

RESEARCH REPORT - No. 1502 FY 2015

Title of research project	Draft guidelines on safety assessments of nutrients and processing aids
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【Abstract】 As is clear from the fact that there are some countries where nutrients or processing aids are not categorized into food additives, it should be concerned about their characteristics. The aim of this research project is to provide draft guidelines on safety assessments of nutrients and processing aids. In terms of nutrients, we noted the criteria of human hazards, the preparation of evidence table and its evaluation methods, and introduction of Highest Observed Intake (HOI) as a safety assessment parameter. Since safety assessment for food additives should be comprehensively performed based on the various data such as the estimated exposure level and the toxicological data in humans, the draft guidelines mentioned the basic consideration about NOAEL, HOI and analysis for animal data. In addition, simulation of safety assessment for vitamin D and leucine was conducted according to the draft guidelines and then, the issues in the guidelines were confirmed. In terms of processing aids, digestion of substances with enzyme activities in the intestinal tract and safety assessment of allergenic substances were particularly noted and we proposed new aspects of margin of exposure in safety assessments for processing aids. Though some issues remain unsolved, this draft guidelines could be helpful for establishment of guidelines of nutrients and processing aids.	