

Monthly Update on Activity of the Food Safety Commission of Japan (FSCJ)

April 2015

Discussions from the 556th to 559th Meetings of the Commission held on the 7th, 14th, 21st and 28th of April 2015 are summarized as follows:

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

Veterinary medicinal products	<ul style="list-style-type: none"> • Florfenicol • Flunixin meglumine • An injection for veterinary use in cattle, Resfrol, which contains florfenicol and flunixin meglumine as active components. • A feed additive for use in cattle and an additive to drinking water for pigs, Florocol 2% solution, which contains florfenicol as an active component.
Prions	<ul style="list-style-type: none"> • Cattle meat and offal imported from Denmark.
Genetically modified foods / feeds	<ul style="list-style-type: none"> • Maize MON874112 • Glutamyl-valyl-glycine produced using DP-No.2 line and GG-No.1 line.

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

Exempted Substances³

Item	Conclusion
<ul style="list-style-type: none"> • Itaconic acid • Polyglyceryl fatty acid esters 	FSCJ conclusion: FSCJ concluded that risks of the assessed items on human health through remaining in livestock products are negligible as long as normally used as pesticides.

Veterinary medicinal products

Item	ADI
Closantel	0.025 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
Dimetridazole	FSCJ conclusion: FSCJ could not specify the ADI for this substance because of the following facts. <ol style="list-style-type: none"> 1. Relevant substance has a potential to form a residue covalently bound to DNA. 2. Potential of genotoxicity could not be judged while carcinogenicity was suggested for this substance. 3. An index such as NOAEL which is appropriate for specifying an ADI could not be obtained.

Apparatus and Containers /Packages

Item	ADI
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¹ E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

² Maize resistant to Coleoptera and tolerant of glyphosate herbicide.

³ On May 29, 2006 the Ministry of Health, Labour and Welfare (MHLW) introduced the positive list system for agricultural chemicals remaining in foods to prohibit the distribution of foods that contain agricultural chemicals above a certain level if maximum residue limits (MRLs) have not been established. Exempted Substances are designated as substances having no potential to cause damage to human health by the Minister of Health, Labour and Welfare, based on the provision of Paragraph 3, Article 11 of the Food Sanitation Law, and these substances are not subjected to the positive list system.

Butyl benzyl phthalate	0.2 mg/kg bw per day
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Prions

Item	Conclusion
<ul style="list-style-type: none"> • Cattle meat and offal imported from Sweden • Cattle meat and offal imported from Norway 	FSCJ conclusion: A difference between “the ban on import” and setting a restriction of cattle age and definition of SRMs for import in the risk to human health that could arise from consumption of BSE prion in meat and offal would be extremely small. Therefore, the effects of this change in the border measure on human health are negligible.

Genetically modified foods/feeds

Item	Conclusion
Alfalfa KK179 line with low level of lignin (foods).	FSCJ conclusion: According to the “Stance on the safety assessment of genetically modified foods (seed plants)” ⁴ , Alfalfa KK179 line was evaluated not to affect human health.
Alfalfa KK179 line with low level of lignin (feed).	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)” ³ . Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.
Alpha-amylase produced using NZYM-S0 line.	FSCJ conclusion: According to the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” ⁶ , the item was evaluated not to affect human health.
Glutamyl-valyl-glycine produced using DP-No.2 line and GG-No.1 line. Monosodium L-glutamate produced using GLU-No.7 strain.	According to the “Stance on the safety assessment of amino acids and other end products” ⁷ , FSCJ concluded that livestock products derived from animals which consumed the item have no concern relevant to human health.
Cotton 1910 line ⁸ (foods).	According to the “Stance on the safety assessment of genetically modified foods (seed plants)” ³ , the item was evaluated not to affect human health.
Cotton 1910 line ⁹ (feeds)	According to the “Stance on the safety assessment of genetically modified feeds and feed additives” ⁴ , the item did not require further assessment through the “Stance on the safety assessment of genetically modified foods (seed plants)” ³ . Hence, livestock products derived from animals which 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)”

⁶ “the Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)”

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 Cotton tolerant of aryloxyalkanoate and glufosinate herbicides

⁹ Cotton tolerant of aryloxyalkanoate and glufosinate herbicides

Antimicrobial resistant bacteria

Item	Conclusion
Ceftiofur	FSCJ conclusion: The use of the item, as a veterinary medicinal product in cattle 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. FSCJ concluded that food safety risk of the item is moderate after evaluating all the risk factors.