

**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**

1507xNK603 MAIZE
(DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 MAIZE)

EFSA-GMO-RX-008

PART VII – Summary

Submitted by:

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**Original submission
19 October 2016**

PART VII – SUMMARY

1. GENERAL INFORMATION

1.1 Details of application

<p>a) Member State of application</p> <p>-</p>
<p>b) Application number</p> <p>[To be provided]</p>
<p>c) Name of the product (commercial and other names)</p> <p>The product described in this application is 1507xNK603 maize.</p> <p>The unique identification code assigned to 1507xNK603 maize is: DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize.</p> <p>The commercial name assigned to 1507xNK603 maize seed in the US market is Herculex® I Insect Protection¹ × Roundup Ready® Corn 2².</p>
<p>d) Date of acknowledgement of valid application</p> <p>[To be provided]</p>

1.2. Applicant

<p>a) Name of applicant</p> <p>Pioneer Hi-Bred International, Inc. as represented by Pioneer Overseas Corporation and Dow AgroSciences LLC as represented by Dow AgroSciences Europe</p>																				
<p>b) Address of applicant</p> <table border="0"> <tr> <td>Pioneer Hi-Bred International, Inc.</td> <td>and</td> <td>Dow AgroSciences LLC</td> </tr> <tr> <td>7100 NW 62nd Avenue</td> <td></td> <td>9330 Zionsville Road</td> </tr> <tr> <td>P.O. Box 1014</td> <td></td> <td>Indianapolis, Indiana 46268-1054</td> </tr> <tr> <td>Johnston, IA 50131-1014 (U.S.A.)</td> <td></td> <td>U.S.A.</td> </tr> <tr> <td></td> <td></td> <td>(previously Mycogen Seeds,</td> </tr> <tr> <td></td> <td></td> <td>c/o Dow AgroSciences LLC)</td> </tr> </table> <p>As represented by:</p>			Pioneer Hi-Bred International, Inc.	and	Dow AgroSciences LLC	7100 NW 62 nd Avenue		9330 Zionsville Road	P.O. Box 1014		Indianapolis, Indiana 46268-1054	Johnston, IA 50131-1014 (U.S.A.)		U.S.A.			(previously Mycogen Seeds,			c/o Dow AgroSciences LLC)
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¹ Herculex® I Insect Protection technology by Dow AgroSciences and Pioneer Hi-Bred; Herculex® is a registered trademark of Dow AgroSciences LLC; Herculex® I Insect Protection is identified by the OECD unique identifier DAS-Ø15Ø7-1.

² Roundup Ready® is a registered trademark of Monsanto Technology LLC. Roundup Ready® Corn 2 is identified by the OECD unique identifier MON-00603-6. Note that maize is referred to as corn in the United States.

Pioneer Overseas Corporation Avenue des Arts, 44 1040 Brussels Belgium	and	Dow AgroSciences Europe European Development Center, 3B Park Square Milton Park, Abingdon Oxon OX14 4RN United Kingdom
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 1507xNK603 maize according to Articles 11 and 23 of Regulation (EC) No 1829/2003.

(a) Genetically modified food

☒ Food containing or consisting of genetically modified plants

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

(b) Genetically modified feed

☒ Feed containing or consisting of genetically modified plants

☒ Feed produced from genetically modified plants

(c) Genetically modified plants for food and feed use

☒ 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] 1507xNK603 maize and its uses have already been authorised in the EU as detailed in sections 1.3. and 1.6.	No []
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1.5. Has the GM plant been notified under Part B of Directive 2001/18/EC?

Yes [x]	No []
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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] Decision authorisation number and date under	No []
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<p>Regulation (EC) No 1829/2003 :</p> <p>Commission Decision 2007/703/EC of 24 October 2007 authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize 1507xNK603 (DAS-Ø15Ø7-1xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, issued on 24 October 2007.</p> <p>An overview has been published in the Community Register (http://ec.europa.eu/food/dyna/gm_register/index_en.cfm).</p>	
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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 []
<p>1507xNK603 maize was first authorised for food, feed and cultivation purposes in the United States (US) in 2003 and has been commercially cultivated in the US since 2004. Cultivation of 1507xNK603 maize has also been authorised in Argentina, Brazil, Canada, Colombia, Honduras, Japan, Pakistan, Philippines and Uruguay. 1507xNK603 maize has been authorised in many major grain trading countries in the world: to date, 45 countries (including the EU-28) around the world have authorised 1507xNK603 maize for import and/or food and feed use.</p>	

1.8. General description of the product

<p>a) Name of the recipient or parental plant and the intended function of the genetic modification</p> <p>The recipient plant is maize (<i>Zea mays</i> L.), which is extensively cultivated and has a long history of safe use. The 1507xNK603 maize has been derived by traditional breeding methods from two GM maize, 1507 maize (expressing the CRY1F and PAT proteins), and NK603 maize (expressing the CP4 EPSPS protein). The CRY1F protein confers resistance to certain lepidopteran insect pests, such as the European corn borer and <i>Sesamia</i> spp. The PAT protein confers tolerance to glufosinate-ammonium herbicide and the CP4 EPSPS protein confers tolerance to glyphosate herbicide. No new genetic modification has been introduced in 1507xNK603 maize.</p>

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 1507xNK603 maize according to Articles 11 and 23 of Regulation (EC) No 1829/2003. The types of products placed on the market according to the renewal of the authorisation applied for include 1507xNK603 maize for all food and feed uses, and for all food, feed and processed products derived from 1507xNK603 maize in accordance with Regulation (EC) No 1829/2003. However, this application does not include authorisation for the cultivation of 1507xNK603 maize seed products in the EU.

c) Intended use of the product and types of users

The 1507xNK603 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 1507xNK603 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 1507xNK603 maize has shown that no specific instructions and/or recommendations for use, storage and handling of 1507xNK603 maize are necessary. Therefore, 1507xNK603 maize can continue to be used, stored and handled in the same way as is currently done for commercial maize. Labelling of 1507xNK603 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

1507xNK603 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 1507xNK603 maize in the European Union. The 1507xNK603 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 1507xNK603 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 (1) and (2) of Commission Decision 2007/703/EC.

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 2015, a total of approximately 10.5 million tonnes of maize grain were imported into the EU, approximately 73% from Ukraine, 9.9% from Brazil and 5.4% from the Russian Federation. Spain is the most important market for extra-EU maize imports with a share representing approximately 35% of the total extra-EU maize grain imports in 2015. Other significant import markets for extra-EU maize in 2015 were the Netherlands with a share of approximately 19.6 %, Italy, Portugal and the United Kingdom, each with a share between approximately 5.3% and 12.2%, while other countries individually contribute less than 5% to imports.

In EU export markets

The application does not cover cultivation of 1507xNK603 maize in the European Union.

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

DAS-Ø15Ø7-1xMON-ØØ6Ø3-6

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 1507xNK603 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 endogenous 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 1507xNK603 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 and glyphosate).

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 1507xNK603 maize for the same uses as any other maize, with the exception of cultivation, was authorised by Commission Decision 2007/703/EC.

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 1507xNK603 maize imports, Pioneer Overseas Corporation and Dow AgroSciences, as authorisation holders, have continued to implement the monitoring requirements in accordance with the relevant article 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 1507xNK603 maize imports, is functioning well. It provides for monitoring of potential unanticipated adverse effects that might arise from the presence of GMO material (including 1507xNK603 maize) during import, handling and processing of crop commodities and ensures that any observed adverse effects are reported immediately to the authorisation holders. Furthermore, the trade associations provide annual reports to the authorisation 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 1507xNK603 maize imports. Thus, no adverse effects have been reported by the trade associations from the date of approval of 1507xNK603 maize for import and use as or in food, feed and processing to date.

As a consequence, the results of the general surveillance of 1507xNK603 maize carried out from October 2007 to date confirm that no adverse effects on human and animal health or the environment have arisen from the import of 1507xNK603 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) introduction to 1507xNK603

As stated in the EFSA GMO Panel opinion related to 1507xNK603 “Maize 1507 x NK603 is produced by crosses between maize inbred lines containing maize events 1507 and NK603 to combine the lepidopteran resistance trait and glufosinate tolerance in maize 1507 with glyphosate tolerance in maize NK603. No new genetic modifications were introduced” (EFSA, 2006).

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

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 1507xNK603 maize.

Bioinformatic analysis

The latest performed bioinformatic analyses do not change the conclusion of the food/feed safety assessment of 1507xNK603 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 1507xNK603 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 authorisation holders consider that the environmental monitoring plan, including the general surveillance system, in place for the monitoring of 1507xNK603 maize imports is fully appropriate and does not require amendment. However, the format of the monitoring plan for 1507xNK603 maize has been updated based on the agreed harmonized monitoring plan.