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)

January 2017

Discussions from the 634th to 636th Meetings of the Commission held on the 10th, 17th and 31st of January 2017 are summarized as follows:

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

Pesticides	・Etofenprox ・Gibberellin
Pesticides and veterinary medicinal products	・Cypermethrin ・Fenitrothion
Genetically modified foods / feeds	・Maize MON87403[2] ・L-Tryptophan produced using TRP-No.2 strain ・Amendment of Notification of the Ministry of Welfare, No. 233, 2000[3] ・Glucoamylase produced using NZYM-BE 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
Fluthiacet-Methyl	0.001 mg/kg bw per day	Not required
Triforine	0.023 mg/kg bw per day	1.5 mg/kg bw
Pyridalyl	0.028 mg/kg bw per day	Not required

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

[2] Notification on the procedure for safety evaluation of foods and additives that are produced by using recombinant DNA technologies.

[3] Notification on the procedure for safety evaluation of foods and additives that are produced by using recombinant DNA technologies.

Veterinary medicinal products

Item	ADI
Melengesterol acetate	0.025 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
Vecoxan containing Diclazuril as an active ingredient, for veterinary use by oral administration into cattle.	FSCJ conclusion: Risks to human health from the intake of this product through food are negligible as long as appropriately used.

Prions

Item	Conclusion
Meat and offal of cattle, sheep and goats imported from Austria	FSCJ conclusion: FSCJ concluded that the restriction of age and definition of Specific Risk Materials (SRMs) for meat and offal of cattle, sheep and goats imported from Austria make negligible change in the safety risk, thus the effect on human health of this change of the border measure is negligible.

Genetically modified foods/feeds

Item	Conclusion
Maize MON87419[4] (foods)	FSCJ conclusion: According to the "Stance on the safety assessment of genetically modified foods (seed plants)"[5], maize MON87419 was evaluated not to affect human health.
Maize MON87419[6] (feeds)	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 "Stance on the safety assessment of genetically modified foods (seed plants)"[34]. Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.

[4] Maize tolerant of dicamba and glufosinate herbicides.
[5] "Stance on Safety Assessments of Genetically Modified Foods (seed plants) (Decision of the Commission dated 29 January 2004)"
[6] Maize tolerant of dicamba and glufosinate herbicides.

FSCJ conclusion: Amendment of Notification of the Ministry of Welfare, No. 233, 2000[7]	FSCJ conclusion; FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear[8].

Antimicrobial resistant bacteria

Item	Conclusion
Colistin sulfate, an antibiotic designated as a feed additive in food animals	FSCJ conclusion: The use of colistin sulfate, as a veterinary medicinal product and as a feed additive in food animals, may possibly cause the selection of hazards in livestock products, resulting in a decrease and/or abolishment of therapeutic effects of antibiotics for human. This potential is undeniable. FSCJ concluded that food safety risk of the item is moderate after evaluating all the risk factors.

[7] Notification on the procedure for safety evaluation of foods and additives that are produced by using recombinant DNA technologies.

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

February 2017

Discussions from the 637th to 640th Meetings of the Commission held on the 7th, 14th, 21st and 28th of February 2017 are summarized as follows:

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

Pesticides	・Cyantraniliprole ・Triflumezopyrim
Pesticides and Veterinary medicinal products	・Fluvalinate
Veterinary medicinal products	・Melengestrol Acetate ・Revision of the assay method for diethylstilbestrol designated in standards for foods and additives[10], and addition of the assay method for melengestrol acetate in the said standards.
Genetically modified foods / feeds	・Maize MZHGOJG (foods)[11] ・Maize MZHGOJG (feeds)[12]

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

Pesticides

Item	ADI	ARfD
EPN	0.0014 mg/kg bw per day	0.0066 mg/kg bw
Metaldehyde	0.022 mg/kg bw per day	0.3 mg/kg bw
Difenoconazole	0.0096 mg/kg bw per day	0.25 mg/kg bw
Cyflumetofen	0.092 mg/kg bw per day	Not required
Pyrifluquinazon	0.005 mg/kg bw per day	1 mg/kg bw for ordinal people 0.05 mg/kg bw for pregnant women and women expected to be pregnant

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

[10] 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 of 1947.

[11] Maize tolerant of glyphosate and glufosinate herbicide.

[12] Maize tolerant of glyphosate and glufosinate herbicide.

DCIP	0.027 mg/kg bw per day	0.05 mg/kg bw
Cyanazine	0.00053 mg/kg bw per day	0.045 mg/kg bw
Pyribencarb	0.039 mg/kg bw per day	1.1 mg/kg bw

Pesticides and Veterinary medicinal products

Item	ADI	ARfD
Dinotefuran	0.22 mg/kg bw per day	1.2 mg/kg bw

Veterinary medicinal products

Item	Conclusion
Porcine reproductive and respiratory syndrome (PRRS) virus live, attenuated vaccine (Fostera PRRS)	FSCJ conclusion: Risks to human health from the intake of this product through food are negligible as long as appropriately used.
Zactran Merial; an injection for veterinary use in pigs containing gamithromycin 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.
Melengestrol Acetate	FSCJ conclusion: The item falls under (1) of 1 of the Decision of the Commission Dated 8 October 2009. 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[13].
Revision of the assay method for diethylstilbestrol designated in standards for foods and additives[14], and addition of the assay method for melengestrol acetate in the said standards.	FSCJ conclusion: The assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act[15].

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

[14] 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 of 1947.

[15] Item (i) of paragraph (1) of article 11 of the Food Safety Basic Act, where assessment of food safety risk is evidently unnecessary.

Food for specified health use

Item	Conclusion
Risk assessment of a food for specified health uses (FOSHU), *Pyuakamu-yosan and Pyuakamu-yosan MV*, and "the stance for a risk assessment of folic acid (pteroylmonoglutamic acid) as a FOSHU (labeled with reduction of disease risk claims)".	FSCJ conclusion: FSCJ concluded based on the stance for a risk assessment of folic acid (pteroylmonoglutamic acid) as a FOSHU that *Pyuakamu-yosan and Pyuakamu-yosan MV* have no concern relevant to human health as far as pregnant women and women expected to be pregnant consume the item following the recommended daily intake for the limited period up to the third month of pregnancy.

March 2017

Discussions from the 641st and 644th Meetings of the Commission held on the 7th, 14th, 21st and 28th of March 2017 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations[16].

Food additives	・Revision of the standards for foods and additives[17], following the amendment of Japanese Standards of Food Additives ・Peracetic acid ・Peracetic acid products ・Aluminium Ammonium Sulfate ・Aluminium Potassium Sulfate
Pesticides	・1,3-Dichloropropene ・Cyanophos (CYAP) ・Pyflubumide ・Fluxametamide ・Metalaxyl and Mefenoxam ・Lepimectin ・Bulk deletion of 25 products related to the positive list system. ・2-(1-Naphthyl)Acetamide ・2,2-DPA ・Sec-Butylamine ・Imazamethabenz Methyl Ester ・Endothall ・Oxabetrinil ・Oxycarboxine ・Carbetamide ・Chloroneb ・Tebuthiuron ・Clodinafop Acid ・Trifloxysulfuron ・Cycloate ・Pyrithiobac-Sodium ・Terbutryn ・Furathiocarb ・Naphthalophos ・Florasulam ・Butroxydim ・Bensulide (SAP) ・Flupropanate ・Metosulam ・Pebulate ・Phosphamidon ・Carbonyl Sulfide
Pesticides and Veterinary medicinal products	・Teflubenzuron ・Bulk deletion of 3 products related to the positive list system. ・Azamethiphos ・Tetrachlorovinphos (CVMP) ・Phenothrin
Veterinary medicinal products	・Bulk deletion of 28 products related to the positive list system.

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

[17] 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 of 1947.

	・Aspoxicillin ・Metoserpate Hydrochloride ・Oxacillin ・Kitasamycin ・Alchol ethoxylate ・Sulfamethoxypyridazine ・Sulfaguanidine ・Sulfacetamide ・Sulfatroxazole ・Sulfanitran ・Sulfanilamide ・Sulfapyridine ・Sulfabromomethazine Sodium ・Sulfabenzamide ・Sulfamethoxypyridazine ・Sulfamerazine ・Cefacetrile ・Temephos ・Tripelennamine ・Novobiocin ・Buquinolate ・Baquiloprim ・Haloxon ・Famphur ・Fenprostalene ・Polymyxin B ・Methylbenzoquate (Nequinate) ・Laidlomycin
Genetically modified foods/feeds	・Chymax (CHY-MAX M) ・Monosodium L-Glutamate produced using Glu-No.9 strain. ・L-Alanine produced using RITE-A5 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
Captan	0.1 mg/kg bw per day	3 mg/kg bw for ordinal people 0.3 mg/kg bw for pregnant women and women expected to be pregnant.
Fenquinotrione	0.0016 mg/kg bw per day	Not required
Flometoquin	0.008 mg/kg bw per day	0.044 mg/kg bw
Folpet	0.1 mg/kg bw per day	Not required for ordinal people 0.1 mg/kg bw for pregnant women and women expected to be pregnant
Mandipropamid	0.05 mg/kg bw per day	Not required
Mepiquatchloride	0.3 mg/kg bw per day	0.3 mg/kg bw
Pyraziflumid	0.021 mg/kg bw per day	Not required
Myclobutanil	0.024 mg/kg bw per day	2.4 mg/kg bw for ordinal people 0.31 mg/kg bw for pregnant women and women expected to be pregnant

Food additives

Item	Conclusion
Revision of the standards for foods and additives [18], following the amendment of Japanese Standards of Food Additives ・Bulk deletion of 25 products related to the positive list system. ・2-(1-Naphthyl)Acetamide ・2,2-DPA ・Sec-Butylamine ・Imazamethabenz Methyl Ester ・Endothall ・Oxabetrinil ・Oxycarboxine ・Carbetamide ・Chloroneb ・Tebuthiuron ・Clodinafop Acid ・Trifloxysulfuron ・Cycloate ・Pyrithiobac-Sodium ・Terbutryn ・Furathiocarb ・Naphthalophos ・Florasulam ・Butroxydim ・Bensulide (SAP)	FSCJ conclusion: 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[6] on condition that the items currently are not used domestically and internationally, for agricultural products for foods and feeds, and that agricultural products using the items are not imported.

[18] 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 of 1947.

・Flupropanate ・Metosulam ・Pebulate ・Phosphamidon ・Carbonyl Sulfide	

Veterinary medicinal products

Item	Conclusion
・Bulk deletion of 28 products related to the positive list system. ・Aspoxicillin ・Metoserpate Hydrochloride ・Oxacillin ・Kitasamycin ・Alchol ethoxylate ・Sulfamethoxypyridazine ・Sulfaguanidine ・Sulfacetamide ・Sulfatroxazole ・Sulfanitran ・Sulfanilamide ・Sulfapyridine ・Sulfabromomethazine Sodium ・Sulfabenzamide ・Sulfamethoxypyridazine ・Sulfamerazine ・Cefacetrile ・Temephos ・Tripelennamine ・Novobiocin ・Buquinolate ・Baquiloprim ・Haloxon ・Famphur ・Fenprostalene ・Polymyxin B ・Methylbenzoquate (Nequinate) ・Laidlomycin	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[6], on condition that the items currently are not used domestically and internationally for agricultural products for foods and feeds, animals for human consumption, and animals for obtaining food products such as eggs and milk, or that the items are not used domestically for agricultural products and animals, and that agricultural products, meat, milk and other products for food produced using the items are not imported.

Chemicals and contaminants

Item	Conclusion
Deletion of Gutzeit method for detecting arsenic in beverages from the standards for foods and additives[19].	FSCJ conclusion: FSCJ concluded that the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act[20]

[19] 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 of 1947.
[20] 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.

Natural toxins / mycotoxins

Item	Conclusion
The liver of farm raised Japanese pufferfish[21]	FSCJ conclusion: Present findings and submitted documents are insufficient for confirming that a series of specific toxicity inspections by the procedures proposed by the applicants can secure food safety of the item[22]. The said proposal claims to approve marketing a conventionally inedible part of fishes in the case when TTX level in the part is determined to be below the detection limit through instrumental analysis, thus requesting to shift the current administrative structure to a new structure. FSCJ considers that data from instrumental analysis need to be sufficiently accumulated to shift an administrative structure to a new one, as was the case for diarrheic shellfish poisons. Then, risks to human health from the proposed administrative structure need to be assessed, not only a mortal risk, based on the detailed toxicological data.

Genetically modified foods/feeds

Item	Conclusion
Hybrid stack of Oilseed rape: DP-073496-4[23] x RF3[24]	FSCJ conclusion: Based on the "Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)"[25], FSCJ concluded that Hybrid stack of Oilseed rape: DP-073496-4[26] x RF3[27] has no concern relevant to human health.

Food for Specified Health Use

Item	Conclusion
Matsutani no mini bisuketto[28]	FSCJ conclusion: FSCJ concluded that the assessed item is of no safety concern as long as the documents submitted are concerned. However, since safety risk

[21] Japanese pufferfish that are kept under the controlled procedures from farm to market as was proposed from Saga prefecture and stakeholders in the prefecture.

[22] The liver of Japanese pufferfish that are kept under the controlled procedures from farm to market as was proposed from Saga prefecture and stakeholders in the prefecture.

[23] Oilseed rape tolerant of glyphosate herbicide.

[24] Oilseed rape tolerant of glufosinate herbicide and recovering fertility.

[25] decision of Commission dated 29 January 2004

[26] Oilseed rape tolerant of glyphosate herbicide.

[27] Oilseed rape tolerant of glufosinate herbicide and recovering fertility.

[28] "*Matsutani no mini bisuketto*" is a name romanized the product name in Japanese using Hepburn's method for this provisional English translation.

(A small buiscuit containing highly cross-linked starch (distarch phosphate made from tapioca starch)	from consumption of this food by children including infants has not been evaluated, a reminder of this point needs to be labeled. In addition, a caution for excess consumption of this food shall be clearly labeled considering the sort (biscuit) and form of this food.