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KENMERK CGM/140820-01
ONDERWERP Advies n.a.v. EFSA opinie over vergunning voor import van genetisch gemodificeerde katoenlijn MON15985

Geachte mevrouw Mansveld,

Naar aanleiding van het verschijnen van de European Food Safety Authority (EFSA) opinie over de vergunningaanvraag voor import en verwerking van de genetisch gemodificeerde katoenlijn MON15985 is de COGEM gevraagd of haar eerdere commentaren met betrekking tot deze aanvraag zijn beantwoord. De COGEM adviseert u als volgt.

Samenvatting:

In 2008 heeft de COGEM geadviseerd over import en verwerking van de genetisch gemodificeerde katoenlijn MON15985. Deze katoenlijn bevat de *cry1Ac* en *cry2Ab2* genen waardoor de planten resistent zijn tegen sommige vlinderachtigen. Daarnaast bevat MON15985 de genen *nptII* en *uidA*, die de selectie van getransformeerde planten mogelijk maakt. De COGEM concludeerde dat de milieurisico's van import en verwerking van katoenlijn MON15985 verwaarloosbaar klein zijn.

Recent heeft de EFSA een positief advies uitgebracht over de import en verwerking van katoen MON15985. Naar aanleiding van het verschijnen van het EFSA advies ziet de COGEM geen reden om haar eerder afgegeven advies te herzien. De COGEM acht de milieurisico's van import en verwerking van katoenlijn MON15985 verwaarloosbaar klein.

De COGEM wijst erop dat een beoordeling van de voedselveiligheid, inclusief incidentele consumptie, door een andere instantie wordt uitgevoerd en geen onderdeel is van de risicoanalyse in dit advies.

Additional advice on import and processing of genetically modified cotton MON15985

COGEM advice CGM/140820-01

Introduction

Cotton line MON15985 was produced by insertion of the *cry2Ab2* and *uidA* genes into the genome of the genetically modified cotton line MON531, which already contains the *cryIAc* and *nptII* genes. The *cry* genes confer resistance to certain insects of the lepidopteran order, while the *nptII* and *uidA* genes are used as markers during transformation. In addition, the *aad* marker gene is present. The *aad* gene is not expressed in MON15985, because it is under control of a prokaryotic promoter, which is not functional in cotton.

Recently, EFSA published her opinion for placing on the market for feed and food uses, import and processing of cotton MON15985. EFSA concludes that cotton MON15985 is as safe as its conventional counterpart and non-GM cotton commercial varieties, and is unlikely to have adverse effects on human and animal health and the environment in the context of the scope of these applications.

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 import and processing of cotton line MON15985.

Previous advice

In 2008, COGEM advised positively on the import and processing of cotton line MON15985.¹ COGEM noted that the molecular characterization of MON531, which was used to produce MON15985, contained weaknesses. Consequently, the molecular characterization of MON15985 contained weaknesses as well. However, since cotton line MON531 has a history of safe use and considering the fact that cotton is unable to grow in the Netherlands, COGEM was of the opinion that the proposed import and processing of the genetically modified cotton line MON15985 does not pose a significant risk to the environment in the Netherlands.

COGEM made an additional remark about the presence of the *aad* gene in MON15985. In 2004, EFSA published an opinion on the use of antibiotic resistance genes as marker genes in genetically modified plants.² EFSA concluded that the frequency of horizontal gene transfer of antibiotic resistance genes from genetically modified plants to other organisms is very low. Furthermore, it has been shown, or is extremely likely, that there is a considerable pool of resistance genes already present in the microbiota in the environment. In spite of these considerations, EFSA was of the opinion that the *aad* gene should be restricted to field trial purposes and should not be present in GM plants which will be placed on the market. On the other hand, EFSA stated that there is no rationale for restricting or prohibiting the use of *nptII* in plants to be placed on the market; in

particular, because *nptII*, among others, has a history of safe use in food crops. COGEM is of the opinion that the presence of both the *nptII* and *aad* antibiotic resistance genes poses no risk to the environment or to human health.¹

Advice

In 2009, EFSA published a new opinion stating that adverse effects on human health and the environment resulting from the transfer of the *nptII* and *aad* genes from GM plants to bacteria, associated with the use of GM plants, are unlikely.³ EFSA concludes in her Scientific Opinion on MON15985 that the analysis of horizontal gene transfer from cotton MON15985 to bacteria does not indicate a risk to human or animal health or to the environment in the context of its intended uses. This is in line with the conclusion of COGEM.

In response to the publication of the EFSA opinion, COGEM sees no reason to revise its previous advice. In conclusion, COGEM is of the opinion that the import and processing of genetically modified cotton line MON15985 poses negligible risks to the environment in the Netherlands. COGEM points out that a food/feed safety assessment is carried out by other organizations.

References

1. COGEM 2008. Import and processing of MON15985. COGEM advice CGM/081020-01.
2. European Food Safety Authority (2004). Opinion of the scientific panel on genetically modified organisms on the use of antibiotic resistance genes as marker genes in genetically modified plants (Question N° EFSA-Q-2003-109). The EFSA Journal 48: 1-18.
3. European Food Safety Authority (2009) Consolidated presentation of the joint Scientific Opinion of the GMO and BIOHAZ Panels on the “Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants” and the Scientific Opinion of the GMO Panel on “Consequences of the Opinion on the Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants on Previous EFSA Assessments of Individual GM Plants” The EFSA Journal 1108, 1-8.