

## Monthly Update on Activity of the Food Safety Commission of Japan (FSCJ) January 2014

Discussions from the 499th to 501st Meetings of the Commission held on the 7th, 20th and 27th of January 2014 are summarized as follows:

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

Pesticides	<ul style="list-style-type: none"> <li>• Metconazole    • Nitenpyram</li> <li>(Deletion)</li> <li>• 1,1-Dichloro-2,2-bis(4-ethylphenyl)ethane    • Azaconazole    • Anilazine,</li> <li>• Aramite    • Chlozolate    • Chlorbufam    • Chlorbenseide    • Chloroxuron</li> <li>• Dioxathion    • Dinoterb    • Diphenamid    • Dimethirimol    • Sulprofos</li> <li>• Diallylate    • Naptalam    • Nitrothal-isopropyl    • Barban    • Pyrazophos</li> <li>• Bromophos    • Bromophos-ethyl    • Foramsulfuron    • Formothion</li> <li>• Mecarbam    • Methacrifos    • Monolinuron</li> </ul>
Pesticides and veterinary medicinal products	<ul style="list-style-type: none"> <li>• Lufenuron</li> <li>(Deletion)</li> <li>• Fenchlorphos</li> </ul>
Veterinary medicinal products	<ul style="list-style-type: none"> <li>• Moxidectin    • Flumethrin</li> <li>(Deletion)</li> <li>• 2-Acetylamino-5-nitrothiazole    • Bithionol    • Miloxacin</li> </ul>
Genetically modified foods etc.	<ul style="list-style-type: none"> <li>• Amendment of Ordinance of Ministry of Agriculture and Forestry<sup>2</sup> regarding the standards for feed and feed additives.</li> <li>• 25-Hydroxycholecalciferol produced using ATC1562 strain</li> </ul>
Food for Specified Health Uses	<ul style="list-style-type: none"> <li>• Kirin Gogonokoutya Healthy Straight</li> </ul>
Feed additives	<ul style="list-style-type: none"> <li>• 25-Hydroxycholecalciferol</li> </ul>
Exempted Substances <sup>3</sup>	<ul style="list-style-type: none"> <li>• 25-Hydroxycholecalciferol</li> </ul>

<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> Ordinance of Ministry of Agriculture and Forestry, No.35, 1976

<sup>3</sup> On May 29, 2006 the Ministry of Health, Labour and Welfare (MHLW) introduced the positive list system for agricultural chemicals remaining in foods 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 designated as substances having no potential to cause damage to human health by the Minister of Health, Labour and Welfare, based on the provision of Paragraph 3, Article 11 of the Food Sanitation Law, and these substances are not subjected to the positive list system.

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

Additives

Item	Conclusion
Biotin	FSCJ conclusion: The assessed item is considered to be of no concern for the food safety as long as used appropriately as a food additive. Therefore, it is unnecessary to specify ADI.
Asparaginase produced using <i>Aspergillus niger</i> ASP-72 strain	FSCJ conclusion: The assessed item is considered to be of no concern for the food safety as long as used appropriately as a food additive. Therefore, it is unnecessary to specify ADI.

Pesticides

Item	ADI
Clothianidin	0.097 mg/kg bw per day
Halosulfuron-Methyl	0.1mg/kg bw per day
Propamocarb	0.29 mg/kg bw per day
Metalaxyl and Mefenoxam	0.022 mg/kg bw per day
Imazapic	0.27 mg/kg bw per day
Aminoethoxyvinylglycine	0.0002 mg/kg bw per day
Etobenzanid	0.044 mg/kg bw per day
Epoxyconazole	0.0069 mg/kg bw per day
Tricyclazole	0.05 mg/kg bw per day
Pyflubumide	0.0073 mg/kg bw per day
Procymidone	0.035 mg/kg bw per day
Propyzamide	0.019 mg/kg bw per day
Cyazofamid	0.17 mg/kg bw per day

Pesticides

Item	Conclusion
<ul style="list-style-type: none"> <li>• 1,1-Dichloro-2,2-bis(4-ethylphenyl)ethane</li> <li>• Azaconazole • Anilazine • Aramite</li> <li>• Chlozolinate • Chlorbufam • Chlorbenseide</li> <li>• Chloroxuron • Dioxathion • Dinoterb</li> <li>• Diphenamid • Dimethirimol • Sulprofos</li> <li>• Diallate • Naptalam • Nitrothal-isopropyl</li> <li>• Barban • Pyrazophos • Bromophos</li> <li>• Bromophos-ethyl • Foramsulfuron</li> <li>• Formothion • Mecarbam • Methacrifos</li> <li>• Monolinuron</li> </ul>	FSCJ conclusion: Deletion of standards for residue of the assessed items falls under the category which is the case where the contents and degree of adverse effects on human health are clear <sup>4</sup> , on condition that the items currently are not used domestically and internationally, for agricultural products for foods and feeds, animals for human consumption, and animals for obtaining food products such as eggs and milk, or that the items are not used domestically for agricultural products and animals, and that agricultural products, meat, milk and other products for food produced using the items are not imported.

<sup>4</sup> The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

Pesticides and veterinary medicinal products

Item	ADI
Teflubenzuron	0.01 mg/kg bw per day
Fipronil	0.00019 mg/kg bw per day

Pesticides and veterinary medicinal products

Item	Conclusion
Fenchlorphos	FSCJ conclusion: Deletion of standards for residue of the assessed items falls under the category which is the case where the contents and degree of adverse effects on human health are clear <sup>4</sup> , on condition that the items currently are not used domestically and internationally, for agricultural products for foods and feeds, animals for human consumption, and animals for obtaining food products such as eggs and milk, or that the items are not used domestically for agricultural products and animals, and that agricultural products, meat, milk and other products for food produced using the items are not imported.

Veterinary medicinal products

Item	ADI
Norfloxacin	0.014 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
Re-examination of the product for oral administration to chickens (Infec 10% Liquid) and that to pigs (Infec 2% Powder), containing norfloxacin as an active ingredient.	FSCJ conclusion: Risks to human health from the intake of this product through food are negligible as long as appropriately used.
<ul style="list-style-type: none"> <li>• 2-Acetylamino-5-nitrothiazole</li> <li>• Bithionol</li> <li>• Miloxacin</li> </ul>	FSCJ conclusion: Deletion of standards for residue of the assessed items falls under the category which is the case where the contents and degree of adverse effects on human health are clear <sup>4</sup> , on condition that the items currently are not used domestically and internationally, for agricultural products for foods and feeds, animals for human consumption, and animals for obtaining food products such as eggs and milk, or that the items are not used domestically for agricultural products and animals, and that agricultural products, meat, milk and other products for food produced using the items are not imported.

Natural toxins and mycotoxins

Item	TDI
Ochratoxin A	For non-carcinogenic toxicity: 16 ng/kg bw per day For carcinogenicity: 15 ng/kg bw per day

Genetically modified foods/feeds

Item	Conclusion
Amendment of the procedure for safety evaluation of foods and additives that are produced by using recombinant DNA technologies <sup>5</sup> .	FSCJ conclusion: the FSCJ concluded that the amendment is the case where the contents and degree of adverse effects on human health are clear <sup>4</sup> , as long as risk management organizations implement the appropriate risk control measures, in order to make stakeholders be able to evaluate the possibility that relevant microorganisms fall under the amended procedure on the basis of the suggested standards.
Cyclodextrin-glucano-transferase produced by genetically modified strain <i>Bacillus subtilis</i> DTS1451 (pHYT2G) strain	FSCJ conclusion: According to the “the Standards for the Safety Assessment of Food Additives Produced from Genetically Modified Microorganisms” <sup>6</sup> , the assessed item was evaluated not to affect human health.
Hybrid stack of soybean; MON87708 <sup>7</sup> x MON89788 <sup>8</sup>	FSCJ conclusion: According to the “Approach to the Safety Assessment of Genetically Modified Plant Hybrids” <sup>9</sup> , the item did not require further safety assessment.
Amendment of Ordinance of Ministry of Agriculture and Forestry regarding the standards for feed and feed additives <sup>10</sup> .	FSCJ conclusion: the FSCJ concluded that the amendment is the case where the contents and degree of adverse effects on human health are clear <sup>3</sup> , as long as the following measures are implemented: Risk management organizations establish the standards for judgment equivalent to that established by MHLW at the amendment of notification of food and others. Risk management organizations implement the appropriate risk control measures in order to make stakeholders be able to evaluate the possibility that the relevant microorganisms fall under the amended procedure on the basis of the suggested standards.

Antimicrobial resistant bacteria

Item	Conclusion
Avilamycin	FSCJ conclusion: Risk to human health from the assessed item through consumption of relevant livestock products was considered to be negligible.

<sup>5</sup> Notification of the Ministry of Welfare, No. 233, 2000.

<sup>6</sup> “the Standards for the Safety Assessment of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)”

<sup>7</sup> Soybean tolerant to dicamba herbicide.

<sup>8</sup> Soybean tolerant to glyphosate herbicide.

<sup>9</sup> “Approach to the Safety Assessment of Genetically Modified Plant Hybrids (Decision of the Commission dated 29 January 2004).

<sup>10</sup> Ordinance of Ministry of Agriculture and Forestry , No.35, 1976.