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Consideration on health effects of “Specified Agricultural Chemicals” in foods

1. Background

Food Safety Basic Act (Act No.48 of May 23, 2003) mandates the relevant ministers to hear opinions of the Food Safety Commission of Japan (FSCJ) when they intend to register a new specific agricultural chemical or make changes on the listed chemicals, in accordance with the Article 24, paragraph (1), item (ii) and the Article 2, paragraph (1) of Agricultural Chemicals Regulation Act (Act No. 82 of July 1, 1948). FSCJ was requested to conduct evaluations on ethylene, electrolyzed hypochlorous acid water and shochu by the Minister of Agriculture, Forestry and Fisheries (MAFF) and the Minister of Environment (MOE) on 14th March, 2013.

The types of data needed to evaluate the efficacy and safety of these 3 compounds above are arranged by the MAFF and the MOE. Their efficacy and safety for workers and in the environment have been evaluated by the joint meeting of the Pesticide Committee, the Agricultural Materials Council of MAFF and the subcommittee of “Specified Agricultural Chemicals” of the Expert Committee of the Soil Agricultural Chemical Committee, the Central Environment Council of MOE on 5th October, 2012. Recently, both ministries have re-organized the necessary data for the evaluation of human health effects by these compounds and requested the evaluations.

2. Specified Agricultural Chemicals

(1) Definition

Article 2, paragraph (1) of Agricultural Chemicals Regulation Act, “Specified Agricultural Chemicals” indicates their definition as follows:

Agricultural chemicals that are designated by the MAFF and the MOE to be clearly unlikely to

harm crops, humans, livestock, and sea food animals, and flora and fauna in the human living environment.

(2) Registration overview

Article 2, paragraph (1) of Agricultural Chemicals Regulation Act states that manufacturers must register the pesticide before production, except for specified agricultural chemicals that do not require registration for production.

For a chemical to be designated as a specific agricultural chemical, MAFF and MOE provide the guideline for designation process.

(3) Specific agricultural chemicals already designated

Natural enemies, vinegar and baking soda (MAFF and MOE Notification No. 1, 2003) had been designated before the enactment of Food Safety Basic Law, thus, they are not evaluated for human health effects by the FSCJ.

3. Assessment guide of “Specified Agricultural Chemicals”

(1) Needed information for the assessment

Necessary information should be determined individually with consideration of each chemical’s circumstance. In general, the following pieces of information are expected to be the major source of data:

- A) They way of regular usage and intake situation of consumers
- B) Whether any concerns exist under the usage described above
- C) Accumulation in human body (for judgement of over intake)
- D) Toxicology (and its link to the accumulation in human body should be also accounted)
- E) Assessments by international organizations

(2) Principles of the assessment

Regular pesticides have the established acceptable daily intake (ADI) as a part of health effect evaluation of pesticide residues in foods. For “Specified Agricultural Chemicals”, the main assessment should focus on whether the regular use of these chemicals may give human health effect or not. Predicted conclusions are as follows:

- No concern for human health effects when appropriately used.
- No judgement can be reached for human health based on the submitted data. Additional

request for needed data should be sent out to MAFF and MOE with deadlines.

- Judged as having a human health concern

Note:

In “Not Objected Substance Under Positive-list” (Article 11, paragraph (3) of Food Sanitation Act), the substance is defined as follows:

The substance designated by the Minister of Health, Labour and Welfare as being clearly unlikely to harm human health, and its chemically changed production.