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Greenpeace technical critique of EFSA Opinion on genetically modified maize NK603 for import and processing under Directive 2001/18/EC and Regulation 258/97

The two documents "Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference CE/ES/00/01) for the placing on the market of herbicide-tolerant genetically modified maize NK603, for import and processing, under Part C of Directive 2001/18/EC from Monsanto" and "Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the safety of foods and food ingredients derived from herbicide-tolerant genetically modified maize NK603, for which a request for placing on the market was submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto" are nearly identical and this critique applies to both. Both documents are available at: http://www.efsa.eu.int/p_gmo_en.html.

Summary: An unintentional open reading frame is transcribed to RNA and significant differences have been noted between NK603 and its conventional counterpart. The transcription of an open reading frame by itself should render this GE product unsafe. The significant differences noted should be investigated thoroughly. To simply ignore these two critical factors questions the relevance of having an EFSA.

1) **An open reading frame is transcribed**. The document clearly states that the open reading frame created by the unintentional additional (inverted) promoter fragment at the 3' end of the insert is transcribed into RNA. This is one step away from creating an unintended novel protein. This, by itself, clearly indicates that NK603 is not safe for human health, nor the environment.

This RNA should not be transcribed because it reads through a "stop" codon. This undermines one of the GE paradigms, that the "stop" codon ends transcription. It clearly does not.

The documents state that "Data provided demonstrate that in the unlikely event that junction polypeptides were translated they would not share a sufficient degree of sequence similarity or identity to known allergens or toxins." However, no rationale is presented as to why translation into protein or polypeptides would be unlikely. If transcription to RNA occurs, the next logical step is for translation to occur to produce proteins or polypeptides. Secondly, it is quite possible that, should translation occur, there could be sequence similarity with hitherto *un*known allergens or toxins.

The Opinion documents simply state that micro RNAs (which are known to have regulatory functions) are shorter than the RNA produced by this open reading frame.

However, micro-RNAs are very much a new discovery that is, as yet, poorly understood (see, for example, Nature, vol. 420, pg. 732 “2002 in context” which states “2002 has seen an avalanche of discoveries about their [small RNA] roles in influencing gene activity.” It is quite possible that the RNA produced by this open reading frame could interfere with gene regulation is some, as yet, undetected way.

Thus, the transcription of the unintentional open reading frame created by additional fragments of the genetic insert should be ground for rejection. There has been no rigorous scientific analysis of the possible consequences.

2) **Significant differences have not been investigated.** A number of significant differences are noted. For example, a difference in the stearic acid composition was noted in one year but not another. A significant difference between fat pad weights of broilers was noted. However, these are not considered to be of biological significance. The use of the term “biological significance” is not applicable here. There is no rigorous definition or methodology of calculation and, since biological and ecological systems are incompletely understood, it is not possible to state was is and is not of biological significance. This is why rigorously defined statistical analyses are used. These differences must be thoroughly investigated. Else, the process of having an EFSA is a mockery as any significant difference can be described as “not considered to be of biological significance” and thus ignored.

This is also not in keeping with the recent FAO/WHO Codex Alimentarius guidelines (ftp://ftp.fao.org/codex/alinorm03/Al03_34e.pdf) which states: “The concept of substantial equivalence is a key step in the safety assessment process. However, it is not a safety assessment in itself; rather it represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart. This concept is used to identify similarities and differences between the new food and its conventional counterpart. It aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy to date for safety assessment of foods derived from recombinant-DNA plants.” Differences have been identified and therefore their cause must be investigated.

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