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KENMERK CGM/140709-01
ONDERWERP Advies n.a.v. EFSA opinie over vergunning voor Import van genetisch gemodificeerd koolzaad MON88302

Geachte mevrouw Mansveld,

De COGEM is naar aanleiding van het verschijnen van de European Food Safety Authority (EFSA) opinie over de vergunningaanvraag voor import en verwerking van de genetisch gemodificeerde koolzaadlijn MON88302 (EFSA/GMO/BE/2011/101) gevraagd of haar eerdere commentaren met betrekking tot deze aanvraag zijn beantwoord. De COGEM adviseert u als volgt.

Samenvatting:

Genetisch gemodificeerd (gg-)koolzaad MON88302 is tolerant voor glyfosaat bevattende herbiciden. In 2012 heeft de COGEM geadviseerd over een vergunningaanvraag betreffende de import en verwerking van deze koolzaadlijn. De COGEM achtte het noodzakelijk het monitoringsplan behorende bij deze vergunningsaanvraag aan te passen. De EFSA heeft in haar recent uitgebrachte opinie de door COGEM geuite bezwaren niet weggenomen. Deze bezwaren zijn daarom nog onverkort van kracht.

De COGEM adviseert om langs koolzaadistributieroutes en bij koolzaad-overslagstations te monitoren op de aanwezigheid van MON88302 opslagplanten. In Nederland kunnen op verstoorde grond langs transportroutes (wegbermen, spoorwegen) en bij overslagstations kleine koolzaadpopulaties ontstaan. De vestiging van MON88302 opslagplanten kan daarbij niet uitgesloten worden, vooral als glyfosaat voor de bestrijding van onkruid wordt toegepast zoals bij spoorwegen gebruikelijk is. Deze opslagplanten kunnen andere (gg-)koolzaad opslagplanten bevruchten, waardoor verschillende transgene eigenschappen in één plant samen kunnen komen. Het kan op voorhand niet uitgesloten worden dat een mogelijke combinatie van transgene eigenschappen tot een potentieel schadelijk effect kan leiden.

De COGEM is van mening dat voor toekenning van de vergunning aanpassing van het general surveillance plan noodzakelijk is.

Additional advice on the import and processing of genetically modified oilseed rape MON88302

COGEM advice CGM/140709-01

Introduction

Genetically modified (GM) oilseed rape (*Brassica napus*) MON88302 expresses the *cp4 epsps* gene conferring tolerance to glyphosate containing herbicides. Recently the European Food Safety Authority (EFSA) published a Scientific Opinion for the placing on the market of oilseed rape MON88302 for food and feed uses, import and processing.¹ The EFSA concluded that oilseed rape MON88302 is as safe as its conventional counterpart and non-GM commercial oilseed rape varieties with respect to potential effects on human and animal health and the environment. In the opinion of EFSA, the monitoring plan is in line with the intended uses.

The Netherlands' Ministry of Infrastructure and the Environment asked COGEM whether the recently published EFSA opinion sufficiently answers COGEM's comments on the application for renewal of the authorisation of GM oilseed rape MON88302.

Previous COGEM advice

In 2013, COGEM stated that the post-market environmental monitoring plan for import and processing of MON88302 oilseed rape should be improved before a market authorization for this event is granted.²

Opinion

The concerns raised by COGEM in its previous advisory report have not been dealt with in EFSA's scientific opinion. In the opinion of COGEM the general surveillance plan for import and processing of MON88302 oilseed rape should be improved on several points. Most importantly, COGEM advises to include roadsides and railway beddings near oilseed rape transshipment and transport sites for monitoring on the presence of MON88302, in particular if glyphosate is applied for weed control as is usual for railway beddings.

The establishment of small volunteer populations of spilled MON88302 in disturbed environments where glyphosate is frequently applied cannot be excluded. Cross-fertilisation of volunteers harbouring the transgenic traits of MON88302 and other GM oilseed rape events could lead to stacking of different transgenic traits in one plant. A possible combination of these transgenic traits could potentially result in an unexpected, delayed or indirect adverse effect. COGEM is of the opinion that monitoring of MON88302 volunteers along transport routes or transshipment areas is of the utmost importance to enable the identification of a potential adverse environmental effects. If MON88302 volunteers are found, *Brassica rapa* populations in the vicinity of the observed volunteers will have to be included in the general surveillance plan as well, since Oilseed rape x *B. rapa* hybrids have been observed at locations where both species co-occur.

Additionally, the general surveillance plan could be improved by a commitment of the applicant to provide the raw obtained monitoring data and the analysis of these data to the Competent Authorities and the European Commission. Next to the European Commission, Member States should be immediately informed by the authorisation holder on identified unexpected adverse effects.

In summary, COGEM is of the opinion that approval of the application of import and processing of MON88302 should depend on the inclusion of monitoring along transport routes or transshipment areas in the general surveillance plan. Special attention should be paid to the areas where viable MON88302 oilseed rape seeds could be spilled unintentionally, enabling the identification of any direct or indirect, immediate, delayed or unanticipated environmental effects.

References

1. Scientific Opinion on application (EFSA-GMO-BE-2011-101) for the placing on the market of herbicide-tolerant genetically modified oilseed rape MON 88302 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto EFSA Journal 11(2): 3079-3105
2. COGEM (2012). Application for import of MON88302 oilseed rape. COGEM advice CGM/120612-01