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

### January 2020

Discussions from the 769th to 771st Meetings of the Commission held on the 14th, 21st and 28th of January 2020 are summarized as follows:

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

Microorganisms and viruses	<ul style="list-style-type: none"> <li>Handling of setting or amendment of the standards and specification of feeds related to procedures for inactivation of pathogens.</li> </ul>
Fertilizers	<ul style="list-style-type: none"> <li>Setting, amendment or abolition of official specification of pesticides-containing ordinal fertilizers that are used for plants not for use in foods and feeds, among fertilizers contaminated with pesticides and other foreign substances designated by Notification of the Ministry of Agriculture, Forestry and Fisheries (No. 284, 1986) based on the official specification of ordinary fertilizers prescribed in paragraph (1) of Article 3 of the Fertilizer Control Act (Act No. 127 of 1950).</li> <li>Setting of official specification of ordinal fertilizers based on the official specification of ordinary fertilizers prescribed in paragraph (1) of Article 3 of the Fertilizer Control Act (Act No. 127 of 1950).</li> </ul>
Others	<ul style="list-style-type: none"> <li>Partial amendment of Act on Domestic Animal Infectious Diseases Control Enforcement Order</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
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<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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Ipflufenquin	0.048 mg/kg bw per day	1.2 mg/kg bw
Cyflufenamid	0.041 mg/kg bw per day	Not required
Mefentrifluconazole	0.035 mg/kg bw per day	Not required
Imazapyr	2.8 mg/kg bw per day	Not required
Benzpyrimoxan	0.026 mg/kg bw per day	0.1 mg/kg bw

Microorganisms and viruses

Item	Conclusion
Handling of setting or amendment of the standards and specification of feeds related to procedures for inactivation of pathogens.	FSCJ conclusion: FSCJ conclude that the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act <sup>2</sup> .

Prions

Item	Conclusion
Cattle meat and offal imported from France and Norway	FSCJ conclusion: FSCJ concludes that potential variations of BSE risks to human health by removing the age limit on cattle meat and offal (excluding SRMs) imported from the two countries in line with the international standards is negligible.

Food for Specified Health Uses

Item	Conclusion
ヘルシア サット健膳 plain, ヘルシア サット健膳 plain bottle, ヘルシア サット健膳 lemon-olive flavored, and ヘルシア サット健膳 lemon-olive flavored bottle	FSCJ conclusion: FSCJ concluded that “ヘルシア サット健膳 plain, ヘルシア サット健膳 plai bottle, ヘルシア サット健膳 lemon-olive flavored, and ヘルシア サット健膳 lemon-olive flavored bottle” has no obvious risk to human health as far as the documents submitted by the applicant were concerned.  However, a glycidol fatty acid ester content in the assessed item need to be continuously kept as low as possible according to the principle of ALARA (As Low As Reasonably Achievable)

<sup>2</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.

Fertilizers

Item	Conclusion
<p>Setting, amendment or abolition of official specification of pesticides- containing ordinal fertilizers that are used for plants not for use in foods and feeds, among fertilizers contaminated with pesticides and other foreign substances designated by Notification of the Ministry of Agriculture, Forestry and Fisheries (No. 284, 1986) based on the official specification of ordinary fertilizers prescribed in paragraph (1) of Article 3 of the Fertilizer Control Act (Act No. 127 of 1950).</p>	<p>FSCJ conclusion: FSCJ concluded that the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act<sup>3</sup>.</p>
<p>Setting of official specification of ordinal fertilizers based on the official specification of ordinary fertilizers prescribed in paragraph (1) of Article 3 of the Fertilizer Control Act (Act No. 127 of 1950).</p>	<p>FSCJ conclusion: FSCJ concluded 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>4</sup></p>

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<sup>3</sup> The assessed 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.

<sup>4</sup> The assessed item comes under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act, where the contents and degree of adverse effects on human health are clear.

## February 2020

Discussions from the 772nd to 774th Meetings of the Commission held on the 4th, 18th and 25th of February 2020 are summarized as follows:

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

Food additives	<ul style="list-style-type: none"> <li>▪ Ammonium Hydrogensulfite Solution</li> <li>▪ Chitin-glucan</li> <li>▪ Copolymer of polyvinylimidazole- polyvinylpyrrolidone</li> </ul>
Pesticides	<ul style="list-style-type: none"> <li>▪ Ethaboxam</li> <li>▪ Tiadinil</li> <li>▪ Benzovindiflupyr</li> <li>▪ Myclobutanil</li> </ul>
Veterinary medicinal products	<ul style="list-style-type: none"> <li>▪ Dinitolmide</li> <li>▪ Additions to the assay methods for dexamethasone and betamethasone designated in standards for foods and additives<sup>6</sup>.</li> </ul>
Genetically modified foods/feeds	<ul style="list-style-type: none"> <li>▪ Exomaltotetraohydrolase produced using JS1252 strain</li> <li>▪ Alpha-glucosidase produced using Morph TG#626 strain</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
Carbofuran	0.00015 mg/kg bw per day	0.00015 mg/kg bw
Carbosulfan	0.005 mg/kg bw per day <sup>7</sup>	0.005 mg/kg bw <sup>7</sup>

<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> 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.

<sup>7</sup> FSCJ judged that the ADI and ARfD of a metabolite from carbosulfan, when it is carbofuran, are the same to that of carbofuran.

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Benfuracarb	0.0089 mg/kg bw per day <sup>8</sup>	0.0092 mg/kg bw <sup>8</sup>
Prohydrojasmon	0.14 mg/kg bw per day	1.2 mg/kg bw
Flometoquin	0.008 mg/kg bw per day	0.044 mg/kg bw
pyrifluquinazon	0.005 mg/kg bw per day	1 mg/kg bw for ordinary people 0.05 mg/kg bw for pregnant or may be pregnant women
Bixafen	0.019 mg/kg bw per day	0.2 mg/kg bw

Veterinary medicinal products

Item	Conclusion
Additions to the assay methods for dexamethasone and betamethasone designated in standards for foods and additives <sup>9</sup> .	FSCJ conclusion: The assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act <sup>10</sup> .

Genetically modified foods/feeds

Item	Conclusion
A pima cotton MON88701 x MON88913 line tolerant of dicamba herbicide, glufosinate herbicide, glyphosate herbicide	FSCJ conducted risk assessment of pima cotton MON88701 x MON88913 line tolerant of dicamba herbicide, glufosinate herbicide, glyphosate herbicide, based on the “Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)” <sup>11</sup> , since this is a crossbreed above subspecies level described in the “Approach to the Safety Assessment of

<sup>8</sup> FSCJ judged that the ADI and ARfD of a metabolite from benfuracarb, when it is carbofuran, are the same to that of carbofuran.

<sup>9</sup> 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 off 1947.

<sup>10</sup> 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.

<sup>11</sup> Decision of Commission dated 29 January 2004

	Genetically Modified Foods (seed plants) <sup>12</sup> . Consequently, FSCJ concluded that MON88701 x MON88913 line has no concern relevant to human health.
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Antimicrobial resistant bacteria

Item	Conclusion
Calcium halofuginone polystrenesulfonate (HPS) used in livestock <b>anials</b> .	FSCJ conclusion: The risk to human health via food consumption arisen from the antimicrobial-resistant bacteria selected through the use of calcium halofuginone polystrenesulfonate (HPS) in chicken is negligible.

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<sup>12</sup> Decision of the Commission dated 29 January 2004

## March 2020

Discussions from the 775th to 778th Meetings of the Commission held on the 3rd, 10th, 24th and 31st of March 2020 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations<sup>13</sup>.

Pesticides, feed additives and prion	<ul style="list-style-type: none"> <li>Establishment of the standards and compositional standards for manufacturing methods of feed based on the Act on Safety Assurance and Quality Improvement of Feeds (Act No. 35 of 1953)</li> </ul>
Veterinary medicinal products	<ul style="list-style-type: none"> <li>Baycox® iron injection</li> <li>Newcastle disease and avian infectious bronchitis mixed raw vaccine (seed) (ガルエヌテクト S 9 5 - N B L)</li> <li>Thirty items, including didecyldimethylammonium chloride, related to the Positive List System</li> </ul>
Veterinary medicinal products and feed additives	<ul style="list-style-type: none"> <li>Three items related to the Positive List System (amprolium, ethopabate, sulfaquinoxaline)</li> </ul>
Feed additives	<ul style="list-style-type: none"> <li>Two items related to the Positive List System (enramycin, canthaxanthin)</li> </ul>
Veterinary Medical Devices	<ul style="list-style-type: none"> <li>Testing instruments for internal organs (Wireless lumen pH sensor)</li> </ul>
Microorganisms and viruses	<ul style="list-style-type: none"> <li>Amendment of the Ordinance of the Ministry of Welfare, No.52, 1951<sup>14</sup>. (As an exception to the prohibition of other products use for condensed skim milk and skimmed milk powder)</li> </ul>

<sup>13</sup> E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

<sup>14</sup> The Ordinance of the Ministry of Welfare, No.52, 1951, regarding standard of element and others of milk and dairy products.

Microorganisms and viruses, and veterinary medicinal products	<ul style="list-style-type: none"> <li>• Amendment of the Ordinance of the Ministry of Welfare, No.52, 1951<sup>15</sup>. (Three provisions regarding water buffalo milk)</li> </ul>
Genetically modified foods/feeds	<ul style="list-style-type: none"> <li>• Phospholipase produced using JPBL004 strain</li> <li>• Phospholipase produced using JPBL005 strain</li> </ul>

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

Pesticides, feed additives and prions

Item	Conclusion
Establishment of the standards and compositional standards for manufacturing methods of feed based on the Act on Safety Assurance and Quality Improvement of Feeds (Act No. 35 of 1953)	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>16</sup> .

Pesticides and additives

Item	ADI	ARfD
Azoxystrobin	0.18 mg/kg bw per day	1.5 mg/kg bw

Pesticides

Item	ADI	ARfD
Oxazosulfyl	0.05 mg/kg bw per day	0.25 mg/kg bw

<sup>15</sup> The Ordinance of the Ministry of Welfare, No.52, 1951, regarding standard of element and others of milk and dairy products.

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



Veterinary medicinal products

Item	Conclusion
Newcastle disease and avian infectious bronchitis mixed raw vaccine (seed) (ガルエヌテクト S 9 5 - N B L)	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>17</sup> .

Veterinary medicinal products

Item	ADI
Tildipirosin	0.03 mg/kg bw per day

Veterinary Medical Devices

Item	Conclusion
Testing instruments for internal organs (Wireless lumen pH sensor)	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>17</sup> .

Microorganisms and viruses

Item	Conclusion
Amendment of the Ordinance of the Ministry of Welfare, No.52, 1951 <sup>18</sup> . (As an exception to the prohibition of other products use for condensed skim milk and skimmed milk powder)	FSCJ conclusion: FSCJ conclude that the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act <sup>19</sup> .

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

<sup>18</sup> The Ordinance of the Ministry of Welfare, No.52, 1951, regarding standard of element and others of milk and dairy products.

<sup>19</sup> The The case designated by item (i) of paragraph (1) of article 11 of the Food Safety Basic Act, where assessment of food safety risk is evidently unnecessary.

Microorganisms and viruses, and veterinary medicinal products

Item	Conclusion
Amendment of the Ordinance of the Ministry of Welfare, No.52, 1951 <sup>20</sup> . (Three provisions regarding water buffalo milk)	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>17</sup> .

Novel foods

Item	Conclusion
• Pilkul 400	FSCJ conclusion: Pilkul 400 has no obvious risk to human health as far as the documents submitted by the applicant were concerned

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<sup>20</sup> The Ordinance of the Ministry of Welfare, No.52, 1951, regarding standard of element and others of milk and dairy products.