

## Monthly Update on Activity of the Food Safety Commission of Japan (FSCJ)

### February 2016

Discussions from the 593rd to 596th Meetings of the Commission held on the 2nd, 9th, 16th and 23rd of February 2016 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations<sup>1</sup>.

Food additives	<ul style="list-style-type: none"> <li>• Revision (Amendment) of standards for processing “raw fishery products,” “oysters to be eaten raw,” and “frozen food,” related to use of carbon dioxide as an acidity regulator.”</li> </ul>
Pesticides	<ul style="list-style-type: none"> <li>• Acephate    • Cymoxanil    • Tebfenozide    • Triflumizole</li> <li>• Paclobutrazol    • Methamidophos</li> </ul>
Pesticides and Veterinary medicinal products	<ul style="list-style-type: none"> <li>• Etoxazole</li> </ul>
Veterinary medicinal products	<ul style="list-style-type: none"> <li>• Flubendazole</li> </ul>
Genetically modified foods / feeds	<ul style="list-style-type: none"> <li>• L-Histidine produced using HIS-No.2 strain.</li> </ul>
Novel foods	<ul style="list-style-type: none"> <li>• Matsutani’s Mini-biscuit</li> </ul>

(2) The Risk Assessment Reports on the following items were finalized and notified to the relevant risk management organizations concerned.

#### Additives

Item	Conclusion
Revision (Amendment) of standards for processing “raw fishery products,” “oysters to be eaten raw,” and “frozen food,” related to use of carbon dioxide as an acidity regulator.”	FSCJ conclusion: The said use of carbon dioxide following the amended standards is considered to be of no food safety concern. Accordingly, FSCJ concluded that the item falls under the category which is the case where the contents and degree of adverse effects on human health are clear <sup>2</sup> .
Hydrogen peroxide	FSCJ conclusion: The assessed item is considered to be of no food safety concern as long as used appropriately as a food additive. Therefore, it is unnecessary to specify ADI.

#### Pesticides

Item	ADI	ARfD

<sup>1</sup> E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

<sup>2</sup> The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

Isouron	0.017 mg/kg bw per day	0.2 mg/kg bw
Isoxathion	0.002 mg/kg bw per day	0.003 mg/kg bw
Simeconazole	0.0085 mg/kg bw per day	0.2 mg/kg bw for ordinal people. 0.09 mg/kg bw for pregnant women and women expected to be pregnant.
Spirotetramat	0.12 mg/kg bw per day	1 mg/kg bw
Pyriofenone	0.091 mg/kg bw per day	Not required

Veterinary medicinal products

Item	Conclusion
Flubendazole	FSCJ conclusion: The item corresponds to the case where the contents and degree of adverse effects on human health are clear, under the Food Safety Basic Act <sup>2</sup> , because the item falls under item 1 of Decision of the Commission dated 27 January 2014.
Four compounds used as additives for vaccines for veterinary use.	FSCJ conclusion: Risks to human health from these 4 compounds are negligible as long as appropriately used. Therefore, The item corresponds to the case where the contents and degree of adverse effects on human health are clear, under the Food Safety Basic Act <sup>2</sup> .

Genetically modified foods/feeds

Item	Conclusion
Soybeans FG72 strain <sup>3</sup> (foods)	FSCJ conclusion: According to the “Stance on the safety assessment of genetically modified foods (seed plants)” <sup>4</sup> , Soybean FG72 strain was evaluated not to affect human health.
Soybeans FG72 strain <sup>5</sup> (feeds)	FSCJ conclusion: According to the “Stance on the safety assessment of genetically modified feeds and feed additives” <sup>37</sup> , the item did not require further assessment through the “Stance on the safety assessment of genetically modified foods (seed plants)” <sup>34</sup> . Hence, livestock products

<sup>3</sup> Soybeans tolerant of glyphosate and isoxaflutole herbicides.

<sup>4</sup> “Stance on Safety Assessments of Genetically Modified Foods (seed plants) (Decision of the Commission dated 29 January 2004)”

<sup>5</sup> Soybeans tolerant of glyphosate and isoxaflutole herbicides.

	derived from animals which consumed the item have no concern relevant to human health.
--	--

Food for specified health use

Item	Conclusion
Rare sweet	<p>FSCJ conclusion: FSCJ considered it necessary to provide the consumers a complete caution at least for the following points in order to ensure the safety of this food as a food for specified health uses;</p> <ul style="list-style-type: none"> <li>① Intake of this food has a potential to increase LDL-C, therefore patients from high LDL-C viremia or from borderline higher LDL-cholesterolemea particularly need to be careful on its ingestion.</li> <li>② The excessive consumption of this product should be avoided following the recommended daily intake.</li> <li>③ Consumption of this food in combination with another food containing D-psicose as a raw material should be avoided.</li> </ul> <p>Since the assessed item is expected to alter blood-glucose level, care must be taken based on the policy prescribed in the Stance on the Safety Assessment of Each Product of Foods for Specified Use<sup>6</sup>. Hence, it is necessary that the applicant make efforts to collect and provide information on the adverse effects. In addition, a note on the consultation to medical personnel for the patients' intakes needs to be included in a product label.</p>

---

<sup>6</sup> The policy prescribed in (2) of 2 of the Approach to the Safety Assessment of Each Product of Foods for Specified Health Use (Decision of the Commission dated 10 May 2007).