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

July 2017

Discussions from the 656th to 659th Meetings of the Commission held on the 4th, 11th, 18th and 25th of July 2017 are summarized as follows:

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

Pesticides	• Chlorpyrifos • Chlorothalonil • Bicyclopyrone • Fenpyroximate
Genetically modified foods	• L-citrulline produced using CPR-strain
Feeds and Fertilizers	• Revision of official specification of ordinary fertilizers
Exempted Substances ²	• β -Glucan derived from baker's yeast
Food for Specified Health Use	• Sukoyaka Gomayu (Sukoyaka Sesami Oil)

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

Pesticides

Item	ADI	ARfD
Dichlorprop	0.036 mg/kg bw per day	0.3 mg/kg bw
Desmedipham	0.032 mg/kg bw per day	0.9 mg/kg bw
Fenbuconazole	0.03 mg/kg bw per day	0.3 mg/kg bw.
Cyantraniliprole	0.0096 mg/kg bw per day	Not required
Flubendiamide	0.017 mg/kg bw per day	0.15 mg/kg bw for lactating women. ARfD not required for ordinal people

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

² On May 29, 2006 the Ministry of Health, Labour and Welfare (MHLW) introduced the positive list system for agricultural chemicals remaining in foods to prohibit the distribution of foods that contain agricultural chemicals above a certain level if maximum residue limits (MRLs) have not been established. Exempted Substances are designated as substances having no potential to cause damage to human health by the Minister of Health, Labour and Welfare, based on the provision of Paragraph

Pesticides and Additives

Item	ADI	ARfD
Fludioxonil	0.33 mg/kg bw per day	2.5 mg/kg bw
Propiconazole	0.019 mg/kg bw per day	0.3 mg/kg bw

Veterinary medicinal products

Item	ADI
Spectinomycin	0.053 mg/kg bw per day

Prions

Item	Conclusion
Revision of the control measure against use of gelatin and collagen derived from cattle for fertilizers	FSCJ conclusion: 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 ³ .

Genetically modified foods/feeds

Item	Conclusion
Lipase produced using JPAo001 strain	FSCJ conclusion: According to the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” ⁴ , the item was evaluated not to affect human health.
Maize MZHGOJG strain tolerant of glyphosate and glufosinate herbicides (foods)	FSCJ conclusion: According to the “Stance on the safety assessment of genetically modified foods (seed plants)” ⁵ , the item was evaluated not to affect human health.
Maize MZHGOJG strain tolerant of glyphosate and glufosinate herbicides (feeds)	According to the “Stance on the safety assessment of genetically modified feeds and feed additives” ⁶ , the item did not require further assessment through the “Stance on the safety assessment of genetically modified foods (seed plants)” ⁵ . Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.
L-Alanine produced using RITE strain	FSCJ conclusion: The documents was evaluated based on the “Stance on Safety Assessments of Additives Produced Using Generically Modified Microorganisms, whose End Product is a Highly Purified Nonprotein Additive, such as Amino

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

⁴ “the Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)”

⁵ “Stance on Safety Assessments of Genetically Modified Foods (seed plants) (Decision of the Commission dated 29 January 2004)”

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

	Acids ⁷ ” (Supplementary Provisions of “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms ⁸ ”). Consequently, the safety of the additive has been confirmed.
L-(+)Sodium glutamate produced using GLU-No.9 strain	FSCJ conclusion: The documents was evaluated based on the “Stance on Safety Assessments of Additives Produced Using Generically Modified Microorganisms, whose End Product is a Highly Purified Nonprotein Additive, such as Amino Acids ⁷ ” (Supplementary Provisions of “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms ⁸ ”). Consequently, the safety of the additive has been confirmed.

Feeds and Fertilizers

Item	Conclusion
Amendment of the official specification of ordinary fertilizers	FSCJ conclusion: 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 ³ .

Antimicrobial resistant bacteria

Item	Conclusion
Zactran, an injection for pigs, which contains gamithromycin as an active ingredient	FSCJ conclusion: The use of zactran, as a veterinary medicinal product in pigs, may possibly cause the selection of hazards in livestock products, resulting in a decrease and/or abolishment of therapeutic effects of antibiotics for human. This potential is undeniable. FSCJ concluded that food safety risk of the item is moderate after evaluating all the risk factors.

⁷ Decision of the Commission dated April 28, 2005

⁸ Decision of the Commission dated March 25, 2004

August 2017

Discussions from the 660th to 663rd Meetings of the Commission held on the 1st, 8th, 22nd and 29th of August 2017 are summarized as follows:

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

Veterinary medicinal products	<ul style="list-style-type: none"> • An injection for cattle, Imrestor, which contains pegbovigrastim as an active ingredient.
Prions	<ul style="list-style-type: none"> • Meat and offal of cattle, sheep and goats imported from England
Feeds and Fertilizers	<ul style="list-style-type: none"> • Amendment of Ordinance of Ministry of Agriculture and Forestry¹⁰ regarding standards for feed and feed additives (Virginiamycin and Colistin sulfate)

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

Pesticides

Item	ADI	ARfD
Fluopicolide (2,6-dichlorobenzamide, a metabolite of fluopicolide)	0.079 mg/kg bw per day (0.047 mg/kg bw per day)	1 mg/kg bw (0.47 mg/kg bw)
Amisulbrom	0.1 mg/kg bw per day	Not required

Pesticides and Veterinary medicinal products

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

¹⁰ Ordinance of Ministry of Agriculture and Forestry, No.35, 1976

Item	ADI	ARfD
Fenitrothion	0.0049 mg/kg bw per day	0.036 mg/kg bw
Fluvalinate	0.005 mg/kg bw per day	0.06 mg/kg bw

Veterinary medicinal products

Item	ADI
Dicyclanil	0.0071 mg/kg bw per day
Dexamethasone	0.01 µg/kg bw per day

Genetically modified foods/feeds

Item	Conclusion
L-Arginine produced using ARG-No. 4 strain	FSCJ conclusion: According to the “Stance on Safety Assessments of Additives Produced Using Generically Modified Microorganisms, whose End Product is a Highly Purified Nonprotein Additive, such as Amino Acids ¹¹ ” (Supplementary Provisions of “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms ¹² ”), the item was evaluated not to affect human health.

¹¹ Decision of the Commission dated April 28, 2005

¹² Decision of the Commission dated March 25, 2004

Antimicrobial resistant bacteria

Item	Conclusion
<p>Amendment of Ordinance of Ministry of Agriculture and Forestry¹³ regarding standards for feed and feed additives (Virginiamycin and Colistin sulfate)</p>	<p>FSCJ conclusion: Since the amendment is a deletion of the standards for use and the specification along with revocation of designation as a feed additive, the assessed items falls under the category which is the case where the contents and degree of adverse effects on human health are clear⁶</p>
<p>Additive for drinking water used in cattle, pigs and poultry, and feed additive for honeybee (Tylan Soluble Powder)</p>	<p>FSCJ conclusion: Risk to human health from the use of the tylosin tartrate products into honeybee through consumption of relevant food products was considered to be negligible.</p>

¹³ Ordinance of Ministry of Agriculture and Forestry, No.35, 1976

September 2017

Discussions from the 664th to 667rd Meetings of the Commission held on the 5th, 12th, 19th and 26th of September 2017 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations¹⁴.

Pesticides	<ul style="list-style-type: none"> • Revision of the assay methods for propham designated in standards for foods and additives¹⁵. • Dithianon • Fluensulfone • Fluxapyroxad • Methoxyfenozide
Veterinary medicinal products	<ul style="list-style-type: none"> • A feed additive, which contains Oxytetracycline Hydrochloride as an active ingredient, for use into the fishes belong to Tetraodontiformes (Terramycin powder for fisheries and related 12 products) (Reevaluation) • Orbifloxacin
Prions	<ul style="list-style-type: none"> • Resumption of use of MBM, derived from sheep and horses for fertilizers in aquatic animal farming.
Genetically modified foods/feeds	<ul style="list-style-type: none"> • Glucose oxidase produced using GOOX-1 strain • Maize MZIR098 line resistant to Coleoptera and tolerant of glufosinate herbicide (foods) • Maize MZIR098 line resistant to Coleoptera and tolerant of glufosinate herbicide (feeds)
Feeds and Fertilizers	<ul style="list-style-type: none"> • Amendment of official specification of ordinary fertilizers

¹⁴ E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

¹⁵ Notification of the Ministry of Welfare, No. 370, 1959, which was established based on paragraph(1) of article 11 of the Food Sanitation Act, Act No. 233 of 1947.

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

Pesticides

Item	ADI	ARfD
Bicyclopyrone	0.00028 mg/kg bw per day	2 mg/kg bw for ordinal people 0.01 mg/kg bw for pregnant women and women who may be pregnant

Pesticides

Item	Conclusion
Revision of the assay methods for propham designated in standards for foods and additives ¹⁶ .	FSCJ conclusion: 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 ¹⁷ .

Natural toxins / mycotoxins

Item	Conclusion
Fumonisin	FSCJ conclusion: FSCJ specified TDI for fumonisins as 2 µg/kg bw/day. However, the level of contamination with mycotoxins is influenced by climatic and other conditions, thus the level varies depend on the harvesting year. Therefore, risk management institutions should monitor the situation of

¹⁶ Notification of the Ministry of Welfare, No. 370, 1959, which was established based on paragraph (1) of article 11 of the Food Sanitation Act, Act No. 233 of 1947.

¹⁷ The case designated by item(ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

	fumonisin contamination in foods and review the standards and specification as necessary based on the data.
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Genetically modified foods/feeds

Item	Conclusion
Phospholipase C produced using PRF strain	FSCJ conclusion: The item is considered to be of no concern for food safety based on Standards for Safety Assessments of Food Additives Produced using Genetically Modified Microorganisms.

Feeds and Fertilizers

Item	Conclusion
Amendment of official specification of ordinary fertilizers	FSCJ conclusion: The assessed items falls under the category which is the case where the contents and degree of adverse effects on human health are clear ⁴