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To the Minister for the Environment drs. V.L.W.A. Heijnen Postbus 20901 2500 EX Den Haag

DATE August 23, 2022

REFERENCE CGM/220823-01

SUBJECT Additional advice on import and processing of GM oilseed rape MON94100

## Dear Minister.

In May 2021, COGEM advised on the application for the hypothetical import and processing of genetically modified (GM) oilseed rape MON94100 (EFSA/GMO/NL/2020/169). Oilseed rape MON94100 is tolerant to dicamba containing herbicides due to the insertion of a *dmo* expression cassette. MON94100 will be used to produce stacked events via traditional breeding and will not be commercialised as a stand-alone product.

In its previous opinion on GM oilseed rape MON94100, COGEM concluded that the hypothetical import and processing of oilseed rape MON94100 poses a negligible risk to the environment in the Netherlands. In addition, COGEM made two additional remarks about the application, which were submitted to the European Food Safety Authority (EFSA) by the Dutch Competent Authority. EFSA recently published its scientific opinion on import and processing of GM oilseed rape MON94100, which also took into account the comments submitted by the EU member states during the member state consultation period. The Dutch portal for European market applications (the Food-Feed-portal) asked COGEM whether COGEM's remarks on the application were sufficiently answered by EFSA.

One of COGEM's remarks concerned the hypothetical nature of the import of this GM oilseed rape event. COGEM pointed out that the assessment of this single event was irrelevant, because it will not be commercialised as a stand-alone product. EFSA thanked the Netherlands for this comment, but did not respond to the content of the remark. COGEM remains of the opinion that EFSA's requirement to submit a separate application for single events that will not be commercialised, but

<sup>&</sup>lt;sup>1</sup> COGEM (2021). Environmental risk assessment of import and processing of genetically modified dicamba tolerant oilseed rape MON94100. COGEM advice CGM/210531-02 (confidential)

will only be used to produce a stacked event,<sup>2</sup> is an example of an unnecessary procedure which leads to needless administrative workloads and costs as well as delays in the authorisation of stacked events. COGEM therefore urges EFSA to lift this requirement in particular for events that will not be commercialised.

The other remark of COGEM concerned the confidential nature of the application. The applicant stated that the information in the application was confidential, which is in conflict with the Aarhus Convention that regularises the right of the public to access environmental information and has been implemented in the European legislation.<sup>3</sup> In its previous opinion on MON94100 COGEM pointed out that information which is crucial to assess potential risks of a GM crop should not be declared confidential, because lack of transparency undermines public trust in the risk assessment.

In its response to COGEM's remark, EFSA pointed out that the European Commission is in charge of assessing the confidentiality claims. COGEM notes that the confidentiality has not been lifted. COGEM's concerns about the confidential nature of the information in the application therefore remain.

In summary, the two additional remarks that were made in COGEM's previous opinion on MON94100 were not answered sufficiently by EFSA. These remarks do not relate to the environmental safety of MON94100. COGEM remains of the opinion that the hypothetical import and processing of oilseed rape MON94100 poses a negligible risk to the environment in the Netherlands.

Sincerely yours,

Prof. Sybe Schaap Chair of COGEM

c.c.

- Drs. Y de Keulenaar, Hoofd Bureau ggo
- Ministerie van IenW, Directie Omgevingsveiligheid en milieurisico's, DG Milieu en Internationaal
- Ing. M.A.C. Möllers, Food-Feed loket

<sup>&</sup>lt;sup>2</sup> European Food Safety Authority (EFSA) (2010). Scientific opinion. Guidance on the environmental risk assessment of genetically modified plants. The EFSA Journal 8: 1879

<sup>&</sup>lt;sup>3</sup> Aarhus Convention (1998). Convention on access to information, public participation in decision-making and access to justice in environmental matters. 25 June 1998, Aarhus, Denmark