeholders, did, however, believe that a strong research and development sector was important or very important. Just under two-thirds of Competent Authorities believed that the legislation was consistent or very consistent with achieving this, but only 40% of stakeholders agreed. This disparity is important in judging whether stakeholders regard the legislation and its tools as assisting indigenous GM development or not (see section 6.4 for further detail).

5.4.3. Use of Third Country risk assessments and treatment of stacked events

The possibility of using risk assessments carried out by Third Countries to accelerate access to developments from outside the EU was supported by one Competent Authority and just over a fifth of stakeholders, including the majority of feed processors and almost half of the traders. This difference probably reflects the relative responsibilities for public safety and communication of this.

Almost half the Competent Authorities supported the current treatment of stacked events, i.e. that they must receive assessment and authorisation even where the single events have been separately authorised; this position was supported by just over a fifth of stakeholders, mainly NGOs and consumer organisations. In contrast, over half of stakeholders and just under a fifth of Competent Authorities believed that stacked events should undergo a fast-track risk assessment (note that this does not imply a less rigorous process). A substantial proportion of these (three Competent Authorities and almost half the stakeholders) also suggested a fast-track authorisation process, i.e. the risk management phase. A small minority of stakeholders and one Competent Authority felt that stacked events should be automatically authorised if all the individual events had already been authorised singly in the EU. With the exception of consumer organisations and NGOs, stakeholder groups preferred fast-tracking of some kind.

5.4.4. Relations between the EU and Third Countries in terms of regulatory management and trading

With respect to relations with Third Countries, agricultural sector competitiveness and the operation of the supply chain, relatively high proportions of respondents from both groups noted that the impact of the legislation had been negative. Two Competent Authorities pointed out that in the case of Third Country trade this was because of the slow pace of EU authorisations and the zero tolerance for unauthorised presence. Another Competent Authority added that ultimately this would result in increases in consumer prices; they also noted that the current legislation has resulted in an increase in the legislative burden as a result of the need to track and trace GM material. There have been beneficiaries of the situation: one new Member State responded that the absence of GM products in their country had provided an export advantage. Two Competent Authorities explained that the segregation of agricultural supply chains has resulted in price increases for the non-GM segment.

Responses recording a negative impact were more marked among the stakeholders, where the proportion feeling that the legislation had had a very negative impact was substantial, only NGOs standing out as being less critical on this point. It should be noted that almost half of the Competent Authorities and a third of the stakeholders did not know what the impact of the legislation has been on consumer prices which suggests a degree of uncertainty or of difficulty in apportioning costs along supply chains; two Competent Authorities explicitly explained that they could not comment on the impact on consumer safety, choice or price because of the absence of GM labelled products from the market. Several stakeholders commented in the survey that the legislation has impacted negatively on the supply chain, increasing costs, affecting the willingness of Third Countries to supply the EU and in turn reducing the competitiveness of the EU livestock industry. A couple of stakeholders added that the legislation had impacted negatively on the public acceptance of GMOs.

In case study interviews, Competent Authorities tended to support the functioning of the legislation and its ability to manage developments, but agreed that there needed to be some action taken to reduce the impact of LLP incidents relating to events that had either received authorisations in Third Countries and/or had had a positive assessment by EFSA, but not completed the authorisation process in the EU. A Competent Authority noted that, with reference to Third Countries and the WTO conflict, the WTO did not question the legislative framework within the EU, just the application of the law, and that the Cartagena protocol also applies to GM plant material. The EU authorisation system therefore has to be accepted internationally, and increased co-operation within the framework of the

Cartagena Protocol could reduce the tensions due to differences between the different authorisation systems. They noted, however, that some major GM crop producing countries are not party to the Protocol (for example, US, Canada, Argentina and Australia).

Another Competent Authority regarded the probability of LLP incidents resulting from the large pipeline of new events as "non-negligible". They also stated that it is necessary to revisit the zero tolerance policy and to set reasonable parameters within EU law, in order to avoid trade disruptions. In particular, if an event is already authorised in the US and EU approval is sought, it was suggested that the EU could accept the US decision and allow the material at low levels, although no threshold was suggested. Levels accepted by other Third Countries could be used as benchmarks, and the threshold for acceptable LLP should take into consideration the worldwide trade situation. For events where EU authorisation has not been sought, a strict application of zero tolerance is necessary, and shipments should be rejected, since non-authorised products could carry risk.

The point was made that until now, GM crops have been cultivated mainly in the US, Brazil and Argentina, but in future they are likely to be more widely cultivated in other countries, most notably China. Without some action to deal with the LLP situation, the EU will tend to become more isolated, and the asynchronous problem will increase, with consequent political and economic impacts. These will be significant for some EU livestock sectors as some Member States are heavily reliant on imports of maize as well as for soybeans for feed, for example, Spain and Italy. According to the Competent Authorities in Spain, internal calculations (based on import volumes, production rate of feed and the composition of primary materials) suggested that for Spain the effects are likely to be close to the worst case scenario set out in European Commission (2007c).[33]

A branch of the Commission Services explained that, with regard to the LLP problem, there appear to be two potential non-technical solutions: either set a tolerance level (based on consultation with Member States and stakeholders) and/or use the mutual recognition concept for risk assessments, an approach used in other fields such as in relation to imported meat, live animals and various other goods. There is also the possibility of a technical solution[34] which has been under consideration by the European Commission since 2008 and should soon be revealed. However, in the absence of concrete information on the proposed approach, the industry have doubts as to whether such an approach will be capable of presenting a long-term solution to the problem.

Other Commission Services explained that there is an EFSA guidance document on how to handle stacked events combined through conventional crossing which is available on EFSA's website, and that there is actually a simplified approach for risk assessment of stacked events where the single events have already been assessed in the EU. Under this procedure, the risk assessment of stacked events combined by conventional crossing should focus on stability, expression of the events and potential interaction between the events (on the grounds that the single events have already been positively risk assessed). In addition, in the case of multiple stacks, the risk assessment of stacked events can also be applicable to GM stacks containing fewer of these events. Thus a single risk assessment of such a stack could cover all combinations with fewer of these events. However, applicants need to provide a scientific rationale justifying that there is no need for experimental data obtained for the concerned GM stacks containing fewer of these events or they have to provide the experimental data. Some 45% of recent applications have been for stacked events.

[33] Under the worst case scenario, it was estimated that there would be a 25.7-32.3m tonne shortfall of soybean meal equivalent at an EU level, with knock on effects on EU production and the prices of livestock products. Please refer to the original report for full details.

[34] The technical solution under consideration is the definition of a technical zero, along with the recognition of testing methods.

5.4.5. Relevance of the legislation to the possible effects of the authorisation of GM events

Further Commission Service comments include concerns that the current GM legislation is not adequate to reap the benefits of potential GM events with environmental benefits because the authorisation process focuses on risks and no account is taken of any potential benefits; the current legislation is clearly focused on protection. Other parts of Commission Services believe that appropriate guidelines would allow new developments to be adequately dealt with and pointed out that Articles 7(1) and 19(1) of Regulation (EC) No 1829/2003 currently allows for "other legitimate factors" to be considered.

Concerns were also raised in terms of new GM technology where the techniques of genetic engineering cannot be detected in the product. However, the point was made that the EU legislative approach focuses on the process and not the product and therefore these techniques will technically fall under the auspices of Regulation (EC) No 1829/2003. While this approach has up to now been logical because genome modifications created "molecular novelties" which introduced new DNA sequences which can be easily detected, gene-specific mutagenesis poses the problem that there is not the same extent of "molecular novelty" and the results may not be different from those that can be obtained via traditional breeding or the use of random mutagenesis. Even if it is possible to detect the modification, it will not be possible in certain cases to determine whether the modification was based on "old" or "new" procedures.

Another main difficulty concerns the "epigenetic effect" techniques that influence the expression level of genes of interest. Here the genome is not modified, but the level of expression of the existing genes is changed, possibly by gene silencing or by gene promotion enhancement. These techniques cannot be detected using routine techniques so, if the current Regulations are applied, detection may not be possible at an affordable price. Commission Services explained that there is a working group within DG Environment reviewing this topic. The results will be made available to EFSA with a view to identifying and defining new methodologies and characterisation methods, and this will help develop appropriate guidelines. In addition, the JRC-IPTS is currently collecting information that will provide a horizon-scanning of developments in GM technology.

Food and feed chain operators consider, on the whole, that the current legislation is not appropriate for managing new developments and realising their benefits. Some farmer organisations believe strongly that benefits should be considered in addition to risks in the pre-authorisation evaluation process. These should include potential input reductions, for example, pesticides and carbon footprint (the interviewee noted that "organic" food does not have a favourable carbon footprint, see also Foster, *et al*, 2006).

The biotech industry believes that the current system prevents SMEs from making applications in the EU because of the cost and the authorisation delay before the event can begin paying back its development costs (see also section 6.3 and Schenkelaars Biotechnology Consultancy, 2008). The interviewee explained that there are more SMEs in the biotech sector in the US where the cost of submitting an application is lower and the authorisation process quicker.

A feed chain operator considered that the current EU legislation was designed mainly to deal with the first generation of GMOs with agronomic traits; however, the first GM events with output traits are expected on the market in the relatively near future, which means that communication of the consumer benefits will become much more important. The process rather than product-based approach (see above) is perceived by this interviewee to have created suspicion around the technology and this barrier will be hard to overcome. Another feed industry respondent expressed frustration that the authorisation procedure appears to always lag behind market developments.

The food and chain perceive the biggest problem with the current legislation to be the zero tolerance policy for unauthorised events which is likely to become more severe as more events are authorised globally (see section 6.9). The fact that Japan operates a tolerance level for adventitious presence of unauthorised GM material of 5% and Switzerland a tolerance level of 2% was noted. The EU's import requirement for vegetable protein in the feed sector means that it is considered necessary to find a solution to this problem. *En passant*, they also comment that there should also be some tolerance level for low level adventitious presence in seeds.

Judgement

Concerns about the aptness of the current legislation to ensure that the EU can make use of the potential beneficial aspects of current and future GM developments (in the food and feed arena) tend to revolve around current and past experience of the impacts of asynchronous authorisations and rejection of imported seed and grain cargoes containing LLP of unauthorised GM events.

Increasingly, stacked events are expected to be marketed and this will put pressure on the EU authorisation process under which stacked events are treated as new events, unlike in the US where stacked events are automatically authorised where the single events have already been approved. The implication of this is an increased gap between EU and US authorisations which is likely to exacerbate current LLP problems, should the EU continue to import grain for food and feed from the USA and from other Third Countries utilising the same technologies and similar regulatory approaches.

There is an expectation in the industry and amongst Commission Services (although not necessarily shared by NGOs) that a range of new traits will be delivered to the market in the near future. Competent Authorities are much more confident than stakeholders that the current EU legislative framework is apt to ensure that the EU can make use of these new developments. Interestingly, biotechnology providers are more likely to consider the legislation apt (if not effectively implemented) than are food and feed chain operators, perhaps because this latter part of the chain is very concerned about the zero tolerance policy in relation to the LLP of unauthorised GM material. There is, however, little support among Competent Authorities or stakeholders to allow Third Country risk assessments to be used in connection with LLP. That said, stakeholders feel that there is an urgent need to find a solution to the LLP issue and this is shared by many Competent Authorities, especially those from Member States with a high demand for imported livestock feed. The European Commission is considering a technical solution to the LLP issue. However, in the absence of concrete information on proposed approach, the food and feed chain do not feel that a technical solution to this issue will be effective in the longer-term.

5.5. Capturing benefits in the context of regulatory approval

The full title of this Evaluation Question is: *How could the potential benefits [of evolution in the sector] be measured and integrated in the context of the regulatory approval?*

There are two points to consider here. One is specifically whether socio-economic assessment should be introduced, which is an aspect of measurement, and the other is whether accepting Third Country risk assessments can and should be integrated into the authorisation process.

5.5.1. The potential use of socio-economic assessments

Socio-economic assessment has been the focus of recent activities in the EU. Although the main driver behind this has been consideration of cultivation of GMOs in the EU, which is outside the scope of this evaluation, the discussion has extended to questions relating to imports, which has some relevance to GM food and feed.

On 4 December 2008, the "Environment" Council adopted conclusions that relate to socio-economic assessment of GMOs as follows (Council of the European Union, 2008):

> "*[The Council] POINTS OUT that under Regulation 1829/2003 it is possible, under certain conditions and as part of a case by case examination, for legitimate factors specific to the GMO assessed to be taken into account in the risk management process which follows the risk assessment. The risk assessment takes account of the environment and human and animal health.*
>
> *INVITES the Member States to collect and exchange relevant information on socio-economic implications of the placing on the market of GMOs including socio-economic benefits and risks and agronomic sustainability, by January 2010.*
>
> *INVITES the Commission to submit to the European Parliament and to the Council the report based information provided by the Member States by June 2010 for due consideration and further discussions.*"

The main driver for this appears to be the cultivation of GMOs and not the placing on the market of food and feed containing, derived from or made using GMOs. Whilst this evaluation has been underway the European Commission has been preparing its report on the use of socio-economic criteria within the GMO authorisation process; this report is now expected in October or November 2010.

The Netherlands Government, following up its request for Member States to be given full authority to decide on cultivation of authorised GMOs in their own territories (Government of the Netherlands, 2009), held a conference in the Hague in November 2009[35] and took the opportunity to add consideration of socio-economic assessments to the agenda. Discussion of the elements concerning cultivation is outside the scope of this report, but it may be noted that the Dutch Government stated that the question is no longer whether we want to allow the cultivation of GM crops in the EU, but how. Human and environmental safety is the primary concern, but there must also be room for the assessment of the socio-economic impact of GMOs. In a report on socio-economic aspects of GMOs, COGEM, the Dutch advisory body on GM matters, developed a list of criteria that might form the basis for assessment of food and feed derived from GM crops (COGEM, 2009b):

- benefit to society: for example, yield increases or food quality improvements;
- economics and prosperity: such as increased employment and productivity;
- health and welfare for workers: the local population and consumers;
- local and general food supply: which should remain at the same level or improve;
- cultural heritage: to the extent desired, specific elements of cultural heritage or local customs should be preserved;
- freedom of choice: both consumers and producers should be able to choose between GM and GM-free products;
- safety: in terms of both personal health and the environment;
- biodiversity; and,
- environmental quality.

[35] Reported in Ministry of Agriculture, Nature and Food Quality and Ministry of Housing, Spatial Planning and the Environment (2009).

During this conference, the Director General for the Environment noted that criteria for socio-economic assessment must be "verifiable and transparent, in order to avoid discretionary and arbitrary decision". The Conference Report (Ministry of Agriculture, Nature and Food Quality and Ministry of Housing, Spatial Planning and the Environment, 2009) notes that, during a subsequent workshop on innovations in agriculture, it was agreed that the concept of socio-economic criteria is worth exploring, provided they are credible and independently verifiable; participants in discussion suggested that ISO-certification can enhance this credibility, but warned that socio-economic criteria should not further increase costs for stakeholders, since this leads to further concentration of expertise amongst producers, shutting out smaller firms and limiting diversity and freedom of choice. A ministerial round table of ministers and representatives of 13 EU Member States was also held during this conference and the proceedings and outcome are summarised in Ministry of Agriculture, Nature and Food Quality and Ministry of Housing, Spatial Planning and the Environment (2009). Although most of the conclusions relating to socio-economic criteria stem from considerations of cultivation of GMOs, conclusions relevant to the application of socio-economic criteria to GM food and feed included the following:

- Some participants pointed to the generally negative public opinion on GMOs in general. In this regard it was suggested that consumers should be made more aware of the thorough scientific risk-assessment that underpins market authorisations of GMOs.
- Several participants agreed that a further analysis of socio-economic consequences of GMOs, including possible adverse effects, but also socio-economic benefits and opportunities to stimulate innovation, would be worthwhile. In that regard, it was recommended to promote independent socio-economic and agronomic impact studies of GMOs. Furthermore, involvement of all affected stakeholders in the discussions on this issue was considered essential.
- Views diverged as to whether and how socio-economic aspects could be included in EU policies and authorisation procedures. Some participants were in favour of including such aspects, although others expressed reservations, pointing for instance to a possible increase in administrative burdens or complicating the process of authorisation.
- Some participants considered that appropriate and transparent methodologies for the assessment of socio-economic criteria might be required.
- Also, any efforts in the context of socio-economic aspects should not jeopardise the scientifically-based risk assessment procedure.
- Some Ministers and representatives pointed out that the relevance of specific socio-economic aspects can differ between Member States.

It remains to be seen how far these suggestions will be transferred from the sphere of GMO cultivation to GM food and feed.

Respondents to our survey were asked whether they thought that socio-economic criteria should be considered within the EU authorisation process. More than half the Competent Authorities and almost three-quarters of the stakeholders thought that they should not be i.e. there is majority support for the *status quo*. Some respondents insisted that socio-economic criteria were already in use in the discussions about GM events at Standing Committee level, since Member States applied political and consumer arguments to each case. However, among the stakeholders, all NGOs stated that socio-economic criteria should be used and livestock production organisations also tended to support this position.

In contrast, approximately half of industry representatives interviewed during the case studies were in favour of introducing a socio-economic assessment, but there was no consensus about how this should be done. Austrian respondents were strongly in favour and wanted to see clear rules for which criteria

might be used. Case-by-case assessment, by a body separate from both the risk assessment and risk management bodies was recommended by a French food industry interviewee. A French grain/feed industry respondent noted that socio-economic criteria are not health issues and therefore should be integrated into the current risk management process, rather than the risk assessment element (a point also made by NGO survey respondents). Belgian interviewees thought that benefits, not just risks, should be evaluated, but that there should be a Community position on cost-benefit approaches.

Survey respondents who thought that socio-economic criteria should form part of the authorisation process were asked to specify up to five criteria to use. Three of the Competent Authorities and a number of stakeholders took this opportunity and the criteria they suggested between them can be summarised as follows. There was little consistency between the Competent Authorities and it should be noted that some of the criteria can be thought of as reflecting potential benefits while others reflect potential costs (all listed criteria were mentioned more than once):

- economic impact on non-GM/organic farmers and food chain (including co-existence) and on farmer incomes;
- agronomic impact such as yield; agronomic functionality, drought tolerance; energy requirements);
- environmental effects (on the cost side these should have been covered under EFSA's risk assessment);
- impacts on local economies such as on resources, non-farm activities and other impacts;
- nutritional value/functionality of food;
- safety concerns in terms of consumer trust (the issue of known risk versus uncertainty and general safety should have been covered under EFSA's risk assessment);
- sustainability of agricultural practices including pesticide usage;
- availability in terms of matching supply to demand;
- effects on seed production, both generally and non-GM plant breeding;
- impacts on non-EU farms; and,
- impact on public acceptance.

Various other criteria were mentioned by individual Competent Authorities and stakeholders, including regional conditions, farmer acceptance and independence, price, public confidence in the approval process, fair trade, protection of local and traditional products and commodity price effects. Case study respondents added that ethical criteria such as "not grown on land from the Amazon forest", or compliance with the "Round Table for Responsible Soya" should be used.

Case study interviewees who were not in favour of the use of socio-economic criteria (typically from France and Belgium) stated that socio-economic criteria are not applied to other innovations in agriculture and there is no basis to treat GMOs differently. The difficulties of establishing adequate criteria were also noted as reasons not to introduce socio-economic assessment by many of the industry respondents. One French agricultural producers' organisation stated that the use of socio-economic criteria would add further barriers to authorisation and would not solve the real issue which is a lack of public acceptance. The development of the additional national tier of assessment carried out by the HCB in France, with the scientific committee on the one hand and the move to have a socio-economic assessment on the other, was put forward to highlight that the introduction of socio-economic criteria would complicate the EU assessment process. According to this interviewee, this complication will remain as long as the debate is based on political considerations.

Other industry respondents stated that socio-economic criteria have so far always been used negatively and therefore the selection of criteria will be critical if these criteria are to genuinely consider potential benefits as well as costs. Another interviewee added that agreement on such complex criteria was hardly likely since there is little agreement with the more measurable facts of the risk assessment. The point was also made that a socio-economic assessment would add delays in the authorisation process. The R&D interviewee believed that it would be much better to do a post-market analysis, although this would not be able to feed into the authorisation process. A French grain/feed interviewee thought that the farmers and supply chain should decide whether the technology is of value or not, also noting that what is an advantage or benefit in one country could be a disadvantage or cost in another, so that socio-economic aspects are of national or even regional dimension, rather than applying equally across the EU.

One Competent Authority noted that although the facility to consider "other legitimate factors" already exists, the current focus of the legislation is on risk assessment and management and the use of specific socio-economic criteria would allow a better appreciation of the overall advantages and disadvantages of submitted applications. This point was reinforced in the case study interviews which, it should be noted, took place largely before the Hague conference.

Another Competent Authority explained that, as far as the EU is concerned, there is a need for the benefits from GM events to be made clearer, but this was not linked to a specific call for socio-economic criteria to be added. Another saw the issue of whether to consider socio-economic criteria as still being a matter for discussion. Another expressed support for the Environment Council conclusions (Council of the European Union, 2008) and though that the use of socio-economic criteria would lead to a better appreciation of the advantages and disadvantages of specific GMOs.

In June 2008, the Haut Conseil des Biotechnologies in France was charged with defining a methodology to lead to the recommendation and the definition of socio-economic criteria to be included in any evaluation of GMOs. The criteria to be listed should be both European and National ones (i.e. relating to cultivation) and should cover all the food supply chain segments, not just technology providers and users of technologies.

NGOs and organisations involved in "GM-free" labelling schemes supported the inclusion of socio-economic criteria in the authorisation process, arguing that the use of GM technology should be seen within a broader context. They agree that it is not yet clear how this could be done, or what the criteria should be. There is recognition that the use of socio-economic criteria could be very complicated, for example where there are indirect effects such as those caused by displacement of cultivation (for example, the introduction of GMOs in certain Third Countries in environmentally sensitive areas).

Commission Services recalled that the current legislation allows the use of socio-economic criteria under Articles 7(1) and 19(1) of Regulation (EC) No 1829/2003, although not under Directive 2001/18/EC. However, there is no definition of "legitimate factors". It was noted that it would be difficult to define a uniformly accepted battery of criteria, but using socio-economic criteria includes consideration of any potential benefits. Consideration of benefits might make the process less controversial and might therefore be beneficial in terms of improving public acceptance of GMOs. Commission Services expressed a degree of concern that providing authorisation based on benefits might be perceived as a positive endorsement which is not the role of the regulator.

Some stakeholders offered support for the use of socio-economic criteria, partly because this would help to understand Member State positions more clearly and because it would introduce potential benefits into the consideration. Most Austrian respondents were in favour of adding socio-economic criteria and noted that the general rejection of GMOs by Austrians should be taken into account. Some Austrian stakeholders explained that the current EU legislative approach is based solely on

science and the operation of the single market and Austrian citizens wish to have their ethical concerns taken account of[36].

5.5.2. The potential use of Third Country risk assessments

Acceptance of Third Country risk assessments by the European Commission and Member States might be a way of gaining more rapid access to developments in the sector, provided that the risk assessments are adequate enough to satisfy the requirements of EFSA's GMO Panel. This approach could range from complete acceptance of Third Country Risk Assessments, which would seem unfeasible in the current regulatory framework in the EU; or acceptance of those risk assessments carried out to acceptable standards (for example, following Codex Alimentarius guidelines), which would seem negotiable by the European Commission on a bilateral basis with Third Countries exporting GM seeds, food or feed; or use of Third Country risk assessments in cases where unauthorised (in the EU) GM crops that have received a positive EFSA opinion are the cause of an LLP incident, which has already taken place at least at Member State level, to determine the degree of response needed to an incident (see LLP case study).

Some survey and interview respondents are in favour of the use of Third Country risk assessments in the context of potential LLP problems, including industry and competent authorities. Suggestions included accepting selected Third Country risk assessments, agreeing reciprocity in terms of risk assessment with major Third Countries, performing a combination risk assessment between EU and Third Country authorities or accepting Third Country risk assessments as long as they are based on studies conducted according to Codex Alimentarius guidelines. Other interviewees are against any use of Third Country risk assessments on the grounds of potential lack of reliability and trustworthiness; opponents state that the procedures in Third Countries are less stringent than in the EU. This is regarded as especially the case for the USA because of the voluntary nature of the regulatory oversight of FDA with regard to food and feed, once USDA has determined that the genetic techniques used in a GMO plant have not created an agricultural or environmental hazard. NGOs as a group are strongly against the acceptance of Third Country risk assessments.

Stein and Rodríguez-Cerezo (2009) note that participants in their workshop on the global commercial pipeline of GM crops proposed mutual recognition of risk assessments and adoption of the Codex Alimentarius guidelines. FAO held an e-Conference for developing and transition countries which may become sources of asymmetric authorisations in future[37]. Participants in this e-Conference regarded the Codex Alimentarius guideline on GM foods (Codex Alimentarius, 2003) as being highly relevant to developing harmonised GMO regulations.

COGEM (2009a) suggests that the Cartagena Protocol could be used to overcome difficulties in making use of benefits of developments in the sector that might arise from the use of new techniques that are not detectable in the final crop or seed, but which nevertheless may fall, or be taken by individual Member States to fall, within the definition of a GMO. The Cartagena Protocol, which has been enacted in the EU through Regulation (EC) No 1946/2003, states that a living modified organism is one that possesses a novel combination of genetic material; ergo, if a crop or seed does not contain novel genetic material, it can be interpreted that it is not a GMO. COGEM (2009a) propose the Cartagena Protocol as the basis for building a consensus between Third Countries and the EU.

[36] Brook Lyndhurst (2009) notes that ethical concerns are a significant barrier to acceptance.

[37] Regulating GMOs in developing and transition countries: http://www.fao.org/biotech/conf9.htm. Accessed 24/03/10.

Judgement

Following Council of the European Union conclusions of December 2008 and the conclusions of a Ministerial round table in November 2009, the European Commission will report on the use of socio-economic criteria within the GMO authorisation process by October/November 2010. Although the main driver of this is cultivation and the desire of Member States to move ahead or not at the national level, there are potential implications for GM food and feed.

Our survey, interviews and case studies have demonstrated that there is no consensus in terms of whether socio-economic criteria could and should be used in connection with GM food and feed. As a general principle it seems that groups with a known anti-GMO stance tend to be in favour of the use of such criteria while those more in favour of the use of GMOs tend to be against. This suggests that there is a view that socio-economic criteria will not facilitate authorisations. The consideration of "other legitimate factors" is already allowed for under Articles 7(1) and 19(1) of Regulation (EC) No 1829/2003, although there is no facility to consider socio-economic factors under Directive 2001/18/EC. There is a concern that considering benefits overtly in the authorisation process might be perceived as a positive endorsement which is not the role of the regulator.

There is no consensus on the acceptance of Third Country risk assessments as a way of better-accessing benefits of developments in the GM crops sector for food and feed. Those in favour of their use in connection with potential LLP incidents suggested that Third Country risk assessments could be accepted if, for example, they followed Codex Alimentarius guidelines. Opponents state that the procedures in Third Countries are less stringent than in the EU and Third Country risk assessments are therefore unreliable. A third way is offered by those who suggest that the Cartagena Protocol might provide a mutually-agreed understanding of what is, and what is not, a GM crop, allowing harmonisation in this area.

6. The risk assessment and regulatory approval process

This theme comprises nine Evaluation Questions which are answered in the following sub-sections.

6.1. Analysis of the authorisation process

The full title of this Evaluation Question is: *To what extent has the authorisation procedure and its implementation ensured a high level of protection of human life and health, animal health and welfare, environment and consumer interest in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market?*

A "high level of protection" of human health/life and animal health and welfare was first explicitly mentioned in the White Paper on Food Safety (European Commission, 2000a). This document makes clear that assuring the highest food safety standards for EU citizens is a policy priority. To achieve this goal, a radical new approach was proposed, resting on three pillars:

- The establishment of an independent food safety authority (EFSA), which was considered by the European Commission to be the most appropriate response to the need to generate a high level of food safety. Providing policy and decision makers with science based risk analysis is a prime task of EFSA.
- A food safety legislation which was primarily seen as a response to food crises such as generated by BSE and dioxins. These crises were, at the time, diagnosed as resulting largely from poor co-ordination and integration.
- Consumer information: the implementation of all the measures proposed in the white paper should enable the food safety authority to be organised in a more co-ordinated and integrated manner, with a view to achieving the highest possible level of health protection.

Implementation of these policy orientations was to be driven by a few main principles, including: a science-based approach to risk analysis, the use of the principle of precaution in risk management decisions, transparency in the sense of public consultation, implementation of high standards, an integrated and co-ordinated approach and the responsibility of operators.

In a similar way, consumer interest can be defined by fulfilling several conditions such as: being offered a choice of safe and healthy food products and being provided with the necessary information to make informed choices.

The effective functioning of the internal market can be defined as conditions where there are no internal trading barriers or discriminating market or competitiveness restricting conditions on trade between Member States.

The procedure set out under Regulation (EC) No 1829/2003 is designed to meet all the above mentioned white paper requirements for the high level protection of human health and life, by:

- making authorisations dependent upon on a science-based risk assessment provided by EFSA in line with internationally recognised principles as set out, for instance, by the Codex Alimentarius[38];
- increasing centralisation and co-ordination at the EU level;
- including provisions and mechanisms for public consultation and information; and,

[38] Principles for the risk analysis of foods derived from modern biotechnology, CAC/GL-44-2003. Adopted in 2003, amendment in 2008 (WHO and FAO, 2009).

- making ample use of the precautionary principle (European Commission, 2000b).

The current EU legislative system is also considered to be the strictest and most stringent procedure in the world regarding risk assessment, tolerance level and conditions for putting on the market (European Commission, 2008g), as is also confirmed by our comparative study of selected Third Countries legislations (see section 3 of the appendix).

A potential effectiveness indicator of this policy is that, since 1996, no human or animal health problem related to GMO consumption has been reported, although some scientists have suggested that there may be unknown risks (for example, Pusztai, 2002). One interpretation of this result is that the EU science based procedure is indeed effective and achieves a high level of protection for humans and animals by preventing any potentially harmful product to be put on the market. Another interpretation is that this situation simply demonstrates that current GMOs actually present no risk and the whole procedure is disproportionate. Both interpretations were provided in our interviews, depending on the nature of the respondent. Our survey indicates that different groups have different views on the proportionality of the process with 70% of Competent Authorities and 60% of stakeholders of the opinion that the EFSA dossier completeness check is proportionate, whereas 70% of Competent Authorities and 45% of stakeholders think that the EFSA risk assessment is proportionate (see the survey appendix).

Environmental protection is a primary concern for GMO planting and cultivation, and is only secondarily related to authorisations for food and feed, albeit explicitly a part of the risk assessment procedure (Regulation (EC) No 1829/2003, Article 5(5). The applicant's environmental monitoring plan (covering, for example, what could happen to GMO soybeans falling from a truck during transportation) is duly examined and evaluated by the EFSA GMO Panel as part of the risk assessment (see EFSA, 2006c and Bartsch *et al*, 2007).

Consumer interests are addressed through the labelling provisions of the legislation and by public consultation. Whether these provisions are satisfactory and their impact on consumer welfare is examined in section 7.1. However, as all stakeholders agree, current GMOs bring no specific consumer benefit in food and feed products (beyond some potential for price reduction, but see Buckwell *et al*, 1999), any limitation of choice resulting from the implementation of labelling, should this happen (see section 7.6), is not likely to damage consumer interests as they now stand.

Compatibility of the authorisation procedure with the functioning of the internal market, examined from the EU texts and their implementation by some Member States, does, however, raise some questions as they imply that:

- labelling rules are not interpreted uniformly across Member States and sometimes not even regionally within a Member State. For example the 0.9% threshold for adventitious and technically unavoidable presence is not interpreted uniformly across the EU. In some German Länder, for instance, the unavoidability of adventitious presence must be justified, even when the actual GMO content is lower than 0.9% (Koester, 2008); this is not necessarily the case in, for example, Spain; and,
- some Member States have implemented national bans, mainly in relation to cultivation. The Austrian ban on Mon810 for food and feed use was lifted in May 2008[39].

Against this background, our survey provides opinions of Competent Authorities and stakeholders on how the authorisation procedure actually achieves stated policy objectives. Table 6.1 summarises these opinions and indicates the proportion of each respondent category holding the opinion that the procedure, as implemented, fully or slightly enables the accomplishment of stated policy objectives (see the survey appendix).

[39] See Commission Decisions 2008/470/EC and 2008/495/EC.

Table 6.1: The authorisation procedure, as implemented, fully or slightly enables the accomplishment of stated policy objectives

Objective	Competent Authorities (%)	Stakeholders (%)
A high level of protection of the human health	88	64
High level of protection of animal health	70	48
High level of protection of the environment	85	45
High level of protection of consumer interest	71	38
The effective functioning of the internal market	45	35

Source: FCEC survey.

This table suggests that:

- a higher proportion of Competent Authorities believe that the authorisation procedure enables the achievement of policy objectives than stakeholders. This is especially the case with regard to the protection of human life and health, as well as of the environment; and,
- the authorisation process is considered less successful in terms of enabling the effective functioning of the internal market.

Our semi-structured interviews with key EU stakeholders offered the following comments on the above points:

- a frequent claim by NGOs is that there are no studies or analyses of long-term toxicity and therefore long-term risks to health and the environment are not taken into account by EFSA;
- another claim made by some NGOs is that socio-economic factors should be taken into consideration in EFSA risk analysis. However, it was not clear from the interviews which specific factors should be considered, nor how they could be science-based and applied uniformly across the EU territory;
- another NGO claim is that risk assessment is too rapid for assessing possible nutritional benefits/damages and environmental issues linked to climate change. Such comments, however, may arise from some confusion between the time necessary to collect test or trial data and the time to analyse these data under a risk assessment procedure;
- some competent authorities claim that national risk assessments should be given more weight in the EFSA risk assessment; and,
- some NGOs claim that EFSA science is biased by hidden vested interests (links with the industry), and does not always address the right questions[40].

[40] It should be noted that candidates for the GMO Panel are subjected to a vetting procedure which would not allow the appointment of scientists with vested interests. The risk assessment procedure is also compatible with the Codex guidelines and EFSA is in the process of drafting new guidelines for the risk assessment in conjunction with the Member States to replace the current guidelines produced solely by EFSA.

Judgement

The EU authorisation procedure is generally considered to achieve its objectives of the protection of human and animal health through the use of a science-based risk assessment. It should also be noted that there have been no cases of animal or human health problems resulting from GMOs to date (i.e. since their introduction, not just under the current legislative framework). The authorisation procedure also contributes to the protection of the environment, although this is mainly a concern for cultivation. Its contribution to protecting consumer interest is principally linked to the impact of labelling and will be analysed further under section 7.1. There are some concerns that the authorisation procedure may not facilitate the effective functioning of the internal market as well as it might, partly as a result of the potential for different interpretations of the tolerance level for adventitious and technically unavoidable presence. Competent Authorities have a more positive view of the achievement of the legislative objectives than do stakeholders, but in both cases these views are in line with the above, i.e. there is more confidence in the achievement of safety-related objectives and the protection of consumer interests than there is in relation to the functioning of the internal market.

6.2. The EU approach to stacked events

The full title of this Evaluation Question is: *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 the EFSA and the Commission?*

A stacked event is produced by combining, through classical breeding, two or more events individually produced by biotechnology (EFSA, 2007e). An example is the combination of herbicide and insect resistant traits, or resistance to two different herbicides, by sexual crossing. This case is quite distinct from a multi-gene construction obtained directly from biotechnology.

The EU approach to stacked events combined by conventional crossing is characterised by the fact that the stack receives a specific risk assessment in addition to the risk assessments for each of the parental lines, even where the individual events have already received a positive opinion from EFSA. Application for not yet approved traits can be submitted simultaneously with application for the stack, although risk assessment of the single events is a pre-requisite for the assessment of the stack. Where the single events have already been risk assessed, the risk assessment of stacks will focus on stability of the inserts, expression of the events and the potential interaction between the events. Specific additional study may therefore be required.

In addition, in the case of stacks containing more than two transformation events, say with four stacked inserted genes where traits are heterozygous, all sub-stack combinations due to segregation are likely to be present in harvest and exported shipments, and hence cannot be separated. In such a case, a positive risk assessment opinion is also required for all sub-stacks, which must receive an authorisation, i.e. cultivation of a four stack (made up of four events, A, B, C and D) results in an harvest containing ten possible different combinations of events (ABCD, ABC, ABD, BCD, AB, AC, AD, BC, BD and CD) as well as the individual events. Therefore, the application for such a stack will then also cover in its scope all possible sub-stack combinations, the single events having already received a positive opinion from EFSA or being under assessment within EFSA. Thus a single risk assessment of such a stack will cover all sub-stack combinations. However, applicants need to provide a scientific rationale justifying that there is no need for experimental data obtained for the concerned sub-stack combinations or they have to provide the experimental data.

This procedure is not defined as such in Regulation (EC) No 1829/2003, which covers applications for putting "a GMO" on the market. It derives from the assumed rationale that a stack of two GMOs is simply another distinct GMO, a "new" entity requiring as such a full application, just as if it carried

specific risk distinct from that of any of the constituent single events. From a technical perspective, this view is not universally shared by scientists, since, as defined above, the stack is not as such a product of biotechnology, but results from classical breeding (Papazova, *et al*, 2006).

Stein and Rodriguez-Cerezo (2009) report that there are likely to be hundreds of combinations of single events which can be quickly developed by stacking. The number of GM crops that could be submitted for approval could therefore increase dramatically. To date, 37 out of 77 applications submitted to EFSA (48%) concern stacks. This proportion is likely to increase even further.

This approach to stacked events is different from the approach of the US and Canada, where a stack is automatically approved, but has to be notified, if the parental lines have been approved, on the understanding that the addition of existing and well known input traits does not impact on substantial equivalence, does not create a "new" GMO and does not require a new and specific examination. Table 6.2 summarises the main features of stacked GMO approval in the main trading partners of the EU.

Table 6.2: Approach to stacked GMO approval

	Approach to stacked GMO approval
EU	• A stack is a "new" GMO produced by classical breeding • Specific full authorisation • On case-by-case, not all requirements or additional information • Focus on stability, expression of events, potential synergistic or antagonistic effects if single events have been already positively assessed • Risk assessment for higher level stack may cover each sub-stack

USA	• Stack is defined by any way of production, intentional or unintentional. Three modes, hence 3 regulations
	  • USDA considers stacked plants as potential pests
	  • FDA (food) does not require any specific analysis. If the developer suspects some adverse effect, FDA consultation is encouraged
	  • EPA requires registration in some cases

Argentina	• Stack is a "new" GMO • Risk assessment information is reviewed only if events may differ from individual
Brazil	• Case by case review, at CNTBio discretion
Canada	• Request for registration to Competent Authority 60 days before release • Optional environmental safety review

Source: Stein and Rodríguez-Cerezo (2009).

In our survey, respondents were asked whether they consider the EU procedure for authorising stacked events a strength or a weakness of the EU approval procedure (see section 1.4.8 of the appendix). Some 30% of Competent Authorities and 12% of stakeholders believe that it is a strength (including just over half the NGOs). In contrast, some 8% of Competent Authorities and 44% of stakeholders believe that it is a weakness (all feed processors and the majority of traders). Finally, 62% of Competent Authorities and 44% of stakeholders are uncertain or just don't know, which might imply that many consider the answer to this question to require a specific scientific understanding.

Interviews with key EU stakeholders and in our case study Member States resulted in the following comments:

- Most technology providers and scientists hold the position that a separate risk assessment for stacks is generally unnecessary where the single events have already been risk assessed. However, separate risk assessment can be justified if scientists believe that there might be an unknown and un-assessed interaction between events, not just an addition of effects. If no novel interaction is suspected, a distinct assessment is considered disproportionate vis-à-vis the risk. As a consequence, the EU approach would only add to cost and a backlog of applications. The decision to conduct a specific risk assessment or not should be taken on a case by case basis.
- Food and feed manufacturers are generally concerned at the prospect of long approval delays for stacked events, but feel unable to judge if, from a risk avoidance perspective, it is really necessary to bring them through a full risk assessment.
- A majority of NGOs hold the position that, under the precaution principle, a full and distinct risk assessment should be systematically conducted for each combination of events, since it cannot be certain whether there will be novel interactions or not. It should be noted that so far, no stack of events from the current generation has been shown to have different effects than the sum of individual effects.
- The approval time for stacks is longer in the EU than in many Third Countries, contributing to the backlog of applications and to the occurrence of asynchronous approvals.

Judgement

Applications for stacked events are increasing globally and this is expected to be part of a continuing trend in the EU as well. The EU approach to the authorisation of stacked events is different to that in the USA and Canada where stacked events are automatically authorised if the single events have already been authorised. The EU approach differs in the fact that stacks are assessed with regard to the interaction of the already authorised single events. The EU is by no means alone in its approach though; for example, Argentina's approach is fairly similar. The EU approach is a step towards minimising the uncertainty about potential risk associated with GMOs and it thereby assures a high level of protection of human life and health and protection of the environment. However, many (non-EFSA) scientists see this approach as being conservative, at least as far as the current generation of GM events is concerned. The EU approach also increases the workload of EFSA and the Commission, and this situation is likely to become more pronounced as more applications for stacked events are submitted. Finally, the gap between authorisation in the USA and Canada and authorisation in the EU is likely to be more significant with respect to stacked events than single events and therefore the EU approach is likely to result in a larger application backlog and, as a result, more asynchronous authorisations with the consequential impact in terms of LLP incidents.

6.3. Efficiency, timeliness, transparency and proportionality

The full title of this Evaluation Question is: *To what extent are the different steps of the harmonised procedures established by the Regulation for the risk assessment and authorisation for food and feed efficient, time-limited and transparent and correspond to demonstrated risks in a proportionate manner?*

This question is addressed in terms of efficiency, timeliness, transparency and proportionality to risk.

6.3.1. Efficiency of the authorisation process

Efficiency is the ratio of process output versus input. Inputs are resources used to perform the process, such as manpower or equipment. It is often convenient, when feasible, to quantify the use of resources using mono-dimensional metrics such as cost. If the process consists of a number of sub-processes, the output from each sub-process can be viewed as an input for the next sub-process. Outputs are simply the outcome of the process.

Survey respondents were asked to comment on the extent to which they judged specific elements of the authorisation process to be efficient. The percentage of respondents finding elements either efficient or very efficient are shown in Table 6.3.

Table 6.3: Proportion of Competent Authorities and stakeholders finding elements of the authorisation process efficient or very efficient

	Competent Authorities (%)	Stakeholders (%)
Completeness check	65	70
Member State comments on risk assessment	59	11
Risk assessment by EFSA	67	58
Member State voting in Standing Committee	36	12
Comitology	30	39

Source: FCEC survey.

The Table suggests that some parts of the authorisation process are considered reasonably efficient by survey respondents whereas some other parts are seen as being less efficient, in particular the sub-processes relating to Member States comments, the voting in the Standing Committee (SCoFCAH) and the use of Comitology. Elements of the process relating to EFSA are considered to be relatively more efficient than elements post-risk assessment.

These results are confirmed by our interviews, a majority of our respondents pointing out that the authorisation process is efficient on paper, but not in its implementation. Most of the blame for this alleged lack of efficiency is apportioned to the risk management sub-process, and more specifically on the inability of SCoFCAH and Council voting sessions to produce a qualified majority (in either direction). This generalised lack of decision making ability at this stage has several important consequences, namely:

- a waste of resources since no output is generated;
- a significant extension of approval time which creates asynchronicity with authorisation decisions in exporting countries (see EQ7a and EQ7b); and,,
- a loss of credibility and legitimacy of EFSA, whose opinions are seen as incapable of feeding a democratic voting process.

Attempts to quantify views on process efficiency can be undertaken from the following perspectives:

- estimation, in absolute terms, of resources and output indicators;
- comparison of the situation before and after 2003; and,
- comparison with Third Countries.

Table 6.4 looks at the main process output, namely the number of approvals per year.

Table 6.4: Number of authorisations between 1996 and end February 2010[41]

Year	96	97	98	99	00	01	02	03	04	05	06	07	08	09	10
Approvals	1	3	2	0	0	0	2	0	2	2	3	6	4	5	5

Source: Community Register of GM in food and feed.

The table shows that between 1996 and 2003, 8 authorisations were granted, one per year on average. Since 2004, 27 authorisations were granted, an average of almost four a year. This increase in approvals indicates a very marked improvement of process productivity since 2003.

6.3.2. Specific elements of the authorisation process

Let us now focus on sub-process efficiency and look respectively at outputs from risk assessment and risk management.

A relevant indicator of risk assessment efficiency is the ratio of opinions issued by EFSA versus the number of submitted applications. Evolution of this ratio is presented in Table 6.5.

Table 6.5: Throughput of authorisation procedure (to April 2010)

	2004	2005	2006	2007	2008	2009	2010	Total
New applications received	8	20	7	14	14	13	2	**78**
Renewal applications received				25				**25**
Withdrawn applications				2	3	3		**8**
EFSA opinions issued		5	4	5	5	18	5	**42**
Authorisations			**1**	**4**	**4**	**5**	**4**	**18**

Source: DG SANCO and EFSA.

Examination of the above table suggests that:

- since 2005, an average of 13 new applications per year have been submitted for authorisation (this figure is likely to increase as 2010 includes data only up to April);
- opinion issuing by EFSA initially lagged behind this rate, which generated a growing backlog of applications. However, in 2009, EFSA opinions exceeded the number of new applications received, largely due to the improvement of internal procedures, and if this trend continues (and application numbers do not rapidly increase), the backlog will be slowly reduced;
- the authorisation rate has consistently been around 4 to 5 a year, thereby contributing to a growing backlog of pending dossiers. As at March 2010, the backlog includes 36 pending dossiers for new applications. At the current rate of throughput, it will take two and a half to three years to approve these dossiers. In the meantime, the backlog of EFSA opinions waiting to complete the risk management stage will increase.

[41] Some GM events in the register are given two distinct authorisations, at different dates: one for food and one for feed. In our table, the two authorisations are listed separately.

On the basis of the above, the risk assessment process can be said to be efficient and current EFSA resources (staff and expert pool) sufficient to carry out its mission in the short-term. However, as EFSA itself points out, future risk assessment may become much more complex. Then, EFSA current resources, methods and organisation could need to be reviewed and adapted.

Also on the basis of the above, the risk management sub-process cannot be considered efficient. Because of the low throughput, a backlog of unprocessed EFSA opinions is steadily building up, largely as a result of the indecisive voting sessions at SCFCAH and the Council of Ministers which necessitates the use of Comitology. In view of the foreseeable increase in the number of applications, this backlog at the risk management stage is likely to grow even further.

6.3.3. Resources and costs

In terms of the use of resources and their cost, one should distinguish the cost to the applicant and to the authorising institutions.

A thorough cost analysis is presented in Schenkelaars Biotechnology Consultancy (2008), a study undertaken on behalf of COGEM[42], on a sample of 7 applications[43], both in the USA and in the EU. The study concludes that:

- The application cost to the applicant relates to data collection. Required data sets are increasingly similar in the USA and in the EU. These relate to: molecular characterisation, toxicity and allergenicity, environmental impact, detection, some management fee (to FDA, in the USA);
- The average application cost was €5.474 million in the USA, with a range from €3.335 million to €8.257 million;
- The average application cost for the same event sample was €6.788 million in the EU, with a range from €3.820 million to €10.388 million.

Comparison of Schenkenaars' results with other cost studies (for example, Kalaitzandonakes, *et al*, 2007) suggests that:

- The cost to the applicant is some 25% higher in the EU compared to the USA. Schenkelaars states that this results mostly from differences in data requirements for the sub-dossier "phenotype analysis", amounting to some 40% of total cost, and the sub-dossier "construct", amounting to some 25% of total cost. The sub-dossier "event specific detection method", including the compulsory delivery of certified gg-material and the sub-dossier "JRC validation" amounted together to 10% of the extra cost. Finally, there is also a €90,000 fee to the JRC to validate the applicant's detection method.
- The current cost to the applicant, which is largely determined by data requirements, is currently of the same order as before 2003, with the main exception of the JRC fee.

Institutional costs incurred in the process are associated with:

- the functioning of the EFSA GMO panel: 24 EFSA GMO staff in Parma, 21 external experts on the GMO Panel and a pool of approximately 50 *ad hoc* external experts holding regular work meetings;
- DG SANCO monitoring and management activities, including SCoFCAH meetings;
- Competent Authority reviews in 27 member states; and,

[42] Commissie Genetische Modificatie.

[43] Applications: maize NK603, T25, MON810, BT11, 1507; soya 40-3-2; rapeseed MS8*Rf3.

- some portion of the Council of Ministers meetings, including their preparation.

No data were available to quantify cost estimates of the above activities. Examining EFSA budget lines within the EU budget would be misleading since costs associated with the GMO Panel are not separately identified.

To this set of consumed resources, one should add the opportunity cost incurred by various actors because of the time length of the process. These costs are essentially linked to the issue of asynchronous approvals and are considered elsewhere (see section 6.8 and section 6.9).

In conclusion:

- the centralised authorisation process is definitely much more efficient than the pre-2003 one, since it delivers a significantly larger output;
- the cost to applicants is some 25% higher in the EU than in the USA;
- the institutional cost is substantial, but is not quantified;
- some hidden costs are linked to the time duration of the process; and,
- it should be possible to improve overall process efficiency, in particular from an output perspective.

6.3.4. Timeliness of the authorisation process

Evaluation of the time associated with the authorisation process refers to both respect of the time lines defined by the legislation and the adequacy of these.

Our survey respondents were asked whether they considered the process timescales to be clear. Their responses are extensively laid out section 1.4.5 of the appendix, and can be summarised as follows:

- three quarters (75%) of Competent Authorities, but only 22% of stakeholders hold the opinion that the EFSA risk assessment is timely or very timely;
- two thirds (66%) of Competent Authorities and 43% of stakeholders believe that Member State comments on the risk assessment are handled in a timely or very timely fashion;
- just over half (55%) of Competent Authorities, but only 15% of stakeholders hold the opinion that Member State voting on the European Commission's Draft Decision is timely or very timely; and,
- just under half (47%) of Competent Authorities and only 12% of stakeholders believe that the European Commission's use of the comitology procedure is timely or very timely.

These comments are rather severe vis-à-vis the procedure timeliness with stakeholders systematically having a more negative perception than Competent Authorities on this. It should also be noted that the timeliness of the risk assessment elements is considered better than the elements associated with risk management.

In our interviews, the following main comments were made by respondents, including Competent Authorities, industry and NGOs, in this respect:

- the timing of some of the risk management steps is not well defined in the Regulation (EC) No 1829/2003;
- some procedural steps have well defined timing in the text, but in practice this time is often exceeded; and,

- applicants submitting incomplete dossiers which requires the provision of additional details are responsible for some of the time delays (the Executive Director of EFSA noted recently that applicants are asked to provide more data in around 95% of the dossiers (EuroBiotechNews, 2009)). Such additional data gathering, involving clock stopping, can take from a few days to, in one case, a couple of years. In order to reduce the number of pauses, EFSA updated its guidelines for applicants which are now in the stage of a draft Regulation (European Commission, 2009f).

Table 6.6 describes the theoretical timing of the approval process and shows that several procedural steps have undefined timelines, particularly in the risk management phase. It should be noted that the last three steps shown in the Table fall under the current general Comitology procedures with the undefined timescales resulting from the open wording of Council Decision 1999/468/EC. Risk assessment also has some undefined sub-steps, but the total cycle time is prescribed: if one step is slower, this must be theoretically compensated elsewhere in the procedure. Besides, there is no mechanism to ensure that deadlines are actually respected.

Table 6.6: Authorisation procedure timeline

Procedure step	Theoretical timeline
Member States to acknowledge and notify EFSA	2 weeks
EFSA completeness check	6 weeks (plus clock stopping)
EFSA write to applicant requesting any additional information necessary to allow EFSA to declare the application complete and valid. If the application is complete and valid, risk assessment begins (see below)	Included within the 6 weeks for completeness check above (the need to write the first letter to the applicant within this 6 week period has been in place since November 2007)
Applicant supplies requested additional information	Undefined
EFSA declares the application complete and valid	3 weeks (from reception of additional information to statement of validity)
EFSA risk assessment and opinion	6 months (+ clock stopping)
Commission draft proposal to SCoFCAH	3 months
SCoFCAH voting	Undefined
Transmission of proposal to Council, in case SCoFCAH does not reach qualified majority or votes against proposal	Without delay
Council if SCoFCAH undecided	3 months
Commission if Council undecided or misses deadline	Undefined
Total	**54 + 3 weeks + undefined + clock stopping**

Source: after van der Meulen and van der Velde (2009), Chapter 9, p. 284.

Table 6.7 shows the average duration of authorisations in weeks and reveals that this exceeds the timing set out in the legislation by more than three times. Although the risk assessment process accounts for most of the duration, this includes periods when the clock is stopped while applicants provide answers to EFSA questions.

Table 6.7: Average duration of GMO food/feed authorisation in the EU (weeks), as at 5 February 2010

From application submission to EFSA opinion	To vote in the standing committee	To transmit and vote in the AG council	To commission decision	Total
139	35	6	7	187

Source: GMO Compass, EFSA homepage[44].

6.3.4.1. Risk assessment and risk management sub-processes

Table 6.8 summarises the timing, in weeks, for application validation, a key and time consuming pre-risk assessment step, and its evolution over time. Some data were not available for all years.

Table 6.8: Timing of application validation (weeks)

Step	Actual duration	Period of application reception	Remarks
From reception of the application to first letter to the applicant	18.75 (s=19.76)[45]	2004-2009	N= 76 Max: 75 weeks Min: <1 week
Breakdown of the period	*25.3* *5.6*	*2004-07* *2008-09*	
To validation	23 (s=8.9)	2004-07	N=76 Min: 6 weeks Max: 163 weeks
Completeness check: applicant side	7 11	2008 2009	
Completeness check: EFSA side	12 10	2008 2009	
To first round of questions during risk assessment	30 11	2008 2009	
From validation to risk assessment opinion	12 22 20 15 50	2004 2005 2006 2007 2008	http://www.gmo-compass.org/

Source: EFSA.

[44] http://www.gmo-compass.org/eng/gmo/db and http://efsa.europa.eu.

[45] Average and (standard deviation). It is worth noting that the standard deviation exceeds the average. This reflects the asymmetric distribution of durations and, at least prior to EFSA's new operating procedures, a long biased tail towards very large durations.

Examination of Table 6.8 and Table 6.6 above reveals that:

- While the sending of the first letter upon application reception is supposed to be done within 6 weeks, in practice this takes, on average, three times as long as it should. A closer examination of the evolution of the timing of this element shows that, following internal procedural improvements within EFSA, the 6 week timeframe for sending the first letter to applicants under the completeness check is now respected[46]. Indeed the average duration during the 2004-07 period was 25.3 weeks was reduced to 5.6 weeks between 2008 and 2009 following the implementation of the internal GMO procedure and standard operating procedure 11.
- When including periods during which the clock was stopped, EFSA systematically exceeded the defined time limit of 6 months, but a significant part of that excess was on the applicant's side. Removing periods when the clock was stopped would reveal that the deadlines were respected in the vast majority of cases.
- Other timing aspects of application validation depending on EFSA either remained constant or improved over time (the time from validation to risk assessment opinion of applications in 2008 is an anomaly as there is only one case).

Table 6.9 summarises the total average time taken for the entire authorisation process. It shows that between 2006 and 2009 the total average authorisation time increased and that this results from risk assessment rather than from risk management.

Table 6.9: Timing of complete authorisation procedure, including periods of clock stopping (months)

Year of adoption	2006	2007	2008	2009	Average
Number of authorisations	1	4	4	5	
Risk assessment (EFSA)	22.0	23.75	24.75	37.5	28.75
Risk management	13.0	14.75	11.5	9.0	11.5
Total	35.0	38.5	36.25	46.5	40.25

Source: DG SANCO.

Table 6.10 compares EU authorisation times with those in the USA and in Brazil. This confirms that the approval process is much longer in the EU than in the USA, although the process in Brazil is considerably more variable, sometimes longer than that in the EU and sometimes shorter. This will, however, reflect the fact that Brazil has not authorised events until they have been authorised in the EU and the timing of the Brazilian system therefore depends on that in the EU and when applications are submitted relative to this.

[46] Two internal procedures were introduced at EFSA: Internal GMO Procedure from AP48 (received in 11/2007) followed by Standard Operating Procedure (SOP11) in 10/2008. After enforcement of these two procedures, the duration for sending out the first letter was consistently reduced to 6 weeks.

Table 6.10: Timing of total authorisation procedure in the EU, USA and Brazil for opinions adopted during the periods indicated (months)

Origin	2004	2005	2006	2007	2008	2009
EU	-	-	35.0	38.5	36.25	46.5
USA	13.6	12.6	-	14.8	16.9	22.3
Brazil	-	20.0	-	95.0	42.0	15.0

Sources: EuropaBio (Brazil) and FDA (USA)[47].

In conclusion, it can be stated that:

- time to authorisation is substantially longer in practice than as prescribed in the legislation;
- time to authorisation in the EU is considerably longer than in the USA;
- the duration of some steps in the procedure is considered to be ill defined by some stakeholders;
- a significant part of the duration of the risk assessment phase results from clock stopping when applicants are asked to provide additional data;
- the administrative parts of the risk assessment phase are increasingly being brought under EFSA's control to match the timings anticipated in the legislation;
- some uncertainty in the completeness check phase results from applicants submitting incomplete or unsatisfactory dossiers; and,
- the timing of the risk management phase broadly follows the anticipated timing in the legislation, but can still be lengthy as elements of it are undefined in terms of time. However it has proven shorter than the time needed for the overall risk assessment procedure which includes time for applicants to answer EFSA's questions.

6.3.5. Transparency of the authorisation process

Transparency of the authorisation process is important so that applicants, stakeholders and Competent Authorities can be kept informed about the progress of applications, the nature and the content of discussions, the rationale for decisions and the position of decision makers. This is recognised by Regulation (EC) No 1829/2003 as a legitimate concern, although it is equally acknowledged that some data submitted by applicants will remain confidential for competitiveness reasons.

There are two main elements of the process where transparency is important: risk assessment by EFSA and voting by the SCoFCAH.

On the EFSA web site[48], the following information on the GMO Panel and the status of applications can be freely accessed by stakeholders and the public:

- working procedure;
- Panel members, including their declaration of interest;
- Working Group[49] meeting minutes;

[47] Completed consultations on bioengineered foods: http://www.fda.gov/Food/Biotechnology/Submissions/ucm155765.htm.

[48] www.efsa.europa.eu.

[49] EFSA GMO Panel working groups relevant for risk assessment of applications are: molecular characterisation, food and

- minutes of meetings with the Member States;
- scientific documents;
- register of past and on-going applications including: dates of submission, correspondence, subject and status;
- opinions; and,
- reports and mandates.

The DG SANCO web site announces the outcome of SCoFCAH voting sessions, without disclosing individual positions or their rationale. This is a general practice of the Commission and the Council for all voting procedures and does not apply only in relation to GMOs.

At first sight, this information display might be viewed as characterising a fairly transparent process. Table 6.11, constructed from our survey (section 1.4.4 of the appendix), suggests that the situation is only partially perceived as such by Competent Authorities and stakeholders. Respondents were asked whether specific elements of the authorisation process are transparent.

Table 6.11: The extent to which elements of the authorisation process are considered transparent or very transparent

Procedure stage	Competent Authority (%)	Stakeholders (%)
Member State comments on risk assessment	80	48
EFSA risk assessment	79	55
EFSA check of completeness	65	48
Member State voting on draft decisions	63	20
Comitology	70	40

Source: FCEC survey.

As was noted with respect to efficiency and timeliness, stakeholders are more critical than Competent Authorities. The most critical element within the stakeholders are the NGOs who find the process untransparent, claiming that:

- selected company data are kept confidential;
- EFSA experts' background is not clear with respect to possible conflict of interest; their "declaration of interest" is not considered sufficient;
- EFSA independence is questionable. The agency maintains privileged relationships with the industry, as is illustrated by the hiring, in 2008, of the co-ordinator of the GMO Panel support unit by a major GMO manufacturer after the expiration of the co-ordinator's contract (Le Monde, 2010);
- EFSA opinion is not clear on underlying assumptions and uncertainties; and,

feed, environmental assessment, allergenicity, statistics, comparators, ERA guidance document and NTO self-task.

- the Standing Committee voting decisions are not documented: only the global result is made available. It is not possible to know about individual Member State positions and their underlying arguments.

In conclusion, it can be stated that, although the process appears to be fairly transparent, there is still a demand by some stakeholders, particularly NGOs, for more insight into the process.

6.3.6. Proportionality of the authorisation process

To address the question as to whether the authorisation procedure is proportionate to demonstrated risk, one has first to clarify the nature of demonstrated risk. In the case of GMO in food and feed, this means possible harm to human or animal health due to ingestion of GM material and, to some extent, to possible environmental risk linked to food and feed products.

The EU authorisation procedure is nonetheless specifically designed to address potential risks by:

- including three major risk analysis steps: risk assessment, risk management and risk communication;
- carrying out a science-based approach to risk assessment;
- following this science-based step by an openly democratic risk management phase; and,
- thoroughly applying the Precautionary Principle throughout the whole process.

In our survey, both Competent Authorities and stakeholders were asked to state their opinion in terms of the proportionality of the authorisation procedure (section 1.4.5 of the appendix). Table 6.12 summarises the percentage of respondents finding specific elements of the procedure proportionate or very proportionate to demonstrated risk.

Table 6.12: The extent to which elements of the authorisation process are considered proportionate or very proportionate

Procedure step	Competent Authorities (%)	Stakeholders (%)
EFSA completeness check	70	61
EFSA risk assessment	70	44
Member State comments	52	41
Use of comitology	39	15
Member State voting on draft decisions	45	15

Source: FCEC survey.

This table suggests that:

- Competent Authorities consider the procedure to be more proportionate than do stakeholders; and,
- the comitology procedure and Member State voting on Draft Decisions are not considered proportionate by either group.

Main comments made in this respect in interviews were:

- given the sensitivity of the EU society vis-à-vis food borne risk and a lack of acceptance of GM products, there is a solid citizens' demand for strong food safety protection and a very low tolerance for risk, including a component of expectation for zero risk (which is somewhat irrational given that this is impossible to achieve);
- risk assessment methodology and tools are based on internationally recognised science and standards;
- EFSA risk assessment is widely viewed as fully adequate, hence proportionate, to deal with human and animal health risks associated with current generation (input trait) GMOs;
- EFSA risk assessment may seem adequate for now relatively well known short-term risks, but is not considered to be fully adequate to assess long-term risks which are still unknown, unidentified and not evaluated; this is a constant claim by NGOs;
- the existing risk management step is considered to be very disproportionate vis-à-vis the risk to be managed. Since this risk was scientifically assessed by EFSA, the risk management phase is effectively redundant and is therefore a waste of time and resources when the decision will be referred to the comitology procedure in any case. Some interviewees find that this apparent disregard for EFSA's opinion by the Member States undermines EFSA's legitimacy and credibility; this is largely a claim made by industry operators. On the other hand, NGOs claim that this situation results in a non-democratic decision being taken by civil servants rather than by political representatives (the decision is actually taken by the Commission College which comprises Commissioners appointed by democratically elected national governments and approved by the European Parliament, so this claim may result from a misunderstanding);
- the precautionary principle is being overplayed; and,
- the existing risk assessment methods might not remain adequate to deal with new generation GMOs, involving metabolic traits for which risks and assessment methods are still undefined.

In conclusion, the EU authorisation procedure seems, overall, to be proportionate to existing demonstrated risks. However, it might need some adjustment in future in order to remain proportionate to possible newly developing risks.

Judgement

Based on the preceding analysis, the risk assessment carried out by EFSA is considered to be efficient, although it is recognised that more resources might be needed in the future to deal with advancements in GM technology. In contrast, the risk management procedure is not considered to be efficient and a backlog of EFSA opinions is building up, largely because the Standing Committee and the Council do not deliver a qualified majority opinion. This backlog is likely to grow if current rates of authorisation are not increased. That said, the centralised authorisation process is more efficient than the system in place prior to the 2003 legislation in terms of the outputs (authorisations) delivered. The cost to applicants is around 25% higher in the EU compared to the USA.

In terms of timeliness, the actual time to authorisation exceeds that envisaged in the legislation by a substantial margin and the process is considerably longer than that in the USA (although it is recognised that the process is different and this does not necessarily imply inefficiency). Applicants often submit incomplete dossiers and are often asked to provide additional data for the risk assessment and the stopping of the clock results in delays. For its part, EFSA has improved its performance in administrative terms and this has brought the actual timings closer to those anticipated. Some stakeholders consider certain elements of the process to be ill defined, and the aspects of the risk management process which are not defined in terms of time do contribute to delays (however, some of these undefined time periods are part of the general Comitology procedure and are not linked specifically to GMOs).

The authorisation process is considered to be fairly transparent, although certain stakeholders believe transparency could and should be improved. Further communication might provide further insight into the process. Finally, the EU authorisation process is considered to be proportionate to the potential risks, although it should be recognised that some stakeholders will find fault in terms of a perceived lack of consideration of potential long-term risks while others believe that the process is already too overbearing. It is noted that the risk assessment system should be re-examined as necessary in the light of future developments in the biotech sector which might have implications in terms of the nature and magnitude of risk.

6.4. Impact of the Regulations on the evolution of the sector

The full title of this Evaluation Question is: *What has been the impact of the Regulations on GM food and feed on the evolution of the sector and the EU society at large?*

This answer is structured as follows:

- The extent to which EU legislation on GM food and feed has had an impact on the evolution of the biotechnology sector.
- The rationale for current research directions.
- The potential benefits to EU society from the biotechnology industry.

It is widely acknowledged, both by the industry and by EU institutions, that the biotech sector has a huge positive potential for society, which needs to be harnessed. This view is not shared by some influential environmental NGOs, nor by some sections of the public (see section 8.1).

The wider concept encompassing this potential is that of the bio-economy, that is a world where biotechnology contributes a significant share of economic output. According to OECD (2009), the emerging bio-economy is likely to be global and guided by principles of sustainable development and environmental sustainability and involving three elements:

- biotechnological knowledge;

- renewable biomass; and,
- integration across applications.

In this context, the contribution of green biotechnology emphasises improvements in agricultural productivity through developments such as herbicide resistance and insect resistance, the latter especially targeting the American corn borer, which remains of limited interest in the EU because only certain regions are affected by this pest. Emerging technology platforms might, in the near future, allow a much-extended range of deliveries from green biotech. These developments will involve genetic modifications of both plants and micro-organisms (fermentation, enzymes). According to OECD (2009), potential benefits from these technologies include, among others:

- improved feed efficiency;
- functional food;
- novel nutritional attributes for feed and food;
- bio-materials, e.g. renewable plastics;
- bio-fuels (bio-ethanol and bio-digester);
- soil remediation;
- plant resistance to stress; and,
- plant resistance to pests specific to EU regions.

Important emerging society issues are climate change and sustainability. The industry (EuropaBio, 2009a) claims that agriculture biotechnology could enable agriculture to produce more from less whilst reducing the carbon footprint. This view should be contrasted with the established benefits to date set out in EQ13b and in the JRC-IPTS report on the economic impact of dominant GM crops worldwide (Gómez-Barbero and Rodríguez-Cerezo, 2006a). EuropaBio (2009a) note that specifically biotech crops are thought to be capable of:

- increasing yields by between 6% and 30% on the same amount of land;
- permanent reductions in fuel use and CO2 emissions due to less tillage;
- increasing the economic viability of bio-fuels and bio-based products by reducing production costs of raw materials;
- better tolerating stress such as cold, drought, salt, heat and flood allowing adaptation to climate change;
- improving plant response to inputs such as fertiliser and water and hence reducing the related emission of greenhouse gases; and,
- reducing the environmental impact of livestock farming by introducing changes in clover and grass so that cattle eating them produce less methane.

In the context of sustainability, Commission Services note that a potential development area of green biotechnology is the "bio-refinery", which could make a relevant contribution to environmental sustainability by producing, from plants, chemicals comparable to those produced from fossil fuels, low toxicity food and feed materials and bio-chemicals with low CO_2 emissions.

Insofar as such claims prove justified, it is clear that harnessing agriculture biotechnology inside the EU would generate qualitative and quantitative benefits to EU society. Whereas in the mid-2000s, biotechnology represented less than 1% of GDP in OECD countries, the sector's mid-term potential contribution could be between 5% and 6% of GDP (OECD, 2009).

Key questions are:

- Is the EU willing to see biotechnology promises come true and to capture its benefits, or is it content to maintain a defensive position and to rely on carefully filtered imported traits?
- To what extent is EU GMO legislation, in particular the food and feed Regulations, promoting or hindering the development of the agriculture biotechnology sector?
- What should be done to achieve EU objectives?

On the first point, it is clear that, while seeking a high level of protection of human and animal health, the EU Regulations on GMO, including those on food and feed, do not encourage the development of the green biotech sector in the EU which, after a bright start, stopped developing and even regressed. This view is supported by responses, in our survey, to the question: "to what extent is EU legislation on GMO food and feed adequate to allow the potential benefits of biotechnology to be realised in the EU". Only 4% of Competent Authorities and 8% of stakeholders think that EU legislation is very adequate, and respectively 76% and 33% think it is adequate in this respect (see survey appendix). A significant percentage of stakeholders (50%) are indeed of the opinion that this legislation is not adequate in this respect. Reasons mentioned for this inadequacy are deficiencies in the decision making process and the fact that potential benefits are not taken into account in the authorisation process. This point refers to the wider claim that socio-economic factors should be taken into consideration. However, it may be considered that the polarised debate and the difficulties that this creates for policy makers is ultimately responsible for the legislative framework.

It should be recalled that green biotechnology was first developed in the EU. In Belgium, in the 1980s, Plant Genetics Systems pioneered GM tobacco, followed by Novartis and ICI-Zeneca and, even later, by BASF and Bayer. At this point in time, it appeared as though European green biotechnology would become a world leader in the sector. Nowadays, although biotechnology is still a significant economic sector in the EU, this is mostly in terms of the health sector. The US has, at least according to a report commissioned by the biotech industry, replaced the EU as the world leader as measured by a range of indicators (Critical I, 2006). Large European groups active in green biotechnology, such as Syngenta, Bayer and BASF have, at least partly, relocated their research activities to the US. Reasons mentioned by the industry are:

- the negative attitude of EU opinion, which is reinforced by labelling rules;
- a larger number of traits are approved in the US and faster;
- research is difficult in the EU, particularly field trials;
- the US market is uniform; and,
- the EU market for cultivation is limited and fragmented by moratoria, punitive co-existence rules and lack of authorisation.

Another regulatory factor is the cost of applications and the time taken to authorisation (see section 6.3), which make it difficult for small or medium-sized enterprises to place products on the market, with the result that the sector becomes concentrated and tends towards an oligopoly. Since biotech multinationals have their centres of gravity abroad, mostly in the US, they tend to develop traits not ideally suited for EU agricultural conditions. An example is MON810 that targets the American corn borer, which infests only limited areas in Europe; there is no insecticide resistance GM event targeted specifically at EU pests and conditions.

One of the results of the above is the regression of GMO-oriented R&D in the EU. An illustration is given by the subjects of successive EU framework programmes. Under Framework 5 (FP5), the

proposed projects were mostly technical[50], with subjects such as plant genome analysis, supported by FAIR research projects. These, for example, led to the genetic improvement of a traditional European cereal crop (spelt, which may be used as an alternative source of protein for animal feed) which resulted in an 18% increase in protein yield[51]. Under FP6 and FP7[52] the focus, in addition to continuing research on technical development, included socio-economic and regulatory-oriented subjects. Examples include SIGMEA[53], CO-EXTRA[54] and CONSUMERCHOICE (reported in King's College London, 2008).

Achieving a bio-economy at EU level involves an EU biotechnology sector strategy. Such a strategy was elaborated by the European Commission in 2002 (European Commission, 2002b) and reviewed at the mid-term point in 2007 (European Commission, 2007a). The strategy stated that "life-science and biotechnology are widely recognised to be, after information technology, the next wave of the knowledge based economy, creating new opportunities for our societies and economies".

The responsibilities to harness and manage this potential fall across a broad range of policies and actors, food safety policy being only one of these. According to European Commission (2002b), aspects of these policies and strategies relating to plant biotechnology include:

- extending the knowledge base via research and development;
- facilitating the innovation process, including the stage of "putting on the market";
- reinforcing the industry's resource base: education, networking, incubators and venture capital; and,
- governing the policies on how public authorities prepare, decide, implement and explain policies and actions, including: societal dialogue and scrutiny, alignment with ethical values and societal goals, informed choice, science-based regulatory oversight, safeguard of the EU single market and international obligations.

Several of these concerns are met by Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003 in terms of governance principles. What should now, according to the strategy, attract more attention is how legislation can help foster the development of research and innovation, assist in developing consumer acceptance and ensure the functioning of the internal market.

The biotech industry would like to see some improvements in the legislation to reduce the hurdles for the development of the sector. EuropaBio (2009b) highlights five key issues in respect of the legislation:

- the need for effective implementation of GM crop authorisation (Directive 2001/18/EC);
- the need to enable a European single market in seeds;
- respect of other countries' freedom to trade in commodities (asynchronous approvals);
- the need to promote coherent policies and information on green biotech; and,
- the promotion of coherence of policies with development goals.

[50] http://cordis.europa.eu/fp5/.

[51] http://www.biomatnet.org/secure/Fair/F660.htm.

[52] http://cordis.europa.eu/fp6/, http://cordis.europa.eu/fp7/ and http://www.biomatnet.org/secure/EC/S2095.htm.

[53] http://ec.europa.eu/research/fp6/ssp/sigmea_en.htm.

[54] http://www.coextra.eu/.

The positive role that authorities and legislation could play in promoting biotechnology is not approved by all stakeholders. This is illustrated by Friends of the Earth Europe's (FoEE) comments on the EU biotech strategy (Friends of the Earth Europe, 2007b), stating that:

- green biotechnology has had a low performance in terms of job creation and competitiveness;
- there is a lack of data to back the claims for benefits;
- biotechnology is approached by EU policies as a homogeneous sector, whereas it should be segmented;
- EU research funding focusing on biotechnology is side-lining agri-environmental farming sectors;
- sector consolidation is hindering competition; and,
- regulatory provisions provide room for technical and financial risks of GMO contamination.

One can say that, even if this viewpoint is not shared by EU institutions, it has contributed to creating a rather defensive attitude vis-à-vis the green biotech sector. This attitude has permeated the legislative framework via its impact on perceived public acceptance and is likely to be one of the causes of the relatively low development of the green biotech sector in the EU. As European Commission (2002b) puts it (page 8), "uncertainty about social acceptance has contributed to detracting attention in Europe from the factors that determine our capacity for innovation and technology development and uptake. This has stifled our competitive position, weakened our research capability and could limit our policy options in the longer term".

Judgement

The EU's green biotechnology sector could, in the mid-term, generate benefits to EU society in excess of the current benefits. The legislation has been designed to meet public concern relating to the technology and to provide a high level of protection of human and animal health and this has had an impact on the development of the sector in that the EU is no longer a world leader, despite the technology being first developed in the EU. Even the focus of public sector research has, in addition to technical development, used its resources to also include socio-economic and political subjects. According to the EU's biotechnology strategy, more attention is needed in terms of how legislation can help foster the development of research and innovation, assist in developing consumer acceptance and ensure the functioning of the internal market.

In conclusion, there is a limited yet significant possible role for the food and feed regulations to orientate the future of the biotech sector and to create or forbid the necessary conditions for its development. The main thing is for the EU to decide an appropriate balance between potential economic risk and potential economic benefits, which include those to EU society from a well developed green biotechnology sector.

6.5. Analysis of Article 34 in dealing with national "emergency measures"

The full title of this Evaluation Question is: *To what extent does the procedure foreseen by the Regulation (Article 34 in conjunction with Articles 53 and 54 of Regulation (EC) No 178/2002) ensure an appropriate way to deal with "emergency measures" taken by Member States?*

Article 34 of Regulation (EC) No 1829/2003 states that "where there is evidence that products authorised with this Regulation are likely to constitute a serious risk to human health, animal health or the environment, or where, in the light of an opinion of the Authority issued under Article 10 (modification, suspension and revocation of authorisations - food) or Article 22 (idem – feed), the need to suspend or modify urgently an authorisation arises, measures shall be taken under the procedures provided for in Articles 53 and 54 of Regulation (EC) no 178/2002."

Articles 10 and 22 state that, under request from a Member State or the European Commission, the Authority shall issue an opinion on whether an authorisation for a product still meets the conditions set by the Regulation.

Article 53 and 54 of Regulation (EC) No 178/2002 ("The food law") define emergency measures for food and feed in the Community, stating that:

- where it is evident that food or feed in the Community is likely to constitute a serious risk to human or animal health, or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the European Commission shall adopt one or more measures, depending on the gravity of the situation;
- such measures could include: suspension of the placing on the market or use of the food/feed; laying down special conditions for the food/feed in question; suspension of imports or transit of the food/feed in question; any other appropriate interim measures;
- where a Member State officially informs the Commission of the need to take emergency measure and the Commission has not acted in accordance with Article 53, the Member State may adopt immediately interim protective measures.

6.5.1. Use of Article 34

Article 34 of Regulation (EC) No 1829/2003 has only been invoked twice, both concerning cultivation of MON810 only. It has never been used for food and feed uses. The only national prohibitions on feed uses have been adopted by Austria on maize MON863 and oilseed rapes GT73 and Ms8Rf3 under Directive 2001/18/EC.

In April 2007 Monsanto applied for renewal of maize MON810 under Regulation (EC) No 1829/2003. Greece and France adopted the measures in 2007 and 2008 respectively.

Greece notified the measure under Directive 2001/18/EC (Article 23) and the Directive on seeds (2002/53/EC, Article 18). A mandate was sent to EFSA in April 2008, and EFSA delivered an Opinion in July 2008 confirming the safety of MON810. Since this product had been notified for renewal under Regulation (EC) No 1829/2003, the Commission submitted a proposal to the Standing Committee on the Greek measure using as legal base the "emergency measure" of Article 34 of the Regulation.

France adopted its measure in February, 2008 and notified it under Article 23 of the Directive and under Article 34 of Regulation (EC) No 1829/2003. Seven other Member States implemented a ban of MON810 on their territory under the provisions of Article 23 of Directive 2001/18/EC[55], or of the seed directive[56], or of a national ruling[57].

In order to illustrate the complexities of the use of Article 34, the French case is examined in detail[58]. Under Commission Decision 98/294/EC of 22 April 1998, pursuant to Council Directive 90/220/EEC, it was decided that consent was to be given for the placing on the market of genetically modified maize (*Zea maïs* L. line MON810). On 3 August 1998, the French Competent Authority gave its consent.

In July 2004, Monsanto notified MON810 to the Commission under Articles 8(1)(a) and (b) - and 20(1)(a) and (b) of Regulation (EC) No 1829/2003 as an existing product. The notification included

[55] Ban of MON810 under Art. 23 of Dir. 2001/18: Austria, Greece, Hungary, and Luxemburg.

[56] Ban of MON810 under the "seed directive" 2002/53/EC: Poland.

[57] Ban of MON810 under Ministry announcement (Germany) or Ministerial Circular (Italy).

[58] Register European Council: AGRILEG Env.36, 5685/09-23 January 2009.

cultivation and for further food and feed use. As a consequence, the product remained legally on the market as an existing product as defined by Articles 8 and 20 of Regulation (EC) No 1829/2003 even though the consent granted under Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms had expired.

On 18 April 2007, Monsanto submitted an application under Article 8(4) and 20(4) for the renewal of the authorisation of MON810, including for cultivation and for further food and feed use. In accordance with Articles 11(4) and 23(4) of the Regulation, MON810 will remain legally on the market until a decision is taken on its renewal.

On 8 February 2008, the French authorities informed the Commission of the adoption on 7 February 2008, as an emergency measure, of a Ministerial Order whose Article 1 prohibited "the cultivation in view of the placing on the market" of varieties of seeds derived from GM maize MON810 until a decision has been taken on the renewal of the authorisation to place this organism on the market. This was confirmed by further communication and notification from the French authorities who designated Article 23 of Directive 2001/18/EC as the legal base of their order and informed the Commission of the reasons supporting its adoption, highlighting that new scientific elements were available concerning the impact of this maize, when cultivated, on the environment; the scientific committee set up by the government had expressed "serious doubts" about the possible negative impacts of MON810 on flora and fauna[59].

However, according to Article 8(5) and 20(5) of Regulation (EC) No 1829/2003, products falling under the scope of these two articles (existing products) are subject to the provision of that Regulation, in particular as regards Article 34 "emergency measures". The French authorities acknowledged this in their second notification, dated 12 February 2008, by which they designated this provision as the legal base of their measure.

On the substance, given the complexity of the matter and the scientific content of the studies, the Commission sought, on 27 February 2008, the opinion of EFSA, as established by Regulation (EC) No 178/2002, to assess the evidence and justifications submitted by the French authorities.

On 29 October 2008, EFSA issued an opinion (published on 30 October 2008) stating that it "did not identify any new data subject to scientific scrutiny or scientific information that would change previous risk assessments conducted on maize MON810 which currently has marketing consent in the EU. Having considered the overall information package submitted by the French authorities, as well as a broad range of relevant scientific literature, the GMO Panel is of the opinion that there is no specific scientific evidence, in terms of risk to human and animal health and the environment, that would justify the invocation of a safeguard clause under Article 23 of Directive 2001/18/EC and an emergency measure under Article 34 of Regulation (EC) No 1829/2003". Consequently, there is no reason to consider that the product constitutes a risk to human or animal health or to the environment.

The Commission proposed a draft decision stipulating that the French Republic is not authorised to prohibit the cultivation of seeds of maize hybrids with the genetic modification MON810 and must therefore repeal its measures against the cultivation of seeds of genetically modified maize MON810.

The standing committee of 16 February 2009 examined two draft Commission decisions asking Greece and France to repeal their safeguard measures on the cultivation of maize MON810[60]. The proposals concern emergency measures submitted under Article 34 of Regulation (EC) No 1829/2003 and processed under Article 54 of Regulation (EC) No 178/2002.

[59] http://www.gmo-safety.eu/en/news/611.doc.

[60] Draft Commission decision of (…) concerning the provisional prohibition in France of the cultivation of seeds (…) of MON810 (…), http://www.saveourseeds.org/downloads/COM_draft_french_ban_MON810_D003704-01-00-EN.pdf.

EFSA presented two Scientific Opinions as well as its procedures with respect to safeguard measures[61], concluding that the scientific evidence currently available does not sustain the arguments provided by Greece and that cultivation of maize MON810 in Greece is unlikely to have an adverse effect on human and animal health and the environment. EFSA also had not identified in the French submission any new data subject to scientific scrutiny or scientific information that would change previous risk assessments conducted on maize MON810.

France and Greece, supported by nine other Member States, requested a postponement of the vote on the two decisions until a decision on the renewal of the authorisation of maize MON810 is adopted, underlining that EFSA has not yet finalised the risk assessment of MON810 in the context of this renewal procedure.

The proposed Commission Decision to lift the ban was not adopted. Reasons given by Member States were:

- procedural issues (decisions on national safeguard measures to be taken after assessment/decision on renewal of authorisation of maize MON810);
- environmental concerns (evidence submitted by France and Greece on potential negative effects of MON810 on the environment); and,
- political reasons (no further explanation).

This process took one year for what was, theoretically, an emergency measure. The French ban remains in place until the end of the re-approval process and in spite of the EFSA opinion because under Article 54 of Regulation (EC) No 178/2002 (to which Article 34 of Regulation (EC) No 1829/2003 refers), Member States should first inform the European Commission of the need to take emergency measures. In the case of MON810 in France, the measure was adopted first and then the European Commission was notified.

Survey respondents were asked to consider the extent to which the procedure foreseen in Article 34 of Regulation (EC) No 1829/2003 is appropriate to deal with emergency measures taken by Member States. Four-fifths of Competent Authorities and just under a third of stakeholders commented that the procedure is appropriate while a small minority in both cases noted that the procedure is very appropriate. Generally stakeholders were more likely to find the procedure inappropriate or very inappropriate; however, it should be noted that only feed processors were particularly negative about the Article 34 procedure.

Just over a third of stakeholders, including the majority of technology providers stated "don't know", which perhaps reflects the hypothetical nature of this question in that the procedure has not yet been used in relation to food and feed. Some stakeholders commented that emergency measures may undermine the internal market, while others said that the current safeguard clause provides Member States with less power than that of Article 23 in Directive 2001/18/EC.

The history and timescale of the use of Article 34 suggests that this may not be the most appropriate instrument to use with respect to cultivation, and this is probably also a valid conclusion with respect to GM food and feed, although it should be reiterated that there has so far been no experience of this application in these sectors. The Article was designed to be used in the case of genuine emergencies such as BSE/CJD and this is why a reaction time of 10 days is specified; the concerns raised by the French authorities were linked to uncertainty over long term impacts. An examination of Article 23 of Directive 2001/18/EC is outside the scope of this report, but this would appear to offer more time for

[61] EFSA opinions: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902001981.htm and http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902156394.htm.

an appropriate consultation with EFSA on what are likely to be complex issues. This Article will be examined in the parallel cultivation evaluation.

Judgement

Article 34 of Regulation (EC) No 1829/2003 has only been invoked twice, both times with regard to cultivation of MON810. This legal base was used for technical reasons, instead of the safeguard measure of Directive 2001/18/EC (cultivation of MON810 had already been transferred under the Regulation since Monsanto applied for renewal under that legal act). Greece and France adopted the measures in 2007 and 2008 respectively. The procedure took one year for what was, theoretically, an emergency measure. Ultimately, the French ban remains in place until the end of the re-approval process and in spite of the EFSA opinion. That said, more than four-fifths of Competent Authorities feel that the procedure is appropriate or very appropriate, a view shared by only around a third of stakeholders who were generally more likely to find the procedure inappropriate or very inappropriate. On balance, the history and timescale of the use of Article 34 suggests that this may not be the most appropriate instrument to use with respect to cultivation, and this is probably also a valid conclusion with respect to GM food and feed, although it should be reiterated that there has so far been no experience of this application in these sectors.

6.6. Analysis of the "one door, one key" principle

The full title of this Evaluation Question is: *To what extent is the common and centralised procedure foreseen by Regulation (EC) No 1829/2003 (one door one key principle) efficient compared to the situation prevailing before the adoption of the Regulation?*

"One door one key" features apply to two main aspects of the approval procedure namely the facts that before the implementation of Regulation (EC) No 1829/2003:

- risk assessment and risk management were conducted at Member State level, and ratified by mutual recognition or by validation by the Commission, whereas risk assessment is now centralised under EFSA and risk management is a Community procedure; and,
- authorisations for GMO presence in food and feed were delivered under different directives.

In our survey, four-fifth of Competent Authorities and stakeholders noted that centralised risk assessment is a strength of the procedure. However, none of the NGO respondents considered it as a strength (see section 1.4.8 of the appendix) with one, for example, noting reduced Member State participation and scrutiny and others raising concerns about perceived differences in opinion between EFSA and Member State Competent Authorities. Our interviews also clearly indicate that both Competent Authorities and stakeholders, particularly food and feed chain operators, consider the post-2003 legislation as vastly superior to the pre-2003 one in terms of efficiency.

Irrespective of whether efficiency refers to the ratio of authorisations per year or to the ratio of authorisations to new applications, as was demonstrated under section 6.3, the post-2003 process is clearly performing better with an average of almost four authorisations a year from 2004 compared to just one per year between 1996 and 2003. This is particularly the case with regard to the risk assessment elements of the procedure which is now coping with the flow of incoming applications and simultaneously processing the backlog (this is not the case with respect to the risk management process).

Efficiency on the input side can be considered from the point of view of the applicant or the approval authorities. On the applicant side, it was shown under section 6.3 that the application cost is essentially the same pre- and post-2003, with the exception of the €90,000 fee that the applicant must now pay to JRC-IHPC to validate a detection method.

On the institutional side, it is not easy to make a comparison between the pre- and the post-2003 situations because EFSA did not exist. If one assumes that risk assessment by the Member States is largely unchanged, but now the EFSA GMO Panel exists as well, one must consider the cost of this Panel as an additional cost compared to pre-2003. However, there are no data available to consider this cost.

Judgement

The main judgement of efficiency pre and post-2003 must be the outputs, i.e. authorisations. On this basis the post-2003 "one door, one key" approach is considered more efficient with an average of four authorisations a year since 2004 compared to just one per year between 1996 and 2003.

6.7. Coherence with other procedures under the food safety *acquis*?

The full title of this Evaluation Question is: *To what extent is this procedure coherent with other procedures applying to similar sectors of the food safety* acquis*?*

The relevant Community approval procedures from the food safety *acquis* are summarised in Table 6.13 together with their legal framework basis.

Table 6.13: Relevant approval procedures under the food safety acquis

Scope	Legal basis
Pesticides	Directive 91/414 (to be replaced by Regulation 1107/2009 in 2011)
Seed and plant propagating material (S&PM)	Directives 2002/53, 2002/55 and 10 other basic Directives
Ingredients	no approval for conventional ingredients with a history of safe use
Food additives (including enzymes)	Directive 89/107 and Regulation 1331/2008
Food supplements	Directive 46/2002 of the EP and of the Council of 10 June 2002
Feed additives	Council regulation 1831/2003
Functional food	no specific approval directive

In addition to the above, relevant aspects of the Regulation on food contaminants (Commission Regulation 629/2008) will also be briefly considered.

Other possibly relevant approval procedures, such as for novel foods, functional food, pharmaceuticals or veterinary drugs will not be discussed here, either because they address specific issues (for example, health claims) or because they fall outside the food law.

The question of consistency arises because of the need to verify if:

- the interplay between GMO approval and other legislations is correctly established;
- GMO approval is approached in the same way as for other categories of substances covered by the food safety *acquis*;
- possible presence of GMO in these categories of products is labelled in the same way as for those covered by Regulation (EC) No 1829/2003; and,
- there exist any differences in tolerance levels for unapproved substances.

Table 6.14 compares approval procedures.

Table 6.14: Comparison of approval procedures

Scope	Who receives the application	Who conducts risk assessment	Who does risk management
Pesticides	Member State	Rapporteur Member State Competent Authority. A peer review on the RA of the active substance is performed by EFSA.	EU (DG SANCO) for active substances) and Member State for commercial products of already EU approved active substances.
Seed and plant propagating material (S&PM)	Member State	N/A. Seed varieties are registered based on 3 requirements (VCU, DUS and suitable variety denomination). All data required for assessing the registration of the variety is produced by official bodies or under official supervision.	
Ingredients	No application if history of safe ingredient	N/A	N/A
Food additives	European Commission	EFSA: Food additives & nutrient sources panel	Comitology
Food supplements	European Commission	EFSA: Food additives and nutrient sources added to food panel	Comitology
Feed additives	European Commission	EFSA: Additives and products or substances used in animal feed panel	Comitology
GMO	National Competent Authority	EFSA: GMO panel[62]	Comitology

Source: EU legislation.

This table shows that procedures are comparable for GMO, pesticides, additives and supplements in the fact that, in each case, a risk assessment is conducted by EFSA or a Member State Competent Authority and feeds either a national decision, which is communicated and accepted by mutual recognition, or a Community procedure. These differences may not appear to be fundamental, yet they can affect the efficiency and the effectiveness of the process. Differences in length of the procedure or on SCoFCAH voting outcome do not result from differences in the procedure, but from differences in the way GMOs are perceived by Member States.

An important question is whether each EFSA panel works along its own lines and does not interact with other panels on possibly joint issues. For example, interviews with Commission Services hinted that the Pesticide Panel and the GMO Panel did not cross-examine issues such as whether a GMO will increase or reduce the overall quantity of pesticide in agriculture. This, however, was not confirmed by EFSA interviews were the view was expressed that Panels do interact.

Another question is whether possible GMO presence is uniformly risk assessed and labelled across the different legislative areas. Table 6.15 addresses this question.

[62] EFSA publishes the opinion based on the applicants data, other available data and questions and comments from Member State Competent Authorities. EFSA takes responsibility, but it is a collaborative process.

Table 6.15: Treatment of possible GMO presence

Scope	Possible GMO presence	Specific GMO risk assessment	GM labelling	GMO or other threshold
Pesticides	No (GM events can produce toxins that are pesticides (*BT* toxin, but GM events are not present in pesticide products)	No	No	MRL[63]
Seed and plant propagating material (S&PM)	Yes	See GMO. There is no specific risk assessment per variety	Yes	Impurity levels
Food ingredients	See GMO	See GMO	If adventitious presence > 0.9%	If adventitious presence > 0.9%
Food additives	Yes (e.g. aspartame)	Yes	No	No
Food supplements	Yes (e.g. vitamin)	No	No	No
Feed additives	Yes (e.g. lysine)	Yes	Yes	0.9%
Process aids	Yes (e.g. amylase)	No	No	No
GMO	Yes	Yes	Yes if > 0.9%	0.9% adventitious presence

Source: EU legislation.

In our survey (section 1.4.11 of the appendix), when asked if approval regulation is correctly established in terms of the interplay with other areas of food safety:

- for food additives: 84% of Competent Authorities and 59% of stakeholders were of this opinion;
- for feed additives, the proportions were respectively 83% and 43%;
- for plant protection agents (pesticides), the proportions were respectively 46% and 46%; and,
- for seeds respectively 17% and 18%.

The main stakeholder comments on this issue were that:

- technology providers and feed manufacturers feel that there is uncertainty as to how GMOs of micro-biological origin will eventually be treated in feed additive approvals;
- the interplay of seeds with cultivation is much more relevant than with food and feed;
- an inconsistency between the GMO and the seeds regulation is the lack of threshold for adventitious presence in seeds;
- the Belgian and the Austrian Competent Authorities thought that risk assessment for GMO and pesticides should be more harmonised in the case of herbicide tolerant and insect resistant traits. GMOs and pesticides are indeed risk assessed by different panels which do not systematically interact (which has been confirmed by EFSA). To illustrate this, EFSA (no date b) notes that

[63] Maximum Residue Levels.

studies of a herbicide's impact on biodiversity within crops is considered as part of the risk assessment of a herbicide tolerant GMO, but not when the active substance (Annex I of Directive 91/414/EC) and the commercial products (Annex II of Directive 91/414/EC) of a given herbicide are risk assessed;

- the UK Competent Authority added that there is a need for greater understanding of the scope of the respective risk assessments in relation to herbicide resistant GM events;
- this view was echoed by the Hungarian Competent Authority who added that this argument also applies to insect resistant events;
- the French Competent Authority argued that clarification is necessary in the case of herbicide tolerant GM events in order to ensure that duplication is avoided. They added that in future GM events tolerant to a herbicide may be affected by the new legislative framework on plant protection products if the associated herbicide is not approved for use; and,
- another claim made for inconsistency is the existence of non-zero tolerance levels for food contaminants (which are by definition unauthorised and harmful substances) whereas there is a zero tolerance for unauthorised GMOs, even for those for which EFSA has given a positive opinion.

Judgement

In conclusion, while it can be said that the approval procedures are overall consistent, there still remain, across food safety regulations for different categories of products, some points of non-consistency. This inconsistency includes the labelling of some products of GMO origin (for example, oil or lecithin) while others (for example, the use of enzymes) are not labelled. There is also an inconsistency in the use of zero tolerance levels for unauthorised GM material and non-zero maximum residue limits for harmful substances like food contaminants. The lack of interaction in the risk assessment for products yielding complementary risks, such as herbicide and herbicide tolerant GMOs is also a point of inconsistency.

6.8. Trend in authorisations in the EU compared to Third Countries

The full title of this Evaluation Question is: *What is the foreseeable trend of the GM authorisations in the EU when compared with the authorisations granted in Third Countries and taking into account the evolution of the GM sector?*

In this section, we examine in turn:

- The trends in GMO development and approval in the international trading environment of the EU.
- The capacity of the current authorisation procedure to handle these developments.
- The likelihood of future LLP incidents.

The global pipeline of new GM crops has been extensively investigated by the JRC-IPTS in 2008 (Stein and Rodríguez-Cerezo, 2009), together with the implications of asynchronous approvals for international trade. The pipeline situation described in 2008 is regularly updated by JRC-IPTS[64], while the BioDec data base of FAO[65] more specifically monitors progress in developing countries.

Stein and Rodríguez-Cerezo (2009) reported 33 **traits** (for example, insect resistance) approved and in commercial use worldwide in 2008 and predicted that there would be 122 by 2015. However, the

[64] http://agrilife.jrc.ec.europa.eu/pipeline.htm.

[65] http://www.fao.org/biotech/inventory_admin/dep/default.asp.

OECD's Bio Track Product Database reported 130 **events** (specific GM varieties, for example, MON810) in February 2010[66] (see section 3.4 for a breakdown of these events by crop and trait). Table 6.16 shows the distribution of the anticipated pipeline by crop and **trait** according to Stein & Rodriguez-Cerezo (2009), the number of **events** will be considerably higher.

Table 6.16: GM traits evolution 2008-2015

Crop	2008	2015
Soybeans	1	5
Maize	2	5
Rapeseed	4	7
Cotton	2	2
Rice	1	8
Potato	0	6
Total	**10**	**33**

Source: Stein and Rodríguez-Cerezo (2009).

Soybean is of particular interest because of the protein dependence of the EU (see section 7.5 and section 7.6). In 2008, according to OECD Biotrack there was only one authorised and commercialised soybean trait, but three authorised traits. According to Stein and Rodríguez-Cerezo (2009), there are currently three new traits in the regulatory pipeline and nine new traits at the advanced R&D stage to be released on the market by 2015, of which two are metabolic traits and three stacked agronomic traits.

Stein and Rodríguez-Cerezo (2009) also note that:

- Many of the new approved GMOs will be stacks, some of them possibly involving up to 8 parental lines. Even with reference only to maize stacks, double stacking could result in 300 combinations by 2015 (not all would make sense). Triple stacking would lead to 2,300 possible combinations and quadruple stacking to in excess of 12,000. A number of these stacks will imply exchanges of genes between technology providers. Plans are already underway in this regard, see for example, the rapeseed MS8xRF3xGT73, stacking Monsanto GT73 with Bayer Crop Science MS8xRF3, currently under approval procedure. The current approach in agricultural crops is to develop a portfolio of varieties together with a portfolio of GM traits based on a baseline that includes herbicide tolerance. HT is an easy marker for Intellectual Property and therefore the industry can check what is being used by farmers. Based on the first problems of weed resistance in North America, most of the technology providers have decided to exchange their technology to allow rotation of events for a given trait.
- About half of the new GMOs would come from national technology providers in Asia or Latin America, who will develop them for their domestic agriculture market and will, in all likelihood, not seek EU approval (leading to asymmetric approvals). This implies that future incidents from LLP in imports of crops or food products from these countries are very likely, with a difficulty

[66] http://www2.oecd.org/biotech/default.aspx. Accessed 02/07/0911/02/10. A comparison with DG SANCO information and GMO Compass suggests that Stein and Rodríguez-Cerezo (2009) have not included many approved events, events within the authorisation process or events which are authorised, but no longer commercialised.

linked to the absence of validated tests to enforce current regulatory provisions and no incentive on the side of the technology provider to provide any assistance.

- At the moment, the GMO scene is dominated by two traits: herbicide tolerance and insect resistance. At the horizon of 2015, input traits will still be prevalent, but new traits will increasingly be put on the market, such as crop composition, nutritional improvement, improved yield (better photosynthesis or nitrogen absorption), new pest resistance including viruses, tolerance to abiotic stress resistance, which will require new detection methods and, possibly also, more complex approaches to risk analysis. This will in particular be the case when products derived from detection-free technologies such as cis-genesis or gene silencing are approved in Third Countries. The question will also arise as to whether benefits (nutritional, health, etc.) of novel traits will need to be evaluated as well.

On the other hand, it was shown in section 6.3 that, under current regulatory arrangements, the approval rate of EU institutions is in the range of 4 to 5 approvals a year, risk management being the constraining factor while, at least for now, the risk assessment step is currently coping with the rate of new applications. It is also possible to envisage an increase in EFSA's capacity to allow it to increase its throughput; this appears less straightforward in terms of risk management.

Judgement

In conclusion, it is to be expected that, in the coming years, the number of GMO authorisations will steeply increase worldwide. New authorisations will increase not only in number, but also in complexity (new technologies), range (more different crops) and geographical origin (not only traditional exporting countries, but also approvals where there is no intention to export resulting in asymmetric authorisation). Stacked GMOs are likely to become the norm and there are likely to be increasing gene exchanges between technology providers.

6.9. Consequences of asynchronous authorisations

The full title of this Evaluation Question is: *What would be the consequences of possible differences between the pace of authorisations between the EU and its trading partners?*

Under the conditions set out in section 6.8, the likelihood of more frequent and complex Low Level Presence (LLP) incidents occurring in the coming years appears almost certain. These incidents may arise from three different causes as elaborated by Stein and Rodríguez-Cerezo (2010) and Rodríguez-Cerezo (2010b):

- **Asynchronous approvals**, where a GMO is approved in an exporting country and, while seeking EU authorisation, it is not yet approved (see section 6.4 for the causes of delay).
- **Asymmetric approvals** (or Isolated Foreign Approvals, the former term is preferred because these approvals may not be isolated in the future), where a GMO is approved for use in a Third Country where there is no intention to export to the EU and as such, the GMO is not submitted to the EU authorisation process. This is considered especially likely in developing countries where biotech developments are focused on addressing domestic concerns rather than the agri-business sector.
- **Research approvals**, where GMOs in field trials find their way into the commercial crop supply (examples to date include LL rice in 2006 and GM flax Triffid line in 2009 from University of Saskatchewan). The fact that this type of LLP has already occurred demonstrates that even low adoption rates can result in LLP and as the number of GM events increases, so will the number of field trials.

DG AGRI has launched a study entitled "implications of asynchronous GMO approvals for EU imports of animal feed products". This will report in 2011 and will examine this issue in detail (European Commission, 2009b).

The main LLP issue relates to soybeans and meal because of the dependence of the European livestock sector on imported protein. In this case, a likely chain of possible consequences of LLP incidents is, according to Landmark Europe (2009):

- all operators in the chain incur an economic risk. In the current trading system, and also under the European Food Law, risk and responsibilities are passed along the supply chain from one operator to the next. This is problematic because tests to detect LLP can deliver different results at the origin of the shipment and at the port of destination;
- supply can be interrupted either because shipments are blocked in port or because exporters are not willing to take the risk of having their responsibility engaged and prefer to ship their products to countries with strong demand and less exacting authorisation systems;
- in the event that unauthorised GMO such as soybeans are detected and blocked in the incoming port, processing units might fall short of raw material and might be stopped altogether;
- in case of strict application of zero tolerance and severe disruption of soya imports, the protein supply for the livestock sector could become highly problematic. According to the analysis in European Commission (2007c), only 10% to 20% of soybean imports could be substituted from EU production;
- interruption or sudden reduction in protein supply would result in a combination of a drop in European livestock production, exports and consumption, loss of domestic production and an increase in imports. In a dynamic process, there could also be price impacts. The effects would principally affect the poultry and the pig meat sectors. For beef, production would be less affected, but exports would be dramatically reduced. The magnitude of these effects would depend on the severity of the loss of supply, for example, whether unapproved GMO soybeans would be cultivated only in the USA, or also in Argentina and in Brazil.

6.9.1. Impacts of LLP incidents to date

To date a number of LLP incidents have resulted from asynchronous authorisations and research approvals. There has not, as yet, been a case of asymmetric approval.

Typical examples of such recent incidents include:

- export of unauthorised linseed (FP97) from Canada to Rotterdam since September 2009 (research approval);
- detection of unauthorised presence of GM maize MON88017 in soybean protein from the US, via Switzerland and Belgium, notified by France via RASFF no 2009.1037 of 06/09/2009 (asynchronous approval); and,
- notification by The Netherlands (RASFF no 2009.1165 of 07/09/2009) of unauthorised presence of GM maize MON88017*MIR604 in soybean products from the Netherlands, with raw material from the USA (asynchronous approval).

Such incidents originate at the point of detection, frequently large importing ports. If unnoticed at that stage, but only detected after they have spread into the food or feed chain, they can result in a range of damaging practical consequences for operators. These effects can be complex, depending on the stage at which incidents are identified. The following indicative Table lists such potential consequences at various stages of the supply chain.

Table 6.17: Possible effects of asynchronous events

Operator	Potential effects
Port	• Impounding of boats by authorities • Impounding of silos and unavailability for new stock • Shipping cost/demurrage • Delivery delays by additional sampling & testing • Difficulties of disposing of or rerouting illegal consignments • Managing recalled material from customer (storage/disposal, new packaging)
First processing (crushing, milling)	• Silos blocked to new product • Cleaning of silos/processing equipment • Additional sampling and testing demanded by authorities or customer • Build up of delivery delays to customers, including delayed delivery fees • Alternative supplies must be urgently found and accessed • Affected consignments returned to supplier, rerouted or destroyed • Damage to customer relations (including short or long-term lost business) • Managing recalled material from customers (storage/disposal, new packaging)
Food manufacturer	• Warehouse space blocked • Cleaning of silos/processing equipment • Additional sampling and testing for certification • Shortage of raw material, inability to replace raw material or adapt production process (production stoppage) • Affected consignment returned to supplier, rerouted or destroyed • Damage to customer relations • If recipe changes, replace labels/packaging consumer/sensorial testing, etc.
Retail/consumer	• Product recalls: withdrawal of products (including consumer communication and media announcement) • Potential empty shelves or diversion of supplies from elsewhere • Increased sampling and testing additional certification requirements from retailers • Damage to short and long-term consumer confidence • Additional resources/personnel time dedicated to managing incident, consumer care, damage to company/image/brand reputation

Source: after Landmark Europe (2009).

In addition, as pointed out by Landmark Europe (2009), individual operators will face potentially significant administrative and legal costs, damage to supplier and/or customer relationships, potential long-term loss of customers and potentially lengthy litigation with suppliers/customers. Such effects extend to public authorities. For example, the Dutch Competent Authorities explained that LLP incidents generate a lot of political pressure and require substantial energy from them to meet the numerous and pressing information and documentation requests from the political side, mostly MPs.

Practical consequences arising from LLP incidents which have occurred to date were analysed and documented in detail by the Dutch farmers' organisation LTO. Their findings are summarised in the Table below.

Table 6.18: Nature and concrete effects of past asynchronous events

Material	GM Event	Origin	Period	Effects
Linseed	FP967	Canada	2009	0.05%-0.5% FP967 in imported linseed Effects: a, b, c, d, h, g
Maize	GA21	Argentina	2007-2008	Effects: d, e, f, g
Maize	MIR604/MON88017 & 10 stacked events	US	Since 1996	Effects: d, e, f
Maize in soybean	MIR604/MON88017	US	2009	Effects: e, f
Corn gluten feed and DDGS	DAS59122-7	US	2006-2008	1.1% to 2.7% DAS-59122-7 in imported maize Effects: a, b, c, d, e, f
Corn gluten feed and DDGS	MIR604/MON88017	US	Since 2008	Effects: d, e, f
Rapeseed	T45	Canada	Since 1996	Effects: d, e, f
Rice	LL601	US	2006-2008	Effects : a, b, c, e, f, g, h
Rice	Bt63	China	Since 2006	Effects: a, b, g

Legend for effects:

a) RASFF notification.

b) Blocked shipment.

c) Diverse measures by exporting parties.

d) Imports stopped or no longer possible from this origin.

e) Price effect from material substitution or alternative supplier.

f) Material substitution.

g) Systematic testing of all shipments from this origin.

h) Recalls of consumer products from supermarkets.

Source: LTO (NL).

There is no overall estimate of actual cost of these incidents for the entire European economy. There are, however, some case studies on the economic effects on individual operators in the food/feed supply chain. An illustration is provided by Landmark Europe (2009) which analysed the actual costs of LLP up to the end of September 2009 and the total potential cost for two soybean ingredient producers and one food manufacturer following the RASFF 2009.1165 incident of 07/09/2009

(unauthorised presence of GM maize MON88017/MIR604 in soybean products from the Netherlands, with raw materials from the USA). These estimates (Table 6.19, Table 6.20 and Table 6.21) provide a lower bound for economic effects to the sector, since only selected operators are identified and evaluated.

Table 6.19: Soy ingredient producer 1: The LLP was estimated to have affected 3,000 tonnes in total

Process	Actual cost €	Potential cost €
Testing	50,000	
Recall	300,000	
Total cost at 30/09/09	350,000	
Total forecast cost	800,000	2,000,000

Source: Landmark Europe (2009).

Table 6.20: Soy ingredient producer 2: The LLP was found to affect a consignment of 25,000 tonnes of soybeans and 5,000 tonnes of soy protein products

Process	Actual cost €	Potential cost €
Testing	989	
Silo and process cleaning	10,280	
Additional shipping cost/demurrage	287,900	
Alternative supplies	120,000	
Production process adaptation	347,000	
Customer care staff	22,500	
Legal counsel and communications	274,150	
Total cost to 30/09/09	2,051,330	
Total forecast cost	c. 3,500,000	10,000,000 – 14,000,000

Source: Landmark Europe (2009).

Table 6.21: Food manufacturer having purchased 50 tonnes of soy protein concentrate

Process	Actual cost €	Potential cost €
Testing	1,100	
Reformulation	147,000	
Customer care and legal	54,000	
Total cost at 30/9/09	202,000	
Total forecast cost		2,200,000

Source: Landmark Europe (2009).

In conclusion, the above analyses clearly indicate how asynchronous approvals coupled with zero tolerance can, and already have, serious effects, both economic and operational, on the food and feed sector. However, our interviews with feed sector operators in the Czech Republic, a landlocked country, indicated that impact from asynchronous approvals had been almost unnoticeable. This suggests that these impacts are felt more strongly in countries with big importing ports, such as Rotterdam or Hamburg. Moreover, due to on-going international GMO developments, it is widely recognised that, under unchanged legislation and assuming increased incoming application flow and approval rate, such incidents are likely to multiply in frequency and gravity in future. Prospective development and possible future consequences of asynchronous approvals were examined further under section 6.8.

6.9.2. Possible future impacts of LLP

Both DG Agri (European Commission 2007c) and LEI Wageningen (Backus, *et al*, 2008; Aramyan, *et al*, 2009; van Wagenberg, 2009; van Wagenberg, *et al* 2009) have examined the potential future impact of asynchronous authorisation. Models were constructed addressing two related issues, with a focus on the Netherlands situation, particularly sensitive because of the Rotterdam port:

- in the short-term (October 2009 to March 2010): the potential economic impact of soya trade disruption on food/feed chain operators (van Wagenberg, 2009); and,
- in the mid-term (2009-2013): the economic impact on European soybean supply of alternative tolerance thresholds for EU unapproved GMO soy in combination with alternative delay periods of EU approval for use in feed compared to approval for production in soybean exporting countries (Backus, *et al*, 2008).

The first study elaborates on a LLP incident of June 2009, whereby minute traces of GM maize not yet authorised in the EU were discovered in US soybean and meal consignments in Rotterdam. This could have resulted in a problem in the period from October to March because this is when the EU imports most soybean products from the US. Table 6.22 shows first order costs as estimated for the EU crushing industry, the compound feed industry and the food sector and livestock producers under the current zero tolerance regime.

Table 6.22: Estimated additional first order costs (million €) for EU food and feed industry

Operator	Type of costs	Estimated additional first order costs (million €)
If crushing of soybeans remains in the EU		
Crushing industry	Sourcing costs soybeans	160 - 650
Compound feed industry	Sourcing costs soy meal	290 - 700
	Sourcing substitute protein	210 – 1 010
Food sector	Sourcing soybean oil	40 - 150
	Sourcing other vegetable oils	380 – 1 460
Total		**1 090 – 3 980**
If no crushing is possible in the EU		
Crushing industry	Foregone margin	230 – 260
Compound feed industry	Sourcing cost soybean meal	420 – 1 010
	Sourcing substitute protein	210 – 1 010
Food sector	Sourcing soybean oil	170 – 1 460
	Sourcing other veg. oil	380 – 1 460
Total		**1 420 – 4 390**

Source: van Wagenberg (2009).

According to van Wagenberg (2009), these additional costs account for 1.8-2.0% of the farmer purchases of compound feed. The additional costs for the food sector account for 4.6% to 21.3% of the input costs of vegetable oil in the EU and 0.1-0.5% of retail sales during the period under review.

Backus, *et al* (2008) examined a three-segment supply chain of soybean producers in USA, Brazil and Argentina, EU importers and feed producers. The model is applied for Netherlands with a time horizon of four years. Under these assumptions and with the hypothesis of an introduction of a new GMO variety in the US, and of EU demand of 33 million tonnes a year (2008 level), model simulations suggest that:

- a one year delay in EU approval for new varieties results in a sufficient supply of EU-approved soybean to meet EU demand in the first year of approval, for any threshold from 0.0% to 100%;
- for all later production years, a delay in EU approval for new varieties of one year results in insufficient supply of EU approved soybean to meet EU demand for any threshold up to the level of 0.9%;
- if production of a new variety of GM soybean in Brazil closely follows EU approval for this variety, for all tolerance thresholds of unapproved GM soybeans, total supply of EU-approved soybean exceeds demand;

- a delay in EU approval for new varieties for only one year only affects estimated soybean prices marginally;
- however, a delay of two or more years increases estimated soybean prices to over €7,747 per tonne, or higher, for all thresholds up to 0.9%;
- if soybean price increases from €290 per tonne to €7,747 per tonne, farm level production will increase by a factor of 8 for cattle, 10 for sows, 14 for finishing pigs and 18 for layers and broilers; and,
- at these price levels, there will be no demand for soybean as a raw material for feed and the livestock industry will face a severe loss of competitiveness.

In conclusion of this section, under the growing global trend of new GMO authorisations in Third Countries (exporting and non-exporting), the current EU authorisation regime, specifically the pace at which it operates and its use of zero tolerance, is likely to generate severe economic problems for the food and feed sectors (Stein and Rodríguez-Cerezo (2010) estimate that in early 2009 there were more than 40 individual GM events that may become potential sources of LLP).

It is important to note that this view is absolutely not shared by a number of NGOs such as the "GMO-free Ireland Network[67], which asserts that: "the agri-biotech PR machine fabricated the term "asynchronous approval" to falsely imply that the difference in approval between the EU and the US is simply a matter of timing. This is pure propaganda. Contrary to what the agri-business industry, commodity traders and animal feed cartels want [Irish] farmers to believe, safe certified non-GMO animal feed is affordable and widely used…".

In this respect, in 2008, CPE, Greenpeace and Friends of the Earth Europe (CPE, *et al*, 2008) enjoined the EU to acknowledge that:

- zero tolerance and the speed of the EU procedure do not need to be changed: it is the US procedure which is too rapid and unsafe;
- assistance should be provided to China, Argentina and Brazil to establish GMO regulations similar to those of the EU;
- products from GMO fed animals should be labelled;
- the EU livestock industry must be helped to source GM-free feed;
- the CAP and the trade policy should be reformed with a view to reducing the EU's dependence on imported protein;
- strict traceability and liability systems should be developed, such that biotech companies, not feed importers, pay for unauthorised GM contamination; and,
- the target for biofuels should be dropped as it increases demand for raw materials which might otherwise be used in feed and is one of the drivers of feed price increase.

[67] http://www.gmfreeireland.org/network/index.php.

Judgement

There are three distinct causes of LLP: asynchronous authorisations, asymmetric authorisations and escaped research approvals. Asynchronous approvals are clearly a concern given that this term refers to cases where a Third Country is seeking to export products which the EU requires, but where the EU has yet to authorise GM events authorised in exporting countries. There have been a number of LLP incidents arising from asynchronous authorisation to date. Asymmetric authorisation has not yet resulted in an LLP incident, but is expected to do so in the future as the number of GM events, especially in developing countries, increases. There have been two recent well known cases of LLP resulting from research trials.

LLP incidents can result in potentially significant administrative and legal costs, damage to supplier and/or customer relationships, potential long-term loss of customers and potentially lengthy litigation with suppliers/customers for individual operators in the food and feed chains. The actual costs resulting from LLP incidents to date range from €0.8 million to €3.5 million for individual operators, although the potential cost, had the co-mingled product been used in the food chain could have amounted to considerably more. Estimates of potential future impact of LLP are considerable, especially when the replacement of raw material supply is considered. Under the growing global trend of new GMO authorisations in Third Countries, the current EU authorisation regime, specifically the pace at which it operates and its use of zero tolerance, is likely to generate severe economic problems for the food and feed sectors. It should, however, be noted that this view is not shared by some NGOs. Further research on this issue is underway under the auspices of DG Agri and is expected to report in 2011.

7. The compulsory labelling of GM food and feed

This theme comprises ten Evaluation Questions which are answered in the following sub-sections.

7.1. Labelling rules and consumer informed choice

The full title of this Evaluation Question is: *To what extent are the current labelling rules for GM food/feed facilitating an informed choice and precluding misleading of consumers?*

The answer to this question is organised along the following lines:

- The labelling provisions for GM food and feed products.
- Consumer expectations in terms of labelling of GM food, including oil and livestock products.
- Consumer expectations in terms of labelling of GM feed and feed ingredients.
- Consumer understanding of labelling of food/feed products.
- The extent to which relevant stakeholders perceive labelling to present an informed choice.
- The extent to which could labelling be seen as misleading.

7.1.1. Labelling provisions for GM food and feed products

Provisions for labelling of GM food and feed products are set out in Regulations (EC) No 1829/2003 and 1830/2003. According to Articles 12 and 24 of Regulation (EC) 1829/2003, these provisions apply to:

- foods and feed consisting of or containing GMOs;
- food produced from or containing ingredients produced from GMOs;
- feed produced from GMOs; and,
- GMOs for feed use.

According to the approach under this Regulation, food and feed produced from GMOs have to be labelled. However food/feed produced with GMOs (for example, meat, egg and milk from animals fed with GMOs or enzymes used as processing aids) do not have to be labelled.

Moreover, according to Article 13, operators should ensure that:

- for pre-packaged food consisting of, or containing, GMOs, the words "this product contains genetically modified organisms" or "this product contains genetically modified (name of organism)" must appear on a label; and,
- for non pre-packaged food offered to the final consumer, the words "this product contains genetically modified organisms", or "this product contains genetically modified (name of organisms(s))" must appear on, or in connection with, the display of the product.

With regard to pre-packaged food, the above-mentioned provisions apply to the list of the ingredients and therefore each ingredient which is GM should be labelled.

According to Article 12(2) and 24(2) of Regulation (EC) No 1829/2003, labelling shall not apply to foods or feeds containing material which contains, consists of, or is produced from GMOs in a proportion no higher than 0.9% of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

In practical terms, this means that all food or feed products containing in excess of 0.9% of GM material must be labelled as such. This means that if food contains 1% of an ingredient which itself contains 10% GM material, the food must be labelled as GM even though it actually contains 0.1% GM material.

This obligation of positive labelling also applies to products such as oil, starch derivatives or lecithin whenever they are produced from GM crops, even though they do not themselves contain or consist of GMOs in the sense that they contain neither modified DNA nor protein; the obligation does not apply to processing aids (for example, enzymes).

Before examining the effects of the labelling provisions, it is worth providing a short comparative look at approaches in some Third Countries. During the past twelve years or so, more than 40 Third Countries have adopted labelling legislation, but the character of this and the degree of implementation differ widely (Guillaume, *et al*, 2007). The most relevant of these regulatory frameworks are reviewed in detail in section 3 of the appendix, here some key differences and characteristics are set out.

First, there is a quasi-generalised requirement to label products of GM origin that are not considered to be substantially equivalent to their conventional counterpart, with a view that the consumer be informed on novel traits and food properties to facilitate informed choices. Labelling can be mandatory (Australia, EU, Japan, Brazil, China) or voluntary (Canada, Hong-Kong, USA).

For products that are considered to be substantially equivalent, because they possess only input traits, there exists a large heterogeneity of approaches, summarised below together with references to selected examples:

- Labelling scope can include all products (including livestock products, Brazil) or be less extensive (EU: no label for livestock products or additives, although voluntary schemes are allowed; Japan: only processed products);
- Thresholds for defining GMO presence where labelling is compulsory differ: EU: 0.9%; Brazil: 1%;
- Labelling can be product (Australia, New-Zealand, Japan, USA) or process-based (EU, Brazil, China); and,
- Extent to which the law is implemented may vary by country.

These examples, as well as our detailed analysis in the appendix, suggest that in the EU, as in most Third Countries, labelling is intended to provide consumers with information about the product and is not linked to food safety which is primarily assessed before placing the product on the market. Countries with process-based labelling believe that consumers make decisions not only on product related issues, but also on issues related to production process which include environmental, economic, ethical and religious considerations (see Aslaksen, *et al* (2006). Countries with product-based labelling believe that consumers make their decisions solely on product information. These differences refer to an underlying debate as to whether labelling essentially supports the consumer's right-to-know or his autonomy (see Costa-Font and Mossialos (2005) for a discussion on this issue).

7.1.2. Consumer expectations in terms of labelling of GM food and feed

Consumers' expectations and information requirements are not easy to describe with certainty as no first hand evidence from consumer surveys is available on this matter. We therefore rely on the primary evidence collected as part of this evaluation, although it should be noted that this relies on the views of Competent Authority and stakeholders. This raises the question of who is really able to present consumer requirements. Consumer organisations and NGOs assert that they represent consumers, while this is questioned by industry, especially in the latter case, and a distinction is drawn

between consumers, who actually make purchasing decisions, and citizens, who express opinions and demands. An answer to this dilemma would be to run a consumer survey, but this is outside the scope of this evaluation.

First it should be acknowledged that there are different approaches to labelling philosophies which are set out in various Codex Alimentarius documents[68]. GM labelling may address one or several of the following issues:

- indicate the presence of allergens;
- signal significant differences in composition or in nutritional content from the non-GM equivalent;
- protect the consumer from false and misleading information; and,
- satisfy consumer preferences, that is "consumer right to know about the food they purchase, as based on personal preferences" (Codex Alimentarius, 2007).

In the EU legislation, providing consumer information is a primary rationale for issuing detailed labelling provisions. Indeed in its response to Codex remarks on the EU GMO labelling provisions, the Commission states that: "*all food consisting of or produced from GMO has to be labelled as such, irrespective of the presence of modified protein or DNA. The objective of this legislation is to allow the consumer to make an informed choice about whether the food he purchases is GMO or not*"[69]. In the same document, the Commission further invites Codex to notice that: "*EU GMO labelling is not the only example for a labelling based on production process. Codex itself developed a General Guideline for the use of the term "halal" (which includes some process related aspects)*".

Regulation (EC) No 1830/2003 states that: "*it is necessary that consumers are fully and reliably informed about GMOs and the products there from, so as to allow them to make an informed choice of product*". Since this formulation appears tautological ("be informed to make an informed choice"), it is worthwhile considering in more detail the nature of "informed choice" and the consumer need for information. The assumptions are that consumers seek to optimise their welfare by making informed choices and that labelling provides relevant information to allow this.

While numerous surveys and studies review consumer purchasing attitudes and expectations vis-à-vis food products, there are few studies on consumer expectations vis-à-vis labelling information, and particularly about GMO labelling (see GMO Compass). Most available studies on consumer purchasing behaviour stress that:

- labelling is only one factor influencing purchase decisions;
- brand and pricing are considered the most important information on the label; and,
- ingredients and content, as indicated on the label, are given very limited attention by the consumer[70].

This does not take us far enough with respect to GMO labelling. In the absence of detailed survey evidence, our main source of information on consumer expectations is our interviews, particularly with consumer organisations and operators in the retail sector who are in close contact with consumers.

[68] For example, Codex Alimentarius (2001).

[69] EC Comments on Codex Circular Letter CL – 2007/38-FL, 4 Dec. 2007 ftp://ftp.fao.org/codex/ccfl36/fl36_08e.pdf

[70] See for example survey under Foods Standards Agency (UK): 'Consumer Choice & Standards Programme' (2003/04): only 14% consumers claim ever to look at food packaging. Respondents in our case study mention, however, that up to 50% of consumers may pay attention to labelling. See also Genewatch UK (2002) and Davies, et al (2010).

These interviews revealed that a majority of consumer organisations support GM labelling as a right for consumers to express their preference for GM or non-GM products. In the view of these organisations, as well as of NGOs, demand for labelling reflects most consumers' rejection of GM products hence the need to identify them in order to allow consumers to avoid them. This identification may be either explicit, based on labelling requirements set out in the legislation, or implicit and associated with a package of positive attributes including "non-GM", such as "Organic" or "Bio". According to a majority of these organisations, consumers' requests for information extend to products such as oil and other ingredients deriving from GM material, as well as to livestock products such as meat and dairy, even they are not or do not contain GM material. This is corroborated by Sheldon, *et al* (2009).

This reflects a concern to enable the consumer to inform his purchasing behaviour from labelling information on possible GMO presence in the entire supply chain. Currently the presence of GMOs in the entire supply chain is not always clear, since the absence of labelling of livestock products means it is not necessarily apparent to the consumer that animals may have been GMO fed (and GM technology may have been used in other parts of the chain). The overall position of these organisations is that GMOs carry potential risks, both known and unknown and these permeate the entire food chain. There is an obligation from operators and an absolute right on the part of the consumer to be informed about the existence of such potential risk. Consumer organisations and NGOs claim that it is most important for the consumer to know about the use of GMOs in products because there is public concern about the use of the technology which goes beyond perceived safety concerns and this knowledge is therefore an essential part of the informed choice. The reason why only this specific aspect of the production process (and not all other aspects including, for example, pesticide use) must be communicated reflects the specific nature of the concern that the public has in relation to GM technology, i.e. there are ethical and environmental concerns (Brook Lyndhurst, 2009), not simply product-based health concerns, despite the fact that EFSA has provided a positive risk assessment in relation to all authorised GMOs.

On the "right to know", the Codex Executive Committee "*noted that the claimed right to know was ill-defined and variable and in this respect could not be used by Codex as the primary basis of decision-making on appropriate labelling*" (Codex Alimentarius, 2007). However, respondents from the retail sector generally insisted on their willingness to meet the consumer right to make informed choices, and view GM labelling as a way to do this.

Industry operators generally acknowledge labelling as being a market request, but question whether consumers really demand process related information in the case of oil and other GMO derived products not containing modified DNA or protein. Why, do they ask, do consumers particularly expect, among many others items of possible interest, this specific process characteristic to be pointed out? They often also question the consumer benefit in having attention specifically drawn to products or ingredients which have been given a positive safety assessment by EFSA. Their position is that relevant information for the consumer relates to content or nutritional value, not production process and there is therefore no need to provide additional information on labels.

A number of Competent Authorities do not hold or express specific views on consumer expectations as they merely implement EU regulatory provisions. Those who do, generally in Member States with an anti-GMO position, also refer to the consumer right and willingness to know about origin and processes.

A distinction should be made between awareness and understanding of labelling by consumers.

First, available consumer studies and surveys indicate that labelling awareness and reading generally is quite low and Sheldon, *et al* (2009) note there is little knowledge specifically about GM labelling requirements in the UK. Only a minority of significantly less than 20% of consumers declares reading

labels "sometimes" (Grunert, *et al*, 2010[71]). These consumers are generally concerned with nutrition and environmental issues and also constitute the market segment for "organic" and "bio" products.

A number of our stakeholder respondents, from all sides, commented on whether labelling is understandable. Remarks by NGOs, consumer organisations and food chain operators are generally in agreement. They all point out the difficulties in terms of understanding:

- the difference between "containing/consisting" and "produced from";
- the difference between products containing respectively 0.89% and 0% GM material;
- a threshold value for GM material presence, whatever its number;
- the nature of the risk supposedly signalled by labelling; and,
- the nature of GMO ingredients and why/how they are GMO.

7.1.3. The extent to which relevant stakeholders perceive labelling to present an informed choice

It is difficult to address this question given the lack of GM labelled food products on the market (see section 7.4). The extent to which consumers are able to perceive labelling as presenting an informed choice is therefore compromised. This situation is interpreted from different angles, as indicated below.

Our survey revealed that 95% of Competent Authorities and 56% of stakeholders are in agreement that the current labelling provisions facilitate consumer choice and 70% of Competent Authorities, but only 35% of stakeholders consider that the labelling provisions avoid the misleading of consumers. Part of this difference might be explained by the fact that 78% of Competent Authorities, but only 22% of stakeholders consider that the information is easy to understand. Perhaps as a result of these difficulties, only 43% of Competent Authorities and 27% of stakeholders agree with the statement that consumers understand and accept the current labelling provisions (this point will be dealt with in more detail in section 7.2). Finally, 70% of Competent Authorities, but only 35% of stakeholders agree with the statement that the scope of the current labelling scheme is adequate, which indicates some concerns, especially among the stakeholders.

Competent Authorities generally hold more positive opinions than stakeholders on the contribution of labelling to informed choice. On the other hand, negative opinions are expressed by all categories of stakeholders, operators, consumer organisations and NGOs alike, although for differing reasons.

This is illustrated by our semi-structured interviews with key European stakeholders. According to NGOs the lack of GM labelled food products for sale clearly indicates that labelling has performed its task, informed consumers and the lack of demand for these products has resulted in their minimal presence on the market; labelling has provided the information necessary for consumers to implement this choice and as a result there are few available products.

According to food chain operators, the widespread withdrawal and avoidance of GM labelled products has resulted from hostile campaigning and media pressure which preceded the introduction of labelling provisions under the 2003 legislation. The absence of GM labelled products is therefore an operator decision, not consumer choice; the labelling legislation therefore removed consumer choice and it does not facilitate an informed consumer decision (a point also made by Davison and Bertheau, 2008). Labelling effectively maintains this no-choice situation nowadays by acting as a watchdog keeping GMO away from the market.

[71] A study on 11,800 consumers in 6 EU countries indicated that only 16.8% of shoppers examine nutritional information on food labels.

Feed is almost entirely labelled (see section 7.5), but these labels are neither seen by the consumer nor openly attacked by anti-GMO parties[72]. As a result, consumer awareness if low and labelling plays a negligible role in the purchasing decision of animal products (although does form the basis for "GM-free" labelling of livestock products, see section 7.8).

Interviewees in our case studies made the point that the consumer generally makes un-informed choices as far as labels are concerned because they are either unaware of the information available or simply do not read labels. A majority of consumers are said to make purchasing decisions primarily on price and brand considerations.

The point was made in the UK that the vast majority of consumer information on labels is provided by voluntary labelling which carries a marketing rather than an information function, for example the French Label Rouge label which represents a set of implicit attributes, including the use of non-GM material, none of which are individually acknowledged at the point of sale.

Interviewed operators suggested that GM labelling implies that there is something is to be concerned about, but there is no further information on the nature and extent of the risk which does not help consumers to make a fully informed choice. Others reported that information should be primarily related to nutrition and safety and that labelling information is disproportionate if points of no relevance to the consumer are mentioned. Finally, others pointed out that GM labelling is not about health concerns, but reflects a citizen's fundamental (political) right to know what he is eating, i.e. returning to the importance of process-based labelling.

7.1.4. The extent to which GM labelling could be seen as misleading

Misleading in this context means that the information conveyed does not help the consumer to make an informed choice. Some respondents believe that the fact that GMO are labelled at all is misleading. This claim is made by operators, particularly food processors, who see GMO labelling as being of no value to the consumer while having a negative effect on their activities. This argument rests on the notion that labelling products for GM content is often interpreted as a warning of a health risk when, according to EFSA's risk assessment there is no health risk. Those who make this argument point out that there are no similar labels relating to health hazards in the food chain such as pesticide residues. Sheldon, *et al* (2009) found that, at least in the UK, the labelling system is considered confusing[73].

The threshold used to allow for the adventitious and technically unavoidable presence of GM material is also seen by some interviewees as being misleading. Most respondents, Competent Authorities and stakeholders alike, find this threshold misleading both because it seems to be set arbitrarily without a scientific basis, and because it seems to imply that products containing less than 0.9% GM material are equivalent to products containing no GMO material at all. Additionally, the concept of adventitious presence is considered to be beyond the typical consumer. This concept is in any case challenged in some German Länder where there is concern that it can be confused with a tolerance level.

The fact that oil (and other ingredients derived from GM material) is labelled even though they contain no modified DNA, nor protein, is seen as misleading by operators. On the one hand, they claim, this labelling constitutes process-based information, which the consumer does not require and which brings no added value. Insofar as GMOs are perceived as a risk factor, labelling products which do not contain GMOs associates these products with a risk they do not carry. The labelling of oil products may further mislead consumers who may find the difference between "containing/consisting" and "produced from" difficult. NGOs and consumer organisation, on the other hand, insist on the

[72] There are some exceptions such as Soil Association (2008).

[73] This finding is based on a predominantly focus group methodology and may not have wider relevance.

absolute right of the consumer to be informed about the presence, direct or indirect, of GMOs in the food chain.

The absence of labelling on livestock products is considered by NGOs and consumer organisations as a gap in process information, although the biotech industry and the food industry see the lack of labelling here as appropriate because it reflects EFSA's conclusion that to date, a large number of studies have not detected modified DNA in livestock products fed on GM feed. In terms of labelling consistency, some interviewees pointed out that additives derived from GMO fermentation are not labelled and the labelling scope is therefore lacking in coherence.

Judgement

The labelling provisions do provide the consumer with information, although it is not clear whether this really helps to provide an informed choice, first because there is little evidence that labelling is an important factor in consumer purchasing decisions. However, those consumers who are concerned about GM content are certainly able to find information. Second, our survey revealed that less than half of Competent Authorities and less than a third of stakeholders believe that consumers understand and accept the labelling provisions and if this is the case, the provisions cannot be facilitating an informed choice. Third, the introduction of the labelling provisions under the 2003 legislation coincided with a general withdrawal of products which would have to be labelled from shelves and this has not facilitated choice, informed or otherwise. Finally, there are elements of the labelling provisions which might be considered misleading, at least for some consumers, in terms of the threshold for adventitious and technically unavoidable presence, the inclusion of oil products within the labelling scope and the exclusion of livestock products. In conclusion, the labelling provisions do provide information to the consumer, but it is not clear whether this information actually facilitates an informed consumer choice.

7.2. Consumer acceptance of the existing labelling rules

The full title of this Evaluation Question is: *What is the consumers' acceptance of the existing labelling rules?*

Consumer acceptance of the existing labelling rules can be judged to some extent by uptake of GM food products. However, the low number of GM food products on the market means that it is difficult to draw conclusions; consumers have not had the products available to demonstrate a clear preference (or not) for GM labelled food (see section 7.4).

This evaluation question is addressed as follows:

- The extent to which consumers are aware of labelling rules.
- The extent to which consumers care about labelling.
- The extent to which they accept these rules and see them as appropriate, useful, etc.
- The extent to which this acceptance is reflected in the up-take of labelled products.

7.2.1. Awareness of labelling rules

Section 7.1 has shown that consumers typically do not read labels. However, this question is concerned with labelling rules rather than the labels themselves. As also noted in section 7.1, there is a distinction between the opinions of individual consumers/citizens and those of organisations representing their welfare: NGOs, consumer organisations, Competent Authorities and food industry operators. With only limited exceptions, individual consumers are not likely to be aware of labelling

rules (this is the conclusion of Sheldon, *et al* (2009)); they may, however, be aware of labels to the extent that they are familiar with the small number of GM labelled products available.

A first response to this question concerns whether consumers can accept labelling rules where there is such restricted experience with them. Another way to look at acceptance is by examining to what extent consumers and concerned organisations:

- are or were informed about labelling;
- accept labelling rules; and/or,
- reacted to labelling before GMO products largely disappeared from the market?

Following the adoption of Regulations (EC) No 1829/2003 and 1830/2003, there were, according to some of our respondents, some government led campaigns explaining the labelling system in a few countries including Germany, Finland, Denmark and the Netherlands. There were no campaigns in the Czech Republic (not an EU Member State at the time in any case), Ireland or Portugal. No details (themes, timing, targets, etc.) could be provided on these campaigns and no information is available on what happened in other Member States.

7.2.2. The extent to which consumers care about labelling

Since the late 1990s, on the other hand, a numerous campaigns on GM food and/or feed took place in the EU, some of them in favour of the technology, but many of them not. Almost all of these campaigns focused on the products, the technology, the processes and/or the supposed risks or benefits. We are not aware of any campaign specifically addressing labelling rules. However, some of these campaigns incidentally promoted "GMO-free" labelling or the labelling of livestock products. In the late 1990s and early 2000s, Greenpeace's "Green and red list" ("Guya rojo verde") targeted branded products and retailers, but referred to GM content, not specifically labelling. Current internet versions of such lists, which signal a few isolated products, allow zooming on their label for verification of their GM content (see section 7.4). During the course of 2005 and 2006, Greenpeace[74] collected 1 million signatures, in 21 Member States, on a petition for labelling livestock fed with GM feed.

7.2.3. The extent to which labelling rules are seen as appropriate, useful, etc

In 2006, DG SANCO launched a public consultation over food labelling, including GM labelling (European Commission, 2006d). It received 175 responses. As might be expected, the industry would like minimum legislative requirements; consumer connected NGOs would like a more restrictive system.

This consultation found that overall, provisions of GM labelling seem to be well respected in the EU (European Commission, 2006c). Both the food and the feed industry reported no desire to change the current labelling rules for GM food and feed and declared that they could operate satisfactorily with them. That said, they raised a number of criticisms:

- They believe that GM labelling is interpreted by some consumers as a warning and, in response to this concern, they avoid the need to label by simply not using GMO ingredients and by reformulating products accordingly.
- They question the need for labelling oil and other products where no trace of modified DNA or protein can be detected. They believe that some provisions can be misleading (see section 7.1)

[74] www.Greenpeace.org.

and that the existing rules do not give the consumer a chance to make an informed choice because there is no choice as a result of the removal of GM material from food supply chains.

- In connection with the above, they point to the need for a dedicated traceability system for non-GM material such as oil, which, in their opinion, is unjustified, difficult to enforce and open to fraud since GM presence is not detectable.
- They do not want livestock products to be labelled because of the difficulties in sourcing non-GM feed materials (see section 7.5).
- Finally, they noted that labelling is costly, provides no consumer benefit and only results in the exclusion of GM material from the food supply chain and therefore actually reduces consumer choice.

Farmers and retailers expressed themselves satisfied with current labelling provisions. Consumer organisations and NGOs also accept the current labelling rules which they see as supporting the consumer right to process-based information. Under this principle, they would like the scope of labelling provisions to be extended to cover livestock products and products from micro-organism fermentation. NGOs expressed strong support for the current labelling provisions, but would like to ensure that the 0.9% labelling threshold is always interpreted as covering adventitious and technically unavoidable presence only, i.e. this should not be understood as a tolerance level.

7.2.4. The extent to which this acceptance is reflected in the up-take of labelled products

Marks, *et al* (2004) report on a retailer scanner data study which was conducted in the Netherlands before GMO ingredients were largely removed from the food supply chain and when there were GM labelled food products for sale. It showed that, at the time, labelling had no influence on consumer demand.

Noussair, *et al* (2002) concluded in a study carried out in France that consumers would probably not read GM labels were they available. Their experiment demonstrated that a group of literate consumers were unable to see the message "genetically modified corn" written on the ingredient list of chocolate bars, even when they could observe the label for several minutes, but that they would alter their purchasing behaviour having had their attention drawn to the label.

In these studies, a difference between the citizen's and the consumer's positions should be highlighted. While the citizen is generally aware (if not informed) on GMO and tends to hold negative views (see section 8.1), the consumer, as evidenced by purchasing behaviour, appears to be much less concerned. Most opinion studies and panels, including Eurobarometer, relate to the citizen, and it is not always straightforward to link citizens' positions to consumers' behaviour.

This is further illustrated by Sheldon, *et al* (2009) which addressed GM labelling in the UK, but only to a limited extent. Its respondents stated that: "*all products which involve GM processes should be labelled*". On the other hand, it also concluded that many people were not always very well informed on GM issues (see the labelling case study for more details).

Generally, awareness of GM labelling among consumers seems to be very low, perhaps not surprisingly given the limited experience that consumers have with the labels. King's College London (2008) ran focus groups on purchasing factors in 7 Member States and reported that: "*overall awareness of GM-products and labels are very low. The participants did not mention labels related to gene technology as a factor influencing their decisions either in those countries where GM-products are available in stores or in those where products labelled "GM-free" are on sale*". This study also concluded that where GM products are available, consumers buy them.

Judgement

In conclusion, the answer to this question is largely a matter of interpretation. Either the consumer wholeheartedly accepts labelling rules, and they so closely meet expectations that consistent use is made of them to reject all but a small number of GM labelled food products from the market, or the question of acceptance cannot be answered because there are insufficient labels on the market to be accepted or rejected. However, it should be noted that at least 1 million EU citizens would like to see GM labelling extended to encompass livestock products, which implies a lack of acceptance of the current scope of labelling, if not its current application, by this group of citizens.

7.3. Impact of labelling on the food/feed market

The full title of this Evaluation Question is: *What impact have the rules on labelling of GM food/feed had on the different actors of the food/feed market?*

This question leads to the following sub-questions and should be looked at from the perspective of food and feed products respectively:

- The extent to which operators have changed their operations or practices to accommodate labelling rules.
- The operational and cost implications.

7.3.1. The extent to which operators changed their operations to accommodate labelling rules

7.3.1.1. Food supply chain

In the case of food products, a development over three time periods must be considered.

Between 1996 and 1997, the food industry initially supported GMOs, including major food manufacturers such as Nestlé and Unilever. They continued to use GM raw materials including oil, iso-glucose and lecithin, and even introduced products with explicit biotechnology claims. Major food manufacturers groups produced GM products: Nestlé introduced a maize snack "Butterfinger" which was labelled voluntarily under the Novel Food Directive[75]; Novartis launched cereal bars within its "health food" range; and, Unilever made a soya based Ice Protein[76]. In the UK, ICI-Zeneca commercialised a paste produced from the Flav-r-Savr tomato developed by Calgene[77]. However, no retailer positioned themselves as an advocate of GMOs. The retail sector in the EU is very concentrated, with some oligopolistic features (see, for example, Smith, 2006 and Burch and Lawrence, 2007) and retail chains tend to mimetically align their behaviour on each other. According to our respondents, it was felt that once one of them would have taken a stance to differentiate by positioning itself on the GMO segment, others might have positioned themselves as non-GM, resulting in a first mover disadvantage effect. This resulted in a wait-and-see steady state equilibrium.

Then, in the late 1990s retailers backed away from GM technology and issued specifications to their suppliers requesting total absence of GMOs in food products in order to avoid the forthcoming use of GM labels. This specification was passed back along the supply chain. Non-GM specification for food products implies identity preservation when GM presence can be detected and traceability when it cannot, as in the case of oil.

[75] http://askville.amazon.com/butterfinger/Topic.do?tag=butterfinger.

[76] http://www.themilkweed.com/Feature_06_Dec_1.pdf.

[77] http://fr.wikipedia.org/wiki/Flavr_Savr.

Our retail and industry respondents unanimously claim that this move came in reaction to hostile campaigning by anti-GMO NGOs (for example Greenpeace's "red and green" list) and media (for example the UK Daily Mail campaign on "Frankenfood"). Our NGO respondents claim that this move reflected a lack of consumer interest and demand which made these products unprofitable.

The rationale for the change of attitude notwithstanding, the net result was that food manufacturers started publicly declaring that they had no stake in GMOs and followed retailers in either withdrawing GM labelled products altogether or avoided developing and launching new ones. To protect their brands and image, major groups, such as Zeneca[78], Unilever and Novartis, followed by Nestlé, withdrew their GMO products and issued widely publicised statements totally banning GMO ingredients[79]. This banning was achieved through a combination of reformulation, new specifications to suppliers, identity preservation and change of suppliers. For example, soya oil was replaced by other vegetable oils such as sunflower or rapeseed. Soya lecithin from the US was replaced with (lower quality) egg or rapeseed lecithin, or by lecithin from Brazil (where no GM crops were authorised at the time). These changes also implied reinforced traceability, testing and controls as well as, in some cases, insurance costs. Generally speaking, identity preservation was neither exceedingly difficult nor costly to set up, because, in the case of food products, it involved only a few thousand tonnes of ingredients, such as soybeans, protein extracts or lecithin, despite their widespread use in food products as shown by Landmark Europe (2009).

Reformulation costs were not excessive because of the limited quantity of concerned ingredients in food products. For example, doubling the price of lecithin (because of identity preservation), constituting less than 1% of a chocolate bar content, will increase the cost of ingredients by only 1% to 2%. Ingredients will constitute 30-40% of production cost, itself largely diluted in the value chain before reaching the consumer. The final impact on consumer price and industry/retail margin will be negligible (see Buckwell, *et al*, 1998). In any case, the marginal cost of reformulating is lower than the potential cost of lost sales and potential damage to the brand image.

The example provided by a few significant players in the food industry set a standard. Since then, the overall concern has been to avoid at all costs being identified as a producer or seller of GM food products. This implied making sure that no GM material, even where adventitious, could be detected, and that no products would fall under the scope of the GM labelling provisions. To counter the risk of GMO content accumulation along the supply chain eventually exceeding the labelling threshold (at the time 1% under the Novel Food Directive), processors imposed significantly lower thresholds on their suppliers. This is still the case today. In Spain, in regions where GM maize cultivation is relatively abundant, starch manufacturers such as Amylum require co-operatives to deliver maize to them at a maximum of 0.1% GM content (Daems, *et al*, 2007).

Some retailers were then keen to acquire a competitive advantage from this "GMO avoidance" pattern and initiated product lines voluntarily labelled "GM free". Carrefour launched a "Carrefour quality label" with provision for meat from animals fed with non-GM soya. To ensure its suppliers' compliance, Carrefour itself set up and managed an import scheme of some 300,000 tonnes of certified non-GM soybean meal from Brazil. In the UK, Tesco also had a non-GM specification for their suppliers of own-brand livestock products. Food producers, particularly of livestock products such as dairy, were not keen at all to follow this trend because it involved doubling logistic circuits (milk collection and storage), production (doubling production lines or incurring high set up costs) and packaging (bottling and labelling). All these arrangements reflected in additional cost that the retail was not prepared to pass to the consumer.

[78] The Zeneca tomato : http://www.ncbe.reading.ac.uk/NCBE/GMFOOD/tomato.html.

[79] Tesco and Unilever: http://www.independent.co.uk/news/tesco-and-unilever-ban-gm-products-banned-1090100.html; Nestlé on BBC: http://news.bbc.co.uk/2/hi/uk_news/330865.stm.

As a matter of consequence, when the labelling provisions within Regulation (EC) No 1829/2003 were introduced, companies had already introduced traceability and audit to ensure non-GM supply. The new provisions generated no significant labelling costs, but did generate additional identity preservation cost. This is because, in the meantime, it became increasingly difficult to source large quantities of non-GM soybean from Brazil.

7.3.1.2. Feed supply chain

In the feed supply chain, particularly the compound feed segment that is the most affected, actors reacted somewhat differently than in the food sector.

In a first phase, which lasted until 2007/08, the market for feed and feed ingredients divided into two segments: GM and non-GM. A number of non-GM certified schemes[80] and specifications[81] were developed and implemented in the livestock and meat supply chains. These schemes were generally implemented in response to retail demand. One newly developing segment was the "organic" or "bio" product line which, by definition, is "GM-free", albeit with a 0.9% threshold for adventitious and technically unavoidable presence. A number of these schemes were based on the possibility to source, at the time, relatively large quantities (as noted above, 300,000 tonnes for the Carrefour contract) of non-GM soybean meal from Brazil at an affordable additional cost (for cost estimates, see later in this section). Indeed, in the late 1990s and early 2000s, the Matto-Grosso region (Centre-West of Brazil) was still largely free of GMO planting, because varieties growing in the South (Parana) had not yet been adapted. Soft (documentation based) identity preservation was still highly reliable, and the additional cost was limited. Since the non-GM identity had to be preserved throughout the whole supply chain, additional cost accumulated. However, since the raw material cost was also diluted in the value chain, the final effect at consumer level was negligible (for quantified data, see later in this section).

In the meantime, two major changes appeared:

- GMO acreage grew very strongly, and Matto-Grosso, initially the area preserved for sourcing non-GM, but also the most industrialised one, became a GMO powerhouse (Bernard, 2004; Valbuena, 2009). Also, the number of GM events increased. Since large-scale commodity export logistics involves co-mingling and numerous exposures to adventitious presence (silo and ship cleaning, the famous Paranagua "commodity exportation corridor", etc.), it became increasingly difficult to reliably source non-GM soybean products. Running two supply chains in parallel became unsustainable, unreliable and too costly.
- Regulation (EC) No 1829/2003 introduced new labelling provisions which included the need to label oil products, but not livestock products.

As a result, manufacturers of feed and feed ingredients tended gradually to disregard non-GM supply schemes and to take for granted that all feed and ingredients containing soybean would be labelled as GMO, irrespective of actual presence. This is also the case for feed containing maize in Spain because collecting co-operatives cannot absolutely guarantee lower than 0.9% GM material presence. Bemefa, the Belgian feed industry organisation, announced to its members in 2008 that they were discontinuing their "GM-free" specification, which had proved un-sustainable. Hence, a large majority of European feed is nowadays labelled under the provisions of Regulations (EC) No 1829/2003 and 1830/2003 (see section 7.5) and the trend is upwards. Our respondents indicate that there may also be protective "over labelling", i.e. if imports include 3 out of 5 approved events, operators may label for all five, just in case material is present and to avoid labelling infringements. Importers also become careful not to

[80] For example: Cert ID: www.cert-id.com.

[81] For example, BEMEFA issued a non-GMO specification in 2001 (www.bemefa.be).

import from countries or regions growing events not approved in the EU and this is now normal practice with the intention to avoid the legal risk of LLP. On the other hand, this practice restricts the actual availability of non-GM feed.

Such alignment to changes in the market place generated additional costs throughout the whole supply chain. Depending on the case these costs can be associated with either:

- identity preservation;
- reformulation;
- changes in suppliers;
- reinforcement of tests, controls and administration;
- re-engineering of operations: production and logistics;
- insurance;
- price shifts resulting from changes in demand; and,
- foregone opportunity.

The only cost that can be described quantitatively is identity preservation. Other costs are either multi-factor, not solely associated with GM avoidance, or are undocumented.

Identity preservation (IP) costs were first established around 1999/00. At the time, IP cost to import soybean from Brazil at 0.1-1.0% tolerance was estimated at some 10% of commodity price, whereas the additional cost for lecithin from identical origin amounted to only 0.1% of its price (Buckwell, *et al*, 1999). It was also shown that:

- at each stage of the supply chain, the main cost component is the additional price to purchase IP material from preceding stages; and,
- while cost of identity preservation piles up in absolute terms in the supply chain, it also dilutes in relative terms in the value chain. In the case of livestock products, the net result is that, assuming full price transmission across the supply chain, the additional cost of IP would result in only a small increase (about 1%) in consumer price (de Borchgrave, *et al*, 2003). This outcome is rather insensitive to thresholds and IP method (soft/hard).

For the reasons given above, mainly the restriction in supply of non-GM soybeans, these conclusions are by and large now outdated. Indeed, IP costs have increased substantially and the impact on consumer prices cannot be seen as negligible any more. Estimates and comments on future additional cost, as provided by our respondents in the food and feed sectors, are provided below:

- Segregation and certification costs amount to some 10-15% of the soybean meal price. This means that non-GM soybean costs around $330-345 per tonne, instead of about $300 per tonne. However, seasonal differences can amount to a premium of some $100 per tonne (industry estimates provided in interview).
- The impact of demand for non-GM soybean on price is difficult to isolate because price change is a multifactor, dynamic process which depends, inter alia, on climate, worldwide demand, technology, etc.
- The premium for non-GM soybean meal ranges from $20 to $80 per tonne, whereas the base price fluctuates between $200 and $500 per tonne (Dronne and Gohin, 2005; Index Mundi[82]).

[82] http://www.indexmundi.com/commodities/?commodity=soybean-meal.

This premium will increase as the proportion of GM crop and the number of GM events increases in exporting countries, particularly in Brazil.

- According to European commodity trading and storing organisations, the additional costs of IP for Brazilian soybean meal is now about $30-35 per tonne, or 10% of price[83]. Identity Preserved imports of corn products from the US incur between 50% and 80% additional operations cost, including 28% on unloading cost and 105% on storage cost.
- Interviewees in the UK retail sector believe that non-GM poultry meat results in an additional 10% consumer price.

Judgement

The history of GM food products reveals that operators made changes to their supply chains before the introduction of the 2003 legislation either in response to pressure from NGOs and/or consumer demand. This means that the introduction of labelling provisions under Regulation (EC) No 1830/2003 had limited direct impact on the actors in the food sector in terms of logistical arrangements. However, as supply of non-GM raw materials has become more restricted, the cost of segregation and Identity Preservation has increased, although the impact is diluted in final consumer prices. The situation is a little different in the feed supply chain. Initially the feed supply chain divided into GM and non-GM segments with the additional costs of segregation and Identity Preservation borne on the non-GM side. This process has been exacerbated by reductions in the availability of non-GM supply and this has resulted in high segregation and Identity Preservation costs for this market segment, although these costs will be diluted to some extent in the value chain depending on the use of IP feed and feed conversion ratios for different species. That said, Identity Preservation costs have increased substantially and the impact on consumer prices cannot be seen as negligible any more.

7.4. Food products on the market labelled as GM

The full title of this Evaluation Question is: *To what extent is food on the market labelled as GM?*

In addressing this question it is useful to decompose it into the following sub-questions:

- What food products can contain GM material (soybean, maize) and would need to be labelled under the 2003 legislation? How numerous, diverse and widespread are these products?
- Which products actually on the market are labelled as GM and where are these found?
- What is the market share of these products, i.e. do consumers actually buy GM food products?
- Are there any variations in GM presence by category or by product?
- How has the market for GM labelled food products evolved over time?

7.4.1. Food products which might contain GM material

In the first place, there is theoretically a very large potential range of products containing GM material. This potential range includes all products containing soybean derivatives (such as protein extract, oil, lecithin or isoflavones) and maize derivatives (such as grits, isoglucose syrup and its numerous hydrolysis derivatives (sorbitol, etc.). In total, this amounts to literally thousands of food products, ranging from confectionery through bakery, margarines, meat products (sausages), sauces, drinks (beer), complex dairy products (ice creams), etc. (see Landmark Europe, 2009).

[83] Soy meal: $303 per tonne in February 2010. Source: Index Mundi.

Another indicator to assess the presence or non-presence of GM labelled food products is the width of the range of food products offered by a typical retail chain. It is well established that the retail sector controls the majority of the food market in the EU (Planet Retail, 2006[84]). A major UK retailer indicated that they hold some 30,000 to 35,000 SKU (Stock Keeping Units), including up to 15,000 own brand SKU. This is corroborated by literature indicating that a large food retailer may hold up to 50,000 SKU (Food Marketing Institute, 2006), of which some 3,000 are own-brand SKUs (Mazurek, 2005). Although not all will represent a different product, they may just indicate various packaging formats, and neither are all SKU food products, nonetheless, the net outcome is that a retail chain holds several tens of thousands of food products, out of which several thousand could possibly contain GM material.

7.4.2. GM labelled food products on the EU market

Against this potential for significant presence of GM labelled products there are some key sources concerned with the actual presence of GM labelled food products available in the EU:

- King's College London (2008) documents an EU-wide FP6 research project on the theme "Do European consumers buy GM Foods"?
- Answers provided by Competent Authorities and stakeholders to our own survey (see survey appendix); and,
- NGO listings, including consumer monitoring and reporting, for example from Greenpeace.

Table 7.1 indicates the number of GM labelled products found in various EU countries. Data were available for 20 Member states. However, these 20 Member States constitute a large, diversified and representative sample which provides a fair description of the overall EU situation.

[84] This study mentions 9 EU countries, where the 5 larger retail chains own more than 70% of the food market, including Finland where they own over 90%.

Table 7.1: Number of GM labelled food products in EU stores

	King's College London (2008) 2006-2007	King's College London (2008) 2007-2008	Survey results/ stakeholder interviews (2009)	Greenpeace (2005)	Nature of products
Austria	-	-	0-1	-	-
Bulgaria	-	-	-	-	According to Competent Authority response to survey, 10% of soya containing products
Czech Republic	21	23	-	12	-
Denmark	-	-	0-1	-	-
Estonia	9	13	Several dozen	0	Mayonnaise, maize flour
Finland	-	-	0	-	-
France	-	-	-	16	Soya oil (7 brands), Cereals (US), Gingerbread (imp), Mixes (2 brands imported), Sauces (3 brands), Root-beer (US), Marshmallow (imp)
Germany	1	1	≈ 15	19	Catering oil in barrels e.g. chip fryers
Greece	0	-	-	0	-
Hungary	-	-	≈ 5	-	-
Italy	-	-	0	-	-
Lithuania	-	-	48	-	-
The Netherlands	18	-	≈ 12	16	-
Poland	1	-	-	6	Soya cooking oil
Romania	-	-	1	-	Soya oil
Spain	6	-	20-30	-	Some maize products from Colombia, mayonnaise, bakery, catering oil
Slovenia	0	-	-	0	-
Sweden	1	0	-	-	Beer
UK	3	-	≈4-14	2	Soya oil in Asian stores

Sources: King's College London (2008); own survey/stakeholder interviews (2009); and Greenpeace (2005a).

Table 7.1 clearly indicates that, as compared with the range of potential GM products, their actual presence is extremely limited in terms of the number of products for sale. GM labelled products appear to be concentrated in some soybean oil for cooking and in some imported products.

These findings were by-and-large confirmed by our retail and industry respondents, who provided the following additional indications:

- A major UK retailer said they have 14 GM labelled products, including vegetable oil in catering volumes, cake decoration, bacon bits and American bagels. Most of these products are imported from the US or from Asia and contain soybean oil or corn starch.
- The same respondent has about 15,000 own-brand SKUs, out of which some 1,500 contain a soybean derivative. However, none of this is derived from GM material.
- No European retailer has own-brand GM labelled food products.
- In the UK, each main retailer must have, on average, approximately 10 GMO labelled items (SKU).
- Some retail chains point out that, unless they are labelled as "organic" or "bio", all their livestock products are obtained from livestock fed on GM feed (King's College London, 2008); our interviews with the retail sector reveal that other retail chains operate non-GM livestock supply chains.
- In those countries in which GM labelled foods are on sale, most are oils derived from GM soybean sold either as cooking oil or incorporated into other products such as margarine. However, some oil and products containing other GM ingredients derived from maize are also on sale. The number of different labels varies. In Estonia, there are nine brands of GM labelled oils, in the UK only two. This probably reflects organisational differences among suppliers and whether items for retail sale are bottled and labelled domestically or imported. According to interviews in the retail sector, these products are cheaper as a result of the more direct link between the GM commodity (and hence no segregation or Identity Preservation costs) and the final product.

Based on the findings above, most GM labelled products are vegetable oil rather than more complex manufactured food products, although products containing large amounts of oil, such as mayonnaise, are also labelled. Where these products are available they tend to be cheaper than non-GM variants. In conclusion, it appears that the number of GM labelled food products for sale in the EU is, at best, extremely limited.

7.4.3. Market share of GM labelled food products

An adjacent question relates to the market share of GM products, that is the sales or volume percentage of any given GM labelled food product against total sales or volume on the market for this product. Unfortunately, there are no hard data available on this, and one has to rely on qualitative respondent estimates or to indirect approaches. In no Member States examined under this study did industry or retail respondents believe that the market share for any GM labelled food product exceeds 1% and is probably significantly lower.

In the absence of available hard sales data, a market share proxy was constructed by King's College, London (2008), which assessed the extent to which consumers actually buy (the few) GM products available on the market. This was done via an analysis of bar code data for a sample of consumers. This yielded a "market penetration" index (which is not the same as market share) of the proportion of the sample who have bought GM labelled products over the last year. The survey also asked these consumers whether they were aware of buying GM labelled products. **Error! Reference source not found.** shows the results.

Table 7.2: Market penetration and consumer awareness in eight countries (2006-2008)

Country	Type of label	Market penetration (%)	Correct buyer response (%)
Czech Republic	GM	13.7	80
The Netherlands	GM	10.9	76
Poland	GM	2.7	62
Spain	GM	2.0	93
United Kingdom	GM	0.0	-
Germany	"GM-free"	4.4	69
Sweden	"GM-free"	2.1	60
Greece	-	0.0	-

Source: King's College, London (2008).

Table 7.2 suggests that GM labelled products placed on the market are indeed purchased, and in some cases at a level higher than expected, however, "market penetration" is limited to a small number of Member States. While being slightly above 10%, this level is nonetheless significantly higher in countries like the Czech Republic and the Netherlands, where GMO acceptance is greater, than in the other examined Member States. It is also noteworthy that a sizeable proportion of buyers have no knowledge of what they are actually buying, or simply do not care. This is especially the case in Sweden, Germany and Poland, three Member States where acceptance of GMOs is relatively low.

7.4.4. Evolution in the market for GM labelled food products

Finally, we need to briefly examine the evolution of GM labelled food presence in the EU (see section 7.3 for further information on the evolution of GM labelled food products in general). GM labelled food products first appeared on the market around 1997. These products included a variety of soybean or maize ingredients. Some of these products were launched by international food or ingredient companies. They were initially either unlabelled or voluntarily labelled as containing GM material. Examples are a GM derived tomato puree by Zeneca, sold in the UK by Sainsbury's and Safeway labelled as such and sold at a small price discount. The product sold well, but was withdrawn in 1999 (Soil Association; 2003; Golden Harvest Organic LLC, no date).

Following hostile press campaigns, notably by the Daily Mail in the UK, and the publication by Greenpeace of its "Red-green list", industry soon withdraw GMO products: Novartis in 2000 and Unilever/Nestlé in 1999. Nabisco withdrew a biscuit made with GM Maize in 1998. Nestlé had a maize based snack called "Butterfinger", which sold between 2002 and 2005 in the UK and was then withdrawn. Retailers did not want to appear on Greenpeace's "red/green" list and issued non-GM specifications to their suppliers. In 2003, when the requirement to label oil was introduced, products using GM derived oil were reformulated to avoid the need to label. Ever since, the market for GM labelled products has not developed over time, in fact, the market has reduced in size since there are now very few products available (see above).

Judgement

There is strong secondary evidence that the availability of GM labelled food products in the EU is extremely limited. This evidence is corroborated by our more recent primary research comprising survey findings, the semi-structured interviews with key stakeholders and the thematic case study. The range of GM labelled products consists primarily of soybean oil for cooking and some imported products. Where GM labelled products are available, they are purchased by at least some consumers. The main external factor limiting the choice of the European consumers with respect to their purchases of GM food is their availability in stores: there are no retailer own-brand labelled GM products.

7.5. Feed on the market labelled as GM

The full title of this Evaluation Question is: *To what extent is feed on the market labelled as GM?*

The key questions necessary to address this EQ are as follows:

- What feed products on the market are labelled GM?
- What is the market share of these products?
- Are there any variations by category or by product?
- How have these market shares evolved over time?

7.5.1. Background to the labelling requirements with respect to feed

The provisions of Regulations (EC) No 1829/2003 and 1830/2003 for labelling and traceability apply to feed consisting of, containing, or produced from GMOs, including:

- operator at first stage of placing on the market to provide information on the GMO content and its identification;
- subsequent stages of placing on the market to transmit this information to the following stage (i.e. traceability requirement);
- in the case of mixtures of GMOs (as can be the case for compound feed), the above information may be replaced by a declaration of use and the list of identifiers;
- for pre-packaged products containing or consisting of GMOs, the words "this product contains genetically modified organisms/ name of organism" should be used on labelling; and,
- for non-pre-packaged products offered to the final consumer, the words "this product contains genetically modified organisms" should be used on labelling.

If a trader buys soybeans after crushing, then the label only states that they contain products "produced from GMOs". However, shipments of soybeans prior to crushing must specify the specific event(s). Prior to Regulation (EC) No 1829/2003 shippers could use a "may contain…" label; this is no longer an option, but there is no requirement for all the listed events to actually be present. This allows for the possibility of adventitious presence of other GM events which must themselves be authorised in the EU. Compound feed is simply labelled as GM. This can be as a footnote to the ingredients or it can follow the ingredient in parenthesis.

European Commission (2006e) criticised some Member States for not applying the labelling legislation correctly. Germany, for example, decided to label all feed as GM, just in case. Although the Commission criticised this position, ultimately the German Competent Authorities supported the industry. The way in which Member States set out the approach to avoiding adventitious presence differ with Germany having a fairly tough regime under which a burden of proof is placed on

manufacturers to demonstrate why the presence was technically unavoidable. In Italy, however, the authorities allowed manufacturers to continue using "may contain…" labels in case the operator could not guarantee that the GM level was below 0.9%. The legal base for this was drawn from general food law.

COCERAL and FEDIOL (2010) point out that some Member States have been applying the labelling legislation irrespective of whether the presence of GM material is composed of grains of the same plant species (e.g. GM maize in maize) or grains from different plant species (e.g. GM soybean in maize). They contend that this is not in accordance with Directive 96/25/EC which provides, for raw materials, a labelling exemption for botanical impurities where these do not exceed 5% and could result in, for example, sunflower oil being labelled as "sunflower oil made from GM maize".

It should be noted that a lot of additives used in the feed industry are produced from fermentation by GMOs, but these are precluded from the scope of Regulation (EC) No 1829/2003 and products resulting from this process do not have to be labelled. In the German legislation there is specific exclusion of these products.

Also, a substantial part of feed used in the EU is mixed on-farm and this does not carry a label, although home mixers may use GM feed materials.

7.5.2. GM labelled feed products on the EU market

EU feed is particularly exposed to GMO presence as a result of vegetable protein dependence. In 2008, the EU-27 livestock sector consumed some 468 million tonnes of feed, of which, according to the EU feed industry, some 151 million tonnes were produced by compound feed manufacturers. Table 7.3 breaks this production down by main user segments.

Table 7.3: Use of compound feed per segment in '000 tonnes

User segment	2006-2007	2007-2008	2008-2009
Cattle	38,603	37,858	35,202
Pigs	52,951	52,402	49,195
Poultry	47,876	48,843	47,735
Other	11,764	11,465	11,214
Total	**151,194**	**150,568**	**143,346**

Source: FEFAC compound feed production (1989-2009).

The remaining demand for livestock feed is met through forage, pasture or feed produced on farm.

The main operators in the feed sector are:

- exporters/importers;
- compound feed manufacturers;
- ingredient wholesalers;
- distributors; and,
- farmers.

Protein is a key component of feed for all user segments. Its main source is meal from oilseeds such as soybean, sunflower, rapeseed and palm. Soybean meal is particularly valuable because it contains over 45% protein, including most of the essential amino-acids. According to the EU feed industry, in 2008, the EU used 42.6 million tonnes of oilseed meals/cakes (FEFAC, 2008b).

Most of the EU requirement for protein is imported since the EU does not produce enough to meet demand[85]. Table 7.4 illustrates the extent to which the EU depends on imported protein and highlights the predominant role of soybean.

Table 7.4: EU protein self-sufficiency of crops with a GM comparator (2006/07, tonnes)

Ingredient	EU production (T)	EU production (protein T)	EU consumption (T)	EU consumption (protein T)	Self sufficiency in protein (%)
Soybean meal	983,000	452,000	36,500,000	16,583,000	3
Sunflower meal	3,386,000	1,016,000	4,975,000	1,493,000	68
Rapeseed meal	9,191,000	3,317,000	9,825,000	3,439,000	94
Corn gluten feed	2,311,000	485,000	3,189,000	670,000	72
Total*	-	7,111	-	29,953	28

* all protein crops, including those without a GM comparator

Source: FEFAC (2008b).

Table 7.5 describes EU imports of feed ingredients. It indicates the dominant role of oilseed cakes, meaning principally soybean, as well as the sharply declining weight of maize by-product imports (see below).

Table 7.5: Imports of feed ingredients ('000 tonnes)

Ingredient	2002	2006	2007	2008
Corn gluten feed	4,417	2,442	706	215
Maize germ meal	42	1	0	0
DDGS[86]	867	575	-	221
Oilcakes	23,349	27,195	-	27,259
Total	**49,456**	**40,998**	**49,575**	**45,253**

Note: soybean is not separated in the original data, and therefore falls under oilcakes. It is likely that the bulk of imports under the oilcake category are soybean. Between 2005/2006 and 2008/2009 an average of 22.912 million tonnes of soybean cake and cake equivalent was imported by the EU-27 from Third Countries according to European Commission (2010b).

Source: FEFAC (2008b).

Practically all soya imports in the EU originate from the US, Argentina and Brazil; three countries where plantings of GMOs dominate and where this domination is growing to the extent that it is

[85] The current situation was exacerbated by the ban on using meat and bonemeal (MBM) following the BSE crisis.

[86] DDGS: Dry Distillers Grain Solids, a by-product of corn processing.

becoming increasingly difficult to source non-GM soybeans or meal from these countries and almost impossible to obtain material without some probability of adventitious presence (see section 3.4). Additionally, due to growing demand in Third Countries, particularly from China, the EU is less and less considered as a privileged consumer for Brazilian exporters and non-GMO soybean supply is proving increasingly difficult to obtain (Layadi, 2007).

The EU ceased imports of US maize by-products in 2006 after shipments were blocked because it was found that they contained traces of non-authorised varieties after US corn processors had decided to stop exclusively using varieties authorised in the EU.

Because of the growing planted acreage and the logistics of commodity trading, implying co-mingling, plus conditions of international shipping, an overwhelming majority of imported soybean products contains over 0.9% GM material and, as a result, the majority of feed containing soybean products is labelled as GM (for bags or containers) or traced (for bulk) accordingly. Hence, a large majority of EU feed contains GMO ingredients and is labelled as such. No hard data on the relevant sales or market share are available for the EU. However, feed industry sources indicate that some 85% to 90% of compound feed and 95% of soybean meal in the EU is labelled as GM (see table in descriptive part). The proportion of EU compound feed containing GM material was estimated by our respondents to be only around 70% in 2004, so it is clear that market share is increasing.

A number of Competent Authorities and stakeholder respondents provided estimates of the proportion of GM labelled feed currently on the market in their Member State, as summarised in Table 7.6.

Table 7.6: Market share of GM labelled feed by Member State

Austria:	80% of feed containing soya
Belgium:	80% of feed
Bulgaria:	10% of feed
Denmark:	65% of feed
Finland:	4% of feed
France*:	About 80-85% of feed containing soybean
Germany:	90%
Ireland:	95% of feed
Italy:	100% of feed
The Netherlands:	100% of feed
Romania:	40% of feed
Spain:	95% +
Other Member States:	data not available

Source: FCEC survey. * estimate provided by interviewees

It should be noted that the percentage of labelled feed indicated here represents an upper limit because some countries (for example, Germany and Spain) allow the GM labelling of all feed, irrespective of whether there is actually GM material or not. This policy avoids the risk of GM material being found

in un-labelled feed. However, the fear of this risk prevents suppliers from producing non-labelled products which generates difficulties for the livestock sector in terms of sourcing non-labelled feed.

7.5.3. The evolution of market shares over time

The drivers of market share appear to be:

- protein dependence of the EU livestock sector;
- a lack of substitution possibilities, while substitutes for corn by-products are abundant and the extra cost is reasonable, there are no substitute for soybean protein in the EU, either in terms of quantity or nutritional quality;
- the steadily increasing proportion of GMO acreage, as well as the growing range of GMO events in exporting countries limits the substitution options and raises the cost of non-GM supply.

The GM feed market is stable or increasing. According to the feed industry, the proportion of GM labelled feed grew from some 70% in 2004 to some 85%-90% currently.

All operator respondents indicated that the 2003 legislation did not have much effect on the market beyond the need to label. The general impact of the introduction of mandatory labelling has not been significant and there was no market (farmer) reaction. There has been no surge in demand for non-GM supply either, in fact, this market segment has been declining in importance.

There was initially a significant market for non-GM feed, with some retailers imposing non-GM specifications on their suppliers of livestock products, particularly poultry. Some manufacturers have now supplied a non-GM alternative for around ten years. However, this was difficult because there was no legal definition of what was not GM (i.e. there was no defined tolerance level and it is not easy to convincingly advertise fully GM-free status). Different manufacturers wanted different qualities of non-GM soya based on different tolerance thresholds. The legal tolerance for GM presence in organic feed is 0.9%, although in practice many organic standards are stricter (and will differ from one another).

Examples of companies using non-GM supply chains include Carrefour, which secured a non-GMO supply and BEMEFA, the Belgian Feed sector federation, which launched a non-GMO specification in 2001. However, these schemes became increasingly unsustainable as it became increasingly difficult to reliably supply non-GM ingredients. In 2006, 20% of 215 supposedly "non-GMO" feed samples were tested at over 0.9% GM content, and 6% of them contained in excess of 3.5% GM material. In 2007, these proportions had grown to respectively 35% and 20% (Dejaegher, 2008) and the schemes were discontinued. In 2008, BEMEFA wrote a letter to its affiliates to announce the end of the scheme. Following campaigns by farmer unions and the feed industry, Poland had to suspend its feed law forbidding the use of GMOs. Carrefour stopped its supply scheme because the required quantity became unavailable in Brazil and the additional cost became excessive. In the UK, the poultry sector has operated a non-GM feed supply chain, but has indicated that this may not be possible moving forward because it is no longer sustainable.

Judgement

The main exposure to GM material in feed in the EU results from a dependence on imported vegetable protein, mainly soybean as this cannot be easily substituted. The vast majority, 85%-90% of feed is labelled as GM and up to 95% of soybean imports are labelled as GM and these proportions have been increasing as planting of GM events increases. There are some national variations in the interpretation and implementation of labelling provisions, for example relating to the requirement to demonstrate that the presence of GM material is adventitious and technically unavoidable. Finally, there is a relatively small niche market of non-GM feed for the "organic" segment and non-GM supply chains.

7.6. Reasons for this situation

The full title of this Evaluation Question is: *What are the reasons for this situation?*

The extent to which food on the market is labelled as GM was set out in section 7.4 and the extent to which feed on the market is labelled as GM was set out in section 7.5. Here, the reasons for the current extent of labelling are examined.

One important driver of the development of both markets is the EU authorisation process in that GM events have to be authorised for use as food and feed in the EU before labelled products/feed stuffs can be sold. The authorisation of GM events in the EU is set out in (section 3.4).

There is also one crucial point of difference between the two sectors. The labelling regime means that in the food sector, the final consumer is aware of the presence/use of GMOs. In the feed sector, there is no label on livestock products and therefore the use of GM feed is not communicated to the final consumer. The link between consumer attitude and purchasing decision is therefore substantially weakened in this case.

To summarise the current situation:

- There are practically no GM labelled food products for sale in the EU. The few GM products that were launched by European manufacturers in the late 1990s have been withdrawn.
- Practically all compound feed and feed ingredients from soybean are currently labelled as GM. This has been and still is an increasing trend.

7.6.1. GM labelled food products

Both NGOs and the food industry agree that there are almost no GM labelled products on the market. Our respondents give two basically divergent versions of this market development, depending on whether they represent consumers or are NGOs, or whether they are industry and food chain operators. These two versions prove eventually not to be mutually exclusive. We will also look at the version of selected Competent Authorities.

NGOs claim that there are no GM labelled food products on the market simply because there is no demand. Consumers do not want to eat GM food products, either because they see them as harmful to health or the environment, or carrying no benefit. They spot these products by their label and avoid buying them. Therefore producers/retailers have to withdraw them from the market because they are unprofitable. This claim is partly substantiated by existing opinion polls reflecting a generally low level of acceptance of GMOs by EU citizens (see section 8.1). The extent to which citizens' opinion is reflected in consumers' buying patterns is however not clear, since existing surveys tend to indicate that consumer decisions are largely driven by price and that label awareness is limited. In addition, King's College London (2008) indicated that GM labelled products are indeed purchased when made available to consumers.

The biotech and food industry version of events is quite different. According to these sectors, some GM food products were successfully put on the market in the late 1990s, that is before mandatory labelling made them highly visible. This was the case in the UK, in respect of the previously mentioned ICI-Zeneca tomato paste launched in 1996 and explicitly labelled as GM. Very soon, however, anti-GM NGOs launched hostile campaigns supported by the media. Examples, indicated above, were the Daily Mail campaigns in the UK which introduced the term "Frankenfoods". These campaigns generated an awareness and hostile climate for GMOs in several Member States and, in particular, a consumer rejection of GM food products.

At the time, labelling was not a legal provision. Among anti-GM NGOs, Greenpeace was particularly active and effective by producing and widely circulating its "Red-orange-green" list. On this list, all

producers or retailers not prepared to explicitly declare that they did not use any GM ingredient were singled out in Greenpeace's "red" list, irrespective of whether there were effectively using GMOs or not. In other words, refusal to declare the total absence of GMO was interpreted as the presence of GMO. The impact and visibility of this list were effectively supported by intense media coverage. Against a background of mounting hostile opinion in several Member States, and indifference in others, this could have been very damaging to industry and retailer businesses stocking GM products.

In April 1999, Unilever and Tesco declared the removal of all GM ingredients from their products. According to the Independent newspaper in the UK, "Peter Melchett, executive Director of Greenpeace UK, said the spotlight was now on Nestlé to phase out the ingredients" (The Independent, 1999). In June 2000, Novartis withdrew its cereal bars and other products containing GM material, as was revealed in a letter to the Belgian office of Greenpeace, in an attempt to get the environmental group to include Novartis on its list of "GM-free" food producers (Reuters, 2000).

Retailers were indeed a main target of activist campaigns for the withdrawal of GM products. In Germany, Metro withdrew GM products in 2003. Under such widespread and successful pressure, retailers rapidly withdrew all GM products from their shelves and issued non-GM specifications to their suppliers, in particular their own-brand ones. Some retailers even attempted to acquire a competitive advantage by creating and positioning themselves within a "non-GM" market segment, for example, Tesco (UK) and Carrefour (France) which both offered lines of "non-GM" products, particularly livestock products from non-GMO fed animals. In reaction, food manufacturers stopped using GM raw materials and reformulated their products accordingly. By the time the current labelling legislation was implemented this withdrawal movement had been completed across the EU and there were no products left to label. Ever since, retailers and food manufacturers have largely avoided the need to display GM labelling which they believe would be interpreted as a warning of some (unspecified) risk and a signal for hostile campaigning.

7.6.2. GM labelled feed products

The case of feed and feed ingredients is somewhat different. Here, the key drivers for market dynamics were:

- The dependence of the EU livestock sector on soybean protein imported from the USA, Argentina and Brazil and the non-availability of substitutes in sufficient quantities and with equivalent quality.
- The increasing proportion of GMO planted acreage in these countries which, coupled with the co-mingling nature of exporting logistics, made it increasingly difficult and costly to source large quantities of non-GM soya.
- The lack of sensitivity of consumers to GM feed issues, which is largely the result of the fact that the scope of GM labelling does not extend to livestock products.
- The lack of sensitive leverage points (at least compared to GM food) for anti-GMO campaigns targeting feed because such campaigns address consumers who are not generally aware of modern livestock production methods and the role of feed and because credible large scale alternatives to GMO feed are not apparent.

As a result of these factors, the market share of GM feed ingredients, particularly those deriving from soybean, has developed continuously since the late 1990s. When labelling provisions were introduced under the 2003 legislation they were easily adopted and implemented without causing any significant disruption. Non-GM supply chains became gradually marginal and are today confined to the "organic/Bio" segment and some retailer own-brand non-GM supply chains in some Member States.

Judgement

After some attempts to develop a dual market, characterised by the co-existence of a GM and a non-GM segment, food markets have evolved towards the dominant use of non-GM supply chains and the conventional feed sector (more slowly) towards the dominant use of GM supply chains. The important conclusion for this evaluation is that the labelling regulation played only a limited role in these evolutions. It reinforced market trends, but did not have a directional influence on them. Mandatory labelling requirements were introduced after market forces had determined the direction and pace of market evolution in the late 1990s and early 2000s. In the case of food products, these factors were mostly internal to the EU consumer market. In the case of feed, they were largely external.

7.7. Consequences of labelling of livestock products as GM

The full title of this Evaluation Question is: *What consequence would an extension of the scope of the labelling rules including the labelling of animal products have?*

In answering this EQ, three areas will be examined:

- The current situation; use of GM feed and consumer awareness and expectations of labelling.
- Impacts of an extension to include livestock products.
- The scope of a potential extension.

7.7.1. The current situation

7.7.1.1. The use of GM feed

As seen in section 7.5, the vast majority of compound feed in the EU (85-90%) is labelled as GM. However, as noted the exact proportions of GM labelled feed varies between Member States, from around 4% in Finland to 100% in Italy and the Netherlands. There is some difficulty in estimating the exact proportion of compound feed which contains GM (opposed to the proportion labelled GM) because compound feed is labelled as "may contain" GM in some Member States, and in others it is considered acceptable to label compound feed as GM regardless of whether it contains GM material. It is therefore possible that the actual percentage of feed containing GM is lower than that labelled as containing GM; nonetheless, based on the EU's high reliance on imported soybean (around 95% of which is labelled as GM), it is unlikely that the proportions differ greatly.

The use of GM feed and the possibility to substitute varies between livestock species. EU stakeholders and interviewees in case study countries corroborated this, commenting that soybean is essential in poultry and pork feed due to requirements for large amounts of high quality protein, but is more substitutable in dairy feed. From interviewees in case study countries, it can be seen that the use of GM feed varies by livestock sector. In Spain all sectors have a high reliance on GM feed, though extensive production (sheep plus some beef and iberic pork) is less reliant on GM feed. In Finland and France the pig and poultry sectors rely more on GM feed, while the Finnish beef and dairy industries try to avoid its use. Despite the reliance on soybean in the poultry industry, the majority of poultry production (50% of turkey and 70% of chicken) in Germany uses non-GM feed, while the percentage of non-GM compound feed in the dairy sector is relatively low (5%). Similarly in the UK, the poultry sector has up to now been non-GM.

7.7.1.2. Consumer perceptions and awareness of the use of GM feed and demand for an extension to labelling to include livestock products

EFSA concluded that genetically modified DNA cannot be found in livestock products fed on GM feed (EFSA, 2007f). Several interviewees and survey respondents commented on the lack of any scientific basis for the labelling of livestock products. Furthermore, some believed that such labelling could mislead consumers who might conclude from labelling that the animal was itself genetically modified, or that genetically modified DNA can be found in the final product. This is corroborated by a survey carried out by the Competent Authority in Finland which revealed that 60% of respondents believed that if pigs are fed on GM feed, humans eat GM ham.

Evidence as to consumer awareness of the use of GM feed in livestock production is inconclusive. In a survey by GfK and NOP (2006) carried out for a UK NGO, UK consumers were asked whether the following statement is true or false: "most… animal products... which are sold in Britain come from animals which have been fed on a diet containing GM ingredients". Some 43% of respondents judged the statement to be true, 35% judged it to be false, and 22% replied "do not know". Evidence from case study countries is also divided. However, it is worth noting that several case study interviewees thought consumers would feel confused and misled if the majority of livestock products went from being unlabelled to labelled over night.

There have been several campaigns for positive livestock product labelling or "GM-free" labelling of livestock products, including Greenpeace's 2007 petition of 1 million signatures for the obligatory labelling of livestock products (O'Callaghan, 2009). According to several surveys such as GfK and NOP (2006) in the UK, see also Sheldon, *et al* (2009) who employed a focus group approach, Efficience (2009) in France and GfK (2007) in Germany, the majority of consumers favour some form of GM labelling (either positive or negative) for livestock products. However, several interviewees pointed out that the methodology and questions used in such surveys and petitions were designed to influence the results given by respondents[87]. EU stakeholders and case study interviewees were divided as to whether consumers expect livestock products to be labelled, either positively or negatively. As might be expected, consumer organisations and NGOs predominantly believed the labelling of livestock products fed on GM was a consumer expectation; industry interviewees believed it was not. Finally, as seen in section 7.1 and the labelling case study, while consumers may be in favour of more information, it is not clear if they look at labels, at least in detail.

7.7.2. Impacts of an extension to include livestock products

7.7.2.1. Demand and prices

In their review of global literature on consumer attitudes towards, and valuation of, GM food, Costa-Font, *et al* (2006) note that consumers are willing to pay a 10-110% premium for non-GM fed or hormone treated beef, though they note that general willingness to pay varies between countries. In a US-based study, Li, *et al* (2004) arrive at lower figures, concluding that with an 8% discount, consumers will choose GM-fed beef over non-GM fed beef. However, King's College London (2008)

[87] One possible example is from the French Efficace survey (2009):

Lorsqu'un produit alimentaire contient des OGM (Organisme Génétiquement Modifié), cela doit être mentionné sur son emballage. Actuellement, il y a une exception à cette règle pour les productions d'origine animale. Lorsque la nourriture des vaches, boeufs, moutons, porcs ou volailles contient des OGM, leurs produits que sont la viande, les oeufs, le lait ou les produits laitiers n'ont aucune obligation de mentionner la présence d'OGM. Trouvez-vous cela normal?

English: When a food product contains GM, this must be indicated on the packaging. Currently there is an exception to this rule for products of animal origin. When the feed for dairy or beef cows, sheep, pigs or poultry contains GM, their products which are meat, eggs, milk or dairy products have no obligation to mention the presence of GM. Do you find this normal?

mentions the case of a Danish retailer whose sales of specifically non-GM pork fell short of expectation. In summary, academic literature suggests that consumers may be willing to pay a premium for non-GM fed livestock products.

At the same time, literature and interviewees suggest that the price of producing non-GM fed livestock products is higher than that of producing GM-fed livestock products. Thorne, *et al* (2005) estimated the economic impacts of a ban on GM feed products to the Irish beef and dairy industries. They concluded that a non-GM policy would cost the Irish dairy industry between €2.8 million and €17.7 million, and the beef industry between €4.8 million and €18.6 million, although no time frame for this cost was explicitly stated. Lawlor (2008) estimated that if Irish pigs were fed on a non-GM diet, the cost of feeding a pig would increase by €2.50 based on a premium for non-GM soybean of €40 per tonne. One retail industry interviewee corroborated this estimate of the premium for non-GM soybean, stating that it generally fluctuates between 10% and 15% (or €30 and €50 per tonne at current prices). However, according to the Soil Association (2007), the price difference is a lot lower; it has been estimated that pork would cost only £0.01 and bacon £0.018 more per kg, and milk £0.0017 per litre (based on a non-GM premium of 3.6%).

Survey responses largely corroborate the conclusion above that consumers appear willing to pay a premium for non-GM fed livestock products. With the introduction of livestock labelling, over 60% of Competent Authorities and just under 40% of stakeholders expected the price of GM labelled products to decrease (either modestly or greatly), while roughly 25% and 35% respectively expected the price to stay the same. In contrast, just under 60% of Competent Authorities and roughly 65% of stakeholders expected no change in the price of unlabelled non-GM products, with roughly 40% and 20% respectively expecting an increase in price. In the case that non-GM products were labelled as such, roughly 85% of Competent Authorities and 60% of stakeholders expected their price to increase. With respect to demand, the majority of survey respondents expected demand for unlabelled non-GM products to remain unchanged, while demand for GM labelled products would decrease. Respondents expected demand for non-GM products to increase if they were labelled as such. However, several survey respondents commented that changes in demand would be dependent on price differentials, and various interviewees believed that consumers are ultimately price-driven (see also section 8.1). Some respondents also commented that presentation of labelling in the media would also affect demand.

Case study interviewees focused more on demand than on price. Comments here were more nuanced than those of survey respondents (perhaps reflecting the different research technique), and they do not entirely corroborate the replies of survey respondents. Interviewees generally believed that an extension of labelling to livestock products would affect overall demand for meat in the short-term, but over the long-term consumption would return to normal. That said, a minority thought that overall demand for meat would not be affected, and another minority thought that it would decrease over the long-term. Interviewees were divided in terms of expected impact on demand for GM and non-GM fed meat. A couple believed that there would be a long-term shift in demand towards non-GM fed meat. Some interviewees, predominantly Finnish, believed that there would only be a short-term shift in demand to non-GM fed meat. Other interviewees did not foresee any change in demand.

Case study interviewees identified further price and demand linked issues. These are listed below:

- the ability of some livestock sectors to avoid GM feed may result in some distortions in demand;
- campaigns may be needed to mitigate consumer confusion, and consumer reaction would depend on how livestock products are presented; and,
- retailers would largely determine which livestock products appeared on shelves as they hold considerable power.

7.7.2.2. Supply: availability

Given that the extension of labelling to livestock products may result in shifts in demand, it is necessary to examine the feasibility of producing non-GM fed meat. As seen in section 7.5, the main limitation to supply of non-GM feed is the availability of imported non-GM soy, and about 23 million tonnes of oilcakes (including soybean meal) are imported into the EU each year for use in feed. Traceconsult (2010) made some estimates as to the availability of GM-free soybean for import. The results of the calculations, shown in Table 7.7 show a non-GM soybean supply after harvest of 20.1 million tonnes, and a potential supply of between 34.5 million and 37.4 million tonnes (the difference being due to difficulty in identity preservation which results in some non-GM soybean being mixed with GM soybean and therefore no longer being capable of sale as non-GM). This equates to roughly 14.5 million tonnes current and between 24.9 million and 27.0 million tonnes potential supply of non-GM soybean meal. Roughly 6.4 million tonnes of certified non-GM soybean was imported into the EU from Brazil and 0.8 million tonnes from India in 2009 according to Traceconsult (2010).

Table 7.7: GM-free soybean in India and Brazil in 2009

Source	Soybean harvest (million tonnes)	GM-free at time of harvest (% and (million tonnes))	GM-free after harvest (% and million tonnes)
Brazil	57.3	45%-50% (25.8-28.7)	20% (11.4)
India	8.7	100% (8.7)	100% (8.7)

Note: the source indicates 45%-50% of Brazilian soybean is GM-free at time of harvest and provides a range of 27-30 million tonnes. These figures are not consistent with the soybean harvest quoted and the GM-free range in the Table here has therefore been recalculated.

Source: TraceConsult (2010) and FCEC calculations.

CertID (2009) certified only 2.7 million tonnes of Brazilian soybean meal and 0.5 million tonnes of soybeans (equivalent to roughly 0.37 million tonnes soybean meal) as non-GM in 2009, and declared a further 2.5 million tonnes of soybean meal and 1.5 million tonnes of soybeans (1.1 million tonnes soybean meal) as certifiable[88], providing a total of 6.7 million tonnes of certified and certifiable non-GM soybean meal. As seen inTable 7.8, the quantity of CertID certified and certifiable soybeans has slightly reduced since 2004. It should be noted that the difference between Traceconsult estimates and CertID's certified and certifiable quantities is probably due to the partial coverage (and limited testing) performed by CertID.

Table 7.8: Certified and certifiable non-GM soybeans

Year	2004	2005	2006	2007	2008	2009
Quantity (million tonnes)	12.1	13.8	9.1	11.5	9.0	9.4

Source: CertID (2009).

From the above calculations, it can be concluded that sufficient non-GM soybean is theoretically available for the EU livestock sector. However, internal Brazilian and Indian consumption, and demand from other trading partners is not taken into account in the above calculations. According to

[88] Certifiable is defined as soybean which could have been certified as non-GM had interest been expressed from purchasers sufficiently in advance.

James (2009), China is the most important market for the export of Brazilian soybeans importing 11.8 million tonnes (48% of all Brazilian soybean exports) in 2008.

Several case study interviewees believed that it would be difficult or impossible to produce any significant quantity of non-GM fed livestock. Spanish interviewees in particular believed that it would not be possible due to Spain's reliance on GM raw materials in feed (primarily imported soybean, but also domestically cultivated GM maize). One German interviewee thought that while it would not be easy to produce non-GM fed meat on a large scale, given 18 months the supply chain (from the Brazilian grower to slaughtered animal) could be set up. Due to the low proportion of GM feed in the country, Finnish interviewees were not concerned by the availability, but did see some limitations in terms of segregation.

To summarise, while sufficient supplies of non-GM soybean meal theoretically exist for the production of non-GM fed livestock on a large scale, feasibility of the large-scale production of non-GM fed livestock products is at best unclear, primarily due to uncertainty as to actual post harvest non-GM quantities, demand for soybean from other trading countries, and seasonality issues relating to supply.

7.7.2.3. Supply: Identity preservation and segregation costs

The second part of the supply equation is identity preservation. Identity preservation needs to be considered at three broad stages; (1) crop/cereal stage, (2) feed stage, (3) livestock and final product stage. The first two stages, crop/cereal and feed, will be considered together.

Segregation of cereal and feed

Soler, *et al* (2007) consider the issue of segregation within the feed chain. Their findings are as follows:

- At a growing level, extra costs are generated in order to avoid co-mingling during and after harvest. These costs are relatively low in the case of Brazil at between €0.24 and €0.80 per tonne.
- Import and trade activities are controlled by a small number of operators. To meet the demands of EU and Japanese customers, they have implemented Identity Preservation systems. The extra prices, in comparison with standard soymeal depends on the threshold, intensity and traceability of the system.
- For feed manufacturers, there are two options: specialisation or production of both GM and non-GM feed. Companies which deal in both GM and non-GM feed have to check supply channels, segregate products at the entrance and segregate processing lines.
- From a survey of feed manufacturers, it was found that there are separate unloading pits at the entrance to the factory. Feed manufacturers may specialise plants in production of GM or non-GM feed. For manufacturers who do not specialise their plants, the costs of specialised processing lines and stopping processing lines between batches for cleaning are too high, therefore other solutions are used. It is possible to purge between batches by using non-GM ingredients in a GM batch to clean the machine (the most commonly used method). The extra cost of this depends on the firm, but one manufacturer reported extra costs of €1 per tonne (60% connected to raw material, 40% connected to associated management charges and checking).

According to Schumacher (2002), IP systems require substantial investments and higher operating costs and suffer from reverse economies of scale, meaning that costs increase as demand for non-GM feedstuffs increases.

While food chain interviewees in case study countries were concerned about segregation costs, feed industry interviewees were generally less concerned. Several interviewees commented that there

would be more problems with the segregation of livestock and livestock products, i.e. there would be an impact if labelling scope were to be extended to cover livestock products.

Segregation of livestock and livestock products

As mentioned above, interviewees in some case study countries were more concerned by the issue of segregating livestock and livestock products. One interviewee commented that it would be complicated and costly to operate a segregated identity preservation system in slaughterhouses, and as a result, slaughterhouses would probably specialise. Several interviewees agreed that specialisation at the final stage of the chain (slaughterhouse, dairy, egg processing plant) would be the only realistic option. One interviewee speculated that larger slaughterhouses would concentrate on the GM-fed segment (as this is expected to be larger), and smaller slaughterhouses on the non-GM fed segment. Some interviewees commented that the level of integration of livestock operation would affect the ability to segregate, with segregation easier in integrated operations. This is corroborated by a report by the Soil Association (2007) which concentrates on the possibility to use non-GM feed, though the report notes that ultimately non-integrated operations should be able to adapt to non-GM feed as well. One interviewee commented that segregation of milk may be more difficult than that of meat due to its liquid nature.

Several interviewees commented that livestock labelling would probably not create a competitive distortion within the EU as it would apply to all producers, but it would result in extra costs. Interviewees were divided as to whether these costs could be passed on to the consumer. However, interviewees were concerned about the competitiveness of EU livestock producers vis-à-vis Third Country ones. These concerns were based on two factors: (1) doubts as to whether any labelling obligations could be imposed on imports from Third Countries within the framework of the WTO; and, (2) questions as to whether the authorities could perform the necessary tests in order to assure Third Country compliance if labelling could be applied to imports.

7.7.2.4. Certification and control costs for public authorities

NERA (2001) consider the Net Present Value (NPV) costs of enforcement over 20 years under the scenario that foods derived from GM material, livestock products fed on GM feed and food produced with GM processing aids must be labelled. Vis-à-vis a situation where only foods derived from GM material must be labelled, the costs are estimated to be 37% higher. The authors comment that the number of inspections would increase, the paper trail would have to go back further in order to trace the sources of animal feed, and processing aids would have to be monitored. It should be noted that the inclusion of processing aids in this estimation may inflate the figure.

Just over a third of Competent Authorities who responded to the survey expected increased costs associated with traceability and the implementation of control. Only one Competent Authority stated that they expected any additional costs to be minimal (the remaining Competent Authorities did not consider this aspect). Several Competent Authorities said that there would be problems in terms of verification, and that greater emphasis would have to be placed on traceability given the absence of the ability to test livestock products.

Competent Authorities from case study countries roughly corroborated the survey results. Two commented on the difficulty of operating a labelling scheme where it is not possible to test products. One noted that some of the traceability systems are already in place, but due to the size of the affected sector, the cost of developing a suitable system may be disproportionately high in view of the absence of GM material in the final product. In contrast to the other three, one Competent Authority thought it would be possible to implement a control system using a document-based IP system. This Competent Authority commented that the necessary documentation exists due to the obligations of Regulation (EC) No 1830/2003 and could be checked at different stages of production. This Competent Authority

believed that more co-ordination between food and feed authorities would be necessary, but ultimately was not concerned by the extra burden.

As a final comment, it should be noted that some Competent Authorities and industry interviewees identified a potential for fraud due to the lack of ability to test products.

7.7.3. Scope of a potential extension

7.7.3.1. Extension to include processed products

According to Food for Thought (2009a, 2009b), the Western European (16 countries) processed meat market was worth €117 billion in 2008 or 10.6% of the total food and drink market. In comparison, the fresh meat market was worth €147 billion. The processed meat market was forecast to grow at 0.9% per year for the period 2008-11, while the fresh meat market was forecast to grow at the lower rate 0.08%.

The extent of necessary labelling with the inclusion of processed products was an issue which several interviewees perceived as problematic. Some interviewees also thought that the labelling of processed meat products would be complex (for example traceability would be difficult) and costly. One interviewee thought that consumers would be less concerned about processed products in which meat, milk or dairy products are not the main ingredient.

That said, some EU and case study interviewees believed it logical that any extension to labelling scope should include processed products. According to one interviewee, the French Haut Conseil des Biotechnologies had concluded that there was no reason to differentiate between raw and processed products in the French "GM-free" scheme.

7.7.3.2. Extension to include the catering sector

It should be noted that the labelling obligation for origin of beef under Regulation (EC) 275/2007 extends to the catering sector. This provides a theoretical precedent for labelling of meat in the catering sector. Furthermore, several Competent Authorities interpret Regulations (EC) No 1829/2003 and Regulation (EC) No 1830/2003 as applying to the catering sector as well as the retail sector. However, the limited range of GM labelled products (see section 7.4) means that labelling in the catering sector is not currently an issue; and, in the cases where the catering sector uses GM labelled products it is not clear if labelling for the final consumer is applied in reality.

Several interviewees thought that it would be hard or impossible to extend labelling to the catering sector. For example, Spanish interviewees considered labelling in restaurants an alien concept. Some German interviewees commented that GM labelling in Germany theoretically currently extends to the catering sector, but in reality the catering sector does not apply it. Similarly, one UK interviewee commented that theoretically the use of GM must be indicated in the catering sector, but the verification of this is not a priority. One interviewee said that labelling in the catering sector would be difficult due to the high turnover of suppliers; this would make it difficult to keep track of ingredients, particularly for smaller restaurants.

Some interviewees believed that an extension to labelling should include the catering sector. One commented that by excluding the catering sector, customers could be misled. Another interviewee said that a lot of Third Country meat is used in the catering sector, and for this reason it would be important to include the sector in any labelling obligation. A couple of interviewees commented that the use of organic ingredients and their labelling in the catering sector implies that there is some consumer interest, although this argument presumably only applies in the case of negative labelling.

Judgement

Currently some 85%-90% of livestock feed in the EU is labelled as GM, meaning that any extension of labelling scope to include livestock products would result in the vast majority of products being labelled, providing consumers with information, but would provide limited choice in the absence of far reaching/in-depth reorganisation of the supply chain. However, it may be possible to increase the proportion of non-GM livestock feed and hence unlabelled (or non-GM labelled) products. Theoretically there is still potential supply of non-GM soybean, although it is not clear how much of this could be sourced as a result of segregation difficulties and competing demand from other sources. Some Member States would find it easier to produce non-GM fed meat than others.

Some interviewees and evidence indicate expectations for non-GM fed livestock, but the size of market and premium which consumers are willing to pay remains unclear. It should be noted that many consumers are not very aware either of the use of GM feed in the livestock sector, or EFSA's conclusion that to date, a large number of studies have not detected modified DNA in livestock products fed on GM feed. There is a possibility that some consumers will misinterpret any GM labelling on livestock products.

There may be some issues with segregation and enforcement. Segregation of livestock production is generally seen as more problematic than segregation of feed. Enforcement is generally seen as complicated, open to fraud and costly.

It is not clear if any extension to labelling could be imposed on and controlled in terms of imports from Third Countries. An extension to labelling scope which included processed products would considerably increase the scope of labelling, and would be more complicated, but may also be more logical from a consumer point of view. There is a precedent for an extension of scope to also include the catering sector, but attitudes vary. It is possible that the idea will not be accepted in some Member States, and it may cause problems for some catering businesses. On the other hand, there is some support for the inclusion of the catering sector in terms of allowing consumers to make an informed choice.

7.8. Current national approaches to "GM free" labelling

The full title of this Evaluation Question is: *What are the approaches currently used in MS in the field of "GM free" labelling?*

In order for this question to be addressed meaningfully we focus only on schemes used by more than one operator and with independent accreditation/certification.

This answer is organised as follows:

- An overview of GM-free labelling in the EU
- Details of schemes used by more than one operator

7.8.1. Overview of "GM-free" labelling schemes in the EU

7.8.1.1. National "GM-free" labelling laws

There is no specific provision for "GM-free" labelling under Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003, although according to Commission Services, the Regulations do not preclude such labelling as long as it is not misleading.

Some Member States have gone beyond the EU regulations and provided national laws or provisions to allow for the use of "GM-free" labelling. According to a report by GM-Free Ireland (O'Callaghan,

2009), **Germany** and **Austria** have national laws or provisions for the "GM-free" labelling of livestock products and **France** is expected to become the Third Country with such laws. This understanding was confirmed by our case study visits. O'Callaghan (2009) suggests that **Ireland** might become the fourth country to introduce laws governing the use of the term "GM-free". Interviewees and survey respondents explained that there is a legal definition of "GM-free" in France (which was originally defined in 2000, and updated in a note of the DGCCRF of 16 August 2004[89]) and that there are relatively advanced discussions regarding the regulation of "GM-free" labelling in **Finland**.

The use of "GM-free" labelling is explicitly banned in the Netherlands (King's College London, 2008). The Dutch Competent Authority notes that the Food and Commodities Act (Warenwet) prohibits the designation "GMO-free" on the label of a food because it is misleading to the consumer because products can never be guaranteed to be 100% free of GMO's (the 0.9% labelling rule for technically unavoidable presence always applies). However, the phrase "produced without the use of genetic technology" may be used if the entire production process makes no use of genetic technology.

7.8.1.2. National multi-operator "GM-free" labels

In Austria, the provisions for "GM-free" labelling are implemented through the national Arge-Gentechnikfrei scheme, an independent coalition of stakeholders (O'Callaghan, 2009). Case study interviewees confirmed that in **Germany**, the current "GM-free" law entered into force in May 2008, and a national "GM-free" logo was introduced in August 2009. According to one report, as of October 2009 there were products on the market both using both the national logo and company specific logos (vzbv & Slow Food Deutschland e.V., 2009). In **France**, the regional government of Brittany introduced two "GM-free" stickers in June 2009; one for organic products, and one for livestock products fed on non-GM feed (O'Callaghan, 2009). According to O'Callaghan (2009) there is lobbying for a "GM-free" label in **Greece**, though no Greek interviewees mentioned this.

Respondents to the stakeholder survey identified Intertek Food Services and CertID as two European bodies involved in non-GM certification.

7.8.1.3. "GM-free" products in the EU

In addition to national multi-operator specific labels, there are operator specific schemes and "GM-free" labelled products outside the schemes.

Italy's largest retailer, Co-op Italia uses its own "GM-free" label and has around 300 "GM-free" labelled own-brand products. Several livestock producers are using non-GM feed, and in some cases this is stated on the label (O'Callaghan, 2009). Case study interviewees confirmed that some poultry and egg producers label their products as "GM-free". O'Callaghan also notes that in **France**, **Germany** and the **UK** several retailers and livestock producers use non-GM supply chains; this was confirmed by our case studies. According to one survey respondent in France, Poulets de Loue, Porc de la Sarthe, Buerre d'Echire and some AOC cheeses use "GM-free" labelling, although it has not been possible to corroborate this. According to survey respondents and case study interviewees, there are some operator specific "GM-free" labelling schemes in **Finland** for sausages, imported cheese and cooked sweetcorn.

King's College London (2008) found "GM-free" labelled products on supermarket shelves in 9 of 10 visited Member States, including the following previously-unmentioned countries: **Czech Republic**, **Estonia**, **Spain**, **Poland**, **Sweden**, **Slovakia** and **UK**. One product was even found in the **Netherlands**, although this contravenes the Food and Commodities Act (see above).

[89] Available at: http://www.minefi.gouv.fr/conseilnationalconsommation/avis/2009/annexe%202.pdf.

7.8.1.4. Summary of "GM-free" laws, schemes and labelled products

Table 7.9 summarises data obtained on the use of "GM-free" labelling in the EU.

Table 7.9: Data obtained on "GM-free" labelling in the EU: laws, schemes and number of products

Member State	National schemes and provisions	Number of "GM-free" products	Source(s)
Austria	Arge Gentechnikfrei scheme (a coalition of stakeholders) based on the directive in Codex Alimentarius Austriacus	652-800	O'Callaghan (2009) Case study appendix www.gentechnikfrei.at[90]
Czech Republic	No information provided	41 (2006) 75 (2008)	King's College London (2008)
Estonia	No information provided	6 (2006) 17 (2008)	King's College London (2008)
Finland	Some operator specific schemes. Provisions under development	A few	Case study appendix
France	Brittany regional government; possibly some operator specific schemes. "GM-free" defined by 2004 DGCCRF note; ongoing discussions on a new national scheme	Some livestock products	Stakeholder survey Case study appendix O'Callaghan (2009)
Germany	National logo introduced August 2009, based on EGGenTDurchfG, updated May 2008	Various (20 according to vzbv)	Vzbv & Slow Food e.V. (2009) King's College London (2008) Case study appendix
Greece	Lobbying ongoing	0	King's College London (2008) O'Callaghan (2009)
Ireland	Plans exist to introduce a label	No information provided	O'Callaghan (2009) Irish Government (2009)
Italy	Scheme of retailer co-op. Some private schemes for livestock products.	300	O'Callaghan (2009) Case study appendix
Netherlands	"GM-free" labelling is prohibited	1	King's College London (2008)
Poland	No information provided	≈20	King's College London (2008)
Slovakia	No information provided	10 (2006) 13 (2008)	King's College London (2008)
Spain	No legal framework	A small number (21 according to King's College)	King's College London (2008) Case study appendix
Sweden	No information provided	60-63	King's College London (2008)
UK	No specific legislation	5	King's College London (2008) Case study appendix

Sources: various, indicated in table.

[90] Accessed 16 March 2010.

7.8.2. Details of schemes

This section lays out the key details of the Austrian and German national schemes, and provides an overview of the existing French definition for "GM-free".

7.8.2.1. Austria

Details on the "GM-free" scheme in Austria are taken from the case study, and the Codex Alimentarius Austriacus.

GM crops covered	Not specified
GM-free feeding periods defined for livestock products	• bovine meat: 12 months • dairy: 2 weeks • eggs: 6 weeks • pork: the entire fattening phase • fish: the entire fattening phase
Coverage of further processed products	No specific provisions (see below for general restrictions).
Threshold and restrictions	• 0.9% threshold for adventitious presence (in line with the definitions in Regulations (EC) 1829/2003 and 1830/2003, but with an emphasis on "technically unavoidable"). • GMOs or GM products cannot be used in/as: food, feed, additives or production aids, plant protection products, fertiliser, soil conditioner, seeds, plant propagating material, micro-organisms or animals. • Feed additives produced using GM may not be used. • There is an exception for animal pharmaceuticals, and exceptions may be made for certain additives, enzymes, etc. and feed additives if there is no non-GM alternative.
Labelling requirements	Food can be labelled "gentechnikfrei erzeugt" (GM / genetic engineering-free production) or similar if it meets the requirements set out in the Austrian guidelines.
Traceability requirements, accreditation and certification	• Certification from an accredited body. • Self controls and external controls from an accredited body. Compliance is to be checked at all productions steps, including agricultural production steps. • Tools for documenting and implementing self controls must be used.

7.8.2.2. Germany

Details on GM free labelling in Germany are taken from the case study appendix and the German labelling implementation law (EGGenTDurchfG). The EGGenTDurchfG regulates GM-free labelling in Germany and was updated in May 2008. A logo was introduced in August 2009.

GM crops covered	**Not specified**
GM-free feeding periods defined for livestock products	• bovine meat: 12 months or ¾ of the animal's life • dairy: 3 months • eggs: 6 weeks • pork: 4 months • poultry: 10 weeks • small ruminants: 6 months
Coverage of further processed products	GM food, additives or production aids may not be used.

Threshold and restrictions	• 0.9% threshold for adventitious presence (in line with the definitions in Regulations (EC) 1829/2003 and 1830/2003, but with an emphasis on "technically unavoidable" in the case of food). More specifically this means:
	  • Any food or feed labelled in accordance with Regulation (EC) No 1829/2003 cannot be used.
	  • Any food or food additives which are exempt from labelling under Regulation (EC) No 1829/2003, but which are nevertheless (e.g. contain under 0.9% GM, but the content is technically avoidable) may not be used.

Labelling requirements	Food can be labelled "ohne Gentechnik" (without GM/genetic engineering).
Traceability requirements, accreditation and certification	Bundeslaender have a monitoring responsibility once the product is on the market.

7.8.2.3. France

According to the 2004 DGCCRF note, only crop products which may contain GM below the detection level of 0.1% can be labelled as "GM-free", with the exception of sweetcorn and young soybean plants, which can be labelled as "GM free in accordance with regulations". Livestock products fed on feed with under 0.1% GM material may be labelled as "GM-free".

The Haut Conseil des Biotechnologies has proposed a basis for "GM-free" labelling, however no law or scheme has yet been introduced (see section 2.4 of the appendix).

7.8.2.4. Finland

The details of the proposed Finnish scheme are not yet available and there are different expectations in terms of how the scheme might operate. Please refer to the extension to labelling case study for more information.

Judgement

Currently there are only national provisions for "GM-free" labelling in three Member States (Germany, Austria and France with its 2004 definition of "GM-free"), and "GM-free" labelling is banned in the Netherlands. However, new national provisions are expected in several Member States (France, Finland, possibly Ireland). Furthermore, there are operator-specific "GM-free" labelled schemes in several Member States, and "GM-free" labelled products can be found in several Member States. The number of "GM-free" labelled products varies between Member States.

7.9. Impact in terms of consumers' informed choice

The full title of this Evaluation Question is: *Do these approaches contribute to improve consumers' informed choice?*

There are very few multi-operator "GM-free" labelling schemes in existence (see section 7.8) and this makes judging their contribution in terms of improving consumers' informed choice difficult. Furthermore, of the multi-operator schemes in existence, only the Austrian ARGE Gentechnik-frei scheme contains a significant number of products, though it should be noted that Co-op Italia's own brand "GM-free" labelling scheme also contains a large number of products.

Despite this difficulty, it is possible to assess the impact of these schemes in terms of consumer's informed choice using an evidence base comprising literature, survey replies, semi-structured interviews with key stakeholders and case studies.

This answer is organised as follows:

- Consumer expectations with respect to a "GM-free" labelling scheme.
- Extent to which existing schemes differ in their requirements.

7.9.1. Consumer expectations with respect to a "GM-free" labelling scheme

7.9.1.1. GM Comparators for "GM-free" labelling

According to Article 16 of Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, "the labelling, advertising and presentation of food or feed… shall not mislead consumers". This should in principle preclude the use of "GM-free" labelling for products without a GM equivalent, for example, a "GM-free" apple. Indeed, according to an interviewee in Spain a "GM-free" labelled product without GM comparator (lentils) was withdrawn from the market as it was deemed misleading.

7.9.1.2. Scope of "GM-free" labelling

As seen in section 7.1, there is some lack of clarity as to consumer expectations for the scope of positive labelling. In section 7.7 it was seen that there is conflicting evidence regarding the expectation of consumers with respect to the labelling of livestock products.

Against this background, with respect specifically to a "GM-free" labelling scheme there is evidence to suggest that there is demand for the inclusion of livestock products. As part of a broader study on "GM-free" labelling in Germany, Herrmann, *et al* (2008) asked subjects how important they consider "GM-free" labelling for different families of products. The results, in Table 7.10 show that "GM-free" labelling is considered particularly important for fresh meat, eggs and milk. The results also indicate that "GM-free" labelling is considered more important for fresh products than for processed ones. Interviewees confirmed that "GM-free" labelling is currently largely limited to fresh products, although this was considered as much due to difficulties in complying with "GM-free" requirements for processed products as it was to lower consumer demand for these products.

Table 7.10: Importance of "GM-free" labelling for different types of food product

Product	Very important	Important	Neither important or unimportant	Not very important	Not important
Fresh meat, meat and sausage products	74.6%	13.6%	8%	2%	2%
Eggs	70.6%	17.1%	8.3%	2%	2%
Milk and milk products	70%	17.4%	8.5%	2%	2%
Fresh fruit and vegetables	68.5%	18.5%	8.7%	3%	2%
Conserved sausage products	54.4%	22.7%	16.2%	4%	3%
Conserved vegetables	48.9%	23.6%	18.6%	6%	3%
Noodles	48.5%	21.6%	20.4%	7%	5%
Chocolate	39.9%	19.6%	22.7%	10%	8%

Source: Herrmann, *et al* (2008).

Totals may not add due to rounding.

As stated by O'Callaghan (2009) and corroborated by interviewees, several major supermarket chains use "GM-free" supply chains for livestock products. Some interviewees believed this was due to consumer wishes; others believed it was a result of NGO pressure. Some interviewees commented that permitting "GM-free" labelling for livestock products would allow supermarkets and livestock producers using non-GM feed to obtain a premium for their production methods. There have also been several campaigns for livestock labelling or GM-free labelling of livestock products, including Greenpeace's 2007 petition of 1 million signatures for the obligatory labelling of livestock products O'Callaghan (2009). According to several surveys (such as French Survey Efficience, 2009) the majority of consumers favour some form of "GM-free" labelling for livestock products.

It is difficult to draw conclusions on demand for "GM-free" labelled livestock products from the existing "GM-free" labelling schemes. On the one hand, there are a large number of "GM-free" labelled livestock products in Austria[91]; according to one interviewee, all milk will soon be labelled as "GM-free", and a significant proportion of egg production and some meat production is already labelled. On the other hand, according to a report by vzbv & Slow Food Deutschland e.V. (October 2009), only 8 livestock product families in Germany (predominantly milk) use "GM-free" labelling, and interviewees confirmed that the take-up of the German scheme had been low.

7.9.1.3. Requirements for the use of "GM-free" labelling

Following the changing of "GM-free" labelling requirements in Germany, Herrmann, *et al* (2008) and Henseleit & Kubitzki (2009) examined the question of whether the updated labelling regime enhanced transparency or misled consumers. The authors note that those in favour of the updated provisions believe they provide consumers with wider "GM-free" choice, while those against it think that consumers are misled in that they will conclude from the labelling that GM technology has not been used at all in the production process and this may not be the case with respect to GM enzymes, nor in

[91] According to the product database: www.gentechnikfrei.at.

terms of the tolerance threshold for the adventitious and technically unavoidable presence of GM material (see section 7.8). The study takes a sample of 1,012 German consumers and asked them a series of questions, primarily centred on the labelling of animal products as "GM-free". Based on subject knowledge of genetic engineering (tested by asking questions from the 2005 Eurobarometer, Gaskell, *et al*, 2006) the authors considered the sample fairly representative of European consumers. Consumer expectations of the "GM-free" labelling scheme are outlined in Table 7.11 below.

Table 7.11: Expectations and fulfilment of standards for German "GM-free" labelling

	Should be allowed to carry "GM-free" label	Should not be allowed to carry "GM-free" label	Don't know	Permission to carry "GM-free" label in German law
Food products containing GM organisms (e.g. yoghurt, cultures, yeast)	25.1%	59.6%	15.3%	No
Food containing enzymes or produced with the help of enzymes obtained from GMOs	26.9%	56.1%	17%	Yes
Livestock products fed on animal feed containing GMOs	8.4%	78.3%	13.3%	Yes and no *
Livestock products fed on animal feedstuff containing additives which have been produced with the aid of GMOs	11.9%	73.5%	14.6%	Yes
Livestock products which have used drugs and vaccines for animals produced with the aid of GMOs	23.4%	61.2%	15.4%	Yes

* GM-free for a certain period before slaughter/milking/laying eggs; see section 7.8.

Source: Herrmann, *et al* (2008).

The results of the study suggest that consumers expect products labelled as "GM-free" not to have used GM technology in the production process. This expectation differs from some of the provisions in the German law. Several industry interviewees from the German case study provided similar comments, and partly attributed the low uptake of the German scheme to its potential to mislead consumers. Some respondents to the stakeholder survey who were against a harmonised EU-wide "GM-free" labelling scheme believed that 100% GM-free food does not exist, and "GM-free" labelling is therefore potentially misleading. Some case study interviewees considered the use of thresholds for adventitious and technically unavoidable presence of GM material in "GM-free" labelling schemes as potentially misleading.

On the other hand, some case study interviewees believed that the scheme is not misleading. One commented that the terms "free" and "without" are not definitive, and provided several examples of food areas where these terms are used in a non-definitive manner (for example, "without alcohol/alcohol free" drinks can contain up to 0.5% alcohol), and that community legislation in other areas provides a precedent for the use of the term "free" with a tolerance level. One interviewee

commented that organic legislation already permits the use of feed with traces of GM[92], and that it also contains GM-free feeding times similar to those found in the German and Austrian laws.

7.9.2. Extent to which schemes differ in their requirements nationally and at the EU level

As demonstrated in section 7.8, the German and Austrian national labelling provisions are relatively similar. ARGE-Gentechnik-frei (2009) contrasted the two and identified the following notable differences:

- As part of the Codex Alimentarius Austriacus, the Austrian provisions are more flexible than the German law.
- Austrian provisions take into account the agricultural production steps; the German law does not.
- There are some differences in the GM-free feeding times for bovine meat, dairy and pork. No GM-free feeding period for poultry and small ruminants is specified in the Austrian provisions, and none for fish in the German law.
- The use of feed additives in livestock feed is not allowed under the Austrian scheme, but is allowed under the German scheme.
- Controls are obligatory in Austria, and include certification. In Germany, there is monitoring by the Bundeslaender. The obligatory Austrian controls provide sellers and consumers with more security.
- Labelling is more flexible in Austria. In Germany, the logo and wording are fixed. In Austria, the controlling authority must be named on the label; this is not the case in Germany.

Case study interviewees provided some comments on the effects of differences between "GM-free" labelling schemes. Interviewees generally believed that the German and Austrian schemes were similar, but nonetheless identified some problems due to differences. One believed that the wording used by the Austrian scheme (Gentechnikfrei - "gene technology free") transmitted a stronger message than that permitted under the German scheme (ohne Gentechnik - "without gene technology"). Another commented that the control provisions in the Austria scheme (which do not exist in the German scheme) impose extra costs on Austrian producers, but assure the "GM-free" status of Austrian labelled products.

More concerns were expressed over the potential differences in the forthcoming French scheme. Several case study interviewees noted that the proposed 0.1% tolerance level for adventitious and technically unavoidable presence in the French scheme differed from the existing 0.9% tolerance level for adventitious presence in Austrian and German laws and also from the general approach to adventitious presence in Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003. One interviewee believed that a private initiative in Italy used a tolerance level of 2%, and hence the introduction of a 0.1% threshold in France would create three different tolerance levels for "GM-free" labelling schemes in the EU. Several interviewees commented that with the possible propagation of "GM-free "labelling schemes, differences would also multiply and become more of an issue.

[92] Up to 0.9% adventitious presence.

Judgement

EFSA's opinion concludes that GM material cannot be found in final livestock products (although detectability is not the basis for current GM labelling). Evidence suggests that consumers are not fully aware of this and may not fully understand the meaning of GM-free labelling on livestock products. Nonetheless, there is evidence to suggest that some consumers want to be able to purchase livestock products labelled as "GM-free". The "GM-free" labelling of primary products is considered more important by consumers than that of processed products.

Evidence suggests that consumers expect a higher level of purity for products labelled as "GM-free" than is in place in some existing "GM-free" labelling schemes. Currently there is limited consumer confusion due to differences between schemes, however there are concerns that confusion will increase with the proliferation of schemes, starting with the potential introduction of the French scheme with a 0.1% tolerance level for adventitious presence. Despite best intentions, it is questionable as to whether existing "GM-free" schemes provide consumers with an informed choice.

7.10. Impact of harmonised "GM free" labelling scheme

The full title of this Evaluation Question is: *What could be the added value (both in terms of information to consumers and market share) of a harmonised "GM free" (or similar) labelling scheme?*

This answer is organised as follows:

- Benefits that an appropriately defined harmonised "GM-free" scheme may bring to consumers, producers and the food sector in general.
- Extent to which a harmonised "GM-free" scheme would help to build this sector.
- Position of a "GM-free" scheme alongside the organic label.

7.10.1. Potential benefits from a harmonised "GM-free" scheme

As was demonstrated in section 7.9, differences between existing "GM-free" labelling schemes are limited, but could become greater with the emergence of new schemes. The benefits of a harmonised "GM-free" labelling scheme should be considered against this background.

7.10.1.1. Attitudes towards, and benefits from, a harmonised "GM-free" labelling scheme

There is some evidence in the literature to support the idea that a harmonised "GM-free" scheme would be beneficial. NERA (2001) commented that the definition and enforcement of consistent standards for the use of the claim "GM-free" would provide consumers with assurance that different producers using the claim are adhering to the same standard. Consumers particularly concerned about environmental impacts and ethical concerns could then express their preferences by purchasing "GM-free" labelled food.

Evidence from the stakeholder survey suggests that respondents were split as to whether a harmonised "GM-free" labelling scheme should exist; there were also differences in the expected impact of such a scheme on different groups. Two-thirds (67%) of Competent Authorities and 40% of stakeholder respondents were in favour of a harmonised "GM-free" labelling scheme, and the majority of each group was in favour of these provisions existing alongside the current, positive, labelling regime. Respondents in favour of a harmonised "GM-free" scheme believe that it would put an end to the confusion and misleading of consumers by existing different national schemes. A couple of

Competent Authorities commented that a harmonised scheme would have to be meaningful, robustly verified and must not mislead the consumer.

Case study interviewees were equally divided on the idea of a harmonised "GM-free" labelling scheme. Broadly speaking, Finnish interviewees were in favour, Spanish interviewees divided, German interviewees rather impartial and French interviewees against (with a few exceptions). Interviewees in favour identified the following possible benefits from a harmonised scheme:

- Consumer confusion caused by different schemes would be avoided (as mentioned above by survey respondents).
- Producers in different Member States would not be disadvantaged due to different national schemes.
- Costs for retailers and the burden for authorities would reduce as a result of harmonisation.

It should be noted that some survey respondents and case study interviewees, whilst against a harmonised "GM-free" scheme, would prefer such a scheme to a multitude of separate national schemes. One case study interviewee in Germany considered a harmonised "GM-free" labelling scheme the second best solution, with the best solution being the mandatory positive labelling of livestock products produced using GM feed.

7.10.1.2. Problems foreseen with a harmonised "GM-free" scheme

NERA (2001) estimated that the Net Present Value (NPV) of 20 years of enforcement costs in the UK would be about 20% higher if voluntary "GM-free" labelling was added to mandatory positive labelling for products containing, or directly derived from GM material. The same study estimates that the NPV of identity preservation costs would increase by about 15%. Due to the proliferation of GM crops since the completion of this study, these figures should be treated as an underestimate.

Survey respondents against a harmonised "GM-free" scheme cited the following reasons:

- "GM-free" labelling is misleading because products can never be guaranteed to be entirely free from GM material.
- As a result of "GM-free" labelling, consumers may interpret GM labelled food as being unsafe or inherently bad.
- A harmonised scheme would be difficult and costly to implement.
- The organic sector already exists for those who wish to avoid GM (although this is subject to a tolerance level for adventitious and technically unavoidable presence and the price includes other attributes as well, see below).

Case study interviewees mentioned some of the issues listed above, plus the following further issues:

- Consumer confusion may occur if positive and negative GM labelling schemes operate in tandem.
- There may be difficulty reaching agreement on an EU level "GM-free" scheme. The consumer information labelling reform demonstrates the difficulties which can occur when trying to agree on harmonised EU labelling provisions. Compromises on scope (for example whether livestock products were included) and parameters would be needed.
- The market for "GM-free" products may in reality be small; several interviewees believed that the group requesting "GM-free" labelling is small, but very vocal.
- Livestock producers in some countries such as Spain may be disadvantaged as it is not possible for them to produce non-GM fed livestock products.

7.10.1.3. Extent to which a harmonised "GM-free" scheme would help to build this sector

As mentioned above, some case study interviewees believed that a harmonised scheme would avoid producers in different countries being disadvantaged by different scheme requirements. Some case study interviewees identified further advantages of harmonisation for the development of the sector:

- it would be easier for operators to build market share in the "GM-free" sector; and,
- operational expenses would be minimised.

However, not all case study interviewees saw benefits for the development of the sector. As seen above, one interviewee thought that operators in some Member States would not be positioned to produce non-GM fed livestock products. The following further problems for the development of the sector were identified by different interviewees:

- producers/retailers may charge an excessive premium for "GM-free" products. That said, one interviewee believed that EU-wide competition would reduce the risk of excessive premiums;
- despite NGO pressure, the level of development of the "GM-free" sector in Germany is considered low in comparison to the situation in Austria by most interviewees, indicating that the market for these products is small;
- in the case of Germany, producers are shunning the "GM-free" scheme for various reasons. These include: the competitive advantage is seen as being low; the decision to produce "GM-free" labelled products is seen as an "all or nothing" decision; and producers consider it a bad strategy to produce "GM-free" products now, but revert to using GM material in the future; and,
- Austrian producers may lose the competitive advantage currently provided by the national "GM-free" labelling scheme.

7.10.2. Position of a "GM-free" scheme alongside the organic label

In their literature review of consumer perceptions towards the organic sector, Bonti and Yiridoe (2006) note that there is some consumer knowledge and awareness of organic products, but consumers are not always consistent with their interpretation of what is organic. According to the study, consumer preference for organic food is driven by the perception that it has more desirable characteristics, most notably effects on human health, food safety and environmental stewardship. Hugner, *et al* (2007) also examine literature on consumer perceptions towards organic and identify nine motives for purchasing organic products: health and nutritional concerns, superior taste, environmental concerns, food safety/lack of confidence in conventional production, animal welfare concerns, support for the local community, perceptions of wholesomeness, nostalgia, and curiosity.

Bernard, *et al* (2006) investigated the willingness to pay for non-GM products when an organic equivalent exists by performing a bidding exercise with US-based participants. Evidence from this study somewhat contradicts Bonti and Yiridoe (2006) and Hugner, *et al* (2007). By nesting the non-GM attribute inside the concept of organic, Bernard, *et al* (2006) find that the willingness to pay for other organic attributes is low, implying that "GM-free" status is the most important organic attribute. However, this finding should be put in to context. Firstly the authors do not consider whether participants are regular consumers of organic or not, implying that the findings of the study are representative of general consumers rather than current consumers of organic. Secondly, the experiment was conducted in the US. With regards to the first point, the authors conclude that the absence of non-GM products may be a market inefficiency. Consumers wishing to avoid GM must currently pay a higher premium for organic products, and provided that production of non-GM is cheaper than that of organic, the market may be better served by the introduction of this niche.

Literature is therefore inconclusive as to whether normal consumers understand the difference between organic and "GM-free", but does imply that existing consumers of organic products are motivated by more than just the (expected) absence of GM material. Evidence from interviews and case studies corroborate these findings. One interviewee agreed that the "GM-free" status of organic products is one of many important aspects for organic consumers. Case study interviewees were divided as to whether normal consumers understand the difference between organic and "GM-free" products.

Some comments were provided as to the interaction between the organic and "GM-free" sectors which largely corroborated the findings of Bernard, *et al* (2006). One interviewee believed that demand for "GM-free" products went beyond the existing organic sector. A German case study interviewee commented that the organic sector had not lost market share to the "GM-free" sector following the introduction of the new "GM-free" labelling scheme (however, as mentioned in section 7.8, uptake of this scheme has so far been limited). The same interviewee believed that with the introduction of a harmonised "GM-free" labelling scheme there may be short-term effects on demand for organic products, but ultimately demand for organic would return to its original growth path. A few case study interviewees believed that "GM-free" labelling could exist alongside organic labelling due to the price difference; one interviewee commented more specifically that not all consumers can afford organic food, and "GM-free" labelling would therefore offer a wider choice to the average consumer. However, evidence from experience is less conclusive. On one hand, the co-existence of organic and "GM-free" schemes in Austria and Germany imply that the two schemes can exist in tandem (though the so far limited take-up of the German scheme should be noted). On the other hand, King's College London (2008) comment on the introduction of "GM-free" milk by Sainsbury's in 2004. This milk was sold at a premium of 10% to conventional, while organic was sold at a premium of 30%. Sales of the "GM-free" labelled milk were reported to initially have been good, but then appear to have fallen.

Judgement

Evidence is divided on the benefits and drawbacks of a harmonised "GM-free" labelling system. There are several potential benefits from harmonisation including reduced consumer confusion, fair competition between producers in different Member States, lower costs for operators and a lower burden for the authorities. However, there may be some problems with the fundamental concept of "GM-free" labelling. Such labelling could be considered as misleading if a tolerance level is used to allow for adventitious and technically unavoidable presence of GM material, may negatively affect consumer perception of GM, may confuse consumers if operated in tandem with positive labelling and could be costly to implement. Furthermore, there may be difficulties in agreeing on criteria and scope of such a scheme at an EU level. Existing "GM-free" schemes cover livestock products, and it is possible that as a result there will be expectations to include these in any EU scheme.

As seen in section 7.9, it is difficult to conclude whether there is significant demand for "GM-free" products. As a result, conclusions with regards to the development of the market for "GM-free" products are speculative. A harmonised scheme would allow fairer competition between operators in different Member States, minimise operational expenses and make it easier to build market share in the "GM-free" sector. However, operators in some countries may face restraints which prevent them from producing "GM-free" labelled products. Furthermore, it can be seen from the German experience that there are several factors which may deter operators from producing "GM-free" labelled products.

It is unclear as to whether normal consumers understand the difference between organic and "GM-free". That said, evidence suggests that existing organic consumers purchase organic products for a multitude of reasons, not just for their "GM-free" status. A "GM-free" labelling scheme may provide an option for consumers who wish to avoid GM, but are not prepared (or able) to pay the higher premium for organic food.

8. Public acceptance

This theme comprises five Evaluation Questions which are answered in the following sub-sections.

8.1. Controversial aspects of the authorisation procedure

The full title of this Evaluation Question is: *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?*

This Evaluation Question is organised as follows:

- Public controversy in relation to GMOs.
- Specific stakeholder concerns with aspects of the approval process which lead to controversy.

8.1.1. Public controversy in relation to GMOs

The controversy surrounding the approvals process for GM events in the EU needs to be seen within the wider context of consumer/public acceptance of GM technology, not least because, as pointed out by King's College London (2008), consumers cannot be expected to be aware of the intricacies of EU regulations. Bonny (2004) notes that the agricultural applications of biotechnology were generally seen worldwide as promising in the 1980s, only for a strong movement opposed to GMOs to develop by the late 1990s/early 2000s, mainly in relation to perceived safety concerns (see section 8.5 for further detail). Whilst this implies concern with safety assessment procedures, this cannot be definitively inferred because questions asked in surveys tend not to be this specific. Findings from a series of Eurobarometer reports are discussed below.

The most up to date EU-wide information on public acceptance of GM technology is provided by European Commission (2008c) in which it is noted that 20% of EU-27 respondents selected the use of GMOs in farming as one of the top five environmental issues that they are worried about[93]. To put this in context, GMOs were ranked 11 out of 15 possible concerns. There were regional variations with concern highest in Austria (mentioned by 43% of respondents and ranked third) and lowest in the Czech Republic (mentioned by 10% of respondents, 13= out of 15). The comparator figure from 2004 was 24% (European Commission, 2005), suggesting a slight decline in concern over the period.

When respondents were asked specifically whether they were in favour or opposed to the use of GMOs, 58% (EU-27) stated opposition with 21% in favour. Some 9% spontaneously pointed out that they had never heard of GMOs and 12% answered "don't know" (European Commission, 2008c). This represents a decrease in support since 2005 where Gaskell, *et al* (2006) found that 27% of EU-25 respondents either "agreed" or "totally agreed" that GM foods should be encouraged[94].

European Commission (2001) asked EU-15 respondents whether they think it is true that food based on GMOs is dangerous. More than half (56%) agreed with this statement while 17% did not; more than a quarter (26%) answered "don't know". It should be noted that the formulation of the question could be considered a little leading in that it links GM food with danger; it would have been interesting to see the results if the question had instead asked whether respondents agreed that GM food was safe.

Research carried out in the UK shows broadly similar levels of support for the use of GM food from 2003 to 2008 (14% to 15%), but a slight reduction in opposition (36% to 31%) and in those claiming

[93] It is possible that that the ranking would change if concerns other than the environment had been considered.

[94] Although the questions are not identical they are close enough to allow a comparison.

not to know (11% to 7%); the proportion of those with a neutral position increased from 39% to 47% (IGD, 2008)[95].

The above findings reveal that average citizens do not appear particularly concerned about the use of GMOs in farming compared to other environmental concerns (a finding corroborated by, for example, USDA (2010); FSA (2009b); and King's College London (2008)). FSA (2002b) suggests that GM is also far down the list of concerns in relation to food and FSA (2002a) shows generally declining concern between 2000 and 2002 in the UK. Nevertheless there is both relatively little support for their use and a group concerned by their use as evidenced by a number of anti-GM campaigns; as Cormick (2007) is quoted in Brook Lyndhurst (2009), there is not a single "public". This has remained the case, with some variation, for the past decade. That said, citizens and consumers are not synonymous and consumer behaviour may differ from the stated preference of citizens (see section 7.2).

European Commission (2008c) reports that respondents selected GMOs as one of the top five environmental issues that they lack information about. The fact that citizens do not consider themselves well informed about GMOs implies a lack of familiarity with the approvals process; attitudes might conceivably be different if citizens were more aware that the approval process for GMOs requires a risk assessment.

8.1.2. Stakeholder concerns with the approvals process

With the above as background, we now turn to more specific concerns with the approvals process itself, including the concerns of stakeholders, which, depending on their remit might be very different to public concerns.

Respondents to our survey were asked which, if any, of a number of aspects of the GM food and feed authorisation process create controversy among stakeholders and the general public (see section 1.6.1 of the appendix). Both Competent Authorities and stakeholders identified differences in approach compared to Third Countries, Member State votes on draft decisions and the speed of the authorisation process as the most controversial areas. There was also agreement between Competent Authorities and stakeholders in terms of the three least controversial aspects with the "one door, one key" approach seen as least controversial followed by EFSA's risk assessment and then the European Commission's involvement in the authorisation process.

There were, however, differences between stakeholders in terms of which aspects of the authorisation process cause controversy. NGOs and consumer organisations believed that the EFSA risk assessment and "one door, one key" policy caused controversy. In contrast, feed processors considered both these aspects to be uncontroversial, while traders considered the EFSA risk assessment, and the food industry the "one door, one key" approach, to be uncontroversial. The food industry and NGOs believed that the safeguard measures caused controversy (although so far these have only been applied in respect of cultivation). NGOs were alone in stating that European Commission involvement in the approvals process caused controversy.

Our case study revealed that different categories of stakeholder hold different views as follows:

- The industry (feed, food and biotechnology) generally noted that the most controversial part of the authorisation process is the Member State voting on the draft decision. The controversy arises because the basis for the vote is deemed to be political (often based on public opinion) rather than being based on the scientific assessment carried out by EFSA.
- Although the risk assessment is considered uncontroversial by most groups of stakeholder, consumer associations and NGOs (in particular in Greece and Italy) find this phase to be the most controversial aspect of the authorisation process. Concerns were raised in particular in relation to

[95] N = 1,363 in Autumn 2003, 5,967 in Spring 2008 and 1,012 in Autumn 2008.

the use of industry-produced data rather than independently generated data. This group of interviewees also highlighted a perceived lack of scientific data on the long-term effects of consumption of GMOs.

- One Competent Authority and two farmer associations also suggested that the risk management phase is very controversial because, through the comitology procedure, the European Commission authorises GM events without the support of a qualified majority of Member States.

The French Competent Authority made clear that public controversy is created by the presence of GMOs rather than any specific aspects of the authorisation process and the Danish Competent Authority explained that the public is not very interested in the risk assessment and approval process and that there has been no public debate on stacked events and their treatment.

Semi-structured interviews with key EU stakeholders and our case study also highlight the lack of public interest in, and awareness of, the approvals process. The point was made (also by Commission Services) that any lack of public acceptance of GMOs results from public perceptions of the technology, including political and ethical implications of its applications, and not the approvals process. In this context the NGOs are considered by other stakeholders to have made very effective use of the media to promote their view of the issue whereas scientists are not widely held to be effective communicators to the public.

According to Commission Services, public comments on European Commission draft decisions tend to express general rather than specific concerns. Where specific concerns have been expressed these have related to the lack of GM labelling on livestock products; a perceived lack of longer-term studies on the impact on public health and the environment; and, the lack of transparency in the approvals process.

Some stakeholders noted that some Member States have undermined the authority of EFSA either through direct criticism or by using emergency measures (in relation to cultivation) and by not voting in favour of draft decisions on the basis of EFSA's risk assessment opinion: both acts are likely to make citizens question the scientific validity of EFSA's work.

Most comments made in interviews and case studies referred to wider issues of public acceptance. For example, an environmental NGO commented on a perceived failure of trust in public food safety bodies and public concerns about multinational control over food (a point also raised in our case study interviews). This NGO pointed out that many citizens have a negative view of the EU in general and EU involvement in the approvals process may not help, especially where Member States occasionally allow the European Commission to be the focus of citizen complaints. A stakeholder from the feed sector added that GMOs were introduced without consultation and outside the framework of specific legislation which resulted in the involuntary exposure of citizens to the technology.

Case study respondents highlighted the lack of clear benefits as being a barrier to acceptance (see section 2.5.1 of the appendix.). For example, IGD (2008) showed that when put in the broader context of food security and climate change, the ratio of acceptance of GM technology in food is higher.

The attitude of the media was also mentioned as a driver of controversy with terms such as "Frankenfood" fuelling citizen concerns. Media attitude also affects the attitude of retailers and their reluctance to stock GM labelled products and, in some cases, to use GM feed in livestock supply chains reinforces consumer concern. It was noted that some retailers, especially in the UK, actively used public concern over GMOs as a marketing tool in the late 1990s. Case study findings suggest that the media, by alerting the public to potential risks, are not neutral actors.

Finally, a representative from the feed industry explained that consumer acceptance is, in many cases, driven by price and that there is little correlation between consumer behaviour and the stated preference of citizens (Brook Lyndhurst (2009) explain that there is a consensus on this from a large

body of evidence). The implication of this is that it is not really possible to assess public acceptance given the lack of availability of GM labelled products (see section 7.4)[96].

Judgement

While average citizens do not appear particularly concerned about the use of GMOs in farming compared to other environmental concerns, there is nevertheless both relatively little support for their use (including as GM food), and a group concerned by their use as evidenced by a number of anti-GM campaigns. It is clear that the public does not hold a unified view and this has remained the case, with some variation, for the past decade. However, it should be noted that there is little correlation between consumer behaviour and the stated preference of citizens. The implication of this is that it is not really possible to assess public acceptance given the lack of availability of GM labelled products in European stores.

Public awareness of the risk assessment process is considered to be generally low and the public acceptance (or otherwise) of GMOs results from general perceptions of the technology rather than specific aspects of the authorisation process. Stakeholders have a number of areas of concern, but these tend not to be with the authorisation procedure *per se*. These also reflect their interest in the authorisation process with those in favour of GMOs being concerned about aspects which slow down authorisations and those against being concerned about aspects which make authorisations more likely.

8.2. Impact/cost of risk aversion

The full title of this Evaluation Question is: *What is the impact/cost of this risk aversion?*

Risk aversion in the context of GMOs is a difficult subject because authorised GMOs in the EU have been positively risk assessed by EFSA and therefore have been deemed to pose no risk. However, it is clear that risks in relation to GMOs are perceived by some irrespective of EFSA's opinion on the matter and, as seen in section 6.1, some parties are concerned with the validity of EFSA's risk assessment. Risk aversion should therefore be understood as referring to perceived risks (as also noted by Brook Lyndhurst, 2009).

The impact/cost of risk aversion depends on the potential benefits and the extent to which these are denied to EU producers and consumers. To date there are no examples of GM food or feed which have been authorised in a Third Country, but have had an application rejected in the EU (there are, however, GM events currently passing through the authorisation procedure in the EU which have been authorised elsewhere).

The impact/cost of this risk aversion is therefore effectively the impact/cost of delayed authorisations in terms of the (temporary) denial of GM events to European farmers and consumers and the impact/cost of measures taken to deal with adventitious Low Level Presence (LLP) of GM events which are not authorised in the EU and arise through asynchronous authorisation. There is also a cost arising from the GM labelling regime and a dynamic feedback process (Costa-Font, *et al* (2008) cite some studies making this point) whereby LLP issues and labelling may contribute to maintaining a relatively high level of public concern. Finally, there is also likely to be an impact/cost from the lack of research on crops of specific benefit in the EU context and on the development of the wider EU agricultural biotechnology sector.

[96] Brook Lyndhurst (2009) report that, in general, attitudes to GM tend to be more positive where GM food is widely available and less positive where there is an ongoing debate about acceptance.

This Evaluation Question is therefore organised as follows:

- The benefits of GM crops.
- Reasons why the EU might not be able to access any benefits.
- Dynamic feedback process.
- The impact/cost of risk aversion.

8.2.1. The benefits of GM crops

A number of authors have reported recently on the economic and environmental benefits (or otherwise) of GM crops. A recent list includes Brookes and Barfoot (2008) in a report funded by Monsanto (but carried out independently), Towery and Werblow (2010), funded by the United Soybean Board, Greenpeace (2008c), Friends of the Earth International (2008 and 2009), Benbrook (2009), an Organic Center publication. As might be expected, these authors take varying positions with respect to the magnitude of benefits. It should be explicitly noted that many NGOs take the view that there are no benefits from GM crops, only costs.

A JRC review of the economic impact of dominant GM crops worldwide (Gómez-Barbero and Rodríguez-Cerezo, 2006a) concluded that:

- on-farm benefits have been derived from reduced production costs (weed control costs for HT crops and pest control costs for *Bt* crops) and, in some cases, yield increases (particularly *Bt* cotton);
- off-farm income may benefit from the increased economic opportunities arising from free time resulting from crop management simplification (especially in relation to HT soybean in the US);
- net economic benefits are regionally variable depending on the extent of weed/pest problems that crops are designed to solve and because traits have yet to be transferred to regionally relevant varieties;
- both small and large-scale farmers have benefited;
- there are benefits in terms of reduced insecticide use (mainly in *Bt* cotton) and several herbicides have been replaced by a single product which is considered less toxic in relation to HT soybean (although use of this herbicide has increased);
- there is an association between HT soybean adoption and reduced fuel consumption per hectare; with the adoption of reduced soil tillage; and, with the conversion of land (usually pasture) to soybean production in Argentina;
- positive changes in economic welfare for countries adopting GM crops;
- larger gross margins for Spanish farmers adopting *Bt* maize, but with large regional variations;
- *ex-ante* assessments of the impact of GM crop adoption in the EU suggest positive on-farm economic benefits;
- segregation and identity preservation costs may, under some tolerance level scenarios, outweigh economic benefits resulting in a reduction in net welfare; and,
- the use of co-existence measures in the EU may further affect net benefits, although more research is needed on this point.

From the above review it is clear that GM crops have introduced some benefits where these crops are cultivated. However, the only GM events authorised for cultivation in the EU are *Bt* maize and the

Amflora potato (the latter was only authorised in March 2010 and has therefore not been cultivated at the time of writing). The performance of GM maize in Spain is set out in detail in Gómez-Barbero, *et al* (2008a). An important reason for the lack of EU cultivation is that most GM crops are simply not suitable for widespread growth in this region (for example, soybean and cotton events). This lack of GM crops suitable for cultivation in the EU may result, at least in part, from the general lack of acceptance of agricultural biotechnology, in other words, risk aversion (see section 6.4 for a discussion of the impact of EU legislation on the development of the EU agricultural biotechnology sector).

Despite the general lack of cultivation of GM crops in the EU, some of the economic benefits noted above should benefit EU users in the form of lower prices as a result of price transmission, although the benefit from this will depend on the nature and extent of the transmission (see Buckwell, *et al*, 1998) for a full treatment of this issue in relation to the introduction of GM technology). Given the relative lack of GM foods in the EU (see section 7.4) the benefits will be felt primarily in the livestock sector where the use of GM feed is widespread (see section 7.5).

8.2.2. Reasons why the EU might not be able to access any benefits

As seen in the previous section, there are some potential benefits from GM crops. EU consumers will receive a price benefit from the use of GM crops as raw material for livestock feed, although this is considered to be small because of dilution in the value chain and imperfect price transmission. However, in the current situation there are four main issues which might restrict access to these benefits in the EU:

- **Lack of cultivation.** In this context it should be noted that most GM crops are not designed for use in the EU and this itself may result in some part from a risk averse attitude (see section 6.4). However, cultivation issues are not within our remit and we focus here on GM food and feed.
- **Lack of availability of GM labelled food products.** This is largely the result of retailer decisions not to stock GM labelled food products. In turn, as is noted in our case study (section 2.5.2 of the appendix) this derives from their perception of consumer demand and the reaction of NGOs. The impact is considered relatively marginal given the overall incorporation rate of GM material in final products. The impact is medium to long-term and is dependent on supply chain logistics and retailer attitude.
- **Non-GM food chains and feed supply chains** for livestock products in certain sectors/Member States which implies a cost for segregation and Identity Preservation which will limit any overall net benefits to society (see section 7.3). This issue is far more significant in relation to GM feed where the cost of feed comprises a much higher proportion of consumer price than is generally the case with respect to food where, for example, soybean derivatives account for a small proportion of total cost and hence even large premia for non-GM supply will not have a substantial impact on final consumer price (Buckwell, *et al*, 1998). This impact is medium to long-term and depends on consumer demand for non-GM/"GM-free" products (at least as perceived by retailers).
- **Asynchronous authorisations** which result in EU producers being denied access to GM events pending their authorisation in the EU (see section 6.9 for a discussion on this subject including an examination of the resulting costs); this is a short-term impact.

In all cases the root cause of the costs/denial of benefit can be traced back to a lack of public acceptance, i.e. risk aversion. If consumers were perceived to accept the use of GMOs, then there would be no demand (or retailer perceived demand) for non-GM food and feed supply chains[97]. The

[97] It should be noted that King's College London (2008) concluded that consumers do buy GM labelled products where these are available, so the issue is not strictly consumer demand, but rather retailer interpretation of this which might also encompass other considerations.

cost of risk aversion in this case might be said to be equal to the total costs of segregation and identity preservation. Where products are labelled as "GM-free" or non-GM it is reasonable to assume that this cost is met by consumers who are willing to pay (see section 7.8 for a discussion on the availability of "GM-free" labelled products in the EU). Where non-GM supply chains are used without point of sale labelling, then the additional costs will be borne involuntarily by all consumers, including those who would have no objection to the use of GMOs.

Asynchronous authorisation can also be thought of as a consequence of risk aversion. First, the EU has what some stakeholders describe as one of the most rigorous risk authorisation procedures in the world[98] which takes time to navigate. Second, the process often takes longer than it might because a qualified majority in favour of European Commission draft decisions has never been achieved resulting in authorisation through the (lengthy) comitology procedure. Our survey of Competent Authorities found that 21 Member State's (84% of those responding) do not vote simply on the basis of EFSA's scientific risk assessment. While 14 Competent Authorities noted that they also take into account the views of their own national risk assessment, others reported that they also take into account parliament and/or public opinion and political factors; any latent risk aversion will therefore form part of this consideration (section 1.4.6 of the appendix).

8.2.3. Dynamic feedback process

There is a dynamic feedback process at work in terms of the impact/cost of risk aversion. The use of positive GM labelling, which derives from the perceived desire of some consumers to avoid products containing or derived from GMOs[99], might be considered to draw attention to the use of GMOs in food products which in turn might be a contributing factor in low public acceptability. Similarly, LLP incidents arising from asynchronous authorisation and resulting in blocked shipments and/or the withdrawal of products might again reinforce public concerns, especially as these are notified under RASFF, which is concerned with safety issues. This is evidenced by survey results where 11 Competent Authorities (48%) and 47% of stakeholders found that public acceptance was "very negatively" affected by the impact of public controversy over GM food and feed and a further 11 Competent Authorities (48%) and 48% of stakeholders reported that public acceptance was "negatively" affected; there was stakeholder consensus on this point (section 1.6.2 of the appendix).

8.2.4. Impact/cost of risk aversion

The survey also revealed broad agreement that the supply of GM food to the market has been negatively affected by public controversy. All stakeholders held this opinion with the exception of NGOs who perceived a positive impact, most likely reflecting their desire to keep GMOs out of supply chains. Overall, a higher proportion of Competent Authorities thought the impact here had been very negative compared to the stakeholder respondents. There was less agreement, and less negative impact, in terms of consumer prices. A higher proportion of stakeholders (especially feed processors and those in the food industry) noted that there had been a negative impact on consumer prices than did Competent Authorities.

Commission Services noted that whilst the medical and industrial biotechnology sectors in the EU are well developed, and that some companies within these sectors are considered world leaders, this is not

[98] European Commission (no date b) says that the EU regulatory framework is one of the strictest in the world.

[99] Regulation (EC) No 1829/2003 calls for the "*clear labelling, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product, meets the demands expressed in numerous surveys by a large majority of consumers, facilitates informed choice and precludes potential misleading of consumers as regards methods of manufacture or production*". Regulation (EC) No 1830/2003 states that "*it is necessary to ensure that consumers are fully and reliably informed about GMOs and the products, foods and feed produced therefrom, so as to allow them to make an informed choice of product*".

the case for the agricultural biotechnology sector[100]. There is a view that although public controversy was reflected by policy makers in relation to the agricultural biotechnology sector, it is difficult to identify the impact of GM legislation on the sector, although there are some concerns that there has been a negative impact. Another branch of Commission Services felt that the EU legislation was probably at least partly responsible for the lack of commercial research in the EU, although it was noted that establishing a causal link would be difficult. The cost of this lack of commercial research was said to be a lack of GM crops developed specifically for use in the EU. Finally, employment in the agricultural biotechnology sector is not as high as it might be given the relative lack of commercial research.

Stakeholders from the biotech industry reported that companies are increasingly carrying out research outside the EU (a point also made by Friends of the Earth Europe, 2007b). One of the main reasons provided for this is the inability to carry out effective field trials in the EU because of vandalism which is possible because trial locations are released to the public (Rodríguez-Cerezo (2010) notes that over 40% of field trials have been destroyed in Germany)[101] . The regulatory framework, and by implication public risk aversion, was said to have held back the development of the EU biotech sector (section 6.4). This has resulted in the lack of applications for cultivation in the EU. The fact that authorisation of the Amflora potato in March 2010 was followed a week later by a similar application and an announcement that another company will put forward two applications for potato events during 2010 (Agra Facts, 2010) supports the contention that a lack of authorisations reduces the likelihood that companies will submit other applications.

The biotech industry also pointed out that, in their opinion, the requirements to adhere to the food and feed legislation are disproportionate, costly and lengthy. This discourages innovation and means that only large companies who can bear the costs of the process (and the lengthy period before returns are apparent) and can deal with the authorisation process can enter the market. This is considered disadvantageous for SMEs[102]. According to this source there are lots of SMEs active in the US and the public sector is more involved in, for example, China.

Finally, the point was made that manufacturers will not invest in the development of GM crops for cultivation for regions where cultivation may not be permitted or may be problematic as a result of a lack of public acceptance. This means that biotech companies have focused their development efforts outside the EU. In this context Commission Services pointed out that big multinational companies tend to breed for the global market in any case and this issue is therefore wider than whether the public accepts GM technology or not.

NGOs agreed that the agricultural biotech sector in the EU has been adversely affected by the political and social backdrop in the EU which, in their view, is not in favour of the use of GMOs, rather than the regulatory framework itself, although to some extent the former informs the latter.

[100] Critical I (2006) report that companies active in agricultural and environmental biotechnology account for 11% of all biotech companies, the smallest sub-section of the overall biotech sector.

[101] El-Beltagy (2010) notes that there were 2,404 field trial in the EU between 1992 and 2008, of which two-thirds took place before 2001. In contrast, there have been 14,300 in the US between 1987 and 2008.

[102] European Commission (2007a) notes that most employment in the European biotechnology industry is in SMEs, but this encompasses medical and industrial biotechnology as well as agricultural biotechnology and the latter sector is dominated by large multinationals (Friends of the Earth, 2007b).

Judgement

The impact of risk aversion on the EU agricultural biotechnology sector has mainly had an impact in terms of commercial development of crops for cultivation and is therefore outside the scope of this evaluation. As might be expected, authors funded by industry and those funded by NGOs take different positions with respect to the magnitude of benefits from GMOs and indeed whether there are any net benefits at all. However, a JRC-IPTS report comprehensively reviews the impact of GM crops and concludes that there are some benefits where these crops are cultivated. An important reason for the lack of GM cultivation in the EU is that most GM crops are simply not suitable for widespread growth in this region. This may result, at least in part, from the general lack of acceptance of agricultural biotechnology in the downstream food chain and more widely; in other words, risk aversion.

The overall economic benefits of GM crops that might be realised at the cultivation stage may be reduced in the EU as a result of the lack of GM food products in the EU, the use of non-GM food chains and feed supply chains for livestock products in certain sectors/Member States which implies a cost for segregation and Identity Preservation which will limit any overall net benefits to society; this issue is far more significant in relation to GM feed. This impact is medium to long-term and depends on consumer demand for non-GM/"GM-free" products (at least as perceived by retailers). Another reason that the EU may not benefit from GM crops is asynchronous authorisation which results in EU producers being denied access to GM events pending their authorisation in the EU; this is a short-term impact. Additionally, asynchronous authorisation and the risk of low level presence incidents can deny access to usual sources of feed material. In all cases the root cause of the costs/denial of benefit can be traced back to a lack of perception of benefit and a lack of public acceptance, i.e. risk aversion. Developments with specific relevance in the EU are less likely given that manufacturers will not invest in the development of GM crops for cultivation in regions where cultivation may not be permitted or may be problematic as a result of a lack of public acceptance driven by risk aversion.

8.3. Variations in the sensitivity of EU-wide opinion in relation to GMOs

The full title of this Evaluation Question is: *Are there variations in the sensitivity of EU-wide opinion between cultivation, food and feed use?*

Evidence on the public acceptance of GMOs (presented in section 8.1) tends to focus on the technology as a whole rather than on the specific aspects of cultivation, food or feed use. The main evidence available to address this question is therefore the primary research carried out in our survey, semi-structured interviews and case studies.

This answer is organised as follows:

- The extent to which sensitivity varies with respect to GM cultivation, food and feed.
- The variation in sensitivity between GM cultivation, food and feed.

8.3.1. The extent to which sensitivity varies with respect to GM cultivation, food and feed

Survey respondents were asked whether public sensitivity varies with respect to GM cultivation, food and feed. Twenty one Competent Authorities (88%) and 88% of stakeholders thought that it did (section 1.6.3 of the appendix)[103] . There were no appreciable differences by stakeholder group. This

[103] There can also be differences in sensitivity within governments. For example, in Belgium, the government of Flanders is in favour of GM cultivation whereas the government of Wallonia is against. This results in the Belgian Federal Government taking no position.

was also borne out by our semi-structured interviews with stakeholders and by our case study findings (section 2.5.3 of the appendix).

8.3.2. The variation in sensitivity between GM cultivation, food and feed

IGD (2008) reports on UK attitude[104] to GM food and the impact of GM crops on the environment, which can be considered a proxy for cultivation. Table 8.1 suggests greater concern in terms of consumer safety. FSA (2002b) also found that food safety concerns were more widespread and immediate than were environmental concerns in the UK when this was raised in focus groups.

Table 8.1: UK attitude to GM food and environment impact of GM crops

	Consumer safety of GM food (%)	Impact of GM crops on the environment (%)
Not at all concerned/very positive impact on the environment	10	2
Not very concerned/quite positive impact on the environment	30	11
Neutral impact on the environment	-	32
Quite concerned/quite negative impact on the environment	34	25
Very concerned/very negative impact on the environment	15	12
Don't know	11	17

Source: IGD (2008).

Our survey revealed some differences in perception in terms of how the public view GM cultivation, food and feed. Two-thirds of Competent Authorities (13) felt that there is most concern with respect to cultivation. A third (6) felt that the public is most sensitive with respect to GM food; no Competent Authorities felt that there was most public sensitivity in terms of GM feed (section 1.6.3 of the appendix).

Surveyed stakeholders felt that public sensitivity in terms of GM cultivation and food were much more similar with 51% and 49% listing these as the main concern respectively, although a higher proportion of stakeholders placed GM food as the second most important concern compared to cultivation (47% c.f. 25%). There were differences in perception between different stakeholder groups with technology providers and feed processors generally citing cultivation as the most sensitive GMO issue, while the food industry considered GM food to be the most sensitive. GM feed was seen by both groups as being the area of least concern, although stakeholders perceive this to be of more concern to the public than do Competent Authorities (section 1.6.3 of the appendix).

Semi-structured interviews with key European stakeholders suggested greater public sensitivity in terms of GM cultivation followed by GM food and then feed. One NGO did point out that there might be differences in sensitivity in urban and rural areas with the former more concerned about GM food and the latter GM cultivation[105]. A stakeholder from the biotech sector felt that while GM is still a very divisive issue, consumer concerns are generally declining.

[104] N = 5,967.

[105] IGD (2008) does not explain the rural/urban breakdown in its sample. It is possible that their finding in Table 8.1 is influenced by this difference in concern.

Some stakeholders added that consumers are not aware of the use of GM feed, hence its low sensitivity, with certain stakeholders identifying the lack of livestock product labelling as the reason for this lack of awareness.

Our case study found that there is more sensitivity in terms of cultivation in Poland because agricultural production is an important component of culture and the economy and is therefore an activity with which people are generally familiar. Sensitivity in Greece was more nuanced with the Competent Authority explaining that cultivation is the most sensitive area as a result of environmental concerns and the desire to protect traditional and organic products. On the other hand, consumer organisations feel that the public does not differentiate between GM cultivation, food and feed, while the biotech and food industries feel that sensitivity with respect to GM food is highest. In all cases, however, it was agreed that sensitivity is lowest with regard to GM feed.

Most case study respondents in the UK felt that sensitivity is highest with regard to GM cultivation, mainly because of concerns over co-existence and potential implications for the organic sector. Consumer organisations, on the other hand, suggested that there was greatest concern in terms of GM food, perhaps reflecting their focus and/or knowledge of the work carried out by IGD (2008). Case study respondents in Italy generally felt that there is greatest sensitivity in terms of GM food because the potential impact on people is considered to be more direct than any environmental impact arising from cultivation. Respondents from the biotech sector disagreed and noted that media reportage focuses on cultivation and, as a result, this is where the greatest concern lies. Again, there is agreement that sensitivity is least with respect to GM feed, probably at least partly due to a lack of awareness given that livestock products do not fall within the labelling scope.

Judgement

The evidence collected through our survey work, semi-structured interviews and case studies reveals that there is a widely perceived difference in sensitivity between the three components of the GM issue. Research in the UK suggests that the public are more concerned about the safety of GM food than the environmental impact of GM crops. Our primary data collection suggests that it is clear that there is least sensitivity with regard to the use of GM feed, probably at least partly due to the exclusion of livestock products from the scope of labelling and the limited knowledge of consumers on the use of GM feed, the relative sensitivity in terms of GM cultivation and GM food is more nuanced. Competent Authorities believe that there is more sensitivity with regard to cultivation whereas stakeholders feel that sensitivity is more comparable between the two. The biotech and feed industries tend to view GM cultivation as more sensitive than GM food whereas consumer organisations tend to find GM food a more sensitive issue. In both cases this might well reflect their respective focus.

8.4. The concept of ALARA (As Low As Reasonably Achievable) risk

The full title of this Evaluation Question is: *Can the risk acceptance of EU citizens be measured against the concept of ALARA ("as low as reasonably achievable") risk? If so, how?*

"As low as reasonably achievable" (ALARA) refers to the concept of "reasonably practicable", i.e. the risk is weighed against the costs involved in control (HSE, 2010). ALARA therefore refers to the level of control where reducing risk further would be disproportionate to the benefit gained. ALARA is sometimes referred to as "as low as reasonably practicable" (ALARP) and "so far as is reasonably practicable" (SFAIRP).

ALARA is therefore a concept for managing known risks. Bouder (2004) explains that the concept of "reasonably practicable" in connection with risk was introduced in the UK in 1949 and became a standard for dealing with risk under the Health and Safety at Work etc. Act 1974. It should be noted that the concept is not widely used in agriculture, if at all, and as a result there is no specific literature in this area and we rely here on our primary research.

This Evaluation Question is organised as follows:

- The extent to which ALARA is considered an appropriate approach in relation to GMOs.
- The potential use of ALARA in relation to GMOs.

The extent to which ALARA is considered an appropriate approach in relation to GMOs

Most stakeholders were not familiar with the term ALARA and this in itself reveals that most have not previously considered its application in relation to GMOs. One stakeholder noted that the consideration of ALARA suggests a misconception in terms of how GMOs are regulated because ALARA is a concept for dealing with known risks and authorised GMOs have been positively risk assessed by EFSA and therefore, by definition, do not represent a known risk. This point was also made by some case study interviewees.

Our case study revealed that there is a widespread perception that consumers are not aware of the concept of ALARA, or indeed of the use of tolerance levels for impurities in agriculture in general (section 2.5.4 of the appendix). As a result, consumers expect products to be free from contaminants and there is usually a strong public reaction when contamination occurs or is revealed.

Some case study interviewees noted that ALARA would not be an appropriate approach in relation to GMOs because the concept is too vague and its operation subjective. This might lead to differences in approach in different Member States (or sectors) which would create problems in terms of the effective functioning of the single market; what is considered as low as reasonably achievable in one Member State might not be considered so in another.

An NGO explained that GMOs should be treated differently to other sources of impurity because many consumers wish to avoid the technology itself rather than specifically the product. They therefore consider a zero tolerance approach to the presence of GM material the only appropriate approach.

8.4.1. The potential use of ALARA in relation to GMOs

One Competent Authority interviewed as part of our case study explained that whilst ALARA would normally refer to a safety risk (to health or the environment), if instead the risk referred to the chance that GM material would be present, then ALARA might have a role in relation to GMOs. However, other respondents felt that such an interpretation of risk would be inappropriate given the generally understood definition of (safety) risk as used in relation to ALARA. Others added that a risk mitigation tool is not appropriate as a means of allowing consumers to avoid the use of a technology which has been risk assessed, considered safe and authorised as a result.

There are two possible cases where ALARA could, in theory, have a role in relation to GMOs:

1. The labelling regime

The concept of adventitious and technically unavoidable presence, used in conjunction with the 0.9% threshold for labelling, is in fact a fairly similar concept to ALARA in that it allows for the presence of GM material at low levels as long as steps have been taken to ensure that there is no presence in so far as is technically possible. The main point of difference is the absence of reasonability, i.e. there is no apparent trade off between what is technically achievable and what is economically proportionate. It might be considered a relatively small step to introduce the concept of reasonable cost here, although there would potentially be issues in terms of defining "reasonable". This issue could be mitigated by applying the concept in conjunction with a lower threshold. The Belgian Competent Authority suggested 0.1% in response to our survey because this is in line with the current limits of detectability (this was also the level suggested by the Austrian Competent Authority; the Czech Competent

Authority suggested 0.3%). However, the Spanish Competent Authority suggested a higher limit for practicable purposes.

2. The Low Level Presence (LLP) of unauthorised GM material

Currently there is zero tolerance of the LLP of GM material unauthorised in the EU. It would be possible to consider an ALARA approach here so that as long as reasonable efforts had been made to avoid LLP, traces of GM material unauthorised in the EU would be permitted. An issue here is whether such material would be considered safe, even in trace amounts. A distinction might be made between GM material which had been subjected to a risk assessment and subsequently authorised in a Third Country and material which had not been risk assessed. Again there would be issues in terms of what is considered "reasonable" and there might be difficulties explaining such a use of the ALARA concept to the public. Clearly this use of ALARA would not allow the public to avoid the use of GM technology should they wish to do so and this may not help foster public acceptance. That said, a retailer interviewed as part of our case study suggested that this use of ALARA could be useful and might help foster public acceptance because it would result in an end to LLP incidents which can result in damaging media coverage.

Judgement

There is a fundamental concern with the use of ALARA in relation to GMOs in that the concept deals with known risks and authorised GMOs do not pose a known risk by definition. That said, the use of ALARA can be envisaged in conjunction with a defined threshold in relation to the labelling of GM products and also in relation to the LLP of GM material not authorised in the EU. In both cases there are also concerns that the term "reasonable" is open to different interpretations which could have consequences in terms of the operation of the single market. Depending on its application, the use of ALARA would also not permit consumers to avoid the use of GM technology if they so wish which might negatively affect public acceptance. On the other hand, if the use of ALARA prevented LLP incidents, then this might improve public acceptance.

8.5. EU-wide trust in science-based risk assessment

The full title of this Evaluation Question is: *Can the quality of the EU-wide trust in science-based risk assessment be improved in the GM context?*

Section 8.1 has demonstrated that there is little general public support for the use of GMOs and that there is a group which is actively concerned about their use and that this has by and large remained the case for the past decade. Section 8.1 and section 8.3 also explained that public concerns tend to be with the technology as a whole rather than with elements of the EU authorisation process (see also Brook Lyndhurst, 2009). Improvement in the EU-wide trust in science-based risk assessment is therefore closely related to increased support for GMOs.

This answer is organised as follows:

- A brief history of controversy over GMOs in the EU.
- Efforts to communicate with the public on the GMO issue.
- The effectiveness of communication efforts.
- Efforts to communicate with the public specifically on the science-based risk assessment.
- Improving the quality of public trust in science-based risk assessment in the context of GMOs.

8.5.1. A brief history of controversy over GMOs in the EU

Section 7.3 and section 7.6 set out the development of the use of GMOs in the EU. Here we focus on the controversy that GMOs have created. One of the main factors in establishing the original controversy in relation to GM food in the EU was the emergence of GM as a technology in the public eye in the late 1990s at the same time as a series of concerns over the performance of institutions responsible for public safety. The three main concerns related to blood contaminated with the AIDS virus, "mad cow disease" and the use of asbestos[106]. OECD (1992) note that agricultural biotechnology had became identified with unrelated food safety and public health concerns by some groups even before this. In all cases known risks were either ignored or action to mitigate the risk was delayed or not taken for economic reasons with the result that public distrust of companies and public authorities increased; there was also an increase in public willingness to listen to critical opinion and widespread reference to precaution (Bonny, 2004). Acceptance was also undermined by the introduction of GMOs without the public's knowledge and by the lack of clear consumer benefit (Noussair, *et al*, 2004).

Bonny (2004) focused on the controversy in France and makes the point that a number of associations ranging from environmental NGOs to groups with an economic interest pursued vigorous anti-GM campaigns[107] which gained significant publicity against the background of general public concern with the performance of safety authorities[108] and the commercial interests of companies. This author also explains that the attitude of the media in general switched in the late-1990s from the position that biotechnology was a promising innovation to a position in which increasingly critical opinions were expressed[109]. Lofstedt (2006) points out that the media acted as an amplifier of risk in the case of GMOs (see section 8.1) and Goldacre (2008) explains that when the (UK) media report major science news stories they often do so without using science correspondents. He argues that non-science journalists are not always able to critically appraise science stories.

Public acceptance of GM food was further hindered by the issue of labelling. Bonny (2004) reports that the 1998 Greenpeace campaign with the slogan "no GMOs on my plate" was instrumental in prompting food manufacturers throughout Europe (and sometimes also the USA) to remove GM ingredients from their products in order to avoid potential loss of market share. The withdrawal of GM ingredients was likely to have further undermined public trust in safety.

Bonny (2004) summarises the situation as follows:

> "*In the late 1990s the public authorities adopted a hesitant attitude…often backtracking and procrastinating, which heightened confusion and perplexity…Thus, faced with strong denunciation by various associations, extensively relayed by the media, there were few actors*

[106] Davison and Bertheau (2007) set out the following more recent concerns which have continued to undermine trust in these institutions: foot and mouth disease in livestock; Listeria in refrigerated products; salmonella in eggs; dioxin in chickens, milk and meat; the impact of radioactivity from Chernobyl; and, Avian Influenza.

[107] Greatly assisted through their use of (at the time) new electronic communication technologies.

[108] According to Bonny (2004), the success of the anti-GM campaigns was reflected in a Eurobarometer survey in 1999 which showed that respondents felt consumers' unions, doctors, the media and environmental groups were "doing a good job for society" in respect of GMOs whereas the industry was the only actor judged as "not doing a good job".

[109] Bonny (2004) advances four main reasons for this shift. First, science writers were mainly responsible for earlier (more positive) articles on GM technology whereas once the issue became more contentious it was covered by the same journalists who had also covered "mad cow disease", etc. (see also Goldacre, 2008). Second, there was an element of competition for audience within the media which was best served by more lurid headlines rather than more moderate and qualified articles. Third, the focus of anti-GM campaigns on pre-announced spectacular actions was attractive to the media while the more traditional forms of communication employed by the industry were less so and advantages that might arise from GM technology were not adequately communicated. Finally, public research institutes, at least in France, failed to clear up points of controversy and generally failed to communicate clearly with the public for a variety of reasons.

> *to present GMOs in a favourable light: firms were judged as having little credibility and public research organisations made few public and official statements on the subject; the few scientists or their allies interviewed by the media were in some cases against GMOs; and, lastly, the authorities seemed confused and hesitant*".

Frewer, *et al* (2004) found that the failure of the regulatory bodies to take full account of the actual concerns of the public resulted in much of the public controversy.

8.5.2. Efforts to communicate with the public on the GMO issue

Against the background set out above, it is clear that efforts to engage with the public were needed. However, our survey revealed that official communication efforts at the Member State level have been sparse (see section 1.6.4 of the appendix). Lofstedt (2006) argues that many of the past regulatory scandals in Europe primarily resulted from a lack of transparency. That said, government communication on potential benefits arising from privately introduced technology which is subject to risk assessment and an authorisation procedure might not be considered appropriate (or necessary) by some given that the beneficiaries of such communication would ultimately be private companies.

According to the respective Competent Authorities, there has been no government communication effort in Portugal and Internet only communication through government websites in Austria, Belgium, Estonia, France, Hungary, Italy and Spain. The Competent Authorities in Germany, Slovakia, Slovenia and Sweden did not answer this question and the assumption is that government communication here has also been minimal.

Communication efforts in some other Member States have been more widespread with responses from Bulgaria, Cyprus, Czech Republic Denmark, the Netherlands and Romania explaining that, in addition to electronic information, brochures, workshops, conferences, press releases, reports, meetings with stakeholders, etc. have been used to communicate with the public on this issue.

More attempts to engage with the public took place in the UK where the government sponsored a public debate on the commercialisation of GM crops in 2003 called GM Nation? The Public Debate (DTI, 2003). The UK Competent Authority also explained that a new programme of public engagement on genetic modification is currently under way. The intention is that this will provide an opportunity to discuss with consumers their understanding of GM and what they think it might bring in terms of risks and benefits. It will also explore how people can be helped to make informed choices about the food they eat[110]. However, following a change of government in May 2010, this engagement may no longer take place (Vidal, 2010).

There have been various efforts by the industry and NGOs to communicate with the public from their own standpoints. Two-thirds of the stakeholders responding to our survey reported that they had carried out communication/campaign activities relating to GM food and feed. Approximately a third of those carrying out campaigns considered them broadly supportive of GM technology (generally the biotech industry), a third against (all NGOs) and a third neutral (typically feed processors, traders and the food industry). Feed users (i.e. farmer organisations) and consumer organisation campaigns were split between the three categories.

8.5.3. The effectiveness of communication efforts on the GMO issue

An evaluation of the impact of GM Nation? found that 71% of the public interviewed[111] shortly after the debate had not heard of it. While 13% had heard of it, they knew nothing about it. Only 15% of those interviewed were to some extent aware of the debate (Poortinga and Pidgeon, 2004). These

[110] Further information is available at: http://www.food.gov.uk/news/newsarchive/2009/sep/gmchair.

[111] N = 1,363.

authors conclude that, in the context that interest in the issue of GM food is high, the debate only partially met its objective to create widespread awareness; they also note that questions of awareness often generate false positives and the level of awareness is therefore probably overstated (see also Lofstedt (2006) for a brief commentary of the outcomes of the debate). Poortinga and Pidgeon (2004) also found a high level of scepticism about the impact of the debate with more than half the general public thinking that the debate will make no difference, because the government has already made its mind up on GM foods and crops. Two-thirds (68%) of respondents felt that the debate did not matter because in the end European and International laws will determine what will happen.

Another way of considering the effectiveness of communication efforts is to consider impact on public opinion. As noted in section 8.1, public acceptance of GM products is relatively low and, although it is not possible to state that this derives explicitly from communication activities undertaken, the suggestion is that those with a predominantly negative slant have been generally more successful.

This is coherent with the nature of the bodies communicating and the extent to which these are trusted by the public. Poortinga and Pidgeon (2004) state that it is generally acknowledged that trust is a prerequisite for effective risk communication and that doctors, consumer rights organisations, environmental organisations and scientists working for universities are consistently identified as being the most trusted sources of information in general. This is also the case in relation to GM food. Poortinga and Pidgeon (2004) go on to note that the least trusted sources in relation to GM food are scientists working for Government, scientists working for the biotechnology industry, Local Authorities, the biotechnology industry, food manufacturers, the EU and the national Governments.

Poortinga and Pidgeon (2004) employed Principal Component Analysis in order to examine whether there was an underlying pattern in people's trust judgements. According to this analysis they found that the various actors could be categorised as follows:

- **government institutions** (scientists working for the government, local authorities, the national government and the European Union);
- **industry** (food manufacturers, the biotechnology industry, scientists working for the biotechnology industry, farmers, FSA[112], and Defra);
- **watchdogs** (consumer organisations, environmental organisations, scientists working for environmental groups, and scientists working for universities); or,
- **personal sources** (friends and family and "people from your own community").

The highest average trust ratings were for watchdogs and personal sources (FSA (2002b) also mentions supermarkets in relation to food issues). Interestingly, Sheldon, *et al* (2009) found that campaigning environmental groups were perceived as having vested political interests. Government institutions were trusted the least to tell the truth about GM food (Sheldon *et al*, 2009) found some trust in official sources of information and communication), although industry appeared to be moderately trusted, partly the result of the inclusion of relatively trusted elements such as Defra, the FSA (trusted by 32% of people to provide accurate information about GM food[113] (IGD, 2008)) and farmers within this group. Costa-Font, *et al* (2008) cite a number of studies supporting these findings and Lofstedt (2006), King's College London (2008), Sheldon, *et al* (2009) and Brook Lyndhurst (2009) also broadly support the findings, although these consider the industry among the least trusted sources.

[112] IGD (2008) also demonstrates a public differentiation between the FSA and "government".

[113] This demonstrates a large increase in trust in the FSA given the fact that the FSA was considered to be mostly an unknown quantity in 2002 (FSA, 2002b).

The above analysis suggests that the success of communication activities depends in the first instance on the awareness generated, but then, and crucially, on the nature of the organisation communicating (these may be inter-related). In this regard it appears that communication efforts by government organisations may not be the most effective. That said, Gaskell, *et al* (2006) conclude from their analysis that there does not appear to be a crisis of trust in most EU countries.

8.5.4. Efforts to communicate with the public specifically on the science-based risk assessment

Our case study (section 2.5.5 of the appendix) found that communication specifically on the science-based risk assessment has not been systematically undertaken by governments. The only Competent Authority which appears to communicate specifically on the issue of risk is Finland (the UK has communicated more widely on the issue, see FSA (2002a) for details). The Food Safety Authority, Evira, provides Finnish translations of EFSA risk assessment summaries on its website and also informs Finnish consumers that they can comment on EFSA risk assessments. Commission Services noted that the majority of public comments originate from Finland and this policy therefore appears to be successful in engaging the public. The Finnish Advisory Board on Biotechnology[114]is currently working on a project which aims to increase public awareness on GM food and by doing so hopes to create constructive discussion on the issue.

Commission Services reported that, in addition to the general transparency on the implementation of policy in this field, there have been at least two specific communication projects funded by the EU: GMO compass[115] and Science4BioReg[116], both of which cover risk assessment within their wider remit:

- **GMO compass:** is a European consumer-oriented website providing easily comprehensible information on issues of safety evaluation of GMOs and GMO products. The website uses a network of correspondents in EU Member States to report the national debate and complements the existing information supply and transparency measures of EU institutions and state bodies, as well as the websites of lobby groups and scientific institutions. GMO Compass was financially supported by the EU under the Framework 6 Programme (01/01/05-28/02/07), but is independent from the European Commission and other EU agencies in terms of content. It should be noted that a major NGO considers that there is a pro-GM bias.
- **Science4BioReg** (Global involvement of public research scientists in regulations of Biosafety and Agricultural Biotechnology): is a three year Framework 6 programme which enabled the Public Research and Regulation Initiative (PRRI) to conduct some of its basic activities during the 2006-2009 period. This included a communication component, the aim of which was to provide public researchers with ready-made communication tools for the purpose of informing their peers and colleagues about regulatory developments and to produce briefing papers to inform regulators, policy makers and the general public about the background, objectives and progress of public research in agricultural biotechnology. Three briefing papers were published on 24 March, 2010 on: public research in plant biotechnology (PRRI, 2010a); GMO regulations in the European Union (PRRI, 2010b); and, the Cartagena Protocol on Biosafety (PRRI, 2010c).

Beyond these projects, Commission Services explained that there have been few efforts at communication with the public, although opportunities to communicate are taken up when they arise; there are no resources to do more than this. It was noted though that it was too early to comment on

[114] http://www.btnk.fi/en/btnk.html.

[115] http://www.gmo-compass.org

[116] Via http://www.pubresreg.org

the impact of these efforts. Finally, case study interviewees in the UK and Poland noted that scientists and the biotech industry have tried to communicate the risk-based scientific assessment to the public.

8.5.5. Improving the quality of public trust in science-based risk assessment in the context of GMOs

As demonstrated above, the issues of trust in risk assessment and trust in GMOs more generally are closely linked. Improving general trust in GMOs is a difficult subject which is ultimately outside the remit of this study. Nonetheless, the findings of some authors serve as useful background to improving trust in science-based risk assessment.

That improved information and communication is needed was recognised as long ago as the early 1990s (OECD, 1992), although the suggested achievement of this through government and industry appears naïve in the light of experience since then and the extent to which these information sources are trusted by the public.

Sinemus and Egelhofer (2007) explain that past communication efforts were often perceived as one-way where scientists tell "their truth" in simple educational approaches and that this has been proven to be inappropriate and unsuccessful.

These authors suggest three factors which should be taken into account in communication strategies:

- **Increased engagement of industry and governmental organisations.** Most information on biotechnology in the media appears in response to highly visible reports and there is a need to proactively build trust. Initiatives such as GMO Compass and national government initiatives such as those planned in the UK and Finland appear to fit here as increased knowledge on GM issues noticeably enhances the likelihood of GM food acceptance (Costa-Font and Mossialos (2005); Costa-Font, *et al* (2008) further report on a large number of studies which come to this conclusion, although Sinemus and Egelhofer (2007) dissent from this general consensus).
- **Better definition of the target audience.** The public is not homogenous (Cormick, 2007) and each group responds best to different formats and styles of communication. Costa-Font, *et al* (2008), based on their comprehensive summary of evidence on the acceptance of GM food, segregate the public into three broad groups according to their attitude to GM food: anti-GM or pessimistic; risk-tolerant or information searchers; and, GM-accepters or optimistic. A similar attempt to differentiate views was undertaken by Sheldon, *et al* (2009) where attitudes to GM food were linked to broader viewpoints on food and food production, attitudes towards science and technology.
- **Focus on the benefits.** Many authors have highlighted the importance of the perception of benefits in the acceptance of new technology (for example, Gaskell, *et al*, 2004; Costa-Font, *et al*, 2008 and Brook Lyndhurst, 2009). A communication strategy which considers consumer benefits rather than solely risk communication might therefore be more effective (and this was suggested by a number of stakeholders and Competent Authorities in interview and survey). Case study respondents added that placing the GM debate within a wider context to include, *inter alia*, food security and climate change would also be beneficial (this has been demonstrated by IGD (2008)). This is not to say that risk communication is not important, as European Commission (2002a) notes, building public confidence and understanding must be a permanent concern.

To conclude on a rather pessimistic note, one stakeholder interviewee explained that if there were a solution to improving the general quality of public trust in the context of GMOs it would have been taken already. Another added that it may simply be too late to improve public trust in the case of GMOs.

Focusing specifically on risk assessment, the Strategy on Life Sciences and Biotechnology (European Commission, 2002a) explains that there is a general need to enhance public trust in the role of science in our societies and that the European Commission has proposed an action plan on science and society to do this (European Commission, 2002d). European Commission (2002a) noted that greater clarity is needed in communicating how regulators deal with potential risk, scientific uncertainty, comparative risks, the different stages of risk analysis, the role of risk management and its proportionality to the risk.

However, Wentholt, *et al* (2009) note that there is evidence of a decline in public trust associated with food risk governance over recent years which suggests that the greater clarity called for has not been delivered; a stakeholder made the same point in interview. Indeed some stakeholders noted in interview that there have not been any significant efforts to communicate the EU's science-based approach to risk assessment and that the fact there are still discussions over the safety of GM food suggests that communication efforts have some way to go.

Our survey asked respondents how the quality of EU-wide trust in science-based risk assessment might be improved in the GM context (see section 1.6.5 of the appendix). Seven Competent Authorities explained that the key was improved communication with the public. Some added that increased public research with a more inter-disciplinary base would be useful.

It was pointed out that the forthcoming harmonised guidelines on risk assessment produced by EFSA in conjunction with the Member States (which will be publicly available) should reduce controversy arising from the risk assessment process and in turn create more public trust in the process. One Competent Authority explained that this will not go far enough and that there is a need to improve the risk assessment procedure itself. Another called for better account to be taken of scientific reservations made by Member States and called for a real exchange between EFSA and the assessment authority of the Member State concerned to resolve differences, as provided for by Article 30 of Regulation (EC) No 178/2002.

Two Competent Authorities explained that, as the most contentious area in their opinion is cultivation, greater national control in this area might result in more constructive attitudes towards food and feed use. Another Competent Authority, and some stakeholders, suggested that an information day with EFSA scientists would be useful. Two improvements were consistently identified by stakeholders. The first was that decisions should be clearly based on scientific risk assessments rather than politics. The second commonly identified improvement was education or communication of some kind. This included education or communication on specifically: the need for technology in agriculture; risk assessment; and, the benefits of GMs. Several respondents stated that public debates on GM need to be more open.

In this context, Meek and Keese (2006) note that developing a risk communication strategy that builds trust with stakeholders and the public presents several challenges. Based on the analysis above, these can be summarised as follows:

- **Belief in the messenger.** Unfortunately, neither national governments, the European Union or government scientists, which includes EFSA scientists, are considered by the public to be trusted sources and it is hard to see which other bodies are in a position to communicate the science-based risk assessment. In this regard it is worth noting that some stakeholders and Competent Authorities in our interview programme, survey and case studies highlighted the need to support EFSA, highlight its independence and to not undermine its credibility (see section 8.1); one stakeholder explained that Member States not supporting draft decisions based on EFSA's scientific opinion were not helpful. The most trusted sources of information include NGOs and scientists affiliated to them and these stakeholders, being generally against the use of GMOs, are more likely to draw attention to their risk assessment concerns such as, as they see it, a lack of long-term studies. One EU stakeholder and a number of case study respondents suggested that

national scientific societies could provide a good independent source of neutral information. However, Lofstedt (2006) argues that public discussions between scientists with opposing views merely increases public distrust of scientists.

- **Communication channels.** It is noted that there is a high degree of transparency around the risk assessment process in that EFSA guidelines and information relating to applications is available via the EFSA website. However, some stakeholders noted that there has been little other communication from EFSA on GMOs and contrasted this to communications on health claims (see section 6.3 for perceptions in terms of the transparency of the EU authorisation process). Wentholt, *et al* (2009) comment on improvements that EFSA has made generally in terms of transparency. However, our survey and interviews revealed that there were a small number of misperceptions among stakeholders in terms of risk assessment procedure and this suggests that this web-based communication has not been fully effective. This is likely to also be the case with respect to the public. Other means of increasing public (and stakeholder) awareness of the science-based risk assessment might therefore be necessary. Case study respondents in Greece and Poland, suggested, for example, the use of television documentaries (see section 2.5.5 of the appendix).
- **Public ability to understand the issues.** Sinemus and Egelhofer (2007) reported that strategies to communicate the science behind GM technology revealed that the level of public understanding of basic science and the level of interest that people have in scientific details had been overestimated. Our case study (section 2.5.5 of the appendix.) found that the communication of science in general is problematic in the EU. This is not helped by the fact that public authorities tend to equate science with stable "truth", interest-free objectivity, etc. which is questioned by a number of philosophers of science (see for example Kuhn, 1962; Popper, 1963; Stengers, 1993; Fourez, 2001; Latour, 2007). The acknowledgement of this debate by institutions might increase understanding and acceptance of "science-based" policies[117]. Meek and Keese (2006) state that acknowledgement of uncertainty carries negative connotations that have the potential to undermine confidence in regulatory decisions. Wentholt, *et al* (2009) found that both European and non-European international stakeholders/risk experts overwhelming felt that uncertainties should be communicated to the public using simple and understandable language; Lofstedt (2006) reports that findings in the literature are mixed on this point. An NGO interviewee agreed that the lack of certainty should be taken into account. How uncertainty is communicated is therefore of critical importance.
- **Public desire to understand the issues.** FSA (2002b) report that public demand for information is low in the UK, although it is noted that demand would increase if the use of GM increased or if the issue received significant media attention. Costa-Font, *et al* (2008) note that individual behaviour is driven by perceptions or beliefs about risks rather than technical risk estimates (see also Brook Lyndhurst, 2009). This begs the question of whether the public is receptive to technical communication on science-based risk assessment at all? If this is the case the issue becomes changing these underlying attitudes rather than focusing on the details of the risk assessment system.

Any attempt to improve the quality of public trust in science-based risk assessment in the context of GMOs will need to bear these points in mind.

[117] Although Brook Lyndhurst (2009) report that the evidence for a link between understanding (knowledge) and acceptance is mixed.

Judgement

The introduction to this answer makes clear that, in many ways, the history of the controversy over GMOs in the EU shows clearly how not to improve the quality of the EU-wide trust in science-based risk assessment. Many actors in the sector have had roles to play here, but it should be noted that the authorities appeared confused and hesitant and failed to adequately take account of actual public concerns. Communication from public authorities in a general sense has been sparse (although there are exceptions) and at times inconsistent between the EU and national level. However, it is accepted that it may not be considered the role of the public sector to communicate too much on privately introduced technology which is subject to risk assessment and an authorisation procedure.

This relative absence of public authority communication has left it up to stakeholders to communicate to the public and many have done so, generally promoting their own views as they did so. The success of communication activities depends in the first instance on the awareness generated, but then, and crucially, on the nature of the organisation communicating. In this regard it appears that communication efforts by government organisations may not be the most effective (although there is no "trust crisis") and the message that appears to have taken hold in the public imagination is biased towards the negative.

In terms of efforts to communicate with the public specifically on the science-based risk assessment, Finland has demonstrated that it is possible to generate greater public interest. Further attempts to communicate more effectively are planned in Finland and also in the UK. The European Commission has undertaken two communication initiatives, but Commission Services explained that there have been few other efforts at communication with the public.

There are three main factors which should be taken into account in general communication strategies on GM: increased engagement of industry and government organisations, i.e. a proactive and not a reactive stance; better definition of the target audience, recognising that the public is not homogenous and different communication methods and media are needed for different groups; and, a need to contextualise potential risks against potential benefits.

In terms of improving the quality of public trust in science-based risk assessment in the context of GMOs, the fact that there are still discussions over the safety of GM food suggests that communication efforts have some way to go. The key to improving trust is seen as being more and better communication although a number of challenges will need to be overcome. These are: belief in the messenger, unfortunately government institutions are not among the most trusted messengers among the public; appropriate communication channels; public ability to understand the issues, especially in relation to uncertainty in science; and, public desire to understand the issues rather than come to judgements based on their preconceived ideas. Any attempt to improve the quality of public trust in science-based risk assessment in the context of GMOs will need to bear these points in mind.

9. Conclusions and options for the future

9.1. Conclusions and recommendations drawn on the basis of the evaluation

This Evaluation Question draws together the judgements made in respect of the preceding Evaluation Questions and highlights points deserving attention that will be further developed under section 9.2 which is concerned with options for the future. There is a degree of overlap in terms of the identification of these points because the Evaluation Questions themselves also overlap.

9.1.1. Overall objectives of the legislation and expected developments in the sector

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?

There is general agreement amongst Competent Authorities and stakeholders with the stated objectives of the legislation, although agreement is weaker in terms of the objective of effective functioning of the internal market, especially among stakeholders. In terms of consistency between the objectives of the legislation and EU societal needs, opinions were much more divergent between the groups. In general, the legislation is seen as answering EU society's needs for safe food and feed; however, stakeholders in particular do not believe the legislation offers a secure all-year-round supply of feed for livestock, or that it offers a fair standard of living for EU food producers. There are strong disparities between the agreement by Competent Authorities compared to that of stakeholders with regard to consistency of the legislation in terms of providing for a secure all-year-round supply of feed, a strong agriculture and food biotech R&D sector in the EU and sustainable standards of production; this in part reflects strong views on these issues by different types of stakeholder.

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?

The majority view is that the current legislative system represents an improvement on the previous situation, mainly as a result of the centralised procedure for authorisation and the coverage of food and feed under the same Regulation. Competent Authorities generally believe that the implementation of the legislation does allow its objectives to be achieved, although stakeholders were less confident about this. Both Competent Authorities and stakeholders agreed that the implementation of the legislation was weakest in terms of enabling the effective functioning of the internal market (no specific qualitative comments on the functioning of the internal market were provided), although NGOs and consumer organisations did not agree. Different stakeholders hold different concerns with consumer organisations and NGOs believing that the legislation has not been made operational in areas of long-term human or animal safety testing, long-term environmental testing or in labelling as a result of the omission of livestock products from the scope. The main concerns for industry relate to the slow pace of authorisation and the effects of the zero tolerance policy for unauthorised GM material, which results in LLP incidents that hinder secure access to year-round feed supplies.

Almost all interviewees believed the legislation had been made correctly operational for the risk assessment phase, with some constructive criticism. However, in terms of the risk management stage, nearly all respondents, whether Competent Authorities or stakeholders, believed this was not fully operational, mainly because of the time taken to reach decisions.

Competent Authorities generally feel that the implementation of the legislation provides a high level of protection of consumer interests, although stakeholders were less positive. It was noted that consumer interests may be better protected if the labelling scope encompassed livestock products (an issue fully investigated in section 7.7). While Competent Authorities think that consumers understand

the labelling provisions, stakeholders are not so sure and there may be a need for more communication on this issue.

The main issues that appear to require attention in relation to the way in which the legislation has been made operational are:

- **Labelling scope:** the fact that livestock products fall outside the current labelling scope is seen by some stakeholders as not allowing consumers to make a fully informed choice about the use of GM technology in food production. However, this "right to know" should not be confused with any potential safety concern.
- **Consumer understanding of labelling:** Competent Authorities and stakeholders hold differing opinions in terms of whether consumers understand the labelling provisions. While to some extent understanding is related to (lack of) experience with labelled products, some communication efforts might be necessary if more GM labelled products appear on the market.
- **Speed of authorisations:** this is considered to be problematic at the risk assessment and, especially, the risk management phase. The constraints of the comitology procedure notwithstanding, continuing efforts should be made to table Draft Decisions in a timely fashion.
- **Zero tolerance policy for adventitious and technically unavoidable presence of unauthorised GM material:** maintaining this policy is likely to result in an increased number of Low Level Presence (LLP) incidents as the global use of GM crops increases (see below). The fact that these are alerted under RASFF, which is concerned with safety issues, is seen as inappropriate by some stakeholders. It is clear that a way has to be found to reduce the number of LLP incidents.

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?

The factual developments expected in the sector include an increase in the number of Third Countries growing GM crops, an increase in the number of GM crops designed for domestic markets (especially in Asia and South America which are not likely to be for export and hence it is unlikely that applications will be submitted to the EU) and a greater number of stacked events in the major crops of interest to the EU. These developments are likely to result in an increasing number of applications to the EU which is likely to result in asynchronous authorisations and more frequent incidents of low level presence of unauthorised GMOs between the EU and Third Countries. This may result in the diversion of export crops to markets with less onerous GM legislation.

Benefits from future developments in the sector may encompass those arising from the traits themselves, for example, crop products of enhanced nutritional composition and those arising from supply-chain management systems. Other potential benefits may include a contribution to food security and quality, global reductions in pesticide use and contribution to meeting the challenges of climate change and environmental damage. Crops for the production of compounds destined for the industry (and not for the food/feed chain), such as the Amflora potato (starch potato, EH92-527-1) that was recently authorised in the EU may become important and developments in drought tolerant crops and GM wheat are expected in the medium-term. The latter could potentially be of great interest in the EU where wheat is a major crop.

The main issue that appears to require attention here is:

- **Low Level Presence of adventitious and technically unavoidable presence of unauthorised GM material:** a suitable mechanism to deal with LLP issues which are considered to be increasingly likely is needed. As these can arise from asymmetric and research authorisations as

well as asynchronous authorisations it is not simply a case of speeding up the EU authorisation process to minimise the time lag between EU approvals and those in exporting Third Countries.

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?

Concerns about the aptness of the current legislation to ensure that the EU can make use of the potential beneficial aspects of current and future GM developments (in the food and feed arena) tend to revolve around current and past experience of the impacts of asynchronous authorisations and rejection of imported seed and grain cargoes containing LLP of unauthorised GM events.

Increasingly, stacked events are expected to be marketed and this will put pressure on the EU authorisation process under which stacked events are treated as new events, unlike in the US where stacked events are automatically authorised where the single events have already been approved. The implication of this is an increased gap between EU and US authorisations which is likely to exacerbate current LLP problems, should the EU continue to import grain for food and feed from the USA and from other Third Countries utilising the same technologies and similar regulatory approaches.

There is an expectation in the industry and amongst Commission Services (although not necessarily shared by NGOs) that a range of new traits will be delivered to the market in the near future. Competent Authorities are much more confident than stakeholders that the current EU legislative framework is apt to ensure that the EU can make use of these new developments. Interestingly, biotechnology providers are more likely to consider the legislation apt (if not effectively implemented) than are food and feed chain operators, perhaps because this latter part of the chain is very concerned about the zero tolerance policy in relation to the LLP of unauthorised GM material. There is, however, little support among Competent Authorities or stakeholders to allow Third Country risk assessments to be used in connection with LLP. That said, stakeholders feel that there is an urgent need to find a solution to the LLP issue and this is shared by many Competent Authorities, especially those from Member States with a high demand for imported livestock feed. The European Commission is considering a technical solution to the LLP issue. However, in the absence of concrete information on proposed approach, the food and feed chain do not feel that a technical solution to this issue will be effective in the longer-term.

Views on the EU's treatment of stacked events are more mixed with a majority of stakeholders (but not including NGOs and consumer organisations) suggesting some form of fast-track procedure (without compromising safety). Support for this among Competent Authorities was more limited and it is noted that stacked events already undergo a form of fast-track risk assessment in that only data on the interaction of events is required by EFSA where the single events have already been risk assessed.

There are concerns that the current legislative framework is too focused on risk and that future events offering a range of benefits may therefore be denied to EU citizens. However, it is noted that Articles 7(1) and 19(1) of Regulation (EC) No 1829/2003 do allow for the consideration of "other legitimate factors" which could include the consideration of benefits. Concerns were also raised about how the current legislative framework would cope with new genetic modification techniques.

In summary, there are concerns that the current legislative framework is not apt to ensure that the EU can make use of new developments, but these concerns are not universally accepted and it may be too early to come to a clear conclusion on this given the uncertainty in terms of what new developments might actually entail and when these might be available.

The main issue that appears to require attention here is:

- **Low Level Presence of adventitious and technically unavoidable presence of unauthorised GM material:** see above.

How could the potential benefits [of evolution in the sector] be measured and integrated in the context of the regulatory approval?

Following Council of the European Union conclusions of December 2008 and the conclusions of a Ministerial round table in November 2009, the European Commission will report on the use of socio-economic criteria within the GMO authorisation process by October 2010; this has been in process during this evalaution. Although the main driver of this is cultivation and the desire of Member States to move ahead or not at the national level, there are potential implications for GM food and feed.

Our survey, interviews and case studies have demonstrated that there is no consensus in terms of whether socio-economic criteria could and should be used in connection with GM food and feed. As a general principle it seems that groups with a known anti-GMO stance tend to be in favour of the use of such criteria while those more in favour of the use of GMOs tend to be against. This suggests that there is a view that socio-economic criteria will not facilitate authorisations. The consideration of "other legitimate factors" is already allowed for under Articles 7(1) and 19(1) of Regulation (EC) No 1829/2003, although there is no facility to consider socio-economic factors under Directive 2001/18/EC. There is a concern that considering non-science based issues overtly in the authorisation process might be perceived as going beyond the role of the regulator.

There is no consensus on the EU acceptance of risk assessments carried out in Third Countries as a way of better-accessing benefits of developments in the GM crops sector for food and feed. Those in favour of their use in connection with potential LLP incidents suggested that Third Country risk assessments could be accepted if, for example, they followed Codex Alimentarius guidelines. Opponents state that the procedures in Third Countries are less stringent than in the EU and Third Country risk assessments are therefore unreliable. A third way is offered by those who suggest that the Cartagena Protocol might provide a mutually-agreed understanding of what is, and what is not, a GM crop, allowing harmonisation in this area.

9.1.2. The risk assessment and regulatory approval process

To what extent has the authorisation procedure and its implementation ensured a high level of protection of human life and health, animal health and welfare, environment and consumer interest in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market?

The EU authorisation procedure is generally considered to achieve its objectives of the protection of human and animal health through the use of a science-based risk assessment. It should also be noted that there have been no cases of animal or human health problems resulting from GMOs to date (i.e. since their introduction, not just under the current legislative framework). The authorisation procedure also contributes to the protection of the environment, although this is mainly a concern for cultivation. Its contribution to protecting consumer interest is principally linked to the impact of labelling and was analysed further under section 7.1. There are some concerns that the authorisation procedure may not facilitate the effective functioning of the internal market as well as it might, partly as a result of the potential for different interpretations of the tolerance level for adventitious and technically unavoidable presence. Competent Authorities have a more positive view of the achievement of the legislative objectives than do stakeholders, but in both cases these views are in line with the above, i.e. there is more confidence in the achievement of safety-related objectives and the protection of consumer interests than there is in relation to the functioning of the internal market.

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 the EFSA and the Commission?

Applications for stacked events are increasing globally and this is expected to be part of a continuing trend in the EU as well. The EU approach to the authorisation of stacked events is different to that in the USA and Canada where stacked events are automatically authorised if the single events have already been authorised. The EU approach differs in the fact that stacks are assessed with regard to the interaction of the already authorised single events. The EU is by no means alone in its approach though; for example, Argentina's approach is fairly similar. The EU approach is a step towards minimising the uncertainty about potential risk associated with GMOs and it thereby assures a high level of protection of human life and health and protection of the environment. However, many (non-EFSA) scientists see this approach as being conservative, at least as far as the current generation of GM events is concerned. The EU approach also increases the workload of EFSA and the Commission, and this situation is likely to become more pronounced as more applications for stacked events are submitted. Finally, the gap between authorisation in the USA and Canada and authorisation in the EU is likely to be more significant with respect to stacked events than single events and therefore the EU approach is likely to result in a larger application backlog and, as a result, more asynchronous authorisations with the consequential impact in terms of LLP incidents.

The main issue that appears to require attention here is:

- **Low Level Presence of adventitious and technically unavoidable presence of unauthorised GM material:** see above.

To what extent are the different steps of the harmonised procedures established by the Regulation for the risk assessment and authorisation for food and feed efficient, time-limited and transparent and correspond to demonstrated risks in a proportionate manner?

Based on the analysis within this evaluation, the risk assessment carried out by EFSA is considered to be efficient, although it is recognised that more resources might be needed in the future to deal with advancements in GM technology. In contrast, the risk management procedure is not considered to be efficient and a backlog of EFSA opinions is building up, largely because the Standing Committee and the Council do not deliver a qualified majority opinion. This backlog is likely to grow if current rates of authorisation are not increased. That said, the centralised authorisation process is more efficient than the system in place prior to the 2003 legislation in terms of the outputs (authorisations) delivered. The cost to applicants is around 25% higher in the EU compared to the USA.

In terms of timeliness, the actual time to authorisation exceeds that envisaged in the legislation by a substantial margin and the process is considerably longer than that in the USA (although it is recognised that the process is different and this does not necessarily imply inefficiency). Applicants often submit incomplete dossiers and are often asked to provide additional data for the risk assessment and the stopping of the clock results in delays. For its part, EFSA has improved its performance in administrative terms and this has brought the actual timings closer to those anticipated. Some stakeholders consider certain elements of the process to be ill defined, and the aspects of the risk management process which are not defined in terms of time do contribute to delays (however, some of these undefined time periods are part of the general Comitology procedure and are not linked specifically to GMOs).

The authorisation process is considered to be fairly transparent, although certain stakeholders believe transparency could and should be improved. Further communication might provide further insight into the process. Finally, the EU authorisation process is considered to be proportionate to the potential risks, although it should be recognised that some stakeholders will find fault in terms of a perceived lack of consideration of potential long-term risks while others believe that the process is already too overbearing. It is noted that the risk assessment system should be re-examined as necessary in the light of future developments in the biotech sector which might have implications in terms of nature and magnitude of risk.

The main issues that appears to require attention here are:

- **Resources within EFSA:** it will be necessary to review the resources available within EFSA periodically to ensure that these are adequate, although this is a more general rather than a specifically GM-related issue. **This is not considered further in section 9.2.**
- **Speed of risk management process:** as the number of applications received increases it will be necessary to ensure that the risk management process does not become a bottleneck.
- **Submission of suitable information by applicants:** efforts should continue to ensure that applicants submit the correct information in the correct format to EFSA to facilitate the authorisation process. The soon-to-be-released new guidelines are therefore welcomed.
- **Overall risk assessment system:** this should be re-examined as necessary in the light of future developments in the biotech sector which might have implications in terms of the nature and magnitude of risk to ensure the continued protection of consumers, animal welfare and the environment. **This is not considered further in section 9.2.**

What has been the impact of the Regulations on GM food and feed on the evolution of the sector and the EU society at large?

The EU's green biotechnology sector could, in the mid-term, generate benefits to EU society in excess of the current benefits. The legislation has been designed to meet public concern relating to the technology and to provide a high level of protection of human and animal health and this has had an impact on the development of the sector in that the EU is no longer a world leader, despite the technology being first developed in the EU. Even the focus of public sector research has, in addition to technical development, used its resources to also include socio-economic and political subjects. According to the EU's biotechnology strategy, more attention is needed in terms of how legislation can help foster the development of research and innovation, assist in developing consumer acceptance and ensure the functioning of the internal market.

In conclusion, there is a limited yet significant possible role for the food and feed regulations to orientate the future of the biotech sector and to create or prevent the necessary conditions for its development. The main issue is for the EU to decide an appropriate balance between potential economic risk and potential economic benefits, which include those to EU society from a well developed green biotechnology sector.

The main issue here is:

- **Balance between potential risk and potential benefits:** the EU and Member States should actively consider what an appropriate balance is between economic risk and potential benefits of adopting or not plant biotechnology.

To what extent does the procedure foreseen by the Regulation (Article 34 in conjunction with Articles 53 and 54 of Regulation (EC) No 178/2002) ensure an appropriate way to deal with "emergency measures" taken by Member States?

Article 34 of Regulation (EC) No 1829/2003 has only been invoked twice, both times with regard to cultivation of MON810. This legal base was used for technical reasons, instead of the safeguard measure of Directive 2001/18/EC (cultivation of MON810 had already been transferred under the Regulation since Monsanto applied for renewal under that legal act). Greece and France adopted the measures in 2007 and 2008 respectively. The procedure took one year for what was, theoretically, an emergency measure. Ultimately, the French ban remains in place until the end of the re-approval process and in spite of the EFSA opinion. That said, more than four-fifths of Competent Authorities feel that the procedure is appropriate or very appropriate, a view shared by only around a third of stakeholders who were generally more likely to find the procedure inappropriate or very inappropriate.

On balance, the history and timescale of the use of Article 34 suggests that this may not be the most appropriate instrument to use with respect to cultivation, and this is probably also a valid conclusion with respect to GM food and feed, although it should be reiterated that there has so far been no experience of this application in these sectors.

To what extent is the common and centralised procedure foreseen by Regulation (EC) No 1829/2003 (one door one key principle) efficient compared to the situation prevailing before the adoption of the Regulation?

The main judgement of efficiency pre and post-2003 must be the outputs, i.e. authorisations. On this basis the post-2003 "one door, one key" approach is considered more efficient with an average of four authorisations a year since 2004 compared to just one per year between 1996 and 2003.

To what extent is this procedure coherent with other procedures applying to similar sectors of the food safety acquis?

While it can be said that the approval procedures are overall consistent, there still remain, across food safety regulations for different categories of products, some points of non-consistency. This inconsistency includes the labelling of some products of GMO origin (for example, oil or lecithin) while others (for example, the use of enzymes) are not labelled. There is also an inconsistency in the use of zero tolerance levels for unauthorised GM material and non-zero maximum residue limits for harmful substances like food contaminants. The lack of interaction in the risk assessment for products yielding complementary risks, such as herbicide and herbicide tolerant GMOs is also a point of inconsistency.

The main issues that appear to require attention here are:

- **Overall scope of labelling:** overall labelling in the field of GMOs mixes product and process based approaches. This may not be considered a problem, but it potentially sends a mixed message to consumers in terms of the rationale for labelling.
- **Zero tolerance policy:** it could be considered inconsistent to allow the Low Level Presence of contaminants with known risks, but not the LLP of unauthorised (in the EU) GM events, which have been authorised in Third Countries, where there is no known risk. This sends a confused message in terms of consumer safety.

What is the foreseeable trend of the GM authorisations in the EU when compared with the authorisations granted in Third Countries and taking into account the evolution of the GM sector?

It is to be expected that, in the coming years, the number of GMO authorisations will steeply increase worldwide. New authorisations will increase not only in number, but also in complexity (new technologies), range (more different crops) and geographical origin (not only traditional exporting countries, but also approvals where there is no intention to export resulting in asymmetric authorisation). Stacked GMOs are likely to become the norm and there are likely to be increasing gene exchanges between technology providers.

The main issue that appears to require attention here is:

- **Low Level Presence of adventitious and technically unavoidable presence of unauthorised GM material:** see above.

What would be the consequences of possible differences between the pace of authorisations between the EU and its trading partners?

There are three distinct causes of LLP: asynchronous authorisations, asymmetric authorisations and escaped research approvals. Asynchronous approvals are clearly a concern given that this term refers to cases where a Third Country is seeking to export products which the EU requires, but where the EU has yet to authorise GM events authorised in exporting countries. There have been a number of LLP

incidents arising from asynchronous authorisation to date. Asymmetric authorisation has not yet resulted in an LLP incident, but is expected to do so in the future as the number of GM events, especially in developing countries, increases. There have been two recent well known cases of LLP resulting from research trials.

LLP incidents can result in potentially significant administrative and legal costs, damage to supplier and/or customer relationship, potential long-term loss of customers and potentially lengthy litigation with suppliers/customers for individual operators in the food and feed chains. The actual costs resulting from LLP incidents to date range from €0.8 million to €3.5 million for individual operators, although the potential cost, had the co-mingled product been used in the food chain could have amounted to considerably more. Estimates of potential future impact of LLP are considerable, especially when the replacement of raw material supply is considered. Under the growing global trend of new GMO authorisations in Third Countries, the current EU authorisation regime, specifically the pace at which it operates and its use of zero tolerance, is likely to generate severe economic problems for the food and feed sectors. It should, however, be noted that this view is not shared by some NGOs. Further research on this issue is underway under the auspices of DG Agri and is expected to report in 2011.

The main issue that appears to require attention here is:

- **Asymmetric authorisations:** while the impact of asynchronous authorisations can at least be addressed, partly by closing the gap between EU and Third Country authorisations, asymmetric authorisations pose a different challenge because there is no intention here (or motivation) for developers of events to seek authorisation in the EU because there is no intent to export to the EU; international co-operation will be required to address this issue.

9.1.3. The compulsory labelling of GM food and feed

To what extent are the current labelling rules for GM food/feed facilitating an informed choice and precluding misleading of consumers?

The labelling provisions do provide the consumer with information, although it is not clear whether this really helps to provide an informed choice, first because there is little evidence that labelling is an important factor in consumer purchasing decisions. However, those consumers who are concerned about GM content are certainly able to find information. Second, our survey revealed that less than half of Competent Authorities and less than a third of stakeholders believe that consumers understand and accept the labelling provisions and if this is the case, the provisions cannot be facilitating an informed choice. Third, the introduction of the labelling provisions under the 2003 legislation coincided with a general withdrawal of products which would have to be labelled from shelves and this has not facilitated choice, informed or otherwise. Finally, there are elements of the labelling provision which might be considered misleading, at least for some consumers, in terms of the threshold for adventitious and technically unavoidable presence, the inclusion of oil products within the labelling scope and the exclusion of livestock products. In conclusion, the labelling provisions do provide information to the consumer, but it is not clear if this information actually facilitates informed consumer choice.

The main issues that appear to require attention here are:

- **Consumer understanding of labelling:** Competent Authorities and stakeholders hold differing opinions in terms of the extent to which consumers understand the labelling provisions, but the majority in both cases suspects that they do not. While to some extent understanding is related to (lack of) experience with labelled products, some additional communication efforts might be necessary if more GM labelled products appear on the market.

- **Potential misleading of consumers:** some consumers may feel misled by the exclusion of livestock products from the labelling scope. The labelling threshold which allows adventitious traces of GM material to be present in unlabelled products might also result in the misleading of some consumers.

What is the consumers' acceptance of the existing labelling rules?

The answer to this question is largely a matter of interpretation. Either the consumer wholeheartedly accepts labelling rules, and they so closely meet expectations that consistent use is made of them to reject all but a small number of GM labelled food products from the market, or the question of acceptance cannot be answered because there are insufficient labels on the market to be accepted or rejected. However, it should be noted that at least one million EU citizens would like to see GM labelling extended to encompass livestock products, which implies a lack of acceptance of the current scope of labelling, if not its current application, by this group of citizens.

The main issue that appears to require attention here is:

- **Labelling scope:** consideration needs to be given to how the concerns of those who wish to see the labelling of livestock products can be addressed and whether this would be proportionate given the potential complexity and likely economic/administrative burden for the food chain.

What impact have the rules on labelling of GM food/feed had on the different actors of the food/feed market?

The history of GM food products reveals that operators made changes to their supply chains before the introduction of the 2003 legislation either in response to pressure from NGOs and/or consumer demand. This means that the introduction of labelling provisions under Regulation (EC) No 1830/2003 had limited direct impact on the actors in the food sector in terms of logistical arrangements. However, as supply of non-GM raw materials has become more restricted, the cost of segregation and Identity Preservation has increased, although the impact is diluted in final consumer prices. The situation is a little different in the feed supply chain. Initially the feed supply chain divided into GM and non-GM segments with the additional costs of segregation and Identity Preservation borne on the non-GM side. This process has been exacerbated by reductions in the availability of non-GM supply and this has resulted in high segregation and Identity Preservation costs for this market segment, although these costs will be diluted to some extent in the value chain depending on the use of IP feed and feed conversion ratios for different species. That said, Identity Preservation costs have increased substantially and the impact on consumer prices cannot be seen as negligible any more.

To what extent is food on the market labelled as GM?

There is strong secondary evidence that the availability of GM labelled food products in the EU is extremely limited. This evidence is corroborated by our more recent primary research comprising survey findings, the semi-structured interviews with key stakeholders and the thematic case study. The range of GM labelled products consists primarily of soybean oil for cooking and some imported products. Where GM labelled products are available, they are purchased by at least some consumers. The main external factor limiting the choice of the European consumers with respect to their purchases of GM food is their availability in stores, there are no retailer own-brand labelled GM products.

To what extent is feed on the market labelled as GM?

The main exposure to GM material in feed in the EU results from a dependence on imported vegetable protein, mainly soybean as this cannot be easily substituted. The vast majority, 85%-90% of compound feed is labelled as GM and up to 95% of soybean imports are labelled as GM and these proportions have been increasing as planting of GM events increases. There are some national variations in the interpretation and implementation of labelling provisions, for example relating to the

requirement to demonstrate that the presence of GM material is adventitious and technically unavoidable. Finally, there is a relatively small niche market of non-GM feed for the "organic" segment and non-GM supply chains.

What are the reasons for this situation?

After some attempts to develop a dual market, characterised by the co-existence of a GM and a non-GM segment, food markets have evolved towards the dominant use of non-GM supply chains and the conventional feed sector (more slowly) towards the dominant use of GM supply chains. The important conclusion for this evaluation is that the labelling regulation played only a limited role in these evolutions. It reinforced market trends, but did not have a directional influence on them. Mandatory labelling requirements were introduced after market forces had determined the direction and pace of market evolution in the late 1990s and early 2000s. In the case of food products, these factors were mostly internal to the EU consumer market. In the case of feed, they were largely external.

What consequence would an extension of the scope of the labelling rules including the labelling of animal products have?

Currently some 85%-90% of livestock feed in the EU is labelled as GM, meaning that any extension of labelling scope to include livestock products would result in the vast majority of products being labelled, providing consumers with information, but would provide limited choice in the absence of far reaching/in-depth reorganisation of the supply chain. However, it may be possible to increase the proportion of non-GM livestock feed and hence unlabelled (or non-GM labelled) products. Theoretically there is still potential supply of non-GM soybean, although it is not clear how much of this could be sourced as a result of segregation difficulties and competing demand from other sources. Some Member States would find it easier to produce non-GM fed meat than others.

Some interviewees and evidence indicate expectations for non-GM fed livestock, but the size of market and premium which consumers are willing to pay remains unclear. It should be noted that many consumers are not very aware either of the use of GM feed in the livestock sector, or EFSA's conclusion that to date, a large number of studies have not detected the presence of modified DNA in tissues, fluids or edible products from livestock fed on GM feed. There is a possibility that some consumers will misinterpret any GM labelling on livestock products.

There may be some issues with segregation and enforcement. Segregation of livestock production is generally seen as more problematic than segregation of feed. Enforcement is generally seen as complicated, open to fraud and costly. Furthermore there may be some difficulty in defining "GM-free" for livestock products, as demonstrated by existing "GM-free" livestock labelling schemes.

It is not clear if any extension to labelling could be imposed on and controlled in terms of imports from Third Countries. An extension to labelling scope which included processed products would considerably increase the scope of labelling, and would be more complicated, but may also be more logical from a consumer point of view. There is a precedent for an extension of scope to also include the catering sector, but attitudes vary. It is possible that the idea will not be accepted in some Member States, and it may cause problems for some catering businesses. On the other hand, there is some support for the inclusion of the catering sector in terms of allowing consumers to make an informed choice.

The main issues that appear to require attention here are:

- **Potential nature of labelling on livestock products:** if labelling scope is extended to include livestock products, the wording of any labelling will have to be carefully formulated to make clear to consumers that the feed, rather than the livestock product, contained GM material; failure to make this clear would mislead the consumer.

- **Consideration of the cost and potential for displacement:** any extension to labelling scope will have to carefully consider the cost implications arising from traceability requirements and the potential consumer reaction; a shift from consumption from domestic (labelled) livestock products to imported (unlabelled) livestock products which may have been fed on GM material not even authorised in the EU could not be considered to enhance consumer protection and there might be wider implications for the EU livestock sector.
- **Coverage of catering sector:** careful consideration should be made of the potential impact in the catering sector should any extension in labelling scope also apply here.
- **Proliferation of labelling:** extending labelling to cover the livestock sector would result in very extensive labelling as GM feed makes up the majority of the compound feed market.

What are the approaches currently used in MS in the field of "GM free" labelling?

Currently there are only national provisions for "GM-free" labelling in three Member States (Germany, Austria and France with its 2004 definition of "GM-free"), and "GM-free" labelling is banned in the Netherlands. However, new national provisions are expected in several Member States (France, Finland, possibly Ireland). Furthermore, there are operator-specific "GM-free" labelled schemes in several Member States, and "GM-free" labelled products can be found in several Member States. The number of "GM-free" labelled products varies between Member States.

The main issues that appear to require attention here are:

- **Operation of the single market:** a plethora of (unharmonised) schemes at the national level may compromise the smooth functioning of the single market.
- **Protection of consumer interests:** different schemes have different requirements and the use of relatively consistent labelling may imply a comparability that does not exist.

Do these approaches contribute to improve consumers' informed choice?

Evidence suggests that consumers are not fully aware that to date, a large number of studies have not detected the presence of modified DNA in tissues, fluids or edible products from livestock fed on GM feed and that consumers may not fully understand the meaning of "GM-free" labelling on livestock products. Nonetheless, there is evidence to suggest that some consumers want to be able to purchase livestock products labelled as "GM-free". The "GM-free" labelling of primary products is considered more important by consumers than that of processed products.

Evidence suggests that consumers expect a higher level of purity for products labelled as "GM-free" than is in place in some existing "GM-free" labelling schemes. Currently there is limited consumer confusion due to differences between schemes, however there are concerns that confusion will increase with the proliferation of schemes, starting with the potential introduction of the French scheme with a 0.1% tolerance level for adventitious presence. Despite best intentions, it is questionable as to whether existing "GM-free" schemes provide consumers with an informed choice.

What could be the added value (both in terms of information to consumers and market share) of a harmonized "GM free" (or similar) labelling scheme?

Evidence is divided on the benefits and drawbacks of a harmonised "GM-free" labelling system. There are several potential benefits from harmonisation including reduced consumer confusion, fair competition between producers in different Member States, lower costs for operators and a lower burden for the authorities. However, there may be some problems with the fundamental concept of "GM-free" labelling. Such labelling could be considered as misleading if a tolerance level is used to allow for adventitious and technically unavoidable presence of GM material, may negatively affect consumer perception of GM, may confuse consumers if operated in tandem with positive labelling and could be costly to implement. Furthermore, there may be difficulties in agreeing on criteria and scope

of such a scheme at an EU level. Existing "GM-free" schemes cover livestock products, and it is possible that as a result there will be expectations to include these in any EU scheme.

As seen in section 7.9, it is difficult to conclude whether there is significant demand for "GM-free" products. As a result, conclusions with regards to the development of the market for "GM-free" products are speculative. A harmonised scheme would allow fairer competition between operators in different Member States, minimise operational expenses and make it easier to build a market share in the "GM-free" sector. However, operators in some countries may face restraints which prevent them from producing "GM-free" labelled products. Furthermore, it can be seen from the German experience that there are several factors which may deter operators from producing "GM-free" labelled products.

It is unclear as to whether normal consumers understand the difference between organic and "GM-free". That said, evidence suggests that existing organic consumers purchase organic products for a multitude of reasons, not just for their "GM-free" status. A "GM-free" labelling scheme may provide an option for consumers who wish to avoid GM, but are not prepared (or able) to pay the higher premium for organic food.

The main issues that appear to require attention here are:

- **The extent to which "GM-free" schemes are meaningful:** given the use of thresholds for adventitious presence of GM material, whether "GM-free" schemes really allow consumers to make an informed choice should be carefully considered.
- **Use of positive and negative labelling schemes:** it would appear disproportionate and potentially confusing to use both approaches so consideration should be given as to which approach better protects consumer interest.

9.1.4. Public acceptance

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?

While average citizens do not appear particularly concerned about the use of GMOs in farming compared to other environmental concerns, there is nevertheless both relatively little support for their use, and a group concerned by their use as evidenced by a number of anti-GM campaigns. It is clear that the public does not hold a unified view and this has remained the case, with some variation, for the past decade. However, it should be noted that there is little correlation between consumer behaviour and the stated preference of citizens. The implication of this is that it is not really possible to assess public acceptance given the lack of availability of GM labelled products in European stores.

Public awareness of the risk assessment process is considered to be generally low and the public acceptance (or otherwise) of GMOs results from general perceptions of the technology rather than specific aspects of the authorisation process. Stakeholders have a number of areas of concern, but these tend not to be with the authorisation procedure per se. These also reflect their interest in the authorisation process with those in favour of GMOs being concerned about aspects which slow down authorisations and those against being concerned about aspects which make authorisations more likely.

What is the impact/cost of this risk aversion?

The impact of risk aversion on the EU agricultural biotechnology sector has mainly had an impact in terms of commercial development of crops for cultivation and is therefore outside the scope of this evaluation. As might be expected, authors funded by industry and those funded by NGOs take different positions with respect to the magnitude of benefits from GMOs and indeed whether there are any net benefits at all. However, a JRC-IPTS report comprehensively reviews the impact of GM crops

and concludes that there are some benefits where these crops are cultivated. An important reason for the lack of GM cultivation in the EU is that most GM crops are simply not suitable for widespread growth in this region. This may result, at least in part, from the general lack of acceptance of agricultural biotechnology in the downstream food chain and more widely; in other words, risk aversion.

The overall economic benefits of GM crops that might be realised at the cultivation stage may be reduced in the EU as a result of the lack of GM food products in the EU, the use of non-GM food chains and feed supply chains for livestock products in certain sectors/Member States which implies a cost for segregation and Identity Preservation which will limit any overall net benefits to society; this issue is far more significant in relation to GM feed. This impact is medium to long-term and depends on consumer demand for non-GM/"GM-free" products (at least as perceived by retailers). Another reason that the EU may not benefit from GM crops is asynchronous authorisation which results in EU producers being denied access to GM events pending their authorisation in the EU; this is a short-term impact. Additionally, asynchronous authorisation and the risk of low level presence incidents can deny access to usual sources of feed material. In all cases the root cause of the costs/denial of benefit can be traced back to a lack of perception of benefit and a lack of public acceptance, i.e. risk aversion. Developments with specific relevance in the EU are less likely given that manufacturers will not invest in the development of GM crops for cultivation in regions where cultivation may not be permitted or may be problematic as a result of a lack of public acceptance driven by risk aversion.

Are there variations in the sensitivity of EU-wide opinion between cultivation, food and feed use?

No articles or reports were identified which considered the degree of sensitivity with respect to GM cultivation, food and feed. The evidence collected through our survey work, semi-structured interviews and case studies reveals that there is a widely perceived difference in sensitivity between these three components of the GM issue. Whilst it is clear that there is least sensitivity with regard to the use of GM feed, probably at least partly due to the exclusion of livestock products from the scope of labelling, the relative sensitivity in terms of GM cultivation and GM food is more nuanced. Competent Authorities believe that there is more sensitivity with regard to cultivation whereas stakeholders feel that sensitivity is more comparable between the two. The biotech and feed industries tend to view GM cultivation as more sensitive than GM food whereas consumer organisations tend to find GM food a more sensitive issue. In both cases this might well reflect their respective focus.

Can the risk acceptance of EU citizens be measured against the concept of ALARA ("as low as reasonably achievable") risk? If so, how?

There is a fundamental concern with the use of ALARA in relation to GMOs in that the concept deals with known risks and authorised GMOs do not pose a known risk by definition. That said, the use of ALARA can be envisaged in conjunction with a defined threshold in relation to the labelling of GM products and also in relation to the LLP of GM material not authorised in the EU. In both cases there are also concerns that "reasonable" is open to different interpretation which could have consequences in terms of the operation of the single market. Depending on its application, the use of ALARA would also not permit consumers to avoid the use of GM technology if they so wish which might negatively affect public acceptance. On the other hand, if the use of ALARA prevented LLP incidents, then this might improve public acceptance.

Can the quality of the EU-wide trust in science-based risk assessment be improved in the GM context?

In many ways, the history of the controversy over GMOs in the EU shows clearly how not to improve the quality of the EU-wide trust in science-based risk assessment. Many actors in the sector have had roles to play here, but it should be noted that the authorities appeared confused and hesitant and failed to adequately take account of actual public concerns. Communication from public authorities in a general sense has been sparse (although there are exceptions) and at times inconsistent between the

EU and national level. However, it is accepted that it may not be considered the role of the public sector to communicate too much on privately introduced technology which is subject to risk assessment and an authorisation procedure.

This relative absence of public authority communication has left it up to stakeholders to communicate to the public and many have done so, generally promoting their own views as they did so. The success of communication activities depends in the first instance on the awareness generated, but then, and crucially, on the nature of the organisation communicating. In this regard it appears that communication efforts by government organisations may not be the most effective (although there is no "trust crisis") and the message that appears to have taken hold in the public imagination is biased towards the negative.

In terms of efforts to communicate with the public specifically on the science-based risk assessment, Finland has demonstrated that it is possible to generate greater public interest. Further attempts to communicate more effectively are planned in Finland and also in the UK. The European Commission has undertaken two communication initiatives, but Commission Services explained that there have been few other efforts at communication with the public.

There are three main factors which should be taken into account in general communication strategies on GM: increased engagement of industry and government organisations, i.e. a proactive and not a reactive stance; better definition of the target audience, recognising that the public is not homogenous and different communication methods and media are needed for different groups; and, a need to contextualise potential risks against potential benefits.

In terms of improving the quality of public trust in science-based risk assessment in the context of GMOs, the fact there are still discussions over the safety of GM food suggests that communication efforts have some way to go. The key to improving trust is seen as being more and better communication although a number of challenges will need to be overcome. These are: belief in the messenger, unfortunately government institutions are not among the most trusted messengers among the public; appropriate communication channels; public ability to understand the issues, especially in relation to uncertainty in science; and, public desire to understand the issues rather than come to judgements based on their preconceived ideas. Any attempt to improve the quality of public trust in science-based risk assessment in the context of GMOs will need to bear these points in mind.

The main issues that appear to require attention here are:

- **Low public acceptance of GMOs:** arguably it is not the responsibility of the public authorities to actively seek to increase acceptance of GMOs and GM food and feed and clearly it is the right of citizens to arrive at their own judgement. However, in changing and implementing policy, the impacts on acceptance should be considered, particularly given that aspects of the legislative framework may have an impact on the existing low level of acceptance and general risk aversion.
- **Public trust in science-based risk assessments in the context of GMOs:** trust is currently low and better communication may be needed. In changing and implementing policy, the impacts on public trust in science-based risk assessments in the context of GMOs should be considered.

9.2. Options for the future and their likely impacts

These two Evaluation Questions are concerned with potential options for the future and their impact. It should be recalled that this exercise has been an evaluation of the legislation, it is not an Impact Assessment which can examine these options in detail. If any changes are made to the legislation or its implementation a thorough Impact Assessment should be undertaken to determine in detail the likely consequences. Such an examination should also include consideration of any potential "sub-

options" or variations on the options set out here. Here we confine ourselves to broad, outline options and our analysis sets out indications of likely impact and their broad directions.

The potential options were identified in the Inception phase of the evaluation and have been put to Competent Authorities and stakeholders during the Observation phase in the survey (the questionnaire for which was validated by the European Commission), the semi-structured interviews and the case study. This has allowed us to build up an idea of the general support for the options and also to identify potential impacts. We have included all options suggested by stakeholders, even where these may not be viable or practicable.

The options for the future are laid out in tabular form in the Appendix, indicating the possible economic, social and environmental impacts of each option. Consultees were asked to select one of a list of options presented to them; this does not imply that other options are necessarily dismissed by those not selecting them. Here the options are presented in narrative form.

The consideration of environmental impacts is problematic because the most obvious environmental benefits or costs arising from the use of GM food and feed arise at the cultivation stage. That said, the use (or not) of GM food and feed implies demand for GM crops which will then result in the realisation of these benefits or costs. However, because cultivation is largely taking place in Third Countries, and because there are significant points of disagreement in terms of the magnitude of environmental benefits, or indeed whether there are any, we confine ourselves to comments on potential environmental impact specifically arising from GM food and feed uses in the EU. As a result, few environmental impacts are identified.

9.2.1. Risk assessment and the regulatory procedure

As has been identified in answering the evaluation questions, in economic terms, there is expected to be an increase in the number of events submitted for authorisation in the near future (section 5.3) and limited resource within EFSA and Commission Services to process these (section 5.4, section 6.2 and section 6.3). The combination of asynchronous authorisations and the zero tolerance approach to unauthorised GM material is already causing issues of Low Level Presence (LLP) and asymmetric authorisations coupled with the zero tolerance policy are expected to pose LLP problems in the relatively near future as Third Countries develop GM crops solely for domestic use (section 6.8 and section 6.9). These issues have implications in terms of consumer food prices. In social terms there is a relatively low level of public trust in the regulators and a generally low level of public acceptance of GMOs with a very vocal segment of society with especially strong views on this issue (section 8.1); the GMO issue in general is therefore a sensitive subject.

9.2.1.1. Risk assessment

The majority of stakeholders and Competent Authorities were in favour of leaving the responsibility for the risk assessment with EFSA (*status quo*). Regulation (EC) No 1829/2003 foresees the possibility for EFSA to sub-contract risk assessment to Member State bodies, although this has to date not been done, partly because it is not clear whether this would be possible within the prescribed timescales. If this option were to be exercised, the impacts would be broadly similar to those expected if risk assessment were to be carried out by a rapporteur Member State. It should be noted that any other solution would require the re-opening of the legislation. While it should be noted that Third Country official controls are considered equivalent (under certain circumstances) in other fields such as livestock product imports and live animal imports, there is little Competent Authority enthusiasms for the use of Third Country risk assessments in relation to GMOs (it is noted that this is not a like-for-like comparison); there was more support among stakeholders, predominately feed processors and traders.

While the maintenance of the *status quo* may result in a possible additional resource requirement, particularly if the number and complexity of submitted dossiers increases as is expected, there is also an "economy of scale" effect in that the necessary skill set does not need to be replicated in individual Member States. It is possible that some questioning of EFSA and its opinions may impact on acceptance (although this would probably also be the case under other options) and that there is a potential concern in terms of a "democratic deficit" in that citizens may feel distant from the authorisation process. On the other hand, the current situation represents a relatively efficient process with which applicants have experience and which is generally supported.

9.2.1.2. Risk management

Half of stakeholders and the majority of Competent Authorities were in favour of maintaining the *status quo* (i.e. the Commission takes a decision after consulting Member States). It should be noted that the comitology procedure is a standard and horizontal decision making tool in the EU and the field of GMOs is the main area where Member States and Council consistently fail to reach a qualified majority (either in favour of Draft Decisions or against them). Considering changes to the comitology procedure is clearly beyond the remit of this evaluation. Other options would probably require the re-opening of the legislation. While there is significant stakeholder support for the option of the Commission taking the decision to authorise alone (38%), it is questionable as to whether Member States would be willing to relinquish their power in this field.

Maintaining the *status quo* would mean no substantial change from the current situation where, in several cases, implementation of the process has been lengthy; the long time required for risk management is arguably part of the reason for asynchronicity. However, the current system does ultimately lead to a decision based on science; this ensures that the EU is not deprived of any economic benefits from risk-assessed GM food and feed as a result of misplaced perceptions of risk aversion. While the opportunity for Member State input should theoretically help with acceptance; due to the political nature of the subject, this is not the case. There is also the potential to authorise in situations where there is little Member State support (if not a qualified blocking majority) which may cause controversy and raise issues of "democratic deficit".

9.2.1.3. Consideration of explicit and systematic inclusion of socio-economic criteria in the authorisation process

As a pretext, it should be noted that several interviewees thought that socio-economic/political criteria are at least partly included in the current authorisation process, as Member States do not vote on science alone. There is also the facility to explicitly consider "other legitimate factors" under Articles 7(1) and 19(1) of Regulation (EC) No 1829/2003.

Competent Authorities were split over the explicit and systematic inclusion of socio-economic criteria in relation to GM food and feed. On the other hand, stakeholders, and in particular the biotech industry and operators of the food/feed chain were generally against their inclusion with NGOs the only stakeholder group systematically in favour of the explicit and systematic inclusion of socio-economic criteria.

It should be noted that there may be difficulty in defining criteria. This was reflected in our survey where only 3 of 10 Competent Authorities in favour of the use of socio-economic criteria provided suggestions for criteria; the proportion of stakeholders suggesting criteria was also low. Without clear criteria, any discussion of socio-economic factors is likely to be very subjective, and may be used to advocate or block authorisation. Even if criteria are identified, it may be difficult for Member States to agree on their use. Furthermore, the explicit and systematic use of socio-economic criteria might require re-opening the legislation if this use would go beyond that currently envisaged. The

underlying assumption in terms of socio-economic criteria in the options below is that they are appropriately defined.

The Appendix contains a summary of likely impacts in tabular form. The main difference between the options economically is that not considering socio-economic criteria means that the potential economic costs and benefits of GMO marketing will not be considered. Other differences implied by not providing explicit and systematic inclusion of socio-economic criteria are that Member State voting rationale will remain untransparent and some citizens may feel that some of their concerns are not taken into account. Additionally, dependence on science may not build confidence in the authorisation process given past experience with crises in the food sector. Risk management would remain, officially at least, little different from risk assessment if votes are taken strictly on the science; there may be an impact here in terms of a perceived "democratic deficit". An advantage of not formally considering socio-economic criteria is that possible lengthy debates on (subjective) socio-economic implications are avoided. It might prove difficult to define uniform socio-economic metrics across entire EU, the inclusion of socio-economic criteria may result in a longer authorisation process to allow proper discussion, there may be greater scope for disagreement and less likelihood of achievement of a qualified majority and there may be difficulties in fitting socio-economic criteria into the risk assessment and risk management processes. On the other hand, a discussion of benefits and a clear balance between costs and benefits might increase public acceptance in some cases.

9.2.1.4. Public comments

Stakeholder views were united on the need to allow for some form of public comment, but were divided on the exact form this should take. There was significant support for the *status quo*, and for more targeted comments (e.g. only with regard to specific aspects of an application if needed). There was a little less support for only seeking general comments (e.g. when the authorisation of a new type of GM event is considered).

9.2.1.5. Risk assessment data generation

The majority of Competent Authority and stakeholder survey respondents are in favour of the use of independently generated data in the risk assessment where this is possible and where it can be used to supplement data generated (namely financed and commissioned) by the applicant (this is already allowed for under the current system). On one hand, the current system of data generation primarily by applicants (albeit to certain standards) is coherent with the procedures for other food and feed subject to pre-market authorisation and for pharmaceuticals. Moreover, it fulfils the requirements of general food law (Article 17 in conjunction with 14 of Regulation (EC) No 178/2002) according to which food and feed business operators are primarily responsible to ensure that foods and feeds are not placed on the market if unsafe. Additionally, the economic burden lies with the applicant and potential beneficiary of authorisation.

On the other hand, the use of data generated by the applicant might raise questions in terms of the possibility for EFSA to rely on information and evidence that has been collected in a fully objective manner. In the extreme case, where all studies would be financed by public budgets, it might be considered inappropriate since private companies would at the end benefit following authorisation. It may therefore be necessary to charge applicants some sort of fee to cover the cost of independent data generation. The need for applicants to generate risk assessment data may limit applications to those with knowledge and financial backing to produce the necessary data (and dossier). This may be a barrier to entry for smaller companies and researchers which in turn might restrict the development of the EU green biotech sector with consequential economic impacts. The current system is probably faster as data from applications in other countries can be used (knock on effects from lower delays). This also increases efficiency for the applicant. Finally, under the current approach there is no

incentive for applicants to submit dossiers speculatively (data for the risk assessment have to be rigorous or approval will not follow).

Greater use of risk assessment data not generated by applicants would make it more likely that developers of GMOs in Third Countries where there is no intention to trade (i.e. potential asymmetric authorisations) may be more likely to submit GM events to the EU authorisation process if they do not have to carry out trial work themselves. Independent data generation is also perceived as neutral and this may help with acceptance issues, although neutrality may still be questioned by some.

Survey respondents suggested the following possible methods of independent data generation: by EFSA; by an academic institute with public funding; by Member States and through public tender. Taking into account qualitative interpretations provided by respondents, the intention of the majority of those expressing a preference for this option is that independent data should be used to supplement data generated by applicants. This reflects concerns about applicant data generation in terms of whether this is sometimes perceived as not being sufficiently impartial. Any mandatory generation of independent data would require the re-opening of the legislation. It should be noted that it is already possible under the existing legislation to include in the application independent, peer-reviewed studies where available (Article 5(3)(e)/17(3)(e)).

9.2.1.6. Stacked events

The term "fast-track" in connection with risk assessment should be interpreted as speeding up the process without compromising safety. In the case of stacked events, this might be done by reducing the six month period for the risk assessment in cases where the single events have already been risk assessed in recognition that it is not necessary to repeat this work. It should be noted that it is possible to think of the current approach to stacked events as already being fast-tracked in that only the interactions between already risk assessed single events are considered. Whilst, our survey clearly identified the current system as the *status quo*, some respondents indicating support for a fast-track risk assessment did note that this should be possible within the current legislative framework. Against this background, and considering the responses to the fast-track risk assessment and fast-track risk management option, **there is majority support for a system which uses a fast-track risk assessment and current risk management procedure; such a system could be considered akin to the *status quo***. However as explained below, consultees perceived the term "fast track procedure" in different ways (for example, under risk assessment or management or both).

A minority of Competent Authorities and stakeholders proposed some other solutions for the handling of stacked events. One proposal was a pre-notification system, whereby stacked events must be notified before being placed on the market. Another proposal was a case-by-case system. It is difficult to evaluate the impacts of a case-by-case system; presumably such a system would in the first instance decide whether a full risk assessment is necessary or not. Such a system would probably imply a mixture of the impacts outlined below, the exact mix dependent on the specificities of each case.

A more tailored risk assessment might speed up the risk assessment process; however, there would still be delays in the risk management phase. Such an approach would reduce the burden on EFSA which may be important if the number of applications increases. On the other hand, such an approach might result in a perception that the protection of human health, animal welfare and the environment is diminished.

9.2.1.7. Summary

In most areas relating to risk assessment and risk management there is substantial or majority support for the *status quo*. This is coherent with general satisfaction with the legislation in this area, and reflects the idea that the legislation per se is appropriate, though there may be problems with implementation (see section 5.2).

The one area with majority support for change is the method of data generation to feed the risk assessment. As noted above, independent data generation submitted to the risk assessment process alongside data generated by the applicant may have a number of positive impacts, above all on acceptance. However, it would involve significant public costs and would raise a question of principle in terms of whether it is appropriate for public bodies to carry out research which will ultimately provide private benefits to applicants. An application fee could be used to cover these costs at least partly, although independent data generation would still imply a burden on public authorities. Furthermore, independent data generation as a basis for safety assessment would require re-opening the legislation.

9.2.2. Labelling

Whilst the current labelling rules can in theory help facilitate an informed choice for consumers (section 7.1), the relative absence of GM labelled products from the shelves mitigates against this (section 7.3, section 7.4 and section 7.6). While it may be considered that the absence of GM labelled products on the shelves reflects consumer demand, the situation may also be due to the policies of food producers and retailers that would be driven by their perception of consumer preference. One area where consumers do not have the ability to make an informed purchasing choice at point of sale (information is usually available when sought) is with respect to non-organic products from livestock fed on feed made from GM materials or produced using GM technology (section 7.2 and section 7.7), even though the use of GM labelled feed is widespread (section 7.5 and section 7.6). Some consumers buying organic products will also be selecting these on the basis that they are "GM-free". There is a limited number of "GM-free" schemes in operation in the EU (section 7.8), although the extent to which they contribute to improving consumers' informed choice is debateable (section 7.9); a harmonised approach may have some merit here (section 7.10).

In considering options for the future for labelling, it is worth taking into account the findings of section 7.1 and section 7.2 with respect to consumer expectations and behaviour. Consumers may say that they want information, but it is unclear to what extent they read it. Consumer awareness and knowledge of GM appears to be low.

9.2.2.1. Positive labelling (explicit indication that products contain or consist of GMOs)

The majority of Competent Authorities were in favour of maintaining the *status quo*, although stakeholder opinion was more divided. Options changing the scope of labelling, or for a switch to voluntary labelling and abolition of mandatory labelling, would require re-opening the legislation and did not receive any strong support from the consultees. Support for the labelling of livestock products was mainly amongst NGOs while support for a restriction of scope to remove oil from labelling requirements drew support mainly from the food industry and feed processors.

In comparing the impacts of mandatory and voluntary positive labelling, the following should be noted:

- It is unlikely that operators will label under voluntary labelling due to acceptance issues, at least with respect to the current generation of GM events.

- Voluntary labelling is likely to be viewed very negatively by some Member States and stakeholders because it may not be considered to facilitate informed consumer choice.
- However, voluntary positive labelling may become more likely if public acceptance increased and/or if GM events with wider consumer/societal benefits were introduced. Theoretically voluntary positive labelling may lead to increased use of GM materials in food products because there would be no obligation to label; in practice, NGO campaigns would probably stop this from happening.

The main consequences of the current positive labelling regime include the fact that labelling the majority of feed implies a compliance cost on the larger market segment and the lack of detectability for oil products increases the risk of fraud and may imply additional control resource. However, removing the requirement to label oil products might cause some controversy and raise questions as to whether oil products should have been labelled in the first place. It would also removed the ability of consumers to make a fully informed choice at point of sale with regard to oil products, although there would be economic benefits arising from the removal of the need to segregate (where there are joint products which would still require labelling; for example, soybean meal for livestock feed; this benefit would not be realised). Finally, the current labelling scope makes it difficult for consumers to make a fully informed choice at point of sale with regard to livestock products.

Removing the requirement to use positive labelling would reduce costs associated with segregation and identity preservation, but would not allow consumers to make a fully informed choice, at least at point of sale. Such a move might also invoke negative reactions by Member States and several stakeholders might also raise questions as to whether products should have been labelled in the first place and why they no longer require labelling. The removal of positive labelling would result in a reduction in the amount of labels produced and the removal of the need to segregate may allow the more efficient transport of commodities. On the other hand, the traceability of GMOs should the withdrawal of products be necessary or in order to ensure risk management in accordance with Recital 3 of Regulation (EC) No 1830/2003 would be removed.

An extension of labelling scope to include livestock products including meat, eggs and milk produced using GM feed would imply additional segregation and identity preservation costs and would potentially be open to fraud given the lack of a testing mechanism for the use of GM feed. Such a move may also decrease overall demand for livestock products (at least in the short-term) and may increase demand for (more expensive) non-GM fed livestock products. It may not be possible to meet this demand hence leading to further price increases. There might also be an implication in terms of the displacement of domestic livestock production by imports of livestock products from Third Countries where there would be no obligation to label (such imports may also be fed on GM materials not authorised in the EU. This could have large impacts on agricultural systems in the EU. Finally, such an extension of scope would raise the question of the need to authorise livestock products fed on GM which, if implemented, would have significant economic implications.

On the other hand, labelling livestock products fed on GM feed would introduce entirely process-based labelling which may reduce consumer confusion and facilitate a fully informed, process-based choice. The widespread use of GM labelling would increase consumer familiarity with labelling and potentially understanding, although it would not be consistent with a science-based policy and may harm EU consumer educational needs by suggesting that GM-fed livestock products contain traces of GM materials. There might also be a degree of consumer confusion as most livestock products will be labelled when they were not previously. There is also difficulty in defining what is meant by "fed on GM feed". There are, for example, many differences in approach with respect to "GM-free" schemes.

9.2.2.2. Negative labelling (indication that products do not contain, or are not produced using, GMOs, i.e. "GM-free")

There are some potential impacts of negative labelling which transcend scope or obligation. **A majority of Competent Authorities support the use of some form of negative labelling, although this view is not shared by the majority of stakeholders. Issues relating to scope and obligation follow. It should be noted that the *status quo* option in this discussion is the use of negative labelling only under voluntary schemes.**

Any use of negative labelling could involve appropriate scope, criteria and purity levels being defined at the EU level, national level or privately; it could also, in theory, be mandatory or voluntary. It should be noted that agreement over any EU-level harmonised scheme (mandatory or voluntary) may be problematic. **There is majority support among Competent Authorities and stakeholders in favour of the use of negative labelling under a voluntary rather than a mandatory approach and within this for harmonisation at the EU level.**

The use of negative labelling would place the burden of proof and cost with operators (and consumers) in this market segment, i.e. those who are not willing to pay a higher cost do not have to, and would provide additional consumer choice. However, the existence of a three-tier system (positive labelled, "GM-free" labelled and unlabelled) would probably confuse consumers and would increase the amount of labels produced. It might also imply to consumers that GM food is inherently bad which may result in lower acceptance of GM food products.

The prohibition of any negative labelling would have consequences for operators currently using "GM-free" labelling and would not satisfy the consumer group who wish to avoid the use of GM material in livestock feed. A ban on negative labelling may be seen as a restriction of consumer choice, although it would avoid the potential misleading of consumers through negative labelling.

A harmonised approach would result in efficiencies through the smooth operation of the single market, although depending on the scope of the scheme, not all operators may be able to take advantage (e.g. livestock producers in Spain where there is little access to non-GM feed). A harmonised approach would provide consistent consumer information and would facilitate an informed choice across the EU. A national approach might result in consumer confusion and there would be the potential for the consumer to be mislead by different criteria and standards. Privately set standards would result in the potential for confusion between schemes within Member States as well as between Member States and would entail a greater risk of the misleading of consumers through unregulated schemes.

9.2.2.3. Threshold above which products containing GM material (food and feed) must be labelled

With respect to tolerance levels, there are three broad options:

- 0.9% (*status quo*).
- Lower than 0.9% (including zero tolerance).
- Higher than 0.9%.

As the options are effectively a continuum, it is not possible to isolate detailed individual impacts. Generally speaking, one would expect that implementation costs increase with lower thresholds. There is no scientific basis for any level other than the detection level (circa 0.1%), although science is not the only basis on which to label. More general impacts for the three broad options are identified in the table below. **There was a clear majority in relation to both food and feed in support of the *status quo***.

The use of a lower labelling threshold would generally exacerbate the impacts under the *status quo* and might lead to an increase in products labelled as GM. An increase in the labelling threshold would generally mitigate the impacts under the *status quo* and might lead to lower operator costs, which could ultimately benefit consumers as well. On the other hand, an increase in threshold might reduce the incentive for operators to ensure the absence of GM material in unlabelled products and could undermine public confidence in the labelling regime.

A further issue is as to whether any labelling threshold level should be for adventitious and technically unavoidable presence (as it is currently) or a fixed level. The differences in impacts between the two approaches are outlined below:

- The term "adventitious and technically unavoidable" is open to subjective interpretation. This interpretation can change between Member States and even within Member States where authorities are regionalised. This can lead to different implementations of the law, and the disadvantaging of producers in some regions. This is not the case with respect to fixed thresholds.
- Adventitious and technically unavoidable levels cause operator uncertainty, as operators may be liable despite having content under the maximum tolerance level. Fixed levels provide greater operator (and consumer) certainty.
- Adventitious and technically unavoidable presence requires efforts which go beyond the simple observance of a threshold.
- Deliberate mixing of products containing GMOs at levels higher than 0.9% with products without GMOs to a content below 0.9% is not allowed.
- The use of fixed levels would require re-opening the legislation.

9.2.2.4. Summary

The current labelling system is accepted by a majority of Competent Authorities and stakeholders. The existing regime is neither entirely product-based nor entirely process-based. Taking the process-based approach, there is an issue with the absence of labelling for livestock products. There are two fundamental questions: first should this be addressed given the lack of scientific basis; and, second how might this be addressed. Whilst a mix of positive and negative labelling approaches might appear confusing; the use of positive labelling for livestock products might appear disproportionate given scientific opinion, and the fact that the majority of livestock products would end up labelled. There is widespread support for the continuation of the 0.9% labelling threshold for adventitious presence.

9.2.3. Threshold for adventitious presence of unauthorised GM material

It has been seen in section 6.8 and section 6.9 that the Low Level Presence of unauthorised GM material is an issue which has the potential to cause significant economic impacts in the future. Nonetheless, solutions to LLP need to be considered against the backdrop of public acceptance (Chapter 8). The survey focused on options concerning maintaining or amending the existing legislation and not on technical improvements of its implementation. The option of establishing any tolerance threshold (for example, 0.5% as stipulated in Article 47 of Regulation (EC) No 1829/2003) would require amendment of the legislation.

The majority of Competent Authorities and stakeholders believe that some kind of solution for the adventitious and technically unavoidable presence of unauthorised GM material is required.

It should be noted that the Commission's proposal under the current legislative framework had not been defined at the time of writing and is therefore not discussed in this evaluation.

The option of a tolerance level for events risk assessed in Third Countries would require some kind of equivalency. There is a precedent for this, as equivalency is used in other fields such as livestock product and live animal imports (however these fields are not as politically sensitive as GMOs). The selection of Third Countries with which to seek equivalency may be an issue and would have to take account of current, and expected future, trade patterns. The choice of partners, should this option be pursued, would ultimately determine whether asynchronous approvals can be adequately addressed or not.

The current zero tolerance approach to the presence of GM events not authorised in the EU gives rise to problems with LLP which can be costly. It also restricts supply to Third Countries which can segregate and identity preserve. The expected increase in the cultivation of GM events globally may increase the economic consequences of this policy arising from asynchronous and asymmetric authorisations; these problems may ultimate negatively impact on EU industry and consumer prices. A zero tolerance approach also implies the highest possible costs of segregation and identity preservation as there is no tolerance level for adventitious presence. This approach in itself might also increase consumer concerns by suggesting safety concerns which may not be justifiable or may be disproportionate for GMOs already assessed in Third Countries. LLP incidents, which arise from this approach, suggest safety concerns which may not be justifiable; these may raise consumer concerns. On the other hand, this approach does provide full and clear consumer protection from unauthorised (and therefore potentially unsafe) products.

A tolerance level of other than zero, for GM events that have received a positive opinion at risk assessment, but are not yet authorised in the EU would most likely alleviate only partially the problems that operators are having with asynchronous authorisations. However, it would not offer a substantial solution because it usually takes only a few months between the EFSA opinion and the EU authorisation. This would not alleviate problems relating to asymmetric authorisations. In addition, introducing a tolerance level for non-authorised GMOs (for example, 0.5% or 0.9%) could cause controversy as it could be seen as a weakening of the system and not all stakeholders may agree with a tolerance level for unauthorised events. It might also call into question the necessity of the risk management process, or at least imply that this is a formality. Finally, such an approach would require confidence in the risk assessment of Third Countries.

A tolerance level other than zero for GM events authorised in Third Countries, but not risk assessed in the EU would end all problems with asynchronous and asymmetric authorisations, although would not offer full consumer protection and might result in higher perceived risk and impact on acceptance. This would be the most far reaching option to address. Such an approach would also call into question the need for an EU authorisation system if GM material authorised elsewhere is permitted, even at low levels.

Another issue surrounding the area of the low level presence of unauthorised GMOs in food and feed is that of testing methods. The fundamental issue is which harmonised methods will be available for testing purposes. The different impacts of harmonised testing are outlined below:

- Harmonised testing would eliminate uncertainty for operators in situations where different tests produce different results.
- With harmonised testing there may be some difficulty in terms of agreeing on testing methods and ensuring that agreed testing methods are properly implemented.

9.2.3.1. Summary

As noted in section 9.1, LLP is an issue which does require a solution and this is accepted by the majority of stakeholders and Competent Authorities. A technical solution under the current legislative framework (currently being developed by the European Commission) would be the least controversial solution, and would alleviate the problem in the short-term. However, it is questionable as to whether a technical solution under the current legislative framework would work in the long-term, given that the number of GM events is expected to increase, and that there are likely to be problems arising from asymmetric authorisations in the future. However, there is no clear support for legislative amendments to address the issue.

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11. List of contacts

It should be noted that while most organisations contacted did agree to provide evidence for the evaluation, there were some which did not. These organisations are not listed below.

In some cases individual member companies of organisations were also present during meetings. These individual companies are listed in brackets after the organisation which represents them.

11.1. Semi-structured interviews with EU stakeholders

- Association of Poultry Processors and Poultry Trade (AVEC)
- Carrefour
- Comité du Commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures (COCERAL)
- Confederation of the Food and Drink Industries of the EU (CIAA)
- Committee of Professional Agricultural Organisations/General Committee for Agricultural Cooperation in the European Union (COPA-COGECA)
- Dow Chemical Company
- European Association of Professional Storekeepers for Agribulk Commodities within the European Union (UNISTOCK)- written comments
- European Dairy Association (EDA)
- European Seed Association (ESA)
- EU Oil and Protein meal Industry (FEDIOL)
- European Landowners Organisation (ELO)
- European Livestock and Meat Trading Union (UECBV) (also a CELCAA member)
- Eurocommerce
- Eurocoop
- Europabio
- European Vegetable Protein Federation (EUVEPRO)
- Fédération Européenne des fabricants d'Aliments Composés (FEFAC)
- Federation of European Rice Millers (FERM)
- Friends of the Earth
- Greenpeace
- International Federation of Organic Agriculture Movements (IFOAM)- written comments
- LEI (University of Wageningen)
- Liaison Centre for the Meat Processing Industry in the European Union (CLITRAVI)
- Trace Consult

11.2. Case studies

Case study coverage was agreed with the Steering Group and was designed to provide comprehensive geographical coverage across the EU-27 in order to capture a wide range of attitudes and opinions.

11.2.1. Austria

- AGES - Österreichische Agentur für Gesundheit und Ernaehrungssicherheit (Austrian Agency for Health and Food safety)
- BMG Bundesministerium für Gesundheit (Competent Authority)
- Bundesgremium Agrahandels (Austrian cereal trading board)
- Fachverband der Futtermittelindustrie Österreichs (Austrian feed industry association)
- Gentechnikfrei (Austrian GM-free labelling scheme)
- Lebensmittelverband Österreichs (Austrian food industry association)
- OERV - Österreichische Raiffeisenverband (Austrian organisation of co-operatives, including farming co-operatives)
- Saatgut Österreich (Austrian seed industry association)
- Umweltbundesamt (Austrian Environment Agency)

11.2.2. Belgium

- Association professionnelle des fabricants d'aliments composes pour animaux (BEMEFA)
- Belgian biotechnology industry organisation (BIO.BE)
- Boerenbond
- Federation Belge de la Distribution (FEDIS)
- Federal public service health, Food Chain safety and Environment
- Federation de l'industrie alimentaire (FEVIA)
- Fédération Wallonne des agriculteurs (FWA)
- Syndicat national du commerce des céréales et légumes secs (Synagra)
- Vlaams instituut voor biotechnologie (VIB)

11.2.3. Czech Republic

- Asociace soukroumeho zemedelstvi (ASZ)
- Ceskomoravské Sdruzeni Organizaci Zemedeleskeho zasobovani a Nakupu (CSOZZN)
- Ministertsvo Zemedelstvi Ceské Republik
- Monsanto
- Potravinaska Komora Ceske Republik (PKCR)
- Scientific Committee
- Sdruzeni obrany spotrebitelu (SOS)

- Ssruzeni ceskych spotrebitelu (SCS)
- Zemedelsky svas Ceske Republik (ZSCR)

11.2.4. Finland

- Animalia (Federation for the Protection of Animals)
- Central Union of Agricultural Producers and Forest Owners (MTK)
- Elintarviketeollisuusliitto (Finnish Food and Drink Industries Federation)
- Finfood
- Finnish Bioindustries
- Finnish Food Safety Authority Evira
- Kuluttajat-Konsumenterna ry (Consumers)
- LUOMU-Liitto ry (Union for Organic Farming)
- Ministry of Agriculture and Forestry, Department of Food and Health (Competent Authority)
- Päivittäistavararakauppa ry (Finnish Grocery Trade Association)
- Suomen Eläinsuojeluyhdistys (Finnish Federation of the Animal Protection Association)
- Suomen Kuluttajaliitto (Finnish Consumers' Association)
- Valio Ltd (Dairy processor)

11.2.5. France

- Association Nationale des Industries Agroalimentaires (ANIA)
- Coop de France
- Direction Générale de la Consommation et de la Répression des Fraudes (Competent Authority)
- FNCG (oil and fat producers)
- Fédération des entreprises du Commerce et de la Distribution (FCD)
- Fédération Nationale des Syndicats des Exploitants Agricoles (FNSEA)
- Ministère de l'Ecologie, de l'Energie, du Développement Durable et de l'Aménagement du Territoire
- Ministère de l'Agriculture - DGAL
- ORAMA
- Que Choisir
- Secrétariat Général des Affaires Européennes (SGAE)
- SYNACOMEX
- Syndicat National de l'Industrie de la Nutrition animale (SNIA)
- Union des Syndicats des Industries des Produits Amylacés (USIPA)

11.2.6. Germany

- Bio Deutschland (German bioindustry association)
- BGA – Bundesverband Grosshandel, Auslandhandel und Dienstleistung (German association of wholesale and foreign trade)
- BLL – Bund für Lebensmittelrecht und Lebensmittelkunde (German Food Industry Confederation)
- BMELV - Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz (Competent Authority)
- BÖLW - Bund Ökologische Lebensmittelwirtschaft (German Organic Farming Federation)
- BVVF - Bundesverband Vieh und Fleisch (German livestock and meat association)
- Deutscher Verband Tiernahrung (German animal feed association)
- DRV - Deutscher Raiffeisenverband (German organisation of co-operatives, including farming co-operatives)

11.2.7. Greece

- DIO (Organic producers' Association)
- EKPIZO (Consumers' Association)
- ESAV (Agro biotechnology industry)
- Filiki Certification (Organic Producers' Association)
- GESASE (General Confederation of Greek Agrarian Associations)
- Greenpeace (NGO)
- INKA (Consumers' Association)
- KEPKA (Consumers' Association)
- SEVIZ (Hellenic Feed Industry Association) [written comments]
- SEVT (Federation of Greek Food Industries)

11.2.8. Italy

- ACU – Associazione Consumatori Utenti (Consumers' Association)
- ADICONSUM (Consumers' Association)
- AIRI – Associazione Industrie Risiere Italiane (Rice Industry Association)
- ANACER (National Association of cereal Producers)
- ASSALZOO – Associazione Nazionale Produttori di Alimenti Zootecnini (National Association Feed Producers)
- ASSICA - Associazione Industriali delle Carni (Meat processing industry)
- ASSITOL - Associazione Italiana dell'Industria Olearia (Italian Association Oil Industry)
- Assobiotech-Federchimica (Biotechnology industry)

- ASSOCARNI – Associazione Nazionale Industria e Commercio Carni e Bestiame (Livestock and meat industry and trade)
- CIA – Confederazione Italiana Agricoltori (Italian Farmers Federation)
- Coldiretti (Farmers' Association)
- Confagricoltura (Farmers' Association)
- Confcommercio (General Confederation for Commerce, Tourism and Services)
- Federconsumatori (Consumers' Association)
- Fondazione Diritti Genetici (Fundation Genetic Rights - Research on GMOs)
- Ministry of health (Competent Authority)
- UNA – Unione Nazionale dell'Avicoltura (National Union of poultry production)
- UNICEB - Unione Importatori Esportatori Commissionari Grossisti Ingrassatori Macellatori Spedizionieri Carni Bestiame Prodotti Derivati (Livestock and meat trading union)

11.2.9. Netherlands

- Hoofdproductschap Akkerbouw (HPA)
- Koninglijke Vereniging Het Comité van Graanhandelaren
- Levensmiddelenwetgeving en Voedselveiligheid (FNLI)
- Ministerie van Volksgezondheid, Welzijn en Sport
- Ministerie van Landbouw, Natuur en Voedselkwaliteit – Afdeling Bio-economie
- Nederlandse Vereniging Diervoederindustrie (NEVEDI)
- Productshap Dierevoeder (PDV)
- Productshap LTO
- University of Wageningen – LEI

11.2.10. Poland

- Federacja Konsumentow
- IZBA Gospodarcza
- Krajowa Rada Drobiartswa (KRD)
- Krajowy Zwiazek Rolnikow Kolek I Organizacji Rolniczych (KZRKIOR)
- Ministerstwo Rolnictwa I Rozowu Wsi
- Monsanto
- National Food and Nutrition Institute
- Polskie Mieso
- Polskie Stowarzyszenie Producentow Oleju (PSPO)
- Polsus

- Solae Europe

11.2.11. Spain

- ACCOE - Asociación de Comercio de Cereales de España (Spanish Association of Grain Traders)
- AECEC - Asociación Española de Comercio Exterior de Cereales y Productos Análogos (Spanish Association of Foreign Grain Traders)
- AFOEX Asociación Nacional de Empresas para el Fomento de las Oleaginosas,
- su Extracción y su Refino (Spanish Association of Oil and Proteinmeal Industries)
- ANOVE - Asociación Nacional de Obtentores Vegetales (Spanish seed association)
- ASEDAS - Asociación Española de Distribuidores, Autoservicios y Supermercados (Spanish Association of Distributors and Supermarkets)
- ASEBIO - Asociación Española de Bioempresas (Spanish Association of Biotech Companies)
- ASOCARNE - Asociación Española de Empresas de la Carne (Spanish association of meat companies)
- ASAJA - Asociación Agraria - Jóvenes Agricultores (Spanish Association of Farming Co-operatives)
- CECU - Confederación de Consumidores y Usuarios (Spanish Consumer Confederation)
- CESFAC - Confederación Española de Fabricantes de Alimentos Compuestos para Animales (Spanish Compound Feed Manufacturers' Association)
- COAG - Coordinadora de Organizaciones de Agricultores y Ganaderos (Spanish Association of Farming Co-operatives)
- FIAB - Federación Española de Industrias de la Alimentación y Bebidas (Spanish Association of Food and Drink Industries)
- MARM – Ministerio del medio ambiente y medio rural y marino (Competent Authority)
- SEAE - Sociedad Española de Agricultura Ecológica (Spanish Organic Farming Society)

11.2.12. UK

- Agricultural Biotechnology Council (Bayer Crop Science, Monsanto)
- Agricultural Industries Confederation
- British Poultry Council
- British Retail Consortium
- Country Land and Business Association
- Food and Drink Federation
- Food Standard Agency (Competent Authority)
- Friends of the Earth UK
- GeneWatch
- GM Freeze

- National Farmers' Union
- Seed Crushers and Oil Processors Association
- Which?

11.3. EFSA

- GMO unit
- Panel member (Professor Du Jardin)

11.4. Commission Services

- DG Agriculture and Rural Development
- DG Enterprise
- DG Environment
- DG Health and Consumers
- JRC-IHCP (Institute for Health and Consumer Protection)
- JRC-IPTS (Institute for Prospective Technological Studies)
- DG Research
- DG Secretariat-General
- DG Trade

11.5. Analytical laboratories

A number of analytical laboratories were contacted in order to request interviews, but none agreed.