Application of the Margin of Exposure Method Using the Benchmark Dose Approach for Risk Assessment of Food Contaminants in JECFA

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＜Summary＞

Trend of the risk assessment methodology using benchmark dose (BMD) approach in the recent JECFA meetings, especially for the food contaminants assessment, is reviewed in this report. Since the 64th meeting (2005), JECFA have introduced the Margin of Exposure (MOE) approach as quantitative dose-response assessment of genotoxic carcinogens. At the meeting, three kinds of genotoxic carcinogens, including acrylamide, were evaluated by calculating the MOEs between a point of departure (POD) on the dose-response for oral carcinogenicity in animal studies and estimates of human dietary exposure. It is well known that the MOE would be helpful to support prioritization or decision of risk management action. Also the 64th meeting suggested that the strengths and weaknesses inherent in the data used to calculate the MOE should be given as part of the advice to risk managers, together with advice on its interpretation. In case of acrylamide, the relatively lower MOE indicated that the possibility of health concern with uncertainties associated with the MOE derivation, including the issues of species differences of metabolism and dose-response. After collecting the latest information of acrylamide, the re-evaluation was conducted at the 72nd meeting. Although the final values of the MOEs for acrylamide were almost same as the previous results, the reliability of the values per se was increased due to the intelligible and reproducible research results. But the more longitudinal epidemiological studies were required in order to better estimate the risk from acrylamide in food for humans. At the 72nd meetings, five other contaminants were also evaluated by using the BMD approach. As various types of (epidemiological, continuous parameters, etc.) data were selected for the BMD calculation, some of the calculation steps (the level of BMR, the criteria of a model selection, etc.) were modified or optimized depending on the nature of the critical endpoints. However, the application of dose-response modeling is still a developing field, and establishing the detailed guidance for BMD methods as well as developing the guidance for risk management options based on the MOE evaluation would be needed in future.