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KENMERK CGM/170322-01
ONDERWERP Advies hernieuwing van de vergunning voor import van de gg-koolzaadlijn GT73

Geachte mevrouw Dijkma,

Naar aanleiding van een adviesvraag betreffende de hernieuwing van de vergunning voor import van de genetisch gemodificeerde koolzaadlijn GT73 (EFSA/GMO/RX/002), ingediend door Monsanto Europe S.A., deelt de COGEM u het volgende mee.

Samenvatting:

De COGEM is gevraagd om te adviseren over de hernieuwing van de vergunning voor import van de genetisch gemodificeerde (gg-) koolzaadlijn GT73.

De koolzaadlijn is door toevoeging van de genen *cp4 epsps* en *goxv247* tolerant voor glyfosaat bevattende herbiciden. De aanvraag voor de hernieuwing bevat onder andere geactualiseerde bioinformatische analyses, een recente literatuurreview en de resultaten van de verplichte 'post-market environmental monitoring'. Hieruit komen geen nieuwe inzichten over mogelijke risico's voor mens en milieu naar voren. Er zijn geen redenen om aan te nemen dat de geïntroduceerde eigenschap het verwilderingspotentieel van de gg-koolzaadlijnen vergroot, behalve op locaties waar glyfosaat wordt gebruikt.

Door het morsen van zaden kan er opslag optreden en komen er in Nederland koolzaadpopulaties voor langs transportroutes en bij overslagstations. Koolzaad kan kruisen met zijn wilde verwant Raapzaad. De COGEM kan op voorhand niet uitsluiten dat als gevolg van 'gene flow' op termijn "stapeling" van transgene eigenschappen in koolzaad- en raapzaadplanten kan optreden. Een mogelijke combinatie van transgene eigenschappen of een mogelijke interactie tussen producten van deze transgenen zou potentieel tot een schadelijk milieueffect kunnen leiden. Daarom acht de COGEM het noodzakelijk dat er bij import van gg-koolzaadlijnen verplicht gemonitord wordt op locaties waar de kans het grootst is wilde gg-koolzaadpopulaties aan te treffen, zoals langs spoorwegen. De COGEM is van mening dat een dergelijk monitoringsplan moet worden geïmplementeerd alvorens de vergunning voor import van GT73 kan worden hernieuwd.



De door de COGEM gehanteerde overwegingen en het hieruit voortvloeiende advies treft u hierbij aan als bijlage.

Hoogachtend,

Prof. dr. ing. Sybe Schaap
Voorzitter COGEM

c.c. Drs. H.P. de Wijs, Hoofd Bureau ggo
 Mr. J.K.B.H. Kwisthout, Ministerie van IenM

Renewal of the authorisation for import of feed of genetically modified oilseed rape GT73

COGEM advice CGM/170322-01

- The present application (EFSA/GMO/RX/002) concerns the renewal of the authorisation for import of feed and other products (containing or consisting) of genetically modified (GM) oilseed rape GT73;
- Oilseed rape GT73 has previously been authorized for import of feed and other products (containing or consisting of) in 2005, and for feed (produced from) and food in 2015;
- Oilseed rape GT73 expresses the *cp4 epsps* and *goxv247* genes, which confer tolerance to glyphosate containing herbicides;
- Feral oilseed rape populations occur across the Netherlands, with a small number of plants (<25 or less) per location, along distribution routes and handling areas as a result of spillage of oilseed rape seeds during transport and transshipment;
- Oilseed rape can hybridise with *Brassica rapa* which is a common plant along Dutch roadsides. To a lesser extent it can also hybridise with *Brassica juncea* and *Brassica oleracea*;
- Stable incorporation (introgression) of genes from *B. napus* into wild populations of *B. rapa* may be possible;
- The molecular characterisation of GT73 has been updated and meets the criteria of COGEM;
- Oilseed rape GT73 in itself poses a negligible risk to the environment in the Netherlands;
- There are no indications that the introduced trait alters the fitness of oilseed rape GT73 under natural conditions, except in places where glyphosate containing herbicides are used for weed control;
- In the long term, prolonged use of herbicides may lead to the establishment of feral herbicide tolerant GM *B. napus*, including plants with stacked events, or feral *B. rapa* harbouring GM traits, such as herbicide tolerance;
- The applicant wants to discontinue the monitoring of GT73 oilseed rape and did not submit a monitoring plan. COGEM is of the opinion that a monitoring plan which includes monitoring along transport routes (including roadsides and railway beddings) and transshipment areas is a prerequisite to grant an authorisation for import of GM oilseed rape.
- Because such a monitoring plan was not provided, COGEM cannot advise positively on the renewal application for import of GT73 oilseed rape.

1. Introduction

The present application (EFSA/GMO/RX/002), filed by Monsanto Europe S.A., concerns the renewal of the authorisation for import of feed and other products containing or consisting of GM oilseed rape GT73, with the exception of cultivation and uses as or in food. This authorisation was granted in 2005 (2005/635/EC).

GT73 has also been authorised for feed (produced from), and existing food (processed oil), foods and food ingredients containing, consisting of, or produced from GT73 oilseed rape since 2015 (2015/701/EU). This authorisation is valid until 2025 (2015/701/EU).

Since import and processing authorisations remain valid for a period of 10 years, the applicant filed an application for the renewal of the authorisation granted in 2005. The application contains amongst others monitoring reports, an updated molecular characterisation and an updated literature search.

2. Previous COGEM advices

COGEM has previously issued several advices on the import and processing of oilseed rape GT73.^{1,2,3,4,5,6} In 2013, COGEM issued a generic advice on aspects relevant for import and processing of GM oilseed rape in the Netherlands.⁷

In case of GM oilseed rape, COGEM is of the opinion that an elaborate post-market environmental monitoring (PMEM) plan is needed. In the view of COGEM, monitoring of oilseed rape transport routes (including roadsides and railway beddings) and transshipment areas is a prerequisite to grant an authorisation for import and processing of all GM oilseed rape events. Multiple applications filed for import and processing of GM oilseed rape lacked such elaborate monitoring plans. Therefore, COGEM issued several opinions in which it has advised negatively on import and processing of GM oilseed rape events.^{4,5,6,8}

3. Environmental risk assessment

3.1 Aspects of the crop

Oilseed rape (*Brassica napus*) is a member of the *Brassicaceae* family, which also includes *Brassica rapa*, *Brassica juncea*, *Brassica oleracea* (cabbage), *Brassica nigra* (black mustard) and *Brassica carinata* (Ethiopian mustard). *B. napus* is a hybrid that originates from the interspecific hybridisation of *B. oleracea* and *B. rapa*.^{9,7}

B. napus reproduces by self- and cross-pollination. It produces a huge amount of pollen, which are dispersed by both wind and insects. In fields, the average rate of cross-pollination is 30%. The seeds of *B.napus* develop in a fruit, and are small, light and produced in large quantities. Oilseed rape seeds generally do not display dormancy when they leave the plant, but they can acquire so-called dark dormancy after burial. The seed bank of oilseed rape has quite a rapid turnover but a small portion of the seeds can remain viable for several years.^{10,11,7}

In the Netherlands, *B. napus* is grown as a crop and its seeds are imported for oil production. Wild *B. napus* populations grow on disturbed soil. *B. napus* is able to form volunteers in distributed environments near roadsides, railways and handling areas. The spillage of oilseed rape seeds during transport and transshipment has led to the establishment of feral populations, with a small number of plants (<25 or less) per location, along distribution routes and handling areas.¹²

Oilseed rape can cross-pollinate with its more common wild relative *B. rapa* and to a lesser extent with *B. juncea* and *B. oleracea*.^{7,10} Oilseed rape x *B. rapa* hybrid plants have been observed in the Netherlands.¹³ Stable incorporation (introgression) of genes from *B. napus* into wild *B. rapa* has not been documented in the Netherlands, but has been reported in Canada.¹⁴

Conclusion: Wild *B. napus* populations exist in the Netherlands. *B. napus* can hybridise with its wild relative *B. rapa*. Therefore, GM volunteers from spilled seeds can lead to dispersal of genes to wild populations of *B. napus* and *B. rapa*.

3.2 Description of the introduced genes and traits

Oilseed rape event GT73 is tolerant to glyphosate containing herbicides and was produced by means of *Agrobacterium tumefaciens* mediated transformation, using the PV-BNGT04 plasmid.

Introduced genes	Encoded proteins	Traits
<i>cp4 epsps</i>	Encodes the 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein, which has a reduced affinity for glyphosate compared to EPSPS naturally occurring in plants	Confers tolerance to glyphosate containing herbicides
<i>goxv247</i>	Encodes the glyphosate oxidoreductase (GOX) protein, which degrades glyphosate into aminomethylphosphonic acid (AMPA) and glyoxylate	Confers resistance to glyphosate containing herbicides
For a detailed description of the introduced genes and traits, see for example reference ⁴		

3.3 Updated bioinformatics analyses and molecular characterisation

The application for the renewal of the authorisation for feed, import and processing of GT73 oilseed rape contains an updated molecular characterisation. According to the applicant, no new elements that would invalidate the conclusions of the initial risk assessment were identified.

Conclusion: The molecular characterisation of GT73 oilseed rape has been updated and is adequate.

3.4 Systemic literature search

The applicant performed a literature search using two different bibliographic databases, covering publications published from 2007 to 2016. The search identified 114 references from the Web of ScienceTM Core Collection database, and 135 from the CABI CAB Abstracts database. Only two references were deemed relevant. According to the applicant, these articles did not indicate any potential adverse effects on human and animal health.

According to Article 23 under the Regulation (EC) No 1829/2003 the applicant is obliged to provide all new information that has become available with regard to the evaluation of the safety in the use of feed and risks of feed to animals, humans and the environment. The systemic literature search yielded papers on GT73 volunteers in countries where cultivation is not authorised, or on the

persistence of GT73 outside agricultural fields.^{15,16,17} These papers were considered irrelevant by the applicant. COGEM, however, is of the opinion that such information, which concerns potential environmental risks associated with import of GT73 oilseed rape, needs to be provided and discussed.

Conclusion: The systemic literature search did not include literature on potential environmental risks of GT73. It must be improved by including and addressing literature on potential environmental risks associated with GT73 oilseed rape import and processing.

3.5 Annual monitoring reports

The applicant supplied annual reports on the monitoring carried out between 2008 and 2015. Monitoring was performed by operators involved in the import, handling and processing of viable oilseed rape GT73, i.e., COCERAL, UNISTOCK and FEDIOL. Also, to monitor the safety of GT73 oilseed rape, the applicant performed a yearly review of the scientific literature. The monitoring results and literature search did not provide indications of adverse health or environmental effects associated with import or use of GT73 oilseed rape.

COGEM notes that in the yearly monitoring reports it is stated that “transport to inland crushing plants are not a viable economic option for processing imported oilseed rape”, and that “crushing plants located at ports are the only facilities likely to process imports of oilseed rape”. This is, however, not true for the situation in the Netherlands where transport to inland crushing plants does occur.¹⁸

Conclusion: The information in the annual monitoring reports gives no indication of adverse effects or incidents resulting from import and processing of GT73 oilseed rape.

4. Food/feed assessment

This application is submitted under Regulation (EC) 1829/2003, therefore a food/feed assessment is carried out by EFSA and national organisations involved in the assessment of food safety. In the Netherlands, a food and/or feed assessment for Regulation (EC) 1829/2003 applications is carried out by RIKILT. The outcome of the assessment by other organisations (EFSA, RIKILT) was not known when this advice was completed.

5. Post-market environmental monitoring (PMEM)

COGEM has previously raised concerns with regard to the PMEM of GM oilseed rape. COGEM is of the opinion that an elaborate PMEM plan is required for feed, import and processing of GM oilseed rape (see e.g.^{19,20,21}). The current PMEM efforts do not include monitoring of the occurrence of GM oilseed rape plants along import and transport routes and around processing plants, and is therefore considered insufficient by COGEM. In the current application, the applicant proposes to discontinue the PMEM efforts for GT73 oilseed rape.

Feral GT73 oilseed rape populations can arise at roadsides, railways and handling areas where spillage of seeds occurs during transshipment and transport (e.g. in Switzerland and Argentina^{16,22}, where cultivation of GT73 is not permitted). Plants arising from spilled GT73 seeds will have a selective advantage over other plants in places where glyphosate containing herbicides are used for weed control (for example along railways²³), because the use of these herbicides actively selects for herbicide tolerant GT73 *B. napus*. In the long term, prolonged use of herbicides may lead to the establishment of feral herbicide tolerant GM *B. napus*. This has been observed in *B. napus* cultivation areas in Canada, the USA, and Australia, that are sprayed with herbicides.^{17,24,25} In Germany, during an extensive environmental monitoring of import of GT73 oilseed rape, only a single transgenic volunteer (GT73) was identified out of 1918 tested, which suggests that spread of GT73 in Germany has not yet occurred.^{26,27}

B. napus is able to cross-pollinate with its more common wild relative *B. rapa* and hybrid populations are present in the Netherlands.¹³ Also, stable incorporation (introgression) of transgenes from *B. napus* into wild *B. rapa* has been reported.¹⁴ Gene flow of transgenes could therefore potentially lead to incorporation of transgenes into the gene pool of *B. rapa* populations and lead to the establishment of feral herbicide tolerant *B. rapa* with GM traits.

It cannot be excluded that a possible combination of GM traits and/or a possible interaction between gene products, expressed by the genetic modification, may result in an adverse effect. In the view of COGEM, PMEM (i.e. general surveillance) is *the* instrument to identify such direct or indirect, unanticipated, delayed, potentially adverse environmental effects.^{19,20,21}

Based on these considerations, COGEM is of the opinion that the monitoring of GT73 oilseed rape should be continued, and should be expanded to include monitoring along transport routes (including roadsides and railway beddings) and transshipment areas. When GM oil seed rape is observed, *B. rapa* populations in the vicinity of the observed population should be monitored as well. COGEM considers this a prerequisite to grant an authorisation for feed, import and processing of all GM oilseed rape events. The PMEM plan of GT73 oilseed rape needs to be continued and expanded before a market authorisation for the renewal is granted.

6. Overall conclusion

There are no indications that expression of the introduced traits will alter the fitness of oilseed rape GT73 under natural conditions. Import and processing of oilseed rape GT73 in itself poses a negligible risk to human health and the European environment.

However, gene flow of transgenes in GM oilseed rape could potentially lead to *B. napus* and *B. rapa* containing GM traits from several events. It cannot be excluded that a combination of GM traits and/or interaction between transgene products in *B. napus* or *B. rapa* may result in an unanticipated adverse effect.

Therefore, COGEM is of the opinion that a monitoring plan is a prerequisite and should include monitoring along transport routes and transshipment areas. Because such a monitoring plan was not submitted, COGEM cannot advise positively on the renewal application for feed, import and processing of oilseed rape GT73.

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