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KENMERK CGM/180807-02
ONDERWERP Advies hernieuwing van de vergunning voor import van de gg-koolzaadlijn T45

Geachte mevrouw Van Veldhoven,

Naar aanleiding van een adviesvraag betreffende de hernieuwing van de vergunning voor import van de genetisch gemodificeerde koolzaadlijn T45 (EFSA/GMO/RX/012), ingediend door Bayer CropScience LP, 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 T45. T45 brengt het *pat* gen tot expressie en is daardoor tolerant voor glufosinaat-ammonium bevattende herbiciden.

Sinds 2006 wordt er wereldwijd geen zaaizaad meer verkocht voor de teelt van T45, omdat de lijn commercieel niet interessant meer is. De producenten en verkopers van T45 hebben hun voorraden vernietigd. De vergunninghouder heeft een aanvraag voor hernieuwing van de vergunning ingediend, omdat de aanwezigheid van kleine hoeveelheden T45 in geïmporteerd koolzaad niet volledig uitgesloten kan worden.

De aanvraag bevat onder andere geactualiseerde bioinformatische analyses, een recente literatuurreview, gegevens over de aanwezigheid van T45 in geïmporteerd koolzaad en resultaten van de verplichte 'post-market environmental monitoring'. Hieruit komen geen nieuwe inzichten over mogelijke milieurisico's van T45 koolzaad naar voren.

De COGEM is van oordeel dat bij import van gg-koolzaad verplicht gemonitord moet worden op locaties waar de kans het grootst is om wilde gg-koolzaadpopulaties aan te treffen, zoals langs spoorwegen. In het monitoringsplan dat deel uitmaakt van deze vergunningaanvraag is dit niet opgenomen. Gg-koolzaad T45 zal echter hoogstens in minimale hoeveelheden als onbedoelde vermenging van andere koolzaadpartijen geïmporteerd worden. De COGEM is daarom van mening dat het huidige monitoringsplan in het geval van T45 volstaat.

Concluderend acht de COGEM de risico's voor mens en milieu van de import van kleine hoeveelheden T45 verwaarloosbaar klein. Omdat andere instanties een voedselveiligheidsbeoordeling uitvoeren, heeft de COGEM de risico's van incidentele consumptie niet beoordeeld.



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 IenW
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Renewal of the authorisation for import of genetically modified oilseed rape T45

COGEM advice CGM/180807-02

- The present application (EFSA/GMO/RX/012) concerns the renewal of the authorisation for import and processing for use in food, feed and other products containing or produced from genetically (GM) oilseed rape T45;
- Its purpose is to cover the adventitious presence of T45 resulting from the commercialisation of T45 in other countries until 2005;
- T45 oilseed rape expresses the *pat* gene, conferring tolerance to glufosinate-ammonium 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 bioinformatic analyses of T45 have been updated and meet the criteria of COGEM;
- The information in the annual monitoring reports, the scoping literature review and several unpublished studies do not contain any indication of potential environmental risks or incidents resulting from import and/or processing of T45 oilseed rape.
- In general, COGEM is of the opinion that the monitoring plan for import and processing of GM oilseed rape should include monitoring along transport routes (including roadsides and railway beddings) and transshipment areas;
- Import of T45 oilseed rape will, however, be limited to trace amounts of T45 inadvertently commingled with commodity rapeseed;
- Therefore, in this specific case, COGEM is of the opinion that the current PMEM plan is sufficient;
- COGEM is of the opinion that the adventitious presence of T45 in commodity rapeseed poses a negligible risk to the environment in the Netherlands;
- COGEM abstains from giving advice on the potential risks of incidental consumption since other organisations carry out a food/feed assessment.

1. Introduction

The present application (EFSA/GMO/RX/012), filed by Bayer CropScience LP, concerns the renewal of an authorisation for food, feed and other products containing or produced from genetically modified (GM) oilseed rape T45. This authorisation was granted in 2009 for a period of 10 years. Its purpose is to cover the adventitious presence of T45 resulting from the commercialisation of T45 in third countries until 2005.¹ T45 oilseed rape expresses the *pat* gene, conferring tolerance to glufosinate-ammonium containing herbicides.

1.1 Adventitious presence of T45

Oilseed rape T45 was cultivated from 1998 to 2005 in Canada and the United States of America. The commercialisation of T45 was stopped after the 2005 planting season. The parties involved in its production and sale certified the destruction of T45 stocks. According to the applicant, it is not possible to fully assure the complete absence of T45 because of a.o. adventitious presence of T45 in certified seed, storage of seed by farmers, or volunteer plants germinating from the soil seed bank.

Import of T45 will be limited to low levels of T45 in commodity rapeseed. As required by the authorisation granted in 2009, the applicant monitored the presence of T45 in shipments of oilseed rape imported into the European Union and originating from a country in which T45 was commercialised. These oilseed rape shipments were sampled and tested using PCR. None of the shipments sampled in 2015 (N=8) and 2016 (N=19) were positive for T45. In 2017, 28 shipments were sampled. One of the samples of one shipment tested positive for T45 (measured target concentration 0.004%). These results indicate that imported oilseed rape may still contain trace amounts of T45.

2. Previous COGEM advices

COGEM has previously assessed the risks of spillage of imported oilseed rape contaminated with trace amounts of T45. COGEM considered the risk of T45 to human health and the environment to be negligible.²

3. Environmental risk assessment

3.1 Aspects of the wild-type 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*.^{3,4}

B. napus reproduces by self- and cross-pollination. It produces high amounts 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.^{3,5,6}

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.⁷

Oilseed rape can cross-pollinate with its more common wild relative *B. rapa* and to a lesser extent with *B. juncea* and *B. oleracea*.^{3,5} Oilseed rape x *B. rapa* hybrid plants have been observed in the Netherlands.⁸ 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.⁹

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

T45 was produced by *Agrobacterium*-mediated transformation. It expresses the *pat* gene resulting in tolerance to glufosinate-ammonium containing herbicides.

Introduced genes	Encoded proteins	Traits	Regulatory elements
<i>pat</i>	Encodes the phosphinothricin acetyltransferase (PAT) protein. ²	Confers tolerance to glufosinate-ammonium containing herbicides	35S promoter and 35S terminator from <i>Cauliflower mosaic virus</i> (CaMV)
<i>See reference for a detailed description of the trait</i>			

3.3 Updated bioinformatics analyses and molecular characterisation

The applicant did not generate new sequence data, because T45 is no longer commercialised. The insert and its flanking regions were sequenced in 2002 and 2004, respectively. Recent databases were used to update the bioinformatic analyses of T45. According to the applicant, the results of these analyses do not change the conclusions of the original risk assessment.

Conclusion: The molecular characterisation of T45 oilseed rape has been updated and is adequate.

3.4 Annual monitoring reports and literature review

The applicant supplied annual reports on the monitoring carried out between 2009 and 2017. Monitoring was performed by operators involved in the import, handling and processing of viable oilseed rape potentially including commingled T45, i.e. COCERAL, UNISTOCK and FEDIOL. 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, except under extreme

circumstances”, 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.¹⁰

The applicant performed a yearly review of the scientific literature. In 2017, the applicant performed a ‘scoping’ review of the literature published over a longer period (i.e. from March 2009 until September 2017) using several bibliographic databases. In addition, an overview was provided of unpublished studies (produced, controlled or sponsored by the applicant) on the PAT protein and T45 oilseed rape.

Conclusion: The information in the annual monitoring reports, the scoping literature review and the unpublished studies do not contain any indication of potential environmental risks or incidents resulting from import and/or processing of T45 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

On several occasions, COGEM has raised concerns with regard to the post-market environmental monitoring (PMEM) plan of GM oilseed rape. COGEM is of the opinion that a PMEM plan is required that includes monitoring along transport routes (including roadsides and railway beddings) and transshipment areas.³ The applicant is of the opinion that the current PMEM plan, which does not include monitoring of transport routes and transshipment areas, does not need to be revised.

The commercialisation of T45 oilseed rape was stopped after the 2005 planting season and the parties involved in its production and sale certified the destruction of T45 stocks. Import of T45 will be limited to trace amounts of T45 inadvertently commingled with commodity rapeseed. Therefore, in this specific case, COGEM is of the opinion that the PMEM plan is sufficient. In the future, COGEM will continue to assess case-by-case whether the submitted general surveillance plan is adequate for the specific authorisation that is being considered.

6. Overall conclusion

The requested authorisation covers import and processing of T45 resulting from the commercialisation of T45 in other countries until 2005 (adventitious presence). COGEM is of the opinion that the adventitious presence of T45 in commodity rapeseed poses a negligible risk to the environment in the Netherlands. COGEM abstains from giving advice on the potential risks of incidental consumption since other organisations carry out a food/feed assessment.

References

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