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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

Introduction

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 organisms², fully applicable on 16 April 2004.

The labelling and traceability requirements of the Regulation extend to products that are placed on the market and which contain or consist of genetically modified organisms (GMOs). The Regulation also includes provisions for the traceability of food and feed products produced from GMOs.

The objectives for traceability under the Regulation are to facilitate;

- control and verification of labelling claims
- targeted monitoring of potential effects on the environment, where appropriate
- identification and withdrawal of products that contain or consist of GMOs should an unforeseen risk to human health or the environment be established

To ensure traceability and labelling, the provisions of the Regulation require operators to transmit and retain specified information for the above GM product types at each stage of their placing on the market. Notably;

- operators are required to have systems and procedures in place to identify to whom and from whom products are made available
- for *GMOs intended for deliberate release into the environment (eg. seeds)*, operators are required to transmit specified information on the identity (unique identifier) of the individual GMO(s) a product contains
- for *GMOs intended for food, feed or for processing*, operators may either transmit the specified information detailed above or transmit a declaration that the product shall only be used as food or feed or for processing, together with the identity of the GMO(s) that *have been used* to constitute the mixture

¹ OJ L 268, 18.10.2003, p. 24.

² OJ L 10, 16.01.2004, p. 5.

- for *food and feed produced from GMO(s)* operators are required to inform the next operator in the chain that the product is produced from GMO(s)
- operators are required to retain the information for a period of 5 years and make it available to competent authorities on demand
- thresholds have been established below which adventitious or technically unavoidable traces of certain GMOs and GM material, in food, feed and processing products, do not require labelling or tracing

Transmission and retention of the above information is intended to reduce the need for sampling and testing of products, which is not an obligatory requirement for the operators under the Regulation. Nevertheless, to facilitate a co-ordinated approach for inspection and control by the Member States, the Commission has developed technical guidance³ on sampling and testing methods.

In view of the requirements of the Regulation, it is important to note that at the time of finalising this report, a decision on documentation requirements for *GMOs intended for food, feed or for processing*⁴ to be used in international trade was adopted under the Cartagena Protocol on Biosafety (Third Meeting of the Parties, 13 to 17 March 2006, Curitiba, Brazil).

According to this decision, Parties to the Protocol must take measures to ensure that documentation accompanying international shipments of GMOs in commercial production includes the identity of the GMOs contained in the shipment, when their precise identity is known. In cases where the identity of GMOs in a shipment is not precisely known, documentation should make clear that the shipment "may contain" GMOs, together with the identity of the GMOs that may be contained in the shipment.

The decision is consistent with the traceability requirements of the Regulation, in particular with regard to its Article 4(3). The implementation of this decision will be reviewed in 2012⁵, when the feasibility of extending the requirement for precise information on the identity of the GMOs contained in an international shipment will be assessed. For this purpose, experience gained with the Regulation should provide useful information.

Interplay with Regulation (EC) No 1829/2003

Regulation (EC) No 1829/2003 on genetically modified food and feed⁶ was developed alongside the Regulation and was also adopted on 22 September 2003. The two regulations are intended to operate in tandem and rely on each other for certain requirements. Notably, the Regulation provides traceability requirements for all food and feed products that fall under the scope of Regulation (EC) No 1829/2003. These traceability requirements are of fundamental importance when labelling of the final product relies on information transmission in the absence of detectable GM material in products.

Similarly, the labelling requirements for food and feed products produced from GMOs, subject to the traceability requirements under Article 5 of the Regulation, are provided for by

³ OJ L 348, 24.11.2004, p. 18.

⁴ Article 18.2(a) of the Cartagena Protocol on Biosafety

⁵ 6th Meeting of the Parties to the Cartagena Protocol on Biosafety

⁶ OJ L 268, 18.10.2003, p.1.

Chapter II, Section II and Chapter III, section II of Regulation (EC) No 1829/2003. In addition, Regulation (EC) No 1829/2003 lays down threshold values for food and feed products below which adventitious traces of such products are exempted from its labelling requirements. The same thresholds have been utilised by the Regulation to provide the same exemption from its own labelling and traceability requirements ensuring a coherent and consistent Community approach.

Article 12 of the Regulation states that; ‘no later than 18 October 2005, the Commission shall forward to the European Parliament and to the Council a report on the implementation of the Regulation, in particular with regard to Article 4(3)’.

In accounting for this requirement, the Commission compiled a questionnaire comprising questions on implementation in five sections as follows;

- Traceability requirements
- Labelling requirements
- Exemptions from traceability and labelling requirements
- Inspection and control measures
- Other issues

The questionnaire was submitted to all competent authorities, as well as relevant stakeholders from all sectors, including members and associations of the food, feed and seed industry, trading partners, NGOs and relevant government departments of Member States. A list of respondees is presented in Annex 1.

The responses, as well as other information received and retrieved by the Commission from the date of application of the Regulation to the current time, have been taken into account in the report as laid down in the following sections.

Regulation (EC) No 1829/2003 contains a similar requirement (Article 48) for the Commission to produce a report, no later than 7 November 2005, concerning experiences gained with this regulation. The Commission has taken account of the above interplay between the two regulations and has attempted to avoid duplication in the two reports.

The food production and distribution chains

The European food and retailing industries remain reticent to market GM food and food products due to the perception of negative consumer reaction. As a result, only a limited number of products are currently being marketed and imported GM material is currently not utilised in food products to any great extent.

The European industry recognises that consumer and public perception drives market forces and that a high level of health and environmental protection must be ensured in order to be able to market GM products. The industry currently appears to be responding to retailer/consumers demands of non-GM products and is, therefore, attempting to avoid purchasing ingredients containing or produced from GMOs.

Trading partners do not appear to share this view. Indeed, a large third country food exporter has stated that it no longer exports any processed food products to the European Union. It alleges that this is due to the burden of the regulatory framework, which specifically includes the traceability provisions of the Regulation, rather than to market demand.

A third country industry association has stated that many companies marketing food products in the European Union have stopped using internally produced GM soybean oil and protein ingredients to avoid what are perceived as onerous and costly mandatory traceability requirements of the Regulation. It has also stated that the requirements have allegedly led to a decrease in the export of certified organic commodities containing soybean material. This problem has been attributed to the 'restrictive' 0.9% threshold for adventitious presence.

A second food association also argues that an additional layer of administrative and financial costs is imposed by the labelling and traceability requirements and highlights, in particular, that this has created an unacceptable burden on small food exporters. It also suggests that conflicting national regulations and different approaches to enforcement in individual Member States adds to the regulatory burden of business transactions.

An overseas Government Department, in its response to the questionnaire, similarly claims that the Regulation is a barrier to trade arguing that it is too restrictive and provides a disincentive for manufacturers to place GM products on the market. However it should be noted that available data - and in particular the relevant market share of GM products in the **feed** distribution chain - do not confirm this view, indicating, on the contrary, that GM **food** trade patterns are largely market (consumers) driven.

This Government Department also alleges that the reluctance of European industry to offer GM products to consumers, the lack of implementation of the Regulation by certain Member States and delays in new product approvals have provided major obstacles in obtaining relevant information in terms of implementation of the Regulation, notably with respect to its Article 4(3). The Department further suggests in its response that it is difficult for stakeholders to provide practical input to this report (as a means to improve the consistency of the Regulation) given that they do not have the necessary experience with its implementation as yet.

In particular, the US Government (and certain third country food associations) has urged that the European Commission joins with trading partners to work towards harmonisation and some form of mutual recognition of the trade of GM products that relieves small enterprises of such administrative burdens. They suggest, in particular, a need for guidance on documentary requirements to address the issue of consistent implementation. It should be noted that the Commission has actively engaged in and remains open to international discussions with trading partners but since 2002, the US Government has been reticent to engage in bi-lateral discussions on issues pertaining to GMOs.

In terms of the limited number of food products that are currently marketed, certain NGO groups express that in general, the labelling rules have a positive effect in facilitating informed choice.

However, they also state that it is not acceptable and misleading that the traceability of products (milk, meat, eggs, wool etc) derived from animals fed with GM material is excluded from the scope of the Regulation. They perceive this as a 'loophole' that undermines the credibility of the whole labelling system. It should be noted that the labelling and traceability

of such products was extensively discussed by both the Council and European Parliament during preparation of the Regulation but their inclusion was not adopted.

The feed production and distribution chains

The majority of GM products placed on the European market are destined for animal feed and originate from imported commodities, largely soybean, either containing or produced from GMOs. Millions of tonnes of soybean material are imported into the European Union every year, largely from the US, Argentina and Brazil. These countries grow a high proportion of GM soybean crops and shipments into the Community will, therefore, inevitably contain GM soybean material.

Certain trading partners state that because soybeans exported within a given shipment for feed use are often thoroughly mixed by the US commodity-handling system (and may also contain soybeans from Canada), it is not feasible to transmit the information required by the Regulation. This viewpoint is somewhat surprising given that the European feed industry and competent authorities have reported that the correct information (in accordance with the Regulation) has been provided with imported shipments of soybean. Moreover, members of the European feed industry have stated that the requirements of the Regulation have not altered sales of animal feed although many consider the provisions as burdensome and unnecessary. Interestingly, industry contacts have suggested that certain crushers of non-GM soybeans have had some difficulties in selling the resultant material as operators are not prepared to pay the associated premium costs.

At the current time, the Monsanto Round-up Ready soybean accounts for the majority of GM soybean grown in the Americas and indeed, world-wide. This variety is the only GM soybean product that has received Community approval (for import and use in food and feed). Meeting the traceability and labelling requirements for imports of bulk commodity soybean shipments does not appear to have created many problems given the predominance of a single variety. The situation may change, however, as further GM soybean varieties are approved in exporting countries.

Labelling and traceability of GM seed products for cultivation

Cultivation of GMOs is not practised in the vast majority of Member States although Bt-maize is commercially grown (approximately 60 000 ha) in certain regions of Spain. This and other GM maize varieties are also grown in France, Germany, the Czech Republic and Portugal but on a much smaller scale. The harvested products from these crops are largely used for animal feed 'on farm' although some are destined for processing via the starch industry. Very few, if any, of these GM maize products are subsequently exported.

Reports suggest that marketing of 'internally produced' GM products has not created problems given the continued experience of both farmers and subsequent operators (although it must be noted that the majority of products remain 'on-farm'). Labelling of GM seed stocks appears to have been complied with although some problems have been reported concerning the 'interpretation' and calculation of adventitious traces of GMOs in conventional seed lots.

The experience of the plant biotechnology industry (technology providers and integrators, including seed companies) has been somewhat limited to date as GM crop varieties have not been widely available to growers in the EU for commercial cultivation. Nevertheless, the industry has reported that no serious problems have been encountered concerning

interpretation of the Regulation and in countries where GM varieties are available (notably in Spain) no particular difficulties have been encountered in implementing the Regulation. Indeed, the requirements for documentation of transactions and the labelling of GM varieties appear to have been implemented as a standard business practice. These requirements have, however, apparently added to the administrative requirements and associated costs (although actual figures have not been provided).

Enforcement of the Regulation

Many national authorities, as for organisations from other sectors, have deemed that there has been an insufficient period of time in which to gather relevant experience and information concerning implementation of the Regulation. Nevertheless, a large majority of Member States consider that the requirements of the Regulation have had a positive effect on the provision of relevant information, consumer choice as well as the necessary safety guarantees. The necessity of these requirements has been highlighted notably by Member States where organic production is viewed as important. Other Member States consider that the Regulation should be made stricter for imported goods with tighter control measures to ensure compliance.

Certain Member States have reported difficulties with sampling and testing, pointing to the complexity of the techniques, particularly where detection of adventitious presence is required. 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 confusion still exists in terms of the units in which GM content should be expressed and some Member States have referred to a need for conversion factors allowing for a harmonised approach irrespective of whether GM content is expressed according to DNA, weight or seed number. Further queries of this nature have extended to the introduction of ‘stacked-gene’ varieties of GM crops and clarification requested.

The approach to inspection and control, followed by many Member States, appears to be one of random sampling and testing or where there is a suspicion that the labelling of a product may not be correct. Whilst a number of Member States have found the Commission Recommendation on sampling and testing to be useful, others have reported that it is either too detailed or too vague. Certain Member States have also pointed to a need for legislation rather than guidance to ensure a harmonised approach to sampling and testing. Others have requested a practical ‘operating manual’ as a means to ensure harmonisation and uniform implementation of the Regulation. It has also been highlighted that individual Member States need to exchange more information and experience to ensure a harmonised approach.

Reports from Member States suggest that the relevant information required under the Regulation is certainly being made available by operators with transactions although in some cases, it appears that hard copies of documentation may not be present. In addition, a few Member States have reported that unique identifiers are not always included in the documentation from exporters accompanying bulk shipments of products containing GMOs. Certain Member States have also pointed towards an initial reluctance of importers to provide the relevant documentation to subsequent operators but state that this situation has dramatically improved as further experience has been gathered.

One Member State has also reported a situation where wholesalers had not passed on the necessary information to individuals further down the chain. This again was put down to a

lack of experience and has since been rectified. Indeed, Member States appear fully aware of the necessity for the correct information at the start of the distribution chain if the system is to be effective throughout the entire chain. Some Member States clearly believe that a harmonised format for documentation would assist both operators and national authorities with implementation and enforcement and avoid such problems. Industry members and trading partners, on the otherhand, do not believe that harmonised documents are necessary and that the relevant information can be detailed satisfactorily on existing commercial invoice documentation.

Conversely, other Member States have reported that there have been no problems in interpreting, implementing and enforcing the Regulation. These Member States point to the fact that general labelling and traceability rules have been long-since implemented by the food and feed industries and considerable experience has already been gained with such rules. The Regulation is, therefore, viewed basically as an extension to these rules. Some confusion has, however, appeared to have arisen where the labelling of mixtures of GMOs is concerned.

Further issues that have been reported include, as mentioned by other sectors, the means to reliably detect the presence of non-approved GMOs in bulk shipments and other products as well as the means to enforce labelling and traceability requirements where DNA and protein are absent in products. Moreover, there appear to have been some difficulties in linking such products to origin when attempting to determine if or not they were derived from GM material.

Certain Member States have reported that they consider the costs of sampling and testing to be excessive and have requested that such costs be reviewed. In addition, other national authorities have reported that the correct testing of bulk shipments requires too much time, creating problems particularly where perishable goods are concerned. The lack of accessible reference material has also been raised by some authorities in terms of delays but reference to specific products was not provided. It should be noted that Regulation (EC) No 1829/2003 requires that notifiers must, as part of their notifications (including those for existing products) include the place where reference material can be accessed.

Conclusions

The majority of stakeholders have pointed to the fact that the Regulation has only been operational for a limited period of time and that experience in terms of its implementation is extremely limited. This has been exacerbated by the limited number of GM products currently being marketed in the European Union. Consequently, this report realistically can only be viewed as preliminary and further experience and reporting will be required to gain a true picture of implementation of the Regulation.

In spite of the above, it appears that the provisions of the Regulation are being correctly applied. Whilst some early ‘teething’ problems have been reported, they appear to have been, in the main, largely resolved.

Many stakeholders have pointed to a need to specifically address the adventitious presence of ‘non-approved’ GM material, notably in terms of available detection methodology. It should, however, be made clear that the Regulation covers only GM products that have received Community authorisation for their placing on the market. The Commission, via its Joint Research Centre (JRC), continues to address this issue and information pertaining to GMOs

approved in other countries, where available, will be placed on a Community register in accordance with Article 9(3) of the Regulation.

Whilst certain stakeholders, have highlighted that the sampling and detection guidelines in the Commission Recommendation are useful, others consider that they are complicated and difficult to apply. The bottom line is that sampling and detection are complex issues and only a limited number of methodologies were available prior to on the entry into force of this Regulation. The JRC and the European Network of GMO Laboratories (ENGL) subsequently developed a methodology for sampling bulk shipments of grain and this has since been accepted as an international standard. The JRC and ENGL continue to validate specific detection methods for individual GMOs but this work is time-consuming (and costly) given the precision and accuracy required for validation. It is, however, clear that continued efforts in this area must and will have to continue.

Certain trading partners continue to allege that the Regulation introduces an excessive administrative burden. Imports of soybean and maize, including their derived products such as soy-meal or corn gluten feed do not appear to have been affected by the Regulation. In practice, consumer and market demand for foodstuffs in particular has certainly had a far greater effect than the provisions of the Regulation in terms of trade in products containing GM material. The asynchronous approval regime for GMOs between countries remains the major obstacle to trade. Whilst some trading partners have been able to successfully manage this issue to avoid trade disruption, others seem either unable or unwilling to address it.

However, it remains clear that only a limited amount of information and experience concerning the implementation of the Regulation is available at the current time. Therefore, the Commission will draw up a second report, following a further period of 24 months to enable a more complete picture of implementation to be obtained.

ANNEX 1

Department for Environment, Food and Rural Affairs, United Kingdom

State Veterinary and Food Administration of the Slovak Republic

Central Control and Testing Institute for Agriculture (Slovak Republic)

Ministry of Agriculture, Forestry and Food (Slovenia)

Ministry of Health (Slovenia)

Ministry for the Environment and Spatial Planning (Slovenia)

National Food Administration (Sweden)

Swedish Board of Agriculture

Swedish Work Environment Authority

Directorate-General for Veterinary Services (Portugal)

Directorate-General for Crop Protection (Portugal)

DGFCQA - Directorate-General of Food Quality Inspection and Control (Portugal)

Ministry of Health, Welfare and Sport (Netherlands)

Ministry of Agriculture, Nature and Food Quality (Netherlands)

Ministry of Housing, Spatial Planning and the Environment (Netherlands)

Malta Environment and Planning Authority

Malta Standards Authority

Ministry of the Environment (Lithuania)

Ministry of Agriculture and Rural Development (Hungary)

Ministry of Rural Development & Food- Directorate of Processing, Standardization and Quality Inspection (Greece)

Ministry of Development, Hellenic Food Safety Authority (Greece)

Ministry of Economy and Finance, General Chemical State Laboratory, Food Division (Greece)

Board for Gene Technology (Finland)

Ministry of Trade and Industry (Finland)

National Food Agency (Finland)

Customs Laboratory (Finland)

Plant Production Inspection Centre (Finland)

National Product Control Agency for Welfare and Health (Finland)

Sub-directorate-General for the Means of Livestock Production (Spain)

Ministry of Health and Consumer Affairs: Spanish Agency for Food Safety (Spain)

Ministry of Agriculture, Fisheries and Food (Spain)

Veterinary and Food Board (Estonia)

Danish Veterinary and Food Administration

Danish Plant Directorate

German Federation for Food Law and Science

Ministry of the Environment (Czech Republic)

Ministry of Agriculture (Czech Republic)

Central Institute for Supervising and Testing in Agriculture (Czech Republic)

Reference laboratory for GMO identification and DNA fingerprinting (Czech Republic)

Research Institute of Crop Production (Czech Republic)

Ministry of Health (Cyprus)

Department of Agriculture (Cyprus)

Federation of European Food Additives and Food Enzymes (Belgium)

FPS Public Health, Food Chain Safety and Environment (Belgium)

FAVV/AFSCA (Belgium)

Greenpeace

FEDIS – La Fédération belge des entreprises de distribution

FEDIMA (Federation of the European Union Manufacturers and Suppliers of Ingredients to the Bakery, Confectionery and Patisserie Industries)

European Association for Bio-industries (EuropaBio)

ELC – Federation of European Food Additives and Food Enzymes Manufacturers

CIAA - The Confederation of Food and Drink Industries of the European Union

BEUC - The European Consumers' Organisation

The National Association for the Speciality Food Trade, Inc., New York, USA

Nestlé

US Government

American Soybean Association

Florigene (Australia)