

Aan de minister van
Infrastructuur en Waterstaat
drs. C. van Nieuwenhuizen-Wijbenga
postbus 20901
2500 EX Den Haag

DATUM 21 februari 2020

KENMERK CGM/200221-01

ONDERWERP Aanvullend advies over de importvergunning van de genetisch gemodificeerde sojalinj SYHT0H2

Dear Mrs Van Nieuwenhuizen,


In 2013, COGEM issued an advice on an application for import and processing of genetically modified (GM) soybean (*Glycine max*) SYHT0H2 (EFSA/GMO/DE/2012/111).¹ This event is tolerant of several herbicides due to the expression of the *avhppd-03* gene derived from oat (*Avena sativa*), and two *pat* genes derived from the bacterium *Streptomyces viridochromogenes*. COGEM was of the opinion that the environmental risks associated with import and processing of soybean line SYHT0H2 are negligible, but noted that some data underpinning the molecular characterisation (e.g. the so-called blast results) were missing. COGEM was of the opinion that these results should be made available to verify that the conclusions of the applicant were correct.

Recently, the European Food Safety Authority (EFSA) published its scientific opinion on import and processing of soybean SYHT0H2. The opinion also took into account the scientific comments submitted by the EU Member States.² The Dutch portal for European market applications (the Food-Feed-portal) has asked COGEM whether its comments have been sufficiently answered by EFSA.

COGEM notes that the previous bioinformatics analyses on the AvHPPD-03 protein submitted in 2012 did not identify proteins with adverse effects. The applicant provided new data,

¹ COGEM (2013). Advisory report concerning import of herbicide tolerant soybean SYHT0H2. COGEM advisory report CGM/130325-01

² EFSA (2020). Scientific Opinion on the assessment of genetically modified soybean SYHT0H2 for food and feed uses, import and processing, under regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2012-111). EFSA Journal 18(1):5946

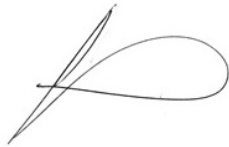


including the previous missing blast results. The bioinformatics analyses using recent protein, toxin and allergen databases revealed a 30% sequence identity of the AvHPPD-03 protein to bacterial haemolysins. No other noteworthy issues were detected.

The applicant has performed in vitro and in vivo studies with the AvHPPD-03 protein. Under the experimental conditions tested in vitro, the protein did not induce haemolysis. Toxicological studies in mice and rats showed no adverse effects related to the AvHPPD-03 protein. COGEM notes that the AvHPPD-03 protein is derived from oat. Based on the data provided, COGEM has no indications that the AvHPPD-03 protein has an adverse effect.

In conclusion, COGEM is of the opinion that the applicant has addressed the comments posed by COGEM, and that the environmental risks associated with import and processing of soybean line SYHT0H2 are negligibly small.

Sincerely yours,



Prof. dr. ing. Sybe Schaap
Voorzitter COGEM

c.c. Dr. J. Westra, Head of the GMO Office
Mr. J.K.B.H. Kwisthout, Ministry for Infrastructure and Water Management
Ing. M.A.C. Möllers, Food-Feed-portal