

Monthly update on Activity of the Food Safety Commission of Japan (FSCJ) October 2012

448th to 451st Meetings of the Commission held on 1st, 15th, 22nd and 29th of October 2012 had discussion summarized as follows:

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

Food additives	<ul style="list-style-type: none"> • Asparaginase produced by genetically modified strain ASP-72 • 5-methylquinoxaline
Pesticides	<ul style="list-style-type: none"> • Imidacloprid
Veterinary medicines	<ul style="list-style-type: none"> • “Mpac” (Inactivated mycoplasma hyopneumoniae vaccine) (adjuvant/oil adjuvant mixture) • “Respifend MH-One FDAH “ (Inactivated mycoplasma hyopneumoniae vaccine) (carboxyvinylpolymer adjuvant/oil adjuvant mixture) • “EquineTect ERP “ (Equine rhinopneumonitis live vaccine) • “Ingelbach PRRS Live Vaccine “ (Porcine reproductive and respiratory syndrome live vaccine) • “Kyoto Biken Poulsaver IB “ (Avian infectious bronchitis Live Vaccine) • “Kyoto Biken Cattlewin-6” (Mixed vaccine against bovine infectious rhinotracheitis-bovine virus diarrhea-mucosal disease-bovine parainfluenza-bovine RS virus-bovine adenovirus)
Genetically modified foods	<ul style="list-style-type: none"> • Asparaginase produced by genetically modified strain ASP-72
Food with health claims	<ul style="list-style-type: none"> • “SUHADA Water” (beverage)

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

Food additives

Item	Conclusion
5-methylquinoxaline	The item has been assessed for risks on human health by FSCJ, and new scientific finding on safety risks of the item was not available. Consequently, FSCJ concluded that the item comes under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

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

Pesticides

Item	ADI
Thifluzamide	0.014 mg/kg bw per day
Fluopyram	0.012 mg/kg bw per day
Bifenazate	0.01 mg/kg bw per day
Pyraclostrobin	0.034 mg/kg bw per day
Flubendiamide	0.017 mg/kg bw per day
Difenoconazole	0.0096 mg/kg bw per day
Flufenacet	0.011 mg/kg bw per day
Dinotefuran	0.22 mg/kg bw per day
Tebuconazole	0.029 mg/kg bw per day
Flonicamid	0.073 mg/kg bw per day
Benthiavalicarb-isopropyl	0.069 mg/kg bw per day
Ipfencarbazone	0.00099 mg/kg bw per day
Dicamba	0.3 mg/kg bw per day
Propargite	0.0098 mg/kg bw per day

Pesticides

Item	Conclusion
Imidacloprid	FSCJ conclusion: Relevant changes in the application for the risk assessment do not influence the exposure level of the item being within the range of ADI, thus were evaluated not to be affecting human health. Accordingly, FSCJ concluded that the item comes 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.

Veterinary medicines

Item	ADI
Azaperone	0.0013 mg/kg bw per day

Chemicals and contaminants

Item	TDI
In beverages, Nitrate/nitrite nitrogen Selenium Barium	Nitrate nitrogen: 1.5 mg/kg bw per day, Nitrite nitrogen: 15 µg/kg bw per day Selenium: 4.0 µg/kg bw per day Barium: 20 µg/kg bw per day

Prions

Item	Conclusion
Consideration of risk variations in Japan derived from the proposed revisions of the current countermeasures against BSE.	FSCJ conclusion: <ul style="list-style-type: none"> • Variation in potential BSE risks to human health would be very small, if it arises, hence an effect of the variation on human health is negligible. • FSCJ decided to inform the risk management organization (MHLW) the fact of numerous public opinions concerning risk management of this item. • Since the proper implementation of the present feed control measures is the assumption for this conclusion, FSCJ decided to demand MHLW periodical reports on state of implementation of such measures in countries that are targets of the risk assessment.

Genetically modified foods and feeds

Item	Conclusion
Soybean tolerant to imidazolinone herbicide line BPS-CV127-9.	FSCJ conclusion: <ul style="list-style-type: none"> • According to the “Approach to the safety assessment of genetically modified foods (seed plants)”², BPS-CV127-9 was evaluated not to be affecting human health. • According to the “Approach to the safety assessment of genetically modified feeds and feed additives”³, the item did not require further assessment through the “Approach to the safety assessment of genetically modified foods (seed plants)”². Consequently BPS-CV127-9 was evaluated not to be affecting livestock animals.

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 genetically modified feed and feed additives (Decision of the Commission dated 6 May 2004)”

Feed, Fertilizers, etc.

Item	Conclusion
Asparagine	The assessed items belong to reliability to be decided by MHLW based on paragraph (3) of article 11 of the Food Hygiene Law, that its risk on human health is evidently negligible. Consequently FSCJ concluded that risks of the assessed items on human health through remaining in livestock products are negligible as long as appropriately used as veterinary medicines and feed additives.
Alanine	
Arginine	
Glycine	
Glutamine	
Serine	
Tyrosine	
Valine	
Histidine	
Methionine	
Leucine	