# 73496 oilseed rape (DP-Ø73496-4 oilseed rape) Fact-sheet for operators

2022

# 73496 oilseed rape

# **Fact-sheet for operators**

The placing on the market of products containing, consisting of, or produced from genetically modified oilseed rape 73496¹ was authorised, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, by the European Commission on 21 March 2022 under Commission implementing decision (EU) 2022/529 (EC, 2022)².

The authorisation decision for 73496 oilseed rape granted to Corteva Agriscience LLC, represented in the Union by Corteva Agriscience Belgium B.V, is published at: http://data.europa.eu/eli/dec impl/2022/529/oj

The following products are authorised:

- (a) Foods and food ingredients containing, consisting of or produced from 73496 oilseed rape
- (b) Feed containing, consisting of or produced from 73496 oilseed rape
- (c) products containing or consisting of 73496 oilseed rape for uses other than those provided for in points (a) and (b), with the exception of cultivation

# **General Characteristics of 73496 oilseed rape**

The 73496 oilseed rape plants have been genetically modified to express the GAT4621 (glyphosate acetyltransferase) protein. The 73496 oilseed rape line is a GM plant that confers tolerance to glyphosate herbicides. The availability of 73496 oilseed rape product will provide an alternative to currently available glyphosate-tolerant canola lines.

#### Safety of the 73496 oilseed rape

In May 2012, Pioneer Overseas Corporation, on behalf of Pioneer Hi-Bred International Inc. (hereafter referred to as Pioneer³) submitted an application for the placing on the market of 73496 oilseed rape for food and feed uses, import and processing in accordance with articles 5 and 17 of Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2012-109). On 17 May 2021, the European Food Safety Authority (EFSA) Panel on Genetically Modified Organisms (GMO) first published a positive scientific opinion in which it concluded: "The GMO Panel concludes that oilseed rape 73496, as described in this application, is as safe as its conventional counterpart and the non-genetically modified oilseed rape reference varieties tested with respect to potential effects on human and animal health and the environment⁴.

<sup>&</sup>lt;sup>1</sup> Also known as DP73496

<sup>&</sup>lt;sup>2</sup> Commission Implementing Decision (EU) 2022/529 of 31 March 2022 authorising the placing on the market of products containing, consisting of or produced from genetically modified oilseed rape 73496 (DP-Ø73496-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

<sup>&</sup>lt;sup>3</sup> Member of Corteva Agriscience group of companies

<sup>&</sup>lt;sup>4</sup> EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H,Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachini B, Messéan A,Nielsen EE, Nogué F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M,Alvarez F, Ardizzone M, Paraskevopoulos K, Broll H, Devos Y, Fernandez Dumont A, Gomez Ruiz JA, Lanzoni A, Neri FM, Olaru I and Papadopoulou N, 2021. Scientific Opinion on assessment of genetically modified oilseed rape 73496 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2012-109). EFSA Journal 2021;19(6):5280 https://doi.org/10.2903/j.efsa.2021.6610

The EFSA GMO panel scientific opinion is available at: <a href="https://www.efsa.europa.eu/en/efsajournal/pub/6610">https://www.efsa.europa.eu/en/efsajournal/pub/6610</a>

# Monitoring Conditions for 73496 oilseed rape

As indicated in the positive EFSA GMO Panel opinion on 73496 oilseed rape, "Based on the outcome of the comparative and nutritional assessments, the consumption of oilseed rape 73496 does not represent any nutritional concern, in the context of the scope of this application. The implementation of a post-market monitoring plan is recommended to confirm the predicted consumption data and to verify that the conditions of use are those considered during the pre-market risk assessment." (EFSA, 2021)<sup>5</sup>.

In line with the recommendation stated in the Commission decision (EC, 2022) a post-market monitoring (PMM) plan will be put in place to confirm the predicted consumption data and to verify that the conditions of use are those considered during the pre-market risk assessment.

As specified by Commission decision (EC, 2022), a post-market environmental monitoring (PMEM) plan for 73496 oilseed rape is in place and consists of a general surveillance plan, not based on a particular hypothesis, to report observed unanticipated adverse effects on human and animal health or the environment arising from handling or use of viable 73496 oilseed rape, if any. As stated by the EFSA GMO Panel in its scientific opinion on 73496 oilseed rape for food and feed uses, import and processing "The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of oilseed rape 73496" (EFSA, 2021)<sup>5</sup>.

The monitoring takes place in cooperation with monitoring networks of trade associations representing operators importing, handling and processing viable oilseed rape commodity, which report back to the CropLife Europe. The result of the monitoring activities is reported back to the European Commission by Corteva Agriscience LLC on an annual basis.

The post-market environmental monitoring plan for 73496 oilseed rape has been published on the EU register for genetically modified food and feed:

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC

# Conditions for traceability and labelling for 73496 oilseed rape

Operators importing, handling and processing 73496 oilseed rape grain and derived foods and feeds in the EU shall comply with the conditions for traceability and labelling outlined in Regulations (EC) No 1829/2003 and 1830/2003 and in Commission Implementing Decision (EU) 2019/1304 for 73496 oilseed rape.

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<sup>&</sup>lt;sup>5</sup> EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H,Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachini B, Messéan A,Nielsen EE, Nogué F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M,Alvarez F, Ardizzone M, Paraskevopoulos K, Broll H, Devos Y, Fernandez Dumont A, Gomez Ruiz JA, Lanzoni A, Neri FM, Olaru I and Papadopoulou N, 2021. Scientific Opinion on assessment of genetically modified oilseed rape 73496 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2012-109). EFSA Journal 2021;19(6):5280 https://doi.org/10.2903/j.efsa.2021.6610

For the purposes of the specific labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the name of the organism shall be oilseed rape.

The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of 73496 oilseed rape with the exception of foods and food ingredients containing, consisting of or produced from 73496 oilseed rape.

The unique identifier assigned to 73496 oilseed rape is DP-Ø73496-4.

# Methods for detection and reference material for 73496 oilseed rape

Validated 73496 oilseed rape detection method

In accordance with Regulation (EC) No 1829/2003 and in line with the above-mentioned application for authorisation of the 73496 oilseed rape, a validated event-specific detection method for the quantification of 73496 oilseed rape has been published by the European Union Reference Laboratory (EURL) of the Joint Research Centre (JRC). The validated detection method is publicly available from the JRC-EURL website:

https://gmo-crl.jrc.ec.europa.eu/method-validations

73496 oilseed rape certified reference material

In accordance with Regulation (EC) No 1829/2003 and in line with the above application for authorisation of 73496 oilseed rape, certified reference material is available at Joint Research Centre's GMO Reference Unit. The corresponding certified reference material set ERM®-BF439 can be obtained via the JRC website:

https://crm.jrc.ec.europa.eu/

#### **Contact points for Operators**

As there are other technology providers for GM oilseed rape and shipments entering the European harbours may be commingled, an industry wide approach has been developed. Therefore, CropLife Europe is the central communication point for the GM plant technology providers.

CropLife Europe is the primary address for reporting general surveillance activities or any unanticipated adverse effects and is skilled to provide adequate response. In addition, CropLife Europe will transfer the messages to the relevant industry partner if further action is required.

Operators are requested to report, if possible via their branch representative, any unanticipated adverse effect to CropLife Europe at: <a href="https://croplifeeurope.eu/product-information/">https://croplifeeurope.eu/product-information/</a>

If required, additional comments or questions can also be addressed to:
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Rue Montoyer 25
1000 Bruxelles
Belgium
CortevaEUBiotech@corteva.com