



Application for renewal of the authorisation of MIR162 maize import in the European Union under Articles 11 and 23 of Regulation (EC) No 1829/2003

Part III: SUMMARY

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SUMMARY

APPLICATION FOR RENEWAL OF AUTHORISATION OF MIR162 MAIZE UNDER REGULATION (EC) NO 1829/2003

1.0 GENERAL INFORMATION

1.1 Details of application

(a) Member State of application

Not Applicable: Articles 11 and 23 of the Regulation (EC) No 1829/2003 specify that renewal of authorisations should be submitted to the European Commission.

(b) Application Number

Not available at time of submission, *EFSA-GMO-RX-XXX*

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

MIR162 maize, Unique identifier SYN-IR162-4. Associated with the trademark Agrisure Viptera®¹.

(d) Date of acknowledgement of valid application

Not available at time of submission

1.2 Applicant

(a) Name of applicant

Syngenta Crop Protection NV/SA, Brussels, Belgium acting on behalf of Syngenta Crop Protection AG.

(b) Address of applicant

Syngenta Crop Protection NV/SA
Avenue Louise, 489
1050 Brussels
Belgium

(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 Viptera® is a registered trademark of a Syngenta Group Company. https://www.syngenta-us.com/agrisure/images/agrisureviptera_aboveground_sellsheet.pdf

1.3 Scope of the application

Application for renewal of the authorisation granted by Commission Implementing Decision of 18 October 2012 (2012/651/EU) authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR162 (SYN-IR162-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2012) 7198):

The scope corresponds to:

- (a) GM food
 - ☒ Food containing or consisting of SYNIR162-4 maize
 - ☒ Food produced from SYNIR162-4 maize or containing ingredients produced from SYNIR162-4 maize
- (b) GM feed
 - ☒ Feed containing or consisting of SYNIR162-4 maize
 - ☒ Feed produced from SYNIR162-4 maize
- (c) GM plants for food or feed use
 - ☒ Products other than food and feed containing or consisting of SYNIR162-4 maize with the exception of cultivation
 - ☐ Seeds and plant propagating material for cultivation in the EU

1.4 General description of the product

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

MIR162 is a genetically modified (GM) maize that expresses the insecticidal protein Vip3Aa20, used to confer field protection against certain lepidopteran pests, including *Spodoptera frugiperda* and *Helicoverpa zea*. It also expresses a phosphomannose isomerase (PMI) protein which was used as a selectable marker in the development of MIR162 maize.

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

MIR162 maize is approved for cultivation: in Argentina, Brazil, Canada, Colombia, Japan, Paraguay, Philippines, United States of America and Uruguay.

MIR162 maize is approved for feed use: in Brazil, Canada, China, Colombia, the European Union, Indonesia, Japan, Korea, Malaysia, Mexico, Nigeria, Paraguay, Russian Federation, Singapore, South Africa, Taiwan, Turkey, the United States, Uruguay, and Vietnam

MIR162 maize is approved for food use: in Argentina, Australia, Belarus, Brazil,

Canada, China, Colombia, the European Union, Indonesia, Japan, Korea, Malaysia, Mexico, Nigeria, New Zealand, Paraguay, Philippines, Russian Federation, Singapore, South Africa, Taiwan, the United States, Uruguay, and Vietnam.

More information on the regulatory status of the product in the EU and third countries can be retrieved from the EU Register of authorised GMOs² and the CropLife International database³.

2.0 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

Commission Implementing Decision of 18 October 2012 (2012/651/EU) authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR162 (SYN-IR162-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2012) 7198)⁴

Commission Implementing Decision (EU) 2019/60 of 11 January 2019 amending Implementing Decision 2012/651/EU as regards the representative of the authorisation holder⁵

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

In accordance with Article 4 of Commission Implementing Decision 2012/651/EU, the authorisation holder has ensured the implementation of the monitoring plan for environmental effects as reported to the EC on an annual basis.

The Annual Post Market Environmental Monitoring reports for the genetically modified maize MIR162 covering the monitoring period from October 2012 until June 2020 are provided as part of the renewal application.

The general surveillance considering the placing on the market of MIR162 maize in the EU indicates that there have been no adverse health or environmental effects associated with the import or use of MIR162 maize.

² http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

³ <https://croplife.org/plant-biotechnology/regulatory-2/biotradestatus/>

⁴ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:290:0014:0017:EN:PDF>

⁵ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D0060&from=EN>

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

2.3.1 Systematic search and evaluation of literature

A scoping review was performed for MIR162 maize and its newly expressed proteins Vip3Aa20 and PMI. There were no studies published in the scientific literature which would impact the previous conclusions on the safety of MIR162 maize for human and animal health or the environment.

2.3.2 Updated Bioinformatics

The latest bioinformatic analyses performed confirm the previous conclusions regarding the safety of MIR162 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

Based on the information provided above, for the renewal application of MIR162 maize for food and feed uses, the conditions of the original authorisation should not be amended or complemented and should therefore remain unchanged.