FOOD SAFETY

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Risk assessment report

Phytase produced using *Schizosaccharomyces pombe* ASP595-1 strain (Genetically Modified Feed Additives)

Summary

Food Safety Commission of Japan

Food Safety Commission of Japan (FSCJ) conducted two sets of risk assessment on phytase produced using *Schizosaccharomyces pombe* ASP595-1 strain. One is the safety assessment on feed additives produced using genetically modified microorganisms. None of new harmful substance is generated in the additive and thus not transferred to animal products, such as meat, milk and eggs. Components associated with genetic modification in the additive are unlikely to yield harmful substances to be accumulated in animal products. The components are unlikely to affect the metabolism of the target animals to generate new harmful substances. No safety concern is thus raised in the products from animals fed with this phytase. The other is the risk assessment related to the revision of the Standards and Specifications of Feeds and Feed Additives. The feed additive was considered to have no genotoxicity relevant to human health. No adverse effects were observed in 14-day and 90-day subacute toxicity studies in rats as well as in feeding trials in pigs and poultry. On the formulations with polyvinyl alcohol, human intake of polyvinyl alcohol via animal products was recognized to be negligible. Consequently, FSCJ judged that the risk on human health via food is negligible as long as the 6-phytase produced using *S. pombe* ASP595-1 strain is properly used as a feed additive.

Conclusion in Brief

On the use of a new feed additive, phytase, Food Safety Commission of Japan (FSCJ) was requested to implement two sets of risk assessment from Minister of Agriculture, Forestry and Fisheries, i.e. 1) a safety assessment of animal products fed a feed additive produced using genetically modified microorganisms, and 2) a risk assessment related to the revision of the Standards and Specifications of Feeds and Feed Additives, according to the relevant regulations.

FSCJ conducted the assessments at the Expert Committee on Genetically Modified Foods and at the Expert Committee on Feeds and Fertilizers. Each committee elaborated the assessment report respectively. The summaries of both the reports are described below.

Effectiveness and safety of the phytase to the target animals (pigs and chickens) were evaluated by the Ministry of Agriculture, Forestry and Fisheries.

Safety Assessment on Feed Additives Produced Using Genetically Modified Microorganisms

FSCJ conducted a safety assessment for a feed additive of phytase, produced using *Schizosaccharomyces pombe* ASP595-1 strain based on the documents submitted by the

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Acknowledgement: FSCJ wishes to thank the members of Expert Committee on Genetically Modified Foods and Feeds, and Expert Committee on Feeds and Fertilizers for the preparation of the original full reports elaborated respectively.
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applicant.

S. pombe ASP595-1 strain was obtained through the insertion of the phytase gene originated from *Escherichia coli* B strain to the host cell of *S. pombe* ATCC 38399. For enhancing the availability of phosphate from feeds, the 6-phytase is used, as a feed additive, to liberate inorganic phosphate from phytic acid.

None of new harmful substance is generated in the additive and thus not transferred to animal products, such as meat, milk and eggs. Components associated with genetic modification in the additive are unlikely to yield harmful substances to be accumulated in animal products. The components are unlikely to affect the metabolism of the target animals to generate new harmful substances.

The full assessment through applying the "Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms" is not thus necessary, as described in the "Stance on Safety Assessments of Genetically Modified Feed and Feed Additives". FSCJ concluded that no safety concern is raised in the products from animals fed with this phytase.

Risk Assessment Related to the Revision of the Standards and Specifications of Feeds and Feed Additives

On the revision of the Standards and Specifications of Feeds and Feed Additives under the provisions of Article 3 paragraph (1) of the Act on Safety Assurance and Quality Improvement of Feeds, FSCJ conducted a risk assessment on the addition of 6-phytase produced using *S. pombe* ASP595-1 strain to the list of feed additives, based on the documents required for designation of new feed additives.

No pharmacokinetics and residue studies had been conducted on the feed additive.

None of genotoxicities were obtained consistently in a reverse mutation test *in vitro* using bacteria, a gene mutation test in mouse lymphoma, and *in vivo* mouse bone marrow micronucleus test. The feed additive thus was considered to have no genotoxicity relevant to human health.

No chronic toxicity and carcinogenicity studies as well as reproductive and developmental toxicity studies are available. No adverse effects were, however, observed in 14-day and 90-day subacute toxicity studies in rats as well as in feeding trials in pigs and poultry.

On the formulations with polyvinyl alcohol, human intake of polyvinyl alcohol via animal products was recognized to be negligible, as long as the recommended amount of 6-phytase is considered.

Consequently, FSCJ judged that the risk on human health via food is negligible as long as the 6-phytase produced using *S. pombe* ASP595-1 strain is properly used as a feed additive.