

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

**DP51291**  
**(DP-Ø51291-2) maize**

**GMFF-2021-0071**

**PART IV – Labelling**

**Submitted by:**

**Corteva Agriscience LLC.**  
**9330 Zionsville Road**  
**Indianapolis, Indiana 46268-1054**  
**U.S.A.**

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## PART IV - LABELLING

### Introduction

This application is for the authorisation of genetically modified DP51291 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 DP51291 maize in accordance with Part C of Directive 2001/18/EC. This application does not include authorisation for the cultivation of seed products of DP51291 maize in the European Union (EU).

In accordance with the requirements of Articles 4 and 16 of Regulation (EC) No 1829/2003, information contained in the risk characterisation demonstrates that:

- a) Consumption of food and feed derived from DP51291 maize is as safe as food and feed from conventional maize and no adverse effects on human or animal health are expected;
- b) Food derived from DP51291 maize is comparable to food from conventional maize and is not nutritionally disadvantageous for the consumer compared to food which it is intended to replace;
- c) Food from DP51291 maize does not mislead the consumer;
- d) Feed from DP51291 maize does not harm or mislead the consumer by impairing the distinctive features of the animal products;
- e) Feed from DP51291 maize is comparable to feed from conventional maize and is not nutritionally disadvantageous for animals or humans compared to the feed which it is intended to replace.

Furthermore, DP51291 maize products are not claimed for altered nutritional composition, nutritional value or health effects.

### 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 DP51291 maize is as follows:

DP-Ø51291-2

### B. LABELLING – SCOPE, REQUIREMENTS, IMPLEMENTING MEASURES

#### *Labelling Threshold*

In accordance with Articles 12(2) and 24(2) of the Regulation (EC) No 1829/2003 on genetically modified food and feed, Article 21(2) of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, and Article 7(2) of the Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and food and feed products produced from genetically modified organisms, we propose that a labelling threshold of 0.9 % be applied for the placing on the market of this genetically modified maize and derived products.

#### *Unique identifier*

In accordance with guidance from the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology, the unique identifier for these maize products is indicated above.

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The internationally accepted format guidance from OECD also formed the basis for Commission Regulation (EC) No 65/2004, establishing a system for the development and assignment of unique identifiers for genetically modified organisms.

### **PROPOSAL FOR THE LABELLING OF PRODUCTS CONSISTING OF, OR CONTAINING, DP51291 MAIZE ACCORDING TO REGULATION (EC) NO 1830/2003**

#### Labelling of foods and feeds consisting of or containing DP51291 maize

In accordance with Articles 12-14 and 24-26 of Regulation (EC) No 1829/2003, Article 13(2)f and Annex IV of Directive 2001/18/EC, and with Article 4 of Regulation (EC) No 1830/2003, operators are required to label products containing or consisting of DP51291 maize with the words “genetically modified maize” or “contains genetically modified maize”, and operators are required to declare the unique identifier in the list of GMOs that have been used to constitute the mixture that contains or consists of this GMO.

#### Labelling of foods and feeds produced from DP51291 maize

For food and feed products produced from DP51291 maize that are not exempted according to Article 5(4) of Regulation (EC) No 1830/2003, operators are required to label foods and feeds derived from DP51291 maize with the words “produced from genetically modified maize”, in accordance with Articles 12-14 and 24-26 of Regulation (EC) No 1829/2003 and the requirements of Article 5 of Regulation (EC) No 1830/2003. In the case of products for which no list of ingredients exists, operators are required to ensure that an indication that the food or feed product is produced from GMOs is transmitted in writing to the operator receiving the product.

#### Measures taken by the applicant

Although Corteva Agriscience LLC is the applicant under Regulation (EC) No 1829/2003 for authorisation to place DP910521 maize on the market for all food and feed uses as any other maize in the EU, Corteva Agriscience LLC is not anticipated to be an operator handling or using the product in the EU.

Operators handling or using DP51291 maize and derived foods and feeds in the EU are required to be aware of the legal obligations regarding traceability and labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No 1829/2003 and 1830/2003, and that authorised foods and feeds shall be entered in the Community Register, operators in the food/feed chain are expected to be fully aware of the traceability and labelling requirements for DP51291 maize. Therefore, no further specific measures are to be taken by the applicant.