Provisional translation

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Updated Activities of the Food Safety Commission of Japan (FSCJ)

April 2021

Discussions from the 811st, 812nd, 813rd and 814th Meetings of the Commission held on the 6th, 13th, 20th and 27th of April 2021 are summarized as follows:

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

Additives	・Potassium bicarbonate
Genetically modified foods/feeds	・Alpha-glucosyltransferase produced using *Bacillus subtilis NT104* (*pHY2TD*) strain

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

Pesticides

Item	ADI	ARfD
Pendimethalin	0.12 mg/kg bw per day	1 mg/kg bw

Veterinary medicinal products

Item	Conclusion

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

Albendazole	FSCJ conclusion: FSCJ specified a group ADI for Albendazole and Albendazole sulfoxide to be 0.01 mg/kg bw per day as Albendazole.

Antimicrobial resistant bacteria

Item	Conclusion
Zinc bacitracin for use in livestock	FSCJ conclusion: The results of hazard identification indicate that the use of zinc bacitracin in livestock animals could cause the selection of resistant bacteria. However, the resistant bacteria would not pose human health hazards via food consumption. Thus, FSCJ concludes that the risk to human health via food consumption arisen from the antimicrobial-resistant bacteria selected through the use of zinc bacitracin in livestock animals is negligible.

Genetically modified foods/feeds

Item	Conclusion
・Xylanase produced using JPBL006 strain ・Xylanase produced using JPAo004 strain ・Xylanase produced using JPAo005 strain ・Phospholipase produced using JPBL004 strain ・Phospholipase produced using JPBL005 strain	FSCJ conclusion: The safety of the items was evaluated based on the "Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms"[2]. Consequently, FSCJ concluded that the assessed items have no concern relevant to human health.

[2] Decision of the Commission Dated 25 March 2004.

May 2021

Discussions from the 815th, 816th and 817th Meetings of the Commission held on the 11th, 18th and 25th of May 2021 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations[3].

Pesticides	・Broflanilide ・1-Naphthaleneacetic acid ・Cyantraniliprole ・Fenpyroximate ・Pencyclon
Pesticides and Veterinary medicinal products	・Etoxazole ・Permethrin
Veterinary medicinal products	・Veterinary medicinal product for dermal application to cattle (ダニレス) that contains etoxazole as the active component. ・An injection for use in pigs (Improvac) that contains gonadotropin releasing hormone-diphtheria toxoid conjugate as the active component. ・A feed additive for use to fishes belonging Perciformes (including a Bluefin tuna) that contains praziquantel as an active component. (Venesar for fisheries, ハダクリーン)
Genetically modified foods/feeds	・Canola synthesizing DHA and tolerant of glufosinate herbicide (NS-B50027-4) (foods) ・Canola synthesizing DHA and tolerant of glufosinate herbicide (NS-B50027-4) (DP23211) (feeds) ・Carboxypeptidase produced using JPAo007 strain ・Aminopeptidase produced using JPAo008 strain

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

Pesticides

Item	ADI	ARfD

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

Cadusafos	0.00025 mg/kg bw per day	0.005 mg/kg bw
Clethodim	0.01 mg/kg bw per day	1 mg/kg bw
Fenazaquin	0.0046 mg/kg bw per day	0.1 mg/kg bw
Uniconazole P	0.02 mg/kg bw per day	1 mg/kg bw for general people, 0.05 mg/kg bw for women of child bearing age

Veterinary medicinal products

Item	Conclusion
Broflanilide	FSCJ conclusion: FSCJ concluded that the assessed items is the case where the contents and degree of adverse effects on human health are clear[4].

Veterinary medicinal products

・Maduramicin ・Robenidine	FSCJ conclusion: FSCJ considers that the assessed item is a component which falls under (1) of 3 of "Guidance on Risk Assessments of Veterinary Medicinal Products and Feed Additives for which the Provisional Standards are Established". Therefore, FSCJ conclude that the effect of food on human health is negligible as long as used under the current risk management.

Veterinary medicinal products and feed additives

・Halofuginone	FSCJ conclusion: FSCJ considers that the assessed item is a component which falls under (1) of 3 of "Guidance on Risk Assessments of Veterinary Medicinal Products and Feed Additives for which the Provisional Standards are Established". Therefore, FSCJ conclude that the effect of food on human health is negligible as long as used under the current risk management.

[4] The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

Others

・Addition of Gentian violet test and Trenbolone acetate test to the Standards for foods/food additives[5]	FSCJ conclusion: FSCJ concludes that the item is the case designated under item (i) of paragraph (1) of article 11 of the Food Safety Basic Act where assessment is not necessary.

[5] The Standards (Notification of the Ministry of Welfare , No. 300, 1959) established based on the provision of Paragraph 1, Article 13 of the Food Sanitation Law (Law No. 233 of 1947).

June 2021

Discussions from the 818th to 822nd Meetings of the Commission held on the 1st, 8th, 15th, 22nd and 29th of May 2021 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations[6].

Additives	・Potassium ferrocyanide
Pesticides and veterinary medicinal products	・Specification of the standards of residue in food for 40 items of pesticides and veterinary medicinal products
Feed additives	・Amendment of test methods of feed additives

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

Pesticides

Item	ADI	ARfD
Propargite	0.0098 mg/kg bw per day	1 mg/kg bw
Polyoxin D zinc salt	7.2 mg/kg bw per day	Not required
Polyoxin complex	2.5 mg/kg bw per day	Not required
Oxathiapiprolin	3.4 mg/kg bw per day	Not required
Pyribencarb	0.039 mg/kg bw per day	1.1 mg/kg bw
Benthiavalicarb-isopropyl	0.069 mg/kg bw per day	Not required
Fenarimol	0.006 mg/kg bw per day	0.03 mg/kg bw for general people, 0.017 mg/kg bw for women of child bearing age
Bentazone	0.09 mg/kg bw per day	0.5 mg/kg bw
Foramsulfuron	0.5 mg/kg bw per day	Not required
MCPA	0.0019 mg/kg bw per day	0.32 mg/kg bw

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

Pyraufen-ethyl	0.17 mg/kg bw per day	Not required
Flufenoxuron	0.037 mg/kg bw per day	Not required

Pesticides and Veterinary medicinal products

Item	Conclusion
Specification of the standards of residue in food for 40 items of pesticides and veterinary medicinal products	Increase in the intake after this new specification of residue standards is even small as remaining within the results of the risk assessment by FSCJ, thus the effect on human health is not changed. Consequently, FSCJ concluded that the item falls under the category which is the case where the contents and degree of adverse effects on human health are clear[6].

Pesticides and veterinary medicinal products

Item	ADI	ARfD
Cyfluthrin and β- cyfluthrin	0.023 mg/kg bw per day	0.023 mg/kg bw
Spinosad	0.024 mg/kg bw per day	Not required

Veterinary medicinal products

Item	Conclusion
A feed additive for use to fishes belonging Perciformes (Spochiru 100) that contains albendazole as an active component	FSCJ conclusion: FSCJ concluded that the risk to human health from the intake of this product through consumption of foods is negligible as long as it is appropriately used.
Veterinary medicinal product for dermal application to cattle (ダニレス) that contains etoxazole as the active component.	FSCJ conclusion: FSCJ concluded that the risk to human health from the intake of this product through consumption of foods is negligible as long as it is appropriately used.
An injection for use in pigs (Improvac) that contains gonadotropin releasing hormone - diphtheria toxoid conjugate as the active component	FSCJ conclusion: FSCJ concluded that the risk to human health from the intake of this product through consumption of foods is negligible as long as it is appropriately used.

A feed additive for use to fishes belonging Perciformes (including a Bluefin tuna) that contains praziquantel as an active component. (Venesar for fisheries, ハダクリーン)	FSCJ conclusion: FSCJ concluded that the risk to human health from the intake of this product through consumption of foods is negligible as long as it is appropriately used.

Veterinary medicinal products

Item	ADI
Praziquantel	0.30 mg/kg bw/day.

Veterinary medicinal products and feed additives

Item	Conclusion
Bacitracin	FSCJ conclusion: FSCJ considers that the assessed item is a component which falls under (1) of 3 of “Guidance on Risk Assessments of Veterinary Medicinal Products and Feed Additives for which the Provisional Standards are Established”. Therefore, FSCJ conclude that the effect of food on human health is negligible as long as used under the current risk management.

Feed additives

Item	Conclusion
Amendment of test methods for feed additives	FSCJ conclusion: Relevant test methods has been established for the purpose of securing quality of feed additives, and the methods to be applied hereafter are managed the same as before and measures to ensure compliance with the standards are not changed. Therefore, the effect on human health is not changed. Consequently, FSCJ concluded that the item falls under the category which is the case where the contents and degree of adverse effects on human health are clear[6].

Benzoic acid	FSCJ conclusion: It is not necessary to consider the ADI in the evaluation of the item as a feed additive. Therefore, FSCJ concluded that risks of the assessed item to human health through residues in foods are negligible as long as normally used as a feed additive.
A feed additive containing benzoic acid as the active component	FSCJ conclusion: FSCJ concluded that risks of the assessed item to human health through residues in foods are negligible as long as normally used as a feed additive.
Muramidase JPTR003 product which contains technical grade Muramidase JPTR003 produced using *Trichoderma reesei* JPTR003 strain	FSCJ conclusion: FSCJ concluded that risks of the assessed item to human health through residues in foods are negligible as long as normally used as a feed additive.

Genetically modified foods/feeds

Item	Conclusion
・Alpha-amylase produced using BML780 MDT06-221 strain ・Alpha-glucosidase produced using Morph TG#626 strain ・Glucoamylase produced by JPAN003 strain ・Hemicellulase, produced using JPAN007 strain	FSCJ conclusion: According to the "Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms"[7], FSCJ concluded that the item has no concern relevant to human health.
Muramidase JPTR003 produced using *Trichoderma reesei* JPTR003 strain	FSCJ conclusion: According to the "Stance on the safety assessment of genetically modified feeds and feed additives"[37], the item did not require further assessment through the "Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms"[8]. Hence, livestock products derived

[7] "The Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)"
[8] "The Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)"

	from animals which consumed the item have no concern relevant to human health.
Pectinase produced using JPAN005 strain	FSCJ conclusion: According to the "Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms"[9], FSCJ concluded that the item has no concern relevant to human health.
Maize MON87429 line glyphosate-induced male sterile and tolerant of dicamba herbicide, glyphosinate herbicide, aryloxyalkanoate herbicide, and glyphosate herbicide (foods).	FSCJ conclusion: According to the "Stance on the safety assessment of genetically modified foods (seed plants)"[10], FSCJ concluded that Maize MON87429 has no concern relevant to human health.
Maize MON87429 line glyphosate-induced male sterile and tolerant of dicamba herbicide, glyphosinate herbicide, aryloxyalkanoate herbicide, and glyphosate herbicide (feeds).	FSCJ conclusion: According to the "Stance on the safety assessment of genetically modified feeds and feed additives"[37], the item did not require further assessment through the "Stance on the safety assessment of genetically modified foods (seed plants)"[34]. Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.

Working group on Antimicrobial resistant bacteria

Item	Conclusion
・Sulfonamide synthetic antibacterial agents for use in livestock	FSCJ conclusion: (1) A single sulfonamide synthetic antibacterial Although the use of a single sulfonamide synthetic antibacterial in livestock could cause the selection of resistant bacteria, the resistant bacteria would not pose human health hazards via food consumption. Thus, FSCJ concludes that the risk to human health via food consumption arisen from the antimicrobial-resistant bacteria selected

[9] "The Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)"

[10] "Stance on Safety Assessments of Genetically Modified Foods (seed plants) (Decision of the Commission dated 29 January 2004)"

	through the use of a single sulfonamide synthetic antibacterial in livestock animals is negligible. (2) ST mixture of sulfonamide with trimethoprim or ormetoprim FSCJ concluded that the level of risk from each hazard was low, although the following possibilities cannot be excluded: 1) selection of hazards such as *staphylococci* and *E. coli* as a result of the use of the assessed ST mixture in livestock as a veterinary medicinal product; 2) loss or reduction of the efficacy of antimicrobial treatment of human diseases as a result of human exposure to the hazards through consumption of livestock products derived from cattle, pigs and chicken. The risk for the hazard was, however, judged to be low as a result of the overall estimation of the risk.

Working group on Allergen containing foods

Item	Conclusion
Allergen containing foods (Egg)	FSCJ conclusion: There are inter-individual variations in the eliciting dose to induce allergy symptoms where some microgram of chicken egg protein may cause allergic symptoms at individual level. Therefore, food allergic patients not only chicken egg allergy need to intake foods following the family doctor's consultation. Nonetheless, it is considered that most processed foods of targets of mandatory labelling may not induce allergic symptoms in chicken egg allergic patients because of current labelling measure for allergen foods. Hence, this WG concluded that the current risk management measures for allergen labelling on food product are mostly appropriate in regard to "egg".

Working group on Zinc

Item	Conclusion
Allergen containing foods (Egg)	FSCJ conclusion: As a consequence of comprehensive evaluation of the findings from previous epidemiological studies, it was suggested that blood Pb level even at the level of 1-2 μg/dL potentially affects children's neurobehavioral development or adult renal function.

	However, results from different epidemiological studies are inconsistent depend on the effects, confounding could not be excluded completely so that it is difficult to evaluate the effect of Pb exposure only, evidence is insufficient for presume a causal relationship between Pb exposure and the observed effect, and clinical significance and public health significance of the observed effects are obscure. Hence, the FSCJ concluded that it is difficult at present to estimate blood Pb level without adverse effects using the data from epidemiological studies. FSCJ estimated the average blood Pb level in current Japan as 1 μg/dL or less which is close to the level suggested by epidemiological studies to have some effects, 1-2 μg/dL. Therefore, continuous effort to implement measures to reduce Pb exposure will be required.