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Consideration on data required for re-evaluation (Article 8 of Agricultural Chemical Regulation Act) of pesticide residues

The principle on re-evaluation (Article 8 of Agricultural Chemical Regulation Act)

In re-evaluation of a pesticide, its residual's human health effects from foods should be conducted based on all the data submitted from the risk manager, and the latest scientific base should be applied.

Each pesticide has different set of toxicological and metabolic profiles, their years of studies performed vary, and varied degree of gap from guidelines exist, thus the necessity of additional data for the re-evaluation should be judged case-by-case..

The basic concept for data necessity

1. All studies should be performed in accordance with the most current guidelines of the Ministry of Agriculture, Forestry and Fisheries (MAFF). If not, specific reasons should be identified. When Food Safety Commission establishes a guideline for the assessment of the effect of pesticide residue in food on health, this guideline should be prioritized for implementation of tests. In case that the toxicological or metabolic profiles were already available, but their ways of conducting was not meeting all the criteria listed in the latest guideline, their data sufficiency will be judged first, then a new test may not be exempted if they are determined to be adequate.
2. Ideally, the studies should be all conducted in compliance with good laboratory practice (GLP). However, for toxicological and metabolic profiles, non-GLP or pre-GLP data may be accepted if these data were thought to be adequate.
3. For evaluations that have previously set to apply an additional safety factor, or that have been through discussions and determined to need additional data for evaluation, submissions of the corresponding data of these pesticides are recommended to carry re-evaluation to meet the latest

scientific criteria.

4. Upon the reception of data for re-evaluations, the Expert Committee on Pesticides takes into account of the re-evaluation results of other countries.