

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

Discussions from the 484th to 486th Meetings of the Commission held on the 5th, 19th, 26th of August 2013 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations<sup>1</sup>.

Food Additives	<ul style="list-style-type: none"> <li>• Biotin</li> </ul>
Pesticides	<ul style="list-style-type: none"> <li>• (Residue standards for pesticides in foods)            Imazapic, Kasugamycin, Dimethomorph, Spinetoram, Sulfoxaflor, Fludioxonil, Flufenacet, Flonicamid, DBEDC, Asulam, Imazapyr, Copper Nonylphenolsulfonate, Fluazifop, Imazamox-Ammonium, Hymexazol, Phenmedipham, Metribuzin, Linuron</li> <li>• (Residue standards for pesticides in feeds)            Imazapyr, Imazapic and Deltamethrin, and Tralomethrin</li> </ul>
Pesticides and Veterinary medicinal products	<ul style="list-style-type: none"> <li>• Oxolinic acid</li> <li>• Dinotefuran</li> <li>• Deltamethrin and Tralomethrin</li> <li>• Dihydrostreptomycin and Streptomycin</li> </ul>
Pesticides, Veterinary medicinal products and Feed additives	<ul style="list-style-type: none"> <li>• Oxytetracycline</li> </ul>
Veterinary medicinal products	<ul style="list-style-type: none"> <li>• "Pyceze" A disinfectant, containing bronopol as an active ingredient, for use in medicated bath to treat Pleuronectiformes juvenile</li> <li>• " "KYOTO BIKEN,, PIGWIN PRRS2", Porcine Reproductive and Respiratory Syndrome (bivalent) Vaccine, Live</li> <li>• " "KYOTO BIKEN,, CATTLEWIN-5Hs" Infectious Bovine Rhinotracheitis, Bovine Viral Diarrhea-Mucosal Disease, Bovine Parainfluenza, Bovine Respiratory Syncytial Virus, Bovine Adenovirus and Histophilus somni Infection Vaccine (Live virus and Bacterin)</li> <li>• Diclazuril</li> <li>• Albendazole</li> </ul>
Veterinary medicinal products and Feed additives	<ul style="list-style-type: none"> <li>• Avilamycin</li> <li>• Narasin</li> </ul>
Feed additives	<ul style="list-style-type: none"> <li>• Dibutylhydroxytoluene</li> </ul>
Genetically modified foods	<ul style="list-style-type: none"> <li>• Soybean tolerant to herbicide of para-Hydroxyphenyl-pyruvate Hydroxylase inhibitor type and glufosinate herbicide SYHT0H2 line.</li> </ul>
Food for specified health uses	<ul style="list-style-type: none"> <li>• Rare Sweet</li> </ul>

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

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

Food Additives

Item	Conclusion
Glutamyl-valyl-glycine	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.

Pesticides

Item	ADI
Fenpyroximate	0.0097 mg/kg bw per day
Prothioconazole	0.011 mg/kg bw per day
Mandipropamide	0.05 mg/kg bw per day
Milbemectin	0.03 mg/kg bw per day
Ethofenprox	0.031 mg/kg bw per day
Lufenuron	0.014 mg/kg bw per day
Cyantraniliprole	0.0096 mg/kg bw per day
Pyrimidifen	0.0015 mg/kg bw per day

Pesticides

Item	TDI
Aldrin and Dieldrin	Aldrin; 0.000025 mg/kg bw per day , Dieldrin; 0.00005 mg/kg bw per day

Specified Pesticides\*\*

Item	Conclusion
Ethylene Shochu Electrolysed hypochlorous acid water	FSCJ conclusion: Risk to human health from the assessed items through food consumption is negligible as long as normally used as a pesticide.

\*\* The items belong to Specified pesticides provisionally established by the Minister of Agriculture, Forestry and Fisheries, and by the Minister of Environment, as those that will not pose adverse effects on agricultural produce, humans and animals, and aquatic animals and plants, based on proviso of paragraph (1) of article 2 of the Agricultural Chemicals Control Act.

Veterinary medicinal products

Item	ADI
Propetamphos	0.0005 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
<ul style="list-style-type: none"> <li>• ” “KYOTO BIKEN,, PIGWIN PRRS2” Porcine Reproductive and Respiratory Syndrome (bivalent) Vaccine, Live</li> <li>• ” “KYOTO BIKEN,, CATTLEWIN-5Hs” Infectious Bovine Rhinotracheitis, Bovine Viral Diarrhea-Mucosal Disease, Bovine Parainfluenza, Bovine Respiratory Syncytial Virus, Bovine Adenovirus and Histophilus somni Infection Vaccine (Live virus and Bacterin)</li> </ul>	FSCJ conclusion : Risk to human health from the assessed item through food consumption is negligible as long as it is appropriately used. Accordingly, concerning the approval of marketing and setting the standard of residue, FSCJ concluded that the item comes under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act, where the contents and degree of adverse effects on human health are clear.
“Gosh” Insecticide against poultry mite containing Etoxazole as an active ingredient, for use in poultry house.	FSCJ conclusion : Risk to human health from the assessed item through food consumption is negligible as long as it is appropriately used.

Veterinary medicinal products and feed additives

Item	ADI
Morantel	0.012 mg/kg bw per day

Veterinary medicinal products and feed additives

Item	Conclusion
<ul style="list-style-type: none"> <li>• Avilamycin</li> <li>• Narasin</li> </ul>	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 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.

Genetically modified foods/feeds

Item	Conclusion
Soybean tolerant to Dicamba herbicide MON87708 line	FSCJ conclusion: According to the “Approach to the safety assessment of genetically modified foods (seed plants)” <sup>2</sup> , MON87708 was evaluated not to affect human health.

Not objected substances in positive-list

Item	Conclusion
Azadirachtin*	FSCJ conclusion: It is highly unlikely that risks of Azadirachtin on human health through remaining in livestock products are negligible.

\* 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.

<sup>2</sup> “Approach to the safety assessment of genetically modified foods (seed plants) (Decision of the Commission dated 29 January 2004)”