

**ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES****INSECT PROTECTED GENETICALLY MODIFIED MAIZE MON 863****Issue**

At its meeting in May 2004 the Committee expressed concern that there was insufficient data regarding the flanking sequences of the MON 863 insert to allow the site of insertion in the maize genome to be completely identified. Members are invited to consider the applicant's response to the Committee's request for further sequence data.

**Background**

1. In July 2003 the ACNFP considered the German competent authority's initial opinion on an application from Monsanto Europe S.A. for authorisation of grain and grain-derived food ingredients from a GM insect-resistant maize line, MON 863 and the hybrid MON 863 x MON 810 under article 4 of regulation (EC) No. 258/97. The Committee considered information on composition, food/feed safety, toxicity, allergenicity and molecular characterisation of the lines and raised no concerns over the safety of MON 863 maize.
2. At the meeting in May 2004 the Committee considered the opinion from EFSA's Scientific Panel on GMOs on these lines (ACNFP/66/3). This opinion was provided following reasoned objections raised by some Member States (MS), including the UK, during the authorisation process for food products derived from these types of maize. The EFSA Panel concluded that the MON 863 line would not have an adverse effect on human or animal health in the context of its proposed use.
3. Having considered the information provided by the applicant in response to concerns raised by other MS at the May meeting, the Committee noted that additional data on the flanking sequences in MON 863 now indicated that both the 5' and 3' regions showed homology to mitochondrial DNA and therefore did not allow complete characterisation of the insertion point (annex 1 page 5 {section 2.2}). The Committee acknowledged that, on the basis of the other studies on MON 863 maize, there was unlikely to be a safety issue but was of the opinion that the ability to describe the insertion point in detail is fundamental to the analysis of any GMO.
4. Members therefore considered that the applicant should provide additional data on the sequences of the flanking regions, to determine whether the mitochondrial sequences reported to EFSA had been inserted into the plant genome during the GM transformation and, if so, whether this insertion might have disrupted a functional DNA sequence. Members suggested that this issue could be addressed relatively easily using standard sequencing methods.
5. The applicant has responded that it does not plan further analysis on the mitochondrial sequences that are contiguous to the insert. There are technical

difficulties in extending the data and they argue that any uncertainty associated with the insertion point is outweighed by data from other studies that lead to the conclusion that MON 863 was as safe as conventional maize.

6. The applicant refers to its response to EFSA on this particular point (annex 1), where they provide detailed arguments to justify this position. The main arguments presented are that:

- a) Due to the repetitive nature of mitochondrial DNA there are technical difficulties in obtaining additional sequence data in order to identify genomic maize DNA adjacent to the insert (annex 1, page 6 {section 2.3}).
- b) Mitochondrial proteins are unlikely to be expressed from a nuclear genome (annex 1, pages 5 - 9 {section 2} and appendix 2, pages 39 - 44).
- c) MON 863 maize is agronomically, compositionally and nutritionally comparable to conventional maize except for the introduced trait (annex 1, page 9 {sections 3.1 and 3.2}).
- d) Feeding studies were performed on test animals without detecting any adverse effects (annex 1, pages 10 - 11 {section 3.3.1} and pages 17 - 23 {sections 3.3.2 and 3.4} and appendix 3, pages 45 - 64).
- e) That there is a very high margin of safety for MON 863 maize (annex 1, pages 11 - 17 {section 3.3.1.1}).

### **Committee Action Required**

7. Members are invited to consider the applicant's response and to advise whether they wish to maintain their position of July 2003 on the safety of the MON 863 maize line.

**Secretariat  
July 2004**