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 2020

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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 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[1] of 21 December 2017

1.4 Unique identifier

DAS-444Ø6-6

1.5 Reporting period from

July 2019 - June 2020[2]

1.6 Other monitoring reports have been submitted in respect of cultivation

Yes ☐ No ☒

[1] Article 4 (1) and (2) of Decision (EU) 2017/2450 require the implementation and annual reporting on the results of the monitoring plan in accordance with Annex VII to Directive 2001/18/EC, submitted as part of the application under Regulation (EC) No 1829/2003. The monitoring plan for DAS-44406-6 soybean is publicly available on the EU Register for Food and Feed: http://ec.europa.eu/food/dyna/gm_register/PMEM_DAS-44406-6_final_register.pdf

[2] Submission dates and reporting periods of all the Dow AgroSciences monitoring reports are aligned with those of the rest of the plant biotechnology industry as of end of December 2008.

2 EXECUTIVE SUMMARY

DAS-44406-6 soybean has been developed by Dow AgroSciences LLC [3] and M.S. Technologies LLC. 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.

Dow AgroSciences[4] is the authorisation holder 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 for this annual reporting period.**

[3] Member of Corteva Agriscience group of companies

[4] Dow AgroSciences Distribution S.A.S, member of Corteva Agriscience group of companies, is the authorisation holder as per Commission Implementing decision (EU) 2019/239 of 6 February 2019 amending Decision (EU) 2017/2450 (EC, 2019)

3 USES OF GMOs OTHER THAN CULTIVATION

3.1 Commodity imports into the Community

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

Country of origin[1]	Quantity (tonnes) 2019-2020[3]	Estimated data of potential DAS-44406-6 soybean share in imports (where not possible approximate share of cultivation in the country of origin)[4]
Brazil	6 758 543	NA
United States of America[2]	**5 191 446**	**0-10%**
Canada[2]	**1 662 325**	**0-10%**
Ukraine	725 699	NA
Paraguay	198 990	NA
Uruguay	166 193	NA
Serbia	119 333	NA
Argentina	72 937	NA
Other Countries	130 464	NA
Total from countries cultivating DAS-44406-6 soybean (GM and non-GM soybean)	**6 853 711**	
Total from all countries (GM and non-GM soybean)	**15 025 930**	

[1] Main countries exporting soybean to the EU, which combined make up > 99% of total soybean imports into the EU. The countries representing collectively less than 1% of the total imports to the EU are indicated as "Other countries". The full list of countries exporting soybean to the EU, as collected by EuropaBio (source EUROSTAT 2020), is provided in Annex 1.

[2] Exporting country where DAS-44406-6 soybean was cultivated in 2019.

[3] Quantity in tonnes of commodity crop (GM and non-GM soybean) imported during the reporting period (1st July 2019-30 June 2020) (rounded to the nearest ton). Source: EUROSTAT 2020 (extracted August 2020) collected by EuropaBio (see Annex 1).

[4] The authorisation holder is not an operator directly involved in the import of soybean oilseed into the EU for food/feed and processing. Therefore, it is not in a position to report directly on globally traded volumes of DAS-44406-6 soybean. However, in order to provide an estimate of the amount of DAS-44406-6 soybean that could possibly be imported into the EU, the approximate share of cultivation in the country of origin is provided, expressed as "NA" (not applicable, DAS-44406-6 soybean was 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 DAS-44406-6 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 into the Community by country of destination

Destination[1]	**Quantity (tonnes) 2019-2020**[2]
Austria	57 554
Belgium	508 715
Bulgaria	143
Croatia	260
Cyprus	0,1
Czech Republic	1 170
Denmark	8 572
Estonia	1,0
Finland	8 162
France	620 409
Germany	2 312 041
Greece	290 537
Hungary	66 383
Ireland	15 309
Italy	1 961 938
Latvia	-
Lithuania	626
Luxembourg	-
Malta	8
Netherlands	4 321 218
Poland	26 072
Portugal	955 457
Romania	155 633
Slovakia	163
Slovenia	7 428
Spain	3 317 838
Sweden	8 520
United Kingdom	381 771
EU Total	**15 025 930**

[1] EU Member States into which the commodity crop (GM and non-GM soybean) is imported.

[2] Quantity in tonnes of commodity crop (GM and non-GM soybean) imported during the reporting period (1st July 2019-30 June 2020) (rounded to nearest ton). Source: EUROSTAT 2020 (extracted August 2020), collected by EuropaBio (see details Annex 1).

3.1.3 Analysis of data provided in tables 3.1.1 and 3.1.2

The soybean oilseed (GM and non-GM) import data from suppliers to the EU from outside the EU-28 (extra-EU) is presented in section 3.1.1 and 3.1.2, and is based on EUROSTAT data collected by the European Association of Bioindustries (EuropaBio) for the reporting period from July 2019 to June 2020. During this period, total extra-EU soybean imports represented approximately 15.025 million tonnes (Section 3.1.1). Extra-EU soybean imports vary from year to year depending on several factors (e.g. annual EU soybean harvest yields, the international currencies exchange rates, soybean oilseed price, transportation costs).

The largest suppliers of extra-EU soybean to the EU during the July 2019 - June 2020 period were Brazil, United States of America (USA), Canada, Ukraine, Paraguay and Uruguay. Together, they accounted for approximately 97,8 % of total extra-EU soybean imports into the EU during the reporting period. Brazil, by itself, accounted for approximately 45 %, and the USA (the second largest supplier) accounted for approximately 34.5 %. Section 3.1.1 also provides estimates for potential DAS-44406-6 soybean share based on data from the authorisation holder.

Section 3.1.2 summarises the total soybean imports from outside the EU by destination. During the July 2019 - June 2020 period, the Netherlands, with a share of approximately 28.7%, was the main importer of extra-EU soybean in the EU. Other significant import markets for extra-EU soybean during the reporting period were Spain and Germany with a share of approximately 22 % and 15.4 %, respectively, followed by Italy and Portugal with a share of approximately 13 % and 6.4%, respectively.

Bulk shipments of soybean entering the EU 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 Member State 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 EuropaBio and has been endorsed

by the operators involved in the trade of viable soybean commodity (listed in Section 3.2.2).

Dow AgroSciences 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 EuropaBio 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 EuropaBio 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 EuropaBio website under http://www.europabio.org/information-operators-productinformation, 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
  - A contact point at EuropaBio 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 EuropaBio
  - 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 EuropaBio of the results of the general surveillance on an annual basis. EuropaBio shall forward this report to the respective authorisation holder 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 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. 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, 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 EuropaBio, 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 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 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 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. EuropaBio 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 2019 to June 2020.

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 EuropaBio 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 2019 to June 2020 (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 EuropaBio or the authorisation holder since July 2020 to date.

3.2.5 Additional information

Contact points for Dow AgroSciences 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 EuropaBio 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 2019 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 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 one 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

Dow AgroSciences, as authorisation holder, has continued to implement the monitoring requirements in accordance with the relevant articles of the authorising decision and as required under Article 4 of Decision (EU) 2017/2450 (EC, 2017).

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 EuropaBio 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 2019 to June 2020 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 EuropaBio 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 2019 to June 2020 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: 21.12.2020

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