

# Flies in the soup—European GM labeling legislation

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Beginning April 18, the European Union (EU)'s labeling legislation will extend to all foods and ingredients produced from genetically modified (GM) organisms (GMOs), including animal feed and pet foods, irrespective of whether they contain detectable GM material. Over 30 ingredients from maize and soya—estimated to involve over 70% of processed foods—will require labeling unless manufacturers and suppliers take the necessary steps to avoid their use. Needless to say, the new legislation will have a major impact on the food industry. It takes little account of the commercial consequences that derive from the complexity of modern food and ingredient manufacturing and the global supply chain.

## European sensitivities

GM crops could scarcely have arrived in Europe at a worse time. They have encountered considerable European consumer resistance, which in turn has prompted legislators to introduce comprehensive controls on the GMOs themselves and statutory labeling of foods and animal feeds in which they and their derivatives are used.

There are several reasons for the entrenched resistance of European consumers to GM technology. One major factor is that the European public has been exposed to a succession of (non-GM-related) food and health crises—including thalidomide, *Salmonella* contamination of eggs, *Listeria* in chilled foods, dioxins and, particularly, bovine spongiform encephalopathy (BSE)—that scientists and politicians said “could not happen.” Numerous other ‘scares’ have fuelled a deep suspicion of

science, politicians and the agri-food industry. Widespread lack of knowledge about food production, composition and regulatory control has led to speculation, skepticism, concern and even alarm among consumers. There is widespread distrust of the agri-food industry and deep concern in some quarters over the ‘excessive’ influence of global corporations.

The independence and reliability of scientific advice have also been questioned. Developers of new technologies are increasingly challenged to ‘prove the negative’ before any new development can be accepted. This has been reflected in the emergence, and stringent (some would say overstringent) application, of the ‘precautionary principle’ as a basis for regulation by the EU.

Regulatory procedures are also poorly understood by the public. A lack of confidence that legislation is adequate or is properly enforced has resulted in wide-ranging demands for ‘transparency and independence’ of the process, and ‘information’ and ‘assurance’ for consumers. The truth, however, is that food is probably safer than it has ever been. All reputable companies consider safety to be non-negotiable. Significantly, most recent ‘scares’ have resulted from fraudulent practices that no legislation, *per se*, could have prevented.

## New rules and muddled waters

The new regulations<sup>1–3</sup> to be implemented on April 18 are applied to three food types: GMOs for food and feed use; food and feed containing, or consisting of, GMOs; and food and feed produced from, or containing ingredients produced from, GMOs. Foods and feeds that have an “adventitious or technically unavoidable” presence of GMOs and their derivatives are exempt from mandatory identification and labeling (see Box 1).

The European Commission has also stated

that meat, eggs, milk, and other products from animals fed on GM feed are not within the scope of the new rules; however, this is not stated anywhere in the text of the regulations. In fact, on close reading, the legislation contains several omissions or ambiguities that will likely compromise its effective implementation.

First, neither ‘adventitious’ nor ‘technically unavoidable’ are defined in the text. As a result, courts will be forced to base interpretations on everyday usage. ‘Adventitious’ describes contamination that occurs, despite every effort being taken to prevent it. One can argue that, if the origin of contamination can be determined, steps necessary to prevent it can be identified and future occurrences would no longer be ‘adventitious’. One can also argue that persistent, low-level contamination is not permitted, persistent contamination not being adventitious. ‘Technically unavoidable’ does not equate to ‘economically unavoidable’.

Although adventitious *contamination* is exempt from GM labeling, it is illogical not to exempt *knowingly used* ingredients, such as additives and flavorings, derived through several stages from GM crops, when these are used at levels well below the adventitious thresholds. This increases the complexity and cost of sourcing these materials from identity-preserved supplies, but it does not serve as a sound basis either for consumer information or to enhance consumer confidence.

A second problem is that Regulation 1829/2003 (ref. 1) introduces post-market monitoring of GM derivatives, but without guidance on how this might be achieved. Although feasible for prescription medicines used on an individual basis, it is difficult to see how this can provide a basis for valid diagnoses in relation to as-yet-unidentified problems without an extremely complex, globally applicable bureaucratic procedure being introduced

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and maintained for many years. One must ask, therefore, how this will work.

Third, possible distinctions between foods produced 'from' and produced 'with' a GMO have been considered but are not apparent within the legal text, which consequently is open to wide interpretation and unlikely to form a sound basis for rigorous legislation. Many questions remain unanswered concerning refined ingredients produced by sequential separation, purification or conversion stages, particularly where microorganisms or enzymes are used. It is unclear whether the use of free or bound enzyme systems affects the status of products. For example, is dextrose obtained from glucose syrup from GM maize, using a non-GM enzyme, to be regarded differently from dextrose produced from conventional (non-GM) glucose syrup, but using an enzyme obtained from a GM microorganism? Other questions relating to fermentation-derived products, such as certain vitamins and refined chemicals, are also outstanding.

### Implications

For the food industry as a whole, cross-contamination during cultivation, harvest, transport and processing is unavoidable—this has been recognized in numerous legal and commercial purity criteria over many years (and is not a problem unique to GMOs). Because the new EU rules affect shipments not only of GM products, but also of non-GM products that may contain adventitious levels of GMOs, the labeling laws potentially affect all food producers.

Many businesses have already taken steps to exclude ingredients derived from GMOs and are unlikely to be affected immediately; however, many more will now seek to legitimately avoid GM labeling by sourcing ingredients either from non-GM supplies (putting pressure on the price of documented, segregated supplies) or from alternative species that have not been genetically modified. The latter is, of course, only a short-term option as increasing numbers of GM crop varieties become available. Others, less reputedly, are unlikely to seek the more expensive alternatives, and, equally, are unlikely to label the GM derivatives, with little risk of detection.

Another problem is that no validated analytical methods can distinguish refined GM derivatives from their traditional counterparts. It is difficult to envisage how positive labeling or numerical thresholds can be enforced with sufficient rigor to prevent fraudulent non-declaration. If a seller claims that a product, without protein or DNA, has not been derived from a GMO, it will be costly, if not impossible, to prove otherwise. As authenticated non-GM

materials will attract a premium price, the invitation to fraud is obvious.

As a result of the above, audit trails will replace analytical methods, imposing costly burdens on industry without adding significantly to consumer protection. These paper trails will themselves carry a risk of fraud that experience shows will occur as soon as financial gain is possible. In countries where GM crops are widely grown without reliable segregation, GM derivatives will be present in numerous processed foods and ingredients. It is likely that no foods or ingredients (regardless of their degree of refinement) that might be obtained from GMOs could be sourced from these countries unless full traceability and identity preservation systems are in place.

### What is needed?

When considering future global food security, pressure on the environment and the increasing need for sustainable agricultural practices, it is clear GM technology will become a ubiquitous part of global agricultural production whether for food, textiles or fuel. It has already been widely used in microbiological processes involved in food production for over 30 years without any apparent problem or consumer interest. Any system of GM regulation,

whether related to safety approval or labeling, needs to be developed with this vision in mind.

In Europe, 'consumer protection' predominates over the broader need for economies to be founded on soundly based R&D that supports viable industries, providing secure, profitable employment and fair returns to investors and generating proportionate taxes to fund the overall needs of society.

The new rules and information on illustrate the peril of promulgating legislation to satisfy consumer demands for 'absolute safety' without due regard for how rules can be applied in practice. Legislation should be worded in such a way that there is no room for doubt or interpretation. It also needs to be developed on the basis of practical limitations, proportionality, economics and enforceability on a global basis.

The essential requirement is for a robust set of regulations that will be as relevant in the future as today. Current EU labeling legislation falls far short of this goal.

1. The European Parliament and the Council of the European Union. *Official J. Eur. Union* **L268**, 1–23 (2003).
2. The European Parliament and the Council of the European Union. *Official J. Eur. Union* **L268**, 24–28 (2003).
3. The Commission of the European Communities. *Official J. Eur. Union* **L10**, 5–10 (2004).

## Box 1 What the new regulations mean

Three new EU regulations—1829/2003 (ref. 1), 1830/2003 (ref. 2) and 65/2004 (ref. 3)—concerning GMOs and foods and feeds derived from them are to be implemented in Europe beginning April 18. They cover three areas: authorization, labeling and traceability:

**Authorization.** Articles 5 and 17 of Regulation 1829/2003 describe the information to be provided by an applicant seeking authorization to place a product on the market. The product goes through the approval procedure between the European Food Safety Authority (Brussels), the European Commission and member states before being entered into the Register of GM Food and Feed. The authorization is valid for ten years and is renewable for further ten-year periods, on application to the European Commission. Products already on the market in Europe before 18 April 2004 have to be notified to the Commission by 18 October 2004, along with information required by Regulation 1829/2003, including methods for detection, sampling and identification of the transformation event. The products will be entered in the Register once the information package is complete and reviewed.

**Labeling.** Any food or feed containing, consisting of, or produced from GMOs will need to be labeled in a way that indicates it contains GMOs. For GMOs that are currently approved in the EU, 'adventitious' levels of up to 0.9% will be permitted without the need for labeling; for GMOs that have not yet been fully approved in the EU but have received a favorable safety evaluation from a Community Scientific Committee, 'adventitious' levels of up to 0.5% will be permitted without the need for labeling. GMOs that have received neither EU approval nor a favorable risk evaluation will be forbidden. The labeling requirements do not apply to food products for which the manufacturing process has commenced before April 18, 2004.

**Traceability.** The legislation provides a framework for the traceability of food, feed or products consisting of, containing or produced from GMOs. For viable GMOs, companies must provide the unique identifier(s) assigned to that GMO (or GMOs) as per the system established through Regulation 65/2004 (ref. 3). In the case of materials derived from GMOs, this fact must be transmitted to the recipient throughout the chain. Records must be kept for five years in all cases.