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NOTE

from :	General Secretariat
to :	Delegations
Subject :	European Policy on GMOs and the role of EFSA

Delegations will find annexed information from the Italian delegation on the above subject, which will be dealt with under "other business" at the meeting of the Council (Environment) on 30 October 2007.

EUROPEAN POLICY ON GMOs AND THE ROLE OF EFSA

Following the initiative promoted by Denmark and Luxembourg on future approach to the use of GM technology for food and crops, and the 2005 December Environment Council, the Austrian Presidency prepared two questions for Member States to discuss at the March 2006 Environment Council focused on:

- EFSA procedures;
- Decision making procedure and transparency.

On this occasion Member States made several criticisms concerning current comitology rules for the authorization of GMO products.
Furthermore, some Member States, and Italy in particular, were concerned about the national scientific evaluations that were partly taken into account by EFSA in delivering its final opinion for the authorization of GMOs. Moreover, some complaints were made regarding the impartiality of the scientific documentation consulted and taken into account by EFSA, and the lack of harmonized procedures concerning standardized methods for risk assessment.

In order to have a productive exchange of views between Member States, the Austrian Presidency organized a workshop in Vienna in April 2006. The most important conclusion of this workshop was the need to fill a substantial gap in the process concerning a harmonized, common and scientifically-based procedure for GMO authorizations, including the use of the Precautionary Principle not only to tackle the uncertainties and lack of scientific knowledge but also as a tool to achieve the final goal of protecting the environment and human health. Other important issues raised during the workshop were: further to consider the use of the precautionary approach for long-term effects, the importance of scientific innovation in dealing with evaluation, and the improvement in public participation and communication.

In order to enhance further the development of the discussion generated during the workshop, the role of the precautionary approach was stressed during the 2006 June Environment Council.
A significant number of Member States asked the Commission for information about action taken in order to improve the transparency of the decision-making process and the role of independent experts in the authorization procedure at the ESFA level, as well as about contamination of organic crops. This last request was given particular emphasis by Italy.
In response to all of these concerns the European Commission offered Member States a package of measures to improve confidence in the risk assessment procedure by means of a number of measures, namely:

(a) EFSA was to liaise more fully with national scientific bodies as a means to resolve diverging scientific opinions within Member States, in full compliance with the procedural modalities set out in the basic legislation;

(b) EFSA was to provide more detailed justification in its opinions on individual applications for not accepting scientific objections raised by national competent authorities;

(c) EFSA was to clarify which specific protocols should be used by applicants to carry out scientific studies (toxicology, animal) demonstrating safety, detailing, for example, species and type of animals, numbers and duration of studies;

(d) The Commission was to exercise its regulatory competences fully as provided for in the basic legislation to specify the legal framework within which EFSA assessment was to be carried out;

(e) Potential long-term effects and biodiversity issues were to be addressed more explicitly and in line with the uses of the product, via adequate research and within the framework of monitoring plans, by applicants in their risk assessment for the placing on the market of GMOs and by EFSA;

(f) To address specific risks identified in the risk assessment or substantiated by Member States by introducing on a case-by-case basis additional proportionate risk management measures in draft decisions to place GMO products on the market, as appropriate;

(g) To lay down in any appropriate way, that where, in the opinion of the Commission, a Member State's observation raises important new scientific questions not properly or completely addressed by the EFSA opinion, the Commission may suspend the procedure and refer the question back to EFSA for further consideration;

Since June 2006, many events have occurred and a number of authorizations have been issued by the Commission; most of them conflicting with the general aim expressed by the majority of Member States, and despite the commitments agreed by Member States and shared by the Commission.

Therefore, many of the outstanding issues are still on the table, namely:

1. the role of the European Authority under EU legislation concerning GMOs;
2. the use of the Precautionary Principle;
3. long-term impact assessment;
4. the need for independent studies to be considered in evaluating the request for authorization;
5. the co-existence issue;
6. the issue of risk communication;
7. the consistency of the impact assessment procedure in relation to the use of GMOs.

MEMBER STATES' COMMENTS ON EFSA ASSESSMENT REPORTS

The main issues raised by Member States in responding to EFSA Assessment Reports concern the information dealing with GM plants and their safety, the monitoring plan and the environmental effects. Objections relating to health and safety and molecular characterization were also raised for products where the application concerned import and processing.
The concerns about GM plants relate to very important issues such as protein expression, compositional analysis, potential toxicity and allergenicity of the new GM product. As to monitoring activities, they refer mainly to the lack of a case-specific monitoring plan and to the need for methods and procedures to conduct general surveillance and a post-market monitoring plan.
In spite of all those objections, EFSA's GMO Panel provided a positive final opinion for all the applications that they had examined and several products are now awaiting the Commission's final decision.

Some examples:

Application EFSA-GMO-UK-2005-14 (Potato EH92-527-1)

This potato line is intended for use in the starch production industry, with the pulp used for animal feed. However, the applicant states that "it can not be excluded that the GM potato and some products of the starch processing may be used as, or be present in, food"; this inaccurate statement is the first evidence of the lack of transparency of this application.
Member States have raised 38 significant points that have not been answered convincingly, in particular as regards:

- clarification regarding the use of GM potato as food;
- concerns about antibiotic resistance marker genes of the GM product;
- further study of the stability of the insert and phenotypic stability of the GM plant;
- ecotoxicity-studies on plant-associated organisms;
- studies of possible negative effects on human health due to the processing of theGM product;
- information on differences between GM line andrecipient in reproduction, dissemination and survivability;
- further studies of the effects of the GM product on non target organisms;
- environmental monitoring plan preventing accidental release of the GM product.

EFSA's GMO Panel of considers that the information available addresses the outstanding questions raised by Member States and concludes that the potato EH92-527-1 is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses.

Application EFSA-GMO-UK-2004-08 (H7-1 Sugar Beet)

The scope of this application is either for food produced from or containing ingredients produced from sugar beet H7-1 and feed produced from sugar beet H7-1 (developed to provide tolerance to glyphosate-containing herbicides).

The 12 main issues raised by MS relate to:

- clarification of the possibility that some GM plant residuals could undergo regrowth and contaminate the environment;
- clarification of the inserted DNA sequence;
- analysis of DNA sequences flanking the junctions of H7-1 sugar beet insert;
- information on the expression of the insert;
- levels of the protein insensitive to glyphosate-containing herbicides in H7-1 sugar beet;
- the need to extend compositional analysis making the comparison also in the isogenic lines;
- clarification regarding different values obtained by the comparative assessment;
- the need to improve the detection analytical model to evaluate protein content;
- environmental monitoring plan preventing accidental release of GM product.

EFSA's GMO Panel concludes that the information available for sugar beet H7-1 addresses the outstanding questions raised by Member States and considers that products produced from sugar beet H7-1 are unlikely to have any adverse effect on human and animal health or the environment in the context of its intended uses.

Application EFSA-GMO-DE-2004-03 (MON863 x MON810 maize)
Application EFSA-GMO-UK-2004-06 (MON863 x NK603 maize)
Application EFSA-GMO-BE-2004-07 (MON810 x MON863 x NK603 maize)

MS have raised several objections to all three products, mainly on molecular characterisation, genetic stability, health safety and compositional analysis, but a main point is that they all contain a much discussed component , namely MON 863.
MON863 is a genetically modified corn that expresses the Bt-toxin aimed at protecting maize plants against a pest called corn rootworm (Diabrotica spp.). The application contains a 90-day rat feeding study not performed by the applicant company itself but by a third company (Covance Laboratories) that concludes that the product is safe. Experts from the French Genetic Engineering Commission were critical about the toxicological test data derived from the rat feeding study and presented different results.

In their conclusions EFSA's experts state, “The results of the 90-day sub-chronic rodent studies do not indicate adverse effects from consumption of MON863 and concludes that there are no concerns over their safety.”

CONCLUSION

Italy believes that the EFSA reform process now underway is very positive, but should do more to clarify the mandate of the European Authority under EU legislation concerning GMOs, guaranteeing at the same time a real and independent long-term impact assessment from the health viewpoint and a transparent and wide synergy with Member States on environment impact assessments.

The Governments of many European Member States have to deal with the concerns of consumers and producers, asking for transparency, liability and freedom of choice. A real reform of the decision-making process concerning GMOs that takes account of and meets these expectations, will certainly contribute to creating a positive perception of the European Union’s role with regard to food safety, environmental protection and biodiversity.
During the reform process, and pending its finalization, all authorizations of GM crops should be suspended.