This is provisional English translation of an excerpt from the original full report.

Safety Assessment Report

Potato with potato late blight resistance, low free asparagine, lowered reducing sugars and low polyphenol oxidase (SPS-00X17-5 line)

(Genetically Modified Feed)

Food Safety Commission of Japan (FSCJ) January 2021

ABSTRACT

The FSCJ conducted a safety assessment of "Potato with potato late blight resistance, low free asparagine, lowered reducing sugars and low polyphenol oxidase (SPS-00X17-5 line)", based on the documents submitted by the applicant.

This line is resistant to potato late blight. It was generated through the introduction of potato late blight resistant gene (derived from a wild potato species) into a cultivated potato species, *Solanum tuberosum* subsp. *tuberosum*. It was introduced by the fragments of asparagine synthetase gene, water dikinase gene promotor region, phosphorylase-L gene promotor region and vacuolar invitase gene. These gene fragments derived from potato cultivated species induce gene silencing, which suppresses the expression of their endogenous genes and reduces the amount of acrylamide production during high-temperature heat processing. The 3'untranslated region (3'UTR) fragment of the potato polyphenol oxidase-5 gene derived from wild potato species also suppresses the expression of their endogenous genes and reduces black spot bruising.

In accordance with "Stance on Safety Assessments of Genetically Modified Feed and Feed Additives", the following possibilities were considered:

- i. new harmful substances derived from recombinants are generated in said genetically modified feed and transferred to meat, milk, eggs and other livestock products;
- ii. components in said genetically modified feed which are derived from genetic modification are transformed into harmful substances and accumulate in livestock products; and
- iii. components in said genetically modified feed which are the result of genetic modification interact with the metabolic system of livestock animals and produce new harmful substances.

As a result of assessing this line, none of these possibilities could be putative. Accordingly, the FSCJ determined that it is unnecessary to assess this line based on "Standards for the Safety Assessment of

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¹ Decision of the FSCJ dated May 6, 2004

Genetically Modified Foods (Seed Plants)"2.

The FSCJ concluded that there is no concern about safety of products derived from livestock fed this line.

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² Decision of the FSCJ dated January 29, 2004