

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.

## Supplement<sup>1</sup>

### **Approach for the Risk Assessment of Processing Aids (Food Disinfectants and Extractants)**

The Food Safety Commission of Japan (FSCJ) has conducted risk assessments of food disinfectants and extractants (referred to as “disinfectants etc.” hereinafter) that are used as processing aids<sup>2</sup>, according to the “Guideline for Assessment of the Effect of Foods on Human Health Regarding Food Additives” (May 27, 2010) (hereinafter referred to as “Guideline for Assessment of Additives”). Recently, a study entitled “Study on the Procedure for the Risk Assessment of Food Additives for Fortification and Processing Aids in Japan” (Principal Investigator: Takashi Umemura, National Institute of Health Science) was conducted with the support of a FSCJ grant for Research and Survey Program. The study summarized the guidelines for the risk assessment of processing aids<sup>3</sup>, taking into account the previously conducted risk assessments of food disinfectants and extractants and the survey report on approaches for risk assessment of processing aids employed in international organizations. The FSCJ finalized the approach for the risk assessment of disinfectants etc. based on the research report by Umemura’s group. From now on, evaluation of findings on safety, estimation of daily intake, and risk assessment of disinfectants etc. shall be conducted according to this approach.

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<sup>1</sup> Supplement for “Guidelines for Assessment of the Effect of Food on Human Health Regarding Food Additives” (May 2017).

<sup>2</sup> “Processing aids” in this Supplement designates the substance that meets one of the following conditions, among food additives used in food processing.

- 1) An additive that is removed from the food before final packaging.
- 2) An additive that is converted to a naturally contained component in food, and the amount of the component does not significantly increase the amount of the natural component.
- 3) An additive that is found only in trace amounts in the final food product and has no effect on the food.

<sup>3</sup> A research on methods for assessment of the effect of foods on human health, “Study on the Procedure for the Risk Assessment of Food Additives for Fortification and Processing Aids in Japan”. By Takashi Umemura et al., (Res. No. 1502) (March 2016) (in Japanese)

## Information relevant to safety

Evaluation procedure follows Article 2 of Chapter 2 of Guideline for Assessment of Additives<sup>4</sup>. The evaluation may need to be conducted on a decomposition product from the additive that might be produced during the usage, since it is described in Article 4 of Chapter 1 of the Guideline as follows: “8. The necessity of evaluating decomposition products, contaminant impurities and human metabolites of food additives shall be considered. The stability of food additives and their stability in food shall be considered as well. When they are unstable, the composition products and their levels shall also be examined.” Particularly in risk assessments of disinfectants etc., the necessity of evaluating decomposition products that might be produced from the additive through the usage may arise.

## Estimation of daily intake

Article 4 of Chapter 2 of “Guideline for Assessment of Additives” is not applied for estimating the daily intake. For estimating the daily intake, basically, the maximum residue in the final product shall be calculated based on the residue analysis and multiplied by the daily intake of food in which the disinfectants etc. are to be added. If the residue level is below the detection limit, the detection limit is taken as the maximum residue in principle. Daily intake of a food shall be estimated appropriately based on the daily intake of each food group reported in the National Health and Nutrition Survey or other documents. As for decomposition products that might be produced from the additive through usage, the daily intake shall be estimated by the same calculation as mentioned above, that is; the maximum residue in the final product shall be calculated based on the residue analysis and multiplied by the daily intake of food in which the disinfectants etc. are to be added. Body weight used for the estimation shall be the average body weight designated in the latest decision of FSCJ.

## Risk Assessment

In principle, the approach described in “1. Approach for establishing ADI” in Article 7 of Chapter 1 of Guideline for Assessment of Additives is not applied for the assessment of disinfectants etc., while Margin of Exposure (MOE) shall be evaluated as follows.

- (1) When multiple NOAELs are obtained from comprehensive evaluation of toxicity studies, in principle, the minimum value obtained by comparing NOAELs among animal species and among toxicity studies shall be used for the evaluation.
- (2) Evaluation of MOE shall be based on the comparison of NOAEL with the estimated daily intake. However, in case where disinfectants and extractants are eliminated or decomposed during the process of food production, the daily intake may be overestimated.

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<sup>4</sup> “Guidelines for Assessment of the Effect of Food on Human Health Regarding Food Additives” (May 2010) is available at <http://www.fsc.go.jp/english/RiskAssessment.data/guidelineforfoodadditives.pdf>