Molecular characterization of soybean MON89788

COGEM advice CGM/080827-01

Summary

In August 2007, COGEM advised negatively on the application EFSA/GMO/NL/2006/36. The application concerned the import and processing for use in feed and food of genetically modified herbicide tolerant soybean MON89788. COGEM stated that there was a lack of information regarding the molecular analysis. As a result of these comments, the European Food Safety Authority (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 the flanking regions consist of soybean genomic DNA. Furthermore, by providing a more detailed monitoring plan, the former objections by COGEM regarding the general surveillance are dispelled. Therefore, COGEM reconsiders her previous opinion and advices positively on this application.

Previous COGEM advice

The application concerns the commercial import for food and feed purposes of soybean event MON89788. This soybean line has been genetically modified by introduction and expression of the *aroA* (*epsps*) gene which confers tolerance to herbicides containing the active ingredient glyphosate.

Molecular characterization

In August 2007, COGEM advised on this application (1). In this advice, COGEM stated that the applicant did not provide evidence for its statement that the flanking regions of the insert were soybean genomic DNA. The results of bioinformatic analyses on the DNA sequences were not shown and because the sequence was confidential and, consequently, could not be subjected to BLAST analyses, the applicant's conclusions could not be confirmed. In addition, the conclusion that the insert was not inserted into an active gene was not substantiated with data. Furthermore, COGEM was of the opinion that it was not sufficiently proven that the complete chromosomal integration site was characterized. The presence of soybean genomic DNA in the flanking regions could also be explained by co-integration of soybean DNA from other parts of the genome.

In view of the crop's characteristics, COGEM was of the opinion that environmental risks of the import of MON89788 are probably negligible. However, this opinion could not be substantiated because the molecular characterization was incomplete.

General surveillance

Next to the molecular characterization, COGEM placed some comments regarding the general surveillance plan. The applicant stated that general surveillance will be performed either by selected networks and/or specific company stewardship programs. The permit holder will request key stakeholders and networks to participate and ask them to be informed if any unanticipated adverse effects occur. However, it was unclear to COGEM how these adverse effects are monitored if key stakeholders and networks fail to cooperate. In COGEM's opinion the permit holder should ascertain that information on adverse effects is obtained also when key stakeholders and networks do not participate.

In addition, the applicant made a distinction between reporting direct and indirect effects in the monitoring plan. According to the applicant direct effects will be reported annually, whereas indirect effects will only be reported at the stage of re-evaluation or at the end of a given permit. In COGEM's opinion the applicant should report both direct and indirect effects annually.

Evaluation of the additional information

As a result of the comments mentioned above, EFSA asked the applicant for additional information. Based on this information, the EFSA scientific panel concluded that the import and processing of MON89788, poses no risk to human health or the environment. COGEM was asked by the ministry of VROM whether the additional information gives reason to reconsider her former advice.

Flanking regions consist of soybean genomic DNA

The applicant performed PCR analysis to prove that the flanking regions consist of soybean genomic DNA. A primer pair that hybridized to the 5' and 3' genomic flanking regions of the *cp4epsps* insert in MON89788 was used. A PCR was done on the conventional soybean DNA. Subsequently, the PCR product was sequenced and compared to the DNA sequences flanking the insert of MON89788. The results show that a 40 bp genomic deletion occurred in MON89788. This indicates that during T-DNA integration a deletion of 40 bp has taken place. Furthermore, there are six bases at the 3' end and ten bases at the 5' flanking regions that are not present in this region of the conventional soybean genome. COGEM is of the opinion that these alterations do not affect the outcome of the risk analysis negatively.

Further comparison shows that bases 1-227 and 268-482 from conventional soybean are identical to respectively the 5' and 3' genomic DNA sequences flanking the MON89788 insert. Therefore, COGEM is of the opinion that the applicant proved that the flanking regions of the insert of MON89788 consist op soybean genomic DNA.

Insert is not inserted into a known gene

The EFSA scientific panel is of the opinion that there is no indication that a known soybean gene was interrupted by the insertion. Based on the molecular analysis performed and the

conclusion, COGEM agrees with this opinion. In addition, effects due to an interrupted gene probably would have been detected during field trials with MON89788. Results of these field trials show no difference between MON89788 and traditional soybean in the mode or rate of reproduction, dissemination, survivability or other agronomic, phenotypic or ecological characteristics.

Integration site is characterized

By the previous mentioned PCR and sequence analyses, the applicant showed that the 5' and 3' flanking regions from conventional soybean are identical to the 5'and 3' regions from MON89788. COGEM is of the opinion that in this way, it was adequately proven that the integration site was characterized.

Questions on general surveillance answered satisfactory

The applicant provided more detailed information on monitoring to EFSA. COGEM is of the opinion that the general surveillance plan is now sufficient to observe and register adverse effects of MON89788 timely. Many stakeholders are invited to participate in the general surveillance. Existing monitoring systems are considered a useful tool to collect data on the performance and impact of the genetically modified plant. Following the initial placing on the market, general surveillance reports on direct and indirect effects, are submitted on an annual basis.

The monitoring plan and associated methodology will be reviewed and updated or adapted when necessary. COGEM would like to strongly suggest an adaptation of the methodology.

Operators involved in the import, handling and processing of soybean MON89788 will notify the authorization holder directly or via the European Association of Bioindustries (EuropaBio) of the results of the general surveillance. EuropaBio is an association of members of the plant biotechnology industry which hosts a website containing information on approved genetically modified plants subject to general surveillance. COGEM remarks that this website contains only an e-mail address and a telephone number to exchange information on the plants. She points out that to gather general surveillance data a questionnaire would be helpful. By placing such a list on the website, essential information on adverse effects can be collected in a more coherent and systematic manner.

Conclusion

In view of the above mentioned, there are no scientific reasons to assume that the genetic modification of soybean MON89788 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 this soybean are negligible.

References

1. COGEM (2007). Import and processing of glyphosate tolerant soybean MON 89788. Advice CGM/070807-01