



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,

**COMMUNICATION TO THE COMMISSION (from the President in association with
Mrs Fischer Boel, Mr Dimas, Mr Kyprianou and Mr Mandelson)**

For an orientation debate on Genetically Modified Organisms and related issues

1. INTRODUCTION

At its last orientation debate of 28 January 2004¹, the Commission agreed on the way forward for pending decisions concerning Genetically Modified Organisms (GMOs) in view of the coming application of the new regulatory framework.

In short, the College endorsed the approach that pending decisions concerning the placing on the market of new GM products and the lifting of national safeguard measures (bans) should be progressed through the relevant comitology procedures without any further delay, in accordance with the provisions of relevant EU legislation.

Through 2004, the Commission has implemented the above approach.

Three decisions concerning the placing on the market of GM products have been adopted by the Commission following the failure of Member States to reach qualified majority in the Regulatory Committee or Council.

The Commission also agreed to the inscription of 17 plant varieties derived from an authorized GM maize line (MON810) on the Common Catalogue allowing the marketing of seeds of such GM varieties throughout the Community.

Further draft decisions continue to progress through the administrative procedures, but, in spite of improvements in the new regulatory framework, public and political concerns with GMOs continue.

The purpose of this paper is to:

- provide information on pending decisions concerning genetically modified organisms (GMOs) requiring agreement from the Commission as a means to progress towards their formal adoption, including potential timings, and
- to draw the attention to the political background surrounding GMOs, including the positions of Member States, international developments and other related issues, which should be further considered.

2. STATE OF PLAY AUTHORISATIONS AND NATIONAL SAFEGUARD MEASURES

So far, **every single one of the 13 Commission's proposals failed to get the required qualified majority**, even for those GMOs not intended for cultivation, but for import and processing only.

Further applications are at various stages of the approval procedure;

- **Two draft decisions for authorisation of GM food under the Novel Food Regulation are ready to be submitted to the Regulatory Committee,**

¹ SEC(2004) 80

- **12 applications** for GM food and feed under Regulation 1829/2003 are currently being considered by the European Food Safety Authority (EFSA), the first of which is ready for decision and the others will follow in the coming months,
- **11 notifications** of GMOs are pending under 2001/18/EC, including six with cultivation as requested use,
- In addition, a number of GM varieties are pending national catalogues inscriptions. Once inscribed in national catalogues, the Commission is required on the basis of the information supplied by the Member States to inscribe them into the common catalogues.

3. THE POLITICAL BACKGROUND

3.1. Societal aspects

The rigorous safety assessments and traceability and labelling requirements established by the new regulatory framework on GMOs, so far, have not yet succeed in gaining social acceptance of agricultural biotechnology. Whilst medical applications involving the use of GMOs have continued to make progress, this is not the case for the use of GMOs in agriculture, where so far there are no obvious perceived benefits for European farmers and consumers.

Major food companies and retailers remain reluctant to market labelled GM food under their brand names and as a result the European food market of GM labelled food remains limited for the time being. On the other hand, in the feed sector, GM feed is more widely accepted although interest groups are now exercising pressure on the dairy and meat industries to require them to market only products from animals fed on non-GM feed.

A number of regions and local communities are taking steps to implement highly restrictive national or regional measures, aiming at limiting (as much as possible) or preventing cultivation of GMOs. The Commission continues to receive an important amount of correspondence from regions and municipalities declaring themselves “GMO- free”. A **network of “GMO-free” regions** has been set up under an initiative from Upper-Austria and Tuscany and now comprises twenty regions throughout Europe, notably in Spain, France, Germany, Greece and UK. This network is gaining popularity and an increasing number of members.

3.2. Positions of Member States

In spite of the application of the new regulatory framework, so far it has proven impossible to obtain support of a majority of Member States when it comes to its implementation, namely the adoption of decisions on specific products. However, the legislation itself is not contested.

At the current time, only few Member States vote consistently in favour while several Member States vote consistently against and many abstain. Other Member States’ position varies; some of them consistently follow the advices of their own scientific bodies which sometimes diverge from the European Food Safety Authority (EFSA) assessments

Against this background, it will be difficult if not impossible to obtain a qualified majority in favour or against of the approval of the pending decisions in either the Regulatory Committee or the Council.

In view of the above, it is highly likely **the Commission will** have to continue to take ultimate responsibility **for adoption of pending decisions for the placing on the market of new GMO products** at least for the immediate future.

In terms of the draft decisions regarding the **lifting of pending national safeguard clauses**, under the best case scenario, the Commission would also have to take the final decision for their adoption. However, if one or two abstaining Member States were to vote against certain of these decisions in the Council, then the Commission would be required to re-examine its proposal. This would require either submission of an amended proposal to the Council, re-submission of its original proposal or the presentation of a legislative proposal on the basis of the Treaty.

3.3. Co-existence of GM crops with conventional and organic agriculture, and related issues

In line with the subsidiarity based approach concerning the co-existence of GM crops with conventional and organic agriculture chosen by the Commission in 2003, a Recommendation aimed to support Member States in the development of national strategies on co-existence was adopted².

Whilst the Commission Recommendation provides guidelines for establishing a framework for co-existence, many Member States and regions are now seeking clarification as to precisely what type of measures would be legally acceptable. In addition, certain Member States and regions, sections of the European Parliament and other sectors are also calling for Community legislation for co-existence measures, while others oppose to this.

Several Member States notified draft co-existence legislation to the Commission. The Commission has analysed the notified measures in line with Community legislation and, in most cases, issued detailed opinions or comments in accordance with Directive 98/34/EC on technical regulations. Where potential conflicts with Community legislation have been observed, the Member States in question have been requested to modify those provisions deemed as disproportionate to their objective and representing a potential barrier to free circulation of authorised GMOs. However, not all the recommendations from the Commission have been taken into account.

The issue of labelling thresholds for the adventitious presence of authorised GM seeds in conventional seeds is linked to the co-existence debate. In September 2004, the Commission decided to postpone the adoption of labelling thresholds while awaiting a more detailed assessment of the economic impact of such a proposal.

3.4. WTO challenges on GMOs

The on-going **trade dispute in the World Trade Organisation (WTO)** was started in 2003 by the United States, Argentina and Canada. The main focus of the WTO complaint is not the EU legislation on GMOs, but the Community alleged failure to apply its own regulatory regime for a period starting in October 1998.

The complainants challenge three types of measures:

² Recommendation 2003/556/EC

- An alleged ‘moratorium’ or *general suspension* of consideration of applications for approval of GMOs and GM food products under the relevant EU legislation.
- The alleged failure to consider for approval *specific* products, or the unjustified delays in the procedures.
- National restrictions on EU-approved products (so-called “safeguard measures”) taken by six Member States.

In its statements and submissions, the Commission has rejected the misguided notion that there was a ‘moratorium’ on GMOs in Europe. On the other hand, the completion of the regulatory framework for biotechnology products might have led to certain delays in the processing of some authorisations. However, the Commission has explained that all procedures are running normally: applications are being examined under the relevant authorisation procedures, on a case by case basis and on their own individual merits. The final report of the Panel - including the Panel’s finding - should be released by late June.

4. THE WAY FORWARD

Following the application of the new regulatory framework on GMOs, the Commission has complied with its legal responsibility to adopt decisions at the end of the comitology procedure. As guardian of the Treaty, the Commission must continue to fulfil its legal obligations and implement Community legislation. The regulatory framework has only recently entered into force³ and is recognized as one of the strictest in the world. It provides a high level of scientific assessment and safeguards the consumers’ right to choose. These legislations, built in close dialogue with Member States and all stakeholders, have all been adopted by the European Parliament and the Council in co-decision and little experience has been gained so far on their implementation.

In light of the above, the Commission should therefore:

- **adopt a decision for the placing on the market of the GMO GT73 oilseed rape;**
- **adopt a draft Council proposal for the placing on the market of the GMO MON863 maize** and submit it to the Environment Council for adoption;
- **adopt 8 draft Council proposals concerning the lifting of the eight safeguard clause cases** and submit them to the Environment Council also for adoption.

The Commission should also endorse

- the **continued submission of draft decisions for the placing on the market of new GMO products**, on a case-by-case basis, to the Regulatory Committees if there are no risk to human health and to the environment.
- **to proceed with the inscription into the common catalogues of GM varieties** once that new GM varieties are inscribed in national catalogues and this has been notified to the Commission by the Member States in question.

³ Directive 2001/18/EEC on the environmental release of GMOs started to apply in October 2002, while Regulation 1829/2003 on GM food and feed and Regulation 1830/2003 on traceability and labelling of GMOs started to apply in April 2004.

Both Commission and Member States have a respective role to play in implementing this legislation. However, so far, Member States have tended to avoid taking position in the Regulatory Committee and in Council effectively opting out the political process. Member States should be called upon to participate effectively in the process with a view to reaching clear positions.

- when submitting proposals following inconclusive opinion of the Regulatory Committee, **the concerned Councils should be requested to hold a thorough debate** in order to avoid adoption by abstention and to openly discuss the reasons of their reluctance to support the authorisation of products which comply with the EU regulatory framework.

Efforts are necessary to address identified outstanding issues which could increase co-operation in decision making and ultimately result in a wider consensus amongst institutions and other stakeholders;

- in order to increase the possibility of resolving diverging scientific opinions in Member States, the **networking of national scientific bodies should be promoted** and fully exploited by the European Food Safety Authority in line with Article 36 of Regulation (EC) 178/2002 on food law.
- the Commission should continue to enhance its co-ordination role on co-existence issues as defined in Directive 2001/18/EC. To this end, the Commission will accelerate the establishment of a **co-ordination network** in order to facilitate the exchange of information on co-existence, to help Member States in the interpretation of the co-existence guidelines and offering them guidance to address their legitimate concerns and considerations. The Commission will reflect on possible further steps to take on the basis of a **report on the experience gained in the Member States on the implementation of co-existence measures** to be finalised by the end of the year.
- the Commission should continue its work on the establishment of **labelling thresholds** for the adventitious or technically unavoidable presence of authorised GM **seeds** in seeds of non-GM varieties.

5. CONCLUSION

The Commission is invited to endorse the approach set out in the above part 4 of this paper.