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

### January 2018

Discussions from the 680th to 682nd Meetings of the Commission held on the 16th, 23rd and 30th of January 2018 are summarized as follows:

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

Additives	· Dimethyl dicarbonate
Pesticides	· Triflumizole · Chinomethionat · Fluazifop
Pesticides and veterinary medicinal products	· Etoxazole
Veterinary medicinal products	· Methylprednisolone
Feed additives	· Guanidinoacetate

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

Exempted Substances<sup>4</sup>

Item	Conclusion
Glycerylcaprylate	FSCJ conclusion: Risk to human health from intake of the assessed items through food is negligible as long as normally used as a pesticide.

Pesticides

Item	ADI	ARfD
Picoxystrobin	0.046 mg/kg bw per day	0.2 mg/kg bw
Pyribencarb	0.039 mg/kg bw per day	1.1 mg/kg bw

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

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Gibberelline	0.11 mg/kg bw per day	Not required
Fenpyroximate	0.0097 mg/kg bw per day	0.015 mg/kg bw

Pesticides and Veterinary medicinal products

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

Veterinary medicinal products

Item	ADI
Flumequine	0.071 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
An injection for cattle, Imrestor, which contains pegbovigrastim as an active ingredient.	FSCJ conclusion: Risk to human health from the assessed item through food consumption is negligible as long as appropriately used.
Methylprednisolone	FSCJ conclusion: 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 <sup>2</sup> .

Microorganisms and viruses

Item	Conclusion
Amendment of standards for Tofu	FSCJ conclusion: FSCJ concluded that the food safety risk to human health is not different before and after changing the standards for aseptic-filled tofu from refrigerated to room temperature storage.

Genetically modified foods/feeds

Item	Conclusion
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<sup>2</sup> The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

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<p>Soybean DP-305423-1 x MON89788 x MON87708                  (Hybrid stack of MON89788 line x MON87708 line of which the safety assessments have already been completed was excluded from the assessment.)</p>	<p>FSCJ conclusion: According to the “Stance on the safety assessment of genetically modified foods (seed plants)”<sup>3</sup>, the item was evaluated not to affect human health.</p>
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Feed additives

Item	ADI
Butylated hydroxyanisole	0.5 mg/kg bw per day

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<sup>3</sup> “Stance on Safety Assessments of Genetically Modified Foods (seed plants) (Decision of the Commission dated 29 January 2004)”

## February 2018

Discussions from the 683rd to 686th Meetings of the Commission held on the 6th, 13th, 20th and 27th of February 2018 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations<sup>4</sup>.

Additives	• Items related to the amendment of standards for foods and food additives following to the amendment of Japanese Standards of Food Additives.
Natural toxins / mycotoxins	• Deoxynivalenol
Genetically modified foods/feeds	• Protease produced using JPFV001 strain

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

Exempted Substances<sup>4</sup>

Item	Conclusion
Zinc	FSCJ conclusion: Risks to human health through residues in livestock products are negligible as long as it is appropriately used as veterinary medicinal products and feed additives.

Pesticides

Item	ADI	ARfD
Acibenzolar-S-methy	0.077 mg/kg bw per day	0.5 mg/kg bw
Acrinathrin	0.016 mg/kg bw per day	0.03 mg/kg bw

Pesticides and veterinary medicinal products

Item	ADI	ARfD
Cypermethrin	0.022 mg/kg bw per day	0.04 mg/kg bw

Veterinary medicinal products

Item	ADI
Monepantel	0.03 mg/kg bw per day

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<sup>4</sup> E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

Prions

Item	Conclusion
Meet and offal of cattle, sheep and goats imported from England	<p>FSCJ conclusion: the restriction of cattle age and definition of Specific Risk Materials (SRMs)</p> <p>As for the meat and offal imported from England, a difference between “the ban on import” and setting the restriction of age and definition of Specific Risk Materials (SRMs) in the risk to human health that could arise from consumption of BSE prion in meat and offal would be extremely small. Therefore, the effect on human health of this change of the border measure is negligible.</p>

Genetically modified foods/feeds

Item	Conclusion
L-threonine	<p>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<sup>5</sup>” (Supplementary Provisions of “Standards for Safety Assessments of Food Additives produced Using Genetically Modified Microorganisms<sup>6</sup>”). Consequently, the food safety risk from the assessed item through livestock products derived from livestock animals that have consumed the feed additives in question was evaluated to be negative.</p>

Feed additives

Item	Conclusion
2-deamino-2-hydroxymethionine zinc	<p>FSCJ conclusion: FSCJ concluded that risks of the assesses item to human health through residues in foods are negligible as long as normally used as feed additives.</p>

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<sup>5</sup> Decision of the Commission dated April 28, 2005

<sup>6</sup> Decision of the Commission dated March 25, 2004

**March 2018**

Discussions from the 687th to 690th Meetings of the Commission held on the 6th, 13th, 20th and 27th of March 2018 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations<sup>7</sup>.

Pesticides	<ul style="list-style-type: none"> <li>• Revision of specimens of Cacao beans in the standards for foods and food additives<sup>8</sup> established in accordance with Article 1, paragraph 1 of 11 of the Food Sanitation Act<sup>9</sup>.</li> <li>• Cyclopyrimorate</li> </ul>
Pesticides and Veterinary medicinal products	<ul style="list-style-type: none"> <li>• Isoprothiolane</li> <li>• Cypermethrin</li> </ul>
Genetically modified foods/feeds	<ul style="list-style-type: none"> <li>• Pullulanase produced using JPBL002 strain</li> <li>• Cotton GHB811 tolerant of glyphosate and of HPPD<sup>10</sup>-inhibitory herbicides</li> </ul>
Fertilizers	<ul style="list-style-type: none"> <li>• Regarding establishment of the official specification of ordinary fertilizers</li> </ul>

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

Exempted Substances<sup>4</sup>

Item	Conclusion
Tocopherol	FSCJ conclusion: Risks to human health through residues in livestock products are negligible as long as it is appropriately used as veterinary medicines and feed additives.

## Pesticides

Item	ADI	ARfD
Quinomethionate	0.0064 mg/kg bw per day	1.5 mg/kg bw
Fluazifop	0.0044 mg/kg bw per day	0.02 mg/kg bw for women who are or may be pregnant. Not required for general population
Tetraconazole	0.004 mg/kg bw per day	0.05 mg/kg bw

<sup>7</sup> E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

<sup>8</sup> Notification of the Ministry of Health, Labor, and Welfare. No.370 of 1959.

<sup>9</sup> Act No. 233, 1947

<sup>10</sup> 4-Hydroxyphenylpyruvate Dioxygenase

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1,3-Dichloropropene	0.02 mg/kg bw per day	0.2 mg/kg bw
Triflumizole	0.015 mg/kg bw per day	0.25 mg/kg bw
Chlorothalonil (2,5,6-trichloro-4-hydroxy isophthalodinitrile)	0.018 mg/kg bw per day (0.0083 mg/kg bw per day)	0.6 mg/kg bw (0.025 mg/kg bw)
Probenazole	0.01 mg/kg bw per day	2 mg/kg bw
Methoxyfenozide	0.098 mg/kg bw per day	Not required

Pesticides

Item	Conclusion
Revision of specimens of Cacao beans in the standards for foods and food additives <sup>11</sup> established in accordance with Article 1, paragraph 1 of 11 of the Food Sanitation Act <sup>12</sup> .	FSCJ conclusion: FSCJ conclude that the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act <sup>13</sup> .

Pesticides and veterinary medicinal products

Item	ADI	ARfD
Etoazole	0.04 mg/kg bw per day	Not required
Cypermethrin	0.022 mg/kg bw per day	0.04 mg/kg bw

Veterinary medicinal products

Item	ADI
Neomycin	0.036 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
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<sup>11</sup> Notification of the Ministry of Health, Labor, and Welfare. No.370 of 1959.

<sup>12</sup> Act No. 233, 1947

<sup>13</sup> The item 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.

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<p>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)</p>	<p>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.</p>
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Fertilizers

Item	Conclusion
<p>Regarding establishment of the official specification of ordinary fertilizers</p>	<p>FSCJ conclusion: FSCJ conclude that the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act<sup>14</sup>.</p>

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<sup>14</sup> The item 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.