

**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**

**59122 MAIZE
(DAS-59122-7 MAIZE)**

**EFSA-GMO-RX-XX
PART VII – Summary**

Submitted by:

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**Original submission
19 July 2016**

PART VII – SUMMARY

1. GENERAL INFORMATION

1.1 Details of application

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| <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 59122 maize.</p> <p>The unique identification code assigned to 59122 maize is: DAS-59122-7.</p> <p>The commercial name assigned to 59122 maize seed in the US market is Herculex® RW Rootworm Protection ¹.</p> |
| <p>d) Date of acknowledgement of valid application</p> <p>[To be provided]</p> |

1.2. Applicant

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

¹ Herculex® RW Rootworm 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 59122 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?

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| <p>Yes [<input]<="" checked="" p="" type="checkbox"/> <p>59122 maize has already been authorised in the EU as detailed in sections 1.3. and 1.6.</p> <p>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 <i>pat</i> gene is authorised according to Commission Regulation (EC) No 149/2008.</p> </p> | <p>No [<input]<="" p="" type="checkbox"/> </p> |
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1.5. Has the GM plant been notified under Part B of Directive 2001/18/EC?

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| Yes [<input]<="" checked="" td="" type="checkbox"/> <td style="width: 50%;">No [<input]<="" td="" type="checkbox"/> </td> | No [<input]<="" td="" type="checkbox"/> |
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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?

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|--------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| Yes [<input]<="" checked="" td="" type="checkbox"/> <td style="width: 50%;">No [<input]<="" td="" type="checkbox"/> </td> | No [<input]<="" td="" type="checkbox"/> |
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| <p>Decision authorisation number and date under Regulation (EC) No 1829/2003 :</p> <ul style="list-style-type: none"> • Commission Decision 2007/702/EC of 24 October 2007 authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, issued on 24 October 2007. <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 [<input checked="" type="checkbox"/>] | No [<input type="checkbox"/>] |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| <p>59122 maize was first authorised for food, feed and cultivation purposes in the United States (US) in 2005 and started to be commercially cultivated in the US in 2006. Cultivation authorisations are also in place in Canada and Japan. 59122 maize has been authorised in many major grain trading countries in the world: to date, 42 countries (including the EU-28) around the world have authorised 59122 maize for import and/or food and feed use.</p> | |

1.8. General description of the product

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| <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. 59122 maize has been genetically modified to express proteins, Cry34Ab1 and Cry35Ab1, that act together to provide protection against certain coleopteran pests, including Western corn rootworm (WCR, <i>Diabrotica virgifera virgifera</i>). 59122 maize also express the PAT protein which confers tolerance to glufosinate-ammonium herbicidal active ingredient and serves as a marker to select transformed maize plants in laboratory.</p> |
| <p>b) Types of products planned to be placed on the market according to the authorisation applied for</p> <p>This application is for renewal of authorisation of food and feed produced from genetically modified 59122 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 59122 maize for all food and feed uses, and for all food, feed and processed products derived from 59122 maize in accordance with Regulation (EC) No 1829/2003. However, this application does not include authorisation for the cultivation of 59122 maize seed products in the EU.</p> |

c) Intended use of the product and types of users

The 59122 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 59122 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 59122 maize has shown that no specific instructions and/or recommendations for use, storage and handling of 59122 maize are necessary. Therefore, 59122 maize can continue to be used, stored and handled in the same way as is currently done for commercial maize. Labelling of 59122 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

59122 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 59122 maize in the European Union. The 59122 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 59122 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 2007/702/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 2014, a total of 13.3 million tonnes of maize grain were imported into the EU, approximately 63% from Ukraine, 10.7% from Canada and 7.8% from the Russian Federation. Spain is the most important market for extra-EU maize imports with a share representing 30% of the total

extra-EU maize grain imports in 2014. Other significant import markets for extra-EU maize in 2014 were the Netherlands with a share of approximately 21.8 %, Italy, Portugal and the United Kingdom, each with a share between approximately 7.4% and 12.5%, while other countries individually contribute less than 5% to imports.

In EU export markets

The application does not cover cultivation of 59122 maize in the European Union.

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

DAS-59122-7

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 59122 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 59122 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 59122 maize for the same uses as any other maize, with the exception of cultivation, was authorised by Commission Decision 2007/702/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 eight year reporting period of the placing on the market of 59122 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 59122 maize imports, is functioning well. It provides for monitoring of potential unanticipated adverse effects that might arise from the presence of GMO material (including 59122 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 59122 maize imports. Thus, no adverse effects have been reported by the trade associations from the date of approval of 59122 maize for import and use as or in food, feed and processing to date.

As a consequence, the results of the general surveillance of 59122 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 59122 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 59122 event submitted in the EU

An overview of the applications for EU authorisation of the single event 59122 has been described in the application.

Maize 59122 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 59122 maize event has been extensively risk assessed and there is no information that impacts on the previous conclusion that 59122 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

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 59122 maize.

Bioinformatic analysis

The latest performed bioinformatic analyses do not change the conclusion of the food/feed safety assessment of 59122 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 59122 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 59122 maize imports is fully appropriate and does not require amendment.

However, the format of the monitoring plan for 59122 maize has been updated based on the agreed harmonized monitoring plan.