Monthly Update on Activity of the Food Safety Commission of Japan (FSCJ) March 2014

Discussions from the 505th to 509th Meetings of the Commission held on the 3rd, 10th, 17th, 24th and 31st of March 2014 are summarized as follows:

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

Pesticides	Kresoxim-methyl	
	Phenmedipham	
Veterinary medicinal	Trenbolone acetate	
products	· Robenzidine · Mosapride	
	• "PRONAMID Powder 1%", containing mosapride citrate as an active	
	ingredient, for veterinary use by oral administration into horses.	
Microorganisms and viruses	· Amendment of Ministerial Ordinance on Milk and Milk products	
	Concerning Compositional Standards, etc. ²	
	[1] Specific gravity and acidity of raw milk and others, and milk fat and others	
	of pasteurized goat's milk.	
	[2] Composition standards of fermented milk.	
Genetically modified foods	• Soybean 44406 line ³	
etc.	• Soybean FG72 ⁴	
	• Hybrid stack of cotton; COT102 ⁵ x 15985 line ⁶ x MON88913 ⁷ .	

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

Pesticides

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Item	ADI
Imazapyr	2.8 mg/kg bw per day
Phosalon	0.002 mg/kg bw per day
Benthiavalicarb-isopropyl	0.069 mg/kg bw per day
Metconazole	0.02 mg/kg bw per day
Ethiprole	0.005 mg/kg bw per day
Kasugamycin	0.094 mg/kg bw per day
Pirimicarb	0.018 mg/kg bw per day

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

² Ministry of Health and Welfare Ordinance No. 52, December 27, 1951

³ Soybean tolerant to aryloxy alkanoate, glyphosate and glufosinate herbicide.

⁴ Soybean tolerant to glyphosate and isoxaflutole herbicides.

⁵ Cotton resistant to Lepidoptera.

⁶ Cotton resistant to Lepidoptera.

⁷ Cotton tolerant to glyphosate herbicide.

Veterinary medicinal products

Item	ADI
Moxidectin	0.003 mg/kg bw per day

Veterinary medicinal products

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Item	Conclusion
Chloramphenicol	FSCJ conclusion: Concerning chloramphenicol, possible
	genotoxicity is considered, potential of carcinogenicity
	cannot be ruled out, and it is likely to have an association
	with aplastic anemia without dose-dependency in
	human. Therefore, it is not appropriate to specify an
	ADI for chloramphenicol.
Reexamination of Prid Teizo, an intravaginal	FSCJ conclusion: Risk of the use of the assessed item on
intercalating agent containing progesterone and	human health through food consumption is negligible as
estradiol benzoate as active ingredients, used for	long as appropriately used.
estrous cycle synchronization in cows.	

Microorganisms and viruses

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Item	Conclusion		
Amendment of Ministerial Ordinance on Milk	FSCJ conclusion: Since the item does not concern an		
and Milk products Concerning Compositional	amendment of the elements directly relevant to hygienic		
Standards, etc. ²	issues, the amendment is unlikely to increase risk to human		
[1] Specific gravity and acidity of raw milk and	health from intake of milk. Therefore, the item is		
others, and milk fat and others of pasteurized	considered to be of no concern for food safety.		
goat's milk.	Accordingly, the FSCJ concluded that the item falls under		
	the category which is the case where the contents and		
	degree of adverse effects on human health are clear ⁸ .		
Amendment of Ministerial Ordinance on Milk	FSCJ conclusion: The assessed amendment is composed		
and Milk products Concerning Compositional	of: an addition of pasteurized fermented milk to the		
Standards, etc. ²	elements of fermented milk, an increase of pasteurizing		
[2] Composition standards of fermented milk.	temperature for fermented milk, and an addition of an		
	examination adapted to the optimum temperature for		
	multiplication of the bacteria used for the fermentation.		
	The amendment is unlikely to increase risk to human health		
	from intake of the fermented milk, and the item is		
	considered to be of no concern for food safety.		

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

Accordingly, the FSCJ concluded that the item falls under the category which is the case where the contents and degree of adverse effects on human health are clear⁹.

*FSCJ decided to notify the relevant conclusion to the risk management organizations, with an additional remark that this assessment is not that of lactobacillus or yeast itself used for producing fermented milk.

Genetically modified foods/feeds

Item	Conclusion
Hybrid stack of cotton; COT102 ⁹ x 15985 line ¹⁰ x	FSCJ conclusion:
MON88913 ¹¹ .	Based on the "Approach to the safety assessment of
(Two events from the relevant crosses, for which the	Genetically Modified Plant Hybrids" 12, the item did
assessment has been done, are not included.)	not require further safety assessment.

⁹ Cotton resistant to Lepidoptera.

¹⁰ Cotton resistant to Lepidoptera.

¹¹ Cotton tolerant to glyphosate herbicide.

¹² "Approach to the safety assessment of Genetically Modified Plant Hybrids (Decision of the Commission dated 29 January 2004).