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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C3 - Management of scientific committees II; scientific co-operation and networks

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OPINION

OF THE SCIENTIFIC COMMITTEE ON FOOD

ON

**THE EVALUATION OF TOXICOLOGICAL INFORMATION
RELATED TO THE SAFETY ASSESSMENT OF GENETICALLY
MODIFIED TOMATOES**

Adopted on 7 September 2000.

Terms of reference

The Committee is requested to comment on the relevance of the findings provided by Calgene to FDA on gavage studies¹ for the safety assessment of genetically modified tomatoes.

Background

The US Food and Drug Administration (FDA) approved Calgene's genetically modified FLAVR SAVR™ tomato in 1994 based on information submitted and on consultations with the company. During the assessment by FDA's Center for Food Safety and Applied Nutrition (CFSAN) the interpretation of short-term gavage studies attracted particular scientific and public attention. In its final memorandum¹ CFSAN concluded that:

“The three studies consistently demonstrated no biologically significant changes in body weight, organ weight, food consumption, hematologic parameters and clinical chemistry findings. There was a disparity among the three studies regarding the incidence of rats with gastric erosions. Data and information supplied by Calgene fail to clarify or explain the factors responsible for this disparity. Based on the information Calgene has provided, no definitive conclusions can be drawn regarding the etiology(ies) of the gastric erosions. Regardless of the etiology(ies), however, the gastric erosions as described by Calgene are no more severe in transgenic tomatoes than in nontransgenic tomatoes.”

As concerns about these conclusions were raised recently² the Commission has asked the SCF to review the results and implication of the three gavage studies for the safety of genetically modified tomatoes.

Discussion and Conclusion

From the data available from the FDA memorandum¹ concerning gastric erosions in studies with the FLAVR SAVR™ tomato, the Committee notes that inconsistent results were obtained in the three separate gavage studies conducted. In the first study, gastric lesions were observed in one of 40 animals in the FLAVR SAVR™ tomato group, but none in those in the nontransgenic or water control groups. In the second study, the incidence of gastric erosions was 10 out of 80 animals in the group given FLAVR SAVR™ tomatoes but none in those given nontransgenic control tomatoes, nor in water controls. In the third study gastric erosions were observed at a similar incidence in the water controls (5 out of 40), nontransgenic tomato controls (6 out of 80) and FLAVR SAVR™ tomato group (3 out of 95).

The Committee concurs with the conclusion reached by the US FDA that there is an unexplained disparity between the three studies. The results are not supportive of a substance-related effect of the FLAVR SAVR™ tomato and the Committee notes that gastric erosions can be readily produced in rats as an artefact of gavage studies.

Therefore, the Committee finds that the gastric erosions noted in the rat gavage studies considered by the FDA are of no relevance to the safety assessment of genetically modified tomatoes.

Explanatory remark:

The Committee wishes to point out that the FLAVR SAVR™ tomato developed by Calgene was intended for the American market to be eaten as a fresh product. The processed tomato products for which a marketing application was considered by the SCF³ were manufactured from a genetically modified tomato developed by another company, Zeneca, from a different tomato variety modified in a different manner.

References

¹ US Food and Drug Administration. Memorandum dated May 17, 1994 ‘Summary of consultation with Calgene Inc., concerning FLAVR SAVR™ tomatoes’.

² Question by MEP Hiltrud Breyer to the European Commission (E-1064/00).

³ Opinion of the SCF on a request for consent to place on the market a tomato fruit genetically modified to down-regulate the production of polygalacturonase (PG), and solely intended for processing, expressed on 23/09/99.

http://europa.eu.int/comm/food/fs/sc/scf/out42_en.html