Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2001/0180(COD)
Genetically modified organisms GMOs: traceability and labelling Amending Directive 2001/18/EC 1998/0072(COD) Subject 3.10.09.06 Agro-genetics, GMOs 4.60.02 Consumer information, advertising, labelling 4.60.04.04 Food safety	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health, Consumer Policy	PPE-DE TRAKATELLIS Antonios	13/09/2001
Former committee responsible		
ENVI Environment, Public Health, Consumer Policy	PPE-DE TRAKATELLIS Antonios	13/09/2001
Former committee for opinion		
ITRE Industry, External Trade, Research, Energy	GUE/NGL SEPPÄNEN Esko	18/09/2001
AGRI Agriculture and Rural Development	PPE-DE REDONDO JIMÉNEZ Encarnación	12/09/2001

Council of the European Union

Council configuration	Meeting	Date
Agriculture and Fisheries	2524	22/07/2003
Agriculture and Fisheries	2494	17/03/2003
Agriculture and Fisheries	2481	27/01/2003
Environment	2473	09/12/2002
Environment	2457	17/10/2002
Environment	2439	25/06/2002
Environment	2399	12/12/2001
Agriculture and Fisheries	2377	23/10/2001
Competitiveness (Internal Market, Industry, Research and Space)	2371	27/09/2001

European Commission

Commission DG	Commissioner

	Environment

Key events

24/07/2001	Legislative proposal published	COM(2001)0182	Summary
03/09/2001	Committee referral announced in Parliament, 1st reading		
27/09/2001	Debate in Council	2371	
23/10/2001	Debate in Council	2377	
12/12/2001	Debate in Council	2399	
04/06/2002	Vote in committee, 1st reading		Summary
03/06/2002	Committee report tabled for plenary, 1st reading	A5-0229/2002	
25/06/2002	Debate in Council	2439	Summary
02/07/2002	Debate in Parliament		
03/07/2002	Decision by Parliament, 1st reading	T5-0353/2002	Summary
12/09/2002	Modified legislative proposal published	COM(2002)0515	Summary
17/10/2002	Debate in Council	2457	
27/01/2003	Debate in Council	2481	Summary
16/03/2003	Council position published	15798/1/2002	Summary
27/03/2003	Committee referral announced in Parliament, 2nd reading		
22/05/2003	Vote in committee, 2nd reading		Summary
21/05/2003	Committee recommendation tabled for plenary, 2nd reading	A5-0204/2003	
01/07/2003	Debate in Parliament		
02/07/2003	Decision by Parliament, 2nd reading	T5-0315/2003	Summary
22/07/2003	Act approved by Council, 2nd reading		
22/09/2003	Final act signed		
22/09/2003	End of procedure in Parliament		
18/10/2003	Final act published in Official Journal		

Technical information

Procedure reference	2001/0180(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Directive 2001/18/EC 1998/0072(COD)

Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/16439

Documentation gateway

Legislative proposal		COM(2001)0182 OJ C 304 30.10.2001, p. 0327 E	25/07/2001	EC	Summary
Economic and Social Committee: opinion, report		CES0358/2002 OJ C 125 27.05.2002, p. 0069	20/03/2002	ESC	
Committee of the Regions: opinion		CDR0033/2002 OJ C 278 14.11.2002, p. 0031	16/05/2002	CofR	
Committee report tabled for plenary, 1st reading/single reading		A5-0229/2002	04/06/2002	EP	
Text adopted by Parliament, 1st reading/single reading		T5-0353/2002 OJ C 271 12.11.2003, p. 0196-0275 E	03/07/2002	EP	Summary
Modified legislative proposal		COM(2002)0515 OJ C 331 31.12.2002, p. 0308 E	13/09/2002	EC	Summary
Council statement on its position		06903/2003	04/03/2003	CSL	
Council position		15798/1/2002 OJ C 113 13.05.2003, p. 0021-0030 E	17/03/2003	CSL	Summary
Commission communication on Council's position		SEC(2003)0362	25/03/2003	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0204/2003	22/05/2003	EP	
Text adopted by Parliament, 2nd reading		T5-0315/2003 OJ C 074 24.03.2004, p. 0099-0611 E	02/07/2003	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(2003)0461	18/07/2003	EC	Summary
Implementing legislative act		32004R0065 OJ L 010 16.01.2004, p. 0005-0011	14/01/2004	EU	Summary
Follow-up document		COM(2006)0197	10/05/2006	EC	Summary
Follow-up document		COM(2008)0560	17/09/2008	EC	Summary

Additional information

European Commission	EUR-Lex

Final act

Regulation 2003/1830
OJ L 268 18.10.2003, p. 0024-0028 Summary

Genetically modified organisms GMOs: traceability and labelling

PURPOSE : to provide a framework for the traceability of GMOs and food and feed produced from GMOs, with the objective of facilitating

accurate labelling, environmental monitoring and withdrawals of products. CONTENT : this proposal concerns the traceability of GMOs, as defined under Directive 2001/18/EC, as or in products including seeds, as well as food and feed product produced from GMOs. It provides for legal certainty as well as a coherent and consistent approach that should contribute to the effective functioning of the internal market. The proposal lays down the following requirements to ensure a harmonised framework for traceability of such products at all stages of their placing on the market: - operators shall have in place systems and procedures to identify to whom and from whom products are made available; - operators shall transmit specified information concerning the identity of a product in terms of the individual GMOs it contains or whether it is produced from GMOs; - operators shall retain specified information for a period of five years and make it available to competent authorities on demand. The proposal does not specify the means to transmit and retain this information given that existing systems to do so are already in place in many organisations. The objectives for traceability of GMOs and products produced from GMOs are not identical and therefore the specified information to be transmitted and retained differs for each. This proposal provides for the traceability of individual GMOs within a product on the basis of authorised transformation events. In addition, the proposal provides that the Commission shall establish a system to develop and assign simple numeric or alphanumeric unique codes to GMOs. Moreover, the proposal provides for the establishment of a system to develop and assign unique codes to GMOs.?

Genetically modified organisms GMOs: traceability and labelling

The committee adopted the report by Antonios TRAKATELLIS (EPP-ED, GR) amending the proposal under the codecision procedure (1st reading). While broadly approving the proposal, the committee felt it did not go far enough and therefore wanted its objectives to be fleshed out and the rules to be made more stringent. It pointed out for example that, in order to be effective, the rules on traceability and labelling must be applicable to both products produced within the Community and those imported from third countries. The committee wanted it to be explicitly stated in the introductory article that the precautionary principle should apply and that the objectives should include protection of human and animal health, ensuring the smooth operation of the internal market while giving priority to human health and the environment, giving consumers a free choice and allowing effective measures to prevent the accidental presence of GMOs or products thereof in other food or feed. It added that the regulation should enable products to be withdrawn immediately if they proved harmful or hazardous. One amendment proposed a new article extending the traceability scheme so as to cover animals which have been fed with GM feed. It also stipulated that, when placing pre-packaged food products on the market which have been derived from such animals, operators must ensure that either the words 'This product is derived from an animal fed with GM feed' or 'This product contains [ingredient] derived from an animal fed with GM feed' appear on the label or in any advertising for the product. Another amendment deleted an article in the Commission proposal which, referring to a parallel draft proposal on genetically modified food and feed, would have excluded from the traceability scheme food and feed produced from unauthorised GMOs. The committee also felt that, given that health or other problems may take time to become evident, a period of ten years (rather than five as proposed) was the absolute minimum period necessary for the maintenance of operators' records. Other recommendations included drawing up guides to good segregation practice for businesses in the food industry to help avoid accidental contamination of foodstuffs with GMOs and setting up a central register containing sequencing information and reference material for authorised GMOs and also relevant information concerning unauthorised GMOs. At the final vote, the rapporteur voted against the report, arguing that the adopted amendments on traceability and labelling would prove 'inapplicable in real life'.?

Genetically modified organisms GMOs: traceability and labelling

The Council took note of the progress made, pending the European Parliament's Opinion, on the proposal for a Regulation concerning traceability and labelling of genetically modified organisms (GMOs) and traceability of food and feed products produced from GMOs. This dossier was the subject of a public debate during the Council meeting on 29 October 2001 and an interim report was submitted to the Council at its meeting on 12 December 2001. Work remains to be done on various issues including the scope of the Regulation, communication of information on the potential presence of GMOs in products, traceability of derived products and threshold values for the adventitious presence of GMOs. A political agreement is expected at the meeting on 17 October 2002 at the earliest.?

Genetically modified organisms GMOs: traceability and labelling

The European Parliament adopted a resolution on GMO labelling, where the rapporteur was Antonios TRAKATELLIS (EPP-ED, Greece). The rapporteur voted against the report. (Please refer to the summary of 04/06/02.) The recitals make a specific reference to the precautionary principle. In exceptional cases, where there is a risk to health or environment, but where scientific data is still uncertain, the precautionary principle may be used to determine which risk management measures or other steps will be taken to ensure the high level of health protection that the Community desires. Parliament stated that, to cover cases of adventitious or technically unavoidable traces of material produced from GMOs, a threshold should be set up. As and when advances in science and technology allow, appropriately lower thresholds should be established. When placing products produced from GMOs on the market, operators must ensure that the words this product is produced from GMOs" or the words "This product contains [ingredient] produced from GMOs" appear on a label and in connection with the display and the advertising of the product.?

Genetically modified organisms GMOs: traceability and labelling

The following are amongst those amendments that have been accepted in part or in principle by the Commission: - the exemption of certain organisms from the definition of "GMO" as per the exemption under Article 3(1) Directive 2001/18/EC; - the definition of "operator" clarifying that a person handling products placed on the market in the Community could be either from a Member State of the EU or from a third country; - on labelling, one amendment retains the wording of Directive 2001/18/EC for products containing GMOs but provides for an alternative in that the name of the crop or GMO can be included on the label; - operators who receive pre-packaged products have to retain certain information; - the close co-operation of Member States in the development of guidance; - an additional recital stating that account should be taken of the registers containing information on genetic modifications in GMOs to be established by the Commission. The Commission does not accept the following amendments: - the reference to the precautionary principle in the context of this proposal. The principle relates to the risk analysis of

products and is accounted for as part of the approval process under the authorising legislation (Directive 2001/18/EDC and Regulation 178/2002/EC). Any safety measure to protect human health and the environment arise directly from this authorising legislation. Traceability is not a safety measure per se but can be used to facilitate the application of other measures, such as product withdrawals and monitoring, as a means to ensure safety. The precautionary principle cannot, therefore, be taken into account when implementing traceability requirements. - the removal of the derogation concerning traceability requirements for products intended for direct use as food, feed or processing. The derogation allows operators to state that these products are intended for direct use as food, feed or processing and provide the unique codes of the GMOs that the products 'may contain'. The Commission believes that this derogation is essential for an operational traceability system for such products. - the extension of the period for retention of information by operators from 5 to 10 years - even if traceability were possible after 5 years, the benefits of this information would be minimal with no practical value. - the introduction of additional labelling requirements for pre-packaged products produced from GMOs; - the amendment requiring that the GMOs from which food and feed products are derived have to be precisely identified with provision of their unique codes cannot be accepted. It is not necessary to establish the detailed history and origin of individual GMOs. To provide appropriate information to the consumer, it is sufficient to label that the product is produced from GMOs. Measures for co-existence and segregation cannot be accepted. The objective of this regulation is to trace products and not to avoid adventitious or technically unavoidable presence of GM material in food. - the amendments stating that no new products could be authorised prior to the entry into force of the system to assign uniquecodes under the proposal are not acceptable. The intention of the Commission proposal is to provide that products containing traces of GMOs and GM material below a threshold do not have to traced. This possibility has been deleted by the above amendments. This will not only undermine the feasibility of tracing and labelling requirements but also have major restrictions for trade.?

Genetically modified organisms GMOs: traceability and labelling

The Danish delegation, supported by the French, Italian, Austrian, Portuguese and Luxembourg delegations, drew the attention of the Council and the Commission to the conditions for further approval of Genetically Modified Organisms (GMO) since a political agreement had been reached at the Council on 28 November 2002 (refer to the previous summary). Some of these delegations supported in particular the view that no new procedure of authorisation for placing on the market new GMOs should be granted as long as this Regulation had not yet entered into force. Commissioner BYRNE recalled that political agreements had been reached on a proposal for a Regulation on genetically modified food and feed at the Agriculture and Fisheries Council on 28 November 2002 and on a proposal for a Regulation concerning the traceability and labelling of GMOs and of food and feed products produced from GMOs at the Environment Council on 9 December 2002. He noted that the application for an authorisation regarding a GM product would be managed under either of these two Regulations. He mentioned that current application were managed under current EC rules prior to the approval of these two texts by the European Parliament in second reading.?

Genetically modified organisms GMOs: traceability and labelling

The Council adopted the common position by qualified majority without the support of Danish, Luxembourg, Netherlands and the UK delegations. It accepts 15 out of the 30 amendments adopted by the European Parliament at first reading. With regard to the scope of the Regulation, the Council fully accepts the Commission proposal. Exemptions from the traceability and labelling scheme shall be allowed for the adventitious or technically unavoidable presence of traces of GMOs. The thresholds for these exemptions are introduced in this Regulation by way of reference to the respective Articles of the Regulation on genetically modified food and feed (as discussed in parallel with this Regulation - refer to COD/2001/0173), where the threshold level has been set at 0,9% and can be lowered via a regulatory committee procedure, as well as by way of reference to Directive 2001/18/EC. While the exemptions generally cover only GMOs that have been authorised in the EU, the adventitious or technically unavoidable presence of such GMOs that have not been authorised but have benefited from a favourable risk evaluation will be permitted below a threshold level of 0,5%, or lower as set by a regulatory committee procedure, for a transitional period of three years. The Council has tightened the Commission proposal with regard to the information that has to accompany bulk shipments of products containing mixtures of GMOs by allowing only for "a list of the unique identifiers for all those GMOs that have been used to constitute the mixture", instead of " unique codes for the GMOs that the product may contain" as originally proposed by the Commission. Complementary to this provision, the Council has introduced a review clause in order to call on the Commission - to present a report after the first experiences with the provision of Article 4(3) have been gained in practice and - where appropriate, to make proposals for changes to the Regulation. While the Regulation generally covers all stages of placing on the market of the products, the Council has filled a gap by introducing that inspection and control measures can also target the holding of a product. The Council has introduced the following main innovations in the text of the Regulation: - new Recital addressing feed for animals not destined for food production (pets); - further detailing of Recital 10, addressing the need for thresholds for the exemption of the adventitious or technically unavoidable presence of GMOs from the traceability and labelling rules; - revision of the definitions: elimination of the definitions of food/feed additives, (compound) feedingstuff, flavourings and feed materials and the inclusion of the definitions of "Final consumer" and "Ingredient". - re-structuring of the Articles that describe the traceability and labelling rules and the exemptions thereof; - amendment of Directive 2001/18/EC by way of inclusion of a new Article which provides for an exemption from labelling for GMOs intended for direct processing.?

Genetically modified organisms GMOs: traceability and labelling

In general terms, the Common Position follows the structure of the original Commission Proposal and takes full account of the European Parliament amendments introduced in the amended Commission Proposal. The Commission was in a position to support the Common Position, which was adopted by qualified majority. The majority of the changes introduced by the Council increase the consistency and coherence of the original Proposal, notably with regard to links, particularly for thresholds, with Directive 2001/18/EC and the Proposal on GM Food and Feed (refer to COD/2001/0173). In a declaration the Commission recognises that it would be highly desirable that this Regulation and the Regulation on GM Food and Feed are applicable at the same time given the links between the two regulations.?

Genetically modified organisms GMOs: traceability and labelling

The committee adopted the report by Antonios TRAKATELLIS (EPP-ED, GR) amending the Council's common position under the 2nd reading of the codecision procedure. It reinstated a number of amendments adopted by Parliament at 1st reading, sometimes in modified form: - the introductory article should explicitly state that the precautionary principle should apply and that the objectives should include protection of human and animal health, ensuring the smooth operation of the internal market while giving priority to human health and the environment, and giving consumers sufficient information to make a free and independent choice; - pre-packaged products produced from GMOs should be described as such, using the words "This product is produced from GMOs" or "This product contains [ingredient] produced from GMOs" on the label and also as part of any display or advertising; - the period during which operators must maintain records should be 10 years rather than 5 years; - GMOs from which a product is made should be precisely identified, with provision of their unique codes; - a central register should be set up containing sequencing information and reference material for authorised GMOs as well as relevant information concerning GMOs not authorised in the EU; - no new products should be approved for marketing prior to the entry into force of the system provided for under the proposal for assigning unique codes. The committee also voted to delete the clause providing for precise descriptions of mixtures of GMOs in a single product to be replaced by a "declaration of use" by the operator. Moreover, it added a new article on co-existence, stipulating that the Member States should ensure that the notifier or any person selling the product took "appropriate measures to prevent the unintended presence of the GMO or part thereof in other products". On the basis of observed developments in the Member States, the Commission should develop guidelines on the co-existence of genetically modified, conventional and organic crops. Lastly, MEPs called for Member States to report regularly (every 3 years) on their experience with inspections and other control measures and for the Commission to report regularly to Parliament and Council on these experiences.?

Genetically modified organisms GMOs: traceability and labelling

The European Parliament adopted a resolution which approved some of the amendments in the report drafted by Antonios TRAKATELLIS (EPP-ED, Greece). The amendments adopted include the following: - a central register should be set up containing sequencing information and reference material for authorised GMOs as well as relevant information concerning GMOs not authorised in the EU. The competent authorities in the Member States will have access to the register; - a new recital states that the Commission must submit a report on the implementation of the Regulation and the effectiveness of the rules on traceability and labelling.?

Genetically modified organisms GMOs: traceability and labelling

Six amendments (or parts thereof) were adopted by the Parliament and the Commission can accept these amendments in full: - a new recital referring to the Commission's reporting obligations; - a new recital on the need for consumer choice; - the introduction of the need for standardised procedures for the holding of traceability information for products containing GMOs and products produced from GMOs; - the need to publish the guidelines for sampling and testing; - central registers will have to be introduced under Directive 2001/18/EC and the Proposal on GM Food and Feed. These registers will contain very similar if not identical information and will be inter-linked.?

Genetically modified organisms GMOs: traceability and labelling

PURPOSE : to provide a framework for the traceability of products consisting of or containing genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objectives of facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products. LEGISLATIVE ACT : Regulation 1830/2003/EC of the European Parliament and of the Council 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. CONTENT : the Council formally adopted two European Commission proposals on genetically modified organisms (GMOs) which establish a clear EU system to trace and label GMOs and to regulate the placing on the market and labelling of food and feed products derived from GMOs (refer to COD/2001/0173). It should be noted that Luxembourg, the United Kingdom and the Danish delegations voted against this Regulation. This new legislation will consolidate a trustworthy and safe approach to GMOs, GM food and GM feed. It will ensure full traceability of GMOs throughout the chain from farm to table and will provide consumers with comprehensive information by labelling all food and feed consisting of, containing or produced from a GMO. The new Regulation calls for a Commission report to be submitted to the Council and the Parliament on the outcome of the Regulation's implementation in the Member States, for the standardisation of procedures that allow the holding of information on GMOs, for the publication of the Commission's technical guidance on sampling and testing, as well as for the setting up of a Central Register at Community level containing all available information and reference material for at least those GMOs authorised in the Community. - Traceability : the new Regulation on traceability and labelling will require business operators when using or handling GM products to transmit and retain information at each stage of the placing on the market. Information concerning the presence of GMOs in products must be transmitted throughout the commercial chain and must be retained for five years. The industry will therefore have to ensure that systems are in place to identify to whom and from whom GM products are made available. Transmission and storage of information will reduce the need for sampling and testing of products. To facilitate a co-ordinated approach for inspection and control by Member State, the Commission will develop technical guidance on sampling and testing methods prior to the application of this Regulation. - Labelling : in addition to the current rules the labelling of all foods produced from GMOs irrespective of whether there is DNA or protein of GM origin in the final product is included. - GM-food : the Regulation The new law will extend the current labelling requirements to also cover such food (soya or maize oil produced from GM-soya or GM-maize) and food ingredients produced from GMOs (biscuits with maize oil produced from GM-maize). and to allow consumers to exercise their freedom of choice. The label has to indicate "This product contains genetically modified organisms" or "... produced from genetically modified (name oforganism)". - GM-feed : the Regulation also introduces for the first time comprehensive labelling requirements of GM-feed based on the same principle as for GM food. Currently there are no labelling requirements in place for feed produced from GMOs. The Regulation will require labelling of, for example, GM-soy meal and any compound feed that includes in its composition the GM-soya meal. It will also require labelling of corn gluten feed produced from GM maize. - Threshold for labelling : under current legislation the presence of GM material in conventional food does not have to be labelled if it is below 1% and if it can be shown to be adventitious and technically unavoidable. The Parliament confirmed today a threshold of no higher than 0,9%. Equally, under present legislation, there is no tolerance threshold for the adventitious presence of GM material in food or feed which has not yet been authorised but which has received a favourable EU scientific risk assessment. The Parliament has endorsed today a 0,5% threshold for the adventitious or technically unavoidable presence of such GM material, provided that the operator can demonstrate that its presence was

technically unavoidable. Above this threshold the product will not be allowed on the market. This provision will expire after 3 years. - Authorisation procedure : this Regulation establishes a "one door one key" procedure for the scientific assessment and authorisation of GMOs and GM food and feed resulting in a centralised, clear and transparent EU procedure where an operator is able to file a single application. The Regulation provides that GMOs that could be used as food or feed must be authorised for both uses or not at all. The scientific risk assessment will be carried out by the European Food Safety Authority. Its opinion will be made available to the public and the public will have the possibility to make comments. Products authorised shall be entered into a public register of GM-food and feed. - Co-existence : measures to ensure that the production of organic and conventional crops can co-exist with GM-crops were introduced into the draft Regulation on GM Food and Feed during the second reading of the Parliament. In this context, Member States will be allowed to take appropriate measure to avoid the unintended presence of GMOs in other products. The Commission will bring forward a Recommendation to Member States providing a framework to put this into practice. The United Kingdom and the Netherlands delegations have made a public statement on the provisions of the Regulation. ENTRY INTO FORCE : 07/11/2003.?

Genetically modified organisms GMOs: traceability and labelling

LEGISLATIVE ACT : Commission Regulation 65/2004/EC establishing a system for the development and assignment of unique identifiers for genetically modified organisms. CONTENT : Under Regulation 1830/2003/EC, an operator placing on the market products containing or consisting of GMOs is required to include the unique identifier assigned to each GMO as a means of indicating its presence and reflecting the specific transformation event covered by the consent or authorisation for placing that GMO on the market. This Regulation provides that applications for the placing on the market of GMOs must include a unique identifier for each GMO concerned. Applicants must, in accordance with the formats set out in the Annex, develop the unique identifier for each GMO concerned, following consultation of the OECD BioTrack product database, and the Biosafety clearing house, to determine whether or not a unique identifier has already been developed for that GMO in accordance with these formats. In addition: - where consent is granted for the placing on the market of a GMO, the consent must specify the unique identifier for that GMO; - the competent authority that has taken the final decision on the original application must ensure that the unique identifier for that GMO is communicated to the Biosafety clearing house; - the unique identifier for each GMO concerned will be recorded in the relevant registers of the Commission; - unique identifiers will be assigned to all GMOs in respect of which, prior to the entry into force of the Regulation, consent has been granted under Directive 90/220/EEC for their placing on the market; they must also be appropriately recorded; - there are provisions dealing with the situation where, prior to the entry into force of this Regulation, consent has been granted for the placing on the market of a GMO but where a unique identifier has not been developed for that GMO in accordance with the formats set out in the Annex. ENTRY INTO FORCE : 16/01/04.?

Genetically modified organisms GMOs: traceability and labelling

Adopted in 2003, Regulation 1830/2003/EC, establishes a system for the traceability and labelling of GMO?s. The requirements apply to products placed on the market containing or consisting of GMO?s and to food and feed products produced from GMO?s. By introducing provisions on traceability, the Regulation intends to control and verify labelling claims; to monitor any effects these products may have on the environment; and to identify and (possibly) withdraw any GMO products in the case of an unforeseen risk to either human health or to the environment.

In order to achieve the objective of traceability the Regulation requires operators to transmit and retain specified information for the GMO product types. Provisions include, inter alia, the need to retain information for a period of five years as well as the establishment of adventitious thresholds (0.9%). The principle of traceability is considered essential for the final labelling of a product. Regulation 1830/2003/EC works in tandem with Regulation 1829/2003/EC on genetically modified food and feed. (See 2001/0173(COD)).

In preparing this report, the European Commission compiled a questionnaire, which was sent to all competent authorities, relevant stakeholders as well as food, feed and seed industry associations and trading partners. NGO?s and relevant Member State government departments were also forwarded the questionnaire, which contained questions on the traceability, labelling, exemptions from traceability and labelling requirements and on the inspection and control measures. The responses were used to compile this report.

Based on the responses received the Commission makes the following findings:

Food production and distribution chains:

- The European food and retailing industries prefer not to market GMO food and food products due to negative consumer reactions. 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.
- Industry, in tune with consumer likes and dislikes, appears to be responding to retailer and consumer demands for non-GM products. Industry, therefore, avoids purchasing ingredients containing GMO products.
- A large, third country food exporter, states that it no longer exports any processed food products to the European Union due to the burden of the regulatory framework ? and cites that this is due to the traceability requirements and not due to a lack of market demand.
- A third-country industry association states that many companies marketing food products in the EU have stopped using internally produced GM soybean oil and protein ingredients in order to avoid what are perceived to be the onerous and costly mandatory traceability requirements.
- A second food association argues that the Regulation has created an unacceptable burden on small food exporters.
- An overseas Government Department claims that the Regulation acts as a barrier to trade and provides a disincentive for manufactures to place GM products on the market.
- The US Government and third country food associations urge the Commission to work together towards a mutual recognition of GM products. The report remarks that the Commission has actively engaged in and remains open to international discussion with the EU?s trading partners but that since 2002, the US Government has been reticent to engage in bi-lateral discussions on issues

pertaining to GMO?s.

- NGO?s, on the other hand, claim that the labelling rules have had a positive effect in facilitating informed choice. Indeed, they argue that labelling should be extended to include products derived from animals fed with GM material - such as milk, meat, eggs, wool etc.

Feed production and distribution chains:

- The majority of GMO products circulating in the EU are destined for animal feed and originate in the form of imported commodities such as GMO soybean products. Millions of tonnes of soybean material are imported every year and stem mostly from the US, Argentina and Bra zil.
- Soybeans exported to the EU for feed are mixed by the US commodity-handling system. According to some third-country trading partners it is, therefore, not feasible to transmit the kind of information required by the Regulation. The Commission counters this argument by stating that the European feed industry have been able to report the correct information. Certain industry contacts have suggested that some crushers of non-GM soybeans have had difficulty in selling material due to higher costs.

Labelling and traceability of GM seed products for cultivation:

- The cultivation of GMO?s is not practiced in the vast majority of Member States. BT-maize is commercially grown in some regions of Spain. Some GM varieties are gown in France, Germany, the Czech Republic and Portugal, but only on a small scale.
- The plant biotechnology industry have had no serious problems concerning the interpretation of the Regulation. In countries where GM varieties are available, such as Spain, no particular difficulties have been encountered vis-à-vis the Regulation?s interpretation.

Enforcement of the Regulation:

- Insufficient time, between the Regulation?s implementation and the presentation of this report, has elapsed to gather the relevant experience and information needed for an objective assessment of the current situation.
- Nevertheless, a large majority of Member States deem that the Regulation?s requirements have had a positive effect in terms of providing relevant information to consumers and in terms of providing safety guarantees.
- Some Member States would like to see even stricter requirements for imported GMO goods with even tighter control measures.
- Difficulties have been reported regarding sampling and testing. Techniques for the detection of adventitious presence is cited an example.
- Some Member States would like to see legislation, rather than guidance, on sampling and testing, in order to guarantee a harmonised approach to this matter.
- Some Member States would also like to see harmonised documentation. This would help both the authorities and economic operators to implement the Regulation?s provisions. Industry does not share this view.
- Conversely, other Member States have reported few problems in interpreting, implementing and enforcing the Regulation.

Conclusion:

The Regulation has been operational for a limited period of time. Experience, in terms of the Regulation?s implementation is, as a result, extremely limited. In spite of the above, it appears that the provisions of the Regulation are being correctly applied. Some early ?teething? problems have been reported but they appear to have been largely resolved. On the matter of sampling and detection, the JRC and European Network of GMO Laboratories (ENGL) have developed a new methodology for sampling bulk shipments of grain, which has been accepted as an international standards. The JRC and ENGL will continue in their efforts to find specific detection methods for individual GMO?s. In spite of accusations that the Regulation is excessive, the import of soy-meal or corn gluten feed does not appear to have been affected by the Regulations. The report argues that consumer and market demand for foodstuffs have a far greater effect than the Regulation?s provisions. Within 24 months the Commission will draw up a second report in order to gain a more complete picture of the Regulation?s implementation.

Genetically modified organisms GMOs: traceability and labelling

The Commission has presented a report 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.

Adopted in 2003, Regulation 1830/2003/EC, establishes a system for the traceability and labelling of GMOs. In 2006, 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. Information from Member States was gathered by means of a 10-part questionnaire concerning the following issues:

Interpretation, implementation and effect of traceability rules: the report states that 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 industry. 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. 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 consumers.

Interpretation, implementation and effect of labelling rules: the report highlights that most Member States reported no problems with the 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. 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. Some Member States indicated that for GMOs such as feeding-stuffs, 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.

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. 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.

The use of unique identifiers: the report notes that most Member States regard unique identifiers as useful tools for identifying and labelling genetically modified products and report no serious problems.

Inspection and control measures: 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 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.

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. Some other Member States have noted that method validation according to ISO 17025, as suggested by the Recommendation, depends on the national accreditation body.

Conclusion: 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.

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.

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.