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

April 2019

Discussions from the 737th to 740th Meetings of the Commission held on the 2nd, 9th, 16th and 23rd of April 2019 are summarized as follows:

(1) Risk assessments on the following items were requested by risk management organizations¹.

| | |
|------------------------------------|--|
| Pesticides | <ul style="list-style-type: none"> • Diethofencarb • Picarbutrazox • Pydiflumetofen • Pyrimidifen • Bentiavalicarv-isopropyl |
| Apparatus, containers and packages | <ul style="list-style-type: none"> • Amount having no potential to cause damage to human health that is designated in the provision of Paragraph 3, Article 18 of the Food Sanitation Act. |
| Genetically modified foods/feeds | <ul style="list-style-type: none"> • L-Serine produced using SKG strain • Oilseed rape MS11 tolerant of glufosinate herbicide and male sterile. • β-galactosidase produced using JPBL003 strain • Monosodium <i>L</i>-glutamate produced using GLU-No.10 strain |
| Feed additives | <ul style="list-style-type: none"> • Phytase produced by <i>Aspergillus niger</i> generated by recombinant DNA technologies. • Amendment of Ordinance of Ministry regarding the standards for feed and feed additives (alkyl trimethyl ammonium calcium oxytetracycline and chlortetracycline) |

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

¹ 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)

Pesticides

| Item | ADI | ARfD |
|------------|------------------------|---|
| Flutianil | 2.4 mg/kg bw per day | Not required |
| bifenthrin | 0.01 mg/kg bw per day | 0.05 mg/kg bw |
| Flonicamid | 0.073 mg/kg bw per day | 3 mg/kg bw for ordinal people. 1 mg/kg bw for women who are or may be pregnant |

Veterinary medicinal products

| Item | Conclusion |
|--|--|
| Safety of food derived from wild boar orally vaccinated with the live vaccine against hog cholera. | FSCJ conclusion: FSCJ concluded that the risk to human health from the assessed item through foods derived from boars vaccinated with the hog cholera oral bait vaccine is negligible, provided it is used appropriately as veterinary medicinal products. |

Food for Specified Health Use

| Item | Conclusion |
|---------------------|--|
| Sukoyaka Sesame Oil | FSCJ conclusion: FSCJ concluded that “Sukoyaka Sesame Oil” has no obvious risk to human health as far as the documents submitted by the applicant were concerned. Since potential drug interaction of this product with anticoagulant drugs such as Warfarin cannot be excluded, caution for such drug interactions needs to be displayed as the information for the recipients and medical personnels, specifically for drugs that may have such a potential but not for every medicinal products. In addition, caution for preventing excess consumption of this product must be displayed clearly as possible, since 12-week continuous consumption study showed that the daily energy intake increased at the end of 12 weeks compared to the level before the start of the study. |

Feed additives

| Item | Conclusion |
|--|--|
| Amendment of Ordinance of Ministry of Agriculture and Forestry ² regarding standards for feed and feed additives (alkyl trimethyl ammonium calcium oxytetracycline and chlortetracycline) | FSCJ Conclusion: FSCJ conclude that the item corresponds to the case where the contents and degree of adverse effects on human health are clear ³ . |

² Ordinance of Ministry of Agriculture and Forestry, No.35, 1976

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

May 2019

Discussions from the 741st to 743rd Meetings of the Commission held on the 14th, 21st and 28th of May 2019 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations⁴.

| | |
|----------------------------------|--|
| Pesticides | <ul style="list-style-type: none"> • Isofetamid • Cyflufenamid • Dazomet • Tolpyralate • Mefentrifluconazole |
| Veterinary medicinal products | <ul style="list-style-type: none"> • An injection for veterinary use in cattle (Florgan) containing Florfenicol as an active substance. |
| Genetically modified foods/feeds | <ul style="list-style-type: none"> • Lipase produced using JPAo003 starin • Disodium 5-ribonucleotide produced using RN-No.3 strain |
| Food for Specified Health Use | <ul style="list-style-type: none"> • Healthya サツと健膳 Plain • Healthya サツと健膳 Plain Bottle • Healthya サツと健膳 Lemonlive tatste • Healthya サツと健膳 Lemonlive tatste Bottle |
| Others | <ul style="list-style-type: none"> • Partial amendment of Ordinance of Ministry following the law for partial amendment of the Food Hygiene Law etc. |

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

Pesticides

| Item | ADI | ARfD |
|------------------|------------------------|---------------|
| Picoxystrobin | 0.046 mg/kg bw per day | 0.2 mg/kg bw |
| Dichlobentiaxox | 0.05 mg/kg bw/day | Not required |
| Tolclofos-methyl | 0.064 mg/kg bw/day | 0.13 mg/kg bw |
| Fenpicoxamid | 0.32 mg/kg bw/day | Not required |

Pesticides and veterinary medicinal products

| Item | ADI | ARfD |
|------------|-----------------------|--------------|
| Permethrin | 0.05 mg/kg bw per day | 0.5 mg/kg bw |

⁴ 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)

Veterinary medicinal products

| Item | Conclusion |
|------------|--|
| Gentamycin | FSCJ conclusion: 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 ⁵ |

Food for Specified Health Use

| Item | Conclusion |
|--------------------|---|
| Vaam smartfitwater | FSCJ conclusion: FSCJ concluded that the assessed item has no obvious risk to human health as far as the documents submitted by the applicant were concerned. |

Feed additives

| Item | Conclusion |
|--|--|
| Amendment of Ordinance of Ministry of Agriculture and Forestry ⁶ regarding standards for feed and feed additives (Astaxanthin, Ethyl ester of β -apo-8'-carotenic acid and Canthaxanthin) | FSCJ conclusion: 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 ⁷ |

Others

| Item | Conclusion |
|---|--|
| Partial amendment of Ordinance of Ministry following the law for partial amendment of the Food Hygiene Law etc. | FSCJ conclusion: 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 ⁸ |

⁵ The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

⁶ Ordinance of Ministry of Agriculture and Forestry, No.35, 1976

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

⁸ The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

June 2019

Discussions from the 744th to 747th Meetings of the Commission held on the 4th, 11th, 18th and 25th of June 2019 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations⁹.

| | |
|----------------------------------|--|
| Pesticides | <ul style="list-style-type: none"> • Ipflufenoquin • Oxazosulfyl • Tebuconazole • Bixafen • Benzpyrimoxan |
| Genetically modified foods/feeds | <ul style="list-style-type: none"> • L-Ornithine hydrochloride produced using ORN-No.1 strain |

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

Pesticides

| Item | ADI | ARfD |
|-----------------------------|---------------------------------------|--|
| Iminoctadine | 0.0023 mg/kg bw per day | 0.053 mg/kg bw |
| Cartap hydrochloride | Group ADI | Group ARfD |
| Thiocyclam hydrogen oxalate | 0.016 mg/kg bw per day | 0.1 mg/kg bw |
| Bensultap | (converted into cartap hydrochloride) | (converted into cartap hydrochloride) |
| Florpyrauxifen-benzyl | 8 mg/kg bw per day | Not required |
| Buprofezin | 0.009 mg/kg bw per day | 0.5 mg/kg bw |
| Fluopyram | 0.012 mg/kg bw per day | 0.5 mg/kg bw |
| Thifluzamide | 0.014 mg/kg bw per day | 0.25 mg/kg bw |
| Pyridalyl | 0.028 mg/kg bw per day | Not required |
| Prothioconazole | 0.011 mg/kg bw per day | 1 mg/kg bw for ordinal people. 0.02 mg/kg bw for women who are or may be pregnant |

Pesticides and veterinary medicinal products

| Item | ADI | ARfD |
|----------------|-------------------------|---------------|
| Difenoconazole | 0.0096 mg/kg bw per day | 0.25 mg/kg bw |

⁹ E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

Veterinary medicinal products

| Item | Conclusion |
|--|---|
| Amostuck LA injection, an injection for veterinary use in cattle and pigs, which contains amoxicilline hydrate as an active substance. | 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. |

Apparatus, containers and packages

| Item | Conclusion |
|---|--|
| Amount having no potential to cause damage to human health that is designated in the provision of Paragraph 3, Article 18 of the Food Sanitation Act. | <p>FSCJ Conclusion: FSCJ considers that the amount having no potential to cause damage to human health can be set to 0.5 µg/kg and less as Dietary concentration. When a risk management measures are implemented for substances used in not directly food-contacting layer, setting the abovementioned amount, the followings shall be concerned.</p> <ul style="list-style-type: none"> • It shall be concerned that the substances used in not directly food-contacting layer have no genotoxic concerns. • When a substance is determined to have no potential to contaminate foods through elution or transition at the amount over that causes no damage to human health, an analytical method of which minimum detection limit is below the concentration in food simulating solution relevant to amount over that having no potential cause damage to human health should be used. |

Prions

| Item | Conclusion |
|---|---|
| Revision of control for use of meet and offal derived from goats and sheep for fertilizers. | FSCJ conclusion: FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear ¹⁰ . |
| Meat and offal of cattle, goats and sheep imported from Spain to Japan | FSCJ conclusion: Concerning the age threshold for import and definition of SRMs, a difference from the current control measure “the ban on import” in the risk to human health would be extremely small. Therefore, |

¹⁰ The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act,

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|--|--|
| | the effects on human health of this change of the border measure are negligible. |
|--|--|

Antimicrobial-resistant bacteria

| Item | Conclusion |
|---|---|
| An injection for veterinary use into pigs, Zuprevo 40 injection, containing Tildipirosin as an active substance | FSCJ conclusion: The use of the assessed macrolide antimicrobial agent. for cattle, pigs and chicken may possibly cause hazards, and humans may be exposed to the hazards through livestock products derived from these livestock animals, resulting in a decrease and/or abolishment of therapeutic effects of antibiotics for humans. Although this possibility is not excluded, food safety risk of the item is evaluated to be low. Regarding honeybee and hives, the degree of the risk was considered to be negligible, since there is no hazard to be caused.. |