

This English version of the Commission Decision is intended to be reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail. The FSCJ shall not be responsible for any consequence resulting from use of this English version.

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

### April 2020

Discussions from the 779th and 780th Meetings of the Commission held on the 9th and 21st of April 2020 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>• Vaxxitek® HVT+IBD (Frozen live vaccine against infectious bursal disease • Marek's disease.)</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   |
|--------------|------------------------|--|
| Myclobutanil | 0.024 mg/kg bw per day | 2.4 mg/kg bw for ordinary people,<br>0.31 mg/kg bw for women who are or may be pregnant. |

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

**May 2020**

Discussions from the 781st Meetings of the Commission held on the 19th of May 2020 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations<sup>2</sup>.

|                                  |  |
|----------------------------------|--|
| Prions                           | <ul style="list-style-type: none"> <li>• Meat and offal of cattle, sheep and goat, imported from Germany and Finland.</li> </ul>   |
| Genetically modified foods/feeds | <ul style="list-style-type: none"> <li>• Muramidase produced using JPTR003 strain</li> <li>• Potato SPS-00X17-5 strain (Feed)</li> <li>• Potato SPS-00X17-5 strain (Food)</li> <li>• Glucoamylase produced using JPAN003 strain</li> <li>• Hemicellulase produced using JPAN007 strain</li> </ul>  |
| Feed additives                   | <ul style="list-style-type: none"> <li>• Amendment of standards and criteria for sodium salinomycin.</li> </ul>  |
| Antimicrobial resistant bacteria | <ul style="list-style-type: none"> <li>• Withdrawal of assessment request for bicozamycin benzoate (veterinary medicinal product).</li> </ul>  |
| Others                           | <ul style="list-style-type: none"> <li>• Partial amendment of Order for Enforcement of the Domestic Animal Infectious Diseases Control Act and Enforcement Regulations of the said Act.</li> <li>• Partial amendment of the Ministerial Ordinance on Milk and Milk products Concerning Compositional Standards, etc. and partial amendment of Enforcement Regulations of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act.</li> </ul> |

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

Feed additives

| Item | Conclusion |
|------|------------|
|      |            |

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

Food Safety Commission of Japan (FSCJ)

|   |  |
|---|--|
| <ul style="list-style-type: none"> <li>• Amendment of standards and criteria for sodium salinomycin.</li> </ul> | <p>FSCJ conclusion: FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear<sup>3</sup>.</p> |
|---|--|

Antimicrobial resistant bacteria

| Item   | Conclusion  |
|--|---|
| <ul style="list-style-type: none"> <li>• Veterinary use of bicozamycin in livestock animals</li> </ul> | <p>FSCJ conclusion: FSCJ concludes that the risk to human health via food consumption arisen from the antimicrobial-resistant bacteria selected by the use of bicozamycin in livestock animals is negligible.</p> |

Others

| Item   | Conclusion  |
|--|---|
| <ul style="list-style-type: none"> <li>• Partial amendment of Order for Enforcement of the Domestic Animal Infectious Diseases Control Act and Enforcement Regulations of the said Act.</li> </ul>   | <p>FSCJ conclusion: FSCJ concludes that the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act<sup>4</sup>.</p> |
| <ul style="list-style-type: none"> <li>• Partial amendment of the Ministerial Ordinance on Milk and Milk products Concerning Compositional Standards, etc. and partial amendment of Enforcement Regulations of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act.</li> </ul> | <p>FSCJ conclusion: FSCJ concludes that the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act<sup>4</sup>.</p> |

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

<sup>4</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.

## June 2020

Discussions from the 782nd Meetings of the Commission held on the 16th of June 2020 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations<sup>5</sup>.

|                               |   |
|-------------------------------|---|
| Pesticides                    | <ul style="list-style-type: none"> <li>• Fenhexamid</li> <li>• Kasugamycin</li> <li>• Cyflumetofen</li> <li>• Thiencarbazone-methyl</li> <li>• Fenbuconazole</li> </ul> |
| Veterinary medicinal products | <ul style="list-style-type: none"> <li>• Tildipirosin</li> </ul>  |
| Genetically modified foods    | <ul style="list-style-type: none"> <li>• Pectinase produced using JPAN005 strain</li> <li>• Glutamyl-Valyl-Glycine produced using EVG-L1 and EVG-G1 strains</li> </ul>  |

(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"> <li>• Calcium carbonate</li> </ul> | <p>FSCJ conclusion: FSCJ specified the ULS<sup>6</sup> of 2,000 mg/person per day for an upper limit of extra-dietary intake of calcium. With regard to amendment of standards for an additive “calcium carbonate”, FSCJ considered that it is of no concern for food safety as long as calcium carbonate is used appropriately as a food additive.</p> |

<sup>5</sup> E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

<sup>6</sup> UL as a supplement. The upper limit of extra dietary intake.

Pesticides

| Item          | ADI                    | ARfD          |
|---------------|------------------------|---------------|
| Fenpropathrin | 0.027 mg/kg bw per day | 0.03 mg/kg bw |
| Pymetrozine   | 0.013 mg/kg bw per day | 0.1 mg/kg bw  |

Pesticides

| Item       | Conclusion  |
|------------|---|
| Fenhexamid | FSCJ conclusion: FSCJ concluded that the assessed item falls under the category which is the case where the contents and degree of adverse effects on human health are clear <sup>7</sup> . |

Veterinary medicinal products

| Item         | Conclusion  |
|--------------|---|
| Tildipirosin | FSCJ conclusion: FSCJ concluded that the assessed item falls under the category which is the case where the contents and degree of adverse effects on human health are clear <sup>7</sup> . |

Genetically modified foods/feeds

| Item | Conclusion |
|------|------------|
|------|------------|

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<sup>7</sup> The item comes under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act

|  |  |
|--|--|
| <ul style="list-style-type: none"><li>• A flavoring, valencene, produced using <i>Rhodobacter sphaeroides</i> 168 strain</li></ul> | FSCJ conclusion: According to the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” <sup>8</sup> , the item was evaluated not to affect human health. |
| <ul style="list-style-type: none"><li>• Exo-maltotetrahydrolase, produced using JS1252 strain</li></ul>                            | FSCJ conclusion: According to the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” <sup>8</sup> , the item was evaluated not to affect human health. |

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<sup>8</sup> “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” (Decision of the Food Safety Commission dated March 25, 2004).