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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

**CONCERNING A SUBMISSION FROM THE ITALIAN AUTHORITIES
RAISING CONCERNS FOR THE SAFETY OF CERTAIN PRODUCTS
APPROVED UNDER THE NOTIFICATION PROCEDURE OF
REGULATION (EC) 258/97.**

Expressed on 7 September 2000.

Terms of reference:

The Committee was asked whether the information provided by the Italian authorities^{1,2} provides grounds, detailed or otherwise, for considering that the use of the novel foods in question endangers human health.

Background:

Article 3, paragraph 4, of Regulation (EC) No 258/97³ on novel foods and novel food ingredients provides that certain novel foods, including food or food ingredients derived from genetically modified organisms (GMOs), but no longer containing GMOs, can be put on the market without undergoing the full authorisation procedure foreseen in Article 4, provided that such products are substantially equivalent to existing conventional foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances they contain.

Seven plant products (oils from three GM oilseed rapes and processed products from four GM maize varieties) were notified under this procedure as the companies that developed them claimed that they were substantially equivalent to existing food products. The companies based their claims on safety assessments carried out by the UK ACNFP^{4,5,6,7,8,9,10}, conducted in 1995 and 1997 prior to the introduction of Regulation 258/97. Subsequently the EU Scientific Committee on Plants reviewed the safety of four of these in 1998 with respect to the environment and animal and human health^{11,12,13,14}. Both Committees considered the data submitted in terms of potential effects of the inserted genes, the toxicity and allergenicity of the gene products, the occurrence of unintentional changes, the transfer of the inserted genes to animals and man and the influence on the micro-organisms in the human intestine.

The Italian authorities have recently informed the Commission that they consider that certain products authorised under the notification procedure are not substantially equivalent within the meaning of Regulation (EC) No 258/97 and should therefore be submitted to a full safety evaluation. In addition, the Italian authorities invoked the so called “safeguard clause” (Article 12) in the Novel Foods Regulation for some of these products and issued a decree of 4 August 2000¹⁵ suspending the trade and use of products derived from maize lines BT11, MON 810, MON 809 and T25.

Discussion:

Two documents on the Italian position were made available to the Committee; one originating from the Italian Consiglio Superiore di Sanità¹ and one from the Italian Istituto Superiore di Sanità².

The first document lists a number of problems that might arise in the generation of transgenic crops and in food or food ingredients derived from them. These are normally considered in a full safety assessment procedure. There is no specific information in the document to indicate that any of these problems affect the safety of the seven products under consideration.

The second document delivers an opinion on the seven GMOs and derived products: The report identifies some shortcomings in the original applications, e.g. the lack of PCR data used currently to detect DNA from the transgenic plant in the product. Although such data would be required in any current application to support the establishment of substantial equivalence of the product to its conventional counterpart, the absence of such data is not evidence of a risk to health. The report also notes the fact that the herbicide glyphosate, used to suppress weed proliferation is metabolised by the herbicide-tolerant GMO to a non-toxic metabolite but that 10% can revert to the parent compound in the gut of test animals. However, provided that the use of glyphosate is in accordance with GAP, exposure from this source would not be expected to lead to the ADI for glyphosate being exceeded. The report also mentioned a recently published observation on occupational allergy to Bt bacterium spores in farmers using Bt pesticides. However, the Bt protein itself has been assessed for allergenicity and has no amino acid sequences associated with known allergenic proteins. The document of the Istituto Superiore di Sanità concludes that in the present state of scientific information there is no evidence that consumption of the derivatives of the seven GMOs poses a risk to human or animal health.

Conclusion

The Committee is of the opinion that the information provided by the Italian Authorities does not provide detailed scientific grounds for considering that the use of the novel foods in question endangers human health.

References

- ¹ Opinion of the Consiglio Superiore di Sanità, Italy, on “Transgenic food. Dossier submitted by the Associazione Verdi Ambiente e Società”, 16 December 1999.
- ² Opinion of the Istituto Superiore di Sanità, Italy, on “7 GMOs and their products”, 28 July 2000.
- ³ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. Official Journal L 043 , 14/02/1997 p. 0001 – 0007.
- ⁴ Report on processed products from genetically modified insect resistant maize (line MON 810). UK ACNFP, 14 February 1997.
- ⁵ Report on processed products from genetically modified glufosinate ammonium tolerant maize (line T25). UK ACNFP, 14 February 1997.
- ⁶ Report on grain from maize genetically modified for insect resistance (line BT11). UK ACNFP, 14 February 1997.
- ⁷ Report on genetically modified insect protected maize: PIONEER HI-Breed International (line MON 809). UK ACNFP, 14 February 1997.
- ⁸ Report on oil from a fertility restorer line for use in a hybrid breeding programme for genetically modified oil seed rape (line B94-2xB91-4). UK ACNFP, 19 September 1995.
- ⁹ Report on oil from genetically modified oilseed rape (line B91-4xB93-101). UK ACNFP, 6 January 1995.
- ¹⁰ Report on oil from genetically modified glyphosate-tolerant oilseed rape (line GT73). UK ACNFP, 24 January 1996.
- ¹¹ Opinion of the Scientific Committee on Plants regarding the genetically modified, insect-resistant maize lines notified by the Monsanto Company (line MON 810) (NOTIFICATION C/F/95/12/02), 10 February 1998, http://europa.eu.int/comm/food/fs/sc/scp/out02_en.html.

¹² Opinion of the Scientific Committee on Plants regarding the genetically modified, insect-resistant maize lines notified by the Novartis Company (line Bt11) (Notification C/GB/96/M4/1), 10 February 1998, http://europa.eu.int/comm/food/fs/sc/scp/out05_en.html.

¹³ Opinion of the Scientific Committee on Plants regarding the submission for placing on the market of genetically modified, insect-resistant maize lines by the Pioneer Genetique S.A.R.L. Company (line MON 809) (Notification C/F/95/12-01/B), 19 May 1998, http://europa.eu.int/comm/food/fs/sc/scp/out10_en.html.

¹⁴ Opinion of the Scientific Committee on Plants regarding “submission for placing on the market of glufosinate-tolerant corns (zea mays) transformation event T25” by the Agrevo Company. (line T25) (Notification C/F/95/12/07), 10 February 1998, http://europa.eu.int/comm/food/fs/sc/scp/out04_en.html.

¹⁵ Decree of the President of the Council of Ministers, Italy, on the suspension of the trade and use of GMO maize products, 4 August 2000.