Provisional translation

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

October 2017

Discussions from the 668th to 671st Meetings of the Commission held on the 3rd, 17th, 24th and 31st of October 2017 are summarized as follows:

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

Pesticides	・Revision of specimen for pears, Japanese pears, quinces and apples designated in standards for foods and additives[2]. ・Acynonapyr ・Tetraniliprole ・Lancotrione-sodium ・Desmedipham ・Acibenzolar-S-methyl ・Flutriafol (Bulk deletion) ・Hydramethylnon ・Fentin ・Flucarbazone-sodium ・Propazine
Pesticides and additives	・Fludioxonil
Veterinary medicinal products	・Monepantel ・Thymol ・A parasiticide for veterinary use to honey bee, Thymovar, which contains thymol as an active ingredient (Bulk deletion) ・Oleandomycin

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

[2] Notification of the Ministry of Welfare, No. 370, 1959, which was established based on paragraph (1) of article 11 of the Food Sanitation Act, Act No. 233 off 1947.

(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
Hydroxypropyl distarch phosphate	FSCJ conclusion: Risk to human health from intake of the assessed items through food is negligible as long as normally used as a pesticide.

Pesticides

Item	ADI	ARfD
Triflumezopyrim	0.032 mg/kg bw per day	1 mg/kg bw
Cyazofamid	0.17 mg/kg bw per day	Not required
Cyanophos (CYAP)	0.001 mg/kg bw per day	0.01 mg/kg bw
Pyflubumide	0.0073 mg/kg bw per day	0.09 mg/kg bw
Metalaxyl and Mefenoxam	0.08 mg/kg bw per day	0.5 mg/kg bw

Pesticides

Item	Conclusion
Revision of specimen for pears, Japanese pears, quinces and apples designated in standards for foods and additives[3]	FSCJ conclusion: FSCJ conclude that the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act[4].
Desmedipham	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[5].
(Bulk deletion) ・Hydramethylnon ・Fentin ・Flucarbazone-sodium ・Propazine	FSCJ conclusion: Deletion of the standards for residues of the assessed items falls under the category which is the case where the contents and degree of adverse effects on human health are clear[5] on condition that the items currently are not used for agricultural products for foods and feeds domestically and internationally, or that the items are not used domestically for agricultural products, and that

[3] Notification of the Ministry of Welfare, No. 370, 1959, which was established based on paragraph(1) of article 11 of the Food Sanitation Act, Act No. 233 off 1947.

[4] 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.

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

	agricultural products for food produced using the items are not imported.

Veterinary medicinal products

Item	ADI
Orbifloxacin	0.012 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
(Bulk deletion) Oleandomycin	FSCJ conclusion: Deletion of standards for residue of the assessed items falls under the category which is the case where the contents and degree of adverse effects on human health are clear[5], on condition that use of the items for animals for human consumption, and animals for obtaining food products such as eggs and milk is improbable domestically and internationally, or that the items are not used domestically for animals, and that meat, milk and other products for food produced using the items are not imported.

Prions

Item	Conclusion
Resumption of use of MBM, derived from sheep and horses for fertilizers in aquatic animal farming.	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[5].

Genetically modified foods/feeds

Item	Conclusion
Maize MON87403[6], a biomass ear maize, at silking stage (foods)	FSCJ conclusion: According to the "Stance on the safety assessment of genetically modified foods (seed plants)"[7], MON87403 was evaluated not to affect human health.

[6] Notification on the procedure for safety evaluation of foods and additives that are produced by using recombinant DNA technologies.
[7] "Stance on Safety Assessments of Genetically Modified Foods (seed plants) (Decision of the Commission dated 29 January 2004)"

Maize MON87403[6], a biomass ear maize, at silking stage (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.
Acid phosphatase produced using OYC-GM1 strain	FSCJ conclusion: According to the "Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms"[8], the item was evaluated not to affect human health.
L-citrulline produced using CPR-strain	FSCJ conclusion: The documents was evaluated based on the "Stance on Safety Assessments of Additives Produced Using Generically Modified Microorganisms, whose End Porduct is a Highly Purified Nonprotein Additive, such as Amino Acids[9]". Consequently, FSCJ confirmed that the safety of the assessed item is equivalent to that of the conventional product as far as it is used in the same way. Hence, FSCJ concluded that the assessment based on the "Standards for Safety Assessment of Genetically Modified Foods (Microorganisms)" is not necessary for this additive.

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

[9] Supplementary Provisions of "Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms" (Decision of the Commission dated April 28, 2005).

November 2017

Discussions from the 672nd to 675th Meetings of the Commission held on the 7th, 14th, 21st and 28th of November 2017 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations[10].

Peaticides	・Tetraconazole ・Picoxystrobin ・Pyribencarb ・Flupyrimin
Veterinary medicinal products	・Spectinomycin
Genetically modified foods/feeds	・Hybrid stacks of soybean: DP-305423-1[11] x MON89788[12] x MON87708[13]. (Hybrid stacks from MON89788[3] x MON87708[4], for which the assessment has been done or the evaluation has been informed to MHLW, are not included)

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

Pesticides

Item	ADI	ARfD
Fluensulfone	0.014 mg/kg bw per day	0.33 mg/kg bw

[10] E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).
[11] Genetically modified soybean with improved oleic acid content.
[12] Soybean tolerant of glyphosate herbicide.
[13] Soybean tolerant of dicamba herbicide

Pesticides and additives

Item	ADI	ARfD
Fludioxonil	0.33 mg/kg bw per day	2.5 mg/kg bw

Veterinary medicinal products

Item	ADI
[Monobis(trimethylammoniu mmethylene chloride)]-alkyltoluene	0.013 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
・Nine components used as additives to vaccine for veterinary use.	FSCJ conclusion: Risk to human health from the intake of the assessed item is negligible as long as appropriately used as additives to vaccine for veterinary use. 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[14].
・Spectinomycin	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[15].
・Pegbovigrastim	FSCJ conclusion: Revise the assessment report.

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

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

Veterinary medicinal products and feed additives

Item	ADI
Semduramicin	0.003 mg/kg bw/day

Genetically modified foods/feeds

Item	Conclusion
・Maize MZIR098 line resistant to Coleoptera and tolerant of glufosinate herbicide (foods)	FSCJ conclusion: According to the "Stance on the safety assessment of genetically modified foods (seed plants)"[16], MZIR098 was evaluated not to affect human health.
・Maize MZIR098 line resistant to Coleoptera and tolerant of glufosinate herbicide (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 assessment of genetically modified foods (seed plants)". Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.

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

December 2017

Discussions from the 676th to 678th Meetings of the Commission held on the 5th, 12th, 19th and 26th of December 2017 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations[17].

Food additives	・Isobutylamine ・Isopropylamine ・sec-butylamine ・Hexylamine ・2-Methylbutylamine
Veterinary medicinal products	・Ectoparasiticide for use to fishes belonging Tetraodontiformes and Percomorphi, Mushiotiru, that contains hydrogen peroxide as an active component.
Genetically modified foods/feeds	・Transgenic tomato plants TU-IPI05B-1 that contains recombinant miraculin (foods) ・Transgenic tomato plants TU-IPI05B-1 that contains recombinant miraculin (feeds) ・L-Threonine produced by using Escherichia coli-K-12 DM235.0 strain. ・Glucoamylase produced by using JAPN001 strain. ・Alkaline protease produced by using JPBL001 strain (food additives) ・Alkaline protease produced by using JPBL001 strain (feed additives)

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

Feed additives	・Alkaline protease

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

Exempted Substances[18]

Item	Conclusion
・Citric acid esters of mono-and di-glycerides of fatty acid	FSCJ conclusion: Risk to human health from intake of the assessed items through food is negligible as long as normally used as a pesticide.
・Methionine	FSCJ conclusion: Risk to human health from intake of the assessed items through food is negligible as long as normally used as a veterinary medicinal product and a feed additive.

Additives

Item	TWI
Aluminium ammonium sulfate and aluminium potassium sulfate	2.1 mg/kg bw per week

[18] On May 29, 2006 the Ministry of Health, Labour and Welfare (MHLW) introduced the positive list system for agricultural chemicals remaining in foods to prohibit the distribution of foods that contain agricultural chemicals above a certain level if maximum residue limits (MRLs) have not been established. Exempted Substances are designated as substances having no potential to cause damage to human health by the Minister of Health, Labour and Welfare, based on the provision of Paragraph 3, Article 11 of the Food Sanitation Act, and these substances are not subjected to the positive list system.

Pesticides

Item	ADI	ARfD
Fluxapyroxad	0.021 mg/kg bw per day	1.2 mg/kg bw
Chlorfluazuron	0.033 mg/kg bw per day	Not required
Chlormequat	0.05 mg/kg bw per day	0.05 mg/kg bw
Dimethenamid	0.051 mg/kg bw per day	0.5 mg/kg bw
Fluxametamide	0.0085 mg/kg bw per day	Not required

Pesticides and veterinary medicinal products

Item	ADI	ARfD
Diajinon	0.001 mg/kg bw per day	0.025 mg/kg bw
Teflubenzuron	0.021 mg/kg bw per day	Not required

Veterinary medicinal products

Item	ADI
Betamethasone	0.01 μg/kg bw per day

Contaminants

Item	TWI
Aluminium	2.1 mg/kg bw per week

Genetically modified foods/feeds

Item	Conclusion
・Riboflavin produced by using RFESC02 strain	FSCJ conclusion: According to the "Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms"[19], the item was evaluated not to affect human health.

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