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)

April 2018

Discussions from the 691st to 694th Meetings of the Commission held on the 3rd, 10th, 17th and 24th of April 2018 are summarized as follows:

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

Food additives, Apparatus and containers / packages, and Microorganisms and viruses	・ Revision of the Ordinance regarding standard of element and others of milk and dairy products. (Ordinance of the Ministry of Welfare, No.52, 1951) and standards for foods/food additives (Notification of the Ministry of Welfare, No. 370, 1959). (Prepared liquid formula for infants)
Pesticides	・ Isopyrazam ・ Spinetoram ・ Difenoconazole ・ Spirotetramat ・ Triforine ・ Pyriofenone ・ Mandestrobin ・ Metaflumizone ・ Simeconazole ・ Bifenazate
Pesticides and Veterinary medicinal products	・ Permethrin
Veterinary medicinal products	・ Fluralaner
Genetically modified foods/feeds	・ Alpha-amylase produced using JSF-07-170-3 strain ・ Cotton MON88702 (foods) resistant to Hemiptera, Order Thysanoptera and Coleoptera.

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

	・ Cotton MON88702 (feeds) resistant to Hemiptera, Order Thysanoptera and Coleoptera.

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

Pesticides

Item	ADI	ARfD
Acynonapyr	0.04 mg/kg bw per day	Not required
Lancotrione-Sodium	0.001 mg/kg bw per day	0.1 mg/kg bw

Veterinary medicinal products

Item	Conclusion
Thymol	FSCJ conclusion: FSCJ concluded that it is not necessary to specify an ADI as long as it is used appropriately as veterinary medicinal products.
A parasiticide for veterinary use to honey bee, Thymovar, which contains thymol as an active substance.	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.

Food additives, Apparatus and containers / packages, and Microorganisms and viruses

Item	Conclusion
Revision of the Ordinance regarding standard of element and others of milk and dairy products. (Ordinance of the Ministry of Welfare, No.52, 1951) and standards for foods/food additives (Notification of the Ministry of Welfare, No. 370, 1959). (Prepared liquid formula for infants)	FSCJ conclusion: FSCJ concluded that the item falls under the categories that are the case where the risk assessment is not necessary[2] and the case where the contents and degree of adverse effects on human health are clear[3].

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

Genetically modified foods/feeds

Item	Conclusion
Glucose oxidase produced using GOOX-1 strain	FSCJ conclusion: The documents, evaluated based on the "Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms[4]". Consequently, no concern relevant to human health is raised on this glucose oxidase produced using GOOX-1 strain.
Alkaline protease produced using JPBL001 strain (food additives)	FSCJ conclusion: The documents, evaluated based on the "Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms[4]". Consequently, no concern relevant to human health is raised on this alkaline protease produced using JPBL001 strain (food additives)
Alkaline protease produced using JPBL001 strain (feed additives)	FSCJ conclusion: The documents, evaluated based on the "Stance of Safety Assessments of Feed and Feed Additives Produced Using Genetically Modified Microorganisms"[5]. FSCJ concluded that the assessment based on the "Standards for Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms"[6] is not necessary for this additive. Consequently, the food safety risk from the assessed item through livestock products was evaluated to be negative.

Food/Feed Additives

Item	Conclusion
Alkaline protease produced by using JPBL001 strain (feed additives)	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.

[4] Decision of the Commission dated 25 March 2004.
[5] Food Safety Commission Decision of May 6, 2004
[6] Food Safety Commission Decision of May 6, 2004

May 2018

Discussions from the 695th to 698th Meetings of the Commission held on the 8th, 15th, 22nd and 29th of May 2018 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations[7].

Pesticides	・ Prothiofos ・ Propanil
Veterinary medicinal products	・ Draxxin 25, an injection for pigs, containing tulathromycin as the active substance. ・マイプラビン 注100, an injection for pigs, containing mirosamicin as the active substance.
Genetically modified foods/feeds	・ Chymosin produced using CIN strain
Feed Additives	・ Astaxanthin

(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
β-Glucan derived from baker's yeast	FSCJ conclusion: Risk to human health from intake of the assessed items through residues in food is negligible as long as normally used by assumable way as a pesticide.

Food Additives[4]

Item	Conclusion
・Isobutylamine ・Isopropylamine ・sec-Butylamne ・Propylamine ・Hexylamine ・Pentylamine ・2-Methylbutylamine	FSCJ conclusion: Risk to human health from intake of the assessed items through residues in food is negligible as long as normally used by assumable way as a pesticide.

Pesticides

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

Item	ADI	ARfD
Difenoconazole	0.0096 mg/kg bw per day	0.25 mg/kg bw
Simeconazole	0.0085 mg/kg bw per day	0.2 mg/kg bw for general population 0.09 mg/kg bw for women who are or may be pregnant
Spirotetramat	0.12 mg/kg bw per day	1 mg/kg bw
Triforine	0.023 mg/kg bw per day	1.5 mg/kg bw
Pyriofenone	0.091 mg/kg bw per day	Not required
Mandestrobin	0.19 mg/kg bw per day	Not required
Metaflumizone	0.12 mg/kg bw per day	Not required
Tebufenpyrad	0.082 mg/kg bw per day	0.15 mg/kg bw
Flutriafol	0.01 mg/kg bw per day	0.075 mg/kg bw

Veterinary medicinal products

Item	ADI
Sarafloxacin	0.0064 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
Draxxin 25, an injection for pigs, containing tulathromycin as the active substance.	FSCJ conclusion: FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear[8].
Ectoparasiticide for use to fishes belonging Tetraodontiformes and Percomorphi, Mushiotiru, that contains hydrogen peroxide as an active component.	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.
マイプラビン 注100, an injection for pigs, containing mirosamicin as the active substance.	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.

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

Veterinary medicinal products and feed additives

Item	ADI
Salinomycin	0.005 mg/kg bw per day (as sodium salt)

Genetically modified foods/feeds

Item	Conclusion
Pullulanase produced using JPBL002 strain	FSCJ conclusion: According to the "Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms"[9], the item was evaluated not to affect human health.

Feed additives

Item	Conclusion
Astaxanthin	FSCJ conclusion: FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear[10].

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

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

June 2018

Discussions from the 699th to 702nd Meetings of the Commission held on the 5th, 12th, 19th and 26th of June 2018 are summarized as follows:

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

Additives	・ Argon
Pesticides	・ Afidopyropen ・ Inpyrfluxam ・ Etofenprox ・ Captan ・ Zoxamide ・ Fenpicoxamid ・ Methoxyfenozide
Genetically modified foods/feeds	・ Hemicellulase produced by using JPTR001 strain ・ Xylanase produced by using JPTR002 strain

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

Additives

Item	Conclusion
Argon	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[12].

Pesticides

Item	ADI	ARfD
Isopyrazam	0.055 mg/kg bw per day	0.3 mg/kg bw
Spinetoram	0.024 mg/kg bw per day	Not required

Veterinary medicinal products

Item	ADI

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

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

Bromofenofos	0.0025 mg/kg bw per day

Genetically modified foods/feeds

Item	Conclusion
Cotton GHB811 tolerant of glyphosate and of HPPD[13]-inhibitory herbicides (foods)	FSCJ conclusion: According to the "Stance on the safety assessment of genetically modified foods (seed plants)"[14], GHB811 was evaluated not to affect human health.
Cotton GHB811 tolerant of glyphosate and of HPPD [15] -inhibitory herbicides (feeds)	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 assessment of genetically modified foods (seed plants)". Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.
Alpha-amylase produced using JSF-07-170-3 strain	FSCJ conclusion: According to the "Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms"[16], the item was evaluated not to affect human health.

[13] 4-Hydroxyphenylpyruvate Dioxygenase

[14] "Stance on Safety Assessments of Genetically Modified Foods (seed plants) (Decision of the Commission dated 29 January 2004)"

[15] 4-Hydroxyphenylpyruvate Dioxygenase

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