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-000Z6-5 line)

(Genetically Modified Food)

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-000Z6-5 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.

Referring to "Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)" 1, the FSCJ assessed the following:

- i. the safety of the donor of the inserted gene;
- ii. the toxicity and allergenicity of the protein expressed from inserted gene;
- iii. the base sequence analysis of the inserted gene, etc.;
- iv. the stability of the inserted gene in successive generations;
- v. the effect on the metabolic pathways in plants; and
- vi. the results of comparison of nutritional and toxic ingredients.

The FSCJ confirmed that any new finding to cause the adverse effects was not observed, compared with conventional potato.

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¹ Decision of the FSCJ dated January 29, 2004



Accordingly, the FSCJ concluded that no concern relevant to human health is raised on the SPS-000Z6-5 line, a potato with potato late blight resistance, low free asparagine, lowered reducing sugars and low polyphenol oxidase enzyme.