



Application for renewal of the Authorisation of Bt11 maize import in the European Union under Regulation (EC) No 1829/2003

LABELLING AND UNIQUE IDENTIFIER

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INTRODUCTION

Bt11 maize is a genetically modified (GM) maize which provides control against feeding damage caused by certain lepidopteran pests and tolerance to herbicide products containing glufosinate ammonium.

Bt11 maize plants contain the transgene *cry1Ab* which encodes the insecticidal protein Cry1Ab, and the transgene *pat*, which encodes the enzyme phosphinothricin acetyltransferase (PAT). PAT confers tolerance to glufosinate-ammonium in herbicide products. PAT was used as a selectable marker in the development of Bt11 maize.

A proposal for labelling of food and feed products derived from Bt11 maize has been prepared in accordance with Articles 12-14 and Articles 24-26 of Regulation (EC) No 1829/2003.

This proposed labelling takes into account the requirements of Article 4 B (6) of Regulation (EC) No 1830/2003 on traceability and labelling of genetically modified organisms, and Annex IV of Directive 2001/18/EC, considering that the scope of this application does not include cultivation.

The labelling requirements specified in Article 5(3)(f) and 17(3)(f) of Regulation (EC) No 1829/2003 are not applicable in this case because the characteristics have been analysed and Bt11 maize and products derived from it are not different from those of its conventional counterpart and do not give rise to ethical or religious concerns.

1. LABELLING OF FOOD

The labelling requirements specified in Article 5(3)(f) and (g) of the Regulation (EC) No 1829/2003 are not applicable in this case because the characteristics have been analysed and Bt11 maize and products derived from it are not different from those of its conventional counterpart and do not give rise to ethical or religious concerns.

In accordance with Article 12(2) of Regulation (EC) No 1829/2003, labelling will apply to foods containing material which contains, consists of or is produced from Bt11 maize in a proportion at or higher than 0.9 per cent of the food ingredients considered individually or 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 falling within the scope of this Section shall be subject to the following specific labelling requirements:

- (a) where the food consists of more than one ingredient, the words 'genetically modified' or 'produced from genetically modified maize' shall 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 'produced from genetically modified maize' shall appear in the list of ingredients;
- (c) where there is no list of ingredients, the words 'genetically modified' or 'produced from genetically modified maize' shall 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 shall 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 cm², the information required under this paragraph must 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.

Reference to the public register in accordance with Annex IV of Directive 2001/18/EC. A public register is available at the EU Commission website: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

Reference to the commercial name in accordance with Annex IV of Directive 2001/18/EC: Bt11 maize seed to be grown in countries where it is approved for cultivation will be labelled with the commercial name. Harvested grain from Bt11 maize, imported into the EU as part of a commodity shipment will have no new commercial name associated with this import or food products derived thereof. Consistent with the provisions of the Cartagena Protocol on Biosafety, the unique identifier assigned to Bt11 maize is SYN-BTØ11-1.

Reference to the name and full address of the person established in the community who is responsible for the placing on the market whether it be the manufacturer, the importer or the distributor in accordance with Annex IV of Directive 2001/18/EC. As described above, grain harvested from Bt11 maize grown in countries where it is approved for cultivation will be imported into the EU as part of a commodity shipment. Importers will be made aware that the name and full address of the applicant is:

Syngenta Crop Protection NV/SA acting on behalf of Syngenta Crop Protection AG.

Syngenta Crop Protection NV/SA
Avenue Louise, 489
1050 Brussels
Belgium

The requirements specified in Articles 13(2)(a) and (b) and Article 13(3) of the Regulation (EC) No 1829/2003 are not applicable in this case because the characteristics have been analysed and Bt11 maize and products derived from it are not different from those of its conventional counterpart and do not give rise to ethical or religious concerns.

2. LABELLING OF FEED

The labelling requirements specified in Article 17(3)(f) and (g) of the Regulation (EC) No 1829/2003 are not applicable in this case because the characteristics have been analysed and Bt11 maize and products derived from it are not different from those of its conventional counterpart and do not give rise to ethical or religious concerns.

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) shall be subject to the following specific labelling requirements laid down below:

No person shall place a feed referred to in Article 15(1) on the market unless the particulars specified below are shown, in a clearly visible, legible and indelible manner, on an accompanying document or, where appropriate, on the packaging, on the container or on a label attached thereto.

Each feed of which a particular feed is composed shall be subject to the following rules:

- (a) for the feeds referred to in Article 15(1)(a) and (b), the words ‘genetically modified maize’ shall appear in parentheses immediately following the specific name of the feed. Alternatively, these words may appear in a footnote to the list of feed. It shall be printed in a font of at least the same size as the list of feed;
- (b) for the feed referred to in Article 15(1)(c), the words ‘produced from genetically modified maize’ shall appear in parentheses immediately following the specific name of the feed. Alternatively, these words may appear in a footnote to the list of feed. It shall be printed in a font of at least the same size as the list of feed;

Reference to the public register in accordance with Annex IV of Directive 2001/18/EC. A public register is available at the EU Commission website: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

Reference to the commercial name in accordance with Annex IV of Directive 2001/18/EC: Bt11 maize seed to be grown in countries where it is approved for cultivation will be labelled with the commercial name. Harvested grain from Bt11 maize, imported into the EU as part of a commodity shipment will have no new commercial name associated with this import or feed products derived thereof. Consistent with the provisions of the Cartagena Protocol on Biosafety, the unique identifier assigned to Bt11 maize is SYN-BTØ11-1.

Reference to the name and full address of the person established in the community who is responsible for the placing on the market whether it be the manufacturer, the importer or the distributor in accordance with Annex IV of Directive 2001/18/EC. As described above, grain harvested from Bt11 maize grown in countries where it is approved for cultivation will be imported into the EU as part of a commodity shipment. Importers will be made aware that the name and full address of the applicant is :

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The requirements specified in Articles 25(2)(c) and (d) and Article 25(3) of the Regulation (EC) No 1829/2003 are not applicable in this case because the characteristics have been analysed and Bt11 maize and products derived from it are not different from those of its conventional counterpart and do not give rise to ethical or religious concerns.

3. UNIQUE IDENTIFIER

A unique identifier for Bt11 maize has been assigned and is in accordance with Commission Regulation (EC) 65/2004. The unique identifier assigned to this product is SYN-BTØ11-1.