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

Discussions from the 532nd to 535th Meetings of the Commission held on the 7th, 14th, 21st and 28th of October 2014 are summarized as follows:

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

Food additives	・Asparaginase produced using *Aspergillus oryzae* NZYM-SP strain
Pesticides	・Isoxaflutole ・Triafamone
Pesticides and Veterinary medicinal products	・Spinosad
Veterinary medicinal products	・Econosad, spray containing spinosad as an active ingredient, for use in poultry house
Genetically modified foods / feeds	・Asparaginase produced using *Aspergillus oryzae* NZYM-SP strain
Feeds and Fertilizers	・Revision of official specification of ordinary fertilizers.[2]

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

Additives

Item	ADI
Canthaxanthin	0.025 mg/kg bw per day

Pesticides

Item	ADI	ARfD
Clothianidin	0.097 mg/kg bw per day	0.6 mg/kg bw
Pyrifluquinazon	0.005 mg/kg bw per day	1 mg/kg bw for ordinal people, 0.05 mg/kg bw for pregnant women and women expected to be pregnant.
Mandestrobin	0.19 mg/kg bw per day	Not required
Asulam	0.36 mg/kg bw per day	3 mg/kg bw
Sulfoxaflor	0.042 mg/kg bw per day	0.25 mg/kg bw

Veterinary medicinal products

Item	ADI
Mosapride	0.03 mg/kg bw per day for mosapride citrate
Meloxicam	0.00063 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
・Components contained as additives in the already approved animal vaccine for which the use restriction period to be set (57 of 97 components) .	FSCJ conclusion: Risk to human health from intake of the assessed items through food is negligible as long as used as additives in veterinary medicinal products. Therefore, the assessed items fall under the category which is the case where the

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

[2] Official specification of ordinary fertilizers prescribed in paragraph (2) of Article 3 of the Fertilizer Control Act (Act No. 127, 1950)

	contents and degree of adverse effects on human health are clear[3].
"Pronamid powder 1%" containing Mosapride citrate as an active ingredient, for veterinary use by oral administration into horses.	FSCJ conclusion: Risk to human health from the intake of the assessed item through food is negligible as long as appropriately used.

Chemicals and contaminants

Item	Conclusion
Amendment of standards for quality of drinking water supplied by the tap. (Chloroacetic acid, Dichloroacetic acid, Trichloroacetic acid)	TDI for Chloroacetic acid: 3.5 μg/kg bw per day TDI for Dichloroacetic acid: ・12.5 μg/kg bw per day in terms of noncarcinogenic toxicity. ・12.9 μg/kg bw per day in terms of Carcinogenicity.Unit Risk: 7.8 x 10^{-3}/(mg/kg bw/day) TDI for Trichloroacetic acid: 6 μg/kg bw per day

Prions

Item	Conclusion
・Revision of the present control of gelatin in the current countermeasures against BSE.	FSCJ conclusion: To the extent that the current risk management, including setting of regulations for raw materials and criteria for food production continues to be implemented, deletion of cattle head skin from specified regions, use of gelatin/collagen derived from skin of cattle from BSE country and use of gelatin derived from born of cattle from BSE country for food products fall under the category which is the case where the contents and degree of adverse effects on human health are clear[4].
・Use of cattle MBM for feeds in fish farming.	FSCJ conclusion: Body region of cattle including MBM used for feeds in fish farming does not include specified regions, and previously evaluated that risks to human health from the assessed item through food consumption is negligible. It has been also evaluated in 2007 that transmission of BSE prions through the intestinal tract and its subsequent amplification within fishes may hardly occur even if feeds in fish farming are contaminated with BSE prions. Moreover, any scientific data indicating such a transmission and amplification are not found. Therefore, risk to human health from the assessed item through consumption of fishes is negligible. Hence FSCJ concluded that the assessed item falls under the category which is the case where the contents and degree of adverse effects on human health are clear[4].

Genetically modified foods / feeds

Item	Conclusion
・Maize (sweet corn) MON88017[5] ・Maize (sweet corn) MON89034[6]	FSCJ conclusion: Risk to human health from intake of the assessed item through food is negligible as long as appropriately used.

[3] The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.
[4] The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.
[5] Maize (sweet corn) resistant to Coleoptera and tolerant to glyphosate herbicide.
[6] Maize (sweet corn) resistant to Lepidoptera.

Food for specified health uses

Item	Conclusion
Kothala extract	FSCJ conclusion: Kothala extract has no obvious risk to human health as long as the documents submitted by the applicant concern. Since the assessed item is expected to alter blood-glucose level, care must be taken based on the policy prescribed in Stance on Safety Assessment of Each Product of Foods for Specified Use[7]. Hence, persons dealing the food business are necessary to make efforts to collect and provide information on the health effects. In addition, a reminder to patients to consult a physician or medical personnel for their taking of the relevant food should be transmitted from the food-business industries.

Feeds and Fertilizers

Item	Conclusion
・Revision of official specification of ordinary fertilizers.[8]	FSCJ conclusion: ・ Relevant specifications deal with official specifications of pesticides-containing fertilizers, and the fertilizers are under the regulation by standards for use based on the Agricultural Chemicals Control Act. Therefor effects of relevant fertilizers on human health are not affected by the assessed items. Hence, the items fall under the category which is the case where the contents and degree of adverse effects on human health are clear[9] ・ Regarding establishment of official specification of fertilizers which contain pesticides for agricultural products not for foods, the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act[10]. ・ Risk management organizations should appropriately control use of relevant fertilizers based on the Agricultural Chemicals Control Act. Regarding pesticides of which risk assessments are not yet done, risk management organizers should revise standards for use of relevant pesticides if necessary.

Antimicrobial resistant bacteria

Item	Conclusion
Enramycin	FSCJ conclusion: Food safety risk of the item on human health through consumption of livestock products is determined to be negligible.

[7] The policy prescribed in (2) of 2 of Stance on Safety Assessment of Each Product of Foods for Specified Health Use (Decision of the Commission dated 10 May 2007).

[8] Official specification of ordinary fertilizers prescribed in paragraph (2) of Article 3 of the Fertilizer Control Act (Act No. 127, 1950)

[9] The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basis Act.