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Commission improves rules on labelling and tracing of GMOs in Europe to enable freedom of choice and ensure environmental safety

The European Commission adopted today an important legislative package on genetically modified organisms (GMOs) which establishes a sound community system to trace and label GMOs and to regulate the placing on the market and labelling of food and feed products derived from GMOs. The new legislation is intended to provide a trustworthy and environmentally safe approach to GMOs, GM food and GM feed. The package consists of a proposal[1] for traceability and labelling of GMOs and products produced from GMOs and a proposal[2] on regulating GM food and feed. It will require the traceability of GMOs throughout the chain from farm to table and provide consumers with information by labelling all food and feed consisting of, containing or produced from a GMO. It will establish a "one door – one key" procedure for the authorisation of GMOs for food and feed, including the deliberate release into the environment. This procedure will consist of a single scientific assessment, carried out by the scientific committees of the European Food Authority. The new system as proposed today ensures a tight and stringent regulatory framework on the use of GMOs in Europe and closes existing legal gaps whilst addressing legitimate concerns of the economic operators. It meets the requests by Member States governments, the European Parliament and consumer organisations and has been drafted in close dialogue with all stakeholders and Member States. Two further proposals relating to GM seed will be brought forward in autumn. Today's proposals are subject to co-decision with the European Parliament and the Council and should enter into force in 2003 at the latest. The labelling provisions in respect of food and feed will be reviewed after two years of operation.

Commenting on the proposals, Environment Commissioner Margot Wallström said: "The provisions for traceability ensure a high level of environmental and health protection and pave the way for a proper labelling system. Certainly, there is a cost for the producers and for trade, but what is at stake is our ability to build public confidence. European companies will only be able to seize the opportunities provided by bio-technology if this confidence is established".

Health and Consumer Protection Commissioner David Byrne emphasised: "These laws will ensure that the regulatory framework in the EU is up to the high standard consumers expect. After that it is for consumers to decide if they want to buy food produced from a GMO.

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[1] Proposal for a Regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms.

[2] Proposal for a Regulation of the European Parliament and of the Council on genetically modified food and feed.

The proposed labelling regime will allow consumers to make that choice. Consumers can be assured that any GMOs in their food have been assessed strictly for their safety.

Equally important to me is that for the first time ever we will have clear rules on GM-feed in place in Europe which is a major contribution to provide trustworthy information to farmers on the feed they buy".

The main European legislation[3] in force on GMOs ensures the scientific safety assessment of GMOs, regulates its authorisation and its use. Its general provisions apply to genetically modified seed, feed and food. The directive also requires traceability and labelling without elaborating on details. Today's proposals specify the details of those requirements designed to protect the environment in case any problem emerges while not imposing too heavy burden on economic operators. Furthermore, the proposals introduce for the first time specific rules on GM-feed in Europe and existing provisions on GM-food[4] are unified and streamlined.[5] The draft legislation presented today takes account the international trade commitments of the European Communities and the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity as regards importer obligations and notifications.

The adoption of today's proposals together with the recent adoption of the revised legal framework on the deliberate release of GMOs into the environment will build up public confidence by responding to questions and concerns raised by the general public and providing a high level of protection for human health and the environment. This will contribute towards the lifting of the de facto moratorium on the commercial release of GMOs.

Traceability

Traceability entails the ability to trace products through the production and distribution chains. Traceability for certain products has existed for many years. However, specific traceability requirements for products that contain GMOs or are derived from GMOs do not currently exist. The proposed regulation makes it possible to trace GMOs through the production and distribution chain. Traceability facilitates monitoring of any effects on human health and the environment, for accurate labelling and for controlling labelling claims. It is also necessary to enable withdrawal from the market in case of unexpected adverse effects.

In the new Regulation traceability is ensured by putting obligations on business operators to transmit and retain information at each stage of the placing on the market. The industry must have systems in place that identify to whom and from whom GM products are made available. Information concerning the presence of GMOs must be transmitted throughout the commercial chain and must be retained for five years.

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 proposed regulation.

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[3] Directive 90/220/EEC on the deliberate release into the environment, revised as Directive 2001/18/EC which will take effect from October 2002 onwards.

[4] Regulation (EC) 258/97 on novel foods and novel foods ingredients ; Regulation (EC) 1139/98 concerning the compulsory indication of the labelling of certain foodstuffs produced from GMOs and Regulation (EC) 49/2000 and (EC) 50/2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings.

[5] A total of 18 authorisations of GMOs have been granted for the placing on the market in the EU, two of which cover use as food (one maize, one soya), and eight cover use in feedingstuffs (one for soya, four for maize and three for rape). Eleven food products produced from GMOs have been notified to the Commission as being substantially equivalent. See also MEMO/01/277.

"The proposal for a harmonised framework for traceability and labelling of GMOs will provide for legal certainty as well as a coherent approach that should contribute to the effective functioning of the internal market," Commissioner Wallström said: "With common rules, we should avoid that Member States establish 15 different systems of traceability. Instead, consumers and operators get one single, effective and transparent system to keep track of GMOs which will operate throughout the EU. "

Labelling

In comparison with the labelling system in place today, the proposal on GM food and feed will add the labelling of:

- All foods produced from GMOs irrespectively of whether there is DNA or protein of GM origin in the final product
- All genetically modified feed.

GM-food

Already today, retailers have to label a food consisting of or containing GMOs. This also includes food produced from GMOs if traces of DNA or protein from the genetic modification is detectable in the final product (such as flour produced from genetically modified maize (see Annex 1). However, the labelling provisions do not cover some foods or food ingredients, such as highly refined soya or maize oil. The effect of today's proposal is to extend the current labelling requirements to also cover such food and food ingredients produced from GMOs and to allow consumers to exercise their freedom of choice. The accidental presence of GM-material in food up to 1% will continue to be exempted from the labelling obligation.

GM-feed

The proposal also introduces for the first time strict labelling requirements of GM-feed along the same principle as for GM food. Currently no labelling requirements are in place for feed produced from GMOs. The proposal 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. The accidental presence of GM-material in feed up to 1% will be exempted from the labelling obligation.

"The objective of the harmonised and comprehensive labelling requirements proposed is to respond to an overwhelming need to enable the consumer or users to make an individual choice and thereby to foster increased public confidence", said David Byrne.

Adventitious presence

An issue which arises from the cultivation of GMOs is the possibility of the presence of minute traces of unauthorised GMOs in food and feed. These traces may be technically unavoidable during cultivation, harvest, transport and processing. Whether we like it or not this has become a reality. This is not a problem which is particular to GMOs. In the production of food, feed and seed, it is practically impossible to achieve products which are 100% pure.

The present proposal acknowledges this fact and sets up specific conditions under which technically unavoidable presence of unauthorised GMOs could be permitted. In the EU, a number of GMOs have already been assessed by the Scientific Committees as not posing a danger to environment and health. However, these GMOs are still pending final approval.

The proposal allows for these GMOs which have received a positive opinion from a EU Scientific Committee to be present in a food or feed up to a maximum of 1%.

Authorisation procedure

Clear rules are set out in the EU for the assessment and authorisation of GMOs and GM-food but responsibilities are divided between Member States and the Community. It is therefore proposed to establish 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 Community procedure where an operator only has to file a single application. Learning from the US experience with StarLink, the proposal provides that GMOs likely to be used as food and feed can only be authorised for both uses or not at all.

The scientific risk assessment will be carried out by the European Food Authority covering both the environmental risk and human and animal health safety assessment. Its opinion will be made available to the public and the public will have the possibility to make comments. On the basis of the opinion of the European Food Authority, the Commission will draft a proposal for granting or refusing authorisation. The proposal will as it is currently the case be approved through qualified majority of the Member States within a Regulatory Committee. Products authorised shall be entered into a public register of GM-food and feed. The authorisation should be granted for a period of 10 years, subject where appropriate to a post-market monitoring plan. Authorisations are renewable for 10-year periods.

The simplified procedure for putting on the market GM-foods which are considered to be substantially equivalent to existing foods will be abandoned.

Current GM-products will remain eligible for marketing. Operators will however be obliged to provide methods for sampling and detection to the European Food Authority within six months of entry into force of today's proposal. The proposal also establishes the Joint Research Centre (JRC) of the Commission as new Community Reference Laboratory which will have the main task of validating sampling and detection methods. The JRC will continue to work with the “European Network of GMO laboratories”.

Existing GM-products shall also be entered into the public register and the time limit of 10 years from the day when the concerned product was first placed on the market equally applies to them.

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ANNEX I

Labelling of GM-Food and GM-Feed – Examples[6]

GMO-type	EXAMPLE	Labelling Required at present	Labelling required in future
GM plant	Chicory[7]	Yes	Yes
GM seed	Maize seeds	Yes	Yes
GM food	Maize, Soybean sprouts, Tomato	Yes	Yes
Food produced from GMOs	Maize flour[8]	Yes	Yes
	Highly refined maize oil, soybean oil, rape seed oil	No	Yes
	Glucose syrup produced from maize starch[9]	No	Yes
Food from animals fed on GM feed	Eggs, meat, milk	No	No
Food produced with the help of a GM enzyme	Cheese produced with the help of chymosin	No	No
Food additive/flavouring produced from GMOs	Highly filtered lecithin extracted from soybean oil used in chocolate[9]	No	Yes
GM Feed	Maize[10]	Yes	Yes
Feed produced from a GMO	Corn gluten feed, Soybean meal	No	Yes
Feed additive produced from a GMO	Vitamin B2 (riboflavin)	No	Yes

[6] The examples include foods which have not been authorised for marketing in the EU. See Annex II for a list of products which can legally be marketed in the EU.
[7] One chicory has been approved for breeding purposes under Directive 90/220/EC, but not for food use
[8] DNA or protein of GM origin detectable in the final product.
[9] DNA or protein of GM origin not detectable in the final product.

[10] The current labelling rules entered into force in 1997, and does not include four GMOs approved prior to that date.

ANNEX II

Overview of GM Food and GM Feed authorised in the EU[11]

	Maize	Soy	Rape seed	Others
Food consisting of, containing or produced from a GMO	5	1	6	1[12]
Feed consisting of, containing or produced from a GMO	4	1	3	0

[11] Double mentioning of a GMO possible. For instance the GM soybean variety mentioned in the 2 categories is in fact the same.
[12] Riboflavin, to be used as Vitamin B2.