



Review

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ABSTRACT

The EU has the probably strictest regulations in the world for the presence of GMOs in food and feed. These require the labeling of food and feed where the level of approved GMO exceeds 0.9% of unintentional adventitious presence. For non-approved GMOs the threshold is 'zero' and thus requires that cargoes containing GMOs non-approved GMOs are returned to the port of origin or are destroyed. The process of GMO safety approval is slow and subject to extensive political interference. However outside of Europe, new GMOs are being created, approved and cultivated at a rate exceeding that of EU approvals. Since current methods of cultivation, storage and transport do not permit complete segregation of GMO and non-GMO crops, some co-mingling must be expected. This leads to a peculiar situation where the EU is dependent on imports (particularly soybean for animal feed) from North and South America and yet, legally, must reject these imports since they contain low levels of unauthorized GMOs. Several authoritative European reports indicate that this is not a sustainable situation and must result in feed shortages and price increases of meat and poultry. The solution is to either to modify EU regulations or to synchronize GMOs approvals on an international level.

The USA has constantly criticized the EU for its unscientific GMO regulations which it says amounts to trade protectionism. Very recently however, the USA has realized that other countries are now producing and cultivating their own GMOs, and that these are not authorized in the USA. The USA is thus proposing to set up its own system of GMO regulations which may bear a close similarity to those in Europe.

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1. Introduction

Several recent publications [1–3] have pointed out the differences in GMO regulations between countries and their impact on global trade. The ways in which GM plants are regulated in the USA and Europe have often been seen as complete opposites, particularly since both are heavily influenced by self-interest, size of farms, and trade-protection including subsidies to farmers for exports. The USA based companies are the major developers of

GM-crops. The USA, Canada, Argentina and Brazil are the major cultivators of GM-crops and export them worldwide, as food and feed. The EU does not cultivate significant quantities of GM-crops, and consequently it heavily depends on imported GM-crops, particularly soybean for animal feed, from North and South America. The EU has possibly the most stringent GMO regulations in the world (GMO safety, GMO thresholds, GMO labeling, GMO detection, and coexistence) and these are difficult to reconcile with its dependence on GMO imports.

2. Food safety

In the EU, GM-crops are regarded as 'new foods' being made by a new process (Regulation 258/97), though there is no provision as

[☆] The personal views expressed in this article do not necessarily represent those of INRA.

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to how a 'new food' may ever become and 'old food'. This regulation is not specific for GMOs and includes, for example, irradiated food. It was subsequently amended for GM-crops by Regulation (EC) 1829/2003 [4,5]. GMO crops are subjected to extensive, case-by-case, science-based food and environmental safety evaluation by the independent European Food Safety Authority (EFSA) established under Regulation (EC) 178/2002. EFSA implements Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and Regulation (EC) 1829/2003 on genetically modified food and feed. On the basis of the EFSA opinion, the EC drafts a proposal for granting or refusing the authorization, which it submits to the Section on GM Food and Feed of the Standing Committee on the Food Chain and Animal Health. If this Standing Committee accepts the proposal, it is finally adopted by the EC. Alternatively, it is passed on to the Council of Agricultural Ministers, which has a time limit of 3 months to reach a qualified majority for, or against, the proposal. Historically, the Council of Agricultural Ministers has never been able to reach a vote with a qualified majority due to political meddling following the EFSA scientific assessment. In the absence of such a decision (which is invariably the case), the proposal is passed back to the EC which then adopts the proposal. The entire system is complicated, slow and inefficient and approval of a new GMO takes more than 2 years. EC Agricultural Minister Mariann Fischer Boel [6] has stated that "the political decision is being knocked around like a ball in a slow-motion tennis match", *"Month after month, GMOs receive a clean bill of health from EFSA, but then get stuck because Member States cannot reach any qualified majority, in favour or against, when it comes to the vote on a proposal for authorisation. So first the relevant committee decides nothing; then the Council decides nothing; and finally, the Commission grants authorisation, as laid down in the rules. This process swallows huge amounts of time. That would be quite legitimate – necessary, in fact – if new scientific information was being put on the table. But in the vast majority of cases, this is not what's happening"*.

The costs of compliance with the EU approval procedure are very high so that only very large international biotechnology companies are able to afford it.

EFSA is severely criticized, using pseudo-scientific justifications, by the anti-GMO NGOs such as Greenpeace and Friends of the Earth. This is natural that since these organizations, having political goals, are naturally driven to contest scientific evaluations which are not in line with their views, in order not to lose their political influence. What is more surprising is that some EC member countries seek to deprive the EFSA-GMO committee of its scientific independence and simply ignore its recommendations. For example following a positive EFSA recommendation, RoundupReady2 soybean was finally (December 2008) approved by the European Commission after the Council of Agricultural Ministers were unable to obtain a qualified majority. The UK, Spain, Netherlands, Sweden and Finland voted for approval, while France, Germany and Italy abstained. Abstention is a curious political choice since these latter countries have highly qualified GMO panels with very clear scientific opinions. Ministers who are unable to agree on the scientific facts are unlikely to be able to formulate a coherent policy.

A good example of anti-science in GMO politics was shown by the French government of President Nicolas Sarkozy, which, for political reasons, refused the cultivation of MON810 (which contains a Bt gene conferring resistance to the European corn borer) which is the only GMO cultivated in Europe and which had been grown in France for several years. The Government disbanded the two pre-existing science-based GMO committees (Commission de Génie Génétique and the Commission du Génie Biomoléculaire) and replaced them by a temporary committee named "Comité de préfiguration de la Haute Autorité sur les biotechnologies". This

committee only sat on one occasion and its conclusion, given by the chairman of the committee Senator Legrand, stated that the committee had "serious doubts" about the safety of MON810. Twelve scientists and two economists on the committee immediately refuted this conclusion and accused the chairman of misinterpreting the report and of abusing it for political reasons. In a later press interview Senator Legrand admitted that the term "serious doubts" had been introduced following the instructions of Nathalie Kosciusko-Morizet, Secretary of State responsible for Ecology. Despite the positive advice of EFSA and its French homologue AFSSA, and despite having been warned by the European Commissioner for Agriculture Mariann Fischer Boel of the illegality of their position, the French Government continues to maintain that MON810 is unsafe and invokes the safeguard clause to prohibit its cultivation on French territory.

France has consistently delayed its duty to transpose the EC Directive 2001/18/EEC (on the marketing and cultivation of GMOs) into French law. This should have been done in 2002 and unsuccessful attempts were made in 2006 under the government of Chirac/de Villepin. The Sarkozy/Fillon government finally made a new attempt in 2008, but did so as a decree rather than by incorporating it into French law. In August 2009, the French State Council annulled the decree as being illegal, so that the entire process must now be repeated in 2010. In the meantime the European Court of Justice has already imposed a fine of 10 million € for repeated infractions of EC regulations.

While the French example is flagrant, five other countries (Austria, Greece, Hungary, Germany, and Italy) maintain a similarly non-scientific ban of MON810 cultivation. For example in Germany, in 2009, Federal Minister Aigner announced an immediate halt to the cultivation and marketing of MON810, invoking, like France, the safeguard clause [7]. The German Central Commission for Biological Safety (ZKBS) considered the ban to be scientifically unfounded. More than 1600 scientists have appealed to Minister Aigner not to sacrifice a future technology with great potential for reasons of short sighted political interest. On a different continent, Indian politicians are currently preventing the cultivation of Bt brinjal, despite a safety assessment by the Indian Genetic Engineering Approval Committee.

There is considerable hypocrisy among many EC member states who forbid their own farmers the possibility of growing GMO crops, while at the same, time importing essential GMO crops from North and South America.

3. Labeling, traceability and detection

In addition, to science-based GMO food-safety assessment, the EU has GM-food and feed labeling regulations that, for non-scientific political reasons [8], fix a threshold of 0.9% for the adventitious presence of EU-authorized-GMO in a cargo, or food and feed samples (Regulations 1829/2003 and 1830/2003) [4,5]. Above this threshold, all foods, including processed foods in which GM material cannot be analytically detected, must be labeled. Issues such as GMO detection, traceability, labeling and coexistence (discussed below) are not food-safety issues and are not part of the EFSA remit. These regulations have the stated aim of providing freedom of food choice for the consumer [9] and since the regulations also apply to feed, one may suppose that livestock also need freedom of choice. In reality, this aim is not achieved many EU retailers (with the exception of a few products in the Czech Republic, Estonia, the Netherlands, Spain), refuse to stock or sell GMO products. Since Europe does not cultivate significant quantities of GM-crops, the labeling threshold particularly applies to imported food and feed from the GMO producing countries (such as USA, Canada, Brazil and Argentina) and has the effect of giving a price premium to non-GMO food producers. Labelling also

has the effect of serving as a warning to the customer. Though this is not its professed intention, the man-in-the-street has difficulty understanding why EFSA certified 'safe food' should be labelled in the same way as allergenic peanuts or cancer-provoking cigarettes.

A new French committee has now been created, the High Council for Biotechnology, to replace the "Comité de préfiguration de la Haute Autorité sur les biotechnologies" (previous section). It should be noted that this committee now has the less distinguished title of High Council as distinct from the previous committee which was the High Authority. The High Council for Biotechnology is composed of two subcommittees; one, dealing with science, and the other with economic, ethical and social aspects. This latter subcommittee has recently given its advice on the definition of "GMO-free" for labeling purposes which since 2008 is permitted by French national law, in contrast to EU regulations. Curiously the committee defines GMO-free as less than 0.1%, in contrast to the obvious answer which would be 0%. If this advice is followed and transposed into French law, then France (like Germany) will have three kinds of GMO food on the market: >0.9% which must be labeled 'contains GMOs', 0.1–0.9% which does not need to be labeled at all, and <0.1% which may be labeled "GMO-free". Similar labeling would apply to meat from animals (again as in Germany). Such a complex definition is unlikely to allay customer fears of GMOs. There was considerable disagreement among committee members, with minority views concerning the utility, the feasibility, the economics problems and the need for greatly reinforced GMO detection capabilities.

In the USA, the concept of substantial equivalence has facilitated the science-based safety testing of GM-crops and, once these are declared substantially equivalent, these may be rapidly deregulated, after which they may be grown and marketed under normal food-safety regulations, in the same manner as the parent plants. As a consequence, and in contrast to the EU, the USA has no GMO thresholds or obligatory GMO labeling. Attempts to introduce state legislation on GMO labeling, e.g. in Oregon, were unsuccessful.

4. Zero tolerance for unapproved GMOs

For GMOs that are not authorized in the EU, the threshold is "zero" (which translates scientifically as the limit of detection) and this may have economically important consequences such as the return of cargoes to the port of origin. In 2006, there was virtual blockage of the port of Rotterdam, because of the overload of the analytical laboratories of the Competent Authorities, due to the arrival of American rice shipments containing unauthorized Bayer Crop Science LLRice601. LLRice601 is an experimental GMO that was never commercialized and despite an extensive investigation by the USDA, the cause of the admixture was never identified. A US Government Accountability Office (2008) report [10] cites the probable total worldwide costs due to the LLRice incidents as being in the order of \$741 million to \$1.2 billion. In the first of a series of court cases, the US federal jury has ordered Bayer Crop Science to pay \$1.9 million and \$53,336 dollars, as compensation, to each of 2 Missouri farmers.

In July 2009, the EU rejected a cargo 180,000 tons of non-GMO soy flour since it was found to contain minute traces of MON88017 maize (which is resistant to the corn borer and the corn rootworm, as well as being herbicide tolerant). A case like this is referred to a "low-level botanical presence" and is probably due to inadvertent admixing somewhere along the supply chain. It should be noted that the EFSA-GMO panel had previously examined a request by Monsanto for MON88017 maize as an import and for its use as food and feed in the EU. The EFSA-GMO panel found that MON88017 is compositionally, phenotypically and agronomically equivalent to the non-genetically modified counterpart and conventional maize

varieties, except for the presence of Cry3Bb1 and CP4 EPSPS proteins in maize MON88017. In addition, there are no indications of potential toxicity and allergenicity of the Cry3Bb1 and CP4 EPSPS proteins expressed in maize MON88017. Despite this positive recommendation MON88017 had not been formally authorized by the EC and the cargo was thus rejected.

It has been pointed out by several stakeholders that European meat and poultry producers depend heavily on soybean from North and South America and that the zero tolerance policy for unapproved GMOs strongly discourages exportation to Europe. During the summer of 2008 the EC had serious discussions as to whether to raise the threshold level of asynchronously authorized GM-crops (i.e. crops authorized in other countries). A positive decision would have had a dramatic effect on EU imports but, eventually, the EC decided to maintain zero tolerance, stating that the problem would be solved by the recent EC authorizations of new GM soybean (Bayer's Liberty Link and Monsanto's Roundup Ready 2 soybeans). However, it should be noted that the cases of low-level unauthorized presence cited above would not have been solved by this reasoning. In view of the slow rate of GMO approval in the EU and the high rate of asynchronous authorizations in the GM-crop cultivating countries, it is not certain that these measures will suffice. In a report by EC Directorate General of Agriculture [11] the possible scenarios of maintaining a "zero"-tolerance threshold for non-authorized GM plants were evaluated. The worst scenario predicted a dramatic increase in the price of meat and poultry in the EU. In 2009, the EC Joint Research Centre [12] analyzed the probable effects of asynchronous approvals and the continued zero threshold policy of the EU. They similarly concluded that Europe is becoming a risky destination for food exporters, who may thus prefer more friendly clients or who may offset the risk by higher prices. The increasing numbers of GMOs in the pipeline with inevitably increase the probability-mingling. Similar predictions were made independently by the UK Department for Environmental Food and Rural Affairs and the Food Safety Authority, Europabio and others [1,13,14]. Thus European politicians have been warned by their own scientists but it remains to be seen whether they can overcome their anti-scientific attitudes and align with scientific and economic reality.

5. Coexistence

In the EU, field coexistence regulations are formulated by national governments, according to the principle of subsidiarity, while the EC simply issues guidelines. As a result there is great heterogeneity in coexistence regulations on buffer zones and isolation distances between GM and non-GM-crops, which vary between 15 m (for silage maize in Sweden) and 800 m (for maize in Luxembourg) depending on the member state [15]. Such national regulations were implemented before the functioning of the new EC Coexistence Bureau. Despite this, the EC has expressed satisfaction with the evolution of national coexistence regulations. In some member states such as Austria, national coexistence regulations, as well as regulations for liability and redress, are designed to discourage, or make GMO cultivation impossible, in defiance of EC Directive 2001/18/EEC [15]. Furthermore, making national coexistence regulations has little sense as long as the EU has still not formulated regulations on the politically sensitive GM threshold in non-GM-seeds for planting. Despite several years of discussion no progress seems to have been made.

Austria, Bulgaria, Cyprus, Greece, Hungary, Ireland, Latvia, Lithuania, Malta, Slovenia and the Netherlands have recently written a joint paper requesting that individual countries have the right to decide whether or not to cultivate GM. This request is in contradiction with present EU GMO legislation, and gives some idea of the turmoil faced by the EC over the issue of GMO

cultivation, which is typified by the conflict between the EC DG Agriculture and EC DG Environment. If such a move succeeds then the word ‘coexistence’ may well disappear from the European GMO glossary.

The USA, in contrast to the EU, has no regulations on coexistence for deregulated GMOs. However, as other exporting countries such as Canada, Brazil and Argentina, it does have a system of “identity preservation” which is a system of private contracts to provide importing countries with guaranteed non-GM products. In Argentina, the large size of the farms is such that very large separation distances may be implemented between GM and non-GM-crops, making it possible to guarantee a product with less than 0.1% GMO (well below the 0.9% threshold posed by the EU). However cross pollination is not the only mechanism for mingling and further precautions must be taken during transport, storage and shipping. The ultimate form of identity preservation is called ‘Hard’ identity preservation in which grain is shipped in sealed containers. Naturally, all of these precautions come at an additional cost which EC importers and consumers may or may not wish to bear.

6. Regulatory convergence of the USA and the EU?

Given the different and contradictory philosophies of the EU and US GMO regulatory processes, it may thus seem surprising to see that the two may now be converging, in that the more flexible US system may be approaching the rigid EU system. This may be seen in two recent US reports; one from United States Government Accountability Office (an investigative arm of Congress) [10] and the other from the USDA Office of the Inspector General [16]. These reports stem from three recent changes in the situation in the USA.

Firstly, there have always been flaws in the functioning of the US food and feed supply-chain system, whereby non-authorized (sometimes experimental) GM-crops have mingled with the food and feed chains [4,5]. One early example was the contamination of the human food chain by Aventis Starlink maize, which was authorized for animal, but not human consumption (Starlink was the first and last product to receive this split registration). In another incident, volunteers of Prodigene maize (designed as a pig vaccine) grew in a field of soybeans which were then sent to the elevator. The USDA destroyed 500,000 bushels of soybean was destroyed and Prodigene was fined 250,000\$ and ordered to provide a trust fund of 1 million \$. Other incidents soon followed, including the unauthorized Bayer Crop Science LL601 rice from an experimental field trial, and the unauthorized Syngenta Bt10 maize which was mistakenly cultivated over several thousands of acres as the authorized Bt11. In 2008, Dow AgroScience discovered a low level of unauthorized Event 32 in its deregulated maize Event 22. In 2008, recently an experimental variety of Monsanto GM cotton was accidentally processed with a commercial variety from a nearby field. In 2009, MON88017 maize which was found to be present at low levels in soybean flour (discussed above) has been cultivated in the USA since 2005 and had a complete EFSA biosafety assessment but lacked formal EC approval and thus was also rejected at the port of entry. The low-level GMO presence of food and feed supplies cited above were deemed harmless for human health by all scientific authorities, and indeed some (such as LLrice601 and Bt10) were very rapidly deregulated by the USDA, while EFSA, though lacking a complete dossier, considered that minute quantities of LLrice601 or Bt10 were unlikely to pose a safety concern to humans or animals. Finally, in September 2009, the EU Rapid Alert System reported the presence of Canadian GMO flax (linseed) (FP967, CDC Triffid) in cereal and bakery products in several EU member states. FP967 is authorized for food and feed in the USA and Canada. From these examples, it is clear that the presence of low-level GMO admixing cannot be avoided using

current procedures. The choice is thus to either to import only food and feed in which the purity has been guaranteed by hard identity preservation, or to change the EC regulations to correspond to the reality of the situation.

The US Government Accountability Office [10] has recommended increased oversight over accidental release of US unauthorized GMOs. In particular, the GAO report states that *the USDA, EPA, and FDA do not have a coordinated program for monitoring and evaluating the use of marketed GE crops to determine whether they are causing (1) undesirable effects to the environment or economic harm to non-GE segments of agriculture through the unintentional spread of GE traits or (2) food safety concerns, such as the unintentional introduction of pharmaceutical or industrial compounds into the food supply*. Thus, the US regulatory authorities are beginning to accept the possible need for European-style GM-crop supply-chain coexistence, detection and traceability regulations.

Secondly, until now the USA based companies have been virtually the only developers of GM-crops and all GM-crops cultivated on a large scale have been previously authorized, and are thus well known, to the USDA/APHIS/EPA regulatory authorities. However, other countries are now producing new GM-crops about which the US (and EU) authorities have little or no information, thus making enhanced oversight more urgent. For example, an experimental Chinese insect-resistant rice, Xianyou63 (Bt63), has already been found in world food supply in the form of rice noodles. China has recently (December 2009) authorized the cultivation of the world's first GM corn expressing phytase. Phytase is well known as a feed additive to help the breakdown of phytic acid which sequesters 60% of the phosphorus so that is less available for animal metabolism and thus causes environmental pollution. Similarly, China has also authorized a new Bt cotton and a new Bt maize.

Since, unknown GMOs are extremely difficult to detect in the absence of knowledge of the insert they contain [4,5], it is impossible to determine in a cost-effective way which other unknown GMOs may presently be in circulation, particularly since an increasing number of countries are developing GMOs (China, India, Cuba, Taiwan, etc.). In contrast to the USA, Europe has for many years invested heavily in GMO coexistence, detection and traceability via several research programs such as the EC-funded project Co-Extra and the European Network of GMO Laboratories which devote a large research effort to the development and validation of GMO detection methods, including those for unauthorized and unknown GMOs. Considerable research on GMO detection has similarly been performed in Japan, Korea and Taiwan.

Thirdly new food-safety concerns arise from the proposals to cultivate GM-crops for pharmaceutical (human proteins, antibodies and antigens) [17,18] or industrial productions. These same crops, usually already used for food and feed, would necessitate stringent EU-style coexistence, detection and traceability measures, probably coupled with US-style IP or EU coexistence protocols. In view of the past experience in complete segregation (discussed above) it seems unlikely that these measures will suffice. A better solution (not presently being followed) might be to produce such products in non-food non-feed plants. In August 2009, EFSA released the first EC guidelines for the safety regulation of what it calls GMOs crops for non-food non-feed purposes [19], which include crops for industry, pharmaceuticals, biofuels and phytoremediation.

The recent audit published by the USDA Office of the Inspector General [16] notes that the USDA is presently competent in dealing with GM-crops originating in the USA. However, it underlines the fact that the *‘USDA has no controls in place to identify undeclared regulated transgenic plants or to identify a shipment of undeclared transgenic plants unknown to the US regulatory system’*. The objective of this monitoring strategy is stated as *‘to mitigate or avoid future risks to the US environment agriculture and trade.’* These

objectives are close, or identical, to those of the EU (as well as Japan and Korea) for the monitoring of imported GMOs from other countries (including the USA) and indeed the USDA Office of the Inspector General audit recommends ‘*cooperating bilateral with countries invested in biotechnology research and with the Codex Alimentarius*’. The USDA-APHIS has now completed a period of public commentary and is presently revising its GMO regulations [20] with regard to importation, interstate movement and environmental release (including plants producing pharmaceuticals). The new regulations will also treat the low-level presence of GMOs, but in contrast to the EU, the USDA/APHIS considers that a zero tolerance for low-level presence to be neither warranted nor practical and recommend a case-by-case approach.

7. Conclusion

Europe has probably the strictest GMO regulations in the world though these derive rather from political considerations, rather than being based upon scientific principles. The European anti-science attitude reaches the highest levels of the EU bureaucracy and the highest levels of national governments, though, happily, not all members are affected. The EC regulations specifying the 0.9% labeling threshold for authorized GMOs and the 0% tolerance for unauthorized or asynchronously approved GMOs now place the EU in a position where they are now causing trade disruptions and a shortage of animal feed. This will inevitably lead to price rises in the meat and poultry industries, with greater importation of foreign meat from animals fed with grain non-authorized in the EU. While these effects have been predicted in authoritative reports, including those of the EC DG Agriculture and the EC Joint Research Centre, there is no reason to believe that they are influencing EU policy. It is clear that worldwide harmonization of GMO approval procedures is urgently required.

For many years the USA has been an ardent critic of EU GMO regulations, claiming that they are not science-based and represent a concealed trade barrier enabling the EC moratorium on GMO authorizations (1998–2004). This prompted the WTO dispute between the EU and the USA, Argentina and Canada. Given this previous logic, it is curious that two new US reports, [10,16], now indicate that admixing of unauthorized and foreign GM-crops in US supply chains, now need to be taken into consideration for GMO regulations in the USA. US GMO regulations may thus converge with the EU regulations in areas of authorizations, coexistence of supply chains, detection and traceability.

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