

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)

July 2020

Discussions from the 783rd, 784th and 780th Meetings of the Commission held on the 7th, 21st and 28th of July 2020 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations¹.

Genetically modified foods/feeds	<ul style="list-style-type: none">• Potato SPS-000Z6-5 strain (food)• Potato SPS-000Z6-5 strain (feed)• Lipase produced using LFS strain
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¹ E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

August 2020

Discussions from the 786th and 787th Meetings of the Commission held on the 4th and 11th of August 2020 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations².

Additives	<ul style="list-style-type: none"> • Amendment of the standard for food additives (Notification of the Ministry of Welfare, No. 370, 1959). • Calcium carbonate
Pesticides	<ul style="list-style-type: none"> • Spinetoram • Tolfenpyrad • Fenquinotrione • Fuoxastrobin • Polyoxin (Polyoxin D zinc salt and polyoxin complex) • Deltamethrin and tralomethrin
Veterinary medicinal products	<ul style="list-style-type: none"> • Exzolt • Deltamethrin and tralomethrin
Feed additives	<ul style="list-style-type: none"> • Alkaline protease produced using genetically modified <i>Bacillus licheniformis</i>.

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

Feed additives

Item	Conclusion
Dipotassium L-tartrate and metatartaric acid	FSCJ conclusion: FSCJ specified a ADI for a group of dipotassium L-tartrate and metatartaric acid as 24 mg/kg bw/day (as L-tartaric acid).
Amendment of the standard for food additives (Notification of the Ministry of Welfare, No. 370, 1959).	FSCJ conclusion: The assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act ³ .

² E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

³ The item 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.

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Calcium carbonate	FSCJ conclusion: FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear ⁴ .
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Pesticides

Item	ADI	ARfD
Cyflumetofen	0.092 mg/kg bw per day	Not required

Pesticides

Item	Conclusion
Deltamethrin and tralomethrin	FSCJ conclusion: FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear ⁵ .

Veterinary medicinal products

Item	ADI
Trenbolone acetate	0.02 µg/kg bw per day

Veterinary medicinal products

Item	Conclusion
Deltamethrin and tralomethrin	FSCJ conclusion: FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear ⁶ .

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

⁵ The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

⁶ The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

September 2020

Discussions from the 788th, 789th, 790th and 791st Meetings of the Commission held on the 1st, 8th, 15th and 29th of September 2020 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations⁷.

Veterinary medicinal products	<ul style="list-style-type: none"> • Pronalgon EZ injection
Fertilizers	<ul style="list-style-type: none"> • Amendment of official specification of ordinary fertilizers⁸. (A case which is evidently unnecessary) • Amendment of official specification of ordinary fertilizers⁹. (A case where degree is clear)

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

Food Additives

Item	Conclusion
<ul style="list-style-type: none"> • Dipotassium DL-tartrate 	FSCJ conclusion: FSCJ concluded that it is of no concern for food safety as long as dipotassium DL-tartrate is used appropriately as a food additive.

Pesticides

Item	ADI	ARfD
Tioxazafen	0.05 mg/kg bw per day	0.5 mg/kg bw

⁷ E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

⁸ Official specification of ordinary fertilizers prescribed in Notification of the MAFF, No. 284, 1986.

⁹ Official specification of ordinary fertilizers prescribed in Notification of the MAFF, No. 284, 1986.

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Prochloraz	0.04 mg/kg bw per day	1.6 mg/kg bw
Ethaboxam	0.05 mg/kg bw per day	0.75 mg/kg bw
Fenbuconazole	0.03 mg/kg bw per day	0.3 mg/kg bw
Tiadinil	0.04 mg/kg bw per day	1.5 mg/kg bw
Benzovindiflupyr	0.048 mg/kg bw per day	0.1 mg/kg bw
Spinetoram	0.024 mg/kg bw per day	Not required.
Validamycin	0.36 mg/kg bw per day (value converted for validamycin A)	3.2 mg/kg bw (value converted for validamycin A)

Pesticides

Item	Conclusion
1-Methylcyclopropene	FSCJ conclusion: FSCJ considered it infeasible to specify the ADI and ARfD precisely based on data of oral administration studies. Nonetheless, as the residue in crops study indicated that 1-MCP remained in crops in a trace amount, FSCJ concluded that risk to human health from the assessed item through consumption is extremely low as long as it is used appropriately in accordance with the usage described in the request for pesticide registration.

Veterinary medicinal products

Item	ADI
Dichloroisocyanuric acid	0.86 mg/kg bw per day
Toltrazuril	0.01 mg/kg bw per day

Fertilizers

Item	Conclusion
Amendment of official specification of ordinary fertilizers ¹⁰ . (A case which is evidently unnecessary)	FSCJ conclusion: The assessment of food safety risk from the item is evidently unnecessary according to Food Safety Basic Act ¹¹ .
Amendment of official specification of ordinary fertilizers ¹² . (A case where degree is clear)	FSCJ conclusion: FSCJ concluded that the item is the case where the contents and degree of adverse effects on human health are clear ¹³ .

Feed additives

Item	ADI
Dibutylhydroxytoluene	0.25 mg/kg bw per day

Feed additives

Item	Conclusion
Feed additive containing alkaline protease produced using <i>Bacillus licheniformis</i> JPBL001 strain as a technical grade product.	FSCJ conclusion: Risk to human health from the assessed item through consumption is negligible as long as it is appropriately used.

Food for specified health uses

Item	Conclusion
Toku-gyu sarashia premium.	FSCJ conclusion: FSCJ concluded, from these test results, that Toku-gyu sarashia premium has no obvious risk to human health. Since the assessed food is expected to alter blood-glucose level, special care must be taken based on the policy prescribed in the Approach to the Safety Assessment of Each Product of

¹⁰ Official specification of ordinary fertilizers prescribed in Notification of the MAFF, No. 284, 1986.

¹¹ The item 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.

¹² Official specification of ordinary fertilizers prescribed in Notification of the MAFF, No. 284, 1986.

¹³ The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

	<p>Foods for Specified Health Use¹⁴. Hence, persons carrying on the food business need to make efforts to collect and provide information on the health effects of their products. In addition, caution label indicating that patients should consult physicians or medical personnel for their ingestion of the food should be required.</p>
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¹⁴ The policy prescribed in (2) of 2 of the Approach to the Safety Assessment of Each Product of Foods for Specified Health Use (Decision of the Commission dated 10 May 2007).