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

April 2017

Discussions from the 645th and 647th Meetings of the Commission held on the 11th, 18th and 25st of April 2017 are summarized as follows:

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

Pesticides	<ul style="list-style-type: none"> • Pyrethrin • Fludioxonil
Microorganisms	<ul style="list-style-type: none"> • Amendment of standards for Tofu.
Genetically modified foods/feeds	<ul style="list-style-type: none"> • L-Arginine produced using ARG-No.4 strain. • Riboflavin produced using RFESCO2 strain.
Antimicrobial-resistant bacteria	<ul style="list-style-type: none"> • Additive for drinking water of cattle, pigs and chicken, and feed additives for honeybees, containing tylosin tartrate as an active ingredient (TYLAN water soluble powder)

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

Food additives

Item	Conclusion
<ul style="list-style-type: none"> • Peracetic acid products and substances contained in the products. • Peracetic acid • Octanoic acid • Glacial acetic acid • Hydrogen peroxide 	<p>FSCJ conclusion: The assessed item is considered to be of no concern for food safety as long as used appropriately as a food additive. Therefore, it is not necessary to specify ADI for peracetic acid</p>

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

• 1-Hydroxyethylidene-1,1-diphosphonic acid	ADI is specified as 0.013 mg/kg bw per day.
• Peracetic acid products	FSCJ conclusion: The assessed item is considered to be of no concern for food safety as long as each component is used appropriately as a food additive.

Pesticides

Item	ADI	ARfD
Chlorantraniliprole	1.5 mg/kg bw per day	Not required
Flutianil	2.4 mg/kg bw per day	Not required
Etofenprox	0.031 mg/kg bw per day	1 mg/kg bw

Veterinary medicinal products

Item	Conclusion
Components contained as additives in the already approved veterinary vaccines	FSCJ conclusion: Risk to human health from the assessed item is negligible as long as it is appropriately used as additives in the already approved veterinary vaccines. Therefore, 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 ² .)

Beverages

Item	Conclusion
Zinc	FSCJ conclusion: Risk on human health from intake of zinc in mineral water will be small, even if zinc is not considered in specification for mineral water (either sterilized or unsterilized) based on the Food Sanitation Act. At the same time, since possible presence of mineral water containing high concentration of zinc is undeniable, risk management organizations should endeavor to follow analytical data on zinc in mineral water and other drinking water.
Ferrum	FSCJ conclusion: Risk on human health from intake of ferrum in mineral water will be small, even if ferrum is not considered in specification for sterilized mineral water based on the Food Sanitation Act.

² The case designated by item(ii) of paragraph(1) of article 11 of the Food Safety Basic Act.

<p>Calcium and Magnesium(Hardness)</p>	<p>FSCJ conclusion: Risk on human health from intake of calcium and magnesium in mineral water will be small, even if calcium and magnesium (Hardness) is not considered in specification for sterilized mineral water based on the Food Sanitation Act.</p> <p>As for magnesium, care need to be taken for preventing excess intake through consumption of extra daily meal.</p>
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May 2017

Discussions from the 648th and 651st Meetings of the Commission held on the 9th, 16th, 23rd and 30th of May 2017 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations³.

Pesticides	<ul style="list-style-type: none"> • DCIP • Chlormequat • Fluopicolide • Fosetyl
Pesticides and veterinary medicinal products	<ul style="list-style-type: none"> • Spinosad • Diazinon
Veterinary medicinal products	<ul style="list-style-type: none"> • Product for gavage administration into cattle (Calcharge) containing calcium propionate, calcium chloride, calcium monohydrogen phosphate and magnesium oxide as active ingredients. (Re-evaluation) • [Monobis(trimethylammonium methylene chloride)]-alkyltoluene
Exempted Substances	<ul style="list-style-type: none"> • HydroxypropylDistarch Phosphate

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

Pesticides

Item	ADI	ARfD
2,4-D	0.0099 mg/kg bw per day	0.15 mg/kg bw
Aminocyclopyrachlor	0.91 mg/kg bw per day	Not required

³ E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

Cadusafos	0.00025 mg/kg bw per day	0.005 mg/kg bw
Metaflumizone	0.12 mg/kg bw per day	Not required
Procymidone	0.035 mg/kg bw per day	0.3 mg/kg bw for ordinary people, 0.035 mg/kg bw for women who are or may be pregnant.

Veterinary medicinal products

Item	Conclusion
Product for gavage administration into cattle (Calcharge) containing calcium propionate, calcium chloride, calcium monohydrogen phosphate and magnesium oxide as active ingredients.	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.

Genetically modified foods/feeds

Item	Conclusion
Exomaltotetrahydrolase produced using MDT06-228 strain	FSCJ conclusion: FSCJ concluded that the assessed item has no concern relevant to human health, based on “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms ⁴ ”
Glucoamylase produced using NZYM-BE strain	FSCJ conclusion: FSCJ concluded that the assessed item has no concern relevant to human health, based on “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms ² ”
L-Tryptophane produced using TRP-No.2 strain	FSCJ conclusion: According to the “Stance on Safety Assessments of Genetically Modified Feed and Feed Additives ⁵ ”, FSCJ assessed the food safety risk from the feed additive in question based on the “Stance on Safety Assessments of Additives Produced Using Genetically

⁴ Food Safety Commission Decision of March 25, 2004

⁵ Food Safety Commission Decision of May 6, 2004

	<p>Modified Microorganisms, whose End Product is a Highly Purified Nonprotein Additive, such as Amino Acids⁶. Consequently, the food safety risk from the item through livestock products was evaluated to be negative.</p>
<p>Low acrylamide potential reduced black spot potato (SPS-00E12-8) (food)</p>	<p>FSCJ conclusion: FSCJ conducted the assessment based on the “Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)”⁷, and concluded that the assessed item has no concern relevant to human health.</p>
<p>Low acrylamide potential reduced black spot potato (SPS-00E12-8) (feed)</p>	<p>According to the “Stance on the safety assessment of genetically modified feeds and feed additives”³, the item did not require further assessment through the “Stance on the safety assessment of genetically modified foods (seed plants)”⁸. Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.</p>

⁶ Supplementary Provisions of Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms, Food Safety Commission Decision of March 25, 2004

⁷ Food Safety Commission Decision 29 January 2004

⁸ Food Safety Commission Decision of January 29, 2004

June 2017

Discussions from the 652nd and 655th Meetings of the Commission held on the 6th, 13th, 20th and 27th of June 2017 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations⁹.

Additives	<ul style="list-style-type: none"> • The item relevant to the amendment of the “Standards for Foods/Food Additives” following to the amendment of “Japanese Standards of Food Additives”.
Pesticides	<ul style="list-style-type: none"> • Amisulbrom • Chloropicrin • Dinitenamid
Veterinary medicinal products	<ul style="list-style-type: none"> • A paraciticide for honey bee (Apivar), containing Amitraz as the active ingredient (Re-evaluation). • An intramammary suspension for cows (Mastrichin) containing monoammonium glycyrrhizinate as the active ingredient (Re-evaluation). • Feed additive for chicken (Larvadex 1%) containing cyromazine as the active ingredient. • Components used as additives for animal vaccines
Prions	<ul style="list-style-type: none"> • Revision of the control measures for use of the gelatin and collagen originated from cattle for fertilizers.
Feed additives	<ul style="list-style-type: none"> • Zinc chelate of 2-deamino-2-hydroxymethionine • Amendment of Ordinance of Ministry of Agriculture and Forestry (1976, No.35) regarding the standards for feed and feed additives.

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

Genetically modified foods	<ul style="list-style-type: none"> • Acid phosphatase produced using OYC-GM1 strain.
Exempted Substances	<ul style="list-style-type: none"> • Zinc • Glycerol Caprate • Citric acid esters of mono-and di-glycerides of fatty acid

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

Food additives

Item	Conclusion
The item relevant to the amendment of the “Standards for Foods/Food Additives” following to the amendment of “Japanese Standards of Food Additives”	<p>FSCJ conclusion: Item to be assessed is the amendment of the standards due to the changes of test methods for improvement of the operability and accuracy without changes in relevant specifications. Hence, the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act¹⁰.</p> <p>The requested item for risk assessment is relevant to the standard for Welan gum changing standard value for ash from “below 10.0 % (when converted into a dry product) to below 16.0 % (when converted into a dry product)”. This is a change within the range of currently applied standard value, and is not a kind of changes that require relaxing the risk managing measures when considered the current distribution. Accordingly, FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear¹¹.</p>

Pesticides

Item	ADI	ARfD

¹⁰ 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.

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

Lepimectin	0.02 mg/kg bw per day	2 mg/kg bw
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Veterinary medicinal products

Item	Conclusion
A paraciticide for honey bee (Apivar), containing Amitraz as the active ingredient	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.
An intramammary suspension for cows (Mastrichin) containing monoammonium glycyrrhizinate as the active ingredient	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.
Feed additive for chicken (Larvadex 1%) containing cyromazine as the active ingredient.	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.

Food for specified health uses

Item	Conclusion
Yogurt containing Lactobacillus gasseri SP as the component relevant to its specified health use.	FSCJ conclusion: FSCJ concluded that the item have no concern relevant to human health as long as consider the documents provided by the applicant.

Feed additives

Item	Conclusion
Amendment of Ordinance of Ministry of Agriculture and Forestry (1976,	FSCJ conclusion: Silicic acid and anhydrous silicic acid are, as light anhydrous silicic acid was, designated as an excipient in Annex Table 2 ¹² of the Ordinance of Ministry of Agriculture and Forestry (1976,

¹² [3 Standards for general methods to produce feed additives.]

<p>No.35) regarding the standards for feed and feed additives.</p>	<p>No.35) regarding the standards for feed and feed additives. While silicic acid and anhydrous silicic acid have been used as feeds, no adverse effect on human health has been determined. Amount of silicic acid and anhydrous silicic acid that transfer into feeds is estimated to be only trace, even if the upper level designated in the standards for methods for production is amended. Upper level of excipients is not specified in the above-mentioned ordinance of MAF. These facts suggest that the effect on human health of the assessed feed additives is not different before and after relevant amendment of the standards. Accordingly, FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear¹³.</p>
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¹³ The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act,