Provisional translation

This English version of the Commission Decision is intended to be reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail. The FSCJ shall not be responsible for any consequence resulting from use of this English version.

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

October 2018

Discussions from the 714th to 718th Meetings of the Commission held on the 2nd, 9th, 16th, 23rd and 30th of October 2018 are summarized as follows:

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

Exempted Substances	・Neem oil
Pesticides	・Fluazinam ・Cartap ・Thiocyclam ・Bensultap ・Amendment of Withhold standard for pesticide registration in accordance with amendment of Agricultural Chemicals Control Act.
Genetically modified foods	・Chitinase produced using pCHC strain.
Food additives and Genetically modified foods	・Psicose eimerase produced using Escherichia coli K-12 W3110(pWKLP) strain.
Chemicals and contaminants	・Revision of the reagents and solutions for arsenic in beverages designated in standards for foods and additives based on paragraph (1) of Article 11 of the Food Hygiene Law.
Feed additives	・Copper bis (2-hydroxy-4-methylthio butyrate) ・L-Methionine

(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

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

Neem oil	FSCJ conclusion: 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.[2]

Additives

Item	ADI
Hypobromous Acid Water	For 5,5-dimethylhydantoin, ADI was specified as 1 mg/kg bw per day. For bromides, ADI was specified as 0.9 mg/kg bw per day as bromide ion. For Hypobromous Acid Water, FSCJ concluded that the item has no safety concern as long as appropriately used as an additive.

Pesticides

Item	ADI	ARfD
Pyflubumide	0.0073 mg/kg bw per day	0.09 mg/kg bw
Inpyrfluxam	0.06 mg/kg bw per day	0.3 mg/kg bw
Thiacloprid	0.012 mg/kg bw per day	0.031 mg/kg bw
Prothiofos	0.0027 mg/kg bw per day	0.05 mg/kg bw

Pesticides

Item	Conclusion
Amendment of Withhold standard for pesticide registration in accordance with amendment of Agricultural Chemicals Control Act.	FSCJ conclusion: The assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act[3].

Veterinary medicinal products

Item	ADI
Fluralaner	0.01 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion

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

6 components contained as additives in the already approved veterinary vaccines	FSCJ conclusion: Since the effects on human health are negligible as long as the item is used as additives in the veterinary vaccines, 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.[4]

Chemicals and contaminants

Item	Conclusion
Revision of the reagents and solutions for arsenic in beverages designated in standards for foods and additives based on paragraph (1) of Article 11 of the Food Hygiene Law.	FSCJ conclusion: FSCJ concluded that the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act[5]

[4] The case designated by 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.

November 2018

Discussions from the 719th to 722nd Meetings of the Commission held on the 6th, 13th, 20th and 27th of November 2018 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations[6].

Pesticides	・1-Methylcyclopropene・Oxpoconazole fumarate ・Dichlobentiazox ・Tolclofos-methyl ・Florpyrauxifen-benzyl ・Penthiopyrad
Veterinary medicinal products	・Tildipirosin ・An injection for veterinary use in pigs, Zuprevo 40 Injection, which contains tildipirosin as an active substance. ・Bovine tuberculosis diagnostics (cattle tuberculin PPD and avian tuberculin PPD)
Genetically modified foods/feeds	・Phospholipase produced using JPAN002 strain. ・Amendment of standards that the Minister of Agriculture, Forestry and Fisheries defined that there is no obstruction to ensure the safety of feed additives which are produced using recombinant DNA technologies.

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

Veterinary medicinal products

Item	Conclusion
Feed additives for pigs which contains valnemulin hydrochloride as an active substance (Econor 1% premix and Econor 10 % premix). (Reevaluation)	FSCJ conclusion: Risk to human health from the assessed item through food consumption is negligible as long as appropriately used.
Safety of the foods derived from cattle that used bovine tuberculosis diagnostics (cattle tuberculin PPD and avian tuberculin PPD).	FSCJ conclusion: FSCJ concluded that the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act[7]

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

[7] The item 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.

Gentian violet	FSCJ conclusion: FSCJ concluded that the ADI should not be specified, since potential genotoxicity of the item could not be excluded and thus carcinogenicity was suggested.

Genetically modified foods/feeds

Item	Conclusion
Amendment of standards that the Minister of Agriculture, Forestry and Fisheries defined that there is no obstruction to ensure the safety of feed additives which are produced using recombinant DNA technologies.	FSCJ conclusion: 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.[8]
Cotton MON88702 (foods) resistant to Hemiptera, Order Thysanoptera and Coleoptera.	FSCJ conclusion: According to the "Stance on the safety assessment of genetically modified foods (seed plants)"[9], Cotton MON88702 (foods) was evaluated not to affect human health.
Cotton MON88702 (feeds) resistant to Hemiptera, Order Thysanoptera and Coleoptera.	FSCJ conclusion: According to the "Stance on the safety assessment of genetically modified feeds and feed additives"[10], the item did not require further assessment through the "Stance on the safety assessment of genetically modified foods (seed plants)"[4]. Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.

[8] The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.
[9] "Stance on Safety Assessments of Genetically Modified Foods (seed plants) (Decision of the Commission dated 29 January 2004)"
[10] "Stance on Safety Assessments of Genetically Modified Feed and Feed Additives (Decision of the Commission dated 6 May 2004)"

December 2018

Discussions from the 723rdth to 725th Meetings of the Commission held on the 4th, 11th, 18th and 25th of December 2018 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations[11].

Pesticides	・Amisulbrom ・Cymoxanil ・Flubendiamide ・Cartap ・Thiocyclam ・Bensultap
Genetically modified foods/feeds	・Phytase produced using LU17257 strain

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

Pesticides

Item	ADI	ARfD
Dithianon	0.01 mg/kg bw per day	0.1 mg/kg bw
Sethoxydim	0.088 mg/kg bw per day	1.8 mg/kg bw
Propanil	0.016mg/kg bw per day	0.57 mg/kg bw
chloropicrin	0.001 mg/kg bw per day	0.5 mg/kg bw

Genetically modified foods/feeds

Item	Conclusion
Phytase produced using Morph ΔE8 BP17 4c strain	FSCJ conclusion: According to the "Stance on the safety assessment of genetically modified feeds and feed additives"[12], the item did not require further assessment through the "Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms"[13]. Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.

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

[12] Stance on Safety Assessments of Genetically Modified Feed and Feed Additives (Decision of the Commission dated 6 May 2004)

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

Chitinase produced using pCHC strain	FSCJ conclusion: According to “Stance on Safety Assessments of Additives Produced by Genetically Modified Microorganisms[14]”, the item is not the subject of this provision, and therefore the item did not require assessments.

Feed additives

Item	Conclusion
A feed additive that contains phytase produced by Trichoderma reesei MorphΔE8 BP17 4c strain as an active substance.	FSCJ conclusion: Risk to human health from the intake of the assessed item through food is negligible as long as appropriately used as a feed additive.
A feed additive that contains phytase produced by Komagataella pastoris (Pichia pastoris) P-132 strain as an active substance.	FSCJ conclusion: Risk to human health from the intake of the assessed item through food is negligible as long as appropriately used as a feed additive.

[14] This additive has been produced using a microorganism that falls under "the case where living cells which have genotypic composition equivalent to the relevant recombinant exist in nature", specified in Chapter 1 General Provisions, Section 3 "Scope and Objective" of Standards for Safety Assessments of Food Additives Produced using Genetically Modified Microorganisms (Decision of the Commission Dated 25 March 2004).