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

October 2016

Discussions from the 624th to 627th Meetings of the Commission held on the 4th, 11th, 18th and 25th of October 2016 are summarized as follows:

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

Pesticides	<ul style="list-style-type: none"> • Aminocyclopyrachlor • Cyanazine • Pyraziflumid • Fluthiacet-methyl • Procymidone • Myclobutanil
Veterinary medicinal products	<ul style="list-style-type: none"> • Porcine reproductive and respiratory syndrome (PRRS) virus live, attenuated vaccine (Fostera PRRS). • Gamithromycin • Zactran Merial; an injection for veterinary use in pigs containing gamithromycin as an active ingredient.
Genetically modified foods/feeds	<ul style="list-style-type: none"> • Lipase produced using JPAo001 strain
Feed additives	<ul style="list-style-type: none"> • 6-Phytase produced by <i>Schizosaccharomyces pombe</i> ASP595-1 strain.

¹ 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
Isofetamid	0.053 mg/kg bw per day	3 mg/kg bw
<i>Cyclaniliprole</i>	0.012 mg/kg bw per day	Not required
Fenazaquin	0.0046 mg/kg bw per day	0.1 mg/kg bw
Flutolanil	0.087 mg/kg bw per day	Not required

Veterinary medicinal products, feed additives and Pesticides

Item	ADI	ARfD
Oxytetracycline, Chlortetracycline Tetracycline	0.03 mg/kg bw per day as a group ADI	0.03 mg/kg bw for Oxytetracycline

Feed additives

Item	Conclusion
6-Phytase produced by <i>Schizosaccharomyces pombe</i> ASP595-1 strain.	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 as feed additive.

November 2016

Discussions from the 628th to 631st Meetings of the Commission held on the 1st, 15th, 22nd and 29th of November 2016 are summarized as follows:

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

Pesticides	<ul style="list-style-type: none"> • Cadusafos • Chlorantraniliprole • Flutianil • Hexaconazole • Metaflumizone • Revision of registration standard for pesticides in feeds
Veterinary medicinal products and feed additives	<ul style="list-style-type: none"> • Tylosin
Genetically modified foods	<ul style="list-style-type: none"> • Phospholipase C produced using PRF strain. • Hybrid stacks of oilseed rape DP-073496-4³ x RF3⁴

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

Additives

Item	Conclusion
Magnesium Stearate	FSCJ conclusion: FSCJ concluded that the assessed item is of no concern for food safety as long as used appropriately as a food additive. Therefore, it is not necessary to specify ADI.

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

³ Oilseed rape tolerant of glyphosate herbicide.

⁴ Oilseed rape restoring fertility and tolerant of glufosinate herbicide.

Pesticides

Item	ADI	ARfD
Spinetoram	0.024 mg/kg bw per day	Not required

Pesticides

Item	Conclusion
Hexaconazole	FSCJ conclusion: The item falls under (1) of 1 of October 8, 2009 Decision of the Food Safety Commission. FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear ⁵ .
Revision of registration standard for pesticides in feeds	FSCJ conclusion: FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear ⁶ .

Veterinary medicinal products

Item	ADI
Pegbovigrastim	Not required
Diclazuril	0.03 mg/kg bw per day

Veterinary medicinal products and feed additives

Item	ADI
Tylosin	0.005 mg/kg bw per day

⁵ The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

⁶ The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

Genetically modified foods

Item	Conclusion
Phospholipase produced using NZYM-LP strain	FSCJ conclusion: According to the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” ⁷ , the item was evaluated not to affect human health.

⁷ “the Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (Decision of the Commission dated March 25, 2004)”.

December 2016

Discussions from the 632nd and 633rd Meetings of the Commission held on the 13th and 20th of December 2016 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations⁸.

Pesticides	<ul style="list-style-type: none"> • Chlorpropham • Cyazofamid • Diphenochonazole • Cyflumetofen • Pyrifluquinazon • Fenbuconazole • Revision of the assay methods for 2,4,5-T and Daminozide designated in standards for foods and additives⁹.
Pesticides and additives	<ul style="list-style-type: none"> • Propiconazole
Veterinary medicinal products	<ul style="list-style-type: none"> • Revision of the assay methods for malachite green designated in standards for foods and additives¹⁰. • Spiramycin • 9 components used as additives to vaccine for veterinary use

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

Pesticides

Item	ADI	ARfD
Acephate	0.0024 mg/kg bw per day	0.1 mg/kg bw
Buprofezin	0.009 mg/kg bw per day	0.5 mg/kg bw
Methamidophos	0.00056 mg/kg bw per day	0.003 mg/kg bw

⁸ E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

⁹ Notification of the Ministry of Welfare, No. 370, 1959, which was established based on paragraph(1) of article 11 of the Food Hygiene Law, Act No. 233 of 1947.

¹⁰ Notification of the Ministry of Welfare, No. 370, 1959, which was established based on paragraph(1) of article 11 of the Food Hygiene Law, Act No. 233 of 1947.

Pesticides

Item	Conclusion
Chlorpropham	FSCJ conclusion: The item falls under (1) of 1 of October 8, 2009 Decision of the Food Safety Commission. FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear ¹¹ .
Revision of the assay methods for 2,4,5-T and Daminozide designated in standards for foods and additives ¹² .	FSCJ conclusion: FSCJ conclude that the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act ¹³ .

Veterinary medicinal products

Item	Conclusion
Revision of the assay methods for malachite green designated in standards for foods and additives ¹⁴ .	FSCJ conclusion: FSCJ conclude that the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act ¹⁵ .
Spiramycin	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 ¹⁶ .

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

¹² Notification of the Ministry of Welfare, No. 370, 1959, which was established based on paragraph (1) of article 11 of the Food Hygiene Law, Act No. 233 of 1947.

¹³ 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.

¹⁴ Notification of the Ministry of Welfare, No. 370, 1959, which was established based on paragraph (1) of article 11 of the Food Hygiene Law, Act No. 233 of 1947.

¹⁵ 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.

¹⁶ The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

Veterinary medicinal products

Item	ADI
Gamithromycin	0.01 mg/kg bw per day