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

October 2019

Discussions from the 759th to 762nd Meetings of the Commission held on the 1st, 8th, 15th and 29th of October 2019 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations¹.

Food additives	<ul style="list-style-type: none"> • L-potassium tartrate • DL- potassium tartrate • Metatartaric acid • Calcium carbonate
Pesticides	<ul style="list-style-type: none"> • Imazapyr
Chemicals and contaminants	<ul style="list-style-type: none"> • Amendment of regulation level of methanol in alcoholic beverage.
Microorganisms and viruses	<ul style="list-style-type: none"> • Examination items for formula milk pertaining the Ministerial Ordinance on Milk, etc. • Amendment of processing criteria of milk and others designated by the Ministerial Ordinance on Milk, etc.
Prions	<ul style="list-style-type: none"> • Resume use of equine MBM for fertilizers for pigs, chicken or Japanese quails. • Use of cattle MBM for feeds in fish farming or for fertilizers.
Genetically modified foods/feeds	<ul style="list-style-type: none"> • Glucose oxidase produced using ZGL strain • Sugarcane resistant to Lepidoptera CTC175-A • Sodium glutamate produced using CA02-1191 strain
Food for specified health uses	<ul style="list-style-type: none"> • Toku Beef Salacia Premium

(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).

Pesticides

Item	ADI	ARfD
Tebuconazole	0.029 mg/kg bw per day	0.3 mg/kg bw
Diquat	0.0058 mg/kg bw per day	0.75 mg/kg bw
Pyrimidifen	0.0015 mg/kg bw per day	0.04 mg/kg bw
Broflanilide	0.017 mg/kg bw per day	Not required
1,3-Dichloropropene	0.02 mg/kg bw per day	0.2 mg/kg bw
Oxathiapiprolin	3.4 mg/kg bw per day	Not required
Cyclanilprole	0.012 mg/kg bw per day	Not required

Chemicals and contaminants

Item	Conclusion
Amendment of regulation level of methanol in alcoholic beverage	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 ² .

Microorganisms and viruses

Item	Conclusion
Amendment of processing criteria of milk and others designated by the Ministerial Ordinance on Milk, etc.	FSCJ conclusion: The assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act ³ .

Prions

Item	Conclusion
Resume use of equine MBM for fertilizers for pigs, chicken or Japanese quails.	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 ² .
Use of cattle MBM for feeds in fish farming or for fertilizers.	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 ² .

² The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

³ Amendment of processing criteria 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.

Genetically modified foods/feeds

Item	Conclusion
Potato SPS-000Y9-7 (foods)	FSCJ conclusion: According to the “Stance on the safety assessment of genetically modified foods (seed plants)” ⁴ , potato SPS-000Y9-7 was evaluated not to affect human health.
Potato SPS-000Y9-7 (feeds)	FSCJ conclusion: According to the “Stance on the safety assessment of genetically modified feeds and feed additives” ⁵ , the item did not require further assessment through the “Stance on the safety assessment of genetically modified foods (seed plants)” ⁴ . Hence, livestock products derived from animals t consumed the item have no concern relevant to human health.
Oilseed rape MS11 tolerant of glufosinate herbicide and male sterile. (food)	FSCJ conclusion: According to the “Stance on the safety assessment of genetically modified foods (seed plants)” ⁴ , oilseed rape MS11 was evaluated not to affect human health.
Oilseed rape MS11 tolerant of glufosinate herbicide and male sterile. (feeds)	FSCJ conclusion: According to the “Stance on the safety assessment of genetically modified feeds and feed additives” ⁵ , the item did not require further assessment through the “Stance on the safety assessment of genetically modified foods (seed plants)” ⁴ . Hence, livestock products derived from animals that consumed the item have no concern relevant to human health.

⁴ “Stance on Safety Assessments of Genetically Modified Foods (seed plants) (Decision of the Commission dated 29 January 2004)”

⁵ “Stance on Safety Assessments of Genetically Modified Feed and Feed Additives (Decision of the Commission dated 6 May 2004)”

November 2019

Discussions from the 763rd to 765th Meetings of the Commission held on the 12th, 19th and 26th of November 2019 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations⁶.

- No items requested.

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

Pesticides

Item	ADI	ARfD
Pydiflumetofen	0.099 mg/kg bw per day	0.3 mg/kg bw

Veterinary medicinal products

Item	ADI
Tildipirosin	0.03 mg/kg bw per day
Nanafrocin	0.01 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
Injection for veterinary use in pigs, Zuprevo 40 injection containing Tildipirosin (PMT) as an active substance.	FSCJ conclusion: Risk to human health from the assessed item through food consumption is negligible as long as it is appropriately used.
Foods derived from pigs received Suvaxyn® CSF Marker Vaccine.	FSCJ conclusion: Risk to human health from the assessed item through food consumption derived from pigs vaccinated with this product is negligible as long as it is appropriately used.

Genetically modified foods

⁶ E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

Item	Conclusion
L-leucine produced using LG-108 strain.	FSCJ conclusion: According to the “Stance on the Safety Assessment of Amino Acids and Other End Products” ⁷ , the item’s safety was confirmed. Therefore, the item did not require further assessment through the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” ⁸ .
Cyanocobalamin produced using SCM2034 strain	FSCJ conclusion: According to the “Stance on the Safety Assessment of Amino Acids and Other End Products” ⁹ , the item’s safety was confirmed. Therefore, the item did not require further assessment through the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” ¹⁰ .
L-methionine produced using K12KCCM11252P and K12KCCM11340P strains	FSCJ conclusion: According to the “Stance on the safety assessment of amino acids and other end products” ³⁸ , FSCJ concluded that livestock products derived from animals which consumed the item have no concern relevant to human health. Therefore, the item did not require further assessment through the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” ¹¹

Formula milk using bacterial powder as a raw material

Item	Conclusion
Examination items for formula milk pertaining the Ministerial Ordinance on Milk, etc.	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 ¹² .

⁷ “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 28 April 2005)”

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

⁹ “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 28 April 2005)”

¹⁰ “the Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)”

¹¹ “the Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)”

¹² The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

December 2019

Discussions from the 766th to 768th Meetings of the Commission held on the 3rd, 17th and 24th of December 2019 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations¹³.

Pesticides	<ul style="list-style-type: none"> • Tioxazafen • Pymetrozine • Pyrifluquinazon • Prochloraz • Prohydrojasmon • Flometoquin
Veterinary medicinal products	<ul style="list-style-type: none"> • "KYOTO BIKEN" Cattlewin-5Hs Bovine Vaccine for prevention of infectious bovine rhinotracheitis, bovine viral diarrhoea- mucosal disease, bovine parainfluenza, bovine respiratory syncytial virus infection, bovine adenovirus infection infection and Histophilus somni infection. • Tildipirosin
Apparatus and containers / packages	<ul style="list-style-type: none"> • Amendment of the Standards and Criteria for Apparatus and containers / packages designated in standards for foods and additives¹⁴ and in the Ordinance of the Ministry of Welfare, No.52, 1951¹⁵, according to paragraph (1) of article 18 of the Food Hygiene Law.
Genetically modified foods/feeds	<ul style="list-style-type: none"> • Xylanase produced using CF307 strain • Xylanase produced using JPBL006 strain. • Xylanase produced using JPAo004 strain • Xylanase produced using JPAo005 strain
Feed additives	<ul style="list-style-type: none"> • Muramidase

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

¹⁴ 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.

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

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

Pesticides

Item	ADI	ARfD
Tolpyralate	0.0076 mg/kg bw per day	0.1 mg/kg bw

Veterinary medicinal products

Item	Conclusion
<p>”KYOTO BIKEN” Cattlewin-5Hs; Bovine Vaccine for prevention of infectious bovine rhinotracheitis, bovine viral diarrhea- mucosal disease, bovine parainfluenza, bovine respiratory syncytial virus infection, bovine adenovirus infection infection and Histophilus somni infection.</p>	<p>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 Act².</p>

Apparatus and containers / packages

Item	Conclusion
<p>Amendment of the Standards and Criteria for Apparatus and containers / packages designated in standards for foods and additives¹⁶ and in the Ordinance of the Ministry of Welfare, No.52, 1951¹⁷, according to paragraph (1) of article 18 of the Food Hygiene Law.</p>	<p>FSCJ conclusion: Regarding amendment of notification on standards and criteria, the item corresponds to the case where the contents and degree of adverse effects on human health are clear, as long as it is complied with the amended standards, under the Food Safety Basic Act¹⁸. Regarding deletion of a part of provision in the standards accompanying the amendment, the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act¹⁹.</p> <p>With regard to amendment of the Ministerial Ordinance on Milk, etc., the following items among those to be deleted from</p>

¹⁶ 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.

¹⁷ The Ordinance of the Ministry of Welfare, No.52, 1951, regarding standard of element and others of milk and dairy products.

¹⁸ The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

¹⁹ Deletion 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.

	<p>standards and to be described with a partial modification in the Ministerial Ordinance on Milk, etc. correspond to the case where the assessment of food safety risk is evidently unnecessary according to Food Safety Basic Act²⁰. The item 1; sorting out of legal affairs in the standards and criteria for apparatus and containers / packages, and item 2; revision of standards and criteria for apparatus and containers /packages (without changes in the standard values).</p> <p>With regard to revision of Standards and Criteria for apparatus and containers / packages (4 items), the items fall under the category which is the case where the contents and degree of adverse effects on human health are clear⁶.</p>
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Natural toxins / mycotoxins

Item	Conclusion
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²⁰ Amendment 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.

Deoxynivalenol	<p>FSCJ conclusion: According to the estimation of exposure level to deoxynivalenol (total), the exposure level in our country was considered to be below the TDI (1 µg/kg bw/day) at the present. Whilst, the exposure level in the cohort of people aged 1 to 6 years old is close to the TDI, and may exceed the TDI depend on their eating situation or on the situation of contamination from deoxynivalenol. Exposure from other than grains is also possible. Therefore, the risk management organizations need to endeavor continuously to take reduction measure, taking into consideration these possibilities.</p> <p>In addition, the exposure level may be under- or over-estimated due to the uncertainty of the used data or characteristics of methodology used for the statistical analysis. In consideration of these points, the risk management organizations must collect information or take a survey that enables an estimation of exposure level of deoxynivalenol (total) as close as the actual situation.</p> <p>As a future subject, risk management organizations should conduct more precise exposure assessment based on the concentration of deoxynivalenol in flour and its final products and food intake level when they are available, and should consider the reduction measures including introduction of Codex standards.</p>
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