Monthly Update on Activity of the Food Safety Commission of Japan (FSCJ)
March 2015

Discussions from the 551th to 555th Meetings of the Commission held on the 3rd, 10th, 17th, 24th and 31st of March 2015 are summarized as follows:

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

Pesticides	・Oxathiapiprolin ・Fluopicolide ・Malathion
Veterinary medicinal products	・ Tulathromycin ・ Draxxin C, an injection for veterinary use into cattle, containing tulathromycin as an active ingredient. ・ Bopriva, an injection for veterinary use into cattle, containing a conjugate of 2-10-gonadotropin releasing hormone analogue with diphtheria toxoid as an active ingredient. ・ Rivision of equimax, an oral administering agent for veterinary use into horses, containing ivermectin and praziquantel as active ingredients. ・ Rivision of dalmazin, an injection for veterinary use into cattle and pigs, containing d-Cloprostenol as an active ingredient.
Prions	Usage of mixed blood meal derived from pigs and poultry in feeds for pigs and other animals.
Genetically modified foods / feeds	・6-α-glucanotransferase produced using NZYM-R0 strain
Fertilizers	Amendment of fertilizer inspection methods: Analysis methods of the main ingredients.
Feed additives	・Avilamycin ・Monensin
Exempted Substances[2]	・Lactoferrin

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

Pesticides

Item	ADI	ARfD
Difenconazole	0.0096 mg/kg bw per day	0.25 mg/kg bw
Fluxapyroxad	0.021 mg/kg bw per day	1.2 mg/kg bw
Flupyradifurone	0.031 mg/kg bw per day	0.35 mg/kg bw
Acibenzolar-S-methyl	0.077 mg/kg bw per day	0.5 mg/kg bw
Tazomet, Metam, Methylisothiocyanate	Group ADI: 0.004 mg/kg bw per day	Group ARfD: 0.1 mg/kg bw
Phenmedipham	0.046 mg/kg bw per day	Not required
Fluoxastrobin	0.015 mg/kg bw per day	Not required
Prohexadione-Calcium	0.2 mg/kg bw per day	Not required
Hexythiazox	0.028 mg/kg bw per day	Not required

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

[2] On May 29, 2006 the Ministry of Health, Labour and Welfare (MHLW) introduced the positive list system for agricultural chemicals remaining in foods to prohibit the distribution of foods that contain agricultural chemicals above a certain level if maximum residue limits (MRLs) have not been established. Exempted Substances are designated as substances having no potential to cause damage to human health by the Minister of Health, Labour and Welfare, based on the provision of Paragraph 3, Article 11 of the Food Sanitation Law, and these substances are not subjected to the positive list system.

Metrafenone	0.24 mg/kg bw per day	Not required

Pesticides

Item	Conclusion
Malathion	FSCJ conclusion: The item corresponds to the case where the contents and degree of adverse effects on human health are clear, under the Food Safety Basic Act[3]. Based on a provision which permits the Commission to notify the relevant conclusion to the Ministers who may concern, FSCJ decided to notify it to the Minister of Health, Labour and Welfare.

Veterinary medicinal products

Item	ADI
Ceftiofur	0.05 mg/kg bw per day

Veterinary medicinal products

Item	Conclusion
Revision of equimax, an oral administering agent for veterinary use into horses, containing ivermectin and praziquantel as active ingredients.	FSCJ conclusion: Risk to human health from the assessed item through food consumption is negligible as long as it is appropriately used.
Revision of dalmazin, an injection for veterinary use into cattle and pigs, containing d-Cloprostenol as an active ingredient.	FSCJ conclusion: Risk to human health from the assessed item through food consumption is negligible as long as it is appropriately used.
Components contained as additives in the already approved animal vaccine for which the use restriction period to be set (10 components).	Nine of 10 components are considered to be of no concern for food safety as long as used appropriately as additives to the animal vaccine. FSCJ concluded that the assessed item corresponds to the case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act[4]. As for the rest 1 of 10 components, the substance could not be specified and thus assessment of which was considered difficult.

Prions

Item	Conclusion
Usage of mixed blood meal derive from pigs and poultry in feeds for pigs and other animals.	FSCJ conclusion: To the extent that control measures for use of mixed blood meal derived from pigs and poultry for feeds are taken, the conclusion of the safety assessment, evaluating the item as of no concern for food safety, is considered not to be different before and after the measures were revised. Accordingly, FSCJ confirmed 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.

[3] FSCJ was asked the opinion about risks to human health from the item, which has been assessed by FSCJ, based on article 24 of the Food Safety Basic Act. However, new scientific finding on safety risks of the relevant item was not available. Consequently, FSCJ concluded that the item corresponds to the case where the contents and degree of adverse effects on human health are clear, which is designated in item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

[4] The item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act designates the case where the contents and degree of adverse effects on human health are clear. The revised standards still prescribe that the assessed additives shall be decomposed, neutralized, or removed before the completion of the final food. Therefore, the additives were evaluated to have no adverse effects on human health when used according to the revised standards, on condition that decomposition or neutralization of the relevant additive does not form new substances.

Feeds and Fertilizers

Item	Conclusion
Amendment of fertilizer inspection methods: Analysis methods of the main ingredients.	FSCJ conclusion: FSCJ confirmed that the assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act[5], because the assessed item is changing of inspection methods which correspond to policies for ensuring relevant administrative responses based on conclusion from food safety risk assessments.

Genetically modified foods/feeds

Item	Conclusion
Hybrid stacks of soybean: MON87769[6] x MON89788[7]	FSCJ conclusion: According to "Stance on Safety Assessments of Genetically Modified Foods (seed plants)"[8], the item was evaluated not to affect human health.

Feed additives

Item	Conclusion
Avilamycin	FSCJ conclusion: The assessed item concerns with addition of methods for including soybean mill run to standards for methods to produce food manufacturing intermediates. Soybean mill run has been used as a feed and as an excipient for avilamycin products. Therefore, FSCJ considered that the assessed item falls under the category which is the case where the contents and degree of adverse effects on human health are clear[9].

Exempted Substances[2]

Item	Conclusion
Lactoferrin	FSCJ conclusion: Risks of the assessed items on human health through remaining in livestock products are negligible as long as appropriately used as a veterinary medicinal product. Hence, FSCJ confirmed that the assessed item falls under the category which is the case where the contents and degree of adverse effects on human health are clear[10].

Novel Foods and Food Additives

Item	Conclusion
Foods containing high levels of diacylglycerol (DAG-rich foods)	FSCJ conclusion: (1) Domestic supply of DAG-rich foods and related products was suspended in September 2009. Thus DAG-rich foods, already refrained from marketing, are unlikely to expose people and additional data for the assessment are unavailable in the situation. Reliable lifetime risk of cancer is not estimated individually from their broadened history of exposure to DAG-rich foods, confounding varieties of life style and consumption of DAG-rich foods (period, amount, age etc.). Hence, the food safety assessment could not be completed, due to the shortage of the exposure information on the DAG-rich foods. (2) Potential tumor promoting activity of DAG-rich oils and properties of GE, a possible contaminants in food oils are summarized in the appendix for the related information as follows. ・ FSCJ considered that cancer-promoting risk in human is negligible from the consumption of DAG-rich oils in ordinary foods.

[5] Change of analysis methods comes under item (i) of paragraph (1) of article 11 of the Food Safety Basic Act, where assessment of food safety risk is evidently unnecessary.
[6] Soybean producing stearidonic acid.
[7] Soybean tolerant to glyphosate herbicide
[8] "Approach to the safety assessment of genetically modified foods (seed plants) (Decision of the Commission dated 29 January 2004)"
[9] The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.
[10] The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

	・ On the assumption that the level of GE in the currently distributed edible oils and food products is maintained as minute and all of the GE is converted to the equimoles of glycidol in the body, margin of exposure (MOE) was estimated to be slightly lower than 10,000, indicating that a certain level of margin is still exist even if the exposure was overestimated. While these data do not suggest directly the adverse effects of consumption of currently distributed edible oils on human health, GE levels should be kept as low as reasonably achievable according to the principle of ALARA (As Low As Reasonably Achievable).