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Minister for the Environment
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DATUM 27 mei 2016

KENMERK CGM/160527-01

ONDERWERP Import and processing of GM cotton GHB614xLLCotton25xMON15985 and GM soybean MON87751

Dear Minister,

In 2015, COGEM advised positively on import and processing of cotton GHB614x LLCotton25xMON15985 (EFSA-GMO-NL-2014-121) and soybean MON87751 (EFSA-GMO-NL-2011-94).[1,2]

Recently, EFSA informed the GMO office that in 2015 not the most recent versions of these applications had been made available. EFSA corrected its mistake by uploading new documents, and re-opened the commenting period for these applications.

The GMO office has asked COGEM whether the information in the updated applications gives COGEM reason to reconsider its earlier advice.

Import and processing of GHB614xLLCotton25xMON1598 cotton

Genetically modified cotton GHB614xLLCotton25xMON15985 expresses the *cry1Ac* and *cry2Ab2* genes, resulting in resistance to certain lepidopteran insects. In addition, it expresses the *bar* and *2m epsps* genes, providing tolerance to glyphosate and glufosinate ammonium containing herbicides. It also expresses the *nptII* and *uidA* genes allowing easy selection of transformed cotton cells.

In its opinion on GHB614xLLCotton25xMON5985, COGEM noted that the molecular characterisation of the parental line MON15985 was flawed.[1] However, considering all aspects relevant to the environmental risk assessment, in particular the biological

[1] COGEM (2015). Import and processing of genetically modified cotton GHB614xLLCotton25xMON15985 and LLCotton25xMON15985. COGEM advice CGM/151008-01

[2] COGEM (2015). Import of genetically modified soybean MON87751 with two insect resistance traits. COGEM advice CGM/150327-01

characteristics of GHB614xLLCotton25xMON5985, COGEM concluded that import and processing of GHB614xLLCotton25xMON15985 poses a negligible risk to the environment.

The information in the updated application contains a.o. updated data on protein expression and information on potential interactions with target organisms. COGEM notes that this application does not contain new information on the molecular characterisation of GHB614xLLCotton25xMON15985. Therefore, the previously identified weaknesses remain unresolved. However, as aforementioned, these weaknesses do not affect the outcome of the environmental risk assessment.

After assessing the updated information, COGEM concludes that its previous conclusion that GHB614xLLCotton25xMON15985 poses a negligible risk to the environment in the Netherlands remains valid.

Import and processing of MON87751 soybean

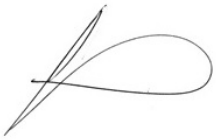
Genetically modified soybean MON87751 expresses the *cry1A.105* and *cry2Ab2* genes resulting in resistance to certain Lepidopteran insects.

The application assessed in 2015 contained the results from bio-informatic analyses carried out to investigate whether Cry1A.105, Cry2Ab2 and putative proteins potentially encoded by novel open reading frames spanning the junctions between the insert and the soybean genome were similar to known allergens, toxins and other potentially harmful proteins. In 2015, complete alignments were provided for the first 25 results and descriptions were given for the remaining top 100 results. The updated application contains a.o. complete alignments for all of the top 100 results.

COGEM assessed the data in the updated application and concludes that its previous conclusion that MON87751 poses a negligible risk to the environment in the Netherlands remains valid.

In conclusion, COGEM remains of the opinion that import and processing of cotton GHB614xLLCotton25xMON15985 and soybean MON87751 pose a negligible risk to the environment.

Yours sincerely,



Prof. Sybe Schaap
Chair of COGEM

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Mr. J.K.B.H. Kwisthout, Ministerie van IenM