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

Discussions from the 487th to 489th Meetings of the Commission held on the 2nd, 9th and 30th of September 2013 are summarized as follows:

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

Mycotoxins and Natural toxins	・Setting the standards for diarrheic shellfish poison in bivalvies

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

Pesticides

Item	ADI
Acephate	0.0024 mg/kg bw per day
Aldicarb	0.00025 mg/kg bw per day
Fenthion	0.0023 mg/kg bw per day

Pesticides and veterinary medical products

Item	ADI
Fenobucarb	0.013 mg/kg bw per day
Fluvalinate	0.005 mg/kg bw per day

Veterinary medicinal productions

Item	Conclusion
“Marinedip” Methyl pyruvate and ectozoon parasiticide containing methyl pyruvate as an active ingredient utilized to Tetraodontiformes	FSCJ conclusion： Risk to human health from the assessed item through food consumption is negligible as long as it is appropriately used.

Genetically modified foods/feeds

Item	Conclusion
・Soybean tolerant to dicamba herbicide MON87708 line ・Oilseed rape tolerant to glyphosate herbicide MON88302 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 based on the “Approach to the safety assessment of genetically modified foods (seed plants)”[3]. Hence, FSCJ concluded that livestock products derived from animals which consumed the item have no concern relevant to human health.

[1] E.g. the Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).
[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 foods (seed plants) (Decision of the Commission dated 29 January 2004)”

・Hybrid stacks between the following two lines: <Soybean tolerant to glyphosate with lower saturated fatty acid and improved oleic acid content MON87705 line> <Soybean tolerant to glyphosate herbicide MON89788 line> ・Oilseed rape tolerant to glyphosate herbicide MON88302 line. (Food)	According to the "Approach to the safety assessment of genetically modified foods (seed plants)"[3], the assessed items are evaluated not to affect human health.
・L-leucine produced using LEU-No. 3 strain. ・L-triptphane produced using TRP-No. 1 strain.	FSCJ conclusion: According to the "Approach to the safety assessment of amino acids and other end product"[4], the item's safety was confirmed.
・L-lysine hydrochloride produced by using LYS-No. 2F strain.	FSCJ conclusion: According to the "Approach to the safety assessment of amino acids and other end products"[4], FSCJ concluded that livestock products derived from animals which consumed the feed additive have no concern relevant to human health.
・Asparaginase produced using ASP-72 strain.	FSCJ conclusion: The assessed item is a food additive produced using microorganisms that fall under "the case where the DNA ultimately introduced to the host through recombinant DNA techniques is only DNA from a microorganism belonging to the same taxonomic species as a microorganism in question" designated in "the Standards for the Safety Assessment of Food Additives Produced from Genetically Modified Microorganisms"[5]. Therefore, the item is not the object of this standard, and FSCJ concluded that the item does not require the risk assessment.

4 "Approach to the safety assessment 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)"

5 "the Standards for the Safety Assessment of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)"

Drug resistant bacteria

Item	Conclusion
・Amprolium ・Ethopabate ・Morantel Citrate ・Nicarbazin	FSCJ conclusion: The items do not exert antibacterial activity against typical enteric bacteria and others. In addition, selection of drug resistant bacteria led in livestock by exposure to the items as feed additives or as veterinary medicinal products has not been reported. Therefore, FSCJ considered that selection of drug resistant bacteria by use of the items is unlikely, thus concluded that the assessed items come 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.