

Monthly Update on Activity of the Food Safety Commission of Japan (FSCJ) April 2013

Discussions from the 469th to 472nd Meetings of the Commission, held on the 1st, 8th, 15th and 22nd of April 2013, are summarized as follows:

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

Chemicals and contaminants	<ul style="list-style-type: none"> • Revision of standards for beverages.
Prions	<ul style="list-style-type: none"> • Cattle meat and offal imported from Ireland and Poland. • Cattle meat and offal imported from Brazil.
Genetically modified foods/feeds	<ul style="list-style-type: none"> • Stacked event of soybean obtained from crosses between the following two lines: <Soybean MON87705 line, tolerant to glyphosate with lower saturated fatty acid and improved oleic acid content > <Soybean MON89788 line tolerant to glyphosate herbicide > • Stacked event of maize obtained from crosses between the following five lines:<Maize MON87427 line, male sterile and tolerant to glyphosate herbicide> <Maize MON89034 line, resistant to Lepidoptera> <Maize 1507 line, resistant to Lepidoptera and tolerant to glufosinate herbicide> <Maize MON88017 line, resistant to Coleoptera and tolerant to glyphosate herbicide > <Maize resistant to Coleoptera and tolerant to glufosinate herbicide B.t. Cry34/35Ab1 Event DAS-59122-7 line> • Stacked event of maize obtained from crosses between the following three lines: <Maize MON87427 line, male sterile and tolerant to glyphosate herbicide> <Maize MON89034 line, resistant to Lepidoptera> <Maize NK603 line, tolerant to glyphosate herbicide> • Alpha-amylase produced by use of bacillus subtilis MDT121 line.

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

Food additives

Item	Conclusion
Calcium acetate	FSCJ conclusion: The assessed item is considered to be of no concern for food safety as long as used appropriately as a food additive. Therefore, it is not necessary to specify ADI.
Calcium oxide	FSCJ conclusion: The assessed item is considered to be of no concern for food

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

	safety as long as used appropriately as a food additive. Therefore, it is not necessary to specify ADI.
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Pesticides

Item	ADI
Famoxadone	0.006 mg/kg bw per day
Fluxapyroxad	0.021 mg/kg bw per day
Penthiopyrad	0.081 mg/kg bw per day
Oxine-copper	0.01 mg/kg bw per day
Flumetsulam	1 mg/kg bw per day
Penflufen	0.02 mg/kg bw per day

Veterinary medicines

Item	Conclusion
Gall N Tect S95-IB (Avian infectious bronchitis (S95-P7 line) vaccine, live)	FSCJ conclusion: Risk to human health from the assessed item through consumption is negligible as long as appropriately used.
Equi N Tect ERP (Equine rhinopneumonitis vaccine, live))	FSCJ conclusion: Risk to human health from the assessed item through consumption is negligible as long as appropriately used.
TSV-2 (Mixed live vaccine against bovine infectious rhinotracheitis and bovine parainfluenza)	FSCJ conclusion: Risk to human health from the assessed item through consumption is negligible as long as appropriately used.
“Kyoto Biken” CATTLEWIN-6 (Infectious Bovine Rhinotracheitis • Bovine Virus Diarrhea Mucosal Disease (bivalent) • Bovine Parainfluenza • Bovine Respiratory Syncytial Virus & Bovine Adenovirus Infection Vaccine, live) : Re-assessment	FSCJ conclusion: Risk to human health from the assessed item through consumption is negligible as long as appropriately used.

Genetically modified foods/feeds

Item	Conclusion
Maize of MON87427 line, male sterile and tolerant to glyphosate herbicide (food)	FSCJ conclusion: According to the “Approach to the Safety Assessment of Genetically Modified Foods (seed plants),” ² MON87427 line was determined not to affect human health.
L-Arginine produced by genetically modified strain ARG-No.3	FSCJ conclusion: According to the “Approach to the Safety Assessment of Amino Acids and Other End Products,” ³ the item’s

² “Approach to the Safety Assessment of Genetically Modified Foods (seed plants) (Decision of the Commission dated 29 January 2004)”

³ “Approach to the Safety Assessment of Amino Acids and Other End Products that are highly purified non-protein

	safety was confirmed.
Maize of MON87427 line, male sterile and tolerant to glyphosate herbicide (feed)	FSCJ conclusion: According to the “Approach to the Safety Assessment of Genetically Modified Feeds and Feed Additives,” ⁴ the item did not require further assessment. Hence, the food safety risk from the item through livestock products was evaluated to be negative.

Chemicals and contaminants

Item	TDI
Dichloroacetic acid in beverages	12.5 µg /kg bw per day for non-carcinogenicity 12.9 µg /kg bw per day for carcinogenicity 7.8 x 10 ⁻³ (mg/kg bw per day) as Unit risk for carcinogenicity
Bis(2-ethylhexyl)phthalate) in beverages	0.03 mg/kg bw per day

Chemicals and contaminants

Item	Conclusion
Revision of standards for beverages.	FSCJ conclusion: Regarding the items for which standards to be established in relation to revision of framework of standards for beverages, except zinc, ferrum, calcium and magnesium (hardness) among others, and sulfides, the FSCJ concluded that the items come under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act, that is the case where the contents and degree of adverse effects on human health are clear. Regarding sorting out of legal affairs and change of analysis methods, the items come under item (i) of the above-mentioned paragraph (1), that is the case where assessment of the food safety risk is evidently unnecessary.

Prions

Item	Conclusion
Use of cattle MBM, derived from regions of body, for fertilizers.	FSCJ conclusion: To the extent that measures established by the Ministry of Agriculture, Forestry and Fisheries are taken, the effect on human health of the fertilizers made with cattle MBM derived from regions of the body is considered not to be different from currently used fertilizers made without it. Accordingly, the FSCJ concluded that the item comes under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act, in

additives among additives produced using genetically modified microorganisms (Decision of the Commission dated 28 April 2005)”

⁴ “Approach to the Safety Assessment of Genetically Modified Feed and Feed Additives (Decision of the Commission dated 6 May 2004)”

	which the contents and degree of adverse effects on human health are clear.
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Feed additives and Veterinary medicines

Item	Conclusion
Inositol, Cobalamin, Tyamine, Niacin, Pantothenic acid, Biotin, Pyridoxine, Folic acid and Riboflavin.*	FSCJ conclusion: Risk to human health from the assessed items through consumption is negligible as long as normally used as veterinary medicines and feed additives.

* The reliability of the assessed items is decided by the MHLW based on paragraph (3) of article 11 of the Food Hygiene Law, and that its risk on human health is evidently negligible.

Antimicrobial resistant bacteria

Antimicrobial-resistant bacteria regarding the approval of Semduramicin	FSCJ conclusion: Food safety risk from the item to human health through consumption of livestock products is determined to be negligible.
Antimicrobial resistant bacteria regarding the approval of Lasalocid sodium	FSCJ conclusion: FSCJ conclusion: Food safety risk from the item to human health through consumption of livestock products is determined to be negligible.