

Monthly Update on Activity of the Food Safety Commission of Japan (FSCJ) September 2015

Discussions from the 575th to 578th Meetings of the Commission held on the 1st, 8th, 15th and 29th of September 2015 are summarized as follows:

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

Pesticides	(Bulk deletion) • 4-Aminopyridine • Chlorobenzilate • Dinoseb • Thiomethone • Thifensulfuron • Sodium trichloroacetate (TCA)
Veterinary medicinal products	• Addition of the brotizolam assay method in standards for foods and additives designated based on paragraph (1) of article 11 of the Food Hygiene Law.

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

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

Additives

Item	Conclusion
Sodium selenite	FSCJ conclusion: FSCJ specified “the upper level of intake for infants of zero month to 2 years old” of 5.9 µg/kg bw/day as selenium. The estimated daily intake level presented by the applicants for designation may exceeds “the upper level of intake for infants of zero month to 2 years old”. Therefore, risk management authorities should revise risk control measures including the standards for use when they newly designate sodium selenite as a food additive.
Zinc sulfate	FSCJ conclusion: FSCJ specified an upper limit for intake of zinc sulfate to be of 0.63 mg/kg bw/day as zinc.

Pesticides

Item	ADI	ARfD
Tebuconazole	0.029 mg/kg bw per day	0.3 mg/kg bw
Fluopyram	0.012 mg/kg bw per day	0.5 mg/kg bw
Prometryn	0.03 mg/kg bw per day	1.5 mg/kg bw
Benzovindiflupyr	0.012 mg/kg bw per day	0.1 mg/kg bw

Pesticides

Item	Conclusion
(Bulk deletion) <ul style="list-style-type: none"> • 4-Aminopyridine • Chlorobenzilate • Dinoseb • Thiomethone 	FSCJ conclusion: The assessed item falls under the case designated by item (ii) of paragraph (1) of article 11 of the

<ul style="list-style-type: none"> • Thifensulfuron • Sodium trichloroacetate (TCA) 	<p>Food Safety Basic Act², 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 agricultural products, meat, milk and other products for food produced using the items are not imported.</p>
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Veterinary medicinal products

Item	ADI
Fluazuron	0.043 mg/kg bw per day
Flumethrin	0.0039 mg/kg bw per day
Albendazole	0.01 mg/kg bw per day Group ADI for albendazole and albendazole sulfoxide: 0.01 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
Addition of the brotizolam assay method in standards for foods and additives designated based on paragraph (1) of article 11 of the Food Hygiene Law.	FSCJ conclusion: The item is to add the newly established assay method but not a change of the standards itself. Therefore, the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act ³
Twelve components contained as additives in animal vaccine	FSCJ conclusion: Risk to human health from the assessed item through food consumption is negligible as long as appropriately used. Therefore, the assessed item falls under the case designated by

² The item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act designates the case where the contents and degree of adverse effects on human health are clear.

³ 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.

	item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act ⁴ .
Baytril oneject injection, an injection for veterinary use into pigs, containing Enrofloxacin as an active ingredient.	FSCJ conclusion: Risk to human health from the assessed item through food consumption is negligible as long as appropriately used.
Draxxin C, an injection for veterinary use into cattle, containing tulathromycin as an active ingredient.	FSCJ conclusion: Risk to human health from the assessed item through food consumption is negligible as long as appropriately used.
An injection for veterinary use in cattle, Resfrol, which contains florfenicol and flunixin meglumine as active components.	FSCJ conclusion: Risk to human health from the assessed item through food consumption is negligible as long as appropriately used.
Two components contained as additives in animal vaccine	FSCJ conclusion: Risk to human health from the assessed item through food consumption is negligible as long as appropriately used. Therefore, the assessed item falls under the case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act ⁵ .

⁴ The item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act designates the case where the contents and degree of adverse effects on human health are clear.

⁵ The item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act designates the case where the contents and degree of adverse effects on human health are clear.