Additional advice on import and processing of herbicide tolerant soybean 356043

COGEM advice CGM/110822-01

Summary

Recently, EFSA published its opinion for placing on the market of genetically modified herbicide tolerant soybean line 356043, expressing the gat4601 *and* gm-hra *genes. EFSA concludes that food and feed uses, import and processing of soybean 356043 are unlikely to have any adverse effect on human and animal health and the environment.*

In 2007 COGEM did not advise positively on the import and processing of soybean 356043. Although the environmental risks were negligibly small in the opinion of COGEM, the molecular characterization was incomplete. Besides, COGEM had its reservations on the quality of the toxicity studies performed and questioned some aspects of the general surveillance (GS) plan. Based on comments and opinions submitted by Member States, EFSA requested the applicant to provide additional information. The new information has been incorporated in the current EFSA opinion.

The revised molecular characterization and GS plan fulfill the criteria as laid down by COGEM. As a food/feed safety assessment is carried out by other organizations, COGEM did not assess new information concerning risks on incidental consumption in this case. In conclusion COGEM is of the opinion that import and processing of soybean line 356043 pose a negligible risk to the environment.

Introduction

Recently, EFSA published its opinion for placing herbicide tolerant soybean line 356043 on the market. EFSA concludes that food and feed uses, import and processing of soybean 356043 are unlikely to have any adverse effect on human and animal health and the environment. Soybean 356043 contains and expresses the *gat4601* and *gm-hra* genes which confer tolerance to glyphosate based and acetolactate synthase–inhibiting herbicides, respectively.

The Netherlands' Ministry of Infrastructure and the Environment (IenM) asked COGEM whether the opinion of the EFSA GMO panel including additional information from the applicant gives reason to reconsider its previous advice.

Previous COGEM advice

In 2007 COGEM did not advise positively on the import and processing of soybean line 356043.[1] COGEM commented on the information regarding the molecular characterization and had its reservations on the quality of the toxicity studies performed. Besides, she questioned some aspects on the general surveillance plan. Comments are as follows.

Comments on the molecular characterization

Based on the DNA sequence analysis of soybean line 356043 it was not clear whether rearrangements and deletions around the insertion site had taken place. Besides, the junctions between the T-DNA and its flanking regions were examined for potential novel open reading

frames (ORFs). The applicant defined an ORF as a region that initiates with an ATG codon and ends with any of the three stop codons TAA, TAG or TGA. COGEM pointed out that translation may initiate with other codons or that an ORF, which does not start with an ATG, may become part of a longer ORF by the process of pre-mRNA splicing. Therefore, COGEM is of the opinion that bioinformatic analyses on the junction between the T-DNA and its flanking regions have to be performed from stop to stop codon.

Comments on toxicity studies

COGEM had its reservations on the quality of toxicity studies performed and therefore could not draw conclusions regarding any potential adverse effects related to incidental consumption.

General surveillance plan

In the opinion of COGEM the applicant should describe in more detail how the general surveillance (GS) is organized and which organizations are involved. In addition, the applicant should ascertain that information on eventual adverse effects is indeed obtained. Direct and indirect effects should be reported annually. However, because soybean can not survive in the North-Western European climate, COGEM noted that a general surveillance plan in this specific case was of less importance for the situation in the Netherlands.

Consideration and advice

In 2008 COGEM revised its criteria for the molecular characterization of genetically modified organisms being placed on the market.[2] On request of EFSA the applicant performed additional bioinformatic analyses to complement the molecular characterisation. The additional analyses fulfill the criteria laid down by COGEM. All 12 putative ORFs spanning the junction between insert and flanking regions were bioinformatically analysed from stop to stop codon. No similarities were found to known toxins and allergens.

Since 2008, COGEM abstains from advices on the potential risks of incidental consumption in case a food/feed safety assessment is already carried out by other organizations. This application is submitted under Regulation (EC) 1829/2003, therefore a food/feed safety assessment is carried out by EFSA. Other organizations who advise the competent authorities can perform an additional assessment on food safety although this is not obligatory. In the Netherlands a food and/or feed safety assessment for Regulation (EC) 1829/2003 applications is carried out by RIKILT. Therefore, COGEM did not assess new information concerning food and/or feed safety and risks on incidental consumption.

On request of EFSA the applicant has updated and complemented the monitoring plan. In 2010 COGEM revised its criteria concerning GS plans for import and cultivation of GM crops.[3] Although the GS plan could be improved by a guarantee that operators will monitor for unanticipated effects, COGEM considers the current GS plan sufficient for import and processing of soybean 356043.

The revised molecular characterization and GS plan fulfill the criteria as laid down by COGEM. As a food/feed safety assessment is carried out by other organizations, COGEM did not assess new information concerning risks on incidental consumption in this case. In conclusion COGEM

is of the opinion that the risks associated with import and processing of soybean 356043 are negligibly small.

References

1. COGEM (2007). Import and processing of herbicide tolerant soybean 356043. COGEM advice CGM/071129-01
2. COGEM (2008). Signalering moleculaire karakterisering. Signalering CGM/081219-01
3. COGEM (2010). General Surveillance. Signalering CGM/100226-01