

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

## **Risk Assessment Report**

## Cinnamaldehyde

(Exempted Substances 1)

Food Safety Commission of Japan (FSCJ) May 2023

## ABSTRACT

The FSCJ conducted a risk assessment of cinnamaldehyde (CAS No. 14371-10-9), a fungicide and flavoring agent, based on various documents. Cinnamaldehyde is an Exempted Substance<sup>1</sup> prescribed by the Minister of Health, Labour and Welfare as carrying no apparent risk of adverse health effects in humans according to the provision of Article 13, paragraph (3) of the Food Sanitation Act (Act No. 233 of 1947).

Major adverse effects of cinnamaldehyde at high doses were observed in body weight (suppressed weight gain) and the stomach (epithelial hyperplasia of the forestomach), which were observed in a subacute toxicity study. Neither carcinogenicity nor biologically significant genotoxicity was observed. Furthermore, no effect on fertility was observed, nor was there concern over developmental toxicity. Cinnamaldehyde was evaluated by both JECFA and EFSA as having no safety concern when used as a food additive (flavoring agent) or feed additive (flavoring agent). Moreover, it was evaluated by the EPA as having no safety concerns over human health when used as a pesticide. Neither ADI nor ARfD was specified by these evaluation organizations.

In Japan, cinnamaldehyde has a long history of use as a food additive (flavoring agent) and has been widely consumed. Its track record as a feed additive has so far not revealed any particular safety issue for livestock or livestock products. Additionally, it is considered unlikely that residual cinnamaldehyde in crops or livestock products attributable to its use as a pesticide or feed additive would add to the existing levels consumed as part of the regular human diet.

Consequently, it was considered that human dietary consumption of residual cinnamaldehyde attributable to its use as a pesticide or feed additive under conditions of its intended use will pose no apparent adverse health effects in humans.

<sup>&</sup>lt;sup>1</sup> On May 29, 2006, the Ministry of Health, Labour and Welfare (MHLW) introduced the positive list system for agricultural chemicals remaining in foods, which is a system that prohibits distribution of foods that contain agricultural chemicals above a certain level if maximum residue limits (MRLs) have not been established. Exempted Substances refer to substances as prescribed by the Minister of Health, Labour and

Welfare that carry no apparent risk of adverse effects on human health pursuant to the provision of Article 13, paragraph (3) of the Food Sanitation Act.