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 2021

Discussions from the 802nd and 803rd Meetings of the Commission held on the 12th and 19th of January 2021 are summarized as follows:

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

Genetically modified foods/feeds	・Soybean GMB151 line resistant to nematode and tolerant of **4**-hydroxyphenylpyruvate dioxygenase inhibitor type herbicide (foods) ・Soybean GMB151 line resistant to nematode and tolerant of **4**-hydroxyphenylpyruvate dioxygenase inhibitor type herbicide (feeds) ・Maize DP202216 line with increased yield and tolerant of glufosinate herbicide (foods) ・Maize DP202216 line with increased yield and tolerant of glufosinate herbicide (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
Chloropicrin	0.001 mg/kg bw per day	0.5 mg/kg bw

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

Cyazofamid	0.17 mg/kg bw per day	Not required
Dimethenamid	0.051 mg/kg bw per day	0.5 mg/kg bw
Metaflumizone	0.12 mg/kg bw per day	Not required

Veterinary medicinal products

Item	Conclusion
Decoquinate	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.
Virginiamycin	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
Glutamyl-valyl-glycine produced using EVG-L1 strain and EVG-G1 strain	FSCJ conclusion: According to the "Stance on the Safety Assessment of Amino Acids and Other End Products"[2], the item's safety was confirmed. Consequently, the item did not require assessments according to "Stance on Safety Assessments of Additives Produced by Genetically Modified Microorganisms"[3].

[2] "Stance on Safety Assessments of Amino Acids and Other End Products that are highly purified non-protein additives among additives produced using genetically modified microorganisms (Decision of the Commission dated 28 April 2005)"

[3] 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).

Potato, SPS-00X17-5 line resistant to potato blight containing low free asparagine, low reducing sugar, and low polyphenole oxidizing enzyme (foods)	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.
Potato, SPS-00X17-5 line resistant to potato blight containing low free asparagine, low reducing sugar, and low polyphenole oxidizing enzyme (feeds)	FSCJ conclusion: The item did not require assessment based on the "Standards for Safety Assessments of Genetically Modified Foods (seed plants)"[5], and livestock products derived from animals which consumed the item have no concern relevant to human health.

[4] Decision of the Commission dated 29 January 2004.
[5] Decision of the Commission dated 29 January 2004.

February 2021

Discussions from the 804th and 805th Meetings of the Commission held on the 2nd and 16th of February 2021 are summarized as follows:

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

Pesticides	・Iprodione ・Cadusafos ・Clethodim ・Pyraflufen-ethyl ・Fenazaquin ・Flufenoxuron ・Metominostrobin
Veterinary medicinal products and feed additives	・Nicarbazin
Veterinary medicinal products	・Albendazole ・A feed additive for use to fishes belonging Perciformes (Spochiru 100) that contains albendazole as an active component
Genetically modified foods/feeds	・Maize resistant to Coleoptera and tolerant of glufosinate herbicide (DP23211) (foods) ・Maize resistant to Coleoptera and tolerant of glufosinate herbicide (DP23211) (feeds) ・Phospholipase produced using pPDX sarin

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

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

Pesticides

Item	ADI	ARfD
Captan	0.1 mg/kg bw per day	3 mg/kg bw for general people, 0.3 mg/kg bw for women of child bearing age
Procymidone	0.035 mg/kg bw per day	0.3 mg/kg bw for general people, 0.035 mg/kg bw for women of child bearing age
Mandipropamid	0.05 mg/kg bw per day	Not required
Methamihop	0.0042 mg/kg bw per day	1.2 mg/kg bw

Veterinary medicinal products

Item	Conclusion
・Pronalgon EZ injection (an injection for veterinary use in cattle, containing dinoprost tromethamine as an active substance)	FSCJ conclusion: FSCJ concluded that the risk to human health of this product through consumption is negligible as long as it is appropriately used.

Antimicrobial resistant bacteria

・Colistin sulfate for use in livestock	FSCJ conclusion: FSCJ concluded that the use of colistin sulfate in cattle and pigs as a veterinary medicinal product may possibly cause hazards, and humans may be exposed to the hazards through livestock products derived from the cattle and pigs, resulting in the decreased and/or abolished therapeutic efficacy of antibiotics for humans. Although such possibilities cannot be neglected, FSCJ judged that the risk for the hazard is low.

Prions

・Cattle meat and offal imported from Spain	FSCJ conclusion: FSCJ concludes that potential variations of BSE risks to human health by removing the age limit on cattle meat and offal (excluding SRMs) imported from Spain.

March 2021

Discussions from the 806th to 810th Meetings of the Commission held on the 2nd, 9th, 16th, 23rd and 30th of March 2021 are summarized as follows:

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

Apparatuses, Containers and Packages	・Partial amendment of the standards for ACP used for milk, certified milk, sterilized goat milk, homogenized milk, low fat milk, skim milk, processed milk and cream. (the case where the contents and degree of adverse effects on human health are clear[8])
Pesticides	・Oxathiapiprolin ・Pyribencarb ・Benthiavalicarb-isopropyl
Pesticides and Veterinary medicinal products	・Spinosad
Genetically modified foods/feeds	・Mustard RF3 line tolerant of glufosinate herbicide and fertility restorative ・Glucoamylase produced using JPAN009 strain ・Lipase produced using JPAN006 strain

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

Apparatuses, Containers and Packages

Item	Conclusion

[7] E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).
[8] The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

・Partial amendment of the standards for ACP used for milk, certified milk, sterilized goat milk, homogenized milk, low fat milk, skim milk, processed milk and cream	FSCJ conclusion: The item is the case where the contents and degree of adverse effects on human health are clear[9].

Pesticides

Item	ADI	ARfD
Pyriofenone	0.091 mg/kg bw per day	Not required
Flutianil	2.4 mg/kg bw per day	Not required
Mandestrobin	0.19 mg/kg bw per day	Not required
Sedaxane	0.11 mg/kg bw per day	0.3 mg/kg bw

Veterinary medicinal products

Item	Conclusion
・Isoeugenol	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.
・Trimethoprim	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,

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

	FSCJ conclude that the effect of food on human health is negligible as long as used under the current risk management.

Veterinary medicinal products and feed additives

Item	ADI
Morantel and Pyrantel	FSCJ specified the group ADI to be 0.012 mg/kg bw/day.

Feed additives

Item	Conclusion
Canthaxanthin	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
・Phytase produced using *Komagataella pastoris* 132 strain	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"[10]. Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.

Working group on formula milk containing bacterial powder as raw materials

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

Item	Conclusion
・Setting matters for examination of formula milk based on the "Ordinance regarding standard of element and others of milk and dairy products". (Ordinance of the Ministry of Welfare, No.52, 1951)	FSCJ conclusion: Regarding the MHLW draft of matters for examination of formula milk containing bacterial powder, FSCJ did not judge it inappropriate based on the following considerations; (1) the draft was prepared referring the guidelines by FAO and WHO, and no findings to deny its scientific reliability is confirmed at present. (2) No report is found on clear health hazard by consumption of bacteria powder containing formula milk for infant. However, FSCJ considered that the MHLW needs to concern the following points for enhancing the safety of bacteria powder containing formula milk for infant; (1) Addition of substantial endpoints for safety confirmation to the items related to implementing intake test of bacteria powder containing formula milk by infants. (2) Additional presentation of bacterial count of added bacteria strain, and of pathogenic microbes such as *Salmonella* and *Cronobacter sakazakii* after formula preparation, to the items regarding effects of formula preparation. In addition, the MHLW should revise the matters for examination when necessary, keeping attention of the future trends of international organizations or foreign countries regarding the safety of bacteria powder containing formula milk for infant.