

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

## Safety Assessment Report

### 25-Hydroxycholecalciferol produced using the ATC1562 strain (Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)  
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#### ABSTRACT

FSCJ conducted a safety assessment of 25-Hydroxycholecalciferol produced using the ATC1562 strain based on the documents submitted by the applicant.

To produce this feed additive, cholestatrienol, produced by the ATC1562 strain of *Saccharomyces cerevisiae*, was converted chemically to 25-Hydroxycholecalciferol. A modified hydroxymethylglutaryl-CoA reductase gene (*tHMG1* gene) originated from the S288c strain of *S. cerevisiae* was introduced to the ATCC740027 strain of *S. cerevisiae*, resulting the ATC 1562 strain to improve the productivity of cholestatrienol.

25-hydroxycholecalciferol is a metabolite of cholecalciferol (vitamin D<sub>3</sub>). Cholecalciferol administered to livestock animals is initially metabolized to 25-hydroxycholecalciferol in the liver and then converted to a physiologically active substance, 1 $\alpha$ , 25-dihydroxycholecalciferol in the kidney. It should be noted that cholecalciferol has already been authorized for its use as a feed additive.

On the safety assessment, FSCJ recognized this additive to be free of hazardous materials in the inactive ingredients, and also to contain marginal amounts of the inactive ingredient in this additive.

Taking into account the added amount of the additive in feed, the amount consumed by livestock would be low. Therefore, FSCJ estimated that the risk to human health through consumption of livestock products is negligible.

This additive has been assessed corresponding to the Approach to the safety assessment of amino acids and other end products that are highly purified non-protein additives among additives produced using genetically modified microorganisms (Decision of the Commission dated 28 April 2005) specified in the Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms<sup>1</sup> based on Approach to the safety assessment of genetically modified feed and feed additives (Decision of the Commission dated 6 May, 2004)

Consequently, FSCJ concluded that the risk to human health through consumption of livestock products is negligible.

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<sup>1</sup> Decision of Commission dated 25 March 2004.