Monitoring and Labeling for Genetically Modified Products

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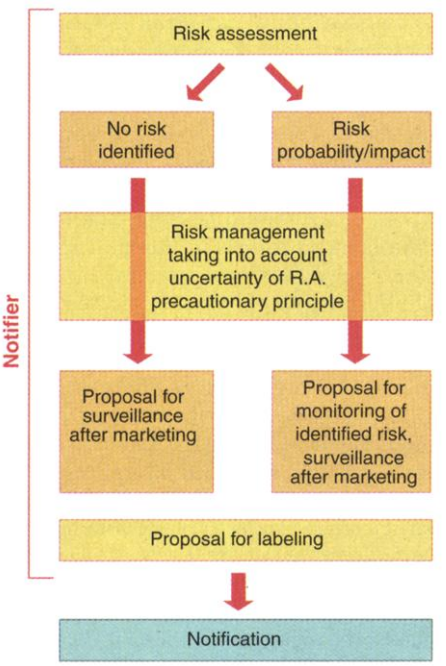
In the last year, opposition to marketing of products made with or containing genetically modified organisms (GMOs) for food and feed uses has increased exponentially in Europe. Broad segments of the general public appear convinced that genetic engineering of these products is dangerous to health and to the environment. There has been much more indifference to the use of GMOs in the United States; however, the resistance in Europe appears to be spreading. Although the risks to health and the environment are far from certain, reports in the popular press regarding potential toxic effects of crops expressing proteins of *Bacillus thuringiensis* (Bt) on nontarget insects such as butterflies (*1*), increased induction of resistance in pests (*2*), as well as possible pleiotropic effects on gene expression (*3*) have raised public anxiety. Increasing caution of scientific organizations like the British Medical Association (*4*), efficient networking of environmental groups, and public distrust (*5*) have resulted in substantial rejection of agricultural products of the new technology.

This led the Deutsche Bank to announce in an attachment to their July report that "Increasingly, GMOs are, or in our opinion, becoming a liability to farmers" (*6*). This apprehension has spread to other parts of the world such as India and Thailand (*7*). In Japan, biosafety restrictions on GMO shipments have been introduced (*8*), and a government committee recently recommended mandatory labeling of genetically modified foods (*9*).

In many recent cases, this has meant that development of new products is being reconsidered or delayed. After a debate on horizontal gene transfer of resistance-encoding genes, a scientific committee of the European Commission (*10*), national scientific boards such as the German Robert Koch Institute, and both the Houses of Lords and Commons in the British Parliament (*11*) concluded that, despite the improbability of danger, marker genes encoding antibiotic resistance should not be engineered into products for food and feed use. At present, many products are inhibited by bans, voluntary moratoriums, or long-lasting notification procedures under the Novel Food Regulation (*12*) and Directive 90/220/EEC of the European Union (EU) (*13*).

European Regulations and Amendments

Directive 90/220/EEC, for which negotiations occurred in the late 1980s, specifies provisions for risk assessment and risk management of deliberate experimental release of genetically modified products and for placing them on the market. Although no major problems have been encountered with provisions for experimental release of GMOs, provisions for risk assessment and management for the marketing of GMOs in the current directive have not resulted in a harmonious viewpoint in Europe. Possible gaps in the risk assessment capabilities and missing provisions for postmarketing surveillance and tracking of GMOs have raised concerns. For example, the present system for identification of genetic constructs and organisms used commercially is not sufficient to allow epidemiological studies to detect increases in allergies. According to Ben Miflin, former director of the Institute of Arable Crops at Rothamsted, only health effects representing "a monumental disaster" would be detectable under the original regulations (*14*).



Flow chart for notification

In the past few months, intensive negotiations on amending Directive 90/220/EEC have taken place within the EU. At the meeting of environmental ministers of the EU in June of 1999, the view was expressed that Directive 90/220/EEC is not working adequately, and many representatives stated that no more products should be approved under the conditions of the old directive (*15*). There was agreement on the importance of implementing an amended directive as soon as possible. The draft for the amendment of Directive 90/220/EEC, agreed to by the Council of the EU Environmental Ministers at the end of June 1999, addresses increased safety provisions, transparency of regulation, and streamlined notification procedures. The European Member States officially adopted the common position on Directive 90/220/EEC at the end of December. If no new problems develop in the final negotiations of the European Parliament, Council, and Commission these amendments could be implemented within the next 6 months.

Monitoring and Labeling

A striking improvement in the amendments is that risk assessment will encompass not only direct and immediate effects but also indirect and long-term effects that can be assessed scientifically.

When a product is ready to be marketed the "notifier" of the product (usually the manufacturer) must submit risk assessment and risk management information to authorities in the first country where it is to be placed on the market (see figure). This authority must evaluate the data and report to the European Commission on whether the product should be allowed on the market (with any necessary conditions) or not. The Commission then reports to all other members of the EU. The amendments specify that if no risks are identified, only a general postmarketing surveillance system to enable the rapid identification of unforseen problems has to be established. However, if a potential risk is found, a specific plan to monitor and explore the extent of the risk must be designed and specified in the notification. An example of monitoring recommendations are those proposed by the European Commission's Scientific Committee on Plants for analyzing the potential for ac-

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celerated development of Bt-resistant pests after exposure to Bt-maize (*16*).

An improved identification system for genetic constructs and modified organisms, based on genetic transformation events and notification numbers, has been discussed recently by member states and the European Commission. These improvements, combined with a register that includes transformation events, notification information, and prerequisites for the identification of GMOs should facilitate tracking and labeling of products.

Approval for marketing may be restricted in time, geographic regions where the product can appear, and conditions for use to enable the protection of specific ecologically sensitive regions. Similar environmentally important measures are in force for certain GMOs under specific regulations in the United States. Time-limited consents, regional restrictions, and monitoring obligations are used for plant pesticide regulatory decisions; e.g., for Bt-maize by the Environmental Protection Agency (*17*). A monitoring system is already used by the U.S. Geological Survey for endangered species and changes in the ecosystem (*18*).

These amendments may help environmentalists by establishing safety provisions without the need of moratoriums, consumers by increasing the likelihood of informed decision-making, and industry by increasing the confidence of consumers. The proposed amendments also indicate a trend toward streamlined notification procedures with more clearly defined time schedules for the decision-making process between member states and the Commission. Furthermore, the possibility of a consultation among scientific committees of the European Commission in cases of disagreement in the risk assessment should enable faster approvals for marketing.

Until implementation of the amended directive, the European Ministers have agreed to follow the main elements of the proposed amendments as much as is permitted within the legal context of the present directive. Right now manufacturers are studying the proposed amendments and considering whether to "upgrade" already submitted or intended notifications. For example, in the notification procedure for two genetically modified rapeseeds and a fodder beet, Monsanto and AgrEvo have already offered to anticipate the proposed amendments to Directive 90/220/EEC (*19*).

International Trading

Discrepancies between the U.S. and the EU regulatory systems may represent significant challenges to be faced. In the United States, more than 50 GMOs are already deregulated (i.e., they can be treated as if they had not been modified); half of the soybean acres and 38% of corn acres were planted with genetically modified plants last year. European restrictions on GMOs and the regulatory differences have resulted in problems for U.S. exports (*20*).

Different regulatory systems and public perception of environmental risks have also caused discrepancies in the use of the precautionary principle in regulations and trade relations. Generally, this principle indicates that risk management provisions have to become more restrictive to match the scientific uncertainty in the risk assessment and the complexity of the system. Whereas many EU member states have expressed support for this principle, there has been no official endorsement by the U.S. government. However, international agreements such as the Rio Declaration from the 1992 United Nations Conference on Environment and Development bind the United States to this approach (*21*).

Furthermore, European labeling requirements, with the subsequent need for segregation of GMOs, still represent a major source of conflict. In an article explaining the policy of the Food and Drug Administration in the United States on labeling, Henry Miller commented that "The FDA's policy toward labeling biotech food is in contrast to that in Europe and Asia, where regulators have permitted politics, public misapprehensions, the blandishments of anti-technology activists, and nescience to dictate policy" (*22*). Furthermore, U.S. agriculture secretary Dan Glickman announced the prospect of vigorous fights in trade negotiations with Europe in which the United States "cannot let others hide behind unfounded, unwarranted scientific claims to block commerce in agriculture" (*23*).

However, GMO food labeling is getting more attention in the United States. Recently, 49 members of the U.S. Congress sent letters to the Food and Drug Administration requesting mandatory labeling of genetically engineered foods (*24*). More extensive labeling of genetically modified foods was demanded by 70% of respondents to a survey in the United States and 40% wanted more stringent regulation of agricultural biotechnology (*25*).

Meanwhile, large food processors, fearful of losing buyers, have emphasized their acceptance of consumer demands for labeling and have asked suppliers for segregation of crops (*26*). Farmers are also concerned that markets for unmodified grain could be threatened by contamination of crops such as maize and canola through cross-fertilization with wind-borne pollen (*26*). Declines in sales of genetically altered seeds, after 3 years of growth, have been predicted (*27*).

This significant public opposition to the use of GMOs in many regions of the world clearly indicates that only by addressing environmental concerns and consumer demands with improved risk management (specifically monitoring) and appropriate labeling will it be possible for the industry to introduce GMOs into worldwide markets without significant resistance. I believe it will be highly important for the biotechnology industry in the United States to accept the challenge of developing and regulating products that take into account regional diverse needs and concerns of consumers and specificities of the environment.

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