



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

## Safety Assessment Report

### Phospholipase produced using pPDX strain

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

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#### ABSTRACT

FSCJ conducted a safety assessment of an additive, phospholipase produced using pPDX strain, based on the documents submitted by the applicant.

The pPDX strain was generated through the introduction of an inserted DNA and an expression plasmid into *Streptomyces violaceoruber* 1326 strain as the host. The origin of the inserted DNA was phospholipase D gene derived from *Streptomyces cinnamoneus* NBRC 12852 strain, to which a promoter derived from *Streptomyces halstedii* NBRC 12783 strain and terminator derived from *Streptomyces cinnamoneus* NBRC 12852 strain were combined. The expression plasmid was obtained by introducing thiostrepton resistance gene derived from *Streptomyces azureus* into the plasmid derived from *S. violaceoruber*. This additive is an enzyme which hydrolyzes choline-phosphate ester of phosphatidylcholine catalyzing the transfer reaction in the presence of alcohols or sugars with phosphatidylcholine.

Since gene exchange among *S. violaceoruber*, *S. cinnamoneus*, *S. halstedii* and *S. azureus* has been considered to naturally occur, natural occurrence of pPDX strain is considered to exist in nature.

This additive has been produced using a microorganism corresponding to the case “where a living cell which has genotypic composition equivalent to the relevant recombinant exist in nature”, specified in Chapter 1 General Provisions, Section 3 Scope and Objective of “Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms (Decision of the Commission Dated 25 March 2004)”. This additive is not categorized into the object of the above-mentioned Standards. FSCJ, thus, concluded that safety assessment is not necessary for this additive.