

# Opinion on the Additional Information from the Austrian Authorities Concerning the Marketing of Ciba Geigy Maize (expressed on 21 March 1997)

## Terms of reference

The provisions of Directive 90/220/EEC have led the Commission to seek advice on the additional information from the three Scientific Committees that expressed opinions on Ciba-Geigy Maize in December 1996 and in particular,

a) does the information submitted by Austria constitute new relevant scientific evidence which was not taken into account by the Committee at the time its opinion was delivered ?

and, if so,

b) would this information thus cause the Committees to consider that this product constitutes a risk to human health or the environment ?

The evaluation of the SCF was limited to consideration of risks to human health.

## Evaluation of the additional Austrian information

The Austrian point of view is described most precisely in the introduction to the additional information where it is stated that "especially new scientific results have questioned the present scientific possibility of a conclusive evaluation of the mechanism of gene transfer as well as the development of resistance to the B.t. toxin. Accordingly, possible risks are very hard to assess and should be avoided at the present state of scientific discussion".

The new data quoted with regard to B.t. toxin relate to potential environmental risks and were not therefore considered by the SCF. With regard to the aspects considered by the Austrian authorities in the section "Assessment of the  $\beta$ -lactamase resistance", the Committee has carefully examined the scientific argument presented therein.

During its evaluation of CG-Maize, the Committee was aware of and took into account the available scientific knowledge concerning the unexpectedly long survival of DNA in the environment and the persistence of fragments of DNA in the human body following the consumption of food. The likelihood of a possible gene transfer to microorganisms in the intestinal tract under specific conditions was also known and taken into consideration. The potential hazard arising from the original transformation of maize by the use of the pUC plasmid harbouring the gene encoding  $\beta$ -lactamase was given particular attention and was even the major topic of the *ad hoc* expert meeting organised jointly by the SCF and the Scientific Committee for Animal Nutrition (SCAN) on 6 December 1996.

In its opinion expressed on 13 December 1996, the Committee made reference to the widespread presence in the intestine and in the environment of bacteria that harbour the naturally occurring genes encoding  $\beta$ -lactam resistance and concluded that the possibility that the product would add significantly to the already widespread occurrence of ampicillin resistant bacteria in animals and man is remote.

The Committee notes that none of its conclusions concerning the toxicology, nutritional value, allergenicity and secondary changes are affected by the Austrian arguments.

## Conclusions

The information submitted by the Austrian authorities support the conclusion of the SCF stating that "the Committee

was conscious of the general question of the use of genes coding for antibiotic resistance in marker gene constructs in the development of novel foods and proposes to scrutinise the future needs and application of marker genes". In the view of the Committee, the Austrian information does not provide new scientific evidence regarding the food use of Ciba-Geigy Maize which was not taken into account by the Committee at the time its opinion was delivered. Thus, the Austrian information does not cause the SCF to consider that the Ciba-Geigy Maize constitutes a risk to human health.