

Policy options regarding the issue of low level presence of non approved GMOs in feed and foodstuffs

This paper represents a follow-up of the College debate on GMOs of 7 May 2008, which concluded that the Commission services should work on a technical solution for the issue of low level presence of non approved GMOs in feed and foodstuffs before the summer.

PROBLEM DEFINITION

The cultivation of GMOs already approved and commercially grown in Third Countries (TC) but not yet authorised in the EU ('asynchronous authorisations') may result in possible cases of contamination of food and feed exports to the EU.

The current EU policy of zero tolerance approach for unauthorised GMOs combined with the effects of asynchronous authorisations is causing increasing difficulties in the import of food and feedstuffs from Third Countries where more GMOs have already been approved or are under development, e.g. the recent cases with contamination of rice and maize product imports from the USA which resulted in an interruption of trade.

The issue is especially sensitive in the case of feed. On the one hand the EU is highly dependent on feed imports (77 % of EU protein feedstuffs need to be imported, EU self-sufficiency is at 22% on average with the worst case for soybean and soybean meal for which more than 35 million tons are needed each year), on the other hand there is an upward trend in number of GMOs being developed and planted around the world (12% increase in 2007 according to ISAAA report) thus suggesting that the chances of unauthorised GMOs being found in imports of food and feed products will certainly increase in the future.

While the import of maize products from the US has already been significantly affected following the commercial cultivation of two GM events (MIR 604 and MON 88017), which are not authorised in the EU, a similar situation is likely to occur for the soybean sector this autumn 2008. This will be due to the multiplication of new and not yet EU-authorised GM seeds in the US, where possible trace level presence are highly likely to be found in the imports to the EU thus putting at risk the competitiveness of the entire EU livestock sector.

Europe's market share in the international agricultural trade has been continuously shrinking over many years, in particular due to China's ever growing role as an importer. Therefore the relative importance of the EU market is decreasing, although the EU is still the major export market for commodities from Brazil and Argentina.

OBJECTIVES

The main objective of the actions considered below is to reduce the impact of asynchronous authorisations (thus facilitating the import of cereals from Third Countries) while guaranteeing a high level of protection of human, animal health and the environment and ensuring a harmonised effective implementation of the EU legislation in this sector.

Based on this, the operational objective is to propose options for a technical solution for the issue of low level presence of non approved GMOs in feed and foodstuffs

POLICY OPTIONS

This paper identifies possible options in this direction and their related implications.

- A. **No action** – this would mean keeping the current approach which implies that the detection of any non approved GMO at whatever level may be considered as an infringement of the EU food and feed law and lead to removal of products from the market.

- B. **Defining a harmonised level of detection taking into account uncertainty due to sampling and analysis**- making use of Article 11.4 of Regulation 882/2004 on Official Food and Feed Control, it would be possible to define - via a legal text to be adopted by comitology - a specific limit of detection to be used in controls. In this context one could take into account also a certain level of uncertainty related to sampling and analysis.

This would mean that - without formally reviewing the principle of zero-tolerance for unauthorised GMOs – no actions would be taken if the level of contamination is below the identified level of detection (0.1%) and that in addition Member States should consider a margin to take into account the uncertainty coupled to sampling and analysis. This approach is used by Member States for the control of other substances such as contaminants or pesticide residues. One may consider that, in the case of GMOs and depending of the type of food and feed tested, such a margin of uncertainty could lead Member States to multiply by a factor 2 to 3 the identified level of detection before taking actions.

This option would apply only for those GMOs for which there is a quantitative detection method that has been validated by JRC in the framework of the authorisation procedure (applicants under Regulation 1829/2003 must indeed submit a method for validation as part of the application process). The level of 0.1% corresponds to the lowest level considered by the JRC for its validation. On the basis of the existing experience one can assume that the JRC will have validated this method as part of the application process within one year after the submission of an application under Regulation (EC) No 1829/2003 and thus in a timing that is coherent with authorisations provided in third countries.

Feasibility/timeline: this measure would require a decision to be taken in comitology on the basis of Regulation 882/2004. It would have the advantage of being a purely technical solution with no implications on the structure/philosophy of the current approach to the GMO policy. Given the urgency of the request following the College debate, a draft measure including this option is already in preparation with the objective to submit it to the Standing Committee before the summer.

- C. **Allowing a tolerance threshold of 0.5% for EU non-approved GMOs** – this option would be based on a precedent: the tolerance allowed - for a period of three years, expired in 2007 - by Article 47 of Regulation 1829/2003. It has to be noted, however, that Article 47 applied only to GMOs already positively evaluated by an EU scientific committee/EFSA.

Feasibility/timeline: The implementation of this option will be difficult in the context of the current legal framework and will probably require an adoption in co-decision.

- D. **Defining a tolerance threshold for non approved GMOs, in line with the current labelling threshold (0.9%)** – this option would be based on the existing tolerance threshold for the application of the labelling and traceability requirements to the case of the adventitious or technically unavoidable presence of authorised GMOs. This would accommodate the requests advanced by the industry (feed industry, traders) to the Commission.

Feasibility/timeline: It has to be noted, however, that the implementation of this option requires a co-decision procedure. If such tolerance is conditional on a favourable EFSA opinion, this option will be limited to the period of time corresponding to the time needed to proceed to the authorisation by Comitology (at least 8 months when there is no qualified majority in the Standing Committee). If such threshold is not conditional on a favourable EFSA opinion, the impact would be more important but safety issues could be raised. This option would also create some confusion vis-à-vis the existing labelling threshold (0.9%) that would also become a threshold relevant to product compliance.

- E. **Defining a generalised tolerance threshold of 5%** - this option is often advocated for by various Third Countries (particularly the US) as the only option guaranteeing smooth trade for biotech commodities.

Feasibility/timeline: The implementation of this option requires a co-decision procedure. It would represent a fundamental change in the EU policy on GMOs as one could question its coherence vis-à-vis the existing labelling threshold (0.9%) for the adventitious or technically unavoidable presence of authorised GMOs. Such a tolerance would certainly need a favourable EFSA opinion and possibly additional steps that would be similar to the existing authorisation procedure.

ANALYSIS OF IMPACT

This analysis is primarily an analysis of the economic impacts linked to the different policy options. The impacts on public health and the environment have not been discussed in this paper as we have limited information/data to assess those impacts in light of the different options proposed. Clearly, the higher the threshold is set, the higher the potential risks in terms of public health and environment would be. But it is difficult at this stage to assess more precisely what the different options would mean.

This analysis is based on the data made available by different sources. One of the most comprehensive is the study published by DG AGRI in July 2007. DG AGRI uses an economic model to analyse the possible impact of different scenarios determined by the evolution of asynchronous authorisations. Some of the conclusions drawn by DG AGRI are supported by the economic data provided by industry, in particular FEFAC for the feed sector and COPA-COGECA for a wider analysis of the agricultural sector. On a different basis we also took into account the information provided on the impact of low level contamination incidents by COCERAL (for GA21 and DAS59122) and CIAA (for the LLRICE601). CIAA has also presented to us an extrapolation of the possible costs of a contamination incident in the soybean sector. Finally the picture is completed by the report published by Friends of the Earth as a counter-analysis to some of the assumptions used by DG AGRI.

A. Possible impacts of the no-change scenario (option A):

Implications: as it becomes almost impossible to guarantee the absolute absence of unauthorised GMOs, and the advancement of analytical techniques to allow the detection of GMOs of ever lower levels of GMOs, less and less EU operators are willing to take the risk of importing their products from third countries developing or growing EU non approved GM.

(1) Impacts on the availability of feed raw materials/substitution possibilities:

- DG AGRI study (July 2007):

- An interruption of imports (7 million tons) of maize grain, corn gluten feed (CGF) and distillers dried grain (DDG) is unlikely to have a strong economic impact on feed availability at the overall EU level as the current imports could be replaced by maize from the EU-27, by other domestic cereals, by other non-grain feed ingredients or by-products or by imports from other trade partners.
- For soybeans and soybean meal (SBM), import volumes are more significant (38m tons), sources are limited (USA, Argentina and Brazil being the major exporters), and much more difficult to replace by alternative protein rich feed. Different scenarios are proposed on the basis of a theoretical economic model. While an import stop from the USA would have a low economic impact and could be compensated by increased imports from other countries, an import stop from the USA in combination with Argentina and/or Brazil would, however, be much more significant, leading to a net reduction of feed availability by 3.3 million t in SBM equivalent). Would the import stop concern the three countries at the same time, the net reduction would rise to 25.7 million t.

- **Friends of the Earth report:** highlights that the EU is the reference market for Brazil and Argentina and therefore questions the possibility of the worst case scenario proposed by the AGRI study.

(2) Impacts on feed prices – while there is much controversy on this issue and bearing in mind that feed prices may greatly vary with time, we refer to a case study of FEFAC as an example of the potential effects on costs of the above scenario on imports of maize into the EU from different countries (US/Argentina/Brazil¹). The industry quantifies the current loss in supply of CGF and DDG from the US (due to the cultivation of two GM maize – MIR604 and MON 88017 - not yet authorised in the EU) at more than 200.000 t/month, with an additional increase in the cost of testing of feed imports. This loss is currently replaced with substitute imports from Argentina and Brazil but at a certain cost: due to the difference in the structure of costs (particularly freight costs): maize imported from Argentina is 10€/t more expensive than from the US, while maize imported from Brazil is 50€/t more expensive than the US. Extrapolating these figures to yearly costs would see cost impacts of between 24 and 120 million euro for the feed sectors.

¹ 2007 average data.

(3) Impacts on EU oilseed sector: (COPA-COGECA presentation/DG AGRI): both DG AGRI and COPA-COGECA indicate that in the worst case scenario the issue of asynchronous authorisations could lead to a decrease of the availability of import for the oilseed sector of more than 70%.

(4) Impacts on the competitiveness of EU livestock industry (COPA-COGECA presentation/DG AGRI):

The highlighted problems of asynchronous authorisations in the soybean sector would have severe impacts for the EU livestock industry. A two-year import stop of soybeans and SBM from the USA and Argentina would see the EU livestock sector facing an increase in feed expenditure of 23%. Would the import stop also concern Brazil, feed expenditure is estimated to rise by more than 600% respectively. As a result, the competitiveness of the EU livestock production would be strongly affected, with increased production costs, increased imports and decreased exports. In particular DG AGRI and COPA-COGECA point out that this could reduce the net reduction of 34,7% in the pork sector and 43,9% for the poultry sector. Given that EU livestock production accounts for about 40% of the total value of agricultural production a loss in competitiveness of the EU livestock sector would have, according to DG AGRI, dramatic implications for agricultural incomes and employment. One should also consider the possible knock-on effects in the upstream and downstream industries with the possible result of increased imports of meat (397,4% according to COPA-COGECA) from Third Countries.

(5) Impacts on certain regions and Member States:

An interruption of imports of maize grain, corn gluten feed (CGF) and distillers dried grain (DDG) is likely to have a significant local impact on certain Member States (ES, UK, PT, NL, IR) or regions, which import substantial quantities of such feedstuffs from overseas. Replacing overseas imports by other sources would be associated with increased transportation costs and possibly transfer of facilities, which imply substantial economic consequences for some Member States.

(6) Impacts on the food sector:

The food industry (CIAA) has recently provided the services of DG SANCO with a study of the possible effects of a contamination incident in the soybean sector. A contamination with a single event, contaminating 3 bulk ships, would affect all the six major food sectors working with soybean (lecithin, soy flour, concentrates and isolates, refined soy oil, derivatives, roasted soybeans). According to a theoretical extrapolation the costs for the six sectors would be approximately between 1 and 2.8 billion € only for the costs related to tests, financial charges, staff time and legal costs. Additional costs related to other components of the costs structure (product withdrawal, stock replacing, plant cleaning, brand reputation loss, compensation, loss of profits) would also apply but have not been calculated by CIAA.

(7) Indirect impacts on consumer meat prices:

This impact of current and future interruptions from one or more of the main importing countries on the consumer price of the final product is certainly difficult to assess. The EU GMO policy factor was mentioned in the recent Communication on food prices²,

² Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions "Tackling the challenge of rising food prices", COM (2008)321.

but the impact if existent is minimal. Many other factors affect food prices increases as highlighted in the Communication. The rising cost of feedstuff can not be attributed solely to the EU GMO law and policy but to many other factors like: increased global demand, surge in oil prices, poor weather conditions including a serious drought in Australia, ethanol and biofuel production, increased export tariff for Argentinean soybean and speculative behaviour by commodity traders. This rise in price is affecting also GM producing countries like Canada and the US.

B. Possible impacts of harmonised level of detection taking into account a defined level of analytical uncertainty (option B):

Implications: This could represent a solution for minimal level of contaminations, like those which are expected prior to the extensive commercialisation of a new GMO. In this respect it would ease the situation in the soybean sector in the phase of the seeds multiplication; between autumn 2008 and beginning of 2009 (methods for A2704-12 (Bayer) and 89788 (Monsanto) soybeans are already validated).

It has to be clear, however, that this option does not represent a long-term solution for the issue of asynchronous authorisations since in the case of extensive cultivation in a Third Country of a EU non approved GMO that does not apply segregation, average levels of these two non approved GMOs are expected to be higher than this level as of autumn 2009. By this time, one may expect that these two soybeans will both be authorised but, according to the company Pioneer, its GM soybean 356043 is planned to be in the phase of seeds multiplication.

Existing data on the possible impact of this option: the most reliable data to assess the economic impacts of this option are the ones provided by the food industry (CIAA) on the cost of the contamination cases of the US long grain rice with the unauthorised GMO LL601. The costs of that incident has been quantified as 3.5 to 7.5 million € per company (for a total cost of 52-111 million €), including the different costs occurred following the contamination cases (products withdrawal, replace of stocks, plant cleaning, reputation loss, loss of profits, compensations not covered by insurance, staff and financial charges, legal costs and the costs related to the testing of stocks). In that case the vast majority of contamination cases were very close to the limit of detection of 0.1%; in other words the above-referred costs could be significantly reduced for low-level contaminations covered by this option.

Similarly we consider that this option would have an impact also on the maize products due to asynchronous authorisations. Under this respect the best reference are the cases of contamination of maize imports with the not yet authorised (at the time) GM events DAS 59122 (from the US) and GA21 (from Argentina). In the case of DAS 59122 notwithstanding a comprehensive channelling and testing system put in place by the operators, certain level of contamination has been found upon arrival in the EU. The same goes for GA21 where level of detections between 0.1% and 0.3% have been found in tests carried out in Argentina. As a consequence, only a part of the shipments would have met the requirements of this option.

These case studies provide good elements to establish that under such an option, the impacts on the availability of feed and competitiveness of the industry would be less negative as compared to option A.

C. Possible impacts of allowing a tolerance threshold of 0.5% for EU non-approved GMOs (Option C)

Implications: If, as it was the case under Article 47, such tolerance is conditional on a favourable EFSA opinion, this option will be limited in time since a tolerance period corresponding to the time needed to proceed to the authorisation by Comitology (at least 8 months when there is no qualified majority in the Standing Committee).

The experience shows that such a threshold would allow the import of products (from soybean easier than for maize) during the first year of commercial cultivation, provided that channelling systems are in place. This option would not represent, on the contrary, a long-term solution for the issue of asynchronous authorisations as – in the case of extensive cultivation in a Third Country of a non approved GMO – even meeting this threshold could be difficult without a dedicated and segregated system of production.

Existing data on the possible impact of this option: the best case studies in this respect are the cases of contamination of maize imports with the not yet authorised (at the time) GM events DAS 59122 (from the US) and GA21 (from Argentina), which have already been referred to for assessing the impacts of option B. According to the information provided by COCERAL (cereal traders) most of the consignments would have been eligible for the EU market with a tolerance threshold of 0.5%, thus easing the situation in terms of feed availability. The same goes for GA21 where level of detections below 0.5% have been found in the tests carried out in Argentina.

D. Possible impacts of defining a tolerance threshold for non approved GMOs, in line with the current labelling threshold (0.9%)

Implications: according to FEFAC, FEDIOL and COCERAL such a tolerance level applied to all GMOs commercially cultivated outside the EU could avoid in the medium term any problem as regards the availability of feed, allowing import of both maize and soybean products not only from Brazil and Argentina, but also – on the condition of specific channelling systems – from the US.

Existing data on the possible impacts of this option: There are no case studies or data to be found to assess the impacts of this option. However, it is likely that with such an option the economic impacts would be similar to option C but with some added margins of flexibility.

E. Possible impacts of defining a generalised tolerance threshold of 5%

Implications: This option would lead to an easy to meet (although still at certain costs) requirement that could avoid disruption of import and supply in the case of extensive cultivation in a Third Country of a non approved GMO.

Existing data on the possible impact of this option: there are no real data for this threshold value, but this is often advocated by the US as only respectable level in the long run, i.e. in a situation of generalised cultivation of GMOs. It is probably worth noting that a threshold of 5% is currently applied by the EU legislation in the feed sector for botanical impurities.

COMPARING THE DIFFERENT POLICY OPTIONS

In conclusion the possible implications and impacts of the different options can be summarised by the following table.

OPTION	Time of application	Impacts	Feasibility
A-No action	-	Negative impact on availability of feed for the EU with consequent negative impacts for the livestock and food industries, the economy of certain regions and potentially on food prices	
B-Harmonised level of detection + analytical uncertainty	After validation of the detection method by the JRC (approx 1 year after the submission of the application)	Solution for minimal level of contaminations prior to commercial cultivation of a new GMO (soybean 2008). Not a long-term solution in case of systematic and long lasting asynchronous authorisations.	Purely technical measure consistent with our legislative framework and adoptable via Comitology under Regulation 882/2004
C-Tolerance threshold at 0.5%	Preferably after positive EFSA opinion	Solution effective in the medium term (first years of commercial cultivation of a product) and preferably combined with specific segregation/channelling systems	It will be difficult under the current legal framework. Need for a co-decision procedure..
D-Tolerance threshold at 0.9%	After positive EFSA opinion	Tolerance level could ease the import of both maize and soybean products not only from Brazil and Argentina, but also – on the condition of specific channelling systems – from the US on the condition that the timing of the EFSA opinion allow to close the "gap" between EU and third country approvals.	Requires a co-decision procedure.. Possible inconsistency with the current philosophy of the legislation which set 0.9% as a labelling threshold for adventitious presence of authorised GMOs.
E-Tolerance threshold at 5%	After positive EFSA opinion	This option would definitively solve the problem of asynchronous authorisations, with a limit easy to meet also in the case of extensive cultivation in a Third Country of a non approved GMO.	Fundamental change in the EU policy on GMOs. A complete change of the existing legislation is required.