



FY2024 Ecosystem Impact Assessment and Trend Survey on Microplastics Study Results

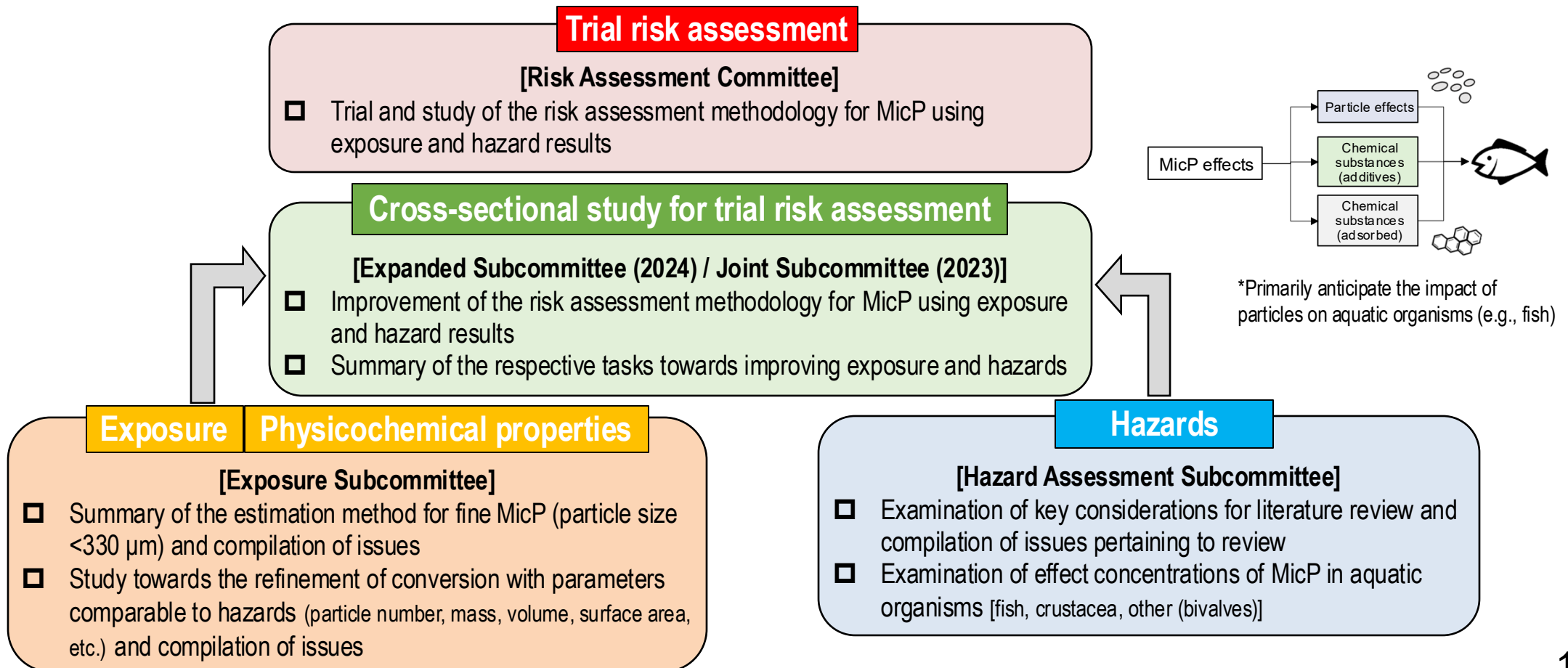
Office of Policies Against Marine Plastics Pollution, Marine Environment Division

Executive Office: Mizuho Research & Technologies, Ltd.

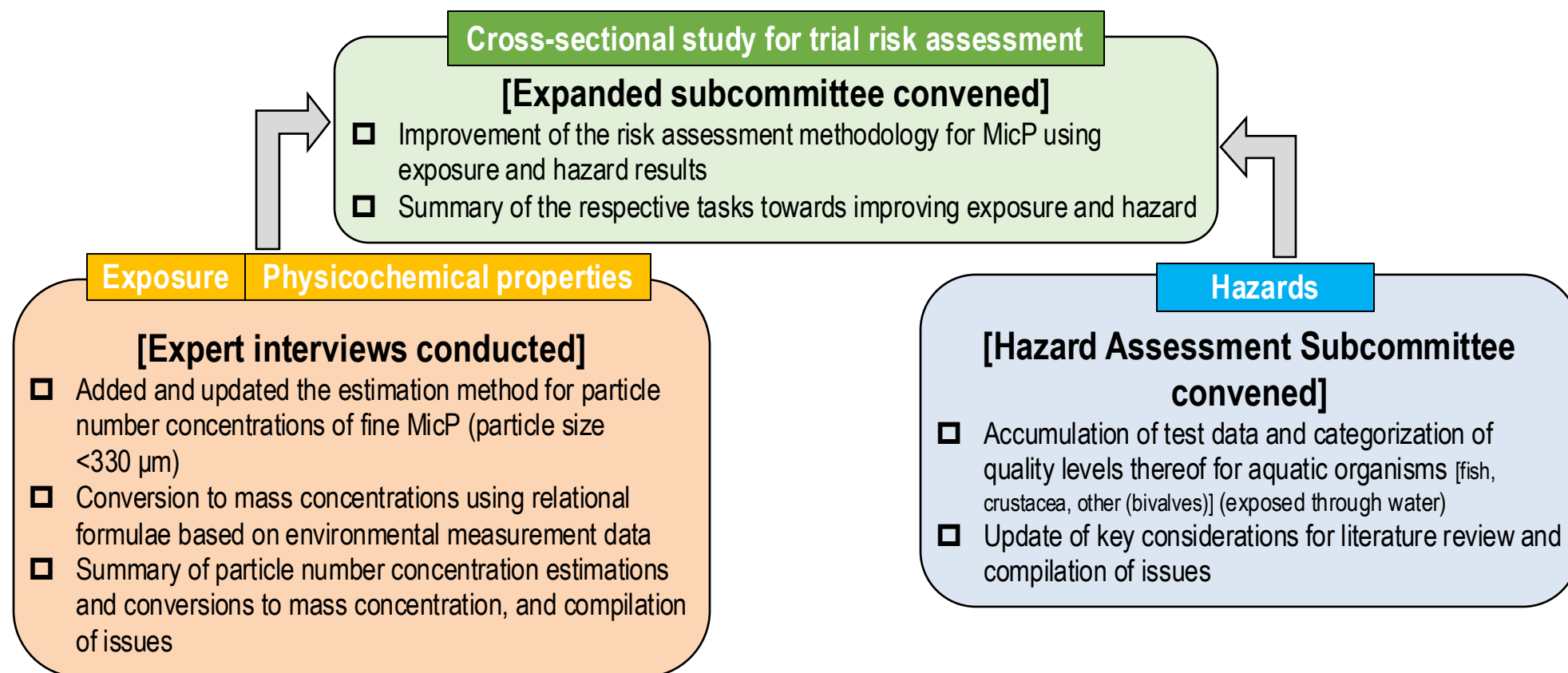


Current Project Overview

- Background: There is concern about the impact of microplastics (MicP) on organisms and ecosystems. There is a need for quantitative data that sheds light on hazards and risk as much as possible.
- Objective: After collecting scientific knowledge on the MicP exposure and environmental fate, hazards to aquatic organisms, among others, the project aims to establish a preliminary risk assessment method to quantitatively assess the impact on organisms and ecosystems and thereby estimate the risk so as to inform government decision-making in the future. (Although there are concerns regarding the impact of MicP particles and chemicals on organisms and ecosystems, this study focused on the effects of particles on aquatic organisms.*)



- Examined further methodological improvements and additional perspectives to consider with respect to a framework for a MicP risk assessment methodology for aquatic organisms as discussed in FY2023.
 - In exposure assessments, added and updated the particle number concentrations estimation formula for fine MicP on the marine surface layer through interviews and literature research. Also used relational formulae to convert to mass concentrations based on environmental measurement data.
 - In hazard assessments, continued to collect test data through review and discriminated these quality levels. Updated the “Key Considerations for Literature Review” as an overview of the basic approaches to determining the usability of test data.



FY2024 Committee List (Expanded Subcommittee)

Name (The honorific titles are omitted, in alphabetical order.)	affiliation
Atsuhiko Isobe (Chair: Exposure)	Distinguished Professor, Center for Oceanic and Atmospheric Research, Research Institute for Applied Mechanics, Kyushu University
Yuji Oshima (Chair: Hazard Assessment)	Professor Emeritus, Kyushu University
Go Suzuki	Head, Material Cycles Science and Engineering Research Section, Material Cycles Division, National Institute for Environmental Studies
Hideshige Takada	Professor, Institute of Agriculture, Division of Environmental Science on Biosphere, Tokyo University of Agriculture and Thechnology
Norihisa Tatarazako	Professor, Graduate School of Agriculture, Department of Science and Technology for Biological Resources and Environment, Ehime University
Shuhei Tanaka	Associate Professor, Graduate School of Global Environmental Studies, Kyoto University
Wataru Naito	Head, Risk Assessment Strategy Group, Research Institute of Science for Safety and Sustainability, National Institute of Advanced Industrial Science and Technology
Haruhiko Nakata	Associate Professor, Graduate School of Science and Technology, Kumamoto University
Hisayuki Nakatani	Professor, Graduate School of Integrated Science and Technology, Chemistry and Materials Engineering Program, Nagasaki University
Hiroshi Yamamoto	Director, Health and Environmental Risk Division, National Institute for Environmental Studies
Haruna Watanabe	Senior Researcher, Ecotoxicity Research Section, Health and Environmental Risk Division, National Institute for Environmental Studies

FY2024 Committee List (Hazard Assessment Subcommittee)

Name (The honorific titles are omitted, in alphabetical order.)	affiliation
Yuichi Iwasaki	Senior Researcher, Risk Assessment Strategy Group, Research Institute of Science for Safety and Sustainability, National Institute of Advanced Industrial Science and Technology
Nobuyuki Ohkubo	Head, Environmental Chemistry and Ecotoxicology Group, Environmental Conservation Division, Fisheries Technology Institute, National Research and Development Agency, Japan Fisheries Research and Education Agency
Yuji Oshima (Chair)	Professor Emeritus, Kyushu University
Norihisa Tatarazako	Professor, Graduate School of Agriculture, Department of Science and Technology for Biological Resources and Environment, Ehime University
Takeshi Hano	Senior Researcher, Environmental Chemistry and Ecotoxicology Group, Environmental Conservation Division, Fisheries Technology Institute, National Research and Development Agency, Japan Fisheries Research and Education Agency
Haruna Watanabe	Senior Researcher, Ecotoxicity Research Section, Health and Environmental Risk Division, National Institute for Environmental Studies
Hiroshi Yamamoto (Vice Chair)	Director, Health and Environmental Risk Division, National Institute for Environmental Studies

Reference: (no-meeting in FY2024) Committee List (Risk Assessment Committee)

Name (The honorific titles are omitted, in alphabetical order.)	affiliation
Koji Arizono	Special Appointment Professor, Graduate School of Pharmaceutical Sciences, Kumamoto University
Atsuhiko Isobe	Distinguished Professor, Center for Oceanic and Atmospheric Research, Research Institute for Applied Mechanics, Kyushu University
Yuji Oshima	Professor Emeritus, Kyushu University
Yoshihisa Shirayama (Chair)	Adviser, Research Institute for Global Change, Japan Agency for Marine-Earth Science and Technology Professor Emeritus, Kyoto University
Go Suzuki	Head, Material Cycles Science and Engineering Research Section, Material Cycles Division, National Institute for Environmental Studies
Hideshige Takada	Professor, Institute of Agriculture, Division of Environmental Science on Biosphere, Tokyo University of Agriculture and Thechnology
Norihisa Tatarazako	Professor, Graduate School of Agriculture, Department of Science and Technology for Biological Resources and Environment, Ehime University
Wataru Naito	Head, Risk Assessment Strategy Group, Research Institute of Science for Safety and Sustainability, National Institute of Advanced Industrial Science and Technology
Hiroshi Yamamoto	Director, Health and Environmental Risk Division, National Institute for Environmental Studies

Reference: (no-meeting in FY2024) Committee List (Exposure Subcommittee)

Name (The honorific titles are omitted, in alphabetical order.)	affiliation
Atsuhiko Isobe (Chair)	Distinguished Professor, Center for Oceanic and Atmospheric Research, Research Institute for Applied Mechanics, Kyushu University
Kameda Yutaka	Professor, Department of Civil and Environmental Engineering, Faculty of Creative Engineering, Chiba Institute of Technology
Go Suzuki (Vice Chair)	Head, Material Cycles Science and Engineering Research Section, Material Cycles Division, National Institute for Environmental Studies
Kazutaka Takahashi	Professor, Laboratory of Aquatic Biology and Environmental Science, Department of Aquatic Bioscience, Graduate School of Agricultural and Life Sciences, The University of Tokyo
Kosuke Tanaka	Researcher, Material Cycles Science and Engineering Research Section, Material Cycles Division, National Institute for Environmental Studies
Shuhei Tanaka	Associate Professor, Graduate School of Global Environmental Studies, Kyoto University
Hisayuki Nakatani	Professor, Graduate School of Integrated Science and Technology, Chemistry and Materials Engineering Program, Nagasaki University
Haruhiko Nakata	Associate Professor, Graduate School of Science and Technology, Kumamoto University
Rei Yamashita	Project Researcher, Biology of Fisheries Resources, Department of Living Marine Resources, Atmosphere and Ocean Research Institute, The University of Tokyo

Exposure Assessment

Implemented Items and Results in Exposure Assessment

[I. Added and updated estimation formulae for particle number concentrations]

- In FY2023, the methods used to estimate MicP concentrations in the marine surface layer were: 1) Cozar model and 2) the Kaandorp model. In FY2024, two models were added: 3) the Aoki model and 4) the sugar lump model, to conduct study
- Ministry of the Environment measurement data for MicP of particle size 330 μm or above was used for estimates after correcting for MicP leaked from nets (up to about 150 μm) using the Tokai et al. (2021) correction formula.
- These methods have limitations and challenges (summarized in P15), making it difficult to determine the most appropriate method, so multiple methods are included for each particle size category. Estimation results varied significantly depending on the estimation formula used and the degree in the power-law distribution.

[II. Conversion to mass concentrations using relational formulae based on environmental measurement data]

- In FY2023, we converted to mass concentrations using hypothetical shapes and densities, while in FY2024 we used relational formulae to convert to mass concentrations based on environmental measurement data. Specifically, we used the relational formula between MicP major axis and projected area (Tokai et al., 2021) and the relational formula between the projected area and mass (Kataoka et al., 2024). (Hereinafter, these two relational formulae will be collectively referred to as the “empirical formulae”) The applicable range of the empirical formulae was set to a particle diameter of 10 μm or larger, as the relationship equation between projected area and weight (Kataoka et al. (2024)) is applicable to particles with a diameter of 10 μm or larger.
- The Cozar model assumes that mass is conserved for each particle size, so mass is expected to be fixed regardless of particle size. However, conversions using the empirical formulae found that total mass would vary by particle size if three-dimensional fragmentation (3D fragmentation) was assumed. This contradicts the assumption of mass conservation, so it is thought unlikely to see three-dimensional fragmentation (3D fragmentation) alone in the actual environment. In this study, the discussions in the subcommittees and interviews were condensed into the assumption of two-dimensional fragmentation mainly for particle sizes of 10 μm and larger, which fall within the applicable range of the empirical formula, with a progression into three-dimensional fragmentation for particle sizes of 10 μm and smaller.
- These methods have limitations and challenges (summarized in P15), making it difficult to set a specific method, so multiple methods are included for each particle size category. Estimation results varied significantly depending on the estimation formula used and the degree in the power-law distribution.

I. Added and Updated Estimation Formulae for Particle Number Concentrations

Four Types of Estimation Methods

- In FY2023, the methods used to estimate MicP concentrations in the environment were: 1) Cozar model and 2) the Kaandorp model.
- In FY2024, two models were added: 3) the Aoki model and 4) the sugar lump model, to conduct study.
- In models 1 and 2, as particle size decreases, the particle number concentration increases monotonically. In models 3 and 4, it is assumed that as particle size decreases, more energy is required for fragmentation. and so fragmentation itself is less likely to occur.

Estimation methods for microplastics with fine particle sizes

Estimation model	Developed by	Characteristics
1) Cozar model ^{*1}	Spain - University of Cádiz Cozar et al. (2014)	Generic formula in which particle number concentration changes exponentially relative to particle size. It was assumed that the total mass summed across all particle sizes remains constant regardless of particle size variation.
2) Kaandorp model ^{*2}	Netherlands - Utrecht University Kaandorp et al. (2021)	Model in which particles fragment in a fractal (self-similar) manner when subject to shocks. Fragmentation probability after a shock depends only on the material (<u>fragmentation probability does not depend on particle size</u>).
3) Aoki model ^{*3}	Meteorological Research Institute Kunihiro Aoki et al. (2021)	Model that applies statistical mechanics to fracture energy occurrence probability. Smaller fragment shapes require larger fracture energy (i.e. <u>fragmentation probability is dependent on particle size</u>).
4) Sugar lump model ^{*4}	France - University of Montpellier George et al. (2024)	Model in which there is threshold set for particle size such that fragmentation probability varies around that threshold (i.e. <u>fragmentation probability is dependent on particle size</u>) This allows for the amount of plastic entering the ocean to be changed depending on the year.

^{*1} Cózar, A., Echevarría, F., González-Gordillo, J.I., Irigoien, X., Úbeda, B., Hernández-León, S., Palma, Á.T., Navarro, S., García-de-Lomas, J., Ruiz, A., Fernández-de-Puelles, M.L., Duarte, C.M., 2014. Plastic debris in the open ocean. Proceedings of the National Academy of Sciences 111, 10239–10244.

^{*2} Kaandorp, M.L.A., Dijkstra, H.A., Sebille, E. van, 2021. Modelling size distributions of marine plastics under the influence of continuous cascading fragmentation. Environ. Res. Lett. 16, 054075.

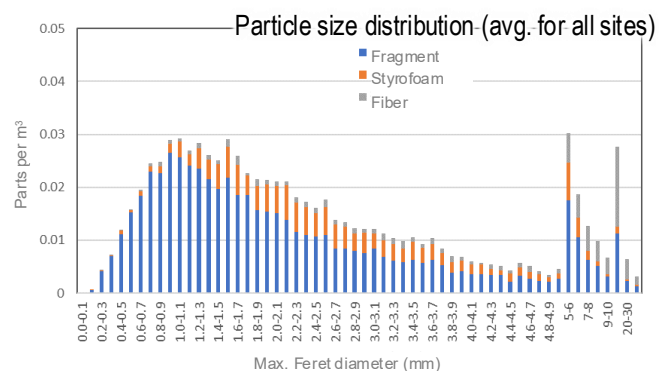
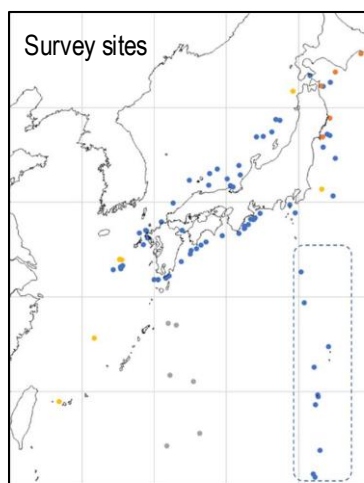
^{*3} Aoki, K., Furue, R., 2021. A model for the size distribution of marine microplastics: A statistical mechanics approach, PloS one, Vol.16 (11), e0259781-e0259781.

^{*4} George, M., Nallet, F., Fabre, P., 2024, A threshold model of plastic waste fragmentation: New insights into the distribution of microplastics in the ocean and its evolution over time, Marine Pollution Bulletin, Vol.199, 116012.

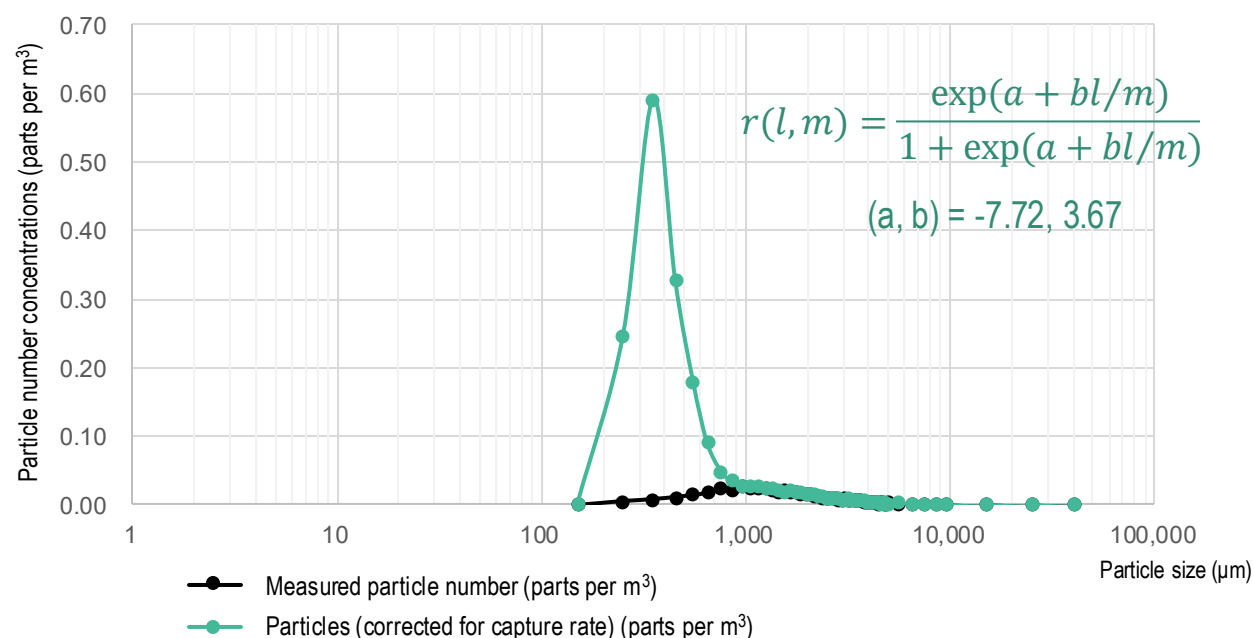
I. Added and Updated Estimation Formulae for Particle Number Concentrations Correcting Measurement Data from the Ministry of the Environment

- In estimations, measurement data was used from the Ministry of the Environment's "FY2021 Offshore Area Survey and Study on the Distribution of Drifting and Seafloor Debris." and "FY2021 Survey on the Actual Conditions of Marine Debris Including Microplastics in Coastal Waters." (Hereinafter "MOE measurement data in FY2021 survey projects". This data was collected at 89 sites off the Japanese coast in 2021-2022 using mesh size 330 μm nets as per "Guidelines for Harmonizing Ocean Surface Microplastic Monitoring Methods." MicP shapes are categorized into fragments, styrofoams, and fibers. This estimation used fragment data.)
- The above measurement data was used for estimates after correcting for MicP leaked from nets (up to about 150 μm) using the Tokai et al. (2021)^{*1} correction formula.

Survey sites and particle size distribution



Corrections to measurement data from the Ministry of the Environment (MOE) based on capture rate



*1 T. Tokai, K. Uchida, M. Kuroda, A. Isobe, Mesh selectivity of neuston nets for microplastics, Mar. Pollut. Bull., 165 (2021), Article 112111

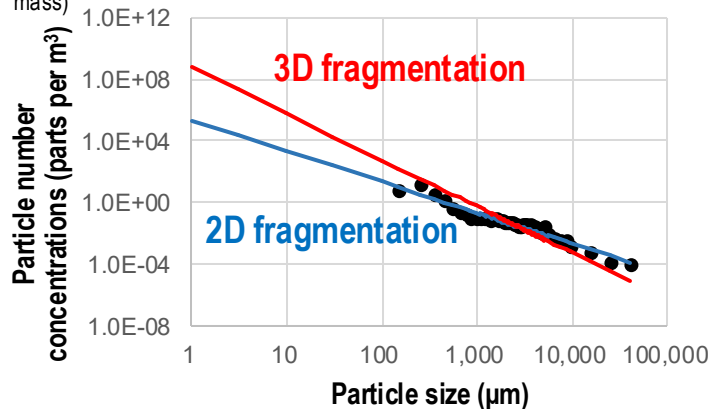
I. Added and Updated Estimation Formulae for Particle Number Concentrations

Results of Estimations of Particle Number Concentrations

- For each model, the results below are MOE measurement data in FY2021 survey projects fitted by the least squares method.

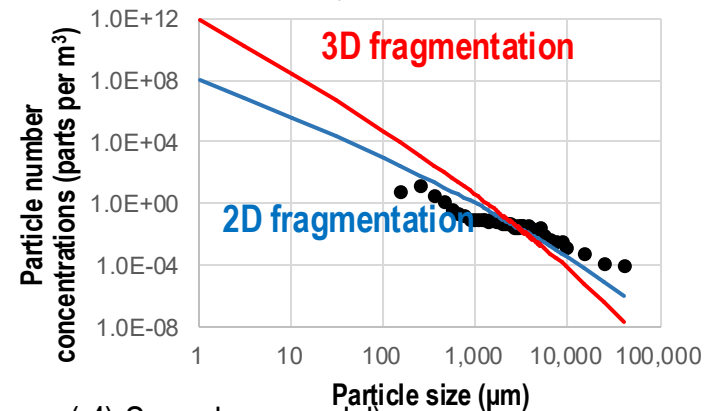
1) Cozar model

[Characteristics] Model in which particle number concentration changes exponentially relative to particle size based on the assumption of MicP equilibrium on the ocean surface. It is assumed that even if particle size changes, the total combined mass of all particles is fixed (conservation of mass)



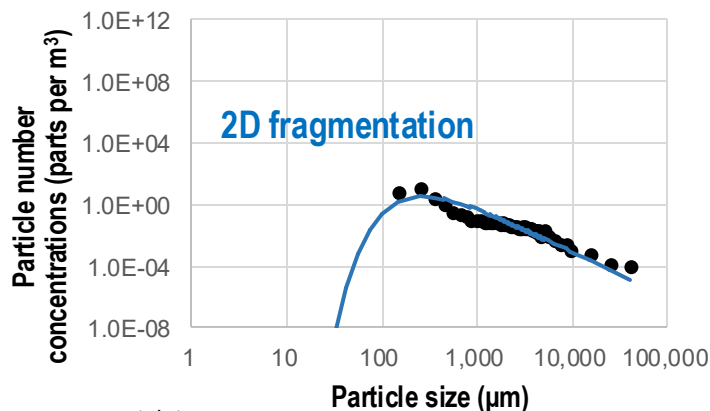
2) Kaandorp model

[Characteristics] Model in which particles fragment in a fractal (self-similar) manner when subject to shocks. Fragmentation probability after a shock depends only on the material (fragmentation probability does not depend on particle size). The analysis focuses on the ocean surface layer, assuming mass conservation within a closed system.



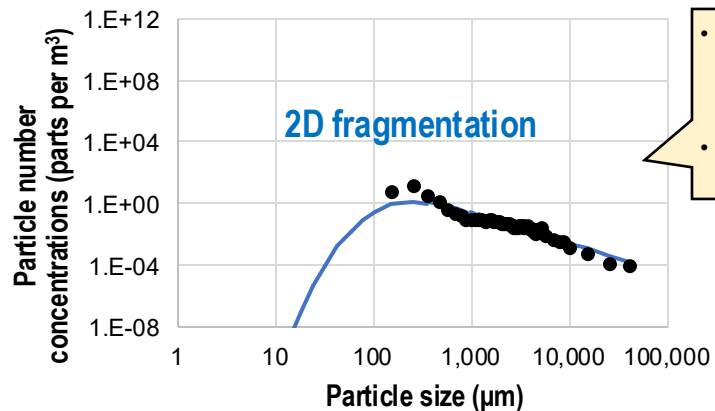
3) Aoki model

[Characteristics] Model that applies statistical mechanics to fracture energy occurrence probability. Smaller fragment shapes require larger fracture energy (i.e. fragmentation probability is dependent on particle size). This means there will be a peak at a certain particle size after which concentration will drop off for smaller parts. The paper assumes only 2D fragmentation



(4) Sugar lump model)

[Characteristics] Model in which there is threshold set for particle size such that fragmentation probability varies around that threshold (i.e. fragmentation probability is dependent on particle size). This means there will be a peak at a certain particle size after which concentration will drop off for smaller parts



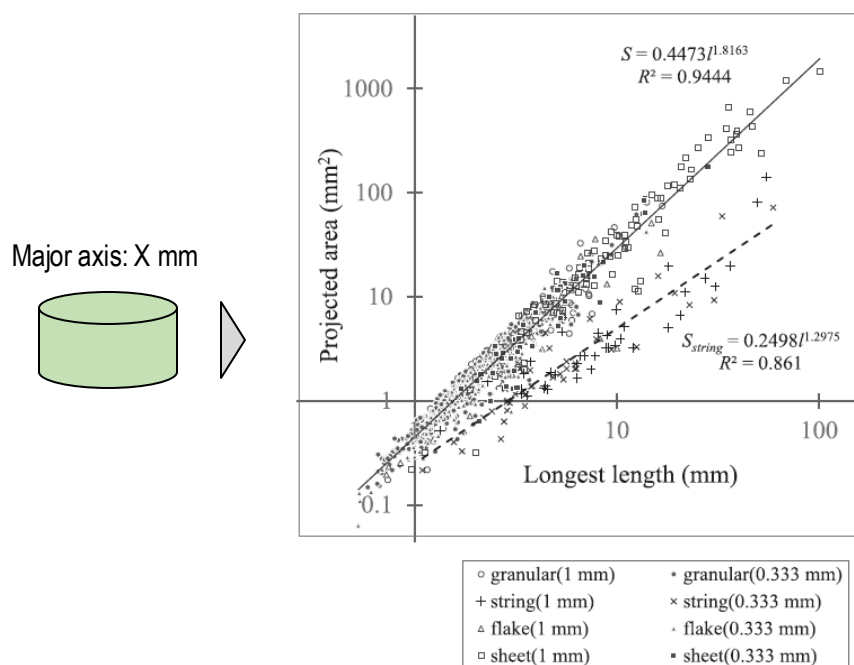
- Large number of variables such that fitting is difficult as long as the peak is unknown.
- Excluded from estimation this time

II. Conversion to Mass Concentrations Using Relational Formulae Based on Environmental Measurement Data

Conversion Method (major axis → area → mass)

- Calculated mass concentration based on MicP major axis data. Specifically, we used the relational formula between MicP major axis and projected area^{*1} to convert from the major axis to projected area, then used the relational formula between MicP projected area and mass^{*2} to convert from the projected area to mass.
- Referenced the relational formula between the major axis and projected area (Tokai et al., 2021) and the relational formula between the projected area and mass (Kataoka et al., 2024).

Relational formula between major axis and projected area



Relational formula derived from particles (333 μm mesh: 354 particles, 1 mm mesh: 188 particles) collected using Neuston Nets (mesh sizes 333 μm and 1 mm) in Tokyo Bay in October 2016

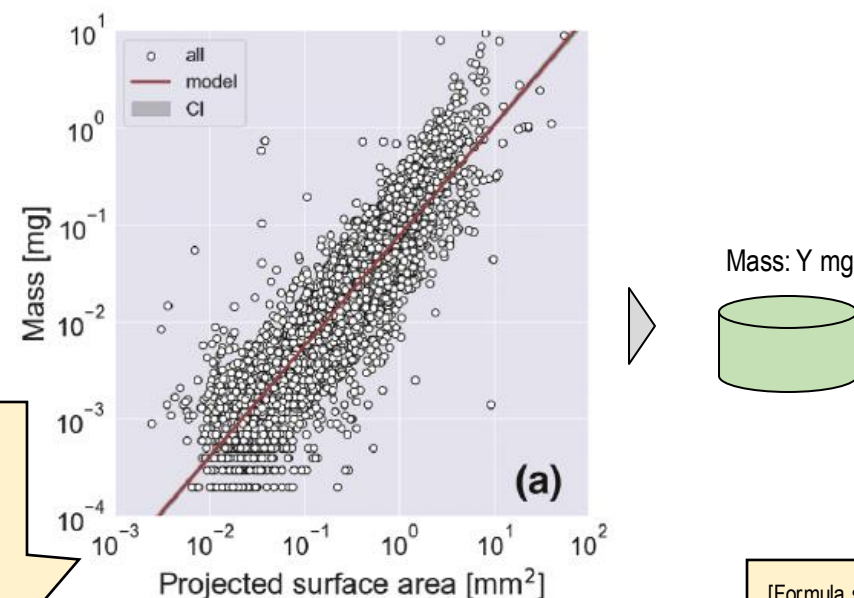
[Relational formulae]

Non-fiber particles: $\text{Projected area (mm}^2\text{)} = 0.4473 \times \text{Major axis (mm)}^{1.8163}$

Fiber particles: $\text{Projected area (mm}^2\text{)} = 0.2498 \times \text{Major axis (mm)}^{1.2975}$

[Range of application]
 Particle sizes of 10 μm or less (10⁻⁴ mm²) are expected to exceed the upper limit for mass when converted, so they are excluded. (Based on interviews)

Relational formula between projected area and mass



Relational formula derived from particles (4,390 particles) collected using plankton nets (mesh size 335 μm) in 17 rivers in Japan from May 2019 to October 2022

[Relational formulae]

All particles: $\text{Mass (mg)} = 10^{-1.12} \times \text{Projected area (mm}^2\text{)}^{1.14}$

Spherical particles: $\text{Mass (mg)} = 10^{-0.49} \times \text{Projected area (mm}^2\text{)}^{1.17}$

Fiber particles: $\text{Mass (mg)} = 10^{-1.62} \times \text{Projected area (mm}^2\text{)}^{0.82}$

Fragment particles: $\text{Mass (mg)} = 10^{-1.05} \times \text{Projected area (mm}^2\text{)}^{1.13}$

Sheet particles: $\text{Mass (mg)} = 10^{-1.31} \times \text{Projected area (mm}^2\text{)}^{1.10}$

[Formula selection]
 If there is no shape-specific detailed data, a conversion formula should be applied that incorporates various particle shapes across the whole. (Based on interviews)

^{*1} Tokai, T., Uchida, K., Kuroda, M., & Isobe, A. (2021). Mesh selectivity of neuston nets for microplastics. Marine Pollution Bulletin, 165, 112111.

^{*2} Kataoka, T., Iga, Y., R. A. Baihaqi, H. Hadyanto, Nihei, Y. (2024). Geometric relationship between the projected surface area and mass of a plastic particle. Water Research, 261, 122061.

II. Conversion to Mass Concentrations Using Relational Formulae Based on Environmental Measurement Data

Results of Estimations of Mass Concentrations

- For each model, the results below are conversions to mass concentrations using empirical formulae.

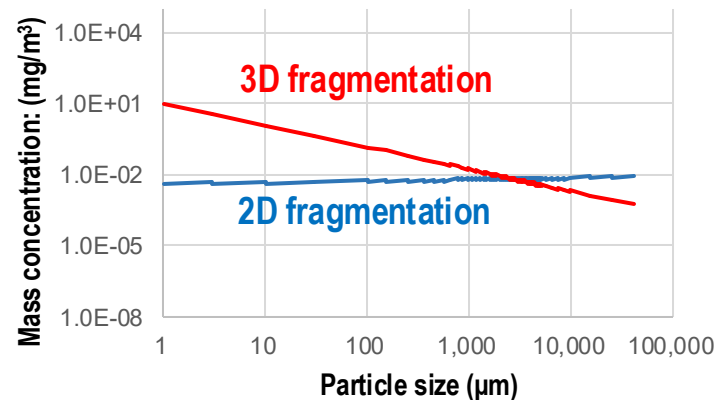
1) Cozar model

[Characteristics] Mass was largely constant regardless of particle size in two-dimensional fragmentation, but in three-dimensional fragmentation, mass concentration increased as particle size decreased.

In the Cozar model, since mass is conserved for each particle size, mass is expected to be fixed regardless of particle size. Since three-dimensional fragmentation is not included in this assumption, it is thought unlikely to see three-dimensional fragmentation alone.

Supplement comment by expert interviews.:

- 3D fragmentation and 2D fragmentation are shown. Many marine MicP are flake- or sheet-shaped. In general, the most common process (flat 2D fragmentation) is for thin sheets to break apart, with steric 3D fragmentation occurring in some particle sizes

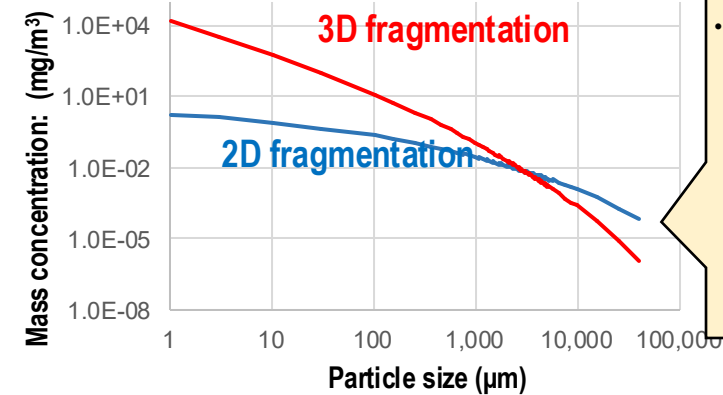


2) Kaandorp model

[Characteristics] In both two-dimensional and three-dimensional fragmentation, mass concentration increases as particle size decreases

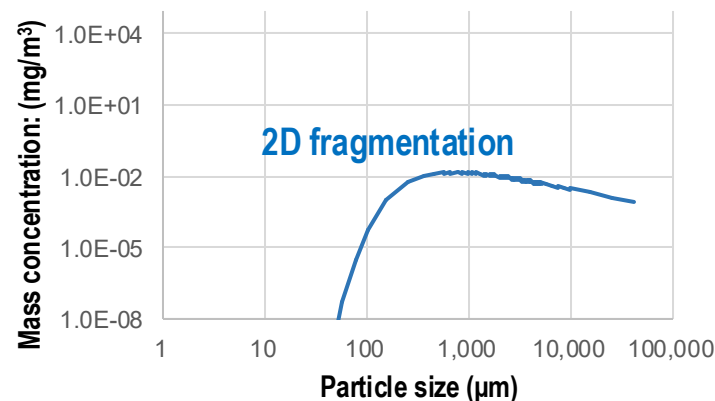
Supplement comment by expert interviews.:

- How microplastics actually fragment depends on particle size. Precipitation behavior from the ocean surface is also decided by particle size, so the assumption that "fragmentation probability is fixed independent of particle size" is a bit of a stretch



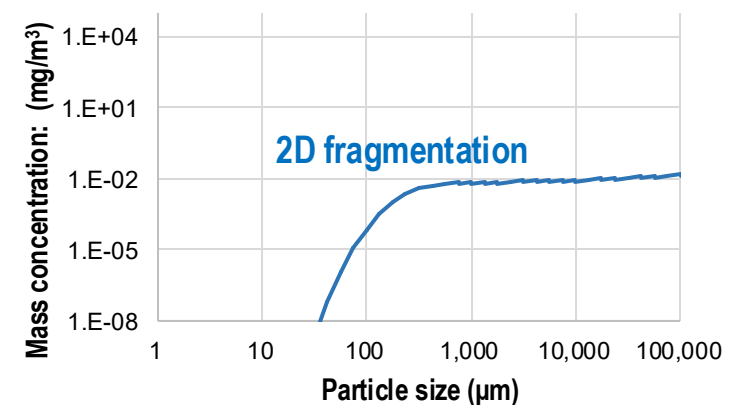
3) Aoki model

[Characteristics] As with particle number concentration, mass concentration decreases as particle size decreases



(4) Sugar lump model)

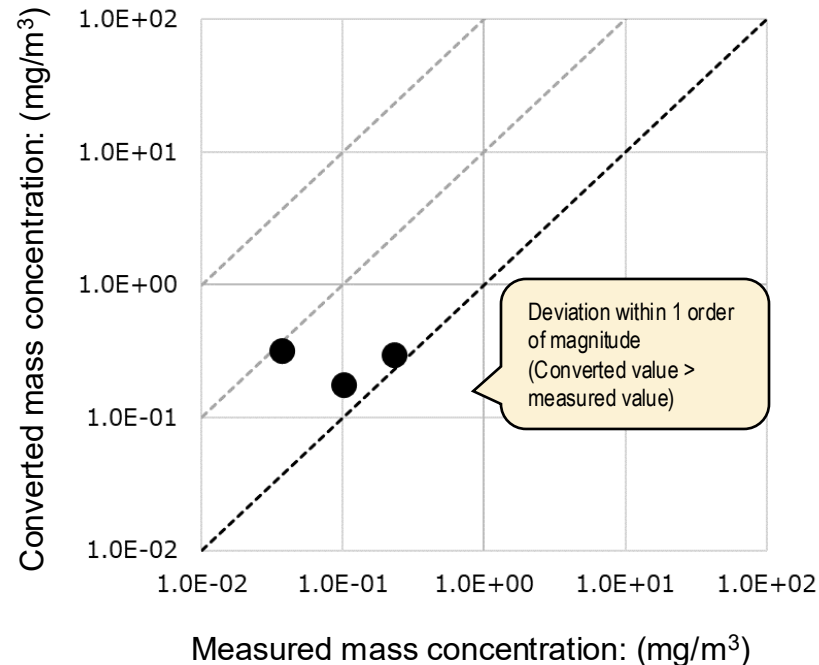
[Characteristics] As with particle number concentration, mass concentration decreases as particle size decreases



II. Conversion to Mass Concentrations Using Relational Formulae Based on Environmental Measurement Data (Reference) Comparison of Measured Values and Conversion Values

- Compared conversion values using MOE measurement data in FY2021 survey projects, and empirical formulae. The MOE measurement data used pulled values from the three sites (coast of Tomari Village, coast of Shika Town, coast of Akabane Town) in the “FY2021 Survey on the Actual Conditions of Drifting Debris Including Microplastics in Coastal Waters.”
- In the MOE measurement data in FY2021 survey projects, mass concentration is only measured from particle sizes of 1-5 mm, so conversion using empirical formulae was also limited to the range of 1-5 mm.
- Results: Deviation remained within one order of magnitude (converted value > measured value), which was a favorable outcome

Measured values vs. converted values using empirical formulae



Survey site	Mass concentration from measurement data: (mg/m ³)	Mass concentration from conversion: (mg/m ³)
Coast of Tomari Village	0.2330	0.1771
Coast of Shika Town	0.1030	0.3186
Coast of Akabane Town	0.0373	0.2941

Current Understanding in Exposure Assessment

■ Estimates of particle number concentrations in the marine surface layer

- Estimates of particle number concentrations in the marine surface layer are calculated from values obtained by fitting particle number concentrations of MicP (adjusted) in the marine surface layer to the model formula curves using MOE measurement data in FY2021 survey projects (89 locations off the coast of Japan), then by extrapolating to fine particle sizes. Differences in estimate values from differing models are large, and the finer the particle sizes are, the greater the uncertainty in the estimates. The 5th and 95th percentile values indicate variance in particle number concentrations among MOE measurement sites.
- MicP in the marine surface layer can move in or out of the system through transfer to sediments and air (aggregation, settling, dispersion) or inflow from rivers and air. However, the Cozar model and the Kaandorp model used for estimations **assume a closed system on the marine surface layer (that fragmented MicP remain on the surface layer) as a prerequisite for their estimations.**
- Still, MicP on the marine surface layer may settle due to the influence of attached organisms and other factors, so **especially for smaller particle sizes, actual particle number concentrations on the marine surface layer are likely to be lower than estimated.** Since the Cozar model and the Kaandorp model also assume that volume and surface area are conserved, particle number concentration increases monotonically as particle size decreases. However, due to the physical limitations on fragmentation in the environment, it is unlikely that particle number concentrations increase monotonically at single- and double-digit μm range. **As such, it is possible that the estimate results are close to the maximum limit or even overestimated.**
- In terms of fragmentation shape, many marine MicP are flake- or sheet-shaped. The most common process (2D fragmentation) is for thin sheets to break apart, with 3D fragmentation occurring as the aspect ratio approaches 1. Particle sizes at the boundary between two-dimensional and three-dimensional fragmentation are being examined by current research. **Based on the determination of experts in the subcommittees, this study assumed that two-dimensional fragmentation was most common for particle sizes of 10 μm and larger, with a progression into three-dimensional fragmentation for particle sizes of 10 μm and smaller. For that reason, in the graph on P56, a quadratic formula is used for particle sizes of 10 μm and larger, and the space between quadratic and cubic formulae is used for particle sizes of 10 μm and smaller.**
- In the Aoki model and the sugar lump model, fragmentation probability depends on particle size, and as particle size decreases, fragmentation is less likely to occur. This means there will be a peak at a certain particle size after which concentration will drop off for smaller parts. Challenges to be addressed include verifying applicability by collecting more measurement data on fine particle sizes.
- In the Aoki model, as particle size decreases, particle number concentration also decreases and exceeds numeric limits, so the graph on P56 omits particle sizes in the range of 1 to 10 μm . In addition, in the sugar lump model, the fragmentation threshold particle size can be set freely. If peak particle size is unknown, fitting is difficult, so it was omitted from the graph on P56.

■ Conversion to mass concentration

- Since the Cozar model assumes that mass is conserved for each particle size, mass is expected to be fixed regardless of particle size. However, conversions using the empirical formulae (relational formulae between the major axis and projected area, and between the projected area and mass, derived from measurement data) found that total mass would vary by particle size if three-dimensional fragmentation (3D fragmentation) was assumed. This contradicts the assumption of mass conservation, so **it is unlikely that three-dimensional fragmentation (3D fragmentation) alone happens in the actual environment.**
- Mass concentrations for particle sizes between 1-10 μm are outside the applicable range of the current empirical formulae, so it **must be noted that mass concentrations are overestimated.**

Current Issues and Directions for Future Study (Draft)

Category	Current Issues	Directions for Future Study (Draft) (*Items possibly discussed in the committees in coming years)
measurement data*	① Unknown how much MicP with fine particle sizes is in the actual environment <ul style="list-style-type: none"> ➤ With current measurement technology, it is difficult to accurately measure MicP particle number concentrations with fine particle sizes (single-digit μm order) in the marine surface layer. 	<ul style="list-style-type: none"> ➤ Development of sampling and analysis techniques to determine how much MicP with fine particle sizes is in the environment
	② MicP mass concentration in the actual environment is unknown <ul style="list-style-type: none"> ➤ Current measurement data on MicP in the marine surface layer generally only contains particle number concentrations 	<ul style="list-style-type: none"> ➤ Measurement of mass concentrations by expert survey of measurement data ➤ Accumulation of mass concentrations by MOE survey of measurement data [*]
	③ Limited information on uneven distributions (horizontal and vertical directions) of MicP in the actual environment <ul style="list-style-type: none"> ➤ Although it is known that there is uneven distribution on coasts near MicP sources, high-concentration sites have not been identified ➤ Limited information on MicP concentration distributions in oceans in the vertical direction (e.g., water columns, sediment) 	<ul style="list-style-type: none"> ➤ More measurement data for the horizontal (geographical spread) and vertical (depth-wise distribution) directions in the ocean [*]
estimations and conversions	④ Insufficient verification of the validity of application of the Cozar model, the Kaandorp model, the Aoki model, and the sugar lump model estimation formulae <ul style="list-style-type: none"> ➤ The Cozar model and Kaandorp model assume a closed system on the marine surface layer (i.e. MicP fragments stay on the surface), so they may overestimate ➤ For the Aoki model and sugar lump model, a future issue includes verifying applicability by collecting more measurement data on fine particle sizes ➤ States of degradation and fragmentation in the actual environment are unknown, so there is limited data on fragmentation type (2D/3D fragmentation) per particle size 	<ul style="list-style-type: none"> ➤ Collecting more literature on environmental concentration estimates for MicP with fine particle sizes [*] ➤ Explaining MicP behavior and fragmentation mechanisms in the water environment ➤ Measurement data for MicP with fine particle sizes (especially particle sizes from 1 to 100 μm)
	⑤ Unclear how valid the conversion formula from particle number to mass is for fine particle sizes <ul style="list-style-type: none"> ➤ Mass concentrations for particle sizes between 1-10 μm are outside the applicable range of the empirical formulae, so mass concentrations may be overestimated 	<ul style="list-style-type: none"> ➤ Measurement of mass concentrations by expert survey of measurement data, targeting fine particle sizes ➤ Accumulation of mass concentrations by MOE survey of measurement data, targeting fine particle sizes [*]

*Measurement data issues include some from the last fiscal year as well

Hazard Assessment

Implemented Items and Results in Hazard Assessment

[Formulating rules pertaining to review]

- In the literature on MicP hazards, there is a wide range of end points and test parameters used by the various papers. Through FY2023, we created the “Key Considerations for Literature Review” as an overview of the basic approaches to determining the usability of test data, organizing the basic approaches to end points that should be used in hazard assessment.
- In addition to differences in end points and testing parameters in the toxicity tests conducted in each literature, the quality levels of test data are varied as well. In FY2024, it was decided to discriminate quality levels of toxicity data to enable test data to be interpreted without error. Specifically, we created a category of data that can be judged to have a confirmed quantitative effect level. In terms of screening of quality levels, we updated the “Key Considerations for Literature Review” created in FY2023 and also added a supporting document, “Perspectives on Decision Making Related to Key Considerations.” Another new perspective added was the “Assessment Perspectives Focusing on Long-term Effects.” Perspectives on Decision Making Related to Key Considerations

[Collecting and reviewing literature (fish, crustacea, bivalves)]

- Focused primarily on literature involving tests on fish and crustacea, for which toxicity testing guidelines for chemicals have been established.
- Algae is unlikely to ingest particles in the micro-scale order range, and the impact of MicP with a particle size of 1 μm or larger, which is the current target size, was considered minimal. Therefore, as was the case in FY2023, algae was again excluded from the scope of review.
- bivalves were included in the scope of review due to being filter feeders and therefore concerns of high sensitivity to MicP.
- Review results were organized by particle number concentration/mass concentration, LOEC/NOEC, and chronic, subacute/subchronic, or acute.

Summarizing 2024 hazard assessment Basic Policy (Category of data quality level)

- Utilize hazard assessment perspectives used in ecological risk assessment for chemical substances by the Ministry of the Environment in the past, as well as other experience and expertise including review of findings and confirmation of reliability.
 - However, in the MicP field,
 - ❑ there is no established standard test methodology for ecological toxicity using particulate matter
 - ❑ Most findings at the current point in time are from academic research, there are some cases where the reliability cannot be fully confirmed due to reasons such as a lack of sufficient descriptions of experimental conditions to consider some kind of standard.
 - ❑ In this context, new data is being collected all the time
- For reasons such as the above, it does not be reasonable to conduct reliability assessments on the same level as ecological risk assessments for chemical substances performed by the Ministry of the Environment in the past, at this stage.
- Therefore, for hazard assessment (in this project), we propose separating test data into the following three categories in order to understand impact level when taking an overarching view of a larger pool of data.
 - ❑ In existing ecological risk assessments conducted under a risk-controlled system, strict reliability testing is not conducted in order to pull in a larger pool of findings. Specifically...
 - Data that can be judged to have a confirmed quantitative effect level **shall be used for hazard assessment, and possibly used for estimating the ecological risk.** [quality level: Acceptable (A)] ▲

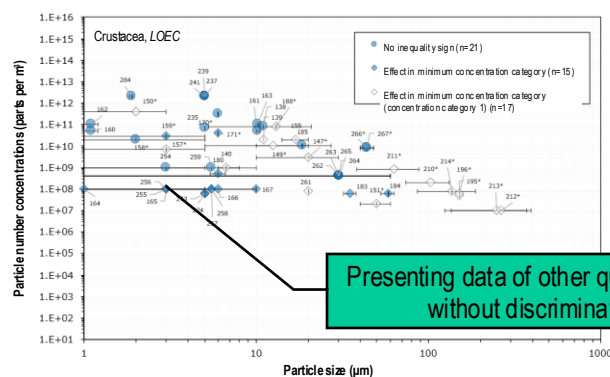
Note: test data categorized as “A” cannot necessarily be used for ecological risk assessment immediately. Even if the goal is to utilize a piece of data for ecological risk monitoring in the future, it should be noted that it is classified from a mere hazard assessment perspective for the time being.

- Even if data cannot be determined to have a quantitative effect due to reasons such as being unable to confirm testing conditions in connection with the broader pool of findings collected, data that can be interpreted as indicating an effect level **shall be used for reference purposes.** [quality level: Supplemental (S)]
- Data that is clearly deficient or cannot be said to be indicating an effect level **shall not be included, as in the past.** [quality level: Unacceptable (U)]

Summarizing 2024 hazard assessment Basic Policy (Presentation of qualified data)

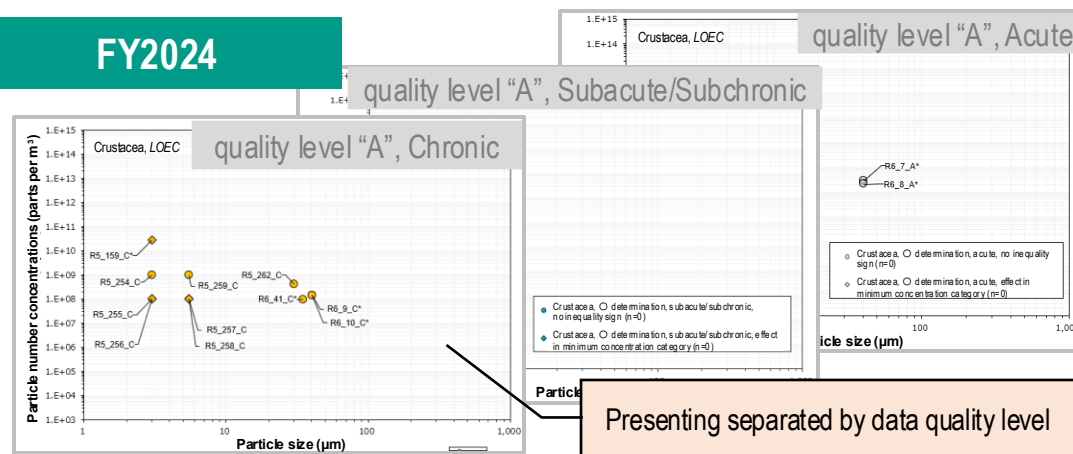
- In FY2023, test data for end points corresponding to Category I (harmful effects related to population maintenance; details on the next page) were illustrated. However, Category I covers various test parameters. Specifically, data of varying quality were mixed together, including cases where “actual concentrations were not measured or reported,” “particle pre-processing was not described,” and “findings addressed only acute effects,” but these differences were not indicated in the presentation.
- Given the above issues, in FY2024 the quality levels of test data will be distinguished in the presentation to ensure plots are not misinterpreted.
- Using the **fundamental approach to review of test data** described in the following pages, data judged to have a confirmed quantitative effect level (quality level “A”) was so discriminated and extracted, after which it was then further categorized and presented as chronic, subacute/subchronic, or acute.

FY2023



Previous presentation method: No distinction between quality levels “A” and “S” (Quality level “U” was already omitted from plots)

FY2024



- Extract data confirmed to have a quantitative effect level (quality level “A”).
- Separate for presentation into chronic, subacute/subchronic, or acute (Quality level “S” is displayed on a separate chart as reference information)

Formulating Rules Pertaining to Review of Literature

(1) Categorizing End Points

- The basic approaches to end points that should be used in MicP hazard assessments are as follows.
 - ✓ [I: Adverse effects related to population maintenance] → Set as end points used
 - ✓ [II: Effects not covered by I or III] → Reference data (continues to be targeted for examination)
 - ✓ [III: Effects at the molecular and genetic levels] → Not covered by this review

I: Adverse effects related to population maintenance

- ✧ Maturity, reproduction, growth, and lethality effects
(Specific examples: Decreased survival rate, growth inhibition, reduced body weight, decreased number of offspring, lower hatching rate, increased rate of abnormal appearance, etc.)

II: Effects not covered by I or III

- ✧ Effects on the individual sample level, but not directly on population maintenance / effects with unknown relevance
(Specific examples: Behavioral abnormalities, reduced swimming speed, decreased swimming distance, etc.)
- ✧ No effect on the individual sample level (cellular or tissue level)
(Specific examples: Intestinal, liver, and kidney lesions; tissue damage; reduced muscle mass; decreased gonad weight, etc.)

III: Effects at the molecular and genetic levels

- ✧ No effect on the individual sample level (molecular or genetic level)
(Specific examples: Changes in stress markers, gene expression, etc.)

Formulating Rules Pertaining to Review of Literature

(2) Key Considerations for Literature Review

- We continued to examine and update the “Key Considerations for Literature Review” compiled in FY2023.
- Currently, there are no test guidelines based on established consensus for evaluating the hazard of MicP. The following serve s only as a non-exhaustive reference and will need to be updated as necessary in the future.

Key Considerations for Literature Review Pertaining to MicP test data

■ [1], [2]: **Experimental conditions not related to MicP**

- [1] Is compliance with domestic and international test guidelines (“TG”) clearly stated?
- [2] Are the following conditions appropriate in cases where TG compliance is not clearly stated or where there are some deviations from TG ?
 - [2-1] Has a control group been established?
 - [2-2] Are there no effects observed in the control group?
 - [2-3] Has statistical processing of the results been conducted appropriately?
 - [2-4] Is the experiment conducted with multiple concentrations?
 - [2-5] Is the experiment reproducible (e.g., is the number of repetitions sufficient)?
 - [2-6] Are the test species common?
 - [2-7] Is the exposure period appropriate for the life stage of the test organisms?
 - [2-8] Is the result measurement methodology clearly described (i.e., is the experiment replicable)?
 - [2-9] Is the dose-response relationship observed?

[3] **Experimental conditions related to MicP**

- [3-1] Is the measured concentration of particles reported?
- [3-2] Are there statements about pre-processing of particles (if purchased, were dispersants, surfactants, preservatives, etc., in the dispersion liquid removed?)
- [3-3] Are the dispersal and agitation methods of particles stated?
- [3-4] Is the particle size reported? (including range, median particle size, distribution)?
- [3-5] Is the particle shape reported?
- [3-6] Is the particle material reported?
- [3-7] Is the source of particles reported? (Is reacquisition or re-preparation possible? Were they sampled from the actual environment?)
- [3-8] Were chemically surface-treated particles used? Etc.

Formulating Rules Pertaining to Review of Literature
(3) Key Considerations for Literature Review,
Appendix: Perspectives on Decision Making Related to Key Considerations

- The “Key Considerations for Literature Review” on the previous page are an important outcome in this work, and we expect to continue to update this going forward. In addition to this, discussions and views in the Hazard Assessment Subcommittee organized and written up as the appendix, “Perspectives on Decision Making Related to Key Considerations.”
- By summarizing the insights and decisions of experts, we aim to reduce “decision variance” in reviews and show the decision making process in an easier-to-understand manner. The appendix must be updated from time to time.

Key considerations		Perspectives related to determinations
[1][2] Experimental conditions not related to MicP	[1] Is compliance with domestic and international test guidelines (“TG”) clearly stated?	There are cases where experiments depart partially from TG, even if TG compliance is clearly stated. These cases will be individually discussed.
	<div> <div>from this?</div> <div> <div>Are the following conditions appropriate in cases where TG compliance is not clearly stated or where the experiment partially departs from this?</div> <div> <div>[2-1] Has a control group been established?</div> <div> <p>If dispersants are used in the test solution, we treat this as follows.</p> <ul style="list-style-type: none"> ▪ If dispersants are used <p>The use of dispersants is permitted in acute toxicity tests for chemical substances, and they will, in principle, be treated the same for MicP. In addition, in order to acquire broader knowledge, the use of dispersants is also permitted for subchronic and chronic tests of MicP, if there is no effect in the solvent control group.</p> <ul style="list-style-type: none"> ▪ If antibiotic substances are used <p>For algae, there may be cases where adding an antibiotic substance is necessary. However, for fish, crustacea and bivalves, this may affect intestinal flora, so we will determine that it will be difficult to adopt.</p> </div> </div> </div> </div>	
	[2-4] Is the experiment conducted at multiple concentrations?	<p>We assign priority in literature for review and approach multiple concentrations as follows.</p> <ul style="list-style-type: none"> ▪ Before determining quality level “A”, “S” or “U,” we select classifications of quality levels work targets from all previous literature and assign them an order of priority using the following standards <p>Standard 1: The targets of quality screening work are “not difficult to adopt, and End Point classification 1, and multiple concentrations”</p> <p>Standard 2: quality level “A” may also be assigned where inequalities are attached (effect present at minimum concentration or no effect at maximum concentration), but it will be treated as having a lower priority</p>

(3) Key Considerations for Literature Review, appendix: Perspectives on Decision Making Related to Key Considerations

Key considerations			Perspectives related to determinations
[1][2] Experimental conditions not related to MicP	[2] Are the following conditions appropriate in cases where TG compliance is not clearly stated or where the experiment partially departs from this?	[2-9] Is a dose-response relationship observed?	<p>We approach the presence or absence of a dose-response relationship as follows.</p> <ul style="list-style-type: none"> In general, where a toxicity effect occurs, it is desirable for there to be a dose-response relationship. <p>However, in the case of MicP, because there may be variance in absorption based on the individual organism, toxicity effects may not necessarily affect exposure concentration.</p> <p>For this reason, dose-response relationships are desirable but not a necessary criteria for MicP hazard assessment.</p>
		Treatment of unusual exposure conditions	In the event of exposure conditions that differ significantly from usual (e.g., heavy fat meal), we will determine that it will be difficult to adopt.
	Other	Approach to short/long-term effects	Reference: "Perspectives on Evaluations Focused on Long-term Effects "
		Aqueous concentration/absorption concentration	<p>We organize the display of toxicity values (NOEC, NOAEL) for MicP as follows.</p> <p>As it is possible that MicP could be ingested then produce effects, it is our approach that it is desirable to use intake volume (NOAEL, etc.). At the same time, as it is exceptionally difficult to measure actual intake volume, we use exposure concentration in test solution.</p> <ul style="list-style-type: none"> In addition, where particle diameter is large, for example, it is desirable to show particle number concentration, so we also take into consideration the interrelationship of size and concentration.

(3) Key Considerations for Literature Review, appendix: Perspectives on Decision Making Related to Key Considerations

Key considerations		Perspectives related to determinations
[3] Experimental conditions related to MicP	[3-1] Is the measured concentration of particles reported?	<p>We organize our approach to the presence or absence of measurement of exposure concentration and quality level "A" candidates (reference: P30 "Collecting and Reviewing Literature") as follows.</p> <ul style="list-style-type: none"> In general, it is desirable for exposure concentration to be consistent throughout the experimental system. MicP are substances that tend to localize, so measurement of exposure concentration are important, and we have come to organize literature that "measured" as having a higher priority. However, as MicP localization will necessarily occur, even if measurements are performed, there remains the possibility that these will not show the real exposure concentration. In addition, there are concerns overlooking if we select articles as quality level "A" candidates in discrimination of quality levels just because they "measured," Even in cases of "not measured," we focus on the existence of MicP of a nominal concentration in the experiment system, expand the scope of quality level "A" candidates to include "not measured," and avoid making "measured" a necessary condition.
	[3-2] Are there statements about pre-processing of particles (if purchased, were dispersants, surfactants, preservatives, etc., in the dispersion liquid removed?)	<p>Removing residue including additive agents, plasticizing agents and monomers, as agents originally included in plastics, can be difficult to remove, so the effects are evaluated including these.</p> <p>However, we will determine that it will be difficult to adopt literature where there are clear concerns that the effects come from other than the particles.</p>
	[3-3] Are the dispersal and agitation methods of particles stated?	<p>We organize our approach to dispersal and agitation methods of test solution and quality level "A" candidates as follows.</p> <ul style="list-style-type: none"> While it is desirable for mention to be made of dispersal, dispersal may be treated as an obvious task and thus not stated in the literature. As it is <u>specific characteristics</u>* of MicP, there is likely to be inconsistent exposure. (*For fish and crustacea, if their food and particle sizes are near, they might actively ingest MicP. And bivalves may be subject to uneven exposure, as they ingest MicP together with sediment, regardless of the particle size.) For these reasons, we do not make stating dispersal or agitation method a necessary condition for quality level "A" candidates.

(3) Key Considerations for Literature Review, appendix: Perspectives on Decision Making Related to Key Considerations

Key considerations		Perspectives related to determinations
[3] Experimental conditions related to MicP	[3-4] Is the particle size reported (including range, median particle size, distribution)?	<p>If a particle size is “clearly not possible to ingest,” this will be treated as follows.</p> <ul style="list-style-type: none"> While the relationship between particle size and ingestion was not taken into account so far, even MicP that are large enough not to be ingested may still interfere with swimming by attaching to the surface of water fleas. For this reason, just because a MicP is of a size that cannot be ingested, this will not make it difficult to adopt. <p>If there is a lack of particle size information, we will treat this as follows.</p> <ul style="list-style-type: none"> While it is desirable to state detailed information such as particle size distribution, only particle size range is reported in some literatures. Even in such cases, this does not affect the conversion from mass concentration to particle number concentration itself (because conversion is done based on the mean or median value between the maximum and minimum particle sizes). In addition, because there is little data which is acceptable for the hazard assessment, it will be accepted with quotation of the final determination in screening of quality levels.
	[3-6] Is the particle material reported?	<p>If the material of particles has specific characteristics, this is treated as follows.</p> <ul style="list-style-type: none"> We have seen some experiments using aged MicP or biodegradable plastic. While there is room for discussion over how to make determinations, because the presence of aging has not, to now, been an axis of evaluation, at present, such literature was accepted with notes in the final determination in discrimination of quality levels. Biodegradable plastic varies in speed and size depending on variety, and it is believed it can turn into MicP during degradation. Literature will not be deemed difficult to adopt for reason of biodegradable plastics, even to “see more data comprehensively.” Discussion will also continue going forward, including the necessity of considering the particular characteristics of biodegradable plastics.
	[3-7] Is the method of acquisition of particles reported? (Is reacquisition or re-preparation possible? Were they sampled from the actual environment?)	<p>If plastics sampled from the environment are used, we treat this as follows.</p> <ul style="list-style-type: none"> For toxicity experiments, it is generally desirable to secure reproducibility and traceability. There is thus a need for caution in case of use of MicP that are not commercial products, particularly MicP sampled from the environment. On the other hand, various chemical substances attach themselves to MicP in the actual environment, so performing toxicity experiments using MicP sampled from the environment may yield results closer to reality. For this reason, even if reproducibility is not secured, such literature will not be treated as uniformly hard to adopt. This will be treated as toxicity effects including the effects of attached chemical substances.

Formulating Rules Pertaining to Review of Literature

(4)-1 Perspectives on Evaluations Focused on Long-term Effects -Evaluating Existing Hazards

- The effects of chemicals over the long term in the environment are evaluated by long-term exposure. Under short-term exposure, the effects that should be ascertained may not be captured sufficiently. (Specific examples: Substances that will not produce effects if they are not of high enough concentration; a suitable endpoint cannot be captured under short-term exposure, etc.).
- When evaluating the effects of aquatic organisms, as knowledge capturing chronic effects is limited, knowledge capturing acute effects has also come to be used. Knowledge capturing subacute and subchronic effects has also come into limited use.
- The basic approach*¹ to acute and chronic toxicity is as follows in risk assessments of chemicals based on the above.

Chronic/ acute	Existing basic approach in hazard assessments	Examples of experimental guidelines this addresses
Chronic	<ul style="list-style-type: none"> ■ Selection criteria*²: <ul style="list-style-type: none"> (1) Details of effects: Effects that cause inhibitions on survival and growth in fish in the embryonic, fry and early developmental stages are chronic effects (2) Attached period (trial period): Period of over 20 days including period from embryonic to early-larvae stage (3) Details of main end points and impacts: LOEC, NOEC and MATC on impacts ■ Used in preference to acute effects 	<ul style="list-style-type: none"> • OECD TG 210: Toxicity trial in early life stages of fish (End points: Hatching rate, survival rate, etc. Exposure period: 40 days)
Acute	<ul style="list-style-type: none"> ■ Selection criteria*²: <ul style="list-style-type: none"> (1) Details of effects: Effects that cause inhibitions on survival in the short term in fish are acute effects (2) Attached period (trial period): Trial (requiring attached period) within four days (96 hours) (3) Details of main end points and impacts: LC50 (Median Lethal Concentration) 	<ul style="list-style-type: none"> • OECD TG 203: Fish acute toxicity trial (End points: Death, Exposure period: 96 hours)

*1 Stated extracting fish from among organisms related to ecological effects

*2 2nd Health Science Council Subcommittee on Revising the Chemical Substances System Expert Committee on the Revision of the Regulatory System for Evaluating Chemical Substances, 9th Industrial Structure Council Chemicals and Biomass Subcommittee Panel on Planning for Management of Chemical Substances and 2nd Central Environmental Council Health Subcommittee Panel on the Regulatory System for Evaluating Chemical Substances Joint Meeting, Reference Materials 2, Comparison of Acute Toxicity Values and Chronic Toxicity Values in Ecotoxicity

(4)-2 Perspectives on Evaluations Focused on Long-term Effects -Evaluating MicP Hazards

- As stated above, the MicP toxicity data gathered so far includes a variety of experimental conditions. In addition to there being variety of settings around exposure periods, life stages and end points, different toxicity indicators such as E(L)C50 and N(L)OEC were mixed together. Acute effects/chronic effects have not been organized.
- There was some level of knowledge capturing or chronic effects or acute effects in MicP. The most of test showed result that “these test look at long-term effects even more than general acute experiments, but not decisive whether they captured chronic effects.” These knowledge were considered to be “subacute” or “subchronic” effects. Given that standard toxicity testing methods have also not been developed for MicP, in this study, we have organized “subacute” and “subchronic” data collectively as “subacute/subchronic.”
- Based on the state of existing hazard assessments and MicP test data, in this study too, we advance assessment assuming the use of knowledge capturing subacute/subchronic effects and acute effects, while **making assessment focused on chronic effects the basis**. The perspectives are also related to point [2-7] of the Key Considerations for Literature Review.

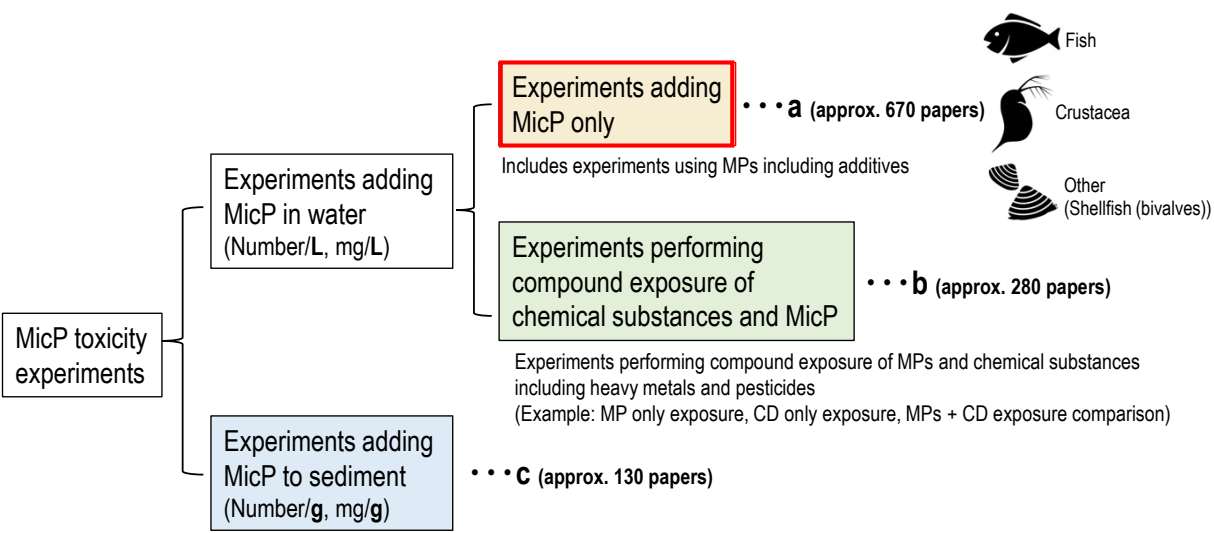
Chronic/ acute	<u>MicP</u> basic approach in hazard assessments	Examples of experimental guidelines this addresses
Chronic	<ul style="list-style-type: none"> ■ Knowledge capturing chronic effects, in line with TG handling chronic effects. Used in preference to acute effects ■ NOEC and LOEC are mainly used, but we will also consider the use of E(L)C50 where it has been calculated and where experts have determined that the use of E(L)C50 is appropriate 	<ul style="list-style-type: none"> • Fish: OECD TG 210 • Crustacea: OECD TG 211 • Bivalves: OECD TG 242* <p>*:TG242 is for snails</p>
Acute	<ul style="list-style-type: none"> ■ Knowledge capturing acute effects, in line with TG handling acute effects. ■ EC50 and LC50 are mainly used, but we will also consider the use of NOEC or LOEC where individual experts have determined that their use is appropriate ■ E(L)C50 is displayed as is, without being converted, having been made identifiable 	<ul style="list-style-type: none"> • Fish: OECD TG 203 • Crustacea: OECD TG 202
Subacute/ subchronic	<ul style="list-style-type: none"> ■ While these look at long-term effects even more than acute effects, data that cannot make determinations capturing chronic effects overall are categorized as subacute/subchronic ■ Appropriate toxicity indicators are selected and indicated for each individual piece of data 	-

Collecting and Reviewing Literature

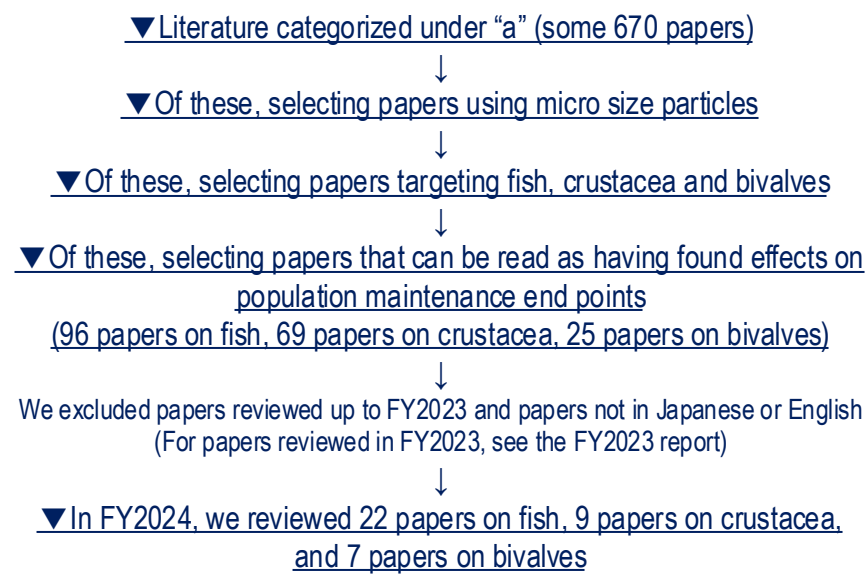
Scoping Literature to Review

- We found literature for review by comprehensively searching using multiple literature search services to search for academic papers related to MicP published after 2000 (however, the portion done this year is the portion from FY2023).
- Scoping Step (1): Making a determination on a scope taken from a population of some 18,000 titles and abstracts, we selected three categories (a: experiments with MicP only added in water, b: experiments with MicP and chemical substances added in water simultaneously, and c: experiments with MicP added to sediment).
- Scoping Step (2): In relation to the literature categorized in a (some 670 papers), we selected literature determined featuring “using micro size particles,” “targeting fish, crustacea and bivalves and “harmful effects on maintenance of population” in the title or abstract and performed a review.

Scoping Step (1)



Scoping Step (2)






Collecting and Reviewing Literature Performing Review (Discriminate of Quality Levels)

- In determining the quality levels of test data, we performed work prioritizing the screening and selection of literature with quality level “A”. Specifically, from FY2022 to FY2024 (until the second subcommittee), we made literature that did non-single concentration experiments the targets of quality classification work, excluding those that would be difficult to adopt, and discriminated as quality level “A” those that had relatively acceptable and useful [for the hazard assessment (in this project)].

Classification of test data related to quality levels (reprinted excerpt from p. 19)

- Data that can be judged to have a confirmed quantitative effect level shall be used to grasp ecological risk. [quality level: Acceptable (A)]
- Even if data cannot be determined to have a quantitative effect due to reasons such as being unable to confirm testing conditions in connection with the broader pool of findings collected, data that can be interpreted as indicating an effect level shall be used for reference purposes. [quality level: Supplemental (S)]
- Data that is clearly deficient or cannot be said to be indicating an effect level shall not be included, as in the past. [quality level: Unacceptable (U)]

- The work procedure was as follows.

- ✓ To streamline the work, the secretariat organized the applicability of experiment conditions and selected quality level “A” candidates. 
- ✓ Multiple members of the Hazard Assessment Subcommittee made primary determinations of whether the quality level “A” candidates were “A”, “S” or “U”. 
- ✓ Based on the primary determinations, the Hazard Assessment Subcommittee held discussions, then decided a final determination. 

Breakdown of test data reviewed from FY2022 to FY2024

	Not difficult to adopt		Subject to work for discriminating quality levels (Experiments that are not difficult to adopt and performed at multiple concentrations)		○ candidate (Lists observation/dispersal procedures or complies with OECD TG)		Final determination is quality level “A”		
	Literature	Record (a)	Literature	Record	Literature	Record	Literature	Record (b)	Ratio (b/a)
Fish	49	118	13	23	5	7	5	5 (Chronic 0, subacute/subchronic 5, acute 0)	4%
Crustacea	43	97	26	60	11	29	6	15 (Chronic 12, subacute/subchronic 0, acute 3)	15%
bivalves	16	57	4	9	2	4	2	4 (Chronic 0, subacute/subchronic 4, acute 0)	7%
Total	108	272	43	92	18	40	13	24	9%

- From the test data that was not marked (“U”) for being not difficult to adopt, we selected the 9% of literature with relatively acceptable [for the hazard assessment (in this project)].
- The results of the review are on the following pages

Collecting and Reviewing Literature

(1) Test data of quality level “A” and Chronic effects (fish)

- Among the effect on fish, the chronic test data of quality level “A” are shown below.

(No applicable data)

Collecting and Reviewing Literature

(1) Test data of quality level “A” and Chronic effects (crustacea)

- Among the effects on crustacea, the chronic test data of quality level “A” are shown below.
- The data regarding the chronic effect were only available for crustacea.

Literature Information			Experimental design								Results						
Literature No.	Record No.	Author(s)	Source of MicP	Particle size (μm)	Polymer type	Particle shape	Test organism	Nominal concentration		Exposure time	Endpoints	mass concentration (μg/L)			particle number concentration (particles/m ³)		
								mass concentration (μg/L)	particle number concentration (particles/m3)			Inequality Sign	NOEC	LOEC	Inequality Sign	NOEC	LOEC
R6_P-1220	R6_9	An G et al. (2024)	Purchased	1~80	PLA	Fragment	<i>Daphnia magna</i>	0,1.0E+03,5.0E+03	–	21d	survival	–	1.E+03	5.E+03	–	3.E+07	1.E+08
R6_P-1220	R6_10	An G et al. (2024)	Purchased	1~80	PLA	Fragment	<i>Daphnia magna</i>	0,1.0E+03,5.0E+03	–	21d	total number of offsprings	–	1.E+03	5.E+03	–	3.E+07	1.E+08
R6_P-0471	R6_41	Yin J et al. (2024)	Purchased	32~38	PE	NA	<i>Daphnia magna</i>	0,4.0E+02,2.0E+03,1.0E+04	–	21d	total number of offsprings	–	4.E+02	2.E+03	–	2.E+07	1.E+08
R6_P-0471	R6_44	Yin J et al. (2024)	Purchased	32~38	PE	NA	<i>Scapholeberis kingi</i>	0,4.0E+02,2.0E+03,1.0E+04	–	21d	total number of offsprings	>	1.E+04	1.E+04	>	5.E+08	5.E+08
R5_6	R5_159	Peixoto et al. (2019)	Purchased	1~5	Thermoset amino formaldehyde polymer	Sphere	<i>Artemia franciscana</i>	0,4.0E+02,8.0E+02,1.6E+03	–	44d	total number of offsprings	<	4.E+02	4.E+02	<	3.E+10	3.E+10
R5_7	R5_254	Jaikumar et al. (2019)	Purchased	1~5	PS	Sphere	<i>Daphnia magna</i>	–	0,1.0E+08,1.0E+09,1.0E+10,1.0E+11	21d	number of offsprings	–	1.E+00	1.E+01	–	1.E+08	1.E+09
R5_7	R5_255	Jaikumar et al. (2019)	Purchased	1~5	PS	Sphere	<i>Daphnia pulex</i>	–	0,1.0E+08,1.0E+09,1.0E+10,1.0E+11	21d	number of offsprings up to 3rd blood	<	1.E+00	1.E+00	<	1.E+08	1.E+08
R5_7	R5_256	Jaikumar et al. (2019)	Purchased	1~5	PS	Sphere	<i>Ceriodaphnia dubia</i>	–	0,1.0E+08,1.0E+09,1.0E+10,1.0E+11	7d	number of offsprings up to 3rd blood	<	1.E+00	1.E+00	<	1.E+08	1.E+08
R5_7	R5_257	Jaikumar et al. (2019)	Prepared	1~10	PS	Fragment	<i>Daphnia magna</i>	–	0,1.0E+08,1.0E+09,1.0E+10,1.0E+11	21d	number of offsprings up to 3rd blood, total number of offsprings	<	9.E+00	9.E+00	<	1.E+08	1.E+08
R5_7	R5_258	Jaikumar et al. (2019)	Prepared	1~10	PS	Fragment	<i>Daphnia pulex</i>	–	0,1.0E+08,1.0E+09,1.0E+10,1.0E+11	21d	number of offsprings up to 3rd blood	<	9.E+00	9.E+00	<	1.E+08	1.E+08
R5_7	R5_259	Jaikumar et al. (2019)	Prepared	1~10	PS	Fragment	<i>Ceriodaphnia dubia</i>	–	0,1.0E+08,1.0E+09,1.0E+10,1.0E+11	7d	number of offsprings up to 3rd blood, total number of offsprings	–	9.E+00	9.E+01	–	1.E+08	1.E+09
R5_36	R5_262	Schür et al. (2022)	Prepared	0.2~60	PS	Fragment	<i>Daphnia magna</i>	–	0,8.0E+07,4.0E+08,2.0E+09,1.0E+10	21d	mortality、reproduction (F0)	–	1.E+03	6.E+03	–	8.E+07	4.E+08

Note 1: For the source documents of each test data, see the Annex List of peer-reviewed publications.

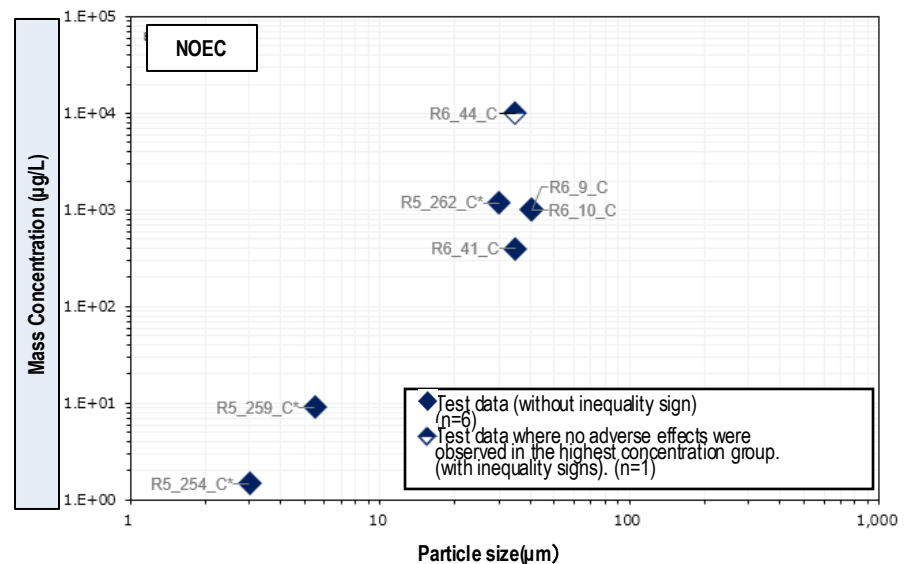
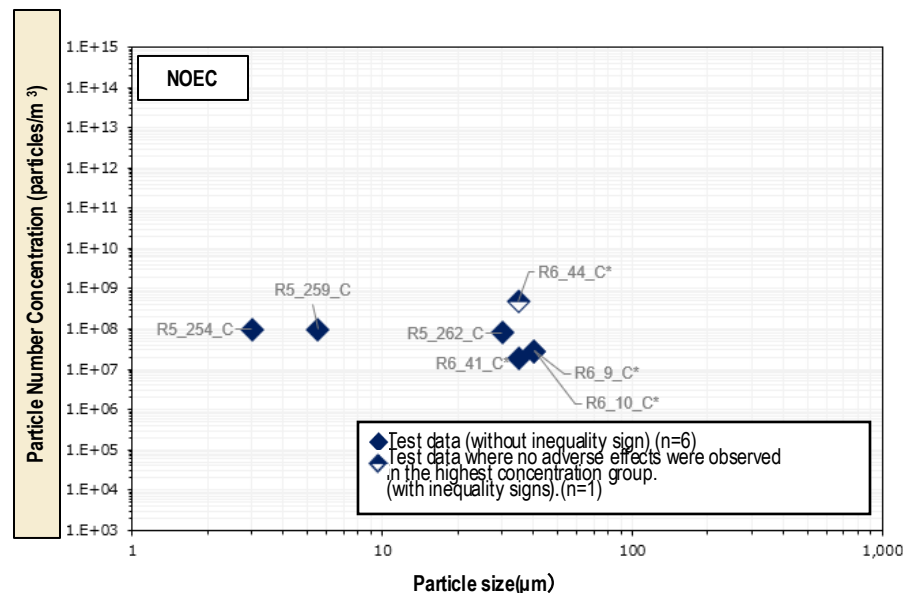
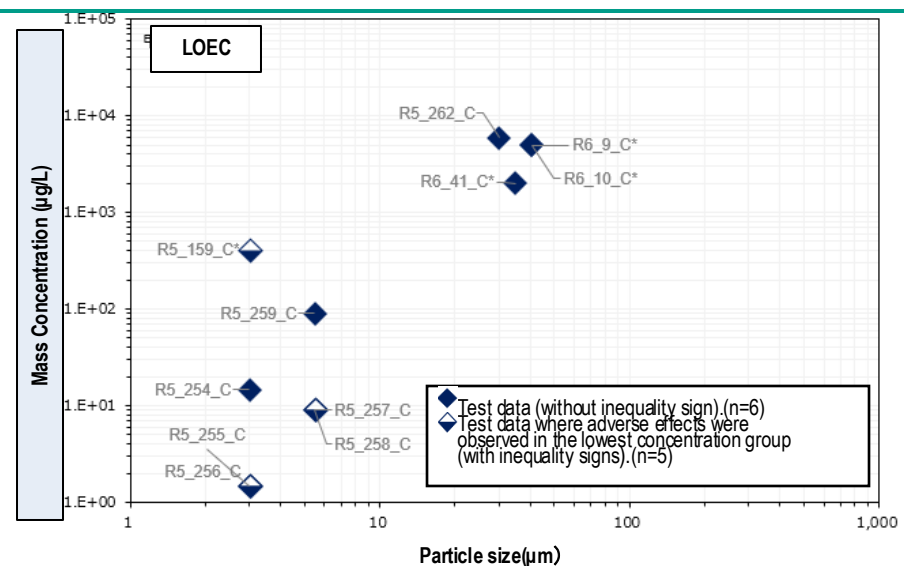
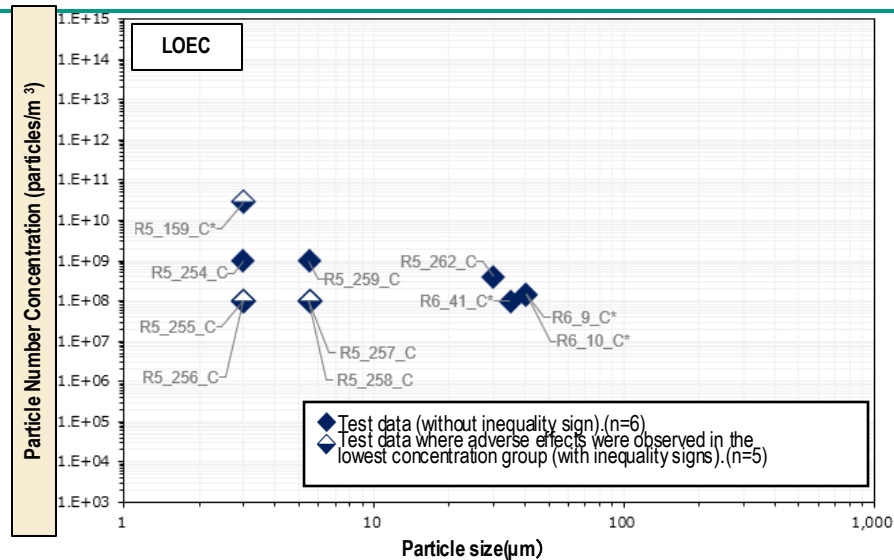
Note 2: In cases where the literature only provides values for number or weight, shape is spherical, density is the density of the material (PE: 0.92, PET: 1.38, PP: 0.9, PS: 1.04, PVC 1.4, others: 1), and particle size is the average of the upper and lower limits, and both are converted (converted values are in italics).

Note 3: If a significant effect was observed in the lowest concentration group, an inequality sign "<" is used, and if no significant effect was observed in the highest concentration group, an inequality sign ">" is used.

Collecting and Reviewing Literature

(1) Test data of quality level “A” and Chronic effects (crustacea)

- The plot of N(L)OEC presented on the previous page, with concentrations on the vertical axis and particle size on the horizontal axis, are shown below.



*The numbers in the plots correspond to record number of effect data. For an overview of each data, see the overview of the test data on the previous page.

Collecting and Reviewing Literature

(1) Test data of quality level “A” and Chronic effects (bivalves)



- Among the effect on bivalves, the chronic test data of quality level “A” are shown below.

(No applicable data)



Collecting and Reviewing Literature
(2) Test data of quality level “A” and Subacute/Subchronic effects (fish)

■ Among the effect on Fish the subacute/subchronic test data of quality level “A” are shown below.

Literature Information			Experimental design								Results						
Literature No.	Record No.	Author(s)	Source of MicP	Particle size (μm)	Polymer type	Particle shape	Test organism	Nominal concentration		Exposure time	Endpoints	mass concentration (μg/L)			particle number concentration (particles/m ³)		
								mass concentration (μg/L)	particle number concentration (particles/m3)			Inequality Sign	NOEC	LOEC	Inequality Sign	NOEC	LOEC
R5_15	R5_1	Zhang et al. (2022)	Purchased	5~50	Polyamide	Fragment	<i>Danio rerio</i>	0,1.0E+03,1.0E+04,2.0E+04	–	10d	standardized body weight	–	1.E+04	2.E+04	–	6.E+08	1.E+09
R5_18	R5_6	Liu et al. (2022)	Purchased	32~40	PS	Sphere	<i>Ctenopharyngodon idella</i>	0,1.0E+02,1.0E+03	–	21d	body weight	–	1.E+02	1.E+03	–	4.E+06	4.E+07
R5_53	R5_72	Chen et al. (2022)	Purchased	6	PS	Sphere	<i>Oryzias melastigma</i>	0,1.1E+00,1.1E+03,1.1E+05	0,1.0E+05,1.0E+07,1.0E+09	14d	body length	>	1.E+05	1.E+05	>	1.E+09	1.E+09
R4_17	R4_26	Wang J et al. (2021)	Purchased	2	PS	Sphere	<i>Oryzias melastigma</i>	0,2.0E+00,2.0E+01,2.0E+02	–	150d	body length、body weight	<	2.E+00	2.E+00	<	5.E+08	5.E+08

Note 1: For the source documents of each test data, see the Annex List of peer-reviewed publications.

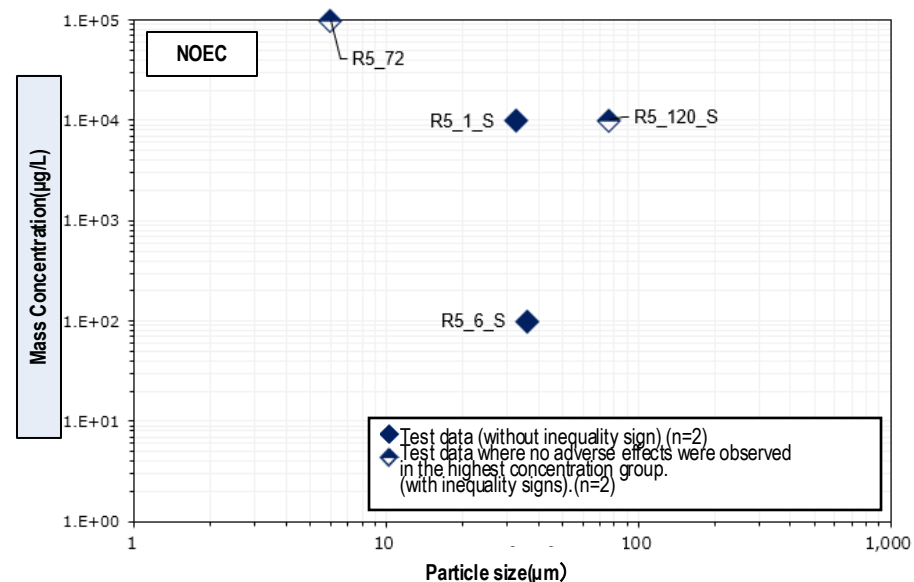
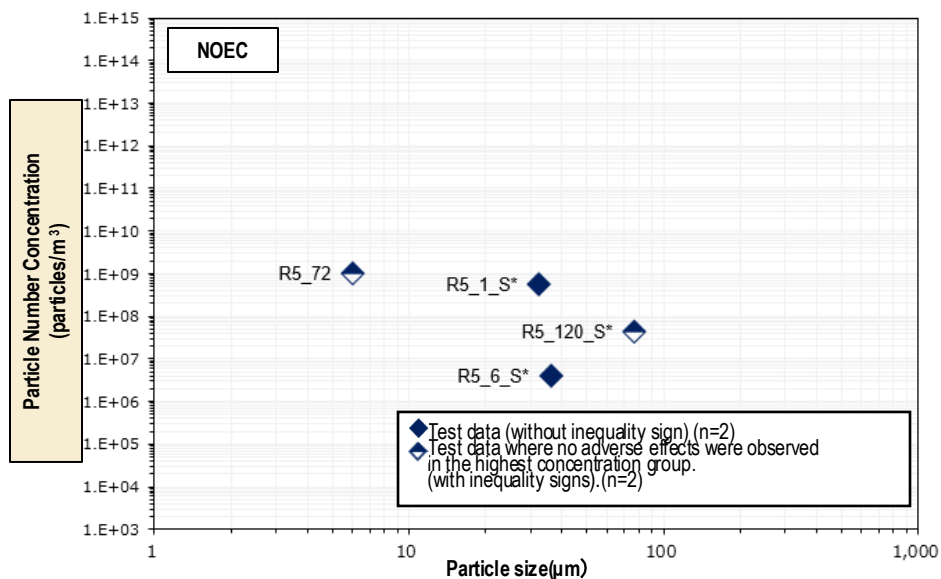
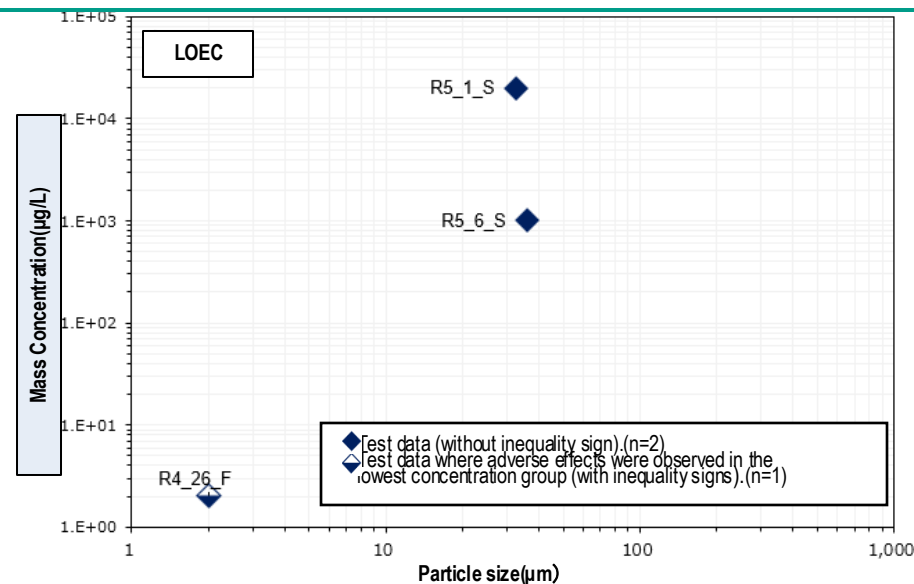
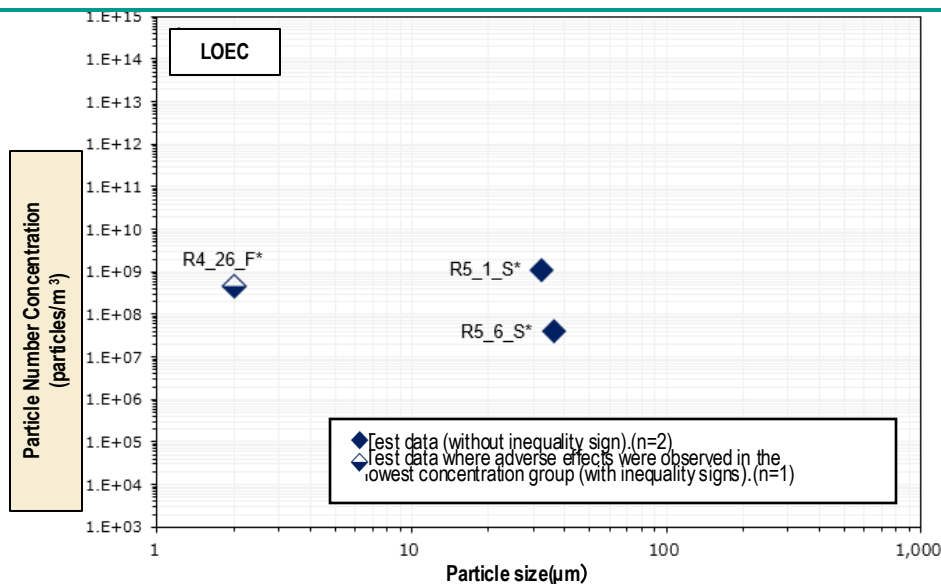
Note 2: In cases where the literature only provides values for number or weight, shape is spherical, density is the density of the material (PE: 0.92, PET: 1.38, PP: 0.9, PS: 1.04, PVC 1.4, others: 1), and particle size is the average of the upper and lower limits, and both are converted (converted values are in italics).

Note 3: If a significant effect was observed in the lowest concentration group, an inequality sign "<" is used, and if no significant effect was observed in the highest concentration group, an inequality sign ">" is used.

Collecting and Reviewing Literature

(2) Test data of quality level “A” and Subacute/Subchronic effects (fish)

- The plot of N(L)OEC presented on the previous page, with concentrations on the vertical axis and particle size on the horizontal axis, are shown below.



*The numbers in the plots correspond to record number of test data. For an overview of each data, see the overview of the test data on the previous page.

Collecting and Reviewing Literature

(2) Test data of quality level “A” and Subacute/Subchronic effects (crustacea)

- Among the effect on crustacea, the subacute/subchronic test data of quality level “A” are shown below.

(No applicable data)



Collecting and Reviewing Literature

(2) Test data of quality level “A” and Subacute/Subchronic effects (bivalves)

■ Among the effect on bivalves, the subacute/subchronic test data of quality level “A” are shown below.

Literature Information			Experimental design								Results							
Literature No.	Record No.	Author(s)	Source of MicP	Particle size (μ m)	Polymer type	Particle shape	Test organism	Nominal concentration			Exposure time	Endpoints	mass concentration (μ g/L)			particle number concentration (particles/m³)		
								mass concentration (μ g/L)	particle number concentration (particles/m3)				Inequality Sign	NOEC	LOEC	Inequality Sign	NOEC	LOEC
R5_1	R5_295	Bringer et al. (2020)	Purchased	1~5	Proprietary Polymer	Sphere	<i>Crassostrea gigas</i>	0,1.0E+02,1.0E+03,1.0E+04	–		24h	body length	<	1.E+02	1.E+02	<	7.E+09	7.E+09
R5_1	R5_296	Bringer et al. (2020)	Purchased	1~5	Proprietary Polymer	Sphere	<i>Crassostrea gigas</i>	0,1.0E+02,1.0E+03,1.0E+04	–		24h	abnormal appearance	–	1.E+02	1.E+03	–	7.E+09	7.E+10
R5_1	R5_297	Bringer et al. (2020)	Purchased	1~5	Proprietary Polymer	Sphere	<i>Crassostrea gigas</i>	0,1.0E+02,1.0E+03,1.0E+04	–		24h	growth	–	1.E+02	1.E+03	–	7.E+09	7.E+10
R5_5	R5_321	Bringer et al. (2022)	Prepared	138.6	Mixture (28% HDPE, 40% PP and 32% PVC)	Fragment	<i>Crassostrea gigas</i>	0,1.0E+02,1.0E+04	–		2m	mortality	<	1.E+02	1.E+02	<	7.E+04	7.E+04

Note 1: For the source documents of each test data, see the Annex List of peer-reviewed publications.

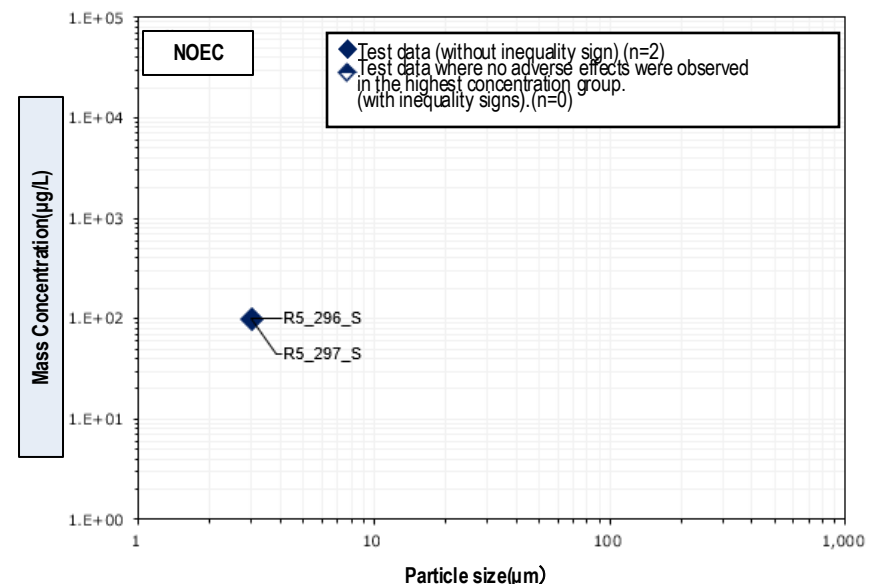
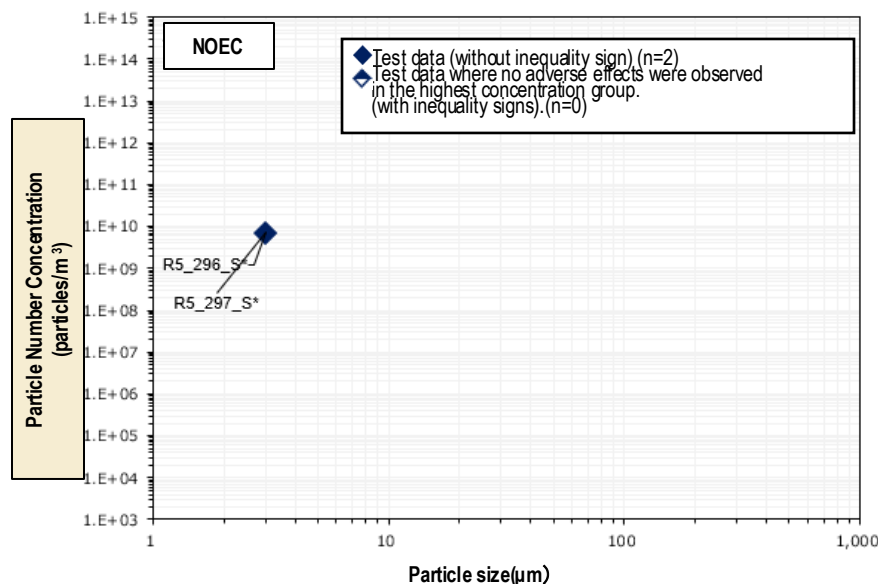
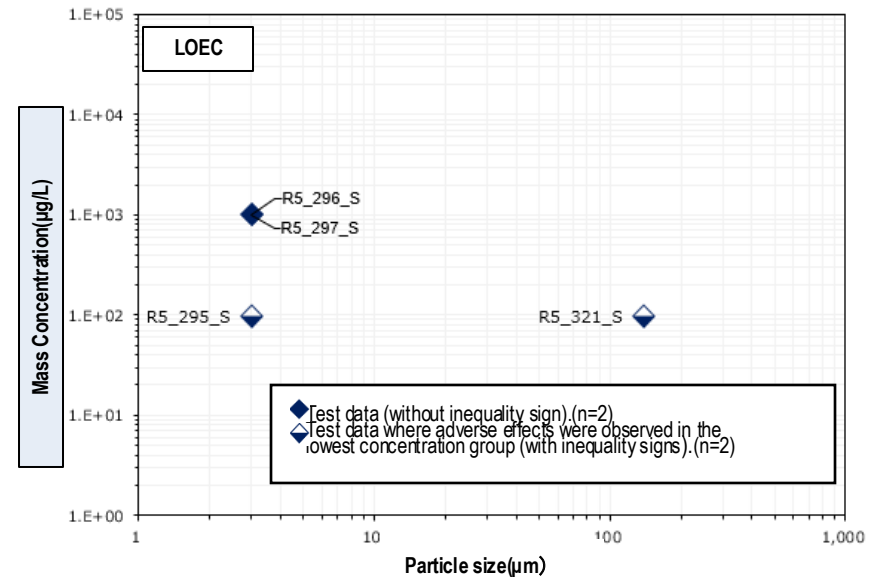
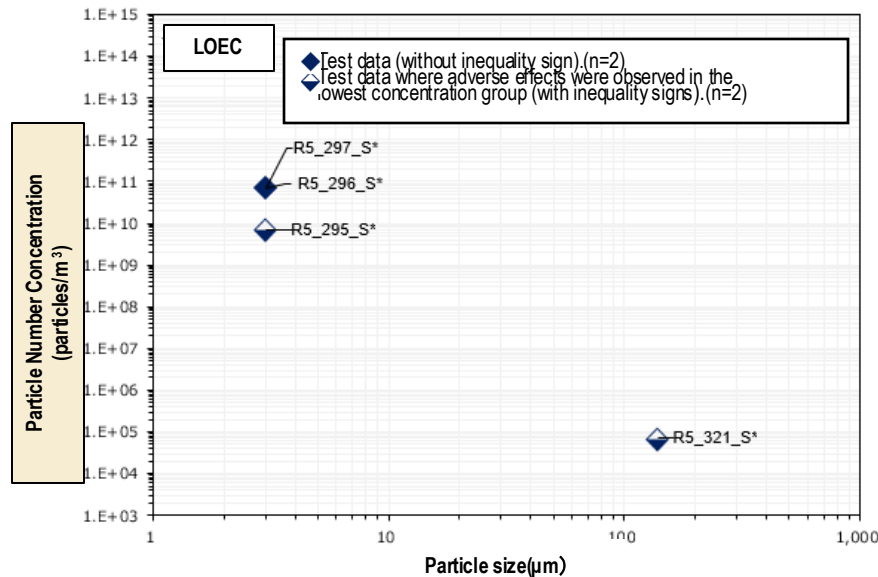
Note 2: In cases where the literature only provides values for number or weight, shape is spherical, density is the density of the material (PE: 0.92, PET: 1.38, PP: 0.9, PS: 1.04, PVC 1.4, others: 1), and particle size is the average of the upper and lower limits, and both are converted (converted values are in italics).

Note 3: If a significant effect was observed in the lowest concentration group, an inequality sign "<" is used, and if no significant effect was observed in the highest concentration group, an inequality sign ">" is used.

Collecting and Reviewing Literature

(3) Test data of quality level "A" and Subacute/Subchronic effects (bivalves)

- The plot of N(L)OEC presented on the previous page, with concentrations on the vertical axis and particle size on the horizontal axis, are shown below.



*The numbers in the plots correspond to record number of test data. For an overview of each data, see the overview of the test data on the previous page.

Collecting and Reviewing Literature

(4) Test data of quality level “A” and Acute effects (fish)

- Among the effect on fish, the acute test data of quality level “A” are shown below.

(No applicable data)



Collecting and Reviewing Literature
(4) Test data of quality level “A” and Acute effects (crustacea)

■ Among the effect on Crustacea, the acute test data of quality level “A” are shown below.

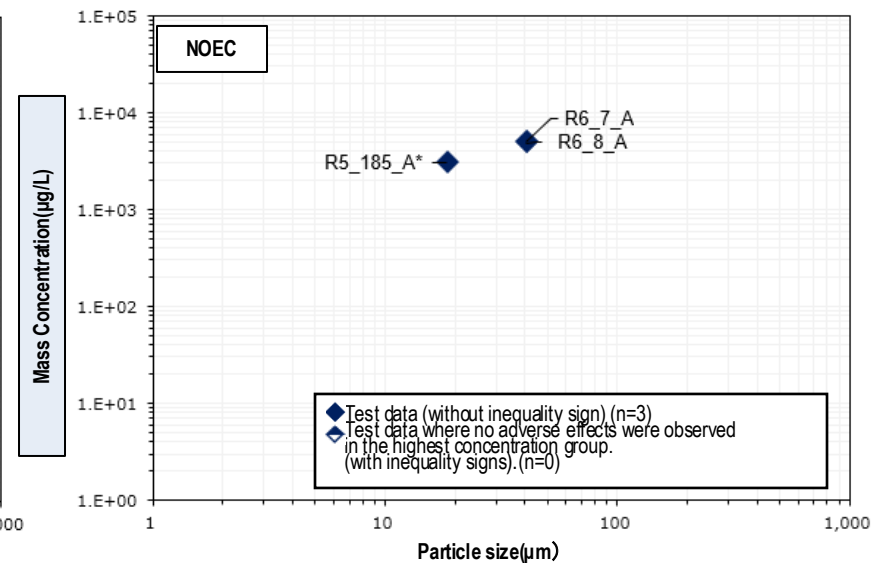
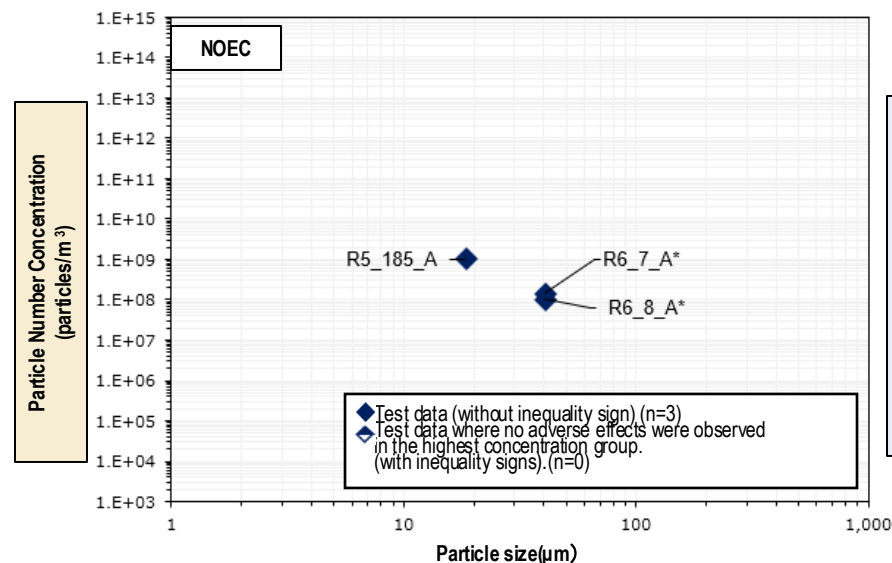
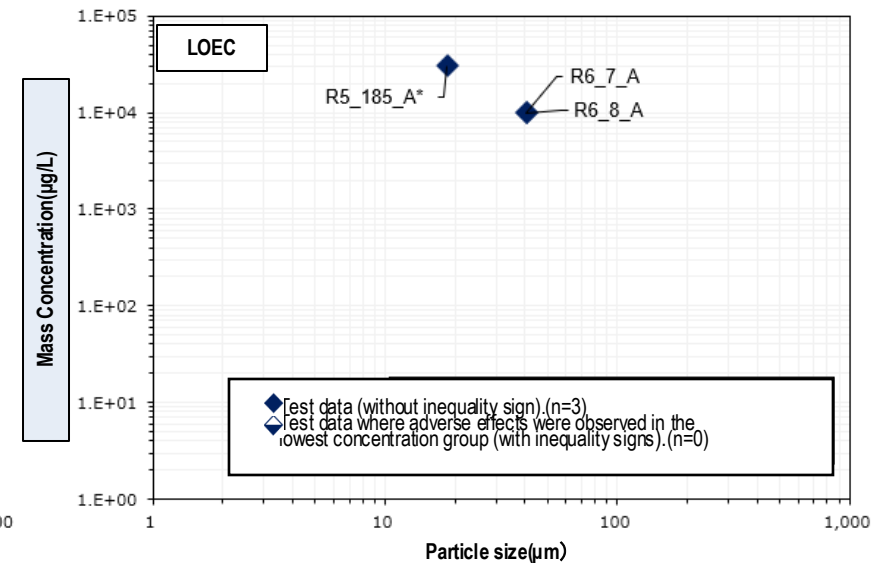
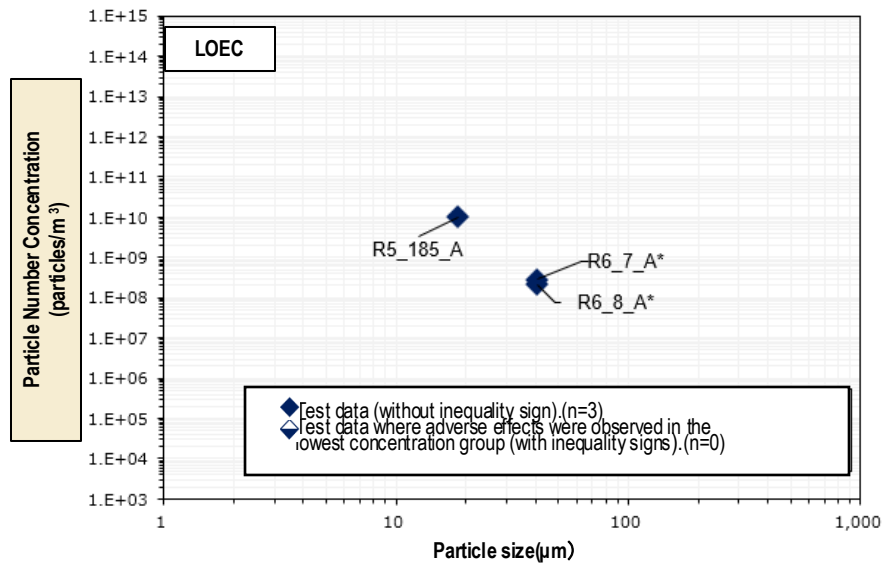
Literature Information			Experimental design							Results								
Literature No.	Record No.	Author(s)	Source of MicP	Particle size (μm)	Polymer type	Particle shape	Test organism	Nominal concentration		Exposure time	Endpoints	Mass concentration (μg/L)			Particle number concentration (particles/m ³)			Notes
								Mass concentration (μg/L)	Particle number concentration (particles/m3)			Inequality Sign	NOEC	LOEC	Inequality Sign	NOEC	LOEC	
R6_P-1220	R6_7	An G et al. (2024)	Purchased	1~80	PLA	Fragment	<i>Daphnia magna</i>	0.1.3E+03,2.0E+03,5.0E+03,1.0E+04,2.0E+04	–	48h	immobilization or death	–	5.E+03	1.E+04	–	1.E+08	3.E+08	EC50=16.41mg/L
R6_P-1220	R6_8	An G et al. (2024)	Purchased	1~80	PET	Fragment	<i>Daphnia magna</i>	0.1.3E+03,2.0E+03,5.0E+03,1.0E+04,2.0E+04	–	48h	immobilization or death	–	5.E+03	1.E+04	–	1.E+08	2.E+08	EC50=18.34mg/L
R5_35	R5_185	Au et al. (2015)	Purchased	10~27	PE	Sphere	<i>Hyalella azteca</i>	–	0.1.0E+07,1.0E+08,1.0E+09,1.0E+10,1.0E+11	10d	mortality	–	3.E+03	3.E+04	–	1.E+09	1.E+10	10d LC50=4.64X10 ⁴ particles/mL

Note 1: For the source documents of each test data, see the Annex List of peer-reviewed publications.
Note 2: In cases where the literature only provides values for number or weight, shape is spherical, density is the density of the material (PE: 0.92, PET: 1.38, PP: 0.9, PS: 1.04, PVC 1.4, others: 1), and particle size is the average of the upper and lower limits, and both are converted (converted values are in italics).
Note 3: If a significant effect was observed in the lowest concentration group, an inequality sign "<" is used, and if no significant effect was observed in the highest concentration group, an inequality sign ">" is used.

Collecting and Reviewing Literature

(4) Test data of quality level “A” and Acute effects (crustacea)

- The plot of N(L)OEC presented on the previous page, with concentrations on the vertical axis and particle size on the horizontal axis, are shown below.



*The numbers in the plots correspond to record number of test data. For an overview of each data, see the overview of the test data on the previous page.

Collecting and Reviewing Literature

(4) Test data of quality level “A” and Acute effects (bivalves)

- Among the effect on bivalves, the acute test data of quality level “A” are shown below.

(No applicable data)

Collecting and Reviewing Literature

(5) Test data of quality level “S” (fish)

- Among the effect on fish, the test data of quality level “S” are shown below.

Literature Information			Experimental design								Results						
Literature No.	Record No.	Author(s)	Source of MicP	Particle size (μ m)	Polymer type	Particle shape	Test organism	Nominal concentration		Exposure time	Endpoints	Mass concentration (μ g/L)			Particle number concentration (particles/m ³)		
								Mass concentration (μ g/L)	Particle number concentration (particles/m3)			Inequality Sign	NOEC	LOEC	Inequality Sign	NOEC	LOEC
R6_P-0492	R6_1	Bucci K et al. (2024)	Purchased	150~500	PE	Fragment	<i>Pimephales promelas</i>	–	0,1.0E+05,2.0E+06	6m	body length	–	2.E+03	3.E+04	–	1.E+05	2.E+06
R6_P-0492	R6_2	Bucci K et al. (2024)	Collected	150~500	PE	Fragment	<i>Pimephales promelas</i>	–	0,1.0E+05,2.0E+06	6m	abnormal appearance	–	2.E+03	3.E+04	–	1.E+05	2.E+06
R6_P-0492	R6_3	Bucci K et al. (2024)	Collected	150~500	PE	Fragment	<i>Pimephales promelas</i>	–	0,1.0E+05,2.0E+06	6m	body length	–	2.E+03	3.E+04	–	1.E+05	2.E+06
R6_P-0492	R6_4	Bucci K et al. (2024)	Collected	150~500	PE	Fragment	<i>Pimephales promelas</i>	–	0,1.0E+05,2.0E+06	6m	maturity	–	2.E+03	3.E+04	–	1.E+05	2.E+06
R6_P-2065	R6_19	La Pietra A et al. (2024)	Purchased	1	PS	Sphere	<i>Danio rerio</i>	0,1.0E+01,1.0E+02,1.0E+03,1.0E+04	–	72h	survival rate	>	1.E+04	1.E+04	>	2.E+13	2.E+13
R6_P-2065	R6_21	La Pietra A et al. (2024)	Purchased	3	PS	Sphere	<i>Danio rerio</i>	0,1.0E+01,1.0E+02,1.0E+03,1.0E+04	–	72h	survival	>	1.E+04	1.E+04	>	7.E+11	7.E+11
R6_P-2196	R6_23	Wen S et al. (2024)	Purchased	10~50	PE	Fragment	<i>Oryzias melastigma</i>	0.2.0E+02	–	60d	body length、body weight、mortality	>	2.E+02	2.E+02	>	2.E+07	2.E+07
R6_P-2196	R6_25	Wen S et al. (2024)	Purchased	100~300	PLA	Fragment	<i>Oryzias melastigma</i>	0,2.0E+02	–	60d	body length、body weight、mortality	>	2.E+02	2.E+02	>	5.E+04	5.E+04
R6_P-1215	R6_106	Tamura Y et al. (2024)	Purchased	2	PS	Sphere	<i>Oryzias latipes</i>	0,1.0E+02	0,2.5E+10	28d	survival	>	1.E+02	1.E+02	>	3.E+10	3.E+10
R6_P-2659	R6_109	Chu T et al. (2024)	Purchased	1.1	PS	Sphere	<i>Gobiocypris rarus</i>	0,1.0E+03,1.0E+04	–	14d	mortality	>	1.E+04	1.E+04	>	1.E+13	1.E+13
R6_P-2659	R6_110	Chu T et al. (2024)	Purchased	1.1	PS	Sphere	<i>Gobiocypris rarus</i>	0,1.0E+03,1.0E+04	–	14d	body length、body weight	–	1.E+03	1.E+04	–	1.E+12	1.E+13
R6_P-3575	R6_133	Sun X et al. (2023)	Purchased	16.94	PS	Sphere	<i>Sebastes schlegelii</i>	0,2.3E+02	–	15d	weight gain	>	2.E+02	2.E+02	>	8.E+07	8.E+07
R6_P-3730	R6_140	Yang H et al. (2024)	Purchased	5	PS	Sphere	<i>Danio rerio</i>	0,1.0E+03	–	7dpf	hatching rate	>	1.E+03	1.E+03	>	1.E+10	1.E+10
R6_P-3730	R6_141	Yang H et al. (2024)	Purchased	5	PS	Sphere	<i>Danio rerio</i>	0,1.0E+03	–	7dpf	body length	>	1.E+03	1.E+03	>	1.E+10	1.E+10

Note 1: For the source documents of each test data, see the Annex List of peer-reviewed publications.

Note 2: In cases where the literature only provides values for number or weight, shape is spherical, density is the density of the material (PE: 0.92, PET: 1.38, PP: 0.9, PS: 1.04, PVC 1.4, others: 1), and particle size is the average of the upper and lower limits, and both are converted (converted values are in italics).

Note 3: If a significant effect was observed in the lowest concentration group, an inequality sign "<" is used, and if no significant effect was observed in the highest concentration group, an inequality sign ">" is used.

Collecting and Reviewing Literature

(5) Test data of quality level “S” (fish)

Hazards



Literature Information			Experimental design								Results						
Literature No.	Record No.	Author(s)	Source of MicP	Particle size (μ m)	Polymer type	Particle shape	Test organism	Nominal concentration		Exposure time	Endpoints	Mass concentration (μ g/L)			Particle number concentration (particles/m ³)		
								Mass concentration (μ g/L)	Particle number concentration (particles/m3)			Inequality Sign	NOEC	LOEC	Inequality Sign	NOEC	LOEC
R5_15	R5_2	Zhang et al. (2022)	Purchased	5~50	Polyamide	Fragment	<i>Danio rerio</i>	0,1.0E+03,1.0E+04,2.0E+04	–	10d	body length、standardized body weight 、hatching rate	–	1.E+04	2.E+04	–	<i>6.E+08</i>	<i>1.E+09</i>
R5_15	R5_3	Zhang et al. (2022)	Purchased	5~50	Polyamide	Fragment	<i>Danio rerio</i>	0,1.0E+03,1.0E+04,2.0E+04	–	10d	standardized body weight	–	1.E+03	1.E+04	–	<i>6.E+07</i>	<i>6.E+08</i>
R5_20	R5_8	Malafaia et al. (2020)	Purchased	38.26	PE	Fragment	<i>Danio rerio</i>	0,6.2E+03,1.3E+04,2.5E+04,5.0E+04,1.0E+05	0,4.4E+05,8.8E+05,1.8E+06,3.5E+06,7.1E+06	144h	survival rate of juveniles	<	6.E+03	6.E+03	<	4.E+05	4.E+05
R5_28	R5_9	Zhang et al. (2021)	Purchased	2	PS	NA	<i>Oryzias melastigma</i>	0,1.0E+04	–	60d	body weight、body length、number of offsprings	>	1.E+04	1.E+04	>	<i>2.E+12</i>	<i>2.E+12</i>
R5_28	R5_10	Zhang et al. (2021)	Purchased	10	PS	NA	<i>Oryzias melastigma</i>	0,1.0E+04	–	60d	body weight、body length、number of offsprings	>	1.E+04	1.E+04	>	<i>2.E+10</i>	<i>2.E+10</i>
R5_26	R5_15	Xia et al. (2022)	Purchased	53~106	PVC	NA	<i>Oryzias melastigma</i>	0,5.9E+02,5.9E+05	0,1.0E+06,1.0E+09	25d	abnormal appearance	>	6.E+05	6.E+05	>	1.E+09	1.E+09
R5_2	R5_33	Wang et al. (2022)	Purchased	5	PS	Sphere	<i>Paramisgurnus dabryanus</i>	0,1.0E+02,1.0E+03	–	21d	Survival	<	1.E+02	1.E+02	<	<i>1.E+09</i>	<i>1.E+09</i>
R5_2	R5_34	Wang et al. (2022)	Purchased	5	PS	Sphere	<i>Paramisgurnus dabryanus</i>	0,1.0E+02,1.0E+03	–	21d	Weight gain	<	1.E+02	1.E+02	<	<i>1.E+09</i>	<i>1.E+09</i>
R5_2	R5_35	Wang et al. (2022)	Purchased	5	PS	Sphere	<i>Paramisgurnus dabryanus</i>	0,1.0E+02,1.0E+03	–	21d	Speific weight gain	<	1.E+02	1.E+02	<	<i>1.E+09</i>	<i>1.E+09</i>
R5_52	R5_89	Kim et al. (2022)	Purchased	14.12	HDPE	Fragment	<i>Danio rerio</i>	0,2.0E+04	0,1.4E+10	96h	mortality	>	2.E+04	2.E+04	>	1.E+10	1.E+10
R5_52	R5_91	Kim et al. (2022)	Purchased	80.32	HDPE	Fragment	<i>Danio rerio</i>	0,2.0E+04	0,7.8E+07	96h	mortality	>	2.E+04	2.E+04	>	8.E+07	8.E+07
R5_52	R5_93	Kim et al. (2022)	Purchased	121	HDPE	Fragment	<i>Danio rerio</i>	0,2.0E+04	0,2.3E+07	96h	mortality	>	2.E+04	2.E+04	>	2.E+07	2.E+07
R5_9	R5_112	De Marco et al. (2022)	Purchased	10	PS	Sphere	<i>Danio rerio</i>	–	0,2.0E+08	120h	hatching day、sub-lethal effects	<	<i>1.E+02</i>	<i>1.E+02</i>	<	2.E+08	2.E+08
R4_19	R4_28	Yao Zhao et al. (2020)	Purchased	5	PS	Sphere	<i>Danio rerio</i>	0,2.0E+01,1.0E+02	–	21d	body weight	<	2.E+01	2.E+01	<	<i>3.E+08</i>	<i>3.E+08</i>

Note 1: For the source documents of each test data, see the Annex List of peer-reviewed publications.

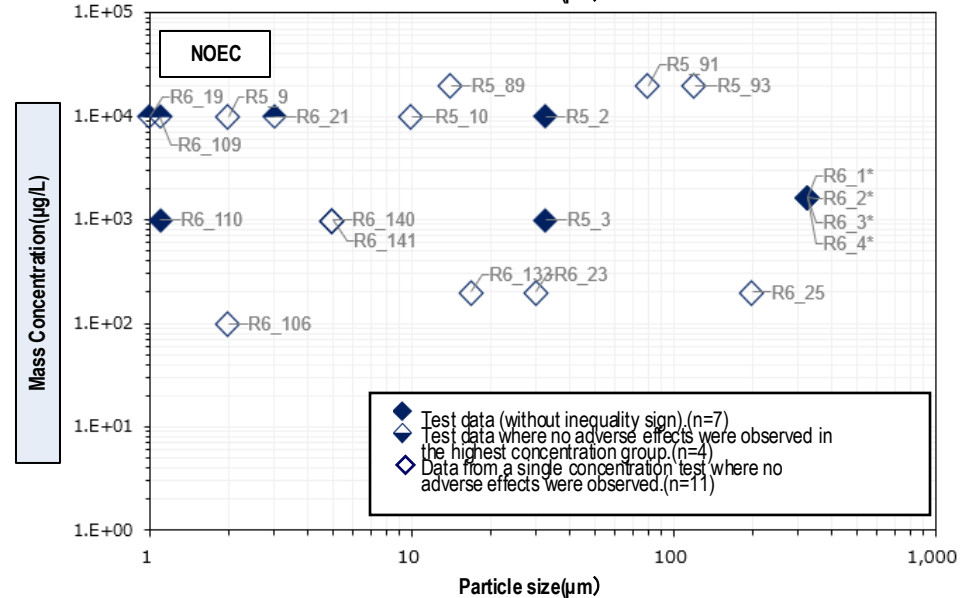
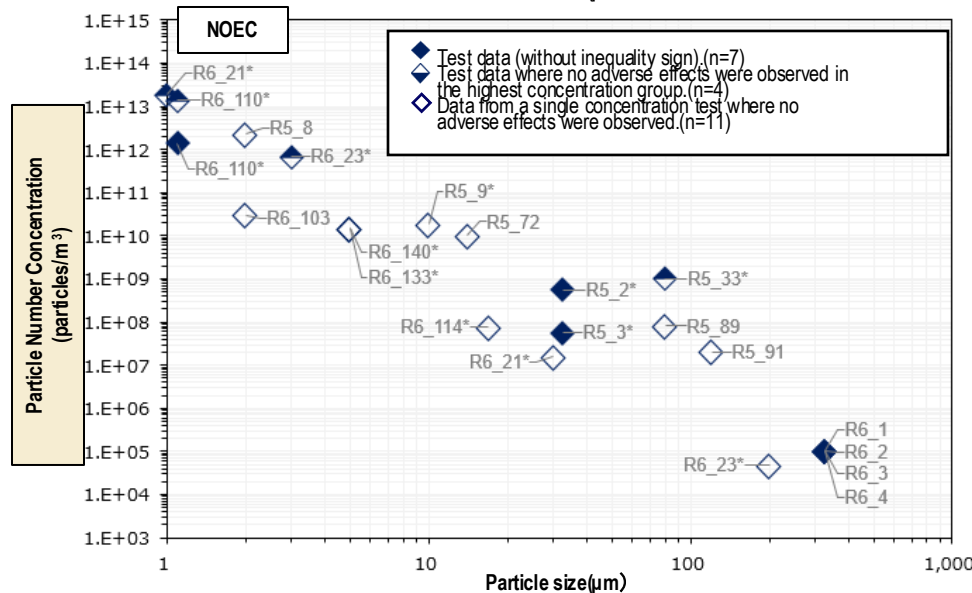
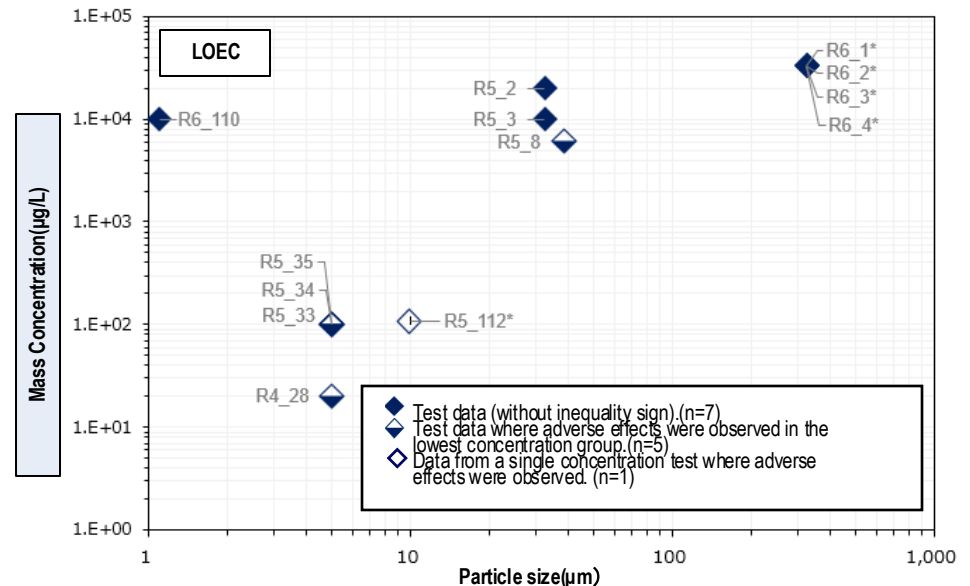
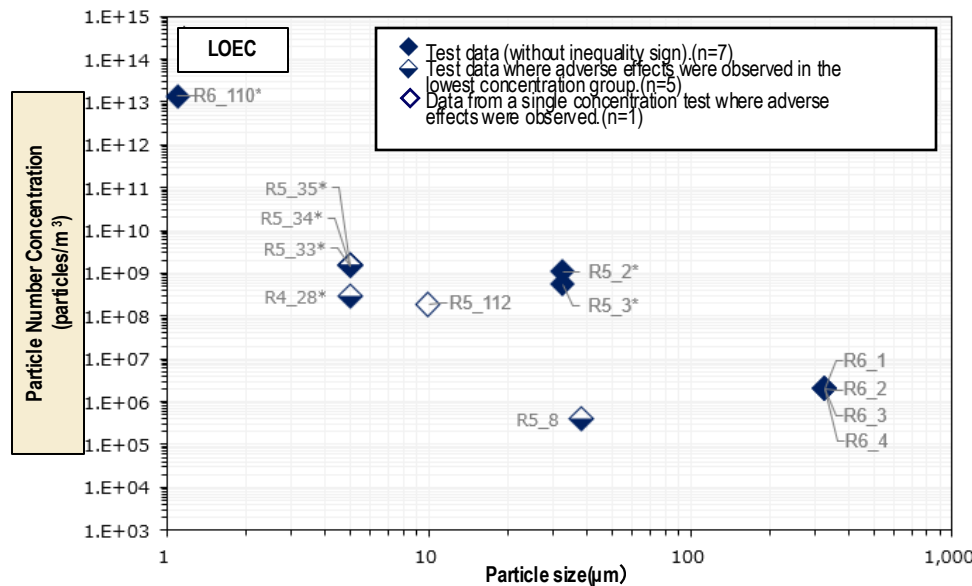
Note 2: In cases where the literature only provides values for number or weight, shape is spherical, density is the density of the material (PE: 0.92, PET: 1.38, PP: 0.9, PS: 1.04, PVC 1.4, others: 1), and particle size is the average of the upper and lower limits, and both are converted (converted values are in italics).

Note 3: If a significant effect was observed in the lowest concentration group, an inequality sign "<" is used, and if no significant effect was observed in the highest concentration group, an inequality sign ">" is used.

Collecting and Reviewing Literature

(5) Test data of quality level “S” (fish)

- The plot of N(L)OEC presented on the previous pages, with concentrations on the vertical axis and particle size on the horizontal axis, are shown below.



*The numbers in the plots correspond to record number of test data. For an overview of each data, see the overview of the test data on the previous pages.

Collecting and Reviewing Literature

(5) Test data of quality level “S” (crustacea)

- Among the effect on Crustacea, the test data of quality level “S” are shown below.

Literature Information			Experimental design								Results						
Literature No.	Record No.	Author(s)	Source of MicP	Particle size (μ m)	Polymer type	Particle shape	Test organism	Nominal concentration		Exposure time	Endpoints	Mass concentration (μ g/L)			Particle number concentration (particles/m ³)		
								Mass concentration (μ g/L)	Particle number concentration (particles/m3)			Inequality Sign	NOEC	LOEC	Inequality Sign	NOEC	LOEC
R6_P-0909	R6_5	Pichardo-Casales B et al. (2024)	Purchased	53~63	PE	Sphere	<i>Minuca rapax</i>	0.2.0E+03	–	56d	mortality, body weight	>	2.E+03	2.E+03	>	2.E+07	2.E+07
R6_P-1935	R6_100	Silveyra GR et al. (2023)	Purchased	1	PS	Sphere	<i>Procambarus clarkii</i>	–	0.1.0E+09,5.0E+09	30d	weight gain	>	3.E+00	3.E+00	>	5.E+09	5.E+09
R6_P-1935	R6_103	Silveyra GR et al. (2023)	Purchased	1	PS	Sphere	<i>Leptuca pugilator</i>	–	0.1.0E+09,5.0E+09	30d	weight gain	–	5.E-01	3.E+00	–	1.E+09	5.E+09
R6_P-3052	R6_114	De Felice B et al. (2024)	Prepared	164~	PLA	Fragment	<i>Daphnia magna</i>	0.5.0E+01,1.0E+02,1.0E+03,5.0E+03,1.5E+04	–	48h	immobilization	>	2.E+04	2.E+04	>	9.E+06	9.E+06
R5_13	R5_134	Watts et al. (2016)	Purchased	8	PS	Sphere	<i>Carcinus maenas</i>	–	0.1.0E+09,1.0E+10	24h	mortality	>	3.E+03	3.E+03	>	1.E+10	1.E+10
R5_17	R5_138	Heindler et al. (2017)	Prepared	11	PET	Fragment	<i>Parvocalanus crassirostris</i>	–	0.1.0E+10,2.0E+10,4.0E+10,8.0E+10	5d	number of eggs	–	5.E+03	1.E+04	–	4.E+10	8.E+10
R5_17	R5_139	Heindler et al. (2017)	Prepared	11	PET	Fragment	<i>Parvocalanus crassirostris</i>	–	0.2.0E+10	24d	population size	<	2.E+03	2.E+03	<	2.E+10	2.E+10
R5_11	R5_140	Shore et al. (2021)	Purchased	6~8	PS	NA	<i>Acartia tonsa</i>	–	0.1.2E+09	5 or 7d	Copepodid: survival, body length Parent Shrimp: number of eggs	<	2.E+02	2.E+02	<	1.E+09	1.E+09
R5_26	R5_147	Yu et al. (2020)	Purchased	10~30	PE	NA	<i>Tigriopus japonicus</i>	0.1.3E+04	–	14d	number of eggs, survival	<	1.E+04	1.E+04	<	3.E+09	3.E+09
R5_26	R5_149	Yu et al. (2020)	Purchased	5~20	PA6	NA	<i>Tigriopus japonicus</i>	0.1.3E+04	–	14d	number of eggs, survival	<	1.E+04	1.E+04	<	1.E+10	1.E+10
R5_27	R5_150	Liu et al. (2022)	Purchased	2	PVC	NA	<i>Daphnia magna</i>	0.2.1E+03	–	21d	number of offsprings	<	2.E+03	2.E+03	<	3.E+11	3.E+11
R5_27	R5_151	Liu et al. (2022)	Purchased	50	PVC	NA	<i>Daphnia magna</i>	0.2.1E+03	–	21d	1st number of offsprings	<	2.E+03	2.E+03	<	2.E+07	2.E+07
R5_30	R5_154	An et al. (2021)	Purchased	40~48	PE	Sphere	<i>Daphnia magna</i>	–	0.3.4E+09	21d	growth, number of offsprings	>	1.E+05	1.E+05	>	3.E+09	3.E+09
R5_30	R5_155	An et al. (2021)	Prepared	17	PE	Fragment	<i>Daphnia magna</i>	–	0.2.1E+10	21d	mortality, growth, number of offsprings	<	5.E+04	5.E+04	<	2.E+10	2.E+10
R5_30	R5_156	An et al. (2021)	Prepared	34	PE	Fragment	<i>Daphnia magna</i>	–	0.1.7E+10	21d	mortality	>	4.E+05	4.E+05	>	2.E+10	2.E+10

Note 1: For the source documents of each test data, see the Annex List of peer-reviewed publications.

Note 2: In cases where the literature only provides values for number or weight, shape is spherical, density is the density of the material (PE: 0.92, PET: 1.38, PP: 0.9, PS: 1.04, PVC 1.4, others: 1), and particle size is the average of the upper and lower limits, and both are converted (converted values are in italics).

Note 3: If a significant effect was observed in the lowest concentration group, an inequality sign "<" is used, and if no significant effect was observed in the highest concentration group, an inequality sign ">" is used.

Collecting and Reviewing Literature

(5) Test data of quality level “S” (crustacea)

Hazards



Literature Information			Experimental design								Results						
Literature No.	Record No.	Author(s)	Source of MicP	Particle size (μ m)	Polymer type	Particle shape	Test organism	Nominal concentration		Exposure time	Endpoints	Mass concentration (μ g/L)			Particle number concentration (particles/m ³)		
								Mass concentration (μ g/L)	Particle number concentration (particles/m3)			Inequality Sign	NOEC	LOEC	Inequality Sign	NOEC	LOEC
R5_4	R5_157	Martins et al. (2018)	Purchased	1~5	Thermoset amino formaldehyde polymer	Sphere	<i>Daphnia magna</i>	0,1.0E+02	–	2 generations	mortality, growth (F0, F1) number of offsprings, first hatching day(F1)	<	1.E+02	1.E+02	<	7.E+09	7.E+09
R5_5	R5_158	Guilhermino et al. (2021)	Purchased	1~5	Thermoset amino formaldehyde polymer	Sphere	<i>Daphnia magna</i>	0,4.0E+01,9.0E+01,1.9E+02	–	21d	growth, number of offsprings, survival of offsprings	–	4.E+01	9.E+01	–	1.E+10	2.E+10
R5_8	R5_160	Lee et al. (2021)	Purchased	1~1.2	PS	Sphere	<i>Neomysis awatschensis</i>	–	0,1.0E+09,5.0E+09,1.0E+10,5.0E+10,1.0E+11	40d	Survival	–	7.E+00	4.E+01	–	1.E+10	5.E+10
R5_8	R5_161	Lee et al. (2021)	Purchased	10~10.35	PS	Sphere	<i>Neomysis awatschensis</i>	–	0,1.0E+09,5.0E+09,1.0E+10,5.0E+10,1.0E+11	40d	Survival	–	6.E+03	3.E+04	–	1.E+10	5.E+10
R5_8	R5_162	Lee et al. (2021)	Purchased	1~1.2	PS	Sphere	<i>Neomysis awatschensis</i>	–	0,5.0E+10,1.0E+11	40d	Number of newborn juvenil female	>	7.E+01	7.E+01	>	1.E+11	1.E+11
R5_8	R5_163	Lee et al. (2021)	Purchased	10~10.35	PS	Sphere	<i>Neomysis awatschensis</i>	–	0,5.0E+10,1.0E+11	40d	Number of newborn juvenil female	>	6.E+04	6.E+04	>	1.E+11	1.E+11
R5_9	R5_164	Eom et al. (2020)	Purchased	1	PS	Sphere	<i>Artemia franciscana</i>	–	0,1.0E+06,1.0E+07,1.0E+08,1.0E+09	30d	Survival	–	5.E–03	5.E–02	–	1.E+07	1.E+08
R5_9	R5_165	Eom et al. (2020)	Purchased	3	PS	Sphere	<i>Artemia franciscana</i>	–	0,1.0E+06,1.0E+07,1.0E+08,1.0E+09	30d	Survival	–	1.E–01	1.E+00	–	1.E+07	1.E+08
R5_9	R5_166	Eom et al. (2020)	Purchased	6	PS	Sphere	<i>Artemia franciscana</i>	–	0,1.0E+06,1.0E+07,1.0E+08,1.0E+09	30d	Survival	–	1.E+00	1.E+01	–	1.E+07	1.E+08
R5_9	R5_167	Eom et al. (2020)	Purchased	10	PS	Sphere	<i>Artemia franciscana</i>	–	0,1.0E+06,1.0E+07,1.0E+08,1.0E+09	30d	Survival	–	5.E+00	5.E+01	–	1.E+07	1.E+08
R5_10	R5_170	Eltemsah et al. (2019)	Purchased	6	PS	Sphere	<i>Daphnia magna</i>	0,5.0E+03,1.0E+04,3.0E+04,5.0E+04,1.0E+05	–	15d	Body length	–	1.E+04	3.E+04	–	9.E+10	3.E+11
R5_10	R5_171	Eltemsah et al. (2019)	Purchased	6	PS	Sphere	<i>Daphnia magna</i>	0,5.0E+03,3.0E+04,1.0E+05	–	21d	Body length	<	5.E+03	5.E+03	<	4.E+10	4.E+10
R5_33	R5_180	Schwarzer et al. (2022)	Purchased	5.4~6.6	PS	Sphere	<i>Daphnia magna</i>	–	0,5.0E+08,5.0E+09	21d	body length	<	6.E+01	6.E+01	<	5.E+08	5.E+08
R5_33	R5_180b	Schwarzer et al. (2022)	Purchased	18~22	PS	Sphere	<i>Daphnia magna</i>	–	0,5.0E+08,5.0E+09	21d	body length		2.E+04	2.E+04		5.E+09	5.E+09
R5_34	R5_183	Gray et al. (2022)	Purchased	32~38	PE	Sphere	<i>Palaemon pugio</i>	0,3.8E+00,3.8E+01,3.8E+02	0,6.3E+04,6.3E+05,6.3E+06	23d	mortality	<	4.E+00	4.E+00	<	6.E+04	6.E+04
R5_34	R5_184	Gray et al. (2022)	Purchased	53~63	PE	Sphere	<i>Palaemonetes pugio</i>	0,2.0E+01,2.0E+02,2.0E+03	0,6.3E+04,6.3E+05,6.3E+06	23d	mortality	<	2.E+01	2.E+01	<	6.E+04	6.E+04

Note 1: For the source documents of each test data, see the Annex List of peer-reviewed publications.

Note 2: In cases where the literature only provides values for number or weight, shape is spherical, density is the density of the material (PE: 0.92, PET: 1.38, PP: 0.9, PS: 1.04, PVC 1.4, others: 1), and particle size is the average of the upper and lower limits, and both are converted (converted values are in italics).

Note 3: If a significant effect was observed in the lowest concentration group, an inequality sign "<" is used, and if no significant effect was observed in the highest concentration group, an inequality sign ">" is used.

Collecting and Reviewing Literature

(5) Test data of quality level “S” (crustacea)

Hazards



Literature Information			Experimental design							Results							
Literature No.	Record No.	Author(s)	Source of MicP	Particle size (μm)	Polymer type	Particle shape	Test organism	Nominal concentration		Exposure time	Endpoints	Mass concentration (μg/L)			Particle number concentration (particles/m ³)		
								Mass concentration (μg/L)	Particle number concentration (particles/m3)			Inequality Sign	NOEC	LOEC	Inequality Sign	NOEC	LOEC
R5_18	R5_188	Trotter et al. (2021)	Supplied	13.03	PS	Sphere	<i>Daphnia magna</i>	0,1.0E+05	–	19d	mortality, body length, number of second offspring	>	1.E+05	1.E+05	>	8.E+10	8.E+10
R5_40	R5_195	Li, et al. (2021)	Purchased	150	PS	Sphere	<i>Artemia parthenogenetica</i>	0,1.0E+05	–	45d	growth	<	1.E+05	1.E+05	<	5.E+07	5.E+07
R5_40	R5_196	Li, et al. (2021)	Purchased	150	PE	Sphere	<i>Artemia parthenogenetica</i>	0,1.0E+05	–	45d	growth	<	1.E+05	1.E+05	<	6.E+07	6.E+07
R5_43	R5_203	Kokalj et al. (2018)	Purchased	102.9	PE	Fragment	<i>Daphnia magna</i>	0,1.0E+05	–	48h	survival, body length	>	1.E+05	1.E+05	>	2.E+08	2.E+08
R5_43	R5_204	Kokalj et al. (2018)	Collected	63.05	PE	Fragment	<i>Daphnia magna</i>	0,1.0E+05	–	48h	survival, body length	>	1.E+05	1.E+05	>	8.E+08	8.E+08
R5_43	R5_205	Kokalj et al. (2018)	Collected	264	PE	Fragment	<i>Daphnia magna</i>	0,1.0E+05	–	48h	survival, body length	>	1.E+05	1.E+05	>	1.E+07	1.E+07
R5_43	R5_206	Kokalj et al. (2018)	Collected	247.9	PE	Fragment	<i>Daphnia magna</i>	0,1.0E+05	–	48h	survival, body length	>	1.E+05	1.E+05	>	1.E+07	1.E+07
R5_43	R5_207	Kokalj et al. (2018)	Collected	136.8	PE	Fragment	<i>Daphnia magna</i>	0,1.0E+05	–	48h	survival, body length	>	1.E+05	1.E+05	>	8.E+07	8.E+07
R5_43	R5_210	Kokalj et al. (2018)	Collected	102.9	PE	Fragment	<i>Artemia franciscana</i>	0,1.0E+05	–	48h	growth	<	1.E+05	1.E+05	<	2.E+08	2.E+08
R5_43	R5_211	Kokalj et al. (2018)	Collected	63.05	PE	Fragment	<i>Artemia franciscana</i>	0,1.0E+05	–	48h	growth	<	1.E+05	1.E+05	<	8.E+08	8.E+08
R5_43	R5_212	Kokalj et al. (2018)	Collected	264	PE	Fragment	<i>Artemia franciscana</i>	0,1.0E+05	–	48h	growth	<	1.E+05	1.E+05	<	1.E+07	1.E+07
R5_43	R5_213	Kokalj et al. (2018)	Collected	247.9	PE	Fragment	<i>Artemia franciscana</i>	0,1.0E+05	–	48h	growth	<	1.E+05	1.E+05	<	1.E+07	1.E+07
R5_43	R5_214	Kokalj et al. (2018)	Prepared	136.8	PE	Fragment	<i>Artemia franciscana</i>	0,1.0E+05	–	48h	growth	<	1.E+05	1.E+05	<	8.E+07	8.E+07
R5_47	R5_235	Wang et al. (2021)	Purchased	5	PE	Sphere	<i>Litopenaeus vannamei</i>	0.5.0E+01,5.0E+02,5.0E+03	0.7.3E+08,7.3E+09,7.3E+10	48h	survival	>	5.E+03	5.E+03	>	7.E+10	7.E+10
R5_48	R5_237	Wang et al. (2021)	Purchased	5	PE	Sphere	<i>Penaeus monodon</i>	0.2.5E+04,5.0E+04,1.0E+05,2.0E+05,3.0E+05	0.3.6E+11,7.3E+11,1.5E+12,2.9E+12,4.4E+12	48h	mortality	–	5.E+04	1.E+05	–	7.E+11	1.E+12
R5_48	R5_239	Wang et al. (2021)	Purchased	5	PE	Sphere	<i>Marsupenaeus japonicus</i>	0.2.5E+04,5.0E+04,1.0E+05,2.0E+05,3.0E+05	0.3.6E+11,7.3E+11,1.5E+12,2.9E+12,4.4E+12	48h	mortality	–	5.E+04	1.E+05	–	7.E+11	1.E+12
R5_48	R5_241	Wang et al. (2021)	Purchased	5	PE	Sphere	<i>Lipopenaeus vanamei</i>	0.2.5E+04,5.0E+04,1.0E+05,2.0E+05,3.0E+05	0.3.6E+11,7.3E+11,1.5E+12,2.9E+12,4.4E+12	48h	mortality	–	5.E+04	1.E+05	–	7.E+11	1.E+12

Note 1: For the source documents of each test data, see the Annex List of peer-reviewed publications.

Note 2: In cases where the literature only provides values for number or weight, shape is spherical, density is the density of the material (PE: 0.92, PET: 1.38, PP: 0.9, PS: 1.04, PVC 1.4, others: 1), and particle size is the average of the upper and lower limits, and both are converted (converted values are in italics).

Note 3: If a significant effect was observed in the lowest concentration group, an inequality sign "<" is used, and if no significant effect was observed in the highest concentration group, an inequality sign ">" is used.

Collecting and Reviewing Literature

(5) Test data of quality level “S” (crustacea)

Hazards



Literature Information			Experimental design								Results						
Literature No.	Record No.	Author(s)	Source of MicP	Particle size (μ m)	Polymer type	Particle shape	Test organism	Nominal concentration		Exposure time	Endpoints	Mass concentration (μ g/L)			Particle number concentration (particles/m ³)		
								Mass concentration (μ g/L)	Particle number concentration (particles/m3)			Inequality Sign	NOEC	LOEC	Inequality Sign	NOEC	LOEC
R5_24	R5_261	Cole et al. (2015)	Purchased	20	PS	Sphere	<i>Calanus helgolandicus</i>	–	0.7.5E+07	2d	hatching rate	<	3.E+02	3.E+02	<	8.E+07	8.E+07
R5_36	R5_263	Schür et al. (2022)	Prepared	0.2~60	PS	Fragment	<i>Daphnia magna</i>	–	0.8.0E+07,4.0E+08,2.0E+09,1.0E+10	21d	mortality、reproduction (F1)	–	1.E+03	6.E+03	–	8.E+07	4.E+08
R5_36	R5_264	Schür et al. (2022)	Prepared	0.2~60	PS	Fragment	<i>Daphnia magna</i>	–	0.8.0E+07,4.0E+08,2.0E+09,1.0E+10	21d	mortality、reproduction (F2)	–	1.E+03	6.E+03	–	8.E+07	4.E+08
R5_36	R5_265	Schür et al. (2022)	Prepared	0.2~60	PS	Fragment	<i>Daphnia magna</i>	–	0.8.0E+07,4.0E+08,2.0E+09,1.0E+10	21d	mortality、reproduction (F3)	–	1.E+03	6.E+03	–	8.E+07	4.E+08
R5_51	R5_270	Rani-Borges et al. (2023)	Purchased	24.5~	PS	Sphere	<i>Hyalella azteca</i>	–	0.5.4E+05,2.7E+06,5.4E+06	7d	survival	>	4.E+01	4.E+01	>	5.E+06	5.E+06
R5_53	R5_273	Sun et al. (2022)	Purchased	5	PS	Sphere	<i>Macrobrachium nipponense</i>	0.2.0E+03,2.0E+04	0.5.6E+07,5.8E+08	4w	body weight	<	2.E+03	2.E+03	<	6.E+07	6.E+07
R5_53	R5_274	Sun et al. (2022)	Purchased	5	PS	Sphere	<i>Macrobrachium nipponense</i>	0.2.0E+03,2.0E+04	0.5.6E+07,5.8E+08	4w	abnormal appearance、hatching rate、mortality	<	2.E+03	2.E+03	<	6.E+07	6.E+07
R5_54	R5_284	Kim et al. (2022)	Purchased	1.88	PS	Sphere	<i>Tigriopus japonicus</i>	0.5.0E+00,1.0E+02,1.0E+03,1.0E+04,1.0E+05	0.1.2E+08,2.3E+10,2.3E+11,2.3E+12,2.3E+13	40d	reproduction	–	1.E+03	1.E+04	–	2.E+11	2.E+12
R4_1	R4_1	Jaehee Kim et al. (2021)	Purchased	2	PS	Sphere	<i>Moina macrocopa</i>	0.1.0E–03,1.0E–02,1.0E–01,1.0E+00,1.0E+01,5.0E+01,1.0E+02,5.0E+02	–	14d	mortality	–	1.E–02	1.E–01	–	2.E+06	2.E+07
R4_7	R4_36e	Rodríguez-Torres R et al. (2020)	Purchased	13.9~30.3	PE	Sphere	<i>Calanus finmarchicus</i>	–	0.2.0E+05,2.0E+07	6d	mortality	>	9.E+01	9.E+01	>	2.E+07	2.E+07
R4_7	R4_36f	Rodríguez-Torres R et al. (2020)	Purchased	13.9~30.3	PE	Sphere	<i>Calanus glacialis</i>	–	0.2.0E+05,2.0E+07	6d	mortality	>	9.E+01	9.E+01	>	2.E+07	2.E+07
R4_7	R4_36g	Rodríguez-Torres R et al. (2020)	Purchased	13.9~30.3	PE	Sphere	<i>Calanus hyperboreus</i>	–	0.2.0E+05,2.0E+07	6d	mortality	>	9.E+01	9.E+01	>	2.E+07	2.E+07

Note 1: For the source documents of each test data, see the Annex List of peer-reviewed publications.

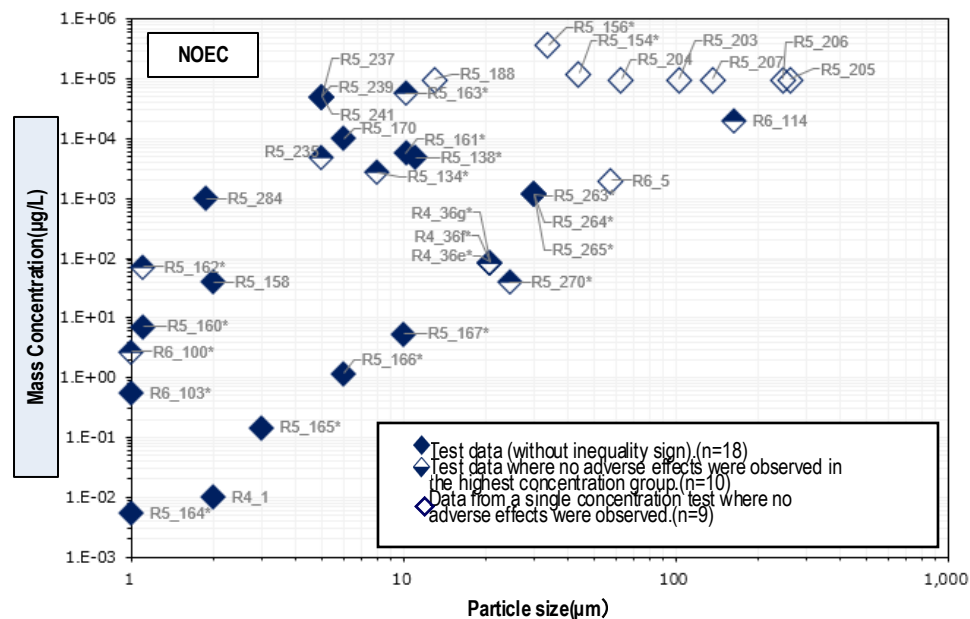
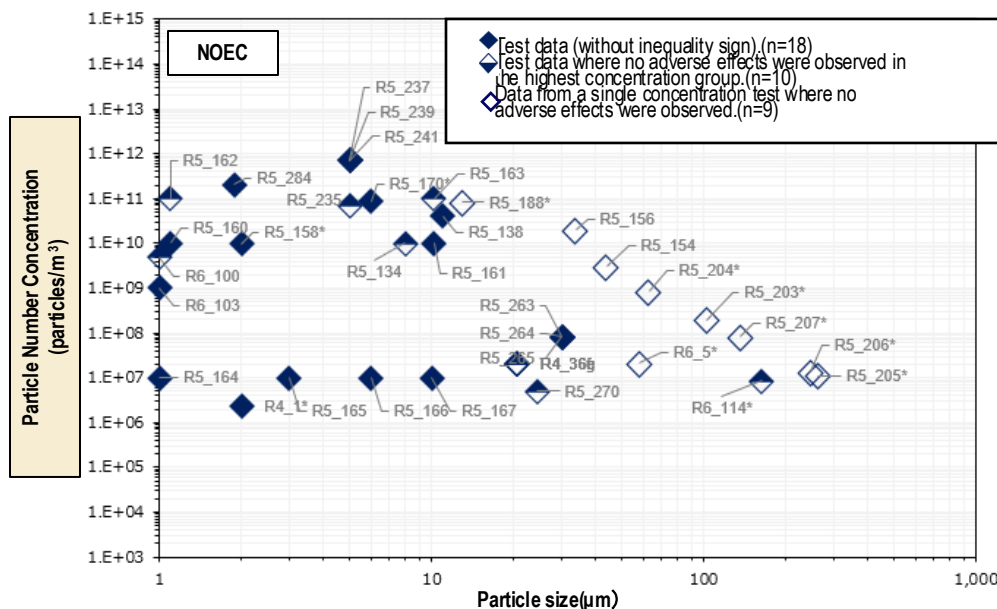
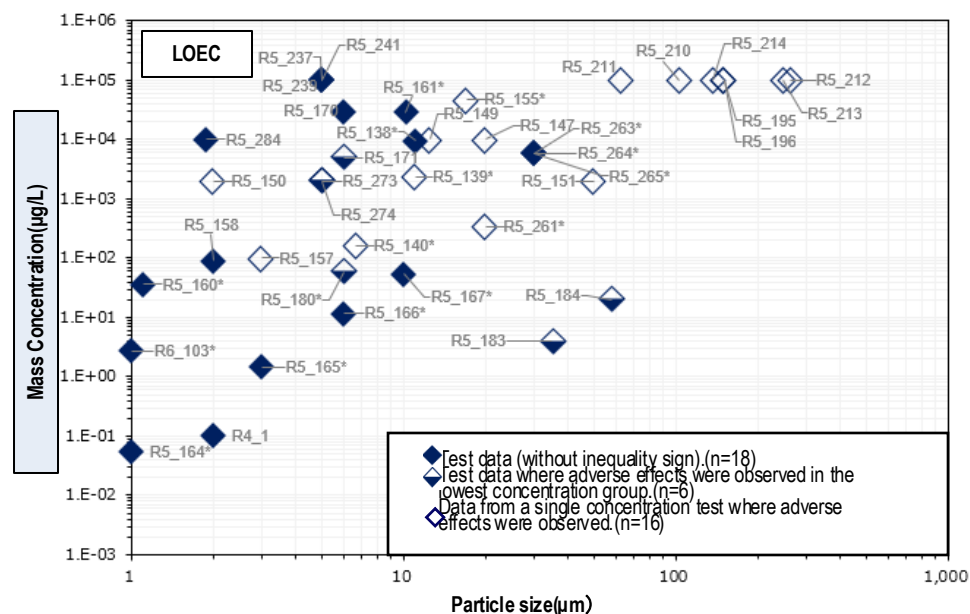
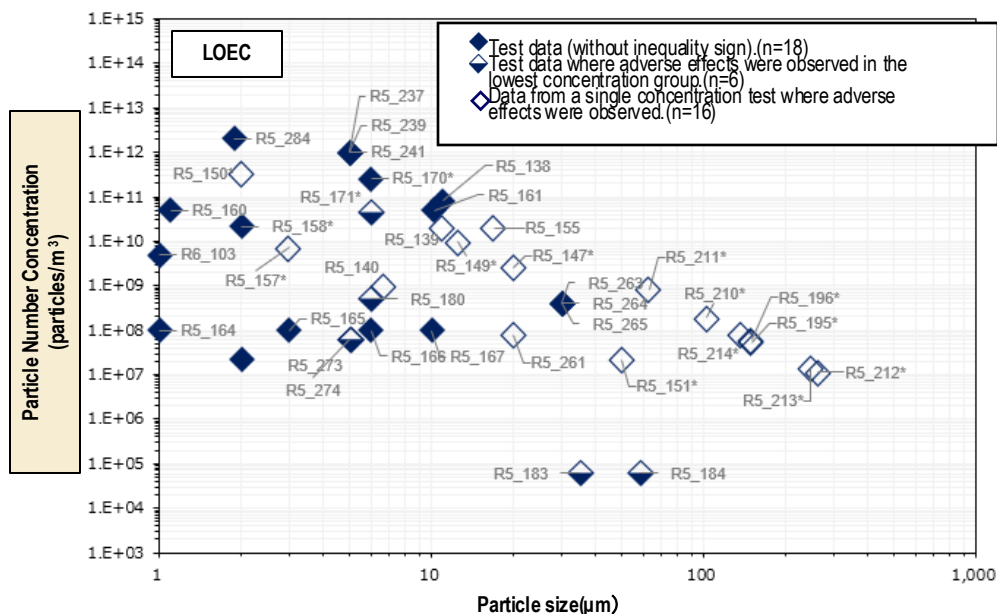
Note 2: In cases where the literature only provides values for number or weight, shape is spherical, density is the density of the material (PE: 0.92, PET: 1.38, PP: 0.9, PS: 1.04, PVC 1.4, others: 1), and particle size is the average of the upper and lower limits, and both are converted (converted values are in italics).

Note 3: If a significant effect was observed in the lowest concentration group, an inequality sign "<" is used, and if no significant effect was observed in the highest concentration group, an inequality sign ">" is used.

Collecting and Reviewing Literature

(5) Test data of quality level “S”(crustacea)

- The plot of N(L)OEC presented on the previous pages, with concentrations on the vertical axis and particle size on the horizontal axis, are shown below.



*The numbers in the plots correspond to record number of test data. For an overview of each data, see the overview of the test data on the previous pages.

Collecting and Reviewing Literature

(5) Test data of quality level “S” (bivalves)



Literature Information			Experimental design								Results						
Literature No.	Record No.	Author(s)	Source of MicP	Particle size (μm)	Polymer type	Particle shape	Test organism	Nominal concentration		Exposure time	Endpoints	Mass concentration (μg/L)			Particle number concentration (particles/m ³)		
								Mass concentration (μg/L)	Particle number concentration (particles/m3)			Inequality Sign	NOEC	LOEC	Inequality Sign	NOEC	LOEC
R6_P-3759	R6_150	Abidli S et al. (2023)	Purchased	40~48	PE	NA	<i>Ruditapes decussatus</i>	0,1.0E+01,1.0E+02,1.0E+03	–	14d	body weight	–	1.E+01	1.E+02	–	2.E+05	2.E+06

Note 1:For the source documents of each test data, see the Annex List of peer-reviewed publications.

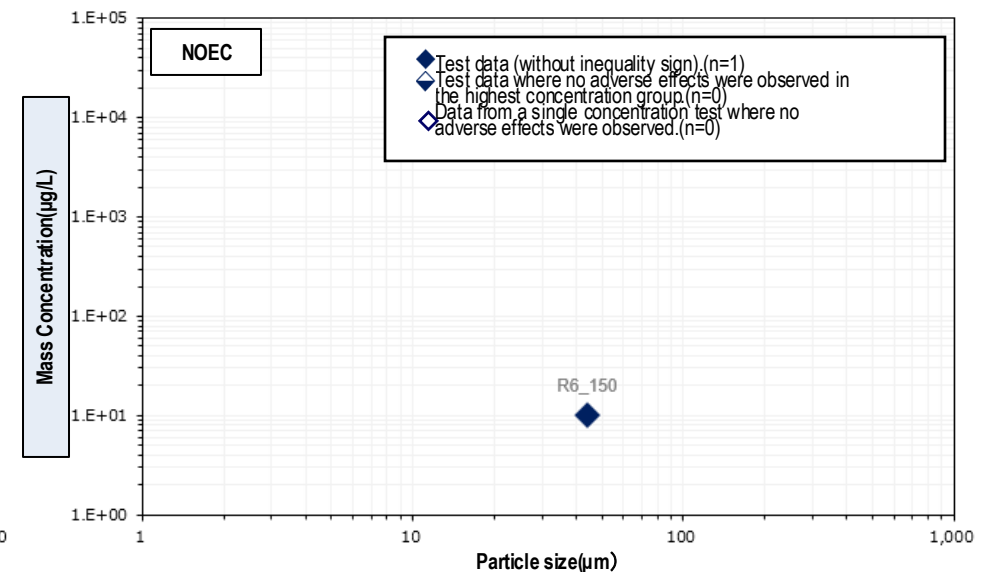
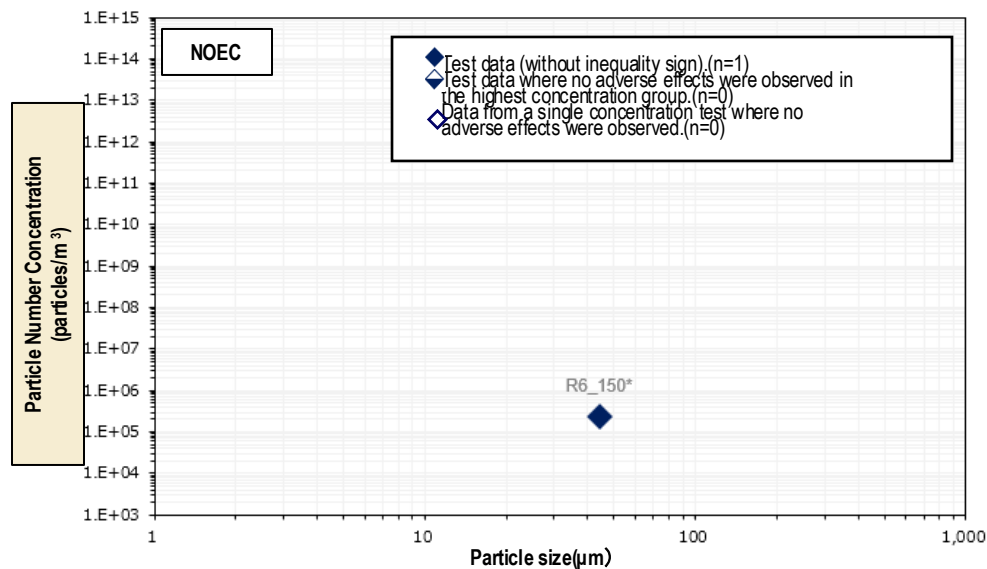
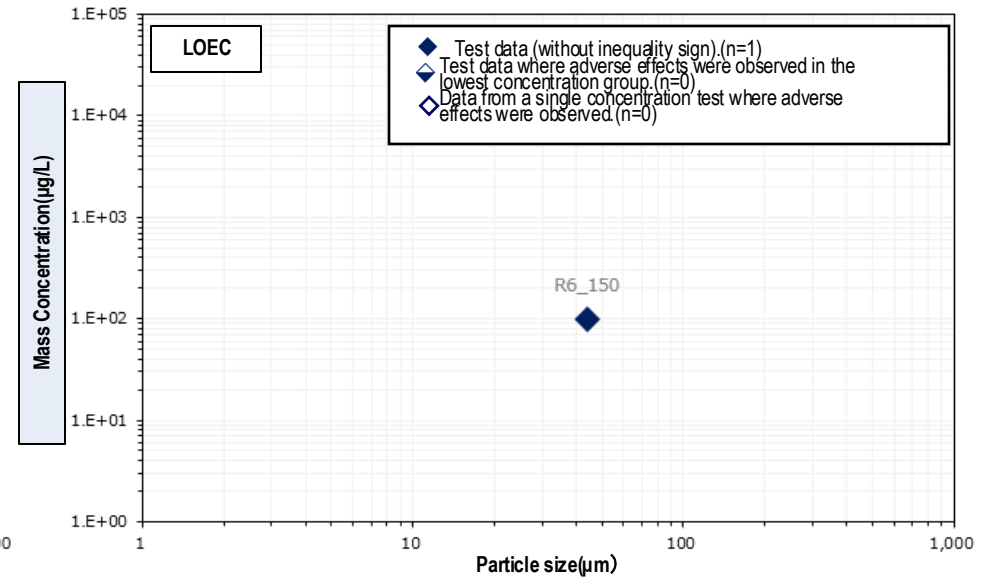
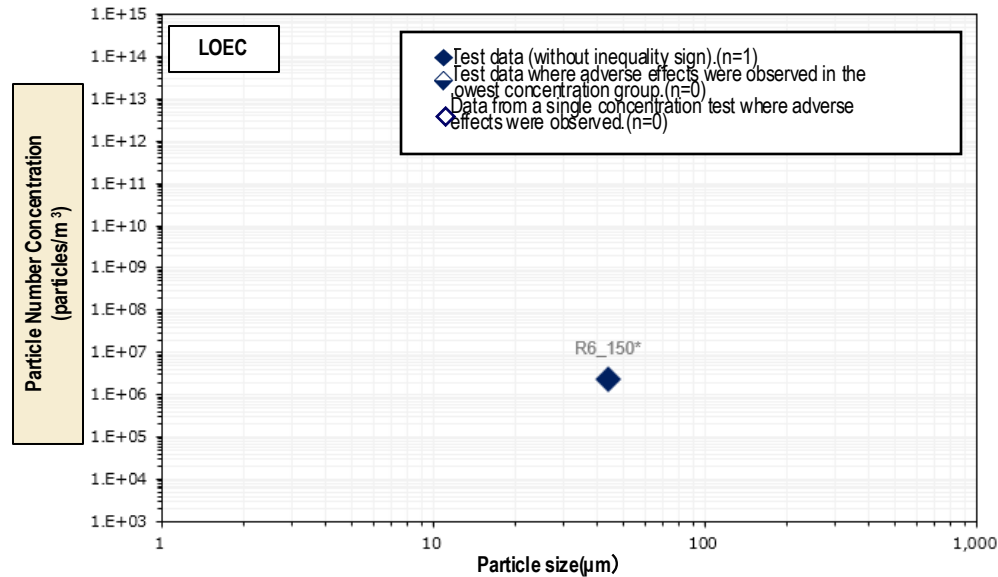
Note 2: In cases where the literature only provides values for number or weight, shape is spherical, density is the density of the material (PE: 0.92, PET: 1.38, PP: 0.9, PS: 1.04, PVC 1.4, others: 1), and particle size is the average of the upper and lower limits, and both are converted (converted values are in italics).

Note 3: If a significant effect was observed in the lowest concentration group, an inequality sign "<" is used, and if no significant effect was observed in the highest concentration group, an inequality sign ">" is used.

Collecting and Reviewing Literature

(5) Test data of quality level “S” (bivalves)

- The plot of N(L)OEC presented on the previous page, with concentrations on the vertical axis and particle size on the horizontal axis, are shown below.



*The numbers in the plots correspond to record number of effect data. For an overview of each data, see the overview of the effect data on the previous page.

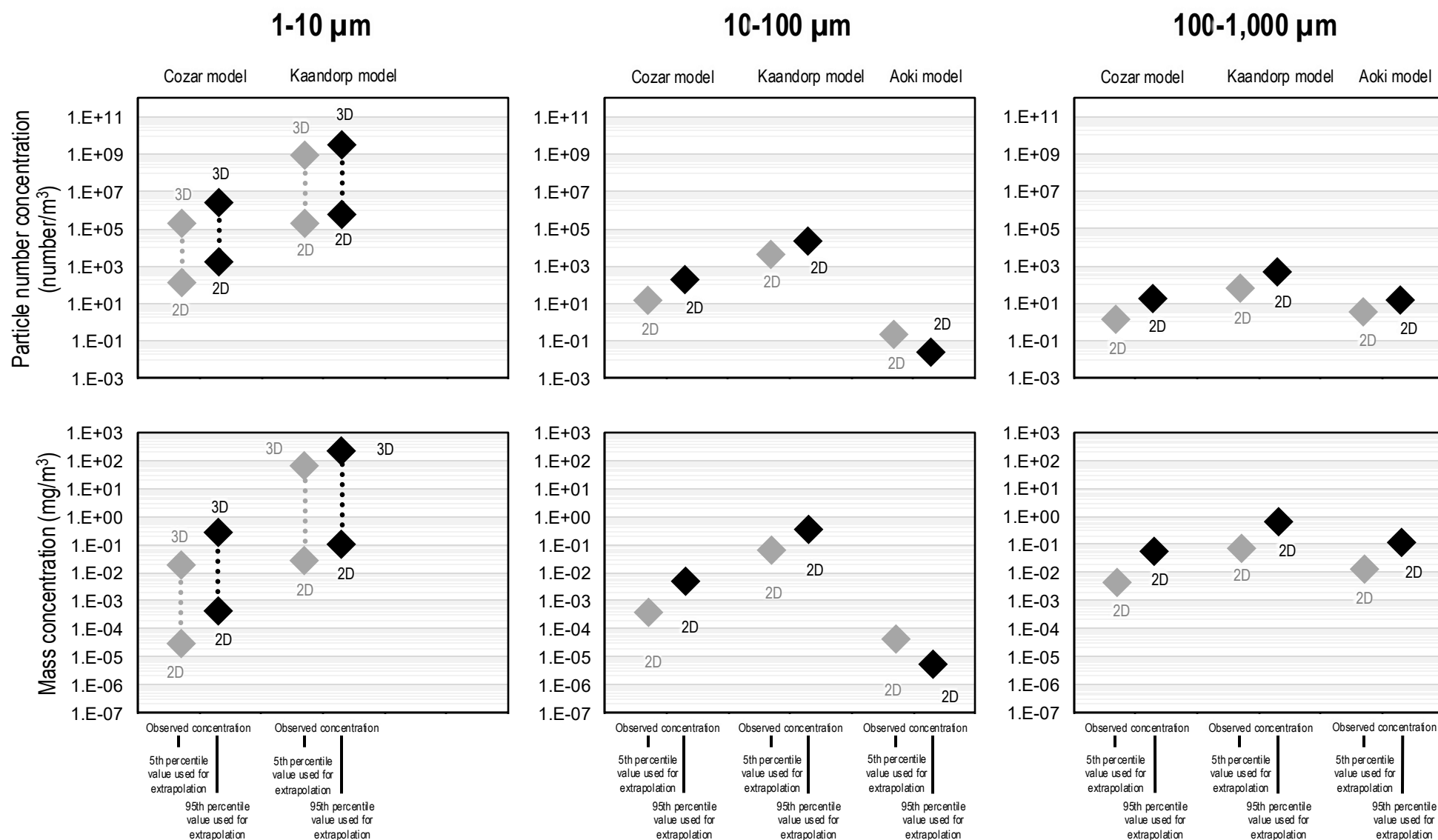
Current Issues and Directions for Future Study (Draft)

Current issues	Directions for future study (draft) (*Items possibly discussed in the committees in coming years)
<p>(1) There is a small number sets of test data that can be used for hazard assessments</p> <ul style="list-style-type: none"> ➤ While the number of research examples so far has increased, the number of sets of data that contribute to hazard assessments is low. ➤ Lack of funds, facilities and personnel needed for experiments (e.g., some of the chronic effects experiments for fish are recommended to be performed in running water, so they will require specialized facilities, which would also cost a lot. It would be impractical to run these at university laboratories) ➤ Discrepancies between the research aims of researchers and government needs 	<p>(1) Continuous collection of test data and research experiments by administration</p> <ul style="list-style-type: none"> ➤ <u>Further storing test data (continuing literature review) and analyzing and investigating reviewed test data</u> [*] ➤ Providing information from the government to research institutions, experimental facilities and international bodies, requesting cooperation or ordering ➤ <u>Identification of policy needs</u> [*]
<p>(2) Biases in the quality levels of test data</p> <ul style="list-style-type: none"> ➤ The quality levels of data varies by experiment, because there is no standardized experimentation methods, including adequate validation method. 	<p>(2) Standardizing test data and discriminating quality levels</p> <ul style="list-style-type: none"> ➤ Establishing a standard experimentation method ➤ <u>Experiments not using a standard experimentation method should continue to be (not excluded but) assessed its quality using the rules pertaining to review of test data. In parallel to this, it is also necessary to update the rules pertaining to review of test data as appropriate.</u> [*]
<p>(3) Discrepancies in toxicity experiment conditions and exposure conditions in the actual environment</p> <ul style="list-style-type: none"> ➤ Many toxicity experiments use spherical polystyrene, but not only do various shapes and materials exist in the actual environment, but there are also cases where they have absorbed chemical substances. ➤ Since the concentration of substances in the actual environment is not consistent, there are locations where localized high concentrations exist (discrete sources on coasts or sediments, etc.) ➤ Interim target of this review is limited to the effects of particles suspended in water only. But exposure paths are varied in the actual environment (sediments, etc.) 	<p>(2) Investigating matters that should be taken into account when applying test data to the actual environment</p> <ul style="list-style-type: none"> ➤ <u>Collating and organizing test data that handles vector effects with chemical substances</u> [*] Comparisons of the shape and materials of MicP used in toxicity experiments with MicP in the actual environment, and comparisons of experimental conditions with conditions in the actual environment (changes in concentration, etc.) Developing experimental methods with environments close to actual environments or investigating conversion methods for applying them to actual environments. ➤ <u>While prioritizing knowledge that captures chronic effects in principle, also organizing knowledge that captures acute effects as needed for reference.</u> [*] ➤ <u>In addition to test data in water, data for exposure via the sediment route is necessary</u> [*]

Summary of Results

Particle Number Concentration and Mass Concentration Estimates in the Marine Surface Layer (Per 1-10 μ m, 10-100 μ m, 100-1,000 μ m Segments)

- Particle number concentration and mass concentration estimates in the marine surface layer are as follows.
- Please be sure to refer to the current understanding on P57 and the key considerations pertaining to comparisons on P65 when interpreting the chart.



Current Understanding in Exposure Assessment

■ Estimates of particle number concentrations in the marine surface layer

- Estimates of particle number concentrations in the marine surface layer are calculated from values obtained by fitting particle number concentrations of MicP (adjusted) in the marine surface layer to the model formula curves using MOE measurement data in FY2021 survey projects (89 locations off the coast of Japan), then by extrapolating to fine particle sizes. Differences in estimate values from differing models are large, and the finer the particle sizes are, the greater the uncertainty in the estimates. The 5th and 95th percentile values indicate variance in particle number concentrations among MOE measurement sites.
- MicP in the marine surface layer can move in or out of the system through transfer to sediments and air (aggregation, settling, dispersion) or inflow from rivers and air. However, the Cozar model and the Kaandorp model used for estimations **assume a closed system on the marine surface layer (that fragmented MicP remain on the surface layer) as a prerequisite for their estimations.**
- Still, MicP on the marine surface layer may settle due to the influence of attached organisms and other factors, so **especially for smaller particle sizes, actual particle number concentrations on the marine surface layer are likely to be lower than estimated.** Since the Cozar model and the Kaandorp model also assume that volume and surface area are conserved, particle number concentration increases monotonically as particle size decreases. However, due to the physical limitations on fragmentation in the environment, it is unlikely that particle number concentrations increase monotonically at single- and double-digit μm range. **As such, it is possible that the estimate results are close to the maximum limit or even overestimated.**
- In terms of fragmentation shape, many marine MicP are flake- or sheet-shaped. The most common process (2D fragmentation) is for thin sheets to break apart, with 3D fragmentation occurring as the aspect ratio approaches 1. Particle sizes at the boundary between two-dimensional and three-dimensional fragmentation are being examined by current research. **Based on the determination of experts in the subcommittees, this study assumed that two-dimensional fragmentation was most common for particle sizes of 10 μm and larger, with a progression into three-dimensional fragmentation for particle sizes of 10 μm and smaller. For that reason, in the graph on P56, a quadratic formula is used for particle sizes of 10 μm and larger, and the space between quadratic and cubic formulae is used for particle sizes of 10 μm and smaller.**
- In the Aoki model and the sugar lump model, fragmentation probability depends on particle size, and as particle size decreases, fragmentation is less likely to occur. This means there will be a peak at a certain particle size after which concentration will drop off for smaller parts. Future issues include verifying applicability by collecting more measurement data on fine particle sizes.
- In the Aoki model, as particle size decreases, particle number concentration also decreases and exceeds numeric limits, so the graph on P56 omits particle sizes in the range of 1 to 10 μm . In addition, in the sugar lump model, the fragmentation threshold particle size can be set freely. If peak particle size is unknown, fitting is difficult, so it was omitted from the graph on P56.

■ Conversion to mass concentration

- Since the Cozar model assumes that mass is conserved for each particle size, mass is expected to be fixed regardless of particle size. However, conversions using the empirical formulae (relational formulae between the major axis and projected area, and between the projected area and mass, derived from measurement data) found that total mass would vary by particle size if three-dimensional fragmentation (3D fragmentation) was assumed. This contradicts the assumption of mass conservation, so **it is thought unlikely to see three-dimensional fragmentation (3D fragmentation) alone in the actual environment.**
- Mass concentrations for particle sizes between 1-10 μm are outside the applicable range of the current empirical formulae, so it **must be noted that mass concentrations are overestimated.**

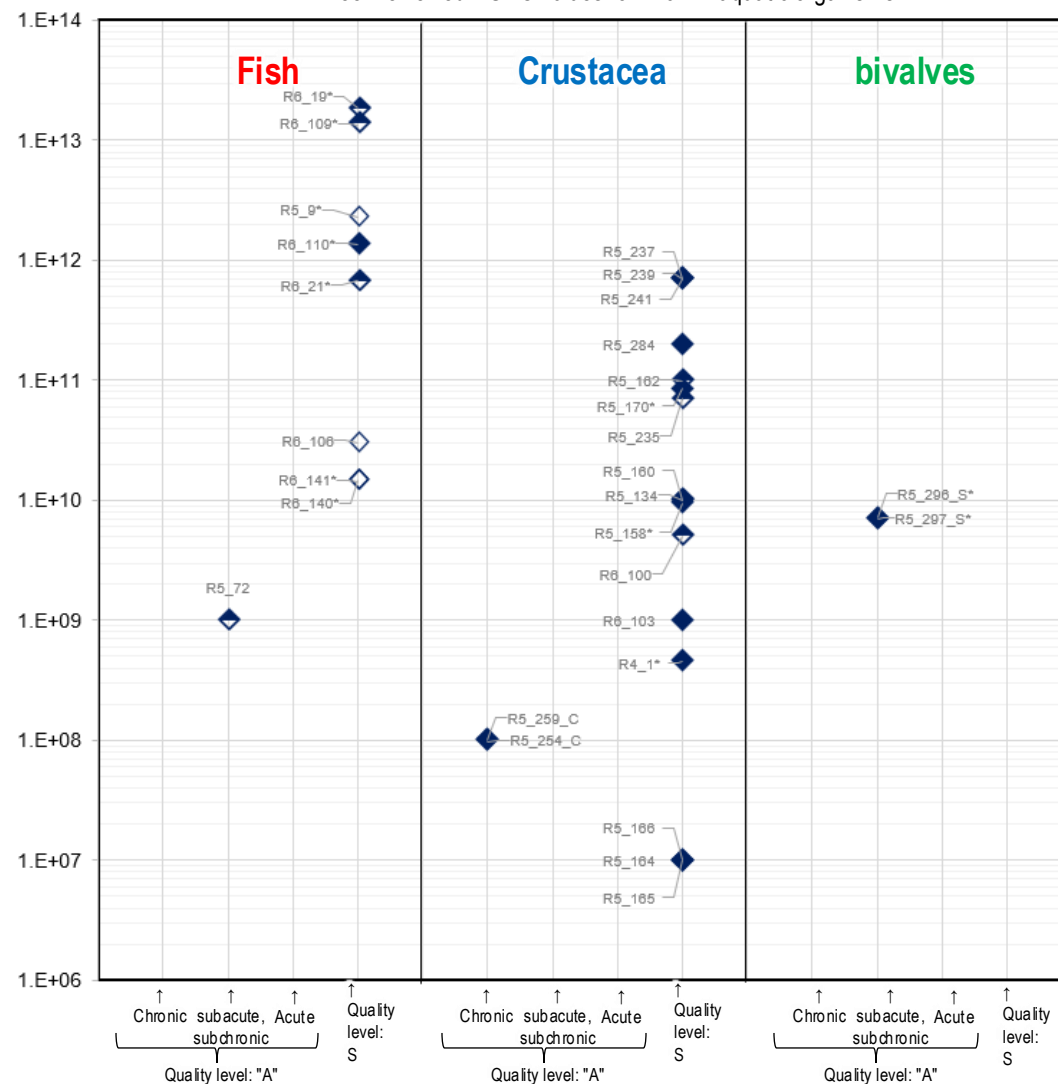
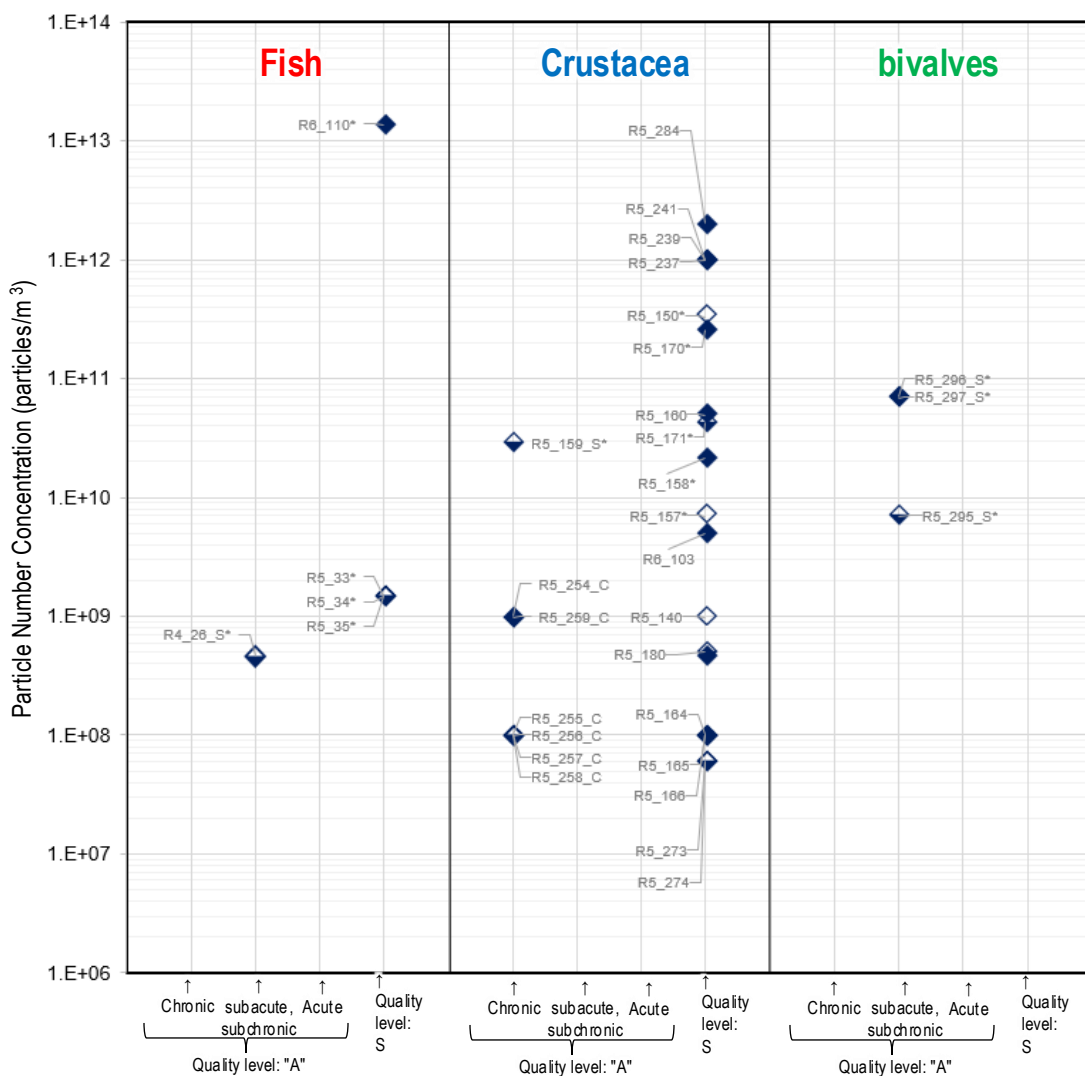
Summary of test data in the 1 - 10 µm range (particle number concentration)

- A summary of test data (particle number concentrations) for particle size range 1-10 µm is shown below.
- To understand the figure, also refer to "the notes on comparison" on pages 65.

[Legend]
 Left figure (LOEC):
 ◆ Test data (without inequality sign)
 ◆ Test data where adverse effects observed in the lowest concentration group (with inequality signs).
 ◆ Data from a single concentration test where adverse effects were observed.
 Right figure (NOEC):
 ◆ Test data (without inequality sign)
 ◆ Test data where no adverse effects were observed in the highest concentration group.
 ◆ Data from a single concentration test where no adverse effects were observed.
 Data labels are displayed as "year_record number." The "" at the end of the label indicates a conversion value provided by the secretariat, and "C/S" indicates chronic/subacute and subchronic, respectively.

Peer-reviewed LOEC values for MicP in aquatic organisms.

Peer-reviewed NOEC values for MicP in aquatic organisms.



Summary of effect data in the 10 ~100 µm range (particle number concentration)

- A summary of effect data (particle number concentrations) for particle size range 10~100 µm is shown below.
- To understand the figure, also refer to "the notes on comparison" on pages 65.

[Legend]

Left figure (LOEC):

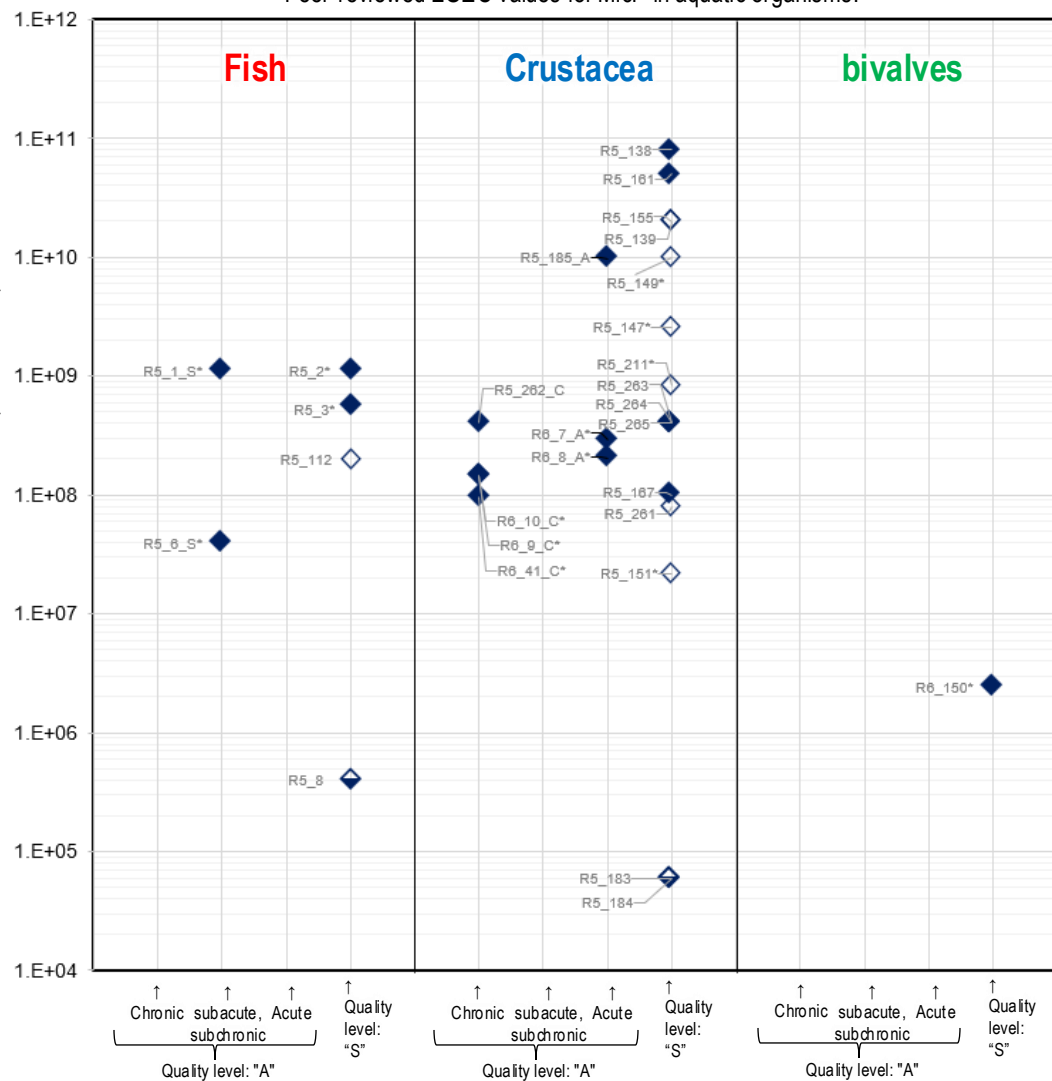
- ◆ Test data (without inequality sign)
- ◆ Test data where adverse effects observed in the lowest concentration group (with inequality signs).
- ◇ Data from a single concentration test where adverse effects were observed.

Right figure (NOEC):

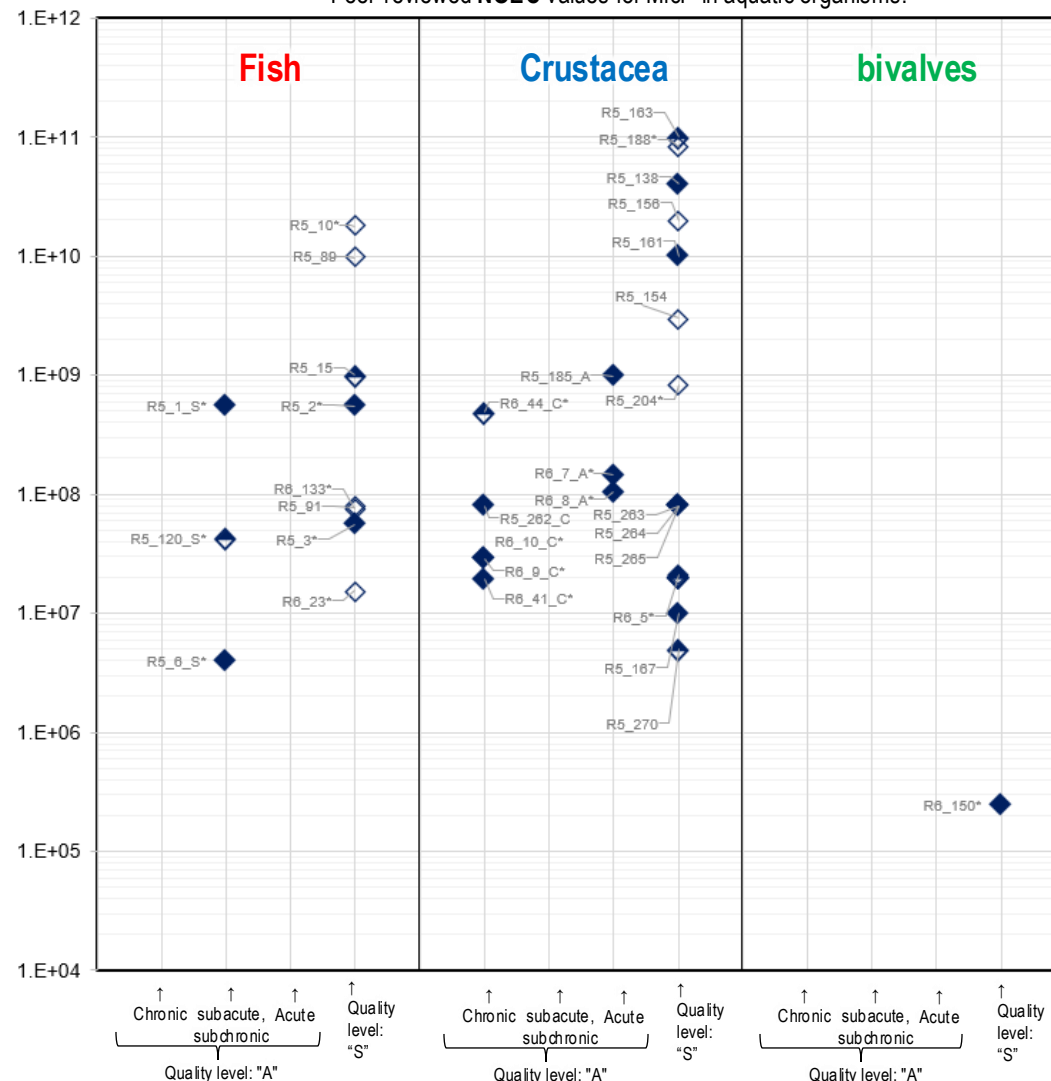
- ◆ Test data (without inequality sign)
- ◆ Test data where no adverse effects were observed in the highest concentration group.
- ◇ Data from a single concentration test where no adverse effects were observed.

Data labels are displayed as "year_record number." The "*" at the end of the label indicates a conversion value provided by the secretariat, and "C/S" indicates chronic/subacute and subchronic, respectively.

Peer-reviewed LOEC values for MicP in aquatic organisms.



Peer-reviewed NOEC values for MicP in aquatic organisms.



Summary of effect data in the 100 ~1,000 μm range (particle number concentration)

- A summary of effect data (particle number concentrations) for particle size range 100~1,000 μm is shown below.
- To understand the figure, also refer to "the notes on comparison" on pages 65.

[Legend]

Left figure (LOEC):

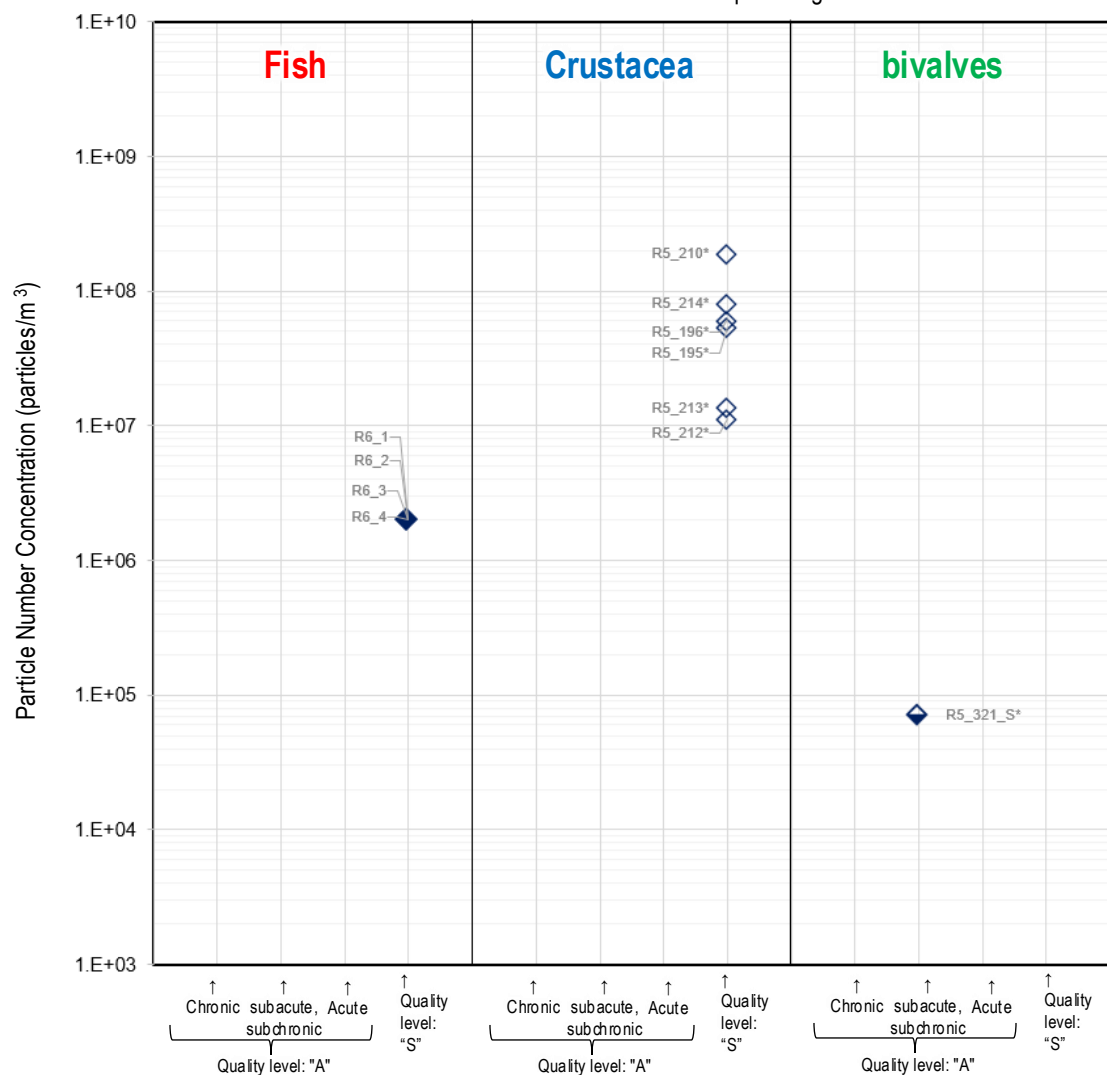
- ◆ Test data (without inequality sign)
- ◆ Test data where adverse effects observed in the lowest concentration
- ◇ group (with inequality signs).
- ◇ Data from a single concentration test where adverse effects were observed.

Right figure (NOEC):

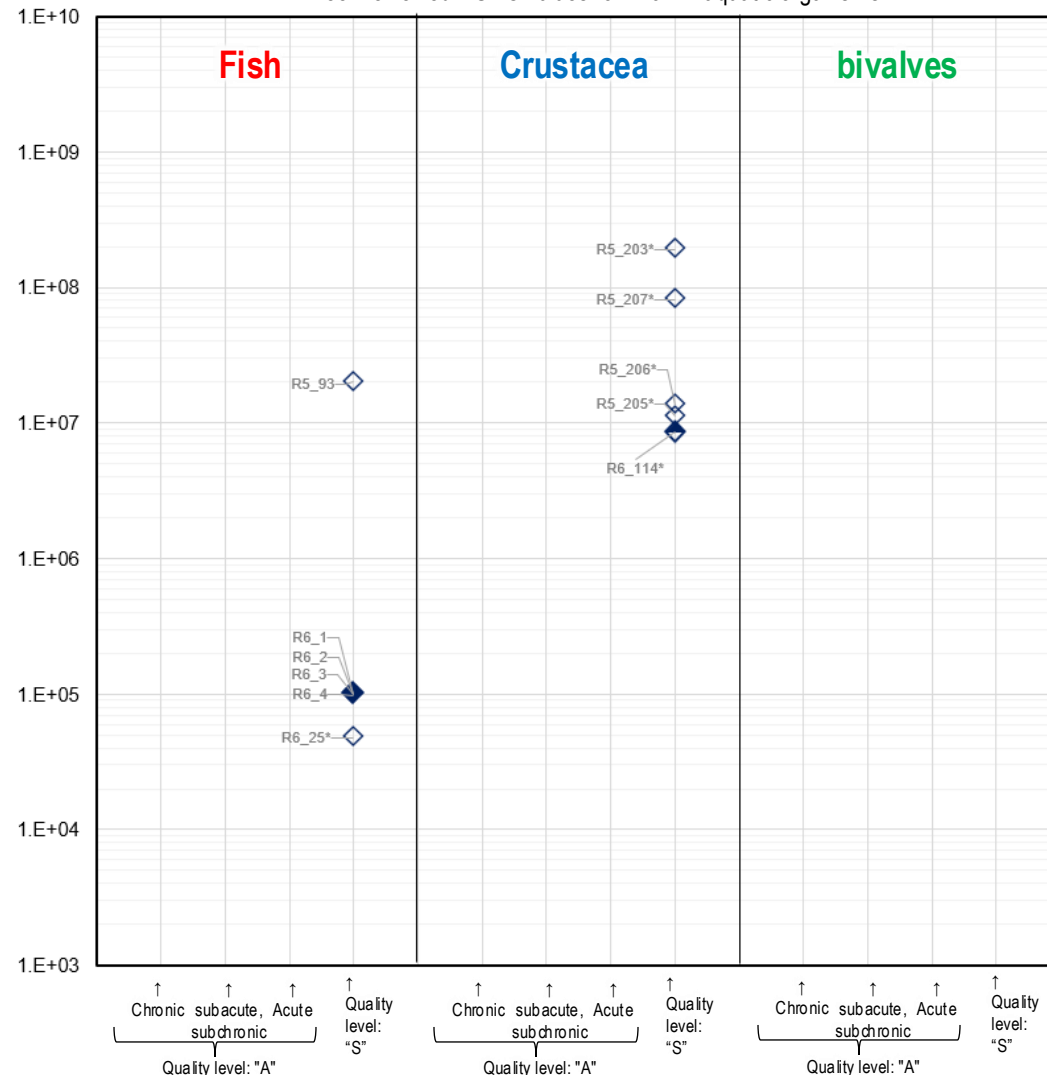
- ◆ Test data (without inequality sign)
- ◆ Test data where no adverse effects were observed in the highest concentration group.
- ◇ Data from a single concentration test where no adverse effects were observed.

Data labels are displayed as "year_record number." The "*" at the end of the label indicates a conversion value provided by the secretariat, and "C/S" indicates chronic/subacute and subchronic, respectively.

Peer-reviewed LOEC values for MicP in aquatic organisms.



Peer-reviewed NOEC values for MicP in aquatic organisms.



Summary of effect data in the 1 ~10 µm range (Mass Concentration)

- A summary of effect data (mass concentrations) for particle size range 1~10 µm is shown below.
- To understand the figure, also refer to "the notes on comparison" on pages 65.

[Legend]

Left figure (LOEC):

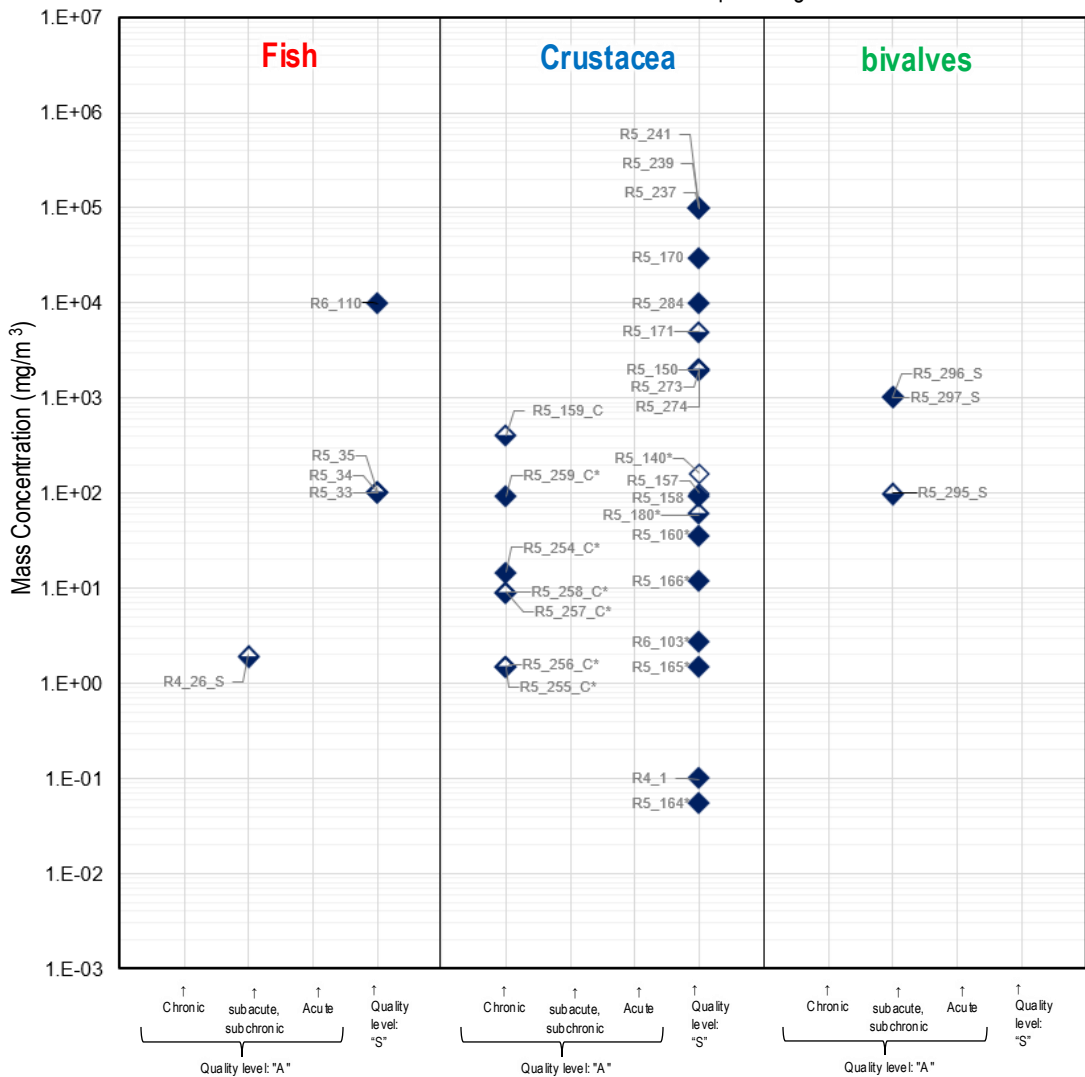
- ◆ Test data (without inequality sign)
- ◆ Test data where adverse effects observed in the lowest concentration group (with inequality signs).
- ◇ Data from a single concentration test where adverse effects were observed.

Right figure (NOEC):

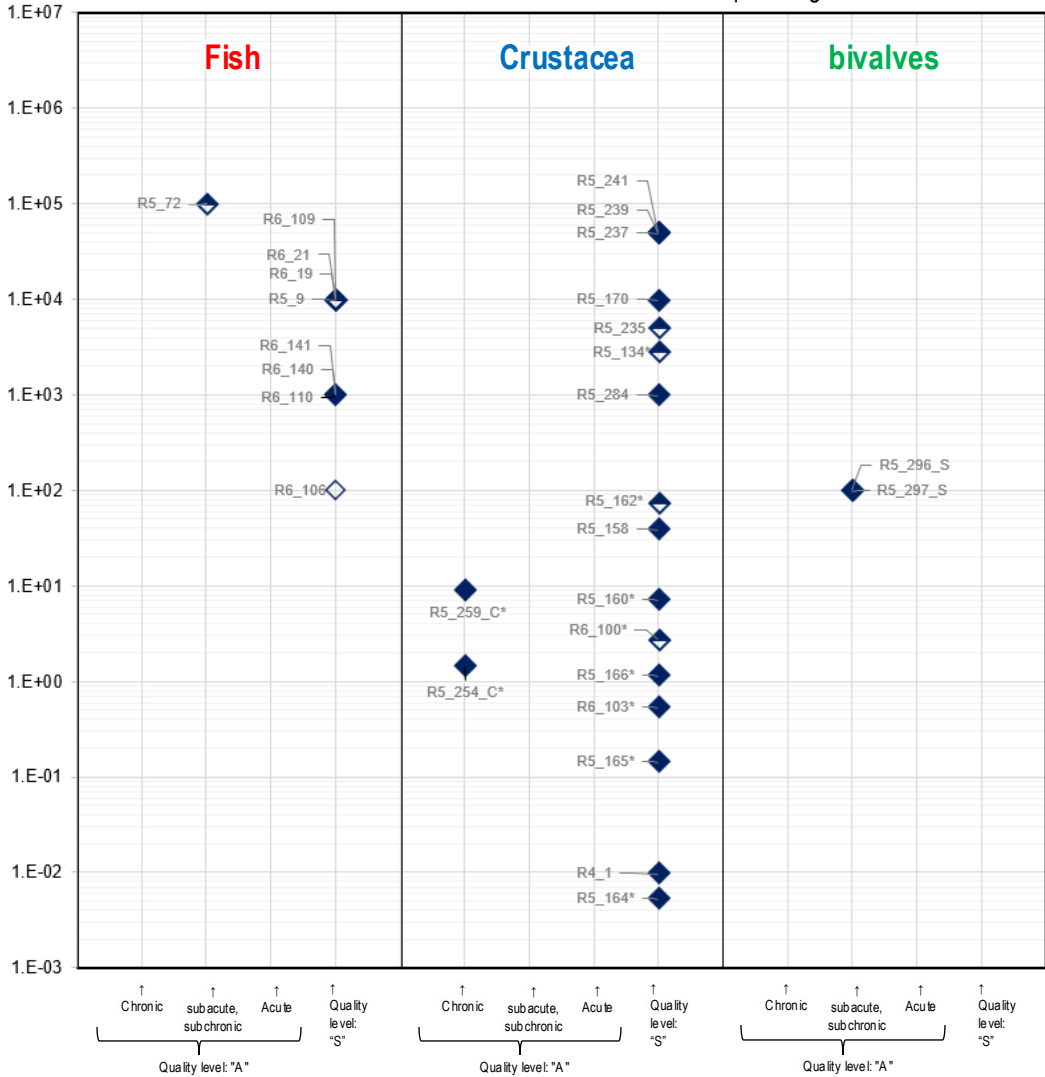
- ◆ Test data (without inequality sign)
- ◆ Test data where no adverse effects were observed in the highest concentration group.
- ◇ Data from a single concentration test where no adverse effects were observed.

Data labels are displayed as "year_record number." The "*" at the end of the label indicates a conversion value provided by the secretariat, and "C/S" indicates chronic/subacute and subchronic, respectively.

Peer-reviewed LOEC values for MicP in aquatic organisms.

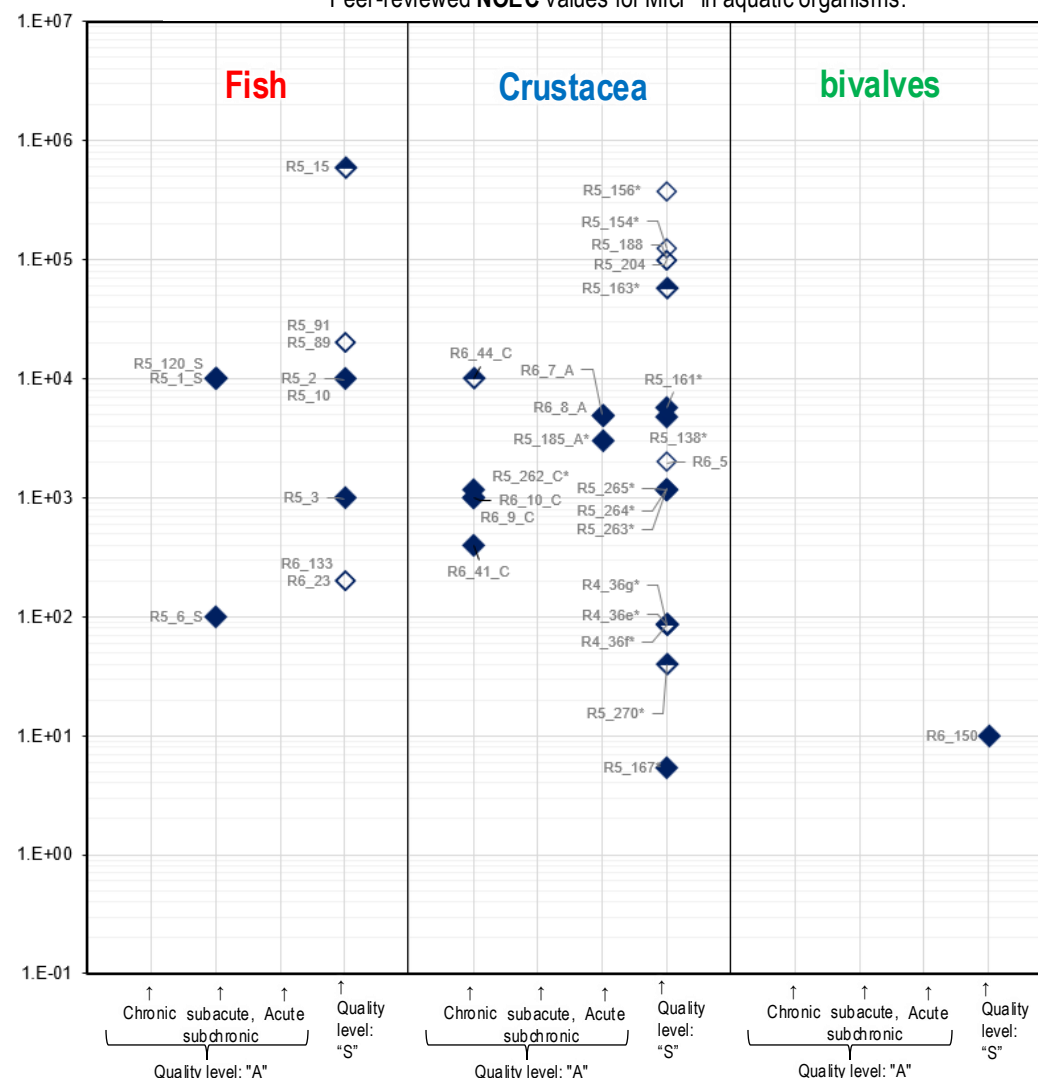
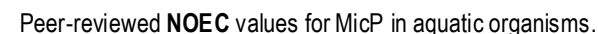


Peer-reviewed NOEC values for MicP in aquatic organisms.



- A summary of effect data (mass concentrations) for particle size range 10~100 µm is shown below.
- To understand the figure, also refer to "the notes on comparison" on pages 65.

- [Legend]
- Left figure (LOEC):
- ◆ Test data (without inequality sign)
 - ◆ Test data where adverse effects observed in the lowest concentration group (with inequality signs).
 - ◇ Data from a single concentration test where adverse effects were observed.
- Right figure (NOEC):
- ◆ Test data (without inequality sign)
 - ◆ Test data where no adverse effects were observed in the highest concentration group.
 - ◇ Data from a single concentration test where no adverse effects were observed.

Peer-reviewed **LOEC** values for MicP in aquatic organisms.

Summary of effect data in the 100 ~1000 μm range (Mass Concentration)

- A summary of effect data (mass concentrations) for particle size range 100~1000 μm is shown below.
- To understand the figure, also refer to "the notes on comparison" on pages 65.

[Legend]

Left figure (LOEC):

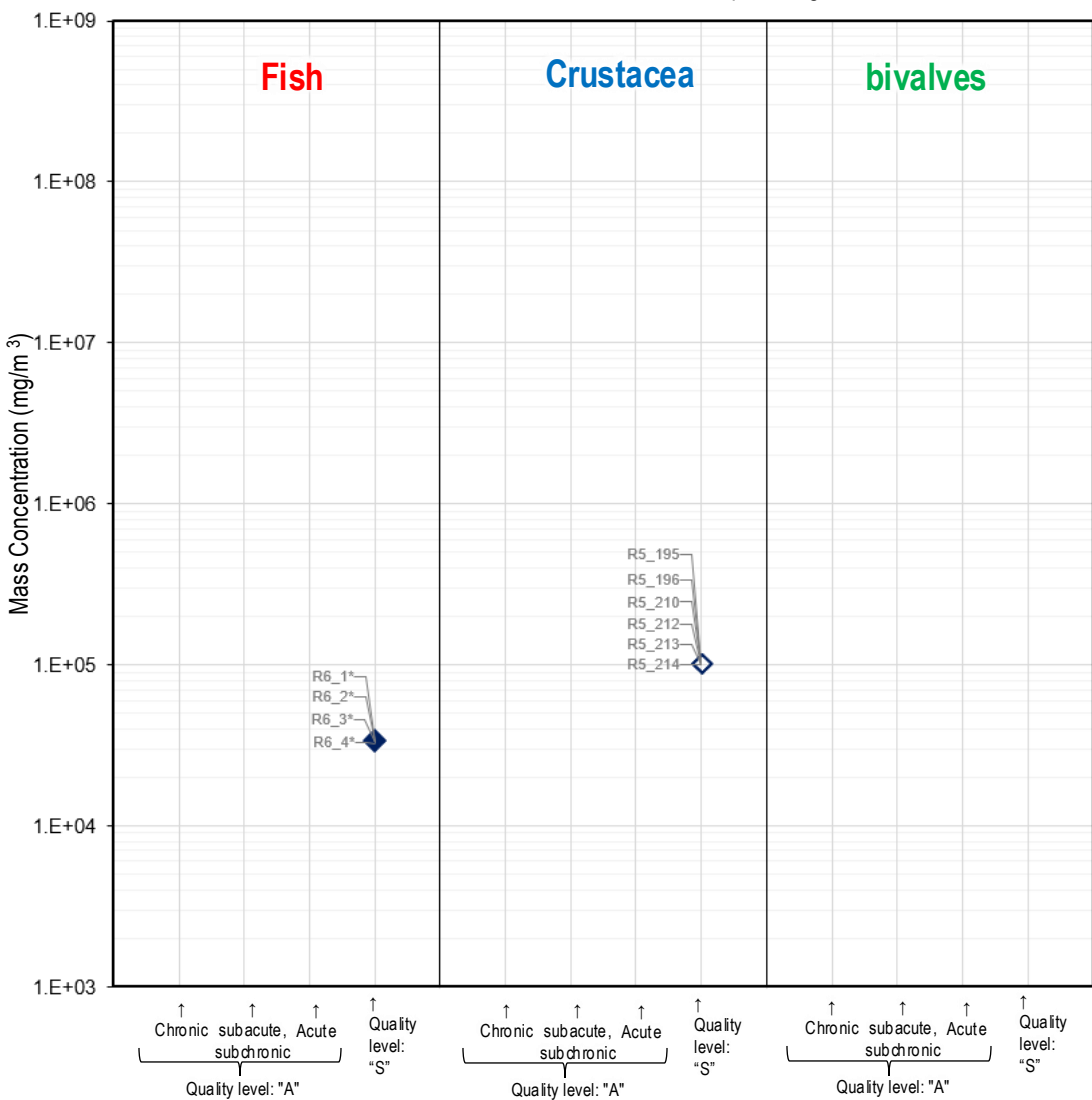
- ◆ Test data (without inequality sign)
- ◆ Test data where adverse effects observed in the lowest concentration group (with inequality signs).
- ◇ Data from a single concentration test where adverse effects were observed.

Right figure (NOEC):

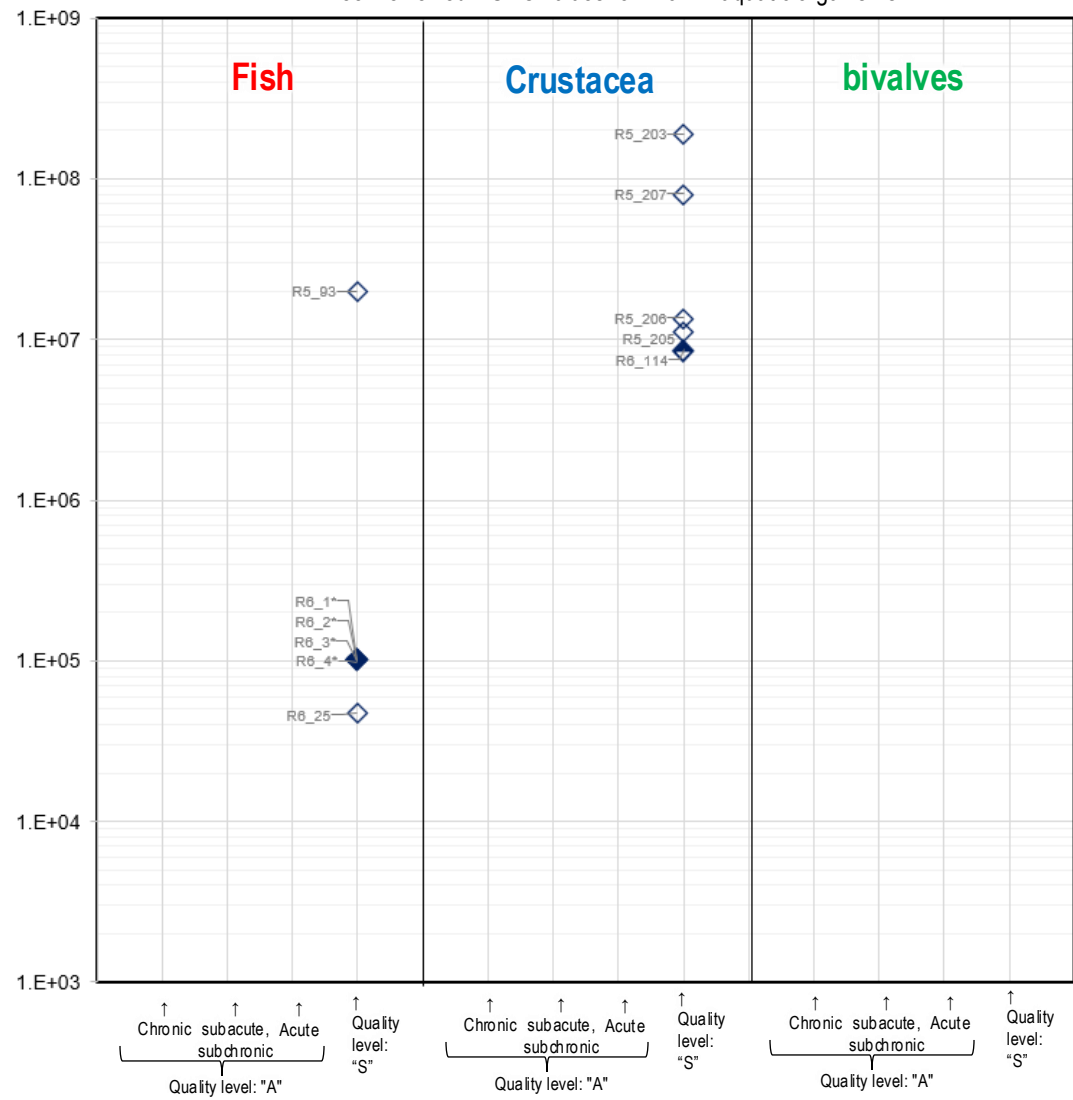
- ◆ Test data (without inequality sign)
- ◆ Test data where no adverse effects were observed in the highest concentration group.
- ◇ Data from a single concentration test where no adverse effects were observed.

Data labels are displayed as "year_record number." The "***" at the end of the label indicates a conversion value provided by the secretariat, and "C/S" indicates chronic/subacute and subchronic, respectively.

Peer-reviewed LOEC values for MicP in aquatic organisms.

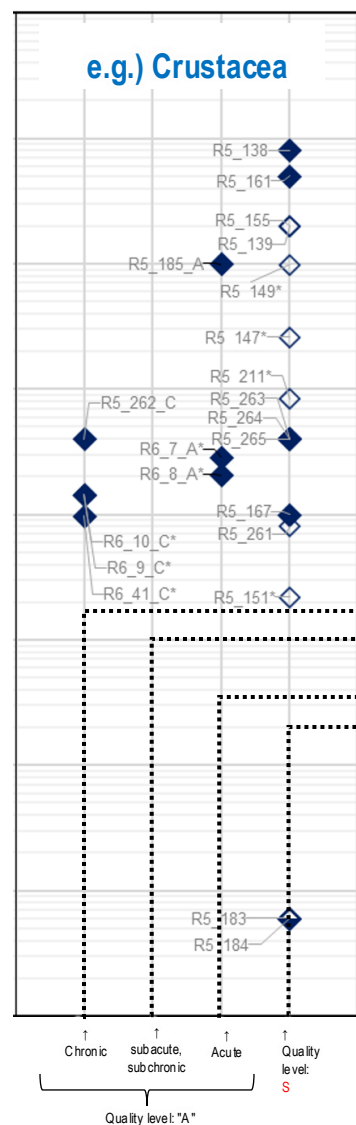


Peer-reviewed NOEC values for MicP in aquatic organisms.



Summary of Hazards (Addendum: Breakdown of test data presented)

- The breakdown of the test data, which are quality level "A" (chronic, subacute/subchronic, acute) and quality level "S", presented in the summary of test data on page 58~63 are as follows:



Breakdown of peer-reviewed test data from FY 2022 to FY 2025 (Reprinted, partially altered)

	Not difficult to adopt		Subject to work for discriminating quality levels (Experiments that are not difficult to adopt and performed at multiple concentrations)		Candidate of "High" (Lists observation/dispersal procedures or complies with OECD TG)		Quality level: "A"			Quality level: "S", which is equal to "Not difficult to adopt" minus "Quality level: A"		
	literature	Record (a)	literature	Records	literature	Records	literature	Record (b1)	Percentage (b1/a)	literature	Record (b2)	Percentage (b2/a)
Fish	49	118	13	23	5	7	5	5 (Chronic 0, Subacute/subchronic 5, Acute 0)	4%	44	113	96%
Crustacea	43	97	26	60	11	29	6	15 (Chronic 12, Subacute/subchronic 0, Acute 3)	15%	37	82	85%
bivalves	16	57	4	9	2	4	2	4 (Chronic 0, Subacute/subchronic 4, Acute 0)	7%	14	53	53%
Total	108	272	43	92	18	40	13	24	9%	95	248	91%

Key Considerations Pertaining to Comparisons of Estimates of Environmental Concentrations and test data



- At this point, a direct comparison between estimated environmental concentrations (exposure data) and toxicity data has not been conducted. As previously mentioned, there are challenges in both exposure assessment and toxicity evaluation, and further consideration must be given to the points outlined below.
- Matters beyond these applicable scopes (fibrous MicP outside the scope of estimates, assessments of vector effects, etc.) are issues for future study. Further investigation is needed.

■ for the Comparison of Exposure and Hazard Assessments

- Exposure assessments: Concentrations are estimated based not on measurement data from the actual environment but on measurement data from the marine surface layer off the coast of Japan. It is necessary to be aware of differences in assumed values and other assumptions across all models. The target for the estimates of this study was the marine surface layer, so it is also necessary to be sufficiently aware that other spots in the ocean such as water columns and sediments are out of scope.
- Hazard assessments: Out of approximately 670 peer-reviewed articles screened from a total of around 18,000 reports, 13 articles were classified as quality level “A”, indicating a limited number of test data available. Data on the chronic effects on fish and bivalves in particular remains limited, and there are biases in the quality of test data for reasons such as the lack of standard experimentation methods. These are organized by set concentrations, so there may be differences in actual exposure concentration in test systems (there may be inconsistencies due to settling, aggregation or variance in absorption). Regarding the effects of MicP on organisms and ecosystems, concerns have been raised over the effects of particles and chemical substances, but it is necessary to sufficiently understand that, in this study, the effects of particles mainly on aquatic organisms are the subject of study.

■ Discrepancies between the actual environment and the conditions of toxicity experiments

- Differences in particle characteristics:
 - Particle size: MicP with a wide distribution of particle sizes exist in the marine surface layer, but toxicity experiments, in principle, use a single particle size.
 - Form: Most MicP detected in the marine surface layer are fragmentary or fibrous, but those used in toxicity experiments are often spherical.
 - Materials: Relatively light MicP have been detected in the marine surface layer, but research fluorescent beads are often used in toxicity experiments, so materials differ to those in the actual environment.
 - Deterioration: It is likely that MicP in the actual environment deteriorate, but the degree of that is not consistent. The MicP used in toxicity experiments are often of a kind that is not made to deteriorate.
 - Chemical substances: It is possible that MicP absorb chemical substances in the water in the actual environment, but this study has, in principle, targeted the effects of particles in hazard assessments.
- Differences in concentration (consistency, etc.)
 - Actual environment: In the actual environment, there are a variety of concentration distributions across horizontal and vertical directions, and those concentrations vary with each passing moment. Localized high concentrations also occur at, for example, the lines where two currents meet or along coasts, so there hotspots may form.
 - Toxicity experiments: Depending on aggregation, settling or variance in absorption, it may not be possible to maintain the nominal concentration consistently.
- Differences in organisms
 - In exposure assessments, estimates are performed targeting the marine surface layer, but MicP toxicity experiments are often done using freshwater organisms such as fish and crustacea in particular.
 - At present, we have not been able to identify organism groups that survive in high exposure concentration environments, so there may be differences between test organisms and organisms that survive in high concentration areas.
 - The susceptibility to MicP of toxicity experiment test organisms and organisms exposed to MicP in the actual environment may differ based on their life-stages and feeding habits.