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 2020

Discussions from the 792nd, 793rd, 794th and 795th Meetings of the Commission held on the 6th, 13th, 20th and 27th of October 2020 are summarized as follows:

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

Pesticides	・Cyazofamid ・Dimethenamid ・Pendimethalin ・Mandipropamid ・Metaflumizone
Veterinary medicinal products	・Oxfendazole, Febantel and Fenbendazole
Genetically modified foods/feeds	・Hybrid stacks of maize: MON87429[2] (food) ・Hybrid stacks of maize: MON87429[3] (feed) ・Protease produced using Ra α 3114 strain ・L-Valine produced using RG-V1 strain ・Oilseed rape LBFLFK[4] (food) ・Oilseed rape LBFLFK[5] (feed) ・Phytase produced using *Komagataella pastoris* 132 strain
Feed additives	・Benzoic acid
Exempted Substances[4]	・Benzoic acid

[1] E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).
[2] Maize male sterile and tolerant of dicamba, glufosinate, aryloxy alkanoate, and glyphosate herbicides.
[3] Maize male sterile and tolerant of dicamba, glufosinate, aryloxy alkanoate, and glyphosate herbicides.
[4] Oilseed rape containing long-chain polyunsaturated fatty acid and tolerant of imidazolinon herbicide.
[5] Oilseed rape containing long-chain polyunsaturated fatty acid and tolerant of imidazolinon herbicide.

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

Pesticides

Item	ADI	ARfD
Fenquinotrione	0.0016 mg/kg bw per day	Not required
Fluoxastrobin	0.015 mg/kg bw per day	Not required
Thiencarbazone-methyl	1.1 mg/kg bw per day	Not required
Kasugamycin	0.094 mg/kg bw per day	Not required

Veterinary medicinal products

Item	ADI
Oxfendazole, Febantel and Fenbendazole	Group ADI 0.007 mg/kg bw per day (as Oxfendazole Sulfone)

Veterinary medicinal products

Item	Conclusion
Marinbantel (A parasiticide containing febantel as main ingredient for use in Tetraodontiformes and Perciformes).	FSCJ conclusion: Risk to human health from the intake of the assessed item through food is negligible as long as appropriately used.
Baycox® iron injection (Injection containing Gleptoferron and Toltrazuril as main ingredients for veterinary use in pigs).	FSCJ conclusion: Risk to human health from the intake of the assessed item through food is negligible as long as appropriately used.
Vaxxitek® HVT+IBD (Frozen live vaccine against infectious bursal disease・Marek's disease)	FSCJ conclusion: Risk to human health from the intake of the assessed item through food is negligible as long as appropriately used
Eugenol	FSCJ conclusion: Risk to human health from the assessed item is negligible as long as used under the current risk

	management, since the item falls under 3-1 of the Approach for the risk assessment of veterinary medicinal products and feed additives with provisional standards.
Oxyclozanide	FSCJ conclusion: Risk to human health from the assessed item is negligible as long as used under the current risk management, since the item falls under 3-1 of the Approach for the risk assessment of veterinary medicinal products and feed additives with provisional standards.
Chlorhexidine	FSCJ conclusion: Risk to human health from the assessed item is negligible as long as used under the current risk management, since the item falls under 3-1 of the Approach for the risk assessment of veterinary medicinal products and feed additives with provisional standards.

November 2020

Discussions from the 796th, 797th and 798th Meetings of the Commission held on the 10th, 17th and 24th of November 2020 are summarized as follows:

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

Pesticides	・MCPA ・Uniconazole ・Captan ・Chloropicrin ・Sedaxane ・Procymidone ・Metamifop
Veterinary medicinal products	・Lubabegron
Genetically modified foods	・Alpha-amylase produced using BML780 MDT06-221 strain

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

Feed additives

Item	Conclusion
Chitin-glucan	FSCJ conclusion: FSCJ concluded that this additive is of no concern for food safety as long as used appropriately.

Pesticides

Item	ADI	ARfD
Tolfenpyrad	0.0056 mg/kg bw per day	0.01 mg/kg bw

Veterinary medicinal products

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

Item	Conclusion
Nafcilin	FSCJ conclusion: Risk to human health from the assessed item is negligible as long as used under the current risk management, since the item falls under 3-1 of the Approach for the risk assessment of veterinary medicinal products and feed additives with provisional standards.
Mecillinam	FSCJ conclusion: Risk to human health from the assessed item is negligible as long as used under the current risk management, since the item falls under 3-1 of the Approach for the risk assessment of veterinary medicinal products and feed additives with provisional standards.
Acetylisovaleryltylosin	FSCJ conclusion: Risk to human health from the assessed item is negligible as long as used under the current risk management, since the item falls under 3-1 of the Approach for the risk assessment of veterinary medicinal products and feed additives with provisional standards.

December 2020

Discussions from the 799th, 800th and 801st Meetings of the Commission held on the 1st, 8th, 15th and 22nd of December 2020 are summarized as follows:

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

Pesticides	・Pyriofenone ・Flutianil ・Propargite ・Foramsulfuron ・Mandestrobin
Genetically modified foods	・Alpha-Amylase produced using MAM strain ・Chymosin produced using DSM32805 strain

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

Food Additives

Item	Conclusion
Ammonium hydrogen sulfite water	FSCJ conclusion: FSCJ concluded that it is unnecessary to specify an ADI for ammonium hydrogen sulfite water since this additive has no safety concern as long as it is used properly as an additive.
Polyvinylimidazole - polyvinylpyrrolidone copolymers (PVI/PVP)	FSCJ conclusion: FSCJ concluded that the additive PVI/PVP has no safety concern relevant to human health as long as used appropriately as an additive.

Pesticides

Item	ADI	ARfD
Flazasulfuron	0.013 mg/kg bw per day	0.5 mg/kg bw

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

Fosthiazate	0.002 mg/kg bw per day	0.007 mg/kg bw for general population, 0.002 mg/kg bw for pregnant or may be pregnant women

Veterinary medicinal products

Item	ADI
Zeranol	1.3 μg/kg bw per day

Veterinary medicinal products

Item	Conclusion
Nitroxinil	FSCJ conclusion: Risk to human health from the assessed item is negligible as long as used under the current risk management, since the item falls under 3-1 of the Approach for the risk assessment of veterinary medicinal products and feed additives with provisional standards.
Menbutone	FSCJ conclusion: Risk to human health from the assessed item is negligible as long as used under the current risk management, since the item falls under 3-1 of the Approach for the risk assessment of veterinary medicinal products and feed additives with provisional standards.
Isometamidium	FSCJ conclusion: Risk to human health from the assessed item is negligible as long as used under the current risk management, since the item falls under 3-1 of the Approach for the risk assessment of veterinary medicinal products and feed additives with provisional standards.
Exzolt[8]	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.

Prions

Item	Conclusion
Cattle meat and offal imported from Denmark and Austria	FSCJ conclusion: With regard to cattle meat and offal imported from Denmark and Austria, the effects on human health are negligible even if lift restriction of cattle age.

[8] A drinking water additive for chicken which contains fluralaner as a main ingredient.

Meat and offal of cattle, sheep and goat imported from Finland	FSCJ conclusion: With regard to cattle meat and offal imported from Finland, FSCJ considered (1) a difference between "the ban on import" and lifting the age threshold for import in the risk to human health is negligible, (2) a difference between "the ban on import" and the import of meat and offal containing no SRMs defined as "tonsils and distal ileum (limited to the part of two meters from the junction to the caecum) from all ages and head (excluding the tongue, cheek meat, skin and tonsils), spinal cord and vertebral column from over 30 months age" in the risk to human health would be extremely small. With regard to meat and offal of sheep and goat imported from Finland, FSCJ considered that a difference between "the ban on import" and the import of meat and offal containing no SRMs defined as head (including tonsils excluding the tongue, cheek meat, skin), spinal cord from over 12 months age, spleen and ileum from all age in the risk to human health would be extremely small.

Genetically modified foods

Item	Conclusion
Xylanase produced using CF307 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.
Glucoseoxydase produced using ZGL strain	FSCJ conclusion: According to the "Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms"[10], the item was evaluated not to affect human health.

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