Annual report on the implementation and the results of the monitoring activities of DAS-44406-6 soybean authorised by Commission implementing decision (EU) 2017/2450 of 21 December 2017

December 2021

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1 GENERAL INFORMATION

1.1 Crop/trait(s)

Soybean/ herbicide tolerance trait
DAS-44406-6 soybean – also referred to as Enlist E3™ soybean [1] in the commercial context

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

- Commission implementing decision (EU) 2017/2450 of 21 December 2017 amended by Commission implementing decision (EU) 2021/1185 of 13 July 2021 as regards the representative or the authorisation holder (EC, 2021)
- Decisions originating from the EU/ 2017 No. 2449 amended by UK Statutory Instruments/ 2019 No. 705/PART3

1.4 Unique identifier

DAS-444Ø6-6

1.5 Reporting period from

July 2020 - June 2021

1.6 Other monitoring reports have been submitted in respect of cultivation

Yes ☐ No ☒

[1] The transgenic soybean event in Enlist E3® soybeans is jointly developed and owned by Corteva Agriscience and M.S. Technologies L.L.C.

2 EXECUTIVE SUMMARY

DAS-44406-6 soybean has been developed by Dow AgroSciences LLC [2] and M.S. Technologies LLC as represented in the EU by Corteva Agriscience Belgium B.V., here referred to as Corteva). After the assessment made by the European Food Safety Authority (EFSA) (EFSA, 2017), DAS-44406-6 soybean received full European Union (EU) approval for import and use as or in food, feed and processing in December 2017 in accordance with:

> **Commission Implementing Decision (EU) 2017/2450** of 21 December 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-44406-6, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed. This decision has been fully transposed to the UK under (UK) Decisions originating from the EU/2017 No. 2450 (amended by UK Statutory Instruments/ 2019 No. 705/PART3).

Corteva and M.S. Technologies are the authorisation holders for the approval for placing on the market of DAS-44406-6 soybean for import, food and feed. 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), Regulation (EC) No 1829/2003 (EC, 2003a), Decision 2009/770/EC (EC, 2009) and as required under Commission Implementing Decision (EU) 2017/2450 (EC, 2017).

The monitoring requirements outlined in Decision (EU) 2017/2450 (EC, 2017) consist primarily of the implementation and reporting on the results of the monitoring plan that was prepared and submitted by the authorisation holder in accordance with Annex VII to Directive 2001/18/EC (EC, 2001). No additional monitoring requirements apply for the use of DAS-44406-6 soybean as or in food. Monitoring applies for the duration of the authorisation, *i.e.* ten years.

Monitoring activities for DAS-44406-6 soybean, in particular general surveillance, were carried out in accordance with the monitoring plan and in line with the conditions laid out in the Decision. The results of the monitoring confirm **no adverse effects on human and animal health or the environment have arisen from the import of DAS-44406-6 soybean into the EU or Great-Britain (GB) for this annual reporting period.**

[2] Dow AgroSciences LLC changed the name to Corteva Agriscience LLC as of 1 January 2021, and will be further referred to as Corteva

3 USES OF GMOs OTHER THAN CULTIVATION

3.1 Commodity imports into the EU and the UK

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

Country of origin[1]	Quantity (EU imports in tons) [3]	Quantity (UK imports in tons)[4]	Estimated data of potential share of these GM soybean in imports (where not possible approximate share of cultivation in the country of origin)[5]
Brazil	7 593 410	412 053	NA
United States of America[2]	5 245 767	188 076	10%-20%
Canada[2]	1 292 383	164 841	0-10%
Ukraine	411 427	11 107	NA
Serbia	128 439	-	NA
Togo	75 062	-	NA
Argentina	70 072	2 330	
Other countries	186 247	5 546	NA
Total from countries cultivating these GM soybean (GM and non-GM soybean)	6 538 150	352 917	
Total from all countries (GM and non-GM soybean)	14 932 735	781 622	

[1] Data are provided for the main exporting countries, which combined make up approximately 99% of total soybean imports from outside the EU and the UK. For the full list of exporting countries and detailed information on commodity types please refer to Annex 1.

[2] Exporting country where DAS-44406-6 soybean was cultivated in 2020.

[3] Source: Eurostat (2021) data covers 27 EU Member States (July 2020 to June 2021). Data extracted October 2021, collected by CropLife Europe (see Annex 1).

[4] Source: HMRC/AHDB (2021) data for the 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 1).

[5] The authorisation holder is not an operator directly involved in the import of soybean oilseed into the EU or UK for food/feed and processing. The approximate share of cultivation in the country of origin is provided, expressed as "NA" (not applicable, these GM soybeans were not cultivated in the country), "0-10%", 10-20%", "20-40%", "40-60%", "60-80%, or 80-100%".

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

Destination	Quantity (tonnes) 2020-2021[1]
Austria	29.033
Belgium	302.519
Bulgaria	462
Croatia	5.043
Cyprus	1
Czech Republic	909
Denmark	2.651
Estonia	227
Finland	14.706
France	530.363
Germany	2.415.300
Greece	259.011
Hungary	55.453
Ireland	172
Italy	2.248.933
Latvia	-
Lithuania	2.603
Luxembourg	-
Malta	-
Netherlands	4.410.358
Poland	13.000
Portugal	1.214.093
Romania	183.557
Slovakia	743
Slovenia	23.953
Spain	3.206.956
Sweden	12.690
United Kingdom	781.622

[1] Sources: Eurostat (2021) data covers 27 EU Member States (July 2020 to June 2021). HMRC/AHDB (2021) data for the 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[3], has collected data on soybean imports (GM and non-GM) into the EU[4] and UK[5] for the reporting period from July 2020 to June 2021.

For the EU, according to this data, total imports of soybean represented approximately 14,9 million tons and the main exporters of soybean to the EU were Brazil, the United States of America, Canada, Ukraine, Serbia, Togo and Argentina 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 DAS-44406-6 soybean based on data from the authorisation holder.

During the July 2020 to June 2021 period, the main importer countries for extra-EU soybean in the EU were the Netherlands, Spain, Germany and Italy. Together, they accounted for approximately 82,2 % of the total extra-EU soybean imports. Other significant import markets for extra-EU soybean in the EU were Portugal and France (Table 3.1.2).

For the UK, according to the collected data, total imports of soybean were approximately 0.78 million tons and the main exporters of soybean to the UK were Brazil, United States of America, Canada, Ukraine 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 DAS-44406-6 soybean based on data from the authorisation holder.

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] As of January 1st, 2021, Corteva ceased to be member of the European Association for Bio-industries (EuropaBio) and continue their post-market monitoring related activities under the umbrella of CropLife Europe.
[4] Source: Eurostat (2021) data covers 27 EU Member States (July 2020 to June 2021).
[5] Source: HMRC/AHDB (2021) data for the 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.

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 DAS-44406-6 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 DAS-44406-6 soybean. These operators are exposed to the imported viable DAS-44406-6 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 DAS-44406-6 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 DAS-44406-6 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 DAS-44406-6 soybean and of the conditions as to general surveillance.
- Set up and maintain a website dedicated to operators including detailed information on DAS-44406-6 soybean. The website, hosted on the CropLife Europe website [6] 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

[6] Hosted on the European Association for Bio-industries (EuropaBio) website until 31 December 2020

  - 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, 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
  - 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 DAS-44406-6 soybean can be established. If the investigation establishes that DAS-44406-6 soybean was present when the adverse effect was identified, and confirms that DAS-44406-6 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 DAS-44406-6 soybean.

The report shall include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of DAS-44406-6 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 DAS-44406-6 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 EU28. 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 DAS-44406-6 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 DAS-44406-6 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 DAS-44406-6 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 DAS-44406-6 soybean to the relevant stakeholders within the first year following the authorisation of DAS-44406-6 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 DAS-44406-6 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 DAS-44406-6 soybean in the time period from July 2020 to June 2021 (see Annexes 2 and 3). Furthermore, no incidents in relation to the placing on the market of DAS-44406-6 soybean have been reported to CropLife Europe or the authorisation holder since July 2020 to date.

3.2.5 Additional information

Contact points for Corteva in Europe have been made available to operators and users as part of the information provided in the fact-sheet on DAS-44406-6 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 DAS-44406-6 soybean have been received.

3.2.6 Review of peer-reviewed publications

A 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 "Does DAS-44406-6 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 this authorisation?", 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 DAS-44406-6 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 DAS-44406-6 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 DAS-44406-6 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 DAS-44406-6 soybean indicate that no adverse effects on human and animal health or the environment have been observed for DAS-44406-6 soybean import and use for food, feed and processing.

4 SUMMARY OF RESULTS AND CONCLUSIONS

The authorisation holders have continued to implement the monitoring requirements in accordance with the relevant articles of the authorising decision.

The general surveillance system put in place by the plant biotechnology industry and the European trade associations and utilised by the authorisation holder for DAS-44406-6 soybean imports, is functioning well. It provides for monitoring of potential unanticipated adverse effects that might arise from the presence of GMO material (including DAS-44406-6 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 2020 to June 2021 revealed no adverse effects in the context of the placing on the market of DAS-44406-6 soybean imports (Annexes 2 and 3). Furthermore, no incidents in relation to the placing on the market of DAS-44406-6 soybean were reported to CropLife Europe or the authorisation holder from July 2020 to date. Thus, no adverse effects have been reported by the trade associations from the date of approval of DAS-44406-6 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 DAS-44406-6 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 DAS-44406-6 soybean carried out from July 2020 to June 2021 confirm no adverse effects on human and animal health or the environment have arisen from the introduction of DAS-44406-6 soybean into the EU.

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 DAS-44406-6 soybean imports is fully appropriate and does not require amendment.

Signed: 

Date: 21.12.2021

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