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from : Secretary-General of the European Commission,  
signed by Mrs Patricia BUGNOT, Director

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to : Mr Javier SOLANA, Secretary-General/High Representative

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Subject: Commission Staff Working Document : Information note concerning  
forthcoming decisions on GMOs and GM food, feed and seed

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Delegations will find attached Commission document SEC(2003) 1131.

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 13.10.2003  
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**COMMISSION STAFF WORKING DOCUMENT**

**Information note concerning forthcoming decisions on GMOs and GM food, feed and seed**

## **COMMISSION STAFF WORKING DOCUMENT**

### **Information note concerning forthcoming decisions on GMOs and GM food, feed and seed**

#### **INTRODUCTION**

The purpose of this note is to inform Member States of proposals for decisions related to genetically modified organisms (GMOs), including their potential timing, which will be presented by the Commission in the coming months. It provides a basis for ensuring consistency between decisions taken under different pieces of Community legislation and by different Committees. Now that all the necessary legislative decisions have been taken and the appropriate procedures have been put in place it is important to demonstrate to the European public that the EU system of authorisation is working as designed.

#### **THE NEW REGULATORY FRAMEWORK**

Directive 2001/18/EC, which replaces Directive 90/220/EEC, is applicable since 17 October 2002. New Regulations on 1) traceability and labelling of GMOs and traceability of food and feed produced from GMOs and 2) GM Food and Feed should be published in the OJ in October 2003 and will subsequently enter into force in November 2003, thus completing the new regulatory framework. The Commission is currently preparing the following implementing measures and guidance for this legislation in order to ensure its full applicability by April 2004:

- A draft Decision for a system to assign unique identifiers to GMOs, allowing for their identity to be designated in documentation accompanying products placed on the market, as required under the new Regulation on labelling and traceability. The proposed format for identification is modelled on OECD formats, which have already been approved by Member States. A draft Decision has been circulated to Member States, whose favourable opinion will be sought in the Regulatory Committee on 4 December 2003;
- Guidance for sampling and detection of GMOs and GM food and feed. A draft document will be presented to Member States, as well as stakeholders, for comments before the end of this year. A formal Commission Decision will be adopted in early 2004.

In terms of the Regulation on GM Food and Feed, the Commission is also planning to present proposals to the Standing Committee on the Food Chain and Animal Health in December 2003 concerning the implementation of the following articles and issues:

- Implementing rules for Articles 5 and 17 concerning the preparation and presentation of the application for authorisation;
- Implementing rules for Articles 8 and 20 concerning existing products;
- Implementing rules for Article 47 concerning transitional measures for adventitious presence of unauthorised GM material.

## **APPROVAL OF NEW GMO PRODUCTS UNDER DIRECTIVE 2001/18/EC**

Twenty-one applications for the placing on the market of GMOs have been submitted to the authorisation procedure under Directive 2001/18/EC (Annex I). Eleven of these applications have scopes restricted to import and processing, while the remainder also include cultivation as a requested use.

The procedure under Part C of Directive 2001/18/EC is divided into three main periods.

- (I) A 'national period' where the lead Competent Authority (CA) has up to 90 days, from the date of receipt of the application, to prepare and submit an assessment report. During this 90-day period the 'clock' can be stopped if the lead CA is awaiting additional information from the notifier to complete the notification, thus extending the deadlines.
- (ii) A 'Community period', which comprises a 105-day period, which can be sub-divided into two phases. During the first 60 days, the competent authorities of Member States can raise reasoned objections to the application. The final 45 days of the 105-day period is akin to a 'conciliation-type step', where the Commission, lead and objecting competent authorities can try and reach agreement.
- (iii) Consultation of the European Food Safety Authority (EFSA) if objections based on environmental or human health considerations are not withdrawn by all Member States at the end of the above 45-day period. EFSA is required to provide an opinion within 90 days.

The most advanced of the above 21 applications in the procedure is the Monsanto NK603 GM maize which is currently being reviewed by EFSA (step iii). This application is for import and processing. It does not include cultivation as a requested use. An EFSA opinion is expected on 4 December 2003 in line with the 90-day deadline.

Directive 2001/18/EC requires the Commission to adopt a Decision following consultation of the Member States in a Regulatory Committee. Taking account of the above EFSA deadline and the necessary administrative procedures, the Commission intends to call a meeting of the Regulatory Committee in early February of next year.

A further application (Monsanto GT73 oilseed rape) is shortly to be formally submitted to EFSA for evaluation and an opinion is expected early in 2004. The scope of this application is also limited to import and processing. The remaining applications are currently being appraised by national authorities under periods (i) and (ii) above. It should be noted that the 'clock' can be stopped at various stages in the procedure, where further information is requested from the applicant, effectively extending the deadlines and making it difficult to predict a time-scale for possible approval of these products.

## **ARTICLE 16 SAFEGUARD CLAUSES UNDER DIRECTIVE 2001/18/EC**

Article 16 of Directive 90/220/EEC (known as the safeguard clause) provided that where a Member State has justifiable reasons to consider that a GMO, which has received written consent for the placing on the market, constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory.

Article 16 has been invoked by Member States on nine separate occasions, three times by Austria, twice by France, once by Germany, Luxembourg, Greece and the United Kingdom (Annex II). The scientific evidence provided by these Member States as justification for the bans was submitted to the Scientific Committee(s) for opinion. In all of these cases, the Committee deemed that there was no new evidence which would justify overturning the original authorisation decision.

National measures notified under Article 16 of Directive 90/220/EEC have now to be dealt with under the safeguard clause provision of Directive 2001/18/EEC (Article 23). In view of the new regulatory framework, Member States should now withdraw their requests under Directive 90/220/EEC and lift the prohibitions.

#### **AUTHORISATION OF GM FOOD UNDER REGULATION (EC) NO 258/97 ON NOVEL FOODS AND NOVEL FOOD INGREDIENTS**

Article 46(1) of the (soon to be published) Regulation on GM Food and Feed provides that applications made under the Novel Foods Regulation which have received a final scientific assessment before the coming into application of the new Regulation are still to be processed under the Novel Foods Regulation.

There are currently eight GM products pending authorisation under the Novel Food Regulation (for details see the list attached in Annex III).

The scientific risk assessment has been completed for two of the applications, a GM sweet maize from Syngenta (Bt11) and a GM field corn from Monsanto (GA21). The Commission is currently awaiting the validation of a detection method by the Joint Research Centre of the Commission (JRC) before submitting a draft Decision authorising the products to the regulatory committee. It is expected that the validation process will be completed in October for Bt11 and at a later stage for GA21.

EFSA is currently evaluating an application from Monsanto concerning a GM maize line (NK603); EFSA opinion is expected in December. The Commission is preparing the request for advice from EFSA on two other maize lines from Monsanto (MON 863 and MON 810 X MON863). In both cases, the Commission has to await the advice from EFSA before proceeding with these applications.

The four remaining applications are currently in the first stage of the authorisation process and are still undergoing risk assessment by a competent authority in a Member State. It is therefore difficult to predict when these products would be ready for authorisation.

In summary, it is likely that the Commission will present a draft Decision for the authorisation of:

- Bt11 either on 10 November or 12 December 2003;
- GA21 in the first half of 2004.

It is too early to predict the outcome of the remaining applications.

## **ARTICLE 12 SAFEGUARD CLAUSE UNDER REGULATION (EC) NO 258/97 ON NOVEL FOODS AND NOVEL FOOD INGREDIENTS**

Only one Member State has invoked the safeguard clause (Article 12) under the Novel Food Regulation. This took place in August 2000, where Italy suspended the trade in and use of products derived from four GM maize varieties (MON 810 from Monsanto; T25 from Bayer Crop Science; Bt11 from Syngenta and MON 809 from Pioneer) which had been notified under the simplified procedure for products considered as “substantially equivalent”.

The Commission immediately sought an opinion from the Scientific Committee for Food (SCF) which concluded, in September 2000, that the information provided by the Italian Authorities did not provide detailed scientific grounds for considering that the use of the GM foods in question endangered human health.

The Commission has recently written to the Italian Government asking it to repeal the Decree of August 2000.

## **GM MAIZE VARIETIES TO BE ACCEPTED INTO THE COMMON CATALOGUE OF AGRICULTURAL PLANT SPECIES**

23 GM maize varieties are inscribed in national catalogues (French, Dutch and Spanish) and are awaiting inscription into the Common Catalogue of agricultural plant species (Directive 2002/53/EC). According to that Directive, the Commission is required to inscribe in the Common Catalogue any varieties which have been added to national catalogues. The GMO must be authorised under Directive 2001/18/EC for its use in cultivation and the GM material for food use must be authorised under the Novel Food Regulation, and in the future, under the Regulation on GM Food and Feed.

The Commission is examining the issue of post-marketing monitoring plans for such varieties and is discussing this aspect with the companies in question, in order to have comprehensive monitoring plans.

It would appear that 12 varieties contain a GM event which should be replaced by another event which is in an advanced stage in the authorisation procedure under Directive 2001/18/EC (Bt176 should be replaced by Bt11). This would explain why there is still some consideration from Syngenta whether to submit monitoring plans for such varieties. If a monitoring plan is submitted to the Commission, it will be sent for opinion to EFSA, which will need a few months time to deliver an opinion. In the case of a favourable opinion, the Commission should proceed with the inscription into the Common Catalogue in accordance with the provisions laid down in Directive 2002/53/EC on the Common catalogue of varieties of agricultural plant species.

Discussions are also underway as regards one variety containing the event T25 of Bayer Crop Science. The Commission is awaiting indication as to whether a monitoring plan will be submitted or not. If a monitoring plan is submitted to the Commission, it will be sent for opinion to EFSA, which will need a few months to deliver an opinion. In the case of a favourable opinion, the Commission should proceed with the inscription into the Common Catalogue.

The discussions concerning the 10 varieties containing the event MON 810 of Monsanto seem to be the most advanced. A monitoring plan has been submitted and evaluated positively by the Scientific Committee on Plants. Consideration is being taken of the monitoring plan

submitted recently in the framework of the inscription in the national Spanish catalogue. If it appears that there is no need to consult EFSA again, the Commission will proceed with the inscription into the Common Catalogue. If an opinion of EFSA is needed, this will take a few months. In the case of a positive opinion, the Commission should proceed with the inscription into the Common Catalogue.

When all elements for an inscription are fulfilled, the next step is to publish the complement to the Common Catalogue in the *Official Journal of the European Union C* about two months later. The Commission will inform the Member States of the inscription of the varieties before the publication in the Official Journal.

#### **ADVENTITIOUS PRESENCE OF GM SEEDS IN NON-GM SEEDS.**

The text for a Commission Directive (doc SANCO/1542/03) establishing labelling thresholds for the adventitious or technically unavoidable presence of authorised GM seeds in seeds of non-GM varieties has been finalised by the Commission services.

It should be stressed that only seeds for which a GMO authorisation for cultivation has been granted, and for which the further use in food or feed has been authorised will benefit from the proposed seed thresholds.

The labelling thresholds in seeds being proposed by the Commission are 0.3% (swede rape), 0.5% (maize, cotton, beet, potato, chicory and tomato) and 0.7% (soybean), as was proposed in July 2002. These seed thresholds take into account the 0.9% labelling threshold established in the Regulation on GM Food and Feed and in the Regulation on traceability and labelling of GMOs and traceability of food and feed produced from GMOs. The opinion of the Scientific Committee on Plants (SCP) concerning the adventitious presence of GM seed in conventional seed has been considered when setting the proposed thresholds. The reduction from 1% of the labelling threshold to 0.9% has no knock-on impact on the seed thresholds proposed in July 2002, which were 0.3%, 0.5% and 0.7% respectively. The SCP opinion clearly shows that starting with seeds at the limit of such thresholds will result in a product with a GM presence of around 0.8%, which still leaves a margin vis à vis the 0.9% threshold for the final product. This has been confirmed in January 2003 by the SCP, after the political agreement in the Council on the 0.9% labelling threshold in food/feed.

The draft Directive was discussed at the Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry on 22 September 2003.

During an orientation debate on coexistence in the Agriculture Council on 29 September, the discussions on the seed thresholds in the Standing Committee on Seeds were raised, in particular with regard to the levels of the thresholds.

The Commission will submit the text to an indicative vote at the next meeting of the Standing Committee on Seeds at the end of October (27-28), after having considered all positions (Management Committee procedure).

The draft measure will then be notified to the WTO.

A vote will take place after the period allowed for comments (January 2004).

The text should be applicable at the same time as the Regulation on GM Food and Feed is applicable as they are interrelated (April 2004).

Sampling and testing conditions of seed placed on the market, in particular as regards GM presence, will be specified in a Commission Regulation on a protocol for sampling and testing of seed lots of non-GM varieties for the presence of GM seeds. This protocol has been prepared with experts of Member States and discussed in the Standing Committee on Seeds on several occasions. A draft Regulation will be discussed in the Standing Committee on Seeds from October on, and voted on in January 2004, with a view to having the Regulation in application at the same time as the text on the thresholds (April 2004).

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