

## Introduction

In the OECD Test Guideline 305<sup>1)</sup> for evaluating bioconcentration factor (BCF) for fish, it has been recommended to evaluate BCF by using two test concentrations. Recently, the test guideline "Aqueous Exposure Bioconcentration Fish Test (305-I)" was revised on October 2012 when adding new method "minimized aqueous exposure fish test (305-II)" in order to reduce the number of test fish from a viewpoint of animal protection. When it is determined that they satisfy government-imposed standard, BCF is evaluated by using one test concentration data. So it is necessary to determine the standard criteria.

In this study, we investigated the applicability of one concentration BCF test by analyzing the concentration dependence of the bioconcentration factor for fish.

## Materials and Methods

The BCF test data for 549 low-molecular-weight existing chemicals<sup>2)</sup> and 201 new chemicals (notification period: Apr. 2007 – Sep. 2013) obtained under the Chemical Substances Control Law in Japan were used for the analysis. The BCF<sub>H</sub> (the BCF value in the high test concentration) and the BCF<sub>L</sub> (the BCF values in the low test concentration) in the data set were compared.

## Results and Discussion

For more than 26.4% of existing chemicals, BCF<sub>L</sub> were more than twice BCF<sub>H</sub> value (Fig.1,2). However, for 342 existing chemicals that were tested in the concentration lower than its water solubility and with BCF<sub>L</sub> ≥ 100, the differences between BCF<sub>H</sub> and BCF<sub>L</sub> were 1.2% (Fig.1). Only 4 chemicals (No.1-4) with BCF<sub>L</sub> more than 100 showed the difference (BCF<sub>L</sub> - BCF<sub>H</sub>) more than double. For the 3 chemicals (No.2-4) out of the 4 chemicals some concerns on the accuracy of determination were found when we checked the test report. Therefore, only one case, Tetrabutyl- Stannane (No.1, BCF<sub>H</sub>=68, BCF<sub>L</sub>=219, BCF<sub>L</sub>/BCF<sub>H</sub>=3.2), tends to have higher BCF<sub>L</sub> value than other chemicals by factors other than the error of measurement. We need to pay attention for this case. Because the organotin compound has a protein binding, its bioconcentration potential may become higher.

Similarly, we compared BCF<sub>L</sub> with BCF<sub>H</sub> in 201 new chemicals that were tested in the concentration lower than its water solubility and with BCF<sub>L</sub> ≥ 100 (Fig.3). The differences for more than double between BCF<sub>H</sub> and BCF<sub>L</sub> were only 3 chemicals (No.5-7). For the these 3 chemicals, it is assumed to be the influence of the adsorption in bioconcentration of chemicals when we checked the test report. And it is found that No.6 is a perfluorochemical and a surfactant.

From these results, METI (Ministry of Economy, Trade and Industry) announced on June 2014 that the BCF value measured by using one test concentration data can be submitted in the registration of new chemicals under the CSCL. However, it is applied in the following conditions:

### 305-I test data:

1. The test concentration is less than one-tenth of its water solubility.
2. The test measurement is a concentration of the lowest possible level.
3. BCFs (the steady-state bioconcentration factor) is measured, and the value is less than 500.
4. It excepts for inorganic metallic compounds, organic metallic compounds, surfactants, perfluorochemicals and multicomponent mixture.

### 305-II test data:

1. The test concentration is less than one-tenth of its water solubility.
2. The test concentration and the fish concentration is more than 10 times for a determination limit of measurement devices.
3. A chemical is not achieved during uptake, provided that uptake and depuration act approximately according to first order kinetic processes.
4. BCF<sub>k</sub> (the kinetic bioconcentration factor) is measured, and the value is less than 200.
5. BCF<sub>k</sub> ≥ Minimised BCFs
6. Limited to a chemical whose logPow is less than six.
7. It excepts for inorganic metallic compounds, organic metallic compounds, surfactants, perfluorochemicals and multicomponent mixture.

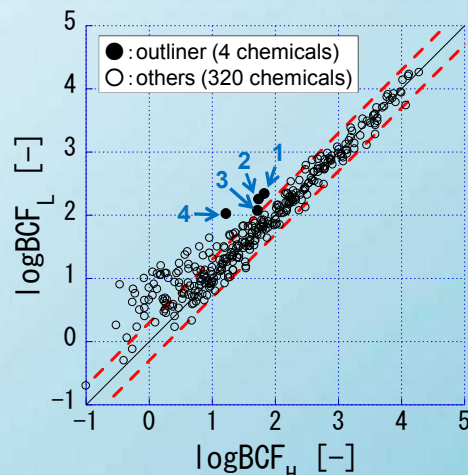
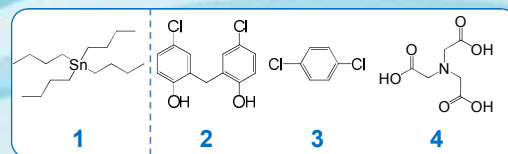


Fig.1 logBCF<sub>H</sub> vs. logBCF<sub>L</sub> plot. (324 existing chemicals that were tested in the concentration lower than its water solubility)

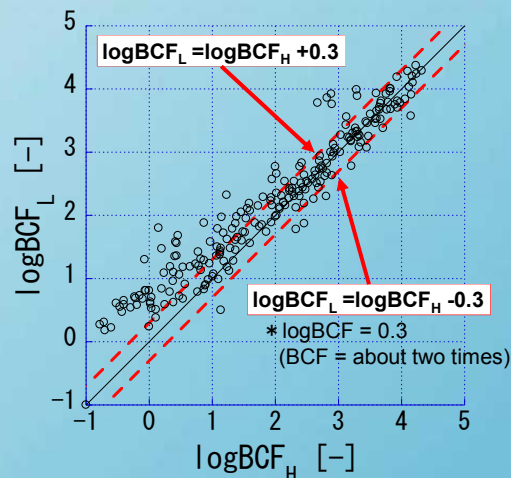


Fig.2 logBCF<sub>H</sub> vs. logBCF<sub>L</sub> plot. (Other 225 existing chemicals)

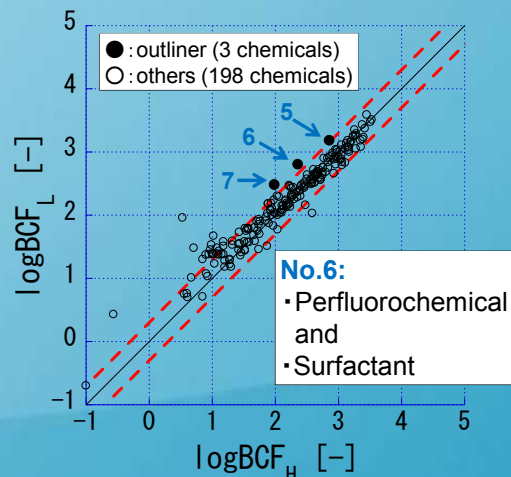


Fig.3 logBCF<sub>H</sub> vs. logBCF<sub>L</sub> plot. (201 new chemicals that were tested in the concentration lower than its water solubility)

1) OECD Test Guideline 305: [http://www.oecd-ilibrary.org/environment/test-no-305-bioaccumulation-in-fish-aqueous-and-dietary-exposure\\_9789264185296-en](http://www.oecd-ilibrary.org/environment/test-no-305-bioaccumulation-in-fish-aqueous-and-dietary-exposure_9789264185296-en)

2) J-CHECK (Japan CHEmicals Collaborative Knowledge database): <http://www.safe.nite.go.jp/jcheck/top.action>