Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2001/0173(COD)
Genetically modified food and feed	
Amended by 2006/0307(COD) See also 2015/3006(RSP) See also 2016/2547(RSP) See also 2016/2548(RSP) See also 2016/2549(RSP) See also 2017/2878(RSP) See also 2017/2879(RSP) Amended by 2018/0088(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		13/09/2001
	PSE SCHEELE Karin	
Former committee responsible		
ENVI Environment, Public Health, Consumer Policy		13/09/2001
	PSE SCHEELE Karin	
Former committee for opinion		
JURI Legal Affairs and Internal Market		11/09/2001
	PSE GEBHARDT Evelyne	
AGRI Agriculture and Rural Development		24/08/2001
	PPE-DE DAUL Joseph	

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
Agriculture and Fisheries	2468	28/11/2002
Agriculture and Fisheries	2456	14/10/2002
Agriculture and Fisheries	2448	23/09/2002
Agriculture and Fisheries	2377	23/10/2001
Competitiveness (Internal Market, Industry, Research and Space)	2371	27/09/2001

European Commission	Commission DG	Commissioner
	Health and Food Safety	

Key events

25/07/2001	Legislative proposal published	COM(2001)0425	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	
04/06/2002	Vote in committee, 1st reading		Summary
04/06/2002	Committee report tabled for plenary, 1st reading	A5-0225/2002	
02/07/2002	Debate in Parliament		
03/07/2002	Decision by Parliament, 1st reading	T5-0354/2002	Summary
23/09/2002	Debate in Council	2448	
08/10/2002	Modified legislative proposal published	COM(2002)0559	Summary
14/10/2002	Debate in Council	2456	Summary
27/01/2003	Debate in Council	2481	
17/03/2003	Council position published	05204/3/2003	Summary
27/03/2003	Committee referral announced in Parliament, 2nd reading		
22/05/2003	Vote in committee, 2nd reading		Summary
22/05/2003	Committee recommendation tabled for plenary, 2nd reading	A5-0202/2003	
01/07/2003	Debate in Parliament		
02/07/2003	Decision by Parliament, 2nd reading	T5-0314/2003	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	2001/0173(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amended by 2006/0307(COD) See also 2015/3006(RSP)

	See also 2016/2547(RSP) See also 2016/2548(RSP) See also 2016/2549(RSP) See also 2017/2878(RSP) See also 2017/2879(RSP) Amended by 2018/0088(COD)
Legal basis	EC Treaty (after Amsterdam) EC 037; EC Treaty (after Amsterdam) EC 095; EC Treaty (after Amsterdam) EC 152
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/16577

Documentation gateway

Legislative proposal		COM(2001)0425 OJ C 304 30.10.2001, p. 0221 E	25/07/2001	EC	Summary
Committee of the Regions: opinion		CDR0033/2002 OJ C 278 14.11.2002, p. 0031	16/05/2002	CofR	
Economic and Social Committee: opinion, report		CES0694/2002 OJ C 221 17.09.2002, p. 0114	29/05/2002	ESC	
Committee report tabled for plenary, 1st reading/single reading		A5-0225/2002	04/06/2002	EP	
Text adopted by Parliament, 1st reading/single reading		T5-0354/2002 OJ C 271 12.11.2003, p. 0196-0283 E	03/07/2002	EP	Summary
Modified legislative proposal		COM(2002)0559	08/10/2002	EC	Summary
Council statement on its position		06780/2003	28/02/2003	CSL	
Council position		05204/3/2003 OJ C 113 13.05.2003, p. 0031-0058 E	17/03/2003	CSL	Summary
Commission communication on Council's position		SEC(2003)0376	25/03/2003	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0202/2003	22/05/2003	EP	
Text adopted by Parliament, 2nd reading		T5-0314/2003 OJ C 074 24.03.2004, p. 0099-0576 E	02/07/2003	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(2003)0459	17/07/2003	EC	Summary
Implementing legislative act		32004R0641 OJ L 102 07.04.2004, p. 0014-0025	06/04/2004	EU	Summary
Follow-up document		COM(2006)0626	25/10/2006	EC	Summary
Implementing legislative act		32006R1981 OJ L 368 23.12.2006, p. 0099-0109	22/12/2006	EU	Summary
Follow-up document		C(2009)8438	03/11/2009	EC	

Additional information

Final act

Regulation 2003/1829
OJ L 268 18.10.2003, p. 0001-0023 Summary

Genetically modified food and feed

PURPOSE: To enshrine under one EU Regulation procedures and measures governing genetically modified food and feed. CONTENT: Based on Actions presented in the Commission's White Paper on Food Safety, the European Commission is proposing a new Regulation bringing together all aspects pertinent to genetically modified food. The objectives of the proposal are: - To provide the basis for a high level of protection of human life and health, animal health and welfare, environment and consumers' interest in relation to genetically modified food and feed. - To lay down Community procedures for the assessment, authorisation and supervision of genetically modified food and feed. - To lay down provisions for the labelling of genetically modified food and feed. Criteria for authorisation of genetically modified food and feed are also laid out. In order to obtain authorisation genetically modified food and feed: - Must not present a risk for human health, animal health or the environment. - Must not mislead the consumer or the user. - Must not differ from foods or feed which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for consumers or animals. In terms of feed, it must not harm the consumer by impairing the distinctive features of the animal products. Concerning the scope of the Directive, the proposal covers food and feed containing, consisting of, or produced from genetically modified organisms (in the Regulation referred to as genetically modified food or feed). It does not refer to novel foods which are not genetically modified or aspects not related to the genetic modification of substances which are subject to an assessment and a regulatory process prior to their inclusion in a positive list or register (such as additives, flavourings, food supplements etc.) Equally, the proposed Regulation seeks to clarify and bring under one roof aspects relating to labelling. Currently, there are at least three EU Regulations laying out provisions for the labelling of genetically modified food. Nevertheless, an appropriate labelling system of GMO food and feed is regarded as one of the key issues in ensuring greater acceptance of the application of gene technology in the agro-food sector. This proposal extends the current labelling provisions to all GMO food and feed irrespective of the detectability of DNA protein food that consists of, contains or is produced from GMOs. This significant change to current Community legislation on the labelling of food produced from GMO foods will result in labelling of a number of foodstuffs, which are currently not required to be labelled, such as highly refined oils of GMO origin.?

Genetically modified food and feed

The committee adopted the report by Karin SCHEELE (PES, D) tabling a large number of amendments to the proposal under the codecision procedure (1st reading) with the aim of toughening up the regulation. It pointed out that the GMO Release Directive (2001/18/EC) provided for the possibility of setting a maximum threshold for the accidental presence in food or feed of authorised GMOs, whereas the proposed regulation was putting forward a threshold for non-authorised GMOs. The committee argued that this would undermine EU legislation on biosafety. It therefore amended and restructured the regulation so as to ensure that the threshold for accidental contamination would apply only to GMOs authorised in the Community and would be 0.5% (rather than 1% as proposed by the Commission). MEPs also deleted the article in the proposal providing for Directive 2001/18/EC to be amended so as to incorporate the specific threshold for accidental contamination. They argued that it made no sense to alter a directive which was adopted only recently (2001) following a complicated conciliation procedure with the Council, and that the new regulation should complement that directive instead. The committee also wanted the precautionary principle to be expressly enshrined in the regulation and amended the introductory article accordingly. It further stipulated that Member States should be in a position to take rapid decisions and apply the precautionary principle on their territory in the event of force majeure, rather than merely informing the European Food Safety Authority and the Commission and waiting for the latter to take emergency measures. Member States should therefore be entitled to take emergency measures themselves in the event of a severe risk or where they received new information giving them grounds to suspect that the use of a food or feed posed a danger to human or animal health or the environment. As regards the scope of the regulation, the committee also wanted it to apply to food derived from animals fed at any stage on genetically-modified feed. This information should be clearly stated on the product label. Other amendments sought to make labelling clearer, for example by ensuring that the print was sufficiently large and easy to read. Lastly, the committee adopted a number of amendments concerning the public's right to information, including a caveat that certain information should remain confidential so as not to harm an applicant's competitive position.?

Genetically modified food and feed

The European Parliament adopted the resolution drafted by Karin SCHEELE (PES, Austria) on genetically modified food and feed. (Please refer to the document dated 04/06/02.) Parliament stipulated that the requirements relating to legislation on the authorisation of food and feed must be identical for all products imported in to the EU, in order to avoid the creation of unequal and unfair conditions of competition. Parliament went on to insert new definitions relating to such terms as "genetically modified feed" and "final consumer". Member States must encourage the drawing up of guidelines on good segregation practice. Parliament also inserted labelling requirements for compound feedingstuff, and made provisions for transitional arrangements.?

Genetically modified food and feed

The European Parliament made 111 amendments to the Commission's proposal at firsts reading. The Commission can accept 16 in their

entirety and 38 in a part or in principle. The following amendments are amongst those accepted: - the summary of the dossier presented by the applicant will be presented in standard form, as this makes the handling and access to the application easier; - there is a time limit of twelve months from the date of application of the proposed Regulation to the transitional measure, so that that the labelling requirements will apply fully to all genetically modified food and feed after this time limit; - the wording confirms that the precautionary principle has been taken into account in the drafting of the Regulation; - the Commission can accept a series of amendments that aim at strengthening information requirements and public involvement within the authorisation and supervision process of genetically modified food and feed. All provisions on public access should, however, be without prejudice to the protection of intellectual property rights relating to the data concerned; -competent authorities may be consulted for the adoption of implementing rules on the submission of application dossiers, but only for matters falling within their remit. Local authorities will not be consulted during this process. Only the EFSA will have responsibility for evaluation. The Commission does not accept the following amendments: - changes to the fact that the proposed legislation will have the status of sectoral legislation, and a centralised procedure will apply; - certain clauses on information requirements and public involvement go too far, such as a period of three months for public consultation, the publication of draft Commission decisions and public access to issues discussed in connection with the risk management decision and the result of the vote. - certain amendments aim at suppressing the derogation for adventitious presence of unauthorised GMOs in food and feed and thus refuse to amend Directive 2001/18/EC in this regard, which is unacceptable. The proposed Regulation would not be feasible if it does not provide for any tolerance under certain conditions, of traces of genetically modified materials that are not authorised in the Community. Only adventitious or technically unavoidable presence of GMOs, which were positively assessed by a European scientific committee, will be tolerated under a threshold of maximum 1%, which can be lowered by comitology in order to take account scientific developments and product particularities. - certain amendments relate to the derogation to the labelling requirements in case of adventitious presence of material produced from genetically modified organisms and provide for a maximum threshold of 0.5%. The Commission feels that the threshold should be established by comitology and that the derogation should also apply to material containing GMO's. These measures should not be confused with actions to prevent the unintended presence of GMOs in non-genetically modified products, which are not the subject of the proposed Regulation. - amendments that include the objective of prevention of the unintended presence of genetically modified material in food and feed are not acceptable. - certain issues on assessment and authorisation procedure are rejected. - amendments on labelling of genetically modified feed are not acceptable because they do not take into account Directive 96/25/EC.?

Genetically modified food and feed

The Council held a policy debate on the basis of a questionnaire from the Presidency, focussed on the three major elements of the proposal, whose results will be taken into account by COREPER in the preparation of the debate to be held at the next session of the Council in November. Regarding the authorisation procedure for the placing of a GMO on the market, a large majority of delegations expressed their wish to keep a centralised procedure as proposed by the Commission. Concerning the transitional provisions on the threshold set for traces of unauthorised GMOs that have nevertheless been assessed as risk-free, a majority of delegations had an open approach on the Presidency suggestion, while others expressed their concerns regarding the level of the threshold or were doubtful on the time limit. The Presidency suggests to limit the application to GMOs which have received a positive scientific assessment before 31 December 2002, and to limit the tolerance at 1% (which could be reduced by means of a committee procedure) for the maximum proportion of GMO during a transitional period of three years. The Commission supported the Presidency suggestion. Lastly, regarding the scope of application for labelling rules and the minimum threshold on this matter for labelled products, a majority of delegations considered that the Presidency suggestion was a good basis for the continuation of the discussion, while others expressed their concerns regarding the exclusion from the scope of application of live animals fed with GMOs, and the proposed level of 1% rate for the threshold applied to labelled products. The Presidency suggests to set a 1% rate threshold for the labelling of GMOs (which could be reduced by means of a committee procedure). ?

Genetically modified food and feed

The Council adopted its common position by qualified majority - the Luxembourg, Austrian and UK voting against - The common position is substantially in accordance with the positions taken by the Commission and the Parliament, insofar as it: - confirms all the objectives and essential elements of the Commission's proposal which were also supported by the European Parliament; - takes the greatest possible account of the opinion of the European Parliament by taking on, in letter or in spirit, a great number of its amendments. On its own initiative, the Council also felt it appropriate to introduce a range of amendments in its common position, either to clarify the scope of certain provisions, or to make the wording of the Regulation more explicit and thus ensure legal certainty, or to increase its consistency with other Community acts. As regards the main provisions of the common position 1) Authorisation procedure established for genetically modified food and feed : the Council has entirely followed the solutions proposed on this subject by the Commission, and supported by the Parliament. The new authorisation procedures for genetically modified food will reproduce the new principles introduced in Directive 2001/18/EC and will make use of the new framework for the food safety risk assessment set by Regulation 178/2002/EC of the European Parliament and of the Council of 28 January 2002. The placing on the market of genetically modified food and feed will therefore only be authorised after an independent and rigorous assessment of the risks which they might carry for human and animal health and, where appropriate, the environment. This assessment, which will be carried out under the responsibility of the European Food Safety Authority, will be followed by a risk management decision taken by the Community, in the framework of a regulatory procedure which will ensure close cooperation between the Commission and the Member States. However, two significant amendments have been introduced to this procedure by the Council: - the request for authorisation must be addressed to the Authority not directly, but through the intermediary of a Member State, - regarding environmental risk assessment, when the request relates to GMOs to be used as seed or other plant propagating material, the Authority will ask a competent national authority to carry out the assessment itself. 3) Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation : to ensure that the Regulation is applicable and feasible, the Council felt it appropriate to consider that below a certain threshold the presence of such traces in a food or feedingstuff should not be considered as a violation of the obligation to hold a marketing authorisation, if strict conditions were otherwise met. The Council has therefore set a threshold which it has fixed at 0,5%, subject to compliance with the following strict conditions: - the GMOs concerned must have received a favourable opinion from a Community scientific authority before the date of applicationof the Regulation, - this tolerance will apply only during the three years following the entry into force of this Regulation, - the threshold may if necessary be lowered in accordance with the committee procedure. The Council also noted that, in the context of the review clause in Article 48 of the Regulation, the Commission undertook to monitor whether the application of the measures was giving rise to any difficulties. It should be noted that the Council here chose a much stricter and more consistent approach than that initially proposed by the Commission (since the threshold has been significantly lowered, and

the measures provided for are now only temporary), and that it has therefore come considerably closer to the position expressed by the European Parliament. 4) Labelling threshold concerning the adventitious presence of GMOs (Articles 12 and 24) The Council took into account the fact that, despite operators' wishes to the contrary, GMO material might nonetheless be present in the form of traces in the food or feed which they produced, as a result of presence which was adventitious or technically unavoidable during the production of seed, cultivation, transport or processing. It therefore judged, like the Commission, that in such cases the food or feed should not be subject to the obligation to indicate the presence of GMOs on the labelling, if that presence was below a certain threshold. The Council set the proportion of adventitious or technically unavoidable presence at a maximum of 0,9% for each ingredient. However, the possibility is also allowed of setting lower thresholds in accordance with the committee procedure, particularly as regards food and feed containing GMOs or consisting of such organisms or to take account of progress in science and technology. It should be noted that the threshold was fixed following careful examination of all the points raised by this issue, and that the Council considers it to represent a good balance enabling the objectives pursued to be attained, while ensuring the applicability of the future Regulation. 5) Status of existing products : the common position extends the scope of the rules applicable to existing products, not limiting these only to GMO products which have already been authorised on the basis of existing legislation but also including GMO products put legally onto the Community market before the Regulation was applied.?

Genetically modified food and feed

The Commission accepted (as such, in principle, in part or subject to re-wording) 54 out of the 111 amendments adopted by the European Parliament at its first reading and revised its proposal consequently. All amendments of the European Parliament included in the Commission proposal have been taken into account, at least in part or subject to re-wording, in the common position. The common position takes the greatest possible account of the European Parliament's opinion and accommodates the specific concerns of most Member States, while maintaining all the essential elements of the Commission proposal. Key elements, such as the scope of the authorisation and labelling sections of the proposal as well as the centralisation of the risk assessment and authorisation procedure, are not affected. The common position makes a compromise between the European Parliament's opinion and the Commission's proposal, in restricting the conditions for derogation to authorisation and to labelling laid down in the Commission's proposal in case of adventitious or technically unavoidable presence of GM material in food and feed. The Commission can accept these restrictions to the tolerance of the unauthorised GM material in food or feed the safety of which has been assessed in the Community and that has been recognised safe. The Commission prefers the original tolerance of 1% which would have had less interference with trade, but accepts the threshold of 0,5% retained in the common position in the context of an overall agreement and considering that the provision concerned will be reviewed (the Commission made a statement on this issue).?

Genetically modified food and feed

The committee adopted the report by Karin SCHEELE (PES, A) amending the Council's common position under the 2nd reading of the codecision procedure. It reinstated a number of key amendments adopted by Parliament at 1st reading: - with regard to the derogation to the labelling requirements in the case of adventitious or technically unavoidable presence of GMOs, the maximum tolerance threshold should be 0.5% for each ingredient rather than 0.9% as proposed in the common position; - the committee proposed deleting the provisions amending Directive 2001/18 (the GMO Release Directive) as regards the derogation to the labelling requirements in the case of adventitious or technically unavoidable presence of unauthorised GMOs. The Council was proposing a three-year transitional period during which a tolerance threshold of 0.5% would apply for unauthorised GMOs which had received positive scientific risk assessments. The committee argued that thresholds for unauthorised GMOs and GMO ingredients did not even exist in US law and that the proposed threshold would undermine the EU biosafety framework; - measures must be taken to ensure the co-existence of GM production and non-GM production. The technical details of co-existence should be decided by means of the commitology procedure; - food and feed which can also be used as seed should only be placed on the market if it has been authorised for all these uses; - as regards emergency measures, the proposal should take up the wording of the provisions laid down in Directive 2001/18 (the GMO Release Directive), thereby enabling Member States to take emergency action themselves (rather than merely informing the EFSA and the Commission) in the event of severe risk or where they receive new information giving them grounds to suspect that the use of a food or feed posed a danger to human or animal health or the environment. The committee also proposed a number of changes aimed at streamlining the procedures relating to applications for initial authorisations and for renewals and interim reports. The common position stipulated that applications for initial authorisations should be submitted to the national competent authority of a Member State but that all applications for renewals and all interim reports should be addressed to the Commission. MEPs pointed out that this division of responsibilities was contrary to the principles of proper administration and called for initial authorisations, renewals and interim reports to be submitted to the competent authority of the Member State where the initial authorisation was applied for.?

Genetically modified food and feed

The European Parliament adopted a resolution which approved some of the amendments in the report drafted by Karin SCHEELE (PES, Austria), and left unchanged the Council's threshold of 0.9% for each ingredient Those amendments adopted include the following: - Parliament deleted the clause relating to exemption from Directive 2001/18/EC; - operators must avoid the unintended presence of GMO in other products. Member States may take appropriate measures to avoid the unintended presence of GMO in other products. The Commission must develop guidelines on the co-existence f GM, conventional and organic crops and make the necessary amendments to Directive 2001/18/EC; - the definition of "placing on the market" is modified".?

Genetically modified food and feed

The Commission has accepted all nine amendments adopted by the Parliament as a compromise package tabled to facilitate the final adoption of the proposal. To sum up, the amendments deal with the following: - they delete the provisions specifying that GMOs for release under Part B of Directive 2001/18/EC and GMOs and genetically modified micro-organisms for contained use activities are excluded from the definition of "placing on the market"; - the definition of traceability is modified. The Commission states that this amendment makes little practical difference,

since there are no enacting clauses in the proposal; - the term "unacceptable risk" is replaced by "adverse effects"; - certain amendments on co-existence allow Member States to take appropriate measures to avoid the unintended presence of GMOs in other products and invite the Commission to develop guidelines in order to provide Member States with a framework for putting this into practice; - the contributions from applicants for authorisation of genetically modified food and feed must not exceed the costs incurred in carrying out the validation of detection methods.?

Genetically modified food and feed

PURPOSE: to lay down Community procedures for the authorisation, supervision and labelling of genetically modified food and feed.

LEGISLATIVE ACT: Regulation (EC) No 1829/2003/EC of the European Parliament and of the Council on genetically modified food and feed.

CONTENT: This Regulation aims to guarantee a high level of protection for human life and health, animal health, the environment and consumers' interests as regards genetically modified food and feed, while ensuring that the internal market functions properly. It also establishes transparent Community procedures to assess, authorise and monitor genetically modified food and feed and a system for the labelling of genetically modified food and feed.

The main points of the Regulation are as follows:

- the provisions of this Regulation also apply to feed intended for animals which are not destined for food production;
- the new authorisation procedures for genetically modified food and feed include the principles introduced in Directive 2001/18/EC. They also make use of the new framework for risk assessment set up by Regulation (EC) No 178/2002. Genetically modified food and feed will only be authorised for placing on the Community market after a scientific evaluation of any risks which they present for human and animal health and, as the case may be, for the environment. This scientific evaluation is followed by a risk management decision by the Community, under a regulatory procedure ensuring close cooperation between the Commission and the Member States.
- a product likely to be used both for food and feed purposes will only be authorised when fulfilling authorisation criteria for both food and feed;
- authorisation may be granted either to a GMO to be used as a source material for production of food or feed and products for food and/or feed use which contain, consist of or are produced from it, or to foods or feed produced from a GMO. Thus, where a GMO used in the production of food and/or feed has been authorised under this Regulation, foods and/or feed containing, consisting of or produced from that GMO will not need an authorisation under this Regulation, but will be subject to the requirements referred to in the authorisation granted in respect of the GMO. Furthermore, foods covered by an authorisation granted under this Regulation will be exempted from the requirements of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, except where they fall under one or more of the categories referred to in Article 1 in respect of a characteristic which has not been considered for the purpose of the authorisation granted under this Regulation.
- food additives containing, consisting of or produced from GMOs will fall also within the scope of this Regulation for the safety assessment of the genetic modification, while the final authorisation should be granted under the procedure referred to in Directive 89/107/EEC;
- flavourings which contain GMOs will also fall within the scope of this Regulation for the safety assessment of the genetic modification; -feed materials containing, consisting of or produced from GMOs will fall within the scope of this Regulation and not Council Directive 82/471/EEC;
- in addition to the authorisation procedure in Directive 70/524/EEC feed additives containing or produced from GMOs will also fall within the scope of this Regulation;
- this Regulation covers food and feed produced "from" a GMO but not food and feed "with" a GMO. The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. Processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore, are not included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation. Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation.
- harmonised labelling requirements are laid down for genetically modified feed to provide final users, in particular livestock farmers, with accurate information on the composition and properties of feed;
- despite the fact that some operators avoid using genetically modified food and feed, such material may be present in minute traces in conventional food and feed as a result of adventitious or technically unavoidable presence during seed production, cultivation, harvest, transport or processing. In such cases, this food or feed is not subject to the labelling requirements of this Regulation. A threshold of 0.9% is established for the adventitious or technically unavoidable presence of genetically modified material in foods or feed, both when the marketing of such material is authorised in the Community and when this presence is tolerated by virtue of this Regulation;
- when the combined level of adventitious or technically unavoidable presence of genetically modified materials in a food or feed or in one of its components is higher than 0.9%, such presence will be indicated in accordance with this Regulation;
- operators must avoid the unintended presence of GMOs in other products. The Commission will gather information and develop on this basis guidelines on the coexistence of genetically modified, conventional and organic crops. Moreover, the Commission is invited to bring forward, as soon as possible, any further necessary proposal;
- there are transitional provisions for products already on the market;
- finally, it should be noted that the traceability and labelling of GMOs at all stages of placing on the market, including the possibility of establishing thresholds, is ensured by Directive 2001/18/EC and Regulation (EC) No 1830/2003.

ENTRY INTO FORCE: 07/11/2003.

Genetically modified food and feed

ACT : Commission Regulation 641/2004/EC on detailed rules for the implementation of Regulation 1829/2003/EC of the European Parliament

and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. CONTENT : Regulation 1829/2003/EC lays down Community procedures for the authorisation and supervision of genetically modified food and feed and for the labelling of such food and feed. The aim of the Commission's Regulation is : - to publish detailed guidance to assist the applicant in the preparation and the presentation of the application, concerning notably the information and data to be provided in order to demonstrate that the product complies with the criteria referred to in Articles 4(1) and 16(1) of that Regulation; - to ensure a smooth transition to the regime provided by Regulation (EC) No 1829/2003 transitional measures laid down in that Regulation as regards requests and notifications of products falling within the scope of other Community legislation, should be subject to implementing rules; - to provide detailed rules on the preparation and presentation of notifications of existing products submitted to the Commission under Regulation (EC) No 1829/2003 as regards products placed on the market in the Community before 18 April 2004. Such rules should facilitate the task of operators, in preparing applications for authorisations and in the preparation of notifications of existing products, and the Authority in evaluating such applications and verifying such notifications. In addition, in the interests of consistency of Community legislation, the scope of the present Regulation should also: - cover existing food consisting of, containing or produced from genetically modified plants and micro-organisms; - cover existing feed, including feed additives consisting of, containing or produced from genetically modified plants and micro-organisms; - exclude existing processing aids. Lastly, Regulation 1829/2003/EC provides that detailed rules are to be adopted for implementing the transitional measures for the adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. In the interests of consistency of Community legislation those rules should in particular clarify which genetically modified material is covered by such transitional measures and how the 0,5 % threshold is to be applied. ENTRY INTO FORCE : 07/04/2004. The Regulation shall apply from 18 April 2004.?

Genetically modified food and feed

PURPOSE: to report on the implementation of Regulation 1829/2003/EC.

CONTENT: article 48 of Regulation 1829/2003/EC obliges the Commission to prepare a report on the implementation of the Regulation (and the transitional measures in particular) and what impact the Regulation has had on human and animal health; on consumer protection; on consumer information and on the functioning of the internal market.

To help prepare the report, the Commission compiled a questionnaire, which all of the Member States? authorities and relevant stakeholders were asked to complete. Having carefully analysed the answers the Commission makes the following findings:

On the implementation of the Regulation:

- By 1 July 2006 the Commission had received 34 applications for authorisation.
- Only one authorisation for a product has been approved in accordance with the procedure set down in the Regulation. It is for food containing, consisting or produced from 1507 maize. It has now been entered on the Community register of GM food and feed.
- By 1 July 2006 the Community Reference Laboratory or CRL, which was set up by the Regulation, had validated 16 methods for the detection and identification of GM food and feed.
- The European Food Safety Authority or EFSA has issued six opinions in relation to the GM authorisation procedure.
- By May 2006, the EFSA had received 26 individual public requests on access to 73 separate applications submitted to the EFSA.
- Of the 26 requests, 18 came from five different NGO?s (mainly environmental). Two accounted for the majority of requests.
- Members from national Parliaments and the European Parliament submitted three requests; national authorities submitted two requests and stakeholders have submitted three requests, for information.

Within the framework of the existing Regulation the Commission will be seeking to create greater transparency and consensus during the authorisation procedure. The Commission, is therefore proposing that the following practices be implemented:

In the scientific evaluation phase: to invite the EFSA to liaise more with national scientific bodies; to request more detailed justifications from the EFSA on its opinions regarding individual applications; and to invite the EFSA to clarify specific protocols on scientific studies.

In the decision making phase: the Commission will address the risk assessment phase by introducing a case by case additional proportionate risk management measure in draft decisions and potentially suspending a procedure if a Member State raises important new scientific questions.

On transitional measures and products legally placed on the market pre-2003:

The Regulation provides transitional measures to allow advanced applications pending at the time of the Regulation?s adoption, to continue under the then existing legislation. The report finds that:

- By 1 July 2006, eight decisions authorising the placing on the market of GM food were adopted in accordance with old legislation (four under Regulation 258/97/EC and four under Directive 18/2001/EC).
- Twenty-six GM products, that were approved prior to the adoption of the 2003 Regulation, have been put on a special Community list and have been approved for use.

On the labelling of GM food and feed:

Currently few ?food? products on the EU market are labelled as genetically modified. As such is can be concluded that the Regulation has not had a large impact on the sale of food labelled as genetically modified. According to the results of the sample analysis reported by the Member States, the frequency of non-compliance to the food labelling requirements may be less than 2% - or 113 out of 7 129 samples analysed.

By contrast ?compound feed? labelled as genetically modified is much more present on the Community market. This can largely be explained by the predominance of GM soy in the production of soy at world-scale level and the difference of costs between non-GM soy and GM soy. The results of non compliance to the feed labelling requirement across the EU may be around 6% - or 153 out of the 2 478 samples analysed.

On unauthorised products:

A number of unauthorised GM products have entered the EU. They are:

- GM Papaya from Hawaii. These were detected in one Member State on seven occasions. Since July 2005 no further discovery of unauthorised GM papaya has been notified.
- GM Maize Bt10. The US Mission informed the authorities of an accidental release in the US of the unauthorised GM maize Bt10 (erroneously commercialised as Bt11). Between April and September 2005, 1 600 analytical tests were carried out in the US on corn gluten feed intended for export to the EU. The EU Member States carried out a further 1400 controls at the import stage. No positive results were recorded.
- GM rice LL601. The US Mission informed the EU authorities of the accidental release in the US of the unauthorised GM rice LL601. The EFSA concluded that the consumption of imported US long grain rice containing trace levels of LL601 posed an unlikely imminent safety concern to humans or animals.

Information on the unauthorised products was transmitted to the other Member States via the Rapid Alert System for Food and Feed or RASFF. The Commission finds that the RASFF worked as an effective communication tool allowing for timely action.

On the outcome of inspections:

The Food and Veterinary Office of DG SANCO carried out thirteen inspections in the EU Member States. The inspection teams made the following findings:

- all of the Member States inspected have GMO controls on both food and feed;
- all had adequate controls on BT10;
- the majority of infringements related to the mislabelling of food and feed;
- six Member States did not perform sampling controls at the point of entry;
- three Member States performed no sampling controls on seed consignments for the adventitious presence of GMO;
- official GMO laboratories were mostly accredited to ISO standards;
- four Member States had limited or no capabilities regarding the quantification of GMO?s in food or feed; and
- six Member States did not take action in all cases when trace amounts in seed consignments were discovered.

C o n c l u s i o n s :
The Commission notes that the Regulation has been operational for short period of time only. Experience, therefore, is limited. This report can only be viewed as preliminary. It is too early to propose any changes to the existing Regulation. A second report will be prepared following a sufficient period of time, which will allow for greater insight into the different aspects of the Regulation?s implementation.

Genetically modified food and feed

LEGISLATIVE ACT : Commission Regulation 1981/2006/EC on detailed rules for the implementation of Article 32 of Regulation 1829/2003/EC of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms.

CONTENT : Regulation 1829/2003/EC provides for a Community reference laboratory (CRL) to carry out certain duties and tasks set out in that Regulation. It also provides that the CRL is to be assisted by national reference laboratories.

This Regulation lays down detailed rules for the implementation of Article 32 of Regulation 1829/2003/EC as regards:

-the contribution to the costs of the tasks of the Community reference laboratory (CRL) and of the national reference laboratories, as referred to in the Annex to the Regulation; and

-the establishment of national reference laboratories.

Contributions: for each application, a flat-rate contribution of EUR 30 000 must be paid by the applicant to the CRL. Where a full validation procedure of a method of detection and identification for a single GMO event according to the requirements laid down in Annex I of Regulation 641/2004/EC is required, the CRL will request the applicant to pay an additional contribution of EUR 60 000. This amount will be multiplied by the number of GMO events to be fully validated. Where the costs of the validation of the detection method proposed by the applicant substantially exceed these amounts, an additional amount will be requested.

However, the CRL will reduce the amount of the additional contribution, in proportion of the costs saved: where the material needed to perform the full validation procedure is supplied by the applicant; and/or where the applicant provides data that refer to modules, such as DNA extraction protocols, already validated and published by the CRL.

The Regulation sets out circumstances where the contribution will be reduced or exempted, for example, where the applicant is a SME or has its head office established in a developing country.

National reference laboratories: laboratories which assist the CRL in testing and validating the method of detection and identification must fulfil the minimum requirements laid down in Annex I to the Regulation. The laboratories listed in Annex II, are meeting those requirements, and are appointed as national reference laboratories under Regulation 1829/2003/EC to assist the CRL for testing and validating the method of detection. The CRL and the national reference laboratories listed in Annex II must enter into a written agreement to define the relations between them, notably in financial matters.

ENTRY INTO FORCE : 12/01/2007.