

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

March 2016

Discussions from the 597th to 600th Meetings of the Commission held on the 1st, 8th, 15th and 29th of March 2016 are summarized as follows:

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

Food additives	• Calcium carbonate
Pesticides	• Triforine • Pyraclostrobin • Famoxadone • Fenquinotrione • Fenpyrazamine • Metamifop • Validamycin
Veterinary medicinal products	• Live vaccine against chicken infectious bursal disease (バックスオンIBD-CA) • Triptorelin Acetate
Genetically modified foods/feeds	• L-Proline produced using ECP strain • Beta-Amylase produced using NZYM-JA 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
Simoxanyl	0.013 mg/kg bw per day	0.08 mg/kg bw
Profenofos	0.0005 mg/kg bw per day	0.05 mg/kg bw
Clethodim	0.01 mg/kg bw per day	1 mg/kg bw

Veterinary medicinal products

Item	ADI
Prednisolone	0.00025 mg/kg bw per day
Methylprednisolone	0.0003 mg/kg bw per day

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).

Live vaccine against chicken infectious bursal disease (バックスオンIBD-CA)	FSCJ conclusion: Risk to human health from the assessed item through food consumption is negligible as long as it is appropriately used. Accordingly, 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 ² .
---	---

Genetically modified foods/feeds

Item	Conclusion
Alpha-Amylase produced using NZYM-AV strain	FSCJ conclusion: According to the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” ³ , the item was evaluated not to affect human health.
Carboxypeptidase produced using PEG strain	FSCJ conclusion: The assessed item is a food additive produced using microorganisms that fall under the category which is the case designated in “Standards for the Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” ² . Therefore, the item is not the object of this standard, and FSCJ concluded that the item does not require the risk assessment.
L-Sodium glutamate produced using GLU-No.8 strain	FSCJ conclusion: According to the “Stance on the Safety Assessment of Amino Acids and Other End Products” ⁴ , the item’s safety was confirmed.
L-Histidine hydrochloride produced using HIS-No.2 strain	FSCJ conclusion: According to the “Stance on the Safety Assessment of Amino Acids and Other End Products” ³ , the item’s safety was confirmed.
Phytase produced using ASP595-1 strain	FSCJ conclusion: According to the “Stance on the safety assessment of genetically modified feeds and feed additives” ⁵ , the item did not require further assessment through the “Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms” ² .

² The case designated under item (ii) of paragraph (1) of article 11 of the Food Safety Basic Act.

³ “the Standards for Safety Assessments of Food Additives Produced from Genetically Modified Microorganisms (March 25, 2004 Decision of the Food Safety Commission)”

⁴ “Stance on Safety Assessments of Amino Acids and Other End Products that are highly purified non-protein additives among additives produced using genetically modified microorganisms (Decision of the Commission dated 28 April 2005)”

⁵ “Stance on Safety Assessments of Genetically Modified Feed and Feed Additives (Decision of the Commission dated 6 May 2004)”

	Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.
Sodium 5'-inosinate produced using RN-No.2 strain	FSCJ conclusion: According to the “Stance on the Safety Assessment of Amino Acids and Other End Products” ³ , the item’s safety was confirmed.
SYHT0H2 soybean ⁶ (Foods)	FSCJ conclusion: According to the “Stance on the safety assessment of genetically modified foods (seed plants)” ⁷ , the item have no concern relevant to human health.
SYHT0H2 soybean ⁸ (Feeds)	According to the “Stance on the safety assessment of genetically modified feeds and feed additives” ⁴ , the item did not require further assessment through the “Stance on the safety assessment of genetically modified foods (seed plants)” ⁶ . Hence, livestock products derived from animals which consumed the item have no concern relevant to human health.

Feed additives

Item	Conclusion
6-Phytases produced using ASP595-1 strain	FSCJ conclusion: Risk to human health from the assessed item through consumption is negligible as long as it is used appropriately as a feed additive.

⁶ Soybean line tolerant of HPDD-inhibiting herbicides and glufosinate herbicides.

⁷ “Stance on Safety Assessments of Genetically Modified Foods (seed plants) (Decision of the Commission dated 29 January 2004)”

⁸ Soybean line tolerant of HPDD-inhibiting herbicides and glufosinate herbicides.