Provisional translation

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Updated Activities of the Food Safety Commission of Japan (FSCJ)

January 2019

Discussions from the 726th to 728th Meetings of the Commission held on the 15th, 22nd and 29th of January 2019 are summarized as follows:

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

Food additives	・ Items related to amendment of "Standards for foods/food additives" for establishing the Addendum to Japanese Standards of Food Additives ・ 25-hydroxycholecalciferol
Pesticides	・ Ametoctradin ・ Ddiquat ・ Pyriproxyfen ・ Pyroxasulfone ・ Flutianil ・ Metyltetraprole
Veterinary medicinal products	・ Sarafloxacin ・ Neomycin

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

Exempted Substances[4]

Item	Conclusion
Methionine	FSCJ conclusion: Risks of the assessed items on human health through remaining in livestock products are negligible as long as appropriately used as a veterinary medicinal product and feed additive.

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

Food additives

Item	Conclusion
Items related to amendment of "Standards for foods/food additives" for establishing the Addendum to Japanese Standards of Food Additives	FSCJ conclusion: 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[6].
Dimethyl dicarbonate and related substances (methanol, methoxycarbonyl compounds, ethyl methyl carbonate, methyl carbamate, dimethyl carbonate)	FSCJ conclusion: The assessed item is considered to be of no concern for food safety as long as dimethyl dicarbonate is used appropriately as a food additive.

Pesticides

Item	ADI	ARfD
Cyenopyrafen	0.05 mg/kg bw per day	Not required
Zoxamide	0.47 mg/kg bw per day	Not required

Veterinary medicinal products

Item	Conclusion
Sarafloxacin	FSCJ conclusion: 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[2]
Neomycin	FSCJ conclusion: 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[2].

Prions

Item	Conclusion
Cattle meat and offal imported from the U.S.A., Canada and Ireland.	FSCJ conclusion: BSE risk to human health is negligible even if the age restriction of the assessed items are changed to "No restriction."

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

Genetically modified foods/feeds

Item	Conclusion
CHY-MAX M	FSCJ conclusion: According to “Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms (Decision of the Commission Dated 25 March 2004)”, the assessed item was evaluated not to affect human health.

Feed additives

Item	Conclusion
L-Methionine	FSCJ Conclusion: Risk to human health from the assessed item through consumption is negligible as long as it is used appropriately as a feed additive.

February 2019

Discussions from the 729th to 732nd Meetings of the Commission held on the 5th, 12th, 19th and 26th of February 2019 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations[3].

Peaticides	・ Picoxystrobin ・ Broflanilid
Pesticides and additives	・ Difenoconazole
Veterinary medicinal products	・ Dichloroisocyanuric acid ・ Amendment of Chlorpromazine test method in "Standards for foods/food additives" designated on the basis of paragraph (1) of Article 11 of the Food Hygiene Law.
Veterinary medicinal products and feed additives	・ Tylosin
Genetically modified foods/feeds	・ Pullulanase produced using BML780PULm104 strain ・ Valencene, a fragrance, produced using Rhodobacter sphaeroides 168 strain

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

Food additives

Item	Conclusion
Amendment of Chlorpromazine test method in "Standards for foods/food additives" designated on the basis of paragraph (1) of Article 11 of the Food Hygiene Law.	FSCJ conclusion: Since the relevant assessment concerns change of analysis methods, the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act[4].

Pesticides

Item	ADI	ARfD
Amisulbrom	0.1 mg/kg bw per day	Not required

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

[4] 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.

Cymoxanil	0.013 mg/kg bw/day	0.08 mg/kg bw
Flubendiamide	0.017 mg/kg bw/day	0.15 mg/kg bw for lactating women, Not required for ordinary people
Frametpyr	0.007 mg/kg bw/day	0.3 mg/kg bw
Fluazinam	0.01 mg/kg bw/day	0.5 mg/kg bw for ordinary people 0.02 mg/kg bw for pregnant or may be pregnant women

Veterinary medicinal products

Item	Conclusion
Amendment of Chlorpromazine test method in "Standards for foods/food additives" (Notification of the Ministry of Welfare , No. 370, 1959) designated on the basis of paragraph (1) of Article 11 of the Food Sanitation Act (Law No. 233 of 1947).	The assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act[5].

Feed additives

Item	Conclusion
Amendment of Ordinance of Ministry of Agriculture and Forestry[6] regarding standards for feed and feed additives (Tylosin phosphate)	FSCJ conclusion: FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear[7].

Antimicrobial-resistant bacteria

Item	Conclusion
Macroride antibiotic agents for use in livestock animals	FSCJ conclusion: The use of the item for cattle, pigs and chicken may possibly cause hazards, and humans may be exposed to the hazards through livestock products derived from these livestock animals, resulting in a decrease and/or abolishment of therapeutic effects of antibiotics for humans. Although this possibility is not excluded, food safety risk of the item is evaluated to be low. As for honeybee and horses, food safety risk of the item is evaluated to be negligible since there is no hazard to be specified.

[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] Ordinance of Ministry of Agriculture and Forestry, No.35, 1976
[7] The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act

March 2019

Discussions from the 733rd to 736th Meetings of the Commission held on the 5th, 12th, 19th and 26th of March 2019 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations[8].

Resitcides	・ Thifluzamide ・ Pyridalyl ・ Buprofezin ・ Fluopyram ・ Prothioconazole
Pesticides and Veterinary medicinal products	・ Oxolinic Acid
Veterinary medicinal products	・ Food safety of livestock products derived from wild boars that ingested oral live vaccine against classical swine fever ・ Amostuck LA injection ・ Acetate Ringer's solution containing glucose – V injection ・ TSV-3 ・ バックスオン Pox/MD/IBD
Prion	・ Meat and offal derived from cattle, sheep and goats imported from Spain.
Genetically modified foods/feeds	・ Phytase produced using JPAo002 strain

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

Additives and genetically modified foods/feeds

Item	Conclusion
Psicose epimerase produced using Escherichia coli K-12 W3110 (pWKLP)	The documents, evaluated based on the "Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms[9]". Consequently, FSCJ concluded that the assessed item has no concern relevant to human health.

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

[9] Decision of the Commission dated 25 March 2004.

Pesticides

Item	ADI	ARfD
Afidopyropen	0.08 mg/kg bw per day	0.18 mg/kg bw
Oxpoconazole fumarate	0.03 mg/kg bw per day	0.2 mg/kg bw

Veterinary medicinal products

Item	Conclusion
Acetate Ringer's solution containing glucose – V injection: An injection which contains sodium chloride, potassium chloride, Calcium chloride hydrate, Sodium acetate hydrate and glucose as active ingredients.	FSCJ Conclusion: FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear[10].
Mixed live vaccine against infectious bovine rhinotracheitis, cattle parainfluenza, and cattle RS virus infection (TSV-3)	FSCJ Conclusion: FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear[11].

Veterinary medicinal products and feed additives

Item	ADI
Tylosin	0.005 mg/kg bw per week

Genetically modified foods/feeds

Item	Conclusion
Phospholipase produced using JPAN002 strain	FSCJ conclusion: According to the "Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms"[12], the item was evaluated not to affect human health.

Feed additives

Item	Conclusion
Manganese bis(2-hydroxy-4-methylthio butyrate)	FSCJ conclusion: FSCJ concluded that the risk to human health from the intake of this product through consumption of foods is negligible as long as it is appropriately used as a feed additive.

[10] The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act

[11] The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act

[12] "Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms" (Decision of the Food Safety Commission dated March 25, 2004)

Cupper bis(2-hydroxy-4-methylthio butyrate)	FSCJ conclusion: FSCJ concluded that the risk to human health from the intake of this product through consumption of foods is negligible as long as it is appropriately used as a feed additive.

Antimicrobial-resistant bacteria

Item	Conclusion
Tetracycline antibiotics for veterinary use in livestock animals	FSCJ conclusion: The use of the item for cattle, pigs and chicken may possibly cause hazards, and humans may be exposed to the hazards through livestock products derived from these livestock animals, resulting in a decrease and/or abolishment of therapeutic effects of antibiotics for humans. Although this possibility is not excluded, food safety risk of the item is evaluated to be low.