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

July 2021

Discussions from the 823rd, 824th, 825th and 826th Meetings of the Commission held on the 1st, 6th, 13th and 27th of July 2021 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations¹.

The assessed items belong to reliability to be decided by MHLW based on paragraph (3) of article 13 of the Food Hygiene Law, that its risk on human health is evidently negligible.	<ul style="list-style-type: none"> • Absciscic acid
Pesticides	<ul style="list-style-type: none"> • Afidopyropen • Sulfoxaflor • Tetraniliprole • Fluazinam • Florasulam • Penthiopyrad
Genetically modified foods/feeds	<ul style="list-style-type: none"> • Alpha-amylase produced using JPBL008 strain • Alpha-amylase produced using JPBL009 strain • Alpha-amylase produced using JPBL010 strain • MON95379, a maize resistant to Lepidoptera (Food) • MON95379, a maize resistant to Lepidoptera (Feed)

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

Pesticides

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

Food Safety Commission of Japan (FSCJ)

Item	ADI	ARfD
Cyantraniliprole	0.0096 mg/kg bw per day	Not required
1-Naphthaleneacetic acid	0.15 mg/kg bw per day	0.15 mg/kg bw

Pesticides and Veterinary medicinal products

Item	ADI	ARfD
Etoxazole	0.04 mg/kg bw per day	Not required

August 2021

Discussions from the 827th, 828th, 829th and 830th Meetings of the Commission held on the 3rd, 17th, 24th and 31st of August 2021 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations².

Additives	<ul style="list-style-type: none"> • Calcium L-tartrate
Pesticides	<ul style="list-style-type: none"> • Picoxystrobin • Etofenprox • Glufosinate • Tetraconazole • Flometoquin
Feed additives	<ul style="list-style-type: none"> • L-isoleucine

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

Pesticides

Item	ADI	ARfD
Fenpyroximate	0.0097 mg/kg bw per day	0.015 mg/kg bw
Metominostrobin	0.016 mg/kg bw per day	0.78 mg/kg bw
Sulfoxaflor	0.042 mg/kg bw per day	0.25 mg/kg bw
Fluazinam	0.01 mg/kg bw per day	0.5 mg/kg bw for general people, 0.02 mg/kg bw for women of child bearing age

² E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

Pesticides

Item	Conclusion
Picoxystrobin	FSCJ conclusion: FSCJ concluded that the assessed items is the case where the contents and degree of adverse effects on human health are clear ³ .

Pesticides and Veterinary medicinal products

Item	ADI	ARfD
Permethrin	0.05 mg/kg bw per day	0.05 mg/kg bw

Veterinary medicinal products

Item	Conclusion
• Coumaphos	FSCJ conclusion: FSCJ considers that the assessed item is a component which falls under (1) of 3 of “Guidance on Risk Assessments of Veterinary Medicinal Products and Feed Additives for which the Provisional Standards are Established”. Therefore, FSCJ conclude that the effect of food on human health is negligible as long as used under the current risk management.
• Ampicillin • Phenoxymethylpenicillin	FSCJ conclusion: FSCJ considers that the assessed item is a component which falls under (1) of 3 of “Guidance on Risk Assessments of Veterinary Medicinal Products and Feed Additives for which the Provisional Standards are Established”. Therefore, FSCJ conclude that the effect of food on human health is negligible as long as used under the current risk management.

Genetically modified foods/feeds

Item	Conclusion
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³ The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

<ul style="list-style-type: none"> • Mustard RF3 line tolerant of glufosinate herbicide and fertility restorative 	<p>FSCJ conclusion: The documents were evaluated based on the “Standards for Safety Assessments of Genetically Modified Foods (seed plants)”⁴, and FSCJ concluded that the food safety risk from the assessed item was negative.</p>
<ul style="list-style-type: none"> • Phospholipase produced using pPDX strain 	<p>FSCJ conclusion: According to “Stance on Safety Assessments of Additives Produced by Genetically Modified Microorganisms”⁵, the item is not the subject of this provision, and therefore the item did not require assessments.</p>
<ul style="list-style-type: none"> • Chymosin produced using DSM32805 strain • Lipase produced using JPAN006 strain • Lipase produced using JPAo003 strain 	<p>According to the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms”⁶, the item was evaluated not to affect human health.</p>

⁴ Decision of the Commission dated 29 January 2004.

⁵ This additive has been produced using a microorganism that falls under "the case where living cells which have genotypic composition equivalent to the relevant recombinant exist in nature", specified in Chapter 1 General Provisions, Section 3 "Scope and Objective" of Standards for Safety Assessments of Food Additives Produced using Genetically Modified Microorganisms (Decision of the Commission Dated 25 March 2004).

⁶ “The Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)”

September 2021

Discussions from the 831st, 832nd and 833rd Meetings of the Commission held on the 7th, 14th and 28th of September 2021 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations⁷.

Veterinary medicinal products	<ul style="list-style-type: none"> • An agent for oral administration into horses, Eqvalan Gold, which combines two active ingredients – ivermectin and praziquantel.
Genetically modified foods/feeds	<ul style="list-style-type: none"> • Oilseed rape MON94100⁸ (foods) • Oilseed rape MON94100⁸ (feeds)

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

Pesticides

Item	ADI	ARfD
Tetraniliprole	0.88 mg/kg bw per day	Not required
Penthiopyrad	0.081 mg/kg bw per day	1.2 mg/kg bw

Veterinary medicinal products

Item	ADI
Lubabegron	3.2 µg/kg bw per day

Veterinary medicinal products

Item	Conclusion
An agent for oral administration into horses, Eqvalan Gold, which combines two active ingredients – ivermectin and praziquantel.	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.

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

⁸ Oilseed rape tolerant of dicamba herbicide.