Provisional translation

This English version of the Commission Decision is intended to be reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail. The FSCJ shall not be responsible for any consequence resulting from use of this English version.

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

October 2021

Discussions from the 834th, 835th, 836th and 837th Meetings of the Commission held on the 5th, 12th, 19th and 26th of October 2021 are summarized as follows:

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

Additives	・Copper sulfate
Genetically modified foods/feeds	・Alpha-amylase produced using JPAN004 strain ・L-Citrulline produced using CIT-No.1 strain ・L-Valine produced using VAL-No.5 strain
Fertilizer	・Amendment of official specification of ordinary fertilizers[2] (Fertilizers composed of biomass ash derived from the combustion of plants and fused silicate fertilizers)

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

Additives

Item	Conclusion

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

[2] Official specification of ordinary fertilizers prescribed in paragraph (1) of Article 3 of the Fertilizer Control Act (Act No. 127, 1950) which concerns ensuring quality of fertilizers.

Potassium hydrogen carbonate	FSCJ conclusion: FSCJ concluded that the assessed item is 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	ARfD
Afidopyropen	0.08 mg/kg bw per day	0.18 mg/kg bw
Pencycuron	0.053 mg/kg bw per day	Not required
Tetraconazole	0.004 mg/kg bw per day	0.05 mg/kg bw
Flometoquin	0.008 mg/kg bw per day	0.044 mg/kg bw

Veterinary medicinal products

Item	Conclusion
・Carbadox	FSCJ conclusion: The ADI for the assessed item has not been specified inside and outside of the county. And, potential genotoxic carcinogenicity of the item is undeniable, thus a toxicological threshold cannot be established. Therefore, FSCJ considers that the assessed item is a component which falls under (2) of 3 of "Guidance on Risk Assessments of Veterinary Medicinal Products and Feed Additives for which the Provisional Standards are Established". The item has been specified in standards as a substance that should not be contained in foods, and regulated as a substance that should not detected. Therefore, FSCJ conclude that the effect of food on human health is negligible.
・Sodium nifurstylenate	FSCJ conclusion: The ADI for the assessed item has not been specified inside and outside of the county. And, potential genotoxic carcinogenicity of the item is undeniable, thus a toxicological threshold cannot be established. Therefore, FSCJ considers that the assessed item is a component which falls under (2) of 3 of "Guidance on Risk Assessments of Veterinary Medicinal Products and Feed

	Additives for which the Provisional Standards are Established". The item has been specified in standards as a substance that should not be contained in foods, and regulated as a substance that should not detected. Therefore, FSCJ conclude that the effect of food on human health is negligible.
・Roxarsone	FSCJ conclusion: The ADI for the assessed item has not been specified inside and outside of the county. And, potential genotoxic carcinogenicity of the item is undeniable, thus a toxicological threshold cannot be established. Therefore, FSCJ considers that the assessed item is a component which falls under (2) of 3 of "Guidance on Risk Assessments of Veterinary Medicinal Products and Feed Additives for which the Provisional Standards are Established". The item has been specified in standards as a substance that should not be contained in foods, and regulated as a substance that should not detected. Therefore, FSCJ conclude that the effect of food on human health is negligible.

Fertilizer

Item	Conclusion
Amendment of official specification of ordinary fertilizers[3] (Fertilizers composed of biomass ash derived from the combustion of plants and fused silicate fertilizers)	FSCJ conclusion: The assessed amendment is an addition of a vegetal ash to the standards of materials for fertilizers. Vegetal ash has been used for a long time as a fertilizer or a material for fertilizer in agricultural production sites. Regarding harmful effect on human health, it has not been determined in some of such vegetal ash. The present amendment intends to add the ash with particularly low potential of such harmful effect to the standards of materials for fertilizers. As for fertilizers of which use become approved after this amendment, regulation for harmful component is to be set equally to that for by-product fertilizers whose official specification has been already established. Therefore, compering to the current situation, the present amendment unlikely raise a risk of being exposed to adversely health affecting heavy metals through crop consumption. Consequently, FSCJ considers that risk to human health from this amendment is negligible since food safety is ensured equally to that ensured by the current

[3] Official specification of ordinary fertilizers prescribed in paragraph (1) of Article 3 of the Fertilizer Control Low (Low No. 127, 1950) which concerns ensuring quality of fertilizers.

	regulation even after this amendment. Materials for fertilizers that are newly designated by the amendment of official specification of fused silicate fertilizers contain heavy metals sufficiently low. For these fertilizers, regulation for harmful component is to be set equally to regulation for fertilizers whose materials and manufacturing method are similar (such as Slag fertilizer and Molten sludge ash silicic acid phosphorus fertilizer). Therefore, compering to the current situation, the present amendment unlikely raise a risk of being exposed to adversely health affecting heavy metals through crop consumption. Consequently, FSCJ considers that risk to human health from this amendment is negligible since food safety is ensured equally to that ensured by the current regulation even after this amendment.

November 2021

Discussions from the 838th, 839th and 840th Meetings of the Commission held on the 2nd, 16th and 30th of November 2021 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations[4].

Veterinary medicinal products	・Mixed live vaccine against avian coccidiosis (Brunetti Necatrix) (NIBS Avian cocci attenuated divalent live vaccine (BN))
Genetically modified foods/feeds	・Phospholipase produced using DIDK-0176 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
Iprodione	0.02 mg/kg bw per day	Not required for general people, 0.9 mg/kg bw for women of child bearing age
Ethofenprox	0.031 mg/kg bw per day	1 mg/kg bw

Pesticides

Item	Conclusion
Abscisic acid	FSCJ conclusion: Risk to human health from intake of the assessed items through food is negligible as long as normally used as a pesticide.

Veterinary medicinal products

Item	Conclusion

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

・Mixed live vaccine against avian coccidiosis (Brunetti Necatrix) (NIBS Avian cocci attenuated divalent live vaccine (BN))	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 falls under the category which is the case where the contents and degree of adverse effects on human health are clear[6].
・Didecyldimethylammonium chloride	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.
・Nitarsone	FSCJ conclusion: The ADI for the assessed item has not been specified inside and outside of the county. And, potential genotoxic carcinogenicity of the item is undeniable, thus a toxicological threshold cannot be established. Therefore, FSCJ considers that the assessed item is a component which falls under (2) of 3 of "Guidance on Risk Assessments of Veterinary Medicinal Products and Feed Additives for which the Provisional Standards are Established". The item has been specified in standards as a substance that should not be contained in foods, and regulated as a substance that should not detected. Therefore, FSCJ conclude that the effect of food on human health is negligible.

Genetically modified foods/feeds

Item	Conclusion
・Lipase produced using LFS strain	FSCJ conclusion: According to the "Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms"[5], the item was evaluated not to affect human health.

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

December 2021

Discussions from the 841st, 842nd and 843rd Meetings of the Commission held on the 7th, 14thand 21th of December 2021 are summarized as follows:

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

Pesticides	・1,4-Dimethylnaphthalen ・Acequinocyl ・Trinexapac-ethyl ・Triflumizole ・Pyraziflumid ・Fluensulfone ・Flutriafol ・Flonicamid
Veterinary medicinal products	・Amendment of Ordinance of the MAFF based on the provision in Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices, item (1) of paragraph (5) of Article 83. ・Mixed live vaccine against bovine infectious rhinotracheitis and bovine parainfluenza (TSV2) ・A component used as an additive in vaccine for animals (manganese sulfate

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

Veterinary medicinal products

Item	Conclusion
Amendment of Ordinance of the MAFF based on the provision in Law for Ensuring	FSCJ conclusion: FSCJ concludes that the item falls under the case where the contents and degree of adverse effects on human

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

the Quality, Efficacy, and Safety of Drugs and Medical Devices, item (1) of paragraph (5) of Article 83.	health are clear, under the Food Safety Basic Act[7], since this amendment does not result human exposure to Gentian Violet through food consumption.
Mixed live vaccine against bovine infectious rhinotracheitis and bovine parainfluenza (TSV2)	FSCJ conclusion: Reassessment of this product falls under the case where the contents and degree of adverse effects on human health are clear, under the Food Safety Basic Act[8].

Genetically modified foods/feeds

Item	Conclusion
MON95379, a maize resistant to Lepidoptera (Food)	FSCJ conclusion: According to the "Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms"[9], the item was evaluated not to affect human health.
MON95379, a maize resistant to Lepidoptera (Feed)	FSCJ conclusion: According to the "Stance on the safety assessment of genetically modified feeds and feed additives", the item did not require further assessment through the "Stance on the safety assessment of genetically modified foods (seed plants)". Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.

[7] The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.
[8] The case designated by item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.
[9] "The Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)"