

305423 soybean
Plenish[®] High oleic soybeans with
increased monounsaturated fat and
reduced polyunsaturated fats
Fact-sheet for operators

2021



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The placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423, also referred to as Plenish® high oleic soybean with increased monounsaturated fat and reduced polyunsaturated fats¹ in the commercial context, was authorised pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council by the European Commission on 24 April 2015 under Commission implementing decision (EU) 2015/698².

The authorisation decision for 305423 soybean is published at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015D0698&from=EN>

The following products are authorised by Commission implementing decision (EU) 2015/698:

- (a) Food and feed ingredients containing, consisting of, or produced from 305423 soybean
- (b) Feed containing, consisting of, or produced from 305423 soybean
- (c) 305423 soybean in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation

Soybean oil is the second most abundant vegetable oil in the world. Common soybean varieties produce oil high in polyunsaturated fatty acids. This composition makes the oil unstable, easily oxidized and subject to rancidity. When heated extensively, soybean oil develops objectionable flavours and odours, making it unsuitable for many applications.

The traditional solution to soybean oil instability has been to partially hydrogenate the oil. Hydrogenation is the addition of hydrogen atoms across the double bonds in unsaturated fatty acids so that they become increasingly saturated. However, this chemical process also introduces side reactions including conversion of double bonds from the cis to the trans molecular configuration, resulting in trans fatty acids.

Trans fats have been associated with increased heart health risks. In some Member States, the labelling of foods containing trans-fats is mandatory.

Food manufacturers are sourcing new oils to eliminate trans-fats from their products. One solution to meeting food processor and industrial needs for more stable vegetable oils has been to change the oil composition of oilseed plants such as the soybean through the use of molecular biology techniques and/or breeding. Researchers have successfully increased the proportion of oleic acid relative to linoleic and linolenic acids in several oilseeds. This results in an overall reduction of double bonds in the oil, which mimics the process of hydrogenation and results in higher oxidative stability similar to partially hydrogenated oils without the trans-fat byproduct.

¹ Plenish® technology by Pioneer Hi-Bred; Plenish® is a registered trademark of Pioneer Hi-Bred International, Inc.

² Commission Implementing Decision (EU) 2015/698 of 24 April 2015 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 (DP-3Ø5423-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

General Characteristics of the 305423 soybean

The genetically modified 305423 soybean has been obtained by introducing the *gm-fad2-1* gene fragment and the *gm-hra* gene into the soybean genome by means of particle bombardment. Transcription of the *gm-fad2-1* gene fragment in 305423 soybean seeds acts to suppress transcription of endogenous omega-6 desaturase, resulting in the high oleic phenotype conferring a high oleic acid profile. Expression of the GM-HRA protein in 305423 soybean, used as a selectable marker, confers tolerance to ALS-inhibiting.

Additional information on Plenish® High Oleic Soybean Oil Performance, food uses and industrial applications

Plenish® High Oleic Soybean Oil Performance

Product application testing is critical to the success of new trans-fat alternative oils. So far, extensive testing conducted at both university and commercial pilot facilities has shown that:

- Plenish® High Oleic soybean oil is an **attractive alternative** to partially hydrogenated oils.
 - Foods tested include French fries, fried meats, tortilla chips, crackers, and salad oil.
- Plenish® High Oleic soybean oil typically **equalled or outperformed partially hydrogenated soybean oil** in many industry-standard performance metrics.
 - Polars, polymers, p-anisidine, free fatty acids, and peroxide value were measured.
- Plenish® High Oleic soybean oil generated **less objectionable flavours and environmental odours** during frying studies.

Food Uses

Product application testing continues to open new uses for Plenish® high oleic soybean oil. Research has shown that they can use it to replace canola, soy, and partially hydrogenated oils in edible applications where increased stability is required. For example, oxidative stability testing of high oleic soybean oil has demonstrated that it is two to three times as stable as commodity soybean oil and as stable as commonly used partially hydrogenated oils.

Plenish® high oleic soybean oil has been used successfully in snack food preparation for frying or spraying to enhance mouth feel and palatability. In pan release applications, high oleic soybean oils form a barrier in pans that allows for a clean release of the cooked product without flavour contribution. The increased oxidative stability of high oleic oil results in lower polymerization and less gummy build-up on equipment. Bakery products such as breads, cakes, muffins and pizza also can benefit from the functional properties of this oil.

Industrial / Non-Food Applications

In addition to food uses, high oleic oils also have advantages in industrial applications. The industrial oleochemicals business is investigating the use of high oleic soybean oil to act as feedstock for the production of numerous products. These products not only have the ecological benefit of being biodegradable and derived from a renewable resource, but they also can provide different and increased functionality.

High oleic soybean oil is being tested and utilized as a machine lubricant (e.g., high temperature engine, transmission, hydraulic, gear and grease applications). Independent testing has shown that these new oils may actually perform better than petroleum-based products in some uses.

Long-term projections indicate that continued advancement in industrial applications research could result in an even greater value for high oleic soybean oils in industrial applications than in some food applications.

Safety of the 305423 soybean

The European Food Safety Authority (EFSA) GMO Panel assessed the application for the placing on the market of 305423 soybean for food and feed uses, import and processing and concluded in its opinion that *“the soybean 305423, as described in the application, is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment in the context of the scope”* of the application (EFSA, 2013).

The Environmental Risk Assessment for 305423 soybean has not identified any adverse effects to the environment in the context of the intended uses as summarized by the EFSA GMO Panel in its opinion on 305423 soybean (EFSA, 2013): *“There are no indications of an increased likelihood of establishment and spread of feral GM soybean plants”* and *“Potential biotic and abiotic interactions of soybean 305423 were not considered to be an issue owing to the low level of environmental exposure.”*

Monitoring Conditions for 305423 soybean

No potential adverse effects to human and animal health or the environment have been identified in the Environmental Risk Assessment for the uses of 305423 soybean. Therefore, case-specific monitoring of 305423 soybean is not necessary, as confirmed by the EFSA GMO panel in its scientific opinion (EFSA, 2013)³. However, a post-market environmental monitoring plan for 305423 soybean was implemented and consists of a general surveillance plan to report any unanticipated adverse effects on human and animal health or the environment arising from handling or use of 305423 soybean.

Plenish® high oleic soybeans are managed under Identity Preserved (IP) production to separate high oleic soybeans from commodity soybeans in order to maintain their identity in the context of a higher value, special use soybean oil. However, it is recognised that the possibility for commingling of 305423 soybean with other commercial authorised GM soybeans cannot be excluded and the authorisation holder is working together with other members of the plant biotechnology industry within CropLife Europe and trade associations representing the relevant operators in order to implement harmonised monitoring/surveillance methodology.

The monitoring takes place in cooperation with monitoring networks of trade associations representing operators importing, handling and processing viable maize commodity, which report back to CropLife Europe. The result of the monitoring activities is reported back to the European Commission by Pioneer Hi-Bred International⁴.

As stated by the EFSA GMO Panel in its scientific opinion on 305423 soybean for food and feed uses, import and processing:

“The post-market environmental monitoring plan is in line with the scope of 305423 soybean.”

The post-market environmental monitoring plan for 305423 soybean can be found at: https://webgate.ec.europa.eu/dyna/gm_register/monitoringplan305423.pdf

³ EFSA. (2013). Scientific Opinion on application EFSA-GMO-NL-2007-45 for the placing on the market of herbicide-tolerant, high-oleic acid, genetically modified soybean 305423 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Pioneer. EFSA Journal. 11. 10.2903/j.efsa.2013.3499.

⁴ Member of Corteva Agriscience group of companies and hereafter referred to as Pioneer

In addition, considering the intended altered nutritional composition of 305423 soybean (high oleic soybean with increased monounsaturated fat and reduced polyunsaturated fat, which results in higher oxidative stability similar to partially hydrogenated oils without the *trans*-fat by-product), a post-market monitoring plan of the 305423 soybean oil is required as per Commission implementing decision (EU) 2015/698 and as recommended by the EFSA GMO Panel in its positive opinion on 305423 soybean.

As previously indicated, Plenish® high oleic soybeans are managed under Identity Preserved production and Pioneer works with exporters to ensure the post-market monitoring plan of the 305423 soybean oil is put in place and implemented.

Plenish® High Oleic Soybean Identity Preserved Production

Plenish® high oleic soybeans will be managed under “identity preserved” or “IP” high oleic soybean contracting programs with farmers. All members of the supply chain will have an incentive to keep the high oleic soybeans separate to maintain the identity as a higher value, special use soybean oil.

Soybean contract production programs are designed to ensure that an appropriate acreage is produced in a given geography to supply the oil demand for the product. Contracts specify the production practices required to keep the high-value soybeans identity-preserved so that the required oil specifications can be achieved.

Contract growers are incentivised with a processor-paid premium for producing and delivering high-value soybeans that meet the specifications required. Processors and elevators participating in the contracting programs work to make the marketing and delivery experience for farmers as close to that of commodity soybeans as possible.

Conditions for traceability and labelling for 305423 soybean

Operators importing, handling and processing 305423 soybean seeds⁵ 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) 2015/698 for 305423 soybean.

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 soybean.

For the purposes of the labelling requirements laid down in Articles 13(2)(a) and 25(2)(c) of Regulation (EC) No 1829/2003, the words ‘with increased monounsaturated fat and reduced polyunsaturated fat’ shall appear after the name of the organism on the label or, where appropriate, in the documents accompanying the products.

⁵ Also referred to as soybean grain

The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of DP-3Ø5423-1 soybean with the exception of products referred to in point (a) of Article 2" (i.e foods and food ingredients containing, consisting of, or produced from 305423 soybean).

In accordance with Commission Regulation (EC) No 65/2004 and the OECD guidance for the designation of a unique identifier for transgenic plants, the unique identification code assigned to 305423 soybean is DP-3Ø5423-1.

Methods for detection and reference material for 305423 soybean

Validated 305423 soybean detection method

A validated event-specific detection method for the quantitation of 305423 soybean event has been published by the Community Reference Laboratory for GM food and feed of the Joint Research Centre (JRC). The validated detection method is publicly available from the JRC website:

<http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>

305423 soybean certified reference material

Certified reference material for 305423 soybean is available at the Institute for Reference Materials and Measurements (IRMM). The corresponding certified reference material set ERM®-BF426 can be obtained via the IRMM website:

<https://crm.jrc.ec.europa.eu/e/92/Catalogue-price-list-pdf>

References

Commission Implementing Decision (EU) 2015/698 of 24 April 2015 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 (DP-3Ø5423-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_112_R_0016&from=EN

EFSA (2013) Scientific opinion on application EFSA-GMO-NL-2007-45 for the placing on the market of herbicide-tolerant, high oleic, genetically modified soybean 305423 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Pioneer. *EFSA Journal* 2013; 11(12):3499, 35pp. doi:10.2903/j.efsa.2013.3499

<http://www.efsa.europa.eu/en/efsajournal/pub/3499.htm>

References for further reading are available under: <https://www.healthyoils.corteva.com/>

Contact points for Operators

As there are other technology providers for GM soybean 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: www.ecpa.eu/product-info

If required, additional comments or questions can also be addressed to:

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