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

July 2015

Discussions from the 568th to 571st Meetings of the Commission held on the 1st, 7th, 14th and 28th of July 2015 are summarized as follows:

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

Genetically modified foods / feeds	・L-cysteine hydrochloride produced using CYS-No.1 strain. ・Hybrid stacks of alfalfa J101[2] x alfalfa KK179[3]. ・Amendment of Ordinance of Ministry of Agriculture, Forestry and Fisheries, No.35, 1976[4]

[1] E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).
[2] Alfalfa tolerant of glyphosate herbicide.
[3] Alfalfa with a low content of lignin.
[4] Amendment of Ordinance of Ministry of Agriculture and Forestry (1976, No.35) regarding the standards for feed and feed additives.

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

Pesticides

Item	ADI	ARfD
Oxathiapiprolin	3.4 mg/kg bw per day	Not required
Fluazifop	0.0044 mg/kg bw per day	0.02 mg/kg bw for pregnant women and women expected to be pregnant. Not required for ordinal people.
Benthiavalicarb-isopropyl	0.069 mg/kg bw per day	Not required
Thiamethoxam	0.018 mg/kg bw per day	0.5 mg/kg bw

Pesticides and Veterinary medicinal products

Item	ADI	ARfD
Diflubenzuron	0.02 mg/kg bw per day	Not required

Veterinary medicinal products

Item	ADI
Enrofloxacin	0.002 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
・ Bopriva, an injection for veterinary use into cattle, containing a conjugate of 2-10-gonadotropin releasing hormone analogue with diphtheria toxoid as an active ingredient.	FSCJ conclusion: Risk to human health from the assessed item through food consumption is negligible as long as appropriately used.

Veterinary medicinal products and Feed additives

Item	Conclusion
Monensin	FSCJ conclusion: FSCJ specified ADI for Monensin to be 0.003 mg/kg bw per day.

	As for monensin sodium, FSCJ concluded that the risk to human health from the item through food consumption is negligible as long as appropriately used as a feed additive.

Apparatus and Containers /Packages

Item	Conclusion
Apparatus and Containers /Packages made with synthetic resin of which the main component is polyethylennaphtalate (PEN).	FSCJ conclusion: Considering that specific standards for the assessed item based on the Food Hygiene Law are not yet established, setting of new standards unlikely increases a potential to raise risk to human health as long as conventional usage is not changed and conventional dosage is not increased.

Prions

Item	Conclusion
Cattle meat and offal imported from Denmark	FSCJ conclusion: A difference in the risk to human health that could arise from consumption of BSE prion in meat and offal, before and after the changes in restriction of cattle age and definition of SRMs, would be extremely small. Therefore, the effects on human health of this change of the border measure are negligible.

Genetically modified foods/feeds

Item	Conclusion
Amendment of Ordinance of Ministry of Agriculture and Forestry[5]regarding standards for feed and feed additives.	FSCJ conclusion: Effects on human health from livestock products derived from animals which consumed relevant feed additives are not affected by this amendment, because the safety of relevant feed additives is examined the same as that of the food additives produced using genetically modified

[5] Ordinance of Ministry of Agriculture and Forestry, No.35, 1976

	microorganisms. Hence, FSCJ concluded that the item comes under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act[6].
Glutamyl-valyl-glycine produced using DP-No.2 strain and GG-No.1 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.

Antimicrobial resistant bacteria

Item	Conclusion
Draxxin C, an injection for veterinary use into cattle, containing tulathromycin as an active ingredient.	FSCJ conclusion: The use of the item for cattle as an injection for veterinary use may possibly cause hazards, and humans may be exposed to the hazards through livestock products derived from cattle, 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.

[6] The item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act designates the case where the contents and degree of adverse effects on human health are clear.

[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)"