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

### July 2018

Discussions from the 703rd to 707th Meetings of the Commission held on the 2nd, 10th, 17th, 24th and 31st of July 2018 are summarized as follows:

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

Veterinary medicinal products	<ul style="list-style-type: none"> <li>• A feed additives for pigs which contains valnemulin hydrochloride as an active ingredient, Econor 1% premix. and 10% premix)</li> <li>• A feed additives for pigs which contains valnemulin hydrochloride as an active ingredient, Econor 10% premix.</li> </ul>
Genetically modified foods	<ul style="list-style-type: none"> <li>• Potato SPS-000Y9-7</li> </ul>
Feed additives	<ul style="list-style-type: none"> <li>• Phytase obtained from <i>Pichia Pastoris</i></li> <li>• Phytase obtained from <i>Trichoderma reesei</i></li> </ul>
Fertilizers	<ul style="list-style-type: none"> <li>• Establishment of 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.

#### Pesticides

Item	ADI	ARfD
Etofenprox	0.031 mg/kg bw per day	1 mg/kg bw
Captan	0.1 mg/kg bw per day	3 mg/kg bw for general population 0.3 mg/kg bw for women who are or may be pregnant.
Methoxyfenozide	0.098 mg/kg bw per day	Not required
Chlorpyrifos	0.001 mg/kg bw per day	0.1 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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Flupyrimin	0.011 mg/kg bw per day	0.08 mg/kg bw
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Veterinary medicinal products

Item	ADI
Amoxicillin	0.0013 mg/kg bw per day

Genetically modified foods/feeds

Item	Conclusion
Glucoamylase produced using JPAN001 strain	FSCJ conclusion: According to the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” <sup>2</sup> , the item was evaluated not to affect human health.
Protease produced using JPFV001 strain	FSCJ conclusion: According to the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” <sup>2</sup> , the item was evaluated not to affect human health.

Fertilizers

Item	Conclusion
Establishment of official specification of ordinary fertilizers	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>3</sup> .

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<sup>2</sup> “The Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)”

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

**August 2018**

Discussions from the 708th and 709th Meetings of the Commission held on the 21st and 28th of August 2018 are summarized as follows:

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

Additives	• Hypobromous Acid Water
Pesticides	• Cyenopyrafen • Bifenthrin • Pyflubumide • Furametpyr • Flonicamid
Veterinary medicinal products	• Gentian Violet

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

## Pesticides

Item	ADI	ARfD
Cyclopyrimorate	0.063 mg/kg bw per day	Not required
Captan	0.1 mg/kg bw per day	3 mg/kg bw for general population 0.3 mg/kg bw for women who are or may be pregnant.
Methoxyfenozide	0.098 mg/kg bw per day	Not required
Chlorpyrifos	0.001 mg/kg bw per day	0.1 mg/kg bw
Flupyrimin	0.011 mg/kg bw per day	0.08 mg/kg bw

## Pesticides and veterinary medicinal products

Item	ADI	ARfD
Isoprothiolane	0.1 mg/kg bw per day	0.5 mg/kg bw for general population 0.12 mg/kg bw for women who are or may be pregnant.

## Veterinary medicinal products

<sup>4</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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Item	ADI
Gentamicin	0.011 mg/kg bw per day

Genetically modified foods/feeds

Item	Conclusion
Chymosin produced using CIN strain	FSCJ conclusion: According to the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” <sup>5</sup> , the item was evaluated not to affect human health.
Hemicellulase produced using JPTR001 strain	FSCJ conclusion: According to the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” <sup>2</sup> , the item was evaluated not to affect human health.
Xylanase produced using JPTR002 strain	FSCJ conclusion: According to the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” <sup>2</sup> , the item was evaluated not to affect human health.

Feed additives

Item	Conclusion
Guanidineacetic acid	FSCJ conclusion: FSCJ concluded that the ADI was unnecessary to be specified as long as it was appropriately used as a feed additive.
A feed additive composed of guanidineacetic acid as the source material	FSCJ conclusion: FSCJ concluded that risks to human health through residues in livestock products were negligible as long as it was appropriately used as a feed additive.

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<sup>5</sup> “The Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)”

## September 2018

Discussions from the 710th to 713rd Meetings of the Commission held on the 4th, 11th, 18th, and 25th of September 2018 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations<sup>6</sup>.

Veterinary medicinal products	<ul style="list-style-type: none"> <li>• 6 components contained as additives in the already approved veterinary vaccines</li> <li>• Revision of mixed live vaccine against Newcastle disease/avian infectious bronchitis (Avitect NB/TM)</li> <li>• Revision of live vaccine against avian infectious bronchitis (Avitect IB/AK 1000)</li> </ul>
Genetically modified foods	<ul style="list-style-type: none"> <li>• Phytase produced using Morph Δ E8 BP17 4c strain</li> </ul>
Food for Specified Health Use	<ul style="list-style-type: none"> <li>• VAAM smartfit water</li> </ul>
Feed additives	<ul style="list-style-type: none"> <li>• Manganese bis(2-hydroxy-4-methylthio butyrate)</li> </ul>

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

### Pesticides

Item	ADI	ARfD
MCPB ethyl	0.012 mg/kg bw per day	0.2 mg/kg bw
Tetradifon	0.13 mg/kg bw per day	Not required
Tetraniliprole	0.88 mg/kg bw per day	Not required
Bifenazate	0.01 mg/kg bw per day	0.1 mg/kg bw

### Pesticides and veterinary medicinal products

Item	ADI	ARfD
Carbaryl	0.0073 mg/kg bw per day	0.01 mg/kg bw

### Veterinary medicinal products

Item	ADI

<sup>6</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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Cephapirin	0.002 mg/kg bw per day
Valnemulin	0.008 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
Revision of live vaccine against avian infectious bronchitis (Avitect IB/AK 1000)	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 <sup>7</sup> .
Revision of mixed live vaccine against Newcastle disease/avian infectious bronchitis (Avitect NB/TM)	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 <sup>2</sup> .

Beverages

Item	TDI
hexavalent chromium	1.1 µg/kg bw per day

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<sup>7</sup> The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.