RESEARCH REPORT - No. 1204 FY 2012–2013

Title of research project	Usage of safety factor for evaluation of non-observed adverse effect level (NOAEL) in risk assessment of chemicals to high risk group people of life style related diseases.
Research project no.	(1204)
Research period	FY 2012–2013
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【Abstract】

In risk assessment of chemicals including food additives, a safety factor conventionally 100, to account for the differences between test animals and humans（factor of 10）and possible differences in sensitivity between humans（another factor of 10）is used for quantifying the food safety as ADI and other values, based on No Observed Adverse Effect Level (NOAEL) which is taken from experiments with healthy animals generally. However, applicability of this value of safety factor needs to be considered for the case of humans with lifestyle related disease such as diabetes, hypertension and hyperlipidemia, because of high incidence rate of such lifestyle related disease in Japan. Particularly, it seems to be important to examine whether a factor to account for individual differences in sensitivity, between these patients and healthy people, is fit within“10”or not. In this study, accordingly, 90-day repeated oral toxicity of acetaminophen and 3-MCPD was studied in healthy and diabetes-, hypertension- and hyperlipidemia-model animals comparing each NOAEL value between healthy animals and the disease model animals.

As a results, difference of each NOAEL between healthy animals and diabetes model and hyperlipidemia model animals was within a factor of 10 for acetaminophen and 3-MCPD. In hypertension model animals, difference of NOAEL for acetaminophen to healthy animals was within a factor of 10. But for 3-MCPD, NOAEL could not be specified though LOAEL was determined, therefore a further study with lower dose is required.

In conclusion, these result suggest that it is unnecessary to use a safety factor different from the conventional 10 for the people with life style related disease such as diabetes, hypertension and hyperglycemia in risk assessment of at least acetaminophen and 3-MCPD.