

Fact-sheet

Cultivance®
Soybean CV127
Unique Identifier BPS-CV127-9

July 2019

CV127 Soybean: Information for Operators

This document summarizes the main characteristics of CV127 soybean. It is directed to operators handling commodity mixtures of imported soybean that may contain viable grain from this product.

CV127 Soybean Product Information

Herbicide-tolerant CV127 soybean plants were developed by BASF Plant Science and the public Brazilian Agricultural Research Corporation Embrapa. CV127 soybean contains a mutant AHASL protein from *Arabidopsis thaliana*, which confers tolerance to the imidazolinone class of agricultural herbicides.

The herbicide-tolerant CV127 soybean varieties (commercial name Cultivance®) were developed to address weed control challenges to soybean growers primarily in Brazil and Argentina. Introduction of CV127 soybean varieties will offer soybean growers an additional tool for controlling problem weeds in these countries, as well as an important option for weed resistance management.

The imidazolinone herbicides provide broad-spectrum weed control and possess high biological efficacy at low application rates. Herbicides based on the imidazolinone active ingredient offer an alternative mode of action to control weeds that may be or may become tolerant to other active ingredients. Due to the favourable characteristics of the imidazolinone herbicides, their use in combination with CV127 soybean varieties will provide a safe and environmentally beneficial system of weed control.

Safety of CV127 Soybean

The food and feed safety of CV127 soybean was established based on results of a series of inter-related safety assessment studies. CV127 soybean was exhaustively analysed for potential effects on human and animal health. The studies included a molecular characterization of CV127 soybean demonstrating the stability of the inserted genetic elements, characterization of AHAS proteins produced in the CV127 soybean plant, lack of any allergenicity or toxicity characteristics associated with the AHAS protein and CV127 soybean, as well as the nutrient composition of the soybean grain, forage and grain processed fractions. The results of these studies show that CV127 soybeans are as safe for food and feed uses as conventional soybeans.

The environmental safety of CV127 soybean was demonstrated based on an evaluation of the agronomic and phenotypic characteristics of CV127 soybean and determination of the ecological impact of culturing CV127 soybean. Data from these studies demonstrated that CV127 soybean has no different agronomic or phenotypic characteristics, disease or insect interactions, seed germination or pollen number and germination characteristics, than conventional soybean varieties.

EFSA Assessment of CV127 Soybean

The Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) was asked to deliver a scientific opinion on the safety of CV127 soybean for import, processing and food and feed uses within the European Union (EU).

On 17 January 2014, EFSA issued a positive scientific opinion stating that:

“In conclusion, the EFSA GMO Panel considers that the information available for soybean BPS-CV127-9 addresses scientific comments raised by Member States and that the soybean BPS-CV127-9, as described in this application, is as safe and nutritious as its conventional counterpart and commercial soybean varieties with respect to potential effects on human and animal health and the environment in the context of its intended uses.”

The complete Scientific Opinion can be retrieved from the EFSA website at:

<http://www.efsa.europa.eu/de/efsajournal/pub/3505.htm>

Authorisation of CV127 Soybean in the EU

On 24 April 2015, Commission Decision (EU) 2015/691 authorised the placing on the market of genetically modified soybean BPS-CV127-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. The authorisation holder is BASF Plant Science GmbH.

The following products are authorised

- a) foods and food ingredients containing, consisting of, or produced from BPS-CV127-9 soybean;
- b) feed containing, consisting of, or produced from BPS-CV127-9 soybean with the exception of forage;
- c) BPS-CV127-9 soybean, in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

Please also refer to the Community Register of GM Food and Feed using the following link:

http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=66

Labelling of Food and Feed Derived from CV127 Soybean in the EU

No specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from CV127 soybean. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of products containing or consisting of the GMO for which authorisation is requested, with the exception of food products, should be complemented by a clear indication that the products in question must not be used for cultivation.

Regulation (EC) No 1830/2003 of the European Parliament and of the Council lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs.

Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

The Unique identifier assigned to CV127 soybean is **BPS-CV127-9**.

For the purpose of the 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' will be 'soybean'. The words 'not for cultivation' will appear on the label of and in documents accompanying products containing or consisting of CV127 soybean.

The label will also declare the unique identifier BPS-CV127-9. In addition, the labelling will indicate how to access the information in the publicly accessible part of the register. Operators handling CV127 soybean can refer to a public register that is available on the European Union Commission website. The Community register of genetically modified food and feed can be accessed via http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

The labelling information that is required by Annex IV of Directive 2001/18/EC on a label or in an enclosed document will include a statement '*This product contains genetically modified soybean*' and the commercial name of the GMO (Cultivance®).

Method for Detection

An event-specific real-time PCR based method for the quantification of CV127 soybean has been validated by the European Union Reference Laboratory (EURL) of the Joint Research Centre (JRC) and was published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>.

Certified reference material of CV127 (AOCS 0911-B and AOCS 0911-D) is available from the American Oil Chemists Society (AOCS) at <http://www.aocs.org/tech/crm>.

Specific Conditions for Handling and Post Market Environmental Monitoring of CV127 Soybean in the EU

The Decision does not require specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling of CV127 soybean. Likewise, post-market monitoring for the use of the food and feed is not required.

However, a post-market environmental monitoring plan for CV127 soybean was developed as required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No. 1829/2003. The proposed monitoring plan for CV127 has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC.

Since traders may commingle soybean BPS-CV127-9 with other commercial soybean, including authorised GM soybean, BASF Plant Science 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 a harmonised monitoring methodology.

Consequently, the European trade associations COCERAL, UNISTOCK and FEDIOL shall

notify EuropaBio of the results of the general surveillance on an annual basis. EuropaBio, shall forward this report to the respective authorisation holders for inclusion in their annual report to the European Commission. The general framework for monitoring of GMOs including soybean BPS-CV127-9 that the different parties agreed on is described in the Monitoring Plan that is available online via the Community Register of GM Food and Feed: http://ec.europa.eu/food/dyna/gm_register/MonitoringplanBPSCV1279.pdf.

Contact Points for Operators

EuropaBio, the European Association for Bioindustries, hosts a website that intends to provide operators who are handling GM commodities in the EU with a list of GM products currently authorised for import and use in the Community according to Directive 2001/18/EC and/or Regulation (EC) No 1829/2003 and which are subject to General Surveillance (<http://www.europabio.org/information-operators-introduction>). For each GM product, an extensive documentation on the product is provided once the product is authorised in the European Community.

EuropaBio acts as the central communication point for reporting general surveillance activities or any unanticipated adverse effects, and is skilled to provide adequate response. In addition, EuropaBio will transfer the messages to the relevant authorisation holder.

Operators are requested to report, any unanticipated adverse effect to EuropaBio at info-operator@europabio.org.