

EN

EN

EN



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17.9.2008
COM(2008) 560 final

**REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN
PARLIAMENT**

**on the implementation of Regulation (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 and amending Directive
2001/18/EC**

REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

on the implementation of Regulation (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 and amending Directive 2001/18/EC

Regulation (EC) No 1830/2003¹ (hereinafter "the Regulation") was adopted on 22 September 2003 and, following the publication of Commission Regulation (EC) No 65/2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms, became fully applicable on 16 April 2004.

On 10 May 2006, and in accordance with Article 12 of the Regulation, the Commission forwarded to the European Parliament and to the Council a report on the implementation of the Regulation. However, since only a limited amount of information and experience was available to underpin Member States' input (2005), the Commission has drawn up the current report to give a more complete picture of its implementation. 23 Member States submitted their input, as well as two industry associations (Annex). Other stakeholders were consulted as well, but did not submit their input.

Information from Member States was gathered by means of a 10-part questionnaire: interpretation of traceability rules, implementation and effect of traceability rules, traceability of mixtures of GMOs, interpretation of labelling rules, implementation and effect of labelling rules, exceptions for traceability and labelling requirements below the thresholds, unique identifiers, inspection and control measures, decision on documentation requirements under the Cartagena Protocol and other issues.

1. THE MARKETING OF GMOs IN THE EUROPEAN UNION

No new patterns have emerged after the publication of the first report. While the European food and retailing industries remain resistant to marketing GM food and food products, the majority of GM products placed on the European market are destined for animal feed and originate from imported commodities, largely soybean and maize. Many Member States reported that no living GMOs are imported for cultivation. In 2006 MON810 remained the only GMO cultivated in six Member States, with a total area of approximately 60 000 ha (mainly in Spain, but also in France, Germany, Czech Republic, Slovakia and Portugal). This area increased in 2007 to some 110 000 ha..

With regard to the traceability and labelling of GMOs, many Member States still report limited or no experience and as a result submitted no new information. The Commission (Eurostat) is examining the possibility of obtaining official statistics on extra-EU imports and feed market penetration of GM based products.

¹ OJ L 268, 18.10.2003, p. 24. A report from the Commission to the Council and the European Parliament on the implementation of this Regulation was published on 25.10.2006, COM(2006)626 final.

2. INTERPRETATION, IMPLEMENTATION AND EFFECT OF TRACEABILITY RULES

Despite some concerns about the complexity of legislation and overlapping requirements between the Regulation and Regulation (EC) No 1829/2003², the majority of Member States reported no problems with interpreting the traceability rules. They noted that overall the system is progressing. As a standard business practice, operators ask suppliers for the necessary documentation, and more and more business operators declare GM modifications in the accompanying documents. However, significant experience suggests that this refers mainly to the feed industry³.

The majority of Member States have found that the effect of traceability rules on labelling and informed choice is positive, because they facilitate official controls, risk management and the functioning of the entire system. The effect on imports is also reckoned to depend on the product and is particularly important where exporters from third countries submit little information about the presence of GMOs. However it should be noted that the traceability rules of the Regulation make no distinction between EU products and imports from third countries. So the challenges concerning the availability of documentation remain the same for EU and third countries operators⁴.

Traceability rules have an overall positive influence on public opinion on food safety, and a favourable impact on the marketing of non-GM products due to the persisting negative perception of GM products by consumers⁵. One Member State also reported that these rules had a positive effect on small enterprises thanks to the improved control framework, thus resulting in less economic damage. Another Member State reported that small enterprises avoid buying GM ingredients because of the administrative and financial burdens associated with the EU traceability rules⁶.

Several other problems have been indicated. One Member State reported that only large enterprises have systems for requesting assurances and certificates, and verification systems, such as demanding analytical reports or taking samples (though it should be noted that analytical reports and/or sampling are not required under the Regulation). Under Article 4(1) of the Regulation, operators are solely responsible for the written transmission of the unique identifier and of information to the effect that the product contains or consists of GMOs.

Another Member State reported that operators are not always aware of their obligation to keep the respective documentation for five years and that only in a few cases is this done. Some Member States mentioned practical problems in applying the traceability rules, such as when the origin of GMOs cannot be proved or when the products are not labelled properly at the beginning of the production chain.

² OJ L 268, 18.10.2003, p.1

³ It should be noted that Member States have already gained experience with the implementation of Article 18 of Regulation (EC) No 178/2002 on traceability. The Commission has published guidelines which make reference to the traceability requirements for GMOs. (http://ec.europa.eu/food/food/foodlaw/traceability/factsheet_trace_2007_en.pdf).

⁴ Moreover there is no legal basis requiring third countries or exporters to supply information under Article 5 of the Regulation. However importers' responsibilities are defined in Article 11 of Regulation (EC) No 178/2002 which make importers in Member States ultimately responsible for ensuring that imports meet EU requirements at the point of entry relating to more specific EU legislation, e.g. on traceability and labelling.

⁵ Eurobarometer 64.3, Europeans and Biotechnology in 2005: Patterns and Trends

⁶ On this point it should be noted that operators are required to implement traceability rules under Article 18 of Regulation (EC) No 178/2002, irrespective of whether or not their products contain GMOs.

It is generally agreed that the EU food industry remains reluctant to use GM products. In some Member States, the majority of food and feed operators initially refused GM products to avoid compulsory labelling, which in their view would entail additional costs. However feed operators later compromised against the background that almost all marketed soybean meal imported into the EU was genetically modified. One overseas association expressed concern at the fact that EU food processors and retailers had stopped using soybean oil from the US, because the resulting food and feed products would be labelled as GM even if no DNA from the modification appears in the oil, and deplored the fact that such products required labelling.

3. INTERPRETATION, IMPLEMENTATION AND EFFECT OF LABELLING RULES

Most Member States reported no problems with way labelling rules were being interpreted by officials. A few Member States noted a lack of clarity about the precise differences between the scope of the Regulation and Regulation (EC) No 1829/2003 for GM food and feed. Another Member State was unclear about the labelling of some types of food and feed produced from GMOs which are used only for industrial purposes (e.g. oil used for cleaning frying pans) and about the precise interpretation of the term "food and feed produced from GMOs". A further Member State reported a lack of clarity among industry representatives concerning the need for labelling of particular products (e.g. fermentation products *vis-a-vis* soya oil)⁷.

Member States generally consider the labelling rules to be running smoothly. Identified problems concern mislabelling (e.g. labels indicating that a product "may" contain GMOs), negative labelling in breach of national legislation (e.g. "non-GM" or "GM-free"), lack of documentation indicating GM presence in non pre-packaged products, and lack of labelling despite the 0.9% threshold being exceeded. One Member State felt that the option for operators to indicate either that "This product contains GMOs" or "This product contains genetically modified (name of organism(s))" on a label (Art. 4(6) of the Regulation) might prevent the final recipient from knowing precisely how much GMO the product contained.

Most Member States reported that labelling rules produced effects on the market and consumers, such as more informed choice, more efficient prevention of deceptive practices and an increase in consumer demand for non-GM ingredients in the food chain. However, and because of the 0.9% threshold, some Member States indicated that for GMOs such as feedingstuffs, the unavailability of information about the adventitious or technically unavoidable presence of GMOs below the 0.9% made it impossible to purchase entirely GM-free products.

4. LABELLING THRESHOLDS AND ADVENTITIOUS PRESENCE OF GMOs

The majority of Member States have indicated no particular problems with the proper application of thresholds (0.9%) for the exemption from labelling of food and feed products. Random samplings and laboratory analyses are the usual practice, and a few infringements (such as mislabelling) have been noted. Member States usually check certificates from suppliers, technical data sheets and identity preservation of the product.

⁷ A new regulation on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC and Council Directive 2001/112/EC which clearly define GMOs for enzymes has been proposed by the Commission (http://ec.europa.eu/food/food/chemicalsafety/additives/prop_leg_en.htm).

However some Member States pointed to the need to resolve the threshold issue in the case of stacked events. There are practical difficulties when a mixture of grains, flours or a processed product has to be analysed, as they might contain different ingredients produced from the same raw material, e.g. starch and flour from maize. Some Member States and stakeholders also pointed to the need for labelling thresholds for the presence of GMOs in seeds. The Commission is currently carrying out an impact assessment to examine this issue.

One professional association notes that the 0.9% threshold constitutes an arbitrary choice and should be raised to a more pragmatic level. An overseas organisation considers that as a result of the labelling rules importers have stopped importing soybean oil for food use, forcing industries to use high priced conventional rapeseed oil instead. They also note that labelling requirements are based on origin rather than detection, i.e. on the availability of the necessary certificates and not the possibility of detecting GMOs in the products. In their view this places an unfair burden on operators in the food and feed sector to verify compliance of refined material⁸.

Several Member States reported their views on how to interpret "adventitious presence". The assessment of whether GMOs are present in the food and feed chain by accident or due to operators' negligence is on a case-by-case basis, and Member States seem to follow different methods. Operators usually have to provide evidence of their intention to avoid GM presence at all stages of production. This evidence includes certificates of ordering and purchase of non-GM material, use of separate storages areas, and production lines free of GMOs. Some Member States also check the order of production, the cleaning procedures and all necessary measures to conclude that any presence is adventitious and technically unavoidable. A few Member States reported that, if the original material in the food and feed chain is labelled as GM, then the final product is labelled GM as well, even if the traces are below 0.9%, because in that case their presence is not considered to be adventitious.

5. THE USE OF UNIQUE IDENTIFIERS

Most Member States regard unique identifiers as useful tools for identifying and labelling genetically modified products and report no serious problems. Overall they reported limited but positive experience with regard to the implementation of Regulation (EC) No 65/2004 and the use of unique identifiers.

One Member State where GM-maize is cultivated reported that unique identifiers are included in the documentation transmitted from the seed suppliers to farmers and the processors. One industry association also felt that the requirements for transaction and labelling of GM varieties had been implemented as standard business practice where requested, but that these requirements had increased existing administrative obligations and costs. These unique identifiers, such as MON-04032-6, are readily available at:

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

A few Member States pointed to the fact that unique identifiers are not always included in the documentation accompanying the products – in that case traceability is not reliable and business operators endeavour to get these codes by requesting additional information from the suppliers.

⁸ It should be noted that in the context of this report, any reference to "origin" should be associated with the production and processing methods and not the geographic origin, which is not important in terms of the traceability and labelling of GMOs.

6. ENFORCEMENT OF THE REGULATION BY THE MEMBER STATES AND IMPLEMENTATION OF RECOMMENDATION 2004/787/EC

The majority of Member States reported that overall controls and official inspections are carried out without serious problems. However it should be noted that some of their practices differ significantly. In some Member States the majority of checks are documentary, while sampling and analysis are limited due to the cost factor. Other Member States reported that control officers principally check whether the operators perform "in house" controls in accordance with the regulations.

Several Member States reported problems with the limited resources available, and the resultant reduction in inspections and controls. In several Member States additional staff are needed on a seasonal basis, e.g. on auditing seed installations. One Member State reported lack of resources for testing food in accordance with the Recommendation 2004/787/EC, which requires separate analysis of file incremental samples.

Several Member States made reference to the benefits of training programmes for inspectors, such as the ones provided by the JRC and within the framework of TAIEX, and the advantages of having their laboratories involved in the ENGL network.

National provisions have established sanctions for infringing the respective Community and national legislation, including warnings, withdrawal of products, return to country of origin, re-labelling, fines and imprisonment. No serious patterns of infringement have been noted, while most of the identified violations of the law concern non-labelling and insufficient operating procedures for traceability of GM products. A professional organisation notes that some penalties have been disproportionate for the adventitious presence of EU-authorised events, including mandatory destructions and criminal prosecutions.

Several Member States have reported enforcement problems with products derived from GMOs which do not contain any detectable and identifiable GMO-material but still have to be labelled. The main challenge in this area lies with the fact that the competent authorities can carry out only documentary checks on preventive measures, while due to the absence in many cases of detectable DNA, sampling would not necessarily be an option. Therefore they sometimes face problems where exporters and authorities in third countries are unwilling to provide importers with the necessary information to comply with traceability and labelling legislation. On the other hand it should be noted that importers are obliged to demand this information. Otherwise they would be in breach of Community law by importing products which fail to comply with the respective provisions. An industry organisation considers that the obligation of labelling these products creates a competitive disadvantage for European industry. An overseas association claims that the mandatory traceability and labelling of refined soybean oil is open to fraudulent practice, since it cannot be verified by any sort of scientific test.

As in the previous report, Member States indicated problems with the implementation of Recommendation 2004/787/EC on sampling and detection. The majority of Member States consider its implementation as expensive and time-consuming, especially with regard to big shipments. They claim that checking and sampling imported bulk shipments according to the technical guidance of the Recommendation places a major burden on control authorities and the results are not in proportion with the time spent or the financial burden. They report that the required number of incremental samples is too high, especially in ships above 500 tonnes. A few Member States reported that they employ methods for sampling feeds based on the old feeding sampling Directive 76/371/EEC, establishing the quantitative method of sampling for the official control of feedingstuffs. A Member State also reports that sampling of bulk commodities is in accordance with the general principles and methods described in ISO

standard 13690 (1999). It is also claimed that the Recommendation is impossible to apply for pre-packaged food or for small amounts of an ingredient.

As indicated in the first report, there are still problems in terms of the units in which GM content should be expressed. Recommendation 2004/787/EC advises that "the results of quantitative analysis should be expressed as the percentage of GM DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes". Nevertheless, some Member States ask their laboratories to express measurements of authorised GM materials in weight-% rather than haploid genomes-%, as the labelling threshold in their view must be with respect to weight or number of grains and not DNA content. One Member State reported that they use haploid genomes-% only when plasmid-based reference material is available.

Some other Member States have noted that method validation according to ISO 17025, as suggested by the Recommendation, depends on the national accreditation body. Requirements differ significantly between Member States. It has been claimed that ISO 17025 accreditation is more of a bureaucratic device, which guarantees good traceability and documentation inside a laboratory, than a tool which guarantees scientific harmonisation. It should be noted that ISO 17025 is a system for quality assurance in laboratories, not a method for the qualitative and quantitative analysis of GMOs. There are CRL methods for all authorised GMOs under Regulation (EC) No 1829/2003 which are then validated in Member States' laboratories according to the framework quality control rules set out in ISO 17025.

As indicated in the previous report, a further problem concerns the difficulty in inspecting unauthorised GMOs or stacked gene events without validated detection methods and certified reference material.

7. CONCLUSIONS

Member States and stakeholders have gained additional experience on the implementation of the Regulation since the publication of the last report. This is particularly true of the feed sector, and it has been evident in their input on a series of practical matters. However, the overall experience in the food sector remains modest, mainly due to the limited number of GMOs and derived products currently being marketed in the European Union.

As also mentioned in the last report, Member States indicated that the Regulation's provisions were being properly interpreted and implemented. They consider the provisions as steps towards more informed choice, more efficient prevention of deceptive practices and better official controls. However, several problems concerning the application of business practices pose major challenges for GMO policy making and its enforcement in the European Union.

Industrial associations and exporters from third countries continue to argue that the Regulation introduces excessive administrative burdens. It restricts the export of GMOs to the European Union, and forces European operators to use high priced conventional products. They consider the labelling thresholds as arbitrary choices and claim that labelling products produced from GMOs, where no GM material can be detected, places an unfair burden on operators in the food and feed sector to verify compliance of refined material.

As also indicated in the first report, the Commission considers that several factors, like consumer demand for non-GM products, higher prices in the feed sector and asynchronous approval for GMOs between countries, have had a far greater effect on the trade in GMOs. The requirement for labelling aims to deliver free choice for operators and consumers and should not be considered as an obstacle to the marketing of authorised GM products.

The Commission will continue to work with the Competent Authorities of Member States to ensure the appropriate implementation of the Regulation. At the same time it will continue to examine with stakeholders all possible aspects of implementing and possibly improving the policy on the traceability and labelling of GMOs. The Commission (Eurostat) will also continue its efforts to obtain official statistics on GM based products, in particular on the volume of EU imports of GM based products from non-EU countries, on feed market penetration and on GMO cultivated surfaces.

ANNEX

Institutions which contributed their input

Ministry of Health, Family and Youth, Austria
Federal Public Services Public Health, Food Chain and Environment, Belgium
FAVV / AFSCA: Federal Agency for the Food Chain Safety, Belgium
Department of Agriculture, Cyprus
Ministry of the Environment, Czech Republic
Danish Plant Directorate
Ministry of Trade and Industry, Finland
Ministry of Agriculture and Forestry, Finland
Finnish Food Safety Authority Evira
Customs Laboratory, Finland
Ministry of the Environment, Finland
Federal Office of consumer Protection and Food Safety, Germany
Ministry of Rural Development and Food, Greece
Ministry of Development, Hellenic Food Safety Authority, Greece
Ministry of Economy and Finance, General Chemical State Laboratory, Greece
Ministry for Environment and Water, Hungary
Ministry for the Environment and Territory, Italy
Food and Veterinary Service, Latvia
Ministry of Agriculture, Latvia
Ministry of Environment, Lithuania
State Food and Veterinary Service, Lithuania
Ministry of Health, Luxembourg
Malta Environment and Planning Authority
Malta Standards Authority
Ministry of Housing, Spatial Planning and the Environment, Netherlands
Ministry of the Environment, Department of Nature Conservation, Poland
GPP, Cabinet of Political Planning, Portugal
DGADR, General Directorate of Agriculture and Rural Development, Portugal
National Sanitary Veterinary and Food Safety Authority, Romania
State Veterinary and Food Administration, Slovakia
Central Controlling and Testing Institute for Agriculture, Slovakia
Ministry of Agriculture, Forestry and Food, Slovenia
Ministry of Health, Slovenia

Ministry for the Environment and Spatial Planning, Slovenia

Ministry of Environment, Spain

National Food Administration, Sweden

Department for Environment, Food and Rural Affairs, UK

European Association for Bio-industries (EuropaBio)

American Soybean Association (ASA)