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Trade Policy Monitoring

"Safe as Conventional" Corn

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Report Highlights:
On December 4, 2000 the European Food Safety Authority (EFSA) announced a positive risk assessment for the biotech variety NK603, a corn produced by Monsanto.

EFSA stated unequivocally that "The Panel has concluded that the herbicide-tolerant GM maize NK603 is as safe as conventional maize and therefore that the placing on the market—for import for processing and food or feed use—is unlikely to have an adverse impact on human or animal health, or in this context, on the environment."

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"Safe as Conventional" Corn

On December 4, 2000 the European Food Safety Authority (EFSA) announced the results of a positive risk assessment for the biotech variety NK603, a corn produced by Monsanto.

EFSA stated unequivocally that "The Panel has concluded that the herbicide-tolerant GM maize NK603 is as safe as conventional maize and therefore that the placing on the market—for import for processing and food or feed use—is unlikely to have an adverse impact on human or animal health, or in this context, 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. The Regulatory Committee is expected to meet in February 2004.

NK603 is resistant to the herbicide glyphosate roundup. The scope of the application was restricted to importation and subsequent use in human food and animal feeds, 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 that 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.

For NK603, the EFSA Scientific Panel on Genetically Modified Organisms received two separate dossiers from the Commission requesting scientific opinions related to applications for placing on the market and use in foods and feed of the GM corn, NK603, under the framework of Regulation (EC) 258/97 (novel food and ingredients), and Directive 2001/18/EC (deliberate release into the environment).

The first question was to assess the safety of foods and food ingredients derived from NK603 corn; and in the second instance, the Panel was requested to determine whether there was any scientific reason to believe that placing of NK603 on the market, for import and processing was likely to cause any adverse effects on human health, or within the context of the usages, and adverse effects on the environment.

The Panel considered issues related to molecular characterization, toxicology and allergenicity studies, compositional analysis, etc. Because the two applications were received under different regulatory frameworks, the Commission insisted on receiving two separate opinions. While the EFSA opinions provide a common risk assessment based on the information provided in both applications, differences in legislation were highlighted in the background section. Additionally, the opinions pay specific attention to the scientific

objections raised by the competent authorities of the Members States in the context of Directive 2001/18/EC and Regulation (EC) 258/97.[1]

The proposed uses of NK603 are no different than would be expected for any other corn, which is primarily used for animal feed. It is also processed for use in food and industrial products, such as ethyl alcohol by fermentation, corn meal by dry milling, and highly refined starch by the wet milling process. The majority of the corn used for food and industrial uses is processed by wet milling to produce starch and sweetener products for use in foodstuffs.

EFSA's approval of NK603 is its second opinion supporting the safety of GMO products. The previous opinion found that there was no new scientific evidence (adverse health or environmental effects) to support a proposed ban on the introduction of GMOs in upper Austria.

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E23231	European Food Safety Authority	12/8/2003

[1] The press release can be found at: http://efsa.eu.int/pdf/pressrel_gmo_0203_final_en.pdf . A link to the full scientific opinion may be found within the press release.