2021 Annual Report on the General Surveillance of CV127 soybean in the EU

BASF Plant Science GmbH

Submitted on

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ANNUAL REPORT ON THE GENERAL SURVEILLANCE OF CV127 SOYBEAN IN THE EU

1. General information

1.1 Crop/trait(s): CV127 soybean / Imidazolinone herbicide tolerance

1.2 Decision authorisation number pursuant to Directive 2001/18/EC and number and date of consent pursuant to Directive 2001/18/EC: NA[1]

1.3 Decision authorisation number and date of authorisation pursuant to Regulation (EC) No 1829/2003: Commission Implementing Decision (EU) 2015/691 of 24 April 2015

1.4 Unique identifier: BPS-CV127-5

1.5 Reporting period from: July 2020 to June 2021

1.6 Other monitoring reports have been submitted in respect of cultivation: No

2. Executive summary

On 24 April 2015, Commission Implementing Decision (EU) 2015/691[2] authorised the placing on the market of CV127 (BPS-CV127-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. This authorization is addressed to BASF Plant Science GmbH and covers the following products:
a) foods and food ingredients containing, consisting of, or produced from CV127 soybean;
b) feed containing, consisting of, or produced from CV127 soybean with the exception of forage;
c) products other than food and feed containing or consisting of CV127 soybean for the same uses as any other soybean with the exception of cultivation.

In accordance with Directive 2001/18/EC and Article 4 of Commission Implementing Decision (EU) 2015/691, the authorisation holder for CV127 soybean, BASF Plant Science GmbH, shall ensure that the monitoring plan, contained in the application and consisting of a general surveillance plan, is put in place and implemented. In addition, Article 4 of Commission Decision (EU) 2015/691 stipulates that the authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan.

Since BASF Plant Science GmbH as the authorization holder for CV127 soybean is not involved in soybean commodity trade, the general surveillance is based on routine observations by European trade associations, namely operators that are involved in import, handling or processing

[1] NA: not applicable.
[2] Commission Implementing Decision of 24 April 2015 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean BPS-CV127-9 (BPS-CV127-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council ((EU) 2015/691). *Official Journal of the European Union* L 112/40, 30.4.2015.

of soybean. Considering the reports that are provided by the operators, there are no indications of any unanticipated adverse effect of the GM product towards the human health or the environment that have arisen from handling and use of viable CV127 soybean. In addition, no adverse findings related to CV127 soybean were reported in the public scientific literature. Taking into account the available information, there is no occurrence of adverse effects arising from CV127 soybean, and therefore a revision of the general surveillance plan is not considered necessary.

3. Uses of GMOs other than cultivation

3.1 Commodity imports into the Community

3.1.1 Commodity crop (GM + non-GM) imports into the EU and UK by country of origin

Country of origin[3]	Quantity[4] (EU import in tons)	Quantity[5] (UK import in tons)
*Brazil**	7.593.409,9	412.053,1
*United States**	5.245.767,0	188.075,9
*Canada**	1.292.383,1	164.840,5
Ukraine	411.426,7	11.106,7
Serbia	128.439,2	0
Argentina*	70.071,9	2.330,0
Paraguay*	29.697,3	0
Uruguay*	8.614,4	0
All Other Countries	152.925,2	3.215,9
TOTAL	**14.932.734,7**	**781.622,1**

[3] Data are provided for the main exporting countries (*italic*), which combined make up approximately 98 % of total soybean imports from outside the EU and approximately 99 % of total soybean imports from outside the UK. Data for exporting countries where CV127 soybean is authorised for cultivation are marked with "*". For the full list of exporting countries and detailed information on commodity types please refer to Annex 2 and Annex 3.

[4] Source: Eurostat (2021) data covers 27 EU Member States (July 2020 to June 2021). Data extracted October 2021, collected by CropLife Europe (see Annex 2).

[5] Source: HMRC/AHDB (2021) data for UK covers Great Britain and Northern Ireland (July 2020 to June 2021) as it is not possible to extract the data for Great Britain separately. Data extracted October 2021, collected by CropLife Europe (see Annex 3).

3.1.2 Commodity Crop (GM + non-GM) imports from outside the EU and the UK by country of destination

Destination country	Quantity[6] (tons) July 2020 - June 2021
Netherlands	4.410.358,1
Spain	3.206.955,7
Germany	2.415.299,7
Italy	2.248.932,9
Portugal	1.214.093,4
United Kingdom	781.622,1
France	530.362,8
Belgium	302.519,6
Greece	259.011,0
Romania	183.556,7
Hungary	55.452,5
Austria	29.032,9
Slovenia	23.953,3
Finland	14.705,8
Poland	12.999,7
Sweden	12.689,6
Croatia	5.043,2
Denmark	2.651,1
Lithuania	2.603,0
Czechia	908,7
Slovakia	742,9
Bulgaria	462,4
Estonia	226,5
Ireland	171,9
Cyprus	1,3
Luxembourg	0,2

[6] Sources: Eurostat (2021) data covers 27 EU Member States (July 2020 to June 2021). HMRC/AHDB (2021) data for UK covers Great Britain and Northern Ireland (July 2020 to June 2021).

3.1.3 Analysis of data provided in tables 3.1.1 and 3.1.2

The authorisation holder, via CropLife Europe, has collected data on soybean imports (GM and non-GM) into the EU and UK for the period of July 2020 to June 2021.

For the EU, according to this data, total imports of soybean were 14.932.734,7 tons and the main exporters of soybean to the EU were Brazil, the United States, Canada, Ukraine, and Serbia which together accounted for approximately 98 % of total extra-EU soybean imports (**Table 3.1.1)**.

CV127 soybean was authorised for cultivation in Brazil, the United States, Canada, Argentina, Paraguay, and Uruguay. The total EU soybean imports from Brazil, the United States, Canada, Argentina, Paraguay, and Uruguay were 7.593.409,9, 5.245.767,0, 1.292.383,1, 70.071,9, 29.697,3 and 8.614,4 tons respectively. Brazil, the United States, Canada, Argentina, Paraguay, and Uruguay soybean exports to the EU accounted for around 95 % of total extra-EU soybean imports (**Table 3.1.1**).

The main import countries for soybean in the EU were the Netherlands, Spain, Germany, Italy, and Portugal. They are accounting together for 90 % of the total soybean imports. Other main import markets of extra-EU soybean are France, Belgium, Greece, and Romania (**Table 3.1.2**).

For the UK, according to this data, total imports of soybean were 781.622,1 tons and the main exporters of soybean to the UK were Brazil, the United States, Canada, and Ukraine which accounted for approximately 99 % of total extra-UK soybean imports (**Table 3.1.1)**.

CV127 soybean was authorised for cultivation in Brazil, the United States, Canada, and Argentina. The total UK soybean imports from Brazil, the United States, Canada, and Argentina were 412.053,1, 188.075,9, 164.840,5 and 2.330,0 tons respectively. Brazil, the United States, Canada, and Argentina soybean exports to the UK accounted for nearly 98 % of total extra-UK soybean imports (**Table 3.1.1**).

3.2 General Surveillance

3.2.1 Description of General Surveillance

The current approach used for general surveillance represents the consensus between all authorisation holders within CropLife Europe and has been endorsed by the operators involved in the trade of viable soybean commodity (listed in Section 3.2.2).

The authorisation holder is not involved in commodity trade with CV127 soybean. The monitoring methodology hence needs to be predominantly based on collaboration with third parties, such as operators involved in the import, handling and processing of viable CV127 soybean. They are exposed to the imported viable CV127 soybean and therefore are the best placed to observe and report any unanticipated adverse effects in the framework of their routine surveillance of the commodities they handle and use. The routine surveillance is based on the HACCP principles.

Since traders may commingle CV127 soybean with other commercial soybean, including authorised GM soybean, the authorisation holder is working together with other members of the industry within CropLife Europe and trade associations representing the relevant operators

in order to implement a harmonised monitoring methodology.

The different parties agreed to collaborate on the following basis:

⇒ The consent holder represented by CropLife Europe shall:

- Agree with the operators before adding or amending activities that fall under their responsibility in accordance with the proposed monitoring plan.
- Inform the operators in a timely fashion of any newly approved GM plant products for import and processing under Regulation (EC) No 1829/2003 or Directive 2001/18/EC subject to general surveillance.
- Set up and maintain a website dedicated to operators that provides an overview and detailed information on approved GM plant products subject to general surveillance. The website, hosted on the CropLife Europe website under https://croplifeeurope.eu/product-information/, contains the following information:
  - An introduction to the purpose of the website
  - A table giving an overview of all currently approved GM plant products subject to general surveillance
  - A profile for every approved GM plant product providing documentation on characteristics and safety, positive EFSA opinion(s) and Commission Decisions(s) authorising the GM plant product in the EU
  - A contact point at CropLife Europe for information exchange on any of the GM plant products

The website will be regularly updated in order to further facilitate and ensure a transparent process for general surveillance and easy access to relevant information for operators.

- Contact the selected networks of operators annually, providing them with an update on the approved GM plant products subject to general surveillance and reminding them of their agreement to report on any unanticipated adverse effects (or absence thereof).

⇒ The selected networks of operators (European trade associations) shall:

- Inform and remind their member organisations and companies on an annual basis
  - to monitor for potential unanticipated adverse effects
  - 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 consent holders directly or via CropLife Europe
  - at least annually, regardless of whether an adverse effect was observed or not
  - immediately any adverse effects reported to them

Consequently, the European trade associations shall notify CropLife Europe of the results of the general surveillance on an annual basis. The report shall cover all approved GM plant products subject to general surveillance. CropLife Europe shall forward this report to the respective authorisation holders for inclusion in their annual report to the European Commission.

The general surveillance information reported to and collected by the authorisation holder from the European trade associations or other sources shall be analysed for its relevance.

Where information indicates the possibility of an unanticipated adverse effect, the authorisation holder will immediately investigate to determine and confirm whether a significant correlation between the effect and CV127 soybean can be established. If the investigation establishes that CV127 soybean was present when the adverse effect was identified and confirms that CV127 soybean is the cause of the adverse effect, the authorisation holder shall immediately inform the European Commission. The authorisation holder, in collaboration with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, shall define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the observed effect.

As described in the bullet points above, the authorisation holder shall submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report shall contain information on any unanticipated adverse effects that have arisen from handling and use of viable CV127 soybean.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of CV127 soybean and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

3.2.2 Details of industry, environmental, food and/or feed related surveillance networks used during General Surveillance

The authorisation holder, together with other members of the industry and CropLife Europe, will implement general surveillance of viable GM soybean, including CV127 soybean, with the help of the selected networks described below, according to the methodology outlined in the authorisation holder's general surveillance plan and as detailed in Section 3.2.1. The following networks are currently involved:

⇒ *Importers / Traders*

COCERAL is the European association of trade in cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agrosupply. It represents the interests of the European collectors, traders, importers, exporters, and port silo storekeepers of the above-mentioned agricultural products. The main importers of cereals and feedstuffs into the EU are members of COCERAL.

Also see: http://www.coceral.com

⇒ *Silo Operators*

UNISTOCK is the European association representing professional storekeepers for agribulk commodities within the EU. UNISTOCK full and extraordinary members are present in twelve countries and UNISTOCK is itself a full member of COCERAL. Commodity imports enter the EU by sea and transit through sea-port silos. The main storekeepers managing these silos are members of UNISTOCK.

Also see: http://www.unistock.be/

⇒ *Processors*

FEDIOL, the federation of the EU vegetable Oil and Protein Meal Industry, represents the interests of the European crushers of oilseeds, meal producers and vegetable oil producers/processors.

Also see: http://www.fediol.eu/

These associations represent the majority of European operators importing, handling and processing viable soybean commodity. They work closely together with a continuous and efficient flow of communication between them, particularly, through the documentation that needs to accompany any shipment containing GMOs in accordance with the labelling and traceability requirements of Regulation (EC) No 1830/2003 and are therefore best placed to observe and report any unanticipated adverse effects.

Other networks consisting of operators further down the food and feed chain have not been selected for the general surveillance of viable CV127 soybean, because they focus on processed, non-viable material.

3.2.3 Details of information and/or training provided to importers, traders, handlers, processors, etc.

The authorisation holder directly informed the selected network of operators (i.e., COCERAL, UNISTOCK and FEDIOL) that CV127 soybean was authorised pursuant to Regulation (EC) No 1829/2003 by Commission Implementing Decision (EU) 2015/691 and that a website dedicated to operators that provides an overview and detailed information on the authorised CV127 soybean has been made available as described below.

Specific information concerning the safety, general characteristics and the general surveillance conditions for CV127 soybean was uploaded in a website dedicated to trade associations representing the relevant operators that import, handle and process viable soybean commodity in the EU, providing an overview and detailed information on approved GM plant products subject to general surveillance. The website, hosted on the CropLife Europe website under https://croplifeeurope.eu/product-information/, contains the following information:

-An introduction to the purpose of the website

-A table giving an overview of all currently approved GM plant products subject to general surveillance

-A profile for every approved GM plant product providing documentation on characteristics and safety, positive EFSA opinion(s) and Commission Decision(s) authorising the GM plant product in the EU. The document providing documentation on characteristics and safety for CV127 soybean is attached as Appendix 1 to this annual monitoring report.

-A contact point at CropLife Europe for information exchange on any of the GM plant products

The website will be regularly updated in order to further facilitate and ensure a transparent process for general surveillance and easy access to relevant information for operators.

3.2.4 Results of General Surveillance

The reporting by the trade associations takes place at the end of their business year, i.e., end of June. Therefore, CropLife Europe reminded the trade associations to provide their annual report on any occurrence of unanticipated adverse effects arising from the approved GM products, including CV127 soybean placed on the market during the period from July 2020 to June 2021.

The trade associations implemented the monitoring in the framework of their routine surveillance of the commodities (GM and non-GM) they handle and use. As required in the monitoring plan, they reminded their members "*to monitor for potential unanticipated adverse effects; that, in the framework of their management or safety standards (ISO, HACCP, etc), procedures must be in place and implemented to limit losses and spillage of viable GMOs and to routinely eradicate adventitious populations on their premises – any such adventitious populations, resisting routine eradication procedures, shall be treated as potential adverse effects; To inform and remind their own member companies of this requirement; and to report back any adverse effect reported to them to the European trade associations;*" .

COCERAL, UNISTOCK and FEDIOL members have in place Good Hygiene Practices and Good Manufacturing Practices in their daily operations, at the level of imports, storage, handling, and internal transport of grains and oilseeds commodities, as well as at the level of oilseed crushing and vegetable oil refining, irrespective of the botanical species of the commodity. Such practices form the pre-requisite programmes which are the foundation upon which their HACCP systems are built. Measures implemented in this context to limit losses and spillage of viable grains and oilseeds, as well as clean-up and eradication measures (in case of accidental spillage), allow trade associations to report any adverse effect that would be considered as "unusual" or "unanticipated" and potentially attributable to GMOs.

The trade associations informed CropLife Europe in a format that reiterates the terms of the agreement of the general surveillance system and reports on the outcome of the monitoring. The format allows the authorisation holder to comply with the requirement to give evidence to the Commission and the Competent Authorities that the system is in place; that the trade associations are aware of the requirement to monitor; and, that they are providing information on any observed unanticipated adverse effects, if any.

The reports received from COCERAL, UNISTOCK and FEDIOL indicate that no adverse effects were reported from their members, thus implying that no adverse effects were linked to the presence of CV127 soybean in the time period from July 2020 to June 2021 (see Appendix 2 and Appendix 3). Furthermore, no incidents in relation to the placing on the market of CV127 soybean have been reported to CropLife Europe or the authorisation holder since July 2021 to date.

3.2.5 Additional Information

Not applicable since no adverse or unanticipated effects were reported.

3.2.6 Review of peer-reviewed publications

The authorisation holder actively monitors peer-reviewed scientific literature related to its products. In the light of the 2021 annual general surveillance report for CV127 soybean, a scoping review was performed for CV127 and its newly expressed protein, AHAS. The

objective of this scoping review was to determine if there were studies about the molecular characterization of CV127 soybean, its effect on food and feed safety or environmental safety, that might require an in-depth examination. A set of broad literature searches was performed using several bibliographic databases covering the scientific literature from October 1, 2020 to September 30, 2021. Additional sources of information, such as web pages of food safety, agriculture, and biotechnology-related authorities were searched for the same time window, along with the bibliographies of relevant reviews. The references identified were evaluated for potential relevance to the scoping review questions according to pre-defined criteria.

These literature searches identified a total of 517 unique publications, which were subject to rapid assessment to exclude obviously irrelevant publications. A total of eight publications were progressed for detailed assessment.

Two of the eight publications were determined to be relevant after detailed review. The relevant articles did not constitute new data on molecular characterization of CV127 soybean, or the AHAS protein, nor did it suggest any potential adverse effects on human and animal health or on the environment. No evidence was identified that would warrant conducting a systematic review.

In summary, these literature searches and review of the retrieved articles identified two relevant publications that support the existing safety assessment of CV127 soybean (Annex 1_CV127 literature review).

3.3 Case-Specific Monitoring

3.3.1 Description and results of Case-Specific Monitoring (if applicable)

The scientific evaluation of the characteristics of CV127 soybean in the environmental risk assessment (ERA) has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of CV127 soybean. It is therefore considered that there is no need for case-specific monitoring.

3.3.2 Processing (if applicable)

Not applicable.

3.3.3 Monitoring and reporting of adverse effects resulting from accidental spillage (Not applicable)

3.4 Concluding remarks

The information reported to and collected by the authorisation holder within the frame of the general surveillance accompanying the placing on the market of CV127 soybean in the EU indicates that there have been no adverse health or environmental effects associated with the importation or use of CV127 soybean. The reports received from COCERAL, UNISTOCK and FEDIOL show that no adverse effects linked to the presence of CV127 soybean were recorded and no adverse findings from independent research relating to CV127 soybean have been published.

4. Summary of Results and Conclusions

To date, the general surveillance accompanying the placing on the market of CV127 soybean in the EU indicates that there have been no adverse health or environmental effects associated with the importation or use of CV127 soybean.

Taking into account:

a) the favourable scientific evaluations by scientists and regulatory agencies around the world;
b) our experience with this product;
c) the reports from the European trade associations (operators involved in the import, handling and processing of viable CV127 soybean) who are selected as the most appropriate participants in the general surveillance network;
d) the lack of adverse findings from independent research, available through the public literature;
e) the fact that no adverse effects for CV127 soybean have been reported to the authorisation holder

there is, to the best of our knowledge, no information available that questions the conclusion that CV127 soybean does not pose any greater risk to health or the environment than conventional soybean.

5. Adaptation of the Monitoring Plan and Associated Methodology for future years

In view of the results given in this report, no revisions to the general surveillance plan are considered necessary for CV127 soybean.

Signed: **BASF Plant Science GmbH**

Date: **14th December 2021**