

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

## **Risk Assessment Report**

### **Thymovar**

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)  
April 2018

#### **ABSTRACT**

FSCJ conducted a risk assessment of thymovar, in accordance with the request from the risk management authority for the approval of manufacture and sales of new veterinary medicinal products, based on the written application. Thymovar is a paraciticide for use in honey bees which contains thymol as an active ingredient.

FSCJ has judged that it was unnecessary to specify an ADI for thymol, a main ingredient of this product, as long as it is used appropriately as a veterinary medicinal product.

Regarding the additives used in this product, FSCJ concluded that the risk to human health from the intake of these additives as ingredient of this product was negligible, considering the usage and the dosage and administration.

Residue analyses of this product showed thymol concentration in honey as 0.08~1.3 µg/g after 4-week treatment in bees, and the maximum concentration at 4 weeks after the end of treatment was 0.17 µg/g. As the result from safety study, FSCJ considered that this product has no concern relevant to safety of bees as long as it is used appropriately at regular dose.

Hence, FSCJ concluded that the risk to human health from the intake of this product through consumption of foods is negligible as long as it is appropriately used.