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

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Appendices to Final Report

Submitted by:

Food Chain Evaluation Consortium (FCEC)

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Prepared by the Food Chain Evaluation Consortium (FCEC)
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1. 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 potential options, even where these may not be viable or practicable.

The options for the future are laid out in tabular form in the sections below, indicating the possible economic, social and environmental impacts of each option. The final column contains the level of support from the survey, with CA indicating the level of Competent Authority support, and SH the level of stakeholder support. Consultees had 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.

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.

1.1. Risk assessment and the regulatory procedure

As has been identified in answering the evaluation questions in the main report, in economic terms, there is expected to be an increase in the number of events submitted for authorisation in the near future and limited resource within EFSA and Commission Services to process these. 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. These issues have implications in terms of consumer food prices, especially for livestock products. 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; the GMO issue in general is therefore a sensitive subject.

1.1.1. 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 set out in the third option in the Table, namely risk assessment carried out by a rapporteur Member State. It should be noted that any other solution would require the re-opening of the legislation which would create problems with other aspects of the current regulatory framework. 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; there was more support among stakeholders, predominately feed processors and traders.

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	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Option preferred by the majority of MS and stakeholders				
Carried out by EFSA (<i>Status quo</i>)	<ul style="list-style-type: none"> Possible additional resource requirement, particularly if the number and complexity of submitted dossiers increases as is expected. May have “economy of scale” effects for the authorities in that the necessary skill set does not need to be replicated in individual Member States. 	<ul style="list-style-type: none"> Some questioning of EFSA and its opinions may impact on acceptance (although this would probably also be the case under other options). May fuel potential concerns of a “democratic deficit” in that citizens may feel distant from the authorisation process. Relatively efficient process with which applicants have experience and which is generally supported. 	<ul style="list-style-type: none"> No relevant impacts identified. 	91% CA 70% SH
Other discussed options				
The use of agreed Third Country risk assessments where available	<ul style="list-style-type: none"> No resource issues; considerable savings for public authorities. Risk management based on Third Country risk assessments may be difficult. This may ultimately lead to a lack of authorisations and the associated economic impacts of this. 	<ul style="list-style-type: none"> May fuel potential concerns of a “democratic deficit” in that citizens may feel distant from the authorisation process. Potentially faster authorisations, easier application procedure for industry. No Member State input into risk assessment might ultimately lead to a negative impact on public acceptance. Perceived lack of responsibility of authorities may lead to possible negative effects on their image. 	<ul style="list-style-type: none"> May be concerns in terms of safety. 	5% CA 22% SH
Carried out by a rapporteur	<ul style="list-style-type: none"> Possible that some Member State resources (skill sets and financial) are insufficient to 	<ul style="list-style-type: none"> Distrust of other Member State agendas may lead to poorer acceptance. 	<ul style="list-style-type: none"> No relevant impacts identified. 	5% CA

	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Member State¹	<p>fulfil this function (the centralisation of risk assessment under Regulation (EC) No 1829/2003 removed a burden from Member States).</p> <ul style="list-style-type: none"> Possible difference between quality of risk assessments in different Member States leading to different costs of compliance. 	<ul style="list-style-type: none"> Possible difference between Member States in terms of methods, decision criteria (or interpretation of criteria) and timeframe (if any flexibility is built into the system); some Member States may be seen as “easier” than others leading to a concentration of applications in a few Member States (see also above). The potential to distribute applications between Member States may balance the burden and speed up the system (if the ability to do this were part of the system). 		7% SH

1.1.2. 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.

¹ It is currently possible under Regulation (EC) No 1829/2003 for EFSA to contract out elements of the risk assessment to Member State Competent Authorities, although this has not been done in relation to GM food and feed. The survey question here related to the *status quo* prior to the implementation of this Regulation.

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	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Option preferred by the majority of MS and stakeholders				
A decision to authorise or not is taken by the Commission after consulting Member States as under regulation (EC) No. 1829/2003 (status quo)	<ul style="list-style-type: none"> 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. Ultimately leads 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. 	<ul style="list-style-type: none"> The opportunity for Member State input should theoretically help with acceptance; however due to the political nature of the subject, this is not the case. Potential to authorise in situations where there is little Member State support (if not a qualified blocking majority) may cause controversy and raise issues of “democratic deficit”. 	<ul style="list-style-type: none"> No relevant impacts identified. 	73% CA 49% SH
Other discussed options which would though require a change of Comitology thus not feasible under the GMO legislation				
A decision to authorise or not is taken by the Commission alone, i.e. no Member State involvement	<ul style="list-style-type: none"> Should lead to a quicker, more obviously science-based decision. This would assist with the economic impacts of asynchronicity. 	<ul style="list-style-type: none"> Lack of Member State input may cause controversy and acceptance issues. May fuel fears of a “democratic deficit” in that citizens may feel distant from the authorisation process. 	<ul style="list-style-type: none"> No relevant impacts identified. 	9% CA 38% SH

	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
A decision to authorise or not at the Community level is taken by Member States with no input from the Commission (as allowed for under Directive 2001/18/EC)	<ul style="list-style-type: none"> Decisions will probably be based more on political positions, rather than science. Unlikely that a majority will be obtained in either direction, leading to stalemate and the related economic consequences of this. 	<ul style="list-style-type: none"> By relying solely on Member State votes, the final decision should theoretically represent citizens' will. May be controversy in some Member States against the use of GM food and feed if GM events are effectively imposed upon them. Similarly, Member States in favour of GM food and feed may be denied its use by the views of others. 	<ul style="list-style-type: none"> No relevant impacts identified. 	18% CA 13% SH

1.1.3. 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 formal inclusion. Furthermore, the explicit and systematic inclusion of socio-economic criteria would require re-opening the legislation. The underlying assumption in terms of socio-economic criteria in the options below is that they are appropriately defined.

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Options	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Socio-economic criteria are not considered (status quo)	<ul style="list-style-type: none"> Potential economic costs and benefits of GMO marketing not considered. 	<ul style="list-style-type: none"> Some Member States will continue to vote on grounds other than the science. Lack of transparency in terms of Member State voting rationale. Lack of ability to (formally) include wider considerations in the decision making process resulting in a feeling for some citizens that their concerns are not taken into account. Lack of a formal mechanism to include consideration of potential benefits in the authorisation procedure. Dependence on science may not build confidence in the authorisation process given past experience with crises in the food sector. Risk management is, officially at least, little different from risk assessment if votes are taken strictly on the science; there may be an impact in terms of a perceived “democratic deficit”. Would go against Member State initiatives in this area. Lack of consideration of potential public benefits of GM crops. Avoids possibly lengthy debates on (subjective) socio-economic implications. 	<ul style="list-style-type: none"> Focus on potential environmental/health risk only; no possibility of interference of other factors (including socio-economic costs or benefits that would play either in favour or against authorisations). 	52% CA 71% SH

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Options	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Socio-economic criteria are considered	<ul style="list-style-type: none"> Potential economic costs and benefits of GMO marketing would be considered. 	<ul style="list-style-type: none"> Formalisation of the use of socio-economic criteria would increase transparency. Discussion of benefits and a clear balance between costs and benefits might increase public acceptance in some cases. Citizens might feel that their concerns are more clearly taken into account. Might be difficult to define uniform socio-economic metrics across entire EU. May result in a longer authorisation process to allow proper discussion (and related economic effects of this). May result in greater scope for disagreement and less likelihood of achievement of qualified majority. Difficulty in fitting socio-economic criteria into the risk assessment and risk management processes. 	<ul style="list-style-type: none"> Might allow the authorisation of events with some negative environmental consequences to be authorised if potential benefits are considered to outweigh these. 	48% CA 29% SH

1.1.4. 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).

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Options	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Public comments are sought for each application on release of the EFSA opinion (<i>status quo</i>)	<ul style="list-style-type: none"> Increased requirement for resources in the regulatory bodies as applications increase. Slows down the authorisation process in comparison to other options. 	<ul style="list-style-type: none"> Increases “ownership” of the process amongst the public and stakeholders. Increases transparency. May result in frustration if stakeholders feel that their comments are not taken into account. 	<ul style="list-style-type: none"> No relevant impacts identified. 	38% SH
Public comments are sought by the Commission in a more targeted manner (e.g. only with regard to specific aspects of an application if needed)	<ul style="list-style-type: none"> Would limit the range of comments with positive implications for the resources required. 	<ul style="list-style-type: none"> Generally as the <i>status quo</i>, but on a more limited scale. By restricting the opportunity for comment some areas may be overlooked. Interested groups may feel that their involvement in the process has been curtailed. 	<ul style="list-style-type: none"> No relevant impacts identified. 	37% SH
Public comments are only sought for more general questions on the implementation of the GMO legislation	<ul style="list-style-type: none"> Would limit the range of comments with positive implications for the resources required. Comments may help identify areas where legislation could be improved with benefits for all. 	<ul style="list-style-type: none"> Generally as the <i>status quo</i>, but on a more limited scale. By restricting the opportunity for comments some areas may be overlooked. Interested groups may feel that their views are not considered. 	<ul style="list-style-type: none"> No relevant impacts identified. 	24% SH

Options	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Public comments are not sought	<ul style="list-style-type: none"> • Would reduce the resources required within the regulatory bodies. • Could speed up the authorisation process. 	<ul style="list-style-type: none"> • May make the public feel less able to communicate their views. • May undermine trust in the regulatory bodies to take account of the views of the public. • May impact negatively on public acceptance. 	<ul style="list-style-type: none"> • No relevant impacts identified. 	1% SH

1.1.5. 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. 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.

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.

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)).

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Options	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
<p>Data generation for risk assessment primarily by applicant (<i>status quo</i>)</p>	<ul style="list-style-type: none"> • Burden lies with the applicant and potential beneficiary of authorisation. • Costs of data generation to support applications in the EU range from €3.8 million to €10.4 million (see main text). • Limits 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. • This may restrict the development of the EU green biotech sector with consequential economic impacts. 	<ul style="list-style-type: none"> • Risk assessment may not be considered as truly independent by some being based on data supplied by applicants. • This may impact on public confidence in the risk assessment and ultimately on acceptance of GMOs. • The barrier to entry for smaller companies and researchers may limit the range of GMOs developed which might result in a lack of development of GMOs with environmental/societal benefits. • This may restrict the development of the EU green biotech sector with consequences for society in terms of access to jobs and opportunities. • Faster system, as data from applications in other countries can be used (knock on effects from lower delays). This also increases efficiency for the applicant. • There is no incentive for applicants to submit dossiers speculatively (data for the risk assessment have to be rigorous or approval will not follow). • Coherence with principles of applicant's responsibility for food/feed safety under general food law 	<ul style="list-style-type: none"> • Regardless the origin of data, the quality of application has to be checked by EFSA on a case-by-case basis and in accordance with the standards established by the legislation. 	<p>27% CA 40% SH</p>

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Options	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Independent data generation for risk assessment (not by applicant)	<ul style="list-style-type: none"> • Potentially large cost for the public authorities (unless adequately covered by a fee). • Duplication of effort as applicants would have to conduct their own trial work in any case for other markets and also to at least ensure efficacy. 	<ul style="list-style-type: none"> • Independent generation is perceived as neutral and may help with acceptance issues, although neutrality may still be questioned by some. • Would shift the responsibility to demonstrate the safety of products from the applicant to the public authority. • Incentive to submit dossiers speculatively, i.e. without a clear idea that the event is safe. • Resultant implications in the time to approval and hence increased risk of asynchronous authorisation and possibly lengthy period of asynchronicity. • 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. 	<ul style="list-style-type: none"> • As above, regardless the origin of data, the quality of application has to be checked by EFSA on a case-by-case basis and in accordance with the standards established by the legislation. 	73% CA 60% SH

1.1.6. 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).

Three Competent Authorities (13%) and 10% of 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.

	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Option preferred by the majority of Member State Competent Authorities				
Stacked events must receive authorisation even where the single events have been separately authorised (<i>status quo</i>)	<ul style="list-style-type: none"> Additional resource requirements compared to a system of automatic authorisation (as in the US). However, this should not be over-stated: currently only the interaction between events is considered separately in stacked events, the single events having already been separately assessed. Expected increase in stacked events will increase resource requirements and might result in a backlog of applications and ultimately more asynchronous authorisations. 	<ul style="list-style-type: none"> Potentially higher public confidence in safety. 	<ul style="list-style-type: none"> Potential risks due to interactions of single events are assessed. 	48% CA 22% SH

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	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Other options discussed				
Stacked events are automatically authorised where all the events have already been authorised singly in the EU	<ul style="list-style-type: none"> • Would eliminate any problems with large volume of applications for stacked events. This would have knock on effects on the speed of authorisation of other events, and in turn on the asynchronicity issue. 	<ul style="list-style-type: none"> • Likely to cause controversy as the number of authorised GMs would increase rapidly. 	<ul style="list-style-type: none"> • Potential risks due to interactions of single events are not assessed. There may be concerns that the overall level of human and animal health and environmental protection will be reduced. 	4% CA 6% SH
Stacked events must undergo a fast-track risk assessment based on previous EU risk assessment of single events and the current authorisation process	<ul style="list-style-type: none"> • Might speed up the risk assessment process. However, there would still be delays in the risk management phase. • Would reduce the burden on EFSA; this may be important if the number of applications increases. 	<ul style="list-style-type: none"> • There might be a perception that the protection of human health, animal welfare and the environment is diminished. 	<ul style="list-style-type: none"> • As automatic authorisation, but with a weaker impact. 	4% CA 31% SH

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	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Other options discussed which would though require a change of Comitology and are thus not feasible under the GMO legislation				
Stacked events must undergo the current risk assessment process and a fast-track authorisation process	<ul style="list-style-type: none"> This could speed up the risk management process with consequential impacts in terms of asynchronous authorisations. 	<ul style="list-style-type: none"> Fast-track authorisation may cause some controversy. This could partly be mitigated by explaining that the scientific risk assessment has not changed. There might be a perception that the overall protection offered is lower. There would be no change in the burden on EFSA which could have implications in terms of delays if the number of applications for stacked events increases as widely expected. 	<ul style="list-style-type: none"> As automatic authorisation, but with a weaker impact. 	17% CA 7% SH
Stacked events must undergo a fast-track risk assessment based on previous EU risk assessment of single events and a fast-track authorisation process	<ul style="list-style-type: none"> Might speed up the risk assessment process. This could speed up the risk management process with consequential impacts in terms of asynchronous authorisations. 	<ul style="list-style-type: none"> There might be a perception that the protection of human health, animal welfare and the environment is diminished. Fast-track authorisation may cause some controversy. There might be a perception that the overall protection offered is lower. Would reduce the burden on EFSA; this may be important if the number of applications increases. 	<ul style="list-style-type: none"> As automatic authorisation, but with a weaker impact. 	13% CA 24% SH

1.1.7. 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.

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. Industry reaction to independent data generation is unclear, but might be expected to be unfavourable. Furthermore, independent data generation would require re-opening the legislation. In conclusion, although this option was widely supported, it would entail a number of risks.

1.2. Labelling

Whilst the current labelling rules can in theory help facilitate an informed choice for consumers, the relative absence of GM labelled products from the shelves mitigates against this. 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, even though the use of GM labelled feed is widespread. 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, although the extent to which they contribute to improving consumers’ informed choice is debateable; a harmonised approach may have some merit here.

In considering options for the future for labelling, it is worth taking into account the findings of the main report with respect to consumer expectations and behaviour, i.e. 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.

1.2.1. Positive labelling (explicit indication that products contain or consist of GMOs)

The table below examines the impacts of mandatory positive labelling. Support for voluntary positive labelling was low; 9% of Competent Authorities (scope: products containing GM only) and 5% of stakeholders (scope: 3% produced from or containing GM material; 1% containing

GM material only; 1% produced from GM material, containing GM material or livestock products fed on GM materials). 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.
- 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.
- 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.

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 by 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. Finally, one stakeholder (1%) suggested another approach based on the education of consumers.

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	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Option preferred by the majority of Member State Competent Authorities and stakeholders				
For food produced from and/or containing GM material (<i>status quo</i>)	<ul style="list-style-type: none"> • Little use of GM material in food products, although the economic impact of this on consumers is not thought to be substantial. • Widespread use of GM feed in the livestock sector implies reduction in feed costs. • Segregation and identity preservation costs for feed and food products. • Labelling the majority of feed implies a compliance cost on the larger market segment. • Lack of detectability for oil products increases risk of fraud and may imply additional control resource. 	<ul style="list-style-type: none"> • Potential for consumer confusion because the system is neither entirely process nor product based (for example, oil products labelled, livestock products not labelled). • Lack of ability for consumers to make a fully informed choice at point of sale with regard to livestock products. • Lack of detectability for oil products increases risk of fraud which would mean that consumers wishing to avoid the use of GM may be misled. 	<ul style="list-style-type: none"> • Segregation may imply less efficient transport of commodities with consequential environmental impact. 	74% CA 35% SH
Other discussed options				
Only for products containing GM material (rDNA), i.e. no labelling of oil	<ul style="list-style-type: none"> • Generally as for food produced from and/or containing GM material. • Reduction of segregation and IP burden in the oil sector (although where there are joint products which would still require labelling; for example, soybean meal for livestock feed; this benefit would not be realised). • Reduction in the opportunity for fraud. 	<ul style="list-style-type: none"> • Would introduce consistency as labelling would be clearly product based. This may reduce consumer confusion. • The removal of labelling from products previously labelled might cause some controversy and raise questions as to whether oil products should have been labelled in the first place and why they no longer require labelling. • Lack of ability for consumers to make a 	<ul style="list-style-type: none"> • Potential reduction in the need to segregate may allow more efficient transport of commodities, but only where joint products do not require segregation. • Reduction in amount of labels produced. 	4% CA 28% SH

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	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
		<p>fully informed choice at point of sale with regard to oil products.</p> <ul style="list-style-type: none"> • Would be consistent with “science-based “ policy. 		
<p>For products currently labelled and livestock products including meat, eggs and milk produced using GM feed</p>	<ul style="list-style-type: none"> • As <i>status quo</i> for non-livestock products. • Would imply segregation and identity preservation of livestock products and additional cost. • Lack of testing mechanism for livestock products increases risk of fraud and may imply additional control resource. • May decrease overall demand for livestock products (at least in the short-term). • 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. • Unless the same labelling requirements applied to imports of livestock products from Third Countries there may be a move away from (labelled) domestic production to (unlabelled) imports. This could have large impacts on agricultural systems in the EU. • Unlabelled imports may be fed on GM materials not authorised in the EU. • Would raise the question of the need to authorise livestock products fed on GM 	<ul style="list-style-type: none"> • Would introduce entirely process-based labelling. This may reduce consumer confusion and facilitate a fully informed, process-based choice. • Widespread use of GM labelling would increase consumer familiarity with labelling and potentially understanding. • Would not be consistent with a science-based policy. • May harm EU consumer educational needs by suggesting that GM-fed livestock products contain traces of GM materials. • May lead to confusion as most livestock products will be labelled when they were not previously. • Difficulty in defining what is meant by “fed on GM feed”. See current differences in approach with respect to “GM-free” schemes (for example, duration of animal's feeding time with GMOs before they become available for consumption). 	<ul style="list-style-type: none"> • Increase in amount of labels produced. 	<p>13% CA 20% SH</p>

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	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
	which, if implemented, would have significant economic implications.			
For all products using GM technology (currently labelled products, livestock products produced using GM feed, enzymes, processing aids, etc.)	<ul style="list-style-type: none"> Widespread labelling will incur extra costs for operators and control authorities, especially as this would be process-based labelling. Unless the same labelling requirements applied to imports of products using this type of GM technology from Third Countries there may be a move away from (labelled) domestic production to (unlabelled) imports. This could have large impacts on the EU fermentation sector. 	<ul style="list-style-type: none"> Would provide an entirely process-based labelling framework. Provides consumers with the information to make a fully informed choice at point of sale. However, the labelling of all products may lead to cases where there is no non-GM alternative and hence a restriction of consumer choice. Would improve consumer awareness of the use of GM technology which may or may not have an impact on public acceptance. 	<ul style="list-style-type: none"> Increase in amount of labels produced. 	Not asked in survey
No positive labelling	<ul style="list-style-type: none"> Reduction in costs associated with segregation and identity preservation. Potential widespread use of GM ingredients in food, although this would not have a substantial impact on consumer prices (and would depend on retailers and food manufacturers using GM ingredients which is by no means certain). 	<ul style="list-style-type: none"> 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. Lack of ability for consumers to make a fully informed choice, at least at point of sale. 	<ul style="list-style-type: none"> Reduction in the need to segregate may allow more efficient transport of commodities. Reduction in amount of labels produced. Would not permit 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. 	0% CA 11% SH

1.2.2. 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. These are laid out and compared to a prohibition on negative labelling in the table below. 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 there is no *status quo* option in this discussion; negative labelling is currently exercised only under voluntary schemes.

Options	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Adoption of specific legislation regarding negative labelling (at EU and/or Member State level)	<ul style="list-style-type: none"> The burden of proof and cost lies with operators (and consumers) in this market segment, i.e. those who are not willing to pay a higher cost do not have to. This is already the case in Member States where “GM-free” labelling is used. Depending on the content of adopted rules (e.g. scope of controls, purity standards) the compliance costs might affect some sectors more than others. Level playing field operators/consumers interested in negative labelling; may bring economic advantages to some of them. 	<ul style="list-style-type: none"> Depending on the threshold level, scope and positive labelling requirements, the existence of a three-tier system (positive labelled, “GM-free” labelled and unlabelled) would probably confuse consumers. Provides additional consumer choice. May imply to consumers that GM food is inherently bad which may result in lower consumer acceptance of GM food products. 	<ul style="list-style-type: none"> Increase in amount of labels produced. 	73% CA 42% SH
Prohibition of any negative labelling (at EU and/or Member State level)	<ul style="list-style-type: none"> May adversely affect operators currently using “GM-free” labelling. 	<ul style="list-style-type: none"> 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. Would avoid the potential misleading of consumers through negative labelling. 	<ul style="list-style-type: none"> No relevant impacts identified. 	27% CA 58% SH

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The table below examines the impacts of different negative labelling options. The survey support is drawn only from those in favour of negative labelling (from the Table above) and hence does not sum to 100%. The impacts of different definitions of scope for **voluntary** negative labelling are considered separately whereas the impacts for different scopes of **mandatory** negative labelling have been placed together. The scope of **mandatory** negative labelling would have to be determined at EU or Member State level. It should be noted that agreement over any EU-level harmonised scheme (mandatory or voluntary) may be problematic. There is majority support for voluntary rather than mandatory labelling and within this for harmonisation at the EU level.

Options	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Voluntary; appropriate scope, criteria and purity levels defined at the EU level	<ul style="list-style-type: none"> • Efficiencies through the smooth operation of the single market. • 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). 	<ul style="list-style-type: none"> • Provides consistent consumer information and facilitates an informed choice across the EU. 	<ul style="list-style-type: none"> • Probable increase in amount of labels produced. 	45% CA 19% SH
Mandatory negative labelling (all scopes)	<ul style="list-style-type: none"> • Would impose a cost on a market segment which is not “responsible” for the creation of these costs. • Other impacts would be as above, but would be imposed. 	<ul style="list-style-type: none"> • May be seen as unjust. • There may be legal uncertainty related to the testing margin of error. This may also have economic repercussions. • Other impacts would be as above, but would be imposed. 	<ul style="list-style-type: none"> • Increase in amount of labels produced. 	19% CA 15% SH
Voluntary; scope, criteria and purity levels defined nationally	<ul style="list-style-type: none"> • Potential for interference with the smooth operation of the single market resulting in an uneven playing field for operators. • Criteria could be set to reflect the logistics of national supply chains. 	<ul style="list-style-type: none"> • Potential for consumer confusion. • Potential for the consumer to be misled by different criteria and standards. 	<ul style="list-style-type: none"> • Probable increase in amount of labels produced. 	5% CA 4% SH

Options	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Voluntary; scope, criteria and purity levels defined privately	<ul style="list-style-type: none"> As above with criteria set at Member State level. 	<ul style="list-style-type: none"> As above, but with potential for confusion between schemes within Member States as well as between Member States and the greater risk of misleading of consumers through unregulated schemes. 	<ul style="list-style-type: none"> Probable increase in amount of labels produced. 	5% CA 4% SH

1.2.3. 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. Some 4% of Competent Authorities and 6% of stakeholders (for both food and feed) suggested options not set out here and hence the survey support column does not sum to 100%. **There was a clear majority in relation to both food and feed in support of the *status quo*.**

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Options	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
0.9% (<i>status quo</i>)	<ul style="list-style-type: none"> There are costs associated with providing the labelling and costs in terms of Identity Preservation for the non-GM food and feed market segments. There has been some switching of suppliers to avoid Third Countries where comingling is more likely. 	<ul style="list-style-type: none"> Arguably it has been accepted by all parties. There is no scientific basis, however, and for the same reason, it would be hard to change it since it has proven implementable. 	<ul style="list-style-type: none"> No relevant impacts identified. 	<u>Food</u> 88% CA 69% SH <u>Feed</u> 87% CA 65% SH
Lower than 0.9% (including labelling of every detectable trace)	<ul style="list-style-type: none"> Generally would exacerbate the impacts under the <i>status quo</i>. May be difficult to achieve in view of the increase in GM events worldwide. In practical terms it may be almost impossible to implement a level of zero, and those implementing may have to pay considerable extra costs, i.e. this may not be considered proportionate. Would increase the cost of the non-GM segment. 	<ul style="list-style-type: none"> A labelling level of 0.1% (effectively the detection limit) would have a scientific basis. A level of zero would ensure that consumers are not misled (if there is no GM, there is no label). A level of zero might create legal uncertainty that would depend on the evolution of technical analysis and laboratories' capacity. Increase in products labelled as GM. 	<ul style="list-style-type: none"> Increase in amount of labels produced. 	<u>Food</u> 8% CA 10% SH <u>Feed</u> 9% CA 8% SH

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Options	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Higher than 0.9%	<ul style="list-style-type: none"> • Generally would mitigate the impacts under the <i>status quo</i>. • May reduce the incentive for operators to ensure the absence of GM material in unlabelled products. • May lead to lower operator costs, which could ultimately benefit consumers as well. 	<ul style="list-style-type: none"> • An increase in the level may undermine public confidence in the labelling regime. 	<ul style="list-style-type: none"> • Reduction in amount of labels produced. 	<u>Food</u> 0% CA 15% SH <u>Feed</u> 0% CA 22% SH

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 discourages operator negligence. This is not relevant with respect to fixed levels.
- The use of fixed levels would require re-opening the legislation.

1.2.4. 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.

1.3. Threshold for adventitious presence of unauthorised GM material

It has been seen demonstrated in the main report 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. 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 proposed technical solution, which however requires no legislative amendment, had not been defined at the time of writing. It was therefore not listed as an option in the survey; nonetheless two Competent Authorities and one stakeholder identified it as a solution under the option "other", although stakeholder support for a number of different approaches was greater within this category.

The fourth 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.

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Options	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
Zero tolerance of the presence of GM events not authorised in the EU (<i>status quo</i>)	<ul style="list-style-type: none"> • Results in problems with LLP which can be costly. • 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. • Implies the highest possible costs of segregation and identity preservation as there is no tolerance level for adventitious presence. 	<ul style="list-style-type: none"> • Provides full and clear consumer protection from unauthorised (and therefore potentially unsafe) products. • May increase consumer concerns by suggesting safety concerns which may not be justifiable or may be disproportionate. • LLP incidents suggest safety concerns which may not be justifiable. These may raise consumer concerns. • No harmonised method used by Member States. 	<ul style="list-style-type: none"> • No relevant impacts identified. 	33% CA 22% SH
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	<ul style="list-style-type: none"> • Would most likely alleviate the problems that operators are having with asynchronous authorisations. • Would not alleviate problems relating to asymmetric authorisations. 	<ul style="list-style-type: none"> • Would not offer a substantial solution to the issue of asynchronous authorisations, because it usually takes only a few months between the EFSA opinion and the EU authorisation. • As material will have been risk assessed in the EU, there should be no risk or perceived risk, or negative effects. • Nonetheless, this approach could cause controversy as it could be seen as a weakening of the system. • Not all stakeholders may agree with a 	<ul style="list-style-type: none"> • No relevant impacts identified. 	50% CA 24% SH

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Options	Potential impacts			Survey support
	Economic	Social (including administrative and institutional)	Environmental, animal and human health	
		tolerance level for unauthorised events. <ul style="list-style-type: none"> • Calls into question the necessity of the risk management process, or at least implies that this is a formality. 		
A tolerance level other than zero for GM events authorised in Third Countries, but not risk assessed in the EU	<ul style="list-style-type: none"> • Would end all problems with asynchronous and asymmetric authorisations. 	<ul style="list-style-type: none"> • Full protection of consumers would not be offered. • The lack of EU risk assessment may result in higher perceived risk and impact on acceptance. • Likely to cause controversy. • Calls into question the need for an EU authorisation system if GM material authorised elsewhere is permitted, even at low levels. 	<ul style="list-style-type: none"> • No relevant impacts identified. 	8% CA 38% SH
Other				8% CA 17% SH

A second 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.

1.3.1. Summary

As noted in the main report, 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

2. Survey results

2.1. Introduction

Two surveys were carried out, one of Member State Competent Authorities and the other of stakeholders. The questions asked were broadly the same, although there were some additional questions in each survey to reflect the different groups targeted.

The survey of Competent Authorities was launched on 18 September, 2009 with a deadline of 28 October, 2009 which was subsequently extended by one week (06/11/09) to facilitate responses. Competent Authorities who had not responded after this additional week were contacted directly and responses from a further two Competent Authorities were provided by early December. Ultimately replies were received from 24 of the 27 Member State Competent Authorities².

The survey of stakeholders was sent to 601 identified contacts on 25 September, 2009 with a deadline of 30 October, 2009. A number of further invitations to participate were sent to organisations where it had not been possible to identify the relevant individual. These invitations requested that the organisation identify an individual to take responsibility for completing the questionnaire if this was of interest to them. Finally, notices advising stakeholders of the survey were sent out in DG SANCO's daily news email which has a distribution list amounting to 15,499 organisations/individuals³. It should be noted that an extensive list of stakeholders with potential interest in this area was compiled in order to avoid omissions. We are therefore confident that all stakeholders with an interest in this topic were approached and indeed took part in the survey. The deadline for this survey was also extended to 06 November, 2009 in order to facilitate responses and ultimately 82 were received, 20 of which were from EU level stakeholders and a further 10 from global organisations.

In accordance with the requirements of the terms of reference, the questionnaires were available in English, French and German with replies possible in these languages plus Spanish, Italian and Polish. Whilst this may have prevented some organisations from submitting responses, the range of possible languages makes this unlikely.

It should be noted that the survey results are not analysed statistically because the sample is not considered to be representative in that in some cases a European-level body answered on behalf of its national members whereas in other cases (albeit a minority) national members answered in addition to the European body. Where this was the case, most answers were broadly similar, although there were occasional differences. Statistical analysis might therefore suggest significant differences in response which simply result from the balance of respondents. A further conceptual problem with surveys of organisations and companies rather than individuals is one of scale; responses are not equivalent in terms of weight as they would be if the survey was of individuals. The main objective of the surveys was to ensure that all Competent Authorities and stakeholders had the opportunity to contribute their views and opinions to the research and have these taken into consideration.

Many questions used a four-point Likert scale designed to force respondents to provide either a "positive" or "negative" answer since a middle option of "neither agree nor disagree" was not included. The intention was to avoid central tendency bias where a disproportionate number of respondents select the neutral option⁴. In practice feedback from respondents suggested that the "don't know" option had been used by many as a neutral option. For this reason it was decided to consider

² No replies were received from Greece, Luxembourg or Malta.

³ As at 07 December, 2010.

⁴ See Garland (1991) on the advantages and disadvantages of using a mid-point on rating scales.

“don’t know” responses as “neither agree nor disagree”. Respondents not answering the question were assumed to have offered a genuine “don’t know” response.

Finally, the number of respondents to individual elements of questions is presented in each Figure and a breakdown of stakeholder response by group is set out in italics where there are differences in responses according to stakeholder sub-categories. All Figures in this Chapter are drawn from our survey results and are not individually sourced.

2.2. Background to stakeholder sample

Two thirds of stakeholder respondents defined themselves as an industry association. Some 18% described themselves as an NGO (not all of which were environmental NGOs), 12% as a company and 2% as a research organisation.

Companies and associations were asked to specify their field(s) of interest, i.e. more than one response was possible. Almost a third identified their company/association as being either a user of GM feed (29%) or a food manufacturer (28%). Just over a fifth (22%) were involved in GM technology provision and just under a fifth (19%) identified themselves as (commodity) traders. Of the remaining organisations, 12% were identified as feed processors and 6% as consumer organisations. Four percent of responses (3 organisations) fell outside this classification, but were nonetheless organisations with a valid interest in the topic. Classification was verified by means of an Internet review of organisation websites.

National and regional organisations accounted for 62% of total responses distributed among the Member States as shown in Table 2.1. Member States from where no stakeholder responses were drawn are omitted.

Table 2.1: Distribution of national and regional respondents by Member State

	Respondents	Percentage of total
Austria	4	8%
Belgium	5	10%
Denmark	2	4%
Estonia	1	2%
Finland	2	4%
France	3	6%
Germany	5	10%
Greece	3	6%
Hungary	2	4%
Ireland	1	2%
Italy	2	4%

	Respondents	Percentage of total
Lithuania	1	2%
Netherlands	4	8%
Poland	1	2%
Portugal	1	2%
Romania	1	2%
Slovenia	1	2%
Spain	4	8%
Sweden	3	6%
United Kingdom	5	10%
Total	51	

Of those providing an answer, approximately one third of respondents (36%) defined themselves as an SME.

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

2.3.1. The food needs of EU society

Respondents were asked to identify the food needs of EU society. Perhaps unsurprisingly both Competent Authorities and stakeholders generally reported that safe food is important or very important (Figure 2.1 and Figure 2.2). It was also considered generally very important to maintain secure all year round food and feed supplies. Relatively less importance was attached to providing food with improved functionality, although this was a more noticeable response with regard to stakeholders. A small minority of two Competent Authorities and 8% of stakeholder respondents did not believe that a strong research and development sector is important to EU society. The response from the Netherlands explained that maintaining consumer and producer choice is also important and the Italian Competent Authority noted that the provision of public information concerning food production is important.

A handful of stakeholders identified additional important food needs of EU society. *Feed processors and a food producer believed competitive production in the EU to be a need of society. NGOs and a feed user identified the need to secure the supply of food using certain production methods (e.g. GM-free, organic and locally-produced) so that consumers can choose, and avoid certain production methods if they wish.*

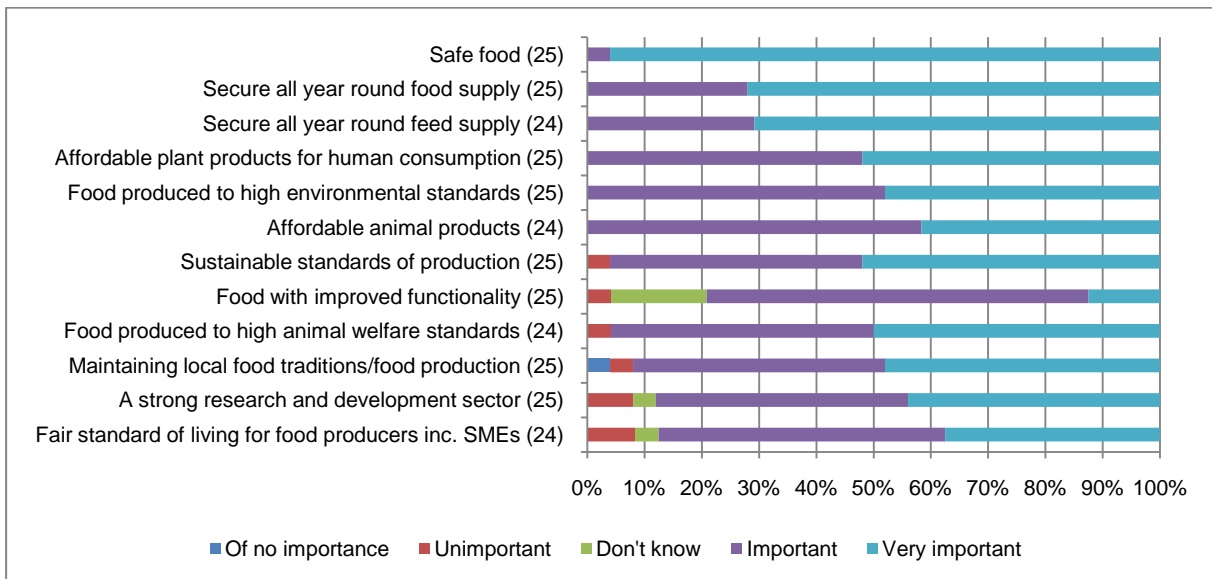


Figure 2.1: Competent Authority response: identification of the perceived food needs of EU society (i.e. consumers, food producers and technology providers)

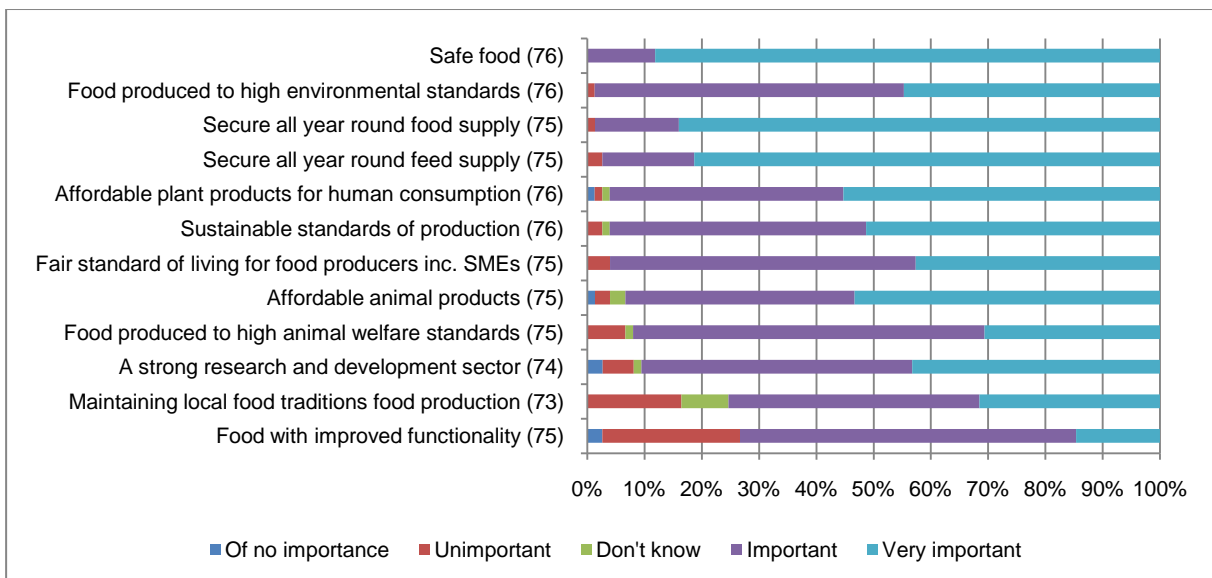


Figure 2.2: Stakeholder response: identification of the perceived food needs of EU society (i.e. consumers, food producers and technology providers)

The Greek Competent Authority said that the legislation is very inconsistent in terms of ensuring sustainable standards of production and in terms maintaining local food traditions and ways of producing food. One Competent Authority (Latvia) commented that the EU GM legislation is very inconsistent in terms of providing safe food. However, 15 Competent Authorities believed that the legislation is very consistent with this aim while a further 7 noted that the legislation is consistent with this need (Figure 2.3). This combined figure of 22 (88%) compares to 76% amongst stakeholders.

A comparison between Competent Authority and stakeholder responses (Figure 2.4) reveals that stakeholders typically have more concerns about the extent to which the legislation meets food needs compared to Competent Authorities. For example, only in the cases of maintaining local food traditions and ways of producing food and of ensuring a fair standard of living for farmers did less than 50% of Competent Authorities report that the legislation is either consistent or very consistent with identified food needs and in the latter case 9 (36%) responded “don’t know”⁵.

A majority of stakeholders stated that the legislation is either inconsistent or very inconsistent in terms of providing secure all year round livestock feed supplies, a strong research and development sector (in both cases the legislation was seen as being particularly inconsistent), a fair standard of living for food producers, sustainable standards of production or food with improved functionality. *Generally speaking, technology providers found the legislation relatively consistent. NGOs and feed processors found the legislation relatively inconsistent, particularly in areas of specific interest to them (for example, sustainability for NGOs and feed supply for processors).*

There is typically greater uncertainty in the Competent Authority responses which might reflect a greater likelihood that stakeholders hold more polarised viewpoints.

The legislation is considered reasonably consistent by Competent Authorities and stakeholders in terms of the top food need that they identified in Figure 2.1 and Figure 2.2, i.e. safe food. However, this was not the case with respect to the need to secure all year round food or feed supplies, although stakeholders appeared more concerned relative to Competent Authorities. There is more concern in both cases with regard to the supply of feed than there is with regard to the supply of food.

Comments from a feed producer and a feed user suggested that the current legislation is not consistent with affordable feed or competitive livestock production. Some stakeholder comments suggested that the current legislation is not consistent with labelling demands and the aforementioned need to support certain production methods (in order to enable consumer choice) such as organic.

⁵ Probably because this aim, although set out in the Treaty of Rome, is somewhat subjective.

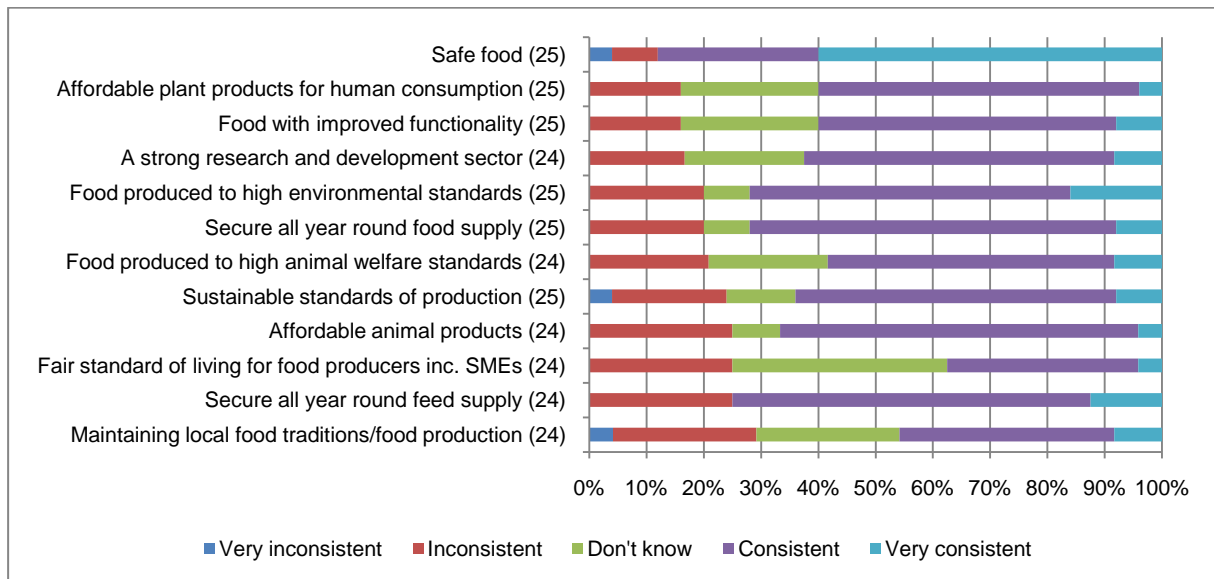


Figure 2.3: Competent Authority response: the extent to which EU GM food and feed legislation is consistent with these needs

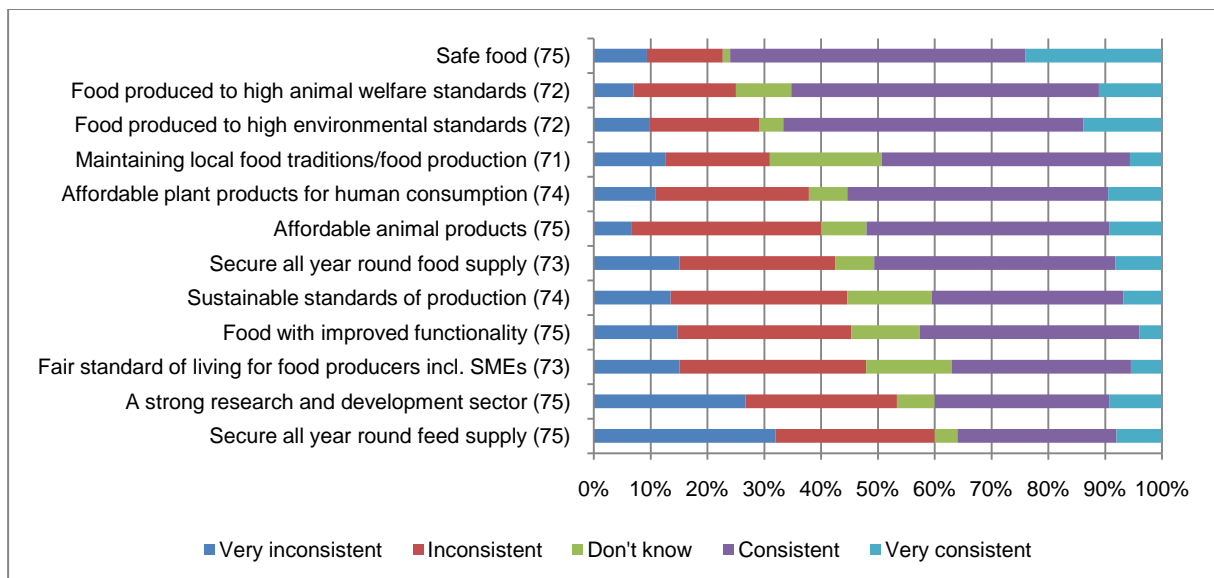


Figure 2.4: Stakeholder response: the extent to which EU GM food and feed legislation is consistent with these needs

2.3.2. Agreement with and implementation of the stated aims of the GM legislation

Competent Authorities agreed with the stated aims of GM legislation, although this agreement was noticeably less firm with regard to the effective functioning of the single market where 40% of Competent Authorities responded “slightly agree” (Figure 2.5). Stakeholders broadly agreed, with at least 70% strong agreement in all cases (Figure 2.6) and *consensus among the different stakeholder groups*. 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.

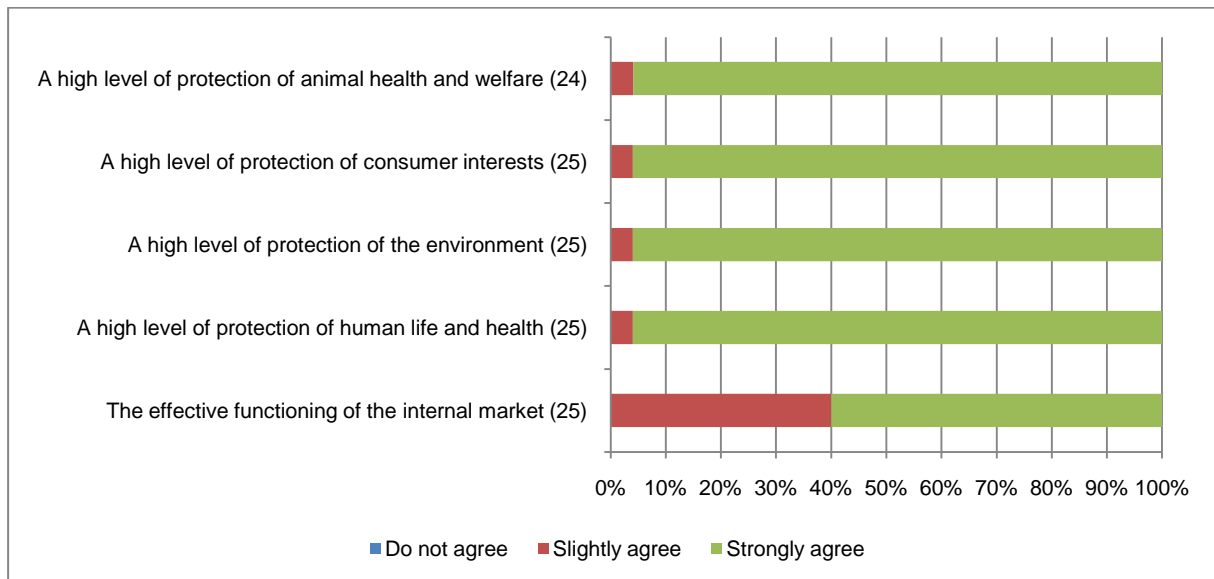


Figure 2.5: Competent Authority response: level of agreement/disagreement with the stated legislative objectives

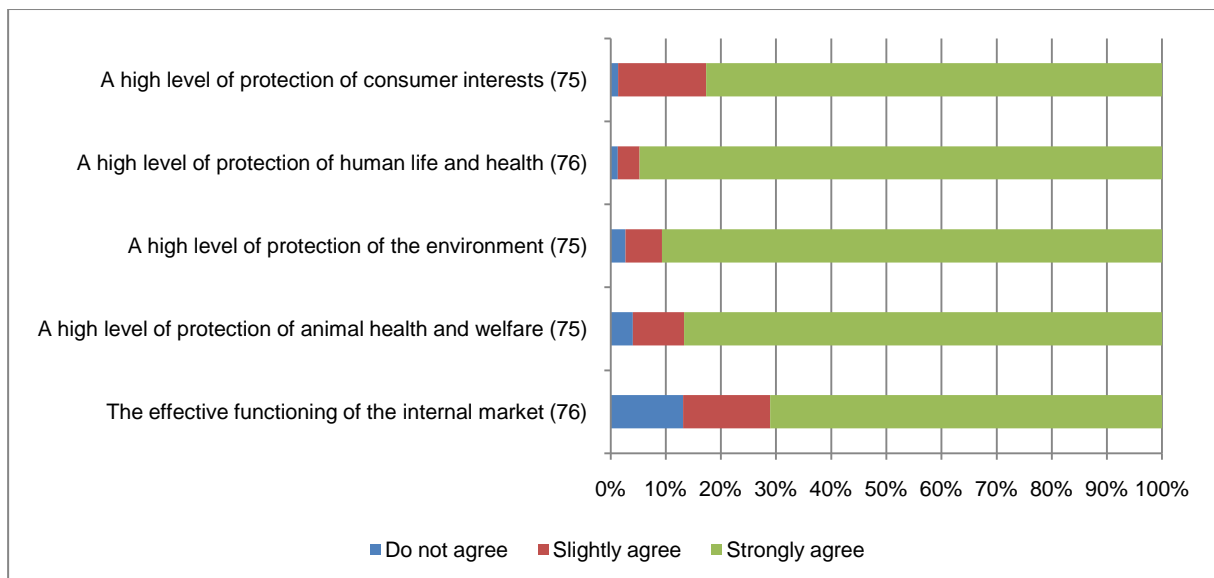


Figure 2.6: Stakeholder response: level of agreement/disagreement with the stated legislative objectives

No Competent Authorities felt that the implementation of the GM legislation greatly hinders the achievement of its objectives. This was not the case for the stakeholder sample where at least 10% selected this option with respect to each objective. *NGOs and consumer organisations in particular thought the current implementation hinders all objectives except the functioning of the internal market. Technology providers were generally more positive, as were feed processors with the exception of the facilitation of the internal market.*

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.

There was generally much less confidence in the implementation of the legislation to enable objectives to be met amongst the stakeholders. *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 effects are not assessed and the assessments rely on the applicant's data.*

Two Competent Authorities (Italy and Hungary) raised concerns that the risk assessment process does not adequately consider the potential for long-term impacts on human and animal health or the environment. The Hungarian Competent Authority noted that they would send a detailed explanation of their concerns to the European Commission. The Italian Competent Authority also noted that, whilst there have been no major negative impacts in terms of the functioning of the single market, the high cost of implementing traceability requirements should be acknowledged. This response also explained that the low availability of non-GM feed material (especially soybean) has impacted negatively on feed supply in the EU. The UK Competent Authority noted that delays in the authorisation of GMOs in the EU and a failure to date to agree on a workable approach to the Low Level Presence of unauthorised GMOs have resulted in a degree of trade disruption which is contrary to the consumer interest and drives up prices⁶. With regard to consumer interest, the Belgian Competent Authority noted that the protection of consumer interests could be improved through the development of an EU framework and criteria for “GM-free” labelling. This view was also expressed by the French Competent Authority. The Danish Competent Authority added that some Danish consumers would like to see the current labelling regime extended to cover livestock products.

⁶ The Belgian Competent Authority added that the effective functioning of the single market is also hindered by the use of the safeguard clause by certain Member States, although this refers to cultivation rather than food and feed.

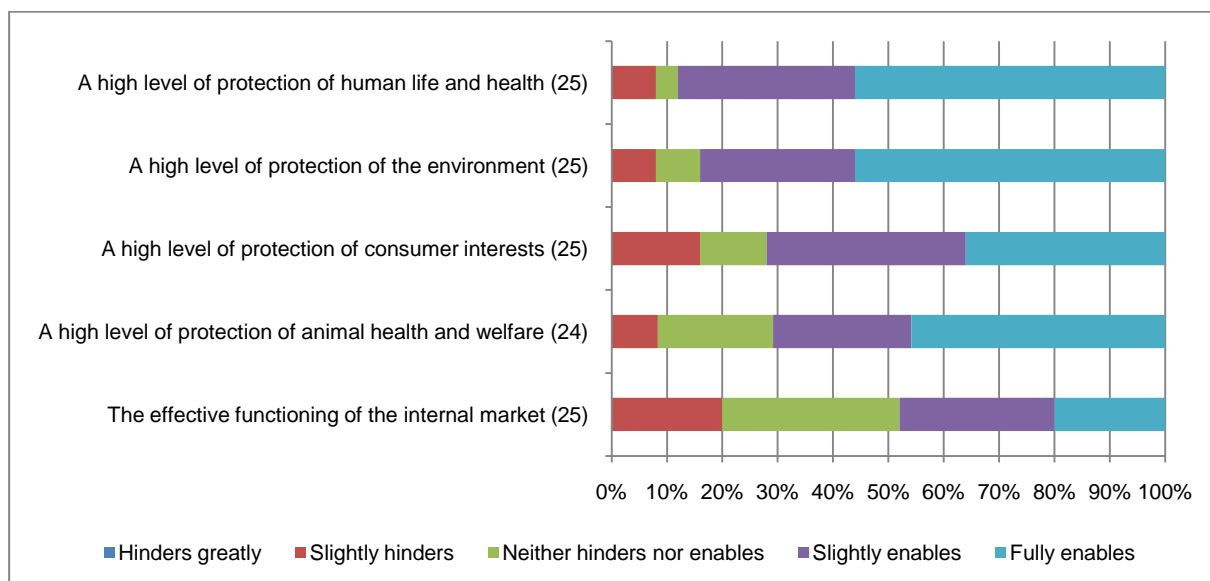


Figure 2.7: Competent Authority response: the extent to which the implementation of Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003 enable their objectives to be achieved

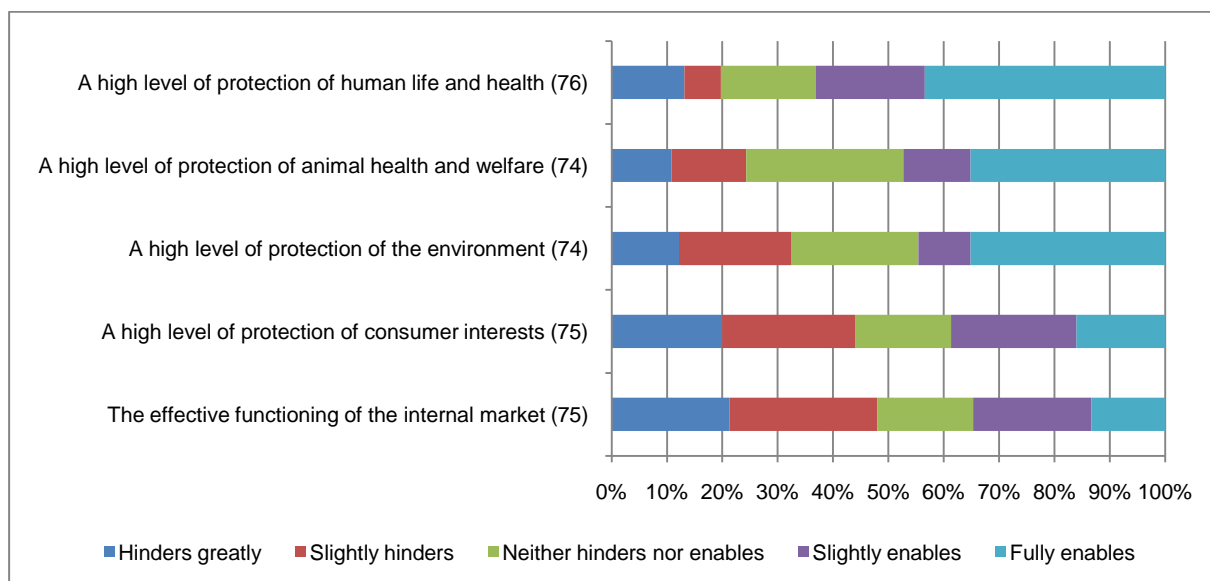


Figure 2.8: Stakeholder response: the extent to which the implementation of Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003 enable their objectives to be achieved⁷

Stakeholders from the food, feed and technology provision industries identified some legislative barriers in some Member States. 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 and coexistence measures were also cited as barriers by some

⁷ Respondents answering “don’t know” were included in the “neither hinders nor enables” category.

respondents. 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.

Respondents were asked whether the current legislation is adequate with regard to food and feed to allow the potential benefits of future GMO traits⁸ to be realised in the EU (Table 2.2). Nineteen Competent Authorities (76%) responded that the legislation is either adequate or entirely adequate. In contrast, just 41% of stakeholders agreed with this. Four Competent Authorities (16%) and 38% of stakeholders felt that the legislation is inadequate with a further 12% of stakeholders noting that the legislation is entirely inadequate; again, stakeholders took a more polarised position than the Competent Authority.

Different stakeholder groups had different attitudes towards the 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. On the other hand, the majority of feed and food industry respondents considered the legislation inadequate to allow the benefits of future traits to be realised. The reasons 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 irrelevant as, based on past experience, they believe it unlikely that radically new traits will be developed by the industry.

Table 2.2: 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%

Competent Authorities who found problems with the current legislation were asked to specify these. Six of the eleven which did cited the lengthy decision making process, i.e. risk management, although this is a generic problem and is not unique to the potential authorisation of future GMOs. There was no suggestion from these Competent Authorities that future GMOs would be at any particular disadvantage under the current legislation. The Hungarian Competent Authority also noted that there would be no differential impact for potential future GM events, but once again noted that the current system does not offer an adequate assessment of risks, especially longer-term ones.

The French Competent Authority noted that the current legislation, being focused on risk assessment, is not naturally suited to deal with GM events which might provide benefits specifically for consumers or the environment, although it is possible for the risk manager to consider these issues alongside the outcome of the risk assessment. The point was made that the establishment of socio-economic criteria

⁸ Such as those developed to provide nutritional advantages compared to natural foods such as higher content of certain nutrients and those developed to address adverse agronomic conditions such as drought tolerance or salt tolerant varieties.

would allow a better appreciation of the overall advantages and disadvantages of submitted applications.

The Belgian Competent Authority explained that a longer nutritional and toxicity test might be appropriate for GM events offering nutritional benefits and that a careful assessment of the invasiveness of GM events with potential climate change benefits would be necessary.

Finally, the German Competent Authority explained that there is a lack of acceptance of the current legislation by policy makers and consumers.

2.4. The risk assessment and regulatory approval process

2.4.1. The current system compared to the pre-2003 system

Despite the perceived inadequacies of the legislation, 17 Competent Authorities (68%) reported that the current system is more suitable than the pre-2003 system, 3 (12%) that it is less suitable with 5 (20%) answering “don’t know”. In most cases “don’t know” reflects the fact that the Member State concerned had not been part of the EU prior to the introduction of the current legislation and could therefore not make a comparison. Stakeholder views were fairly similar with 61%, *disproportionately feed processors*, noting that the current authorisation process is more suitable than the system in place prior to 2003 whilst only 17% felt that it was not. In this instance the high proportion of those answering “don’t know” (22%) should be acknowledged. *Feed users in particular stood out as being uncertain on this point.*

The centralised procedure for authorisation was noted by eight Competent Authorities as being an improvement on the previous situation. The same number explained that covering both GM food and feed within the same Regulation is more suitable. Other advantages of the current legislation 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.

The Austrian Competent Authority noted that the current system is inferior to the previous one because the centralisation of the authorisation process does not allow regional aspects to be taken into consideration and therefore allows for only limited Member State responsibility. The Lithuanian and Slovakian Competent Authorities also stated that the previous legislation was more suitable, but neither provided an explanation.

Stakeholders who considered the post-2003 system to be more suitable generally than that which it replaced commented that the system was, in principle better, and that centralisation and the inclusion of feed as well as food were positive changes. However, *all types of stakeholders* reported that the actual implementation of the legislation, and the fact that not all Member States adhere to it are problems with the current system.

2.4.2. Tools and guidelines available for carrying out risk assessment

Survey respondents were asked to consider the extent to which the tools and guidelines available for carrying out risk assessment are considered satisfactory. Fifteen Competent Authorities (63%) felt that the tools were satisfactory (38% of stakeholders) while two (8%) considered that they were excellent (7% of stakeholders). Four Competent Authorities (17%) noted that the tools were unsatisfactory (12% of stakeholders). No Competent Authorities considered the tools a failure, although this was the position of 12% of stakeholders. Almost a third of stakeholders answered “don’t know”, which probably suggests an unfamiliarity with these tools amongst those companies/organisations who do not need to involve themselves with this level of detail; *a significant proportion of these “don’t knows” came from feed processors and traders who commented that it was*

not within their domain. In contrast, only three Competent Authorities (13%) felt unable to take a position on this question. *As might be expected a priori, the vast majority of technology providers considered the tools satisfactory, while all NGOs considered them unsatisfactory.*

Stakeholders who found the tools and guidelines unsatisfactory commented on the lack of long-term assessments, the absence of guidance for dealing with anomalies, the poor handling of uncertainties and the need for more stringent environment guidelines.

2.4.3. Approach to stacked events

The vast majority (21, 84%) of Competent Authorities believed that it is necessary to complete a **risk assessment** for stacked events where the single events have already been risk assessed in the EU. Where reasons for this view were provided they tended to focus on the possibility for interactions between combinations of single events. One Competent Authority noted that it might become necessary to risk assess all possible crosses with other, already authorised, GM events as part of the risk assessment process.

One Competent Authority (4%) felt that a separate risk assessment is not necessary and three (12%) answered “don’t know”. Just under a quarter of stakeholders answered “don’t know” to this question and a slightly higher proportion of stakeholders felt that a risk assessment is necessary (41%) than felt it is not (35%). *Perhaps unsurprisingly, feed processors and technology providers thought it unnecessary to complete a risk assessment for stacked events, while NGOs and consumer organisations took the opposite view.*

Several stakeholders commented that a fast-track or case-by-case system may be appropriate for dealing with stacked events. This will be explored further in section 2.7.1.

Similar responses were elicited when respondents were asked whether **authorisation** for stacked events is necessary where the single events have already been authorised in the EU with 22 Competent Authorities (88%) in favour (44% of stakeholders), although some Competent Authorities indicated that a fast-track procedure might be possible. One Competent Authority (4%) did not believe that a separate authorisation is necessary (35% of stakeholders). Two Competent Authorities (8%) answered “don’t know”, as did 21% of stakeholders. Once again, the responses of different stakeholder groups were generally as might be expected.

Although the majority of Competent Authorities (20, 80%) indicated that their Member State had never voted differently for a GM event when submitted as a single event and when part of a stacked event, five indicated that their Member State had voted differently. Two Competent Authorities indicated that although they had not yet voted differently, they may do so in the future on a case-by-case basis. Three Competent Authorities explained that they voted against a stacked event having voted in favour of the single events because of analytical difficulties with the stacked event which would have implications in terms of the enforcement of legislation. The German Competent Authority indicated that a lack of regional unanimity has resulted in a vote against stacked events where a vote in favour had occurred for the single events.

2.4.4. Overall transparency of current system

Forty-four percent of stakeholders considered the overall system for regulating GM food and feed to be untransparent with 11% considering it very untransparent *with all NGOs selecting one of these options.* In contrast a third of stakeholders (32%) noted that the system was transparent with 7% considering it very transparent (6% answered “don’t know”). *Traders stood out amongst the stakeholders as having a considerably more positive view on transparency.* As a general comment, many stakeholders stated that the regulatory **process** is transparent, but its **implementation**, above all

by Member States, is not. A couple of stakeholders commented that the data used in the risk assessment are not transparent.

2.4.5. Assessment of specific aspects of the authorisation process

Survey respondents were asked to comment on the extent to which specific elements of the authorisation process for GM food and feed are efficient, carried out to clear timescales, transparent and correspond to demonstrated risks in a proportionate manner.

Efficiency

Figure 2.9 and Figure 2.10 show that the EFSA check on dossier completeness is considered to be relatively efficient by both Competent Authorities and stakeholders, *mainly technology providers*. While this is less true of the risk assessment itself, this is still considered relatively efficient by both Competent Authorities and stakeholders compared to the post-EFSA elements of the process, *although not by NGOs*.

Competent Authorities indicated that the most inefficient elements of the process are the European Commission use of the comitology procedure and Member State votes on draft decisions. Stakeholders agreed that Member State voting is inefficient and took a more extreme view of this than the Competent Authorities with more than 40% noting that this element is very inefficient and a further 36% considering it inefficient. *All technology providers considered the voting to be inefficient*. Stakeholders also considered Member State comments on the risk assessment to be relatively inefficient and *there was consensus between different stakeholder groups on this point*, although, in contrast, 14 Competent Authorities (61%) considered this element to be efficient. Generally both groups of respondents considered efficiency to decline post-EFSA, although Competent Authorities suggested that the area of greatest inefficiency resulted from European Commission input with the stakeholders suggesting that Member State areas of input were the least efficient.

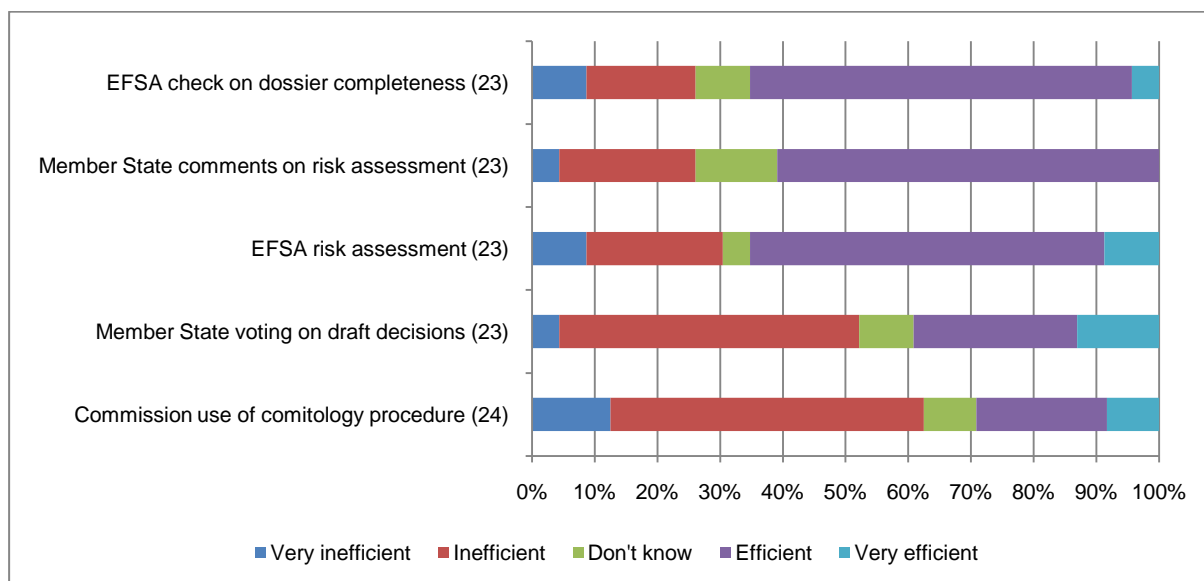


Figure 2.9: Competent Authority response: extent to which specific elements of the authorisation process are efficient

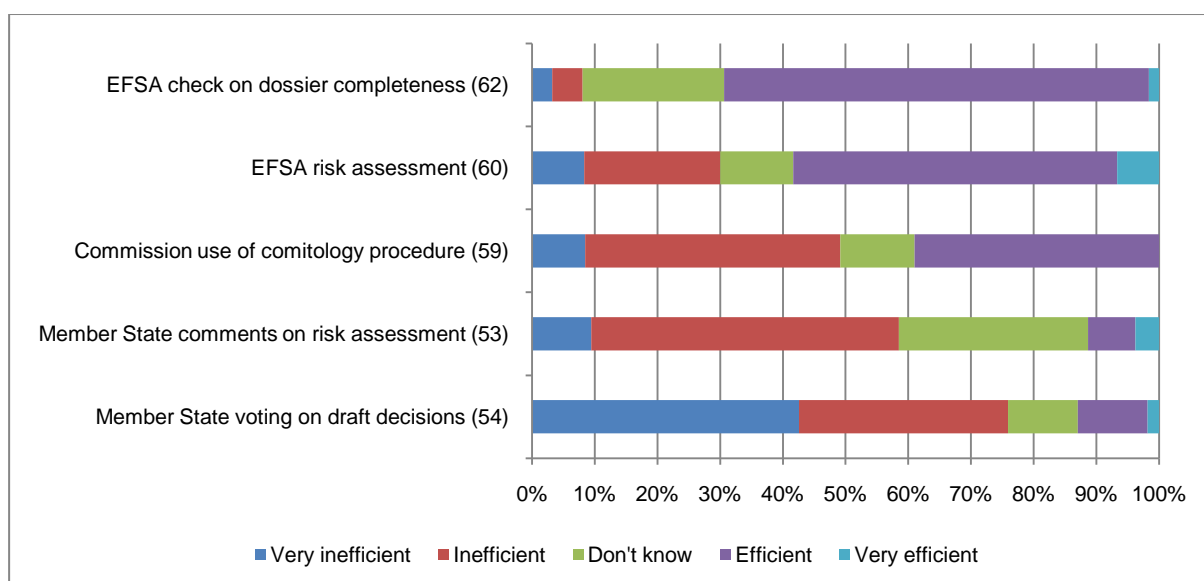


Figure 2.10: Stakeholder response: extent to which specific elements of the authorisation process are efficient

Timeliness

Figure 2.11 and Figure 2.12 illustrate respondent perceptions on the timeliness of the authorisation process. It is notable that Competent Authorities considered the elements of the authorisation process to be generally much timelier than stakeholders did, although 12 Competent Authorities (48%) stated that the European Commission use of the comitology procedure is carried out to an unclear or very unclear timescale.

Very few stakeholders felt that any stage in the process was carried out to a very clear timetable and *generally there was stakeholder consensus on this*. However, just over 40%, including the vast

majority of technology providers, felt that the EFSA check on dossier completeness was carried out to a clear timetable. As previously noted with regard to efficiency, the risk management elements of the process are generally considered less favourably by both groups of respondents than those relating to risk assessment, although two thirds of stakeholders noted that the EFSA risk assessment process has either unclear or very unclear timescales.

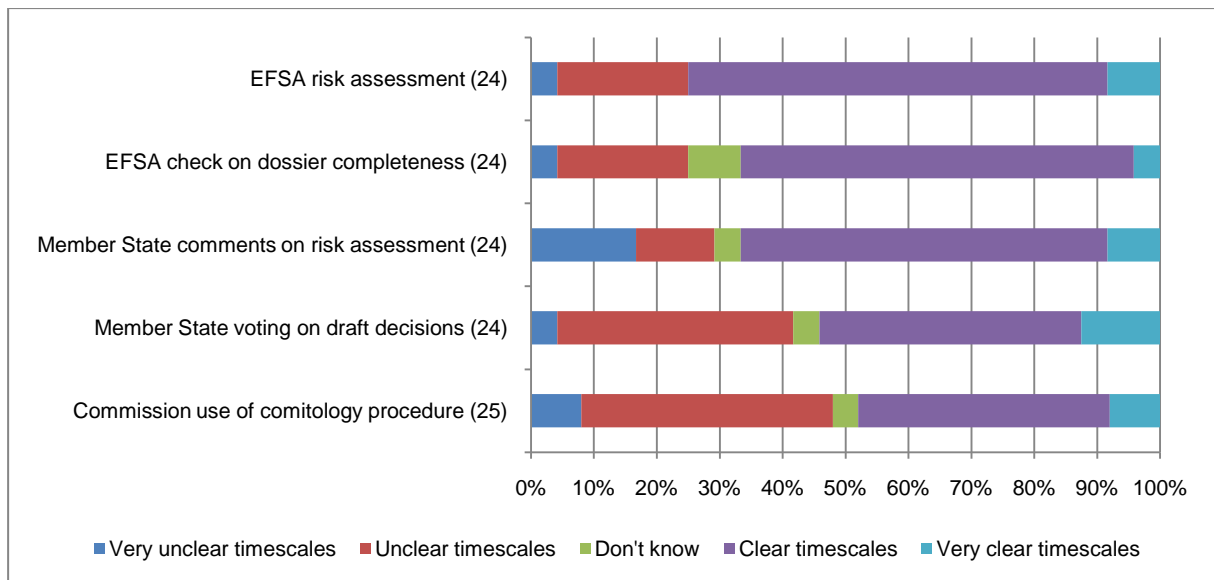


Figure 2.11: Competent Authority response: extent to which specific elements of the authorisation process are timely

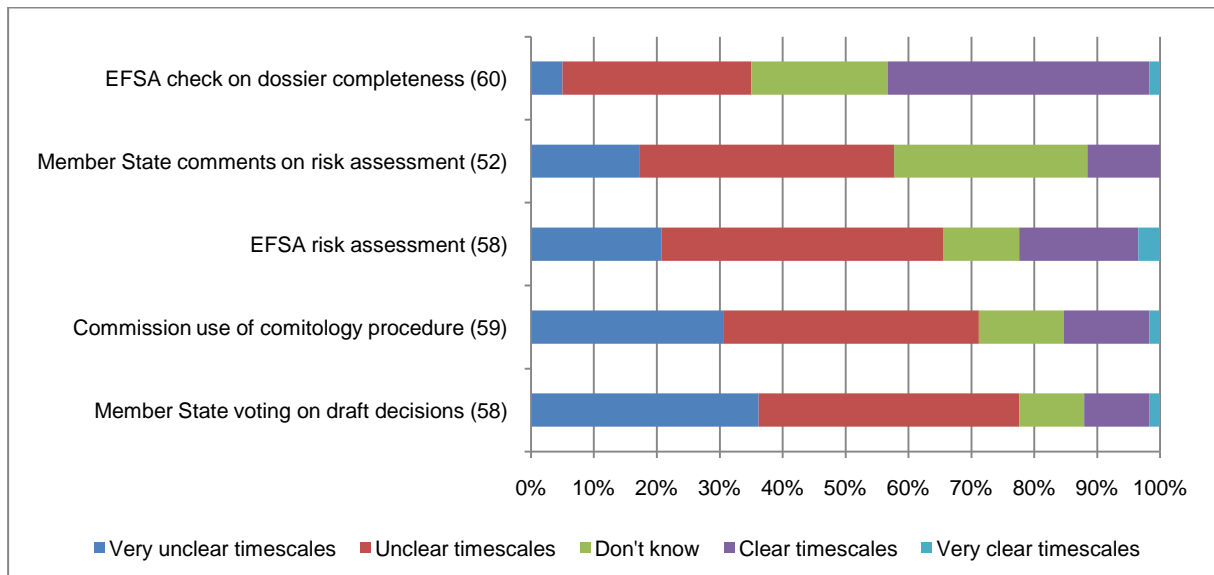


Figure 2.12: Stakeholder response: extent to which specific elements of the authorisation process are timely

Transparency

The extent to which the risk authorisation processes are considered transparent is assessed in Figure 2.13 and Figure 2.14. Again, Competent Authorities provided more positive feedback than stakeholders; at least 16 Competent Authorities (64%) reported that each specific element was either transparent or very transparent. The main element highlighted by the Competent Authorities as being untransparent was the Member State voting on draft decisions. This was also the element considered least transparent by stakeholders where just under a third (29%) felt that it is very untransparent while a further 40% noted that this element is untransparent. While stakeholders appeared to view EFSA’s involvement in the authorisation process as relatively transparent, this was less the case amongst the Competent Authorities. The high level of transparency assigned to Member State comments on risk assessment by Competent Authorities probably, at least to some extent, reflects the respondent’s familiarity with this process. *NGOs and consumer organisations were generally more negative about the transparency of the processes, while technology providers were more positive.*

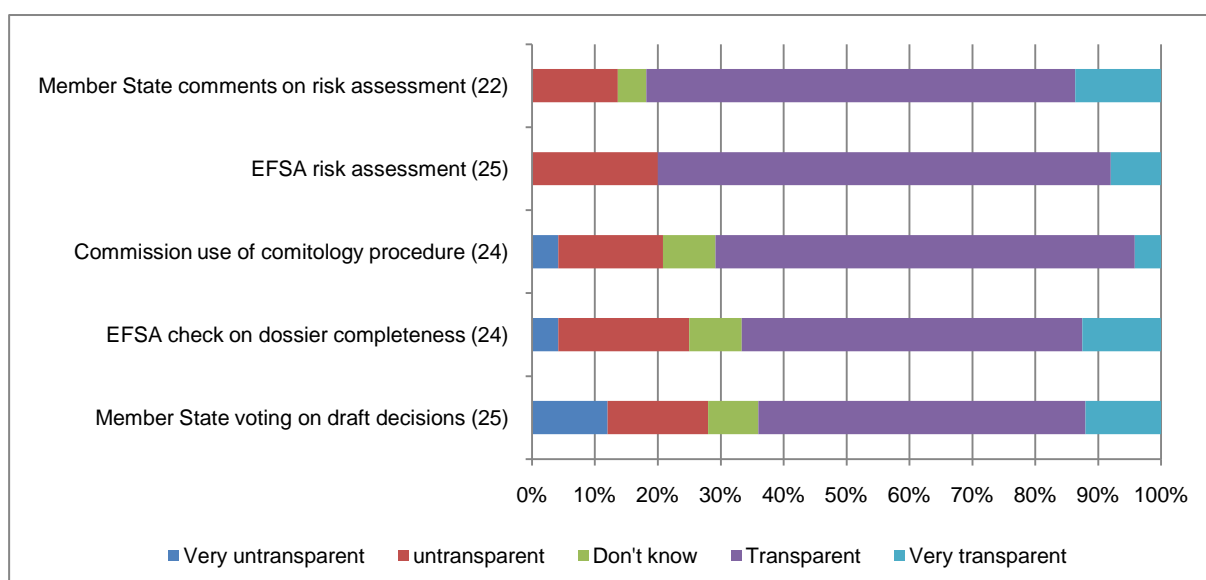


Figure 2.13: Competent Authority response: extent to which specific elements of the authorisation process are transparent

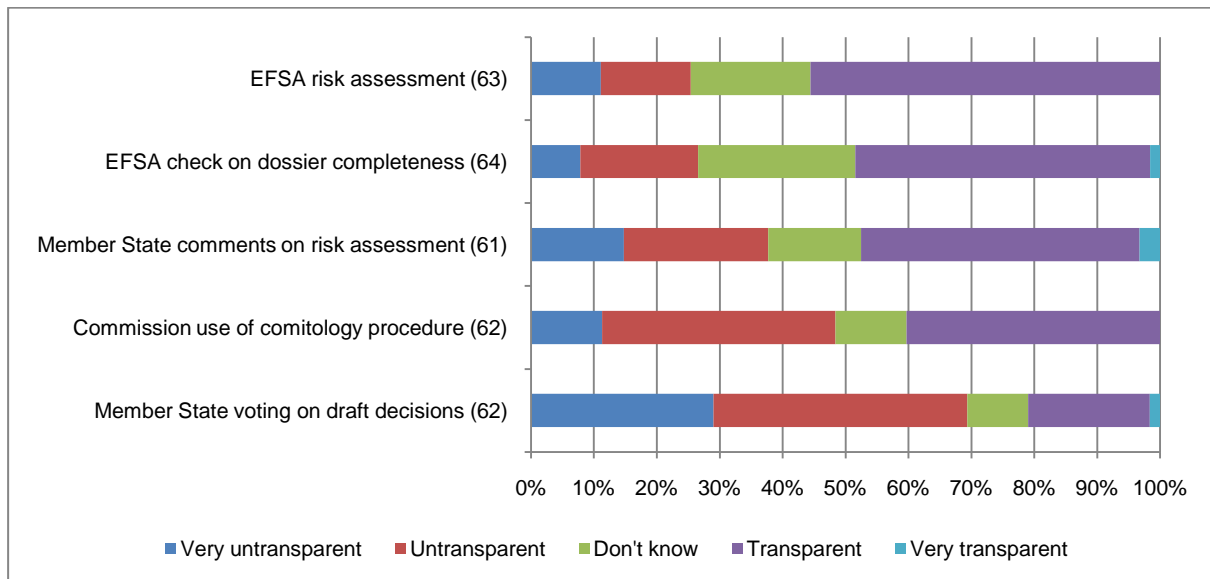


Figure 2.14: Stakeholder response: extent to which specific elements of the authorisation process are transparent

Proportionality

Views on the proportionality of specific elements of the authorisation process are presented in Figure 2.15 and Figure 2.16. It is noticeable here that the proportion of respondents answering “don’t know” is generally higher than for the elements examined previously, especially amongst the stakeholder group.

Few respondents felt that the EFSA check on dossier completeness or the risk assessment were disproportionate, although the large proportion of “don’t know” responses amongst the stakeholders should be acknowledged in both cases. The proportion of respondents finding the elements of the authorisation process either disproportionate or very disproportionate were fairly similar between the two groups, although slightly higher amongst stakeholders who were also more likely to find elements very disproportionate, especially the Member State vote on draft decisions. This element was identified by both groups as being the least proportionate.

Different stakeholder groups had differing views on the proportionality of the processes. NGOs found the dossier completeness check, risk assessment and the use of comitology procedure more disproportionate, but along with consumer organisations they found Member State comments and voting more proportionate. In contrast, technology providers found Member State comments and voting more disproportionate. Feed processors were more likely to find the dossier check, risk assessment and use of comitology more proportionate.

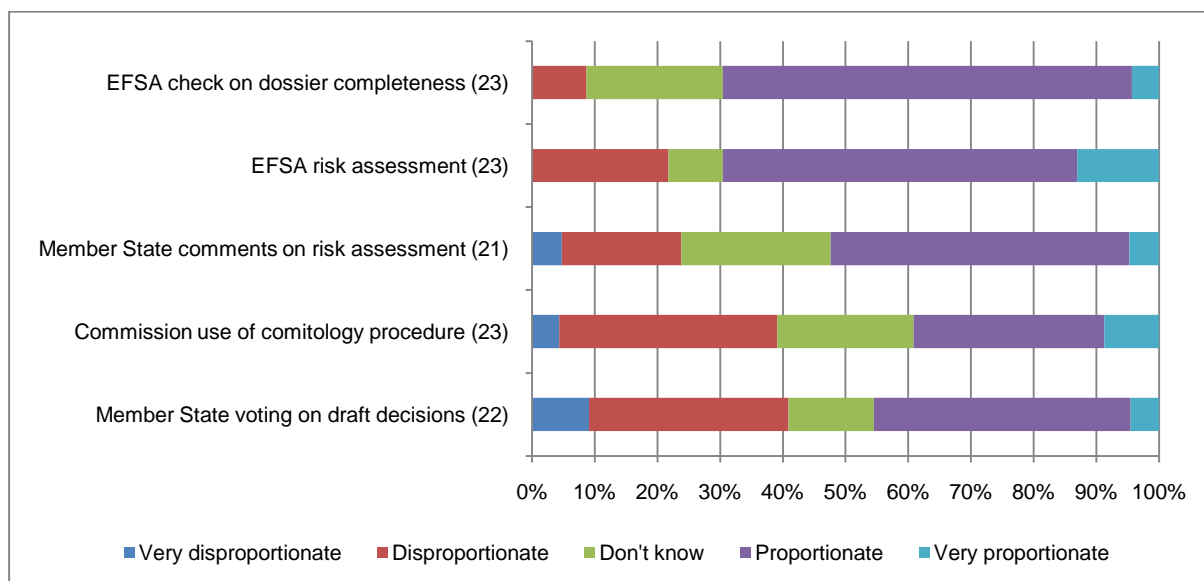


Figure 2.15: Competent Authority response: extent to which specific elements of the authorisation process are proportionate

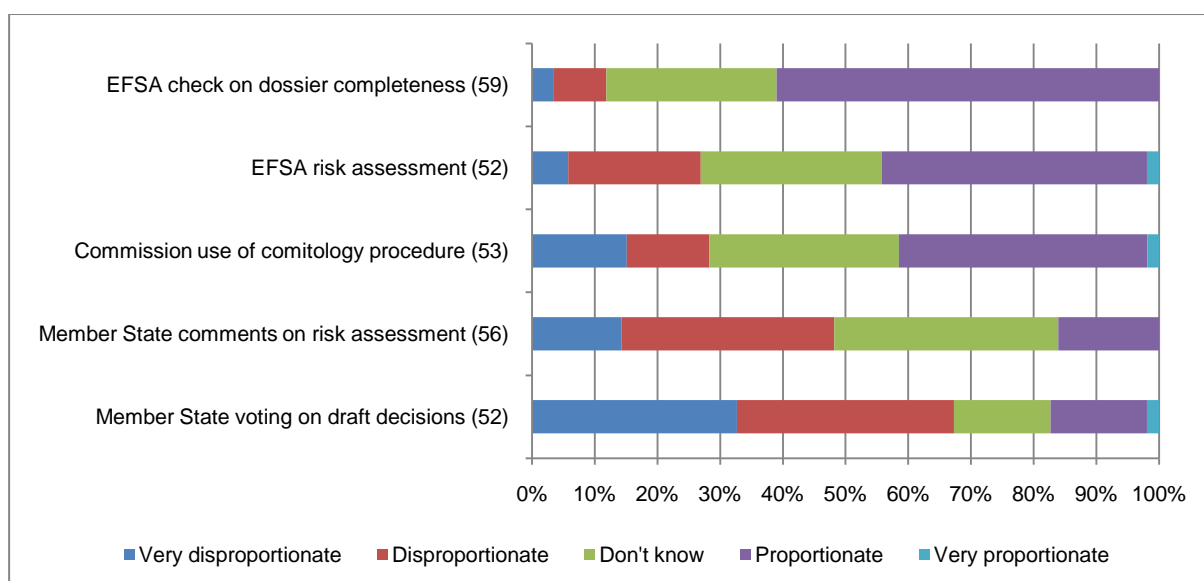


Figure 2.16: Stakeholder response: extent to which specific elements of the authorisation process are proportionate

The preceding analysis reveals that, in general terms, Competent Authorities and stakeholders tend to find EFSA’s check on dossier completeness and risk assessment to be more efficient, timely, transparent and proportionate than the other elements in the authorisation process. However, it is clear that in absolute terms stakeholders do not consider the EFSA risk assessment to be carried out to clear timescales. Views on the European Commission’s use of the comitology procedure and Member State comments on risk assessment and voting on draft decisions were more mixed with stakeholder groups holding different opinions on different elements of the process.

2.4.6. Member State voting criteria

Competent Authorities were asked whether EFSA's risk assessment is the only criterion considered when voting on draft decisions; in the majority of cases (21, 84%), it is not. Fourteen Competent Authorities explained that they also take into account the views of their own national risk assessment. In some cases wider opinions are also considered, for example, in Lithuania parliament, government and public opinion is also taken into account; the Danish and Latvian positions are also determined by parliament. Political factors are an important decision criterion in some Member States including Germany and Italy.

2.4.7. Impact of GM legislation on the evolution of the GM food and GM feed sectors

Respondent views on how the overall legislative framework for GM food and feed has impacted on the evolution of the food and feed sector in the EU are presented in Figure 2.17 and Figure 2.18. The impact in terms of consumer safety was considered positive or very positive by 20 Competent Authorities (80%) and just over 50% of stakeholders, although NGOs and consumer organisations did not share this view.

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, although the Danish Competent Authority pointed out that it is difficult to comment on the impact without more products on the shelves. Stakeholders were generally negative about the effect that legislation has had on consumer prices. Just over half (14, 56%) 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.

Responses in terms of Third Country trade; agricultural sector competitiveness and changes in the operation of the supply chain were more similar where relatively high proportions of respondents from both groups noted that the impact of the legislation had been negative. The Danish and Belgian 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. The Dutch Competent Authority added that ultimately this would result in increases in consumer prices. The Hungarian Competent Authority explained that the absence of GM products in Hungary had provided an export advantage for Hungarian exports. The Hungarian and Austrian Competent Authorities explained that the segregation of agricultural supply chains has resulted in price increases for the non-GM segment. The Dutch Competent Authority 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.

The negative impact was more marked among the stakeholders where the proportion feeling that the legislation had had a very negative impact was substantial, *only NGOs stood out as being less critical on this point*. It should be noted that 12 Competent Authorities (48%) and 34% of stakeholders did not know what the impact of the legislation has been on consumer prices which suggests a degree of uncertainty here; the UK Competent Authority explained that it could not comment on the impact on consumer safety, choice or price because of the absence of GM labelled products from the market, a point also made by the French Competent Authority.

Several stakeholders commented 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.

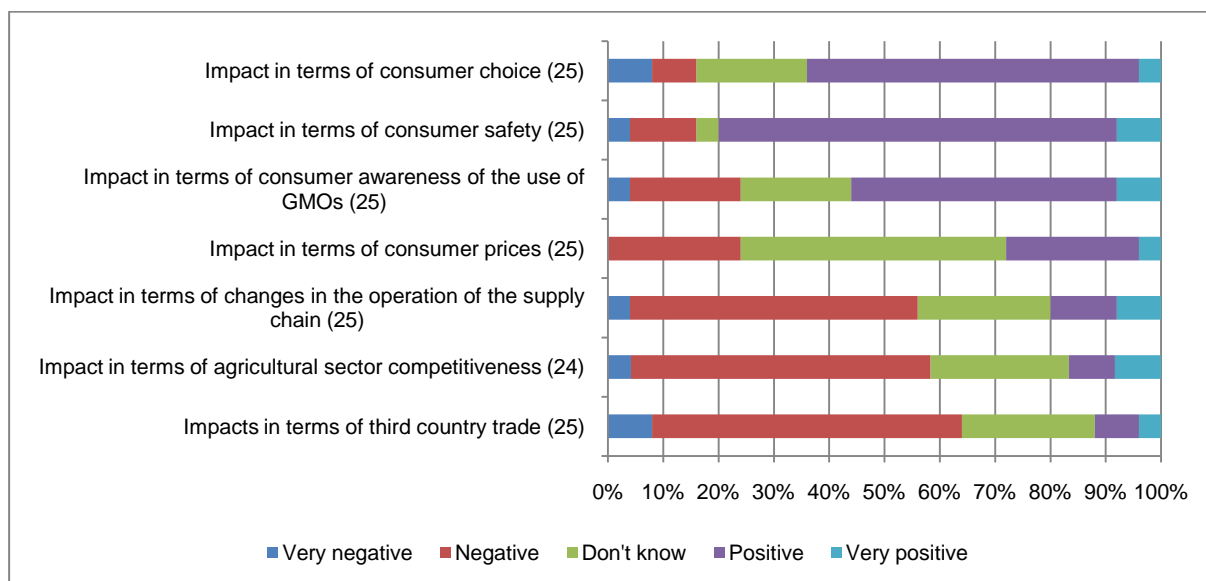


Figure 2.17: Competent Authority response: the impact of the overall legislative framework for GM food and feed on the evolution of the food and feed sector in the EU

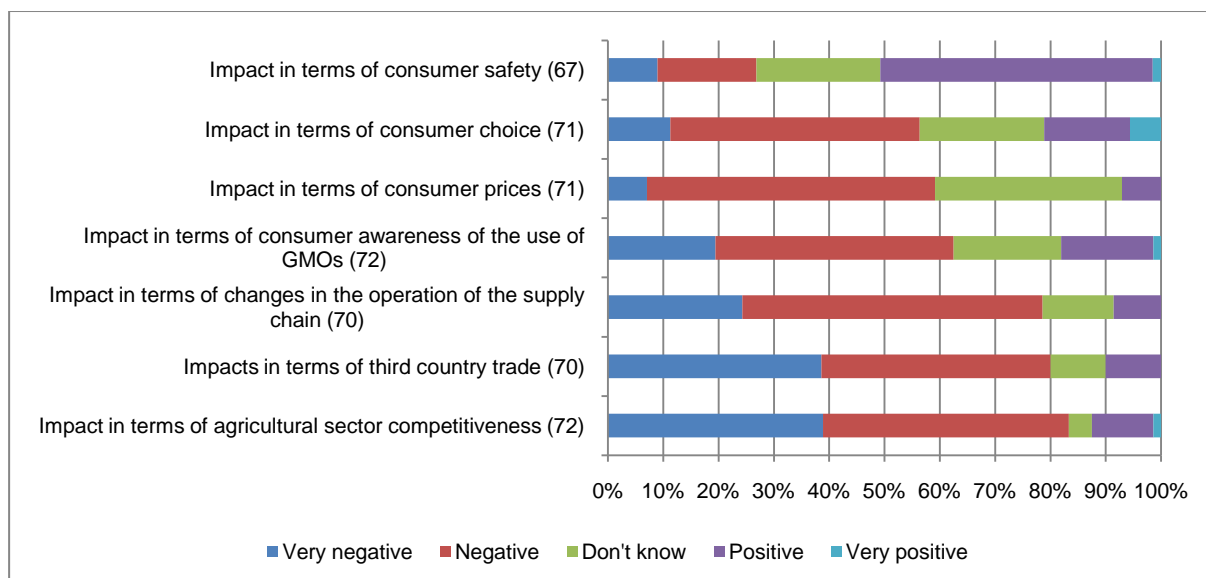


Figure 2.18: Stakeholder response: the impact of the overall legislative framework for GM food and feed on the evolution of the food and feed sector in the EU

2.4.8. Strengths and weaknesses of the EU authorisation system

Respondents were asked about the main strengths and weaknesses of the EU authorisation system (Figure 2.19 and Figure 2.20). Four-fifths of both Competent Authorities (20) and stakeholders noted that centralised risk assessment through EFSA was a strength of the EU system (although there are issues concerning specific elements of the process, see above). *With the exception of NGOs, none of which considered it a strength, all stakeholder groups were in agreement on this point.* One NGO, for example, noted reduced Member State participation and scrutiny and others raised concerns about perceived differences in opinion between EFSA and Member State Competent Authorities. One of the

Competent Authorities which cited the centralised procedure as a weakness was Hungary where concerns were raised about the quality of the risk assessment rather than the centralisation *per se*.

A higher proportion of Competent Authorities noted that specific elements of the process were strengths compared to stakeholders. The area of most concern for both groups of respondents was the (lack of) predictability of the process in terms of time with 12 Competent Authorities (48%) and 64% of stakeholders citing this as a weakness. The Dutch Competent Authority also raised concerns over the time required to deal with each application from submission to authorisation.

The complexity of the process is also seen as being a weakness by the majority of stakeholders (and eight (32%) of Competent Authorities) and half of all stakeholders felt that authorisation through the comitology procedure is a weakness. This position was shared by seven Competent Authorities (28%). The Belgian Competent Authority noted that new concerns are sometimes raised by Member States at the last minute which adds further delay to the authorisation process and the Spanish Competent Authority also raised concerns about interference in the comitology procedure. The Danish Competent Authority held a more nuanced position and noted that although the comitology procedure was inefficient, it does confer legitimacy on the decisions.

The treatment of stacked events was not really seen as a strength or a weakness by Competent Authorities and while more than 40% of stakeholders cited this as a weakness (*including all feed processors and the majority of traders*), 17% answered “don’t know”.

Overall, certain stakeholder groups perceived more negatives than others; the vast majority of feed processors and food industry stakeholders considered authorisation through the comitology procedure and the complexity of the process as weaknesses. Feed processors also saw the predictability in terms of time and the treatment of stacked events as weaknesses, as did traders.

Stakeholders added further comments to justify their consideration of certain aspects as weaknesses. Several commented on a lack of transparency in the comitology process, making it hard to determine whether progress on dossiers is being made. Some stakeholders commented that the European Commission failed to move the dossiers through the authorisation process as foreseen in the legislation. Voting was criticised by various stakeholders, generally as some Member States were not perceived to vote based on science, i.e. on the outcome of the risk assessment. However, some stakeholders, *mainly NGOs*, identified weaknesses in EFSA’s risk assessment; most notably a lack of involvement of Member State Competent Authorities and stakeholders and a lack of independence which results from the data and studies used.

Finally, the Danish Competent Authority noted that there is no simplified procedure for simple cases and stated that this is a weakness of the system.

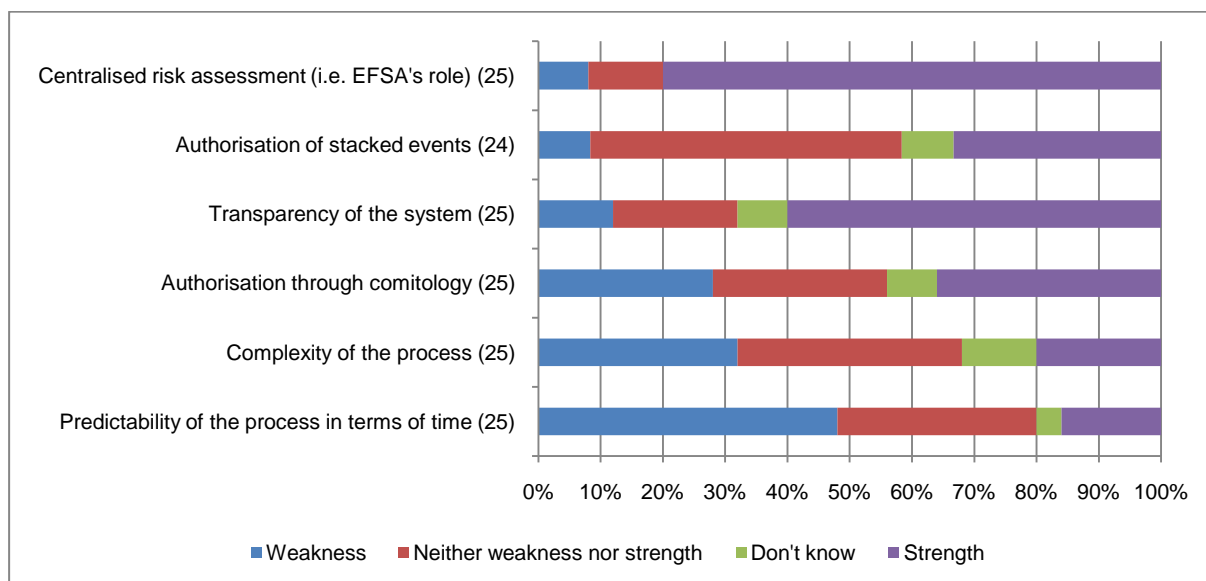


Figure 2.19: Competent Authority response: strengths and weaknesses of the EU authorisation system

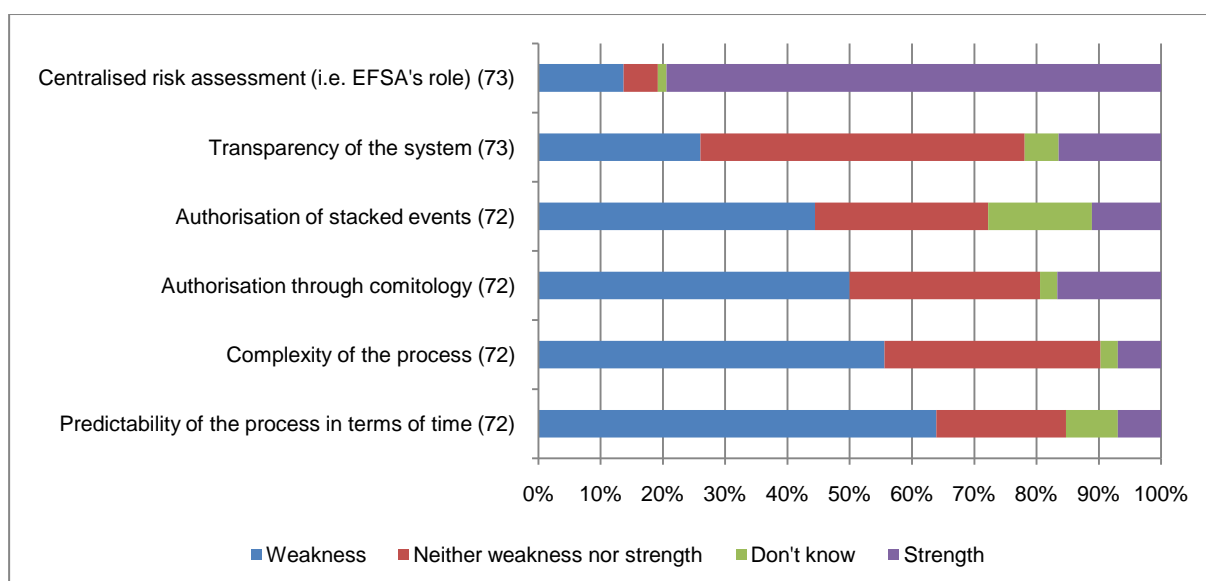


Figure 2.20: Stakeholder response: strengths and weaknesses of the EU authorisation system

2.4.9. Use of and satisfaction with public comments in the authorisation process

Most stakeholders (51%) have not submitted a comment in the context of the authorisation process. Forty percent of stakeholders have submitted a comment and the remaining 9% commented that they did not know whether their organisation had or had not submitted a comment. *NGOs and technology providers had more commonly submitted comments, while the majority of traders and the food industry respondents had not.*

Stakeholders who had never submitted comments generally stated either that following the EFSA risk assessment was outside their mandate, or that they trusted EFSA to carry out a science-based risk

assessment. A few stakeholders said that they had never been asked for comments, implying a lack of awareness of the opportunity to comment.

Little additional information was provided by stakeholders who had submitted comments. A few stakeholders stated that they had submitted more general comments on the authorisation process and not specifically relating to an individual application. *Two NGOs which had submitted comments felt that their comments had been ignored and concluded that the submission of comments is therefore futile.*

A third of stakeholders (32%) commented that they were unsatisfied with the way public comments are currently sought and handled during the authorisation process; 15% were very unsatisfied. *All NGO respondents selected one of these options. In contrast, just 30%, disproportionately technology providers, claimed to be satisfied. Some 23% of stakeholders, including a significant proportion of traders and feed processors answered “don’t know”.*

Several industry stakeholders expressed concern over public comments, as they believed most comments to be politically or emotionally based, rather than science based; the concern was expressed that these may influence the (science-based) authorisation process. On the other hand, NGOs stated that the tight timeframes and lack of access to application data made it impossible to make detailed comments. They also believed that comments were not taken into account.

The role that the submission of public comments plays at the present time in the authorisation process **in terms of the safety assessment** was considered to be unhelpful by 36% of stakeholders and very unhelpful by 13%. *Feed processors and traders were particularly negative about the role of comments with their concerns relating to the perception that comments are not science-based and that they served to weaken EFSA’s opinion and hence slow down the authorisation procedure. A fifth of stakeholders considered the role helpful and 3% very helpful. Consumer organisations were particularly positive about the role of comments, while NGOs were on average more positive than negative. Respondents with a positive perception considered the ability to comment an important part of the process, although several respondents felt that comments were not taken into account. The remaining 28% of stakeholders answered “don’t know”.*

The role that the submission of public comments plays at the present time in the authorisation process **in terms of labelling requirements** was considered unhelpful by 39% of stakeholders and very unhelpful by a further 6%. Fifteen percent of stakeholders commented that this use of public comments was helpful with 12% considering this very helpful. The remaining 27% of stakeholders answered “don’t know”. *Food industry and feed processor respondents were disproportionately negative about the role of comments relating to labelling requirements, while the opinion of consumer organisations tended to be positive.*

2.4.10. Appropriateness of Article 34 to deal with emergency measures

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. Twenty Competent Authorities (80%) and 30% of stakeholders commented that the procedure is appropriate while two (8%) and 3% respectively noted that the procedure is very appropriate. The UK Competent Authority pointed out that this is standard procedure which works well in other areas. Generally stakeholders were more likely to find the procedure inappropriate (17% stakeholders compared to 8% (two) Competent Authorities) or very inappropriate (13% stakeholders, but no Competent Authorities); *however, it should be noted that only feed processors were particularly negative about the Article 34 procedure.*

More than a third of stakeholders (36%), *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. The fact that Competent Authorities were both more likely to provide an answer to this question and the more positive nature of their responses probably reflects the fact that a qualified majority of EU-15 Member States voted for the legislation in place and new Member States implicitly accepted the legislation when acceding to the EU. 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.

A number of Competent Authorities, including Finland and Spain, noted that although the procedure is considered to be appropriate to deal with emergency measures in principle, these are not always appropriately used. For example, the Danish Competent Authority noted that any use of emergency measures should be based on sufficient demonstrated risk; the Netherlands government said that the demonstrated risk should be “serious”, which is not always the case at present. The Belgian Competent Authority explained that the safeguard clause should only be used in the case of new scientific data which had not previously been assessed by EFSA. Finally, the Austrian Competent Authority explained that the procedure is not consistent with the safeguard clauses within Directive 2001/18/EC and the Hungarian Competent Authority noted that Article 23 of Directive 2001/18/EC is more appropriate.

When asked about the timescale envisaged for reaction by the European Commission to emergency measures taken by Member States (10 days), again a large proportion of stakeholders answered “don’t know” (41%). In this case two Competent Authorities (8%) provided the same answer.

Nineteen Competent Authorities (76%) and 42% of stakeholders felt that the timescale of 10 days is about right with 8% and 6% respectively stating that this is not long enough and 8% and 11% respectively that it is too long.

The Danish Competent Authority explained that in the case of a real emergency, a short time scale is important. The UK Competent Authority added that the time required to respond to an emergency situation does depend on the nature and complexity of the situation, but in cases of genuine risk, a 10 day period provides a good mechanism for sharing information between the European Commission and Member States.

2.4.11. Interplay with legislation in other areas

Respondents were asked whether the authorisation procedure for GM food and feed defined by Regulation (EC) No. 1829/2003 is correctly established in terms of the interplay with the legislation applying in other areas as set out in Table 2.3. The main point to note is that a large proportion of respondents, particularly stakeholders, did not feel able to provide an answer, probably because their remits do not cover these other sectors. The proportion of Competent Authorities and stakeholders who considered that the GM authorisation procedure was not correctly established was the same at 8% (two Competent Authorities) with regard to food additives and was comparable at two Competent Authorities (8%) and 9% stakeholders with regard to feed additives. However, as a result of the proportion of stakeholders which responded “don’t know”, the proportion of Competent Authorities which noted that the interplay was correctly established amounted to a much higher proportion of 21 (84%) with respect to both food and feed.

In all cases a majority of Competent Authorities felt that the interplay was correctly established whereas a majority of stakeholders felt that the interplay with regard to seed and plant propagating material was not correctly established. Many stakeholders identified the lack of a threshold for adventitious presence in seeds as the problem with the interplay. *With the exception of seed and plant propagating material, technology providers stood out as being very positive about the interplay between GM food and feed and other legislation.*

Some stakeholders commented that the legal uncertainty relating to GMOs in feed additives was a problem. With regards to plant protection product legislation, many stakeholders commented that interplay with cultivation legislation is more important than interplay with GM food and feed legislation.

Table 2.3: Stakeholder response: the extent to which the authorisation procedure for GM food and feed is correctly established in terms of the interplay with the legislation applying in other areas

	Competent Authorities			Stakeholders		
	Yes	No	Don't know	Yes	No	Don't know
Food additives	21 (84%)	2 (8%)	2 (8%)	59%	8%	33%
Feed additives	20 (83%)	2 (8%)	2 (8%)	43%	9%	48%
Plant protection production active ingredients	11 (46%)	6 (25%)	7 (29%)	46%	10%	43%
Seed and plant propagating material	17 (74%)	2 (9%)	4 (17%)	18%	37%	46%

Note:

Rows do not always sum due to rounding.

The Belgian and Austrian Competent Authorities felt that the risk assessment for GMOs and for plant protection products under Directive 91/414/EC should be more harmonised. 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; a view 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.

2.4.12. The consequences of asynchronous authorisation

Competent Authorities were asked to set out the main consequences arising from asynchronous authorisations for their Member State. Nine commented that asynchronous authorisation results in a shortage of supply of feed raw materials and that this has implications for prices. The Spanish Competent Authority considered the impact in Spain to be particularly acute due to the dependence of the livestock sector on imported feed. The UK Competent Authority added that there may also be inconsistencies in that livestock products imported from Third Countries may have been fed on GM raw materials which are not yet authorised in the EU and that this might disadvantage UK livestock producers.

Eight Competent Authorities noted the problems caused by Low Level Presence (LLP) which manifest themselves in terms of additional control requirements and cost for both private actors (ports) and public authorities. Ultimately this results in higher prices for the national feed sectors. The Belgian Competent Authority explained that the measures taken in the case of identified LLP, i.e. the blocking of goods, recall operations, destruction of material or the sending back of material may be considered

disproportionate to the risk and involves significant cost; the Austrian Competent Authority also mentioned the cost implications. The Finnish Competent Authority added that the measures taken and their rationale are difficult to explain to consumers.

The Bulgarian Competent Authority raised the potential for fraud in terms of the use of false certificates to allow the import of not yet authorised GM events; this would deny the consumer the opportunity to exercise an informed choice.

The Competent Authorities in Hungary, Latvia and Estonia reported that there had been no direct impacts in their respective countries arising from asynchronous authorisation to date.

Generally Competent Authorities felt that the impacts of asynchronous authorisation in the EU as a whole would be the same as the consequences in their Member State, but on a larger scale. The Netherlands noted that asynchronous authorisations can lead to shortages of certain commodities which will ultimately affect the competitiveness of the EU food and feed sectors resulting in job losses and higher consumer prices. Some of those Competent Authorities which had not reported a national impact from asynchronous authorisation did note that the EU as a whole might experience supply shortages of feed raw materials, for example, Latvia and Estonia.

The French Competent Authority added that in addition to the problems experienced at the national level, different approaches to asynchronous authorisation might result in some unfair competition between operators from different Member States which might ultimately result in new barriers to trade.

The majority of stakeholders identified negative impacts on the EU food industry (*in particular the livestock and associated industries such as feed processing*) as a main consequence of asynchronous authorisations. More specifically, asynchronous authorisation was seen to result in fewer sources for imports, higher raw material prices and the production of meat overseas (possibly fed on non-EU authorised GMOs), in turn leading to higher risk in meat products. A few respondents believed that LLP findings for events which have passed the EFSA risk analysis were leading to scientifically unsubstantiated food scandals.

Stakeholders generally believed the risk of negative impacts from asynchronous authorisations to be increasing. Some stakeholders foresaw negative future effects on the use of GMs from asynchronous authorisations, leading to the EU being left behind Third Countries; one stakeholder speculated that the asynchronous authorisation problem could end up moving key decision making in the GM field outside the EU.

That said, a few stakeholders, *led by NGOs*, did not see negative consequences. Several commented that the term “asynchronous authorisations” is misleading. One stakeholder believed that the EU should insist on better Identity Preservation systems because Third Countries will want access to the (sizeable) EU market. One stakeholder commented that there had been no negative effects to date, and another commented that maintaining zero tolerance will force the US to adjust its policy as Brazil and Argentina consider the status of GM event authorisation in export markets prior to authorisation (the so-called “mirror policy”). These stakeholders anticipate problems from the removal of zero tolerance.

Unless there are changes to the current authorisation system, more than two-thirds of stakeholders (68%) expected these issues to increase in magnitude compared to just 3% (*consisting only of NGOs*) who noted that they would stay about the same and 29% who expected them to decrease in magnitude.

2.5. The compulsory labelling of GM food and feed

2.5.1. Perceptions of the current labelling regime

Respondents were asked a series of questions on consumer understanding of labelling provisions and their scope. As Figure 2.21 and Figure 2.22 show, Competent Authorities held a generally more positive view than stakeholders. For example, almost all Competent Authorities (24, 96%) believed that the current labelling provisions facilitate an informed consumer choice; this view was shared by only 57% of stakeholders. However, some ten Competent Authorities (42%) and 45% of stakeholders felt that consumers do not understand or accept the current labelling provisions, which suggests that there is a gap between what consumers need to understand to allow them to make an informed choice and what they actually understand and accept. Four Competent Authorities (17%) answered “don’t know” to this question which underlines the difficulty in understanding consumer perceptions.

Only 27% of stakeholders reported that the current labelling provisions are easy for consumers to understand, although 19 Competent Authorities (76%) held this view. Other large differences in opinion between the two respondent groups with respect to whether labelling avoids the misleading of consumers and in terms of whether the labelling scheme is appropriate. These large differences suggest that some further research could usefully be undertaken to investigate consumer perceptions and understanding of GM labelling.

This finding is borne out by some of the qualitative comments added by some Competent Authorities. For example, the UK Competent Authority noted that consumers tend to have little knowledge or firsthand experience of GM labelling and may not therefore be as knowledgeable as they might be. The UK Competent Authority went on to comment that the vast majority of consumer information in the UK is provided through voluntary labelling by manufacturers and retailers who wish to be more informative. However, depending on the criteria employed by different manufacturers and retailers, consumers may be misled by “GM-free” or non-GM labelling. They added that the current labelling provisions do not allow consumers to avoid foods produced with the use of GMOs, for example, processing aids. Consumers are also unlikely to be aware of the requirement to label/provide a notice regarding GM ingredients used in catering establishments or that GM ingredients may be used. Some consumers may also be unaware of the use of GM raw materials in animal feed used to produce meat, milk and eggs.

The Hungarian Competent Authority pointed out that there may be some consumer confusion over the use of a 0.9% tolerance threshold for adventitious and technically unavoidable presence both for conventional and organic produce. The Bulgarian Competent Authority added that some consumers are not clear about the use of a threshold for adventitious and technically avoidable presence, or why it is set at 0.9%. The Belgian Competent Authority commented that positive labelling means that it is not clear when products are genuinely GM-free and that this might cause some consumer confusion and implies that there are no GM-free products on the market when this is clearly not the case. The Estonian Competent Authority called for the use of a symbol on the front of pack to more clearly communicate GM content; 48% of a representative sample of 500 Estonian consumers supported such a move.

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, at least in Denmark.

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 animal 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 regards 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.

With the exception of facilitating an informed choice, technology providers generally replied “don’t know”, commenting that there is little experience with food labelling due to the small range of labelled products.

Stakeholders from various groups questioned whether consumers pay attention to labels or know enough about GM, and others believed that GM labelling may have a negative impact on consumer acceptance.

Many stakeholders were aware of campaigns relating to the labelling of GM food and feed in the EU as a whole and in individual Member States. Consumer organisations and NGOs were identified as the main drivers of these campaigns. Germany stood out as a Member State with strong campaign activity, including pressure for “GM-free” labelling and for “GM-free” milk. Other Member States with campaigns identified by respondents include: France, Italy (by the ministry), Austria (for “GM-free” milk), Denmark (by consumers, authorities and industry), Greece (by various consumer organisations), Spain (for 0% “GM-free” production) and Romania and Hungary (by consumer organisations).

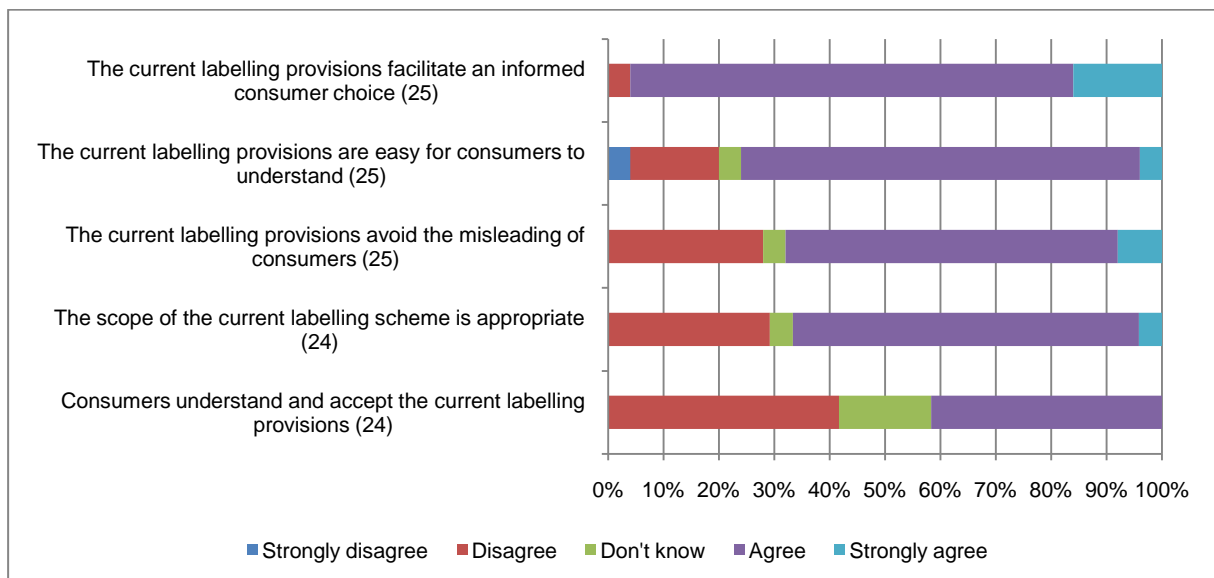


Figure 2.21: Competent Authority response: the extent to which there is agreement with statements relating to consumer understanding of labelling provisions and their scope

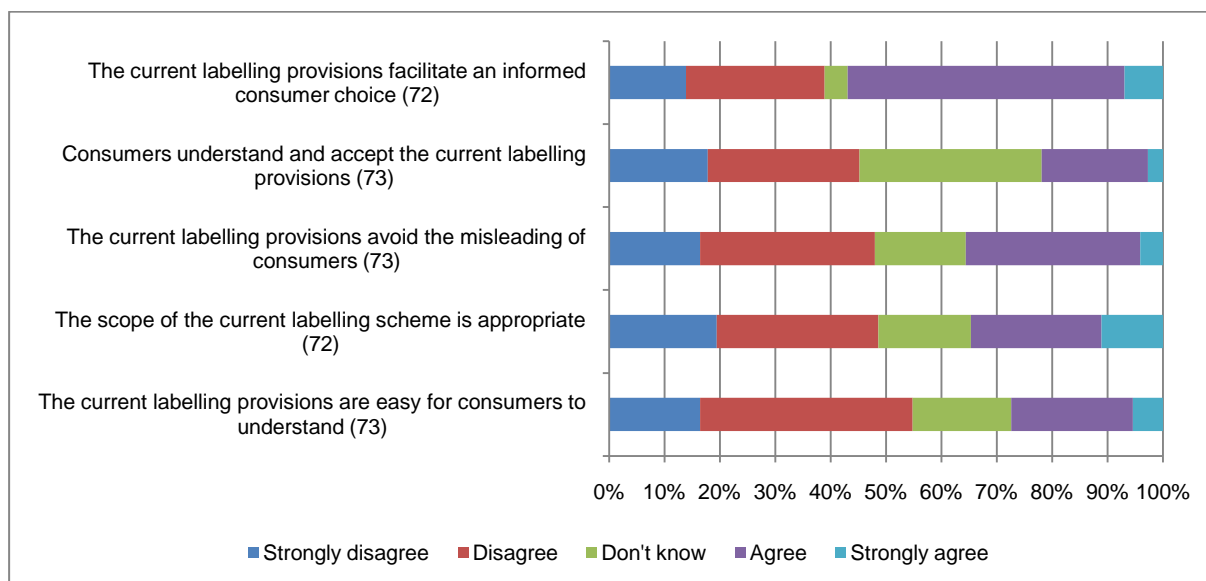


Figure 2.22: Stakeholder response: the extent to which there is agreement with statements relating to consumer understanding of labelling provisions and their scope

2.5.2. Consumer campaigns related to GM food and feed labelling

When asked whether there had been any consumer campaigns related to the labelling of GM food and feed in their Member States, two Competent Authorities noted that there had not been (the Czech Republic and Portugal). The Competent Authorities in nine Member States did not provide an answer which suggests that there have probably not been significant campaigns in these Member States.

The Hungarian and Belgian Competent Authorities explained that while there had been no specific consumer campaigns in their Member States, information on the labelling rules are available on government websites. The Romanian Competent Authority held press conferences, released press releases and produced brochures to support the information available on the government website. A PHARE project entitled “Informed Civil Society: GMOs and Consumer Protection” was carried out in Bulgaria to inform consumers, *inter alia*, on GM labelling. In Cyprus there was an attempt to place GM food on separate shelves in store to make GM status clear to consumers, although it is believed that this was discontinued.

More wide ranging information campaigns have been undertaken in some Member States, for example, Finland, where the Food Safety Authority (Evira) dedicated August 2009 to GM labelling issues within its broader food labelling information campaign. This was considered important because of the lack of labelled GM products on the shelves in Finland which has not allowed consumers to develop familiarity with the approach to labelling. The Danish Veterinary and Food Administration and the Danish Plant Directorate carried out an information campaign in 2004 and the Danish Consumer Council carried out a consumer survey on GM labelling in 2005. The Netherlands has set up a government subsidised foundation (Voedingscentrum⁹) to provide independent, science-based and reliable information about food in general and this has included information on GM food labelling.

The Competent Authorities in Austria, Italy, Sweden and the UK noted that there had been NGO campaigns in their Member States; often these focused on the fact that livestock products are outside the scope of the labelling legislation. The Estonian Competent Authority explained that there had been some articles in the national media.

⁹ <http://www.voedingscentrum.nl/nl/voedingscentrum/english.aspx>.

2.5.3. Costs of controlling current labelling legislation

Competent Authorities were asked to provide the annual costs of controlling labelling provisions, however, most were unable to do this because either the information is not specifically collected or the costs of control are conflated with other activities¹⁰.

Table 2.4 sets out the costs as quantified by those Competent Authorities that were able to do so.

Table 2.4: Costs of controlling labelling provisions

Member State	Cost	Notes
Austria	€75,000	This is the cost of analysing feed samples only. It does not include staff time, nor does it include costs associated with food which are said to be high, but which cannot be specified.
Denmark	€400,000	This cost covers both food and feed.
Finland	€20,000	This is the cost of sampling only, there is also a requirement for one full time employee, but this is not costed.
Lithuania	€79,650 (275,000 Lt)	This is the cost of laboratory analysis only.
Romania	€165,000	This is the cost of laboratory testing only. There are also unspecified salary, sample transportation, equipment, training and other logistical costs.

2.5.4. Costs of implementing current labelling legislation for food

Respondents were asked where they see the main costs of implementing the labelling provisions for food derived from GM plants arising (Figure 2.23 and Figure 2.24). Both Competent Authorities¹¹ and stakeholders agreed that the main costs fell on food manufacturers/processors and importers. *Among stakeholders, traders and feed processors in particular believed the main cost lay with food manufacturers.* Competent Authorities were more likely to report that they would bear costs than were stakeholders where just over 20% stated that Competent Authorities would bear the main cost. Stakeholders were more likely than Competent Authorities to identify consumers as bearers of cost.

Two responses (Hungary and the Netherlands) made the point that the costs tend to arise from the non-GM supply chains. The Hungarian Competent Authority made the additional point that this did not seem equitable given that the suppliers of GM products do not have to bear the costs arising from their presence on the market.

Stakeholders who replied “other” identified organic farmers, social movements and feed producers as the parties bearing the cost.

¹⁰ It should be noted that Regulation (EC) No 1981/2006 implements Article 32 of Regulation (EC) No 1829/2003 on Member State contributions to the costs of the tasks of the Community Reference Laboratory. This contribution is not considered here.

¹¹ Some Competent Authorities made clear that their answers here were based on their perceptions rather than research. This also applies to the next question.

Comments from stakeholders generally fell in one of three categories. Some stakeholders believed that costs would be passed through the chain and would ultimately be paid by consumers. Several stakeholders thought that the food industry would pay significant costs due to the number of changes required such as reformulation, changing labels, testing, and the need to operate Identity Preservation systems. A third group of stakeholders saw labelling cost as being based on Identity Preservation, and hence commented that grain importers would bear a significant cost.

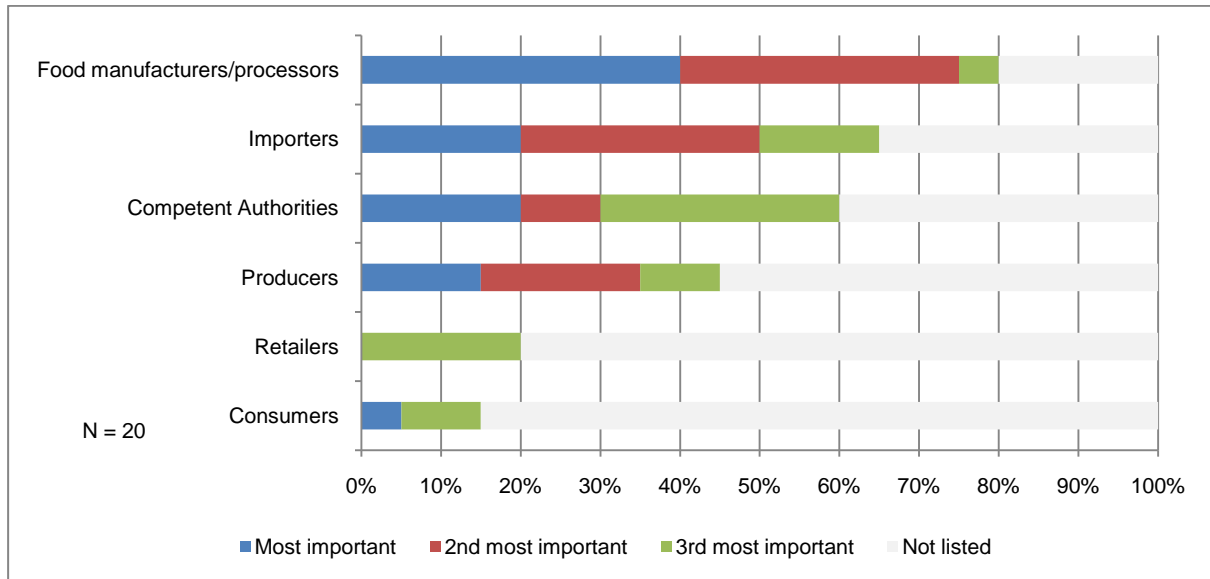


Figure 2.23: Competent Authority response: views on where the main costs of implementing the labelling provisions for food derived from GM plants arise

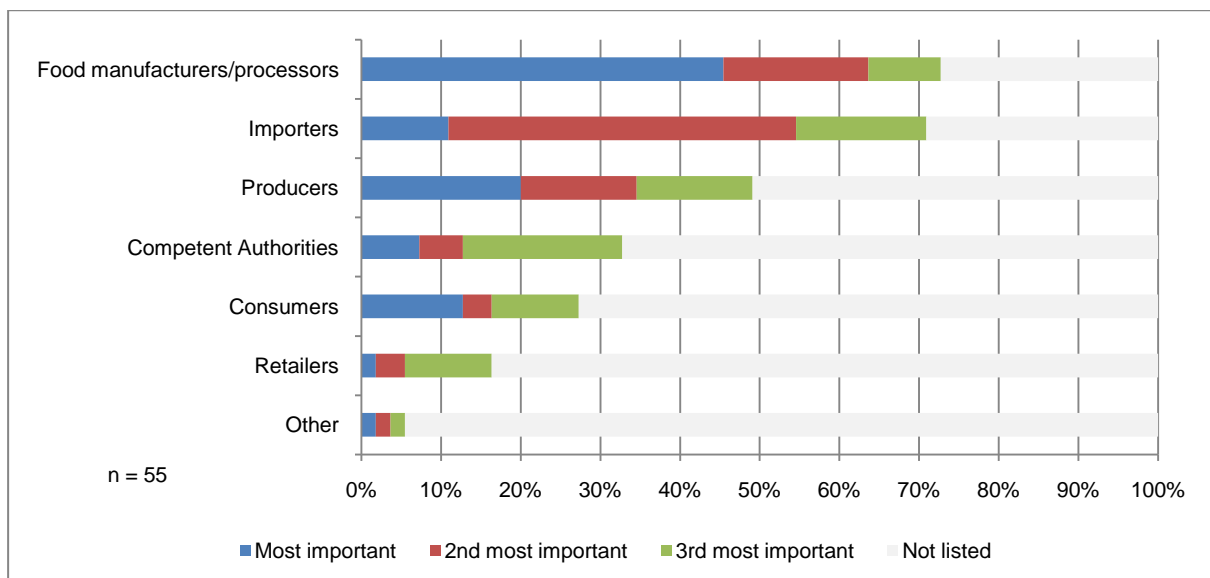


Figure 2.24: Stakeholder response: views on where the main costs of implementing the labelling provisions for food derived from GM plants arise

Both groups of respondents were clear in their view that the main costs of avoiding the use of GM raw materials in food fell on food manufacturers and processors (Figure 2.25 and Figure 2.26). Some 45% of stakeholders considered that food manufacturers/processors pay the highest cost, *though it should be noted that the vast majority of food industry respondents chose this option*. Many respondents also felt that much of the cost falls on importers, although Competent Authorities were much more likely than stakeholders to identify this as the area of main cost. Again stakeholders (from all groups) were more likely to note that consumers bear costs than were Competent Authorities.

Stakeholders who replied “other” identified GMO-free producers, social movements and bee-keepers as the parties bearing the cost.

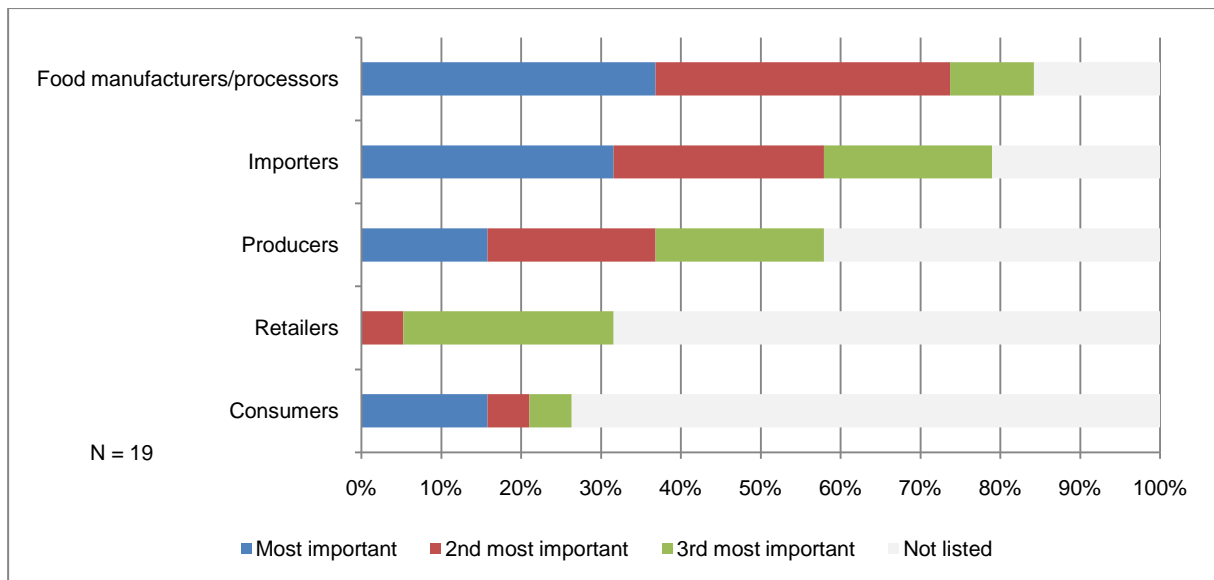


Figure 2.25: Competent Authority response: location of the main costs when Food Business Operators avoid using food derived from GM plants

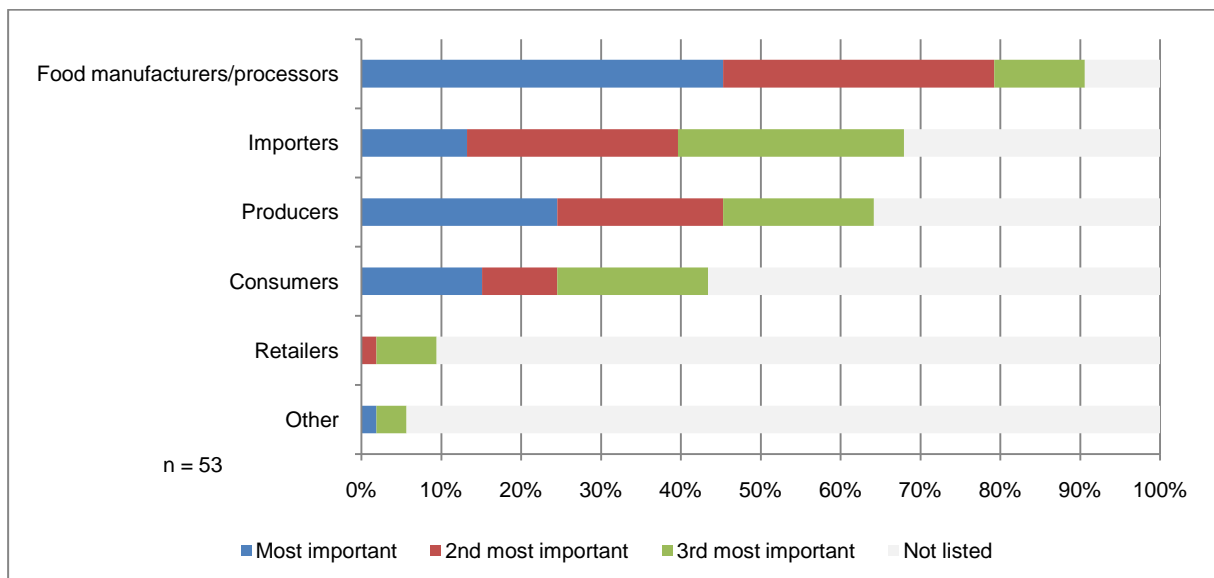


Figure 2.26: Stakeholder response: location of the main costs when Food Business Operators avoid using food derived from GM plants

2.5.5. Costs of implementing current labelling legislation for feed

With respect to the costs of labelling GM feed, food and feed producers were clearly identified by both Competent Authorities and stakeholders as the bearers of most cost (Figure 2.27 and Figure 2.28), although Competent Authorities placed food and feed importers a close second; however, the proportion identifying this stage of the chain as the most or second most important bearers of cost was much smaller. Competent Authorities again were more likely to consider themselves as being substantially affected by costs, perhaps from a greater awareness of control costs. *Similarly, among stakeholders, feed processors were more likely to consider themselves affected by the costs.* Once again, stakeholders appeared more likely to believe that costs are ultimately passed to consumers than did Competent Authorities; they were also more likely to identify livestock producers as bearers of cost, with some stakeholders providing comments to this effect. Although consumers were not thought to be a main bearer of **direct** cost, the Danish Competent Authority explained that ultimately costs would be passed to consumers.

The stakeholders who replied “other” identified social movements as the parties bearing the cost.

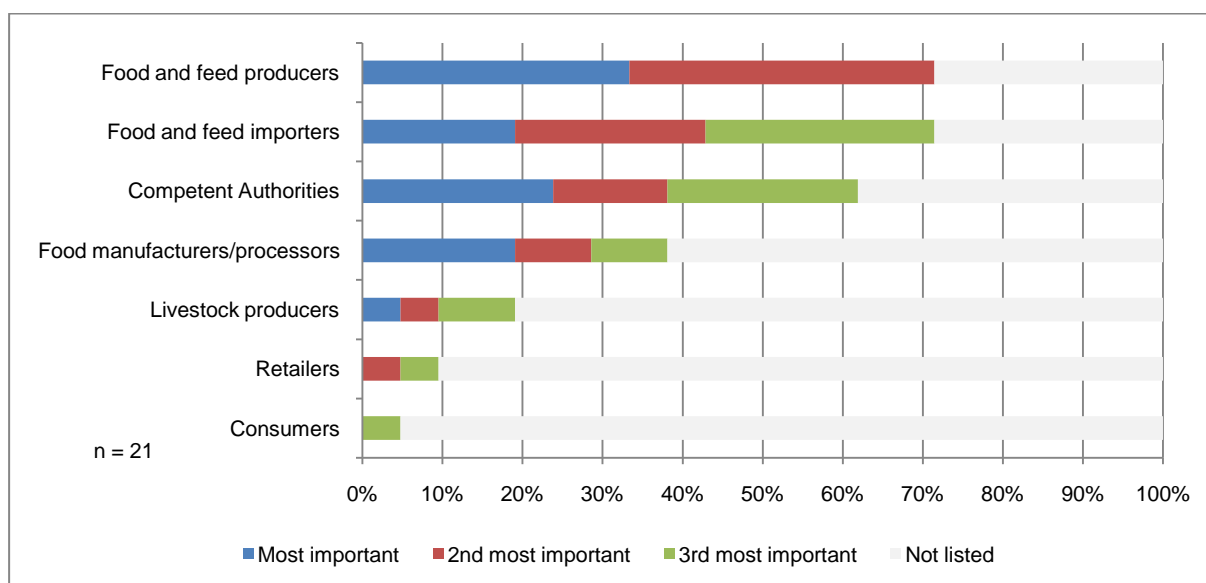


Figure 2.27: Competent Authority response: location of the main costs of implementing the labelling provisions for GM feed

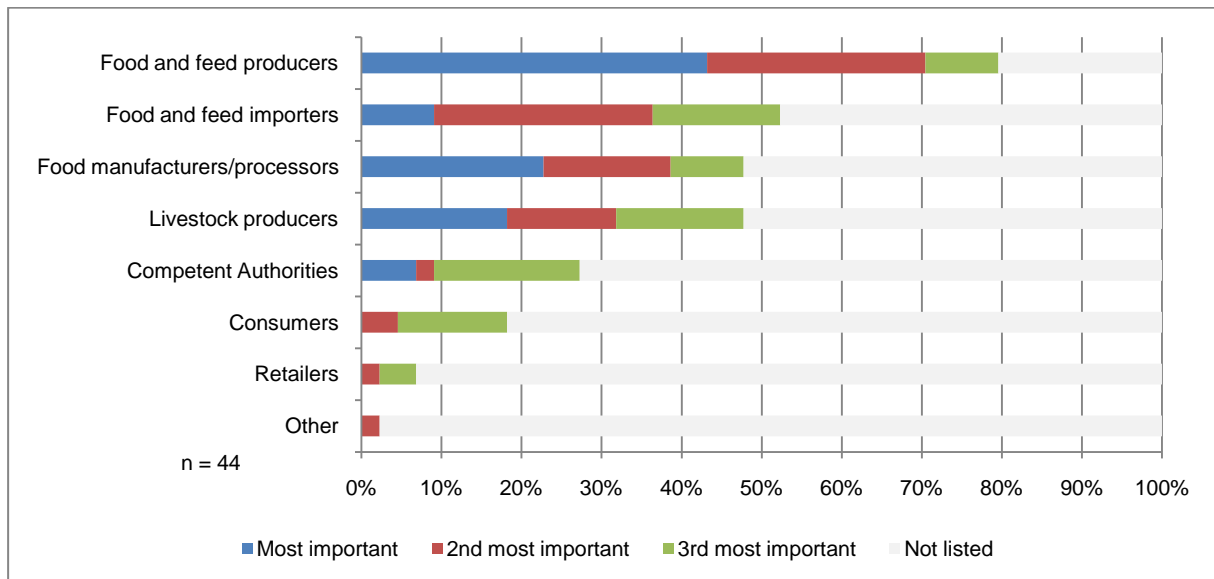


Figure 2.28: Stakeholder response: location of the main costs of implementing the labelling provisions for GM feed

Whilst Competent Authorities identified food and feed producers as the main bearers of costs when avoiding GM feed, with livestock producers in second place (Figure 2.29), stakeholders reversed this order (Figure 2.30). In keeping with the previous few findings, stakeholders were more likely to identify consumers as cost bearers than were Competent Authorities, reflected by some comments suggesting that costs are passed down the chain to the consumer. However, some comments from other stakeholders suggested that retailers and food manufacturers do not reward farmers for avoiding GM feed, meaning that the costs are not passed up the chain. Competent Authorities were more likely to identify retailers as bearers of cost than were stakeholders.

The stakeholder who selected “other” identified “GM-free” producers as the bearers of cost.

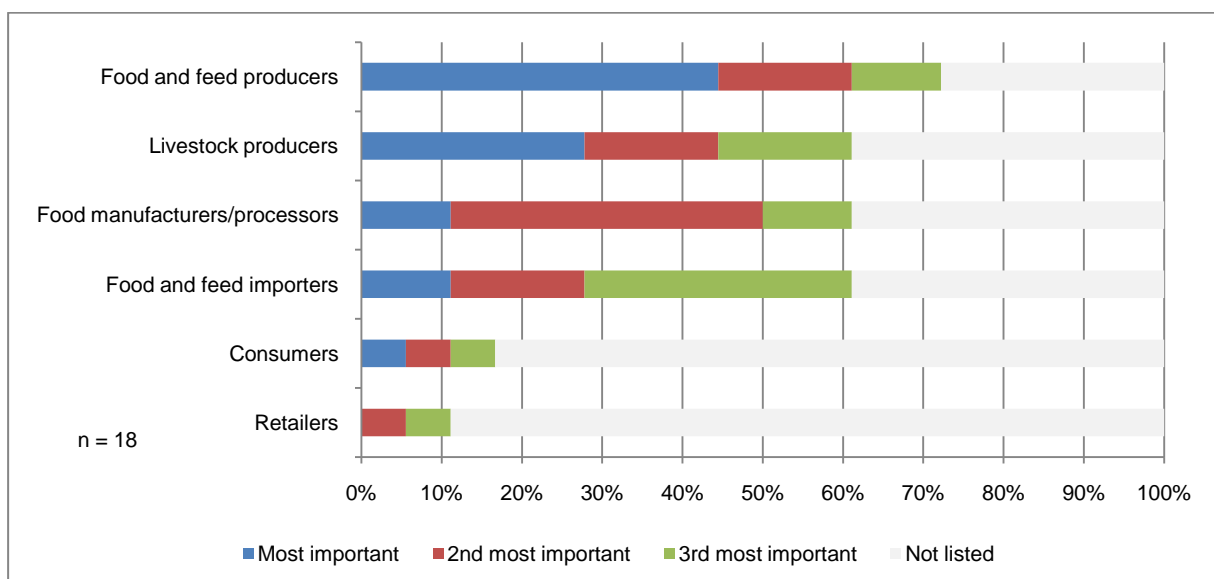


Figure 2.29: Competent Authority response: location of the main costs when Food Business Operators avoid using GM feed

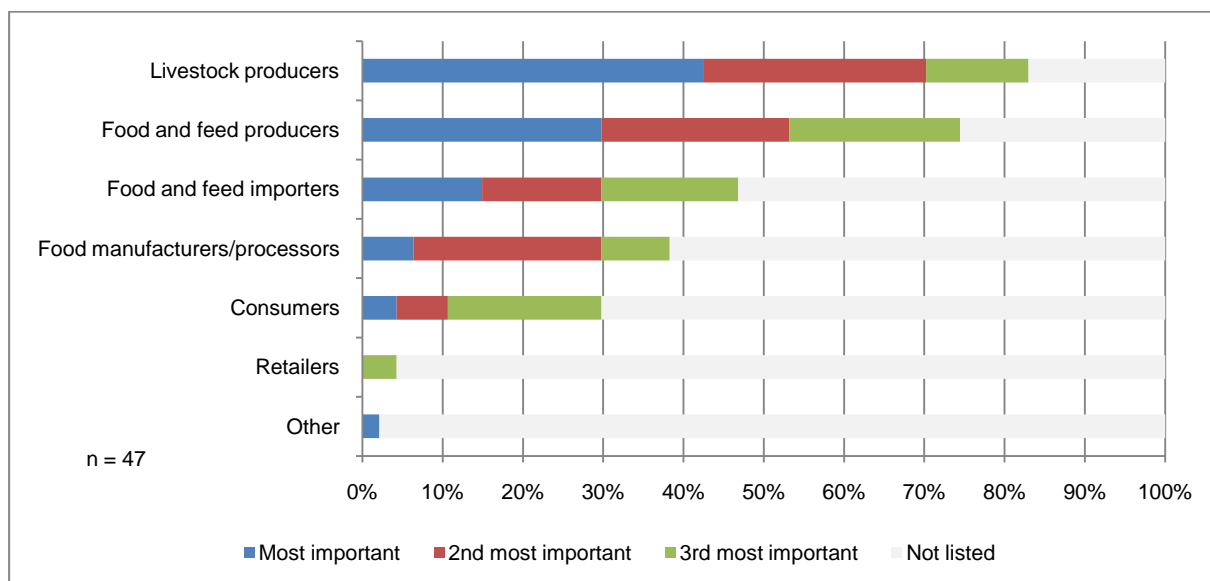


Figure 2.30: Stakeholder response: location of the main costs when Food Business Operators avoid using GM feed

2.5.6. Presence of GM labelled food on national markets

Competent Authorities were asked to report how many labelled GM food products are present on their national markets. Three Competent Authorities indicated that there is no information on the presence of GM labelled food products and a further ten did not provide an answer to this question. Based on our understanding of the availability of GM foods generally in the EU this probably reflects a lack of availability. Where Competent Authorities provided an estimate of the market penetration of GM labelled foods it was minimal. Three Competent Authorities (Austria, Denmark and Finland) explicitly commented that there are no GM labelled food products on the market in their Member States.

The Lithuanian Competent Authority stated that there are 31 GM labelled food products currently on the Lithuanian market, the Romanian Competent Authority noted that there were 44,000 tonnes of GM labelled soya oil on the market in 2008, but added that this is a small proportion of the total market. The Greek Competent Authority said that GM material is present in waffle mix, coffee and chocolate mixtures and soybean oil. Finally, the Bulgarian Competent Authority claimed that approximately 10% of total soy-based products are labelled as being derived from GM soybeans.

Stakeholders provided more information on the availability of GM labelled products as set out in Table 2.5.

Table 2.5: Estimates of availability of GM labelled food products by Member State

Member State	Number of estimates	Highest estimate	Lowest estimate	Estimate/mean estimate
Austria	3	2	0	0-1
Denmark	1	-	-	0
Finland	1	-	-	0
Germany	2	Under 20	10	15
Hungary	2	under 10	0	5
Italy	2	0	0	0
Lithuania	1	-	-	48
Netherlands	3	20	0	11-12
Spain	1	-	-	Several dozen
UK	1	-	-	4-5

In addition, several respondents provided qualitative estimates. For the Member States in Table 2.5 these corroborated the quantitative estimates. For Member States where there were no quantitative estimates, one stakeholder from Belgium believed there to be “almost no” products, and a stakeholder from Poland stated that there were “a few” products.

Stakeholders were also asked about the volume and value of GM labelled products on the market and for an estimation of market share. However, no stakeholders were able to provide the first two pieces of data. Stakeholders generally believed the market share of GM products to be very low.

2.5.7. Presence of GM labelled feed on national markets

The picture is very different for GM labelled feed as shown in Table 2.6, Competent Authority estimates and Table 2.7 and Table 2.8, stakeholder volume and value estimates respectively. It should be noted that respondents had more difficult estimating the value of market share, leading to fewer estimates. Respondents who did estimate value shares generally believed them to be in line with volume shares suggesting that GM feed is not significantly different in price to non-GM feed, or that the volume of non-GM feed is so small that it has little influence on the calculation.

There were also some qualitative answers which generally corroborated the qualitative estimates, with one exception, Italy, where a stakeholder claimed that the livestock industry does not use GM feed. In addition, a Polish stakeholder speculated that the majority of feed in Poland is GM. Amongst Competent Authorities, only that in Lithuania claimed that there was no GM labelled feed on the national market.

Table 2.6: Competent Authority estimates of GM labelled feed on national markets

Member State	Comments
Austria	80% of feed containing soya is labelled as GM. Other crops are not relevant in the Austrian context.
Belgium	Approximately 80%.
Bulgaria	Approximately 10% of feed on the market.
Denmark	Approximately 3 million tonnes.
Finland	7%.
Germany	“High”.
Greece	GM labelled imports of soybean account for between 60% and 65% of the market. GM labelled soymeal imports account for between 16% and 22% of imports.
Hungary	No data, but the Hungarian livestock sector is dependent on soymeal imports from Third Countries and a large proportion of this is labelled as GM.
Italy	Almost all feed containing soymeal is labelled as GM.
Netherlands	Almost all conventional compound feed is labelled as GM.
Romania	Approximately 1.318 million tonnes were labelled as GM in 2008.
Spain	A very high percentage of feed is labelled as GM. Given the difficulties in ensuring that feed is non-GM, feed is often labelled as GM by default.

Table 2.7: Stakeholder estimates of GM labelled feed on national markets (volume)

Member State	Number of estimates	Highest estimate	Lowest estimate	Estimate/mean estimate
Austria	2	70%	65%	67-68%
Belgium	2	80%	75%	77-78%
Denmark	1	-	-	90-95%
Finland	1	-	-	5%
Germany	4	90%	80-90%	88-89%
Hungary	1	-	-	50% +
Italy	1	-	-	90%
Netherlands	3	95%	85%	90%
UK	2	85%	85%	85%

Table 2.8: Stakeholder estimates of GM labelled feed on national markets (value)

Member State	Number of estimates	Highest estimate	Lowest estimate	Estimate/mean estimate
Austria	1	-	-	70%
Belgium	2	85%	Under 80%	Ca 80%
Denmark	1	-	-	90-95%
Germany	2	90%	90%	90%
Netherlands	2	95%	90%	92-93%
UK	1	-	-	85%
Hungary	1	50%+	50%+	50%+

2.5.8. Factors driving market share of GM labelled food

When asked to identify factors which drive market share of GM food products, both groups of respondents identified price and availability in store in first and second place (Figure 2.31 and Figure 2.32). Given the relatively low level of GM labelled products in stores in the EU (see above), price as a driver of market share perhaps ought to be considered hypothetical. Where Competent Authorities and stakeholders answered “other”, this was generally specified as either retailers or lack of consumer

demand/consumer choice. “Other” can therefore reasonably be grouped together with availability in stores. From the answers provided it appears as though currently the market for GM labelled food is driven by a lack of availability, i.e. consumers do not have the option of buying GM products, although where GM products are, or become, available, price will drive their market share.

Eight Competent Authorities and several stakeholders explained that this question is largely hypothetical due to the lack of availability of GM labelled food in their Member States. A couple of respondents commented that retailers are not prepared to stock GM-labelled food. For imported soy and maize-based GM food in Germany, price was identified as the key factor driving market share.

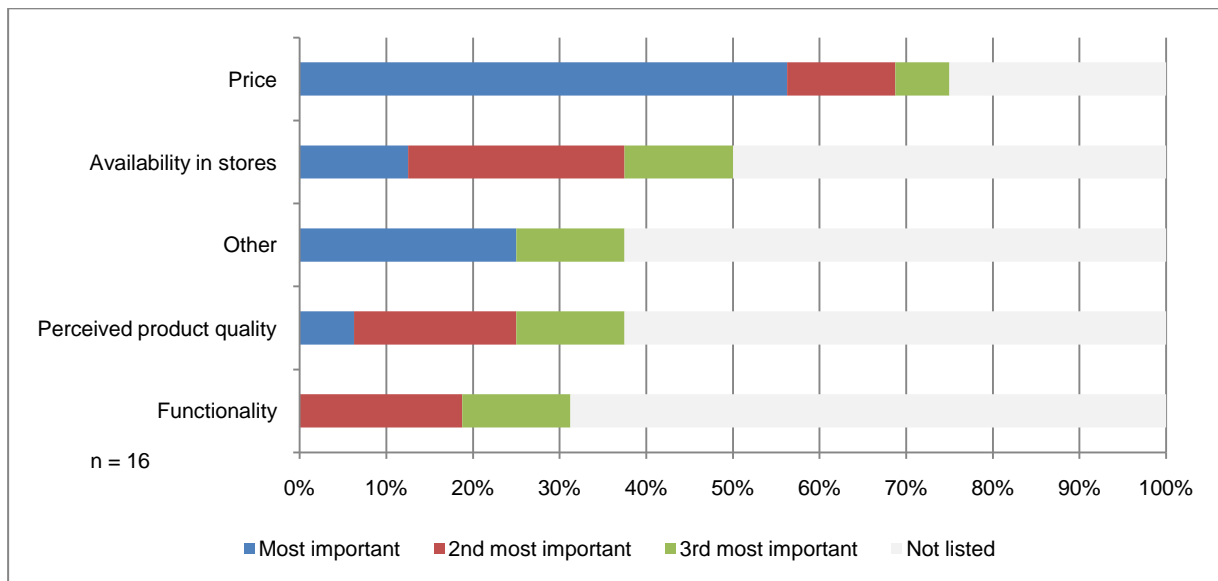


Figure 2.31: Competent Authority response: factors driving market share of GM food products

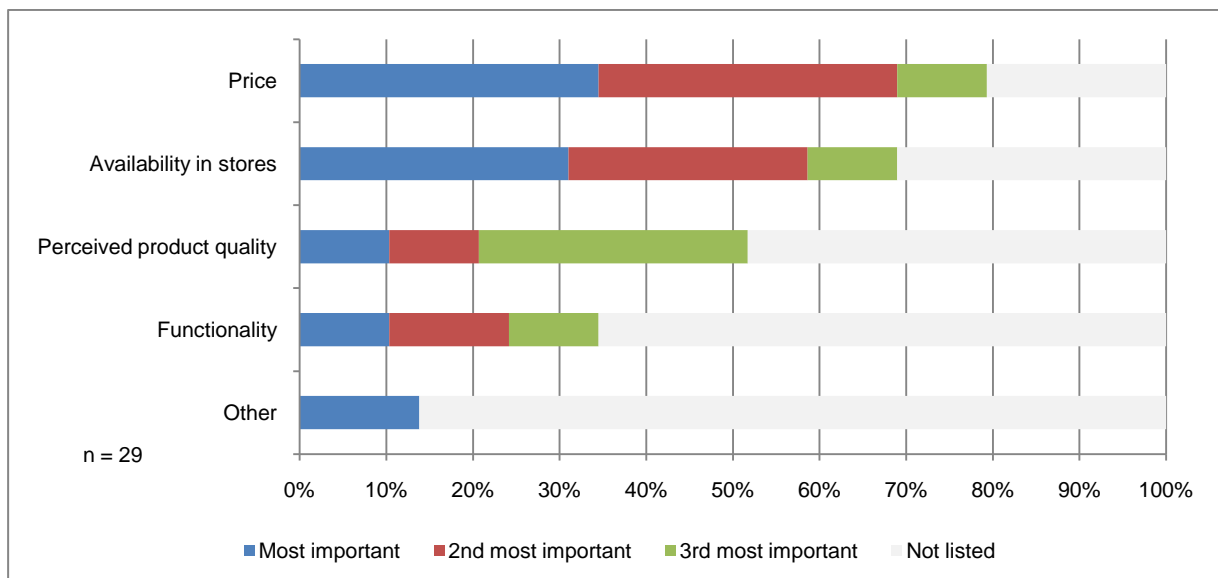


Figure 2.32: Stakeholder response: factors driving market share of GM food products

2.5.9. Factors restricting market share of GM labelled food

Both Competent Authorities and stakeholders identified consumer concerns over GM technology as the main factor restricting development of market share of GM food products (Figure 2.33 and Figure 2.34). *In the case of stakeholders, there was a difference between different groups; a proportion, but not the majority, of each group considered consumer concern to be the main factor, with the exception of NGOs where this was considered the main factor.*

Around a third of stakeholders and four Competent Authorities (21%) also noted that the main restricting factor is restricted availability in stores which is, at least to some extent, a reflection of consumer concern. *In the case of stakeholders, the majority of technology providers, traders and feed processors held this view, although this view was not held by any NGOs.*

Overall, these findings are consistent with the answers to the previous question on drivers of the market for GM foods. It is also worth noting that there were some concerns in terms of perceived product quality.

Again, a number of Competent Authorities explained that this question is largely hypothetical given the lack of GM labelled products on shelves, although this in itself demonstrates the restricted availability in stores which may reflect consumer concerns.

Most stakeholders who selected “other” identified the lack of will of retailers to stock GM products as a factor restricting GM food market share. This was corroborated by stakeholder comments. A couple of respondents commented that the lack of will of retailers to sell GM food was due to NGO campaigns; however another UK-based respondent considered retailer policies to be consumer driven. One respondent considered the information campaigns of social movements a factor restricting market share.

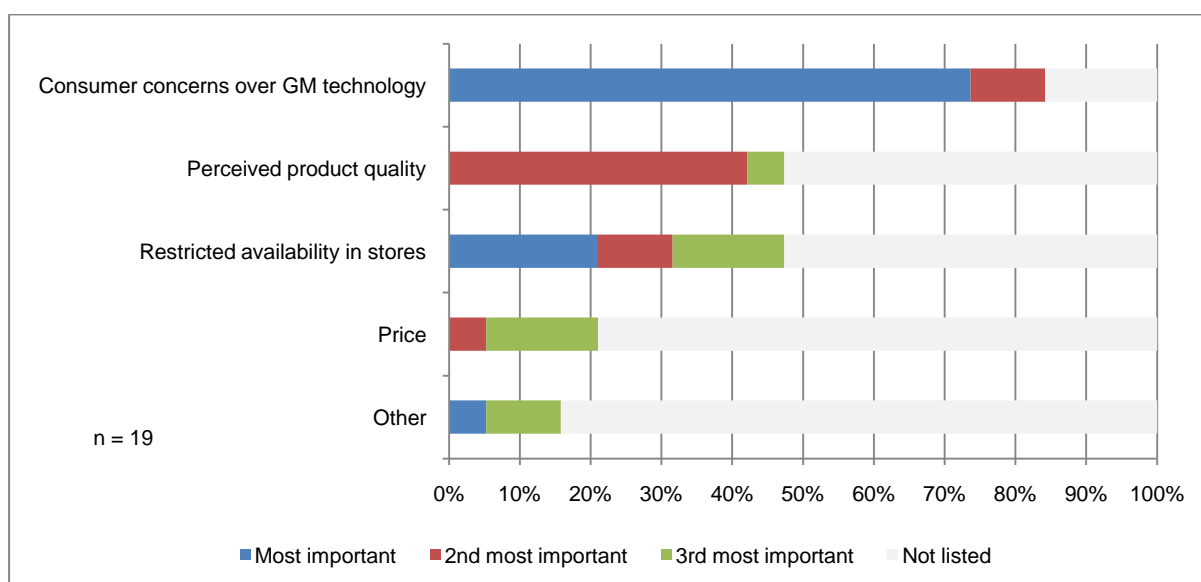


Figure 2.33: Competent Authority: factors restricting market share of GM food products

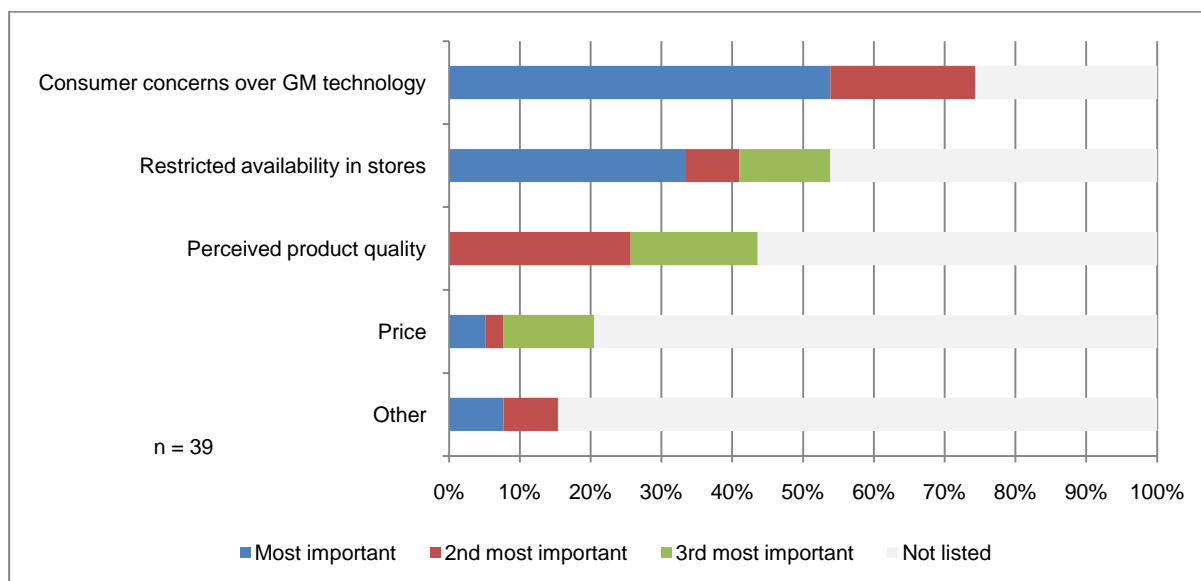


Figure 2.34: Stakeholder response: factors restricting market share of GM food products

2.5.10. Factors driving market share of GM labelled feed

Figure 2.35 and Figure 2.36 present the factors driving the market share of GM feed. Both groups of respondents were clear that price and the use of GM in essential raw materials drive market share, although there was more agreement on this in the Competent Authority sample. Stakeholders were more likely to note the lack of need to label livestock products as a market driver, although this was also ranked highly by Competent Authorities.

The difference in opinions between stakeholder groups should be noted. The majority of technology provider, trader, food industry and feed user respondents considered the use of GM in raw materials as the main driver. The majority of feed processor and respondents considered price the key driver, although these are related through supply and demand. Half of NGO respondents considered the lack of need to label livestock products the main driver of market share.

Stakeholders selecting “other” identified the monopoly of commodity traders on imports, availability (or lack of non-GM), possible liability for false negative labelling and consumer concern as factors driving the market share of GM feed.

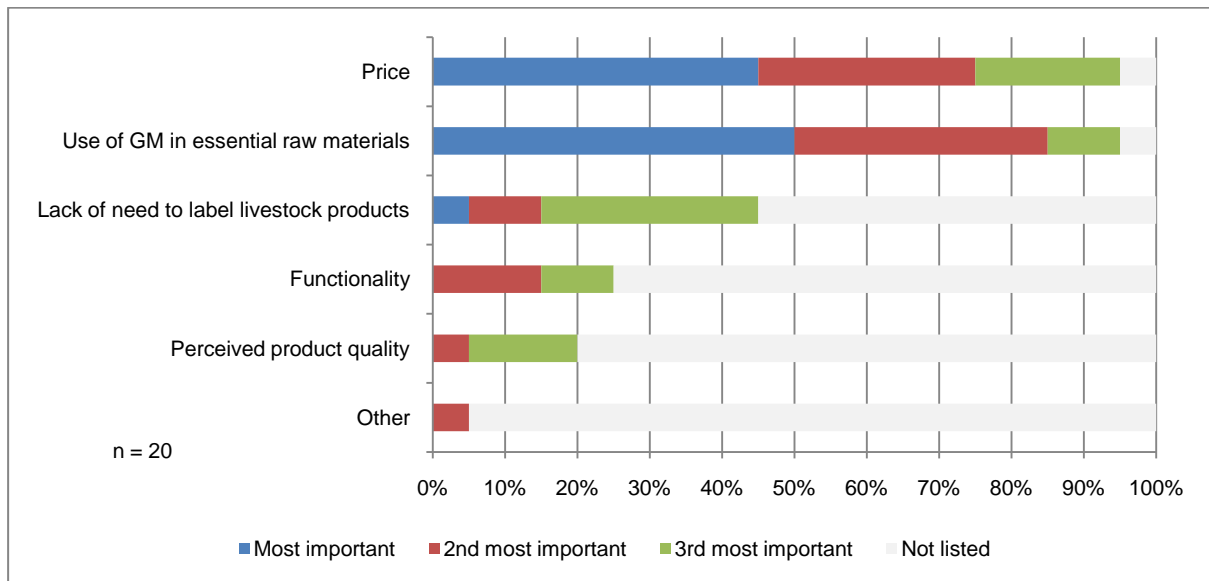


Figure 2.35: Competent Authority response: factors driving market share of GM feed

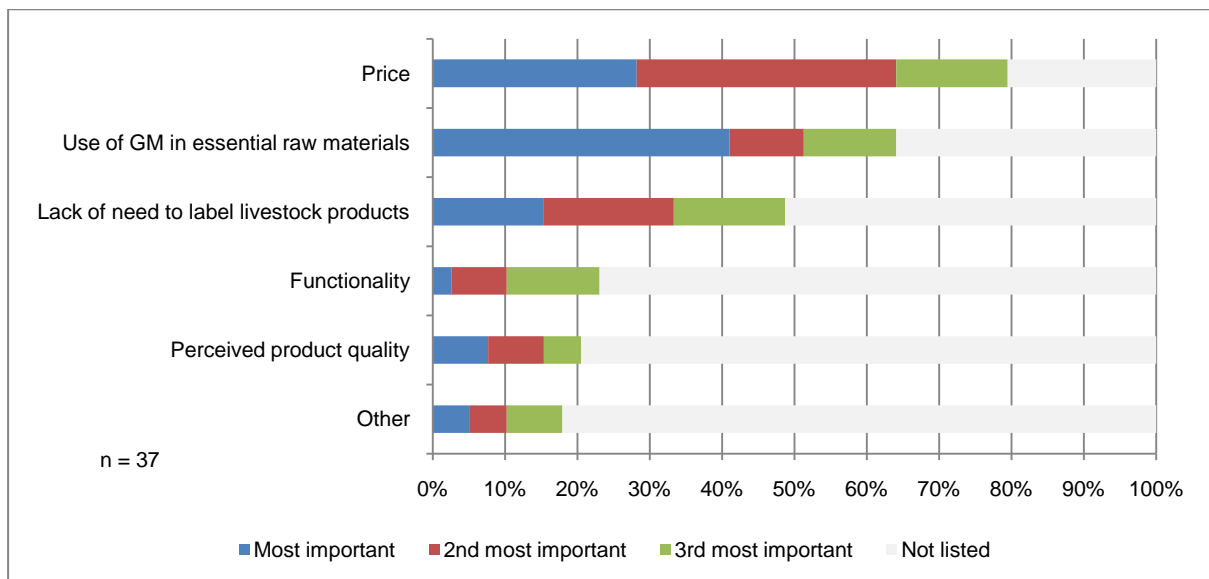


Figure 2.36: Stakeholder response: factors driving market share of GM feed

2.5.11. Factors restricting market share of GM labelled feed

Although both groups of respondents identified consumer perceptions as the main factor restricting the market share of GM feed, Competent Authorities, *traders and NGOs were more likely to list this as the main factor* while a higher proportion of stakeholders as a whole identified this as one of the three main factors. Livestock producer perceptions also appear important in terms of restricting the use of GM feed, although to a much lesser extent. Five Competent Authorities (28%) felt that a lack of supply of raw materials, i.e. the impact of asynchronous authorisation, was the most important factor constraining the market share of GM feed. Although 43% of stakeholders identified this issue as one of the three most important factors, the proportion identifying it as the most important factor was less than a fifth.

Although “other” was listed by the smallest proportion of stakeholders, almost a quarter (*including over half of all technology providers and feed processor respondents*) felt that the factors listed here were the most important with retailer policy/requirements and asynchronous authorisation the most cited factors. These factors were also commented on as being additional restrictions on the use of GM feed by various stakeholders. Where Competent Authorities answered “other” retailer policy was again an important factor.

The UK and Dutch Competent Authorities pointed out that the GM feed supply may be heavily adversely impacted by the issue of asynchronous authorisation (combined with a zero tolerance for not yet approved GM events) and that this would be far more important than any other potentially restricting factors.

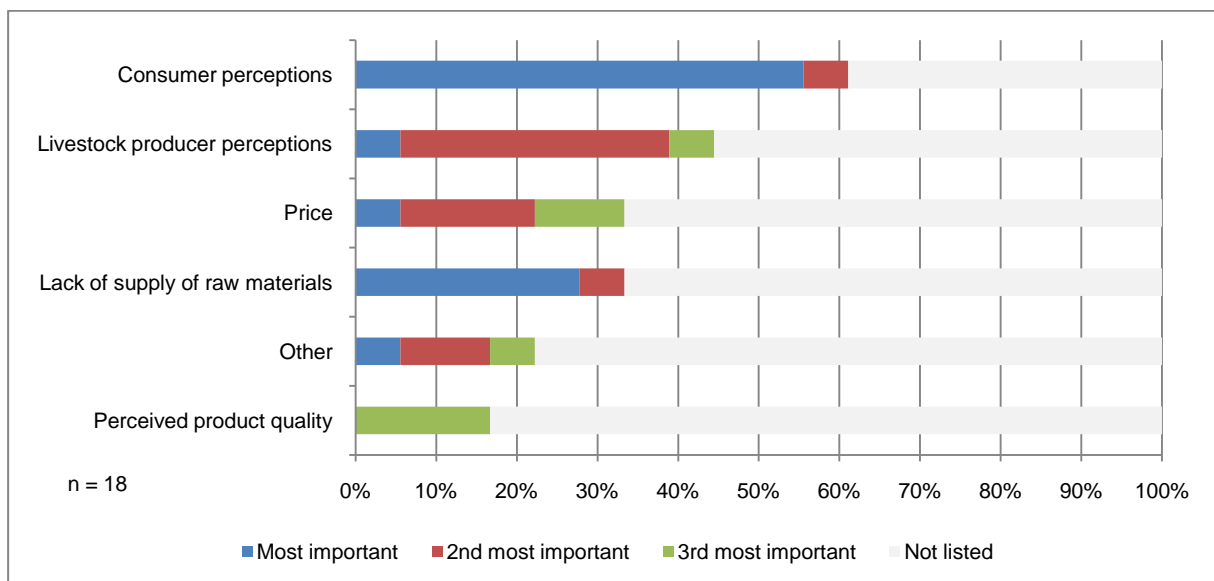


Figure 2.37: Competent Authority response: factors restricting market share of GM feed

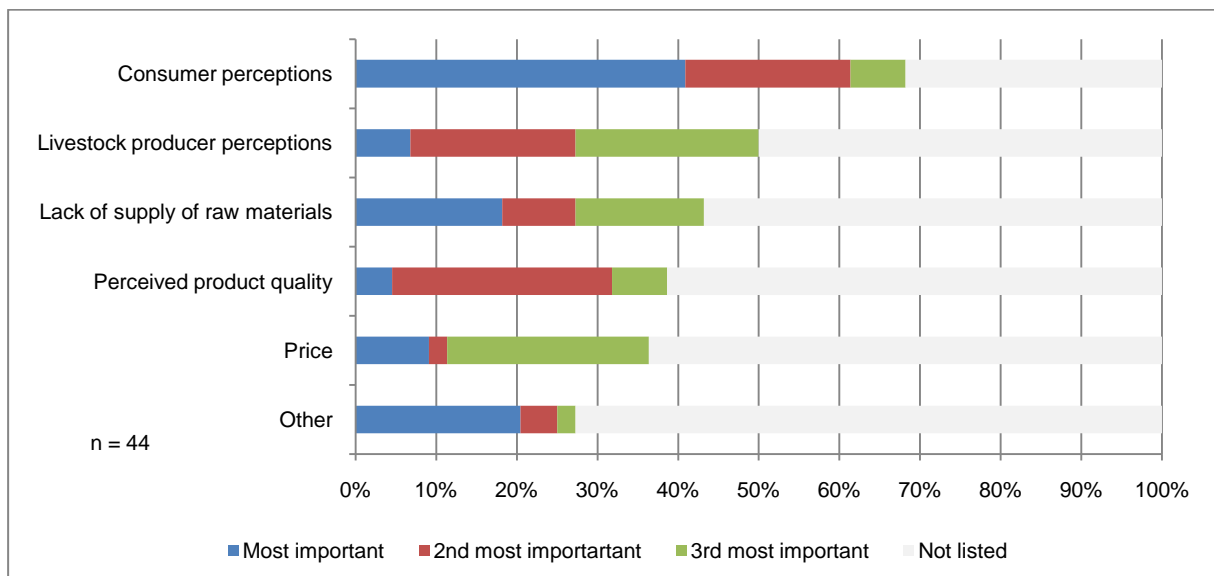


Figure 2.38: Stakeholder response: factors restricting market share of GM feed

2.5.12. Potential benefits and costs of extending GM labelling to encompass livestock products

Respondents were asked to identify benefits from extending labelling provisions to include livestock products. The majority of Competent Authorities (15, 63%) cited increased information to allow consumers to make a more informed choice, although two Competent Authorities noted that such an extension of scope might be considered misleading, presumably because livestock products contain no GM DNA. The Finnish Competent Authority explained that small companies might be provided with an opportunity to provide niche products (presumably livestock products fed on non-GM feed). Five Competent Authorities claimed that there would be no benefit from such an extension of scope.

When asked to identify the costs and/or problems that might arise from extending labelling provisions to include livestock products, nine Competent Authorities cited increased costs associated with traceability and the implementation of official control. In contrast, the Cypriot Competent Authority felt that any additional costs would be minimal. The Netherlands response explained that labelling livestock products would probably cause consumer confusion in that these products had not previously been labelled. They added that if food manufacturers and retailers tried to avoid the need to label, prices for unlabelled livestock products might increase. The Austrian Competent Authority also noted that this might result in a reduction in consumer choice; the Hungarian Competent Authority felt that greater consumer choice would result. Many other Competent Authorities agreed with this analysis with some, for example, the Finnish and Greek Competent Authorities adding that labelling livestock products would create a problem in terms of verification because it would not be possible to analyse livestock products to detect whether they were produced using GM feed or not. The UK and Belgian Competent Authorities noted that greater emphasis would have to be placed on traceability schemes with the latter setting out a number of potential problems that might arise from this increased reliance.

Finally, the French Competent Authority explained that the question of including foods derived from animals fed with GMOs within the scope of the labelling system had arisen during the negotiations of Regulation (EC) No 1829/2003. Concerns were raised at the time that such labelling would be technically difficult to implement given the lifecycle of certain animals and the diversity of their diets. Concerns were also raised in terms of the potential distortion of competition between EU products and those imported from Third Countries. The fact that it would not be possible to test a product raises the question of the relevance of such labelling.

Stakeholder responses varied greatly between stakeholder groups. *Feed processors, technology providers and food industry respondents could not see any benefits of an extension of scope, citing EFSA's opinion that GM material cannot be detected in livestock products. Furthermore, some could not see how such provisions could be applied to imported products. With regard to problems, they foresaw considerable difficulties with segregated supply chains, ultimately leading to higher costs for consumers. Furthermore, they believed that the market for meat could become further segmented and that there might be misplaced consumer concern and cases where consumers might feel misled.*

Traders generally agreed that there were no scientific grounds for labelling livestock products. However, they saw potential benefits either in terms of consumer choice or consumer education/acceptance of GMOs. Traders were however generally concerned about the costs.

Feed users were split regarding the benefits. Roughly half saw advantages in terms of transparency, consumer awareness of GMs and/or consumer choice. The other half saw no benefits, and thought that labelling would be misleading for consumers. While divided on the benefits, there was more consensus regarding the costs. Most respondents foresaw problems with traceability and enforcement. They were particularly concerned as to who would pay these costs. A couple of respondents foresaw short-term problems with sourcing, but believed that these would be resolved in the long-term.

NGO and consumers organisations thought that labelling livestock products would improve consumer choice. They also commented that “GM-free” producers would be in a more competitive position. Most respondents thought that there would be no costs if the industry was given a period of adjustment, for example, between six months and one year.

2.5.13. Potential impact on demand for livestock products if included within positive labelling scope

Figure 2.39 and Figure 2.40 show the expected impact on demand for unlabelled non-GM products, labelled non-GM products and labelled GM products if the scope of the labelling provisions were extended to include livestock products. A higher proportion of Competent Authorities would expect to see reductions in demand for GM labelled products compared to stakeholders (17, 81% compared to 69%) with a higher proportion expecting large decreases in demand. A broadly similar proportion of Competent Authorities and stakeholders would expect to see large increases in demand for labelled non-GM products, although a higher proportion of Competent Authorities would expect to see modest increases in demand compared to stakeholders. A majority in both respondent groups would expect to see no change in demand for unlabelled non-GM products although a slightly higher proportion of Competent Authority respondents would expect to see a modest increase in demand here.

Among stakeholder respondents, *only NGOs stood out as having a stronger view than other stakeholders; all NGOs thought that labelling livestock products would decrease demand for GM labelled products, and the majority thought it would lead to an increase in demand for non-GM unlabelled products.*

Several respondents pointed out that other factors would be important in changing demand, for example presentation in the media and price. The power of retailers over these two factors was highlighted by one respondent. Some respondents speculated that the lack of “GM-free” feed would limit the market size for non-GM fed livestock products. Finally, several respondents considered the question too speculative to provide a clear answer, or that it was not possible to provide an answer as imported livestock products would not be labelled as GM.

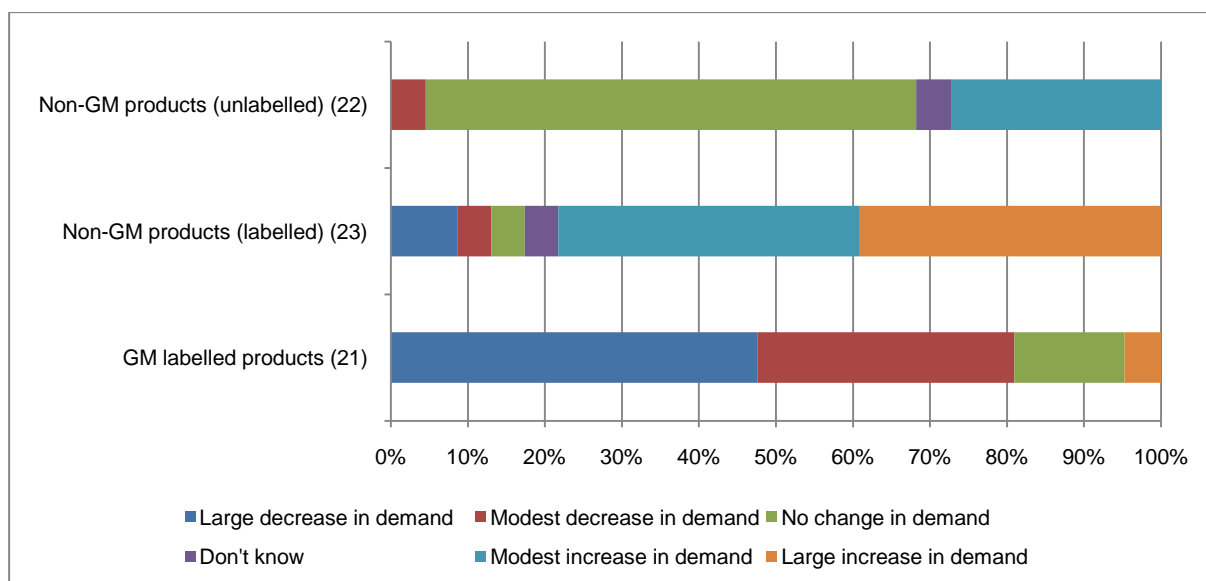


Figure 2.39: Competent Authority response: likely impact on demand if the scope of the labelling provisions were extended to include livestock products

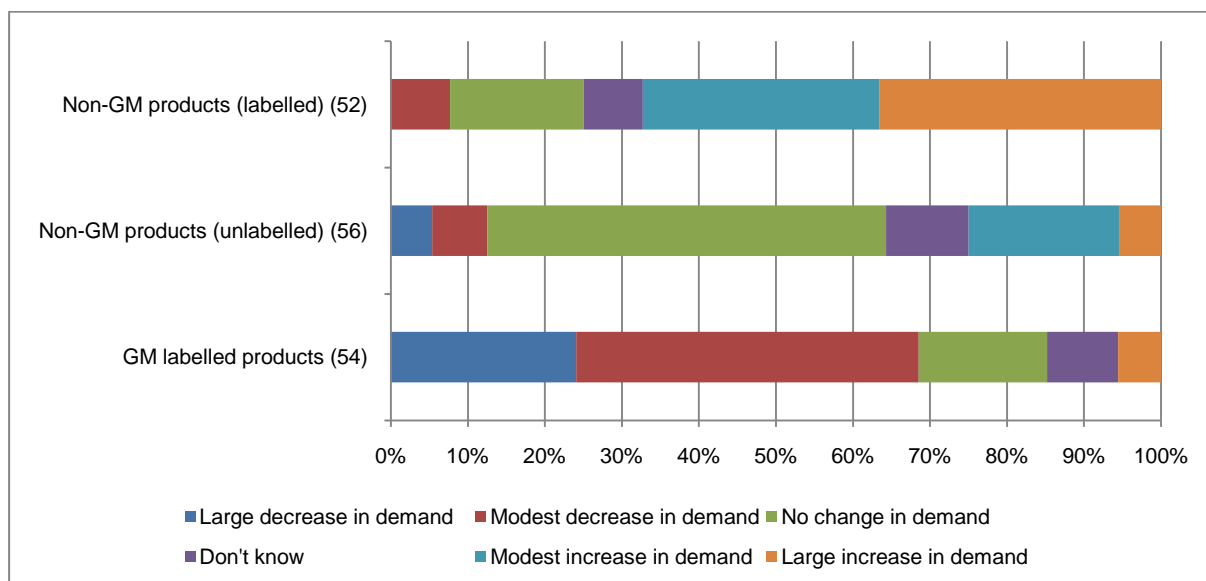


Figure 2.40: Stakeholder response: likely impact on demand if the scope of the labelling provisions were extended to include livestock products

2.5.14. Potential impact on prices for livestock products if included within positive labelling scope

Figure 2.41 and Figure 2.42 present the expected impact on price if labelling were extended to cover livestock products. A majority of Competent Authorities and stakeholders would expect price increases for labelled non-GM livestock products. Respondents who expected no price change believed that supply of non-GM feed would adjust to keep the price of the final product stable. A majority in both respondent groups would also expect no change in the price of unlabelled non-GM products. A majority of Competent Authorities would expect price decreases (mainly modest) for GM labelled products, although three Competent Authorities (14%) would expect price increases. A majority of stakeholders would also expect price decreases for GM labelled products, but again, a minority would expect price increases.

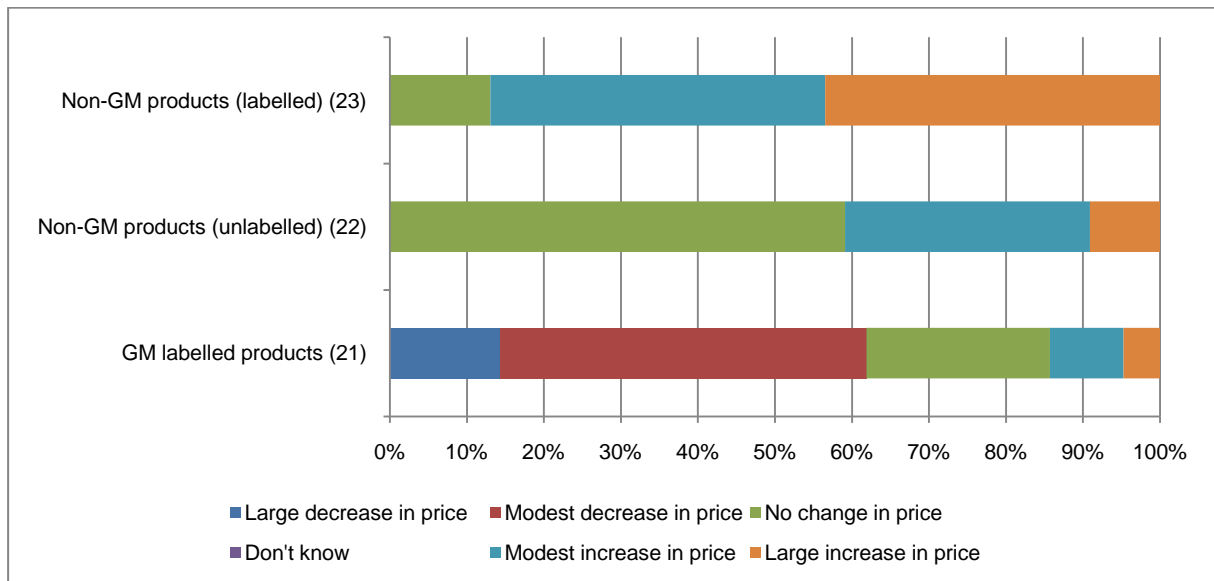


Figure 2.41: Competent Authority response: likely impact on price if the scope of the labelling provisions were extended to include livestock products

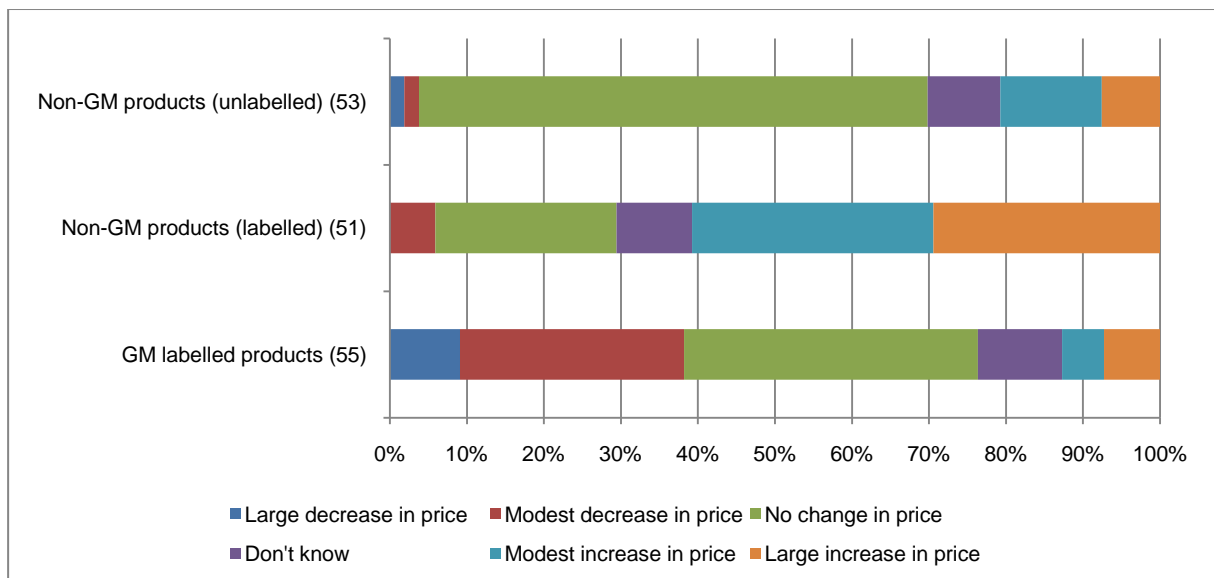


Figure 2.42: Stakeholder response: likely impact on price if the scope of the labelling provisions were extended to include livestock products

2.5.15. The current use of “GM-free” labelling schemes

Respondents were asked to identify any “GM-free” labelling schemes used by more than one operator in their Member States. There are no such schemes in the vast majority of Member States.

There is some use of “GM-free” labelling in some Member States, although this tends to be on a relatively small scale. For example, the Finnish Competent Authority explained that one small meat company has labelled some products as “GM-free” (see the labelling case study for more information on this). The UK Competent Authority explained that UK retailers operate a number of voluntary

(and different from one another) non-GM or “GM-free” schemes for their own brand products, although these are often not labelled as such on the shelf. Stakeholders noted that FEMAS¹² provides certified non-GM feed in the UK. The Belgian Competent Authority explained that it strongly discourages “GM-free” labelling because such labelling can be misleading.

The French government sought to regulate the use of “GM free” labelling in 2000 by defining, in conjunction with consumer groups, the criteria that operators must meet. To date, this type of labelling has been on a voluntary basis and there has been no requirement for independent certification. Stakeholders noted the following schemes in France: Poulets de Loué; Porcs de la Sarthe; beurre d'Echiré and some AOC cheese. The voluntary arrangements may change in the short-term following the recent opinion of the High Council Biotechnology (HCB) and the French Agency for Food Safety (AFSSA)¹³.

The Italian Competent Authority and stakeholders explained that some lines in the Coop (eggs, baby food and some organic products) are labelled as “GM-free” by operators.

The Austrian Competent Authority noted that the labels “gentechnikfrei”, “ohne Genetechnik”, etc. are used by multiple operators. This scheme is controlled according to the guidelines of the Austrian Codex Alimentarius and covers in particular milk production and starch products. Stakeholders also noted that there are some national “GM-free” schemes in Germany with Intertek Food Services being active in non-GM certification here and also in Austria. CertID is a pan-European certification organisation.

The majority of Competent Authorities explained that there are no national laws governing the use of “GM-free” labelling. In some Member States the use of such labelling is actively prohibited, for example in the Netherlands (although here the phrase “produced without the use of genetic technology” is permitted as long as the entire production process makes no use of genetic technology).

Although there is no legal basis for the use of the terms “GM free” or “non-GM” in the UK, these terms can be lawfully used on a voluntary basis if this is appropriate to the product concerned. Any food on sale labelled as “GM free” is subject to the general requirements of food law, in particular the Food Safety Act 1990 and the Trade Descriptions Act 1968. The view of the UK Competent Authority is that “GM free” should mean food or feed that is completely free from the use of GM technology and without a threshold for the accidental presence of GM material in a non-GM source. The legal use of this term would therefore clearly be limited to a small range of products.

The use of “GM-free” labelling is regulated in Austria under the Austrian Codex Alimentarius guidelines, as noted above. In Germany the use of “GM-free” is regulated under the GM Implementation Act. The French Competent Authority (DGGCRF) published an information note in 2000, updated in 2004 (NI No. 2004-113), which sets out the criteria that must operators must follow if they wish to indicate the absence of GMOs.

Respondents were asked whether there should be a harmonised, EU-wide GM-free labelling scheme in order to facilitate the working of the single market. Although 16 Competent Authorities (67%) thought that there should be, only 40% of stakeholders agreed. *Feed processors and NGOs in particular were in favour of harmonised EU-wide GM-free labelling, while technology providers were strongly against.* Only one Competent Authority thought that non-GM labelling should operate instead of the current, positive labelling while the remainder (93%) stated that this should operate alongside the current labelling regime. Stakeholders were more divided on this issue where a small

¹² Feed Materials Assurance Scheme.

¹³ This opinion, submitted to the French Government, argued for the use of voluntary “GM-free” labelling. According to Agra Europe (2009), the French government has pledged to draw up new laws on the basis of the recommendations.

majority (59%) was in favour of a parallel system. *Only feed processors were strongly against a parallel system.*

The UK and Dutch Competent Authorities pointed out that any EU-wide “GM-free” scheme would have to be meaningful, robustly verified and not mislead the consumer. The Hungarian Competent Authority noted that the German scheme would provide a useful starting point for an EU-scheme, although it should be acknowledged that many Competent Authorities and stakeholders feel that the German scheme is in fact potentially misleading for consumers (see case study).

Stakeholders opposed to harmonised “GM-free” labelling considered such labelling misleading, as entirely GM-free food does not exist and some consumers may interpret GM as being unsafe or inherently bad. Some respondents commented that the organic sector already exists for those who want to avoid GM products. Other respondents feared that a harmonised “GM-free” scheme would be difficult and costly to implement. Some respondents who were against an EU-wide scheme admitted that, if the proliferation of national schemes continues, it would be preferable to have a harmonised EU-wide scheme over national schemes.

Respondents in favour of a harmonised EU-wide GM scheme for “GM-free” labelling to replace current national provisions commented that this would put an end to the confusing and misleading national schemes which currently exist. No rationale for their selection was provided by those in favour of an EU-wide scheme to operate alongside existing national schemes.

2.6. Public acceptance

2.6.1. Aspects of GM authorisation causing controversy

Respondents 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 (Figure 2.43 and Figure 2.44). Both groups 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. Although it was placed third, it should be noted that 40% of stakeholders stated that the speed of the authorisation process is very controversial, a much higher proportion than amongst Competent Authorities.

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.

Some Competent Authorities, for example the French, did make clear, however, that public controversy is created by the presence of GMOs rather than any specific aspects of the authorisation process. The Danish Competent Authority, for example, 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. The UK Competent Authority pointed out that different stakeholders will no doubt perceive different elements of the authorisation process as being controversial according to their specific interest. The Hungarian Competent Authority explained that controversy is caused both by the complexity of the issue and also by the divergent views amongst scientists.

There were 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 caused controversy.

On one hand, several stakeholders commented that EFSA’s risk assessment is undermined by some Member States and pressure groups, causing controversy. On the other hand, a couple of stakeholders questioned the impartiality of EFSA and its scientists.

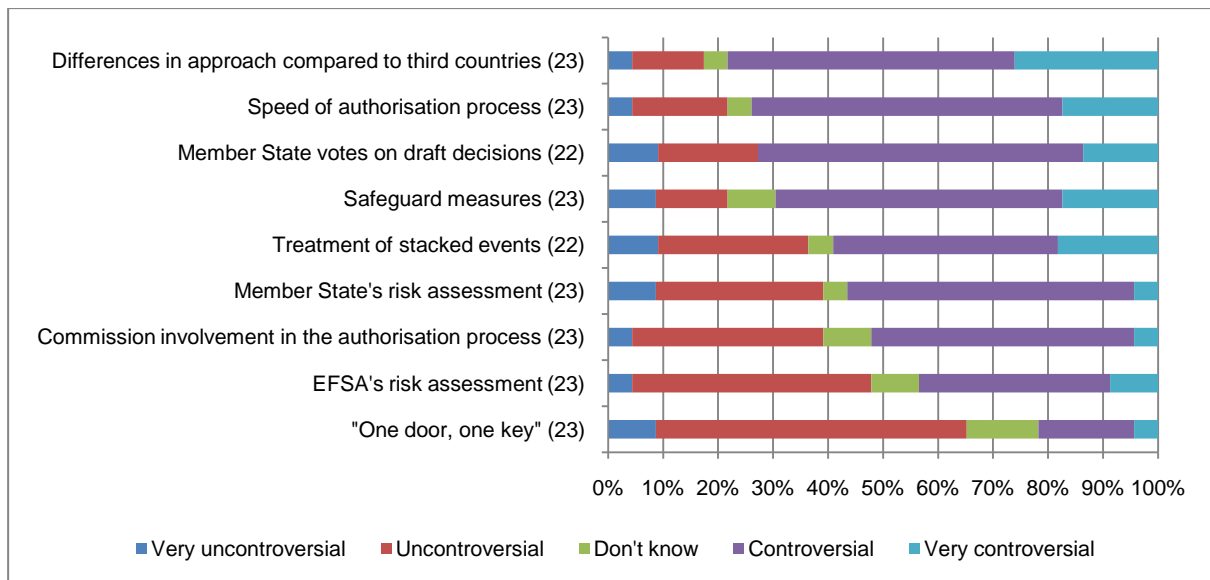


Figure 2.43: Competent Authority response: aspects of the GM food and feed authorisation process which create controversy among stakeholders and the general public

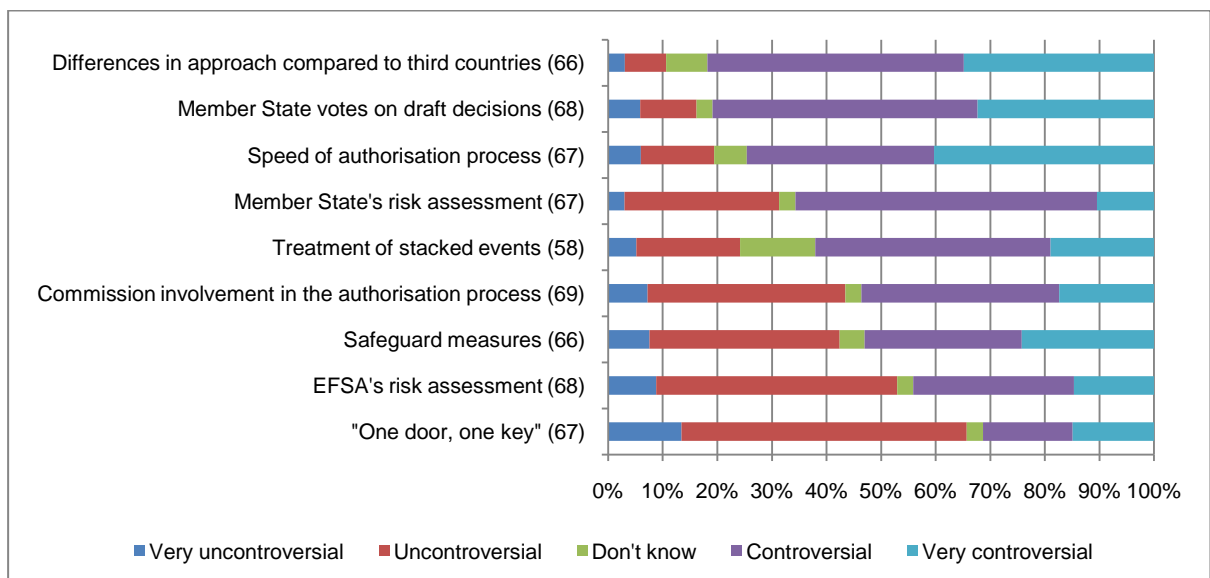


Figure 2.44: Stakeholder response: aspects of the GM food and feed authorisation process which create controversy among stakeholders and the general public

2.6.2. Impact of controversy on GM food and feed

Figure 2.45 and Figure 2.46 illustrate the impact of public controversy in terms of GM food and feed on a number of issues. As might be expected both Competent Authorities and stakeholders identified public acceptance as the area most negatively affected by the controversy. *There was stakeholder consensus on this point. Again there is broad agreement that the supply of GM food to the market has also been negatively affected. All stakeholders held this opinion with the exception of NGOs who perceived a positive impact.* 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.

A few stakeholders identified other relevant factors including: the supply of GM-free food; general acceptance of new technologies; and, citizen's trust in EU risk management.

Several stakeholders made the further comments that (1) there is little freedom of choice due to the absence of GM food from shelves, and (2) consumer perception (measured through, for example, opinion polls) and actual behaviour are different, but the lack of GM food on the shelves makes it difficult to assess consumer behaviour.

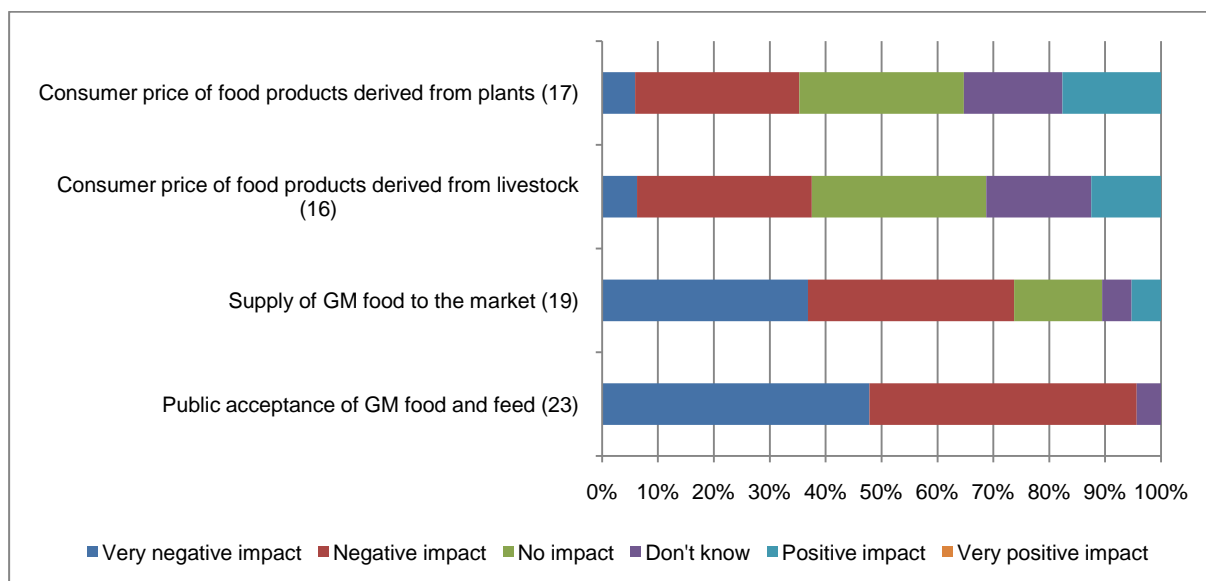


Figure 2.45: Competent Authority responses: the impact of public controversy

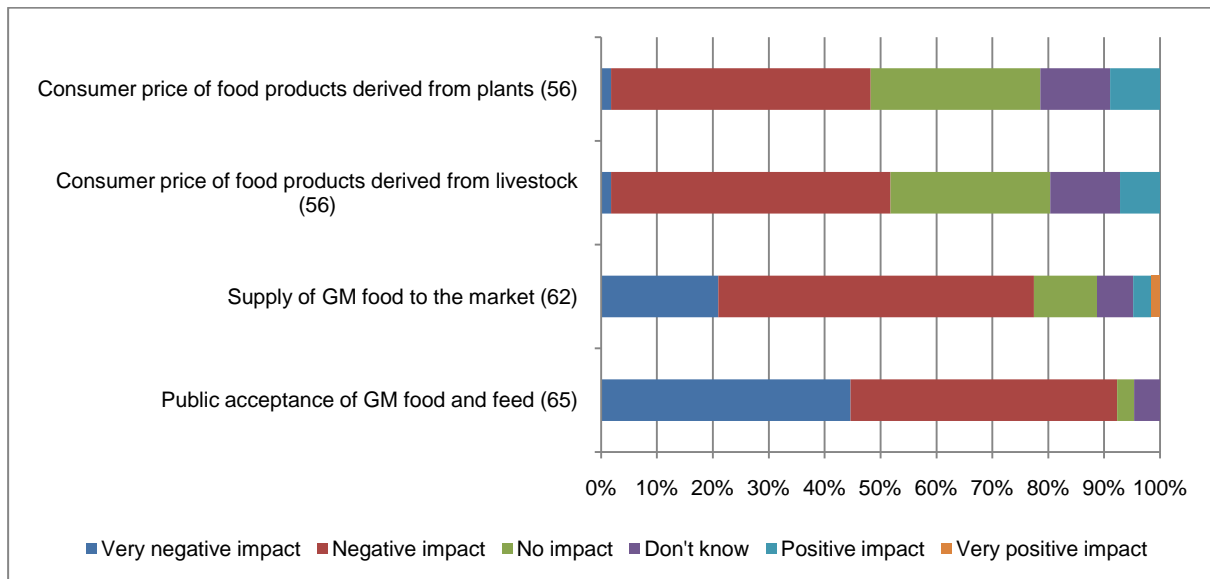


Figure 2.46: Stakeholder responses: the impact of public controversy

2.6.3. Public sensitivity on cultivation, GM food and GM feed

Public sensitivity on the use of GM technology varies for cultivation, food and feed according to 21 Competent Authorities (88%) and 88% of stakeholders (there was general stakeholder agreement on this). Figure 2.47 and Figure 2.48 highlight perceptions of relative public concern. Thirteen Competent Authorities (68%) listed cultivation as the main public concern with six (32%) citing GM food. Stakeholders perceive concern around cultivation and GM food to be 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. A difference between stakeholder groups should be noted; *technology providers and feed processors generally considered cultivation the most sensitive GMO area, 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.

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.

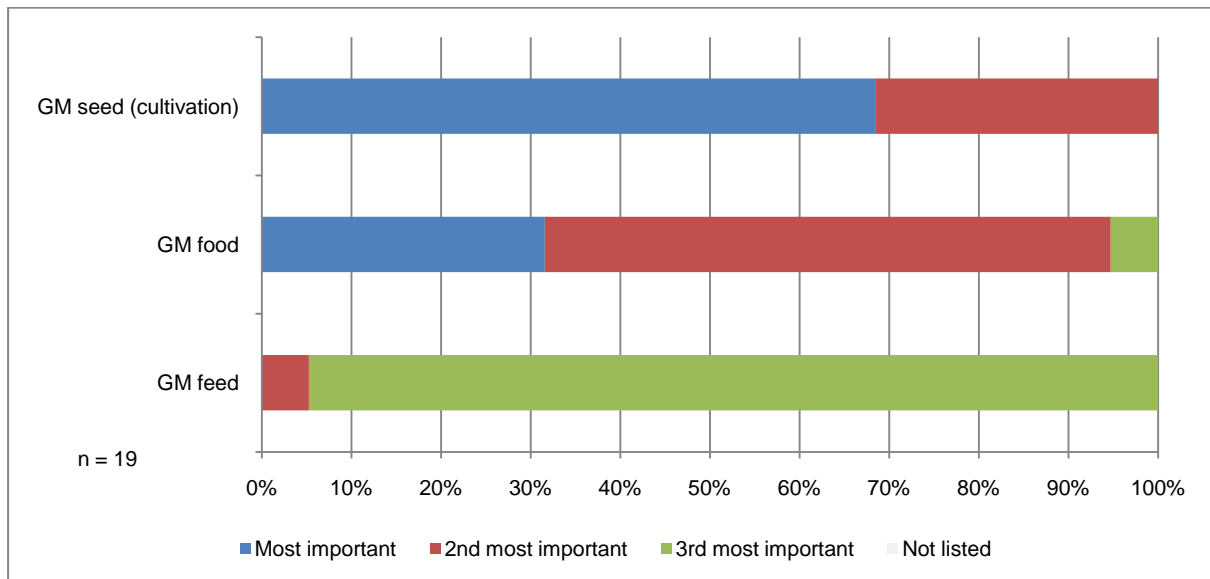


Figure 2.47: Competent Authority response: public sensitivity with respect to GM seed (cultivation), food and feed

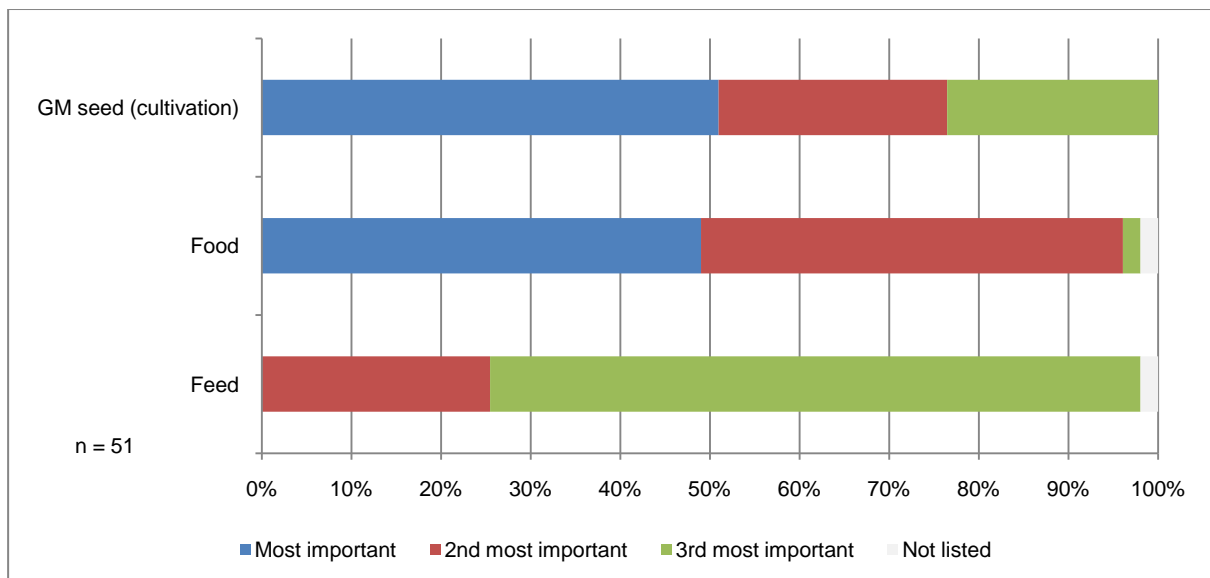


Figure 2.48: Stakeholder response: public sensitivity with respect to GM seed (cultivation), food and feed

2.6.4. National measures taken to communicate risk to the public

Competent Authorities were asked what measures had been taken in the government in their Member State in terms of communicating risk to the public in the context of GMOs. The Portuguese Competent Authority noted that no communication had taken place. A further four Competent Authorities did not provide an answer, although this does not necessarily mean that no communication effort has been made (Germany, Slovakia, Slovenia and Sweden).

Some Member States have confined their communication exercises primarily to providing information on government websites, for example, Austria, Belgium, Estonia, France, Hungary, Italy and Spain.

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.

The UK Competent Authority explained that a new programme of public engagement on genetic modification is currently under way. The Food Standards Agency has been asked by the UK Government to lead a project to explore the subject of GM with consumers. This project 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 eat¹⁴. The Finnish 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. The Advisory Board on Biotechnology 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.

Two-thirds of stakeholders reported that they had carried out communication/campaign activities relating to GM food and feed. *This included the majority of stakeholders from all groups, with the exception of the food industry.* Campaigns have included, *inter alia*, position papers, communication to members, seminars, websites and participation in national events.

A third of those stakeholders who had carried out communication activities stated that their stance had been broadly in favour of GM food and feed whilst 29% claimed that their activities had been broadly against with a further 29% claiming that they had taken a balanced position. However, the differences in attitude between the campaigns of different stakeholder groups should be noted; *the vast majority of technology providers considered their campaigns broadly positive, while all NGOs considered their campaigns broadly negative. The vast majority of feed processors, traders and food industry respondents considered their campaigns neutral. Feed users and consumer organisation campaigns were split between the three categories.*

2.6.5. Potential improvements in EU-wide trust in science-based risk assessment

Competent Authorities were asked how the quality of EU-wide trust in science-based risk assessment might be improved in the GM context. Seven explained that the key was improved communication with the public. The Competent Authorities in Italy and Slovenia noted that increased public research with a more inter-disciplinary base would be useful.

The Belgian Competent Authority explained that the forthcoming harmonised guidelines on risk assessment produced by EFSA in conjunction with the Member States should reduce controversy arising from the risk assessment process. It is anticipated that this will in turn create more public trust in the process. The Hungarian Competent Authority referred to earlier comments making clear that it believes an improved risk assessment procedure is needed; unspecified improvements were also suggested to the decision making system. The French Competent Authority expressed a desire 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. The Estonian Competent Authority suggested that an information day with EFSA scientists would be useful and the Spanish Competent Authority called for increased confidence in EFSA and the promotion of its independent

¹⁴ Further information is available at: <http://www.food.gov.uk/news/newsarchive/2009/sep/gmchair>.

status as lead agency in the context of risk assessment. Finally, the German Competent Authority thought that a more efficient authorisation process would help.

The Finnish Competent Authority noted 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, a point also made by the Cypriot Competent Authority. They also explained that the clearer communication of benefits to consumers and society, perhaps from more novel GM events, might be expected to improve trust in the system.

The UK Competent Authority pointed out that public acceptance of new technologies is a multi-faceted issue. A recent review carried out by the Food Standards Agency indicated that trust is one among several important factors underlying the public's responses to GM food and to food innovation in general (National Centre for Social Research, 2009). Responses are also governed by other variables including attitudes to health, the environment, and science, as well as deep seated values and fundamental world outlook and personal and familial habitual behaviours.

Stakeholders were also asked how the quality of EU-wide trust in science-based risk assessment might be improved in the GM context. Two improvements were consistently identified by stakeholders. The first was that decisions should be clearly based on scientific risk assessments rather than politics. Some stakeholders added that trust is currently undermined as some parties try to discredit EFSA's risk assessment. 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 addition to these two commonly-identified improvements, other suggested improvements included: the need for more transparency/neutral scientists; the need for improvement in EFSA's working methods or for long-term tests; and, the need for GMs which are beneficial to Europeans.

2.7. Options for the future

Respondents were asked to consider a number of potential options covering different aspects of the GM legislation alongside the *status quo* option.

2.7.1. Risk assessment and the authorisation process

With respect to risk assessment, most Competent Authorities (20, 91%) and most stakeholders (70%) noted that the *status quo* should remain, i.e. risk assessment should be carried out by EFSA (Table 2.9). One Competent Authority out of the 22 answering this question stated a preference for returning to risk assessment carried out by a rapporteur Member State (a view shared by 7% of stakeholders, *consisting mainly of the majority of NGOs*) and one felt that risk assessments carried out in agreed Third Countries should be used within the EU authorisation process. Some 22% of stakeholders agreed with the use of agreed Third Country risk assessments; *this included the majority of feed processors and almost half of trader respondents*.

Table 2.9: Summary of support for options relating to risk assessment

	Competent Authorities	Stakeholders
Carried out by EFSA (<i>status quo</i>)	20 (91%)	70%
Carried out by a rapporteur Member State	1 (5%)	7%
Agreed Third Country risk assessments used where available	1 (5%)	22%

While 16 Competent Authorities (73%) stated that the decision to authorise (or not) should be taken by the European Commission after consulting Member States, i.e. the *status quo*, only 49% of stakeholders, including a high proportion of technology providers, agreed (Table 2.10). Some 38% of stakeholders would prefer a system where the European Commission takes the decision to authorise or not without input from the Member States; *this included the majority of feed processors and traders*. Only two Competent Authorities (9%) from the 22 providing an answer agreed supported this option. The proportion of Competent Authorities and stakeholders which suggested that the decision to authorise should be taken by Member States without input from the European Commission was similar at 18% (four) and 13% respectively, *although most of the stakeholders selecting this option were NGOs*.

Table 2.10: Summary of support for options relating to risk management

	Competent Authorities	Stakeholders
A decision to authorise or not is taken by the Commission after consulting Member States as under Regulation (EC) No. 1829/2003 (<i>status quo</i>)	16 (73%)	49%
A decision to authorise or not is taken by the Commission alone	2 (9%)	38%
A decision to authorise or not at the Community level is taken by Member States with no input from the Commission	4 (18%)	13%

Table 2.11 shows that a majority of both Competent Authorities and stakeholders noted that socio-economic criteria should not be considered within the authorisation process (*status quo*), although a higher proportion of stakeholders held this position (71% compared to 11 Competent Authorities, 52%). *Among stakeholder, all NGOs believed in the use of socio-economic criteria and feed users were also disproportionately likely to select this option*.

Table 2.11: Summary of support for options relating to the use of socio-economic criteria

	Competent Authorities	Stakeholders
Socio-economic criteria should not be considered (<i>status quo</i>)	11 (52%)	71%
Socio-economic criteria should be considered	10 (48%)	29%

Respondents who thought that socio-economic criteria should form part of the authorisation process were asked to specify up to five criteria to use. However, most Competent Authorities did not take this opportunity. The criteria that were suggested by Competent Authorities (and how they should be applied) are set out in Table 2.12.

Table 2.12: Competent Authority suggestions for socio-economic criteria and their relevance

Member State	Suggested criteria	Relevance
Austria	Sustainability	GM food and feed
	Regional conditions	GM food and feed
	Precautionary principle	GM food and feed
	Public acceptance	GM food and feed
	Fair trade	GM food and feed
France	National risk assessment	Not stated
Italy	Cost/benefit analysis	GM food and feed
	Protection of local and traditional products	GM food
	Protection of agro-biodiversity	GM food and feed
	Practicalities of coexistence	GM food and feed

Table 2.13 sets out the frequency with which socio-economic criteria were mentioned by stakeholders.

Table 2.13: Stakeholder suggestions for socio-economic criteria and their relevance

Suggested criteria	Number of times mentioned
Economic impact on non-GM/organic farmers and food chain (including coexistence)	5
Agronomic (farmer income; yield; agronomic functionality, e.g. drought tolerance; energy requirements)	4
Environmental effects	4
Impacts on local economies (on resources, non-farm activities and other impacts)	3
Nutritional value/functionality of food	3
Safety concerns (consumer trust; known risks versus uncertainties; general safety)	3
Sustainability of agricultural practices (including pesticide usage)	3
Availability (supply)	2
Effects on seed production (general production and non-GM plant breeding)	2
Impacts on non-EU farms	2
Public acceptance	2

Various other agricultural criteria were mentioned by individual stakeholders, including farmer acceptance and independence. There were also further criteria, such as price, public confidence in the approval process and commodity price effects.

Some 38% of stakeholders agreed that public comments should be sought for each application on release of the EFSA opinion (*status quo*) this included the majority of technology providers and NGOs (Table 2.14). A similar proportion (37%) felt that public comments should be sought in a more targeted manner, for example, only with regard to specific aspects of an application if needed; traders were disproportionately more likely to select this option. A quarter (24%) of stakeholders felt that public comments should only be sought for more general questions on the implementation of the GMO legislation, for example, when the authorisation of a new type of GM event is considered. Only one respondent felt that public comments should not be sought at all. These results show less general agreement than for other aspects of the authorisation process.

Table 2.14: Summary of support for options relating to public comments

	Stakeholders
Public comments should be sought for each application on release of the EFSA opinion (<i>status quo</i>)	38%
Public comments should be sought by the Commission in a more targeted manner (e.g request comments only with regard to specific aspects of an application if needed.)	37%
Public comments should only be sought for more general questions on the implementation of the GMO legislation, for example, when the authorisation of a new type of GM event is considered	24%
Public comments should never be sought	1%

Almost three quarters (16, 73%) of Competent Authorities and 60% of stakeholders felt that the generation of independent data for risk assessment should be considered to feed into the risk assessment, i.e. data generated by trials carried out independently of the technology provider (Table 2.15). *Technology providers, traders and feed processors were generally against independent data generation, while the feed users, NGOs and consumer organisations were generally in favour of it; the food industry was broadly impartial.*

Table 2.15: Summary of support for options relating to the use of independent data

	Competent Authorities	Stakeholders
Independently generated data should be used	16 (73%)	60%
Independently generated data should not be used (<i>status quo</i>)	6 (27%)	40%

A number of practical difficulties were raised by Competent Authorities. The Belgian, Finnish and French Competent Authorities, for example, noted that someone other than the technology provider would have to finance the research; some added that this burden should really be borne by the applicant who will benefit from the technology.

A number of other Competent Authorities suggested that independent data could be generated by research institutes within Member States, although the issue of financing was not addressed. Many added that the research should be peer assessed and some suggested that Member State Competent Authorities should be involved.

The UK Competent Authority pointed out that the use of independent data is not required in other areas, for example, in relation to feed additives; such an approach for GMOs would therefore not be coherent. In contract the Austrian Competent Authority thought that independent data should be used in a system similar to the one which applied to feed additives prior to 2003.

Stakeholders in favour of the generation of independent data mentioned the following possibilities: generation by EFSA; generation by an academic institute with the assistance of public funding; possible generation by Member States; public tender; and, making the whole submitted dossier available for examination by Member States. Some stakeholders suggested that the costs could be financed by charging a registration fee for applications.

On the other hand, some stakeholders against independent data generation commented on the difficulty with GM events under production, most notably intellectual property right problems, liability problems, and a perceived lack of impartiality of “independent” institutes. Some stakeholders also mentioned that for other regulated new technologies such as pharmaceuticals, it is up to the applicant to build a comprehensive dossier for the risk assessor and the approach to GMs is therefore currently coherent. Others expressed concerns as to the effects independent data generation would have on asynchronous approvals due to authorisation delays. A range of views was provided on the authorisation of stacked events as presented in (Table 2.16).

Almost half of Competent Authorities (11, 48%) felt that the current treatment of stacked events, i.e. they must receive authorisation even where the single events have been separately authorised, should continue. Just over a fifth of stakeholders (22%), *mainly NGOs and consumer organisations*, supported the *status quo*.

Almost a third (31%) of stakeholders noted that stacked events should undergo a **fast-track risk assessment** based on previous EU risk assessments of single events and the **current authorisation process**; however, only one Competent Authority (4%) supported this position. A quarter of stakeholders (24%) responded that stacked events should undergo a **fast-track risk assessment** based on previous EU risk assessment of single events and a **fast-track authorisation process**, a view shared by three Competent Authorities (13%). Taking these responses together, more than half (55%) of stakeholders and four Competent Authorities (17%) have a stated preference for a **fast-track risk assessment** for stacked events.

A small minority of stakeholders and one Competent Authority felt that stacked events should be automatically authorised where all the events have already been authorised singly in the EU.

With the *exception of consumer organisations and NGOs*, stakeholder groups preferred a fast-tracking of some kind. *Technology providers generally favoured a fast-track risk assessment and current authorisation process. Other groups were more split, with main interest in either a fast-track risk assessment and the current authorisation process, or both a fast track risk assessment and fast-track authorisation procedure.*

Stakeholders suggesting other approaches mentioned: a case by case approach; pre-notification with a 60 day period for Member States to study the dossier; and, different authorisation systems depending on whether the single event has been authorised in the EU or not.

Some stakeholders commented that experience has shown a risk assessment for stacked events not to be necessary. However, others believed the risk assessment to be necessary as stacked events may have different toxicological and environmental effects. Several stakeholders believed that if there is no fast-tracking, the backlog of applications, and ultimately the asynchronous approvals situation, will worsen.

Table 2.16: Options for the treatment of stacked events within the authorisation process

Option	Competent Authorities	Stakeholders
Stacked events must receive authorisation even where the single events have been separately authorised (<i>status quo</i>)	11 (48%)	22%
Stacked events should be automatically authorised where all the events have already been authorised singly in the EU	1 (4%)	6%
Stacked events should undergo a fast-track risk assessment based on previous EU risk assessment of single events and the current authorisation process	1 (4%)	31%
Stacked events should undergo the current risk assessment process and a fast-track authorisation process	4 (17%)	7%
Stacked events should undergo a fast-track risk assessment based on previous EU risk assessment of single events and a fast-track authorisation process	3 (13%)	24%
Other options (case-by-case approach, Danish Competent Authority, not specified, French Competent Authority)	3 (13%)	10%

The Netherlands government considered that it is worthwhile exploring the option of a fast track procedure for stacked events where the single events have already been authorised, as long as this maintained the current (high) level of protection of health and the environment. The Belgian Competent Authority felt that a full risk assessment should be carried out for stacked events, but that the risk management process could be fast-tracked.

Finally, the UK Competent Authority explained that EFSA has suggested that the risk assessment for stacked events is already simplified by drawing on the assessment of the single events.

2.7.2. Labelling

Competent Authority responses on **positive labelling** options show more agreement than stakeholder responses; three-quarters (17, 74%) noted that there should be mandatory positive labelling for food produced from and/or containing GM material (*status quo*) (Table 2.17). Only a third (35%) of stakeholders supported the *status quo*.

A fifth of stakeholders and three Competent Authorities (13%) suggested that mandatory positive labelling should be extended to cover livestock products (meat, eggs and milk). Some 28% of stakeholders (and one Competent Authority, 4%) noted that mandatory positive labelling should only apply to products containing GM material (and by implication could be subjected to a testing regime), i.e. no labelling for oil products.

Eleven percent of stakeholders felt that there should be no positive labelling at all, although no Competent Authorities held this view. A very small number of Competent Authorities and stakeholders supported voluntary positive labelling.

Replies from different stakeholder groups were generally as might be expected. *Most technology providers preferred the status quo. Most feed processors, feed users, traders and food industry*

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respondents preferred either the status quo, or a loosening of the current requirements (i.e. mandatory positive labelling, but excluding products produced from GMs, or a voluntary system). All NGOs preferred the extension of mandatory positive labelling to include livestock products.

Table 2.17: Summary of support for options relating to the use of positive labelling

	Competent Authorities	Stakeholders
Mandatory positive labelling for food produced from and/or containing GM material (<i>status quo</i>)	17 (74%)	35%
Mandatory positive labelling only for products containing GM material (i.e. no labelling of oil)	1 (4%)	28%
Mandatory positive labelling for products currently labelled and livestock products including meat, eggs and milk	3 (13%)	20%
Voluntary positive labelling for food produced from and/or containing GM material	0 (0%)	3%
Voluntary positive labelling only for products containing GM material (i.e. no labelling of oil)	2 (9%)	1%
Voluntary positive labelling for products currently labelled and livestock products including meat, eggs and milk	0 (0%)	1%
There should be no positive labelling	0 (0%)	11%
Other options (no labelling for products such as honey where GM content cannot be controlled)	0 (0%)	1%

Almost a third (6, 27%) of Competent Authorities and a majority of stakeholder (58%) were not in favour of the use of **negative labelling** (Table 2.18).

Just over half of Competent Authorities (13, 59%) and a quarter of stakeholders supported the use of voluntary negative labelling. Generally respondents felt that appropriate scope, criteria and purity levels should be defined at the EU level (ten Competent Authorities (77%) suggesting voluntary negative labelling, 45% of all Competent Authorities and 70% of stakeholders suggesting voluntary negative labelling, 19% of all stakeholders). Small proportions of both respondent groups suggested either nationally or privately defined schemes.

Four Competent Authorities (18%) and 15% of stakeholders suggested the mandatory use of negative labelling. Almost all respondents felt that this should have appropriate scope, criteria and purity levels defined at the EU level.

The UK Competent Authority noted that any labelling should be both practical and enforceable, whilst a number of Competent Authorities reiterated that any labelling should be harmonised at the EU level. The Finnish Competent Authority pointed out that Finland is against the use of negative labelling because such labelling can mislead the consumer. The Belgian Competent Authority added that there is a need for a legal definition of the term “adventitious and technically unavoidable”. The Danish

Competent Authority explained that there should be no conflict with the nutrition and health claims legislation¹⁵.

Once more, replies from different stakeholder groups were generally as might be expected. The majority of traders, technology providers and food industry respondents were against the use of negative labelling, as were approximately half of feed industry and feed user respondents. Notable proportions of feed industry and feed user respondents favoured voluntary negative labelling with EU-defined criteria. All NGOs favoured negative labelling of some kind, with a significant proportion favouring mandatory EU-defined negative labelling.

Several respondents further commented that negative labelling would be misleading as it is not possible to guarantee the absence of GM material, and that GM technology is used in various enzymes and additives. Some respondents commented that harmonised negative labelling could enhance consumer choice.

Table 2.18: Summary of support for options relating to the use of negative labelling

	Competent Authorities	Stakeholders
Mandatory negative labelling, i.e. “GM-free”, with appropriate scope, criteria and purity levels to be defined at the EU level	3 (14%)	14%
Mandatory negative labelling, i.e. “GM-free”, with appropriate scope, criteria and purity levels to be defined nationally	1 (5%)	0%
Mandatory negative labelling, i.e. “GM-free”, with appropriate scope, criteria and purity levels to be defined privately	0 (0%)	1%
Voluntary negative labelling, i.e. “GM-free”, with appropriate scope, criteria and purity levels to be defined at the EU level	10 (45%)	19%
Voluntary negative labelling, i.e. “GM-free”, with appropriate scope, criteria and purity levels to be defined nationally	1 (5%)	4%
Voluntary negative labelling, i.e. “GM-free”, with appropriate scope, criteria and purity levels to be defined privately	1 (5%)	4%
There should be no negative labelling	6 (27%)	58%

The vast majority of Competent Authorities (21, 88%) stated that the current 0.9% threshold for adventitious and technically unavoidable presence, above which products need to be labelled as containing GM material, should be maintained for **food** (Table 2.19). This view was shared by 69% of stakeholders, *including the majority of all stakeholder groups with the exception of NGOs*. The Belgian Competent Authority pointed out that there would have to be clear justification for changing

¹⁵ Regulation (EC) No 1924/2006.

the current level. The Cypriot Competent Authority felt that a lower level should be used, although did not specify what this should be. Another Competent Authority (Hungary) suggested that while the 0.9% tolerance level for adventitious and technically unavoidable presence should remain for conventional food products, organic products should be labelled for GM content above the detection level. The French Competent Authority noted that the level of tolerance is currently expressed as a percentage of DNA, but that the European Commission has discussed the idea of expressing the percentage in terms of mass; a clarification is needed on this point. This point applies equally to GM feed.

Some 10% of stakeholders, mainly NGOs, felt that a tolerance level for adventitious and technically unavoidable presence lower than 0.9% should be used for food while 15% thought that a higher threshold level should be used. Most stakeholders suggesting lower threshold levels suggested the technical detection limit /0.1%, while one proposed 0%. Stakeholders proposing a higher threshold suggested alignment with trade standards used elsewhere, for example 3% or 5% as in Asia.

Stakeholders who proposed another solution either proposed no threshold, or 0.9% for non-EU authorised GMs.

Some stakeholders provided further comments. Some thought that the threshold should be in line with that of Third Countries, agricultural supply chain standards and/or other thresholds for impurities. Some stakeholders insisted on the need to maintain the idea of adventitious presence rather than to have a threshold alone. Several stakeholders commented that the original threshold was rather arbitrarily set, and one stakeholder believed that any increase of the threshold could undermine public confidence, in turn affecting the acceptance of second and third generation GM events.

Table 2.19: Summary of support for options relating to the use of a labelling threshold for food

	Competent Authorities	Stakeholders
A tolerance level of 0.9% should be used for food (<i>status quo</i>)	21 (88%)	69%
A tolerance level lower than 0.9% should be used for food (please specify below)	2 (8%)	10%
A tolerance level higher than 0.9% should be used for food (please specify below)	0 (0%)	15%
Other approach	1 (4%)	6%

With respect to **feed**, 20 Competent Authorities (87%) felt that the current 0.9% threshold for adventitious and technically unavoidable presence should remain, as did 65% of stakeholders (Table 2.20). Two Competent Authorities (9%) suggested that a lower tolerance level should be used, but did not specify what this should be. Another Competent Authority suggested that while the 0.9% tolerance level for adventitious and technically unavoidable presence should remain with respect to the conventional sector, the organic sector should not use any feed with GM content above the detection level.

Over a fifth (22%) of stakeholders, *including significant proportions of feed users and the food industry*, felt that a higher tolerance level should be used for feed while 8% (*including the majority of NGOs*) felt that the tolerance level should be lower.

As with regard to food, stakeholders proposing a lower threshold for GM feed generally suggested the technical detection limit /0.1%, while one proposed 0%. Stakeholders proposing a higher threshold

suggested: alignment with trade standards; an analogy with feed law and botanical purity; 2%; 3%; and 5%. Stakeholders who proposed another solution proposed no threshold.

Further comments provided by stakeholders were generally similar to those provided in relation to GM food. A few added that this is a botanical impurity, and the threshold level should be set accordingly (for example, in other fields these levels are 1%-2%), or that there was no reason to have different levels for GM food and feed.

Table 2.20: Summary of support for options relating to the use of a labelling threshold for feed

	Competent Authorities	Stakeholders
A tolerance level of 0.9% should be used for feed (<i>status quo</i>)	20 (87%)	65%
A tolerance level lower than 0.9% should be used for feed (please specify below)	2 (9%)	8%
A tolerance level higher than 0.9% should be used for feed (please specify below)	0 (0%)	22%
Other approach	1 (4%)	6%

Half (12, 50%) of Competent Authorities suggested that there should be a tolerance level other than zero for GM material which has been risk assessed, but not yet fully authorised, in the EU, i.e. a system similar to the transitional measures that were provided under Article 47 of Regulation (EC) No 1829/2003 (Table 2.21). Typically a level of 0.5% was suggested in line with this Article. However, only a quarter (24%) of stakeholders agreed with this position. The Belgian Competent Authority suggested an approach based on ALARA with 0.1% used as a threshold because this is in line with the current analytical detection limits. This was also the value suggested by the Austrian Competent Authority. The Czech Republic Competent Authority suggested a level of 0.3%. In contrast, the Spanish Competent Authority explained that the level should be high enough to avoid the rejection of feed shipments, i.e. substantially above the limits of detection.

A third of Competent Authorities (8, 33%) were in favour of maintaining the *status quo*, i.e. maintaining zero tolerance of the presence of GM material not fully authorised in the EU, as were 22% of stakeholders. Some 38% of stakeholders felt that there should be a tolerance level other than zero for GM material authorised in Third Countries, but not risk assessed in the EU, although this view was only shared by the Lithuanian Competent Authority which did not specify a limit to be used.

The UK Competent Authority suggested a different approach, and, although this was not specified, it was noted that any approach to adventitious presence should be consistent with other EU legislation and expressed a preference for a technical solution based on official food and feed controls. The Danish Competent Authority also suggested a different approach, although in this case it was to wait for a European Commission proposal on a common detection limit.

Responses from different stakeholder groups were broadly as might expected. The majority of NGOs and consumer organisations favoured zero tolerance. The majority of other stakeholders favoured a tolerance level of some kind. Feed users and the food industry were split between a tolerance level for EU risk assessed and Third Country risk assessed events. Feed processors and traders generally favoured the most liberal option of tolerance levels for Third Country risk assessed events. Several technology providers selected “other”, and believed that the best solution would be mutual recognition of safety assessments and Third Country authorisations.

One respondent selecting “other” pointed to the Swiss model as a possible solution, and another pointed to a system similar to labelling, where a threshold is used in conjunction with the concept of adventitious and technically unavoidable presence.

Those stakeholders in favour of a tolerance level of some kind commented that it is becoming increasingly difficult to trade with Third Countries (as demonstrated by the problems of 2009) and in the future the situation will become even worse. Several commented that “zero” does not exist and is not practicably achievable. Those advocating a tolerance level for Third Country risk assessments said that this level could be for risk assessments performed to international standards, e.g. Codex Alimentarius guidelines.

Stakeholders in favour of zero tolerance commented that levels of care are likely to fall if thresholds are introduced, even if this is for adventitious and technically unavoidable presence, and citizens could be exposed to potentially harmful GMs. Some stakeholders, *predominantly NGOs*, identified asynchronous authorisation as being a US problem rather than an EU one and/or felt that the EU should use its power as a trading partner to insist on zero tolerance.

Table 2.21: Summary of support for options relating to the use of a tolerance threshold for adventitious and technical presence of unauthorised GM material

	Competent Authorities	Stakeholders
There should be zero tolerance of the presence of GM material not fully authorised in the EU (<i>status quo</i>)	8 (33%)	22%
There should be a tolerance level other than zero for GM material risk assessed, but not yet fully authorised in the EU (similar to the transitional measures that were provided under Article 47 of Regulation (EC) No. 1829/2003, where the tolerance level was set at 0.5%)	12 (50%)	24%
There should be a tolerance level other than zero for GM material authorised in Third Countries, but not risk assessed in the EU	2 (8%)	38%
There should be some other approach (please specify)	2 (8%)	17%

Stakeholders who advocated a tolerance level other than 0.9% for adventitious and technically unavoidable presence were asked to specify an appropriate level. These are presented in Table 2.22.

Table 2.22: Suggested thresholds for adventitious and technically unavoidable presence of GM events not authorised in the EU

Level	Number of stakeholders
0.5% (or at least 0.5%)	18
0.9% (or at least 0.9%)	14
Between 0.1% and 0.9%	4
Dual system: 0.5% / 0.9%	2
0.1%	1
Between 0.3% and 0.5%	1
Botanical impurity	1

Several stakeholders, mainly those specifying a threshold of 0.5% said that the threshold would have to be flexible and must be able to evolve over time taking into account the global market situation of GMs. Some stakeholders who suggested a threshold of 0.5% noted that this would be compatible with the current labelling requirements. Several stakeholders choosing 0.5% or 0.9% further commented that a Swiss-style system would be suitable.

Respondents were asked to set out the single most important improvement that could be made to the risk assessment process. Three main views emerged amongst Competent Authorities.

The first included variations on the theme of increasing the speed of the risk assessment process (responses from the Czech Republic, the Netherlands and the UK); the Netherlands government suggested the capacity within EFSA may need to be increased.

The second main view was that greater emphasis should be based on the scientific risk assessment (Competent Authorities in Estonia and Hungary). The Hungarian Competent Authority made clear that such focus on science requires improved guidelines to include the use of independent and long-term data.

The third main view was that closer collaboration is required between EFSA and national risk assessment bodies (Competent Authorities in Belgium, Cyprus, Finland and France).

Both the Austrian and Slovenian Competent Authorities stated that the assessment of stacked events should not simply rely on the assessments of the single events, i.e. the *status quo* should be maintained. The Italian Competent Authority expressed the wish to introduce a quantitative risk assessment, although this was not elaborated. Finally, the Danish Competent Authority made the practical and specific suggestion that questions asked by the different working groups in the GMO panel should be co-ordinated with the proviso that no questions can be asked on the original application after six months from the date of acceptance of a complete dossier. Additionally, each working group should have its own time limit.

Stakeholder views were broadly similar to those of Competent Authorities. *Feed processors and traders generally identified either faster authorisations (for example, with clearer timelines) or mutual recognition of Third Country risk assessments as the single most important potential improvement. Technology providers almost unanimously identified a purely science-based approach without political considerations as the main possible improvement. The food industry identified either faster*

authorisations or a strictly science-based approach. The opinions of feed users were more divided; some identified faster authorisations and the use of Third Country risk assessments, some the focus on science only, and some more transparency and impartiality from EFSA. NGOs generally identified independent research of some kind or higher quality risk assessments as the most important improvements, with a couple adding the inclusion of socio-economic criteria as a further improvement.

Respondents were asked to set out the single most important improvement that could be made to the risk management process. Three Competent Authorities (Belgium, Denmark and Finland) and the Netherlands government noted that the most important improvement would be a more speedy authorisation process. The Belgian Competent Authority added that the post-marketing monitoring process should be improved and harmonised at the EU level in order to deal with potential foreseen and unforeseen impacts. The Hungarian Competent Authority also called for more thorough monitoring activity post-marketing and added that this should be based on scientific studies rather than simply farmer questionnaires.

The Czech Republic Competent Authority called for the establishment of technical limits for the presence of GM events which have been positively risk assessed, but which have not yet been authorised in the EU. The UK Competent Authority called for Member State voting to be based on the criteria defined in the legislation and for increased transparency with regard to the rationale for positions taken by Member States. The French Competent Authority requested that a minimum performance threshold for detection methods should be established for GM events that have been positively risk assessed by EFSA. The Spanish Competent Authority requested the minimisation of unilateral risk management by individual Member States. Finally, the Austrian Competent Authority insisted that the European Commission, as the most important risk manager, must take more care on the issues of uncertainty and the use of the precautionary principle where EFSA dismisses relevant Member State comments.

Stakeholder views were slightly different. *Feed processors and traders identified de-politicisation (generally through the transference of decision making to the European Commission alone), or the use of a threshold for unauthorised events as the main potential improvements. Technology providers either believed that the risk management procedure should be speeded up (and should respect the timelines in the legislation), or that a threshold for the presence of adventitious and technically unavoidable unauthorised events should be established. Food industry respondents believed that either the process should be speeded up, or that the European Commission should make the decision without input from Member States. Once again feed users were divided. Their suggested improvements included: the de-politicisation of the process; the speeding-up of the process; assurance systems to allow for comingling with GM events; thresholds for the adventitious and technically unavoidable presence of unauthorised events; greater transparency; and, more involvement of EU and national bodies. NGOs suggested the following improvements: better post-market monitoring; guarantee by the European Commission that EFSA's risk assessment fulfils requirements; application of the precautionary principle; the consideration of different opinions and Member State studies to ensure that risk management occurs.*

Respondents were asked to identify the single most important improvement that could be made to the labelling requirements. Nine Competent Authorities suggested that EU-wide, harmonised provision should be put into place to allow "GM-free" labelling. The Romanian Competent Authority noted that mandatory labelling should only apply to products containing GM material, although this does not preclude the use of voluntary "GM-free" labelling.

One Competent Authority requested that labelling only apply where it is possible to detect the presence of GM material, i.e. oil products should no longer be labelled. In contrast, the German Competent Authority suggested that positive labelling should take a process rather than a product-

based approach, i.e. livestock products produced from livestock fed on GM feed should be brought within the labelling scope. Finally, the Czech Republic Competent Authority called for a symbol to label GM food and feed.

Once again stakeholder views were slightly different. Various stakeholders, *including the feed and food industry and traders* suggested that labelling should only apply for products which contain GM material (i.e. where it is detectable). Several stakeholders representing all groups said that voluntary negative labelling with EU-established criteria would be the key improvement. *Most NGOs identified the labelling of livestock products as the main potential improvement.*

Some stakeholders said that positive labelling should be removed as it is misleading; on the other hand, a few stakeholders advocated application of a 0% threshold for positive labelling. Finally a few stakeholders, *mainly technology providers* considered the current labelling provisions to be broadly adequate (though some commented that voluntary rather than mandatory labelling may be preferable).

3. Thematic case studies

Visits were made to twelve Member States, in accordance with the coverage agreed with the Steering Group, and interviews were undertaken with a range of Competent Authorities and key stakeholder organisations. Semi-structured interviews were conducted using a topic guide which was designed to gather evidence which could later be used in the construction of the Evaluation Questions. Interviews typically lasted for up to two hours and often involved multiple participants from the organisations concerned. All interview notes were returned to interviewees for verification.

The interviews were used to construct the following five thematic case studies with Member State coverage as follows. The selection of organisations to interview was guided by this coverage:

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

Each thematic case study is presented in the sub-sections below and a list of Competent Authorities and key stakeholders consulted is presented by Member State in section 11 of the main report.

3.1. Risk assessment and the regulatory approvals process

This case study is based on interviews undertaken in Austria, France and Belgium. Austria was selected as a Member State which is not in favour of GMOs in food or feed, though GM feed ingredients are tolerated, and operates a Parliament-supported “GM-free” scheme for food. France has instituted the Haut Conseil aux Biotechnologies (HCB) following the Law of June 2008, with two committees that mirror the EFSA GMO Panel and the Standing Committee on the Food Chain and Animal Health (SCFCAH) (pFR FNSEA), i.e. they provide scientific opinions on GM applications and make recommendations to public authorities. Belgium has internal federal complexities that create certain tensions with regard to GMOs and their management.

This case study focuses on the following Evaluation Questions which focus specifically on the perceptions and realities of the working of the existing legislation:

- **EQ3a:** To what extent has the EU authorisation procedure and its implementation ensured a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market?
- **EQ3b:** To what extent is the current EU approach on stacked events consistent with the objectives of the legislation and what has been its overall impact on the implementation of the regulatory approval process, including the number of pending authorisations and the workload for both EFSA and the Commission?
- **EQ4a:** To what extent are the different steps of the harmonised procedures established by the Regulation for the risk assessment and authorisation of GM food and feed efficient, time-limited and transparent and correspond to demonstrated risks in a proportionate manner?

- **EQ4b:** What has been their impact on the evolution of the sector and the EU society at large?
- **EQ5:** 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 MS?
- **EQ6a:** To what extent is the common and centralised authorisation procedure foreseen by Regulation (EC) No 1829/2003 (one door, one key principle) efficient compared to the situation that was prevailing before the adoption of the Regulation?
- **EQ6b:** To what extent is this procedure coherent with other procedures applying to similar sectors of the food safety *acquis*?

Seed, feed, food and farming industry interviewees in the three case study countries have provided the following background information:

- About 6 million tonnes of animal feed are produced in **Belgium** each year, which is distributed approximately as follows: 50-60% to pigs, 20-30% to poultry and 15-20% to cattle. Some 1 million tonnes of soybeans and soybean meal are imported, 60% from Brazil, 30% from Argentina and 10% from the USA. Maize by-products have not been imported since 2007 because of problems with LLP in USA imports.
- In **Austria**, feed usage is about 3.8 million tonnes, of which only about 1 million tonnes is produced by the feed industry; the majority is home-mixed by farmers. Some 450,000 tonnes of soybeans are imported, of which approximately 14% is "GM-free". There is no GM maize in Austria according to one industry interviewee, but large amounts of GM maize are used in feed, according to a grain/feed industry interviewee.
- In **France**, 22 million tonnes of animal feed are produced, 50% by cooperatives and 50% by private feed mills, with distribution of approximately 40% to poultry, 30% for pigs and 25% for cattle. Crops used are mainly cereals (60%) such as wheat, and soya beans (15%). France imports about 4.5 million tonnes soybeans each year, mainly as oil-extracted soybean meal (SBM) from Brazil. GM SBM accounts for around 80% of the import requirement, although in 2009 poor South American harvests led to sourcing from North America.

According to interviews, Austria is anti-GM; the country considers itself as "GM-free" for cultivation and food (reaffirmed annually in Parliament by the five political parties) and the possibility of GM-free status and labelling for food products is established in the Austrian Codex Alimentarius via guidelines. A couple of interviewees commented that there is no interest in the authorisation procedure in Austria, just on results, and that the GM discussion in the country is only negative. Due to Austria's "GM-free" status and the lack of interest in the authorisation procedure, few Austrian interviewees could provide significant comments on the risk assessment procedure.

The French Competent Authorities explained that the Haut Conseil aux Biotechnologies is proposing to include socio-economic criteria in HCB evaluations, and to develop a methodology for the definition of these. The criteria, which still have to be listed, should be considered at both the European and national levels and should cover all the food supply chain segments. Industrial interviewees considered that the HCB is not a representative body, as it does not include the food or animal feed industries or farming associations on its main committees, nor in its working groups. Other comments included that it does not make decisions, it provides recommendations to public bodies, and the recommendations seem increasingly anti-GMOs.

3.1.1. The extent to which the EU authorisation procedure and its implementation has ensured a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market

3.1.1.1. Similarities and differences pre- and post-2003

The common major improvement in the legislative framework is seen by the majority of respondents from industry and Competent Authorities, across all three case study countries, to be the bringing together of food and feed in the same legislation with a centralised risk assessment by EFSA. The legislation is overall regarded as fundamentally good and as an improvement on the Novel Foods Regulation (EC) No 258/97, more efficient and clearly explained and understandable; the new framework is also considered to be more simple and transparent. International NGOs were interviewed and felt that the legislative framework is relatively good; there are issues with the implementation, and with the absence of requirement for long-term safety studies, for example¹⁶.

On the other hand, its application is not regarded so positively by a number of producer organisation, biotech and food industry and feed industry interviewees, especially in relation to approvals for cultivation. One food industry respondent explained that the EU system became the strictest in the world with the introduction of Regulation (EC) No 1829/2003. A biotech industry representative noted that while the procedure is better on paper, the current legislative environment has brought only marginal changes, if any, in terms of human life and health, animal health and welfare, environment or consumer interests. The changes that this interviewee did perceive were not considered to be improvements. A feed industry interviewee explained that the legislation has worked as it should in too few cases.

One Competent Authority noted that the new legislation has ensured safe food and feed and environmental protection. However, whether it has enabled the free movement of goods and all-year secure supply of sufficient protein for EU livestock remains questionable. The risk assessment was seen by an Austrian interviewee as working effectively to protect human life and health in theory, but because Austrian people do not want GMOs, they believed there should be some way of bringing socio-economic criteria into the assessment. For Austrian interviewees, the new labelling requirements brought advantages to seed producers and farmers in terms of improving their ability to keep GM and non-GM apart, but brought problems for trading companies as products such as oil or sugar from GM crops cannot be tested.

3.1.1.2. Comparison with Third Countries

USA, Canada and Brazil were mentioned as the most important Third Countries in this context: USA and Canada in terms of regulatory systems and Brazil with respect to trade.

Here, more respondents seemed dissatisfied with the EU legislation. Belgian interviewees across the range of sectors and including the Competent Authority regarded the EU process as taking longer than that in the USA due to delays in the risk management phase resulting from the use of the comitology procedure and also as a result of the overloading of EFSA. In their view it is not clear why the EU should be stricter than Codex Alimentarius, regulate more issues than either Canada or USA or treat

¹⁶ One international NGO stated that the strong points of the legislation (in theory at least) are the use of independent risk assessments; consideration of the long-term environmental and health impacts (although, in their opinion, this is not done in practice); the safeguard clause under which Member States can ban individual GMOs (although Commission and EFSA do not take this seriously in the opinion of the NGO); the reference to socio-economic considerations (although these are not used in practice); and the labelling of products produced from GMOs (although there are issues concerning the 0.9% tolerance level and the fact that livestock products are not labelled).

stacked events in a different way to the USA. These differences were regarded as leading to the near-impossibility of sourcing “non-GMO” feed ingredients and to distortion of competition with Third Countries by industry respondents. Belgian feed industry interviewees in particular noted that exposure of imported feed ingredients or raw material to GMOs has worsened since 2003. In 2001-2003, a 1% tolerance for GMO content in imported feed and ingredients could be achieved. By 2007, 50% of sampled lots in Belgium were above this threshold; the non-GMO specification was discontinued because of the impossibility of keeping GM and non-GM production lines separate. A Belgian industry interviewee stated that the current policy displays a lack of coherence with the objective of increasing the competitiveness of industry, an essential feature of the Lisbon Agenda. The EU system was seen as being based on opinion and politics and not on science by three other respondents from Austria and Belgium, including a Competent Authority.

On the other hand, one international NGO said that it was the USA that was out of step with the EU, and Brazil and Argentina are more in line with the safety protocol of the EU than the USA, where there is a de-regulatory approach and no traceability in place.

Two interviewees in Austria saw advantages of the EU system vis-à-vis Third Country systems. One interviewee commented that the EU system is more focused on safety issues and environmental protection than those in other Third Countries. The same interviewee believed that the EU system is more appropriate to deal with current GM events; and that the system should be internationally accepted as the WTO did not question the legal framework within the EU, just its application. Another believed the US and South American systems to be more market driven than the EU ones and interpreted this as a weakness of these systems.

Despite Austria’s anti-GM stance, a couple of Austrian industry interviewees saw it as important to address the problems of asynchronous authorisation and LLP in Europe, because Austrian importers and feed producers were suffering from the consequences.

On the other hand, the French Competent Authorities commented that the risk assessment process is more developed in the EU than in Third Countries, and noted that the problem of asynchronous authorisations has created issues within the EU, where certain Member States react differently to LLP incidents, based on their own risk analysis of events not authorised in the EU. This approach may result in products containing LLP being dealt with differently, which creates disunity.

A French food sector interviewee considered that the current legislation is aligned to consumer expectations, but that several improvements should be integrated, without specifying what these might be.

Zero tolerance was mentioned as an issue which needs to be addressed by industry and all Competent Authorities across all case study countries. All but one interviewee who mentioned the zero tolerance approach held negative opinions, in some cases in rather strong terms. It was noted that this approach is not proportionate to the risks and that zero tolerance creates severe issues for the soybean crushing industry in Europe. The point was also made that zero tolerance applies to products that have already been assessed for any risk to humans in at least one country through recognised standards [Codex]. The response in favour of the zero tolerance approach noted that a move away from this policy would pose problems for the Austrian national “GM-free” policy.

It was pointed out by industry interviewees, mainly from France, but including organisations from Belgium and Austria, that other substances (i.e. contaminants), some of which are known carcinogens such as mycotoxins, have threshold levels based on scientific criteria, as do dioxins and heavy metals such as lead. Some added that acceptable limits are sometimes relaxed with one interviewee commenting that the 2006 maize harvest was very poor and, as a result, the European Commission doubled the maximum acceptable level of fumonisins to secure enough supply. On the whole, interviewees could not see why thresholds are defined for known unsafe materials, but are not defined

for GM events whose risks have, in the case of many asynchronous authorisation at least, been assessed by EFSA and in any case by risk assessors in Third Countries. Industry interviewees in Austria and France also pointed to a need to decide whether the threshold for adventitious and technically unavoidable presence is applied to total GM content or to each individual gene event, especially in relation to stacked events or in relation to co-mingling with more than one GM crop. The French Competent Authorities believe that LLP problems should be solved by establishing a threshold for adventitious and technically unavoidable presence, but only for events positively risk assessed by EFSA; a level of 0.9% was suggested.

3.1.2. The current EU approach on stacked events

The majority of interviewees, across the range of sectors and in all three Members States, recognised the need to review data on stacked events where there was reason to believe that the characteristics produced by the stacked events might be more than simply the sum of the single event characteristics. For example, the French Competent Authorities noted that there might be unexpected interactions between the protein products of individual events in a stack. However, dissenting opinions came from industry interviewees in Belgium and France, who felt that the procedure for stacked events should be “lighter” and that the approval process should be based on science only, avoiding non-technical and non-scientific arguments at Standing Committee level. Concern was expressed by industry interviewees in Belgium and France that the present system was likely to be overwhelmed by the expected increase in the number of applications for stacked events based on the current numbers of applications in the USA. French interviewees noted that stacking genes (with up to eight events) is becoming the standard in the USA. They were concerned that a separate and complete new evaluation for stacked (already approved) events will result in a blockage at the EFSA level if no additional resources are granted.

Some interviewees were more cautious: the French Competent Authorities want the EU risk assessment process for stacked events to be kept as it is; an Austrian respondent noted that, because of scepticism about the safety of GM in Austria, citizens would favour a cautious approach to stacked events.

The Belgian and Austrian Competent Authorities did, however, note deficiencies in the current EU system for dealing with stacked events. These relate to the dossier information and to the way that EFSA handles the process. In terms of dossier information, it was noted that data provided to EFSA for the assessment of stacked events has sometimes been inadequate (for example, information only provided on the combination of events with no comparison with the single events and *vice versa*). There have also been cases where there has been insufficient information on the single events; cases where the single events have not been authorised in the EU (a prerequisite for authorising a stack); and, examples where there has been insufficient information on stacked effects (only information on single event effects had been provided). On process handling, the Austrian Competent Authorities were uneasy that Member State concerns arising from the original single event authorisations are not taken into account again during the stacked event authorisation.

Specific examples of stacks where the Competent Authorities of one Member State claimed the stack had not been fully investigated includes maize events 1507x59122, 59122x1507xNK603 and Bt11xGA21. EFSA noted that it has reminded applicants that it needs to see applications for individual genes, in order to conduct a risk assessment, followed by the relevant stacked events, not all submitted together; presumably this will aid full investigation.

3.1.3. Efficiency, timeliness, transparency and risk-proportionality of the harmonised procedures established by the Regulation

3.1.3.1. Transparency and access to information

The authorisation process was agreed to be transparent in full or in part by a number of respondents. However, two farming organisations found it not very transparent and complex; a feed industry interviewee said it felt that the information is probably there if a stakeholder does wish to access it, although it did not have a need to look for information itself and so could not verify this. One Competent Authority stated that, with one exception, the risk assessment element of the process is relatively transparent, but that the risk management element is not entirely transparent. The exception related to Member State access to new data and is explored in the next section on efficiency. The same interviewee added that it was, in their opinion, still difficult for the general public to submit comments on applications. Another Competent Authority considered that transparency across the entire process has been established. Support was expressed for the recommendations in the draft guidance document by EFSA on transparency issues. On a related topic, a biotech industry interviewee noted that there is a perception that EFSA does not succeed in promoting or communicating its opinions well.

3.1.3.2. Efficiency

The sub-questions concerning the efficiency of risk assessment and risk management generated the most comments from interviewees.

Risk Assessment

EFSA's performance in risk assessment was rated as effective, good, science-based, very clear and well-defined by a large number of interviewees. Typical comments were that there is absolutely no reason to doubt EFSA's objectivity and scientific rigour and that EFSA's risk assessment is professional and serious and there is no better alternative. A French grain/feed industry respondent commented that EFSA's work had been questioned in the early days as a result of insufficient resource and the fact that a "cut-and-paste" approach to dossiers using material submitted for authorisation in Third Countries was tolerated. However, EFSA has now created a professional and recognised platform of expertise. In the opinion of a Belgian agricultural producers' organisation, EFSA experts tend to be rather pro-GM orientated, although this is considered to be because they have analysed the issues and have therefore come to this evidence-based conclusion; there was no suggestion of bias. Belgian interviewees regarded requests to applicants for additional information as not problematic, as long as these requests are sensible.

Negative comments were received from the Austrian interviewees, and the Competent Authorities noted that Austria still criticises the criteria for risk assessment, risk management and EFSA guidelines, although it was satisfied that EFSA is now beginning to provide sufficient resources for an in-depth risk assessment. The Austrian Competent Authorities provided a detailed critique of the legislative process and of aspects of the EFSA GMO Panel risk assessment that they find problematic. On the other hand, the French Competent Authorities said that they have no particular problems with EFSA, except for the check on dossier completeness, and state that the assessment criteria must be improved. In their view, the single most important improvement would be for Member State Competent Authorities to be able to analyse the complete dossier, including material submitted to EFSA after the initial review, not just the initial dossier.

International NGOs are particularly scathing about the EFSA risk assessments, giving the following reasons, among others: they are based on data generated and submitted by the applicants only, EFSA does not take Member States' questions and comments properly into account, and EFSA experts are

not independent of industry. In particular, they state that, though the Standing Committee and Council are supposed to make decisions, it is effectively the EFSA opinion that the Commission accepts as an approval via the comitology process.

The Austrian Competent Authorities noted their concerns over acceptance by EFSA of incomplete or inadequate data (mentioning use of Southern Blots for transgene stability, wrong models of transgene conformation, toxicology tests on native unmodified protein not on complete food or feed), toxicology tests conducted according to obsolete guidelines (such as GM maize MON863), failure by EFSA to demand long-term toxicology studies (more than 90 days, multi-generation studies) and acceptance by EFSA of comparison data between GM plants and several non-GM varieties that may not resemble the GM plant, rather than their direct non-GM equivalent.

Procedural concerns from the Austrian Competent Authorities concerned a perceived inefficiency in that Member States and EFSA are working in parallel on the dossier (during the first three months), and complaints that EFSA does not share the initial dossier with Member States during the completeness check, nor circulate Member States' comments until the end of the 90-day comment period, so the Competent Authorities cannot have a scientific discussion on points with other Member States, and that, after the 3-month period for Member State comments, EFSA does not share with the Member States the new data sent by the applicant in response to requests for further information.

Further points made were that applications for industrial, non-food-and-feed use, are accepted, such as the Amflora potato (now authorised) and GM maize 3272. The Austrian view is that these dossiers should have been returned to applicants for authorisation under Directive 2001/18/EC. Another complaint was that applications for events unlikely to be imported into the EU, such as rapeseed T45, are accepted; these should be returned to applicants as "out of scope". Case-specific monitoring is not usually requested, but may still be needed, for example, to check on assumptions made during risk assessment or uncertainties. Finally, updated Monitoring Plans should be required by EFSA.

Three industry interviewees, one from each Member State, claimed there is a need for more resources to be allocated to EFSA in order to reduce the current risk assessment process time and allow EFSA to cope with the increasing number of tasks it is expected to perform, as well as manage the anticipated increase in applications for stacked events. The Belgian Competent Authority noted that pressure is put on Competent Authorities when EFSA opens several dossiers at once, since national experts may be unavailable.

Risk Management

The general perception across all three case study countries was that some or all of the risk management process is inadequate or inefficient. Main comments concerned the introduction of politics at the SCFCAH stage (described as 'political games' by one Belgian interviewee), the apparent lack of trust in EFSA opinions shown by Member States and members of the Standing Committee, and the nature of the comitology process itself.

Examples of the points made by Belgian industry interviewees are that EFSA opinions should be supported more by the political process, the Standing Committee should trust the scientific experts more, and that the risk management phase of the procedure is too political, destroying EFSA credibility and legitimacy, a point also made by a French production organisation. Two of the Austrian interviewees noted that some Member States vote based only on their political position, or bring various concerns that may be regarded as legitimate, although they are not scientific; that said it should be noted that the integration of these concerns in the risk management process via socio-economic criteria was welcomed by several Austrian interviewees. According to a French grain/feed industry interviewee, the way risk management is undertaken creates instability and a lack of clarity that leads to additional economic costs. Risk management was seen as much more chaotic than risk

assessment by a French food industry respondent, who noted that, while the legislation allows for decisions to be taken quite fast, decisions are too often postponed.

Comments were received on the positive aspects of political voting and negative aspects of the application of the comitology process from three Austrian interviewees and three French respondents. These noted, for example, that a decision based on science and economics alone is not considered to be sufficient for Austria, and that consumer opinion, influenced by NGOs, should drive the EU system. International NGOs point out that, because of the comitology process, the current system effectively means that EFSA opinions form the sole basis for the approval of GMOs. Further, as GM is considered by many to be a societal issue, decisions should be taken by the representatives of society, that is, elected politicians, not by the Commission. There was a view that such an approach would lead to increased consumer and citizen confidence in the approval system.

The French Competent Authorities and a French producer organisation saw no reason to change the current process, commenting that the system of risk assessment and then risk management is the only sustainable approach; there is also, in their view, no specific reason to modify the general and horizontal decision making process (i.e. the comitology procedure) for GMOs.

The single most important improvement according to the French Competent Authorities might be to consider setting a tolerance threshold for GM events that have gained a positive EFSA recommendation, notwithstanding their progress with respect to authorisation.

Timeliness

Six respondents, consisting of feed industry organisations, producer organisations and biotechnology industry representatives across all three Member States complained that the period from adoption of positive EFSA opinion to final authorisation is too lengthy. Additionally, there is a perceived lack of predictability in terms of the overall timescale for authorisation. Even if the risk management process, based on the comitology procedure, was seen as acceptable, delivery is still considered too slow. Competent Authorities requested more clarity in elements such as the time from receipt of an application by EFSA to emergence of the agreed EFSA opinion, as well as the dossier completeness check itself, and the time to then put EFSA opinions on Standing Committee agendas. The French Competent Authorities noted that the length of the authorisation process is mainly based on the risk assessment stage, which is more complex than in Third Countries, that the risk management phase works correctly and no delays have been observed in the transmission of files from the Commission to the Council. According to the French Competent Authorities, delays that may be observed at Commission level are dossier-specific and no general conclusions can be drawn from this observation, and some dossiers have been treated in a very straightforward manner without any delay.

The risk assessment itself is generally considered to take place in a timely fashion.

Risk-proportionality

Two interviewees from Belgium stated that the risk assessment part of the system is generally considered appropriate or broadly proportionate. However, a biotech industry interviewee stated that, in many instances, the procedural and dossier production effort is disproportionate to the potential risks: it is only proportionate to the obstacles set by NGOs for political reasons rather than in relation to a scientific rationale. Commission Services stated that the risk assessment is proportionate.

3.1.4. The impact of the legislation on the evolution of the sector and the EU society at large

3.1.4.1. The EU biotechnology sector

In general, all comments suggested that, in the opinion of interviewees, the EU GM legislation has a negative impact on crop, food and feed biotechnology R&D. Belgian interviewees saw it as a barrier to technology development, perhaps even leading to the eventual disappearance of the biotech sector from the EU, by withdrawal from EU-based and public-funded research, leading to a lack of resources for detection and identification, sale of EU enterprises to the US and an over-reliance on non-EU research. One Austrian interviewee noted that some Austrian academics had initially supported GM, but were strongly criticised and subsequently they moved to other areas of the EU. Research into GM apricots and potatoes apparently had to be stopped due to public pressure. The prevailing public view of GM does not encourage research in the EU.

3.1.4.2. Economic impacts

Detailed information was not provided in terms of the impact of GM legislation on GDP, skilled jobs or the wider economy because such impacts are considered to be very difficult to identify. The legislation was seen as forming a barrier to SMEs wishing to develop GM crops and ultimately leading to a situation in which EU farmers have become uncompetitive because they lack access to technologies available to their Third Country competitors. Belgian interviewees stated that the legislative framework has pushed up the cost of imported feed ingredients and raw materials, favours monopoly by a few multinational companies and will possibly lead to a reduction in domestic EU production of livestock with imports from Third Countries such as Brazil becoming more competitive.

3.1.4.3. Consumer perception and acceptance

Industry interviewees from Belgium and Austria did not feel that the existence of the legislation *per se* has had any impact on consumer perception or acceptance. The public are not generally perceived to know of or understand the legislation or its purposes, according to several of these interviewees. A Belgian food sector interviewee stated that it is not clear to the consumer why the scientific advice of the EFSA opinion is not systematically the base of decision making; for their part, the Austrian Competent Authorities did not believe that the comitology procedure is clear to consumers, who will not understand why the Commission authorises GM events when they have not been agreed by elected politicians in the Council. One commented that the zero tolerance of adventitious and technically unavoidable presence presented a negative image to consumers and encouraged NGOs and the media to be negative.

3.1.4.4. Specific GM events benefiting the EU

Certain GM events were mentioned (such as abiotic stress traits) by Belgian industry respondents, but the current legislative framework was thought to inhibit the development of these, not support them. The French Competent Authorities noted that the legislation is inadequate to allow potential EU-relevant benefits of future GMO traits because it lacks a socio-economic evaluation, which would allow the advantages to be better appreciated. The Austrian Competent Authorities felt that the current legislation favoured the development of “GM-free” food and feed supply chains through public pressure.

3.1.5. Emergency Measures

Austria has not used emergency measures so far in respect of GM food and feed. France has employed the safeguard measure (in combination with the provision in Directive 2001/18/EC) with respect to GM maize MON 810 and has asked the HCB to reassess the dossier and EFSA's positive opinion, on the grounds that the answers provided by EFSA to French questions during the renewal process were not complete.

Both French and Belgian Competent Authorities stated that the emergency measures procedure under Article 34 of Regulation (EC) No 1829/2003 are appropriate and legitimate; the Belgian Competent Authority believes that Article 34 should only be invoked in the case of new scientific data which has not been previously evaluated by EFSA. The system is thought by the Austrian Competent Authorities to be less effective than Article 23 of Directive 2001/18 which according to the Austrian Competent Authorities offered Member States more responsibilities for taking emergency measures. They are also concerned that, under Regulation (EC) No 1829/2003, it is the responsibility of Member States to prove that there is a safety concern, while before it was up to the applicant to prove that safety is documented. The French industry interviewees commented that the emergency measures are not the answer to the current state of the risk assessment and risk management process, as problems will continue to increase in the future, and that the emergency clause currently allows Member States to apply socio-economic criteria at the Member State level.

3.1.6. The “one-door, one-key” approach

The one door, one key policy was widely seen as being coherent with the operation of the single market and simpler, less expensive, more effective and more equitable vis-à-vis smaller Member States and operators working on an international basis. However, some concerns were raised that the policy might allow consumer sensitivity over GM food issues to translate into concern over the use of GM feed, according to a Belgian producers' organisation. Negative comments came from two Competent Authorities concerning the use of the procedure for cultivation applications rather than only GM food and feed, and its use for crops for industrial purposes (for example, GM potatoes for starch or GM maize/OSR for biofuels).

The Austrian Competent Authorities commented that the risk assessment under Regulation (EC) No 1829/2003 is generally focused on food and feed safety and therefore does not adequately cover the environmental risks associated with non-food and feed applications (i.e. GM crops for industrial use). This Competent Authority therefore supported the general return of responsibilities to Member States for all authorisations for cultivation. The French Competent Authorities have introduced a parallel national evaluation for any dossier, with the HCB carrying out environmental assessment and AFSSA conducting the food/feed evaluation.

No detailed information was provided on application costs. However, an industry interviewee responded in general terms that the costs for applicants were lower than under the previous system. However, three Belgian interviewees, including the Competent Authority, noted that application costs are very high and that only large companies can afford to submit a dossier. The interviewee involved in R&D estimated that the cost of generating a dossier amounts to around €6.5 million and stated that, as a result, many medium sized companies are unable to submit applications, a GM event in chicory in Belgium was mentioned as a case in point.

3.1.7. Coherence with other procedures applying to crop cultivation, feed and food

The other procedures with which there should be coherence are those relating to pesticide active ingredients, seed varieties and plant propagating material. Some interviewees also drew attention to legislation covering impurities and contaminants.

With respect to the assessment of pesticides, the rapporteur Member State carries out a risk assessment to guidelines which is subsequently peer-reviewed by EFSA. Data are generated by the applicant, as is the case for GM authorisations.

Seeds are evaluated at the national level. Data for assessing seed quality is produced and checked by Competent Authorities. EFSA publishes an overall opinion; the Commission drafts a decision, and Member States vote. The internal market is established through a common catalogue which is based on all national catalogues. However, Member States may opt out under certain conditions (related to safety or agronomic issues).

The zero tolerance of adventitious and technically unavoidable presence employed in the GM legislation is seen as providing a negative comparison with other relevant legislation. A typical comment, from a French grain/feed industry interviewee, is that in all the regulations dealing with contaminant issues, for example, pesticides, there is not a single case where zero tolerance is applied.

Similarities and differences were commented upon, noting that, for plant health products, applications for new molecules are centralised, but renewals and reformulations are handled at the Member State level; for medicines or plant health products, the Member State views are normally aligned with the expert panel's opinion because these areas are much less sensitive than GMOs, though one industry respondent noted that the European Medicines Agency considers patient benefits in its assessments, whereas EFSA considers only risk.

Austrian interviewees noted a similarity with the general food law, in that if there is no health risk a material can be used, but the food has to be labelled, and with the draft food additives legislation, where it is stated that everything which is not necessary should be forbidden, commenting that possibly the same approach should be taken for GMOs.

Eight interviewees from Austria and France, including the Competent Authorities, commented on inconsistencies and fundamental incoherence. An Austrian industry respondent and the French Competent Authorities perceived a need to align feed additive and GM food and feed legislation, as currently two applications and two separate authorisations are required. They also noted the need for greater alignment between Directive 91/414/EEC concerning plant protection products and Regulation (EC) No 1829/2003, in the case of herbicide-tolerant plants, to avoid duplication and ensure that the use of the GM plant and the herbicide were both according to the respective regulations.

A grain/feed industry interviewee from Austria commented that the 0.9% tolerance level for adventitious and technically unavoidable presence threshold for labelling in EU law was a political decision and not a technical decision and was concerned that, if a 0.9% tolerance level is introduced for seeds, in place of the current zero tolerance, it would be very possible that the final feed product contained more than 0.9%, which would make the system incoherent. French food industry interviewees commented that the absence of a tolerance threshold for seeds causes problems, stating that it is unacceptable that after nearly a decade of discussions and promises, the threshold for adventitious presence in seeds is not yet defined.

The Austrian Competent Authorities commented on a perceived inconsistency between GM feed and food and the feed additives legislation in the matter of long-term toxicology studies, which should be consistent if GM materials are used as feed additives.

French industry and R&D interviewees were concerned about the approach of the HCB, which is recommending a threshold for adventitious and technically unavoidable presence of 0.1% GM content for "GM-free" food and feed, as well as for co-existence. This is seen by one interviewee as not being consistent with the current regulation (0.9% for authorised events). The HCB's decision of alignment of the co-existence rules to the "GM-free" threshold is linked to a lack of an EU harmonised threshold for adventitious and technically unavoidable presence in "GM-free" supply chains. According to both respondents, such an approach should be harmonised at the EU level.

3.1.8. Conclusions and future options

One biotech industry respondent suggested that a special regime should be devised for SMEs to reduce the costs of GM applications. This could be similar to the European Medicines Agency's mechanisms to reduce costs for SMEs. However, this is outside the remit of this evaluation.

3.1.8.1. Options for risk assessment

Competent Authorities would welcome more communication between EFSA and the Member States during the risk assessment phase of the authorisation process and therefore welcome the proposed bilateral expert meetings with EFSA on specific subjects and the revised guidelines from EFSA. The Austrian Competent Authorities suggested that Member States could work on the dossier for the first three months, and then pass the dossier to EFSA; alternatively it was proposed that a lead Member State could review and then provide a report on the risk assessment to other Member States. The rationale for this is that Member States would be more involved in, and satisfied with, the risk assessment and, as a result, would stop slowing down the voting process. However, the French Competent Authorities stated that risk assessments should continue to be carried out by EFSA, not by a rapporteur Member State; some efficiency might be achieved by harmonising the risk assessment process at international level, for example via Codex Alimentarius.

The Belgian and French industry interviewees commented that there should be better communication to EFSA from the technology providers, with complete dossiers and data packages. The point was also made that where applications are for renewal of authorisation, a supplementary dossier of actual experience should be submitted. It was also suggested that dossiers should be simultaneously submitted in the EU and Third Countries, to aim for synchronisation, although this is obviously an issue for applicants. Three producer organisations in Belgium and France and the French Competent Authorities noted that Third Country risk assessments should not be accepted in the EU on the grounds of reliability and trustworthiness. One Belgian food industry interviewee believed it would be more efficient if products were directly adopted after EFSA has issued a positive opinion on the risk assessment, i.e. if there were no subsequent risk management process.

3.1.8.2. Options for risk management

Six interviewees addressed the question of establishing a threshold for adventitious and technically unavoidable presence as part of the risk management process: various levels were suggested for events given a positive risk assessment by EFSA, but not yet approved in the EU, from 0.1% to no limit. Grain/feed industry respondents from France and Belgium favoured a threshold for adventitious and technically unavoidable presence of 0.9% or higher, in the context of existing experience with LLP in imported grains. One French interviewee asked why a limit should be set at all for EFSA-approved events, when these could be authorised relatively quickly by the Commission through the comitology procedure. The French Competent Authorities also favoured a threshold for adventitious and technically unavoidable presence of 0.9% for both GM food and feed. Most interviewees discussing thresholds believed that events not authorised anywhere should be subject to zero tolerance. However, many felt that events authorised in Third Countries, especially using a risk assessment with at least one study conducted according to Codex guidelines, should have a threshold for adventitious and technically unavoidable presence of at least 0.5%.

With regard to the general process, the Competent Authorities considered that the *status quo* should be maintained, including the use of the comitology procedure. An Austrian producer organisation and an R&D organisation suggested that there could be more subsidiarity in the field of GMs, with a centralised risk assessment as at present, but with decisions on authorisations for all uses taken at a Member State level. Interviewees in other Member States felt that GM food and feed use would need to be authorised centrally in order to ensure the operation of the single market, but that cultivation

decisions could be taken by individual Member States. Individual comments concerning the procedure at SCFCAH suggested developing a standard list of questions permissible for discussion at SCFCAH, and changing the voting procedure to a simple majority for a positive opinion, retaining QMV for negative ones, although in practice this suggestion would require either changes to the comitology procedure or to the decision making process used in relation to GMOs.

3.1.8.3. Use of socio-economic criteria

Responses from interviewees were mixed in terms of introducing socio-economic assessments into the GM food and feed regulatory process. The French Competent Authorities were in favour of including socio-economic criteria in order to better appreciate advantages and disadvantages linked to the development of specific GMOs. The Belgian Competent Authority noted that the topic is still open for discussion.

Approximately half of industry interviewees were in favour of using socio-economic criteria, but there was no consensus about how this should be done. Austrian respondents were strongly in favour and wanted to see clear rules for who such 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. Belgian interviewees thought that benefits, not just risks, should be evaluated, but that there should be a Community position on cost-benefit approaches.

Additional criteria mentioned included using broader criteria such as “not grown on land from the Amazon forest”, or compliance with the “Round Table for Responsible Soya”. The point was also made that the pressure for the introduction of socio-economic criteria into the evaluation process comes from public opinion.

The other half of those industry and R&D respondents interviewed, typically from France and Belgium, stated that a socio-economic assessment should not be introduced. A main reason given for this was 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 cannot be considered to be solving the real issue, namely the better acceptance of the technology by the public. The development of the additional national tier of assessment of 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 as an example to highlight that the introduction of socio-economic criteria complicates the EU assessment process. According to the interviewee who mentioned this, 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. This 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.

3.1.8.4. Public comments

A Belgian producers' organisation was in favour of the use of public comments on the grounds that they can enlarge the pool of expertise available to EFSA. A Belgian food industry interviewee saw the use of public comments in the context of a broader communication effort, stating that improving public acceptance is a necessity, which should be done by communicating more to the consumer on topics including JRC research, EFSA missions and work and public (independent) research.

3.1.8.5. Use of independent data for risk assessment

Two Competent Authorities and an Austrian agricultural producers' organisation were in favour of the use of independent data for risk assessment. The Austrian interviewee commented that doubts are increasing about the risk assessments and a second or third opinion could help address this. The Competent Authorities could see the benefit of using independent data, but were concerned about how the costs would be met given that the costs of putting together an application dossier is high. Any use of public funds would create issues in terms of the private benefits to applicants following authorisation.

3.1.8.6. Treatment of stacked events

The Competent Authorities noted that EFSA was working on guidelines for the treatment of stacked events. These might include simplification for the treatment of stacked events, especially where the characteristics of the stacked cross are specific, or where a large stack has already been approved and where studies on each parental line are available. Also, where there is an already-authorized GM crop with a large stack and the application is for a smaller number of the component events, it may be possible to simplify the assessment or transfer the authorisation. According to one of the Competent Authorities, fast tracking stacked events may be appropriate at the risk management stage, but they noted that the practicalities of this would need careful consideration.

Better detection methods for stacked genes and management of a threshold for adventitious and technically unavoidable presence in relation to GM content are seen as important challenges by Competent Authorities and industry interviewees from all three case study countries. The Competent Authorities and a French grain/feed industry respondent noted that it is still unclear whether quantification of recombinant DNA should be based on the mass or the number of transgene copies. The grain/feed interviewee noted that the requirement in Commission Recommendation 2004/787/EC to use the DNA copy number unit related to the haploid genome is different from, for example, analysing GM mass, and is likely to lead to an overestimation of GMO content for stacked events. Difficulties are also foreseen in terms of discriminating between a single stacked GMO and the presence of several different co-mingled events. An Austrian industry interviewee also raised the issue of whether the 0.9% threshold for adventitious and technically unavoidable presence is for one GM event or for accumulated GM events, noting that different Member States interpret this differently.

3.2. Consequences of EU lagging behind Third Countries in authorisations

This case study is based on interviews undertaken in Italy, the Netherlands, Poland, Spain and the UK. These countries were chosen for varying reasons: Italy and Spain are heavily reliant on imported feedstuffs; GM maize is grown in Spain and, according to interviewees from feed industry and livestock producers' organisations, is not segregated for use in animal feed; the Netherlands is the main importation point into the EU for feed and food raw materials including GM soybeans and so might be more strongly affected by LLP incidents; Poland is a special case, as it has enacted a law that confines the use of GM ingredients to animal feed only (Polish Journal of Laws, 2006), i.e., food must

be GM-free, which is, however, suspended until January 2013 and may, according to a Polish industry interviewee, be replaced by a draft law currently under consideration by the Polish Parliament; the UK is less reliant on imported feed and has so far managed to operate non-GM supply chains, for example, in the poultry industry.

It should be noted that UK NGO interviewees objected to the phrase “lagging behind”, stating that, in their opinion, the USA has no functional authorisation process, and it is therefore the USA that is out of step with the EU.

This case study focuses on the following Evaluation Questions:

- **EQ7a:** What is the foreseeable trend of GM authorisations in the EU when compared with the authorisations granted in Third Countries and taking into account the expected worldwide evolution of the GM sector?
- **EQ7b:** What would be the consequences of possible differences between the pace of authorisations between the EU and its trading partners?

More specifically this case study focuses on the experiences resulting from the disparity between GM events authorised for food and feed in the EU and those that might be present, either intended or unintended, in imported seeds, food or feed, and what might be expected in the future, given trends in development and approval of GM events in the EU and in Third Countries.

This case study is set in the context of three major trends that are creating significant differences between the EU and the rest of the world:

- a continuing increase in the agricultural area planted to GM crops (section 3.4 of the main report);
- an increase in the number of countries adopting GM technologies for use in commercial agriculture (section 3.4 of the main report); and,
- a large increase in the number of authorised GM events and, in particular, the number of crops in which there are stacked events (OECD BioTrack Product Database; Stein and Rodríguez-Cerezo, 2009).

A UK producer interviewee noted that the EU is only around 27% self-sufficient in vegetable protein ingredients for livestock feed and, especially for soybeans, is highly-dependent on imports from the Americas. According to Italian feed industry sources, Italy imports 50% of its overall demand for feed protein, but 95% of its soybean demand; of the approximately 600 shipments of feed materials each year, only around 10 are certified GM-free, according to another green/feed industry respondent. Italian domestic production of soybeans and soybean meal from domestic soybeans amounted to just 418,000 tonnes and 183,000 tonnes respectively in 2008, compared with imports of 1.6 million tonnes of soybeans and 2.4 million tonnes of soybean meal; self-sufficiency in soybean meal is only 5% (feed industry estimates)¹⁷. The feed industry interviewees in Italy report that 96% of feed is labelled as GM (although this does not necessarily mean that this feed actually does contain GMOs). Poland, despite its vision of being a GM-free Member State (according to the majority of Polish interviewees¹⁸), imports 2.0-2.5 million tonnes of soybean meal each year and, according to the Polish poultry producers’ association, 95% of Polish poultry are raised on GM labelled feed. The Netherlands imports about 3 million tonnes of soybeans (beans and meal), 800,000 tonnes maize by-products,

¹⁷ Based by the Italian interviewee on information from Istituto Nazionale de Statistica (2009) and on selected import data available at <http://www.coeweb.istat.it>.

¹⁸ One Polish interviewee referred to the Polish Government policy that states that Poland is against GMOs in agriculture, food and feed and will remain so in the future.

canola (OSR) and linseed (flaxseed), according to a Dutch grain/feed industry interviewee. Spanish industry interviewees commented that Spain imports about 50% of its livestock feed requirements, 7 million tonnes of soybean and 2 million tonnes of maize. It has deficits of 5.5 million tonnes of protein meal, 13 million tonnes of cereals and 1 million tonnes of other by-products such as tapioca (cassava). OSR, sunflower, tapioca (cassava) and cereal by-products are also imported, according to a grain-importing interviewee.

For food ingredients, there is also a substantial need for imports such as long grain rice, for which the EU has to import 40% of its consumption, according to an Italian industry interviewee, soybeans for soy oil and derivatives, and linseed.

3.2.1. Current and projected situation in GM crops world-wide relevant for EU food and feed ingredients

According to NGOs interviewed, earlier projections of GM developments have not yet been fulfilled. Indeed, relevant food and feed traits in the pipeline and expected for the period 2007-2011 included fungus-resistant wheat, oilseed rape and sunflower; virus-resistant sugar beet and potatoes; herbicide tolerant wheat, barley and rice; modified starch content in maize and potatoes, fatty acid content in soybeans and oilseed rape, and protein content in oilseed rape, maize and potatoes; and high erucic acid oilseed rape (Lheureux *et al*, 2003). The UK NGOs comment that a pipeline from 15 years ago would look very similar to the current versions.

ISAAA, an industry-supported organisation, presents global area planted to GM crops annually and claims a steady increase in total area planted since 1996. According to this source, the global area planted to GM crops increased from 114 million hectares in 2007 to 134 million hectares in 2009 while the number of countries growing GM crops increased from 23 to 25 over this period (James, 2009). ISAAA expects to see at least 15 new countries planting GM crops by 2015 and a total global area planted of over 200 million hectares, with GM rice, potatoes, sugarcane, cassava and pulses as well as the currently-recognised GM crops (James, 2008), although it should be recognised that this is an industry prediction.

The European Commission's JRC-IPTS reports that stacked-trait crops are forming a greater percentage of total traits with each passing year (Stein and Rodríguez-Cerezo, 2009); the US Department of Agriculture reports that GM events with 4 stacked traits are currently entering the EFSA approval process (USDA Foreign Agricultural Service, 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).

According to the JRC-IPTS, there were about 30 GM events authorised worldwide in 2008; by 2015, almost 140 are expected, of which about half will be generated in Asia and are most likely to have been designed for domestic markets; as a consequence, JRC-IPTS predicts very strong possibilities for LLP problems, estimating as many as 32 sources in the short-term and over 100 possible sources of asynchronicity in the longer-term in the five main crops of maize, rice, soybean, oilseed rape and cotton (Stein and Rodríguez-Cerezo, 2009).

3.2.2. Views on the likely evolution of GM authorisations in Third Countries

The perception of the majority of respondents, of all types and in all case study countries, was that there will be an increasing number of GM events being authorised globally and that the pace will accelerate as more traits are developed. Part of the reason for the expected increased use of GM technology is, according to a UK producer organisation, that it is an efficient method of plant breeding. According to a wide range of food, feed and seed industry interviewees, the emergence of China and India as GM crop producers and technology providers is expected to result in more LLP

incidents and co-mingling problems for the EU. For example, China is developing GM crops for domestic use and may not seek EU approvals for these, according to industry respondents. New GM events are anticipated in China, Pakistan, the Philippines, Indonesia, Japan, Taiwan, Colombia, Costa Rica, Iran, India and Peru, according to a grain/feed industry interviewee, and are likely to be region-relevant and not EU-tailored events, posing problems of LLP due to asymmetric approval, in cases where originators consider it irrelevant to seek EU approval as there is no intention to trade.

The global trend is for events with multiple traits (stacked events). Farming needs and agronomics are the main drivers of development, including features such as a reduced need to go onto the land for pest treatments or cultivation. It is also anticipated that the pressure outside the EU is more likely to be in terms of increased yields. Nutritional features such as enhanced fatty acid or protein profiles are believed by interviewees to be closer to the market than GM events for abiotic stress tolerance; though salinity and drought tolerance are seen as being near commercialisation. GM events with climate change potential (for example, feed ingredients resulting in reduced methane emissions by farm animals) are considered to be a long way from commercial development. As noted above, UK NGOs point out that progress promised by the biotech industry has not always been achieved and they state that the only certainty is more herbicide tolerant and insect resistant events with more gene stacking.

The process of authorisation in the USA is regarded by the NGO interviewees as being less rigorous than that in the EU. This is expected increasingly to be an issue in terms of stacked events (both the treatment of stacked genes and the definition of stacking are different in the EU and USA (Stein and Rodríguez-Cerezo, 2009). The result of differences in approach is expected to be greater potential for asynchronous authorisation and hence LLP incidents given the EU's zero tolerance approach to adventitious and technically unavoidable presence. There is also an increasing trend for competing companies to collaborate on stacked events (for example, the combination of Roundup Ready and Liberty Link), adding to the potential for a backlog of applications for approval, according to one biotechnology industry interviewee.

It is apparently not just a question of new GM events, it is also the speed of introduction of USA-origin events into other Third Countries from which the EU imports its food and feed materials. RR2-soybean was introduced into Latin America only one planting season after it had been launched in the USA; such a speed of transfer may produce difficulties in future, according to a grain/feed industry respondent in the Netherlands, if Member States are using seasonal alternation of imports from USA and Latin America or rely on Latin America for non-GM supplies, which might be unobtainable or more expensive.

3.2.3. Views on the likely evolution of GM authorisations in the EU under the current legislative framework

Respondents in general expect there to be an increase in submission of applications for stacked events. There is concern that the current approval process, which requires a full assessment of every combination, is unlikely to cope with the number of stacks that will become available. A UK producers' organisation believed that, as EU agriculture is fairly intensive with high inputs and high yields, GM technology could beneficially be used to improve plant responses to specific nutrients such as nitrogen and phosphorus which would provide agronomic benefits as well as environmental ones in terms of increased efficiency of input use. An Italian industry interviewee commented that research on GM technology would be important to rescue certain local products from extinction, such as the sammarzano tomato of Italy.

A UK food industry interviewee noted that there is too much focus in the EU on the cost side of the potential cost-benefit consideration with respect to GM applications; in some Third Countries the cost of not using GM technology is more significant. Also the perceived slow rate of passage of

applications for GM events through the approval process raises concerns for food production and agricultural organisations.

The risk management part of the authorisation process is widely seen as being the most time consuming element and the EU is likely to lag behind some Third Countries in terms of authorisations unless there is a change in political acceptance, according to a UK producers' organisation. There are 10-12 Member States with a political mandate not to vote in favour of any draft decisions to approve GM events, according to one of the Competent Authorities spoken to. Votes against draft decisions are widely held to reflect political considerations and/or perceived consumer (voter) wishes. Political changes in Member States result in changes in voting patterns, generally from positive to negative attitudes (according to one Competent Authority, this has been the case in France, Germany and Ireland, and, according to a consumer organisation, this has also been the case in Poland¹⁹). Two interviewees mentioned that, with the approval of the Treaty of Lisbon, the European Parliament will also be involved in the decision process, but their views on what impact this might have were diametrically opposed; one thought this might be beneficial when there is a need for rapid decisions; the other thought additional delays would occur.

The current legislative framework is perceived by some interviewees to reinforce public concern. A number of food, feed and livestock industry respondents noted that there are other areas of concern in food and agriculture where a zero tolerance approach is not taken (for example, the presence of non-organic material in 'organic' food, feed or seed, presence of alcohol in non-alcoholic beverages, and even presence of GM in 'non-GM' products). As a result of the existing delays in the authorisation process, and the apparent ability of EU Member States to ban the cultivation of GM events using emergency measures following EFSA approval, there is a continuing perception of risk which will not aid public acceptance. This then feeds back into the stance of certain Member States which continue to vote against draft decisions on GM events.

The UK food industry commented that the RASFF system is generally used for food safety incidents; the fact that it is also used for the LLP of unauthorised GM events is inappropriate as the issue is a legal technicality rather than a safety one. According to this interviewee, the use of this system suggests that the situation is dangerous and out of control, even if this is not actually the case. The same respondent noted that most people travelling to the USA do not worry about eating GM food while there and when back in the EU are probably not aware of the costs involved in maintaining non-GM raw material supplies for EU food and feed.

The main concern expressed by interviewees in relation to GM food and feed refers to the zero tolerance for GM events not yet approved in the EU.

3.2.4. Impacts on the food and feed sectors in the EU

The overall impact of asynchronous authorisations is widely regarded by interviewees as economic, resulting from an increasing delay in EU approvals for imported food and feed, an increase in approvals in Third Countries and the maintenance of the zero tolerance approach to not yet authorised GM events. These issues combine to create an expectation of an increase in LLP incidents among interviewees. For example, a Spanish feed industry interviewee stated that "it has become harder to avoid GM material [as unwanted content in imported materials] and in the next 2 or 3 years it will probably become almost impossible to buy "GM-free" commodities from the continent of America without the risk of a shipment containing GM material."

¹⁹ The Polish interviewee pointed out that a 1998 survey in Poland showed 80% acceptance of GMOs; in 2003 this had fallen to 50% according to a Polish survey, and the Eurobarometer survey of 2005 showed only 24% acceptance in Poland (Gaskell, 2005).

For the food industry interviewees this is seen as meaning interruption to secure ingredient supply, costs of removing products, costs of changing sources, and the costs associated with segregation and Identity Preservation (IP). For the feed industry interviewees, the implications and areas of cost are seen to be similar, but the situation is considered to be more critical because of the heavy reliance on imported soybeans and soybean meal. The feed industry does not want to absorb the increased costs of guaranteeing non-GM ingredients because these costs cannot be recouped from the market. Also, because margins in livestock farming, especially pigs and poultry, are very tight and heavily affected by feed costs, the livestock farming sector is seen as being disproportionately affected by the problems caused by asynchronous authorisation, according to a UK producers' organisation.

One industry interviewee commented that, based on his calculated current rate of approvals for GM food, feed and cultivation, it could take 20 years to deal with the remaining applications going through the EU approval process²⁰. The increase in the submission of applications for GM events, stacked and single, is seen as increasing dramatically the backlog of applications in the EU authorisation system, with negative implications in terms of asynchronous authorisation and LLP. Without action to shorten the approval cycle, there are some concerns amongst interviewees that there will be at least a significant delay in the ability to use new traits and perhaps severe trade implications as a result of LLP incidents. According to one consumer association, a consistent global approach to approvals would be beneficial.

UK NGOs noted that if the EU does not have access to GM raw materials for animal feed, this may well increase the price of livestock products. This might induce lower meat consumption and, as a result, lower livestock production, thus resulting in climate-change and health benefits. Some farmer organisations in Italy and Spain believe that continuing problems with asynchronous authorisation should help encourage an increased domestic supply of non-GM alternatives to imported materials, such as supporting production of protein-rich plants or greater production of non-GM soybeans in Italy.

No respondents believed that the legislative environment favoured the development of the EU biotechnology sector. An Italian grain/feed industry organisation stated that the EU was dramatically behind in the development of GM events, which will lead to the EU being dependent on non-EU agriculture and production strategies. Other industry interviewees believe that the regulatory complexity in the EU will encourage companies to locate R&D and commercial investment elsewhere and that, within ten years, according to one R&D respondent, the EU will become isolated from innovation if the current GM situation continues. UK producers' associations added that the lack of public acceptance, as well as the legislative environment, is a factor in the decision of companies not to invest in traits that are relevant for the EU. One organic farming association commented that future GM developments in the EU would be restricted to non-food forestry and biofuel crops because of consumer and environmental concerns over GM food crops.

Increasing development of GM crops outside the EU, especially region-relevant crops, will increase the global presence of EU-irrelevant events (i.e. irrelevant from the point of view of cultivation). An example given by a grain-processing interviewee is a project to genetically-engineer rice for reduced water demand and increased fertiliser efficiency being carried out in China, but supported by Germany with funding of €1.35 million. The same interviewee noted the imminent arrival on the world market of a Chinese rice with increased yield and pest resistance, which they believed would also pose economic competition to EU rice producers in Third Country export markets.

²⁰ In this context, EFSA (2010) notes 14 approvals of 77 applications since the establishment of Regulation (EC) No 1829/2003, ie approx 2.0-2.5 approvals p.a.; there are 12 applications with a favourable EFSA opinion and a further 44 still in process through the system at some stage, i.e. 56 in total, which would take 20 years to assess and approve, at the historic rate of processing.

Seed traders, processors and feed industry interviewees commented that attitudes to GM outside the EU encourage the use of conventional transport chains. A lack of dedicated transport lines and the impossibility of 100% clean-out between shipments will mean LLP events caused by asynchronous and asymmetric authorisation, or even the absence of authorisation, will increase, and non-GM supply chains will become less achievable economically. For example, traces of LL-601 rice were found in some batches of Italian rice simply because these had been moved using equipment previously used for USA-origin rice contaminated by the unapproved rice event, according to an Italian feed industry interviewee.

A range of industry interviewees from the Member States commented on the impacts of availability in general of food and feed materials. Comments included:

- asymmetry and asynchrony in authorisations between the EU and Third Countries have a direct impact on feed, food and livestock producers, whether they are using GM or non-GM source materials;
- supply chain and segregation difficulties have a direct impact on organic producers, but other EU producers of food, feed and livestock will also be disadvantaged because Third Country producers will have access to cheaper raw materials and will therefore be able to produce cheaper food, according to a UK producers' organisation; and,
- the speed of transfer of GM cultivation from the USA to other Third Countries means that EU Member States that have been able to source approved "GM-free" or non-GM commodities from South America in the past may face increasing difficulties in sourcing non-GM supplies in the future.

Interviewees from several Member States, of several types including a Competent Authority, believed that if the EU use of zero tolerance remains, an increasing amount of USA and South American GM crops could be exported to other Third Countries in response to increasing demands for livestock feed for meat production, which would have an impact on the availability of feed raw materials and hence costs of livestock production within the EU. One interviewee pointed out that China currently absorbs 40% of South American soybean production whereas the EU only accounts for 13%. At current levels of domestic production, the EU cannot compensate for a shift in global trade in vegetable protein for food and feed away from the EU, although individual countries, for example Italy, may seek to diversify and find alternatives to soybean, according to a farmers' organisation. Spanish and UK meat industry interviewees noted that, at the same time as the EU is applying zero tolerance to keep out unauthorised GM events, it is possible to import meat from Third Countries which has been fed using GM feed which may not be authorised in the EU. They comment that this has served to increase distrust of the EU regulatory system among actors in these sectors

3.2.5. The consequences of possible differences between the pace of authorisations between the EU and its trading partners

Asynchronous authorisation refers to a situation in which a GM event has been authorised outside the EU and has been submitted for authorisation, but has not yet been authorised in the EU. Asymmetric authorisation refers to a situation in which a GM event has been authorised in a Third Country, but has not (yet) been submitted for authorisation in the EU or where there is no intention to submit an application for authorisation to the EU.

Low Level Presence (LLP) refers to the finding of any GM event not approved in the EU. The main issue with imports of soybeans from the USA has been co-mingling of, for example, (unauthorised in the EU) GM maize traces in soybean shipments; on the other hand, LLP incidents in shipments from Brazil and Argentina are mainly the result of a failure of segregation of GM from non-GM within the same commodity crop, according to a UK agricultural production organisation. The main LLP

incident to date in rice was the research event LL-601 produced by Bayer, for which Bayer CropScience has stated it will never request (EU) marketing authorisation, according to a grain/feed industry respondent. LL-601 was not authorised in the USA either, as it was an event undergoing research only and commercial development had been stopped in 2001. It was found in rice imports to the EU in 2006. Since Rice LL-601 was a research event and not intended for authorisation even in the USA, it is therefore technically neither an asynchronous nor asymmetric authorisation incident.

The rice processing industry expects an increasing number of commercialised GM rice strains from Asia and South America, commenting that in many countries (unspecified) these products may be introduced to the local market without authorisation.

3.2.6. Problems caused to date by asynchronous authorisation

Although none of our respondents reported problems in the food sector as a result of asynchronous authorisation, there are concerns about soy lecithin because an LLP incident affecting this derivative could affect 50% or more of processed food products in the retail chain, according to several food industry and consumer association interviewees. A major UK food industry interviewee noted that about 1,500 of their own-label products contained soybean derivatives (ca. 8.8% of a total of 17,000), and ideally they would not source any commodities or by-products from the USA because of the risk of LLP. According to interviewees, asynchronous authorisation has so far only affected feed. The problems for feed ingredients are directly related to the import requirements of individual Member States, consequently a Member State such as Spain with a relatively high import requirement for feed ingredients was thought likely to experience more LLP incidents than France or Germany, which are more self-sufficient. Respondents referred to problems in feed and food supply more in terms of LLP (as a concept) than asynchronous authorisation, even if this was the root cause of the incident.

A notable case was the USA approval of Herculex™ DAS 59122-7 maize in 2006, which was subsequently authorised in the EU in October 2007 and is therefore a case of asynchronous approval. Although the maize was grown on less than 1% of available farmland, more than two-thirds of samples taken from maize shipments from the USA to the EU contained LLP of this GM event²¹. The direct impact of this was the immediate fall in imports of Distillers Dry Grains with Solubles and corn gluten meal from the USA and replacement by Brazilian material at a higher price (Stein and Rodríguez-Cerezo, 2009). The EU supply chain for maize was further impacted by the asynchronous authorisation of GA-21 maize and the consequent unavailability of imports from Argentina in 2007-2008, according to grain/feed industry respondents in the Netherlands and Spain²².

More recently, in June 2009, 200,000 tonnes of soybeans were turned back from the EU because of commingling with traces of GM maize events (Monsanto's MON-88017 and Syngenta's MIR-604) that had not at that time been authorised in the EU, although they had received a positive risk assessment from EFSA (they were authorised in October and November 2009 respectively). The RASFF reports show that imported soybean derivatives such as meal, hulls and cakes for animal feeds, and pet foods also contained LLP of these unapproved GM events²³. This finding of small traces of GM maize in soybean shipments is, according to several industry interviewees, a new and artificial crisis resulting from the zero-tolerance for LLP of unauthorised events, in the sense that there was no safety risk as judged from the positive EFSA opinion. A Spanish grain-importing interviewee stated that, for one soybean processor alone (Bunge), 92,000 tonnes of soybeans were held back from

²¹ COCERAL and FEFAC (2006) pointed out that the requirement according to ISO 21098 to report any finding of a GM event as positive, even if demonstrably below the limit of quantification, intensified the impact of the Herculex incident.

²² The period concerned was April 2007 to March 2008, when GA-21 maize was approved in the EU for food and feed use.

²³ http://ec.europa.eu/food/food/rapidalert/rasff_portal_database_en.htm searched on MON-88017 and MIR-604, accessed 24.2.2010.

docking in Spain, leading to a complete stop on soybean imports from the USA, and also a stop on cereals imports due to fears of co-mingling. The stop effectively delayed the production of 500,000 tonnes of animal feed, according to another Spanish interviewee. Spanish feed producers were able to compensate for this shortage of supply by using colza (OSR) and sunflower materials and cereal already within the EU, including rye imports from Poland and Hungary. A red alert for food products was issued in Spain, according to a food industry interviewee, but no further action, such as product withdrawal from supermarket shelves, was needed because the affected soybeans did not reach the consumer.

3.2.7. The cost of problems caused by asynchronous authorisation

Many of the respondents stated that it was difficult to quantify costs, partly because there were indirect costs affecting other actors in the supply chain and partly because cost structures did not always depend on just the GM/non-GM status of food or feed ingredients. Several mentioned the report on Economic impact of unapproved GMOs by DG Agri as a useful source of information on costs (European Commission, 2007c) and some, including a Competent Authority, suggested that the medium and worst-case impact scenarios in this report were more likely to represent the actual cost situation than the minimal impact scenario, given the trends in take-up of GM events by Brazil and Argentina and the heavy reliance of some EU Member States on imports for feed. Commission Services mentioned that the original study anticipated the LLP problem, and recognised that the figures are not exact because the elasticities used were static, not dynamic; the most important point remains that this study was the first to consider the problem of asynchronous authorisations. However, it should be noted that European Commission (2007c) notes that the worst-case scenario “goes well beyond the technical limits of the model...as a consequence...the estimated figures should be treated with caution”, a point highlighted by FoE Europe (2008).

In the 2009 incident of MON-88017 and MIR-604 maize LLP in soybean and soy products, costs were variable over the EU countries in which interviews took place. The Italian feed industry experienced price increases of €20-30/tonne soybeans, according to seed importing and feed industry interviewees. In the Netherlands, it was reported that there were some costs for the handling and processing industries, which were not considered large in the short-term²⁴. One Dutch feed industry interviewee noted that traders made a good deal on this incident, as prices had risen for soybeans between cargoes being halted and the maize events being approved. In Spain on the other hand, as noted by industry respondents, 200,000 tonnes of soybeans were withdrawn from use, including the 92,000 tonnes that were the source of the original LLP and other boats carrying non-GM cargoes such as wheat which were also held back because of fears of co-mingling. Despite authorisation by the European Commission of these GM events by November 2009, the estimated loss for Bunge in Spain was “several million Euros”, which included an adverse movement in the price of soybeans in Spain between the import stop and the eventual release after European Commission action to authorise the GM events. Storage and distribution companies in Spain were also affected, according to grain/feed industry respondents; there was less activity for them, as there was no grain import activity. The potential impacts of this incident on the crushing, compound feed, food and livestock industries have been estimated in van Wagenberg (2009)²⁵.

²⁴ Backus *et al* (2008) report that DAS 59122-7 was found in 3 shipments of maize at Rotterdam April-May 2007. Two of these were quarantined, one had unloaded and its cargo of ca. 6,500 tonnes of maize had already reached processors and feed compounders, and most of the feed containing the EU-unapproved GM event had been used. The Dutch Ministry of Agriculture decided not to recall the remaining 160 tonnes of feed as the EFSA GMO Panel had given a positive opinion on DAS 59122-7.

²⁵ The report estimates that, in the period October 2009-March 2010, the primary cost to the crushing and milling sector may be €1.4-€4.4 billion; additional costs in the feed and livestock industries might reach €35/tonne feed (total €2.25 billion); and, in the food sector, costs might reach €2.1 billion, depending on the nature and range of products that may have to be re-

In general, to protect against asynchronous authorisation (and potential LLP incidents) the food, feed and livestock sectors state that they need to source non-GM ingredients. This is an avoidance policy with implicit costs. One Spanish grain/feed organisation noted that maize from Brazil and Argentina is already more expensive than that from the USA without considering any premium for non-GM; the logistics of supply is also more complicated and expensive. In the case of the Herculex incident, the Spanish feed industry said they had to switch source from Argentina to Brazil, and the Brazilian suppliers increased maize cost by 15-20% within a week of the incident. A UK agricultural industry interviewee estimated that the cost to the UK livestock industry of setting up segregation and IP systems was £30-60 per tonne of non-GM soybean. A Spanish grain/feed industry interviewee reported an increase in operating costs of 50% as a result of putting in place complete cleaning processes and a traceability system; operating costs rose by 80% after the change in purchasing strategy meant that an increased number of smaller shiploads of grain began to arrive. As there is an annual import requirement of about 800,000 tonnes soybeans in Spain, this implies annual costs of over €50 million, not all of which can be passed through the food supply chain. In the GA-21 maize case, additional costs in Argentina for segregation were estimated at \$40/tonne and additional costs for supply to the EU from Brazil were ca. \$50-70/tonne²⁶.

In addition, the UK food sector respondents estimated a premium of 10-15% of total cost for supply of non-GM raw materials for food in the UK, including 5-10% for soybeans from Brazil. The Italian meat industry estimated an additional cost of 15-20% for livestock feed. In Poland, an on-cost of 15-20% increase in the price of meat for the consumer is estimated by a Polish livestock producers' association if an LLP incident were to result in the unavailability of the usual soybean supplies. Spanish industry interviewees stated that the cost of pork production is estimated to be already 25-40% less in the USA compared to the EU, and cattle of 600 kg deadweight cost \$300 less to raise in the USA than in Spain.

3.2.8. Problems caused to date by LLP incidents

According to UK interviewees the UK has not experienced any LLP incidents directly, probably because initial imports of raw materials, for example, soybeans, arrive in the Netherlands where they are tested prior to redistribution in the EU. The UK food sector was concerned over FP 967 brown flaxseed (linseed) in September-October 2009, though most shipments went to Belgium and Germany, and were then widely distributed throughout the EU in baked goods, according to RASFF. Two interviewees in Italy reported no LLP problems to date, but five others pointed to LLP causing unquantified problems for the food and feed chain. Poland experienced an LLP incident of LL-601 rice in soybean meal in 2006, and in 2004-2005 shipments intended for Poland were stopped in Germany, but there have been no concrete consequences of LLP, such as supply shortages or excessive costs, according to the majority of Polish consumer organisation and industry interviewees. In this case anyway, most feed oilseed processing within Poland is of home-produced OSR; there are no imports of soybean for crushing, according to a Polish feed industry interviewee. In Spain, respondents agreed that there have been no incidents in which GM events have entered food chains resulting in supermarket recalls; the only significant LLP incident has been the unapproved maize events in soybeans of 2009.

Different Member States have reacted differently to the threat of LLP. The UK FSA is reported by a UK industry respondent to have taken a pragmatic approach, requiring a complete recall only when no safety data are available, i.e. where it is theoretically possible that there could be a risk. For LL-601 rice, for which safety data were available, rice and rice products were taken off the shelves, but there

engineered.

²⁶ Cardy Brown & Co Ltd (2008) estimates that the cumulative cost 2006-2008 as a result of the zero tolerance policy for GA-21 maize was around €2.5 billion for importers and feed processors.

was no complete chain recall; FSA was challenged in the UK courts by NGOs over this decision, but the judicial review supported the FSA's approach. The Dutch approaches to GM maize events in soybean shipments and to GM flaxseed LLP in imported flaxseed are mentioned in footnote 24 above, and below.

One grain/feed industry interviewee described the case of the finding of LLP of Bayer's Liberty Link rice, LL-601, in commercial rice imports from the USA, which immediately led to a slump in EU imports of USA long grain rice: in 2005, prior to the incident, USA rice accounted for 32% of EU demand; in 2007 the USA supplied only 2.5% of EU rice demand, against a background of overall increase in rice imports. The beneficiaries of this reduction in USA supply were mainly Thailand, Uruguay, Pakistan and India, according to the interviewee, who noted that developments in GM rice in these countries may well increase the risk of LLP in future.

In September 2009, traces of flaxseed LP 967 were found in shipments of flaxseed from Canada intended mainly for bakery production. According to the Competent Authorities and a food industry interviewee in the Netherlands, there were recalls from supermarkets in Germany that had made products with imported flaxseed flour and from importers in the Netherlands; the food industry respondent also stated that in the Netherlands the Competent Authorities accepted the opinion of the Canadian authorities that the event was safe and did not ask for a recall of products from supermarkets. This case is interesting because the event itself and the associated linseed variety ("Triffid") were withdrawn from the Canadian market in 2001 in order to protect exports of linseed from Canada to the EU.

3.2.9. The cost of problems caused by LLP incidents

With respect to the costs of LLP incidents, many of the respondents stated that it was difficult to quantify these, though it was easier to suggest which actors in the supply chain may have had to bear them.

Summarising the qualitative responses from a number of industry and Competent Authority interviewees, it is possible to say that the main costs of LLP are perceived as being borne by the animal feed and livestock sectors and the seed importers; several feed and food industry and producers' association interviewees noted in addition that farmers have little ability to pass an increase in price onto food processors and retailers. There is also a cost on anyone in the food and feed chain responsible for checking samples, which is ongoing and increasing. A sample costs €60 to check (£50 per sample in UK, according to the UK Competent Authority), and there are additional costs of access to shipments in port, management of sampling and transport of samples to laboratories. These costs fall mainly on commodity importers and traders and on surveillance authorities. Italian interviewees reported that the rejection of soybean shipments because of LLP of GM maize in mid-2009 almost closed down the soy processors in Italy, imposed a cost increase of €20-30/tonne of soybeans from alternative sources onto the feed industry and produced higher costs in the transport chain as a result of the need for segregation. A Polish consumer organisation noted that the Polish farmer is harmed by competition from Third Countries that use GMOs, though the impact was not quantified.

Brookes (2008), in work carried out for the Federation of European Rice Millers, estimated that the LL-601 incident cost the EU rice milling industry between €50 million and €110 million, or approximately €3.5-€7.4 million per milling company. Commission Decision of the 23 August 2006 (2006/578/EC) on emergency measures regarding the non-authorised genetically modified organism LL RICE 601 in rice products made operators responsible for putting the rice products onto the market also responsible for the cost of carrying out checks (European Commission, 2006e). Costs of disruption and reformulation for the food sector are difficult to quantify. A UK food industry respondent commented that the LL-601 incident cost them between £1 million and £1.5 million across Europe in removing products containing USA-origin rice, switching supplies to Italy for Italian long

grain rice, and replacement production. According to industry interviewees, additional, unquantifiable costs were borne by food producers whose products were withdrawn from retailer shelves, including damage to the reputation of rice-producing countries. In another rice LLP incident, BT63 from China in 2006, there was an added complication that the unapproved event was found in several Member States in small-container rice noodle products imported by specialist Chinese businesses, intended for restaurants, according to UK and Dutch interviewees²⁷. This added additional cost to the problem and the costs of checking.

Flaxseed and its products are used in bakery, mostly by SMEs. As a result of the Flaxseed LP 967 LLP incident, one Dutch bakery company requested €8 million damages to compensate for unusable material, according to the Dutch Competent Authorities.

3.2.10. Conclusions and future options

The potential for asynchronous and asymmetric authorisation appears to be increasing as GM crops become more widely used globally. The risk of LLP is therefore also increasing.

There was almost complete agreement amongst interviewees that adjustments need to be made to the zero tolerance of unauthorised GM events. Polish interviewees in favour of moving from zero tolerance to a threshold stated that the zero tolerance approach is unworkable and unsustainable. In general, the food and feed industry and farmer associations supported the return to a definable threshold for the presence of GM events that have received a positive risk assessment, but have not yet been authorised in the EU. The UK NGOs in principle have no objection to a properly-applied threshold of 0.9% for LLP of adventitious and technically-unavoidable GM events authorised in Third Countries, though they would prefer a zero tolerance approach. Only three interviewees argued for the retention of the zero tolerance approach.

Comments from farm organisation, grain-importing, feed and other industry interviewees suggest support for different responses to new EU-unauthorised GM events which are likely to pose large LLP problems. Suggestions made included accepting Third Country Risk Assessments, agreeing reciprocity in terms of risk assessment with China and India, 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. For events undergoing the EU authorisation process, seed processors, for example, believe that once a positive risk assessment has been provided by the EFSA GMO Panel, the product should immediately be accepted for marketing in the EU pending full authorisation. There was also a suggestion from Spanish and Dutch interviewees that countries that imported a large proportion of their animal feed materials, such as Spain, Portugal or Denmark, should be allowed to decide whether to authorise GM-containing feed and feed components for domestic use only, although it is noted that this would appear inconsistent with the concept of the single market.

Moving away from zero tolerance is also seen as being necessary by Competent Authority interviewees; indeed, it was suggested by one that the EU should accept events for import as food or feed if they had been authorised in the USA, as long as they have been submitted for authorisation in the EU. Also, LLP thresholds have been accepted for unauthorised GM events by countries such as Switzerland, as long as they have been risk-assessed elsewhere, according to a Spanish grain/feed organisation. Threshold levels between 0.5% and 1.0% were suggested by most respondents who suggested a figure, although one livestock producer interviewee noted that the prevalence of GM soybean might make a 0.9% threshold for LLP difficult to achieve.

²⁷ The RASFF database includes reports from Germany, Sweden (via the Netherlands) and the UK - http://ec.europa.eu/food/food/rapidalert/rasff_portal_database_en.htm.

According to interviewees, the difficulties arising from asynchronous and asymmetric authorisation have a direct economic impact in terms of management costs, but also an indirect impact in terms of avoidance costs. The UK poultry industry body (British Poultry Council) has announced that, because of price and the prevalence of GM events and co-mingling possibilities in the supply chain, it can no longer guarantee to source non-GM soybeans for feed used in the sector. It was pointed out by a livestock producers' organisation that non-GM soybeans are currently available from only one part of central Brazil; a feed industry interviewee added that only one port now handles "GM-free" exports from Brazil. The price premium for non-GM Brazilian soybeans was approximately €10/tonne in 2008, but is expected by the industry to reach €50/tonne before mid-2010 in the UK, according to an agricultural organisation interviewee and, as the premium for non-GM cannot be fully-passed on along the supply chain, producers are expected to turn to cheaper, more consistent and more secure supplies.

In addition to the major GM-using countries that are relevant for imports of food and feed materials into the EU (USA, Argentina and Brazil), industry interviewees foresaw that the emergence of China and India as major GM-using nations would reduce still further the scope for availability of non-GM materials for importation into the EU. There is also an expectation by one grain-importing interviewee that the consideration of authorisation in export markets (the so-called "mirror policy") hitherto used in Brazil and Argentina will be discontinued as they begin to export more to countries other than the EU.

Grain/feed industry interviewees in the UK, Spain and the Netherlands expect there to be increasing pressure on the integrity of import chains and increasing difficulties, given the nature of bulk transport of commodity plant products for food and feed, in ensuring that traces of cross-contamination or co-mingling do not occur. This cross-contamination is also likely to increasingly be between unrelated commodities, a phenomena experienced recently with LLP of GM maize in soybean shipments.

Two interviewees from two different Member States, including a Competent Authority, stated their concern about the application of zero tolerance for GM events not authorised in the EU and the fact that action is taken through the RASFF system. This is seen as creating concern which is not justified by the risk and which has an adverse impact on public opinion. This is considered to be especially the case when the GM event has been positively risk assessed and is awaiting authorisation.

A possible future concern mentioned by several interviewees is the LLP of GM biofuel oilseeds in shipments of food and feed materials (GM and non-GM), and the related issue of price pressure on the availability of non-GM feed commodities caused by the diversion of grain and oilseeds to the biofuels sector. This is considered likely to primarily affect soybean and OSR, but may have an impact on soft wheat as well.

3.3. The current labelling regime

This case study is based on interviews undertaken in France, Germany, Spain and the UK. France was selected because of the recent discussion of GM labelling which has culminated in an opinion from the Haut Conseil des Biotechnologies (HCB) that "GM-free" labelling should be permitted, including in the livestock sector. Germany already has experience of "GM-free" labelling and hence there has been a national debate on the labelling of GM products in general. Spain has experience of cultivating GMOs and this may have resulted in a different attitude to GMOs in general to that in other Member States. The UK was selected because there is experience of labelling products from the late 1990s and because of the strong media opposition to GMOs which influenced the withdrawal of labelled products and the generally negative view of GMOs within the retail sector.

This case study focuses on the following Evaluation Questions which focus specifically on the current labelling regime:

- **EQ8a:** To what extent are the current labelling rules for GM food/feed facilitating an informed choice and precluding misleading of consumers?
- **EQ8b:** What is the consumers' acceptance of the existing labelling rules?
- **EQ9:** What impact have the rules on labelling of GM food/feed had on the different actors of the food/feed market?
- **EQ10a:** To what extent is food on the market labelled as GM?
- **EQ10b:** To what extent is feed on the market labelled as GM?
- **EQ10c:** What are the reasons for this situation?

3.3.1. To what extent are the current labelling rules for GM food/feed facilitating an informed choice and precluding misleading of consumers?

3.3.1.1. How GM food is labelled

According to Regulation (EC) No 1830/2003, GM material must be labelled in the ingredient list on the back of packaging. Interviewees confirmed that this is indeed the approach that is followed. Interviewees stated that the few GM labelled food products on shelves were predominantly imported from Third Countries (in particular from South America in the case of Spain, and Asia in the case of Germany). One interviewee commented that Asian imports generally have a multi-lingual label which contains information for EU consumers, as well as “from GM <crop name>” in the ingredients list. (Figure 3.1) shows some GM products on sale in Spain and originating in South America. The small white adhesive labels with additional information for EU consumers can be seen on the first, second and sixth product. The indication of GM content in the ingredients list was corroborated by several interviewees in the UK. One commented that there is no specific design or set words for GM labelling. (Figure 3.2) provides further examples of GM labelling from an article referred to by an interviewee.



Figure 3.1: GM labelled products for sale in Spain

Source: Spanish interviewee



Figure 3.2: GM labelling

Source: <http://www.transgen.de/recht/kennzeichnung/114.doku.html>.

3.3.1.2. Do consumers look at labels when they shop?

General labelling

Spanish interviewees generally believed that consumers either do not pay attention to labels, or else look for certain information relevant to them (for example, price, expiry date, conservation information and how to use). The search for relevant information was corroborated by a 2006 survey performed by the Spanish government (MAPA, 2007). This survey revealed that some 61% of interviewed consumers²⁸ said they “always” or “almost always” look at labels (and, according to one industry interviewee, this percentage has been increasing over recent years)²⁹. The survey asked consumers to rate the importance of different pieces of information on the label using a scale of 1 (unimportant) to 10 (very important). The highest rated was the expiry date (9.3) followed by conservation instructions (8.7) and then ingredients (8.3). There was no mention of the GM status of the product, nor any other similar characteristic.

Some Spanish interviewees provided further comments relating to the ability of consumers to understand labels. Two interviewees believed that even if consumers read labels, they cannot fully understand them. For example, one interviewee provided an anecdotal example that at a food industry conference attended four years ago, participants were asked by the interviewee whether they knew the difference between “best before” and “use by” labelling. Only three out of approximately 100 people claimed to understand the difference.

Two interviewees commented that consumers simply cannot read all the information on labels on all products when shopping. One commented more specifically that the size of the lettering minimises the importance of some information, and that larger lettering was needed for important information. There is weak evidence that consumers have difficulty understanding labels from the 2006 Spanish government survey mentioned above. Consumers were asked about the ease with which they understand information on labels (1= very difficult, 10 = very easy) and provided an average score of 5.9.

According to German interviewees, consumer expectations from labelling are high. Interviewees believed that consumers expect transparency and the ability to make purchase decisions based on labelling; one thought that consumers want extensive labelling for this reason. An industry interviewee said that a challenge for the food industry is how to fulfil the consumer desire for labelling. The industry must make sure that all mandatory and relevant information is on the label,

²⁸ From a base of 2, 006 interviewees.

²⁹ This is broadly in line with the wider European situation reported in Kings College London (2008) where 54% of people questioned in a household panel claimed to read the ingredients label before making a purchase. This research covered the Czech Republic, Germany, Greece, the Netherlands, Poland, Spain, Sweden and the UK.

whether consumers read it or not, but must also decide which voluntary information to provide. The food industry must also decide which other channels (for example, the internet) to use to convey product information.

That said, German interviewees believed that only some consumers actually read labels, despite their expectations for labelling. Evidence from two 2009 surveys in Germany (Dialego, 2009 and MARPLAN Forschungsgesellschaft³⁰) suggests a broadly similar level of consumer attention to labels as in Spain. One survey noted that around half of consumers glance at labels when shopping. The other found that 77% of consumers either always or sometimes read information on ingredients, either in the shop (where it could potentially influence current purchase decisions) or later at home (where it can only influence future purchase decisions).

In the UK, one interviewee referred to research from Mintel which suggested that roughly 50% of consumers look at labels for price, brand and expiry date. Other interviewees in the UK had contrasting views; some thought that consumers do not pay much attention to labels and make purchasing decisions before they shop, others believed that consumers consider labelling important. One interviewee commented that the extent to which consumers read labels depends on the product, situation and importance of issues to them.

An interviewee in France believed that the level of attention that French consumers pay to labels is not significantly different from that paid by consumers in other EU countries. This is corroborated by data from a 2006/7 survey in which 43.6% of respondents declared that they often read nutritional labels either in the shop or at home (DGCAL & CLCV, 2007). According to an earlier survey from 2004 with a wider scope, price, expiry date and brand are the most important details for consumers who read labels in shops. Some 89%, 75% and 71% of label-reading consumers pay attention to price, expiry date and brand respectively (DGCAL & CLCV, 2004). The aforementioned interviewee noted that consumers who look at labels are likely to examine the label in more detail during the first purchase, but pay less attention thereafter.

Information on the use of GM

Due to the small range of GM labelled food products available in the EU, interviewees were generally unable to comment specifically on whether consumers pay attention to labelling on the use of GM material. One interviewee specifically stated that the labelling discussion is a relatively artificial discussion due to limited experience. King College London (2008) compared actual purchase decisions in a number of Member States with later responses to questionnaires and found that 48% of people who had bought GM labelled food products subsequently said that they would not buy such products. This suggests that either consumers are confused about what they are buying, do not understand labelling or do not read labelling.

One interviewee in Germany did comment that consumers want to be able to differentiate between food which uses GM material and food which does not in order to make their purchasing decision. One French interviewee commented that their organisation receives regular queries about the use of GM material in food and responds with relevant information including an explanation of labelling laws. In the UK, several interviewees commented that consumers assume retailers to have a non-GM policy and so do not look for information on the use of GM on specific products. Recent research from the UK based on the observation of study participants³¹ found three distinct consumer attitudes towards labelling: non-readers, common sense approach and detail seekers. The detail seekers were

³⁰ The Marplan survey is reported on here: <http://rundumkiel.de/tag/marplan/> and here: http://www.nikos-weinwelten.de/home/beitrag/archive/2010/january/05/kaum_jemand_beachtet_lebensmittelkennzeichnungen/index.htm.

³¹ Participants were observed in different situations. Fifteen were sent on non-eye tracking visits to shops; 36 were sent on eye-tracking visits to shops; 15 were accompanied to meals; and 20 were sent on an eye-tracking visit to a retail lab. Six of these visits were followed up with eye-tracked tasked purchases.

considered a small proportion of the sample of consumers, however, one of the identified detail-seeker participants was observed looking for information on GM content Enright *et al*, 2010).

3.3.1.3. Consumer expectations of the scope of labelling

As a foreword, several interviewees in all case study countries commented that consumers are relatively uninformed about GM technology, agricultural processes and food production in general. For example, consumers are likely to think that every product with a GM label on it contains actual GM genes according to one interviewee, raising questions about what is understood by labelling on oil products and what would be understood by labelling on livestock products should the scope of the labelling regime be extended. Furthermore, several interviewees commented that consumer knowledge of the current labelling regime was also low, partly the result of a lack of experience with products in store. In view of this, it is difficult to identify what consumers expect in terms of the scope of GM labelling.

Livestock products

In Spain, one interviewee believed that consumers did not expect livestock products to be labelled if they were derived from animals fed on GM feed. Another believed that the current system may result in some consumers who wish to avoid any use of GM in products purchasing livestock which may have been fed on GMOs. A couple of interviewees commented that consumers would probably not understand the use of GM labelling if applied to livestock products (see previous paragraph). However, one of these interviewees was in favour of the labelling of livestock products in conjunction with a consumer education campaign. According to this interviewee, the message would have to be concise and correct, for example “produced from animals fed on GM feed” rather than simply “GM”.

The issue of the labelling of livestock products is more prominent in Germany (see the extension to labelling case study, section 3.4). According to one interviewee, the German parliamentary majority is in favour of the positive labelling of livestock products produced using GM feed. However, industry interviewees were against the positive labelling of livestock products unless the scope of labelling was further extended to include all uses of GM technology in order to ensure that consumers were provided with consistent information on the use of GM material and technology in production.

One interviewee in France believed that consumers did expect livestock products to be labelled if a GM feed supply chain had been used, as demonstrated by the consumer discussions which sparked the creation of the Haut Conseil des Biotechnologies, the body which developed recommendations for a “GM-free” labelling scheme. The same interviewee commented that it receives queries about the use of GM technology in livestock products, a fact which further demonstrates interest in the livestock labelling issue. However, another interviewee in France believed that consumers want to know what is in a product rather than how it was produced, implying that they do not expect livestock products to be labelled for GM feed use.

Interviewees in the UK were divided with regard to consumer expectation for the labelling of livestock products. Some stated that consumers do not expect livestock products to be labelled, or that labelling should not be extended to livestock products. The reasons given for this were the substantial equivalence of the final product and a low level of consumer concern relative to other, more general, food issues. Some interviewees believed that it was hard to judge what consumers really want because they are influenced by media and NGO campaigns, and that surveys may not provide a good measure of actual purchasing behaviour as opposed to (currently hypothetical) stated preferences. One UK interviewee commented that consumers are concerned by the use of GM feed in the livestock sector, but added that concern has decreased over the years and consumers no longer mention these concerns unprompted.

Other UK interviewees believed that consumers expected livestock products produced using GM feed to be positively labelled and that in the absence of such labelling, consumers are not provided with an informed choice.

Generally, the position of the food industry in the UK, based on a lack of media/consumer response to a Soil Association publication setting out the use of GM material in livestock feed (Soil Association, 2007), is that consumers do not expect livestock products to be labelled for GM use. NGOs take the opposite point of view citing a 2006 survey carried out on behalf of Friends of the Earth and GM Freeze in which the majority of respondents said that they wanted the labelling of GM livestock products (GfK NOP, 2006). In the survey, respondents were asked a series of questions³², the last of which related to whether livestock products fed on GM should be labelled. Some 87% of respondents³³ thought that livestock products should be clearly labelled; however it should be noted that only 50% of respondents expressed a preference for livestock products fed on non-GM ingredients when asked and 45% of respondents said that they had no interest or did not care whether the livestock products that they consumed were produced using GM feed or non-GM feed.

As might be expected, the meat industry generally believed that consumers do not expect livestock products to be labelled as produced using GM feed. According to several interviewees from the meat sector, NGOs are running campaigns advocating the positive labelling of livestock products. One interviewee commented that while there have been studies where consumers have said they expect milk and meat to be labelled, these studies do not necessarily reflect consumer opinions as it is not clear how the question was phrased (see also the discussion of GfK NOP (2006) above). One interviewee had completed some internal qualitative research on consumer attitudes to the use of GM livestock feed which found that consumers generally thought that retailers are more likely to stock GM-fed livestock products than butchers, although in reality this is not the case.

Oil products

Views in terms of whether consumers expect oil products to be labelled as derived from GM were split and there was no clear pattern by Member State. Some industry interviewees from different case study countries considered such labelling to be misleading and inconsistent because oil products do not contain GMOs. One French interviewee believed that consumers do not understand the meaning of GM labelling on oil products. Several German interviewees stated that labelling should either be entirely content based (meaning oil products would be excluded from the labelling scope), or entirely process based, in which case livestock products and additives, vitamins, etc. should all be included within the positive labelling scope.

Consumer understanding and consistency aside, some interviewees believed that the labelling of oil products is in line with consumer expectations. One interviewee commented that there is a difference between products derived from GM (such as oil) and livestock products fed on GM material and the fact that the former is labelled while the latter is not is therefore not an inconsistency. Finally, one industry interviewee commented that while consumer organisations certainly expect oil to be labelled, it is difficult to determine if consumers themselves really expect this.

³² (1) Which supermarket do you shop at? (2) Most livestock products that are sold in Britain come from animals with a diet including GM ingredients. True or false? (3) Would you prefer: livestock products fed on a GM diet; livestock products fed on a non-GM diet; no preference? (4) Thinking about your supermarket, would you prefer that they sell: livestock products fed on a GM diet; livestock products fed on a non-GM diet; no preference? (5) Do you think livestock products fed on a diet including GMs should be clearly labelled or not?

³³ From a base of 1,000 respondents stratified for gender, age and social class.

3.3.1.4. Facilitation of an informed choice for consumers under the current labelling regime

As a foreword, some interviewees in case study countries believed that GMOs are not among the main consumer concerns. Several interviewees in Spain commented that GMOs are not a primary concern of Spanish consumers and that Spanish consumers did not have a strong view one way or the other. One Spanish interviewee referred to surveys performed by CIS (Centro de Investigaciones Sociológicas) investigating the three main issues of concern for Spanish citizens. According to the survey, agriculture issues were among the top three concerns for just 0.8% of the population; environmental problems concerned just 0.6%. Food safety crises (for example, BSE and Avian Influenza) were not rated among the top three concerns³⁴. Another interviewee referred to a report from Catalonia (a GM maize growing region), in which citizens were asked about their concerns with agriculture and the environment. Only 1.9% of respondents selected GM (Fundació del Món Rural, 2009). One German interviewee said that according to a study from 2007/8, fewer than 20% of consumers really care about the GM issue; however, another interviewee commented that there is a 60-80% rejection rate of GM in Germany. Some UK interviewees commented that concerns with GM had receded in recent years, and that the issue was no longer at the forefront of consumers' minds. This view is corroborated by the FSA's quarterly tracker; as of December 2009, 4% of respondents expressed concerns with GM when not prompted, while 20% expressed concerns when prompted. According to the FSA's 2009 follow-up paper on GM, unprompted concern peaked in 2003 at 20% (FSA 2009b and Defra and the FSA, 2009).

Furthermore, some interviewees in Germany, France and Spain believed that consumers were poorly informed with regards to GM. It is therefore unsurprising that various interviewees, in different case study countries and representing very different interests (consumers, the feed sector and the biotech industry) believed that more consumer education is needed with regard to GM. One interviewee commented on the ease with which consumers may be influenced by GM "myths" (they mentioned square watermelons, for example), and believed that both full information in terms of the use of GM on labels and education of consumers are necessary in order to facilitate informed consumer choice. One study from the UK refers to several articles which indicate the need for GM labelling to be accompanied by information regarding the reasons for the use of GM technology in order for consumers to better understand the label (Davies *et al*, 2010).

While several interviewees believed that the current labelling regime did enable an informed consumer choice, others were not entirely in agreement. Some further comments relating to scope and the facilitation of choice under the current labelling regime were provided. One German interviewee commented that with full labelling of uses of GM technology (i.e. livestock products, additives, vitamins, etc.) the consumer will become less concerned about GM technology because labelling would be far more widespread and hence not considered unusual. Some interviewees thought that the ability to make an informed choice was damaged by inconsistencies in the current labelling regulation (for example, the lack of livestock product labelling, or the fact that oil products are labelled). One interviewee believed that consumers wanted to be able to decide between products produced with and without GM technology, and that the current provision did not allow this. Another broadly agreed, saying that the current labelling regime is not sufficient for people who want to avoid GM technology.

A couple of other comments were provided on the current labelling regime. One agricultural industry interviewee believed that the provisions are logical and useable by the industry, but not for consumers. One interviewee commented that while the current provisions provide an informed choice for consumers, the indication on labels of the use of GM in a product is not prominent enough. One French interviewee believed that consumers could not make an informed choice because of the

³⁴ http://www.cis.es/cis/opencms/-Archivos/Indicadores/documentos_html/TresProblemas.html.

presence of a tolerance level for adventitious and technically unavoidable presence which means that unlabelled products may contain GM material at low levels. However, another French interviewee commented that lowering or removing the tolerance level for adventitious and technically unavoidable presence may reduce consumer choice, as some products which are currently unlabelled may fall under the labelling obligation and the selection of non-GM labelled products may fall in some areas.

The role of NGO campaigns was seen as a factor inhibiting informed choice by some interviewees (mainly from the biotech industry). One believed that the lack of explanation of the labelling regime had worked in favour of organisations which communicate anti-GM messages. Another believed that the labelling laws in themselves permitted an informed choice, however the pressure of NGOs kept GM products off the shelves and did not allow consumers to make a free choice. On the other hand, a couple of interviewees believed that the combination of anti-GM campaigns and the labelling rules were not enabling an informed choice as the manufacturer reaction has been to reformulate products to avoid the need to label.

Finally, one interviewee added that the “GM-free” label in Germany was not assisting with acceptance in this country either. There were further comments from interviewees on the effects of “GM-free” labelling in their Member State, and these can be found in section 3.4.3 of the extension to labelling case study.

3.3.1.5. The misleading of consumers by the current labelling regime

A few interviewees explained that the 0.9% threshold for adventitious and technically unavoidable presence is misleading for consumers. One consumer organisation interviewee commented that consumers do not know that their food could contain up to 0.9% GM; they added that the threshold encourages negligence in the supply chain. However, another consumer organisation interviewee saw the situation differently; while there were initially concerns that manufacturers would abuse the 0.9% tolerance level for adventitious presence, these fears were not realised. The interviewee added that it would now be hard to reduce the 0.9% tolerance level due to increased co-mingling, and that a reduction of the threshold could result in the labelling of some important products, hence limiting choice for consumers who wish to avoid GM material.

Some interviewees (from different stages of the production chain) commented that the current labelling scheme is disproportionate and/or redundant on the grounds that authorised events have been risk assessed so labelling is not based on product attributes and there is no scientific justification for labelling. A couple of these interviewees commented that the use of many other technologies in crop production is not labelled (one gave the example of pesticides). One interviewee believed that the only reason GM should be labelled is if there is a characteristic difference (for example, nutritional differences in the product such as soybean with an enhanced Omega 3 profile).

As already stated in section 3.3.1.3, some interviewees, in particular interviewees from the biotech and food industries, commented that the labelling of oil products is misleading as the product does not contain GMOs. One interviewee stated more specifically that due to the labelling of oil, consumers may believe that the oil itself contains GMOs. A couple of food industry interviewees commented that labelling based on detection is easier for the industry to deal with, and added that the requirements for labelling oil provided the potential for fraud (and hence consumer deception).

Some interviewees in Germany raised further issues with the scope of labelling. They found it inconsistent that oil was labelled, but that livestock products and enzymes, additives, etc. were not. One commented that the current system is inaccurate in terms of consumer information as consumers may think a product is free from the use of gene technology when it is only actually free of the GM labelling obligation. One UK interviewee thought that the absence of livestock product labelling could be misleading.

3.3.2. What is the consumers' acceptance of the existing labelling rules?

3.3.2.1. Anti GM campaigns

Interviewees in Spain identified Greenpeace's "Lista roja-verde" (red-green list) as the main anti-GM campaign. The guide's green list contains products for which the manufacturer guarantees to Greenpeace the absence of GM material. The red list contains products which are either:

- labelled as containing/derived from GMOs; in which GM material has been detected; or,
- produced by manufacturers who have not guaranteed the absence of GM material.

According to one interviewee, this guide has existed for four or five years and is updated annually. Interviewees believed that the guide is not widely distributed among the wider public, and is mainly confined to certain groups (e.g. the organic sector and rural movements). Some interviewees mentioned smaller campaigns, such as those by Friends of the Earth, organic associations (e.g. Ecologistas en Accion) and local movements against GM cultivation. A couple of interviewees commented that the campaigns in Spain are not as intense as those in some other Member States. This may be due to Spain's experience with the cultivation of GMs; nonetheless it should be noted that there are some notable anti-cultivation movements.

One interviewee commented that in some cases politicians may have made use of the Greenpeace list; for example, in some areas, political parties promised to prohibit food on the Greenpeace red list from being used in public canteens. The interviewee also thought that in some areas (including the Madrid region) some shops had refused to stock products on the Greenpeace red list; the shops were apparently taken to court and lost the case.

Interviewees considered the anti-GM campaigns in Germany to be more intense than those in Spain. Two German interviewees provided considerable information on NGO campaigns. There have been anti-GM campaigns in Germany since at least 1994 when there was a campaign against the margarine "Rama" produced by Unilever, which was labelled as "may contain GMOs". The campaigns have focused mainly on certain food manufacturers or retailers with the aim of preventing products containing GMOs from reaching the shelves. For example, the retailer Metro wanted to stock GM-labelled products to allow consumers to choose for themselves. Due to NGO pressure, the company finally abandoned these plans, and since then no major retailer in Germany has tried to stock GM products³⁵.

Greenpeace is now the main anti-GM campaigner in Germany. There have been other campaigns by Foodwatch (a consumer organisation), and from other consumer and environmental organisations such as Friends of the Earth. The organic sector also has an anti-GM stance; attributed by one interviewee to self interest.

One of the interviewees commented that the GM topic in Germany has been used as a way of winning political votes and that several political parties have entered the GM debate. CSU and ÖDP (the Bavarian based organic party) have involved themselves in the subject, and the current agriculture minister (who is from CSU) is anti-GM. Even the far right NPD have apparently entered the debate by staging protests outside biotech companies and distributing anti-GM leaflets in shopping centres.

³⁵ An interviewee provided the following internet links to this story: Metro beugt sich Greenpeace: www.lz-net.de/news/topnews/pages/protected/show37058.html; BVL press announcement: Lebensmittelhandel erfüllt seine Sorgfaltspflicht; and, Metro bestätigt Kampagne für Gentechnik im Essen; http://www.greenpeace.de/themen/gentechnik/presseerklarungen/artikel/metro_bestaetigt_kampagne_fuer_gentechnik_im_essen/

Interviewees in the UK provided fewer comments on campaigns; however the perception was that the intensity of campaigns in the UK has decreased over time. According to one interviewee, during the 1990s some green NGOs carried out anti-GM campaigns and received considerable publicity. Furthermore, following the BSE crisis, there was considerable public distrust of the food safety authorities. Recently, the Soil Association has carried out some anti-GM campaigns, including the report on the use of GM feed in the livestock sector (Soil Association, 2007), which, according to some interviewees, received relatively sparse media coverage. Consumer tracking research shows a reduction in consumer interest in GM over time, media coverage has become less sensationalist, and there have been some balanced television programmes on the subject of GM according to one interviewee.

According to a French interviewee, historically there have been several campaigns by environmental NGOs, as well as requests from consumer organisations relating to the GM issue. However, the interviewee noted that the campaigns have been followed by public consultations organised by the public authorities. Many of the requests resulting from campaigns have been translated into national regulations; these include provisions to ensure the existence of non-GM food; co-existence; transportation measures; and, disclosure to the public of GM crop cultivation. The interviewee therefore believed that the campaigns had helped to develop a dialogue and had ultimately been constructive.

Finally, some general comments on anti-GM campaigns and communication were provided. One interviewee commented that, in general terms, NGOs have constantly provided pressure in the area of labelling, and that their current demands are roughly the same as the demands that they made 20 years ago. Another interviewee commented that in contrast to the amount of communication performed by NGOs, EFSA and the EU is not communicating enough on the issue, and food producers and retailers do not necessarily consider communication their responsibility.

3.3.2.2. Do consumers buy GM labelled food products?

Due to the low level of GM-labelled food products on the shelves in case study countries, interviewees were unable to provide significant comments as to whether consumers buy GM-labelled food products. According to interviewees, some GM-labelled oil is consumed. In the case of Germany, some interviewees believed that it was purchased for use in the catering sector (see section 3.3.4.1). In the case of the UK, interviewees explained that GM-labelled oil is purchased (usually in bulk) due to price advantages. One interviewee believed this demonstrates that price will be an important factor in consumer purchasing decisions, though another interviewee did not accept that consumers were aware that the oil was derived from GM material (which in turn raises questions about the utility of labelling). A couple of interviewees in Germany and Spain believed that the GM-labelled products which are available are generally imported and purchased by immigrant groups. One interviewee thought that the UK consumers who currently buy GM-labelled products make their decisions based on price or branding.

Some interviewees in the UK commented that GM-labelled tomato puree sold well for a period in the 1990s before it was withdrawn from the market. There was disagreement in terms of why the product was withdrawn with some interviewees citing media and NGO pressure and others that despite the, in their view, price subsidy, consumers ultimately rejected the product.

One interviewee pointed to consumer research from the mid-1990s which showed that consumers would generally accept GM products if they saw a benefit for themselves, though a small group would continue to avoid GM products even in these circumstances (Kuznesof and Ritson, 1996). An interviewee in France shared this view, and commented that the negative perceptions of GM currently outweigh the positive attributes.

More information on reasons for the current market share of GM food can be found in section 3.3.4.1.

3.3.2.3. Consumer views with regard to GM labelling

As already noted in sections 3.3.1.3 and 3.3.1.4, some interviewees believed that GMs are not among the main consumer concerns and some believe that consumer knowledge of the current labelling regime is low. These considerations should be taken into account when examining further comments on consumer views on GM labelling.

One interviewee in France believed that the existing labelling rules are aligned with consumer expectations, and that while improvements could be integrated, the existing rules should not be changed.

Interviewees in Spain considered GM labelling a widely discussed issue. A couple of interviewees believed that the trust of consumers in the authorities and in what they eat is relatively high, unless there are active campaigns to reduce consumer trust. Another commented that there is a certain amount of tradition, and if simply asked whether they want GM or non-GM, consumers in Spain will opt for traditional products/production methods, which they will interpret as being non-GM. This indicates a relatively conservative approach to food in technology; an idea partly corroborated by comments in section 3.3.1.3.

As already highlighted, in Germany there is considerable discussion of the labelling issue. Furthermore, anti-GM campaigns have been considered to be relatively successful by interviewees. This evidence points towards a dissatisfaction with the current labelling rules. However, one interviewee commented that consumer views of GM in Germany are largely driven by NGOs. Furthermore, some interviewees (including one non-industry interviewee) warned that there may be bias in the answers that respondents provide to NGO surveys, and that stated preference as citizens is likely to be different to purchasing behaviour as consumers.

One interviewee referenced a study in which consumers were presented with an actual GM purchasing decision, and commented that the results are different to the results of surveys. In the 2007 study, three varieties of fruit; organic, genetically-modified spray free and conventional, were offered for sale at roadside stalls in five EU countries plus New Zealand. The purchasing decisions of test subjects were not influenced, and the differences were only explained if they asked. The products were offered at different prices relative to the prevailing market price. Market shares for different pricing scenarios were then estimated. (Table 3.1) shows the estimated market share for the scenario where organic products are sold at 15% above the prevailing market price, ordinary products at the prevailing market price, and GM products at 15% below the prevailing market price (Knight *et al*, 2007).

Table 3.1: Estimated market shares for produced using different production methods and differentially priced

Country	Organic (+15%)	Ordinary	Spray-free GM (-15%)
Sweden	20% ***	38% (ns)	43% ***
France	28% ***	39% *	33% **
Belgium	55% (ns)	29% (ns)	17% (ns)
UK	32% ***	38% *	30% **
Germany	33% ***	31% (ns)	36% ⁸⁸

Notes: significance levels *=95%; **=99%; ***=99.9%; (ns) = not significant (i.e. below 95%).

Source: Knight *et al*, 2007.

As already mentioned in section 3.3.1.2, several interviewees in the UK thought that consumers assumed that retailers would not stock GM products, making the labelling discussion somewhat academic. One interviewee commented that consumers make their purchase decisions before entering shops, and that consumers need to be informed at this stage; labelling only makes the final selection easier.

3.3.3. What impact have the rules on labelling of GM food/feed had on the different actors of the food/feed market?

3.3.3.1. Food: Changes when labelling was introduced for food using GM (including direct impacts felt by organisations and impacts on sales or costs)

Interviewees across case study countries commented that in the run up to the introduction of GM-labelling, food producers generally tried to avoid labelling by changing recipes or looking for alternative ingredients. As a result, food manufacturers started requesting non-GM raw materials from their suppliers. One interviewee commented that this is easier for larger companies than for smaller ones as a result of their purchasing power and ability to check ingredients. SMEs are therefore less able to alter their products to avoid GM materials; they also have less market power and are therefore less able to negotiate favourable prices. Another interviewee commented that following the introduction of GM labelling, specifications and contracts in the food industry became more precise in order to avoid labelling obligations.

Some concrete examples of product changes following the introduction of labelling were provided by interviewees. A couple of Spanish interviewees explained that one GM food product (a biscuit produced by Nabisco) was withdrawn from the market following the entry into force of GM labelling under the Novel foods regulation (Regulation (EC) No 258/1997). One interviewee commented that once labelling became obligatory, activists targeted the product by approaching consumers outside supermarkets, and consumers in turn stopped buying the product³⁶. A French interviewee believed that some major producers such as Nestle and Danone tried selling a few GM-labelled products in order to

³⁶ See <http://www.aragonesasi.com/boreas/articulos/arti038.htm> for further details.

test consumer reaction (including a deep-frozen caneloni). According to the interviewee, the reaction was negative and the products were removed from the shelves.

According to another Spanish interviewee, there were some changes following the entry into force of Regulation (EC) No 1829/2003. The interviewee believed that there were several canned fish products which had previously used soybean oil derived from GMOs, but with the new labelling requirements these products were reformulated with olive or sunflower oil in order to avoid the need to label. A French interviewee believed that there were a few GM labelled oil products for a short period following the entry into force of Regulation (EC) No 1829/2003, but they were removed from the shelves. The interviewee did not speculate as to the reason for withdrawal of these products. A German interviewee commented that with the introduction of labelling, Unilever replaced the use of GM derived lecithin with either egg lecithin or non-GM derived soybean lecithin from Brazil (which was easy to source at that moment in time, but is now more difficult). A UK interviewee commented that a major retailer labelled products following the introduction of the novel foods legislation; however, when the media listed the products and referred to them as “Frankenfoods”, sales dropped which prompted reformulations to either remove soybean derivatives from products or to switch to Brazilian rather than US supplies.

Comments were provided on the difficulties experienced by the industry in adjusting to new labelling rules. A couple of industry interviewees commented that as the discussions on labelling were long and it was clear that labelling was going to be introduced, the food industry had plenty time to adjust (for example, UK retailers had already introduced traceability systems and audits to ensure that the supply chain was non-GM). This was corroborated by an interviewee who commented that there was no immediate impact on sales or costs following the introduction of labelling as reformulation had already taken place. While generally no effects were perceived following the introduction of labelling rules, one industry interviewee commented that there were difficulties with interpreting the scope (e.g. how fermented products should be treated, the differentiation between the definition of what is produced from GMs and what is produced with GMs) directly after the introduction of Regulation (EC) No 1829/2003.

Some interviewees commented on the scope of reformulation. According to one interviewee, before the final agreement on Regulation (EC) No 1829/2003, a food industry representative said that GM technology was used in 30,000 food products. However, as the final regulation did not require the labelling of additives and enzymes, many of these products were not ultimately affected. Nonetheless it is likely that a significant quantity of food products contained soybean lecithin without DNA and therefore required either reformulation or new, non-GM supply chains. Another interviewee estimated that in the case of Spain, lecithin may be present in 50% of processed food products. However, other interviewees considered the use of lecithin less widespread. According to one interviewee, while the use of soybean derivatives in the food industry is widespread, the actual quantity used is quite small. According to another interviewee, one major European retailer has over 17,000 own-brand products and only 1,500 of these (8.8%) contain soybean derivatives.

Some interviewees commented that certain issues with the labelling rules have increased in seriousness over time. First, it has become increasingly difficult to source non-GM raw materials; one interviewee said that originally there was almost no cost differential for non-GM soybean, but now it is between 5% and 10% more expensive than GM soybean. Second, according to one interviewee there are still some questions regarding the interpretation of adventitious presence (see the comments in footnote 37 below).

Generally interviewees did not perceive effects on consumer behaviour following the introduction of labelling. According to one interviewee, consumption patterns did not change, although some consumers may have paid more attention to labels.

3.3.3.2. Segregation and identity preservation by oil crushers: the costs and who bears them

Some interviewees provided further detail on the costs of segregation and identity preservation.

One interviewee believed that following the entry into force of labelling obligations, suppliers for food markets had to adapt; the sourcing of raw materials had to change and checks and traceability became more important. Notable issues arose when sourcing from countries inside or outside the EU which were not entirely free from GM cultivation (there was no issue with maize from EU countries without GM cultivation such as France). Certification was requested for maize imports from Third Countries. There was an issue with maize supply from Spain due to GM cultivation in the country. As the agricultural industry was not ready to separate maize (mainly due to a lack of resources to do this) food companies had to introduce an origin programme (including farm inspections) to ensure non-GM status. There are structural costs related to this (e.g. staff), however if operations are large, these costs are not very high in relative terms. Furthermore, maize from all sources is likely to be tested upon reception at the factory, though there is probably no significant cost to this (as the GM test is just one of several measures of quality control).

One cereal industry interviewee provided comments in relation to storage. Sometimes it is possible to have separate warehouses for GM and non-GM supply, but in some cases it is not, in which case warehouses have to be cleaned between uses. The introduction of cleaning and traceability in order to deal with GM material in the supply chain has caused a 50% increase in operation costs for warehouse operators. This increase has been greater (an 80% increase in operating costs) in the last year due to shipments arriving in smaller vessels. Warehouse operators have had to make significant investments in order to satisfy customer requests. In order to ensure profitability, the price charged for unloading would have to increase by 28%, and the price for storage by 105%; many warehouse operators are currently making losses and this is likely to continue unless the prices they charge can be increased.

One oilseed crusher commented on the processes for cleaning between GM and non-GM batches. Identity Preservation (IP) systems are generally dedicated and material is fully traceable through the crushing plants. Segregation involves cleaning down the crushing machinery. The basic process involves running non-GM seeds through the crush and entering these into the GM supply chain for a period of time (or quantity) after which the machinery is considered clean. IP chains are independently audited.

Interviewees commenting on the segregation issue had difficulty in identifying who paid the costs, however, the general feeling was that they are not transmitted entirely to the consumer. One interviewee commented that with competitive markets and customer demands, customers (i.e. the food industry) will look elsewhere if prices are not competitive.

3.3.3.3. Livestock feed: changes when labelling was introduced for GM livestock feed

Effects on the feed industry

Spanish interviewees generally agreed that with the introduction of labelling for GM livestock feed, almost all livestock feed was labelled as “may contain GM”. The reasons for this were to avoid the risk of GM being detected in unlabelled food and to avoid segregation costs (including those relating to domestically produced maize). With reference to the second point, some interviewees commented that without a premium for non-GM, there is no motivation to segregate. According to one interviewee, the feed industry had already examined the GM/non-GM issue, and was in a position to start labelling immediately.

The situation in Germany was relatively similar. According to one interviewee, livestock feed manufacturers started to label most livestock feed whether it contained GM or not and saw this is the only accurate position to take given that small traces of GM material cannot be excluded. According to another interviewee, the market share of GM labelled livestock feed has been a constant 85-90% since the introduction of labelling.

One UK interviewee believed that there were no significant changes for the industry following the introduction of livestock feed labelling.

While most interviewees did not perceive a strong impact on feed processors, one interviewee noted that at the very least the introduction of labelling implied a cost in terms of placing the actual label.

Farmer acceptance

Interviewees generally believed that farmers accepted GM livestock feed. In Spain, some interviewees commented that the price of livestock feed is more important than the label (with the exception of the organic sector). One interviewee provided more background on farmer viewpoints. The Spanish feed industry had been communicating with farmers on the issue before 2004; livestock producers were already aware of the lack of advantages (to them) of GM livestock feed, but the introduction of labelling made the issue a concrete cost issue for farmers and a legal obligation for feed processors rather than a more hypothetical debate. German interviewees generally thought that farmers did not really have a view on the labelling of livestock feed, though one interviewee believed that some effort was needed to explain the labelling to farmers and livestock feed users following its introduction. UK interviewees generally believed that farmers buy based on their needs and the GM content is only an issue if their customers demand non-GM supply chains.

Segregation and non-GM feed

Several interviewees commented on the difficulty and costliness of segregation for feed processors, particularly in the case of soybean. One interviewee elaborated on this point. Segregation is needed at three stages of the livestock feed production process: storage of raw materials; weighing, mixing and dosage; and, storage of final products. The interviewee commented that problems with the interpretation of adventitious presence³⁷ means that machinery must be cleaned between the production of GM and non-GM batches, or separate production lines must be used. As the former is not considered viable, production plants with only one line are more likely to produce only GM labelled or only non-GM labelled livestock feed. This interviewee stated that the cost of segregation depends on the content of GM material demanded by the customer (if the content demanded is 0.1%, costs will be higher than if it is 0.5%). Another interviewee commented that segregation was easier when labelling was first introduced due to the smaller number of GM events. Some interviewees believed that the non-GM livestock feed and the organic sector bear the costs of segregation.

A range of interviewees across all case study countries believed that it has become increasingly difficult to source non-GM feed. One interviewee explained that the labelling of almost all livestock feed as “may contain GM” in Spain had limited the choice of farmers, and the lack of segregation partly resulting from the labelling has also affected farmers who produce non-GM maize.

³⁷ According to this interviewee, there are two problems with adventitious presence. First, whether the 0.9% threshold level is calculated with respect to the final feed or to the raw ingredients. According to the Commission, the threshold applies to a certain raw material. This means that if a feed contains 1% soybean, but 50% of the soybean is GM, the feed must be labelled. This causes a problem if a batch of feed is meant to have no soybean, and is unlabelled, but actually has a small adventitious presence of soybean which happens to be GM. Second, there is the issue of what is adventitious and technically unavoidable.

Competent Authorities

Competent Authorities did not perceive a significant extra burden from the introduction of labelling for livestock feed. One Competent Authority commented that while livestock feed had to be controlled, the GM labelling was just an extra test which was added to the Member State regulations covering the control of livestock feed and was performed alongside other existing controls. Another commented that the infrastructure was already in place as tests were being performed on food and these tests were simply extended to livestock feed. The same Competent Authority said that they had not received a significant level of farmer enquiries following the introduction of livestock feed labelling which does not suggest widespread dissatisfaction.

3.3.4. The extent to which food on the market is labelled as GM and what explains the situation

3.3.4.1. Type, number and market share of food products labelled as GM

Interviewees in all case study countries believed that there were few GM labelled food products on the market in either their countries or in the EU more generally. One Spanish interviewee from the food industry estimated the number of GM labelled products in Spain at between 20 and 30. Generally, Spanish interviewees believed that GM labelling was generally applied to imported maize products (mainly flour) from South America, aimed at specific consumer groups. A couple of interviewees believed that there may be some mayonnaise, salsa and bakery products, plus products used in the catering sector.

No quantitative estimates were provided by interviewees in Germany as to the number of GM labelled food products available. Interviewees stated that there are no GM labelled products in major German supermarkets, but that there are some GM labelled products with soybean derivatives imported from Asia and available for sale in Asian supermarkets. Some GM labelled oil is also used in the catering sector. A couple of interviewees believed that GM labelled products on the German retail market have been limited to a Nestle product called “butterfinger” and possibly a couple of other products. The low number of GM labelled products is corroborated by the German website www.transgen.de; according to the results of market monitoring by the Bundeslaender, there are almost no GM labelled food products in Germany. However, in 2008, traces of GM were detected in over 20% of products containing soybean derivatives and around 3% of products containing maize derivatives; in the case of a few products the percentage GM content was above the 0.9% threshold for adventitious and technically unavoidable presence, but was unlabelled³⁸.

Some quantitative estimates were provided in the UK. One interviewee believed that there were 14 GM labelled products on the shelves of a major retailer; another interviewee placed the number of products at no more than 10. These products included oil, cake decorations, bacon bits and American bagels. These products are generally all imported and contain maize or soy starch. Several interviewees commented that the major retailers do not have own-brand GM labelled products. Interviewees also commented on the presence of GM labelled oil in general and specialist supermarkets and in the catering sector. The use of GM labelled oil in the catering sector was considered problematic by some interviewees as it is apparently often not labelled, although this is a legal requirement. One UK NGO stated that the number of GM labelled products in the UK had declined over time.

Most French interviewees believed that there are no GM labelled products on the shelves, however one believed that there may be a small number of imported products which are sold in smaller outlets

³⁸ <http://www.transgen.de/lebensmittel/ueberwachung/857.doku.html>.

rather than supermarkets. One interviewee felt that there were about 15 products which used considerable amounts of GM raw materials and were not labelled. Furthermore, the interviewee felt that processors may be using GM ingredients. According to one interviewee, there were some GM labelled products on the shelves in 1998, but they disappeared due to lack of consumer demand. Some products reappeared following the implementation of Regulation (EC) No 1829/2003, but again these were subsequently withdrawn. Another interviewee believed that there was a GM-labelled rapeseed oil for sale in major stores at one point in time, but was not sure if the product was still available. The interviewee remarked that the product was very cheap and that it may have been used to test consumer reaction.

3.3.4.2. The reasons for the situation

In Spain, several industry interviewees explained that the low market share of GM labelled food products was explained by Greenpeace's red-green list and other anti-GM campaigns. However, the limited reach of the campaign (see section 3.3.2.1) would suggest that there are further reasons for the low market share of GM labelled food, and other interviewees provided some. One commented that some retailers received direct pressure from anti-GM groups. Two more commented that supermarkets and food producers are requesting non-GM ingredients for food. One industry interviewee believed that the ingredients form a small part of the total cost, and that food producers do not currently consider that the benefits outweigh the disadvantages (i.e. the small competitive advantage in terms of price does not compensate for potential damage to the company image). Another interviewee commented that there is a bias towards marketing products as being traditional in Spain, and that technology in food production is not generally communicated. One industry interviewee identified slightly different reasons for the lack of GM labelled food products. Food companies currently often request a maximum of 0.1% GM content from suppliers as they do not want to label; probably because this fits with consumer expectations. If there was greater communication about GMs in order to increase public acceptance, consumers may not be so demanding in respect of GM presence, and as a result, producers may be able to increase the maximum level of GM content that they request from suppliers.

In Germany, industry interviewees connected the lack of GM labelled food products to pressure campaigns on retailers and food companies. Several commented on the oligopoly in the retail market, the experience of the Metro retailer chain (see section 3.3.2.1), and how no major retailer has sold GM labelled products since. Two interviewees explained that no retailer or production company wants to be the first to offer GM labelled products due to the costs (including to company image). However, if one company moved first, the others would be likely to follow suit. One interviewee added that food manufacturers also want to avoid the use of GM labelling for the same main reasons.

Several German interviewees made connections between the lack of GM labelled products and consumer attitude to GM technology and also commented on the low level of public acceptance amongst German consumers. One believed that there is a strong rejection of GM technology among German consumers. Two interviewees believed that the low level of public acceptance was at least partly due to the effect of anti-GM campaigns on consumers. When confronted with GM products for the first time, consumers probably did not know enough about the subject and the anti-GM campaigns therefore formed their opinion. Currently, consumers cannot see the advantages of GMOs. As long as any retailer which wishes to sell GM labelled products must incur significant costs in communicating the safety and potential benefits of GM, there is unlikely to be a considerable cost advantage for products containing GM. Another interviewee believed that while consumers may say that they are anti-GM, what they say and how they act are different, as demonstrated by Knight, et al (2007) (see section 3.3.2.2).

Three main reasons were identified by UK interviewees for the low availability of GM labelled food.

- **Retailer policy.** Several interviewees commented that retailers have adopted a non-GM policy for their own-brand products. One interviewee commented that retailers are testing the market by stocking a limited range of private label products, while another noted that NGO pressure had played a role in retailer policy. It should also be noted that retailers are now openly discussing using GM feed in own-brand livestock chains (Kings College London, 2008).
- **A lack of consumer benefits.** Several interviewees believed that consumers may accept GM if they saw a benefit for themselves, and that agronomic traits alone are not enough. One interviewee provided the example of GM tomato paste in the 1990s that sold well for a while alongside non-GM alternatives, and another cited 1994 research by the Food and Drink Federation which concluded that most consumers would accept GM if there were benefits.
- **Media and NGO campaigns.** Some interviewees thought that these had affected consumer awareness and helped to form consumer opinion. One interviewee believed that the strong campaigns of the 1990s had affected consumer demand, and that the distrust of the food safety authorities following the BSE crisis had played a further role.

Lack of consumer benefits was also identified as a reason for the absence of GM-labelled products in France. One interviewee commented that negative attitudes about GM (i.e. perceptions of risk) outweigh the positive attributes, and that to date there are no visible benefits for consumers. The interviewee added that factors such as the foreign status of the technology, its ownership by multinationals, the lack of transparency of the development of GMs and the idea of manipulating living organisms were all further reasons why citizens reject GM.

A couple of interviewees in the UK could see the situation changing as retailers wish to benefit from the cost advantages of GM. One commented that retailers are currently absorbing the costs of avoiding GM ingredients. Another believed that retailers may have to move away from the non-GM policy over the medium-term. The same interviewee believed that the potential risk of labelling errors will be an issue in driving changes in retailer use of GM and GM labelling.

Industry interviewees in several Member States commented that the anti-GM campaigns have ultimately prevented consumers from being able to exercise a choice between GM labelled and unlabelled products. One interviewee speculated that if the campaigns had not and were not taking place, there would be a considerably higher quota of GM labelled products. Based on price (which many consumers consider the most important decision factor), the share could reach 80% in market segments where GM exists as an alternative.

3.3.5. The extent to which livestock feed on the market is labelled as GM and the reasons for this situation

3.3.5.1. The use of GM livestock feed covering crops, source and livestock sector, including differences in the use of GM material based on alternatives, and the reasons for this

Germany

Interviewees stated that the majority of livestock feed in Germany is labelled as GM. Actual estimates of market share varied, but all were at least 85% and most were 90% or more. All interviewees agreed that GM soybean was heavily used as a raw ingredient in livestock feed. One interviewee explained that some 4 million tonnes of soybean is imported by Germany (of which 85-90% is GM). Of this, 1 million tonnes goes directly to farms for on-farm mixing (this is mainly GM soybean), while 3 million tonnes is used in the livestock feed industry. Interviewees were divided over the use of other GM crops. One believed that a small amount of imported maize and oilseed rape labelled as GM was also

used in livestock feed. Another believed that no GM oilseed rape was currently used for livestock feed in Germany, although with an increase in GM oilseed rape at the global level and a lack of crushing capacity in the EU, in the future it is likely that oilseed rape imported for livestock feed will be labelled as GM. The same interviewee commented that in the past, approximately 6 million tonnes of GM maize by-products were imported from the US for use in EU livestock feed. However, due to problems with asynchronous authorisations and, as a consequence, the risk of Low Level Presence of unauthorised (in the EU) GM material, maize imports from the US ceased in 2006. That said, imports may resume following the EU authorisations in November 2009.

One interviewee commented that the use of GM livestock feed has become increasingly popular in Germany over the last five to six years (since Brazil began producing GM crops) and is now almost unavoidable. Another believed that demand for non-GM livestock feed has been consistently low (around 10% for composite feed) since the introduction of the labelling requirement.

One interviewee in Germany provided more detail on the use of GM livestock feed by species. The poultry sector uses a large amount of non-GM livestock feed; only 30% of chicken and 40-50% of turkey feed is currently labelled as GM. Almost all beef and pork production uses GM livestock feed. Beef production in Germany is intensive; soybean and maize silage are used extensively.

German interviewees noted that livestock feed labelled as GM is cheaper than non-GM supply.

Spain

There was greater consensus among stakeholders as to the situation in Spain. Interviewees agreed that almost all livestock feed is labelled as GM; the range of estimates varied from 95-99% of total livestock feed. One interviewee believed that the level of GM labelled livestock feed has been relatively constant since the introduction of feed labelling.

Some information was provided on the use of GM livestock feed by species in Spain by interviewees. Pork and chicken production is almost entirely industrial, and hence dependant on GM feed (though one interviewee commented that some higher quality products, such as iberic pork, is extensive and hence does not depend on GM feed). Dairy production is semi-intensive, and hence has a dependency on soybean. Beef production uses maize and soybean extensively in the final fattening stages (although according to one interviewee, some beef production is extensive and hence does not use GM feed). Lamb production does not tend to use livestock feed.

Several interviewees in Spain commented that it is possible to label food as “may contain GM”. Interviewees therefore believed that the high proportion of GM labelled livestock feed in Spain is partly a consequence of this, as well as the high reliance on compound feed in the livestock sectors. In other words, the actual use of GM material may be lower than implied by examining labelled products. The domestic production of GM maize is also a factor. Another interviewee added that Spain imports half of its livestock feed requirements, including its entire soybean requirement and significant amounts of maize and is therefore dependent on GM raw material because it is becoming increasingly difficult to source non-GM soybean.

A few interviewees in Spain commented that farmer acceptance of GM in livestock feed is relatively high. One interviewee said that farmers have realised that there is no alternative for livestock feed, and that on an individual farmer basis, the majority are probably in favour of the use of GM feed.

UK

According to one interviewee, between 80% and 85% of compound feed materials in the UK contain one or more GM events. One interviewee believed that a lot of livestock feed is labelled as GM since it is easier to label than to check, and that the supply chain has made little effort to provide non-GM feed. Comments were provided on the use of GM feed for different species. Limited non-GM livestock chains are possible for beef and lamb, but less so for dairy according to one interviewee as a result of the greater need to use concentrate feed. Another commented that price premium for non-GM feed in the UK is around 10%, and that this mainly affects the poultry sector, which has, at least until the end of 2009, used non-GM supply chains according to one interviewee.

Interviewees generally believed that producers in the UK buy livestock feed based on specification to meet their needs (identified as being cost effectiveness at the time of purchase by one interviewee) while taking into account the demands of their clients. This means that farmers generally do not worry whether feed is labelled as GM unless their clients specify that they require a non-GM supply chain.

France

Interviewees provided various estimates of the percentage of livestock feed which is GM. However, the general consensus was that 80-90% of livestock feed in France is labelled as GM, and 70-80% of soybean used in feed is GM. One interviewee provided more background to the feed market in France. Some 40% of annual feed production is poultry feed, 30% pig feed and 25% bovine feed. Soybean meal constitutes about 15% of feed, making it the second biggest ingredient after cereals. Currently, soybean imports from South America are essential for livestock feed. According to one interviewee, soybean is used more in poultry and pig feed, implying that more of this feed is labelled GM. However, according to another interviewee, the pig sector is least concerned whether feed is GM or non-GM as it is facing more significant economic issues and is therefore more price sensitive.

Farmers are perceived to buy feed based on price as they do not have safety concerns and do not have to label the livestock products. One interviewee provided some estimates of the current cost advantage of using GM soy. The current premium for non-GM soy is €30 per tonne, which equates to a €0.06 increase on the cost of production of 1kg of carcass. At the current market price of €1.04 per kg, this represents 5% of the price producers receive.

According to some interviewees, some suppliers have been communicating the use of non-GM feed for the last decade, and some interviewees were critical of this approach.

Dependency on soybean

Several interviewees from various case study countries commented on the difficulty of replacing soybean as a feedstuff. One interviewee noted that following the BSE crisis, meat and bonemeal were banned as a protein source and this has restricted the sourcing possibilities. Based on interviewee estimates on the proportion of soybean which is GM, the requirement for soybean as a source of protein would appear to be an important driver in the use of GM labelled livestock feed. However, one Spanish based interviewee took a different view. While acknowledging the current dependency on soybean, the interviewee believed that, with the proper systems in place, it should be possible to obtain necessary livestock feed from within the EU, and with the low level of GM cultivation in the EU, this would mean non-GM livestock feed.

3.3.6. Options for the future

Options for the future are considered in section 3.4.5 following the extension to labelling case study as they draw on both labelling case studies.

3.4. Extensions to the labelling regime to include livestock products and GM-free labelling

This case study is based on interviews undertaken in Finland, France, Germany and Spain. Finland was selected because the use of “GM-free” labelling is currently under discussion. France was selected because of the recent discussion of GM labelling which has culminated in an opinion from the Haut Conseil des Biotechnologies (HCB) that “GM-free” labelling should be permitted, including in the livestock sector. Germany already has experience of “GM-free” labelling and hence there has been a national debate on the labelling of GM products in general. Spain has experience of cultivating GMOs and this may have resulted in a different attitude to GMOs in general to that in other Member States.

This case study focuses on the following Evaluation Questions which focus specifically on potential extensions to the scope of the current labelling regime, including the use of “GM-free” labelling:

- **EQ11:** What consequence would an extension of the scope of the labelling rules including the labelling of animal products have?
- **EQ12a:** What are the approaches currently used in MS in the field of 'GM free' labelling?
- **EQ12b:** Do these approaches contribute to improve consumers' informed choice?
- **EQ12c:** 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?

3.4.1. What consequence would an extension of the scope of the labelling rules including the labelling of animal products have?

3.4.1.1. Proportion of livestock products currently fed on GM feed

According to one industry interviewee, approximately 85% of livestock feed in the EU contains GM material with the proportion differing slightly between Member States. According to Spanish interviewees, almost all feed is labelled as GM in Spain (estimates are generally in the range of 95%-98%). However, a couple of interviewees in Spain commented that feed is often labelled as “may contain GM” in order to avoid potential problems with testing; in other words, the proportion of actual GM feed may be slightly lower than the estimates provided. According to Spanish interviewees, GM soybean and GM maize (including almost all Spanish cultivated GM maize) is used in feed rather than food.

The penetration of GM material in feed in Germany is slightly lower with between 85% and 90% of feed labelled as GM according to interviewees. A couple of interviewees believed that feed in Germany may be labelled even if does not necessarily contain GM. This point caused some discussion among interviewees; according to one interviewee, the labelling “may contain” is not permitted in Germany, but according to another the labelling of livestock feed as GM is correct if there are traces of GM. According to one interviewee, the only GM crop currently used in feed in Germany is soybean; there is no GM maize or oilseed rape. Approximately 10-15% of soybean imported into Germany is non-GM. French interviewees believed that 80-90% of livestock feed in France is GM labelled. A couple of interviewees commented more specifically that 70-80% of imported soybean used in feed is GM. The situation in Finland was markedly different; interviewees commented that the proportion of feed in Finland labelled as GM is low, with general agreement that 4% of soybeans

imported to Finland and used in livestock feed are GM. The main compound feed producers in Finland (who together produce 80% of feed for domestic use) do not use GM raw materials.

Some interviewees provided information on the use of GM feed by livestock sector in case study countries. In Germany, the poultry sector is considered to be the main user of non-GM feed. Around 70% of chicken and between 50% and 60% of turkey feed is non-GM (i.e. 30% of chicken and 40-50% of turkey is fed on GM labelled feed). This is explained by the high market share of integrated operations, for whom it is easier to organise non-GM feed as they purchase their own feed. Almost all pork and beef is fed on GM (most German beef production is intensive). Approximately 5% of feed used in the dairy sector is non-GM.

The situation in Spain is more nuanced with one industry interviewee commenting that all feed used in intensive animal production contains GM raw materials, while extensive production (e.g. some beef production and Iberic pork) uses less GM feed. Another industry interviewee provided more detail: pork and chicken production are mainly industrial, and almost entirely depend on GM supply chains. Beef producers are generally medium-sized operations, and maize and soybean (GM or non-GM) is used extensively in the final fattening stage. Spanish dairy production is semi-intensive and has a strong dependency on soybean (GM or non-GM). Sheep production is generally more extensive and does not have feed dependency. In Finland, interviewees commented that the pork, chicken and fur industries are more likely to use GM feed, whilst beef and dairy industries try to avoid its use. However, in considering the situation in Finland, the low overall share of soybean in feed should be taken into account.

Interviewees in several case study countries commented on the reliance of different animals on soybean as a feedstuff. Soybean is an essential component of poultry and pork feed and cannot be replaced. The requirements of the animal change over the fattening period; protein requirement is high at the beginning (hence the need for soybean), however towards the end of the fattening process maize can be used. On the other hand, it is relatively easy to replace soybean in dairy feed with, for example oilseed rape. However, soybean is more important for higher performance dairy cows.

3.4.1.2. Extent to which consumers are currently aware that livestock products produced using GM feed are not labelled

Consumer expectations in terms of the labelling of livestock products was investigated in section 3.3.1.3 of the current labelling case study.

Finnish interviewees overwhelmingly believed that consumers are not aware that livestock may be fed on GM feed and that the final product is not labelled, although some interviewees believed that a small percentage of consumers may be aware of the details of the labelling rules. The Finnish Food Authority completed an information campaign on the use of GM technology in agriculture in August 2009, the results of which are set out in (Table 3. 2). While consumer understanding varies, there are clearly areas where there is a relative lack of awareness, most notably in relation to GM material in unlabelled soybeans.

Table 3. 2: Perceptions on the use of GM technology in agriculture in Finland

	True	False	Answered correctly
GM food is safe to eat (correct)	391 (72%)	154 (28%)	72%
GM content must be labelled (correct)	445 (83%)	91 (17%)	83%
Unlabelled soybean is likely to contain GM soybean (false)	360 (68%)	172 (32%)	32%
The term “modified starch” has nothing to do with genetically modified starch (correct)	388 (74%)	136 (26%)	74%
Genetically modified food is as healthy as conventional food (correct)	332 (63%)	195 (37%)	63%
GM food is on shelves in Finland (false)	262 (50%)	262 (50%)	50%
When pigs are fed on GM feed, humans eat GM ham (false)	314 (60%)	207 (40%)	40%
GM food contains fewer vitamins and other nutrients than conventionally produced food (false)	402 (77%)	121 (23%)	23%
GM foods cause cancer and deformities (false)	408 (69%)	186 (31%)	31%

Source: Finnish Food Safety Authority (Evira).

Some Finnish interviewees commented that the use of GM livestock feed has been discussed in the Finnish media; most notably in 2007 when a feed mill announced its intention to begin using GM ingredients, and when reports surfaced about Danish pork fed on GM. Interestingly it was noted in the latter case that there was almost no impact on the sales of Danish ham (popular around Christmas in Finland) according to an interviewee, which suggests that it may not be possible to discern actual consumer concern from media coverage.

In Spain, a few interviewees commented that consumers either had not formed an opinion of GM, or were not well-educated with regards to GM. One interviewee commented that while consumers may be sensitive to the GM issue in general, they are less aware and less sensitive with regard to the use of GM feed. One interviewee stated that Spanish consumers do not expect GM-fed livestock products to be labelled, while another thought that some consumers may be aware of the use of GM feed. In summary, the evidence from Spain is not conclusive in terms of whether consumers are aware of the use of GM feed or not.

Interviewees in Germany were not able to comment on whether consumers are aware that some livestock products are produced with GM feed. However, interviewees noted that there is currently a debate in Germany about the labelling of livestock products with some discussion among politicians and with some NGOs running campaigns on livestock labelling (targeting the dairy industry in particular).

The discussions on the “GM-free” labelling scheme in France suggest a certain level of interest in the labelling of livestock products. One interviewee commented that the use of GM feed is often

discussed in the media and believed that a relatively large proportion of consumers is aware of the use of GM feed. However, one interviewee believed that consumers are increasingly less interested in how food is produced, and that consumers do not understand modern food supply chains. The interviewee believed that consumers want high quality food at a good price and that the labelling of livestock products was not compatible with this concept.

3.4.1.3. Expected impacts if GM labelling were extended to cover livestock products

As a foreword, and as one interviewee commented, it is hard to evaluate the likely consequence of extending the scope of GM labelling to cover livestock products. Demand for non-GM meat would depend on its price. This would depend on the price of non-GM feed, which would in turn depend on demand. In other words, there is a dynamic relationship between supply and demand and unknown feedback loops which confuse the situation.

Taking this difficulty into account, the effects of extending GM labelling to livestock products as anticipated by interviewees are presented below under the headings: supply; demand and effects on consumers; impact on the industry; and, impacts on Competent Authorities.

Supply

The majority of interviewees in Spain commented that it would simply not be possible to produce any significant quantity of non-GM fed livestock products as a result of Spain's reliance on GM raw materials in feed. As a result, almost all meat would need to be labelled as produced using GM feed. The non-GM segment would be very small (2% according to the estimates of one industry interviewee). Only one interviewee could envisage a situation in which supply in Spain could adjust in order that non-GM fed livestock products could be produced. This interviewee commented that a livestock product labelling scheme would provide incentives to segregate feed supply chains and for producers to produce non-GM labelled products. The same interviewee added that, in general terms, with the proper systems in place, it should be possible to obtain the necessary non-GM raw materials from the EU internal market.

Interviewees in France also saw problems in adjusting the supply chain to different extents. One interviewee in France believed that with an extension of labelling scope to include livestock products, 98% of meat products would be labelled. The estimate of another interviewee was lower; 90% of animal products fed on soybean would be labelled as GM, while another believed that between 50% and 70% of pork products would be labelled. Interviewees were generally concerned about sectors using soybean in feed, in particular poultry and pork. One interviewee warned that it would not be able to substitute raw materials in these chains, and that these supply chains would be adversely affected.

The situation in Germany was different to that in Spain and France. Several interviewees did not consider the supply side, being more concerned with the demand side or the potential effects on different actors. Interviewees who considered the supply side were able to envisage more adjustments in supply, even if they were not straightforward. According to one industry interviewee, the large-scale production of non-GM fed meat would not be easy logistically, but it would be possible. However, it would take approximately 18 months to set up the necessary supply chain (signing contracts with Brazilian growers, growing the soybean, feeding to livestock, etc.). According to another German interviewee, the market for GM feed would probably increase if labelling were extended to livestock products, and if it grew significantly, then the price differential between GM and non-GM soybean would slowly narrow. The same interviewee believed that the supply of non-GM fed meat would increase over the short-term (1 to 2 years), and operators would then decide whether this segment remained economically viable. This view was broadly supported by another interviewee

who added that decisions to switch to non-GM feed would be made on a company-by-company basis, and would depend on the extent to which a company wanted to avoid the use of GM feed labelling on livestock products.

Based on interviewee estimations of the proportion of GM feed used in Finland, it is reasonable to conclude that there is currently no structural impediment to the production of livestock products labelled as non-GM. However, Finnish interviewees were divided over how feasible this would actually be. One interviewee believed that it would not be difficult to segregate supply chains due to the current low level of use of GM raw materials in feed, and the fact that the dairy industry currently maintains a policy of using non-GM feed. One interviewee explained that while the segregation of feed would be relatively simple, segregation in slaughterhouses would be more difficult. For larger slaughterhouses, it could be too costly to operate a segregated Identity Preservation system. It is expected that larger slaughterhouses would therefore concentrate on the commodity market segment, meaning that they would produce livestock products which could not be guaranteed to be fed on non-GM feed while smaller slaughterhouses would probably focus on guaranteed non-GM fed products. A third interviewee thought that segregation in the supply chain would be complicated. Several interviewees commented that traceability in the supply chain would not be a problem, but that verification of the status of products would be given the inability to test for the use of GM feed.

As a final, general comment, one interviewee noted that the availability of non-GM feed is expected to decline in the future, with two main effects: (1) it will become more difficult to know when non-GM feed may be in short supply; and, (2) with reduced supply of non-GM feed, larger companies will be able to maintain non-GM supply due to their contacts and market power, while smaller companies will find it more difficult.

Demand and effects on consumers

Several interviewees speculated on the effects of an extension of GM labelling to cover livestock products on overall demand. Spanish interviewees were split on this issue. Two industry interviewees thought that an extension of labelling scope to include livestock products would have no impact in terms of decreasing demand for meat either through an increase in people not eating meat at all (currently 4% in Spain) or in terms of decreases in consumption *per capita*. In contrast, another interviewee noted that the level of vegetarianism had been increasing in Spain over the last 10 years and that the labelling of meat as fed on GM feed may increase this level still further.

In Germany, interviewees generally expected a fall in the demand for meat in response to an extension in labelling scope, at least in the short-term. Several interviewees used the example of the BSE crisis to demonstrate the attitude of the German consumer; this was followed by a dramatic short-term fall in beef consumption (though according to one interviewee it returned to normal levels in the medium-term). Two interviewees thought that an extension of labelling scope to cover livestock products would result in a short-term decrease in demand, albeit not as strong as the response to the BSE crisis, with a return to normal consumption levels in the medium-term. Some Finnish interviewees agreed that there may be some short-term market disruption due to consumer surprise at the probable extent of labelling and media attention. However, interviewees did not expect any changes over the medium-term. In the case of France, interviewees found it difficult to judge the reaction of consumers and ultimately did not speculate as to the change in demand. However, a couple of interviewees believed that the introduction of animal labelling may damage the image of animal feed manufacturers or of policy makers, implying that consumers may react negatively to an extension to labelling.

Interviewees were split with regard to the likely impact on relative demand for livestock products fed on GM feed compared to those fed on non-GM feed. On the one hand, a couple of interviewees in Germany thought that demand for non-GM fed livestock products would increase, although they were unable to identify the magnitude and duration of this increase. One stated more specifically that once

labelling was introduced, the high level of GM rejection in Germany would lead to increased demand for non-GM fed livestock products.

Finnish interviewees identified two possible effects. Firstly, some thought that over the short-term, demand for non-GM and organic livestock products might increase. Others noted that while there may be a small group of consumers who would specifically purchase non-GM fed livestock products, for general consumers the purchasing decision would depend largely on price, as Finnish consumers are price sensitive. Two interviewees further explained that as the Finnish organic sector is relatively small³⁹, there may be some demand for non-GM fed livestock products which could not be met through the organic sector. At the other end of the scale, some interviewees in both Spain and Germany thought that demand for non-GM fed livestock products would not increase. One interviewee commented that consumers will probably continue to make purchase decisions based on price, while several interviewees in case study countries commented that the low market share of organic products (under 1% in Spain, 4-5% in Germany) shows that the market for non-GM fed meat is small. However, given the perceived lack of awareness of the use of GM feed (see above), it may not be wise to draw any conclusions on demand for non-GM fed livestock products from current demand in the organic sector.

One interviewee commented that an extension of labelling scope to include livestock products may cause market distortions as some meat sectors may be able to avoid labelling due to different production methods. This might result in substitutions of one sort of meat for another. An example of this might be poultry in Germany which could benefit as a large proportion of feed in this sector is non-GM (see section 3.4.1.1 above).

Several interviewees in Spain and Germany believed that labelling livestock products would result in consumer confusion. One interviewee commented that consumers would feel misled in that products not currently labelled would suddenly be labelled as being fed on GM feed. Another interviewee thought that the consumer would be misled because the labelling might imply that non-GM fed meat is superior, although there is no difference in the product. German interviewees commented that thorough information campaigns would have to be undertaken before any extension of labelling scope to help mitigate consumer confusion. This view was echoed by some Finnish interviewees who thought that an information campaign would be necessary to help consumers understand what the use of GM feed in livestock production means for them. They also noted that consumer reaction would also depend on how the labelling is presented on the packaging.

While some interviewees across the case study countries thought that labelling livestock products would facilitate consumer choice, the majority of industry interviewees pointed out the lack of a scientific basis for such labelling, as demonstrated by EFSA's statement on this subject (EFSA, 2007f). Some interviewees in Germany and Spain added that consumer choice would not be enhanced because all livestock products would be labelled as GM-fed which may incur some compliance costs (see sub-section on the effects on industry below). One Spanish interviewee added that the non-GM market segment in Spain would probably be small and expensive and that this would not provide consumer choice. However, these concerns regarding consumer choice were not reflected by Finnish interviewees; probably due to the low proportion of GM feed currently used in Finland.

Several German interviewees said that an extension of labelling scope to include livestock products would only be acceptable if all uses of GM technology (i.e. additives, vitamins, etc.) were included for consistency. Indeed, a couple of German interviewees commented that an extension to all uses of GM technology would probably result in a greater acceptance of GM because almost all products would be labelled and it would become clear to the consumer that GM is unavoidable.

³⁹ An interviewee explained that Finnish consumers generally consider Finnish food to be "pure" and therefore demand for organic production has been generally low.

Finally, several interviewees in all case study countries commented on the power of retailers. They thought that retailers would largely determine whether labelled or non-labelled livestock products appeared on shelves. This was considered a particularly strong issue in the case of Germany due to retail oligopoly; if one supermarket adopted a non-GM feed policy, the others would be likely to do the same to avoid being at a competitive disadvantage. However, one German interviewee considered it unlikely that retailers would immediately demand 100% non-GM fed livestock products because this would constrain purchasing flexibility and would hence reduce purchasing power. This is demonstrated by discussions which retailers have had within the German QS chain (the organisation for the livestock production chain) on the subject of GM feed; retailers requested 20-30% non-GM fed meat, rising over time to 100%⁴⁰. One interviewee in France believed that NGOs would put pressure on retailers to remove GM labelled livestock products from the shelves, as they had done following the introduction of the requirement to label oil products. However, the interviewee was not certain that removing labelled livestock products would be feasible.

Effects on the industry

By and large, interviewees were concerned by the possible impacts that a livestock labelling system would have on them, although there was generally less concern among interviewees in the feed industry. Interviewees from different parts of the chain commented on segregation issues and the lack of a testing regime for livestock products. Some interviewees could only see segregation functioning in the final stage of the supply chain if processors (dairies, slaughterhouses and egg packing plants) specialised in either GM-fed or non-GM fed products. Several interviewees commented that while the introduction of labelling for livestock products would probably not create competitive distortion because all products would have to be labelled, it would create extra costs. Some interviewees believed that these extra costs would ultimately be passed on to the consumer; some did not. One French interviewee commented that the introduction of labelling for oil cost the EU industry €5 billion, inferring that the effects could be similar with the extension of labelling to livestock products. One interviewee commented that, as a result of retailer power, other operators in the chain would be most likely to bear costs. More specifically, there was a concern that importers may be squeezed as they may not be able to obtain the same supply guarantees from Third Countries as can be obtained from within the EU.

Concerns about the competitiveness of the EU meat industry should an extension of GM labelling scope be introduced were raised. These concerns were largely due to the potential problems with: (1) forcing Third Countries to adopt labelling, particularly in the framework of the WTO (one interviewee compared the labelling of livestock products to the WTO panel on imports of beef fed with hormones which decided against the EU); and, (2) difficulties for the EU veterinary authorities to perform all the necessary tests to ensure compliance in Third Countries. Several industry interviewees were worried about a resulting two-tier system whereby EU produced livestock products are disadvantaged as they are labelled as being fed on GM, while imported livestock products carry no such labelling. One interviewee pointed out that if such a two-tier system existed, not only would EU producers be negatively affected, but if more livestock products were to be imported, the safety of the EU consumer could be threatened by the use of GM events not authorised for feed use in the EU.

Further perceived effects on livestock producers varied between Member States. One interviewee believed that segregation in Germany, where the livestock industry is not very integrated, would be more difficult. Another interviewee commented that segregation would be considerably harder with dairy products than with meat because milk is a liquid and can therefore be more easily mixed. Some interviewees in Spain expect a greater impact than in other Member States as a result of the size and importance of the Spanish livestock sector. One interviewee added that any changes which affected

⁴⁰ It was finally decided that decisions on the use of GM feed should not be taken within the QS, but rather on a company by company basis. The QS has therefore introduced a quality management standard for the implementation of GM labelling.

the EU livestock sector would also affect all operators in the chain (feed processors, cereal importers, etc.). As already noted, French interviewees were concerned about the effects on the pork and poultry industries due to the reliance of these industries on soybean as a feed raw material. Finally, one Finnish interviewee thought that operators may respond by using labelling “may have been fed with GM feed” in order to reflect the degree of potential uncertainty and the lack of ability to test products.

Impact on Competent Authorities

There were contrasting views in terms of possible impacts on Competent Authorities. Two Competent Authorities commented on the difficulties of operating a labelling scheme where there is no ability to test products. This view was supported by some industry interviewees who noted the potential for fraud. On the other hand, one Competent Authority saw more potential for the implementation of livestock product labelling using a document-based Identity Preservation system. One stated that documentation to allow traceability already exists due to the obligations of Regulation (EC) No 1831/2003, and that the authorities could check the documentation at different stages (for example, the sales documents of feed producers to see who is buying feed; producers of livestock products who have bought GM to ensure they are labelling their products). Problems would occur if one producer or farmer chose to produce both GM fed and non-GM fed livestock. However, this interviewee ultimately expected more uniformity at, for example, a regional level, making the control system easier. This Competent Authority was not greatly concerned by any extra burden, though better co-ordination between food and feed authorities would be needed. A fourth Competent Authority noted that while some of the traceability systems may already be in place (notably for the beef sector due to the BSE crisis) and an administrative system similar to that for the organic sector could be used, the non-GM sector is considerably larger. This would imply a significant cost in developing a suitable system, plus the system may be disproportionate considering that the GM feed used would be authorised and that there would be no GM material in livestock products in any case.

3.4.1.4. Scope of an extension of labelling: processed products as well as primary products

Many interviewees considered it only logical that processed livestock products be included in any extension of GM labelling scope. However, some interviewees, including several in Finland and France, were strongly against the inclusion of processed meat products, generally due to the complexity and potential further costs of any such extension. One interviewee in France was concerned that including processed products in an extension to labelling scope would disadvantage SMEs as they would be less able to afford the additional costs. One interviewee in Finland commented that consumers may be less concerned about processed products, where livestock products may not be the main component. That said, one French interviewee commented that, in its recommendations for a “GM-free” scheme, the Haut Conseil des Biotechnologies had concluded that there was no reason to differentiate between raw and processed products.

Interviewees in Germany were not able to estimate the proportion of livestock products which is used in processed products. They did, however, speculate that including processed products within the labelling scope would lead to considerably more, and more complex, labelling due to traceability issues. One interviewee in Finland commented that processed products are increasing market share (compared to less processed products), again implying that including processed products within the labelling scope would lead to considerably more labelling. One interviewee in Spain believed that up to 70% of meat in Spain is used in further processed products highlighting the scale of labelling that would be required. However, the Spanish government’s annual book of food put the proportion considerably lower, at 22.4% (by weight) of all meat consumed both inside and outside the home, with the remaining 77.6% being either fresh or frozen meat (MAPA, 2007). The main point here though is

that many processed products will contain livestock products and therefore any labelling requirement would be extensive.

3.4.1.5. Scope of an extension of labelling: catering sector as well as the retail sector

The views of interviewees from different case study countries on GM labelling in the catering sector varied greatly. Spanish interviewees were overwhelmingly against the general idea of labelling in the catering sector (including an extension to include livestock products), saying that there is simply no precedent for this.

German interviewees on the other hand were more open to the idea of extending GM labelling to cover livestock products in the catering sector as well as the retail sector. A few interviewees said that under the German interpretation of the current labelling requirement, GM labelling applies to the catering sector, even if in reality the catering sector does not apply the labelling⁴¹. One interviewee thought that consumers would be misled if the catering sector were excluded from the labelling scope; however, this interviewee found it hard to envisage how labelling in the catering sector would work in practice. Other interviewees in Germany said that there was little or no general precedent for labelling in the catering sector; although there may be some labelling for allergens and vegetarian food, and there may be an obligation to label certain additives. There are ongoing discussions over the extent to which labelling is required in the catering sector.

Finnish interviewees generally thought that labelling should apply to the catering sector for consistency reasons, particularly taking into account the fact that a lot of Third Country meat is used in this sector. However, some interviewees commented that labelling in the catering sector may not be so simple; there is a high turnover of suppliers in the catering sector so it would be hard to keep track of ingredients, and it could be very complicated for smaller catering establishments. Some interviewees commented on the tradition of work place canteens and the taking of the main meal at lunchtime in Finland which results in a large institutional catering sector. This sector currently sources largely on price, and uses a considerable amount of imported Third Country meat as a result. There was a perception that this sector may be reluctant to label livestock products fed on GM feed (some canteens have been strongly against the use of monosodium glutamate and the sector is generally considered to be conservative in terms of supply). According to one interviewee, there is currently no labelling obligation in the catering sector in Finland, although there is an expectation that, if asked, a catering establishment should be able to inform consumers about the use of GM food in their offering. Another interviewee in Finland noted that organic ingredients are often now indicated in the catering sector suggesting that there is some interest in providing production information to consumers.

One interviewee in France commented that it would be difficult to include the catering sector within the scope of labelling livestock products. The interviewee also believed that labelling in the catering sector was not a current priority in France, as discussions regarding the scope of the “GM-free” scheme (e.g. the inclusion of pre-packed food) are still ongoing.

Finally, one interviewee provided a broader comment on the issue of GM labelling in the catering sector. Customers in the catering sector tend to demand higher quality products and therefore they may be more shocked by GM labelling on menus. The interviewee believed that, for this reason, the catering sector would probably be more strongly affected than the retail sector if included in the labelling obligation.

⁴¹ According to several interviewees, some fast food outlets in Germany were found to be using GM oil by Greenpeace, but there was no information to indicate this to consumers.

3.4.2. The approaches currently used by Member States in the field of “GM-free” labelling

3.4.2.1. Legal status of “GM-free” or non-GM labelling in Member States

There is no legislation setting out a framework for “GM-free” labelling in Spain. According to a couple of interviewees, there may, however, be a small number of “GM-free” labelled products available in Spain. Interviewees mentioned that they had seen a yoghurt labelled as “produced with GM-free lecithin” and eggs labelled “hens fed on GM-free feed”.

According to Finnish interviewees, “GM-free” labelling is permitted and there is some small-scale use of such labelling in Finland. There is currently no legislation governing “GM-free” labelling, but legislation will be introduced shortly. Provisions in terms of scope and threshold levels for adventitious and technically unavoidable presence are currently being drafted, based on the premise that consumers must not be misled.

Interviewees in France stated that a law from June 2008⁴² defined the “GM-free” supply chain. On 03 November 2009, the Haut Conseil des biotechnologies made recommendations regarding the definition of “GM-free”. A decree based upon these recommendations is likely to be developed in the near future. According to one interviewee, the current definition of “GM-free” was established by a 2004 note by the DGCCRF, in which “GM-free” labelling was defined. Only vegetable products which may contain GM below the detection level of 0.01% 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 0.01% GM content may be labelled as “GM-free”.

“GM-free” labelling in Germany is regulated under the EGGenTDurchfG. This was updated in May 2008. According to several interviewees, “GM-free” labelling has been permitted in Germany for a long time (1989 according to one interviewee), however it had not generally been used as the requirements in the law had been too difficult to fulfil prior to May 2008 when the criteria were relaxed.

While not a case study country for this topic, it is worth mentioning the status of “GM-free” labelling in Austria due to the size of the “GM-free” market and its proximity to Germany (which will be of relevance in section 3.4.3.2). Provisions for “GM-free” labelling are contained in guidelines of the Codex Alimentarius Austriacus. According to one interviewee, these guidelines were established in 2001.

3.4.2.2. “GM-free” schemes already in use by more than one operator and with independent accreditation/verification

According to Finnish interviewees, “GM-free” labelling is operator specific and does not constitute an organised scheme. According to one interviewee, current “GM-free” labelled products are limited to a few domestic livestock products (including some sausages), some imported cheese and pre-cooked sweetcorn. Another interviewee commented that labelled “GM-free” products come and go from the market quite regularly. A further interviewee said that the products available now are really just testing the market. There is, however, a concern that “GM-free” marketing is quite negative in that it implies there is something wrong with unlabelled products, making “GM-free” labelling potentially a bad strategy for companies selling conventional products as well. Furthermore, companies may have difficulties if they sell “GM-free” labelled products, but need to switch to GM ingredients at a later point in time.

⁴² Loi du 25 juin 2008 relative aux organismes génétiquement modifiés.

According to one French interviewee, the strict definition of “GM-free” under the 2004 DGCCRF note has resulted in no “GM-free” labelled livestock products despite the efforts of some industry players. It remains to be seen if this situation will change with the potential adoption of new provisions. According to one interviewee, the rationale behind the change is to allow operators using non-GM ingredients the opportunity to differentiate their product.

In Germany, the “GM-free” scheme is set out by the EGenTDurchfG. There is an “Ohne Gentechnik” (without GM /genetic engineering) symbol, which was introduced by the Minister for Consumer Affairs in the summer of 2009 (though according to one interviewee, the use of this logo is voluntary). Users of the “GM-free” label have to state their intention to use the label and to conform with the requirements. Products are then monitored in retail outlets at Bundesland level. According to a report by VZBV Hamburg and Slow food (Slow Food Deutschland e.V., 2009) there were 20 groups of products labelled under this scheme as of October 2009. Labelled products were mainly milk and noodles. According to an industry interviewee, there are no further processed products using the scheme due to the extra effort needed to ensure that all the product components are “GM-free”.

One interviewee in Germany believed that the low uptake of the “GM-free” labelling scheme was due to four factors:

1. there is not such a strong competitive advantage;
2. companies are afraid of an accident, or not following the rules correctly;
3. it would be bad long-term strategy to declare products as “GM-free”, only to have to use GM raw materials at some point in the future; and,
4. companies may be reluctant to sell both conventional and “GM-free” products as this may require more complicated logistics and may result in competition between the company’s own offerings.

Several interviewees commented that there are companies in Germany producing livestock products with non-GM feed (e.g. Wisenhof), but that they are not labelling their product as “GM-free” at point of sale (though their use of “GM-free” feed is advertised).

The Austrian “GM-free” labelling scheme is called “Gentechnikfrei”. The “GM-free” guidelines in the Codex Alimentarius Austriacus include controls at the farm level, once when a farmer signs up to the scheme, and at least once every three years thereafter. According to one Austrian interviewee, there are now 800 labelled products (about 350 of which are labelled both as organic and “GM-free”; these tend to be retailer own-brand products which originate from the organic sector and are double labelled). The scheme’s own website places the number of products at 652⁴³. Interviewees consider it likely that all milk in Austria and a large part of egg production will be labelled “GM-free” at some point in 2010. Meat and bakery products are also entering the scheme.

3.4.2.3. Characteristics of schemes in place

One interviewee outlined the principles which have been set out for “GM-free” labelling within Finland. These are: complete traceability; a threshold for adventitious and technically unavoidable presence which does not mislead the consumer; GM medicines and enzymes should be permitted (as they are in organic production); there must be a GM comparator, though livestock products would be permitted. The labelling will probably be similar to “GM-free supply chain” rather than “GM-free product”.

The details of the proposed Finnish scheme are not yet available and different interviewees had different expectations in terms of how the scheme might operate. According to one Finnish

⁴³ www.gentechnikfrei.at accessed 16 March 2010.

interviewee, “GM-free” plant-derived products should be 100% “GM-free” (in practice the detection limit) in order to distinguish from unlabelled produce and to avoid misleading the consumer. Organic products would therefore also have to achieve 0% GM content in order to use a “GM-free” label, i.e. it would be possible to have organic products which would not also be labelled as “GM-free”. However, livestock would be able to eat feed with up to 0.9% GM content (and hence organic livestock products could be labelled as “GM-free”). Article 9 of the Finnish Food Act 23/2006 and Article 4 of the Finnish Trade and Industries Regulation No 1084/2004 prohibit misleading labelling and, one interviewee explained, under this legislation products that are substantially equivalent could not be differentiated by labelling. Applying “GM-free” labelling to poultry and egg products would require a Finnish law to be introduced and notified to the EU in order to comply with Regulation (EC) No 543/2008, Article 11.

The requirements of the existing scheme in France have already been set out. Several interviewees commented on the likely provisions of the expected decree. Interviewees expected a threshold of 0.1% for crop products and 0.9% for animal feed. One interviewee believed that the scope of labelling would be limited to products with a GM comparator; however another thought that the labelling of products without a GM comparator may be permitted under the expected scheme.

Under the German law, the only label which can be used is “ohne Gentechnik” (without GM/genetic engineering). Any food or feed labelled in accordance with Regulation (EC) No 1829/2003 cannot be used, i.e. the 0.9% threshold for adventitious and technically unavoidable presence will apply. However, any food or food additives which are exempt from labelling under Regulation (EC) No 1829/2003, but which are nevertheless GM, may not be used if the presence of GM is technically avoidable. In order to be labelled as “GM-free”, livestock must be fed in accordance with the provisions set out in

The guidelines in the Austrian Codex Alimentarius state that food can be labelled “gentechnikfrei erzeugt” (GM/genetic engineering-free production) or similar if the guidelines are met. 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. Food and feed labelled under Regulation (EC) No 1829/2003 cannot be used, subject to a 0.9% threshold for adventitious and technically unavoidable presence (with an emphasis on the technically unavoidable aspect). The “GM-free” feeding periods are displayed in (Table 3.3). One interviewee explained that the “GM-free” feeding period in the dairy sector had been reduced to two weeks in Austria because animals must be under control the whole time, and cows which are sent to mountain pastures to graze must start the “GM-free” feeding period again from the beginning. The Austrian guidelines contain certification and control requirements.

According to one interviewee, the “GM-free” feeding times for Austria and Germany were generally taken from organic legislation. This interviewee also explained that there is weak scientific evidence to suggest that this is the amount of time needed for an animal to flush feed from its body.

Table 3.3: “GM-free” feeding times for meat, milk and egg production in Germany and Austria

Product	Austrian “GM-free” feeding period	German “GM-free” feeding period
Beef	12 months	12 months or at least $\frac{3}{4}$ of the animal’s life
Pork	The entire fattening phase	4 months
Dairy	2 weeks	3 months
Eggs	6 weeks	6 weeks
Poultry	No rule defined	10 weeks
Small ruminants	No rule defined	6 months
Fish	The entire fattening phase	No rule defined

Source: Codex Alimentarius Austriacus and German EGGenTDurchfG.

3.4.3. The extent to which these approaches contribute to improve consumers' informed choice

3.4.3.1. Extent to which various schemes and approaches provide an informed choice for consumers; tolerance levels and provision of an informed choice

Generally speaking, industry interviewees in Germany considered the national scheme misleading. Several commented that the product is not truly “GM-free”, as animals can be fed on GM feed at certain points in their lifetime. They also noted that GM or genetic engineering can be used in various parts of production processes (e.g. enzymes, additives, vaccines for animals) without labelling. Indeed, one industry interviewee believed that companies were not using the scheme in Germany as they either do not want to mislead the consumer or do not want to explain to the consumer that the products are not entirely GM or genetic engineering-free. Industry rejection of the scheme is ultimately reflected by its low uptake.

Two interviewees in Germany were positive about the German “GM-free” labelling scheme, though both commented that it was a temporary step, and that the ultimate solution would be a change to the EU law to include the positive labelling of livestock products. One interviewee commented in the context of the scheme being potentially misleading that “without” and “free” are not definite terms; for example, “without alcohol/alcohol free” drinks can contain up to 0.5% alcohol; without caffeine coffee may contain some caffeine, and Community legislation in force provides for tolerance levels regarding the terms “fat-free”, “sugar-free” or “food without calories”.

Interviewees in France saw potential problems with the proposed tolerance levels. Several commented that the various different thresholds (0.9% for adventitious and technically unavoidable presence under Regulation (EC) No 1829/2003; the expected 0.1% for “GM-free” crops under the French decree; and the expected 0.9% for feed in the French decree) would confuse consumers. One interviewee commented that products in the “grey area” between 0.1% and 0.9% may suffer as consumers would consider products labelled as “GM-free” as healthier. The same interviewee considered it misleading as the thresholds do not provide strict and reliable information on the “GM-free” status of products,

and the proposed thresholds for livestock products may also confuse consumers. Furthermore, some interviewees in France saw problems with the scope of the expected decree. One interviewee expressed fears that products without a GM comparator may be labelled as “GM-free”. Another believed that this would not be the case, but there could be potential contradictions nonetheless; beef fed on grass could be labelled “GM-free” when there is no GM grass; and as new GM crops are introduced (e.g. wheat) the legislation would have to be updated as otherwise “GM-free” claims for the new crops will not be permitted.

Several Finnish interviewees thought that consumers may be misled by “GM-free” schemes with tolerance levels for adventitious and technically unavoidable presence of GM material, as they would expect the products to be 100% GM-free. There is generally considered to be little consumer awareness of the use of impurity thresholds in agriculture; there is also thought to be little consumer understanding, at least in Finland, of what it means for food to be GM or “GM-free”; though this could be addressed through an information campaign. Two interviewees commented that “GM-free” products may mislead consumers, as they imply that other products contain GM when they may not do so.

To illustrate the potential to mislead consumers, one interviewee in Spain explained that in the mid-2000s “GM-free” labelled lentils were available until the company was forced to withdraw the products because they were considered misleading given that there is no GM comparator.

Interviewees in Austria noted that consumers are generally happy with the implementation of “GM-free” labelling.

3.4.3.2. Consistency between “GM-free” labelling schemes and the impact of consistency on the consumer’s informed choice

Consistency

As there is not more than one scheme used by more than one operator in the case study countries, it is not possible to comment on the consistency of different schemes within a Member State. However, Finnish interviewees said that the different operator specific schemes are probably not consistent with one another.

One interviewee explained that the German and Austrian schemes are generally very similar, as section 3.4.2.3 revealed. However, the main difference is that the German scheme does not include farm level controls which results in higher costs in the Austrian scheme. Interviewees did not think that German producers are currently exploiting this competitive advantage in Austrian markets, but there is a concern that this will be the case in the future, especially in the milk market.

Impact of consistency

One interviewee in Finland commented that different producers using different symbols and texts to convey “GM-free” status may cause a degree of confusion among consumers.

As there is only one authorised scheme in Germany, there is no problem of consistency. However, one interviewee did comment on inconsistencies compared to the Austrian scheme. German “GM-free” products are labelled “ohne Gentechnik” (without genetic engineering), while Austrian products are labelled “Gentechnikfrei (genetic engineering free)”. According to the interviewee, the message of the Austrian labelling is perceived as being stronger by German consumers, hence there may be a preference for Austrian products. This issue is more significant in border regions, for example, Bavaria where imports are greater. In this sense, German producers who use the German “GM-free” logo are at a disadvantage compared to Austrian producers, although they may have lower production costs (see above).

3.4.3.3. Effects of the schemes on the industry

Some German interviewees commented on the effects of the scheme on the industry. Several interviewees commented that parts of the food industry, most notably the dairy industry, were under pressure from NGOs to adopt “GM-free” labelling. One interviewee commented that the question of what is adventitious and technically unavoidable is potentially problematic for the feed industry in terms of liability if GM material is found in “GM-free” labelled livestock feed. There is a concern that feed producers could be liable if livestock was fed with unlabelled feed which contains, for example, 0.4% GM, the presence of which is later considered by the authorities to not be adventitious or technically unavoidable (i.e. the authorities decide that the feed should have been labelled, even though it contained under 0.9% GM material).

According to some interviewees in France, the majority, roughly 80% of the industry (farmers, food producers and the biotech industry) is against the expected “GM-free” decree, though one commented that the scheme arose from the wishes of certain actors to enhance the value of their products. Several interviewees commented that they are against negative claims, as they suggest that GM products are inherently bad. One interviewee believed that there is no market for “GM-free” products in France. An interviewee positioned early in the supply chain was concerned that the actors further down the supply chain would benefit economically while those earlier in the chain would be saddled with higher costs. Finally, two interviewees said that the recommendations for the “GM-free” scheme had been established without a true economic impact assessment, which had been planned and agreed during the Grenelle Environment Round Table according to one interviewee.

Austrian interviewees commented that the “GM-free” labelling scheme had been well-received by the industry; indeed it was originally established to permit the industry to offer products to consumers who wish to avoid GM. One interviewee commented that the Austrian “GM-free” labelling scheme is providing some Austrian companies with a competitive advantage.

3.4.4. Potential added value of a harmonised "GM-free" (or similar) labelling scheme

3.4.4.1. Potential benefits from an appropriately defined harmonised “GM-free” scheme

Several interviewees commented that a harmonised EU “GM-free” scheme would be useful as it would be clear for all consumers and would avoid consumer confusion with regards to different schemes in different Member States, as long as criteria and scope are properly established. One interviewee warned that there is already a problem with tolerance levels for adventitious and technically unavoidable presence in different Member States; while German and Austrian schemes are relatively similar, the French scheme proposes 0.1%, and a regional initiative in the South Tirol area of Italy uses a 2% threshold. Benefits for retailers, producers and authorities were foreseen by some interviewees. Under such a system, costs would reduce for retailers, as would the burden for authorities. Producers in one Member State would not be disadvantaged vis-à-vis producers from other Member States due to differing national “GM-free” initiatives.

One interviewee warned about the potential difficulty in reaching agreement on an EU level “GM-free” scheme citing the example of the consumer information labelling reform (which has been discussed for three years without agreement). This view was echoed by another interviewee, who stated that a degree of compromise would be needed from different Member States when agreeing the scope and parameters of the scheme.

Several interviewees commented that operating both positive and negative labelling together would, in their opinion, result in confusion. One Finnish interviewee added that the main rationale for a

harmonised EU “GM-free” scheme would be to address the current lack of any form of labelling for livestock products; this view was echoed by some German interviewees.

There were slight differences between case study countries with regards to views on harmonised “GM-free” labelling. Finnish interviewees were generally in favour of a harmonised EU scheme. Several French interviewees were against the idea of negative labelling, but believed that if the “GM-free” issue is to be tackled, or if national initiatives continue to appear, the issue should be tackled on an EU level in order to avoid implications for the internal market. German interviewees were less keen due to the existence of the German national scheme. One interviewee commented that harmonisation would resolve possible confusion with products from Austria; however, based on the low number of Austrian products on the German market, this is not considered to be a significant problem. A couple of German interviewees commented that a harmonised EU scheme would be a second-best solution, with positive labelling for livestock products the best solution.

Interviewees in Spain were divided on the benefits of an EU-wide “GM-free” labelling scheme. Several commented that the market for organic products in Spain is small (reflected in part by the fact that a considerable proportion of organic production is sent to Germany), implying that the market for “GM-free” products would also be small. Indeed, two interviewees questioned whether there was significant demand for “GM-free” labelling amongst general consumers, drawing a distinction between these and citizens/public who sign petitions and join campaigns. One interviewee commented that Spanish livestock producers would be unlikely to benefit from a “GM-free” scheme as they would be unable to produce non-GM fed livestock products. On the other hand, another Spanish interviewee commented that a harmonised scheme would be preferable to national initiatives in other Member States which could serve to disadvantage Spanish producers. Another added that there is demand for organic products in Spain, but that there is an insufficient distribution network; on this basis there may be demand for “GM-free” products, but a suitable distribution network will be required.

3.4.4.2. Extent to which a harmonised “GM-free” scheme would help to build this sector

One interviewee believed that it would be easier to build market share in the “GM-free” sector if there was a harmonised labelling scheme at the EU level. Another commented that different labelling regimes in different Member States add complexity and operational expense which would be removed under a harmonised approach.

However, one interviewee warned that “GM-free” labelling schemes are open to producers/retailers charging an excessive premium for “GM-free” products. In this interviewee’s opinion, this happens currently with denomination of origin labels. Because of this risk, one advantage of a harmonised “GM-free” system would be that greater competition across the EU would result in lower consumer prices and a reduced risk of excessive premiums. Another interviewee commented that the low level of development of the “GM-free” label in Germany, even with NGO pressure, demonstrates that there is no market for “GM-free” products. One Austrian interviewee thought that an EU wide scheme could lead to some Austrian producers losing the competitive advantage that their national scheme currently provides them.

3.4.4.3. Position of a “GM-free” scheme alongside the organic label

Opinions on the positioning of a “GM-free” label alongside the organic label varied greatly between case study countries.

The few German interviewees who considered the interaction between the “GM-free” and organic sectors thought that consumers understood the difference between them. One interviewee noted that

the organic sector has so far not lost market share to the “GM-free” sector. This interviewee added that the introduction of a “GM-free” scheme might cause a short-term reduction in demand for organic products, but that this would not last. Spanish interviewees generally stated that the organic sector is very small, and did not comment on the potential interaction with a “GM-free” sector. A French interviewee commented that not all consumers can afford organic food, which is why the French “GM-free” labelling scheme will offer a wider choice to the average consumer. Finnish interviewees were generally unsure whether consumers could differentiate between organic and “GM-free” products, or if there was a market for both. One interviewee commented that there had been campaigns in Finland which had explained that organic production is “GM-free”. Only a couple of interviewees could clearly see a “GM-free” label existing alongside an organic label in Finland; the rationale being price.

Finally, several interviewees commented that an EU-wide “GM-free” scheme would facilitate the procurement of non-GM raw materials (including feed) for the organic sector.

3.4.5. Options for the future

This section draws together information obtained from both labelling case studies on options for the future. The evidence base therefore comprises interviews completed in Finland, France, Germany, Spain and the UK. Some comments from Austria have also been incorporated due to the strong “GM-free” scheme in existence in that country.

3.4.5.1. Positive labelling

Use of positive labelling

Generally speaking, there was an acceptance of the concept of positive GM labelling across case study countries. This acceptance ranged from impartiality to a favourable view of positive labelling as it facilitates consumer choice. A few interviewees expressed the opinion that positive labelling is preferable to negative labelling on the grounds that it is more intuitive to label what a product contains than what it does not contain, and that it makes more sense to use labelling in the minority of cases, which is currently the case given the existing scope of the labelling requirement.

Nonetheless, there were interviewees in several case study countries and from different parts of the production chain who were against positive labelling. This stance was generally taken on the basis that GM events have been risk assessed and are substantially equivalent, hence there is no need for labelling unless there is a characteristic difference (this was explored in section 3.3.1.5 of the current labelling case study). A couple of interviewees expressed a preference for negative labelling over positive.

A couple of interviewees considered the method of labelling. One believed that the use of GM in a product needs to be more clearly indicated so that consumers can clearly identify it. However, another commented that any kind of GM logo would communicate the wrong message (i.e. risks) to consumers. A second interviewee commented that the use of a radioactive label for ionic treatment of spices in the 1970s demonstrated the negative impact of such labels. The same interviewee warned that, if not correctly handled, the situation with GM could end up similar to that of ionic treatment.

Scope of positive labelling and their impacts

For this section, the labelling of GM content is assumed to be the minimum level of labelling, with the next stages being: the labelling of products produced using GM such as oil (i.e. the *status quo*); the labelling of products from livestock fed on GM; and the labelling of all uses of GM (including vitamins, enzymes, etc.).

The scope of positive labelling was largely explored in section 3.3.1.3 of the current labelling case study. As mentioned in that section, interviewees were divided as to whether oil and livestock products should be labelled. Those in favour of the labelling of oil and/or livestock products believe that this facilitates consumer choice. A few believed that an extension to include livestock products would also increase consumer exposure to GM technology, and hence acceptance. It should be noted that a few interviewees considered an extension to labelling to include livestock products to be the best option, with a “GM-free” labelling scheme for livestock products the second best option.

Those against oil and livestock labelling generally used one or both of two arguments. First, some believed that consumers are not knowledgeable enough to understand the differences between GM and non-GM labelled oil or livestock products (this was considered a problem with an extension to livestock products in particular, where consumers could interpret the animal as being genetically-modified). Second, some saw problems with the implementation of process-based labelling. These problems included Identity Preservation and the potential for fraud. In particular, many industry interviewees believed that positive labelling should be limited to what can be detected (i.e. labelling should be based on content not process).

In the case of livestock products, some interviewees identified further issues. Several commented on the lack of scientific difference and hence the absence of a basis for labelling. Some were concerned with the extent of labelling, as the majority of livestock products in the EU would have to be labelled. Some industry respondents were concerned by the effects on the industry (additional costs, possible demand shifts) of an extension of positive labelling to include livestock products, in particular in the case that processed livestock products are included. Finally, a couple of interviewees doubted that any labelling obligation could be imposed on imported meat, and believed that any such loophole would disadvantage EU livestock producers.

A few interviewees commented on the positive labelling of feed and the link to livestock product labelling. One commented that, under the current system, there is no rationale for the labelling of feed, even though operators accept it. A few examined the issue the other way round, and said that in the absence of the labelling of livestock products, there is no advantage of, or premium for, unlabelled GM livestock feed. That said, interviewee comments would suggest that livestock farmers have generally accepted GM feed.

One recurring view in Germany was that positive labelling should either be entirely content based (i.e. exclude oil), or entirely processed based (i.e. include livestock products, enzymes, vitamins, etc.). Several reasons were provided for this: consumers would be provided with complete and consistent information on the use of GM technology; exposure to the widespread use of GM technology may enhance consumer knowledge and understanding of GM; and, including all uses would take the focus off the livestock sector, which is where the GM debate in Germany is currently focused.

Finally, a few interviewees commented that any changes to the scope of the existing labelling rules would require an information campaign for consumers, otherwise they would wonder why products have become labelled or unlabelled from one day to the next. Indeed, the lack of consumer awareness with regard to GM was highlighted in various sections of the labelling and extension to labelling case studies and some interviewees believed that consumers need education on GM in general terms.

Mandatory versus voluntary positive labelling

Interviewees who considered positive labelling only considered it in the current context (i.e. in mandatory form). Indeed, with regard to labelling possibilities in the future, interviewees only considered mandatory positive or voluntary negative labelling as viable options and therefore did not consider the other possible approaches (i.e. voluntary positive and mandatory negative labelling).

Tolerance levels/levels for adventitious presence for food and feed and their impacts

Interviewees in case study countries did not make concrete suggestions for tolerance levels or levels for adventitious presence with respect to positive labelling⁴⁴. However, there were other comments regarding these issues.

A couple of interviewees believed that rules regarding adventitious presence need tightening as they encourage negligence among producers and are misleading for consumers. A few interviewees believed that the interpretation of adventitious presence has to be standardised going forwards; the interpretation by different authorities was seen as problematic by some interviewees because what one authority considers adventitious, another may consider avoidable. One interviewee in the feed industry commented that the fact that the threshold for adventitious presence applies to individual raw materials causes problems with co-mingling. For example if there is a small residue (<0.5%) of soybean in a batch of feed, but the entire soybean trace is GM then the feed batch must be labelled GM. The interviewee commented that while this is not presently an issue, with the introduction of “GM-free” labelling there may be issues in this area. A few other industry interviewees raised concerns that the future potential for co-mingling would have impacts as a result of labelling requirements, without explicitly making the link to the levels for adventitious presence.

3.4.5.2. Negative labelling

Existence of negative labelling

Many interviewees were neutral with regard to the use of negative labelling. However, a few favoured negative labelling over positive; others were against the use of negative labelling at all or favoured positive labelling over negative; and a third group foresaw the co-existence of both positive and negative labelling.

Those who favoured only negative labelling generally believed that either positive labelling is not justified for the reasons outlined in section 3.4.5.1, or that implementing negative labelling only would put the burden of cost clearly on producers who want to produce without GM.

The reasons for favouring positive labelling over negative labelling were examined in section 3.4.5.1. A few interviewees were against negative labelling. The reasons for this were: negative labelling does not provide useful information; it may mislead the consumer by suggesting that a product is inherently better; and there is no rationale or no market for “GM free” products. The latter view was particularly common among UK interviewees, who commented on low demand and failed attempts to introduce “GM-free” products; and among German industry interviewees against the national scheme who commented on the low level of take-up of the German “GM-free” labelling scheme.

Several interviewees commented on the potential for consumer confusion if positive and negative labelling schemes were to operate side by side. However, those interviewees who foresaw the existence of both positive and negative labelling believed either that negative labelling should be used for livestock products only, or that negative labelling could satisfy the set of consumers who have a strong desire to avoid products using GM material. One interviewee commented that permitting negative labelling for livestock products would generally result in the labelling of the smaller market segment.

Definition of scope and criteria

The majority of interviewees who considered negative labelling to be a viable option believed that scope and criteria should be established at EU level. The reason for this generally was harmonisation, facilitation of the internal market and clarity and consistency for consumers. However, a couple of

⁴⁴ The survey results contain some concrete suggestions from stakeholders and Competent Authorities.

interviewees discounted the need for the establishment of scope and criteria at an EU level due to the existence of national schemes in their Member States. One Austrian interviewee further commented that the national scheme provided a competitive advantage for Austrian producers, Austrian labels are better trusted than European ones in the Austrian market and that harmonisation in this area would destroy the possibility for differentiation and hence market advantage.

Mandatory versus voluntary negative labelling

As already mentioned above, interviewees who considered negative labelling only considered voluntary labelling, no interviewees saw a rationale for mandatory negative labelling.

3.5. Public acceptance of GM food and feed

This case study is based on interviews undertaken in Czech Republic, Greece, Italy, Poland and the UK. The Czech Republic was selected as a Member State where public acceptance of the use of GM technology is relatively high and as the first central and eastern European country to adopt legislation on GMOs harmonised with that in the EU. The first public debate in the country took place in 1998 (Kings College London, 2008). Greece was selected to provide a contrast in that public acceptance is extremely low and concern in terms of risk high; there is also a strong tradition of local, small-scale food production, which is also the case in Italy. Poland was selected because it is the largest new Member State and also because there has been a tension in government between the desire to become a “GMO-free zone” and the need to comply with EU legislation (Kings College London, 2008). Finally, the UK was selected because there has been a vigorous GM debate since the mid-1990s, prompted in part by the availability of GM tomato puree.

This case study focuses on the following Evaluation Questions which focus specifically on the public acceptance of GM food and feed:

- **EQ13a:** The approval process is still subject to controversy amongst stakeholders and the general public. What are the aspects of the authorisation procedure that nourish this controversy?
- **EQ13b:** What is the impact/cost of this risk aversion?
- **EQ13c:** Are there variations in the sensitivity of EU-wide opinion, as between seed, cultivation, feed and food use?
- **EQ13d:** Can the risk acceptance of EU citizens be measured against the concept of ALARA (as low as reasonably achievable) risk? If so, how?
- **EQ13e:** Can the quality of the EU-wide trust in science based risk assessment be improved in the GM context?

3.5.1. Aspects of the authorisation procedure that nourish controversy

3.5.1.1. Extent of concern over agricultural biotechnology

Results from Eurobarometer and other national research show that GMOs are still controversial for the public and acceptance of the use of biotechnology in agriculture is lower than for applications in other fields.

The degree of acceptance of biotechnology in the medical and industrial fields (“red” and “white” respectively) is higher in all the case study countries⁴⁵ and citizens tend to be more positive about these technologies than about GM food (Gaskell *et al*, 2006). With regard to GM food, acceptance amongst the case study countries is highest in the Czech Republic and lowest in Greece. Italian, UK and Polish citizens show a rate of acceptance rate of between a quarter and a third of the sample interviewed (Table 3.4).

Table 3.4: Support for biotechnology in different fields and for selected Member States

	Nanotechnology	Pharmacogenetics	Gene therapy	GM food
Czech Republic	71	60	56	46
Greece	46	62	57	14
Italy	54	67	58	34
Poland	50	46	43	23
UK	46	40	44	30

Source: Gaskell *et al*, 2006.

Interviews in the various Member States have confirmed these trends. The majority of interviewees in all the case study countries (with the (slight) exception of the Czech Republic) explained that citizens have a high degree of concern about biotechnology applications in food. Consumers evaluate the risks, benefits and impacts of the use of technology in food when making a purchase decision.

Links between acceptance and perceived risks versus benefits

Interviewees in the various case study countries, and in particular in Italy, Greece, Poland and the UK, specified that citizens are not against new technologies and the benefits that may derive from application in different fields, but acceptance entails recognition of clear benefits and a positive balance when compared against risks. Several interviewees made the point that this is not the case with GMOs, where benefits (including price benefits) are not clearly perceptible. On the other hand, there are perceived risks and potential negative impacts which outweigh the benefits: the major concerns regard safety and what are perceived by many citizens as unpredictable effects on health and for the environment following the release of GMOs. In this context, it has, however, to be noted that there is no real distinction between attitudes to cultivation, food and feed, because the general concerns related to the technology determine the position of the public towards the issue *in toto*, i.e. the debate remains at this general level rather than being focused on specific aspects.

⁴⁵ In this section only results concerning the countries of the thematic case studies are presented; please refer to section 8.1 of the main report for a full presentation.

Many interviewees point out the fact that food is generally regarded in an “emotional” way, and that it concerns other aspects of life, which are not only related to the safety of the products concerned. Whereas industry interviewees (from the feed, livestock, biotechnology and food sectors) generally accept that there is no safety issue with authorised GMOs, the majority of consumer associations and NGOs in the Czech Republic, Greece, Italy and the UK raised concerns in terms of their perception that there is uncertainty over long-term effects of consumption of GM food on human health. Considering that safety is considered to be a prerequisite for food, but not the only trait consumers look for, where there is no perceived gain in taste or other quality attributes including price, risks may not be considered to be proportionate by consumers. The comparison with the other applications of biotechnology is relevant here in that citizens tend to be more likely to perceive clear benefits in the medical and industrial fields. Biotechnology applications in these fields are also often perceived as not having comparable alternatives, i.e. if the benefits are wanted, then the potential risks must be borne. However, it is difficult to be definitive in terms of consumer attitude (as distinct from citizen/public attitude) because there are so few GM labelled products available and hence little experience with actual consumer behaviour (see the current labelling case study, section 3.3 of this appendix, and section 7.4 of the main report).

To illustrate the importance of communicated benefits, 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 potential role of GM technology in combating climate change was interesting with a ratio of 4:1 suggesting that GM could help. There was a similar response with regard to food security. Also, a food industry interviewee in Greece stated that acceptance will come when the technology becomes necessary and hence the benefits are more tangible, for instance drought tolerant GM events in areas suffering water shortages; on the same lines a retailer association in the UK stated that GM events with clear benefits for consumers are required and commented that most consumers would accept GM on a case-by-case basis if they see benefits to themselves. Benefits to farmers, especially in the US, are not seen as being relevant to consumers. It was suggested in Poland that indications of possible health benefits of GMOs in food/feed could improve consumer acceptance, but the fact that they are produced by big (generally US) companies would work in the other direction.

Consumer behaviour and preferences

Although a consumer association in the Czech Republic expressed the view that consumers consider GM food to be somehow unhealthy, the main purchase decision criteria is price, and therefore the majority of the interviewees in this country expect consumers to buy GM labelled products if they are cheaper. It should be noted that the Czech Republic is the Member State with the highest number of GM products among those surveyed (King’s College London, 2008, see also section 7.4 of the main report).

For their part, the Polish feed industry questioned the results of consumer polls and suggested that a more appropriate way of asking questions on willingness to buy GM labelled products would be: “are you prepared to pay more for non-GM food?” rather than simply asking whether respondents are for or against GMOs, in other words, the question should be contextualised with potential benefits. An interviewee in the UK commented that the fact that the UK is much less self-sufficient than many other Member States, and is therefore more affected by increases in global commodity prices, means that the public is more receptive to GM food and feed. An example of this was the GM tomato puree in the late 1990s, which demonstrated that GM labelled food with price benefits was bought by consumers.

Several interviewees (from the retail sector, farmers and consumer associations) in Italy, Greece and Poland placed acceptance of GM technology in agriculture in the wider context of general trends in food consumption and remarked that there is increasing consumer preference for organic products which highlights a consumer desire for food produced in “natural” systems. An interviewee in the UK

explained that there are also some knowledge gaps in terms of the way conventional food is produced and there is no general public knowledge of modern plant breeding. As a result, consumer understanding of the use of biotechnology in plant breeding is also low. The above implies that citizens tend to associate agriculture with a bucolic ideal and are therefore not receptive to industrialisation or the use of artificial processes. An interviewee in the UK stated that being food secure does not provide the incentive to consider the use of technology to increase food production. This position was echoed by an interviewee from the oil industry in Italy who stated that the EU is in a privileged position which allows the use of GM technology in food production to be a choice; this may not remain the case in the future. Finally, one interviewee noted that citizens expect to be able to understand food production processes, whereas this is not the case with regard to technology used in the production of medicines, and this provides another reason for the difference in attitude between the sectors.

Ethical and socio-political factors

The attitudes above are reinforced by several ethical and socio-political factors, which go beyond food safety and embrace other considerations (i.e. culture, cultivation tradition, etc.). Some interviewees made the point that choosing GM food (or not) is, for some, a philosophical and political choice, rather than strictly just a food choice.

Interviewees in Greece and Poland, where agriculture accounts for a substantial part of the national economies and employment, stated that citizens are attached to “natural” ways of production. Citizens also have a generally close attachment to agriculture which, for them, represents a way of life and tradition and they want to protect this from the introduction of new technologies. In Italy it was pointed out by several interviewees (consumer associations, farmer organisations) that consumers and farmers fear that the introduction of GMOs would eliminate all the differences that characterise Italian richness in terms of food by replacing diversity with uniformity through something not-natural and which, in their view, may also carry risk. A loss of food diversity might impact on important economic sectors in Italy such as the production of DOC, IGT and DOP products and would therefore undermine competitiveness and the image⁴⁶ of the country. On this point, however, one farmer association and the biotechnology industry stressed the fact that agriculture is a dynamic industry and has always benefited from technological advance. GMOs can therefore be seen as part of this dynamic process and can help to provide solutions for specific pest problems and can improve the competitiveness of Italian farmers as a result (see below).

Some other interviewees added that moral, existential and epistemological issues also have a role in the acceptance of GM food. Others cited ethical issues, which mainly relate to the current structure of the agricultural biotechnology industry which, in their perception, is dominated by large multinationals that are perceived to impose dependence on farmers through the patenting of biotechnological products and the necessary link between, for example, herbicide tolerant crops and plant protection products which are often produced by the same companies. GMOs are therefore associated with globalisation, multinationals and the industrialisation of food production and thus provide a strong contrast with traditional, local and natural products which are seen as part of the culture and are considered to be entirely risk-free. In Poland, for instance, a consumer association expressed the concern that non-Polish, or even non-EU, companies may penetrate the Polish food market and impose their food products, agriculture inputs and farming methods.

⁴⁶ In a survey of Saba in Inran (2006) on foreign tourists in Italy, 63% of respondents were of the opinion that GMOs in the agro-food system in Italy would worsen the quality of Italian food (for 18%, it would have no impact, for 9% it would improve). Furthermore, 73% of the interviewees considered that GMOs would worsen the image of the Italian product; 29% would continue choosing these products even if GMOs were involved, whereas 57% would keep selecting non-GM varieties; 12% would not eat Italian products any more.

In the view of the majority of respondents, GMOs were controversial in first place because of the timing and method of their introduction; some interviewees noted that the introduction of GMOs took place in a legislative vacuum in the EU. The number of scares related to food safety in the 1990s also seriously undermined the trust that consumers had in Competent Authorities and resulted in very sensitive consumer reactions where food issues are concerned (one interviewee noted that the legacy of this can be seen in the current reactions to Avian Influenza outbreaks in Italy).

The role of media and NGOs

Some interviewees pointed out that the role that NGOs have in public debates is one of alerting potential risks rather than informing and that they are not neutral actors. The level of actual debate in most Member States appears to have been rather low, whereas media coverage is triggered by scandals and therefore generally expresses a negative opinion.

Analysis of media and GMOs in Italy for instance shows that information on the agro food sector, and in particular relating to GMOs, is scarce on public television⁴⁷. Coverage is in fact dominated by information on DOP, DOC and IGT products which represent 85% of the time devoted to the sector; only 10% of the information concerned themes linked to production and research.

Other studies focusing specifically on the issue of media and GMOs highlight the preference for a subjective treatment of the argument, more usually with a negative approach, generally with political reference and requiring a medium to high level of knowledge of the reader. Politicians are more visible in the debate than scientists and the debate itself is polarised rather than being a neutral exposition of facts. The lack of general biological knowledge amongst citizens and a lack of specific knowledge of plant genetics in particular, added to the lack of neutral information, explains the high rates of rejection of GMOs according to interviewees. The effectiveness of the NGO campaigns has also played a significant role in forming opinion.

That said, many interviewees do not think that better information will necessarily result in changing opinions. In Greece, the industry noted the negative approach towards GMOs in the press and explained that use of the term “mutated” rather than “modified” is widespread. An interviewee in the UK suggested however that this trend is changing and that the UK media is now more receptive to science-based stories than was the case previously.

3.5.1.2. Attitudes towards the authorisation process

When analysing the attitudes towards legislation on risk assessment, some consumer associations, NGOs and research bodies made clear that the concerns surround the technology and its application, rather than the specific details of the legislation. Various interviewees in Italy, Greece, the UK and Poland explained that, in their view, there are some fundamental questions around the issue of GMOs that have never been answered satisfactorily, either at the national or EU level. These more fundamental issues influence consumer perception and the details of legislation are too specific to engage consumers at this stage; an open debate with citizens about the real needs for Europe of GMOs should be undertaken before the detail is considered.

However, interviewees also pointed out some aspects of the legislation which are considered to be controversial. Prior to the analysis of these, it is important to note that:

- Industry representatives, and in general associations with significant involvement in the GM issue (including NGOs), are well aware of the phases of the authorisation process; and,

⁴⁷ Centro d’Ascolto dell’Informazione Radiotelevisiva, analysis December 2008-February 2009, on 1.040 TV broadcasts and 540 main editions of TV News on Rai Uno, Rai Due e Rai Tre (980 hours in total).

- Consumer representatives are generally aware of the phases of the authorisation process, however, they state that consumers are probably not aware of this level of detail⁴⁸ and some clearly state that the regulatory framework does not affect the degree of acceptance.

Specific comments on the authorisation process and on risk assessment were made by some of the interviewees. Different categories of stakeholder held 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 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 major concern for the industry is the time taken to authorisation post-risk assessment because of the implications in terms of asynchronous authorisation and the risk of LLP incidents. One Italian interviewee suggested that the authorisation process may somehow be speeded up with the entry into force of the Treaty of Lisbon and the inclusion of Parliament in the voting process because there might be more consideration of the need for the livestock industry to source supplies of soybean and maize. This opinion is, however, only speculative at this point in time. Some other interviewees suggested that the European Commission should have more power to authorise GM events. One organisation also pointed out that the European Commission should come out more clearly in support of the regulatory process, and that the political vote may undermine the confidence citizens have in EFSA if its scientific opinions are rejected (although to date none have been).

With the caveats explained above on the limited knowledge that consumers have on the legislative process, consumers, according to consumer associations, consider EFSA's risk assessment to be the most controversial aspects of the authorisation process.

NGO and consumer representatives in the UK have concerns in terms of a perceived lack of independent risk assessment and also in terms of whether GM food is safe. Interviewees in Greece and Italy observed that the authorisation process lacks credibility because the data submitted for evaluation, on which EFSA's risk assessment is based, are produced by the industry and are not always considered to be completely reliable. Another interviewee from an NGO added that the assessment is done on the basis of existing literature with no specific empirical research. In this context, the point was made that most of the literature is produced in the English speaking world and reflects the environment in which it is produced; the suggestion is that there is a pro-GM bias.

One interviewee noted that the risk assessment can under value some elements of the safety data submitted by applicants because they are not considered to be significant, even though they may show effects on health. In particular, he referred to the case of the authorisation of NK603 and of the paper submitted by CRIIGEN (*Comité de Recherche et d'Information Indépendantes sur le génie Génétique*)

⁴⁸ In this context for instance, National Centre for Social Research (2009) reports that “there was a lack of knowledge [among UK citizens] about how labelling and regulation currently works and a view that the current system is confusing”.

to EFSA⁴⁹. Although the interviewee considered these findings to be significant and to raise doubts about health risks, the interviewee did not feel that this research was adequately considered by EFSA. However, EFSA considered the scientific paper and did not see any reason to re-consider their earlier assessments. This interviewee called for improved transparency in order to increase trust in the authorisation process. In his opinion, confidentiality (in this case covering toxicology results) should be removed as this restricts information.

The timeframe (one month) to submit public comments is considered by an Italian NGO to be minimal and therefore the input of the public is also minimal. This interviewee added that the major NGOs and bodies that in the past were sending comments to EFSA (which required significant input on their part) have now stopped doing so due to the lack of feedback from EFSA. Therefore, in the opinion of this interviewee, while the system appears to request public participation, in reality it does not achieve this objective. This is seen as an element which may undermine confidence in the process. Although not a case study country for this topic, it was noted in Finland that the Finnish Food Safety Authority translates EFSA's summaries into Finnish and advertises public consultation through its website. DG SANCO reported that most public comments are received from Finland and the active involvement of the Finnish authorities therefore appears to result in greater public input.

Interviewees identified some options for improvement:

- Evaluation studies by independent bodies should be made available to EFSA and more public research in this area should be funded. This should include controlled trials in projects funded nationally or at the EU level. However, an interviewee pointed out the current limitations to public research resulting from the ownership of patents by the biotech companies; and,
- One consumer association and an NGO in Italy suggested that public participation should be strengthened in the assessment process, for example, through the participation of public representatives on the EFSA panel. Other interviewees in Italy and Greece suggested more participation of Member States in the choice of EFSA panel members.

Finally, some interviewees suggested that socio-economic aspects should be considered in the authorisation process. In the opinion of interviewees, this would ensure the proper consideration of all factors relevant to the use of biotechnology in agriculture rather than focusing solely on a risk assessment.

3.5.2. The impact/cost of risk aversion

3.5.2.1. The extent of risk aversion

Risk aversion in the context of GMOs is a difficult subject, as authorised GMOs in the EU have been risk assessed by EFSA and therefore have been deemed to pose no risk. However, as seen above there are aspects of the risk assessment procedure which are considered controversial by some. It is also clear that some actors perceive risks in relation to GMOs irrespective of EFSA's opinion on the matter. The analysis here will focus on the extent of risk aversion with respect to these perceived risks.

The best EU-wide source of information on the degree of public acceptance is Gaskell, *et al* (2006) and the degree of public acceptance in the case study countries is considered in 3.5.1. Other indications about the preferences of citizens are provided through national surveys.

⁴⁹ de Vendômois *et al* (2009) re-evaluated data from 90-day feeding studies on rats, provided by Monsanto as part of their application for MON810, MON863 and NK603.

Risk aversion is also demonstrated by the regional declaration of GMO-free status and several regions have declared themselves GMO-free in Greece, Italy, Poland and the UK⁵⁰.

An indication of the low acceptance of GMOs in Greece was highlighted by a consumer association who explained that a 2006 campaign resulted in changes to a text book to add information on the risks associated with GMOs and to note the lack of public acceptance⁵¹. In less than two months more than 1,000 signatures were collected from individuals and associations such as a teachers' union. Another indication was the protests which occurred at the organic EcoFestival 2009 (the biggest Greek organic exhibition) over the use of the 0.9% threshold for adventitious and technically unavoidable present of GM material in organic products.

A large consultation took place in Italy in 2007 covering GMOs and the agro-food model⁵². This was launched by 32 associations and entailed the organisation of more than 2,000 events in public places. The outcome of the consultation was the collection of approximately three million signatures supporting a model of the agro-food system characterised, among others factors, by being free from GMOs⁵³. Other surveys stress the low degree of acceptance among Italian consumers, mainly due to a lack of clear benefits and a perceived lack of evidence on the effects on human health and the environment. Saba in INRAN-MIPAF (2006)⁵⁴ found that one third of survey respondents considered GM food to be safe and adequately tested, whereas 76% were concerned about the unpredictable effects of consumption of GM food on human health. Vento (2008) found that 65% of respondents would not consume GM food because they consider it dangerous to their health and 13% because they felt GM food is not of sufficient quality. This survey found 4% generally in favour of GM food and 18% in favour as long as there are no risks to health or the environment. However, only 11% of the sample claimed that they would buy GM food. The research also highlighted the request for more information on the subject from the interviewees. Coldiretti-SWG (2009) found that 63% of Italian consumers believe that GM foods are less healthy than traditional foods (up from 52% in 2003), whereas 21% disagree with this statement (down from 29% in 2003).

Attitudes in the UK are presented in several studies. Brook Lyndhurst (2009) reviews these studies as follows:

- 52% of respondents were found to neither support nor oppose GM, or to not have an opinion, 15% strongly oppose GM and 3% are strongly in favour of it (IGD, 2008);
- 54% of citizens opposed biotechnology in food and agriculture (Mika, 2005);
- over half the population claimed to be unsure of whether GM should be promoted or opposed (Poortinga and Pidgeon, 2004);

⁵⁰ GMO-free regions across the EU can be seen here: <http://www.gmo-free-regions.org/gmo-free-regions.html>.

⁵¹ In October 2006 the Association started a campaign based on their perception that a text book used in third grade school presented misleading information on green biotechnology: two pictures of tomatoes accompanied the text, one rotten and irregular (with the caption: conventional product), the other healthy (with the caption: GM product).

⁵² 15 September - 9 December 2007, "ItaliaEuropa – LIBERI DA OGM" 3,086,524 votes gathered, of which 3,068,958 yes (99.43%) and 17,566 no (0.57%).

⁵³ The question respondents were asked was about the overall agro-food system of production, and whether this should be: "natural: made up by persons and territories, health and quality, sustainable and innovative, based on biodiversity and free from GMOs?".

⁵⁴ These results are part of a broad research project conducted in 2003-2006 by INRAN (Istituto Nazionale di Ricerca per gli Alimenti e la Nutrizione - National Institute of Research on Food and Nutrition) and funded by the Ministry of Agricultural and Forestry Policies (MIPAF). The project, which also included field trials, examined different aspects including consumers' perceptions relating to the introduction of GMOs to Italy.

- 85% of the population in the UK think that more testing is required (Rigby *et al*, 2004; DTI, 2003; FSA, 2003); and,
- 41% of respondents spontaneously cited “too many unknowns” as a major concern (COI, 2007).

No survey work is available in Poland or the Czech Republic.

3.5.2.2. The impact of risk aversion

The degree of acceptance of GM food and feed, and of GMOs in general, may have an impact on several issues, specifically:

- the supply of labelled products;
- the development of a biotechnological sector; and,
- LLP incidents rising from asynchronous and asymmetric authorisation (see the specific case study on this issue in section 3.2).

The supply of GM labelled products

An overview of the availability of GM food in the Czech Republic, Greece, Poland and the UK is available in section 7.4 of the main report in the main text (see also Kings College London, 2008). Findings in the case study countries confirm the information provided.

In **Greece** interviewees confirmed that there are very few GM labelled products on the market. Those that are available are waffles mix, coffee and chocolate mixtures and soybean oil. A consumer association and a farmer organisation also mentioned processed products such as biscuits, chocolate, a tomato sauce and stock cubes. This information is not based on a systematic review, but rather on information gathered from individual searches or reactions from consumers (following information in the media). There is no information on the price or origin of these products with the exception of chocolate which is cheaper than non-GM alternatives⁵⁵.

The major driver for the limited volume and range of products available is considered to be retailer and producer policy which in turn is driven by their perception of consumer and NGOs reaction which, as noted elsewhere, is informed by a perception of risk and a lack of awareness in terms of potential benefits. The food industry representative noted that the main trend in the food industry is towards the commercialisation of organic products.

Interviewees stated that there are no GM products on the market in **Italy**. The only GM labelled product that has been marketed in Italy is soybean oil, although this was immediately withdrawn because of the reaction of Greenpeace. The retailer association explained that a main reason for the lack of products is the lack of obvious consumer benefit. The retailer association also points out that if GM labelled products were introduced they would have to have a clear price advantage in order to sell.

The biotechnology industry interviewee explained that consumers will select GM products where these are available and cited the distribution of more than 1,000 servings of GM beer and polenta at the 2006 Verona Fair. However, it is assumed that these were distributed free of charge and there is no information in terms of how many people refused a serving which makes this rather weak evidence⁵⁶.

⁵⁵ One consumer association explained that there is a lack of information on the availability on GM labelled products. They also mentioned that consumers are not able to recognise the indication of GM content on the label. This is because in more than 80% of cases GMO content is indicated as Μεταλλαγμένος (“mutated”), rather than Τροποποιημένος (“modified”). The acronym is different and consumer representatives believe that this means consumers cannot identify GM ingredients.

⁵⁶ In this context Kings College London (2008) report on a similar trial in the UK in 2004 where 2,000 passers-by were offered a sample of beer produced using GM maize at the Food and Drink Expo exhibition in Birmingham. Only 12 people

One of the biggest Italian retailers adopted a “GM-free” policy in 1997 which is used for marketing purposes. This retailer switched to non-GMO supply chains for own brand products in 1998. Some of the major Italian food brands have also adopted “GM-free” supply chains for beef and poultry products.

Interviewees reported very few GM labelled products on the market in **Poland**. Again the reason for this is retailer policy and interviewees explained that non-GM specifications are demanded of suppliers. An interviewee mentioned that a company selling meat supplied from Denmark suffered poor sales when it became clear that GM feed had been used.

A **UK** interviewee explained that it is the retailer decision not to stock GM labelled products which has restricted the availability of GM labelled products rather than consumer attitudes *per se*. That said, Sainsbury’s, a major UK retailer, introduced a non-GM labelled milk in June 2004 which sold at a premium of around 10% (Kings College London, 2008). It should be noted, however, that this milk was produced to generally high standards and the premium did not simply reflect the use of non-GM feed. This product was subsequently withdrawn from sale in April 2006 and replaced by a product which did mention use of non-GM feed, but not as a prominent marketing message. Kings College London (2008) surmises that this was the result of poor sales, but makes clear that this has not been confirmed by Sainsbury’s. Retailers are considered to be rather stuck in their use of non-GM supply chains because all realise that the first to move away from non-GM supply chains is likely to bear a degree of hostile publicity, although it is recognised that there are cost savings to be made from the use of GM material, especially in livestock feed (although whether these would be passed on to consumers is unclear).

The development of the EU biotechnology sector

The impact of EU legislation on the development of the EU biotechnology sector is also discussed in section 3.1.4.1 within the risk assessment case study.

The agricultural biotechnology sector is widely perceived to be very high risk (in terms of product failure) and costly. Companies therefore want to operate in an environment with as few other impediments to products reaching the market as possible. There is an agreed perception among interviewees that less research is being carried out in Europe and that this is moving towards other countries, for example, the US, at least partly as a result of the generally negative perception of GM technology in the EU.

This has translated into a loss of competitiveness and a lack of capacity to develop research suitable to the EU needs (specifically in terms of cultivation). According to interviewees, the UK, for example, used to be viewed as a world class centre for plant genetics and this may no longer be the case. This is also the perception in Italy which was, according to the biotechnology industry, a leading developer in the 1990s. According to the interviewee, the fact that there were no authorisations between 1998 and 2004 blocked innovation and led to a cultural lag in the scientific community and public opinion. The authorisation of the Amflora potato in March 2010 was followed a week later by an application for authorisation for another starch potato from AVEBE and an announcement from BASF that it will put forward two applications for potato events, one for human consumption, during 2010 (Agra Facts, 2010). This appears to support the contention that a lack of authorisations reduces the likelihood that companies will submit applications.

Another consequence of the lack of authorisations between 1998 and 2004 was the concentration of research in the public sector which, being less near-market, resulted in the development of fewer

(0.6%) refused a sample because of the GM content. Again, though, this does not show evidence that consumers are actually willing to pay for products containing GM material.

potential GM events. Three major companies (Syngenta, Monsanto and Pioneer) have never actually started research in Italy.

A study conducted by Demoscopea/FuturaGra among maize farmers in the Northeast of Italy showed that farmers in these regions would be in favour of growing GM maize should suitable varieties be available. Furthermore, research on GMOs in agriculture today is considered important by some interviewees because some traditional varieties of vegetables grown in Italy could benefit from the application of gene technology. Examples of these applications are the tomato San Marzano, the apple of Val d'Aosta, the wines Barbera, Aglianico, Nero d'Avola (see Basso *et al.*, 2003 and Morandini, 2010). It is argued that current biotechnology research in Italy is not focused on agriculture.

It is considered paradoxical by some interviewees in Italy that there is State funding for study in biotechnology to train scientists who then will have no job opportunities in Italy, thereby wasting the expertise acquired. The loss of biotechnology expertise is also considered to be an issue in Greece, where again university-trained biotechnologists are forced into other fields or other countries; funding for post-graduate studies in agricultural biotechnology have recently been stopped. Additionally, the Greek biotechnology industry reported that the development of the biotechnological sector has been restricted by the government decision not to grant approval for GM rice field trials which would have formed part of an EU-wide study.

Interviewees also noted that, because of the lack of trial work and commercial cultivation, farmers in Greece have never been able to assess the potential benefits of GM crops for themselves and this contributes to maintaining a low level of demand for GM research. Spain was cited as an example of successful co-operation between academia, the State, farmers and industry enabled by transparent and neutral communication between the different actors.

One interviewee in the Czech Republic stated that there is significant agricultural biotechnology research taking place with good co-operation between research institutes and private companies.

Low Level Presence incidents

Given the politicisation of the risk management process, public acceptance of GMOs, or lack thereof, is believed to have an impact on the speed of EU authorisations resulting in asynchronous authorisations and hence issues with the Low Level Presence (LLP) of unauthorised (in the EU) GM material in imports. The impacts of LLP are dealt with comprehensively in the dedicated case study in section 3.2.

3.5.3. Variations in the sensitivity of EU-wide opinion in relation to seed, cultivation, feed and food use

Interviewees noted that public concerns vary as far as GM cultivation, food and feed are concerned. In general, concerns are considered higher and almost equivalent in relation to cultivation and food and lower in relation to GM feed. This could be due to a view that there is a lower risk to health from GM feed, but might also be explained by the relatively low awareness of the use of GM feed in livestock production.

In **Poland**, the feed and the biotechnology industries point out that given the importance of agriculture in culture and the economy, cultivation is a relevant issue for many and this is why concerns over GM cultivation are relatively high compared to GM food and feed. In the opinion of the biotechnology industry, this is also the result of the NGO campaigns which have tended to focus on the cultivation issue. It was also noted that consumers are not generally concerned about what animals eat. Large-scale livestock producers have a generally positive view on GM feed as they consider it necessary.

Small-scale farmers tend to be more typically against GMOs, but their production is for self-consumption or local markets⁵⁷.

In **Greece**, the Competent Authority explained that whilst the public generally has a negative view of GM, this is stronger in relation to cultivation. The rationale for this is public concern for the environment (biodiversity) following cultivation and for the protection of traditional and organic products. A consumer association explained this attitude with reference to the Greek way of life which involves using open air markets, buying fresh produce and consuming a high proportion of fresh fruit and vegetables. The strong aversion towards the cultivation of GM events is demonstrated by several cases of field destructions in the past. Farmers are generally strongly against cultivation because they believe that GM crops will not bring solution to the agricultural problems facing Greece. Finally, a quarter of Greek farmers use farm-saved seed and are reluctant to use varieties which would not allow them to do this, either for agronomic or licensing reasons.

Greek consumer associations tended to note that the public does not differentiate between GM cultivation, food or feed; in contrast, the biotechnology industry and the food industry believe that the area of greatest public concern is GM food, followed by cultivation and then feed. Organisations in the organic sector stress the complete opposition to GM cultivation and argue that even though consumers are generally against GM food, labelling at least provides a choice. The introduction of labelling is generally seen as being positive (although some issue were, however, noted).

As noted above, the lower concern with respect to GM feed is, to some extent, explained by the lack of awareness about the widespread use of GM material in livestock feed. However, one NGO and the consumer association pointed out that they have some safety concerns. The food industry explained that Greenpeace is exerting pressure to label livestock products, although there appears to be little consumer interest in this and the issue was discussed prior to the introduction of Regulation (EC) No 1829/2003 in any case. That said, several interviewees felt that the extension of labelling scope to encompass livestock products would allow consumers to make a fully informed choice.

In 2001 Greenpeace started producing a “Consumers’ guide” to dairy companies (covering the main companies). This attributed ratings (in the form of traffic light) to each company based on responses to a Greenpeace questionnaire which investigated the use of GM feed in their supply chains. A food industry interviewee reported that when this guide was introduced, most companies were rated “red”, i.e. had not demonstrated non-GM supply chains. This provided the opportunity to one small company to seek “GM-free” certification to obtain a “green” rating from Greenpeace. By advertising this difference the small company very quickly became the market leader in fresh milk (products were not labelled with respect to GM, the increase in market share was attributed simply to the Greenpeace guide and general awareness of their position). Since then, all the major dairy companies have demonstrated non-GM supply chains and price competition is once again the main factor driving market share.

Most **UK** stakeholders felt that cultivation is probably seen as being more controversial by the public than GM food or feed. This is because of issues surrounding co-existence, especially with regard to the organic sector. There have also been some consumer enquiries about whether honey should be labelled if GM crops become widespread. There is least concern in the UK over GM feed. However, it is felt that levels of controversy could change, especially if NGO campaigns focus on GM food and/or feed. Consumer organisations had a different point of view, perhaps reflecting their remit, and felt that consumers are mainly concerned about the potential implication of eating GM food on their health. Consumer organisations explained that issues of cross-contamination and other aspects related to cultivation are too detailed and technical for most members of the public to engage with. They did,

⁵⁷ In order to address the demand for vegetable protein in the livestock sector the Polish government is considering how it might subsidise the growing of beans, as an alternative to soybean meal.

however, note that there will be some consumers who are more concerned about cultivation as a result of the potential environmental implications.

In **Italy**, the Competent Authority pointed out the lack of interest in GM food expressed by consumers and their concerns over safety and impact on health and the environment. Interviewees explained that the level of concern is “proportional” to the direct impact that the use of GM food could have on health or on the environment, i.e. the concerns are founded on the risks as understood by consumers. There is more concern in terms of GM food because the potential impact on human health is more direct and the perception of the risk is more immediate. Consumers are concerned about cultivation because of the risk that GMOs will enter the food chain. The biotech industry felt that cultivation is the most controversial aspect of the GM debate and pointed out that this tends to be the focus of reportage in the media. They also pointed out that for those opposed to GM, it is tactically best to focus on cultivation (in countries where there is currently no cultivation) because GM food and feed are already part of everyday life. Consumer associations explained in the context of the (largely hypothetical to date) availability of GM food that the labelling legislation is useful, but that the 0.9% threshold for adventitious and technically unavoidable presence should be lowered or eliminated.

Several interviewees noted that the Italian public is very attached to the strong food tradition of the country and therefore opposition to GMOs is at a general level and is linked to the cultural background. In Italy, attention to food, its properties and production methods is high and interviewees explained that there is a conservatism in relation to food that means people are instinctively against GMOs because they are considered to be diametrically opposite to the founding elements on which the tradition and richness of Italian food production systems are built⁵⁸. The linkage between the protection of the agricultural environment and food quality is also very strong and is played upon by farmers and the retailers for marketing purposes. There is a concern that the use of GMOs might on the one hand weaken this link and, on the other, provide unfair price competition for products which are not equivalent in quality terms. A farmer association and the biotechnology industry interviewees put this concern in context, however, by pointing out that the “traditional” food market accounts for around €9 billion in a total food market of €40 billion, i.e. 23%. They added that this view also fails to take into account the potential benefits from the use of GMOs (as they see it improved competitiveness, improved varieties of maize, improvements for some crops, see section 3.5.2). The current lack of cultivation is said to limit the opportunities for EU farmers while Third Country producers can use GMOs in exports to the EU which is considered paradoxical.

The use of GM feed is generally seen as least controversial, partly because consumers are not aware of its widespread use because livestock products are not labelled. An NGO stressed that because of this lack of labelling, it is hard to judge consumer acceptance of the use of GM feed. Some interviewees advocated the extension of labelling scope to cover livestock products. In this context, Greenpeace has started a campaign to eliminate GMOs in the feed supply chain of Parmigiano Reggiano. Two farmer associations stated that labelling livestock products would help the development of a non-GM feed supply chain in the country. They believe that the dependency on GM feed results from its price competitiveness. The current lack of livestock product labelling makes it impossible, according to the farming industry, for Italian producers of non-GM soybean (40,000 ha) to compete and they are therefore not able to develop the market. Labelling of livestock products and traceability systems for domestic non-GM soybean would make domestic production more economically viable. A large area of Italy is used to produce arable crops and the industry believes that there is the potential to produce alternatives to soybean to be used as feed raw material. This is highlighted in a number of studies⁵⁹.

⁵⁸ This is of course influenced as well by the levels of attention given to these issues: nowadays, in particularly in the face of the economic crisis there is greater interest in price.

⁵⁹ Martini *et al* (2007); Various articles under research project “Recupero e valorizzazione di fonti proteiche alternative alla soia più idonee per le realtà zootecniche regionali” Arsia e Università degli Studi di Firenze, 2003-2006; Gigli *et al* (2009);

The industry (feed, livestock, biotechnology and rice industry) are against the extension of labelling scope to include livestock products because it would imply control costs for operators and would not satisfy a safety requirement as noted by EFSA (2007f). Retailers oppose an extension of labelling scope on the basis that consumers are not actually interested in this information. They cited the use of country of origin labelling in 2000 where the price premium for Italian meat products (around €0.40) was not met after the initial 15 days. The labelling did not therefore result in increased market share for domestic production. Other interviewees thought that extending the scope of labelling would increase consumer awareness and might therefore prove beneficial in the debate on the use of GM technology in agriculture by forcing consumers to actively select GM labelled products or face paying a premium.

3.5.4. The extent to which the concept of ALARA (as low as reasonably achievable) is meaningful in relation to GM food and feed

The general public are not considered to be aware of the concept of ALARA and most consumers are considered unaware of tolerance levels in food generally. Most consumers therefore expect products to be free from impurities and there tends to be a strong reaction when contamination occurs. One Competent Authority, however, felt that citizens would understand the concept if it was explained to them.

Some interviewees considered the concept of ALARA too vague because there is no specified tolerance level and “reasonable” is a subjective term which might be interpreted differently in different Member States and hence this approach might have implications in terms of the operation of the single market.

One Competent Authority stated that zero tolerance is the appropriate strategy concerning the presence of non-authorized GM events and that ALARA should be applied in conjunction with the 0.9% threshold for adventitious and technically unavoidable presence of authorized GM events in labelled products. Another Competent Authority said that ALARA only makes sense in the context of unauthorized GM events, but in this case, by definition, the risk is not known and it is considered inappropriate to apply ALARA which refers to known risks. The distinction was made between a potential safety risk and the risk that there is low level presence of GM material: as applied to labelled products, ALARA could refer to the risk of presence, although another respondent felt that this would be inappropriate because the concept is associated with known risks and authorized material has been positively risk assessed.

An NGO pointed out that GM needs to be treated differently from contaminants because consumers may wish to avoid the technology itself rather than specifically the product. Other interviewees noted that ALARA is not appropriate as a mechanism for dealing with the desire of consumers to avoid the use of a technology because it is a concept used to deal specifically with risk.

The industry is clear that some tolerance of impurities is necessary because it is not possible to operate to 100% purity, ALARA could therefore have a role. A retailer noted that ALARA could be useful in the GM context as applied to asynchronous authorisation and consequent LLP incidents. This interviewee considered that trace elements do not pose a safety risk, but can result in damaging media scare stories. This issue is therefore ultimately one of public acceptance and not food safety. A rational system for tolerating the LLP of unauthorized GM events would therefore be useful in the context of the (relatively) slow process of authorisation in the EU. Another representative from the industry noted that the use of ALARA would place the onus on the operators in the chain to demonstrate through due diligence that they had taken reasonable measures to avoid co-mingling.

and, Foutry *et al* (2006).

3.5.5. Improvements to the quality of EU-wide trust in science-based risk assessment in the GM context

The GM legislation, and in particular the risk assessment procedure, is well known and understood by operators in the food chain, consumer representatives and the NGOs, but this is not considered to be the case for citizens. Furthermore, communication on this issue in particular, and on GMOs in general, is not systematically undertaken by governments and is mostly undertaken by other operators in the sector as described in section 3.5.1.

Communication on the GM topic suffers from a larger problem, namely the communication of science in general. This is perceived more and more to be a key issue given the role and applications science is acquiring in society. Some consumer associations pointed out that there is a perceived gap between people and science in that people do not have the tools to access scientific information and understand it. This applies widely and was often mentioned in connection with nanotechnologies which is considered an analogous issue.

The Competent Authorities of the Member States interviewed indicated the current efforts undertaken by their Ministries to communicate on the issue of GMOs:

- **Czech Republic:** the Minister of Agriculture created an “Information Centre for Food safety” with a website which receives approximately 5,000 visits per month.
- **Italy:** the Ministry of Health and the other government departments communicate information to the public concerning GMOs and data on the activities they run in this field on their website.
- **Greece:** communication by Competent Authorities is done on an *ad hoc* basis when issues arise (for example, when there is a shortage of feed material). However, there is no authorised central organisation with a remit to inform, instruct and advise the public on all the relevant issues concerning food and feed safety and hygiene hazards.
- **The UK:** the Food Standards Agency (Competent Authority) carried out a broad public debate on the future of GM crops and food in the UK under the title “GM Nation?” which partly aimed at communicating GM issues to the public. Future research into consumer concerns will be undertaken in 2010, from which the FSA expects to gain knowledge on the best way forward in terms of communicating to the public on this issue.

In addition to the above, other information campaigns are run by other organisations including consumer associations and NGOs. These have included campaigns with episodes of field trial destructions. In the UK, one interviewee explained that scientists and biotech companies are constantly trying to communicate explanations about the authorisation process and the rigorous risk assessment. In Poland, technology providers have supplied technical information to the agricultural sector and have produced some general articles for the wider public.

As explained in section 3.5.1, some interviewees ascribe the lack of acceptance of citizens to the information they receive, and in some countries interviewees from the biotech sector explained that, in their opinion, the politicisation of the approach to authorisation and communication activities has not helped the public to appreciate the science-based approach which underpins EFSA’s risk assessments. In Greece, for example, a biosafety committee provided the government with evidence on which to form its opinion prior to 1998, but this was disbanded in the absence of authorisations at this time and was not re-established post-2004. There was a suggestion from the biotech industry in Poland that Government training programmes in this field stress negative aspects and positions with regard to GM rather than a measured, science-based approach, although this cannot be confirmed.

Some interviewees compared the situation with regard to public acceptance in the EU to that in Third Countries and explained that the relative lack of consumer concern in some Third Countries is not the

result of public education campaigns, but stems from a lack of an anti-GMO alliance which is very much present in the EU. Some added that Europe is in general more sceptical about science, politics and business than North America where citizens tend to have a more positive outlook on technology and capitalism in general.

Most interviewees agreed that more communication is needed on the GM issue in general, although some interviewees in the Czech Republic stated that there is no point in communicating on the regulatory process given the low level of knowledge and lack of awareness of citizens. Some interviewees in Greece felt that further communication would not be a sensible use of resources given the entrenched opposition to GMOs.

Interviewees expressed comments in three main areas as set out in the sub-sections below.

3.5.5.1. Scope of information

Some interviewees stressed the necessity for complete and neutral communication on the issue of GMOs and on the EU authorisation process, emphasising the role and the work of EFSA and the rigorousness of the authorisation process which is not as widely appreciated as it might be. Several interviewees stressed the fact that the authorisation process is set up to ensure the safety of the product and therefore this should no longer be in contention. In the opinion of these interviewees, the debate should be brought back to the scientific basis of the risk assessment. Also, the operation of the labelling regime for GM food and feed should be disseminated to citizens, although some interviewees accepted that the relative absence of GM labelled products from the market does not help with consumer understanding of the labelling regime as there is little practical engagement with it.

Many interviewees highlighted the need to place the GMO debate within a broader context of food safety issues in general and in food safety policy and systems (at national and EU level). Consumer associations and the feed industry in Poland believe that communication on the GMO authorisation procedure and EFSA's role would increase public confidence in food safety systems and would therefore reduce indirectly the negative perception that consumers have of approved GM food products. One retailer association in the Czech Republic highlighted the fact that the opinions of consumers in this country go together with the opinion consumers hold in respect of the EU food safety system (i.e. confidence in the system determines acceptance of the products).

Furthermore, NGOs, consumer associations and farmer representatives (particularly in Greece and Italy) agreed that the GM debate should be inserted within a broader debate on agricultural policy and food needs within the EU. In their view, prior to any further debate on this issue the current uses of and needs for GMOs in Europe should be clarified. They point out that the aim should not only be to reassure, but to engage in a debate about risks and benefits of GMOs within the wider context of food security, climate change, etc., providing citizens with appropriate tools to come to an informed decision. Some interviewees explained that one of the main problems is that the EU authorisation process is based around health and environmental risks and there are a lot of issues beyond this which have an impact on public acceptance which need to be addressed: the debate is therefore too narrowly defined. Furthermore, many interviewees noted an apparent incoherence between food security arguments and the need for increased productivity within an agricultural policy context where increased production is not encouraged under the Common Agricultural Policy.

Some interviewees (industry and retailers) stressed the fact that communication would be more effective if it focused on the benefits of GMOs, rather than on safety aspects only: when clear consumer benefits outweigh the perception of risk it is expected that acceptance will increase. In this context it would also be important to communicate the relative lack of non-GM vegetable protein ingredients for livestock feed. This view was echoed by the UK food industry who noted that GM tomato puree sold with a price advantage which consumers could readily appreciate in the late 1990s.

Some interviewees highlight that consumers generally need to be educated about modern food production and that labelling is not sufficient to do this. Interviewees in the UK explained that there have been many recent examples of TV programmes and series on farming and food production which have been balanced and informative.

Finally, the point was made in the UK that it is difficult to see the rationale for a public authority role in the communication of potential benefits of GM technology given that private companies would capture any benefits. In the view of these interviewees it is the users of GM technology (whether this is livestock producers, food processors or retailers) who need to recognise benefits and, if they do, they will take up the technology. If there is no market for GM products, even with a price or some other advantage, then these users will presumably not take up the technology, as would be the case in any other industry sector.

3.5.5.2. Communication tools

The Italian Competent Authority explained that communication needs to be carried out using non-technical language and should make use of the range of potential communication tools available. Many interviewees from different stakeholder groups felt that the main communication effort should be to persuade the mass media to communicate more neutrally. An Italian consumer association suggested that the EU should fund the communication of scientific information, although other interviews noted that the degree of support for the European Union in different Member States would have an impact on any activities undertaken with EU support. A Polish consumer association suggested that TV documentaries might be the most appropriate tool for promoting the EU food safety system and EFSA. A consumer association in Greece also suggested that television would be a suitable media through which to communicate the scope and operation of the labelling regime.

3.5.5.3. Information sources

The majority of interviewees advocated the need for communication to emanate from a neutral body with no vested interest in moving the debate forward in any particular direction. The identity of this body was not, however, clear. One interviewee mentioned the GMO Compass website which is considered neutral as it is funded by the European Commission. Some interviewees, however, did not think that it would be possible to identify a truly independent organisation. An NGO in the UK stated that the lack of independent access to information, for example, data submitted by manufacturers to EFSA for the risk assessment, means that no organisation could ever be considered to be communicating truly independent information.

Some studies (for example, Kings College London, 2008) have identified categories of organisations that seem to be more trusted by public opinion when seeking neutral information. These are medical doctors, consumer organisations and university scientists; government and the industry may be less effective due to existing public doubts in terms of trustworthiness, particularly in some countries such as Greece. However, many interviewees suggested a role for public authorities and institutions, both at the national and EU level (EFSA and Food Safety Authorities) in increasing public awareness on GM issues, engaging in debate and promoting education on the subject. A role for academia was also suggested. Consumer associations, even if trusted by the public, claim that they do not have the resources to carry out extensive campaigns. Industry seems to be in the least suitable position to communicate on this topic because they clearly have a vested interest in improving public acceptance and would therefore be open to accusations of bias.

Interviewees in Greece suggested the foundation of an inter-scientific organisation in co-operation with all the interested stakeholders (i.e. from NGOs through to industry and Competent Authorities). Such a body could take responsibility for the dissemination of science-based information concerning GM food and feed safety as well as issues concerning risk management. The Czech Republic

Competent Authority agreed that neutral information should be provided by governments, food processors and the Scientific Committee. Italy is setting up a National Committee for Food Security, an Authority delivering technical and scientific opinions to administrations in charge of risk management in terms of safety issues (i.e. analogous to EFSA on a national basis). In the UK, it is suggested that the FSA research panel for 2010 may be a model on how the debate could be moved forward.

4. Analysis of Third Country regulatory frameworks

The regulatory framework in seven Third Countries is set out as follows:

- USA, Argentina, Brazil and Canada as exporters to the EU;
- Japan as an importing country in a similar situation with regard to demand for vegetable protein as the EU;
- China and India as potential future developers of GM events.

In the second part of the analysis a comparison between the different regulatory frameworks has been developed for topics covered by this evaluation.

The list of parameters considered for this comparison is as follows:

- approach to legislation;
- process-based versus product-based safety assessment;
- authorisation system (risk assessment and risk management);
- approach to stacking; and,
- labelling rules.

Data collection has been based on desk research and supplemented by interviews with the EU missions of each individual country in Brussels. Interviews with EU stakeholders have been an additional valuable source of information to complete this study.

4.1. Third country regulatory frameworks

4.1.1. United States of America

4.1.1.1. Regulatory Authorities and relevant legislation

Three U.S. agencies share responsibility for regulating agricultural biotechnology:

- the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) is responsible for ensuring that the growth of genetically engineered plants does not harm the agricultural environment;
- the Environmental Protection Agency (EPA) is responsible for assuring the human and environmental safety of pesticide substances engineered into plants; and,
- the **Food and Drug Administration (FDA)** is responsible for assuring that foods derived through genetic engineering are as safe as their traditional counterparts.

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Each of these three regulatory authorities enacts specific laws as follows:

Agency	Jurisdiction	Laws
USDA	Plant pests, plants, veterinary biologics	Federal Plant Pest Act (FPPA)
FDA	Food, feed, food additives, veterinary drugs, human drugs, medical devices	Federal Food, Drug, and Cosmetic Act (FFDCA)
EPA	Microbial and plant pesticides, new uses of existing pesticides, novel organisms	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); FFDCA; Toxic Substances Control Act (TSCA)

4.1.1.2. Regulatory Framework for Biotechnology Products

Products are generally regulated according to their intended use, with some products being regulated under more than one agency, for example, pesticide plants-*Bt*. Notwithstanding this overall product focus, the trigger for regulatory oversight, at least with respect to the environmental release of plants derived via biotechnology (USDA-APHIS) and the registration of plant-pesticides - plant incorporated protectants - (EPA), is the process of genetic engineering.

Before commercialisation, genetically engineered plants/organisms must conform to standards set by State and Federal marketing statutes such as State seed certification laws, the Federal Food, Drug and Cosmetic Act (FFDCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Toxic Substances Control Act (TSCA) and the Federal Plant Pest Act (FPPA), as noted above.

In 1993, the USDA finalised a regulation under the Federal Plant Protection Act (formerly the Federal Plant Pest Act) that described a petition process for determining that particular plants would no longer be regulated and, therefore, could be commercially planted. These procedures were simplified in 1997.

A **regulated article** is defined as any organism which has been altered or produced through genetic engineering if the donor organism, recipient organism, or vector or vector agent belong to any genera or *taxa* designated as, or believed to be, a plant pest. A plant pest is defined as any living stage of invertebrate animals, bacteria, fungi, parasitic plants, viruses or any organisms, agents or substances, which can directly or indirectly damage or cause injury to plants or parts thereof.

APHIS can also designate any product of genetic engineering a regulated article if the article is deemed to be a plant pest. For a crop to achieve non-regulated status, “environmental assessment” and “determination of non regulated status” documents are prepared by USDA that address a number of safety concerns including impacts on agriculturally beneficial organisms and the potential to become a plant pest.

APHIS authority to regulate genetically engineered plants stems from the fact that, to date, these plants have been products of *Agrobacterium tumefaciens* (a bacterial pest causing crown gall disease in plants) mediated transformation and/or contain regulatory sequences derived from a plant pest (for example, cauliflower mosaic virus 35S promoter). The regulations are contained within 7 CFR (Code of Federal Regulations) Part 340, “Introduction of organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests”.

Although APHIS regulations for genetically engineered plants apply only to plant pests, the Agency’s broad discretionary authority provides them with sufficient latitude that any transgenic plant could be considered a plant pest and so fall within their mandate.

4.1.1.3. Stacked events

There is no defined policy for stacked events as yet.

4.1.1.4. Environmental Risk Assessment

Before a genetically engineered crop can be produced on a wider scale and sold commercially, its creators must petition APHIS for a “determination of non-regulated status”. APHIS has published a “Guide for preparing and submitting a petition for genetically engineered plants” that uses a case-study approach to describe the nature and format of field test data that must be provided (USDA, 1996).

The type of information considered includes:

- description of the biology of the non-modified recipient plant and information necessary to identify the recipient plant in the narrowest taxonomic grouping applicable;
- relevant experimental data and publications;
- a complete molecular characterisation of the transgenic plant (in line with the Canada - US harmonised molecular characterisation requirements (CFIA, 1998));
- a detailed description of the differences in genotype between the regulated article and the non-modified recipient organism;
- a detailed description of the phenotype of the regulated article that includes known and potential differences from the unmodified recipient organism that would substantiate that the regulated article does not pose a greater plant pest risk than the unmodified organism from which it was derived, including but not limited to: plant pest risk characteristics; disease and pest susceptibilities; expression of the gene product, new enzymes, or changes to plant metabolism; weediness of the regulated article and impact on the weediness of any other plant with which it can interbreed;
- agricultural or cultivation practices;
- effects on non-target organisms;
- indirect plant pest effects on other agricultural products; and,
- transfer of genetic information to organisms with which it cannot interbreed.

Upon receipt of a petition, APHIS publishes a notice in the Federal Register soliciting public comment as to whether the regulated article presents a plant pest risk. This notification includes a synopsis of the petition (i.e. the general characteristics of the transgenic plant) and explains the role of other regulatory bodies (EPA and FDA), and the process for submitting comments and obtaining more information, including a copy of the petition, with confidential business information redacted.

Following its assessment, and if it determines that the plant poses no significant risk to other plants in the environment and is as safe to use as more traditional varieties, APHIS publishes a “determination of non-regulated status” in the Federal Register. This notice advises the public of the availability of all written comments received and APHIS’ environmental assessment.

4.1.1.5. Plant Incorporated Protectants

For plants with pesticide properties, such as *Bt* corn, APHIS co-ordinates its review with the EPA, which is responsible for the regulation of pesticide substances under FIFRA and FFDCA. In addition to examining data on product characterisation (for example, source of the gene; its expression; nature

of the pesticide substance produced; modifications to the introduced trait as compared to that trait in nature; biology of the recipient plant; effects on non-target organisms; exposure; and, environmental fate), EPA also requires data on toxicology, digestive fate, and potential allergenicity of the pesticide substance. Proposed registrations of plant-pesticides are subject to notification and a period of public comment.

The EPA is responsible for regulating pesticides in the U.S., including pesticide substances produced through biotechnology. Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the EPA ensures that pesticides meet federal safety standards. The Federal Food, Drug and Cosmetic Act (FFDCA) requires that the EPA determine safe levels of pesticide residues in food. In 1994, the EPA published proposed regulations describing policies for pesticide substances expressed in transgenic plants under FIFRA and FFDCA. In 2001, this rule was finalised along with two others that clarify which plant incorporated protectants (PIP) are exempt. A plant incorporated protectant is a pesticide substance that is produced and used by the living plant, typically to protect the plant from pests, such as insects, viruses and fungi. The final rules formalise the EPA's existing process for regulating PIPs, clarify which PIPs must be evaluated under FIFRA and FFDCA, and which are exempt. Under the final rules, most components of PIPs derived from genetic engineering will be subject to FIFRA and FFDCA requirements to ensure that federal safety standards are met. The EPA must also set a food tolerance for residues of a PIP, or determine on a case-by-case basis to exempt it from the food tolerance requirement, before it can be marketed.

4.1.1.6. Food and Feed Safety Assessment

Under the FFDCA, the FDA has the authority to require pre-market review and approval in cases where protection of public health is required, such as when a substance is added intentionally to a food and there are questions about its safety. FDA also has post-market authority to remove a food product from the market and sanction those marketing the food if it poses a risk to public health. In the US, the complex array of criminal and civil sanctions, including tort and contractual remedies, available to governments and private parties provides food producers and manufacturers with every incentive to bring safe, wholesome foods to market.

In 1992, the FDA conducted its first, and only, comprehensive scientific review of a genetically engineered food product, Calgene Inc's Flavr Savr™ tomato. The transgenic variety ripens normally, but experiences less pectin breakdown than conventional tomatoes and, therefore, has increased thickness and consistency that benefits all stages of harvesting and processing. In developing the Flavr Savr™ tomato, Calgene used the kanamycin resistance marker gene that encodes neomycin phosphotransferase II (NPTII), as a selectable marker. This was the only new protein expressed in the transgenic tomato. In its evaluation of the Flavr Savr™ tomato, FDA considered the source, identity, function, and stability of introduced genetic material, compositional and nutritional studies, the safety of the NPTII protein, and the environmental safety of the use of the NPTII encoding gene. FDA's assessment concluded that the Flavr Savr™ tomato was substantially equivalent to, and as safe to eat as other tomatoes currently on the market. This assessment was supported by the agency's Food Advisory Committee, a panel of experts from outside FDA.

During this period, FDA published in 1992 in the Federal Registry a Statement of Policy on its approach to the regulation of foods derived from genetically engineered plants. The purpose of this policy was to provide a risk-based "decision tree" to guide plant breeders and food manufacturers through issues critical to ensuring the safety, nutritional value, and wholesomeness of new foods. Under this "standard of care", which applies equally to new foods produced through traditional breeding as well as biotechnology, FDA also provided guidance on regulatory issues such as when an introduced substance is not generally recognized as safe and would require pre-market approval as a food additive, and when special labelling would be required under FFDCA. Food producers are not

required to seek FDA pre-market approval or apply a special label for a new variety of food if it is substantially equivalent to existing varieties already on the market.

The cornerstone of FDA's 1992 policy is that foods produced as a result of genetic engineering are not inherently more risky than foods produced through more conventional means. Since publishing this policy, FDA has conducted its reviews of genetically engineered foods by consulting with companies about the safety and composition of the variety, and has not required a food additive petition for any other transgenic product, although it could make such a request in the future. Under the guidelines for this voluntary consultation process, which were published by FDA in 1997, developers of food products from transgenic plants are asked to provide summary information of their safety and nutritional assessment, and to make a scientific presentation of their data to FDA scientists. Without exception, all developers of genetically engineered foods have participated in this voluntary scheme.

Food producers in the US have the legal responsibility to ensure the safety of foods they offer consumers. The goal of FDA's voluntary consultation process is to work together with developers, beginning at an early stage in product development, to identify and resolve any issues regarding the food that would necessitate legal action by the agency if the product were placed on the market. Examples of such issues include significantly increased levels of plant toxicants or anti-nutrients, reduction of important nutrients, the presence of new allergens, or the presence in the food of an unapproved food additive.

When the developer has accumulated the data that it believes are adequate to ensure that its product is safe and complies with the relevant provision of the Act, the developer submits a safety and nutritional assessment summary to FDA that typically includes:

- the purpose of intended technical effect of the modification on the plant, together with a description of the various applications or uses of the bioengineered food, including animal feed uses;
- a molecular characterisation of the modification including the identities, sources and functions of introduced genetic material;
- information on the expressed protein products encoded by introduced genes;
- information on known or suspected allergenicity and toxicity of expressed products;
- information on the compositional and nutritional characteristics of the food, including anti-nutrients;
- for foods known to cause allergy, information on whether the endogenous allergens have been altered by the genetic modification; and,
- in some cases, the results of comparisons of wholesomeness feeding studies with foods derived from genetically engineered plants and the non-modified counterpart.

In keeping with the voluntary nature of this process, there are no requirements for public notification in the Federal Register or public consultation. In such a case, FDA does not issue a product approval *per se*, but informs the developer by letter that it has no further questions based on the information presented, and reminds the developer of its legal responsibilities. FDA does publish a list of completed consultations that identifies the name of the developer, the introduced trait, the source and identity of any introduced genes, and the year in which the consultation was completed.

In May 2000, the US government announced a number of new initiatives geared toward reinforcing the strength and transparency of the regulatory system, and enhancing the information provided to consumers and farmers. Among these were:

- a review of Federal environmental regulations by the Council on Environmental Quality and the OSTP;
- steps to be taken by the FDA to implement a requirement for mandatory notification at least 120 days before any new agricultural biotechnology crops or products are introduced into the food supply, and to propose that submitted information and the agency's conclusions be made available to the public;
- the addition by FDA of more scientists with agricultural biotechnology expertise to its food and veterinary medicine advisory committees;
- guidelines to be developed by the FDA for voluntary efforts to label food products under their authority as containing or not containing bioengineered ingredients in a truthful and straightforward manner; and,
- actions by the USDA to provide farmers with reliable information on markets and best farming practices for new crop varieties.

In January 2001, the FDA published a proposed rule for mandatory pre-market notification for GM foods (FDA, 2001)⁶⁰. Under this rule, the FDA will require the submission of data and information about GM foods destined for human or livestock consumption 120 days prior to the commercial distribution of such foods. This means that when the proposed rule is finalised, the FDA will move from its current voluntary system to a mandatory system for the regulatory oversight of GM foods and livestock feeds.

4.1.1.7. Food Labelling Policies

Special labelling requirements for GM foods as a class of foods are not mandated by the FDA. In its 1992 Policy, the FDA states there is no basis for concluding that GM foods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed through genetic engineering present any different or greater safety concerns than foods developed using traditional plant breeding methods. Hence, GM foods, as with conventional foods, are subject to existing labelling regulations under the FFDCA. In short, labelling is required for any food that poses special health or environmental risks (for example, changes in nutritional properties, presence of an allergen), and food labels must be truthful and not misleading (for example, if a food is significantly different from its conventional counterpart so that the common or usual name no longer applies, then the name must be changed to describe the difference).

The FDA recently published a guidance document for industry that addresses the labelling of GM foods. The document was prepared based on comments received by the FDA in response to its 1992 Policy, and in subsequent consultations held in 1993 and 1999. Examples are given of acceptable statements for foods derived from genetic engineering, and for foods that are not genetically modified or do not contain GM ingredients.

⁶⁰ FDA (2001) Federal Register Premarket Notice Concerning Bioengineered Foods. January 18, 2001. <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096149.htm>

Table 4.1: Summary: Product movement through the US regulatory framework

R&D	<ul style="list-style-type: none"> • Compliance with HH Guidelines for work with GMOs is mandatory for all scientists receiving federal funding or working for federal agencies.
Field trials	<ul style="list-style-type: none"> • Following a letter of notification, developers must receive APHIS approval for field trials and submit summary reports. • Trials may be inspected by APHIS and/or state department of agriculture officials. • Developers must comply with APHIS performance standards developed to minimise “out-crossing” and inadvertent environmental release. • APHIS also oversees transport of seed to and from trial site. • For trials of pesticides plants > 10 acres, need an experimental Use permit from EPA, Public notification and comment is required here, but not for field trials generally.
General Environmental Release	<ul style="list-style-type: none"> • Developers must apply to APHIS for a determination of non- regulated status. Public notification and comments solicited. • APHIS review (>=10 months) considers range of risk factors including environmental effects, wildlife effects, and potential to become a plant pest. • For pesticidal plants, the plant pesticide substance (e.g. Cry1A(b)) must be subject to risk assessment (>=18 months) and registration by EPA. Public notification and comments are invited through publication in the Federal Register.
Use as food	<ul style="list-style-type: none"> • Through its voluntary consultation process, FDA works with the producer from an early stage in product development to ensure that all food safety issues have been addressed. • Based on favourable review of summary data and a presentation to FDA scientists, FDA issues a letter stating they have no further questions.
Post Commercialisation	<ul style="list-style-type: none"> • All three regulatory agencies have the legal power to demand immediate removal from the market place of any product should new valid data indicate a question of safety for consumers or the environment.

4.1.2. Canada

The Canadian regulatory system for products of biotechnology is based on a product rather than process philosophy of registration. The rationale for this approach is to provide for the assessment of all “novel” products introduced into Canada which may have a negative impact on human health, the environment, or the agricultural industry. As a result, Canada has adopted a very broad definition of biotechnology, and focused regulations on novel traits rather than “genetic engineering” itself.

“Biotechnology” means the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.

Biotechnology is defined under the federal framework for regulating biotechnology products as *“the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms”*. This broad definition covers all organisms, their parts and products. Both traditionally developed products and those developed through techniques such as genetic engineering are included.

It should be noted that, unlike many other countries, Canada chose to amend existing legislation and regulatory departments to accommodate biotechnology rather than enacting new legislation.

4.1.2.1. Regulatory Authorities

In Canada, the regulation of biotechnology products is co-ordinated between the Canadian Food Inspection Agency (CFIA), Health Canada and Environment Canada (**Table 4.2** and **Table 4.3**). The CFIA is responsible for regulating the importation, environmental release, variety registration and use in livestock feeds of plants with novel traits. Health Canada is solely responsible for assessing the human health safety of foods, including novel foods, in Canada and approving their use in commerce. Under CEPA, Environment Canada is responsible for administering the New Substances Notification Regulations and for performing environmental risk assessments of CEPA toxic substances, including organisms and micro-organisms that may have been derived through biotechnology.

Table 4.2: Federal regulatory responsibilities for agricultural biotechnology products

Department/Agency	Products regulated	Relevant legislation	Regulations
Canadian Food Inspection Agency	Plants and seeds, including those with novel traits, animals, animal vaccines and biologics, fertilisers and livestock feed	<ul style="list-style-type: none"> • Consumer Packaging and Labelling Act • Feeds Act • Fertilisers Act • Food and Drugs Act • Health of Animals Act • Seeds Act • Plant Protection Act 	<ul style="list-style-type: none"> • Feeds Regulations • Fertiliser Regulations • Health of Animals Regulations • Food and Drug Regulations
Environment Canada	Biotechnology products under CEPA such as micro-organisms used in biomediation, waste disposal, mineral leaching or enhanced oil recovery	Canadian Environmental Protection Act	New Substances Notification Regulations (These regulations apply to products not regulated under other Federal legislation)
Health Canada	Foods, drugs, cosmetics, medical devices, pest control products	<ul style="list-style-type: none"> • Food and Drugs Act • Canadian Environmental Protection Act • Pest Control Products Act 	<ul style="list-style-type: none"> • Cosmetics Regulations • Food and Drug Regulations • Novel Foods Regulations • Medical Devices Regulations • New Substances Notification Regulations • Pest Control Products Regulation
Fisheries and Oceans	Potential environmental release of transgenic aquatic organisms	Fisheries Act	Under development

Source: www.AGBIOS.com.

Table 4.3: Delineation of regulatory responsibilities within the Canadian regulatory framework for biotechnology

Category	CFIA	Health Canada
<p><i>Human health and food safety</i></p> <ul style="list-style-type: none"> • Approval of novel foods • Allergens • Nutritional content • Potential presence of toxins 		* * * *
<p><i>Food labelling policies</i></p> <ul style="list-style-type: none"> • Nutritional content • Allergens • Special dietary needs • Food and consumer protection 	*	* * *
<p><i>Safety Assessments</i></p> <ul style="list-style-type: none"> • Fertilisers • Seeds • Plants • Animals • Animal vaccines and biologics • Livestock feeds 	* * * * * *	

Source: www.AGBIOS.com.

4.1.2.2. Regulatory Framework for Biotechnology Products

Canada’s regulatory framework was established through agreement among federal regulatory bodies and was announced in 1993. The need for an investment in this regulatory strategy to meet new challenges was recognised when the Canadian Biotechnology Strategy was renewed in 1998. The principles from this strategy, which are still in place, include reflecting Canadian values; engaging Canadians in open, ongoing, dialogue; promoting sustainable development, competitiveness, public health, scientific excellence, and an innovative economy; and, ensuring responsible action and co-operation domestically and internationally. These principles established that the practical benefits of biotechnology products and processes would be balanced with the need to protect health, safety and the environment.

Aside from the approach taken by U.S. Food and Drug Administration (FDA) towards bioengineered foods, Canada is the only country where regulatory oversight is triggered solely by the novelty of traits expressed by plants or the novel attributes of foods or food ingredients, irrespective of the means by which the novel traits were introduced. This “product-based” approach to regulation has been validated by numerous scientific bodies and expert consultations (Tiedje *et al.* 1989; OSTP 1986; NAS 1987; 2000). Under this regime, all agricultural commodities and food products, whether they are produced using conventional technologies or biotechnologies, are governed under the same acts. Depending on the type of product, the relevant piece of legislation is the *Seeds Act*, *Feeds Act*,

Fertilisers Act, Food and Drugs Act, Health of Animals Act, or the Canadian Environmental Protection Act (CEPA).

Except as noted above, “process-based” regulation is the rule in all countries that have developed national GM food regulatory systems. This is also the case for the Cartagena Protocol on Biosafety, which focuses specifically on living modified organisms (LMOs), defined as “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology”. Very clearly, the Protocol is limited to addressing biosafety concerns that may be associated with the products of modern biotechnology, irrespective of the trait or traits that an LMO may express.

The difference between “novel” vs. “process” triggers for regulatory oversight can be illustrated using the example of herbicide-tolerant canola, varieties of which have been developed using both genetic engineering (for example, glyphosate tolerant) and more established plant breeding tools, such as accelerated mutagenesis (for example, imidazolinone tolerant). Using the former approach, the gene encoding a herbicide tolerant form of a bacterial enzyme (analogous to the same enzyme present in plants) is introduced into the plant genome using recombinant-DNA technology, while with the latter method, mutations in the plant genome are induced by the application of mutagenic chemicals or ionizing radiation. In each case, plants displaying the trait of herbicide tolerance are selected (usually in tissue culture) and the new trait is subsequently transferred into commercially important varieties via traditional cross-breeding. With each technology there is a potential to introduce genetic changes resulting in unintended or unanticipated consequences, and the environmental impact of out-crossing from each of these herbicide-tolerant varieties is the same - recipient progeny could be herbicide-tolerant.

Building upon this example, it is certainly feasible to create glyphosate-tolerant plants using the techniques of accelerated mutagenesis, or similarly to create imidazolinone-tolerant plants using genetic engineering methods. The technology of accelerated mutagenesis has been in use for about 70 years, while the genetic engineering of plants was introduced within the last 20 years, and, in every country other than Canada, the only herbicide-tolerant varieties that are subject to environmental or food safety risk assessment or regulatory oversight are those produced through genetic engineering.

Because the scope of Canada’s regulatory approach is broader than just genetically engineered foods, Canadian regulators have adopted unique terminology and definitions. Rather than referring to GM plants or GM foods, the guidelines and regulations refer to plants with novel traits and novel foods, respectively. As defined in the regulations, a novel food is any food that does not have a history of safe use as a food, or has been manufactured or packaged in a way not previously applied to that food and which causes a significant change in the properties of the food. Novel foods include all GM foods but can also include other foods, such as novel sources of dietary fibre.

Similarly, a plant with a novel trait can be any plant that displays characteristics with which there is no familiarity in that species or that cannot be judged as substantially equivalent to similar traits in other plant species. This can include plants produced through genetic engineering as well as plants produced through accelerated mutagenesis, cell fusion, wide out-crossing, or even conventional cross-breeding.

While Canada’s approach is truest to the scientific principle that biotechnology is not inherently more risky than other technologies that have a long and accepted history of application in agriculture and food production, it presents challenges that are not faced by regulators in other countries. For products that are regulated in the same way because they present equivalent risks, the approach requires that equivalent standards of evidence for safety be upheld. This is increasingly difficult amidst international and other pressures for ever more stringent molecular genetic characterisation and methods of traceability that are geared towards only transgenic plants (and animals). It is more challenging for both developers and regulators to determine when a plant is in fact a “plant with a novel trait”, as defined in Canadian regulations, than the simple test of whether it was produced using

recombinant-DNA (or cell fusion) technology. Additionally, the use of the term “substantial equivalence” within the definition of a novel trait in Canadian regulations has drawn criticism that this much-debated concept is being used as a decision point to exempt certain products from regulatory oversight.

Product movement through the regulatory framework

As previously mentioned, the trigger for regulatory oversight is the novelty of the product rather than the methods used in its production. Within its regulatory framework, Canada has adopted terminology and definitions that are unique among those countries currently regulating biotechnology products. Rather than referring to genetically engineered plants or genetically engineered food products, the guidelines and regulations refer to plants with novel traits (PNTs) and novel foods, respectively (Table 4.4).

Table 4.4: Definitions

Plants with novel traits (PNTs)	A plant variety/genotype possessing characteristics that demonstrate neither familiarity nor substantial equivalence to those present in a distinct, stable population of a cultivated seed in Canada and that have been intentionally selected, created or introduced into a population of that species through a specific genetic change.	Includes plants produced using recombinant DNA (rDNA) techniques, chemical mutagenesis, cell fusion and even conventional cross-breeding.
Novel foods	A substance including a micro-organism, that does not have a history of safe use as a food; A food that has been manufactured, prepared, preserved or packaged by a process that has not been previously applied to that food and causes the food to undergo a major change. A food that is derived from a plant, animal or micro-organism that has been genetically modified such that: <ul style="list-style-type: none"> • The plant, animal or micro-organism exhibits characteristics that were not previously observed in that plant, animal or micro-organism; • The plant, animal or micro-organism no longer exhibits characteristics that were previously observed in that plant, animal or micro-organism; • One or more characteristics of the plant, animal or micro-organism no longer fall within the anticipated range for that plant, animal or micro-organism. 	Includes food products from genetically engineered plants, but also any food product without a history of safe use (e.g. novel fibres, single-cell protein), or an existing food products manufactured or packaged in a manner that results in a major change.
Major change	A change in the food that, based on the manufacturer’s experience or generally accepted nutritional or food science theory, places the modified food outside the accepted limits of natural variations for that food with regard to: <ul style="list-style-type: none"> • The composition, structure or nutritional quality of the food or its generally recognised physiological effects; • The manner in which the food is metabolised in the body; • The microbiological safety, the chemical safety or the safe use of the food. 	

Source: Canadian legislation.

For PNTs and novel foods that may be derived from them, the path from innovation through to commercialisation and marketing is lengthy, costly and subjected to regulatory oversight at a number of points.

Research and Development

All work involving genetic manipulation, including the development of PNTs, is conducted in accordance with voluntary Guidelines for the Handling of Recombinant DNA Molecules and Animal Viruses and Cells, originally published in 1977 by the Medical Research Council of Canada. These Guidelines rapidly caused many research institutions to establish biohazard or biosafety committees. Moreover, the Minister of what was then Health and Welfare Canada stated that the Guidelines would apply to all research carried out or supported by the federal government. The Natural Sciences and Engineering Research Council and the National Research Council of Canada adopted and implemented the Guidelines, as did a number of provincial and private research funding agencies and industrial research centres.

Confined Trials

PNTs that look promising in the laboratory or greenhouse are selected for evaluation in field trials under confined conditions. These trials, which can only be planted after approval from the CFIA, are necessary to evaluate both the agronomic characteristics of the plant and to provide the developer with the opportunity to evaluate safety by collecting the data required to satisfy the regulatory criteria for environmental, food, and feed safety authorisations. The conditions for confinement are mandated by the CFIA and were developed to minimise any environmental impact and prevent any unintended release of the plant into the environment. This means that the transport of seed, planting, cultivation and harvesting of PNTs must be in accordance with strict guidelines and subject to inspection by CFIA staff. These guidelines include provisions to prevent the spread of pollen to other plants, monitoring of the trial site, and post-harvest land use restrictions and inspection of current season and post-harvest trial sites by CFIA inspection staff. Eligibility criteria and performance standards for confined trials are found in Regulatory Directive 2000-07: Guidelines for the Environmental Release of Plants with Novel Traits within Confined Field Trials in Canada (CFIA, 2000).

PNTs are evaluated in confined field trials over a number of years and those that appear to have commercial promise are then subject to rigorous environmental, livestock feed and human food safety assessments before they can be brought to the market.

4.1.2.3. Environmental Safety Assessment

Before any PNT can be grown outside of confined trials, an environmental safety assessment must be completed by scientists at the CFIA. The developer of the PNT submits an extensive data package to meet information requirements that were established by the CFIA in consultation with the scientific community, environmental, consumer and grower groups. Every plant is evaluated on a case-by-case basis and the assessment incorporates an examination of the biology of the PNT as well as its environmental impact. PNTs are compared to their conventional counterparts to see if the new trait(s) they contain have changed the plant in any unintended way.

The environmental safety assessment can be divided into two parts. First the molecular characterisation of the PNT in comparison with its conventional counterpart; and second, the environmental impact of the whole plant, again in comparison with its unmodified complement.

In 1998 the CFIA, the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) and Health Canada harmonised their respective regulatory requirements for the molecular characterisation of PNTs (which in the case of the US, is limited to transgenic plants). Details can be found in the Canada and United States Bilateral on Agricultural Biotechnology Appendix I: Molecular Genetic Characterization Data (CFIA, 1998).

In Canada, information requirements for the environmental impact analysis of a PNT are presented in the Seeds Regulations, Part V and Regulatory Directive Dir 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits, which are summarised below:

- description of the PNT including taxonomy and pedigree of the PNT and details on anticipated use;
- description of the modification: method used to introduce the novel trait(s); molecular characterization if transgenic; parental genome if allopolyploid; data demonstrating stability of the novel traits over multiple generations;
- description of the novel traits: description and activity of gene products, breakdown products, by-products and their metabolic pathways; tissue and/or temporal specificity; description of inducer (if required); toxicity of gene products, breakdown products, and by-products in the environment, including effects on predators, grazers, parasites, pathogens and competitors; and, any potential known adverse effects on human health;
- biology of the PNT: reproductive and survival biology; adaptation to stress factors; if the gene product is toxic data is required on the level of exposure and effect on soil micro flora and fauna;
- agricultural/silvicultural practices: details on proposed release sites; changes in usual habitat or normal geographic distribution for the plant species; changes in cultivation or management practices; and, deployment strategies; and,
- discussion of potential for gene flow from the PNT to related species and details of the consequences of introgression.

4.1.2.4. Stacked events

There is no defined policy for stacked events as yet.

4.1.2.5. Food Safety Assessment

Health Canada is responsible for the safety assessment of all food products, including novel food products under the Novel Food Regulations which came into force in October 1999. Under these regulations a manufacturer or importer of a novel food must notify Health Canada 45 days prior to the sale or advertising for sale of these products. The department undertakes to respond within 45 days should additional safety information of a scientific nature be required and will notify the manufacturer within 90 days of receipt of such information as to whether it is sufficient.

Risks to be assessed relate to major changes brought about by the application of processes to the particular food product which may, based on the manufacturer's experience or generally accepted theory, adversely impact: the composition, structure or nutritional value of the food or its generally recognized physiological effects; the manner in which the food is metabolised in the body; or the microbiological safety, the chemical safety or the safe use of the food.

Safety considerations for foods produced from PNTs are of the same nature as those that arise from other means of altering the genome, such as conventional breeding. Each safety assessment considers a range of both direct and indirect consequences. The former includes the nutritional, toxic or allergenic effects resulting from the presence of new gene products, as well as intentionally altered levels of existing gene products. Indirect consequences would include altered levels of existing gene products or changes in plant metabolism resulting in the production of new components, or altered levels of existing components. The consequences of mutations due to the genetic modification, such as interruption of coding or control sequences or activation of latent genes, leading to new components or altered levels of existing components are also investigated.

In line with internationally accepted practice (FAO/WHO/OECD) Health Canada has developed Guidelines for the Safety Assessment of Novel Foods, Volumes I and II. Volume I provides guidance in classifying a product as “novel” and Volume II contains specifications to manufacturers regarding the data they must provide to regulatory authorities in order to demonstrate the safety of their product.

The safety assessment process examines the new food in comparison with a traditional counterpart that has an established history of safe consumption. This internationally recognised approach has been referred to as the concept of “substantial equivalence”. The aim is to ensure that the new food can be substituted for the traditional food in the diet without adverse nutritional or health consequences. Using the Guidelines for the Safety Assessment of Novel Foods, Health Canada scientists employ a sequential approach that examines:

- how the food crop was developed, including the molecular biological data which characterises the genetic change;
- composition of the novel food compared to non-modified counterpart foods;
- nutritional information for the novel food compared to non-modified counterparts;
- potential for new toxins; and,
- potential for causing allergic reaction.

Safety assessment is fairly straightforward for food components that consist of single-chemical products or well-defined mixtures. However, *“the safety assessment is more complex for undefined mixtures of whole foods. The review may include toxicological and nutritional assessments of the product and a combination of in vitro and in vivo tests”* (McIntyre, 1998).

4.1.2.6. Livestock Feed Safety Assessment

All novel livestock feeds are reviewed by the CFIA for safety and efficacy. Safety considerations include the animal eating the feed, the consumption of the animal product by humans, worker safety and any other environmental impacts related to use of the feed (Dir95-03: Guidelines for the Assessment of Livestock Feeds from Plants with Novel Traits). Data submission for novel feeds include a description of the organism and the genetic modification, the intended use, the environmental fate and a determination of whether the gene products, or their metabolic products, will reach the human food chain. Nutritional, toxicity and stability data are required for the safety assessment.

4.1.2.7. Variety Registration

Canada has a system of variety registration for newly developed crop varieties designed to ensure that only varieties with proven merit are marketed. Varieties are assessed in regional field trials and those selected and supported by national recommending committees move forward for registration. In addition to meeting the standard requirements for variety registration, plant varieties produced through biotechnology cannot be registered, and consequently marketed in Canada, until they have environmental, livestock feed and food safety authorisations.

Regulatory steps in the Risk Assessment of plants with Novel traits can be summarised as follows:

- Step 1:** Contained use of a plant is defined as use within a laboratory, growth chamber, or greenhouse.
- Step 2:** Confined field trials that refer to small test plot of plants that are grown in an open field. Note: before a confined trial can take place, CFIA must undertake an environmental assessment- Stage 1.
- Step 3:** Unconfined field trials for variety registration and seed multiplication purposes. Note: before a confined trial can take place, CFIA must undertake an environmental assessment- Stage 2.
- Step 4:** CFIA must undertake a food and feed safety assessment. Note: food and feed use must be obtained prior to commercialisation, but may sought at any stage of this process.
- Step 5:** Commercialisation. The final step, where applicable, is variety registration. Food and feed or industrial use permits are issued at this step. Even after commercial approval adverse effect monitoring continues.

4.1.2.8. Food Labelling Policies

Various regulations under the Food and Drugs Act and the Consumer Packaging and Labelling Act require manufacturers of food products to include on the labels certain information about the nutrient content (if nutrient claims are made) or the presence of compounds that could result in allergic reaction. Both types of labelling requirement are intended to make the product labels useful to consumers by providing clear, relevant, accurate, readable, informative and non-misleading information. The overall purpose is to enable informed decision making about healthy eating in managing relevant dietary needs.

Health Canada shares the responsibility for food labelling with CFIA under the Food and Drugs Act. The latter is responsible for non-health and safety aspects of labelling, with a focus on consumer protection against fraud and misrepresentation. Health Canada is responsible for health and safety.

In terms of Health Canada's mandate regarding health and safety under the Food and Drugs Act, mandatory labelling would be required for novel foods where safety concerns related to potential allergenicity or major composition and/or nutritional changes may be mitigated through labelling. In this situation, such labels would alert consumers or susceptible groups in the population.

In the case of a food demonstrated to be safe, similar in composition, and nutritionally equivalent to traditional foods already available, Health Canada has no legal mandate to require additional labelling statements.

4.1.3. Argentina

The Argentinean biosafety regulatory system is based on the evaluation of the product and not of the process through which it was obtained. Therefore, the evaluation takes place on a case by case basis, taking into consideration the process only in those cases where the environment, the agricultural production or the health of humans or animals could be at risk.

4.1.3.1. Regulatory Authorities and relevant legislation

The approval process for commercialisation of GMOs involves different agencies within SAGPyA (Secretaria de Agricultura, Ganaderia, Pesca y Alimentos):

- **National Advisory Committee on Agricultural Biotechnology (CONABIA)** in charge of evaluating of impact in the agricultural ecosystem. Ensures compliance with Regulation 39 of July 2003.
- **National Service of Agricultural And Food Health and Quality (SENASA)** responsible for the evaluation of the biosafety of food products derived of GMO crop for human and animal consumption. Ensures compliance with Regulation 412 of May 2002.
- **National Direction of Agricultural Food Markets (DNMA)** evaluates commercial impact on export markets by preparing a technical report in order to avoid a negative impact on Argentine exports. DNMA mainly analyses the status of the event under study in the destination markets in terms of whether the product has been approved or not and, as a result, whether the addition of this event to Argentina's export supply might represent a potential barrier to the access to these markets.
- **National Seed Institute (INASE)** establishes requirements for registration in the National Registry of Cultivars.

Upon completion of all of the steps mentioned above, CONABIA's Office of technical co-ordination compiles all pertinent information and prepares a final report to the Secretary of Agriculture, Livestock, Fisheries and Food for final decision. Regarding its legal and institutional framework, CONABIA is an advisory agency that operates pursuant to a resolution by the Argentine Secretary of Agriculture.

It is worth noting that CONABIA is a multi-sectorial organisation made up by representatives from the public sector, academia and private sector organizations related to agricultural biotechnology. CONABIA members perform their duties as individuals and not as representatives of the sector they represent, and they are active participants in the international debate of biosafety and its related regulatory processes. Additionally, decision-making criteria are exclusively technical and decisions are made through consensus.

Resolution 39 specifies the conditions under which environmental releases of transgenic material should be conducted and is part of the general regulatory system governing the existing agricultural regulations in Argentina related to Plant Protection (Decree-Law of Agricultural Production Health Defense, n° 6704/66 and its amendments), Seeds and Phytogenetic Creations (Seed and Phytogenetic creations law, n° 20.247/73 and its regulatory decree) and Animal Health (Law of Veterinarian Products, and Supervision of Creation and Commercialization, n° 13.636/49).

On February 17, 2006, the Argentine Secretariat of Agriculture issued Resolution 71 that temporarily overrides the two resolutions (Resolution 39 and Resolution 412) that rule over the right a company has to release and trade genetically modified seed in Argentina. This exemption only applies to those corn varieties that carry the RR event known as GA21.

Secretary of Agriculture Campos, for the next 90 days, eased the seed registration rules for companies wishing to register a hybrid variety of RR corn, using the Syngenta GA21 gene. This means that a local company can take the GA21 corn (that is resistant to glyphosate) and cross it with another type of corn, this cross - or hybrid- can then be registered to the local company.

4.1.3.2. Environmental safety assessment

CONABIA is the national advisory commission for agricultural biotechnology and was linked to the Biotechnology office of SAGPyA in 2004. It was originally set up in 1991 by Resolution 124/91 to provide technical support and act as a consultancy body. It defines and administers the Resolutions for the release of GMOs into the environment. The members of CONABIA represent various other public sector bodies as well as private sector companies. CONABIA is responsible for the assessment of applications for the experimental release of GMO events (glasshouse and field trials) and the assessment for release of GMOs into the agricultural environment.

4.1.3.3. Food and feed safety assessment

Food and Feed safety regulation is based on Resolution 412/2002. The assessment uses a risk analysis procedure based on the concept of substantial equivalence.

The SENASA Resolution considers:

- characterisation and concentration of the product;
- nutritional characteristics: composition, nutritional effects associated with genetic modification, alteration of the nutritional properties, or any effect unwanted impact that could result from the gene insertion; and,
- direct effects on health: identification of toxic components suspected to have specific toxic properties, leading to a trend allergic reaction (allergenicity).

In other experiments, it is considered that the approach of substantial equivalence is insufficient and systems are designed to identify any qualitative difference or quantitative terms of traditional plants, and subjected to systematic analysis of toxins.

Table 4.5: List of relevant legislation for agricultural biotechnology crops and food

Resolution number	Legislation related to crops
656/92	Genetically Modified Organisms (crops and micro-organisms for veterinary use)
927/93	Genetically Modified Crops
226/97	Experimental conditions for the isolation distance regarding the release into the environment of genetically modified plants (contained conditions)
289/97	Genetically Modified Crops (Annex for food SENASA)
39/03	Rules for the release into the environment of genetically modified plants
644/03	Production of regulated maize seed
46/04	Register of operators of genetically modified plants (INASE)
212/06	Modification of Resolution No 644/2003 in relation to the authorisation of the production of regulated genetically modified maize seed.
	Legislation related to food and feed
412/02	Requirements for the assessment of food and feed derived from Genetically Modified Organisms. (Issued by SENASA)

Source: FVO report DG SANCO/8118/2006-MR.

4.1.3.4. Traceability

There is no official system in place. To date, only private companies (using authorised labs) have the capability to perform the required tests (for example, the National Institute of Agricultural Technology (INTA) carries out testing on a private basis).

4.1.3.5. Labelling policy for biotechnology products

The current regulatory system is based on the characteristics and identified risks of the product and not the production process of that product. Therefore, there is no regulation governing the use of either positive or negative labelling. Some negative labelling is used by producers on a voluntary basis.

According to SAGPyA, any implementation of a regulatory labelling system should be based on the type of food product derived from a specific GMO taking into account that:

- any food product obtained through biotechnology and substantially equivalent to a conventional food product, should not be subject to any specific mandatory label;
- any food product obtained through biotechnology and substantially different from a conventional food product for any specific characteristic may be labelled according to its characteristics as a food product, not according to aspects concerning the environment or production process;
- differential labelling is not justified, as there is no evidence that demonstrates that food products produced through biotechnology represent any risk for consumer health; and,
- the majority of agricultural products are commodities and as such segregation and an Identity Preservation process would be complicated and expensive. The increased production costs which would result from labelling would be passed on to consumers without any assurance that this would represent better information or increased food security.

4.1.3.6. Stacked events

There is no defined policy for stacked events as yet.

4.1.4. Brazil

The Brazilian regulatory system is based on the strict control of research activities and on a case-by-case evaluation of GMOs in relation to their risk to animal, plant and human life and health and to the environment, taking into account, among other aspects, their conventional and correspondent products. This system is also based on three specific recommendations determined by law: the stimulus to scientific development in the area of biosafety and biotechnology; the protection of human and animal life and health; and, the observance of the precautionary principle for environmental protection according to Articles 1, 10 and 14 of Law 11.105/05.

4.1.4.1. Regulatory Authorities and relevant regulation

The regulatory framework for agricultural biotechnology in Brazil is set out in law 11,105 of 2005, amended by law 11,460 of 2007 and Decree Number 5,591 of 2006. There are two main governing bodies regulating agricultural biotech in Brazil, as follows:

- **The National Biosafety Council (CNBS, in Portuguese).** This Council falls under the Office of the President and is responsible for the formulation and implementation of the national biosafety policy (PNB, in Portuguese) in Brazil. It establishes the principles and directives of administrative actions for the federal agencies involved in biotechnology. CNBS is also responsible for: (i) the assessment of national interest and social and economic implications

regarding the approval for commercial use of biotech products whenever this assessment is requested by CTNBio; (ii) the final decision on the commercial approval of biotech products whenever a legal action against a CTNBIO's decision is submitted to CNBS by the Federal Health Agency, the Federal Environmental Agency, the Ministry of Agriculture, Livestock and Food Supply or the Ministry of Aquaculture and Fishing. It evaluates socio-economic implication and national interests regarding approval for commercial use of biotech products. No safety considerations are evaluated by CNBS. Under the presidency of the Chief of Staff of the President's Office, CNBS is comprised of 11 Cabinet Ministers. A quorum of 6 Ministers is needed for the approval of any relevant subject.

- **The National Technical Commission of Biosafety** (CTNBio, in Portuguese) was initially established in 1995 under the first Brazilian Biosafety law (Law # 8,974). CTNBio is under the auspices of the Ministry of Science and Technology and its main responsibilities are:
- providing technical support and assistance to formulate, update and implement the National Biosafety Policy for GMOs and their by-products;
- authorising, registering and monitoring research activities using GMOs; and,
- issuing the technical opinion, case-by-case, about the biosafety of GMOs and their by-products within the scope of research and commercial use activities.

Imports of any agricultural commodity for animal feed or for further processing, or any ready-to-consume food products and pet food containing biotech events must be pre-approved by CTNBio. Approvals are on a case-by-case basis. As for aspects related to the biosafety of GMOs and their by-products, other administration agencies and entities are bound by CTNBio's technical opinion.

Law 11,105 of March 24 2005, amended by Law 11.460, of March 21 2007, is the biosafety regulatory system that provides the safety norms and inspection mechanisms for all activities that involves GMOs and their by-products. This law establishes that, in the approval process, CTNBio decisions will be taken by favourable votes of the absolute majority of its members.

4.1.4.2. Regulatory Framework for Biotechnology Products

In Brazil, a technology provider must file an application for approval to sell agricultural biotech products with CTNBio. A company must file a single application for each biotech event. CTNBio will evaluate the need for any further environmental impact studies. After the approval of CTNBio, three other ministries have an important role in the registration process:

- Ministry of Agriculture, Livestock, and Food Supply (MAPA) for products used in agriculture, livestock, and agribusiness (processing);
- Ministry of Health, regarding the use of products for humans and pharmaceutical uses; and,
- Ministry of Environment for products that require registration and inspection for use in the natural ecosystem.

Twenty Normative Instructions and two Normative Resolutions related to the analysis of the GMO risk evaluation and to the authorisation and follow-up of GMO research activities have been published by the National Biosafety Technical Commission (CTNBio, 2008).

Of these, the most important are:

- Normative Resolution No 01/06 which deals with an applicant company's Internal Biosafety Commission (CIBios) responsibilities and Biosafety Quality Certificate (CQB) issuance;
- Normative Resolution No 02/06 on GMO risk classification;

- Normative Resolution No 03/96 related to the procedures for planned release of GMO (research); and,
- Normative Instruction No 20 listing the evaluation norms for food and feed safety of GMOs and their parts.

4.1.4.3. Food safety assessment

The Brazilian legislation details procedures and criteria relating to the authorisation of GMO field trials. These include criteria and procedures for the request, issuance, review, extension, suspension and cancellation of the Biosafety Quality Certificate (CQB) which is required for all research institutes that intend to develop projects and activities for experimental release of GMOs. Normative Instruction No. 03/1998 deals with the requirements and procedures for authorisation of a GMO field trial while Normative Instructions No 1 and No 2 deal with the criteria for experimental release.

Figure 4.1 presents the steps necessary to obtain experimental approval.

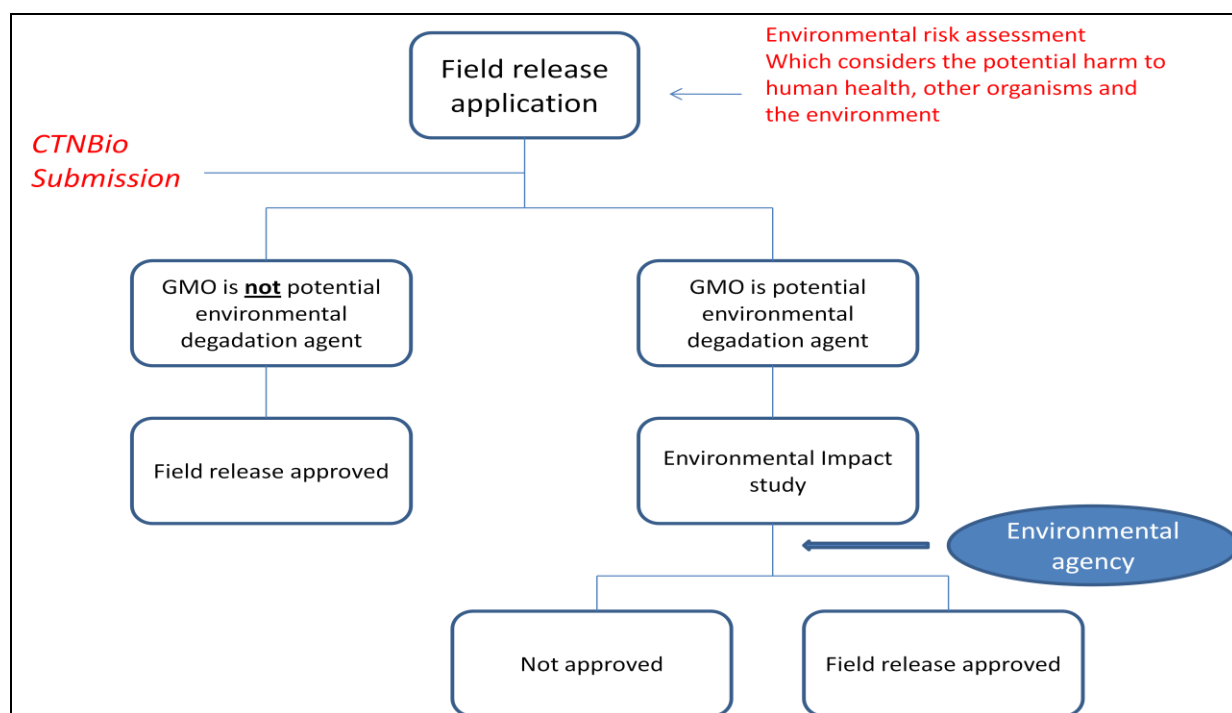


Figure 4.1: Steps for experimental approval

Source: CTNBio.

4.1.4.4. Commercial approval

The steps necessary to obtain commercial approval are presented in **Figure 4.2**.

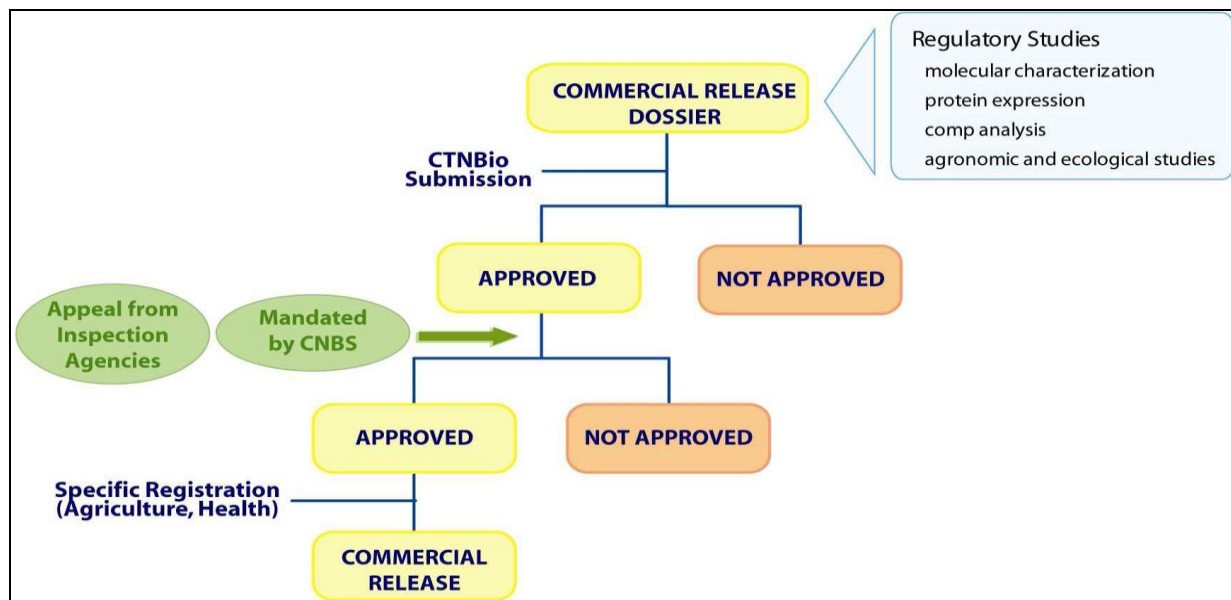


Figure 4.2: Steps for commercial approval

Source: CTNBio.

4.1.4.5. Food Labelling Policies

Packed food and feed containing GMOs and their by-products, at a concentration of 1% or higher, are required to be labelled as “genetically modified (product)” or “contains genetically modified (ingredient)”, according to Decree 4680/03. The Executive Order also declared that consumers need to be informed of the biotech nature of the product.

A symbol for transgenic content, a triangle with a T on a yellow background, was designated. The regulation also applies to the unintended presence of GMOs in food products. In the scope of this legal instrument, labelling is perceived as a consumer’s right to information and not in relation to food safety *per se*. However, the yellow triangle label can be considered to be misleading because it is associated with a warning for “caution”. To date, this Decree has not been enforced by the legal authorities, and products labelled “genetically modified” are not usually found on the market (CTNBio, 2008; Mendonça-Hagler *et al.*,2006a).

The previous Regulation (Executive Order Number 3871 of July 18, 2001) established a 4% threshold which was considered too high by environmentalists and consumer groups. Executive Order 4680/03 revoked Executive Order 3871.

Directive Number 2658/03 approves the regulations for the use of the transgenic logo. It applies for biotech products for both human and animal consumption where GM content exceeds 1%.

4.1.5. Japan

4.1.5.1. Regulatory Authorities and relevant regulation

In Japan, the commercialisation of biotech plant products requires environment, food and feed approvals. Four ministries and one agency are mainly involved in the regulatory framework for agricultural biotechnology:

- Ministry of Agriculture, Forestry and Fisheries (MAFF);
- Ministry of Health, Labour and Welfare (MHLW);
- Ministry of Environment (MOE);
- Ministry of Education, Culture, Sports, Science and Technology (MEXT); and,
- Consumer Affairs Agency (CAA).

Those ministries and agency act as a secretariat in the regulatory framework to obtain the approval of the appropriate ministers. Risk assessments and safety evaluations are performed by each ministry's advisory committees and scientific expert panels. The scientific assessments and evaluations are performed by the scientific expert panels, which mainly consist of researchers of universities and public research institutions. Food feed safety, the decisions by the expert panels are reviewed or consulted by the advisory committees whose members include technical experts and opinion leaders from a broad scope of interested parties such as consumers and industries. The advisory committees report back the decision to the responsible ministries.

4.1.5.2. Environment safety assessment

Japan ratified the Biosafety Protocol in November 2003 and introduced a law (Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms, "Cartagena Law") in February 2004. Under this law, MEXT requires ministerial approval for LMOs in the phase of research and development before permitting early stage agricultural biotech experiments in laboratories and greenhouses (Type 2 use). MAFF and MOE require joint ministerial approval for the use of biotech plants in an isolated field for the evaluation of influences on biodiversity (Type 1 use). After the necessary scientific data are collected through the isolated field experiments, with permission from MAFF and MOE Ministers, a risk assessment for the commercialisation of the event is carried out through the use of field trials (Type 1 use as well). A joint MAFF and MOE expert panel then carries out the environmental safety evaluations for Type 1 use. Currently, non -food biotech plant products, such as flowers, may be produced commercially, though once the Type 1 use risk assessment of many biotech plants has been completed.

4.1.5.3. Stacked events

Japan requires separate environment approvals for stacked events, although it is not always necessary to carry out additional field trials. While MAFF and MOE require an environment safety review to be carried out by their experts, the data and information on the parent lines may be used and it is generally unnecessary to carry out field trials on the stacked event itself.

4.1.5.4. Food safety assessment

Biotech plants that are used for food must obtain food safety approvals from the MHLW Minister. This approval is based on the Food Sanitation Law and follows a petition for review from an interested party (either, but not limited to, the biotech company or industry). The MHLW minister will then request the Food Safety Commission (FSC) to review the food safety of the biotech products. The

FSC is an independent government organisation under the auspices of the Cabinet Office which was established to perform food safety risk assessments by expert committees. Within the FSC is a Genetically Modified Foods Expert Committee which carries out the scientific review and is comprised of plant biotech scientists from universities and public research institutes. Upon completion, the FSC provides its risk assessment conclusions to the MHLW Minister. The standards used by the FSC for food risk assessment of biotech foods are available in English at the following website: http://www.fsc.go.jp/senmon/idensi/gm_kijun_english.pdf.

With respect to food safety approvals, the FSC presented an opinion paper on January 29, 2004 on its reviews of crossed events between biotech and non-biotech events and stacked events. In this paper, the FSC categorised biotech events into three categories:

- introduced genes which do not influence host metabolism and mainly endow the hosts with insect resistance, herbicide tolerance or virus resistance;
- introduced genes which alter host metabolism and endow the hosts with high nutritional component concentration or suppression of cell wall degradation by promoting or inhibiting specific metabolic pathways; and,
- introduced genes which utilise certain metabolites to synthesise new metabolites which the hosts would not otherwise produce.

The FSC requires a safety approval on the crossed event if the crossing occurs above the sub-species level between a biotech event and a non-biotech event, and if the crossing occurs between biotech events in category 1. The FSC also requires safety approvals on stacked events between those in category 1 if the amount consumed by humans, the edible part or processing method is different from that of the parents. The FSC requires safety approvals on stacked events between biotech events in categories 1 and 2, 1 and 3, 2 and 2, 3 and 3, and 2 and 3. Up to now, most stacked events that result from traditional cross-breeding have not required a safety review.

4.1.5.5. Feed safety assessment

Biotech products that are also used as feed must obtain approvals from the MAFF Minister based on the Feed Safety Law. Upon requests from petitioners, the MAFF Minister asks the Experts Panel on Recombinant DNA Organisms, which is part of the MAFF affiliated Agricultural Materials Committee (AMC), to review the event. The Expert Panel evaluates feed safety on livestock animals, which is then reviewed by the AMC. The MAFF Minister also asks the FSC Genetically Modified Foods Expert Committee to review any possible human health effects from consumption of livestock products from animals fed with biotech event under review. Based on the reviews of AMC and FSC, the MAFF Minister grants approval for the feed safety of biotech plants.

For feed safety of stacked events, MAFF requires approvals from the Expert Panel on Recombinant DNA Organisms of the Agricultural Material Committee (AMC). Unlike the feed safety full approvals, the approvals by the Expert Panel are neither subject to MAFF Minister notification nor public comments.

Figure 4.3 presents a schematic chart of the approval process. Biotech products that require new standards or regulations not related to food safety, such as labelling or new risk management procedures including IP handling protocols, may need to be discussed by the Pharmaceutical Affairs and Food Sanitation Council of MHLW, and/or Japan Agricultural Standards Council of MAFF.

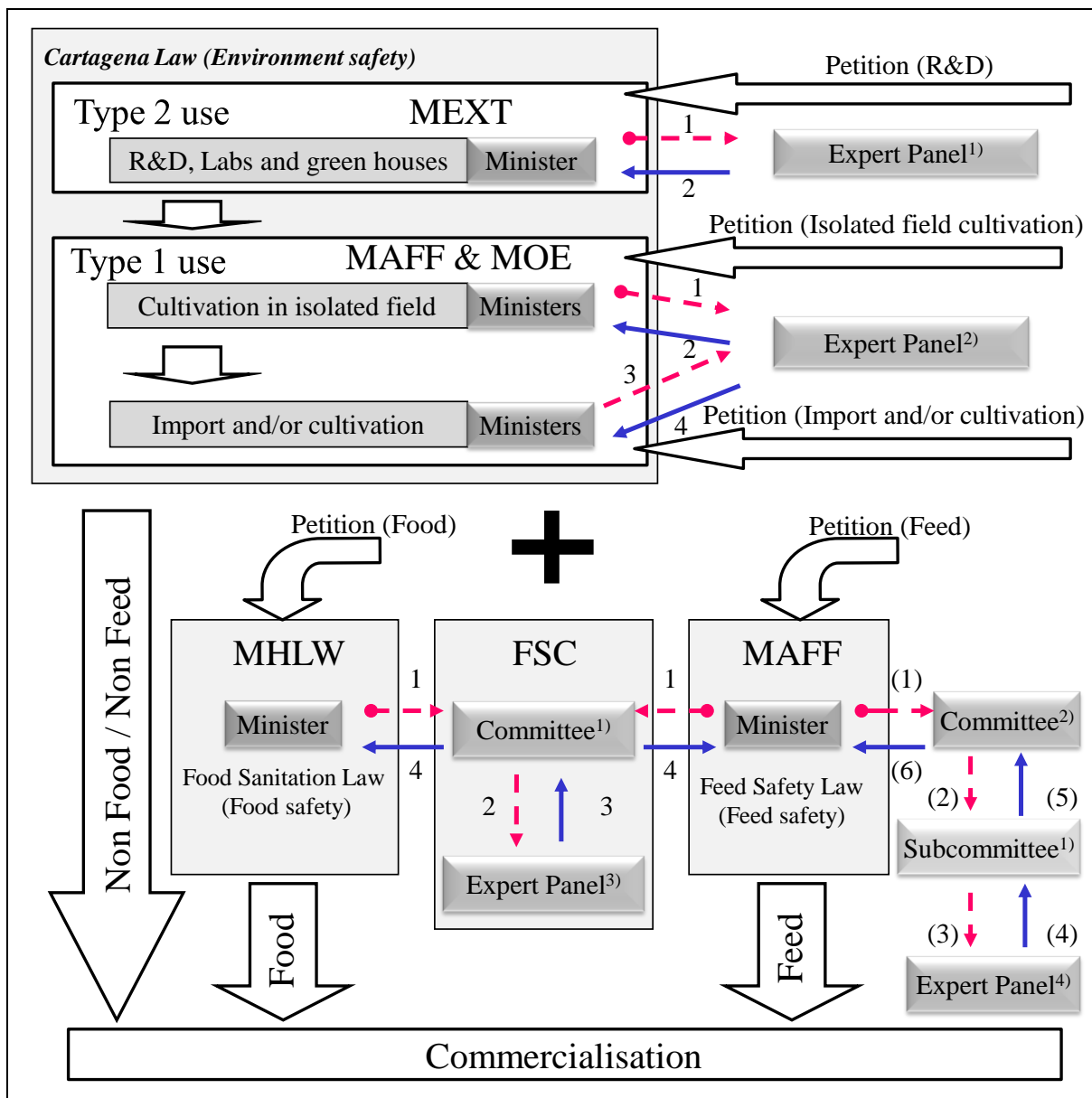


Figure 4.3: Schematic presentation of the Japanese approval process

Source: MAFF.

Notes:

Expert Panel 1): Expert Panel on Recombinant DNA Technology, Bioethics and Biosafety Commission, Council for Science and Technology, MEXT.

Expert Panel 2): Experts with special knowledge and experience concerning adverse effect on biological diversity selected by MAFF/MOE Ministers.

Expert Panel 3): Genetically Modified Foods Expert Committee, FSC.

Expert Panel 4): Expert Panel on Recombinant DNA Organisms, Agricultural Materials Council, MAFF.

Committee 1): Food Safety Commission.

Committee 2): Feed Committee, Agricultural Materials Council, MAFF.

Subcommittee 1): Safety Subcommittee, Feed Committee, Agricultural Materials Council, MAFF.

Red (broken) arrow: Request for review or risk assessment.

Blue (solid) arrow: Recommendation or risk assessment results (thick arrows: with public comment periods).

Numbers beside the arrows indicate the order of requests/recommendations within the respective ministries.

Petitions for products within the R&D stage are reviewed first for Type 2 use under the Cartagena Law and those for import and/or cultivation (products in the R&D stage whose safety has already been confirmed) are reviewed for Type 1 use, and food and/or feed, as necessary. Petitions for products imported only as non-LMO such as processed foods are reviewed only for food and/or feed review.

This chart outlines the principle flow of the approval procedure in Japan, although the process may vary depending on the nature of individual biotechnology products.

4.1.5.6. Labelling policy for biotechnology products

MAFF and MHLW have implemented labelling requirements under the Japan Agricultural Standards (JAS) Law and the Food Sanitation Law, respectively for biotech products that have been approved in Japan. MAFF introduced the biotech labelling aims to respond to a demand of “the consumers’ right to know” while MHLW introduced its labelling from a more scientific standpoint to clarify that the biotech ingredients used are those whose safety has been confirmed. Although the labelling requirements for the Ministries are listed separately, both sets of requirements are basically identical. The labelling policy on biotech traits can be found at the MAFF website: <http://www.maff.go.jp/e/jas/labeling/pdf/modi01.pdf>.

The Consumer Affairs Agency (CAA) was established in September 2009 and took over responsibility for food labelling policy which had previously been administrated by MAFF and MHLW. CAA is required to consult with the consumer commission, a body consisting of consumer affairs experts, when it changes the food labelling policy.

Thirty-two foods are currently subject to JAS labelling requirements (and Food Sanitation Law labelling requirements). Selection was made from ingredients that could include biotech products and because traces of introduced DNA or protein can be identified in the foods. If the weight content of the ingredient to be labelled in these 32 foods exceeds 5% of total weight of the foods, they must be labelled with either the phrase “Biotech Ingredients Used” or “Biotech Ingredient Not Segregated” if the raw ingredient does not accompany certificates of the IP handling. In order to be labelled with either the phrase “Biotech Ingredients Used” or “Non-Biotech”, the processor must be able to show that the ingredient to be labelled was Identity Preserved from production through processing according to the above manuals.

In addition to the 32 food items, Japan applies the biotech labelling to the biotech high oleic acid soybean products even though the oil extracted from the soybean does not contain traces of the introduced genes or proteins.

Japan recognises that even though proper IP handling and distribution methods are used, the possibility exists for adventitious co-mingling of biotech products in non-biotech products. Therefore, for corn and soybeans, Japan set an informal tolerance level of 5% for biotech ingredients in products that are labelled “non-biotech”. This tolerance only applies to events that have been approved in Japan. If “non-biotech” labelled products includes biotech (corn and/or soybeans) over 5%, it is recognised that the IP handling has not been carried out adequately. The regulatory authorities order the manufacturer or importer to present the IP handling certificates to verify them and issues guidance directing it to correct the product label to show that it was made with “Biotech Ingredients”.

4.1.6. China

4.1.6.1. Regulatory Authorities and relevant regulation

The Ministry of Agriculture (MOA) is the primary institution in charge of the formulation and implementation of biosafety regulations on agricultural GMOs and their commercialisation. In order to incorporate representation of stakeholders from different ministries, the State Council established an

Allied Ministerial Meeting comprising leaders from the MOA, the State Development Planning Commission (SDPC), the Ministry of Science and Technology (MOST), the Ministry of Public Health, the Ministry of Foreign Economy and Trade (MOFET), the Inspection and Quarantine Agency and the State Environmental Protection Authority (SEPA). Decree 304 of the State Council provides for the establishment of an Inter-ministerial Joint Conference System for the safety management of agricultural to secure co-ordination and communication.

This Allied Ministerial Meeting co-ordinates key issues related to the biosafety of agricultural GMOs, examines and approves the applications for GMO commercialisation, determines the list of GMOs for labelling and establishes import or export policies for agricultural GMOs and their products. The routine work and daily operations are handled by the Office of Agricultural Genetic Engineering Biosafety Administration (OGEBA) under MOA.

The General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) is responsible for nationwide management of the inspection and quarantine for entry and exit of all GMO products. AQSIQ's local entry and exit inspection and quarantine agencies are responsible for the inspection and quarantine of entry and exit GMO products within each jurisdiction. AQSIQ's Ministerial Decree 62 (CH4017) governs the steps that should be taken at customs when importing or exporting biotechnologically enhanced goods.

The China's State Environmental Protection Administration (SEPA) has the lead authority for the Biosafety Protocol, which China ratified on April 27, 2005, and thus is charged with developing implementing regulations. Although SEPA has taken the responsibility of international biosafety protocol, its focus on biotechnology in China is limited to biodiversity.

The Ministry of Science and Technology (MOST) has also been an active participant in the development of biotechnology policy and implementation. MOST also manages a large amount of central government funds that are distributed to Chinese institutes researching new strains of biotech seeds and foods.

The Ministry of Public Health (MPH) is responsible for food safety management of biotechnology products (processed products based on GMOs). The Appraisal Committee, consisting of food health, nutrition and toxicology experts nominated by MPH is responsible for reviewing and assessing GM foods since they have been designated a novel food.

The biotechnology regulatory environment for agriculture outlined in the State Council's regulations "*Food and Agricultural Import Regulations and Standards; Agricultural Genetically Modified Organisms Safety Administration Regulations 2001*" (CH1056) is largely governed by MOA's implementing regulations, Ministerial Decrees 8, 9 and 10.

These decrees: *Measures on the Safety Evaluation Administration of Agricultural GMOs*, *Measures on the Safety Evaluation Administration of Agricultural GMO Imports*, and *Measures on Agricultural GMO Labelling Administration* (CH2002) cover domestic approval, import approval and labelling respectively.

China requires U.S. regulatory approval for a product before a product may apply for approval in China. This system makes it impossible to apply simultaneously in both markets and thus causes a delay in bringing U.S. agricultural biotechnology products to the Chinese market.

China has only two windows a year when companies can submit applications for new products, one in March and another in September.

4.1.6.2. Stacked events

At the moment China's regulations do not cover stacked events and thus no formal approval process for stacked events exists. However, China has approved some stacked events for local cultivation and

officials have indicated that China will consider approval for importation of products with stacked events for processing on a case-by-case basis. China has not decided how it will regulate this area in the future.

4.1.6.3. Environment safety assessment

The approval process for biotechnology products involves five steps: research, pilot experiment, environmental release, experimental production, and safety certification. Safety certificates are issued by the MOA's Biosafety Office of Agricultural GMO, and apply only in the provinces for which certification was requested, i.e. safety certification is not necessarily national. The Biosafety Office of Agricultural GMO delegates testing to the National Biosafety Committee. The following steps are taken exclusively for products that will undergo local development and cultivation.

- First the applicant must assemble the appropriate materials as outlined in Decree 8, including a report on experimental research the applicant has already undertaken.
- After submitting the materials and following review by MoA's Biosafety Office of Agricultural GMO, the applicant may begin "Medium testing", which comprises controlled, small-scale tests in a controlled environment.
- Upon completion of the tests and passing the safety examination of the National Biosafety Committee, an application is made back to the Biosafety Office of Agricultural GMO to begin the next round of testing known as "environmental release". Environmental release is a medium-scale test in the natural environment with specified safety precautions.
- Upon completion of these tests and passing the safety examination of the National Biosafety Committee, a further application is made to the Biosafety Office of Agricultural GMO to begin the final round of testing known as "production testing". Production testing is large-scale testing conducted prior to final approval.
- Finally, after passing the safety evaluation of the National Biosafety Committee, the applicant may apply to the Biosafety Office of Agricultural GMO for a safety certificate. Upon receipt of the application the Biosafety Office of Agricultural GMO will arrange for the National Biosafety Committee to conduct a safety evaluation.

The applicant, upon passing the evaluation, is granted the safety certificate and is allowed to move on to the usual examinations, registrations, evaluations and approval formalities.

4.1.6.4. Labelling policy for biotechnology products

China's labelling regulations, governed by Ministry of Agriculture Decree 10 (CH2002), require agricultural biotech products listed in the regulations be labelled and prohibits the importation and sale of any unlabelled or mislabelled products. The listed products are:

- Soybean seed, soybean, soybean powder, soybean oil and soybean meal.
- Corn seeds, corn, corn oil and corn powder.
- Rape seed for planting, rape seed, rape oil and rape meal.
- Cotton seed.
- Tomato seed, fresh tomato and tomato jam.

Decree 10 states that the reason for the regulation is "*to strengthen the administration of Ag GMO labelling, standardise the selling activities of Ag GMOs, guide the production and consumption of Ag*

GMOs and protect consumers' right to be informed". The regulations spell out the type of labelling required as well as the specific language that is required on the individual labels.

4.1.6.5. Process for commercialising new GM plant varieties in China

In China, a company must obtain an Agricultural Biotechnology Safety Certificate ("Safety Certificate") to (1) produce or import GM seeds for domestic cultivation; or, (2) to import GM plant varieties for processing. When a company applies for a Safety Certificate, MOA assigns the new GM plant variety to a risk category: no risk, low risk, medium risk, or high risk. Any research on a GM plant variety in the medium or high-risk category requires MOA's prior approval. Any importation or domestic production of a new GM plant variety requires MOA's prior approval regardless of the anticipated risks.

4.1.6.6. Production or Importation of GM Seeds for Domestic Cultivation

To obtain a Safety Certificate to produce or import GM seeds for cultivation, an applicant must undertake a five-step testing program: (1) experimental (laboratory) research; (2) a "medium test" (small-scale research in a controlled environment); (3) environmental release testing (medium-scale field testing with appropriate precautions); (4) production testing (large-scale, pre-production field testing); and, (5) applying for the Safety Certificate itself, which requires reports from the prescribed testing and a report prepared by an MOA-approved safety institute in China.

Starting with the medium test, a company must obtain prior approval from the Agricultural Biosafety Office. The Agricultural Biosafety Committee reviews and approves all test reports at and beyond the medium test and also approves progression from one testing stage to the next. For this purpose, the Agricultural Biosafety Committee collects test reports on March 31 and September 30 of each year and meets twice each year to review the test reports. MOA makes final decisions in individual cases within 20 days of receiving the Agricultural Biosafety Committee's evaluation report.

Importing GM Plants for Domestic Processing

To obtain a Safety Certificate to import a GM plant variety for processing, an applicant must submit the following to the Agricultural Biosafety Office: (1) an import safety administrative form; (2) a safety evaluation application letter; (3) proof of the exporting country's approval of the GM plant variety for commercial use; (4) data developed in the exporting country on the GM plant variety's safety; (5) testing from an MOA-qualified laboratory demonstrating the safety of the GM plant variety; and, (6) measures taken during export to ensure the GM plant variety's safety. The Agricultural Biosafety Committee evaluates the applicant's safety data and develops a recommendation, based on which the MOA makes a final decision to approve or deny the proposed importation.

4.1.7. India

4.1.7.1. Regulatory Authorities and relevant regulation

Rules have been notified by the Ministry of Environment and Forests (MoEF) in 1989 under the Environmental Protection Act, 1986 (EPA), as responsibility for the production and preservation of the environment rests with the government. These rules cover procedures for the manufacture, import, use, research and release of GMOs as well as products made by the use of such organisms. The objective of the rule is to ensure that the use of such products or life forms is environmentally safe and beneficial to humans. The Competent Authorities, and their composition, for dealing with all aspects of GMOs and products are also defined.

Guidelines for safety were issued by the Department of Biotechnology (DBT) in 1990 covering research in biotechnology, field trials and commercial applications. DBT had also brought out separate guidelines for research in transgenic plants in 1998 and for clinical products in 1999. Activities involving GMOs are also covered under other policies such as the Drugs and Cosmetics Act (8th Amendment), 1988, the Drug Policy, 2002, and the National Seed Policy, 2002.

There are currently six Competent Authorities for the implementation of regulations and guidelines:

- Recombinant DNA Advisory Committee (RDAC).
- Review Committee of Genetic Manipulation (RCGM).
- Genetic Engineering Approval Committee (GEAC), (apex bodies) is under the Ministry of Environment and Forests. This is the agency that gives permits for commercial production of GM crops, large-scale field trials of GM crops, and the imports of GM commercial products.
- Institutional Biosafety Committee (IBSC) attached to every organisation engaged in rDNA research.
- State Biosafety Coordination Committees (SBCC).
- District Level Committees (DLC).

The Genetic Engineering Approval Committee (GEAC) has been authorised as the inter-ministerial body under the Ministry of Environment and Forests to be the authority to permit any manufacture, use, import, export and storage of hazardous micro-organisms and genetically modified organisms or cells. In practice, it is the Review Committee on Genetic Manipulation (RCGM) under the Department of Biotechnology that is currently authorising research up to limited field trials and also imports of GM material for research purposes.

Of the above committees, the IBSC is constituted by organisations involved in research with GMOs with the approval of DBT. The IBSC is the nodal point for interaction within the institution for implementation of the guidelines. Every research project using GMOs has to have an identified investigator who is required to get the research project approved from the safety angle and inform the IBSC about the status and results of the experiments being conducted. This committee shall be constituted by an occupier or any person including research institutions handling microorganisms/genetically engineered organisms. The committee shall comprise the Head of the Institution Scientists engaged in DNA work, a medical expert and a nominee of the Department of Biochemistry.

The functions of IBSC include:

- reviewing and giving clearance to project proposals falling under restricted category as per DBT guidelines;
- recommending Category III risk or above experiments to RCGM for approval;
- tailoring biosafety programme to the level of risk assessment;
- training of personnel on biosafety; and,
- adopting emergency plans.

The role of IBSC assumes major importance since it is the only Statutory Committee, which operates from the premises of institutions and hence is in a position to conduct onsite evaluation, assessment and monitoring of adherence to the biosafety guidelines. The decisions taken by the next higher committee i.e. Review Committee on Genetic Manipulation (RCGM), which operates from DBT are

based on the applications submitted by the investigators with the approval of IBSC on the status of the project and its conformity with the regulatory guidelines.

4.1.7.2. Labelling policy for biotechnology products

For GM Foods, there is now a proposed legislation to make labelling mandatory under the Prevention of Food Adulteration Act, under the auspices of the Ministry of Health & Family Welfare. The PFA will itself be replaced by the new Food Safety & Standards Act, which passed through Parliament in the monsoon session of 2006. This new law will also have implications for GM regulation in the country.

4.1.8. Comparison of Third Country regulatory frameworks

There are large differences in import approval and marketing policies for GM food and feed worldwide. At a global level, countries can be divided in three groups according to the status or type of their regulation.

- Countries with a comprehensive and stringent regulatory framework for GM food, including mandatory labelling and mandatory safety approval.
- Countries that have adopted a regulatory approach based on the notion of substantial equivalence, with voluntary labelling rather than mandatory labelling.
- A large number of developing countries that either do not have any approval or marketing regulations for GM food, are in the process of adopting some, or have declared themselves to be GM free.

Countries in the first group fall in two main categories: those whose regulatory procedure depends on the difference between products and those whose regulatory procedure depends on the production process (i.e. also regulating products derived from GM products).

At the international level, harmonisation efforts are led by the *Codex Alimentarius* Commission and the Cartagena Protocol on Biosafety (CPB). While international harmonised guidelines for safety approval have been finalised at *Codex Alimentarius*, there is no clear consensus on labelling regulations for GM food. Food and unprocessed products are subject to more stringent regulations than animal feed and processed products. As a consequence, international regulations are likely to have greater effect on international trade in potential GM food crops than on the current GM crops mostly used for animal feed, processed food, or non-food uses.

Table 4.6 shows that, in particular, both Japan and the European Union, two influential importers, have implemented stringent import-approval regulation and mandatory labelling requirements for GM food.

Table 4.6: Characteristics of trade-related regulations in major GM using countries in 2006

Countries	Food safety approval regulations	Labelling regulations	Specificities
EU	Process-based mandatory	Stringent mandatory, includes derived products	Traceability requirements, 0.9% threshold for adventitious and technically unavoidable presence
Brazil, China, Russia	Process-based mandatory	Stringent mandatory, includes derived products	No traceability, low threshold
Australia, Japan, Korea, Saudi Arabia, Thailand, Taiwan	Process-based mandatory	Mandatory labelling based on product content	With labelling exemptions, 1 to 5% threshold levels
USA, Canada, Argentina, Hong Kong, Philippines, South Africa	Substantial equivalence mandatory (USA: voluntary consultation)	Voluntary for substantial equivalence	5% threshold level for labelling
Chile, Ecuador, Indonesia, Vietnam	Mandatory (in place or pending)	Mandatory, introduced but not implemented	Product-based labelling
India, Kenya	Mandatory (in place or pending)	Intention to require labelling	Slow regulatory process
Bangladesh, most African countries	Considering mandatory	Intention to require labelling	Wait and see approach
A few African countries	No	No	GM free

Source: Gruère (2007).

The following elements characterise the individual regulatory framework of the Third Countries considered in detail in this analysis.

USA:

- Regulation focuses primarily on the characteristics of the products;
- Product-based, case-by-case safety assessment;
- Environment, Food and Feed safety assessment;
- Voluntary labelling.

Canada:

- Regulation based on plants with novel traits (PNTs). (These can be produced through conventional breeding, mutagenesis or recombinant DNA techniques.);
- No specific regulation has been created specifically for GMO;
- Environment, Food and Feed safety assessment;
- Voluntary labelling.

Brazil:

- Recent law adapted with respect to the development, import, use and commercialisation of biotechnology products;
- Quite similar to the EU regulation;
- Process-based approach;
- Mandatory labelling on any packed food products (plants AND animal products).

China:

- China is progressing rapidly with Biotech regulation in light of national food issues;
- Import approval process similar to other major countries;
- Labelling regulation widely implemented but without clear threshold.

Japan:

- Process-based mandatory;
- Environment, Food and Feed safety assessment;
- Labelling regulation designed to be easily implemented.

Argentina:

- Product-based approach;
- Mirroring authorization process to the EU;
- Similar to North-American models.

India:

- Mandatory food safety regulation;
- Slow regulatory process not fully defined yet.

The main comparative elements in relation to the EU regulation can be listed as follows in (**Table 4.7**).

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

Table 4.7: Main comparative elements in relation to the EU regulation

	Argentina	Brazil	Canada	China	India	Japan	USA	EU
<i>Food safety approval regulations</i>								
mandatory based on product vs. mandatory based on process	Product	Process	Product ⁶¹	Process	(pending)	Process	Product (voluntary consultation)	Process
<i>Type of labelling</i>								
Existence of enforced policy labelling	Partly	Partly	Yes	Yes	No	Yes	Yes	Yes
GMO labelling	Voluntary	Mandatory	Voluntary	Mandatory	Mandatory	Mandatory	Voluntary	Mandatory
Coverage	Not specified – all products based on contents Mandatory labelling for seed	Food, feed, products from GM, meat and animal products	all products based on contents	List, products derived from GM, restaurants		List of food items	all products based on contents	Food, feed, additives, flavourings, products derived from GM, restaurants
Major exemptions		None		Outside the list		Processed products		livestock products
Threshold level (%)	5	1		To be defined		5 on three main ingredients		0.9
Specificities		No traceability		No traceability		Labelling exemptions for		Traceability requirements

⁶¹ Canada is the only country that has not developed a specific regulation dedicated to GMO, but instead has integrated provision in existing Novel Plant Regulation.

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	Argentina	Brazil	Canada	China	India	Japan	USA	EU
						list of processed products		Post-marketing monitoring required
<i>Threshold for unauthorised events</i>								
Food (%)	0	0	0	0	0	0	0	0
Feed (%)	0	0	0	0	0	1 (if authorised in another OECD country)	0	0
Specific risk assessment for stacked events	No	No	No	No		Yes (partly)	No	Yes