Consumer Voice

Newsletter on food safety, health and consumer policy
from the European Commission's Health and Consumer Protection DG

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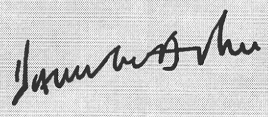
◀ *David Byrne, Commissioner for Health and Consumer Protection*

A structured, safe approach to GMOs

Taken together, two new European Parliament and Council Regulations proposed by the Commission are intended to provide a trustworthy and environmentally safe approach to GMOs, GM human food and GM animal feed. They were drafted by the DG for Health and Consumer Protection and DG Environment in close dialogue with all stakeholders, including consumer organisations, and with the Member States.

◀ *Margot Wallström, Commissioner for Evironment*

They also take account of the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity covering importer obligations and notifications. The proposals were adopted by the Commission on 25th July 2001 and will, taken together, govern traceability, labelling and Community authorisation processes. Subject to co-decision with the European Parliament and the Council, it is hoped these new rules will enter into force by 2003 at the latest.



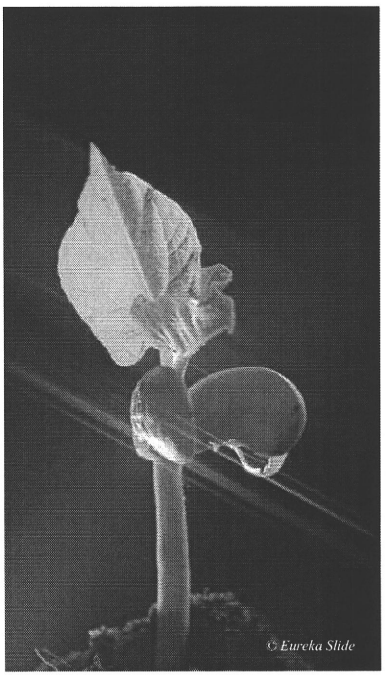
New EU rules to govern GMOs

On 27 and 28 September 2001 a major conference is being held in Brussels to bring together all key interests in European society to hear their views on the future development of life sciences and biotechnology. The discussion will cover a huge range of issues including research, innovation, competitiveness, regulation, public perception and ethical issues. The results of this Conference and the wider consultation process underway will feed into the development of a European policy on these issues for the decade ahead.

There has already been widespread debate and consultation about the use of modern biotechnology in the area of food and feed. Arising from this, the Commission acted to meet public concerns by adopting two proposals on 25 July 2001, that taken together, would govern traceability, labelling and a single Community, science-based and predictable authorisation process for GM food and feed. Prepared jointly by the DG for Health and Consumer Protection and DG Environment, the proposals now begin their move through the co-decision process between the Commission, the European Parliament and the Council. The European Parliament also heard from Commissioner Byrne about the detail and scope of the proposals for the first time on 11 September.

No compromise on food safety

During an informal Agriculture meeting on the 18 September, Commissioner David Byrne called on EU Agriculture ministers to show leadership on the issue of genetically modified organisms (GMOs). Urging them to grasp the difficult issue and act to make sure there is a rational debate and a balanced approach to the subject throughout the EU, he told them, "Now is the time to respond to the concerns of society on this difficult subject. The public need to know," he stressed, "that their legislators are working towards a high level of protection for the consumer, to ensure consumer choice, transparent and open processes and a trustworthy authorisation process through which biotechnology would be used in human food and in animal feed."



Commissioner Byrne and Agriculture, Fisheries and Rural Development Commissioner Franz Fischler, who both attended the meeting in Alden Biesen, are determined that safety is essential for the future success of biotechnology in Europe.

"Compromising on food safety is not the way forward," Commissioner Byrne emphasised. Commissioner Fischler said the question of GMOs, "is extremely important, not only for farmers, industry and the scientific world but also in job terms."

Consumers must have the right to make choices

The first proposal is for a Regulation on the authorisation and labelling of GM food and feed. It puts the general principles and requirements of food law into practice and includes new procedures for food safety. It covers food and feed containing, consisting of, or produced from GMOs, as well as food and feed ingredients, including additives and flavourings where they have been produced from GMOs. It covers all possible uses of GMOS in food and/or feed.

Many European surveys, including Eurobarometer 2000, show that consumers demand clear labelling. They want to know whether products contain, consist of, or have been produced from GMOs so that they can choose. This proposed Regulation recognises that right and extends the current labelling provisions to all GM food irrespective of whether GM of DNA or protein can be detected.

Food and food ingredients that contain or consist of a GMO must, therefore, be labelled as such. Food and food ingredients produced from a GMO will have to be labelled as "produced from genetically modified [name of organism] but not containing a genetically modified organism".

This important change to the current Community legislation on the labelling of food produced from GMOs will result in GM labelling of a number of foods and food ingredients, which are currently not required to be labelled, such as highly refined oils or glucose syrup of GM origin.

EFA to play a crucial role in the authorisation process of GM food and feed

To obtain authorisation for a product under the proposed Regulation, an application will be submitted to the European Food Authority. The application must include all documentation, samples of the food and a method for the detection and identification of the GMO. A complete dossier and a monitoring plan as required under Directive 2001/18/EC will also have to be submitted. The EFA will make a summary of the dossier available to the public.

Following a full risk assessment and validation of the detection and identification methods provided by the applicant, the opinion of the EFA will be made available to the public who will then be invited to make comments to the Commission within 30 days following publication of the opinion.

The Commission has the right as risk manager to propose a decision that differs from the opinion of the EFA (responsible for risk assessment). However, should the Commission so decide, it would have to explain its reasons for doing so.

A register of GM food and feed available to the public

Products authorised under the proposed Regulation will be entered into an EU register of GM food and feed, including product specific information, studies demonstrating the safety of the product and detection methods which have to be provided by the applicant in order to facilitate control. All non-confidential data will be made available to the public.

One door - one key

Under the proposed Regulation, it will be possible to file a single application for obtaining both:

- the authorisation for the deliberate release of a GMO into the environment;
- and the authorisation for the use of this GMO and all products derived from it in food and/or feed.

This authorisation, valid throughout the Community, will be granted subject to:

- a single risk assessment (covering both the environmental and health risks), by of the European Food Authority,
- a single risk management process, involving the Commission and the Member States through a regulatory committee procedure.

The initial authorisation will be granted for a period of 10 years and will be renewable for ten-year periods on application to the EFA at least one year before the expiry date.

Authorisation-holders will be obliged to submit any new information or requested changes related to the conditions of authorisation of the product and any reports as specified in the authorisation to the EFA.

What will happen to those products already authorised and on the market?

Existing authorisations and notifications for GM under Regulation (EC) No 258/97 on novel foods and novel food ingredients and existing authorisations of GM food and feed, granted under Directives 90/220/EEC and 2001/18/EC, Directive 82/471/EEC or Directive 70/524/EEC, will continue to remain in force. It will be necessary, however, to provide additional information concerning the risk assessment, methods for sampling and detection, including samples of the food and feed, to the EFA within six months of the entry into force of the proposed new rules. Should this condition not be met, the food or feed could no longer be considered approved for placing on the market in the Community.

In addition, if on the basis of new information or a reassessment of existing information, Member States or the Commission had detailed grounds for considering that the use of a food or feed authorised in accordance with the proposed Regulation endangered human health, animal health or the environment, safeguard measures will have to be adopted by the Commission.

Tracing GMOs across production and distribution chains

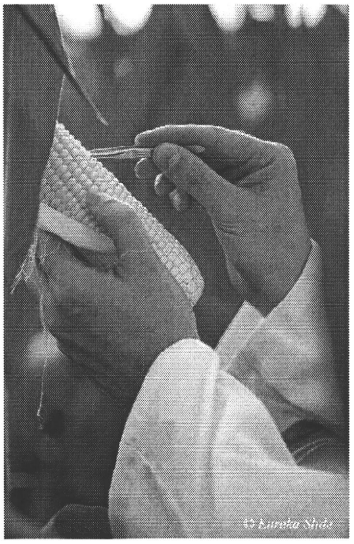
The second proposal is for a Regulation governing traceability and labelling of GMOs, and, traceability of food and feed products produced from GMOs. It aims to ensure that information will be available at all stages of the placing on the market. It will show whether a food or a feed is, consists of, contains, or is produced from a GMO. Traceability can be defined as the ability to trace GMOs and products produced from GMOs at all stages of the placing on the market throughout the production and distribution chains, facilitating quality control and also holds the potential to withdraw products if necessary.

This obligation of traceability is designed to facilitate accurate labelling of the final product and provide the means for inspection and control of labelling claims. It is a direct response to the voices of consumers who have made it clear they want - and have a right - to make informed choices.

Labelling for GM feed would follow the same basic principle, to provide final users - in particular livestock farmers - with accurate information on the composition and properties of feed, so that they too can make informed choices.

This proposal builds on the traceability systems in current food and feed legislation and the proposal for general principles and requirements of food law with the objective of extending these requirements to include information on whether a food or feed is produced from GMOs. It places an obligation on all parts of the distribution chain to provide that information.

It builds also on the current EU food labelling scheme but adds additional provisions to allow for inspection and control of compliance with the current rules and reduces reliance on detection methodology to "discover" the presence of GMOs.



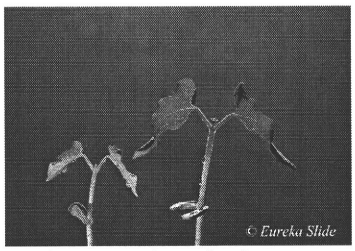
■ Chance or "adventitious" presence of unauthorised GM material

An issue which arises from the cultivation of GMOs is the possibility of the presence of minute traces of unauthorised GM material 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.

The proposed Regulation acknowledges this fact and provides that the technically unavoidable presence of unauthorised GMOs up to a maximum of 1% will not be a considered as a breach of legislation where the GMOs concerned have already been assessed by the Scientific Committees as not posing a danger to environment and health.



▲ *Soyabean is amongst the most planted crops.*

There are a number of key objectives for traceability. It limits discontinuity of product specific information through the chains and facilitates withdrawal of products should an unforeseen risk to human health or the environment be established and it targets monitoring of potential effects on human health or to the environment.

What is the potential of genetic modification

Modern gene technology has immense potential in pharmaceuticals. Human insulin, factor VIII, vaccines and treatments for hepatitis are now routinely made using GMOs - uncontroversial success stories.

In agriculture, genetic modification has so far been used to modify commodity food crops such as corn and soybean by introducing traits or combinations of traits that protect them from insects or provide tolerance to specific pesticides.

Within the next decade, gene technology has the potential to bring about the largest change in food production since the 1960s with GM seeds that are able to withstand drought or provide increased yields. Vitamin A and iron deficiencies could be drastically reduced through GM crops rich in vitamins and minerals.

But, however great the potential, the technology must develop within safe boundaries. Food must not present a danger for consumers. It should not mislead the consumer or differ from food that a GM food would replace to the extent that it would be a nutritional disadvantage to the consumer. Rules are needed to ensure that any GM food placed on the market should undergo rigorous scrutiny, that the GMO should be traceable and that any food produced from a GMO should be labelled accordingly. This should apply to food for both human and animals.

■ What is a GMO?

For hundreds of years, cross-breeding techniques have been used to modify or improve the quality and yield of food production and taste characteristics of food. Those plants and animals with the most desirable characteristics, caused by naturally occurring variations in the genetic make-up of individuals, were chosen for food production and for breeding the next generation. Now, with new technology, it is possible to identify and transfer particular characteristics of living organisms and alter them in a specific and directed way. By introducing a new segment of genetic material coming from any other living organism, whether it is a plant, an animal or a microbe, the resultant plant or animal is what is called "a genetically modified organism" or GMO.

World-wide releases of GMOs

World-wide over 40 million hectares of land are currently used for the commercial production of GM crops. The United States (70%), Argentina (14%) and Canada (9%) are the major producers, but other countries such as China are increasing GM planting. The main crops planted are soybean (53%), maize (27%), cotton (9%) and oilseeds (8%).

In the EU, less than 20,000 hectares (or 0,03% of world-wide area) are used for GM crops, most of which is planted with maize grown in Spain and France.

The EU imports about 30 million tonnes of GM soybean (from the US and Argentina) largely for use in animal feed.

To find more about GMOs

To find out more about this subject, including the two Commission proposals: Regulation of the European Parliament and of the Council on genetically modified food and feed, COM(2001)425 final, 2001/0173 (COD) and 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 and amending Directive 2001/18/EC, COM(2001)182 final, 2001/0180 (COD), speeches by Commissioner Byrne on the subject, questions and answers on GMOs and a consultation document on biotechnology, please go to: *http://europa.eu.int/comm/food/fs/biotech/biotech_index_en.html*

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