

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 2016

Discussions from the 601st to 604th Meetings of the Commission held on the 5th, 12th, 19th and 26th of April 2016 are summarized as follows:

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

Genetically modified foods/feeds	• Soybean MON87751 <sup>2</sup>
----------------------------------	---------------------------------

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

#### Pesticides

Item	ADI	ARfD
Fluopicolide	0.079 mg/kg bw per day	1 mg/kg bw
Its metabolite 2,6-dichlorobenzamide (BAM)	0.047 mg/kg bw per day	0.52 mg/kg bw

#### Pesticides and Veterinary medicinal products

Item	ADI	ARfD
Fipronil	0.00019 mg/kg bw per day	0.02 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).

<sup>2</sup> Soybean resistant to Lepidoptera

Chemicals and Contaminants

Item	Conclusion
Acrylamide in heat-cooked foods	<p>FSCJ conclusion: Non-carcinogenic effects of dietary intake of acrylamide in Japan has a certain range of MOE based on the estimated values. FSCJ, therefore, evaluated level of risk from the dietary intake of acrylamide in Japan extremely low. The effects of the dietary intake on human health remains unclear, because epidemiological studies of the carcinogenic risk in the population including that of high exposure such as occupational exposure did not show any consistent tendency in the association between the acrylamide exposure and cancer incidence. However, MOE calculated based on the BMDL<sup>10</sup> obtained in the animal studies and the estimated dietary intake of acrylamide in Japan was not sufficiently large so that FSCJ could not completely exclude the carcinogenic concern from the point of view of public health. Hence, FSCJ considers that acrylamide contents in foods need to be suppressed continuously to an ALARA (as low as reasonably achievable) level.</p>

Apparatus and Containers/Packages

Item	TDI
Diisodecyl phthalate	0.25 mg/kg bw per day

## May 2016

Discussions from the 605th to 608th Meetings of the Commission held on the 10th, 17th, 24th and 31st of May 2016 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations<sup>3</sup>.

Additives	• Magnesiumstearate
Pesticides	• EPN (ethyl-p-nitrophenylphenylthiophosphonothiate) • Quinclorac • Cyclaniliprole • Spinetoram • Buprofezin • Fluopyram • Flutolanil • Boscalid
Pesticides, Veterinary medicinal products, Feed additives	• Oxytetracycline
Veterinary medicinal products	• Anthorine, an injection for cows to induce superovulation containing FSH as an active ingredient.
Natural toxins/mycotoxins	Liver of Takifugu rubripes that are cultured and marketed under controlled procedures proposed by Saga prefecture and related businesses in Saga prefecture.
Genetically modified foods/feeds	• Hybrid stacks of soybean: MON87705 <sup>4</sup> x MON87708 <sup>5</sup> x MON89788 <sup>6</sup>
Food for Specified Health Use	• Yogurt containing <i>Lactobacillus gasseri</i> SBT2055 as the component relevant to its specified health use. <sup>7</sup>

---

<sup>3</sup> E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

<sup>4</sup> Soybean tolerant of glyphosate herbicide with lower saturated fatty acid and improved oleic acid content.

<sup>5</sup> Soybean tolerant of dicamba herbicide.

<sup>6</sup> Soybean tolerant of glyphosate herbicide.

<sup>7</sup> A fermented milk containing *Lactobacillus gasseri* SBT2055 as the component relevant to its specified health use, which is described as being “helpful to improve dietary life for people who are concerned about body fat or have a tendency to overweight”.

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

Pesticides

Item	ADI	ARfD
<i>Tebfenozide</i>	0.016 mg/kg bw per day	Not required
<i>Triflumizole</i>	0.015 mg/kg bw per day	0.25 mg/kg bw
Nitenpyram	0.53 mg/kg bw per day	0.6 mg/kg bw
Picarbutrazox	0.023 mg/kg bw per day	Not required
Prohydrojasmon	0.14 mg/kg bw per day	1.2 mg/kg bw
Bromacil	0.019 mg/kg bw per day	0.2 mg/kg bw

Pesticides and Additives

Item	ADI	ARfD
Fludioxonil	0.33 mg/kg bw per day	2.5 mg/kg bw

Pesticides and Veterinary medicinal products

Item	ADI	ARfD
Ethoxazole	0.04 mg/kg bw per day	Not required

Veterinary medicinal products

Item	ADI
Tolfenamic acid	0.01 mg/kg bw per day

Genetically modified foods/feeds

Item	Conclusion
L-Histidine produced using HIS-No. 2 strain	FSCJ conclusion: According to the “Stance on the Safety Assessment of Amino Acids and Other End Products” <sup>8</sup> , the item’s safety was confirmed.
Phospholipase A2 produced using PLA-54 strain	According to the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” <sup>9</sup> , the item was evaluated not to affect human health.

Antimicrobial resistant bacteria

Item	Conclusion
Antimicrobial resistant bacteria induced by Virginiamycin used for livestock	FSCJ conclusion: The use of virginiamycin, as a feed additive in chicken and pigs, may possibly cause the selection of hazards in livestock products, resulting in a decrease and/or abolishment of therapeutic effects of antibiotics for human. This potential is undeniable, and FSCJ concluded that food safety risk of the item is moderate after evaluating all the risk factors.

---

<sup>8</sup> “Stance on Safety Assessments of Amino Acids and Other End Products that are highly purified non-protein additives among additives produced using genetically modified microorganisms (Decision of the Commission dated April 28, 2005)”.

<sup>9</sup> “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (Decision of the Commission dated March 25, 2004)”.

## June 2016

Discussions from the 609th to 612nd Meetings of the Commission held on the 7th, 14th, 21st and 28th of June 2016 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations<sup>10</sup>.

Food additives	• Amendment of Standards for Food/Food additives following the amendment of Japanese Standards of Food Additives.
Veterinary medicinal products	• Pegbovigrastim
Genetically modified foods/feeds	• Assessment for use of a food additive, to a feed additive, which was previously evaluated to be of no safety concern as being highly purified.

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

### Additives

Item	Conclusion
Amendment of Standards for Food/Food additives following the amendment of Japanese Standards of Food Additives.	FSCJ conclusion: FSCJ conclude that the assessed item and inquired item correspond to the case where the contents and degree of adverse effects on human health are clear, under the Food Safety Basic Act <sup>11</sup> .

### Genetically modified foods/feeds

Item	Conclusion
β-Amylase produced using NZYM strain	FSCJ conclusion: According to the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” <sup>12</sup> , the item was evaluated not to affect human health.

---

<sup>10</sup> E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

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

<sup>12</sup> The Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (Decision of the Commission dated March 25, 2004).

L-Proline produced using ECP strain	FSCJ conclusion: According to the “Stance on the Safety Assessment of Amino Acids and Other End Products” <sup>13</sup> , the item’s safety was confirmed.
Maize MON87411 <sup>14</sup> (foods)	FSCJ conclusion: According to the “Stance on the safety assessment of genetically modified foods (seed plants)” <sup>15</sup> , Mize MON87411 was evaluated not to affect human health.
Maize MON87411 <sup>16</sup> (feeds)	FSCJ conclusion: According to the “Stance on the safety assessment of genetically modified feeds and feed additives” <sup>37</sup> , the item did not require further assessment through the “Stance on the safety assessment of genetically modified foods (seed plants)” <sup>34</sup> . Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.

Feed additives

Item	Conclusion
<i>Bacillus subtilis</i> JA-ZK strain	FSCJ conclusion: FSCJ concluded that risk to human health from the intake of the assessed item through food is negligible as long as appropriately used as a feed additive.

---

<sup>13</sup> “Stance on Safety Assessments of Amino Acids and Other End Products that are highly purified non-protein additives among additives produced using genetically modified microorganisms (Decision of the Commission dated April 28, 2005)”.

<sup>14</sup> Maize resistant to Coleoptera and tolerant of glyphosate herbicide.

<sup>15</sup> “Stance on Safety Assessments of Genetically Modified Foods (seed plants) (Decision of the Commission dated January 29, 2004)”.

<sup>16</sup> Maize resistant to Coleoptera and tolerant of glyphosate herbicide.