

COMMENTS OR OBJECTIONS TO THE PLACING ON THE MARKET OF A GMO UNDER PART C OF DIRECTIVE 2001/18/EC (ARTICLE 15)

Response of United Kingdom Competent Authority

Notification number: C/DE/02/9

Insect resistant maize (MON 863 and MON 863 x MON 810)

Date: 6 November 2003

1. Reasoned objections

Option 1

The UK Competent Authority is of the view that sufficient information has now been provided by the notifier to demonstrate that MON 863 and hybrids of MON 863 x MON 810 insect resistant maize do not pose a risk to human health and the environment and that marketing of these products for importation and processing in the UK will be no different from that of other maize imported for processing and animal feed purposes. The UK agrees to the issuing of this Part C consent providing the conditions specified in section 2.3 are included. The UK considers that these conditions fall within the scope of the provisions of Directive 2001/18/EC and are not dependent upon the regulations on GM Traceability and Labelling or on GM Food and Feed having entered into effect.

2. Comments

2.1. General comments

The UK competent authority has considered the potential risks to human health and the environment posed by the placing on the market of maize containing transformation event MON 863 conferring insect resistance and hybrids of MON 863 x MON 810. The UK notes that the scope of this application is limited to the import of grain and processing for food and feed, but does not encompass cultivation within the EU and that the German competent authority has issued a favourable assessment.

2.2. Technical comments

2.2.1. *Molecular characterization of MON 863*

The UK is content with the molecular characterisation of MON 863.

2.2.2. *Molecular characterisation of MON 810*

The UK requested clarification concerning the absence of vector backbone sequence and the insert copy number, with any uncertainties being taken account of in the risk assessment and post market monitoring plan. The UK is content that the evidence provided supports the conclusion that vector backbone sequences are absent and that the copy number of the insert is one, therefore there is no requirement to modify the risk assessment or the post market monitoring plan.

2.2.3. Molecular characterisation of MON 863 x MON 810

The UK requested that the risk assessment take into account the fact that it will be the F2 generation which will be imported. The UK is now satisfied that the risk assessment satisfactorily considers the remote possibility of recombination during production of the F2 generation and that there is an extremely low probability that any recombination would generate any additional risk to human health or the environment.

*2.2.4. Presence of the *nptII* gene*

The UK notes that MON 863 contains an antibiotic resistance marker gene *nptII*. Article 4(2) of Directive 2001/18/EC refers to the phasing out of genes expressing resistance to antibiotics which may have adverse effects on human health and the environment or are in use for medical or veterinary treatment. The UK is of the opinion that the *nptII* gene does not pose a risk to human health or the environment and is of the opinion that there is no justification for consent not being granted on the basis of the presence of *nptII* in MON 863. This is without prejudice to the outcome of the Commission expert working group that is currently considering the implementation of Article 4(2).

2.2.5. Detection method for MON 810

A satisfactory event specific detection protocol has now been provided.

2.2.6. Animal Feeding studies

Full details of the broiler chicken feeding study for MON 863 maize has now been provided. The UK is content that the safety assessment of both MON 863 and MON 863 x MON 810 maize lines has been completed, both have been found to be safe as any other maize line.

2.3. Additional consent conditions

2.3.1. Period of consent

The UK sees no reason why consent should not be issued for the maximum period of 10 years.

2.3.2. Post market monitoring plan

The UK considered the revised post market monitoring plan provided and considers that the applicant should be more proactive in obtaining information from end users of any effects that are attributable to the use of the GMO this should be combined with an annual reporting requirement.

2.3.3. Traceability and Labelling

In accordance with Articles 4(6) and 21 of Directive 2001/18/EC or the requirements of Regulation (EC) No 1829/2003 [on traceability and labelling], the UK requests that, at all points in the supply chain, any product containing 0.9% or more (by weight) of MON 863 and MON 863 x MON 810 maize that is adventitious or technically unavoidable should be labelled as "Contains genetically modified organisms". Furthermore, the UK requires the following procedures to ensure traceability of material containing MON 863 and MON 863 x MON 810 maize throughout the supply chain. Each batch of material containing MON 863 and MON 863 x MON 810 maize should be accompanied by a document stating the following:

- That the product contains the GMO designated by the unique identifier MON- ØØ863-5 and MON- ØØ81Ø-6
- The commercial name of the product

- The full address of Monsanto Europe SA
- How to access information about MON 863 and MON 810 maize in the publicly accessible part of the Commission's register maintained under Annex IV.7 of the Directive 2001/18/EC.

This document should be passed on to all users up to, but not including, the final consumer, and the originator and all recipients of the document should be required to retain a record of the document for 5 years.

2.3.4. Packaging

The UK requests that the consent should specify that packaging should be consistent with the requirements of traceability and labelling outlined in section 2.3.3 above.