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

Decision time ahead

For nearly two years now, I have had intensive discussions with Parliamentarians and Ministers, consumers and industry about genetically modified foodstuffs and feed. Although the debate has at times been heated, I was impressed by how determined everyone was to seek a solution.

All arguments are now on the table. On 17 March 2003, the Council agreed two Common Positions on draft Regulations designed to improve the current legislation governing GMOs and GM food and feed. These new rules would provide for clearer and more stringent mandatory labelling of GM food and feed as well as traceability .

The Commission supports the Council's approach, as it is balanced and rational. An approach that meets the needs of consumers and industry alike. I now call on the European Parliament to play its part and move the proposals towards final adoption.

The European Union already has a stringent regime on GMOs. I am confident that the adoption of both Regulations will re-assure consumers that only the most rigorously assessed GMOs are marketed in the EU, and that we can trace them all the way through the food chain and label them accordingly.

IN THIS EDITION

GM food and feed:

A new regulatory framework ahead on authorisation, labelling and traceability

The overhaul of the current EU legislative system on authorisation, labelling and traceability of GMOs in food and feed is entering its final stages. Commissioner David Byrne told Consumer Voice that adoption of two new regulations would give clear rules to industry and protect consumer choice.

"We propose to set up a streamlined system to authorise GMOs in food and feed, with clear decision-making responsibilities at EU level given to the European Food Safety Authority (EFSA), for risk assessment, and to the European Commission for risk management. The other regulation proposes to trace GMOs all the way through the production and distribution chains, and to reinforce the current labelling rules."

The Commissioner explained: "I firmly believe that our regulatory framework – which is the most stringent in the world - will gain consumers' confidence. They will ultimately make the choice whether to purchase GM food or not."

European Parliament second reading

The two ground-breaking regulations, adopted by the Council in March 2003 in the form of "Common Positions", have been transmitted to the European Parliament for second reading.

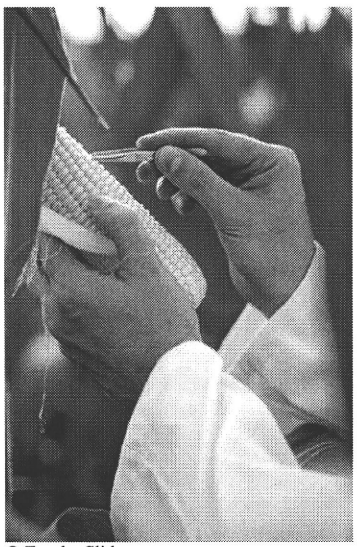
This constitutes the last stage of the co-decision process.

The new system will provide for...

The Council Common Positions reflect the essential elements of the Commission's original proposals, the opinion of the European Parliament in the first reading, and specific concerns of the Member States.

...a single approval process for GMOs

Under the new system, it will be possible to file a single application for obtaining both an authorisation for the deliberate release of a GMO into the environment; and an authorisation for the use of this GMO and all products derived from it in food and feed.



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■ **Risk assessment**

Current EU legislation makes sure that GMOs and GM food should go through a strict risk assessment process before being placed on the market. The safety of GMOs depends on the characteristics of the inserted genetic material, the final organism that is produced, the receiving environment and the interaction between the GMO and the environment.

These assessments include direct or indirect, immediate or delayed effects, taking into account any cumulative and long-term effects on human health and the environment which may arise from the deliberate release or placing on the market of the assessed GMO. The risk assessment also requires evaluation in terms of how the GMO was developed and examines the potential risks associated with the new gene products produced by the GMO (for example, toxic or allergenic proteins), and the possibility of gene-transfer,(for example, antibiotic resistance genes).

■ **A register of GM food and feed available to the public**

Products authorised under the proposed regulation will be entered into a register of GM food and feed that will include product specific information, studies demonstrating the safety of the product and validated detection methods to facilitate control. All non-confidential data would be made available to the public.

■ **Will the meat or milk of an animal fed with GM feed also be labelled as GM?**

In line with the general EU rules on labelling, the proposal does not require labelling of products that are not food ingredients, such as processing aids. It does not require labelling of products such as meat, milk or eggs obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products.

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

■ a single risk assessment (covering both the environmental and health risks), by the **European Food Safety Authority (EFSA)**, and

■ a single risk management process, involving the European Commission and the Member States through a regulatory committee procedure.

Following a full risk assessment and validation of the detection method provided by the applicant, the opinion of EFSA will be made available to the public who can make comments to the Commission within 30 days.

The Commission, acting as risk manager, will propose to the regulatory committee a decision on whether or not to authorise the GMO in question. The Commission can propose a decision that differs from the opinion of EFSA, though only if it has an appropriate justification for doing so.

The initial authorisation, published as a Commission decision, will be granted for a period of 10 years. Its eventual renewal will only be granted after another application.

...traceability across production and distribution chains

Traceability is defined as the ability to trace GMOs, and products produced from them, at all stages of their placing on the market throughout the production and distribution chains, facilitating control and also holding the potential to withdraw products if necessary.

The obligation of traceability is designed to facilitate accurate labelling of the final product and to 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 that they want – and have a right – to make informed choices.

This proposal places an obligation on all parts of the distribution chain to provide that information. It also builds 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 analytical methods to detect the presence of GMOs.

There are a number of key objectives for traceability, including limiting the potential for loss of product specific information through the food and feed chains and making it easy to withdraw products if an unforeseen risk to human health or the environment is established. Traceability also facilitates the monitoring of the potential effects that the GMOs could have on the environment.

...extensive mandatory labelling of GMOs in food and feed

Already today, retailers have to label food consisting of or containing GMOs. This includes food produced from GMOs if traces of DNA or proteins from the genetic modification is detectable in the final product (such as flour produced from GM maize). However, the current labelling provisions do not cover some food or food ingredients where these traces are not detectable (such as highly refined soya or maize oil produced from GM-soya or GM-maize). Neither do they cover certain derived products, such as biscuits produced using GM-maize oil.

With the new regulations, all products containing an authorised GMO will have to be labelled accordingly. They will have to bear a label mentioning: "This product contains genetically modified organisms" or "...produced from genetically modified (name of organism)".

In order to avoid over-labelling, European Ministers agreed that these requirements should only apply if the presence of the GMO in the final product is more than 0.9%, if it is adventitious and technically unavoidable. This threshold is 1% in the current system.

For the first time, the new regulations will also cover all kinds of animal feed made of or containing a GMO, such as GM soy meal or corn gluten feed produced from GM maize.

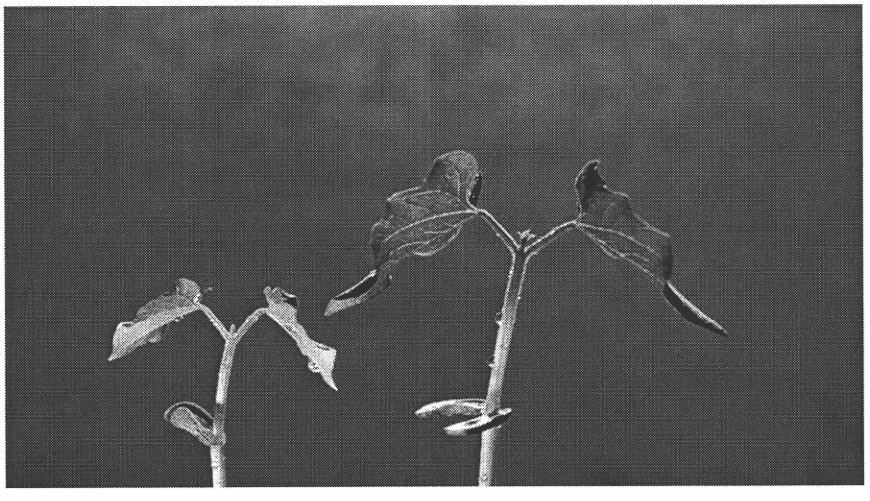
All GM foods, including those approved under the Novel Foods Regulation, will have to be labelled in accordance with the GM Food and Feed Regulation, when it comes into force.

... a labelling threshold for traces of unauthorised GM material

The adventitious or unintended presence of minute traces of GMOs in products placed on the market in the EU is largely unavoidable and can occur during cultivation, handling, storage and transport. This situation already exists and affects products originating both in the EU and in third countries.

It is not a problem unique to GMOs. In the production of food and feed, it is practically impossible to achieve products that are 100% pure.

The Common Positions acknowledge this fact and define a threshold of 0.5% under which a technically unavoidable presence of GMOs, not yet formally authorised, could be permitted. This GMO, however, should have received a favourable scientific risk assessment before the date of application of the Regulation and the operator should be in a position to demonstrate that its presence was technically unavoidable. This exemption applies for a limited time period of three years. It aims to solve the problem faced by operators who have tried to avoid GMOs, but find that their products still contain a very low percentage of GM material.



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■ What is a GMO?

For hundreds of years, cross-breeding techniques have been used to modify or improve the quality, yield and taste characteristics of food. Those plants and animals with the most desirable characteristics, caused by naturally occurring variations in their genetic make-up, were chosen for food production and for breeding the next generations.

Now, with new technology, it is possible to identify and transfer particular characteristics of living organisms and alter them in a specific and direct way. By introducing a new segment of genetic material coming from other living organisms, whether plant, animal or microbe, the resultant plant or animal is what is called "a genetically modified organism" or GMO.

■ Current EU legislation on GMOs

Legislation on GMOs in place since the early 1990s has been extended and refined over time. This evolving process is set to continue.

Directive 90/220/EEC, covering experimental releases and placing on the market of GMOs, was replaced on 17 October 2002 by Directive 2001/18/EC, strengthening and updating the provisions on deliberate release of GMOs.

Both directives cover the approval process through a case by case assessment of the risks to human health and the environment. This assessment is done before any GMO or product consisting of or containing GMOs, can be released into the environment or placed on the market.

The Regulation on Novel Foods and Novel Food Ingredients covers products containing, consisting of or derived from GMOs, such as a GM tomato or tomato paste and ketchup produced from GM tomatoes.

Directive 90/219/EEC amended by Council Directive 98/81/EC, regulates the contained use of genetically modified micro-organisms (GMMs) for research and industrial purposes.

What is the potential of genetic modification?

Modern gene technology holds immense potential in the pharmaceutical field. Human insulin, factor VIII, vaccines and treatments for hepatitis are now routinely made using GMOs resulting in uncontroversial success stories.

In agriculture, genetic modification has so far been used to modify commodity food crops, such as maize 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. This technology can also increase the content in essential nutriments such as vitamins or iron.

But however great the potential, the technology must develop within safe boundaries. GM food and feed must not present a risk to the consumer. It should not mislead the consumer or differ from non-GM food to the extent that it would be a nutritional disadvantage to the consumer.

Worldwide release of GMOs

Worldwide, over 58 million hectares of land are currently used for the commercial production of GM crops. The United States plants the greatest global area of land (66%), followed by Argentina (23%) and Canada (6%). These countries are the major producers, but other countries such as China are increasing their planting of GM products. The main crops planted per million hectares are soybean (62%), maize (21%) and cotton (12%).

In the EU, a very small area of land (representing less than 0.05% of the worldwide area) is used for GM crops. Only maize is commercially grown, mostly in Spain. The most common GM product imported into the EU is soybean for use in animal feed.

To find out more about

- GMOs, the proposed Regulations on GM food and feed, on traceability and labelling, go to: http://europa.eu.int/comm/food/fs/gmo/gmo_index_en.html
- the European Food Safety Authority, go to: http://www.efsa.eu.int/
- EU funded research on biosafety of GM crops, including issues related to coexistence, go to http://europa.eu.int/comm/research/quality-of-life/gmo/index.html
- Economic impact of GM crops http://europa.eu.int/comm/agriculture/publi/gmo/cover.htm

■ Co-existence of GM and non-GM crops

The cultivation of authorised GMOs in the EU raises the question of how to manage the adventitious mixing of GM and non-GM crops (admixture) as well as its possible economic consequences. The ability of the agricultural sector to deliver a high degree of consumer choice is linked to its ability to maintain different production systems.

The EU has launched an Action Plan on "Life Sciences and Biotechnology: A Strategy for Europe". It commits the European Commission to "take the initiative to develop, in partnership with Member States, farmers and other private operators, research and pilot projects to clarify the need, and possible options, for agronomic and other measures to ensure the viability of conventional and organic farming and their sustainable co-existence with genetically modified crops."

On 24 April 2003, the Commission hosted a roundtable meeting to examine the latest research results in this domain. A wide range of stakeholders, representing industry, NGOs, consumers and other players, attended the meeting.

The Commission intends to produce guidelines on co-existence before the summer.

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The views expressed in Consumer Voice do not necessarily reflect the opinion of the European Commission.

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