



# **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**

This document is complete as of February 2021. 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.

### *Statement of Property Rights*

This document contains information which is proprietary to Syngenta and/or constitutes confidential business information. It may not be used by any third party, including but not limited to any registration authority, to support registration of this product or any other product without the prior written consent of the company; all copyrights are reserved. None of the information provided with this document must be published or disclosed to any third party without the prior written consent of the company (disclosure may undermine the protection of commercial interests of the company; Regulation EC No 1049/2001, Art. 4(2)). Access to the information shall in any event be refused until the EC has taken its decision on the relevant matter (disclosure would undermine the ongoing authorization process; Regulation EC No 1049/2001, Art. 4(3)). Personal details naming or capable of identifying any individual's names, contact details or locations are confidential information which need to be protected at all times (Regulation EC No 1049/2001, Art. 4(1)(b)).

## TABLE OF CONTENTS

<b>TABLE OF CONTENTS</b> .....	<b>2</b>
<b>SUMMARY</b> .....	<b>3</b>
1.0 GENERAL INFORMATION .....	3
2.0 INFORMATION TO BE SUBMITTED ACCORDING TO ARTICLES 11 AND 23 OF REGULATION (EC) NO 1829/2003 .....	5

## 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®<sup>1</sup>.

**(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.

---

<sup>1</sup> Agrisure Viptera® is a registered trademark of a Syngenta Group Company. [https://www.syngenta-us.com/agrisure/images/agrisureviptera\\_aboveground\\_sellsheet.pdf](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 GMOs<sup>2</sup> and the CropLife International database<sup>3</sup>.

## **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)<sup>4</sup>

Commission Implementing Decision (EU) 2019/60 of 11 January 2019 amending Implementing Decision 2012/651/EU as regards the representative of the authorisation holder<sup>5</sup>

### **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.

---

<sup>2</sup> [http://ec.europa.eu/food/dyna/gm\\_register/index\\_en.cfm](http://ec.europa.eu/food/dyna/gm_register/index_en.cfm)

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

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

<sup>5</sup> <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.