305423 soybean
Plenish® High oleic soybeans with increased monounsaturated fat and reduced polyunsaturated fats

Safety and General Characteristics – Information for operators

July 2015
Introduction

The 305423 soybean, also referred to as Plenish® high oleic soybean with increased monounsaturated fat and reduced polyunsaturated fats in the commercial context, has been developed by Pioneer Hi-Bred International, Inc. (a DuPont subsidiary) as represented by Pioneer Overseas Corporation, hereafter referred to as Pioneer. The placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council was authorised by the European Commission on 24 April 2015 under Commission implementing decision (EU) 2015/698.

The purpose of this document is to provide information for operators handling and processing bulk mixtures of imported soybean in the EU about the safety and general characteristics as well as the monitoring conditions in the EU for the import, processing and food and feed uses of 305423 soybeans.

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. (TBC)
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, 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 soybeans, 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 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 inhibits the conversion of oleic acid to linoleic acid. The end result is greatly increased levels of oleic acid (monounsaturated fat), and decreased levels of linoleic and linolenic acid (polyunsaturated fats) in 305423 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 305423 soybean will be commercialized for the production of Plenish® high oleic soybean oil and will be used by both the food and industrial oil sectors. The food service industry and food processors will 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 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.

Additional information on 305423 high oleic soybean oil performance, food uses and industrial applications is provided in the text box below.
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 305423 soybeans

Pioneer carries out a full range of studies to confirm the safety of all products throughout the research and product development approval process. These studies support the safety assessment for the approval of the 305423 soybean in the EU and most of the major grain trading countries around the world.

The 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 food and feed safety assessment of 305423 soybeans was established (EFSA, 2013) based on:

- Detailed molecular characterization of the inserts;
- The lack of concerns regarding the potential toxicity and allergenicity of the newly introduced GM-HRA protein;
- Studies showing that feeding stuffs derived from 305423 soybean are safe and as nutritious as those derived from other non-GM soybean varieties for all animal species
- Nutritional assessment on 305423 soybean oil and derived food products, which did not identify concerns on human health and nutrition. There are no concerns regarding the use of feeding stuffs derived from 305423 soybean
- Except for the intended compositional changes, no further differences requiring further analyses were identified in the comparative analysis.

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 soybeans. Therefore, case-specific monitoring of 305423 soybeans is not necessary. However, a post-market environmental monitoring plan for 305423 soybeans has to be 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 soybeans.

Plenish® high oleic soybeans will be 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 soybeans 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 the European Association of Bioindustries (EuropaBio) and trade associations representing the relevant operators in order to implement harmonised monitoring/surveillance methodology.

The selected networks of operators (COCERAL, UNISTOCK and FEDIOL) (European trade associations) will:

- Inform and remind their member organisations and companies on an annual basis:
  - to monitor for potential unanticipated adverse effects;
  - that, in the framework of their management or safety standards (ISO, HACCP, ...), procedures must be in place and implemented to limit losses and spillage of viable soybean and to routinely eradicate adventitious populations on their premises – any such adventitious populations, resisting routine eradication procedures, shall be treated as a potential adverse effect;
  - to inform and remind their own member companies of this requirement;
  - to report back any adverse effect reported to them to the European trade associations.

- Report to the authorisation holders directly or via EuropaBio:
  - at least annually, regardless as to whether an adverse effect was observed or not;
  - immediately, any adverse effects reported to them.

Consequently, the European trade associations COCERAL, UNISTOCK and FEDIOL will notify EuropaBio of the results of the general surveillance on an annual basis. EuropaBio will forward this report to the respective authorisation holders for inclusion in their annual report to the European Commission.

Throughout the period of validity of the authorisation, Pioneer as authorisation holder will ensure that the monitoring plan proposed for 305423 soybeans for import and use for food, feed and processing based on the environmental risk assessment is put in place and implemented. The result of the monitoring activities is reported back to the European Commission on an annual basis.

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

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

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 will be 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.

### Regulatory Status of the 305423 soybean

#### Worldwide
The 305423 soybean was first approved for food, feed and cultivation use in the United States on 8 June 2010 and has been commercially cultivated since 2015. Cultivation approval is also in place in Canada.

As of July 2015, the 305423 soybean has been approved in most of the major grain trading countries in the world: 39 countries around the world (Australia, Canada, China, Mexico, New-Zealand, Singapore, South Africa, South Korea, Taiwan, USA, including the EU-28) have approved 305423 soybean for import and/or food and feed use.

#### European Union
The regulatory system on GMOs in the EU consists of a number of regulations and directives. The GMO authorisation process is in accordance with Directive 2001/18/EC ‘on the deliberate release into the environment of genetically modified organisms’ (repealing Directive 90/220/EEC), and Regulation (EC) 1829/2003 ‘on genetically modified food and feed’ (replacing Regulation (EC) 285/97 ‘concerning novel foods and novel food ingredients’). The rules for labelling and traceability are defined in Regulation (EC) 1830/2003 ‘concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.’
The GMO legislation in the EU is based on a number of regulations and directives, including Directive 2001/18/EC “on the deliberate release into the environment of genetically modified organisms” and Regulation (EC) No 1829/2003 “on genetically modified food and feed”. The rules for labelling and traceability are defined in Regulation (EC) No 1830/2003 “concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms”.

**Approval of 305423 import, processing, food and feed uses**

Pioneer submitted the application for the placing on the market of herbicide-tolerant, high-oleic acid, genetically modified soybean 305423 for food and feed uses, import and processing to the Dutch Competent Authority (CA) under Regulation (EC) No 1829/2003 in June 2007, and the application was then forwarded to EFSA.

The EFSA GMO Panel evaluated the application and adopted a positive safety opinion 4 December 2013, published on 18 December 2013, in which it “considers that the information available for soybean 305423 addresses the scientific comments raised by the Member States and states that the soybean 305423, as described in the application, is as safe as its conventional counterpart with respect to potential effects potential effects on human and animal health and the environment in the context of the scope” of the application (EFSA, 2013).

After consultation of the Standing Committee on the Food Chain and Animal Health consisting of the Competent Authorities of the EU Member States and the EU Agriculture Council, the European Commission approved the import, processing and food and feed uses of 305423 soybean in Commission implementing decision (EU) 2015/698 on 24 April 2015.

The following products are authorised:

(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

**Validated 305423 soybean detection method**

In accordance with Regulation (EC) No 1829/2003 and in line with the above application for approval of the 305423 soybean, Pioneer provided the European Union Reference Laboratory (EU-RL) of the Joint Research Centre (JRC) with an event-specific method for the quantification of 305423 soybean event using real-time PCR for validation. The detection method has been validated and is publicly available from the JRC-CRL website:

305423 soybean certified reference material
In accordance with Regulation (EC) No 1829/2003 and in line with the above application for approval of the 305423 soybean, Pioneer provided the Institute for Reference Materials and Measurements (IRMM) with non-GM and 305423 soybean seed for the production of certified reference material. The corresponding certified reference material set ERM®-BF426 can be obtained via the IRMM website: https://ec.europa.eu/jrc/sites/default/files/rm_catalogue.pdf

305423 soybean labelling and traceability
Operators importing, handling and processing 305423 soybean seeds need to comply with the conditions for labelling and traceability outlined in Commission Implementing Decision (EU) 2015/698 for 305423 soybeans.

“The words ‘with increased monounsaturated fat and reduced polyunsaturated fat’ shall appear after the name of the organism” [genetically modified “soybean”] “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 soybean with the exception of products referred to in point (a) of Article 2” (foods and food ingredients containing, consisting of, or produced from 305423 soybean).

In accordance with Commission Regulation (EC) No 65/2004 (EC, 2004) and the OECD guidance for the designation of a unique identifier for transgenic plants (OECD, 2002a), the unique identification code assigned to 305423 soybean is DP-3Ø5423-1.

References

References for further reading are available under: http://www.plenish.com/

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