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

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Executive Summary

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1. Executive summary

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1.2. The risk assessment and regulatory approval process

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

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

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

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

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

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

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

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

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

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

1.3. The compulsory labelling of GM food and feed

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

The labelling provisions provide the consumer with the possibility to make an informed choice, although there are some doubts as to whether consumers have the necessary knowledge to make an informed choice. Consumers that are concerned about GM content are certainly able to find information, however, a significant minority of Competent Authorities and stakeholders do not believe

that consumers understand and accept the labelling provisions and, if this is the case, the provisions may not be entirely facilitating an informed choice.

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

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

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

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

The vast majority, 85%-90% of compound feed is labelled as GM, up to 95% of soybean imports are labelled as GM and these proportions have been increasing as planting of GM events increases. There is a relatively small niche market of non-GM feed for the “organic” segment and non-GM supply chains. Food markets have evolved towards the dominant use of non-GM supply chains and the conventional feed sector (more slowly) towards the dominant use of GM supply chains. The labelling regulations played only a limited role in these evolutions. Mandatory labelling requirements were introduced after market forces had determined the direction and pace of market evolution in the late 1990s and early 2000s. In the case of food products, these factors were mostly internal to the EU consumer market. In the case of feed, they were largely external.

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

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

It is not clear if any extension to labelling could be imposed on and controlled in terms of imports from Third Countries. An extension to labelling scope which included processed products would considerably increase the scope of labelling, and would be more complicated, but may also be more logical from a consumer point of view.

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

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

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

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

1.4. Public acceptance

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

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

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

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

Whilst it is clear that there is least some public sensitivity with regard to the use of GM feed, probably at least partly due to the exclusion of livestock products from the scope of labelling, the relative public sensitivity in terms of GM cultivation and GM food is more nuanced. CAs believe that there is more sensitivity with regard to cultivation whereas stakeholders feel that sensitivity is more similar between this and GM use in food.

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

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

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

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

1.5. Recommendations

Authorisation process

- The majority of stakeholders and Competent Authorities were in favour of leaving the responsibility for the risk assessment with EFSA (*status quo*).
- Stakeholder views were united on the need to allow for some form of public comment during the risk assessment process, but were divided on the exact form this should take.
- There is majority support for an approach to stacked events which uses a fast-track risk assessment combined with the current risk management procedure; such a system could be considered akin to the *status quo*.
- Efforts should continue to ensure that applicants submit the correct information in the correct format to EFSA to facilitate the authorisation process. The soon to be released new guidelines are therefore welcomed.
- Half of stakeholders and the majority of Competent Authorities were also in favour of maintaining the status quo with regard to risk management (i.e. the Commission takes a decision after consulting Member States).
- The constraints of the comitology procedure notwithstanding, continuing efforts should be made by the European Commission to table Draft Decisions in a timely fashion. As the number of applications received increases it will be necessary to ensure that the risk management process does not become a bottleneck.
- The majority of Competent Authorities and stakeholders believe that some kind of solution for the adventitious and technically unavoidable presence of unauthorised GM material is required other than zero tolerance.
- Maintaining the zero tolerance policy for adventitious and technically unavoidable presence of unauthorised GM material is likely to result in an increased number of Low Level Presence LLP) incidents as the global use of GM crops increases. The fact that these are alerted under the Rapid Alert System for Food and Feed (RASFF), which is concerned with safety issues, is seen as inappropriate by some stakeholders. It is clear that a way has to be found to reduce the number of LLP incidents.

- While the impact of asynchronous authorisations can at least be addressed, partly by closing the gap between EU and Third Country authorisations, asymmetric authorisations pose a different challenge because there is no intention here (or motivation) for developers of events to seek authorisation in the EU because there is no intent to export to the EU. International co-operation will therefore be required to address this issue.
- The majority of Competent Authorities and stakeholders are in favour of the use of independently generated data in risk assessments where this is possible and where it can be used to supplement data generated by the applicant (this is allowed for under the current system).
- The overall risk assessment system should be re-examined as necessary in the light of future developments in the biotech sector to ensure the continued protection of consumers, animal welfare and the environment.
- Competent Authorities were split over the explicit and systematic inclusion of socio-economic criteria in relation to GM food and feed. Stakeholders on the other hand were generally against their inclusion.
- The EU and Member States should actively consider what an appropriate balance is between economic risk and potential benefits of adopting plant biotechnology or not.

Labelling

- The majority of Competent Authorities were in favour of maintaining the status quo with respect to the use and scope of positive labelling, although stakeholder opinion was more divided.
- A majority of Competent Authorities support the use of some form of negative labelling (i.e."GM-free"), although this view is not shared by the majority of stakeholders. Within this there is majority support for voluntary rather than mandatory labelling and for harmonisation at EU level.
- There was a clear majority in relation to both food and feed in support of maintaining the labelling threshold status quo, i.e. 0.9%.
- While to some extent consumer understanding of labelling provisions is related to the lack of experience with labelled products, additional communication efforts may become necessary if more GM labelled products appear on the market.
- Consideration needs to be given to how the concerns of those who wish to see the labelling of livestock products can be addressed and whether this would be proportionate given the potential extent of labelling, complexity and likely economic/administrative burden for the food chain.
- If labelling scope is extended to include livestock products, the wording of any labelling will have to be carefully formulated to make clear to consumers that the feed, rather than the livestock product, contained GM material; failure to make this clear would mislead the consumer.
- Any review of an extension to labelling scope will have to carefully consider the cost implications arising from traceability requirements and the potential consumer reaction; a shift from consumption of domestic (labelled) livestock products to imported (unlabelled) livestock products which may have been fed on GM material not even authorised in the EU could not be considered to enhance consumer protection and there might also be wider, potentially adverse, implications for the EU livestock sector.
- It would appear disproportionate and potentially confusing to simultaneously use a positive and negative approach to labelling; consideration should be given as to which approach better protects consumer interest.
- There is an expansion of (unharmonised) "GM-free" schemes at national level with different requirements, but relatively consistent labelling which may imply a comparability that does not exist. These may currently compromise the smooth functioning of the single market and consideration should be given to introducing an approach harmonised at EU level if "GM-free" labelling is to be used.

- Given the use of thresholds for adventitious presence of GM material, whether "GM-free" schemes really allow consumers to make an informed choice should be carefully considered.

Public acceptance

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