

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

Discussions from the 513rd to 515th Meetings of the Commission held on the 13th, 20th, and 27th of May 2014 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations¹.

Pesticides	• Metconazole
Veterinary medicinal products	• Triclabendazole • Revision of the analysis methods for Olaquinox, Carbadox, and Clenbuterol designated in the standards for foods and additives ² .
Feed additives	• L-Carnitine
Exempted Substances ³	• L-Carnitine

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

Pesticides

Item	ADI
• Malathion	ADI: 0.29 mg/kg bw per day ARfD: 1.5 mg/kg bw
• Diflufenican	0.23 mg/kg bw per day
• Pyrazosulfuron-ethyl	0.01 mg/kg bw per day
• Flumioxazin	0.018 mg/kg bw per day

Veterinary medicinal products

Item	ADI
Diclazuril	0.03 mg/kg bw per day

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

² Notification of the Ministry of Welfare, No. 370, 1959, which was established based on paragraph (1) of article 11 of the Food Hygiene Law, Act No. 233 of 1947.

³ 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.

Veterinary medicinal products

Item	Conclusion
• Triclabendazole	FSCJ conclusion: The item corresponds to the case where the contents and degree of adverse effects on human health are clear, under Food Safety Basic Act ⁴ .
• Metronidazole	FSCJ conclusion: Potential of the assessed products to be a genotoxic carcinogen cannot be ruled out, therefore it is not appropriate to specify ADI for metronidazole.
• Revision of the analysis methods for olaquinox, carbadox, and clenbuterol which are designated in the standards for foods and additives ² .	FSCJ conclusion: Since the revision concerns change of analysis methods, and does not affect the standards itself, the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act ⁵ .

Genetically modified foods/feeds

Item	Conclusion
• Protease produced using <i>Bacillus subtilis</i> BPN01 Strain.	FSCJ conclusion: The assessed item is a food additive produced using microorganisms that fall under "the case where the DNA ultimately introduced to the host through recombinant DNA techniques is only DNA from a microorganism belonging to the same taxonomic species as said microorganism ⁶ ". Therefore, the item is not the object of the standard, and the FSCJ concluded that the item does not require safety assessment.
• Peptidase produced using pSSA strain	FSCJ conclusion: The assessed item is a food additive produced using microorganisms that fall under "the case where living cells that have an equivalent genetic structure as the recombinant exist in natural world ⁶ ". Therefore, the item is not the object of the standard, and FSCJ concluded that the item did not require safety assessment.
• Peptidase produced using pXPO strain	FSCJ conclusion: The assessed item is a food additive produced using microorganisms that fall under "the case where living cells that have an equivalent genetic structure as the recombinant exist in natural world ⁶ ". Therefore, the item is not the object of the standard, and FSCJ concluded that the item did not require safety assessment.

⁴ FSCJ was asked the opinion about risks to human health from the item, which has been assessed by FSCJ, based on article 24 of the Food Safety Basic Act. However, new scientific finding on safety risks of the relevant item was not available. Consequently, FSCJ concluded that the item corresponds to the case where the contents and degree of adverse effects on human health are clear, which is designated in item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

⁵ Change of analysis methods comes under item (i) of paragraph (1) of article 11 of the Food Safety Basic Act, where assessment of food safety risk is evidently unnecessary.

⁶ The case designated in "the Standards for the Safety Assessment of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission).