APPLICATION FOR RENEWAL OF AUTHORISATION OF GENETICALLY MODIFIED PLANTS AND DERIVED FOOD AND FEED IN ACCORDANCE WITH ARTICLES 11 AND 23 OF REGULATION (EC) No 1829/2003

1507 MAIZE
(DAS-Ø15Ø7-1 MAIZE)

EFSA-GMO- XX

PART VII – Summary

Submitted by:

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PART VII – SUMMARY

1. GENERAL INFORMATION

1.1 Details of application

a) Member State of application
-
b) Application number
[*To be provided*]
c) Name of the product (commercial and other names)
The product described in this application is 1507 maize.
The unique identification code assigned to 1507 maize is: DAS-Ø15Ø7-1.
The commercial name assigned to 1507 maize seed in the US market is Herculex® I Insect Protection[1].
d) Date of acknowledgement of valid application
[*To be provided*]

1.2. Applicant

a) Name of applicant	
Pioneer Hi-Bred International, Inc. as represented by Pioneer Overseas Corporation and	
Dow AgroSciences LLC as represented by Dow AgroSciences Ltd	
b) Address of applicant	As represented by:
Pioneer Hi-Bred International, Inc. 7100 NW 62nd Avenue P.O. Box 1014 Johnston, IA 50131-1014 (U.S.A.)	Pioneer Overseas Corporation Avenue des Arts, 44 1040 Brussels Belgium
And	
Dow AgroSciences LLC 9330 Zionsville Road Indianapolis, Indiana 46268-1054 U.S.A. (previously Mycogen Seeds, c/o Dow AgroSciences LLC)	Dow AgroSciences Ltd European Development Center, 3B Park Square Milton Park, Abingdon Oxon OX14 4RN United Kingdom

[1] Herculex® I Insect Protection technology by Dow AgroSciences and Pioneer Hi-Bred; Herculex® is a registered trademark of Dow AgroSciences LLC.

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

Same as applicant

1.3. Scope of the application

This application is for renewal of authorisation of food and feed from genetically modified 1507 maize according to Articles 11 and 23 of Regulation (EC) No 1829/2003.

(a) Genetically modified food

X Food containing or consisting of genetically modified plants

X Food produced from genetically modified plants or containing ingredients produced from genetically modified plants

(b) Genetically modified feed

X Feed containing or consisting of genetically modified plants

X Feed produced from genetically modified plants

(c) Genetically modified plants for food and feed use

X Products other than food and feed containing or consisting of genetically modified 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?

Yes [x]	**No** [ ]
1507 maize has already been authorised in the EU as detailed in sections 1.3. and 1.6. Regulatory compliance in the framework of Article 10 of Regulation (EC) No 396/2005 on the establishment of a maximum residue levels (MRL) for the use of glufosinate in genetically modified maize containing the *pat* gene is authorised according to Commission Regulation (EC) No 149/2008.	

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

Yes [x]	**No** [ ]

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

Yes [x]	**No** [ ]

Decision authorisation number under Directive 2001/18/EC and number and date of consent under Directive 2001/18/EC : • Commission Decision 2005/772/EC of 3 November 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium published on 3 November 2005. • Decision DGM/SAS C/NL/00/10 of 16 March 2006 of the Dutch Directorate General for Environment Management **Decision authorisation number and date under Regulation (EC) No 1829/2003 :** • Commission Decision 2006/197/EC of 3 March 2006 authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, issued on 3 March 2006. • Commission Decision 2011/365/EU of 17 June 2011 amending Decision 2006/197/EC as regards the renewal of the authorisation to place on the market existing feed produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, issued on 17 June 2011. An overview has been published in the Community Register (http://ec.europa.eu/food/dyna/gm_register/index_en.cfm).	

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

Yes [x]	**No** [ ]
The 1507 maize was first approved for food, feed and cultivation use in the United States in 2001 and has been commercially cultivated since 2003. Cultivation approvals are also in place in Argentina, Brazil, Canada, Colombia, Honduras, Japan, Paraguay, Philippines, South Africa and	

Uruguay. 1507 maize has been approved in most of the major grain trading countries in the world: 49 countries (including the EU-28) around the world have approved 1507 maize for import and/or food and feed use.

1.8. General description of the product

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

The recipient plant is maize (*Zea mays* L.), which is extensively cultivated and has a long history of safe use. 1507 maize carries genes encoding for Cry1F and PAT proteins. The Cry1F protein acts to protect against certain lepidopteran pests, such as the European corn borer (ECB, *Ostrinia nubilalis* Hübner), which are major insect pests of maize in agriculture. 1507 maize also express the PAT protein, used as a selectable marker during transformation, which confers tolerance to the application of glufosinate-ammonium herbicide.

b) Types of products planned to be placed on the market according to the authorisation applied for

This application is for renewal of authorisation of food and feed produced from genetically modified 1507 maize according to Articles 11 and 23 of Regulation (EC) No 1829/2003. The types of products placed on the market according to renewal of the authorisation applied for include 1507 maize for all food and feed uses, and for all food, feed and processed products derived from 1507 maize in accordance with Regulation (EC) No 1829/2003. However, this application does not include authorisation for the cultivation of 1507 maize seed products in the EU.

c) Intended use of the product and types of users

The 1507 maize products placed on the market will continue to be used in a manner consistent with current uses of commercial maize grain and maize products. The 1507 maize will undergo existing methods of production and manufacturing used for commercial maize. No novel method of production and manufacturing is envisaged.

d) Specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for

Safety evaluation of 1507 maize has shown that no specific instructions and/or recommendations for use, storage and handling of 1507 maize are necessary. Therefore, 1507 maize can continue to be used, stored and handled in the same way as is currently done for commercial maize. Labelling of 1507 maize products will be carried out in accordance with Community law.

e) Geographical areas within the Union to which the product is intended to be confined under the terms of the authorisation applied for

1507 maize will be used throughout the European Union as any other commercial maize products.

f) Any type of environment to which the product is unsuited

The application does not cover cultivation of 1507 maize in the European Union. The 1507 maize will be used throughout the European Union as any other commercial maize products.

g) Any proposed packaging requirements

The packaging, handling, and storage systems that are currently used for commercial maize will apply. The 1507 maize products will be packaged in the same manner as other commercial maize products.

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

The labelling proposal remains as currently required by Article 3 (d) and (e) of Commission Decision 2005/772/EC and Article 3 and section (c) of the Annex to Commission Decision 2006/197/EC as amended by Commission decision 2011/365/EU.

i) Estimated potential demand

In the EU

Extra-EU maize imports vary from year to year depending on annual EU maize yields and are often influenced by maize yields in the EU for the given year. The international currency exchange rates, maize grain price and transportation costs are also factors influencing commodity crop imports into the EU. In 2013, a total of 10.7 million tonnes of maize grain were imported into the EU, approximately 63% from Ukraine and 22.5% from Brazil. Spain is the most important market for extra-EU maize imports with a share representing one third of the total extra-EU maize grain imports in 2013. Other significant import markets for extra-EU maize in 2013 were the Netherlands, Italy and Portugal, each with a share between approximately 12.5% and 16.5%, while other countries individually contribute less than 7% to imports.

In EU export markets

The application does not cover cultivation of 1507 maize in the European Union.

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

DAS-Ø15Ø7-1

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

Based on the conclusions from the environmental risk assessment of 1507 maize, no specific measures need to be taken in case of unintended release or misuse or for disposal and treatment. There are no sexually compatible wild plant species in Europe with which maize can cross-hybridise and maize plants cannot survive as a weed outside agricultural fields. The establishment of maize volunteer plants is therefore very unlikely.

In case of unintended release of 1507 maize, current agronomic measures taken to control other commercially available maize can be applied, such as use of mechanical means and selective use of herbicides (with exception of glufosinate-ammonium).

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 1507 maize for the same uses as any other maize, with the exception of cultivation, was authorised by Commission Decisions 2005/772/EC and 2006/197/EC, and the final consent of the Dutch Competent Authority, the Rapporteur Competent Authority under Directive 2001/18/EC, issued on 16 March 2006. (Decision DGM/SAS C/NL/00/10 of 16 March 2006 of the Dutch Directorate General for Environment Management).

The authorisation to place on the market existing feed produced from 1507 maize was renewed by Commission Decision 2011/365/EU amending Decision 2006/197/EC as regards the renewal of the authorisation to place on the market existing feed produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003, issued on 17 June 2011.

An overview has been published in the Community Register (http://ec.europa.eu/food/dyna/gm_register/index_en.cfm).

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

During the current nine year reporting period of the placing on the market of 1507 maize imports, Pioneer Overseas Corporation and Dow Agrosciences, as consent holders, have 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 consent holders for 1507 maize imports, is functioning well. It provides for monitoring of potential unanticipated adverse effects that might arise from the presence of GMO material (including 1507 maize) during import, handling and processing of crop commodities and ensures that any observed adverse effects are reported immediately to the consent holders. Furthermore, the trade associations provide annual reports to the consent holders 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 to June every year revealed no adverse effects in the context of the placing on the market of 1507 maize imports. Thus, no adverse effects have been reported by the trade associations from the dates of approval of 1507 maize (March 2006) for import and use as or in food, feed and processing to date.

No scientific articles or reports demonstrating adverse effects arising from 1507 maize import or use as food and feed have been published during the current reporting period, as confirmed by the opinion of the EFSA GMO Panel for the period from 2005 to September 2012 and by the comprehensive literature searches.

As a consequence, the results of the general surveillance of 1507 maize carried out from March 2006 to date confirm that no adverse effects on human and animal health or the environment have arisen from the import of 1507 maize into the EU for the reporting period.

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

(i) An overview of applications with the 1507 event submitted in the EU

An overview of the applications for EU authorisation of the single event 1507 has been described in the application.

Maize 1507 has been combined with other events using conventional breeding to create stacked product with multiple modes of action for control of pest insects and with tolerance to one or more classes of herbicides. An overview can be found on the EFSA website (http://registerofquestions.efsa.europa.eu/roqFrontend)

The 1507 maize event has been extensively risk assessed and there is no information that impacts on the previous conclusion that 1507 maize is unlikely to cause adverse effects in humans or animals.

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

Sequence analysis

Triggered by the finding of Morisset et al. (2009) that the Cauliflower mosaic virus (CaMV) 35S promoter of 1507 maize contains a single nucleotide difference, compared to the reported sequence of the DNA fragment used for transformation, an analysis of the 1507 insert was performed and submitted to the EFSA GMO Panel. The EFSA GMO Panel evaluated the impact of the sequence update in the framework of the stack applications MON 89034 x 1507 x MON 88017 x 59122 and MON 89034 × 1507 × NK603 and agreed that the updated sequence information did not cause a safety concern.

Bioinformatic analysis

The latest performed bioinformatic analyses do not change the conclusion of the food/feed safety assessment of 1507 maize.

Literature searches

No publications have appeared in the scientific literature up to now that invalidate the previously reached conclusions of the food/feed safety assessment of 1507 maize.

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 this application does not include authorisation for the cultivation of 1507 maize seed products in the EU.

In the light of the successful implementation of and results from current monitoring activities, which confirm the risk assessment and findings of previous annual monitoring reports, and the fact that no changes are foreseen to the existing use of the product the consent holders consider that the environmental monitoring plan, including the general surveillance system, in place for the monitoring of 1507 maize imports is fully appropriate and does not require amendment. However, the format of the monitoring plan for 1507 maize has been updated based on the agreed

harmonized monitoring plan currently implemented and agreed upon with the European Commission, monitoring networks of importers and feed manufacturers.