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

January 2016

Discussions from the 590th to 592nd Meetings of the Commission held on the 12th, 19th and 26th of January 2016 are summarized as follows:

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

Pesticides	• Picarbutrazox • Fludioxonil
Microorganisms and viruses	• Amendment of the Ordinance of the Ministry of Welfare, No.52, 1951 ²
Prions	• Usage of proteins made with inosine as feeds
Genetically modified foods/feeds	• Disodium 5'-Inosinate produced using RN-No.2 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
Thifluzamide	0.014 mg/kg bw per day	0.25 mg/kg bw
Fosetyl	0.88 mg/kg bw per day	Not required
Lepimectin	0.02 mg/kg bw per day	2 mg/kg bw

Veterinary medicinal products

Item	ADI
Altrenogest	0.00004 mg/kg bw per day
Lomefloxacin	0.025 mg/kg bw per day

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

² The Ordinance of the Ministry of Welfare, No.52, 1951, regarding standard of element and others of milk and dairy products.

Microorganisms and viruses

Item	Conclusion
Amendment of the Ordinance of the Ministry of Welfare, No.52, 1951 ³	FSCJ conclusion: FSCJ evaluated that the item does not increase risk to human health from intake of the said skimmed condensed milk as long as the standards for manufacturing and preservation are followed, thus the item is considered to be of no food safety concern. Accordingly, 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 ⁴ .

Prions

Item	Conclusion
Cattle meat and offal imported from Italy	FSCJ conclusion: With regard to the age limit for BSE testing and definition of SRMs, variation in potential BSE risks to human health would be very small, if it arises. Hence, an effect of the variation on human health is negligible.
Consideration of risk variations in Japan derived from the proposed revisions of the current countermeasures against BSE in sheep and goat.	FSCJ conclusion: With regard to the age limit for BSE testing, definition of SRMs and border measures in the domestic control measures, variation in potential BSE risks to human health would be very small, if it arises. Hence, an effect of the variation on human health is negligible.

Genetically modified foods/feeds

Item	Conclusion
L-Threonine produced using THR-No.2 strain	FSCJ conclusion: According to the “Stance on the safety assessment of amino acids and other end products” ⁵ , FSCJ concluded that livestock products derived from animals which consumed the item have no concern relevant to human health.

³ The Ordinance of the Ministry of Welfare, No.52, 1951, regarding standard of element and others of milk and dairy products.

⁴ The case designated under item(ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

⁵ “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 April 28, 2005)”.

Antimicrobial resistant bacteria

Item	Conclusion
Florfenicol products used for cattle and pigs: Risk of Antimicrobial-resistant Bacteria	FSCJ conclusion: The use of florfenicol in cattle and pigs could cause the selection of bacteria with a resistance to florfenicol and a cross resistance to chloramphenicol. However, the resistant bacteria would not pose human health hazards via food consumption, because chloramphenicol is not used in human medicines for an infection that can be spread through food consumption. Thus, FSCJ concludes that the risk to human health via food consumption arisen from the antimicrobial-resistant bacteria selected through the use of florfenicol in livestock animals is negligible.

February 2016

Discussions from the 593rd to 596th Meetings of the Commission held on the 2nd, 9th, 16th and 23rd of February 2016 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations⁶.

Food additives	<ul style="list-style-type: none">• Revision (Amendment) of standards for processing “raw fishery products,” “oysters to be eaten raw,” and “frozen food,” related to use of carbon dioxide as an acidity regulator.”
Pesticides	<ul style="list-style-type: none">• Acephate • Cymoxanil • Tebfenozide • Triflumizole• Paclobutrazol • Methamidophos
Pesticides and Veterinary medicinal products	<ul style="list-style-type: none">• Etoxazole
Veterinary medicinal products	<ul style="list-style-type: none">• Flubendazole
Genetically modified foods/feeds	<ul style="list-style-type: none">• L-Histidine produced using HIS-No.2 strain
Novel foods	<ul style="list-style-type: none">• Matsutani’s Mini-biscuit

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

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

Additives

Item	Conclusion
Revision (Amendment) of standards for processing “raw fishery products,” “oysters to be eaten raw,” and “frozen food,” related to use of carbon dioxide as an acidity regulator.”	FSCJ conclusion: The said use of carbon dioxide following the amended standards is considered to be of no food safety concern. Accordingly, 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 ⁷ .
Hydrogen peroxide	FSCJ conclusion: The assessed item is considered to be of no food safety concern as long as used appropriately as a food additive. Therefore, it is unnecessary to specify ADI.

⁷ The case designated under item(ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

Pesticides

Item	ADI	ARfD
<i>Isouron</i>	0.017 mg/kg bw per day	0.2 mg/kg bw
Isoxathion	0.002 mg/kg bw per day	0.003 mg/kg bw
<i>Simeconazole</i>	0.0085 mg/kg bw per day	0.2 mg/kg bw for ordinal people. 0.09 mg/kg bw for pregnant women and women expected to be pregnant.
<i>Spirotetramat</i>	0.12 mg/kg bw per day	1 mg/kg bw
<i>Pyriofenone</i>	0.091 mg/kg bw per day	Not required

Veterinary medicinal products

Item	Conclusion
Flubendazole	FSCJ conclusion: 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 ² , because the item falls under item 1 of Decision of the Commission dated 27 January 2014.
Four compounds used as additives for vaccines for veterinary use.	FSCJ conclusion: Risks to human health from these 4 compounds are negligible as long as appropriately used. Therefore, 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 ² .

Genetically modified foods/feeds

Item	Conclusion
Soybeans FG72 strain ⁸ (foods)	FSCJ conclusion: According to the “Stance on the safety assessment of genetically modified foods (seed plants)” ⁹ , Soybean FG72 strain was evaluated not to affect human health.
Soybeans FG72 strain ¹⁰ (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.

Food for specified health use

Item	Conclusion
Rare sweet	<p>FSCJ conclusion: FSCJ considered it necessary to provide the consumers a complete caution at least for the following points in order to ensure the safety of this food as a food for specified health uses;</p> <p>① Intake of this food has a potential to increase LDL-C, therefore patients from high LDL-C viremia or from borderline higher LDL-cholesterolemea particularly need to be careful on its ingestion.</p>

⁸ Soybeans tolerant of glyphosate and isoxaflutole herbicides.

⁹ “Stance on Safety Assessments of Genetically Modified Foods (seed plants) (Decision of the Commission dated January 29, 2004)”.

¹⁰ Soybeans tolerant of glyphosate and isoxaflutole herbicides.

② The excessive consumption of this product should be avoided following the recommended daily intake.

③ Consumption of this food in combination with another food containing D-psicose as a raw material should be avoided.

Since the assessed item is expected to alter blood-glucose level, care must be taken based on the policy prescribed in the Stance on the Safety Assessment of Each Product of Foods for Specified Use¹¹. Hence, it is necessary that the applicant make efforts to collect and provide information on the adverse effects. In addition, a note on the consultation to medical personnel for the patients' intakes needs to be included in a product label.

¹¹ The policy prescribed in (2) of 2 of the Approach to the Safety Assessment of Each Product of Foods for Specified Health Use (Decision of the Commission dated May 10, 2007).

March 2016

Discussions from the 597th to 600th Meetings of the Commission held on the 1st, 8th, 15th and 29th of March 2016 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations¹².

Food additives	<ul style="list-style-type: none">• Calcium carbonate
Pesticides	<ul style="list-style-type: none">• Triforine • Pyraclostrobin • Famoxadone • Fenquinotrione• Fenpyrazamine • Metamifop • Validamycin
Veterinary medicinal products	<ul style="list-style-type: none">• Live vaccine against chicken infectious bursal disease (IBD-CA)• Triptorelin Acetate
Genetically modified foods/feeds	<ul style="list-style-type: none">• L-Proline produced using ECP strain• Beta-Amylase produced using NZYM-JA strain

¹² E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

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

Pesticides

Item	ADI	ARfD
Simoxanyl	0.013 mg/kg bw per day	0.08 mg/kg bw
Profenofos	0.0005 mg/kg bw per day	0.05 mg/kg bw
Clethodim	0.01 mg/kg bw per day	1 mg/kg bw

Veterinary medicinal products

Item	ADI
Prednisolone	0.00025 mg/kg bw per day
Methylprednisolone	0.0003 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
Live vaccine against chicken infectious bursal disease (IBD-CA)	FSCJ conclusion: Risk to human health from the assessed item through food consumption is negligible as long as it is appropriately used. Accordingly, 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 ¹³ .

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

Genetically modified foods/feeds

Item	Conclusion
Alpha-Amylase produced using NZYM-AV strain	FSCJ conclusion: According to the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” ¹⁴ , the item was evaluated not to affect human health.
Carboxypeptidase produced using PEG strain	FSCJ conclusion: The assessed item is a food additive produced using microorganisms that fall under the category which is the case designated in “Standards for the Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” ² . Therefore, the item is not the object of this standard, and FSCJ concluded that the item does not require the risk assessment.
L-Sodium glutamate produced using GLU-No.8 strain	FSCJ conclusion: According to the “Stance on the Safety Assessment of Amino Acids and Other End Products” ¹⁵ , the item’s safety was confirmed.
L-Histidine hydrochloride produced using HIS-No.2 strain	FSCJ conclusion: According to the “Stance on the Safety Assessment of Amino Acids and Other End Products” ³ , the item’s safety was confirmed.
Phytase produced using ASP595-1 strain	FSCJ conclusion: According to the “Stance on the safety assessment of genetically modified feeds and feed additives” ¹⁶ , the item did not require further assessment

¹⁴ “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)”.

¹⁵ “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 April 28, 2005)”.

¹⁶ “Stance on Safety Assessments of Genetically Modified Feed and Feed Additives (Decision of the Commission dated May 6, 2004)”.

	through the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” ² . Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.
Sodium 5'-inosinate produced using RN-No.2 strain	FSCJ conclusion: According to the “Stance on the Safety Assessment of Amino Acids and Other End Products” ³ , the item’s safety was confirmed.
SYHT0H2 soybean ¹⁷ (Foods)	FSCJ conclusion: According to the “Stance on the safety assessment of genetically modified foods (seed plants)” ¹⁸ , the item have no concern relevant to human health.
SYHT0H2 soybean ¹⁹ (Feeds)	According to the “Stance on the safety assessment of genetically modified feeds and feed additives” ⁴ , the item did not require further assessment through the “Stance on the safety assessment of genetically modified foods (seed plants)” ⁶ . Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.

Feed additives

Item	Conclusion
6-Phytases produced using ASP595-1 strain	FSCJ conclusion: Risk to human health from the assessed item through consumption is negligible as long as it is used appropriately as a feed additive.

¹⁷ Soybean line tolerant of HPDD-inhibiting herbicides and glufosinate herbicides.

¹⁸ “Stance on Safety Assessments of Genetically Modified Foods (seed plants) (Decision of the Commission dated January 29, 2004)”.

¹⁹ Soybean line tolerant of HPDD-inhibiting herbicides and glufosinate herbicides.