

MODIFICATIE

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Aan de minister van Infrastructuur en Waterstaat drs. C. van Nieuwenhuizen-Wijbenga Postbus 20901 2500 EX Den Haag

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KENMERK CGM/200608-02

Aanvullend advies over de importvergunning van de genetisch gemodificeerde

koolzaadlijn MS11

Dear Mrs Van Nieuwenhuizen,

On May 19th 2017, COGEM issued an advice on an application for food and feed uses and import and processing of genetically modified (GM) oilseed rape MS11 (EFSA/GMO/BE/2016/138). GM oilseed rape MS11 contains the *bar* gene conferring tolerance to glufosinate-ammonium containing herbicides. It expresses the *barnase* gene which results in lack of viable pollen and male sterility. MS11 also contains the *barstar* gene which, according to the applicant, enhances the transformation frequency.

The application for import and processing of MS11 was filed, because before a stacked event can be approved for food and feed uses and import and processing, authorisation of the single events included in the stack is required. However, oilseed rape MS11 will never be commercialised as a stand-alone product, because it is designed to be used only for the production of hybrid seed. Therefore, in its advice COGEM pointed out that the environmental risk assessment of the single event MS11 is not relevant and stated that the request for authorisation of the hypothetical import and processing of MS11 is a striking example of following unnecessary procedures.<sup>1</sup>

Recently, the European Food Safety Authority (EFSA) published its scientific opinion on import and processing of oilseed rape MS11. The opinion also took into account the scientific comments submitted by the EU Member States. The Dutch portal for European market

COGEM (2017). Import and processing of genetically modified oilseed rape MS11. COGEM advice CGM/170519-01

applications (the Food-Feed-portal) has asked COGEM whether its comments have been sufficiently answered by  ${\sf EFSA}.^2$ 

COGEM has taken notice of the responses of the EFSA GMO panel on the comments and opinions submitted by Member States during the 3 month consultation period, and the scientific risk assessment of the EFSA GMO panel on the application for authorisation of MS11 for import, processing and food and feed uses.

In the scientific risk assessment EFSA notes that, since oilseed rape MS11 is intended to be used only for the production of hybrid seed and is not intended to be commercialised as a stand-alone product for food and feed uses, import and processing, MS11 is not expected to enter the food and feed chain in the EU, except in the case of accidental presence in products coming from non-EU countries. In this context EFSA notes that oilseed rape MS11 would not pose risks to humans and animals, while the scale of environmental exposure will be substantially reduced compared to a stand-alone product.<sup>2</sup>

EFSA did not address the comment of COGEM that an environmental risk assessment of the single event MS11 for food and feed uses and import and processing, is an unnecessary requisite.<sup>1</sup>

In conclusion, COGEM reiterates that the hypothetical import and processing of MS11 poses a negligible risk to the environment in the Netherlands, but that the permit application of MS11 is an example of following unnecessary procedures which leads to needless administrative workloads, costs and delays in authorisation processes.

Sincerely yours,

Prof. dr. ing. Sybe Schaap

Voorzitter COGEM

c.c. - Dr. J. Westra, Hoofd Bureau ggo

- Ministerie van IenW, Directie Omgevingsveiligheid en Milieurisico's DG Milieu en Internationaal

- Dr. C.P.E. van Rijn, Food-Feed loket

<sup>&</sup>lt;sup>2</sup> EFSA (2020). Scientific Opinion on the Assessment of genetically modified oilseed rape MS11 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA-GMO-BE-2016-138). EFSA Journal 18(5):6112