Provisional translation

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

July 2019

Discussions from the 748th to 751st Meetings of the Commission held on the 2nd, 9th, 23rd and 30tht of July 2019 are summarized as follows:

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

Genetically modified foods/feeds	・ L-leucine produced using LG-108 strain. ・ Cyanocobalamin produced using SCM2034 strain. ・ L-methionine produced using K12 KCCM11252P strain and K12 KCCM11340P strain.
Food for specified health uses	・Pilkul 400

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

Pesticides

Item	ADI	ARfD
Ametoctradin	2.7 mg/kg bw per day	Not required
Diethofencarb	0.42 mg/kg bw per day	2 mg/kg bw
Picarbutrazox	0.023 mg/kg bw per day	Not required
Benthiavalicarb-isopropyl	0.069 mg/kg bw per day	Not required
Penthiopyrad	0.081 mg/kg bw per day	1.2 mg/kg bw
Metyltetraprole	2.5 mg/kg bw per day	Not required

Veterinary medicinal products

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

Item	ADI
Florfenicol	0.01 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
Xylazine	FSCJ conclusion: It is unnecessary to specify ADI for the item as long as it is used appropriately as a veterinary medicinal product.
Diethylstilboestrol	FSCJ conclusion: It is inappropriate to specify an ADI of DES.

Genetically modified foods/feeds

Item	Conclusion
Pullulanase produced using BML780PULm104 strain	FSCJ conclusion: According to the "Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms"[2], the item was evaluated not to affect human health.
Phytase produced using JPAo002strain	FSCJ conclusion: According to the "Stance on the safety assessment of genetically modified feeds and feed additives"[37], the item did not require further assessment through the "Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms"[3]. Hence, livestock products derived from animals that consumed the item have no concern relevant to human health.
Monosodium L-glutamate produced using GLU-No.10 strain	FSCJ conclusion: 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[4]" (Supplementary Provisions of "Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms[5]"). Consequently, the safety of the additive has been confirmed. In conclusion, the assessment based on the "Standards for

[2] "the Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)"
[3] "the Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)"
[4] Decision of the Commission dated April 28, 2005
[5] Decision of the Commission dated March 25, 2004

	Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms" is not necessary for this additive.
L-serine produced using SKG strain	FSCJ conclusion: 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[6]" (Supplementary Provisions of "Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms[7]"). Consequently, the safety of the additive has been confirmed. In conclusion, the assessment based on the "Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms" is not necessary for this additive.

Feed additives

Item	Conclusion
Feed additives composed of 6-phytase produced by Aspergillus niger LU17257 strain as the source material	FSCJ conclusion: Risk to human health from the assessed item through food consumption is negligible as long as appropriately used as a feed additive.

[6] Decision of the Commission dated April 28, 2005

[7] Decision of the Commission dated March 25, 2004

August 2019

Discussions from the 752nd to 754th Meetings of the Commission held on the 6th, 20th and 27th of August 2019 are summarized as follows:

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

Food/feed additives	・Items related to amendment of specification and standards of foods and additives for establishing the supplement to Japanese Standards of Food Additives.
Pesticides	・Oxathiapiprolin ・Cyclaniliprole
Pesticides and additives	・Azoxystrobin
Chemicals and contaminants	・Amendment of standard for quality of drinking water supplied by the tap (hexavalent chromium compounds)

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

Food/feed additives

Item	Conclusion
Items related to amendment of specification and standards of foods and additives for establishing the supplement to Japanese Standards of Food Additives.	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.

Pesticides

Item	ADI	ARfD
Pyriproxyfen	0.1 mg/kg bw per day	3 mg/kg bw
Isofetamid	0.053 mg/kg bw per day	3 mg/kg bw
Dazomet, metam, Methyl isothiocyanate	0.004 mg/kg bw per day as the group ADI	0.1 mg/kg bw
Pyroxasulfone	0.02 mg/kg bw per day	Not required

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

Pesticides and veterinary medicinal products

Item	ADI	ARfD
Oxolinic acid	0.021 mg/kg bw per day	0.06 mg/kg bw

Chemicals and contaminants

Item	Conclusion
Amendment of standard for quality of drinking water supplied by the tap (hexavalent chromium compounds)	FSCJ conclusion: FSCJ considered that the amendment has no potential to affect existing results of assessment. Hence, FSCJ decided to explain only the circumstances of this request for assessment in the assessment report without revising the evaluation contents.

Antimicrobial resistant bacteria

Item	Conclusion
Florgane; an injection for cattle that contains florfenicol (FFC) as an active substance.	FSCJ conclusion: The use of florfenicol products into cattle and pigs may possibly cause the selection of bacteria resistant to florfenicol and crossed resistant to chloramphenicol. However, FSCJ considered that there is no hazard to specify, because chloramphenicol is not used against infections that may spread in human through food consumption, and because fluoroquinolone antimicrobials are recommended first for human infections caused by chloramphenicol resistant bacteria from livestock animals. Hence, FSCJ concludes that the risk to human health via food consumption arisen from the antimicrobial-resistant bacteria selected through the use of florfenicol products in cattle and pigs is negligible.

September 2019

Discussions from the 755th to 758th Meetings of the Commission held on the 3rd, 10th, 17th and 24th of September 2017 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations[9].

Food additives	・Deletion of manufacturing standards for an additive, spice extract restricted to the extract of chervil or its steam distillation products, from standards for food additives prescribed in paragraph (1) of Article 11 of the Food Safety Basic Act.
Pesticides	・*1,3*-Dichloropropene ・Imazapyr ・Fenpropathrin ・Bentazon
Pesticides and veterinary medicinal products	・Cyfluthrin
Veterinary medicinal products	・Foods derived from pigs vaccinated with hog cholera marker vaccines.
Genetically modified foods/feeds	・Pima cotton tolerant of dicamba, glufosinate and glyphosate herbicides, MON88701×MON88913 line.
Feed additives	・Dibutylhydroxytoluene
Others	・Designation of 4 items including pueraria mirifica as specified components. ・Establishment of standards for manufacturing and processing of foods that contain specified components.

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

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

Additives

Item	Conclusion
Deletion of manufacturing standards for an additive, spice extract restricted to the extract of chervil or its steam distillation products, from standards for food additives prescribed in paragraph (1) of Article 11 of the Food Safety Basic Act.	FSCJ conclusion: The assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act[10].

Veterinary medicinal products

Item	Conclusion
Florgane; an injection for cattle that contains florfenicol (FFC) 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.

Genetically modified foods/feeds

Item	Conclusion
Disodium 5-ribonucleotide produced using RN-No.3 strain	FSCJ conclusion: 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” (Supplementary Provisions of “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms”). Consequently, the safety of the additive has been confirmed. In conclusion, the assessment based on the “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms” is not necessary for this additive.

[10] 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.

L-Ornithine hydrochloride produced using ORN-No.1 strain	FSCJ conclusion: 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". Consequently, the safety of the additive has been confirmed to be equivalent to that of conventional products used for comparison. Hence, the assessment based on the "Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms" is not necessary for this additive.
Beta-Galactosidase produced using JPBL003 strain	FSCJ conclusion: FSCJ conducted the assessment based on the Standards for Safety Assessments of Food Additives Produced Using Genetically Modified Microorganisms, FSCJ concluded that the additive has no concern relevant to human health.

Others

Item	Conclusion
Designation of 4 items including pueraria mirifica as specified components.	FSCJ conclusion: FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear[11].
Establishment of standards for manufacturing and processing of foods that contain specified components.	FSCJ conclusion: FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear[12].

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