Annual report on the implementation and the results of the monitoring activities for Corteva Agriscience soybean products

Single events	**Stacks**
DAS-44406-6	DAS-81419-2 x DAS-44406-6
DAS-81419-2	

December 2022

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1 GENERAL INFORMATION

1.1 Crop/trait(s)

Soybean / insect protection and/or herbicide tolerance traits, hereafter referred to as "these GM soybean":

- DAS-44406-6 soybean
- DAS-81419-2 soybean
- DAS-81419-2xDAS-44406-6 soybean

1.2 Decision authorisation number under Directive 2001/18/EC and number and date of consent under Directive 2001/18/EC

Not applicable

1.3 Decision authorisation number and date under Regulation (EC) No 1829/2003[1]

• DAS-44406-6 soybean	Commission implementing decision (EU) 2017/2450 of 21 December 2017 (EC, 2017) amended by Commission implementing decision (EU) 2021/1185 of 13 July 2021 as regards the representative or the authorisation holder (EC, 2021a)
• DAS-81419-2 soybean	Commission Implementing Decision (EU) 2021/1386 of 17 August 2021 (EC, 2021b)
• DAS-81419-2xDAS-44406-6 soybean	Commission Implementing Decision (EU) 2021/1387 of 17 August 2021 (EC, 2021c)

1.4 Unique identifier

- DAS44406-6 soybean : DAS-444Ø6-6
- DAS-81419-2 soybean: DAS-81419-2
- DAS-81419-2xDAS-44406-6 soybean : DAS-81419-2xDAS-444Ø6-6

1.5 Reporting period from

July 2021 - June 2022

1.6 Other monitoring reports have been submitted in respect of cultivation

Yes ☐ No ☒

[1] All Commission decisions adopted prior to 31 December 2020 have been transposed into UK legislation and can be found at https://www.legislation.gov.uk/ and relevant amendments for the UK are provided in the Statutory instruments Statutory Instruments 2019 No. 705, Statutory Instruments 2020 No. 1504

2 EXECUTIVE SUMMARY

DAS-44406-6 soybean has been developed by Corteva Agriscience LLC and M.S. Technologies LLC. DAS-81419-2 and DAS-81419-2xDAS-44406-6 soybeans have been developed by Corteva Agriscience LLC, represented in the EU by Corteva Agriscience Belgium B.V. and in the UK by Corteva Agriscience UK Limited, hereafter referred to as Corteva.

Corteva is the authorisation holder for the approval for placing on the market of these GM soybean for food and feed uses, import and processing. The purpose of this report is to provide information on the implementation and results of monitoring activities carried out by the authorisation holder in accordance with Directive 2001/18/EC (EC, 2001) and Regulation (EC) No 1829/2003 (EC, 2003a), Decision 2009/770/EC (EC, 2009) and as required under the respective authorisations outlined in Section 1.3. The monitoring requirements outlined in the corresponding decisions consist primarily of the implementation and reporting on the results of the monitoring plans in accordance with Annex VII to Directive 2001/18/EC (EC, 2001). No additional monitoring requirements apply for the use of these GM soybean as or in food. Monitoring applies for the duration of the authorisation(s).

During this latest reporting period, monitoring activities for these GM soybean, in particular general surveillance, were carried out in accordance with the monitoring plans and in line with the conditions laid out in the Decisions. The results of the monitoring confirm **no adverse effects on human and animal health or the environment have arisen from the import of these GM soybean into the EU or Great Britain (GB) for this annual reporting period.** These findings concur with those of the previous annual monitoring report.

3 USES OF GMOs OTHER THAN CULTIVATION

3.1 Commodity imports into the EU and UK

3.1.1 Commodity crop (GM and non-GM) imports into the EU and the UK by country of origin for reporting period in tons

Country of origin[1]	Quantity (EU)[5]	Quantity (UK)[6]	Estimated data of potential share of these GM soybean in imports (where not possible approximate share of cultivation in the country of origin), for each specified product[7]
Brazil[2]	8 579 199	426 197	[redacted]
United States of America[3]	4 104 047	188 851	[redacted]
Canada[3]	1 147 654	104 215	[redacted]
Ukraine	442 914	-	NA
Togo	92 907	-	NA
Other countries[4]	111 044	4 223	NA
Total from countries cultivating these GM soybean	13 840 483	719 263	
Total from all countries (GM and non-GM soybean)	14 477 766	723 487	

[1] Main countries exporting soybean to the EU and UK which combined make up approximately 99% of total soybean imports. The countries representing collectively less than 1% of the total imports are indicated as "Other countries". The full list of countries exporting soybeans to the EU and UK, as collected by CropLife Europe is provided in Annex 1.

[2] Exporting country where DAS-44406-6 and DAS-81419-2xDAS-44406-6 soybean was cultivated in 2021 and/or 2022.

[3] Exporting country where DAS-44406-6 soybean was cultivated in 2022.

[4] It shall be noted that DAS-44406-6 and DAS-81419-2xDAS-44406-6 soybean were cultivated in Argentina which exported 9.500 tons to the EU[5].

[5] Quantity imported rounded to nearest ton. Source: EUROSTAT 2022 (extracted October 2022) collected by CropLife Europe (see Annex 1).

[6] Quantity imported rounded to nearest ton. Source: HMRC/AHDB 2022 (extracted September 2022), collected by CropLife Europe (see Annex 1). Data for the UK covers Great Britain and Northern Ireland as it is not possible to extract the data for Great Britain separately.

[7] The authorisation holder is not an operator directly involved in the import soybean oilseed into the EU or UK for food/feed and processing. Therefore, it is not in a position to report directly on globally traded volumes of grain of the GM soybean covered by these authorisations. However, in order to provide an estimate of the amount of these GM soybean that could possibly be imported into the EU, the approximate share of cultivation in the country of origin is provided, for each specified GM soybean product (see footnotes 2-3), expressed as "NA" (not applicable, GM soybean covered by these authorisations were not cultivated in the country), "0-10%", 10-20%", "20-40%", "40-60%", "60-80%, or 80-100%". It must be kept in mind that these figures are estimates only, and that the potential amount of these GM soybean that will be exported to the EU will only represent a portion of the cultivated amounts.

3.1.2 Commodity crop (GM and non-GM) imports from outside the EU and the UK by country of destination for reporting period in tons

Destination	Quantity[1]
Austria	14 396
Belgium	455 901
Bulgaria	1 169
Croatia	500
Cyprus	-
Czech Republic	1 768
Denmark	1 564
Estonia	-
Finland	4 929
France	532 245
Germany	2 153 808
Greece	239 236
Hungary	32 883
Ireland	24 811
Italy	2 231 203
Latvia	-
Lithuania	773
Luxembourg	-
Malta	-
Netherlands	3 997 264
Poland	60 587
Portugal	1 020 033
Romania	245 046
Slovakia	3 867
Slovenia	3 563
Spain	3 441 597
Sweden	10 623
United Kingdom	723 487

[1] Sources: Eurostat (2022) data covers EU, HMRC/AHDB (2022) data for UK covers Great Britain and Northern Ireland.

3.1.3 Analysis of data provided in tables 3.1.1 and 3.1.2

Corteva, via CropLife Europe, has collected data on soybean imports (GM and non-GM) into the EU and UK for the reporting period from July 2021 to June 2022.

For the EU, according to this data, total imports of soybean represented approximately 14.5 million tons and the main exporters of soybean to the EU were Brazil, the United States of America, Canada, Ukraine and Togo which together accounted for approximately 99% of total extra-EU soybean imports (Table 3.1.1). Section 3.1.1 also provides estimates for potential share for these GM soybean based on data from the authorisation holders.

During the July 2021 to June 2022 period, the main importer country for extra-EU soybean in the EU were the Netherlands, Spain, Italy, Germany and Portugal. Together, they accounted for nearly 88% of the total extra-EU soybean imports. Other significant import markets for extra-EU soybean in the EU were France and Belgium (Table 3.1.2).

For the UK, according to the collected data, total imports of soybean were approximately 0.73 million tons and the main exporters of soybean to the UK were Brazil, the Unites States of America and Canada, which together accounted for approximately 99% of total extra-UK soybean imports (Table 3.1.1). Section 3.1.1 also provides estimates for potential share for these GM soybean based on data from the authorisation holders.

Extra-EU and UK soybean imports vary from year to year depending on several factors (e.g. annual EU or UK soybean harvest yields, the international currencies exchange rates, soybean price, transportation costs).

Bulk shipments of soybean entering the EU and UK are typically processed into compound animal feed, whereby the processed feed is unlikely to contain whole soybean seeds. The handling of the shipments is the same across Europe; upon arrival, shipments being unloaded into silos at the port of the importing country and transferred from there to feed processing plants adjacent to the port.

Regulation (EC) No 178/2002 regarding the general principles and requirements of food law and food safety procedures (EC, 2002), Regulation (EC) No 852/2004 on the hygiene of foodstuffs (EC, 2004), and Regulation (EC) No 183/2005 regarding feed hygiene (EC, 2005) contain operational rules and standards applicable to the handling of soybean imports. In accordance with these Regulations, the principles of HACCP (Hazard Analysis and Critical Control Points) apply.

3.2 General surveillance

3.2.1 Description of General Surveillance

The current approach used for general surveillance is based upon a consensus between all consent/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).

Corteva is not involved in commodity trade with these GM soybean. The monitoring methodology is, therefore, predominantly based on collaboration with third parties, such as operators involved in the import, handling and processing of viable these GM soybean. These operators are exposed to the imported viable these GM soybean and therefore are 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 as reflected on the website of the trade associations representing the operators involved in the post-market environmental monitoring (see below).

Since traders may co-mingle these GM soybean with other commercial soybean, including authorised GM soybean, the authorisation holder works together with other members of the plant biotechnology industry within CropLife Europe and trade associations representing the relevant operators in order to implement a harmonised monitoring methodology.

The different parties agreed on a general framework for monitoring of GMOs, including these GM soybean, as follows:

⇒ The authorisation holders represented by CropLife Europe shall:

- Agree with the operators before adding or amending activities that fall under their responsibility in accordance with the proposed post-market environmental monitoring plan.
- Inform operators concerning the authorisation, safety and general characteristics of these GM soybean and of the conditions as to general surveillance.
- Set up and maintain a website dedicated to operators including detailed information on these GM soybean. 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
  - 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 and GB
  - 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 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
  - 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 GMOs and to routinely eradicate adventitious populations on their premises
  - 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 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, COCERAL, UNISTOCK and FEDIOL, shall notify CropLife Europe of the results of the general surveillance on an annual basis. CropLife Europe shall forward this report to the respective authorisation holder for inclusion in their annual report to the European Commission and the Food Safety Agency (FSA).

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 these GM soybean can be established. If the investigation establishes that these GM soybean was present when the adverse effect was identified, and confirms that these GM soybean is the cause of the adverse effect, the authorisation holder shall immediately inform the European Commission and the FSA. The authorisation holder, in collaboration with the European Commission and the FSA 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, if any, that have arisen from handling and use of viable these GM soybean.

The report shall include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of these GM 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 plant biotechnology industry and CropLife Europe, implements general surveillance of viable GM soybean, including these GM soybean, with the help of the selected networks described below, according to the methodology outlined in the authorisation holder' 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 agro-supply. 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 in 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 oilseed, meal producers and vegetable oil producers/processors. Its members represent around 85% of the EU industry.
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 (EC, 2003b), 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 these GM 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 monitoring plan for these GM soybean (and the agreement with the network of operators, see Section 3.2.1) requires that the authorisation holder informs operators and

users of the introduction of these GM soybean into the EU and GB as well as on the safety and general characteristics of the product and of the conditions as to monitoring. Accordingly, the authorisation holder undertook to provide the necessary and relevant information concerning the placing on the market of these GM soybean to the relevant stakeholders within the first year following the authorisation of these GM soybean.

A summary of the information provided to the operators in accordance with the general surveillance system is provided under Section 3.2.1 of this report.

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. 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 these GM soybean, placed on the market during the period from July 2021 to June 2022.

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, the FSA 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 these GM soybean in the time period from July 2021 to June 2022 (see Annexes 2 and 3). Furthermore, no incidents in relation to the placing on the market of these GM soybean have been reported to CropLife Europe or the authorisation holder since July 2021 to date.

3.2.5 Additional information

Contact points for Corteva in in the EU and UK have been made available to operators and users as part of the information provided in the fact-sheet on these GM soybean (published on the CropLife Europe website). This allows operators and users to contact the authorisation holder directly for inquiries or to report any unusual effects observed in relation to the product.

To date, no inquiries or reports of unusual effects observed in relation with these GM soybean have been received.

3.2.6 Review of peer-reviewed publications

An updated systematic search and review of peer-reviewed literature, in line with the EFSA guidance on conducting a systematic review (EFSA, 2010) and taking into account the explanatory note on literature searching (EFSA, 2019), was conducted with the following review question “Do these GM soybean and derived food/feed products, or the intended traits (the newly expressed protein(s)), have adverse effects on human and animal health and the environment in the scope of their authorisations?”, as described in Annex 4. The current systematic search complements the searches previously performed in the frame of the 2021 annual monitoring report.

The review question and the search procedure took into account the product and scope of the authorisation (i.e., authorisation for import into the EU and GB of food and feed containing, consisting of, or produced from these GM soybean) and the objectives of the studies (i.e., assessment of potential adverse effects on human and animal health and the environment of the genetically modified food and feed containing, consisting of or produced from these GM soybean). The systematic searches were performed according to the relevant parts of the EFSA guidance on the application of systematic review methodology to food and feed safety assessments (EFSA, 2010). The fundamental principles followed in this study were (1) methodological rigour and coherence in the retrieval and selection of studies; (2) transparency; and (3) reproducibility. Each search used a procedure that was developed *a priori*.

The systematic search and review of studies published in the scientific literature followed a tiered approach that included: (i) a systematic literature search, (ii) a screening of the retrieved records for relevance to the review question, and (iii) a thorough analysis of potential studies that were considered relevant, if any.

The outcome of this systematic literature search and review showed that no publication was identified as relevant for the review question within the selected time-period (see

Annex 4). No safety concerns have been identified for these GM soybean by this literature search exercise.

3.3 Case-Specific Monitoring

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

The GMO Panel evaluated the monitoring plan proposed by the authorisation holder and from its risk assessment considered that there was no requirement for a case-specific monitoring since no adverse effects were identified. The monitoring plan consisting of a general surveillance plan is in line with the intended uses for the GMO since the scope does not include cultivation.

3.3.2 Processing (if applicable)

Not applicable (see section 3.3.1).

3.3.3 Monitoring and reporting of adverse effects resulting from accidental spillage (if applicable)

Not applicable (see section 3.3.1).

3.4 Concluding remarks

The results of the monitoring plan of these GM soybean indicate that no adverse effects on human and animal health or the environment have been observed for these GM soybean import and use for food, feed and processing.

4 SUMMARY OF RESULTS AND CONCLUSIONS

Corteva, as authorisation holder, has continued to implement the monitoring requirements in accordance with the relevant articles of the authorising decisions.

The general surveillance system put in place by the plant biotechnology industry and the European trade associations and utilised by the authorisation holder for these GM soybean imports, is functioning well. It provides for monitoring of potential unanticipated adverse effects that might arise from the presence of GMO material (including these GM soybean) during import, handling and processing of crop commodities and ensures that any observed adverse effects are reported immediately to the authorisation holder. Furthermore, the trade associations provide annual reports to the authorisation holder via CropLife Europe for the period from July to June, every year at the end of their business year.

The annual reports provided by the trade associations for the period from July 2021 to June 2022 revealed no adverse effects in the context of the placing on the market of these GM soybean imports (Annexes 2 and 3). Furthermore, no incidents in relation to the placing on the market of these GM soybean were reported to CropLife Europe or the authorisation holder from July 2021 to date. Thus, no adverse effects have been reported by the trade associations from the date of approval of these GM soybean for import and use as or in food, feed and processing to date.

No articles or reports demonstrating adverse effects to human or animal health or the environment arising from these GM soybean in the scope of this authorisation were published in peer-reviewed scientific publications during the current reporting period or before.

As a consequence, the results of the general surveillance of these GM soybean carried out from July 2021 to June 2022 confirm no adverse effects on human and animal health or the environment have arisen from the introduction of these GM soybean into the EU and GB. These findings concur with those of the previous annual monitoring report.

5 ADAPTATIONS OF MONITORING PLAN AND ASSOCIATED METHODOLOGY FOR FUTURE YEARS

In the light of the successful implementation of and results from current monitoring activities, the authorisation holder considers that the general surveillance system in place for the monitoring of these GM soybean imports is fully appropriate and does not require amendment.

Signed: [redacted]

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Date: 19.12.2021

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