Application for renewal of the authorisation of GA21 maize import in the European Union under Articles 11 and 23 of Regulation (EC) No 1829/2003

SUMMARY

This document is complete as of September 2016. Since it is submitted as one part of a regulatory application, which is subject to an on-going regulatory review, it may be subject to later amendment or replacement. The information may also be supplemented with additional material requested by regulatory authorities. As such, it may only be considered properly with reference to those later amendments or supplementary materials and in the context of the dossier as a whole.

SUMMARY

APPLICATION FOR RENEWAL OF AUTHORISATION OF GA21 MAIZE UNDER REGULATION (EC) NO 1829/2003

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

Not Applicable: Article 11 of the Regulation (EC) No 1829/2003 specifies that renewal of authorisations should be submitted to the European Commission.

(b) Application Number

Not available at time of submission

(c) Name of the product (commercial and other names)

GA21 maize
In the USA, GA21 maize is marketed under the product name Agrisure ®GT [1]

(d) Date of acknowledgement of valid application

Not available at time of submission

1.2. Applicant

(a) Name of applicant

Syngenta France SAS, Saint-Sauveur, France acting on its behalf and for its affiliated companies.

(b) Address of applicant

Syngenta France SAS
12, chemin de l'Hobit
31790 Saint-Sauveur
France

(c) Name and address of the representative of the applicant established in the Union (if the applicant is not established in the Union)

Not applicable.

[1] Agrisure® GT is a registered trademark of a Syngenta Group Company.
http://www.syngenta-us.com/agrisure/agrisure-gt-3000gt-3122-ez-refuge.aspx

1.3. Scope of the application

(a) GM food

☒ Food containing or consisting of GM plants

☒ Food produced from GM plants or containing ingredients produced from GM plants

(b) GM feed

☒ Feed containing or consisting of GM plants

☒ Feed produced from GM plants

(c) GM plants for food or feed use

☒ Products other than food and feed containing or consisting of GM plants with the exception of cultivation

☐ Seeds and plant propagating material for cultivation in the Union

1.4. Is the product or the uses of the associated plant protection product(s) already authorised or subject to another authorisation procedure within the Union?

No ☐

Yes ☒ (in that case, specify)

Import of GA21 maize is authorised in the EU by Decision 2008/280/EC (EC 2008). It is not approved for cultivation in the EU. Commercial GA21 maize seed will be marketed outside the EU. Where cultivated, the intended use of GA21 maize is to control weeds by providing tolerance to herbicides containing glyphosate. A maximum residue level exists for in genetically modified maize (0.3 mg/kg) with the enforcement residue defined as N-acetyl-glyphosate (EFSA 2009). Maize imported from third countries is not expected to exceed these levels.

1.5. Has the GM plant been notified under Part B of Directive 2001/18/EC?

Yes ☒

No (in that case provide risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC)

1.6. Has the GM plant or derived products been previously notified for marketing in the Union under Part C of Directive 2001/18/EC?

Yes ☒ (in that case, specify) (Monsanto)

No ☒ (Syngenta)

Applications for commercial approval were previously made by Monsanto under Directive 90/220/EEC but have been withdrawn. An application made by Monsanto under Regulation (EC) No 258/97 was approved on 13 January 2006[2] but this decision was repealed when the product was approved under the Regulation (EC) No 1829/2003 (EC 2008).

Although an application under Part C of the Directive 2001/18/EC has not been made by Syngenta, it should be noted that an application for authorisation and use of GA21 maize including cultivation was submitted, by Syngenta, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 on 16 July 2008 (Application EFSA-GMO-UK-2008-60). This application was assessed by the EFSA GMO Panel and the positive opinion may be found on the EFSA website (EFSA 2011). In addition, applications for import of GA21 under Regulation (EC) No 1829/2003 have been submitted and approved in the EU (EC, 2008).

1.7. Has the product been subject to an application and/or authorised in a third country either previously or simultaneously to this application?

No ☐

Yes ☒ (In that case, specify the third country, the date of application and where available, and provide a copy of the risk assessment conclusions, the date of the authorisation and the scope of the application)

GA21 maize is approved for cultivation in Argentina, Brazil, Canada, Colombia, Paraguay, Philippines, South Africa, the United States, Uruguay and Vietnam. It is approved for feed use in Argentina, Brazil, Canada, China, Colombia, the European Union, Japan, Korea, Malaysia, Mexico, Paraguay, Philippines, Russia, South Africa,

[2] EC (2006). Commission decision of 13 January 2006 authorising the placing on the market of foods and food ingredients produced from genetically modified Roundup Ready maize line GA21 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council (2006/69/EC). L34, 29-31.
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006D0069&from=EN

Turkey, the United States, Uruguay, and Vietnam and food use in Argentina, Australia, Belarus, Brazil, Canada, China, Colombia, the European Union, Indonesia, Japan, Kazakhstan, Korea, Malaysia, Mexico, New Zealand, Paraguay, Philippines, Russia, South Africa, Taiwan, the United States, Uruguay, and Vietnam.

1.8. General description of the product

(a) Name of the recipient or parental plant and the intended function of the genetic modification

GA21 maize is a genetically modified maize, which expresses a mutated maize 5-enolpyruvylshikimate-3-phosphate synthase enzyme (mEPSPS). EPSPS is a key enzyme in the shikimate pathway, involved in the biosynthesis of aromatic amino acids and is naturally found in all plants, fungi, and bacteria but absent in animals. EPSPS is highly sensitive to herbicide products containing glyphosate. Maize plants transformed with the mutated epsps (*mepsps*) gene, such as those derived from GA21 maize, synthesize the mEPSPS protein that confers tolerance to herbicide products containing glyphosate.

(b) Types of products planned to be placed on the market according to the authorisation applied for and any specific form in which the product must not be placed on the market (seeds, cut-flowers, vegetative parts, etc.) as a proposed condition of the authorisation applied for

This application is for renewal of authorisation of import, food and feed produced from genetically modified GA21 maize under Articles 11 and 23 of Regulation (EC) No 1829/2003. It does not cover cultivation.

(c) The scope of this renewal application is the same as that already authorised in the EU under Decision 2008/280/EC (EC, 2008). As such it includes all food and feed products containing, consisting or produced from GA21 maize including products from inbreds and hybrids obtained by conventional breeding of this maize product. The application for renewal also covers the import and industrial processing of GA21 maize for all potential uses as any other maize according to its already registered use.

(d) Intended use of the product and types of users

The GA21 maize products placed on the market will continue to be used as it is currently used and as any other conventional maize for all food, feed and industrial purposes.

(e) Any specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for

The characteristics of GA21 maize and products derived from it are not different from those of its conventional counterpart, apart from the introduced trait of herbicide tolerance. GA21 maize has been shown to be

as safe and as wholesome as existing varieties of maize. No additional information has become available that would require specific instructions or recommendations for use, storage and handling of GA21 maize. The product will be therefore continue to be labelled in accordance with the EU community law.

(f) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for

GA21 maize and derived products will be used as any other maize in the EU.

(g) Any type of environment to which the product is unsuited

GA21 maize and derived products will be used as any other maize in the EU. This application does not cover cultivation in the EU.

(h) Any proposed packaging requirements

The characteristics of GA21 maize and products derived from it are not different to those of its conventional counterpart. GA21 maize has been shown to be as safe and as wholesome as existing varieties of maize. Therefore, there are no specific instructions for packaging.

(i) Any proposed labelling requirements in addition to those required by other applicable EU legislation than regulation (EC) N° 1829/2003 and when necessary a proposal for specific labelling in accordance with Articles 13(2), and (3), Articles 25(2)(c), and (d) and Articles 25(3) of Regulation (EC) No 1829/2003.

In the case of products other than food and feed containing or consisting of genetically modified plants, a proposal for labelling which complies with the requirements of point A(8) of Annex IV to Directive 2001/18/EC must be included.

Since no information has become available since 2008 that would impact the outcome of the risk assessment for GA21 maize there is no reason to amend the exising labelling requirements. As such, the labelling requirements outlined by Decision 2008/280/EC (EC, 2008) remain the same. GA21 maize will therefore be labelled as “genetically modified maize” and products derived from it will be labelled as “containing (or produced from) genetically modified maize”. Since GA21 maize and derived products are not different from those of its conventional counterpart, no additional labelling is required.

(j) Estimated potential demand

(i) In the EU

There are no anticipated changes to the intake/extent of use of maize as a result of the introduction of GA21 maize to the maize supply. It is anticipated that the continued commercialisation of GA21 maize will replace some of the maize in existing food and feed products.

(ii) In EU export markets

This application for renewal of authorisation does not cover cultivation.

(k) Unique identifier in accordance with Regulation (EC) No 65/2004

The unique identifier assigned to this product in accordance with Regulation (EC) No 65/2004 is MON-ØØØ21-9 (also referred to as GA21 maize).

1.9. Measures suggested by the applicant to take in case of unintended release or misuse as well as measures for disposal and treatment

The GA21 maize and derived products have been shown to be as safe and as wholesome as existing varieties of maize. Any unintended releases or misuse can be dealt with in the same way as any other conventional maize. Therefore no specific measures are required.

Maize is incapable of sustained reproduction outside domestic cultivation and is non-invasive of natural habitats. The characteristics of GA21maize and products derived from it are not different from those of its conventional counterpart, apart from the intended traits.

The scope of this application for renewal does not include cultivation of GA21 maize in the EU.

In the unlikely event that small amounts of seed from GA21 maize accidentally found their way into the environment, this would represent extremely low levels of exposure and the survival of these seeds to produce flowering plants would be very unlikely. In addition, volunteers could be easily controlled using any of the current agronomic measures taken to control other commercially available maize, with the exception of herbicide products containing glyphosate and glufosinate-ammonium. Since its approval in the EU and commercialisation of GA21 maize, no information has become available to change this assessment.

Exposure to the environment will be limited to unintended release of GA21 maize, which could occur for example via substantial losses during loading/unloading of the viable commodity including GA21 maize destined for processing into animal feed or human food products. In the event that small amounts of GA21 grain accidentally found their way into the environment, this would represent extremely low levels of exposure and the survival of this grain to produce flowering plants would be very unlikely. Exposure can be controlled by clean up measures and the

application of current practices used for the control of any adventitious maize plants, such as manual or mechanical removal and the application of herbicides. In addition, volunteers could be easily controlled using any of the current agronomic measures taken to control other commercially available maize.

2. INFORMATION TO BE SUBMITTED ACCORDING TO ARTICLES 11 AND 23 OF REGULATION (EC) NO 1829/2003

2.1. A copy of the authorisation for placing the food and feed on the market

The placing on the market of products containing, consisting of, or produced from genetically modified maize GA21 was authorised according regulation (EC) no 1829/2003 by Commission Decision 2008/280/EC on 8 March 2008 (EC 2008):

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:087:0019:0022:EN:PDF

2.2. A report on the results of the monitoring, if so specified in the authorisation

Since the authorisation in 2008 of the placing on the market of products containing, consisting of, or produced from genetically modified maize GA21, Syngenta as authorisation holder has ensured that the monitoring plan for environmental effects according to Article 4 of the GA21 maize authorisation (EC 2008) and as referred in the GM register[3] has been put in place and implemented. The annual reports on the implementation and the results of the activities set out in the monitoring plan have been submitted to the European Commission on an annual basis since July 2008.

The general surveillance system in place by the European Association for Bioindustries and the European trade associations (operators involved in the import, handling and processing of viable GA21 maize), who are selected as the most appropriate participants in the general surveillance network, and utilised by the authorisation holder for GA21 maize imports monitors potential unanticipated adverse effects that might arise from the presence of GMO material (including GA21 maize) during import, handling and processing of crop commodities. It ensures that any observed adverse effects are reported immediately to the authorisation holder. Furthermore, the trade associations provide annual reports to the authorisation holders via the European Association for Bioindustries for the period from July to June of the following year.

The annual environmental monitoring reports, provided to the European Commission every year include the reports provided by the European trade associations as described above along with the findings from independent research, available through the open scientific literature. The monitoring did not detect adverse effects as a result of the placing on the market of GA21 maize.

[3] GM register for GA21 maize: http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=3

2.3. Any other new information which has become available with regard to the evaluation of the safety in use of the food and feed and the risks of the food and feed to the consumer, animals or the environment

(a) An overview of applications with event GA21 submitted in the EU

An overview of the applications for authorisation of the single GA21 maize event in the EU has been described in this application.

In addition to the single event, applications have also been made in the EU to cover GA21 in stacked maize products. An overview on these applications can be found on the EFSA website (http://registerofquestions.efsa.europa.eu/roqFrontend).

There is no information from the risk assessments for the GA21 maize or for stacked products containing GA21 that would impact the previous conclusion that GA21 maize will cause adverse effects to humans, animals or the environment.

(b) New information obtained in the framework of applications for authorisation of related

Review of scientific literature and studies performed by the applicant

A review of studies published in the scientific literature and studies performed by the applicant on the potential effects on human and animal health of the GM food and feed has been performed and no information is available which would impact the previous conclusions on the safety of GA21 maize for human and animal health or the environment.

Bioinformatic analysis

The latest bioinformatic analyses performed confirm the previous conclusions regarding the safety of GA21 maize for human and animal health or the environment.

2.4. Where appropriate, a proposal for amending or complementing the conditions of the original authorisation, *inter alia* the conditions concerning future monitoring

The scope of the application remains consistent with the current Decision 2008/280/EC (EC 2008). The scope of this application does not include authorisation for the cultivation of GA21 maize seed products in the EU.

The monitoring plan for environmental effects according to Article 4 of the GA21 maize authorisation (EC 2008) has been successfully implemented and no information has become available which impacts the previous risk assessmentof GA21 maize. Therefore no change is proposed to the existing environmental monitoring plan for GA21 maize.

However, it should be noted that the format of the monitoring plan for GA21 maize has been updated to reflect the current Industry harmonized monitoring plan.

Since GA21 maize was approved for import, food and feed use and processing in the EU (EC 2008), no information has become available that would change the outcome of the original risk assessment or the conditions set out in Decision 2008/280/EC (EC 2008) including to the methods for detection, sampling and reference materials. Therefore all the previous information submitted and reviewed as part of the original application (s) for GA21 maize remain valid and no amendments are considered necessary.

REFERENCES

EC, 2008. Commission Decision of 28 March 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize GA21 (MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document number C(2008) 1112). Official Journal of the European Union. L87, 19-22. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:087:0019:0022:EN:PDF

EFSA, 2007. Opinion of the Scientific Panel on Genetically Modified Organisms on applications (references EFSA-GMO-UK-2005-19 and EFSA-GMO-RX-GA21) for the placing on the market of glyphosate-tolerant genetically modified maize GA21, for food and feed uses, import and processing and for renewal of the authorisation of maize GA21 as existing product, both under Regulation (EC) No 1829/2003 from Syngenta Seeds S.A.S. on behalf of Syngenta Crop Protection AG. http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/541.pdf$

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EFSA, 2011. Scientific Opinion on application (EFSAGMO-UK-2008-60) for placing on the market of genetically modified herbicide tolerant maize GA21 for food and feed uses, import, processing and cultivation under Regulation (EC) No 1829/2003 from Syngenta Seeds. EFSA Journal 2011; 9(12):2480. [94 pp.] doi:10.2903/j.efsa.2011.2480.