

APPLICATION FOR AUTHORISATION OF  
GENETICALLY MODIFIED PLANTS  
AND DERIVED FOOD AND FEED  
IN ACCORDANCE WITH REGULATION (EC) No 1829/2003

**1507xMON810xMIR162xNK603 MAIZE**

(DAS-Ø15Ø7-1xMON-ØØ81Ø-6xSYN-IR162-4xMON-ØØ6Ø3-6 MAIZE)

**EFSA-GMO-NL-2015-xx**

**PART IV – Labelling**

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## **PART IV - LABELLING**

### **Introduction**

This application is for the authorisation of genetically modified 1507xMON810xMIR162xNK603 maize for all food and feed uses in accordance with Articles 3(1) and 15(1) of Regulation (EC) 1829/2003 and for import and processing of 1507xMON810xMIR162xNK603 maize in accordance with Part C of Directive 2001/18/EC. This application does not include authorisation for the cultivation of 1507xMON810xMIR162xNK603 maize seed products in the EU.

### **A. UNIQUE IDENTIFIER**

In accordance with Commission Regulation (EC) 65/2004 and the OECD guidance for the designation of a unique identifier for transgenic plants (ENV/JM/MONO(2002)7), the unique identification code assigned to 1507xMON810xMIR162xNK603 maize is as follows: DAS-Ø15Ø7-1xMON-ØØ81Ø-6xSYN-IR162-4xMON-ØØ6Ø3-6.

The scope of the current application is for all uses of 1507xMON810xMIR162xNK603 maize as any other maize. Since maize is a segregating crop, the 1507xMON810xMIR162xNK603 grain imported in EU will contain a mixture of all possible combinations of the single GM events constituting it (MON810xMIR162xNK603; 1507xMIR162xNK603; 1507xMON810xNK603; 1507xMON810xMIR162; 1507xMON810; 1507xMIR162; 1507xNK603; MON810xMIR162; MON810xNK603; and MIR162xNK603).

### **B. PROPOSAL FOR THE LABELLING OF 1507XMON810XMIR162XNK603 MAIZE FOOD PRODUCTS ACCORDING TO ARTICLES 12 AND 13 OF REGULATION (EC) NO 1829/2003**

#### **Proposal for the labelling of 1507xMON810xMIR162xNK603 maize food products**

In accordance with Article 12(2) of Regulation (EC) No 1829/2003, labelling shall apply except to foods containing material which contains, consists of or is produced from 1507xMON810xMIR162xNK603 maize in a proportion not higher than 0.9 per cent of the food ingredients considered individually or of food consisting of a single ingredient.

In accordance with Article 13 of Regulation (EC) No 1829/2003, and without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, foods containing, consisting of, produced from, or containing ingredients produced from 1507xMON810xMIR162xNK603 maize, should be labelled as follows:

- (a) where the food consists of more than one ingredient, the words 'genetically modified' or 'produced from genetically modified (name of ingredient)' will appear in the list of ingredients provided for in Article 6 of Directive 2000/13/EC in parentheses immediately following the ingredient concerned;
- (b) where the ingredient is designated by the name of a category, the words 'contains genetically modified maize' or 'contains (name of ingredient) produced from genetically modified maize' will appear in the list of ingredients;
- (c) where there is no list of ingredients, the words 'genetically modified' or 'produced from genetically modified maize' will appear clearly on the labelling;
- (d) the indications referred to in (a) and (b) may appear in a footnote to the list of ingredients. In this case they shall be printed in a font of at least the same size as the list of ingredients. Where there is no list of ingredients, they will appear clearly on the labelling;

- (e) where the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers of which the largest surface has an area of less than 10 cm<sup>2</sup>, the information referred to above will be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.

No other particulars such as those referred to in Article 13(2)(a) and (b) and Article 13(3) of Regulation No (EC) 1829/2003 would need to be specified on the label of 1507xMON810xMIR162xNK603 maize food products. Indeed, 1507xMON810xMIR162xNK603 maize has been shown to be equivalent to non-GM maize in composition, nutritional value and nutritional effects, intended use, and health characteristics, and the genetic modification in 1507xMON810xMIR162xNK603 maize does not give rise to any ethical or religious concerns.

#### **C. PROPOSAL FOR THE LABELLING OF 1507XMON810XMIR162XNK603 MAIZE FEED PRODUCTS ACCORDING TO ARTICLES 24 AND 25 OF REGULATION (EC) NO 1829/2003**

##### **Proposal for the labelling of 1507xMON810xMIR162xNK603 maize feed products**

In accordance with Article 24(2) of Regulation No (EC) 1829/2003, labelling shall apply except to feed containing material which contains, consists of or is produced from 1507xMON810xMIR162xNK603 maize in a proportion not higher than 0.9 per cent of the feed and of each feed of which it is composed.

In accordance with Article 25 of Regulation (EC) No 1829/2003, and without prejudice to the other requirements of Community law concerning the labelling of feed, feed referred to in Article 15(1) of Regulation (EC) 1829/2003, *i.e.* 1507xMON810xMIR162xNK603 maize for feed use, and feed containing, consisting of or produced from 1507xMON810xMIR162xNK603 maize, should be labelled as follows:

- (a) where the feed contains or consists of 1507xMON810xMIR162xNK603 maize, or where 1507xMON810xMIR162xNK603 maize is used for the purpose of feed use, the words 'genetically modified maize' will appear in parentheses immediately following the specific name of the feed. Alternatively, these words may appear in a footnote to the list of the feed. It should be printed in a font of at least the same size as the list of feed;
- (b) where the feed is produced from 1507xMON810xMIR162xNK603 maize, the words 'produced from genetically modified maize' will appear in parentheses immediately following the specific name of the feed. Alternatively, these words may appear in a footnote to the list of the feed. It should be printed in a font of at least the same size as the list of feed.

No other particulars such as those referred to in Article 25(2)(c) and Article 25(3) of Regulation No (EC) 1829/2003 would need to be specified on the label of 1507xMON810xMIR162xNK603 maize feed products. Indeed, 1507xMON810xMIR162xNK603 maize has been shown to be equivalent to non-GM maize in composition, nutritional value and nutritional effects, intended use, and health characteristics, and the genetic modification in 1507xMON810xMIR162xNK603 maize does not give rise to any safety concerns.

#### **D. PROPOSAL FOR THE LABELLING OF PRODUCTS CONSISTING OF, OR CONTAINING, 1507XMON810XMIR162XNK603 MAIZE ACCORDING TO ARTICLE 4, B(6) OF REGULATION (EC) NO 1830/2003 AND ANNEX IV OF DIRECTIVE 2001/18/EC**

In accordance with Article 4, B(6) of Regulation (EC) No 1830/2003 and as specified in Section A.8 of Annex IV of Directive 2001/18/EC, the information provided on a label or in an accompanying

document for the purpose of satisfying the labelling requirements of products consisting of, or containing, 1507xMON810xMIR162xNK603 maize will include the following:

- i)* Commercial name of the product;
- ii)* A statement that 'this product contains genetically modified maize';
- iii)* Name of the GMO or the unique identifier code;
- iv)* Name and full address of the person established in the Community who is responsible for the placing on the market; and,
- v)* An indication on how to access the information in the publicly accessible part of the register.