305423 x 40-3-2 soybean Plenish® High oleic soybeans with increased monounsaturated fat and reduced polyunsaturated fats

Fact-sheet for operators

2021

305423 x 40-3-2 soybean

Plenish® High oleic soybeans

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The placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 x 40-3-2 also referred to as Plenish® high oleic soybean with increased monounsaturated fat and reduced polyunsaturated fats[1] in the commercial context, was authorised by the European Commission on 21 December 2017 under Commission implementing decision (EU) 2017/2448[2], pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (EC, 2017).

The authorisation decision for 305423 x 40-3-2 soybean is published at:

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017D2448&from=EN

The following products are authorised:

(a) Food and feed ingredients containing, consisting of, or produced from 305423 x 40-3-2

(b) Feed containing, consisting of, or produced from 305423 x 40-3-2 soybean

(c) 305423 x 40-3-2 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 (PUFAs) containing more than one C=C double bounds in their aliphatic chain. This high PUFA 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 reduce soybean oil instability has been to partially hydrogenate the oil. Hydrogenation is the addition of hydrogen to the oil, with an effect of an increasing saturation of the C=C double bonds in unsaturated fatty acids and thereby increasing the stability of the oils. However, during this chemical process PUFAs can be isomerised as a side reaction, from the favourable cis configuration to the adverse trans configuration, resulting in trans fatty acids.

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 fatty acid 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 eliminates the need for hydrogenation and results in higher oxidative stability similar to partially hydrogenated oils without the trans-fat by-product.

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

[2] Commission Implementing Decision (EU) 2017/2448 of 21 December 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 × 40-3-2 (DP-3Ø5423-1 × MON-Ø4Ø32-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed

General Characteristics of the 305423 x 40-3-2 soybean

The 305423 x 40-3-2 soybean has been obtained from traditional breeding methods between progeny of two genetically modified (GM) soybeans. The two GM soybeans are DP-3Ø5423-1 soybean, referred to as 305423 soybean, and MON-Ø4Ø32-6 soybean, referred to as 40-3-2 soybean. No new genetic modification has been introduced in 305423 x 40-3-2 soybean.

Therefore, 305423 x 40-3-2 soybean contains an increased level of monounsaturated fatty acid (MUFA) (oleic acid) and decreased levels of polyunsaturated fatty acids (linoleic and linolenic acid) due to the downregulation of the endogenous omega-6 desaturase, and is tolerant to ALS-inhibiting herbicides as well as to glyphosate herbicides, due to the presence of GM-HRA and CP4 EPSPS proteins, respectively.

- The 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, conferring a high oleic acid profile and tolerance to acetolactate synthase (ALS)-inhibiting herbicides.
  - The *gm-hra* gene encodes the GM-HRA protein, an optimized version of the soybean acetolactate synthase (ALS). Expression of the GM-HRA protein in 305423 soybean, and in 305423 x 40-3-2 soybean, used as a selectable marker, confers tolerance to ALS-inhibiting herbicides.
  - The inserted *gm-fad2-1* gene fragment, under the control of a seed-preferred promotor, is part of the coding region of the soybean omega-6 desaturase gene 1 (FAD2-1) and does not code for a functional protein. Transcription of the *gm-fad2-1* gene fragment in 305423 (and 305423 x 40-3-2) soybean seeds acts to suppress transcription of endogenous omega-6 desaturase, resulting in the high oleic phenotype. Indeed, a decrease in the level of fatty acid desaturase encoded by the *fad2-1* gene does not provide the necessary enzymatic activity to allow for the conversion of oleic acid to linoleic acid. The end result is greatly increased levels of oleic acid (MUFA), and decreased levels of linoleic and linolenic acid (PUFA) in 305423 and 305423 x 40-3-2 soybean seeds. DuPont Pioneer® brand Plenish® high oleic soybeans have approximately 75 percent oleic acid – one of the highest oleic contents among the oilseed crops. High oleic soybean oil also has lower saturated fatty acid content than commodity soybean oil, making it attractive from a nutritional standpoint.
- The 40-3-2 soybean has been genetically modified to express the 5-enolpyruvylshikimate-3-phosphate synthase gene isolated from the *Agrobacterium* sp. strain CP4 (*cp4 epsps*), which encodes the CP4 EPSPS protein. Expression of the CP4 EPSPS protein in 40-3-2 soybean, and 305423 x 40-3-2 soybean, confers tolerance to glyphosate herbicide.

The 305423 x 40-3-2 soybean is commercialized for the production of Plenish® high oleic soybean oil and used by both the food and industrial oil sectors. The food service industry and food processors benefit from the fact that high oleic soybean oil is a highly stable vegetable oil that is suitable for frying applications without the need for hydrogenation or as an ingredient providing extended shelf life for packaged foods. In the industrial oil sector, high oleic soybean oil will offer base oil that is stable to oxidation for the formulation of cost effective, renewable, environmentally friendly industrial fluids.

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

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 x 40-3-2 soybean

In September 2007, Pioneer Hi-Bred International[3] submitted an application for the placing on the market of herbicide-tolerant, high-oleic acid, genetically modified soybean 305423 x 40-3-2 for food and feed uses, import and processing in accordance with articles 5 and 17 of Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2007-47). On 14 July 2016, the EFSA GMO Panel adopted a positive safety opinion, in which it concluded "*The GMO Panel is of the opinion that the soybean 305423 x 40-3-2 is as safe as the non-GM comparator and non-GM commercial*

[3] Member of Corteva Agriscience group of companies and hereafter referred to as Pioneer

soybean varieties with respect to potential effects on human and animal health and environment in the context of its scope."(EFSA, 2016) [3]

The EFSA GMO panel scientific opinion is available at:

https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4566

Monitoring Conditions for 305423 x 40-3-2 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 x 40-3-2 soybean. Therefore, case-specific monitoring of 305423 x 40-3-2 soybean is not necessary, as confirmed by the EFSA GMO panel in its scientific opinion (EFSA, 2016)[4].

As specified by Commission decision (EC, 2017), a post-market environmental monitoring (PMEM) plan for 305423 x 40-3-2 soybean 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 305423 x 40-3-2 soybean, if any. As stated by the EFSA GMO Panel in its scientific opinion on 305423 x 40-3-2 soybean 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 soybean 305423 x 40-3-2." (EFSA, 2016).* The monitoring takes place in cooperation with monitoring networks of trade associations representing operators importing, handling and processing viable soybean commodity, which report back to CropLife Europe. The result of the monitoring activities is reported back to the European Commission by Pioneer on an annual basis.

The post-market environmental monitoring plan for 305423 x 40-3-2 soybean has been published on the EU register for genetically modified food and feed:

https://webgate.ec.europa.eu/dyna/gm_register/305423%20x%2040-3-2_Monitoring%20plan.pdf

In addition, considering the intended altered nutritional composition of 305423 x 40-3-2 soybean (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 x 40-3-2 soybean oil, required as per Commission implementing decision (EU) 2017/2448 and as recommended by the EFSA GMO Panel in its positive opinion on 305423 x 40-3-2 soybean is implemented.

[4] EFSA, 2016 Scientific opinion on application by Pioneer (EFSA-GMO-NL-2007-47) for the placing on the market of the herbicide-tolerant, high oleic, genetically modified soybean 305423 x 40-3-2 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. *EFSA Journal 2016*; 14(8):4566, 31pp. doi:10.2903/j.efsa.2016.4566

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 incented 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 x 40-3-2 soybean

Operators importing, handling and processing 305423 x 40-3-2 soybean seeds[5] 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) 2017/2448 for 305423 x 40-3-2 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.

The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of DP-3Ø5423-1 x MON-Ø4Ø32-6 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 x 40-3-2 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 identifier assigned to 305423 x 40-3-2 soybean is DP-3Ø5423-1 x MON- Ø4Ø32-6.

Methods for detection and reference material for 305423 x 40-3-2 soybean

Validated 305423 x 40-3-2 soybean detection method

The detection, sampling and identification methods for 305423 x 40-3-2 soybean consist of the same detection, sampling and identification methods available for 305423 and 40-3-2

[5] Also referred to as soybean grain

soybeans, which have been validated by the Joint Research Centre (JRC) of the European Union Reference Laboratory (EU-RL).
In accordance with Regulation (EC) No 1829/2003 and in line with the above-mentioned application for authorisation of 305423 x 40-3-2 soybean, Pioneer provided the JRC-EURL with a PCR detection method that consists of the validated event-specific real-time PCR method for the quantification of 305423 and 40-3-2 soybean, for verification. The detection method has been validated by EURL on 24 March 2016 and is publicly available from the JRC-EURL website:
https://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

305423 x 40-3-2 soybean certified reference material

The Certified Reference Materials (CRM) for 305423 x 40-3-2 soybean consist of the CRMs for 305423 and 40-3-2 soybeans produced by the Institute of Reference Materials and Measurements (IRMM). The corresponding CRM sets ERM®-BF426 for 305423 and ERM®-BF410 for 40-3-2 can be obtained via IRMM website: https://crm.jrc.ec.europa.eu/e/92/Catalogue-price-list-pdf

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 athe 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:
Corteva Agriscience
Rue Montoyer 25
1000 Bruxelles
Belgium
Email address: CortevaEUBiotech@corteva.com