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Commission proposes practical improvements to the way the European GMO legislative framework is implemented

Today the European Commission gave its support to an approach proposed by Health and Consumer Protection Commissioner Markos Kyprianou and Environment Commissioner Stavros Dimas on further steps to improve the scientific consistency and transparency for Decisions on Genetically Modified Organisms (GMOs). The measures proposed aim to bring about practical improvements which will reassure Member States, stakeholders and the general public that Community decisions are based on high quality scientific assessments which deliver a high level of protection of human health and the environment. These improvements will be made within the existing legal framework, in compliance with EC and WTO law, and avoiding any undue delays in authorisation procedures.

In light of recent practical experience acquired with the placing on the market of GMOs, the Commission has decided that practical improvements could be made to the system to improve the scientific consistency and transparency for Decisions on GMOs and develop consensus between all interested parties. These improvements will be made within the existing legal framework, in compliance with EC and WTO law, and avoiding any undue delays in authorisation procedures.

The Commission proposes that the following practices be implemented:

- - in the scientific evaluation phase:
  - to invite the European Food Safety Authority (EFSA) to liaise more fully with national scientific bodies, with a view to resolving possible diverging scientific opinions with Member States;
  - to invite EFSA to provide more detailed justification, in its opinions on individual applications, for not accepting scientific objections raised by the national competent authorities;
  - The Commission will fully exercise its regulatory competences foreseen in the basic legislation to specify the legal framework in which EFSA assessment is to be carried out;
  - to invite EFSA to clarify which specific protocols should be used by applicants to carry out scientific studies (for example regarding toxicology) demonstrating safety;
  - Applicants and EFSA will also be asked to address more explicitly potential long-term effects and bio-diversity issues in their risk assessments for the placing on the market of GMOs;

- - in the decision-making phase:
  - The Commission will also 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; and
  - 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 back the question for further consideration.

This development of the GMO authorisation process is not just the result of the Commission's internal reflections, but draws on discussions with Member States and stakeholders. The Commission will discuss its proposals with the Member States in the Council, and with EFSA, in the coming months with the objective of building greater consensus and transparency in this area of Community policy.

Background

Over the past five years, the EU has put in place a stringent system to regulate the marketing and production of genetically modified food, feed and crops. The EU authorisation procedure ensures that only GMOs which are safe for human and animal consumption and for release into the environment can be placed on the European market. Clear labelling rules allow farmers, other users and consumers to choose whether or not to purchase such products and the rules also ensure that each GMO can be traced at each stage of its use.

The EU regulatory system, one of the strictest in the world, is based on the granting of individual authorisations for placing GMOs on the EU market, following scientific evaluation on a case–by-case basis. Requests for authorisations which do not fulfil all criteria have been and will continue to be rejected.