Provisional translation

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

July 2016

Discussions from the 613rd to 616th Meetings of the Commission held on the 5th, 12th, 19th and 26th of July 2016 are summarized as follows:

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

Pesticides	・Oxathiapiprolin ・Clofentezine ・Pyridalyl ・Pyribencarb ・Flubendiamide ・Metaldehyde ・Mepiquat chloride
Pesticides and Veterinary medicinal products	・Dinotefuran
Veterinary medicinal products	・Closantel ・"Baycox" containing Toltrazuril as an active ingredient, for veterinary use by oral administration into cattle (baycox for cattle) and pigs. (baycox for pigs) (reexamination) ・"Finadyne 50" containing Flunixin Meglumine as an active ingredient of injection for pigs. (reexamination)
Genetically modified foods/feeds	・Additives, produced by using recombinant DNA technologies, of which active ingredients are comparable to that FSCJ approved its safety and other criteria as a highly purified additive. ・L-Glutamine produced by using GGI strain. ・Phospholipase produced by using NZYM-LP strain.

[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.

Pesticides

Item	ADI	ARfD
Quinclorac	0.34 mg/kg bw per day	1.5 mg/kg bw
Fluopyram	0.012 mg/kg bw per day	0.5 mg/kg bw
Imidacloprid	0.057 mg/kg bw per day	0.1 mg/kg bw
Glyphosate	1 mg/kg bw per day	not required

Veterinary medicinal products

Item	Conclusion
Closantel	FSCJ conclusion: The assessed item corresponds to the item 1 of the Food Safety Commission Decision of January 27, 2014. Accordingly, FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear[2].

Genetically modified foods/feeds

Item	Conclusion
・Assessment for use of a food additive, to a feed additive, which was previously evaluated to be of no safety concern as being highly purified.	FSCJ conclusion: Safety of a food additive which was previously confirmed as being highly purified[3] is not changed before and after the additive is diverted to a feed additive because of being highly purified, thus the food safety risk from the item through livestock products was evaluated to be negative. Accordingly, FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear[4].

Apparatus and Containers/Packages

Item	TDI
Phthalic acid dioctyl	0.37 mg/kg bw per day

Antimicrobial resistant bacteria

Item	Conclusion
・An injection for cattle and pigs (Cobactan/cephagard)	FSCJ conclusion: The use of cefquinome sulphate products, as a veterinary medicinal product in cattle and pigs, may possibly cause the selection of hazards in livestock products, resulting in a decrease and/or

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

[3] The documents was evaluated based on the "Stance on Safety Assessments of Additives Produced Using Generically Modified Microorganisms, whose End Product is a Highly Purified Nonprotein Additive, such as Amino Acids[3]" (Supplementary Provisions of "Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms[3]")

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

containing cefquinome sulphate as an active ingredient.	abolishment of therapeutic effects of antibiotics for human. This potential is undeniable. However, FSCJ concluded that food safety risk of the item is moderate after evaluating all the risk factors.

August 2016

Discussions from the 617th to 620th Meetings of the Commission held on the 2nd, 9th, 23rd and 30th of August 2016 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations[5].

Pesticides	・Hexythiazox
Veterinary medicinal products	・Amendment of Coumaphos testing procedure in standards for foods/food additives[6] designated based on the provision of paragraph 1, article 11 of the Food Sanitation Law[7]. ・Albendazole "Vecoxan" containing Diclazuril as an active ingredient, for veterinary use by oral administration into cattle.

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

Pesticides

Item	Conclusion
Hexythiazox	FSCJ conclusion: The assessed item corresponds to the item 1 of the Food Safety Commission Decision of January 27, 2014. Accordingly, FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear[8].

[5] E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).
[6] Notification of the Ministry of Welfare, No. 370, 1959
[7] Law No. 233 of 1947
[8] The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

Veterinary medicinal products

Item	Conclusion
"Baycox" containing Toltrazuril as an active ingredient, for veterinary use by oral administration into cattle (baycox for cattle) and pigs. (baycox for pigs)	FSCJ conclusion: FSCJ conclusion: Risks to human health from the intake of this product through food are negligible as long as appropriately used.
"Finadyne 50" containing Flunixin Meglumine as an active ingredient of injection for pigs.	FSCJ conclusion: FSCJ conclusion: Risks to human health from the intake of this product through food are negligible as long as appropriately used.
Amendment of Coumaphos testing procedure in standards for foods/food additives[9] designated based on the provision of paragraph 1, article 11 of the Food Sanitation Law[10].	FSCJ conclusion: FSCJ conclusion: Risks to human health from the intake of this product through food are negligible as long as appropriately used.
Albendazole	FSCJ conclusion: The assessed item corresponds to the item 1 of the Food Safety Commission Decision of January 27, 2014. Accordingly, FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear[11].

[9] Notification of the Ministry of Welfare, No. 370, 1959
[10] Law No. 233 of 1947
[11] The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

Prions

Item	Conclusion
Revision of the current countermeasures against BSE ; Repeal of BSE test of slaughtered healthy cattle.	FSCJ conclusion: Difference in the risk to human health before and after repeal of BSE test which is currently conducted in slaughter house with healthy cattle of age over 48 months slaughtered for foods would be extremely small. Therefore, the effects on human health of this change of the border measures are negligible

Genetically modified foods/feeds

Item	Conclusion
Hybrid stacks of soybean: MON87705[12] x MON87708[13] x MON89788[14]	FSCJ conclusion: FSCJ concluded that hybrid stacks of soybean MON87705[15] x MON87708[16] x MON89788[17] has no concern relevant to human health, based on the "Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)"[18].
Soybean MON87751[19] (foods)	FSCJ conclusion: FSCJ concluded that the assessed item has no concern relevant to human health, based on the "Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)"[20].
Soybean MON87751[21] (feeds)	FSCJ conclusion: According to the "Stance on the safety assessment of genetically modified feeds and feed additives", the item did not require further assessment through the "Stance on the safety

[12] Soybean tolerant of glyphosate herbicide with lower saturated fatty acid and improved oleic acid content.
[13] Soybean tolerant of dicamba herbicide.
[14] Soybean tolerant of glyphosate herbicide.
[15] Soybean tolerant of glyphosate herbicide with lower saturated fatty acid and improved oleic acid content.
[16] Soybean tolerant of dicamba herbicide.
[17] Soybean tolerant of glyphosate herbicide.
[18] decision of Commission dated January 29, 2004
[19] Soybean resistant to Lepidoptera
[20] decision of Commission dated January 29, 2004
[21] Soybean resistant to Lepidoptera

	assessment of genetically modified foods (seed plants)". Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.

September 2016

Discussions from the 621st to 623rd Meetings of the Commission held on the 6th, 13th and 27th of September 2016 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations[22].

Prions	・Meat and offal of cattle, sheep and goats imported from Austria.
Genetically modified foods/feeds	・Maize MON87419[23]

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

Additives

Item	Conclusion
Calcium carbonate	FSCJ conclusion: FSCJ specified an upper limit for intake of calcium from other than ordinary meal to 2,000 mg/person per day (as calcium).

Pesticides

Item	ADI	ARfD
Oxathiapiprolin	3.4 mg/kg bw per day	Not required
Clofentezine	0.017 mg/kg bw per day	Not required
Paclobutrazol	0.02 mg/kg bw per day	0.3 mg/kg bw
Metamifop	0.0042 mg/kg bw per day	1.2 mg/kg bw

[22] E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).
[23] Maize tolerant of dicamba and glufosinate herbicides.

Pyraclostrobin	0.034 mg/kg bw per day	0.05 mg/kg bw
Famoxadone	0.006 mg/kg bw per day	Not required
Fenpyrazamine	0.12 mg/kg bw per day	0.8 mg/kg bw
Boscalid	0.044 mg/kg bw per day	3 mg/kg bw

Veterinary medicinal products

Item	ADI
Triptorelin Acetate	Not required.
Spiramycin	0.025 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
Anthorine, an injection for cows to induce superovulation containing FSH 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.

Genetically modified foods/feeds

Item	Conclusion
L-Glutamine produced using GGI strain.	FSCJ conclusion: According to the "Stance on the Safety Assessment of Amino Acids and Other End Products"[24], the item's safety was confirmed.
Additives, produced by using recombinant DNA technologies, of which active ingredients are comparable to that FSCJ approved its safety and other criteria as a highly purified additive.	FSCJ conclusion: Degree of adverse effects of food additives that fulfill all items to compare designated in Notification No.0706 issued by Ministry of Health and Welfare, appendix No.1, as of July 6, 2016, to human health is not different from that of items of which safety evaluation has been completed by FSCJ. Consequently, FSCJ conclude that the item corresponds to the case where the contents and degree of adverse effects on human health are clear, under the Food Safety Basic Act[25].

[24] "Stance on Safety Assessments of Amino Acids and Other End Products that are highly purified non-protein additives among additives produced using genetically modified microorganisms (Decision of the Commission dated April 28, 2005)".

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