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KENMERK CGM/070904-01
ONDERWERP Advies aanvullende informatie EFSA/GMO/NL/2005/18

Geachte mevrouw Cramer,

Naar aanleiding van aanvullende informatie omtrent dossier EFSA/GMO/NL/2005/18 adviseert de COGEM als volgt.


Samenvatting:

In april 2006 heeft de COGEM een negatief advies uitgebracht over de vergunningaanvraag EFSA/GMO/NL/2005/18, voor de import en verwerking van herbicidentolerante soja A2704-12. De COGEM stelde destijds dat de moleculaire karakterisering van de sojalijn onvolledig was. In het dossier ontbraken gegevens die duidelijkheid moesten verschaffen over de 5' flankerende sequentie. Hierdoor kon niet volledig uitgesloten worden dat er ten gevolge van de insertie nieuwe open leesramen waren ontstaan die theoretisch tot toxische of allergene producten konden leiden.

Naar aanleiding van dit commentaar heeft de European Food Safety Authority (EFSA) de aanvrager, in dit geval Bayer CropScience, om aanvullende informatie gevraagd. De EFSA heeft op basis van deze aanvullende informatie geoordeeld dat er geen risico's te verwachten zijn bij de import en verwerking van sojalijn A2704-12 in Europa.

De COGEM is verzocht te beoordelen of aan de hand van deze nieuwe gegevens het eerder afgegeven advies geactualiseerd moet worden.

De COGEM is op basis van de nieuwe informatie van mening dat de moleculaire karakterisering op een adequate wijze is uitgevoerd en op afdoende wijze is aangetoond dat de nieuw ontstane open leesramen niet coderen voor toxische of allergene producten. De COGEM acht de risico's van import en verwerking van de sojalijn A2704-12 daarom verwaarloosbaar klein en adviseert daarmee positief over deze aanvraag.



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

Hoogachtend,



Prof. dr. ir. B.C.J. Zoeteman
Voorzitter COGEM

cc. Dr. D.C.M.Glandorf
Dr. I. van de Leij

Molecular characterization of soybean A2704-12

COGEM advice: CGM/070904-01

Summary

In April 2006, COGEM advised negatively on the application EFSA/GMO/NL/2005/18. The application concerned the import and processing for use in feed and food of genetically modified herbicide tolerant soybean A2704-12. COGEM stated that there was a lack of information regarding the molecular analysis. In particular, the data presented on the 5' flanking sequence were incomplete. On basis of the data available it could not be ruled out that new chimeric open reading frames (ORFs) were created due to the insertion. New putative ORFs could theoretically give rise to potential toxic or allergenic products. In view of this deficiency in the molecular analysis, COGEM advised negatively on this application. As a result of this comment, EFSA asked the applicant, Bayer CropScience, for additional information regarding the molecular characterization.

Based on this information, COGEM is of the opinion that the molecular characterization has been performed adequately and the data presented indicate that newly formed ORFs do not code for any known toxic or allergic products. Therefore, COGEM reconsidered her previous opinion and advises positively on this application.

Previous COGEM advice

The present application concerns the commercial import for food and feed purposes of soybean event 2704-12. This soybean line has been genetically modified by introduction and expression of the *pat* gene which confers tolerance to herbicides containing the active ingredient glufosinate ammonium.

In April 2006, COGEM advised on this application (1). In this advice, COGEM stated that the analysis of the flanking regions of the A2704-12 insert demonstrated that both the 5' and 3' flanking sequences were of soybean origin. However, the 5' flanking sequence of the insert appeared to be chloroplast genomic DNA. Most likely the chloroplast sequences were co-integrated during the transformation process. Since no data were provided on the actual 5' integration site, it could not be completely excluded that upstream of the chloroplast sequences other sequences were integrated. Moreover, the insertion of the chloroplast sequences or other putative sequences may have resulted in new chimeric open reading frames (ORFs) at the insertion site.

COGEM stated that the entire nucleotide sequence of the inserted chloroplast DNA should be determined and that the sequence analysis should be extended into the 5' nuclear genomic plant sequence. In addition, according to COGEM the applicant had to provide a more detailed study of the 5' flanking sequence of the insert and chloroplast DNA, before a positive advice could be issued.

Evaluation of the additional information

As a result of the comments mentioned above, EFSA asked the applicant for additional information and in August 2006, the additional information was delivered. Based on this information, the EFSA scientific panel concluded that the import and processing of A2704-12, poses no risk to human health or the environment. COGEM was asked whether the additional information gives reason to reconsider her former advice.

The applicant extended the sequence of the 5' flanking sequence of the insert and discovered that the total length of the inserted chloroplast DNA equals 2566 base pairs. Subsequently, ORF search tools to predict the presence of newly created coding sequences in the 5' flanking genomic/chloroplast DNA junction were applied. Seven other ORFs that originated as a result of the genetic modification were found during the first analysis. The additional information indicated that one additional ORF (ORF number 8) was present in the 5' junction. Theoretically, ORF8 could give rise to a protein of 25 amino acids long. However, no regulatory elements (CAAT- and TATA-box) are found in the vicinity of ORF8 (200 base pairs upstream the start codon (ATG)), which makes it improbable ORF8 is translated and that mRNA will be produced. On the other hand, COGEM comments on the choice of checking only two regulatory elements. As many more regulatory sequences exist the absence of CAAT and TATA boxes can not give absolute certainty about mRNA production. COGEM is of the opinion that the chances of mRNA formation are rare but can not be totally excluded.

All newly created or chimeric ORFs (including ORF8) originating as a result of the genetic modification were analyzed on their potential to give rise to toxic or allergic proteins. A comparison with sequences of known toxins and allergens did not show any homology. So if any transcript is formed, it does not code for any known allergen or toxin.

As stated in her former advice, there are no reasons to assume that the inserted genes will increase the potential of soybean A2704-12 to run wild. Furthermore, establishment of feral populations in soybean producing countries has never been observed. COGEM is of the opinion that, soybean volunteers can not survive and establish themselves in the wild. Therefore, COGEM is of the opinion that incidental spillage of the soybeans will pose no risk to the environment in the Netherlands or in other European countries.

As a result, there are no scientific reasons to assume that the genetic modification results in a risk to human health or the environment. Because of this, COGEM is of the opinion that the environmental risks of import and processing of soybean A2704-12 are negligible.

References

1. COGEM (2006). Import and processing of herbicide tolerant soybean A2704-12. Advice CGM/060410-04