

## Monthly Update on Activity of the Food Safety Commission of Japan (FSCJ) January 2013

Discussions of the 459th to 461st Meetings of the Commission held on 7th, 21st and 28th of January 2013 are summarized as follows:

(1) Risk assessment requests on the following items were made by risk management organizations<sup>1</sup>.

|                                  |   |
|----------------------------------|---|
| Genetically modified foods/feeds | <ul style="list-style-type: none"> <li>• Stacked event of maize obtained from crosses between the following four lines: &lt;Maize resistant to Lepidoptera MON89034 line&gt; &lt;Maize resistant to Lepidoptera and tolerant to glufosinate herbicide 1507 line&gt; &lt;Maize tolerant to glyphosate herbicide NK603 line&gt; &lt;Maize tolerant to aryloxy alkanooate herbicide 40278 line&gt;</li> <li>• L-Arginine produced by genetically modified strain ARG-No.3.</li> <li>• Disodium 5'-inosinate produced by genetically modified strain RN-No.1.</li> <li>• Disodium 5'-ribonucleotide produced by genetically modified strain RN-No.1.</li> </ul> |
| Fertilizers and feeds            | <ul style="list-style-type: none"> <li>• Revision of official specification of ordinary fertilizers prescribed in paragraph (1) of Article 3 of the Fertilizer Control Act (Act No. 127 of 1950).</li> </ul>  |

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

### Additives

| Item              | Conclusion   |
|-------------------|--|
| Potassium sulfate | FSCJ conclusion: The assessed item is considered to be of no concern for food safety as long as used appropriately as a food additive. Therefore, it is not necessary to specify ADI.  |
| Potassium lactate | FSCJ conclusion: The assessed item is considered to be of no concern for food safety as long as used appropriately as a food additive. Therefore, it is not necessary to specify ADI. However, appropriate regulations will be required for the usage of potassium lactate as an additive, and for the usage of food additives containing lactic acid and lactates as a main ingredient in foods for infants, because it may result in metabolic acidosis. |

### Pesticides

| Item          | ADI                     |
|---------------|-------------------------|
| Ametoctradin  | 2.7 mg /kg bw per day   |
| Fenpyroximate | 0.0097 mg/kg bw per day |

<sup>1</sup> E.g. Ministry of Health, Labour and Welfare (MHLW), Ministry of Agriculture, Forestry and Fisheries (MAFF), Consumer Affairs Agency (CAA).

|            |                         |
|------------|-------------------------|
| Phenthoate | 0.0029 mg/kg bw per day |
|------------|-------------------------|

Pesticides

| Item                  | TDI  |
|-----------------------|--|
| Aldrin* and Dieldrin* | 0.000025 mg /kg bw per day and 0.00005 mg /kg bw per day |

\*Since the collected information is limited because the production and use of these substances are currently prohibited, the FSCJ considers that the risk managing organization needs to continue its efforts to collect relevant information.

Veterinary medicines

| Item       | ADI                     |
|------------|-------------------------|
| Lincomycin | 0.0032 mg/kg bw per day |
| Zilpaterol | 0.083 µg/kg bw per day  |
| Narasin    | 0.005 mg/kg bw per day  |

Veterinary medicines

| Item  | Conclusion  |
|---|---|
| A disinfectant for use in herring hatcheries, containing bronopol as an active ingredient (Pyceze). (Reexamination) | FSCJ conclusion: Risk to human health from the assessed item through consumption is negligible as long as appropriately used. |

Fertilizers and feeds

| Item    | ADI                    |
|---------|------------------------|
| Narasin | 0.005 mg/kg bw per day |

Fertilizers and feeds

| Item   | Conclusion   |
|--|--|
| Revision of official specification of ordinary fertilizers prescribed in paragraph (1) of Article 3 of the Fertilizer Control Act (Act No. 127 of 1950). | FSCJ conclusion: Relevant changes in the application for the risk assessment consist of physical procedures, but do not include any chemical procedure. Therefore, relevant changes do not influence the current usage and the exposure level of the item, which were evaluated to not affect human health. Accordingly, the FSCJ concluded 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. |

Genetically modified foods/feeds

| Item   | Conclusion  |
|--|---|
| <p>Stacked event of maize obtained from crosses between the following five lines: &lt;Maize resistant to Lepidoptera MON89034 line&gt;; &lt;Maize resistant to Lepidoptera and tolerant to glufosinate herbicide 1507 line&gt;; &lt;Maize resistant to Coleoptera and tolerant to glyphosate herbicide MON88017 line&gt;&lt;Maize resistant to Coleoptera and tolerant to glufosinate herbicide B.t.Cry34/35Ab1 Event DAS-59122-7 line&gt;; &lt;Maize tolerant to aryloxy alkanoate herbicide 40278 line&gt; (11 stacked events from the relevant crosses, for which the assessment has been done, are not included)</p> | <p>FSCJ conclusion: According to the “Approach to the Safety Assessment of Genetically Modified Plant Hybrids”<sup>2</sup>, the item did not require further assessment.</p>                    |
| <p>Stacked event of maize obtained from crosses between the following four lines: &lt;Maize resistant to Lepidoptera MON89034 line&gt; &lt;Maize resistant to Lepidoptera and tolerant to glufosinate herbicide 1507 line&gt; &lt;Maize tolerant to glyphosate herbicide NK603 line&gt; &lt;Maize tolerant to aryloxy alkanoate herbicide 40278 line&gt; (7 stacked events from the relevant crosses, for which the assessment has been done, are not included)</p>  | <p>FSCJ conclusion: According to the “Approach to the Safety Assessment of Genetically Modified Plant Hybrids”<sup>2</sup>, the item did not require further assessment.</p>                    |
| <p>Maize resistant to Coleoptera Event 5307 line</p>   | <p>FSCJ conclusion: According to the “Approach to the Safety Assessment of Genetically Modified Foods (seed plants)”<sup>3</sup>, Event 5307 line was evaluated not to affect human health.</p> |

<sup>2</sup> “Approach to the Safety Assessment of Genetically Modified Plant Hybrids (Decision of the Commission dated 29 January 2004)

<sup>3</sup> “Approach to the Safety Assessment of Genetically Modified Foods (seed plants) (Decision of the Commission dated 29 January 2004)”