

Title of research project	Research on Development of Software Calculating the Benchmark Dose Using Dichotomous Response Data
Research project number	1907
Research period	FY 2019 - 2020
Name of principal research investigator (PI)	Hiroshi Nishiura

Abstract/Summary

The Benchmark dose (BMD) method is an emerging method for toxicological risk assessment, using multitudes of statistical models. Under the BMD method, multiple statistical models are fitted to empirical dose-response data to obtain benchmark dose lower limit, also known as BMDL value. BMDL is known to be a proxy of non-observed adverse effect level (i.e., NOAEL) as in classical toxicological assessments. Our study aimed to implement the BMD calculation for dichotomous response data, which is unique to the risk assessment guidance in Japan. We developed the Japanese and English versions of software with a graphical user interface (GUI), so that the implementation of this method becomes more familiar both in Japan and overseas.

To achieve the goals, the following six subjects were explored: (i) determining the specification of the software, (ii) implementing the BMD calculation by GUI software with averaging function only for models with the good adaptability, (iii) checking and revising bugs (errors in programming), and explaining the software to those involved, (iv) updating the software in Japanese and adapting the English environment, (v) implementing GUI software and assessing its performance, and (vi) giving a software demonstration to people involved in the development, from the aspect of comparison to the preexisting software.

We successfully developed the software of BMD calculation in Japanese and English that is well aligned with the guidance for dichotomous data analysis. For toxicological risk assessment, the developed software enables users to choose among the model selections and average processing functions. This development of Japan's original software would allow us to offer a convenient assessment method to a broad range of users with toxicological data, including government agencies and domestic/global users who are interested.

<p>This report provides outcome of the captioned research program funded by Food Safety Commission Japan (FSCJ). This is not a formal publication of FSCJ and is neither for sale nor for use in conjunction with commercial purpose. All rights are reserved by FSCJ. The view expressed in this report does not imply any opinion on the part of FSCJ.</p>
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1. List of papers published on the basis of this research
None.

2. List of presentations based on this research
Nishiura H, Yamaguchi T. Benchmark Dose Software for Toxicological Risk Assessment in Japan. Session Title: Biological Modeling, Session Time: 3/18/2020 9:00:00 AM to 3/18/2020 10:45:00 AM. SOT 59th Annual Meeting & ToxExpo, March 15-19, 2020, Anaheim, California. (Withdrawal of participation due to the pandemic of COVID-19)
Yamaguchi T, Nishiura H. Developing GUI software of the benchmark dose method combining the model selection and average processing function. The 90th Annual Meeting of the Japanese Society for Hygiene. March 26-28, 2020, Iwate.
Yamaguchi T, Kayano T, Nishiura H. Developing software of the BMD method and comparing the performance with other software for toxicity data evaluation. The 91st Annual Meeting of the Japanese Society for Hygiene. March 6-8, 2021. Poster presentation.

3. Number and summary of patents and patent applications
None.

4. Other (awards, press releases, software and database construction)
The 9th Hiroshi Fujiwara Prize for Mathematical Science, Grand Prize. Hiroshi Nishiura. November 2020.