

15 DIC. 2016

Ref. KL/Ig (2016) – out – 16453000

Monsanto Europe S.A./N.V.

By e-mail ONLY

Subject: Acceptance of the valid Application under Regulation 1829/2003 for renewal of authorisation of feed containing or consisting of genetically modified oilseed rape GT73 and products other food and feed containing or consisting of it

EFSA Question number: EFSA-Q-2016-00478

EFSA Application number: EFSA-GMO-RX-002

Dear

On **20 July 2016**, the European Food Safety Authority (EFSA) received from the European Commission the application under Regulation (EC) No 1829/2003 referring to **Application under Regulation 1829/2003 for renewal of authorisation of feed containing or consisting of genetically modified oilseed rape GT73 and products other food and feed containing or consisting of it** submitted by Monsanto Europe S.A./N.V.

Please find enclosed the **statement of validity** for the application with reference **EFSA-GMO-RX-002**.

You are kindly asked to submit to EFSA within 10 working days from the date of this letter:

- 1 copy in electronic format of Public Version (CD-ROM)

According to Regulation (EC) No 1829/2003, EFSA shall respect the deadline of **6 months** to deliver a scientific opinion. However, during the assessment of the dossier, EFSA may request the applicant for additional information if necessary. In such case, the time limit of 6 months shall be extended in compliance with the Regulation.

Please be informed that as the application is considered valid, non-confidential parts of the application, including additional information submitted further on, will be considered as publicly available upon request and will be disclosed to third parties without additional written consent from your part.

The application has been registered under the references **EFSA-Q-2016-00478** and **EFSA-GMO-RX-002**. Please use these references for further communication with EFSA concerning this application. You can monitor the status and progress of the application from the Register of Questions on the EFSA website:
(<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00478>).

The scientific unit GMO is taking over the handling of the application. The contact scientific officer for your application is the coordinator of applications Sylvie Mestdagh (Sylvie.MESTDAGH@efsa.europa.eu).

Yours sincerely,



Karine Lheureux
Head of Applications Desk Unit

cc: (Monsanto Europe S.A./N.V.)
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Encl: Statement of validity

Parma, 15 DIC. 2016

Statement of validity

EFSA Question number EFSA-Q-2016-00478

EFSA Application number EFSA-GMO-RX-002

On **20 July 2016**, the European Food Safety Authority (EFSA) received the application **EFSA-GMO-RX-002** referring to **Application under Regulation 1829/2003 for renewal of authorisation of feed containing or consisting of genetically modified oilseed rape GT73 and products other food and feed containing or consisting of it** submitted by Monsanto Europe S.A./N.V.

On **01 September 2016** and **24 October 2016**, EFSA requested the applicant to provide missing information.

On **03 October 2016** and **24 November 2016**, missing information was made available to EFSA.

On **30 November 2016**, complementary information was made available spontaneously by the applicant.

After checking the content of the full dossier, EFSA considers that:

- the application **EFSA-GMO-RX-002** is **valid**
- the date of validity is **15 December 2016**



Karine Lheureux
Head of Applications Desk Unit