



**Friends of
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Europe**

QUESTIONS REMAINING OVER MONSANTO'S NK603 MAIZE

EU REQUIREMENTS

1. Risk Assessments

The Commission Decision of 24 July 2002 established the guidance notes for the environmental risk assessment, which includes consideration of human health impacts, required under EU Directive 2001/18. It deals clearly with the estimation of risks posed by GMOs (section 4.2.4):

The overall uncertainty for each identified risk has to be described, possibly including documentation relating to:

- assumptions and extrapolations made at various levels in the ERA,*
- different scientific assessments and viewpoints,*
- uncertainties,*
- the known limits of mitigation measures,*
- conclusions that can be derived from the data.*

Although the public does not have access to the whole dossier, there is no indication from the public data that is available that the uncertainties surrounding the safety of this GMO have been analysed as required by these EU guidance notes. Surprisingly, there is also no mention of the uncertainties in the EFSA's opinions. Considering the lack of scientific consensus surrounding the safety of GMOs, this information is essential in order to for decision makers to make an informed decision and for there to be public confidence in it.

If an analysis of the uncertainties and their management is not available, Member States should reject this application. The EFSA should be asked to analyse the application for the uncertainties that exist to aid Member States in their decision-making.

2. Long term effects

The EFSA operates under Regulation 178/2002 that sets out EU food safety requirements to ensure that foods placed on the market are not injurious to health. Article 14(4) explicitly states that regard must be given to not only short-term effects, but effects on subsequent generations, cumulative toxic effects and the effects on health sensitive consumers. Inclusion of these is very welcome, especially considering some of the scientific gaps in our knowledge with regard to GM foods. However EFSA have failed to even mention these important aspects.

Member States must call on EFSA to re-analyse NK603 to take into account the legal obligations set out in Article 14(4) of Regulation 178/2002.

This is not a theoretical matter, because compounds in maize have been linked with both carcinogenic and endocrine disrupting effects.

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- Maize products have been shown to disrupt the oestrous cycle of rats, either by consumption or through exposure in bedding¹
- Extracts of fresh maize and maize cob products² have been shown to stimulate breast and prostate cancer cell proliferation in vitro, with sensitivity occurring at μ Molar concentrations
- Research identified a mixture of THF-diols in maize that produce endocrine disrupting effects at concentrations 200 times lower than those of classical plant estrogens³

EFSA must re-analyse NK603 to ensure that a thorough assessment of whether the production of these newly identified carcinogenic and endocrine disrupting compounds has been increased as a consequence of genetic modification.

3. Precautionary principle

EU law clearly states that the precautionary principle must be taken into account. However, there are a number of important areas where EFSA clearly disregard uncertainties without calling for further investigations.

a. Unintended sequences not investigated¹

The EFSA has noted that new unintended RNA sequences are present in the genome of NK603. However, instead of asking for more evidence as necessary under the precautionary principle, they make speculative and largely unsupported assumptions about its safety. For example, they state that the unpredicted transcription “**is not expected to have a regulatory function.**” but supply no evidence to support this claim. In describing the transcription they also state that “**This could create 2 or more mRNA species, a smaller one at 1.4 kb (predicted as the cp4 epsps L214p transcript) and a larger species at >1.4 kb (a product likely to be the result of incomplete termination at the NOS 3' genetic element due to “read through”).** [our emphasis.]. There is evidence that “read through” transcription can shut down neighbouring genes⁴ yet this does not appear to have been investigated. Whilst the public does not have access to the dossier to make any further analysis it is clear from the EFSA opinion that the unintended sequence has not been sufficiently studied.

Member States should fully investigate the unintended sequences.

b. insufficient assessment of allergenicity

The evidence presented by Monsanto on whether or not NK603 could cause allergic reactions appears to be limited to a theoretical comparison, *in vitro* digestion studies and a short-term toxicity test with mice. This type of approach has been criticised by various scientists for being inadequate⁵. In their opinion, the GMO panel state that “*some Member States raised questions about the suitability of approaches used for allergenicity testing*”, but then go on to dismiss these concerns, concluding that the Panel are not aware “*of any new tests which produce more relevant or accurate information on possible allergenicity of the protein and which provide a higher guarantee of safety*”. Yet in guidance produced in March 2003 by the GMO Panel’s predecessors, the Joint

¹ Markaverich BM et al (2002) Identification of an endocrine disrupting agent from corn with mitogenic activity *Biochemical and Biophysical Research Communications* 291: 692-700

² Markaverich BM et al. (2002) A Novel Endocrine-disrupting agent in corn with mitogenic activity in human breast cancer and prostatic cancer cells. *Environmental Health Perspectives* 110: 169-177

³ Markaverich BM et al. (2002) A Novel Endocrine-disrupting agent in corn with mitogenic activity in human breast cancer and prostatic cancer cells. *Environmental Health Perspectives* 110: 169-177

⁴ Kusaba M, et al (2003) Low glutelin content1: A dominant mutation that suppresses the glutelin multigene family via RNA silencing in rice *Plant Cell* 15 (6): 1455-1467

⁵ Spök A, Hofer H, Valenta R, Kienzl-Plochberger K, Lehner P, Gaugitsch H (2002) *Toxikologie und Allergologie von GVO-Produkten - Empfehlungen zur Standardisierung der Sicherheitsbewertung von gentechnisch veränderten Pflanzen auf Basis der Richtlinie 90/220/EWG (2001/18/EG)*. UBA-Monographien M-109 .

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Working Group on Novel Foods and GMOs, it is stated quite clearly that, for example, studies using human sera should be conducted (para 4.5.2) to test for the potential to cause allergies. It is of serious concern that EFSA should so casually dismiss questions raised by the member states and that they should apparently be unaware of existing guidance on a more thorough approach.

Further, the GMO panel dismiss concerns that the allergenicity of the whole crop could have been altered, stating that such concerns do “*not appear relevant to the Panel since maize is not considered a major allergenic food*”. Yet, the OECD's consensus report on compositional considerations for GM maize states that maize can, on occasion, give rise to allergic reactions including skin, gastrointestinal and respiratory complaints and that the specific cause of these reactions remains unclear. Thus it is perfectly correct of member states to want further evidence on this issue. The increasing amount of maize being consumed, particularly in processed foods, means that consumers could be widely exposed to NK603 maize. Even uncommon allergic reactions could therefore be an issue, because of very wide exposure.

Member States must ensure that EFSA fully addresses the potential for genetic modification to increase of the existing allergic potential of this maize.

Does EFSA have insufficient oversight?

The role of the EFSA in the context of GM regulation is to provide independent scientific advice in order to assist member states in the decision making process. From this perspective it would seem logical that the committee members should not themselves be involved in the decision-making process. Yet from our calculations 8 out of 21 members of the EFSA GMO panel were involved in the safety assessment process of NK 603 at national level. This calls into question exactly what role the EFSA should be providing.

Poor scientific standard

In general, the application by Monsanto and the corresponding opinions by EFSA are of a questionable scientific standard. The general approach is that of ‘no evidence equating with no harm’. This approach has been widely rejected as being inappropriate to the risk assessment of GMOs. For example, the USA's National Academy of Science commenting on the use of the phrase by regulators in the USA, the Academy emphasised how little it told people⁶: “*The term ‘no evidence’ can mean either that no one has looked for evidence or that the evidence provides contrary evidence. Lack of evidence is not typically useful in making regulatory decisions about risk*” (p10).

Despite the presence of unexpected impacts upon genetic functioning, this does not appear to have been thoroughly investigated and the evaluations based upon speculation rather than evidence that this has not caused unexpected alterations in the metabolism of the GM maize.

In view of this unexpected transcription, it is therefore of serious concern that studies examining the toxicity and allergenic potential of the GM maize are far from thorough and do not even follow guidance set down by the scientific committees.

The environmental risk assessment and EFSA's opinion do not give sufficient consideration to areas of uncertainty and scientific disagreement.

Member States must reject this application until proper testing and analysis is carried out into its long-term safety

Friends of the Earth Europe, February 2004

⁶ National Academy of Sciences (2002) *Environmental impacts of transgenic plants: the scope and adequacy of regulation*. National Academy Press: Washington.

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