

Mr Andreas Klepsch  
DG SANCO – Unit D2  
European Commission  
200 Rue de la Loi  
BRUSSELS  
B-1049

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Reference: NFU 443

Dear Mr Klepsch

**Initial Opinion from the German Competent Authority on the application under Regulation (EC) No 258/97 – insect resistant maize MON863 and MON863 X MON810**

The Food Standards Agency is the UK Competent Authority for assessment of novel foods according to Regulation 258/97. The Agency has sought comments from the Advisory Committee on Novel foods and Processes (ACNFP) on the Initial Opinion from Germany under the 60-day rule (Article 6(4) of Regulation (EC) No 258/97).

In the light of the ACNFP's comments, the UK Competent Authority would like to present its reasoned objection to the Initial Opinion on this application to place on the market grains and grain derived food ingredients from maize line MON863 and hybrids between this line and another GM maize line, MON810.

The ACNFP considers that there is insufficient information on MON863 X MON810 insect resistant maize hybrids for the purposes of safety assessment. This is the first novel food application for hybrids between two GM lines and the Committee has noted

that there are no guidelines for the data which should be submitted in this situation before a safety assessment can be made. The applicant has presented only limited data relating to the hybrids and argues that an adequate assessment can be made by reference to data on the individual parent lines. However, this approach does not allow all the properties of the hybrids to be assessed. In particular the potential for interactions between the two sets of inserted genes needs to be considered.

The ACNFP also notes that the available data do not adequately address potential allergenicity of products derived from the hybrids and there is insufficient data to demonstrate compositional equivalence. Data on the composition of the hybrids indicate that there are significant, unexpected differences in some constituents (for example, in the levels of copper) and this reinforces the need for further assessment.

Yours sincerely

***Submitted by e-mail***

Dr Sandy Lawrie

Novel Foods Division