

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

Discussions from the 480th to 483rd Meetings of the Commission held on the 1st, 8th, 22nd and 29th of July 2013 are summarized as follows:

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

Veterinary medicinal products	• Reevaluation of an injection for cattle (Metacam 2% injection) containing Meloxicam as an active ingredient.
Genetically modified foods/feeds	• Hybrid stacks between the following three lines: <Cotton tolerant to glyphosate herbicide GHB614 line> <Cotton resistant to Lepidoptera and tolerant to glufosinate herbicide T304-40 line> <Cotton resistant to Lepidoptera and tolerant to glufosinate herbicide GHB119 line> • Maize resistant to Lepidoptera, resistant to Coleoptera and tolerant to glufosinate herbicide DP-004114-3 line.

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

Food additives

Item	ADI
Advantame	5.0 mg/kg bw per day

Food additives

<ul style="list-style-type: none"> • Sunflower lecithin • Polyvinylpyrrolidone 	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.
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Pesticides and additives

Item	ADI
Azoxystrobin	0.18 mg/kg bw per day

Pesticides

Item	ADI
Glufosinate	0.0091 mg/kg bw per day
Chlorfenapyr	0.026 mg/kg bw per day
Cyazofamid	0.17 mg/kg bw per day
Bifenthrin	0.01 mg/kg bw per day
Metconazole	0.02 mg/kg bw per day
Acetochlor	0.011 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).

Pesticides

Item	TDI
Heptachlor	0.00012 mg/kg bw per day

Pesticides and veterinary medicinal products

Item	ADI
Fenvalerate	0.017 mg/kg bw per day

Veterinary medicinal products

Item	ADI
Apramycin	0.030 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
<ul style="list-style-type: none"> • “Banamine Paste” oral administrating agent containing Flunixin Meglumine as active ingredients for horses • Reevaluation of “Metacam 2% injection” Injection for cattle containing Meloxicam as an active ingredients • “Kyoto Biken MARINA-4 ” Iridoviral Disease, Vibriosis in Yellowtail, α-haemolytic Streptococcosis & Pseudotuberculosis combined Vaccine (Polysaccharide adjuvant), Inactivated 	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	ADI
Flavophospholipol	0.048 mg/kg bw per day

Chemicals and contaminants

Item	TDI
Nitrite nitrogen related to standard for quality of drinking water supplied by the tap.	Nitrate nitrogen: 1.5 mg/kg bw per day Nitrite nitrogen: 15 μ g/kg bw per day

Prions

Item	Conclusion
Use of cattle MBM, derived from regions of body, for fertilizers.	FSCJ conclusion: To the extent that measures designated from the MAFF are taken, the effect on human health of “fertilizers and others made with cattle MBM” are considered not to be different from currently used fertilizers without cattle MBM. Accordingly, FSCJ concluded that the item comes under article 11 paragraph (1) item (ii) of the Food Safety Basic Act where the contents and degree of adverse effects on human health are clear.

Natural toxin / mycotoxin

Item	Conclusion
Aflatoxin M1 in milk and Aflatoxin B1 in feeds	FSCJ conclusion: Risks of Aflatoxin B1 in feeds on human health through milk and other livestock products are considered to be extremely low at present. However, Aflatoxin M1 and some of its metabolites possibly remaining in these livestock products are genotoxic carcinogenics. Consequently contamination of feeds with Aflatoxin B1 and contamination of milk with Aflatoxin M1 should be suppressed to an ALARA (as low as reasonably achievable) level.

Genetically modified foods/feeds

Item	Conclusion
Cotton tolerant to glufosinate herbicide and resistant to Lepidoptera T304-40 line. (feed)	FSCJ conclusion: As a result of the assessment based on the “Approach to the Safety Assessment of Genetically Modified Feeds and Feed Additives” ² , the item did not require further assessment. Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.
<ul style="list-style-type: none"> • Hybrid stacks between the following three lines: <Maize male sterile and tolerant to glyphosate herbicide MON87427 line> <Maize resistant to Lepidoptera MON89034 line> <Maize tolerant to glyphosate herbicide NK603 line> (1 species from the relevant crosses, for which the assessment has been done, is not included) • Hybrid stacks between the following five lines:<Maize male sterile and tolerant to glyphosate herbicide MON87427 line> <Maize resistant to Lepidoptera MON89034 line> <Maize resistant to Lepidoptera and tolerant to glufosinate herbicide 1507 line> <Maize resistant to Coleoptera and tolerant to glyphosate herbicide MON88017 line> <Maize resistant to Coleoptera and tolerant to glufosinate herbicide B.t. Cry34/35Ab1 Event DAS-59122-7 line> (11 species from the relevant crosses, for which the assessment has been done, are not included) 	FSCJ conclusion: According to the “Approach to the Safety Assessment of Genetically Modified Plant Hybrids” ³ , the item did not require further assessment.

² “Approach to the safety assessment of genetically modified feed and feed additives (Decision of the Commission dated 6 May 2004)”

³ “Approach to the Safety Assessment of Genetically Modified Plant Hybrids (Decision of the Commission dated 29 January 2004)”

<ul style="list-style-type: none">• Hybrid stacks between the following four lines: <Cotton resistant to Lepidoptera and tolerant to glufosinate herbicide 281 line> <Cotton resistant to Lepidoptera and tolerant to glufosinate herbicide 3006 line> <Cotton resistant to Lepidoptera COT102 line> <Cotton tolerant to glyphosate herbicide MON88913 line> (2 species from the relevant crosses, for which the assessment has been done, are not included)	
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