The European Commission's Position on GMOs: Will Consumers be Convinced?

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The European public has become increasingly aware of potential impacts on human health and the environment arising from the application of genetically modified organisms (GMOs). In order to ensure that society as a whole will be able to profit from the potential benefits of this new technology, the European Commission is working to create a safe and effective regulatory framework for GMOs. The aim is also to restore public and market confidence in GMOs by promoting an open and informed debate on the potential risks and benefits of biotechnology.

The latest Eurobarometer[1] survey on biotechnology indicates that many Europeans object to specific applications of biotechnology, such as genetically modified foods and the cloning of animals. However, the public's perception of medical biotechnology and environmental applications is more positive. In addition, the same survey reveals that Europeans have much confidence in consumer organizations and only slightly less confidence in medical and environmental protection organizations. Further, only very few Europeans view national government authorities as their most trusted source of information, while companies and political parties are at the bottom of the list.

European legislation requires authorization prior to the commercialization of any GMOs. This includes a comprehensive assessment of potential risks to human health and the environment. In spite of this comprehensive authorization procedure and the fact that no peer-review scientific article has reported adverse effects from such products, the public continues to raise concerns with regard to the effect of GMOs.

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At the same time, the European market is reacting to consumer demands by moving towards non-GM foods, thus avoiding the use of food and food ingredients derived from GMOs. Current opposition to GM foods is also impacting areas beyond concern over the commercial release of GMOs and the marketing of GM foods; for example, the competitiveness of the European biotechnology industry, particularly small and medium-sized enterprises has been affected. In turn, this could impact job creation and the further development of biotechnology in Europe.

The European Commission faces the challenge of addressing the present concerns and contributing to the restoration of public and market confidence in the authorization procedure for GMOs. An important building block of this strategy is the revised horizontal legislation regulating the release of GMOs and products derived thereof on the market. This includes proposals on traceability and labeling as well as the development of an action plan on biotechnology. The implementation of the Cartagena Protocol on Biosafety adopted in Montreal in January 2000[2] will also be an important factor in restoring market and consumer confidence.

THE CURRENT STATE OF PLAY IN EUROPE

To date, eighteen GMO products have been authorized for commercialization on the European market. The majority of these products are genetically modified crop plant species, but genetically modified vaccines and flowers have also been approved. In 1999, a mere 0.1 million hectares (ha) of genetically modified crops were cultivated in Europe. In comparison, more than 44 million hectares of genetically modified crops were cultivated worldwide in 2000, 99 percent of which were cultivated in four countries—the U.S. (30 million ha), Argentina (10 million ha), Canada (2.5 million ha), and China (1 million ha).

Directive 90/220/EEC on the deliberate release of GMOs into the environment provides the backbone of the European regulatory framework regarding GMOs. Rules for the commercial release of GMOs are set out in Part C of the Directive, stipulating that products may not be commercialized without a prior assessment of any risks to human health or the environment, and without explicit Community approval. Applications for the commercialization of genetically modified crop plants must also consider the product's use and results obtained from research and development under Part B of the Directive.[3]

Since the deliberate release of GMOs into the environment and the application of modern biotechnology to food and plants is currently the focus of intense public and political debate in Europe, certain member states have become increasingly reluctant to approve the commercialization of new GMOs under Directive 90/220/EEC. As a result, the current authorization procedure within

Europe has ground to a standstill, resulting in a *de facto* moratorium on the commercial release of GMOs, particularly those which could end up in the food chain. A parallel situation has arisen in relation to GMO foods and seeds covered by sector-based legislation (Directive 258/97/EC on Novel Food[4] and Directive 98/95/EC on Novel Seed).[5]

In 1998, the European Commission, therefore, proposed a revision of Directive 90/220/EEC as a means of providing a balanced response to this new challenge. The main objective was to restore both public and market confidence by establishing a safe, efficient, and transparent regulatory framework. The revised directive was formally adopted in mid-February 2001. The revised Directive was published in the Official Journal on April 17, 2001 and the EU Member States have 18 months to transpose it into national legislation. It will provide a high level of protection for consumer health and the environment while still allowing society to profit from the benefits of this new technology.[6]

THE COMMISSION STRATEGY: LOOKING FORWARD

In July 2000, in order to meet public and political concerns, the European Commission proposed an interim approach to GMO regulation. This approach aims to integrate the stricter requirements of the revised Directive 90/220/EEC into the authorization process for new GMO products on a voluntary basis, until the member states have fully implemented the directive into their respective national legislations. This would allow regulatory bodies to consider applications for new GMO products under the new rules at an earlier stage, resulting in higher standards of public safety.

This interim approach also includes consideration of the entire regulatory framework for GMOs. This goes beyond Directive 90/220/EEC and includes legislation governing GM food, feed, and seeds. The aim is to ensure that Europe has a fully coherent set of laws in line with the approach of Directive 90/220/EEC. The European corpus of legislation must be updated in a logical and rational way and gaps must be filled in.

To complement the revised directive, the European Commission in July 2001 adopted legislative measures concerning traceability and labeling of GMOs, and food and feed products derived from GMOs. Traceability of GMOs will facilitate the targeting of monitoring to examine potential effects on human health and the environment, and speed up the withdrawal of products where appropriate. Traceability for products derived from GMOs will similarly facilitate withdrawal of such products should an unforeseen effect emerge. Accurate labeling is required to provide consumers with the information they need to make choices.

The importance of a well-functioning traceability system was illustrated in the United States last year when traces of a GM maize variety, which had not

been authorized for human consumption, were detected in the food chain. If GMOs cannot be traced, companies risk having to withdraw large quantities of products, resulting in economic loss, a decrease in consumer confidence, and damage to brand names.

Having a satisfactory legislative framework is important in addressing public concerns, but the public debate in Europe has also raised other issues. This is why the European Commission is also currently working on an action plan on biotechnology which will lay down the building blocks for a long-term strategy on biotechnology and its implications for European agriculture, trade, competitiveness, and employment.

THE NEED TO INVOLVE ALL STAKEHOLDERS

Following recent food crises in Europe, such as the foot-and-mouth outbreak, the re-emergence of the BSE-crisis, and dioxin and sewage scandals, the European consumer has become very sensitive to food issues. A new regulatory framework for the release of GM products, even if very stringent, might not be enough to meet current consumer concerns. It is also necessary that all stakeholders—including the European Union institutions, the member states, industry, the scientific community, as well as NGOs, and the media—assume the responsibility of providing a transparent and balanced response to the questions raised by the general public. This point was stressed by Swedish Secretary of State Anna Ekström, in January 2001, at a seminar in Brussels on biotechnology. She argued that:

> It is essential for policymakers and industry to understand and take into account the moral and ethical dimensions of biotechnology that underlie public concerns. All stakeholders—industry, the scientific community, consumer associations, environmental protection organizations, and other interest groups—need to interact to participate in an active dialogue on these issues. Public acceptance based on confidence and trust is crucial for the future development of the biotech sector.

There is a need for the European political leadership, together with key stakeholders, to take the debate on GMOs and biotechnology forward. First and foremost, the European Commission's role is to provide a safe and reliable framework for the authorization and control of GMOs. In addition, industry and the scientific community have a special responsibility to inform the public more fully about the potential benefits and ethical aspects of GMOs as they see them.

As outlined in the proposal for a new "Sixth Environmental Action Program" for the European Union, it is essential that policymakers find new ways of working closer with the market via business and consumers. The European

Commission has endeavored to broaden the dialogue with stakeholders by developing more open and transparent consultation mechanisms with NGOs and business representatives, as well as with consumers. Moreover, the European Commission will organize a stakeholder dialogue on GMOs in Autumn 2001.

Biotechnology issues have cross-border implications and should therefore also be debated and addressed in broader international fora. In this respect, the establishment of an EU-U.S. Biotechnology Consultative Forum was welcome. It has allowed an independent group of experts representing diverse views on both sides of the Atlantic to discuss the full range of concerns in biotechnology in the U.S. and the EU.

The forum's final report includes a list of recommendations on the use of biotechnology in the context of agriculture. The report provides useful information that can improve the understanding of biotechnology issues and provide insight into how to best address them.

Another important dimension of the European Commission's policy on biotechnology is the need to strengthen the European science base. The importance of scientists' training was stressed at the EU Lisbon Summit last year. In Europe, there is a tendency for students to prefer social sciences to natural sciences. It is important to turn this development around. For instance, sciences could be made more attractive to students by increasing funding for biotechnology studies. In particular, more attention should be paid to the research conducted in universities and hospitals.

Academia has a key role to play in the overall biotechnology debate and can provide an essential bridge between science and consumers. Establishing this link will provide consumers with sound scientific information on which to base their concerns and make their choices. Against this background, the further involvement of academia in this debate is likely to be a very important step towards ensuring public confidence in biotechnology.

CONCLUSION

It should be stressed first and foremost that the European regulatory framework regarding GMOs and biotechnology must provide for a high level of protection for human health and the environment. At the same time, it should also allow society to profit from the benefits of these new technologies. The adoption of the revised Directive 90/220/EEC is a very important step towards restoration of public and market confidence in the authorization procedure for GMOs and products derived thereof. The proposed package of associated measures should further this goal. However, a new, more stringent regulatory framework might not be sufficient on its own to regain public confidence in GM food products. It will also be necessary for all stakeholders to provide an open and balanced debate

to respond to the questions raised by the public. We are all responsible for contributing to striking the right balance between the need for a high level of protection of human health and the environment, while at the same time allowing for the potential of biotechnology to develop. The associated package of measures should further this goal. ■

APPENDIX 1: COMMERCIALIZATION OF GMOS IN THE EU

Directive 90/220/EEC includes rules regarding the commercialization of GMO products. The authorization procedure, which requires input from all member states of the European Community, can be summarized as follows:

- The manufacturer or importer must submit an application to the authorities of the member state where the product is first to be marketed.
- The authorities evaluate the product application and, in the case of a negative evaluation, the notification is rejected. In the case of a favorable opinion, the dossier is forwarded to the Commission and the authorities of the other member states who then have the right to raise objections to the application.
- If there are no objections, the authorities that carried out the original evaluation grant the consent for commercialization of the product, which may then be placed on the market throughout the European Union.
- Where at least one objection is made, the Commission consults Scientific Committees and, depending on the opinion of the Committee, drafts a decision as to whether the product should be approved.
- This decision is then examined by a Regulatory Committee, which comprises representatives from all member states. If the Regulatory Committee approves the decision, the Commission adopts the proposed measures and the member state that originally received the application is obliged to issue or refuse the consent accordingly.
- If the Regulatory Committee does not deliver an opinion, the issue is transmitted to the Council for a decision within three months.
- In the absence of the Council giving an opinion, the Commission is required under the directive to adopt the proposed measure.

APPENDIX 2: REVISION OF DIRECTIVE 90/220/EEC

In February 1998, the Commission presented a "Proposal for a Directive Amending the Regulatory Framework under Directive 90/220/EEC" on the deliberate release of GMOs into the environment. The proposal took account of the growing public concerns and the need for increased transparency of the decision making process. In 1999, the European Parliament introduced additional amendments that focus on the precautionary principle, antibiotic resistance marker genes, and the strengthening of control measures.

THE REVISED DIRECTIVE:

- Seeks to increase the efficiency and transparency of the decision-making process while ensuring a high level of protection for human health and the environment.
- Clarifies a number of operational aspects including the scope, definitions, and administrative procedures.
- Promotes a harmonization of the risk assessment, introduces mandatory consultation of the Scientific Committees, and establishes time-limited authorizations.
- Improves transparency of the decision-making through consultation and reporting on ethical issues, and the involvement of the public in the authorization process.
- Improves the control of genetically modified organisms released into the environment by requiring member states to take measures to ensure labeling and traceability at all stages and by reinforcing the monitoring of approved organisms.

NOTES

1 Eurobarometer is a European Commission public opinion survey and research instrument, and is administrated by Directorate-General of Education and Culture. *Eurobarometer 52*, April 2000. http://europa.eu.int/comm/dg10/epo/eb/eb52/eb52.html

2 Available on the Internet at http://www.biodiv.org/biosafety.

3 See appendix 1 for more information on the approval procedure for the release of GMOs onto the market in Europe.

4 *Official Journal of the European Communities* (OJ) L 43 (February 14, 1997): 1.

5 *Official Journal of the European Communities* (OJ) L 25 (February 1, 1999): 1.

6 See appendix 2 for further information on the content of the revised Directive 90/220/EEC.