

## **Risk Assessment Report**

### **Citric acid**

(Exempted Substances <sup>1</sup>)

Food Safety Commission of Japan (FSCJ)

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#### **ABSTRACT**

The FSCJ conducted a risk assessment of citric acid (CAS No. 77-92-9) referring to OECD assessment reports and other documents. The purpose of this assessment is to apply to a designated exempted substance defined by the Ministry of Health, Labour and Welfare (MHLW). This substance does not have adverse effects on human health in accordance with the provision of Article 13 paragraph (3) of the Food Sanitation Act (Act No. 233 of 1947).

Citric acid occurs naturally in foods and plants. Humans commonly consume this substance via foods because it has been used as a food additive for many years. It is also biosynthesized as an intermediate in the glycometabolism of living organisms.

It is presumed that citric acid absorbed or synthesized in the living organisms is metabolized in the citric acid cycle. It is mostly excreted in urine, feces and exhaled breath.

The FSCJ believed that citric acid administered in animals would not accumulate in their bodies. Therefore, the FSCJ concluded that consumers would not excessively take citric acid derived from veterinary medicinal products and feed additives via foods.

The FSCJ determined that citric acid does not raise concerns with respect to genotoxicity, particularly affecting living organisms.

In the subacute toxicity, chronic toxicity and carcinogenicity studies, neither toxicity nor carcinogenicity was observed after administration of citric acid. In the reproductive and developmental toxicity study, effects on fertility and teratogenicity were not observed, either.

No particular safety problem attributed to citric acid has been identified in its use of various areas such as human medicines, food additives and others. Furthermore, concerns have not been noted with regard to established dietary patterns of foods containing citric acid.



Considering the above facts, the FSCJ has determined a reasonable certainty that no adverse effects will occur in human health from dietary exposure to the residues of citric acid as long as the substance is normally used as a veterinary medicinal products or a feed additive.

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<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 – the system to prohibit the distribution of foods that contain agricultural chemicals above a certain level if maximum residue limits (MRLs) have not been established. Exempted Substances are defined by the MHLW as substances having no potential to cause damage to human health, based on the provision of Article 11, paragraph (3) of the Food Sanitation Act. These substances are not subject to the positive list system.