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THE IMPACTS OF DROPPING EUROPE'S ZERO TOLERANCE TO GM FEED IMPORTS

No legal certainty for feed and food sectors

December 2011

1. Introduction: - 'zero tolerance' dropped

The EU's 'zero tolerance' policy bans any food or animal feed imports found to be contaminated by a genetically modified organism (GMO) that has not been approved in the EU. Even if the GMOs are only found in 'trace amounts', the import and marketing is illegal. Any removal of this 'zero tolerance' policy and its implementing measures would significantly increase the likelihood of contamination of food and seeds by non-authorised GMOs.

After a prolonged campaign by agri-business, the 'zero tolerance' policy for animal feed imports was dropped in July 2011.¹ There are now moves by the European Commission to also relax rules for food imports and seeds, under the official name 'low level presence'. This would mean that our food and seeds could be contaminated by GMOs that have been approved in countries such as the US but not approved in the EU.

This briefing looks at what dropping 'zero tolerance' for animal feed means, and the legal uncertainties and weaknesses related to this decision. It also considers what the consequences are likely to be, in terms of the contamination of our food, if the European Commission and EU Member States decide to extend their 'pro-contamination' approach to what we eat.

2. Why was the zero tolerance' policy for feed dropped

The 'zero tolerance' for feed policy was dropped following a concerted three-year lobbying campaign conducted by the biotech industry, the animal feed industry, and some food industry lobby organisations.

The arguments for dropping the policy put forward by pro-GM advocates were unjustified. Claims that the policy caused a crisis by disrupting trade in feeds when contamination cases occur were incorrect. The number of contamination incidents and the amounts of contaminated animal feed have been so low that it cannot be argued that the EU 'zero tolerance' policy had caused any kind of a feed crisis: as of May 2010, for example, no more than 0.2 % of all soya imports used as animal feed (for livestock) had been found to contain EU non-approved GM soya.

¹ The weakened import measures entered into force in July 2011 (Regulation 619/2011) laying down the methods of sampling and analysis for the official control of feed as regards the presence of genetically modified material.

The European Commission and European governments² moves to drop 'zero tolerance' rules reflects their increasing unwillingness to implement the EU's existing GMO laws properly³, and to stand up to the biotech industry and GMO cultivating countries. No doubt this is also the reason why the Commission has failed to push the animal feed and commodity industries to introduce modern segregation and traceability systems, and ensure that GMO varieties are authorised and cultivated in accordance with the EU approvals process.

In addition the Commission and the Member States have failed to ensure that the GM industry compensates those impacted by contamination incidents it has caused. In Europe, the food and feed sectors had to pay for the economic damage caused by the GM industry, following a contamination incident involving Bayer's Liberty Link rice 601 (which was never approved or foreseen for commercial use). This cost the German food sector, for example, 10 million Euros in 2006, when they had to recall and replace products.⁴

By dropping the 'zero tolerance' policy the Commission and Member States have protected the interests of the GM industry and global commodity traders², at the expense of EU safety standards including the precautionary principle and EU citizens' demands to keep GMOs out of the food chain.

Friends of the Earth Europe has published a detailed briefing paper with examples and figures demonstrating why there was no reason to drop the zero tolerance policy. This can be downloaded at: http://www.foeeurope.org/sites/default/files/zero_tolerance_paper_20101.pdf

Rejection of non-authorised GMOs in USA and China

The GM industry often argues that Europe should accept GMOs that have been exported from other countries where they have already been approved for commercial use, rather than using its own independent approval procedure. Yet this implies that the EU should give up its own legislation, forfeiting the right to make any further decisions about what it wishes to import and market, based on concerns about health and safety, and the right to conduct its own tests. Furthermore, other countries also operate similar 'zero tolerance' policies.

China, for example, which is the principal destination for GMO exports from South and North America, has its own rules on GMOs, and rejected a US shipment of GM corn in 2010, because it contained GM corn that was not one of the 11 varieties authorised by China at that time.⁵ The USA, the source of most GMO exports, is also unwilling to import GMOs that have not been previously approved by its own regulatory authorities. In order to prevent feed and food imports contaminated with such GMOs, the Inspector General of the US Department of Agriculture (USDA) demanded stronger import controls in 2008.⁶

The US legal system has also ruled that it is acceptable for grain traders to refuse to purchase GM maize varieties on the basis that they have not been authorised for import by other countries. Swiss GM giant Syngenta had sued Bunge (one of the world's largest agribusiness and food companies) in August 2011 for refusing to accept a type of GM maize,⁷ but Bunge argued that 'major' export

² Only Malta, Cyprus, Greece, Lithuania, Latvia, Poland and Slovenia voted against the proposal.

³ Directive 2001/18 and Regulations 1829/2003 and 1830/2003 are the major GMO laws for the European Union. They regulate the authorisation of GMOs for food, feed or cultivation, as well as the labelling and traceability rules for GM food and feed. For examples Article 12(2) and Article 24(2) of regulation 1829/2003 define labeling of authorised GMOs, even for small traces.

⁴ Response German Government, 2006, Drucksache 16/3118, Verunreinigte Lebensmittelprodukte mit gentechnisch verändertem Reis,

⁵ China Rejects U.S. Corn Cargo, Citing GMOs. Thomson Reuters, 29.10.2010, <http://www.reuters.com/article/idUSTRE69S23U20101029>

⁶ USDA, OIG 2008. Audit Report. United States Department of Agriculture Controls over Importation of transgenic plants and animals. Report No. 50601-17-Te. December 2008. <http://www.usda.gov/oig/webdocs/50601-17-TE.pdf>

⁷ Syngenta Sues Bunge Over Rejection Of GMO Corn Type. Thomson Reuters, 22.08.2011, <http://www.reuters.com/article/2011/08/22/syngenta-bunge-corn-idUSN1E77L16H20110822>

destinations would not accept it, including Australia, Brazil, Canada, Japan, Mexico, New Zealand, the Philippines, Korea and Taiwan. However, the responsible US District Court said, in September 2011, that “Bunge’s decision to reject Viptera corn at all of its locations was a legitimate and reasonable business decision.”⁸

Other companies refusing to accept Syngenta’s corn included Archer Daniels Midland and Cargill. Cargill underlined its “right to accept or restrict products of agricultural biotechnology, dependent on the approval status in export markets and needs of our customers.”⁹

The Syngenta-Bunge case confirms that exporters are aware of ‘zero tolerance’ and other GM policies in the regions and countries that they are exporting to, and that this is reflected in their decisions about which GM crops they choose to market.

3. The new rules and how the Commission has disguised the infringement of current EU law

The decision to allow non-authorized GMOs to contaminate imported feed materials was taken in one of the Member States’ expert committees, chaired by the European Commission.¹⁰

The decision was Commission driven. The Commission’s initial proposal failed to gain the support it needed from Member States, and the Commission edited it several times over the course of a number of meetings between October 2010 and February 2011. Eventually, the Commission produced a draft that secured the majority needed, on 8 February 2011.

However, these committees are tasked with the technical implementation of EU laws; they are not supposed to make decisions about substantial changes to EU laws. But what happened in this case was that a committee for technical issues acted as a political body. The committee appears to have attempted to disguise its work as a technical approach. To camouflage the core decision - which actually infringes current EU law by introducing a threshold for EU non-approved GMOs – they adopted the term ‘technical zero’ instead of using correct terms that stated that a new legal threshold had been introduced.

The main components of the resulting Regulation EC No.619/ 2011 are as follows:

- The Commission has introduced a threshold of 0.1% for non-authorized GMOs in the feed sector, with the following conditions:
 1. The regulation demands that a GMO is authorized in a third country.
 2. It demands that the authorisation application under Regulation 1829/2003 has been submitted at least three months previously and that the European Food Safety Authority (EFSA) has not identified “*adverse effects on health or the environment*” (Article 2(a)) for the non-authorized GMO. However, this requirement is not as useful as it seems: even though it appears to be a prior risk assessment, in practice the data delivered by applicants is often incomplete, and EFSA regularly asks applicants for additional information. The regulation does not demand that EFSA has actually completed the assessment process, and this provides a significant loophole.
 3. The applicant must deliver methods and reference materials that allow the presence of the GMO to be tested for.

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<http://www.reuters.com/article/2011/09/02/cargill-com-idUSN1E78017Q20110902>

Standing Committee on the Food Chain and Animal Health - Section Genetically Modified Food and Feed and Environmental Risk, http://ec.europa.eu/food/committees/regulatory/scfcah/modif_genet/sum_22022011_en.pdf

- Under the new regulation only contaminations above 0.1% must be reported to other Member States immediately. However, for incidents of contamination below the 'technical zero' of 0.1% they are only required to report annually.
- GMOs whose authorisation has expired are also included.

The list of GMOs which can legally contaminate feed imports up to 0.1% can be found here: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm#EC6192011

In official statements the European Commission announced this regulation as a continuation of the EU's 'zero tolerance' policy on GMOs: "Not only does the Regulation not deviate from the zero tolerance policy but it renders this notion even clearer by means of defining the technical zero in realistic and operational terms. The level of 0.1% is the lowest level which the EU Reference Laboratory for GM food and feed has set for the validation of event specific methods under the authorisation process."¹¹

4. Legal analysis of the new rules

A legal opinion, commissioned by Friends of the Earth Europe in January 2011¹², concluded that the EU's GMO laws clearly deviate from the principle of 'zero tolerance', which means zero, not allowing a 0.1% threshold for contamination. The legal opinion doubts about the legitimacy of the new rules.

The opinion found that:

1. According to the relevant rules of GM Regulation 1829/2003, the case law of the European Court of Justice (C-286/02)¹³ and the previous decisions of the Commission,¹⁴ even the smallest traces of non-approved genetically modified material must not be tolerated in animal feed (or food).
2. The EU's current GMO laws have adequately regulated all methods of sampling and analysis of GMOs including official controls.

The lawyer therefore concluded that the way the European Commission changed the rules concerning the contamination of animal feeds is probably illegal.¹⁵ The Commission does not have the right to introduce a GM contamination threshold of 0.1% by redefining testing and analysis methods in the feed control law (Regulation 882/2004).

Interestingly, the conclusions of this legal opinion are very similar to the ruling about contamination of honey by GM maize MON810 by the European Court of Justice (ECJ) (C-442/09). On 6 September 2011, the ECJ ruled that minor traces of GM maize MON810 in honey still need a full authorisation,

¹¹ <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/11/451&format=HTML&aged=1&language=EN&guiLanguage=en>

¹² Willand, Achim February 2011, Legal opinion on a proposal by the European Commission for the meeting of the SCFAH on 8 February 2011; Provisions concerning sampling and analysis of animal feed for genetically modified material on the basis of Regulation (EC) No 882/2004

¹³ In the context of traces of genetically modified organisms in fish meal, the European Court of Justice has stated clearly that the absence of a defined threshold level means that no contamination whatsoever will be tolerated.

¹⁴ The European Commission has also intervened in the case of the Upper Austrian Law on the Prohibition of Genetic Engineering 2002, which set a tolerance level of 0.1% genetically modified seed. In its opinion, "Directive 2001/18/EC contains no (de minimis) threshold levels for the presence of chance or technically unavoidable, non-approved genetically modified organisms in seed".

Recitals 55 and 20 of Commission Decision 2003/653/EC of 2 September 2003, OJ L 230, 16.9.2003, p. 34.

¹⁵ The procedure used for this decision: the European Commission suggested the proposal, representatives of Member States voted in the so called Standing Committee and the European Commission finalised and published the regulation.

regardless of whether the contamination has been accidentally caused or not (see Articles 2 and 3 of the ruling).¹⁶ In other words: what is not fully authorised is illegal.

The case was brought by a Bavarian beekeeper after GM proteins were detected in samples of his honey and pollen. Germany's Court then consulted the ECJ on the status of the honey according to EU law. Maize MON810 is authorised for cultivation and for a restricted list of food purposes including maize flour, gluten, starch and glucose, but not for pollen as a foodstuff. The ruling means that any European honey contaminated by the GM maize MON810 should be withdrawn from the market.¹⁷

5. Impact of the new rules for the feed and food sector

The new rules make avoiding contamination with non-authorised GMOs more complicated. Previously, the strict implementation of the 'zero tolerance' policy in the food and feed sectors prompted exporters to EU to test the raw materials before they are exported to Europe (to avoid the additional costs of recovering and re-exporting products to alternative markets).

This new approach does not result in easier procedures for the food and feed sectors however. It is often easier to check whether or not raw materials are contaminated with non-authorised GMOs at all, rather than determine the exact level of any contamination. But this new regulation requires that there must be such a test, quantifying the degree of contamination, if a EU non-authorised GMO has been found.

Furthermore, the introduction of a 0.1% threshold does not provide any sort of legal certainty for the feed sector, since it is difficult to test at this or even higher levels with uniform accuracy across all official national controls. National competent authorities conduct their own tests and analyses, and companies often have their own private standards. This means that the same case of contamination by a non-authorised GMO could be considered legally acceptable under controls employed in one member state, even though tests used in another laboratory elsewhere or in the private sector could result in the same batch being declared illegal and having to be destroyed. Thus instead of delivering protection against expensive recalls for the feed sector, the new threshold could be even more challenging and expensive for the industry than implementing the 'zero tolerance' policy.

Genetic ID, one of the leading laboratories for GMO analysis concluded, in their assessment of the new regulation, that: "*more testing might be required, to avoid raw materials and feed with GMOs above the technical zero or if buyers have their own strict policy against unapproved GMOs.*"¹⁸

The new rules also endanger traceability and transparency in the feed sector. Instead of ensuring that the responsible authorities are immediately informed of any contamination, the new regulation bypasses the EU's well-established Rapid Alert System for Food and Feed (RASFF). National

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The ECJ concluded in its ruling that: "*105 With regard to the tolerance threshold of 0.9% per ingredient laid down in Article 12(2) of Regulation No 1829/2003, this relates to the labelling obligation and not to the authorisation and supervision obligation.*

106 An application by analogy of that threshold to the latter obligation would deprive Article 12(2) of any utility, as it would exclude the foodstuff in question from the scope of Regulation No 1829/2003."

The ruling says:

On those grounds, the Court (Grand Chamber) hereby rules: that honey containing pollen of GM maize MON810,

Article 2.1, 2.10 and 2.13 and Article 3(1)(c) of Regulation No 1829/2003, must be interpreted as meaning that, when a substance such as pollen containing genetically modified DNA and genetically modified proteins 'food ... containing ingredients produced from [genetically modified organisms]' within the meaning of Article 3(1)(c) of Regulation No 1829/2003. That classification may be made irrespective of whether contamination by the substance in question was intentional or adventitious.

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=74459&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&id=564487>

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<http://curia.europa.eu/juris/document/document.jsf?text=&docid=74459&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=564487>

¹⁸

http://www.genetic-id.de/images/stories/downloads/Understanding_Regulation_EC619-2011_low-level_presence_of_GMOs_in_feed_imports_v1.01.pdf

authorities are only obliged to inform each other about contamination by non-authorized GM in the feed sector if it is above the threshold of 0.1%. This will completely undermine effective information exchange and coordination amongst Member States.

A lack of transparency and traceability with respect to non-authorized GMOs could also result in increasing costs for those stakeholders who want to meet European citizens' demands for completely GM-free products. With reduced and incomplete information about GMO feed contamination below 0.1%, the food sector will be obliged to resort to additional and expensive testing and analysis to demonstrate that food products are GM free. Cert ID states in its assessment of the new regulation: *"However the food sector may be affected indirectly. The more feed with unapproved GMOs is traded the higher the risk of adventitious contamination of food products. This might require additional preventative testing and modified testing parameters."*¹⁹

6. Plans to lift zero tolerance in the food sector

In October 2011, the European Commission stated that they are now preparing to table proposals about lifting the 'zero tolerance' policy with respect to various parts of the food chain, basing the changes on the feed model.

The markets for food and feed have major distinctions however. These include differing sensitivity of various stakeholders and consumers, and the cost of monitoring.

Compound or blended feeds containing soy products are in general already labelled as containing GM; it is easier for the producer to take this approach than to segregate the products. Raw material for the feed sector is sourced from the main GM soy-producing countries such as Argentina, Brazil or the USA, and the industry has not introduced a segregation system in most cases.

The situation is completely different for GM foods. After vocal objections from consumers, leading supermarkets decided not to stock GM-labelled foods some ten years ago. It is almost impossible to find any GM-labelled food products in the EU. Food processors and retailers re-organised where they were sourcing their supplies from, before the GM-labelling regulation 1829/2003 entered into force in 2004. Companies in the food sector are very cautious about potential GM contamination, and the food sector buys ingredients such as soy lecithin from regions without any GM soy cultivation, such as India. This avoids the risk of contamination and reduces the costs of testing. A monitoring system for detecting potential sources of GM contamination is also fully implemented for the food sector across Europe.²⁰

The food sector has also had to deal with two major contamination incidents in recent years. In 2006 and subsequent years this was caused by LibertyLink rice LL 601 from Bayer, a GMO that had been tested in field trials in the US but was never put forward for authorisation. In 2009, a further incident was triggered by linseed FP 967, which was once authorised in Canada but was then de-listed subsequently withdrawn from the market.

¹⁹ http://www.genetic-id.de/images/stories/downloads/Understanding_Regulation_EC619-2011_low-level_presence_of_GMOs_in_feed_imports_v1.01.pdf

²⁰ *"The RASFF is a tool enabling the quick and effective exchange of information between Member States and the Commission when risks to human and animal health are detected in the food and feed chain. All Members of the RASFF (EU-27, European Commission, EFSA as well as Norway, Liechtenstein, Iceland and Switzerland as partial member) have a round-the clock service to ensure that urgent notifications are sent, received and responded to in the shortest time possible."* <https://webgate.ec.europa.eu/rasff-window/portal/>

Implementing 'zero tolerance'

Liberty Link LL601, a long grain rice, was never approved for commercial use, but had been grown by Aventis (bought by Bayer) in small-scale field trials in the US many years earlier.²¹ By the autumn of 2006, however, LL601 was found in shipments of imported rice in 24 countries worldwide. In this situation, the EU applied its 'zero tolerance' policy, and developed a testing protocol to be used to ensure that rice importers provide certificates demonstrating that their rice is not illegally contaminated. Following the implementation of this policy, the last imports found to contain the non-approved GM rice were identified in June 2008.

The EU's 'zero tolerance' policy was also applied in 2009, when Canada discovered that its linseed fields and exports were contaminated with non-authorized GM linseed. Canada is the world's biggest producer and exporter of linseed (also known as flax), and around 70% of the 900,000 tonnes it harvests annually is exported to Europe. In 2001, a GM linseed known as Triffid (or FP967) was de-listed from the official register of varieties amidst concerns about a loss of linseed export markets because of potential contamination, and the linseed was never used for commercial production. However, in autumn 2009, traces of the Triffid linseed were found in European shipments from Canada. After a short ban on Canadian linseed imports, an import protocol to test for the presence of Triffid was agreed between the EU and Canada²², allowing Canadian industry-certified Triffid-free linseed to be exported to the EU.

The two cases clearly illustrate the way in which the European Union's 'zero tolerance' policy can be successfully and effectively applied in the food sector - even for contamination incidents with unknown and unexpected GMOs. But both cases also show that there is a gap in EU legislation: the polluter pays principle is absent and there is no liability regime in force. Thus it was the European food industry which had to cover all the costs for product recalls, rather than the biotech industry which was actually responsible for the damage in the first place. According to various estimations the LL 601 contamination incident cost the food sector between US\$ 0.741 billion and 1.285 billion.²³

It is important to note that a lifting of the 'zero tolerance' policy – which would mean the introduction of a 0.1% threshold for EU non-approved GMOs in food – would not have saved the EU food sector from these heavy financial impacts because neither GMOs would have been covered by the planned new regulation anyway. This is because they neither were authorised in the exporting countries (LL 601 was not authorised, and FP967 had been authorised but then de-listed).

7. Conclusions:

There was no need to drop the 'zero tolerance' policy for feed. The new regulation fails to reduce costs for the food and feed sector, since testing is still required, and it limits traceability for all operators, which makes it harder to demonstrate that food is *non*-GM without additional testing. Additionally, dropping the policy raises further legal uncertainties, since 'zero tolerance' is an integral part of the EU's existing laws on GMOs.

'Zero tolerance' for food is working. Following the implementation of the EU's 'zero tolerance' policy for rice, there were no further contamination cases after the summer of 2008. Similarly, the implementation of the 'zero tolerance' policy for Canadian linseed in 2009 meant that in 2011 just one

²¹ Clapp, J., 2008. Illegal GMO Releases and Corporate Responsibility: Questioning the Effectiveness of Voluntary Measures. *Ecological Economics*, Vol.66, No.2-3: 348-58.

²² http://ec.europa.eu/food/committees/regulatory/scfcah/modif_genet/sum_16112009_en.pdf

²³ Neal Blue, risky business. Economic and regulatory impacts of the unintended release of genetically engineered rice varieties into the rice merchandising system of the US. Greenpeace International 2007. <http://www.greenpeace.org/international/Global/international/planet-2/report/2007/11/risky-business.pdf>

case of contamination by non-authorized Canadian linseed was reported. It is clear that exporters respond and can implement the current 'zero tolerance' policy, and it has effectively protected European citizens against non-authorized GMOs in food imports. This flies in the face of the European Commission's plans to weaken GM laws and allow imports contaminated with non-authorized GMOs.

If food companies want to be protected against expensive recalls caused by the illegal contamination of their products, they should call for and support the high standards inherent in the 'zero tolerance' policy, as applied in the incidents with US rice and Canadian linseed.

Friends of the Earth Europe believes that the EU's 'zero tolerance' policy upholds the safety and well-being of European citizens and should not be dismantled as a result of the unfounded claims of the biotech industry.

8. Friends of the Earth Europe demands that:

- The EU's 'zero tolerance' policy for non-approved GMOs remain in force. EU law must not be undermined, and food and seed laws must not be weakened.
- In order to avoid product recalls, shipments from GMO-producing countries destined for the EU must be regularly analysed and certified in the exporting country. This would involve developing and implementing a standard protocol for sampling and analysis with the aim of maintaining zero tolerance. These standards would be published and made available for importers and control authorities. As already applied in most GMO producing countries, exporting countries have to compare EU approvals with GM crops they have cultivated.
- In order to identify EU non-approved GMOs, a comprehensive global register for all GMOs that have been trialled is needed. It has to include all authorised GMOs, and all GMOs tested in field trials, whether or not they were subsequently put forward for authorisation.
- The polluter pays principle and a liability regime must be established in order to ensure that those who contaminate food, seeds and feed with GMOs are held responsible and pay compensation for the economic damage caused by such contamination.

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