

(別紙) 研究成果の概要 (英文)

Title of research project	Study on migration test in risk assessment for synthetic resin for apparatus, containers and packaging
Research project number	1706
Research period	FY 2017 – 2019
Name of principal re- search investigator (PI)	Motoh Mutsuga (National Institute of Health Sciences)

Abstract/Summary

The positive list system for synthetic resin for apparatus, containers and packaging will come into effect in June 2020. By this effect, the Food Safety Commission is to conduct risk assessment of new substances on the positive list. However, no specific risk assessment method had been shown at the start of this study. Therefore, there is an urgent need to develop a risk assessment method centered on the migration test method. We compared the current legislative frameworks of Japan, the United States of America (USA) and the European Union (EU), and investigated the latest migration test methods for risk assessment in the USA and the EU. Based on these results, we developed a draft of estimation method of dietary concentration (DC) and a migration test for risk assessment of synthetic resin for apparatus, containers and packaging in Japan.

The estimation method of DC was constructed by comparing Japan's positive list system with the systems of the USA and the EU. Eight model samples, which contain 8-10 kinds of substances, such as polyethylene, polypropylene, polyethylene terephthalate, polystyrene, polyamide, rigid polyvinyl chloride, soft polyvinyl chloride and polyvinylidene chloride were prepared. The migration tests were performed under various conditions using these model samples.

Regarding additives that are listed in the voluntary standards of Japanese industry associations, we conducted a survey on the consistency between the voluntary standards and the regulations of the USA and the EU. About 75% of the substances has been authorized for use in the USA or the EU. On the other hand, about 5% of the substances is not approved for use in the USA nor the EU. The estimation method of DC was proposed considering the Japanese positive list system: The DC is calculated from the consumption factor (CF) and distribution factor (DF) of the seven plastic group and the migration amount (Q) of the five food categories. In the migration test conditions, the sample types (physical properties, content of target substance, shape, thickness) and test conditions (food simulant, simulant volume/sample surface ratio, migration temperature and time) were considered. The test conditions were based on the results of actual and *in silico* migration tests using model samples. Particularly, we performed various migration tests to set conditions for (i) accelerated conditions of long-term preservation food, (ii) dry food, (iii) alternative conditions of oils and fatty

food, (iv) microwave heating. These results were reflected in the draft.

The report of this study has been adopted in the "Guidelines for the Risk Assessment of Food Apparatus, Containers and Packaging" (May 2019), and will serve as an important document on applying the guidelines.

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1. List of papers published on the basis of this research

None.

2. List of presentations based on this research

- 1) Miku Yamguchi¹, Yutaka Abe¹, Asako Ozaki², Eri Kishi², Daichi Asakawa³, Tomoyuki Abe⁴, Toru Nakanishi⁵, Kazunari Watanabe⁶, Motoh Mutsuga¹, Kyoko Sato¹ (¹National Institute of Health Sciences, ²Osaka Institute of Public Health, ³Osaka City Institute of Public Health and Environmental Sciences, ⁴Japan Food Hygiene Association, ⁵Japan Food Research Laboratories, ⁶Japan Chemical innovation and Inspection Institute), Study on migration test conditions for fatty food in "Guidelines for the Risk Assessment of Food Apparatus, Containers and Packaging", The 25th general meeting and academic convention of the Japanese Society and Food Chemistry, Nagano (June, 2019)
- 2) Eri Kishi¹, Asako Ozaki¹, Daichi Asakawa², Yutaka Abe³, Miku Yamguchi³, Tomoyuki Abe⁴, Toru Nakanishi⁵, Kazunari Watanabe⁶, Yukihiko Yamaguchi¹, Tetsuo Yamano¹, Motoh Mutsuga³, (¹Osaka Institute of Public Health, ²Osaka City Institute of Public Health and Environmental Sciences, ³National Institute of Health Sciences, ⁴Japan Food Hygiene Association, ⁵Japan Food Research Laboratories, ⁶Japan Chemical innovation and Inspection Institute), Comparison of predicted migration levels for synthetic resin for apparatus, containers and packaging using simulation software with actual measured values, The 25th general meeting and academic convention of the Japanese Society and Food Chemistry, Nagano (June, 2019)
- 3) Chiharu Mizuguchi¹, Asako Ozaki¹, Eri Kishi¹, Daichi Asakawa², Yutaka Abe³, Miku Yamguchi³, Tomoyuki Abe⁴, Toru Nakanishi⁵, Kazunari Watanabe⁶, Yukihiko Yamaguchi¹, Tetsuo Yamano¹, Motoh Mutsuga³, (¹Osaka Institute of Public Health, ²Osaka City Institute of Public Health and Environmental Sciences, ³National Institute of Health Sciences, ⁴Japan Food Hygiene Association, ⁵Japan Food Research Laboratories, ⁶Japan Chemical innovation and Inspection Institute), Study on migration test for long-term preservation food in risk assessment for synthetic resin for apparatus, containers and packaging, The 115th Meeting of Japanese Society for Food Hygiene and Safety, Tokyo

(October, 2019)

- 4) Daichi Asakawa¹, Asako Ozaki², Eri Kishi², Yutaka Abe³, Miku Yamaguchi³, Motoh Mutsuga³, (¹Osaka City Institute of Public Health and Environmental Sciences, ²Osaka Institute of Public Health, ³National Institute of Health Sciences), Study on migration test for dry food in risk assessment for synthetic resin for apparatus, containers and packaging, The 115th Meeting of Japanese Society for Food Hygiene and Safety, Tokyo (October, 2019)

3. The number and summary of patents and patent applications

None.

4. Others (awards, press releases, software and database construction)

The report of this study has been adopted in the "Guidelines for the Risk Assessment of Food Apparatus, Containers and Packaging" (May 2019).