



USDA Foreign Agricultural Service

GAIN Report

Global Agriculture Information Network

Template Version 2.09

Voluntary Report - public distribution

Date: 3/4/2004

GAIN Report Number: E24045

European Union

Biotechnology

"Safe as Conventional Rapeseed"

2004

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Report Highlights:

On March 1, 2004, the European Food Safety Authority (EFSA) announced a positive risk assessment for the biotech variety GT73, an oilseed rape produced by Monsanto.

EFSA stated unequivocally "that GT73 oilseed rape is as safe as conventional oilseed rape and therefore the placing on the market of GT73 oilseed rape for processing and feed use is unlikely to have an adverse effect on human or animal health, or in the context of its proposed use, on the environment."

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Brussels USEU [BE2]
[E2]

On March 1, 2004 the European Food Safety Authority (EFSA) announced the results of a positive risk assessment for the biotech variety GT73, an oilseed rape produced by Monsanto. EFSA's approval of NK603 is the third opinion supporting the safety of GMOs.

EFSA stated unequivocally that "that GT73 oilseed rape is as safe as conventional oilseed rape and therefore the placing on the market of GT73 oilseed rape for processing and feed use is unlikely to have an adverse effect on human or animal health, or in the context of its proposed use, on the environment."

The assessment will now be forwarded to the EU Commission for review. In accordance with Directive 2001/18, the Commission will consult with Member States in a Regulatory Committee and issue a final Decision whether to permit this variety to be imported and sold in the EU market.

GT73 is resistant to the herbicide glyphosate roundup. The scope of the application was restricted to importation and processing for feed use, not cultivation, and the assessment covers only those aspects.

While EFSA's decision can be viewed as a positive step, Scientific Committee (s) in the past have issued positive risk assessments only to see various Member States invoke "national safeguard measures" thereby blocking the marketing of biotech crops. This occurred on nine separate occasions, three times by Austria, twice by France, and once each by Germany, Luxembourg, Greece and the United Kingdom. The Member States were then requested to provide new evidence to justify their use of the safeguard measures. In all of these cases, the Committee (s) deemed that there was no new evidence which would justify overturning the original authorization decisions.

Directive 90/220/EEC under its Article 16 (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 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. While Directive 90/220/EEC has since been repealed, Directive 2001/18 (its successor) provides for similar safeguard measures under Article 23.

In its review of GT73, EFSA's GMO Panel was requested to consider whether there is any scientific reason to believe that the placing on the market of GT73 oilseed rape, for import and processing, is likely to cause any adverse effects on human health and the environment. The question followed a scientific assessment which was initially made by the competent authority of the Netherlands and subsequently evaluated by all other Member States. An assessment of the GT73 oilseed rape was requested by the Commission because of questions raised by several Member States following the evaluations at the national level. When this is the case, the EU legislation requires that EFSA carries out a further assessment and provides an opinion.

In delivering its opinion the GMO Panel considered the notification and additional information provided by the applicant and the specific questions and concerns raised by the Member States. Specific objections raised by the competent authorities of the Member States included potential allergenic risk of GT73 oilseed rape, issues of pesticide residues, clarification of data obtained

from rat feeding studies and the potential need for additional feeding studies using the actual animal species which would be fed the GM product commercially. Some Member States also requested a more detailed environmental monitoring plan.

The GT73 oilseed rape has been planted for field trials within the EU and has been marketed in several countries outside the EU. The present notification concerns import and processing, but not cultivation. If approved it would therefore make it possible to import, process and use GT73 oilseed rape and derived products as animal feed. This is in addition to the present use of oil derived from GT73 for food purposes, which was notified in 1997 under the Regulation (EC) 258/97.

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