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Towards **ecological risk assessment of microplastics** for regulatory purposes

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E. Swart et al.

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Synopsis

Towards ecological risk assessment of microplastics for regulatory purposes

Microplastics can be found in the environment all over the world. An ‘ecological risk assessment’ can be used to examine the chance that microplastics are harmful to plants, animals and ecosystems. The first step is to determine what amounts result in harmful effects based on existing data. These amounts are then compared to the concentrations of microplastics in the environment.

Several obstacles need to be overcome to make this comparison possible. For example, there are many different kinds of microplastics, with different forms, sizes and types. Because of these different characteristics, different kinds of microplastics have different effects. Moreover, measuring microplastics is very difficult, and the microplastics often used in experiments to determine toxicity do not resemble those found in the environment. This currently makes it impossible to carry out an effective risk assessment, since it would be like comparing apples to oranges. Finally, the quality of the data is often poor.

The Koelmans method, developed by Wageningen University & Research, offers a solution for this. This method uses ways to assess the risks of the particle effects of microplastics better. A study by RIVM shows that experts in the Netherlands and abroad support the Koelmans method.

The RIVM also considers the method suitable for use in policy. This approach can be used to estimate the harmful effects of current microplastic pollution. Based on these estimates, the government can take policy measures to address microplastic pollution. For this reason, RIVM recommends first further investigating the extent of microplastic contamination in the Netherlands.

However, guidelines are needed on how microplastics in the environment should be measured and on how the toxicity and risks of microplastics should be determined. These guidelines are necessary in order to establish reliable risk limit values.

RIVM conducted this study at the request of the Ministry of Infrastructure and Water Management.

Keywords: microplastics, ecological risk assessment, framework, plastics

Publiekssamenvatting

Op weg naar een ecologische risicobeoordeling van microplastics voor beleidsdoeleinden

Microplastics zijn over de hele wereld te vinden in het milieu. Met een zogeheten ecologische risicobeoordeling is te onderzoeken hoe groot de kans is dat microplastics schadelijk zijn voor planten, dieren en ecosystemen. Hiervoor wordt eerst op basis van bestaande data bepaald bij welke hoeveelheden schadelijke effecten optreden. Deze hoeveelheden worden daarna vergeleken met de concentraties microplastics in het milieu.

Er zijn een aantal grote hindernissen voordat deze vergelijking kan worden gemaakt. Zo zijn er heel veel verschillende soorten microplastics, die verschillen in bijvoorbeeld vorm, grootte en type. Door deze verschillen in kenmerken kunnen verschillende soorten microplastics andere effecten hebben. Verder is het heel moeilijk om alle microplastics te meten. Ook lijken de microplastics die veel gebruikt worden in experimenten om de giftigheid te bepalen niet op de microplastics die in het milieu zitten. Een goede risicobeoordeling is daarom nu niet mogelijk want vergelijkt in feite appels en peren. Ten slotte is de kwaliteit van de data nog vaak niet goed.

De Koelmans-aanpak van de Wageningen Universiteit heeft hier een oplossing voor. De aanpak gebruikt manieren om het risico van de deeltjeseffecten van microplastics beter te kunnen beoordelen. Experts uit binnen- en buitenland steunen de Koelmans-aanpak, zo blijkt uit onderzoek van het RIVM.

Het RIVM vindt de methode ook geschikt om beleid te maken. Met de aanpak kan namelijk worden ingeschat wat de schadelijke effecten zijn van de vervuiling van microplastics die er nu is. Op basis daarvan kan de overheid beleidsmaatregelen nemen om vervuiling door microplastics tegen te gaan. Het RIVM adviseert daarom om eerst de omvang van microplasticsverontreiniging in Nederland verder te onderzoeken.

Wel zijn richtlijnen nodig over hoe microplastics in het milieu moeten worden gemeten en hoe de giftigheid en risico’s van microplastics moeten worden bepaald. Deze richtlijnen zijn nodig om betrouwbare risicogrenswaarden te bepalen.

Het RIVM deed dit onderzoek in opdracht van het ministerie van IenW.

Kernwoorden: Microplastics, Ecologische risicobeoordeling, raamwerk, plastics

Contents

Summary

Background

Microplastics are a global environmental pollutant. Science is clear that at certain concentrations, microplastics have adverse effects on organisms. A key question that still remains is whether ecosystems are at risk from exposure to microplastics at current or predicted (future) concentrations of microplastics.

The assessment of ecological risk presents major challenges. Challenges include, among others, that microplastics may induce different types of effects due to their physical properties, the chemical composition or biota associated with microplastics, that microplastics are very diverse in their characteristics (i.e. variability in size, shape, type, weathering states), that it is very difficult to measure all microplastics in a given sample, and that many effect studies use microplastics that differ from those found in the environment, resulting in a non-alignment of exposure and effect.

A framework for assessing the ecological risks relating to the particle effects of microplastics was proposed by Koelmans and colleagues (Koelmans et al., 2020). This approach provides a solution to the above challenges to ecological risk assessment of microplastics.

Scope, aims and methods

The primary focus of this report is on the *ecological risk assessment* of the *particle effects* of microplastics. However, the risks of plastic-associated chemicals and microbiological risks are discussed throughout the report.

This report evaluates the applicability of the Koelmans approach within the Dutch policy context, evaluates the support for this approach among the scientific community, and proposes a framework for regulatory action based on an ecological risk assessment of the particle effects of microplastics.

To achieve this, we conducted a literature review on ecological risk assessment approaches for microplastics, organised a workshop to identify the needs of Dutch policymakers, consulted scientific experts to evaluate the support for the Koelmans approach within the scientific community, and lastly, implemented the Koelmans approach in R software to gain understanding of the steps and mathematical formulas of the approach.

Policy needs

Among the participating policymakers from the Dutch Ministry of Infrastructure and Water Management, the importance of an ecological risk assessment of microplastics was broadly recognised. The specific relevance varied across participants and included, among others, the identification of hotspots of microplastic pollution, building support for policies that tackle microplastic pollution, setting of environmental quality standards, and encouraging Safe-and-Sustainable-by-Design plastics. Policymakers emphasised it is important that insights derived from microplastic risk assessments provide perspectives for policy actions.

The Koelmans approach

The Koelmans approach can be described in three main steps. The first step involves determining the ecologically relevant metric(s) representing the concentration of microplastics that organisms are exposed to, for example, particle volume or surface area. Ideally, the choice for this metric is supported by a theoretical linkage to (a) specific mechanism(s) of toxicity through which microplastics can have adverse effects, underpinned by quantitative data.

The next step is the exposure alignment. In monitoring campaigns, it is often not possible to measure the full range of microplastics. For example, smaller sizes often fall outside of the detection limits. The approach uses extrapolation based on fitting the best possible distribution of microplastic sizes across the environment (for example, a power law distribution) to consider the missing fraction as well.

The last step is the alignment of exposure and effect data. Microplastics used in effect studies often do not reflect the diversity of microplastics in the environment. This step recalculates the toxicity value by asking what the toxicity value would have been if the study had used an environmentally realistic polydisperse mixture of microplastics rather than, for example, monodisperse particles. This is based on the defined ecologically relevant metric and considers particle size, shape, and species-specific biological availability of microplastics.

Compared to other ecological risk assessments that have been conducted in the literature, the Koelmans approach stands out in its approach to exposure corrections and in its efforts to align exposure and effect data. Thus, the Koelmans approach represents the state of the art.

Use in retrospective and prospective risk assessment

Generally, the Koelmans approach is particularly suited to retrospective risk assessments of existing microplastic pollution. Its use requires specific expertise, which may potentially limit the current practical applicability and necessitates development of practical guidance.

For prospective risk assessments that use environmental quality standards, challenges arise from the diversity and variability of microplastics in size and shape distribution across environments. Implementation of the approach for this purpose requires defining default microplastic distributions. Existing studies provide a basis for such approaches, although further development is needed.

Methodological choices

In the project, the exposure-effect alignment of one application of the Koelmans approach was reproduced using R software. Analysis shows that choices regarding the setting of upper and lower size limits during the effect-exposure alignment may influence the final risk estimate, depending on the specific case. It is important to investigate the implications of these choices, for example, by conducting sensitivity analyses. Going forward, the use of the approach in policy-making requires standardisation and guidance to ensure that the approach is conducted in a robust and reproducible way.

Scientific support

The state-of-the-art character of the Koelmans approach, along with its novelty, and its ability to address current gaps in microplastic risk assessment, was widely recognised among the consulted scientific experts. There was broad support for an ecological risk assessment, such as the Koelmans approach, that focused exclusively on the particle effects of microplastics. However, experts emphasised the importance of clearly communicating the scope of a particle-based environmental risk assessment.

Experts agreed that ecological risk assessments of microplastics should ideally include both plastic-associated chemicals and particle effects. Nonetheless, they highlighted the importance of making progress by deriving (preliminary) risk estimates and cautioned against delaying risk assessment until the full complexity of microplastic pollution is understood.

Further studies on the mechanism of toxicity, particularly for terrestrial species, was identified as one of the most urgent priorities to support ecological risk assessment.

Framework for regulatory application

A framework for regulatory application of ecological risk assessment is presented, consisting of three steps. The first step involves assessing the general environmental status of an area (e.g. the Netherlands, or a specific region or location) by measuring the particle concentration and distributions in the compartment of interest.

The second step is the ecological risk assessment of microplastics based on the Koelmans approach. The approach can be applied to measured microplastic concentrations in the environment and can be applied at local scale or at larger (national) scale to assess the overall distribution of microplastic risks.

The final step involves taking measures on the basis of specific policy principles and risk probabilities. Various policy objectives may require tailored implementation of the risk assessment approach. For example, retrospective assessment may guide mitigation measures, while prospective assessments based on environmental quality standards can inform decisions regarding authorisation of emissions or the movement of soil or sludge materials. Each type of assessment has its own unique developmental needs.

A critical aspect of this framework is ensuring the quality and relevance of the data used. All components of the framework rely on the availability of data of sufficient quality to produce relevant and actionable results.

Further developmental work

We have identified various developmental needs regarding the ecological risk assessment of microplastics. The most important ones are:

- Improving the quantity and quality of effect data. In particular, more effect data on terrestrial species is needed.
- A knowledge gap regarding measured environmental concentrations of microplastics in the Netherlands should be filled.
- A better understanding of the impact of methodological choices on the outcome of the risk assessment is needed, for example, via a sensitivity analysis. This should help determine a minimum quality level for data.
- Test guidelines or guidance documents for effect studies, environmental analysis, and reporting of microplastics, as well as guidance for conducting ecological risk assessment should be developed.

Conclusions

We conclude that the Koelmans approach solves the main challenges for assessing ecological risks of microplastic particle effects. It can already be used for retrospective risk assessment of existing microplastic pollution. Its use for prospective risk assessment in the regulatory domain needs further developmental work. Guidance development will enhance usability and acceptance of the approach.

Furthermore, the RIVM emphasizes that this study focused on the particle effects of microplastics, and that policy should also take into account the broader environmental risks of plastics. For a more comprehensive understanding, it is also necessary to examine the chemical substances in (micro)plastics and their effects. However, these other effects need to be assessed separately.

Samenvatting

Achtergrond

Microplastics zijn wereldwijd aanwezig in het milieu. Uit wetenschappelijk onderzoek blijkt duidelijk dat microplastics bij bepaalde concentraties schadelijke effecten hebben op organismen. Een belangrijke vraag die nog beantwoord moet worden is of ecosystemen bij de huidige of toekomstige (voorspelde) concentraties van microplastics risico lopen door blootstelling aan microplastics.

De beoordeling van ecologische risico’s van microplastics is een grote uitdaging. Uitdagingen zijn onder andere dat microplastics verschillende soorten effecten kunnen veroorzaken door hun fysieke eigenschappen, chemische samenstelling of door organismen die aan microplastics gebonden zijn. Daarnaast zijn microplastics zeer divers in kenmerken (bijvoorbeeld variatie in grootte, vorm, type en mate van verwering). Het is bovendien erg moeilijk om alle microplastics in een specifiek monster te meten. Daarnaast gebruiken veel effectstudies microplastics die verschillen van die in de natuurlijke omgeving, wat leidt tot een discrepantie tussen blootstelling en effect.

Koelmans en collega's (Koelmans et al., 2020) ontwikkelden een aanpak voor het beoordelen van de ecologische risico’s gerelateerd aan de deeltjeseffecten van microplastics. Deze aanpak biedt een oplossing voor de bovengenoemde uitdagingen.

Afbakening, doelen en methode

Dit rapport gaat over de ecologische risicobeoordeling van de deeltjeseffecten van microplastics. Risico’s van plastics-geassocieerde chemische stoffen en microbiologische risico’s worden echter ook benoemd waar relevant.

Dit rapport evalueert de toepasbarheid van de Koelmans aanpak binnen de Nederlands beleidscontext en onderzoekt de steun voor deze aanpak binnen de wetenschappelijke gemeenschap. Daarnaast presenteert het een raamwerk voor beleid gebaseerd op de ecologische risicobeoordeling van de deeltjeseffecten van microplastics.

Om dit te bereiken is een literatuurstudie uitgevoerd naar methoden voor ecologische risicobeoordeling van microplastics, is een workshop georganiseerd om de (kennis)behoeften van Nederlands beleidsmakers in kaart te brengen, zijn wetenschappelijke experts geraadpleegd om de steun voor de Koelmans aanpak binnen de wetenschappelijke gemeenschap te onderzoeken, en is de Koelmans aanpak geïmplementeerd in R software om inzicht te krijgen in de stappen en wiskundige formules die ten grondslag liggen aan de methode.

Beleidsbehoeften

Onder de deelnemende beleidsmakers van het ministerie van Infrastructuur en Waterstaat werd het belang van een ecologische

risicobeoordeling van microplastics breed onderkend. De specifieke relevantie varieerde tussen deelnemers en omvatte onder meer het identificeren van hotspots van microplasticsvervuiling, het opbouwen van steun voor beleid dat microplasticsvervuiling aanpakt, het vaststellen van milieukwaliteitsnormen en het aanmoedigen van 'Safe-and-Sustainable-by-Design' plastics. Beleidsmakers benadrukten dat het belangrijk is dat inzichten uit risicobeoordelingen van microplastics handelingsperspectieven bieden.

De Koelmans aanpak

De Koelmans-aanpak kan worden beschreven in drie stappen. De eerste stap is het bepalen van de ecologisch relevante maat, zoals het volume of het oppervlakte van de deeltjes. Idealiter wordt de keuze voor deze maat theoretisch onderbouwd door een verband met één of meerdere specifieke toxiciteitsmechanismen waardoor microplastics schadelijke effecten kunnen hebben en is deze gestoeld op kwantitatieve data.

De tweede stap is het aanpassen van de blootstellingsdata. Dit is nodig omdat bij de monitoring van microplastics in het milieu het vaak niet mogelijk is om het volledige spectrum van microplastics te meten. Kleinere deeltjes vallen bijvoorbeeld buiten de detectielimieten. De aanpak maakt gebruik van extrapolatie aan de hand van de best passende verdeling van microplasticgroottes in het milieu (bijv. een power-law), zodat ook rekening wordt gehouden met de niet-gemeten microplastics.

De laatste stap betreft het op elkaar aansluiten van de blootstellings- en effectgegevens. Microplastics die in effectstudies worden gebruikt, weerspiegelen vaak niet de diversiteit van microplastics zoals die in het milieu terechtkomen of aanwezig zijn. In deze stap wordt de effect waarde voor schadelijkheid opnieuw berekend door de vraag te stellen: wat zou de waarde zijn geweest als de studie een milieu-realistische, polydisperse mix van microplastics had gebruikt, in plaats van bijvoorbeeld monodisperse deeltjes? Deze stap is gebaseerd op de eerder gedefinieerde ecologisch relevante maat en houdt rekening met factoren zoals de grootte, vorm en soort-specifieke biologische beschikbaarheid van microplastics.

In vergelijking met andere ecologische risicoanalyses in de literatuur onderscheidt de Koelmans-aanpak zich door de manier waarop blootstellingscorrecties worden uitgevoerd en door het streven om blootstellings- en effectdata goed op elkaar te laten aansluiten.

Gebruik in retrospectieve en prospectieve risicobeoordeling

Over het algemeen sluit de Koelmans-aanpak goed aan bij bestaande methoden voor risicobeoordeling. Deze aanpak is met name geschikt voor retrospectieve risicobeoordeling van bestaande microplasticverontreiniging. Het gebruik van de aanpak vereist echter specifieke expertise, wat de huidige praktische toepasbaarheid kan beperken en de ontwikkeling van praktische richtlijnen noodzakelijk maakt.

Voor prospectieve risicoanalyses die gebruikmaken van normen zijn er nog uitdagingen gerelateerd aan de diversiteit en variabiliteit van microplastics in grootte- en vormverdelingen in het milieu. Het gebruik van de aanpak voor dit doel vereist het definiëren van een standaardverdeling voor microplastics. Bestaande studies bieden een basis voor dergelijke benaderingen, hoewel verdere ontwikkelingsstappen nodig zijn.

Methodologische keuzes

In dit project werd de methode om blootstellings- en effectdata op elkaar aan te laten sluiten gereproduceerd met behulp van R-software. De analyse laat zien dat in bepaalde situaties de keuzes met betrekking tot het vaststellen van de boven- en ondergrenzen van deeltjesgrootte van invloed zijn op de uiteindelijke risicoschatting. Het is belangrijk om de implicaties van deze keuzes te onderzoeken, bijvoorbeeld via gevoeligheidsanalyses. Voor toekomstig gebruik van de aanpak in beleid zijn standaardisatie en de ontwikkeling van leidraden nodig om ervoor te zorgen dat de aanpak op een robuuste en reproduceerbare wijze wordt gebruikt.

Wetenschappelijke steun

In het algemeen wordt de Koelmans aanpak door de geraadpleegde wetenschappelijke experts erkend als zijnde state-of-the-art. Dit vanwege de innovatieve benadering van de aanpak en het vermogen om huidige hiaten in risicobeoordeling van microplastics aan te pakken. Er was brede steun voor een ecologische risicobeoordeling die zich richt op de deeltjeseffecten van microplastics. Tegelijkertijd benadrukten experts het belang van het duidelijk communicatie over de reikwijdte van een deeltjeseffecten-gebaseerde ecologische risicobeoordeling.

Experts waren het erover eens dat ecologische risicobeoordeling van microplastics idealiter zowel de effecten van plastic-geassocieerde chemicaliën als de deeltjeseffecten zouden moeten omvatten. Desondanks gaven ze aan dat het belangrijk is om vooruitgang te boeken door (voorlopige) risicobeoordelingen uit te voeren, en waarschuwden ze tegen het uitstellen van het doen van risicobeoordelingen totdat de volledige complexiteit van microplasticvervuiling is begrepen.

De experts zeiden dat meer onderzoek nodig is naar de mechanismen van toxiciteit, en dan met name voor terrestrische soorten. Dit onderzoek is nodig ter ondersteuning van ecologische risicobeoordelingen.

Raamwerk voor beleid

Dit rapport beschrijft een raamwerk voor toepassen van regelgeving op basis van ecologische risicobeoordelingen. Dit raamwerk bestaat uit drie stappen. De eerste stap is het beoordelen van de algemene milieustatus van een gebied (bijvoorbeeld Nederland of een specifieke regio of locatie) door het meten van de concentratie en de verdeling van microplastics in het milieu.

De tweede stap is de ecologische risicoanalyse van microplastics op basis van de Koelmans aanpak. Deze aanpak kan worden toegepast op gemeten concentraties van microplastics in het milieu en kan zowel op lokale schaal als op grotere (nationale) schaal worden toegepast om een beeld van de milieu risico's van microplastics te verkrijgen.

De laatste stap betreft het nemen van maatregelen op basis van specifieke beleidsprincipes en de verdeling van risico's in het milieu. Verschillende beleidsdoelen vereisen mogelijk een verschillende toepassing van een risicobeoordeling. Bijvoorbeeld, retrospectieve beoordelingen kunnen gebruikt worden voor het nemen van maatregelen om emissies te beperken, terwijl prospectieve beoordelingen gebaseerd op grenswaarden beslissingen kunnen ondersteunen op het gebied van emissies-vergunningverlening of de verplaatsing van grond- of slibmaterialen. Elk type beoordeling heeft zijn eigen unieke ontwikkelingsbehoeften.

Een cruciaal onderdeel van dit raamwerk is het waarborgen van de kwaliteit en de relevantie van de gebruikte data. Alle stappen van het raamwerk zijn afhankelijk van de beschikbaarheid van data van voldoende kwaliteit om relevante en bruikbare resultaten te leveren.

Verdere ontwikkeling

We hebben verschillende ontwikkelpunten geïdentificeerd met betrekking tot de ecologische risicobeoordeling van microplastics. De belangrijkste zijn:

- Verbetering van de hoeveelheid en de kwaliteit van toxiciteitsdata. Vooral meer gegevens over effecten op terrestrische soorten zijn nodig.
- Opvullen van kennisleemte omtrent gemeten milieuconcentraties van microplastics in Nederland.
- Het beter begrijpen van de impact van methodologische keuzes op de uitkomst van de risicobeoordeling. Dit kan bijvoorbeeld via een gevoeligheidsanalyse. Dit zou moeten helpen om een minimale kwaliteitsstandaard voor gegevens vast te stellen.
- Ontwikkeling van testrichtlijnen of leidraden voor toxiciteitsstudies, monitoring en de rapportage van microplastics, evenals leidraden voor het uitvoeren van ecologische risicobeoordeling van microplastics.

Conclusies

Dit rapport concludeert dat de Koelmans aanpak de belangrijkste uitdagingen voor het beoordelen van ecologische risico's van de deeltjeseffecten van microplastics oplost. Deze methode is al geschikt voor retrospectieve risicobeoordeling van bestaande verontreiniging van microplastics. Het gebruik ervan voor prospectieve risicobeoordeling binnen beleidskaders vereist echter verdere ontwikkeling. Het ontwikkelen van richtlijnen en leidraden zal de bruikbaarheid en acceptatie van de methode vergroten.

Verder benadrukt het RIVM dat dit onderzoek zich alleen richtte op de deeltjeseffecten van microplastics en dat beleid ook rekening moet houden met de bredere milieurisico's van plastics. Voor een completer beeld is het bijvoorbeeld ook nodig naar chemische stoffen in (micro)plastics te kijken en de effecten daarvan. Deze andere effecten moeten echter apart beoordeeld worden.

1 Introduction

1.1 Context of the study

Microplastics are a global environmental pollutant found in soils, water, air and sediments (Freriks et al., 2023; Mintenig et al., 2020; Rutgers et al., 2022; Tromp and Esveld, 2023). Their sources are diverse and include, among others, wear of plastics used in agriculture (e.g. plastic mulching), packaging, textiles, paints and tyres, and losses in handling of pre-production pellets and plastic waste (EC, 2023a; Quik et al., 2024; Urbanus et al., 2022). With global plastic production projected to grow (Lau et al., 2020; OECD, 2022) and because (macro-) plastics in the environment gradually fragment into microplastics, environmental concentrations of microplastics may increase in the future, depending on policy actions taken (Lau et al., 2020; Rillig et al., 2021). Research has demonstrated that certain microplastic concentrations can adversely affect biota (Redondo-Hasselerharm et al., 2023; Tunali et al., 2023; Zantis et al., 2023), alter the physical properties of soils (Kim and Rillig, 2022; Špela et al., 2025), and negatively impact crop production (Zhang et al., 2020). There is also a growing focus on their potential adverse effects on human health (Gouin et al., 2022; Vethaak and Legler, 2021). As a result, microplastics have become a significant societal concern (Catarino et al., 2021; Kramm et al., 2022).

Policies to tackle (micro)plastic pollution are developed at various levels of government. For example, the United Nations member states are in the process of negotiating an internationally binding agreement to address plastic pollution (UNEP, 2022). Within the European Union, measures are being implemented or developed to restrict intentionally added microplastics under the EU chemical legislation REACH (EC, 2023b) and to prevent plastic pellet losses during storage, handling and transport (EC, 2023c). In the Netherlands, legislation has been introduced to reduce emissions of plastic waste via a deposit scheme on plastic bottles, among others items (IenW, 2020) and via the national circular economy programme (IenW, 2023a). Increasingly, there are also obligations in place to monitor microplastics in surface and marine waters (MSFD Technical Group on Marine Litter, 2023; OSPAR, 2024).

Most of the policies mentioned above focus on reducing plastic or microplastic emissions to the environment and are thus not related to existing policies addressing soil, water or air quality. However, many environmental quality regulations and related regulatory decisions are guided by the presence or absence of (ecological) risks. For example, whether or not to remediate a polluted site or permit the emission of a pollutant into the environment. Furthermore, policymakers may prioritise tackling plastic pollution only when risks are likely to occur, either at present or in the future. Consequently, a key question for further addressing microplastic pollution is: *Are biota expected to be adversely affected by microplastics at current or future levels of exposure?* In other words, to what degree do microplastics pose an ecological risk?

Assessing the ecological risk of microplastics presents a major challenge. This challenge relates to, among others, the complexity of microplastics as environmental pollutants (such as the wide variety of polymer types, shapes, sizes, weathering states, etc.) as well as to the limited availability of high-quality data and the mismatch between exposure and effect data (Koelmans et al., 2020). These factors contribute to uncertainties in estimating ecological risks, which, in turn, may hinder the implementation of effective measure to address microplastic pollution. Furthermore, microplastics may induce various types of effects due to their physical properties, their chemical composition, or the pathogens associated with microplastics. Previous studies have described methods to assess risks relating to the chemicals associated with microplastics (Koelmans et al., 2022, 2013). However, until recently, an approach to assessing the risks relating to physical effects of microplastics that addressed the complexity of microplastics was lacking.

A framework for assessing the ecological risks relating to the physical effects of microplastics was proposed by Koelmans and colleagues (Koelmans et al., 2020). The Koelmans approach has since been further refined (Kooi et al., 2021), applied to multiple environmental compartments (Koelmans et al., 2023; Redondo-Hasselerharm et al., 2024, 2023), and used in policy contexts (Coffin et al., 2022a; Mehinto et al., 2022).

1.2 Study goals and methods

The Dutch Ministry of Infrastructure and Water Management (I&W) commissioned the National Institute for Public Health and the Environment (RIVM) to evaluate the applicability of the Koelmans approach within the Dutch policy context and to evaluate the support for this approach among the scientific community. On the basis of this evaluation, RIVM was asked to propose a framework for ecological risk assessment of microplastics for the Netherlands.

To achieve this, the following activities were conducted (details are provided in the report):

- Conducting literature reviews on ecological risk assessment approaches to microplastics;
- Organising a workshop with policymakers from Dutch national government to identify their specific needs;
- Consulting scientific experts through both a questionnaire and a workshop to evaluate the support for the Koelmans approach within the scientific community;
- Implementing the Koelmans approach in R software (www.r-project.org) to gain an understanding of the steps and mathematical formulas used in the Koelmans approach.

1.3 Scope, definitions, and target audience

This report centres on an *ecological risk assessment of microplastics* with a focus on methodology. No formal risk assessment is conducted in this study. Human health risk assessment falls outside of the scope of the report.

Various definitions for microplastics exist. Typically, microplastics are described as synthetic polymeric particles smaller than 5000 µm with some definitions also including a lower limit, typically between 0.1 and 1 µm (Hartmann et al., 2019; Ho et al., 2024). In this report, we adopt the definition of microplastics used in the EU REACH restriction on intentionally added microplastics (EC, 2023b). In summary, microplastics are synthetic polymeric particles *smaller than 5000 µm,* with the EU REACH restriction temporarily establishing a lower size limit of 100 nm.[1] This lower limit will remain in place until analytical methods become sufficiently reliable to measure polymers below this threshold. In the scientific literature, microplastics are sometimes distinguished from nanoplastics, which are typically defined as synthetic polymeric particles smaller than 1 µm. While we categorise submicron microplastics as part of the broader microplastic definition, we make size-based distinctions throughout the report wherever it is contextually relevant.

As noted above, microplastics may induce various types of effects: the physical particles themselves may cause particle effects, their chemical composition may lead to effects through the leaching of chemicals, and (pathogenic) microorganisms associated with microplastics may contribute to increased disease incidence. The primary focus of this report is on the ecological risk assessment of the *particle effects* of microplastics.

That said, the ecological risk assessment of plastic-associated chemicals and the assessment of microbiological risks are discussed throughout the report, as these types of risks are integral to the broader issue of plastic pollution and require consideration. '*Plastic-associated chemicals*' are defined in this report as chemicals that are either intentionally or unintentionally added or formed during the production or recycling of plastics. Chemicals that are sorbed on plastics in the environment are not considered to be plastic-associated chemicals.

This report is intended for both *policymakers* and *scientists* working in the field of microplastic pollution. Efforts have been made to ensure the content is accessible to both stakeholders groups. However, certain chapters have been tailored to address the needs of specific audiences. For example, Appendix 2 contains scientific details and discussion that are particularly relevant for researchers in the field. The report provides recommendations for policymakers as well as recommendations for further scientific studies.

1.4 Outline of this report

The next chapter (Chapter 2) introduces the needs of Dutch policymakers regarding the ecological risk assessment of microplastics, the key challenges to ecological risk assessment of microplastics, how the Koelmans approach works, and lastly, reviews of existing methods in the field. Chapter 3 analyses the scientific acceptance and the relevance of the Koelmans approach to the Dutch policy context, based on insights gathered from a scientific expert consultation, and explores the practical

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[1] Note that the maximum and minimum length for fibres in the definition used in the EU REACH restriction is 15 mm and 300 nm respectively.

applicability of the Koelmans approach. In Chapter 4, a proposal for a framework for the ecological risk assessment of microplastics in the Netherlands is presented. The report concludes with Chapter 5, which provides final conclusions and scientific and policy recommendations for the (implementation of the) proposed framework.

2 Ecological risk assessment of microplastics: policy needs scientific challenges and solutions

2.1 Needs of policymakers from the Dutch national government

At an in-person workshop, the (knowledge) needs of policymakers from Dutch national government were identified on the topic of ecological risk assessment of microplastics. This served to assess whether the Koelmans approach is able to address those needs. The workshop was attended by twelve policymakers from three departments or agencies within the Dutch Ministry for Infrastructure and Water Management (I&W). The agenda and an extensive summary of the discussions during the workshop are provided in Appendix 1.1 (available in Dutch only).

The following conclusions or points for discussion came up:

- The importance of ecological risk assessment for microplastics was broadly recognised.
- Needs for an ecological risk assessment of microplastics varied across participants and included the identification of microplastic pollution hotspots nationally, building support for policies that tackle microplastic pollution, the monitoring of environment status in general, identification of ways to effectively reduce pollution of microplastics and emissions to the environment, setting of environmental quality standards/risk limits, and encouraging Safe-by-Design plastics.
- The importance of insights (derived from risk assessments) that provide perspectives for policy actions was widely acknowledged.
- There was concern for or awareness of potential side effects of, for example, environmental quality standards or, more generally, ‘outcomes’ of risk assessment that do not provide perspectives for policy actions.
- Among participants, a need for a certain specificity of the risk assessment was stressed. For example, an environmental risk assessment should help to identify risks of specific types or applications.
- The importance of an environmental risk assessment that is supported by the scientific community was broadly acknowledged.
- Human health risks are not considered in this report, but they are of great importance and may often be decisive for policy-making.
- There was a concern for the effects of plastic-associated chemicals that can leach from microplastics.
- Also, risks of nanoplastics and microbiological effects were considered important to know.

The workshop highlighted that policymakers considered ecological risk assessment of microplastics to be important. However, a key takeaway point was that such assessments must address specific needs, and, most importantly, must produce actionable outcomes that can effectively inform policy decisions.

2.2 Challenges for ecological risk assessment of microplastics

In chemical risk assessment, risk is defined as the probability of an adverse effect following exposure to a chemical. Ecological risk assessment focuses on the protection of populations or ecosystems. The risk depends on the hazard of a chemical (the capacity of a chemical to cause adverse effects) and the extent of exposure (how much and how often populations or ecosystems are exposed to the chemical). Microplastics are a very diverse group of environmental pollutants with a broad range of physical and chemical characteristics, which may change over time. Furthermore, they can serve as substrates for biofilms and/or may function as vectors for pathogens. This diversity in characteristics provides a major challenge to making a reliable and relevant estimation of the risks of microplastics. Several challenges can be recognised (summarised in Box 1), which are detailed in the following paragraphs.

Box 1: Challenges to ecological risk assessment of microplastics

To conduct a reliable and relevant ecological risk assessment, the challenges listed below need to be addressed:

1. Microplastics can induce various effect types: physical, chemical and/or biological. *How can an ecological risk assessment cover all effect types?*

2. Microplastics are very diverse, differing widely in size, shape, composition, weathering state, etcetera. *Which characteristics of microplastics should be considered in an ecological risk assessment?*

3. Microplastic monitoring does not cover all microplastics, particularly the smallest particles. *How to account for the missing fraction?*

4. Many effect studies use microplastics that differ from those found in the environment. *How to estimate risks when the microplastics that are used in effect studies are very different from the microplastics in the environment?*

5. The quality of microplastic studies is often insufficient for use in ecological risk assessment. *How to deal with data of limited quality in an ecological risk assessment of microplastics?*

6. Microplastics change over time. *How to consider fate and transport processes of microplastics in ecological risk assessment?*

1. Microplastics may induce various types of effects

First, microplastics may induce various types of effects due to their physical properties, their chemical composition, or biota associated with microplastics. Figure 1 shows a simplified degradation pathway of plastics and various ways through which plastics, including microplastics, may have an impact on biota. Note that the scope of Figure 1 extends beyond impacts of microplastics alone (i.e. it includes both effects of macroplastics and effects of plastic-associated chemicals that have leached anywhere along the degradation pathway).

Effects relating to the physical properties of microplastics include, for example, oxidative stress and inflammation caused by physical interactions between a microplastic particle and a cell, food dilution, or effects relating to the blockage by microplastics of the intestines of organisms (De Ruijter et al., 2020). In the remainder of this report, these effects relating to physical properties are described as *‘particle effects’.*

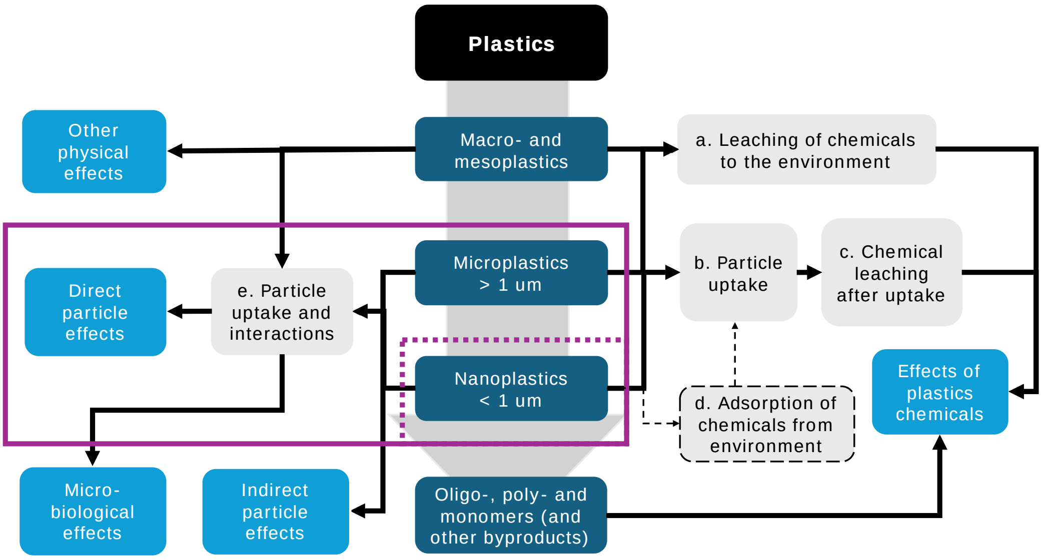
‘Plastic-associated chemicals’ comprise all chemicals in plastics, such as the polymers, unreacted monomers, and the functional additives, but also include chemicals that are unintentionally formed during the production or degradation of plastics (Wagner et al., 2024). Plastic-associated chemicals may leach from microplastics (or indeed anywhere along the degradation pathway of plastics), which may cause effects in organisms when exposed to these chemicals.

Microplastics may also act as a *vector for (pathogenic) microorganisms* and viruses (Stunnenberg and de Roda Husman, 2024; Tavşanoğlu et al., 2025). The presence of microplastics in the environment may increase the exposure to pathogens, which, in turn, may cause adverse health effects in organisms.

The three types of effects (i.e. particle effects, effects due to plastic-associated chemicals, and effects relating to pathogens) may act concurrently, may interact (i.e. antagonistic, additive, or synergistic effects) (Parker et al., 2024), and may each explain part of the adverse effects of microplastics in exposed organisms. The relative importance of these three effect types may depend on multiple factors, including the environmental fate and weathering state of the plastics, the specific environmental conditions, the organism, and/or the microplastic type (Boháčková and Cajthaml, 2024; Gouin et al., 2011; Koelmans et al., 2022, 2016). The hazard and exposure data that is needed for an ecological risk assessment depends on the effect type considered. For example, an ecological risk assessment based on effects of plastics-associated chemicals may use the mass concentration of (certain) chemical additives as a metric for effects, whereas an ecological risk assessment based on particle effects may use the collective volume or the area of the ingested particles.

As stated above, the primary focus of this report is on the ecological risk assessment of the particle effects of microplastics (purple box in Figure 1).

Figure 1 Simplified conceptual model linking potential ecological effects to the plastic degradation pathway from plastics via microplastics to polymers and monomers.



The central dark-blue boxes and the grey arrow indicate a simplified degradation process of plastics from debris down to monomers and other degradation products (mineralisation products fall outside of the scope of this model). Grey boxes indicate fate processes. Blue boxes indicate potential effects in organisms.
‘Other physical effects’ may include birds trapped in (parts of) plastic packaging, etcetera. ‘Direct particle effects’ relate to effects such as food dilution or effects relating to translocation. ‘Indirect particle effects’ may include changes to the environmental matrix (e.g. soil) which may indirectly affect biota. ‘Microbiological effects’ include downstream effects of association of pathogens to plastic particles. ‘Effects of plastic-associated chemicals’ are all effects relating to chemical substances themselves.
Arrows indicate potential links and relationships and do not reflect importance. The dashed arrows indicate the effect route by adsorption of chemicals from the environment that is considered irrelevant and out of scope (Herzke et al., 2016; Koelmans et al., 2016).
The purple box indicates the scope of the ecological risk assessment described by Koelmans et al. (2020) for microplastics larger than 1 µm which might be extended to include smaller microplastics (i.e. submicron microplastics or nanoplastics) (dashed purple box). Source: RIVM

2. *Microplastics have very diverse characteristics*

A next challenge is the diversity in characteristics of microplastic particles that are found in the environment. Microplastics can range up to 5000 µm in size, can have various shapes (e.g. spherical, fibres, fragments, flakes), can have various weathering states, can be made from various types of polymers (e.g. polystyrene, polyethylene, polyamide, etcetera.), have various compositions of intentionally added and unintentionally formed chemicals.[2] Each of these factors may affect the toxicity of microplastics (Cui et al., 2024; Huo et al., 2022; Thornton Hampton et al., 2022a).

3. *Microplastic monitoring does not cover all microplastics*

Another major challenge relates to limitations in measuring environmental concentrations. Microplastic particles are relatively difficult to measure, especially in complex media (e.g. soils and sediments). Specialised laboratory equipment and protocols are needed

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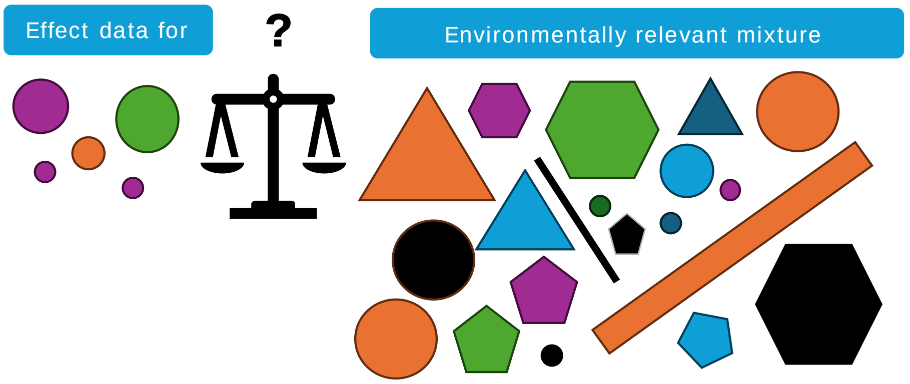
[2] There are more than 16,000 known plastic-associated chemicals (Wagner et al. 2024). This number does not include chemicals without CAS registration numbers or chemicals that are adsorbed from the environment.

to measure and distinguish particles in different chemical compositions and size ranges and differentiate them from other (natural) particulate matter. Especially, particles of smaller size ranges (e.g. below 10-20 µm) are difficult to measure. Furthermore, depending on the analytical method, some types of microplastics (e.g. rubber-based particles, such as tyre wear particles) are difficult to distinguish from their environment due to their dark colour. The unmeasured fraction in the environment results in an underestimate of the true exposure by populations/ecosystems.

4. *Many effect studies use microplastics that differ from those found in the environment*

In part as a result of the above limitations, one of the major challenges to environmental risk assessment of microplastics is the non-alignment of exposure and effect data (Figure 2). Much of the effect data (hazard data) has been generated using only a limited number of (polymer) types, shapes and size ranges. Thus far, most effect data is available for spherical polystyrene or polyethylene microplastics (Cui et al., 2024). This contrasts with the diversity of particles that are found in the environment and to which organisms may be exposed. Thus, the two 'sides' of the equation (i.e. hazard and exposure data) are not comparable.

Figure 2 Diagram demonstrating the non-alignment of exposure and effect (hazard) data, which challenges conducting a reliable and relevant environmental risk assessment of microplastics.

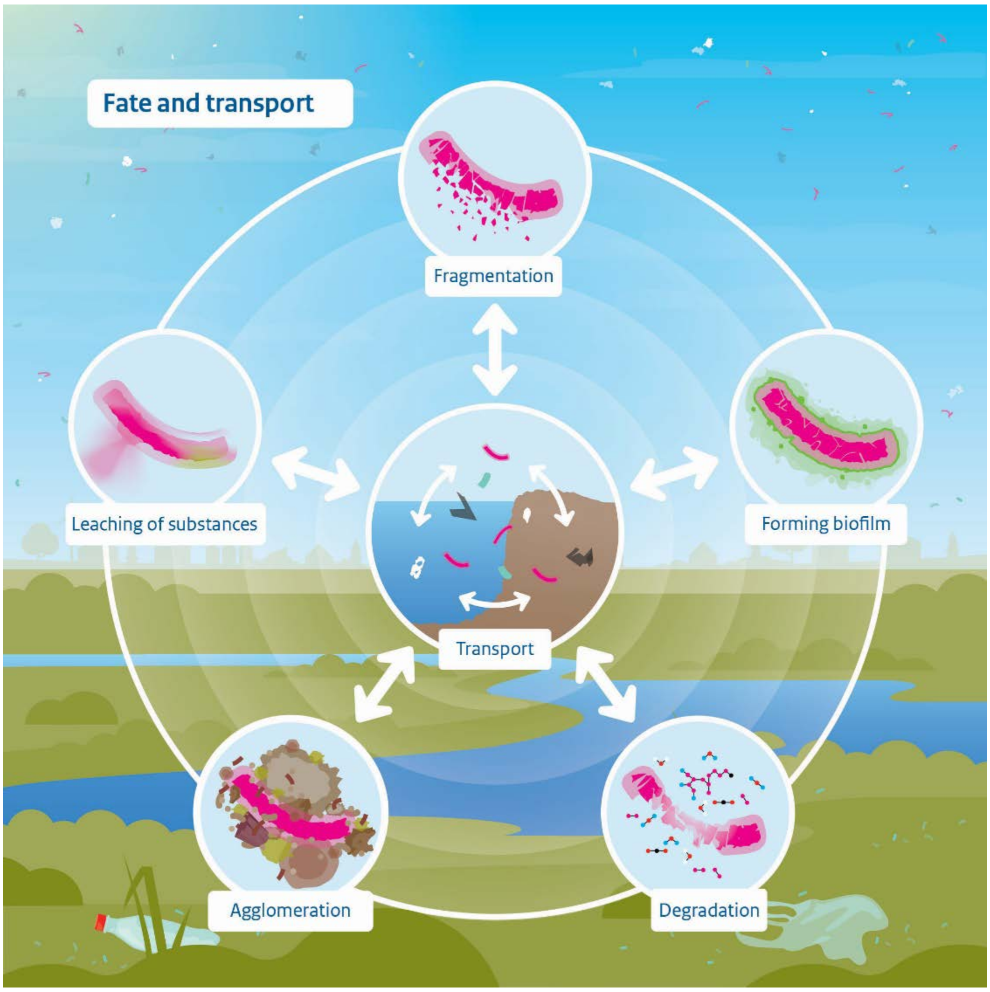


In this diagram, different colours may represent different polymer types. Hazard (effect) data (left of the scale) is often only available for a limited number of polymer types, shapes and size ranges (e.g. often spherical polystyrene particles), whereas the microplastics that organisms are exposed to are much more diverse (right of the scale). The diagram is a simplified reflection of non-alignment of the exposure and effect data which, in reality, is likely to be far greater than represented here. Source: RIVM

5. *The quality of studies is often insufficient for use in ecological risk assessment*

A next key challenge for environmental risk assessment is the quality of exposure and effect data on microplastics. Quality data is key for any reliable estimation of the environmental risks of chemicals. In that sense, this challenge is not unique to microplastics. Generally, the quality of hazard and exposure data for chemicals may be safeguarded through use of standardised protocols (e.g. ISO, OECD) and can be evaluated using quality criteria (Klimisch et al., 1997; Merrington et al., 2024; Moermond et al., 2015). However, the applicability and relevance of existing test protocols and quality criteria for microplastics have been questioned (Hermsen et al., 2018). Additional quality criteria or modifications to criteria and/or test methods may be required to ensure and assess the quality of studies. For example, a relevant substance identification for a microplastic study should include size (distribution), shape, and polymer type, as these features may predominantly affect the toxicity of microplastics (Thornton Hampton et al., 2022a). Furthermore, plastic products are omnipresent, including in laboratories, and therefore extra care and procedures may be required to prevent contamination of samples. Accordingly, quality criteria for microplastic studies have been developed (Brander et al., 2020; de Ruijter et al., 2020; Hermsen et al., 2018; Koelmans et al., 2019; Redondo-Hasselerharm et al., 2024). Applying these criteria has shown that much of the current available exposure and effect data is of insufficient quality for use in environmental risk assessment.

Figure 3 Overview of fate processes affecting transport and exposure to organisms in time.



Source: RIVM

6. Microplastics change over time

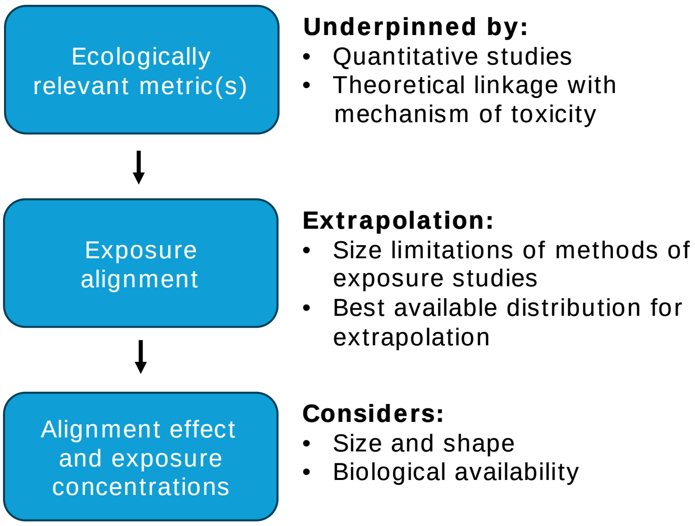
Lastly**,** microplastic properties change over time as they undergo several fate and transport processes (see Figure 3). The time scale at which these processes affect exposure will probably range from weeks to centuries more than hundreds of years, depending on the (intrinsic) characteristics of the microplastic particle, such as polymer type, additives (e.g. UV blockers), and shape, and on (extrinsic) characteristics of the environment, including UV radiation and organic matter content (Chamas et al., 2020). One of the most relevant fate processes affecting exposure to microplastics is fragmentation. Fragmentation causes formation of smaller particles from a larger particle or even macroplastic items. This is an ongoing process, which is highlighted as the cause of saddling the environment with a plastic toxicity debt (Rillig et al., 2021), as smaller particles will keep increasing long after emission to the environment has taken place. The continuous formation of smaller particles is one of the reasons why a power law is suitable for describing microplastic number-size distributions in natural media (Kooi and Koelmans, 2019). This is similar to natural suspended particulates, which are also commonly described using a power law, often referred to as a pareto distribution. However, taking into account the change in time of the particle characteristics due to the above-mentioned fate processes (Figure 3) remains a challenge.

In summary, microplastics are a class of complex pollutants that pose major challenges to ecological risk assessment. As we pointed out earlier, the Koelmans approach addresses several of these key challenges. This approach was taken as a starting point for this report on methods of ecological risk assessment of microplastics. However, before reviewing the Koelmans approach in Chapter 3 (3.1-3.3), the next subchapter reviews the existing methods for assessing ecological risk of microplastics as developed by various authors, including an application of the Koelmans approach. This literature review was conducted to gain a better understanding of the available methods, to compare their key features, and to inform the choice for further assessment of a specific approach.

2.3 How does the Koelmans approach work?

The key feature of the Koelmans approach is that it corrects for differences in size ranges in exposure studies and solves the incomparability of effect and exposure data. To do so, the approach uses the following steps (Figure 4).

Figure 4 Diagram showing key steps in the alignment of exposure and effect data from microplastic studies.



Underpinned by:
- Quantitative studies
- Theoretical linkage with mechanism of toxicity

Extrapolation:
- Size limitations of methods of exposure studies
- Best available distribution for extrapolation

Considers:
- Size and shape
- Biological availability

Source: RIVM

Key step 1: Determination of the ecologically relevant metric
In the Koelmans approach, the ecologically relevant metric is determined first. This is the metric that best describes the effects of microplastics. As explained above (in Chapter 2.1), microplastic concentrations may be described by various metrics, for example, as the number of particles or by their total mass, volume, or surface area. The choice of metric will affect downstream steps (detailed below) and the outcome of the environmental risk assessment. One could pick more than one ecologically relevant metric and use them in parallel assessments. In various publications that used the Koelmans approach, volume and surface area have been selected as metric(s) (Coffin et al., 2022b; Koelmans et al., 2023; Mehinto et al., 2022; Redondo-Hasselerharm et al., 2024, 2023).

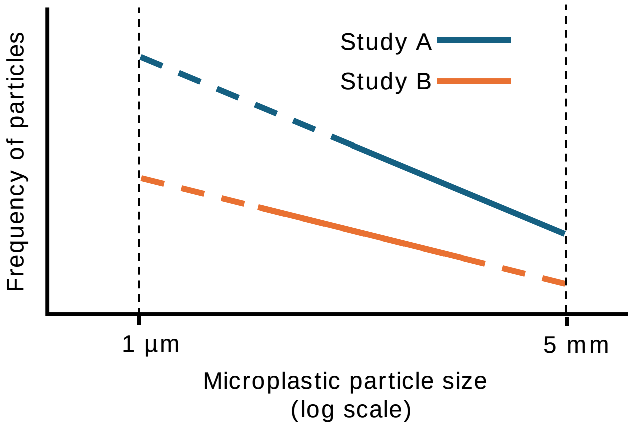
Use of these two metrics (i.e. volume and surface area) for alignment of exposure and effect concentrations is supported by various studies. A weight-of-evidence study by De Ruijter and colleagues showed that there may be multiple food-related mechanisms (e.g. inhibition of food assimilation and/or decreased nutritional value of food) through which microplastics can cause adverse effects in organisms (De Ruijter et al., 2020). If food dilution-related mechanisms of toxicity are indeed most relevant, choosing volume as an ecologically relevant metric to align exposure and effect may be a defensible approach (Koelmans et al., 2020).

Some microplastics may also translocate across membranes (e.g. the intestinal membrane) and cause effects such as inflammation and oxidative stress. Such particle effects are well described for other types of particles (e.g. engineered nanomaterials), and evidence exists that microplastics can have adverse effects through similar mechanisms (de Ruijter et al., 2020; Kögel et al., 2020). When translocation-related effects are most relevant, surface area may be a better metric to align exposure and effect concentrations to, depending on, for instance, type, species or exposure route (Hua et al., 2016; Schmid and Stoeger, 2016).

Use of these two metrics is further supported by a meta-analysis on metrics and particle characteristics for predicting ecotoxicity in aquatic organisms (Thornton Hampton et al., 2022a). On the basis of an analysis of ecotoxicity data from a total of 160 aquatic ecotoxicity studies, this study demonstrates that volume and surface area are the best predictors for ecotoxicity of microplastics in aquatic organisms (Thornton Hampton et al., 2022a). The predictive power of these two metrics may be linked to specific mechanisms of toxicity through which microplastics can have adverse effects in organisms: food dilution and translocation-related effects.

Key step 2: Exposure alignment
The second step in the approach is the exposure alignment. As explained above, measuring all microplastics in a given sample represents a major challenge due to analytical limitations. For example, smaller particles (lower micron-sized plastics, dark-coloured particles) are often not measured, depending on the analytical protocols and tools used. Consequently, results of exposure studies may be underestimates of the true microplastic concentration. Because different studies often use different analytical tools and procedures, this also results in incomparable exposure data (Figure 5). Studies have demonstrated that, similar to natural particles (Buonassissi and Dierssen, 2010), the size distribution of microplastics in the environment follows a power law distribution (Kooi et al., 2021; Redondo-Hasselerharm et al., 2024). Through extrapolation based on a power law distribution, the particles that are not measured (due to technical limitations) are included. This results in a uniform and consistent calculation of exposure. It should be noted that other distributions than power law may be used when they are a better fit for the distribution of microplastics across the environment.

Figure 5 Simplified diagram demonstrating the non-alignment of exposure studies. Vertical dashed lines indicate the size range of microplastics (1 µm to 5 mm).



Studies A (blue) and B (orange) used different analytical procedures and tools to measure microplastic particles for a given sample. Accordingly, their measured size range (solid lines) are not aligned. To be able to compare these studies, alignment with the full relevant size range (in this case from 1 µm to 5 mm) is needed (dashed part of orange and blue lines). The alignment can be based on the well-supported assumption that the size distribution of microplastics across the environment follows a power law. Note that the angles of the lines of the two studies are different. Distributions of microplastics may be dependent on the specific environment or compartment the sample is taken from. Therefore, a compartment-specific power law slope may be applied to compare and align studies. Source: RIVM

Key step 3: Exposure-effect alignment
The next step is the alignment of exposure and effect studies. For environmental risk assessment, it is crucial that exposure and effect data aligns. As detailed above (see Figure 2), effect studies are often based on a limited number of plastic types, shapes and size ranges, which does not reflect the diversity of microplastics in the environment. To align effect and exposure data, the Koelmans approach used the ecologically relevant metric that had been defined earlier. This step recalculates the toxicity value in the metric of number of particles (this can be any value, such as a No Observed Effect Concentration, NOEC) from an effect study by assuming that the study had used an environmentally realistic mixture of microplastics, instead of, for example, monodisperse microplastics. This recalculation is based on the defined ecologically relevant metric. When volume or surface area are taken as ecologically relevant metrics, this calculation would take into account the size and shape of the microplastics. In this step, the biological availability of microplastics also needs to be taken into account. Due to differences in anatomy, the actual exposure may differ between species. For example, the nematode *Caenorhabditis elegans* with a mouth gap width of 5 µm cannot ingest a spherical microplastic exceeding that size. To correct for this, species-specific and microplastic size-based thresholds are used. If one would choose a different ecologically relevant metric, this would affect the calculations needed to align effect and exposure concentrations.

Through these steps, the Koelmans approach addressed some of the key challenges associated with the ecological risk assessment of microplastics. The above three-step approach is a global description; in practice, several intermediate calculation steps are included in the method. An overview of each step in the approach is provided in Appendix 2. This detailed list in the Appendix is designed for an audience with expert knowledge and is thus intended to inform peer scientists working in the field.

2.4 Review of ecological risk assessment approaches for microplastics

Several ecological risk assessments have been published for various environmental compartments including soils (Jacques and Prosser, 2021; Redondo-Hasselerharm et al., 2024; Tunali et al., 2023) and aquatic systems (Adam et al., 2021; Coffin et al., 2022b; Liu et al., 2022; Mehinto et al., 2022; Qiu et al., 2023). To derive a risk estimate, each of these studies made certain choices to address the challenges described above.

This section briefly compares the methods of three selected ecological risk assessments for soil. The studies of Jacques and Prosser (2021), Tunali et al. (2023) and Redondo-Hasselerharm et al. (2024) were selected (Table 1) as they align with existing environmental risk assessment approaches used in chemical regulation and because they focus on the same environmental compartment (i.e. soil) and exhibit relevant methodological variability. It is important to note that this review does not intend to be an exhaustive methodological review. Instead, its purpose is to illustrate the methodological choices available when conducting an environmental risk assessment of microplastics.

The authors of the three methods compared in this analysis have collected ecotoxicity data from experimental studies that examined the effects of microplastics on soil organisms. Using this ecotoxicity data, they determined a safe threshold for soil ecosystems, expressed as the Hazardous Concentration for 5% of the species (HC_5). Then they compared this HC_5 value was to measured exposure levels to derive a risk estimate.

General scope and features of the compared risk assessments
To start with the general scope of the conducted risk assessments, the three studies are similar in terms of the geographical scope and considered soil types. Jacques and Prosser (2021) included more taxonomical groups and considered a broader size range of microplastics than Tunali et al. (2023) and Redondo-Hasselerharm et al. (2024) did.

Quality assessment of the considered exposure and effect studies.
Jacques and Prosser (2021) did not conduct a formal quality assessment of the considered exposure and effect studies. Tunali et al. (2023) defined a limited list of exclusion criteria to remove studies on the basis of a lack of provided information. Redondo-Hasselerharm et al. (2024) applied a more extensive quality control/quality assurance (QA/QC) methodology to score the relevance and reliability of each study for environmental risk assessment on the basis of a set of ten (for exposure studies) or twenty (for effect studies) criteria.

Measured exposure concentration

In all studies, exposure concentrations were based on measurements of microplastics in the environment (rather than on modelling exercises). Jacques and Prosser (2021) included studies that measured concentrations of microplastics in air. For these studies, they calculated particle concentrations of soils on the basis of assumptions regarding aerial deposition. On the other hand, Redondo-Hasselerharm et al. (2024) estimated total particle concentrations (within the set size range of 1 to 5000 µm) by extrapolating the non-measured fraction using a power law model (as detailed in Chapter 2.3 and Appendix 2.1). Tunali et al. (2023) did not carry out any exposure corrections and used the particle concentrations as reported in exposure studies.

Table 1 Comparison of methodological features of three selected environmental risk assessments of microplastics in the soil ecosystem.

Methodological features	**Jacques and Prosser (2021)**	**Tunali et al. (2023)**	**Redondo-Hasselerharm et al. (2024)**
Soil types considered	Agricultural, urban, industrial, natural	Agricultural, urban, industrial, natural	Agricultural, urban, industrial, natural
Geographical scope	Global	Global	Global
Taxonomical groups considered	Invertebrates, plants, bacteria, fungi	Invertebrates, plants	Invertebrates, plants
Size range considered	<5000 µm[1]	1 – 5000 µm	1 – 5000 µm
Particle size considered?	Yes, for mass to particle number calculations	Yes, for mass to particle number calculations	Yes, to align exposure and effect data and to assess biological availability
Particle shape considered?	Yes, for mass to particle number calculations	Yes, for mass to particle number calculations	Yes, to align exposure and effect data
Polymer type considered?	No	No	No
Plastic-associated chemicals considered?	No	No	No
Metric used	Particle numbers	Particle numbers	Particle numbers recalculated to bioavailable volume and surface area
Exposure correction	Aerial deposition data converted to particle concentrations	None	Extrapolation via power law model
Effect concentrations correction	Mass converted to particles when density or composition was known	Mass converted to particles using particle density and volume data	Alignment to ecologically relevant metric
Biological availability considered	No	No	Yes, size-, shape- and species- dependent
Quality studies considered	Not reported	Limited QA/QC screening	Full QA/QC screening
Effect data used[2]	NOEC, LOEC	NOEC, >NOEC, LOEC[3]	>NOEC[4], LOEC,
Dealing with different effect types	Not considered	Not considered	Removal of data when effects entirely caused by plastic-associated chemicals
Probabilistic assessment	Yes	Yes	Yes

[1] Jacques and Prosser (2021) do not specify the size range considered. The supplementary information indicates that all particles <5 mm were considered, including nanoplastics.

[2] NOEC = No Observed Effect Concentration, LOEC = Lowest Observed Effect Concentration, >NOEC values are values where no effects were observed at the highest tested concentration.

[3] In Tunali et al. (2023) and Redondo-Hasselerharm et al. (2024), LOEC values were converted to NOEC equivalents using uncertainty factors.

[4] In Redondo-Hasselerharm et al. (2024), >NOEC values were only used when the number of concentrations exceeded four.

Predicted no effect concentrations
Jacques and Prosser (2021) only used No Observed Effect Concentration (NOEC) values, whereas Tunali et al. (2023) also used >NOEC[3] values, and converted Lowest Observed Effect Concentration (LOEC) values to NOEC equivalents using uncertainty factors. In Redondo-Hasselerharm et al. (2024) >NOEC values were used when the number of tested concentrations was greater than four. Furthermore, only Redondo-Hasselerharm et al. (2024) considered biological availability of microplastics. Here, the biologically available fraction was considered by defining species-specific ingestible particle size ranges.

Characteristics of the microplastics considered
Each of the three studies used particle (or item) numbers as the metric for their risk assessment (note that Redondo-Hasselerharm et al. (2024) recalculated particle numbers to bioavailable volumes and surface areas). While monitoring studies typically measure microplastics as particle numbers, effect studies often use mass as a metric, reporting effect concentrations expressed as mg per kg of soil. Jacques and Prosser (2021) and Tunali et al. (2023) dealt with this discrepancy by converting mass numbers from effect studies to particle numbers, provided that information on the density or composition of the microplastics was given. By contrast, Redondo-Hasselerharm et al. (2024) only used studies where effect thresholds were expressed as particle per kg of soil.

All studies took the size and shape of the particles into account. However, Jacques and Prosser (2021) and Tunali et al. (2023) only used these characteristics for mass-to-particle number conversions, whereas Redondo-Hasselerharm et al. (2024) used these characteristics for the alignment of exposure and effect data and for the assessment of bioavailability. With their alignment approach, only Redondo-Hasselerharm et al. (2024) provides a solution to the non-alignment of exposure and effect data (Figure 2). None of these three ecological risk assessments considered (effects of) polymer type or other plastic-associated chemicals in their risk assessment. Moreover, only Redondo-Hasselerharm et al. (2024) omitted data when effects were entirely caused by plastic-associated chemicals.

Risk assessment (MEC/PNEC)
Each choice is likely to affect the outcomes of the risk assessment. This may be demonstrated by results from Redondo-Hasselerharm et al. (2024), who also compared the HC_5 values from these three studies. The derived HC_5 values differ by several orders of magnitude across these three studies, with the HC_5 values of Redondo-Hasselerharm et al. (2024) being the highest. In part, these differences are likely to be the result of different input data (e.g. the used exposure and effect data both overlaps and varies) but the choices made to estimate risks may also affect the final risk estimate.

Despite the differences in derived effect threshold values (i.e. the HC_5 value), each of the three studies concluded that risks of microplastics to

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[3] >NOEC values are the highest test concentrations of an experiment where no effects were measured. In the paper by Tunali et al., these values are reported as ‘Highest Observed No Effect Concentration’ (HONEC).

the soil environment at current environmental concentrations cannot be excluded. Specifically, Tunali and colleagues found that in 4.8% of the global soils included in their assessment a risk existed (Tunali et al. 2023). Jacques and Prosser found that in 5% of soils considered in the study, 7% of the species may be negatively affected by the current concentrations of microplastics (Jacques and Prosser, 2021). Redondo-Hasselerharm and colleagues calculated risks per likely source of plastic contamination (Redondo-Hasselerharm et al., 2024). No risks were observed in soils where compost applications were the likely sources of microplastics. However, for all other sources considered in this study, risks were expected in 3 to 19% of cases, depending on the sources and the ecologically relevant metrics used.

In summary, each of the reviewed studies made specific choices to derive an estimate of ecological risks. The study by Redondo-Hasselerharm et al. (following the Koelmans approach) stands out in several key aspects: its approach to exposure corrections, its detailed quality scoring, and its efforts to align exposure and effect data (Redondo-Hasselerharm et al., 2024). The present report was commissioned specifically to evaluate the relevance and applicability of the Koelmans approach in a Dutch policy context. Nonetheless, this review provides support for the notion that, among the available ecological risk assessment approaches, the Koelmans approach represents the state of the art.

3 Evaluation of the Koelmans approach

This chapter provides an analysis of the Koelmans approach (Koelmans et al., 2020). It is divided into four parts: outcomes of a scientific consultation (3.1) and reflections thereon (3.2); observations from the application of the Koelmans approach in R (3.3); and, lastly, a description of how the Koelmans approach fits into national and international chemical regulations (3.4).

3.1 Scientific expert consultation

The approach by Koelmans et al. (2020) solves the non-alignment of data needed for a reliable and relevant environmental risk assessment. To this end, the approach makes several choices (see Chapter 2.3 and Appendix 2 for details). For the use of the approach in (science-based) policy-making (e.g. setting environmental quality standards or risk management measures), it is important that the approach is scientifically robust and accepted by the scientific community. One of the aims of the present study was to collect perspectives from the scientific community on methods of environmental risk assessment of microplastics in general, and on the approach of Koelmans in particular. To achieve this goal, two activities were carried out: 1) a questionnaire on environmental risk assessment of microplastics was distributed to scientific experts; and 2) a workshop was held on the topic of ecological risk assessment inviting scientific experts. The following sections summarise the key findings from both activities. This is followed by a reflection on the perspectives that were gathered in the course of these activities.

3.1.1 Questionnaire on ecological risk assessment of microplastics

The first activity was the preparation of a questionnaire consisting of 31 questions on the topic of ecological risk assessment. The questionnaire was circulated to a total of 35 scientific experts in Europe, North America, and Asia. The experts were selected from our network and covered fields such as ecotoxicology, exposure characterisation, ecotoxicological effect testing, and environmental regulation; they worked in academia, research institutes, or government. Most invited experts worked in academia or government. Fifteen responses were collected. The aim of the questionnaire was to gain insight into the key discussion points on the topic of methods of environmental risk assessment and to fuel the discussions of the follow-up workshop. The aggregated results of the questionnaire are provided in Appendix 1.2. Note that the questionnaire was not designed to provide a representative overview of perspectives from the entire scientific community working on microplastics. Given the relatively small number of participants and the non-exhaustive selection process, the collected data should be regarded as informative rather than as a complete overview.

The questionnaire showed that participants considered effects of plastic-associated chemicals to be just as important as particle effects of microplastics. Participants thought that both effects of plastic-associated chemicals and particles should be included in the ecological risk assessment of microplastics. Furthermore, according to the participants, the most pressing need for further development of the Koelmans approach is to gain a better understanding of the true mechanism of microplastic toxicity. Participants also expressed the opinion that microplastic size was the most important characteristic to include in an ecological risk assessment, closely followed by polymer type, plastic-associated chemicals, and shape of microplastics. Further details of the perspectives of the participating scientific experts are provided in Appendix 1.2. On the basis of both these findings and our own expertise on the topic, the subsequent workshop (see below) was partially focused on discussing the inclusion of the various effect types, understanding mechanisms of toxicity, and considering additional characteristics of microplastics.

3.1.2 *Scientific experts workshop*

The outcomes of the questionnaire were used to set the agenda and guide discussions of a follow-up workshop. For this workshop, we invited eleven scientific experts on the topic of environmental risk assessment of microplastics, eight of whom participated. Experts were selected on the basis of their expressed interest in the questionnaire and/or invited on the basis of their known expertise in the field. Experts' countries of residence were the Netherlands (2 experts), the United States of America (2), the United Kingdom (1), Slovenia (1), Belgium (1), Switzerland (1); and participants worked at universities (4), government (2) or a research organisation (2). An overview of main expertise provided by the participating experts is provided in Table 2.

Table 2 Aggregated overview of the expertise of participating experts selected by participating experts, based on a priori provided list of expertise.

Expertise[a]	Count
Soil science/ecology/ecotoxicology	5
Aquatic science/ecology/ecotoxicology	6
Environmental exposure characterisation	2
Environmental transport and fate	1
Environmental risk assessment	4
Modelling	2
Ecotoxicological effect testing	5
Environmental regulation	2

[a] The main expertise of participants was derived from the questionnaire results, where participants could select multiple expertise options, including 'other' (which was not selected by any expert). As for participants who did not participate in the questionnaire, their expertise was obtained via email.

The online three-hour workshop was hosted via the Microsoft Teams platform and was held under the Chatham House Rule, which means that participants could share the outcomes of discussions, but not who participated, nor who said what. The workshop was structured into three rounds in which the following topics were addressed:

1. Considering effects relating to (plastic-associated) chemicals;
2. Mechanism of toxicity and ecologically relevant metric;
3. Any other aspects.

A full summary of the workshop agenda and main findings is provided in Appendix 1.3. A summary of the perspectives collected during the workshop is provided below.

Please note that the following section summarises the perspectives expressed by the participants during the workshop and does not necessarily represent the view of the authors of the present report (or their organisations).

Regarding the topic of considering *plastic-associated chemicals in an environmental risk assessment*, the most important points argued by the participants were:

- The state of-the-art character of the Koelmans approach, as well as its novelty and ability to fill an existing gap in risk assessment was broadly acknowledged.
- There was broad support for an environmental risk assessment that only considers particle effects (see Appendix 1, Table A3).
- Experts noted that it is critical that the scope of a particle-based risk assessment is well communicated.
- Experts also agreed that, ideally, environmental risk assessments of microplastics should include both plastic-associated chemicals and particle effects.
- However, they noted that there is also an urgency to move forward and that it may be undesirable to postpone conducting an environmental risk assessment until the full complexity of microplastic pollution is covered.
- Whether or not (plastic-associated chemical) effects are important may be case-specific, and may depend on the type, source/application, and fate. Thus, a one-size-fits-all answer to the question whether chemical effects are relevant to consider may not exist.
- There are more than 10,000 plastic-associated chemicals. Thus, conducting a relevant risk assessment for chemical effects of microplastics represents a major challenge.
- It was suggested that one could apply a worst-case scenario to consider chemicals, such as the first-pass approach by the World Health Organization,[4] in which it is assumed that the most toxic chemicals in plastics are 100% absorbed by organisms.

Regarding the topics of the *mechanism of toxicity* and the *ecologically relevant metric*, the most important points argued by the participants were:

- It was considered (very) important to gain more knowledge on the mechanisms of toxicity before the approach can be used for formal environmental quality standards/risk limits.
- At the same time, participants acknowledged that setting a requirement to know the full mechanism of toxicity or adverse outcome pathways will limit the ability to conduct environmental risk assessment.
- The risk of underestimating the true risk of microplastics when the mechanism is not well understood was mentioned.

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[4] World Health Organization (2019)

- Reasons included that if another mechanism of toxicity (i.e. other than food dilution and translocation-related effects) is the most relevant, this would require a different approach or alignment procedure.
- Lack of data, especially for soil organisms, was mentioned as another reason why further studies on the mechanism of toxicity are needed.
- It was mentioned that the relative importance of different mechanisms is not well understood.
- Mechanism of toxicity are often assumed in studies but often not further explored.
- Finding a single mechanism of toxicity that applies to all cases may not be possible. The mechanism of toxicity may be dependent on specific plastics, environment, application, source, species, etcetera.
- Some participants expressed doubts as to whether food dilution is relevant in real environmental conditions at expected environmental concentrations.
- Some participants held that specific particle effects, such as fibre toxicity, cannot be captured by volume or surface area metrics, and thus are not considered in the Koelmans approach.
- A limited understanding of the linkage between a metric and an effect may be sufficient, without needing to know what exactly happens at every stage of the adverse outcome pathway.
- It was argued that ongoing analyses have shown that size and shape are typically the best predictors for toxicity, whereas polymer type is usually not an important feature. However, the underlying data from these studies did not contain much tyre wear data.

Lastly, the participants also argued more general points relating to the risk assessment of microplastics, including:
- Several opinions were expressed regarding the use of the Koelmans approach in policy-making. Views ranged from the approach being too premature for use in policy-making to the approach being usable if the scope and limitations are known and stated.
- Participants argued that, given the complexity of microplastic pollution, an approach that is ‘100%’ fit for purpose may not exist and that a first estimate of risk may be better than having no estimate at all. In this light, data requirements should not get in the way of obtaining a (first) estimate of risks.
- Some participants questioned whether we are being overly cautious or imposing stricter requirements for ecological risk assessment of microplastics compared to those typically applied to conventional chemicals.
- Policies cannot change every year. Thus, what is needed from science is different from what is needed from policy-making.
- Insights regarding risk (factors) may evolve over time. A risk assessment framework should be developed so that new insights can be incorporated.
- It was argued that for some plastic types (for example, biodegradable plastics and tyre wear particles) chemical characteristics cannot be ignored. Especially for tyre wear

particles, chemical effects may be much more important and should therefore be considered in a risk assessment.
- Participants argued that mixture effects (due to mixtures of particles, or interactive effects between particles and chemicals) are not well understood.
- Synergistic effects of pathogens may be important to consider.
- Nanoplastics should also be considered. Distribution data for submicron particles are needed to assess whether the power law approach also applies toto these smaller particles.
- Microplastics may cause indirect effects by changing soil properties.
- The microplastic size range is very wide. Within that size range, the most relevant mechanisms of toxicity may vary.
- There is a need for guidance on what particle sizes to use in environmental risk assessment. Changing the size ranges of an assessment can strongly impact the uncertainty of the estimate of the ecological risk assessment.

3.2 Reflections on outcomes of scientific consultation

In this section we would like to briefly reflect on two of the major points of discussion during the expert workshop: 1) considering effects of plastic-associated chemicals; and 2) understanding the mechanism of toxicity.

3.2.1 Effects of plastic-associated chemicals

The effects of plastic-associated chemicals was extensively discussed during the expert workshop. Experts agreed that ecological risk assessments of microplastics should include both plastic-associated chemicals and particle effects (see Appendix 1.3). We agree that plastic-associated chemicals are relevant to consider in ecological risk assessment. However, in our view, the ecological risk assessment of plastic-associated chemicals should be conducted separately from the assessment of particle effects of microplastics. Moreover, this assessment should be carried out comprehensively, which means that it should not be limited to assessing risks of plastic-associated chemicals via intake of microplastics, but rather should consider all relevant exposure routes. In the following paragraphs, we briefly elaborate on this perspective.

Plastic-associated chemicals can leach from plastics directly at any stage of the degradation pathway or be emitted during production or waste processing, where fluxes depend on the environment, the polymer or material type, and other factors. Over time, a dynamic equilibrium may be reached. Roughly, one may distinguish four routes of exposure by organisms to plastic-associated chemicals (see Figure 1):

1. A first route is the leaching of plastic-associated chemicals to the environment along the degradation pathway. In Figure 1, this route is represented by the grey box ‘a. Leaching of chemicals to the environment’.
2. A second route of exposure to plastic-associated chemicals is the route where microplastics are first taken up by an organism and where subsequent release of chemicals from the microplastics

cause effects. In Figure 1, this route is represented by the grey boxes ‘b. Particle uptake’ and ‘c. Chemical leaching after uptake’.

3. Third, a route that has received attention in media and research, is the vector-based pathway where microplastics adsorb chemicals from the environment resulting in potential exposure by organisms to these chemicals following intake of microplastics. In Figure 1, this route is represented by the grey box ‘d. Adsorption of chemicals from environment’.
4. Lastly, plastics may eventually degrade to form smaller polymers, oligomers, monomers, and other degradation byproducts (Pfohl et al., 2025), which, in turn, may cause toxic effects.

There is a substantial body of literature on the relevance of these various routes (Koelmans et al., 2022, 2016; World Health Organization, 2019). For example, various studies have concluded that the vector-based pathway is not relevant (Herzke et al., 2016; Koelmans et al., 2016) and that, in fact, due to their adsorption capacity, microplastics may reduce exposure to persistent organic pollutants (POPs) or hydrophobic organic compounds (HOCs) (Koelmans et al., 2013; Mohamed Nor et al., 2023). In some cases, the second route (i.e. leaching of plastic-associated chemicals from microplastics) may be relevant and alone could cause adverse effects in organisms, whereas in other cases this does not apply.

In either case, we argue that any focus on a single route of exposure to plastic-associated chemicals is incomplete and should be avoided. Instead, risks of plastic-associated chemicals should consider the total exposure to a given (group of) chemical(s) via all exposure routes. However, we do acknowledge the difficulties of conducting such an assessment, as there are more than ten thousand known plastic-associated chemicals. It is our belief that these challenges should be addressed in existing chemical-related regulatory frameworks, where assessments are preferably based on groups of similar chemicals rather than on individual chemicals, as this increases efficiency and can limit regrettable substitutions.

We also acknowledge that for some legislative or regulatory frameworks, it may still be relevant to consider the fate and transport of plastic-associated chemicals via macro-, micro- and nanoplastics in prospective risk assessment. The fate of these chemicals may be different from that of non-plastic-associated chemicals, due to their association with particles that move through the environment differently. Whether such considerations are sufficiently covered in existing legislative of regulatory frameworks is beyond the scope of this report and may require further study.

Lastly, a topic that may merit further consideration in research concerns the potentially toxic effects of polymers, oligomers, monomers, and other degradation byproducts (Pfohl et al., 2025). There is a substantial body of literature on the topic of fate and toxicity of these compounds (e.g. Groh et al., 2023; Shi et al., 2023; Wang et al., 2023; Yang et al., 2024; Yuan et al., 2022; Zhang et al., 2023)). Polymers have been exempt from registration in REACH legislation in the EU and, generally speaking, current understanding of toxicity and fate of these chemicals is limited compared to that of microplastics. Accordingly, more attention to polymers, oligomers and monomers may be required in order to get a complete picture of the environmental impacts of plastics.

3.2.2 *Mechanism of toxicity*

Next to plastic-associated chemicals, the mechanism of toxicity of microplastics was a key discussion point during the scientific expert workshop. In line with previous studies (De Ruijter et al., 2020), there was support among the scientific experts who participated in this study for food dilution and translocation-mediated effects as important mechanisms of toxicity. Yet, some experts also expressed the need for additional research on toxicity mechanisms before the Koelmans approach can be used in policy-making. At the same time, experts said that knowledge gaps should not get in the way of obtaining a first risk estimate. They did note that mechanisms other than food dilution or translocation-mediated effects might be more relevant and that the most relevant mechanism could vary, depending on species and compartment. Furthermore, they pointed out that more studies on terrestrial species need to be carried out to be able to determine these mechanisms of toxicity. It was stressed that if another mechanism proves to be more relevant, a metric relevant to that mechanism should be used. In the following paragraphs, we will briefly reflect on the views of the consulted scientific experts.

Identifying the true mechanisms of toxicity is complex and requires targeted studies. In many ecotoxicological studies, mechanisms of toxicity are often hypothesised but not definitively demonstrated. We know of one review by De Ruijter and colleagues, who explore what scientists believe to be the primary mechanisms of toxicity. However, it does not provide conclusive evidence that the assessed mechanisms are indeed the definitive cause for toxicity (De Ruijter et al., 2020). Understanding the mechanism(s) underlying toxicity is very important for any risk assessment, as it strengthens the scientific foundation and enhances confidence in the results. More specifically, knowledge on the mechanism of toxicity is key for risk assessment choices such as grouping approaches and mixture assessment.

However, in our view, a fully proven mechanism of toxicity is not strictly necessary to conduct a reliable ecological risk assessment for microplastics. It is more relevant to select a metric that best relates to observed ecotoxicological effects. This choice can be guided by conceptual understanding but is ideally supported by quantitative studies. Previous meta-analyses indicate that for aquatic species, volume and surface area are the best metrics for explaining effects of microplastics (Thornton Hampton et al., 2022a). However, similar analyses are currently lacking for terrestrial species. This means that there may be a different metric that best predicts the effects in terrestrial invertebrates, although, to our knowledge, there is no clear evidence that another metric is more relevant for terrestrial invertebrates. Still, it is crucial to address this gap to improve the accuracy and reliability of ecological risk assessment for terrestrial ecosystems. Selection of the metric should also be based on what is measurable and practical. For example, it may not be possible to measure volume, but particles can be counted, and their size can be measured in terms of length and width. Therefore, the selection of a metric for use in risk assessment should be guided not only by its toxicological relevance but also by this rationale of practicality.

If a risk assessor believes that there is too much uncertainty about which metric best explains effects (as may be the case for terrestrial organisms, for example), one solution is to conduct multiple parallel risk assessments using different metrics, as has also been done in various applications of the Koelmans approach (Coffin et al., 2022b; Koelmans et al., 2023; Redondo-Hasselerharm et al., 2024). To be conservative, one could choose the assessment with the highest risk ratio. In our view, a limited understanding of the true mechanisms of toxicity of microplastics (if such limitations indeed exist) should not prevent the derivation of a risk estimate, as some participants of the scientific expert workshop stressed as well. This is particularly important, given the societal and policy demand for answers regarding the risks of microplastics. Rather, a precautionary approach involving parallel assessments with multiple metrics is advisable.

3.3 Observations from applying the Koelmans approach

The expert consultation conducted in this study indicates that the Koelmans approach is broadly accepted at a conceptual level. This aligns with findings from a previous expert elicitation study (Mehinto et al., 2022). It is important to note that the scientific consultation conducted as part of this study focused primarily on the conceptual framework of the approach. However, it is also crucial to understand the details of the calculations and the relationship between uncertainty in the various inputs and the outcome in order to advise on its application in the regulatory domain. A start of such an analysis is being made here, but more robust uncertainty analysis is required.

3.3.1 *Replication in R*

In order to fully understand the details of the Koelmans approach, the main activity was to reprogramme the approach in R (R Core Team, 2024) following the steps as described in Chapter 2.3 and Appendix 2.1. To this end, we replicated the exposure-effect alignment using data from the study by Redondo-Hasselerharm et al. (2024) in which the Koelmans approach was applied to the soil ecosystem. Our starting point was a Microsoft Excel spreadsheet that the authors provided. Also, R scripts from the authors of Mehinto et al. (2022) and Kooi et al. (2021) were a helpful contribution to this activity. Further details are provided in Appendix 2.1.

In part, the replication in R was conducted as a means of verifying the approach. Such replication exercises are particularly important for novel analyses like the Koelmans approach. This relevance is highlighted by the identification and subsequent correction of a mistake in the original analysis by Redondo-Hasselerharm et al. (2024). The mistake related to the calculation of the upper and lower size limits of bioavailable particles, which are used to derive the mean ecologically relevant metric in environment and effect studies (see Appendix 2.1, Equation 4).[5] Our

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[5] The authors of Redondo-Hasselerharm et al. (2024) are aware of the mistake which will be corrected in a forthcoming publication.

replication successfully reproduced the exposure-effect alignment by Redondo-Hasselerharm et al. (2024), confirming the accuracy of the conversion from the original Excel sheet to the R script.

At the time of writing this report, the R scripts that were created for this exercise are draft versions. The R scripts will be made publicly available once the scripts have been finalised, reviewed and tidied up. Until then, the R scripts will only be shared upon request.

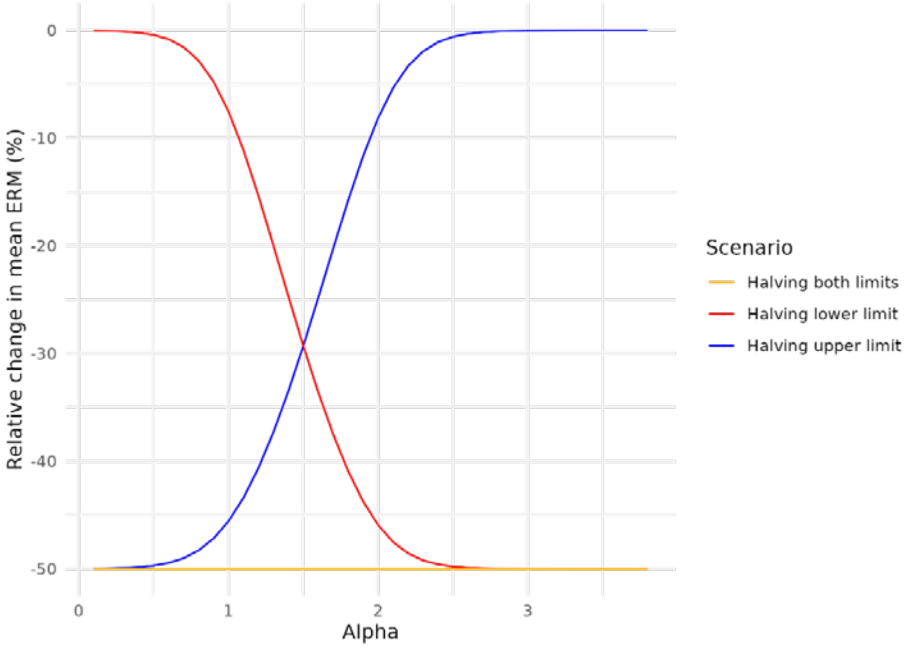
3.3.2 *Impact of changing upper and lower limits*

In the Koelmans approach, alignment of exposure and effect data is based on the calculation of the mean ecologically relevant metric. To calculate this mean value, one needs to define the particle size distribution. In this case, a power law distribution is applied, defining the slope, commonly abbreviated by the alpha value, and the upper and lower size limits as relevant to a particular analysis. For example, these values are based on the defined bioavailability of microplastics. Bioavailability can be done in different ways. Mehinto et al. (2022) do this differently from Redondo-Hasselerharm et al. (2024) and accordingly set different upper and lower size limits.

To further understand the effect of particle shape and size assumptions we performed a set of calculations where we changed the upper and lower limits at different alpha values. Figure 6 and Figure A2.6 (Appendix 2.2) show that changing the upper limit has a greater impact on the mean ecologically relevant metric at lower alpha values, whereas changing the lower limits has a greater impact on the mean ecologically relevant metric at higher alpha values (steeper slopes of the power law distribution).

In the Koelmans approach, ecologically relevant metrics are calculated for effect studies and for exposure studies separately. In the study by Redondo-Hasselerharm et al. (2024) for effect studies, when the tested particles are polydisperse, the actual power law slope of the tested particles is used if this can be derived from the data from the original effect study. If this is not possible, due to unavailability of reported data, a hypothetical power law distribution slope may be presumed. For instance, in such cases, Redondo-Hasselerharm et al. (2024) used a power law slope of 2.5 with a wide error margin (± 0.25) in order to conduct the exposure-effect alignment. The authors based this on the observation that the distributions of microplastics as found in the environment are typically described by power law slopes ranging between 2 and 3. In Redondo-Hasselerharm et al. (2024), for exposure data, the slope is fitted on the basis of a microplastic source-specific default value, which, in turn, is based on the global distribution of microplastics in soils with different microplastic sources. For context, the power law slopes used in Redondo-Hasselerharm et al. (2024) for length, volume and surface area fall within the range where the mean ecologically relevant metric is sensitive to changes in the upper and lower limit.

Figure 6 The influence of halving the upper and lower size limits of a measurement on the mean ecologically relevant metric at a range of alpha values.



The blue and red line show the effect of the upper and lower limit, respectively, whereas the yellow line shows the combination of halving both limits simultaneously. The plot shows that the influence of changes to the lower or upper limit on the mean ecologically relevant metric varies depending on the power law slope (alpha). Appendix 2.2, Figure A2.6 provides a more detailed overview of the (absolute and relative) impact of changing upper and lower limits along a gradient of alpha values.

If one changes the upper limit, for example, because one wants to make a different assumption about which particles are bioavailable, this changes the mean ecologically relevant metric on the exposure and effect side, but not necessarily in the same way on both sides. This is because, depending on the case, one either changes the numerator or denominator of a given step of the approach (see Step 4 and Equation A2.5 in Appendix 2.1). This formula results in a non-linear relationship between the impact of changing the limits on the mean ecologically relevant metric and the power law slope (Figure 6). Figure A2.7 in Appendix 2.2 provides a more detailed overview of the (absolute and relative) impact of changing upper and lower limits along a gradient of alpha values. Accordingly, changes in the calculation of the mean ecologically relevant metric may result in an impact on the final risk estimate. These relationships between input uncertainty and variation in outcomes need to be well understood in order to apply the approach for policy advice. One can imagine advising more stringent requirements for the accuracy of certain parameters when the policy actions are also more stringent.

In summary, we were able to reproduce the effect alignment of Redondo-Hasselerharm et al. (2024) using R. The choices made in the effect-exposure alignment may affect the final risk estimate. Therefore, it is important to clearly report the choices made, support them by means of relevant evidence where possible, and investigate the implications of these choices. Further studies should focus on improving our understanding of how such choices influence the final outcomes of risk assessments.

3.4 How does the Koelmans approach fit into national and international chemical regulations?

Risk assessment of chemicals is performed in several national and international regulatory and policy frameworks concerning, among others, market authorisation, emission control and permitting, and protection of soil and water quality in general. Some of these involve retrospective assessments based on monitoring data or measured environmental concentrations (MEC), others involve prospective risk assessments based on modelled emissions and predicted environmental concentrations (PEC), or a mix in which an initial assessment based on generic models may be refined with actual environmental data. Generally speaking, ecological risk assessment is, thus, based on the comparison of predicted or measured environmental concentrations with risk limits.

The Koelmans approach fits into this generic concept of risk assessment. The major advantage is that it accounts for the unmeasured microplastic fraction, it considers bioavailability and it aligns exposure and effect so that they can be compared in a meaningful way. Thus, it overcomes the problem of insufficient quantification methods often encountered in microplastic monitoring. Bioavailability corrections are commonly accepted in soil and water quality assessment, for example, by discriminating between dissolved and bound fractions for organic chemicals, or implementing relationships between soil and water characteristics and toxicity with regard to metals. In this sense, there are parallels between the Koelmans approach and other established regulatory and scientifically accepted methods for (ecological) risk assessment. However, the specific corrections relating to bioavailability correction and exposure and effect alignment are, of course, novel and may require further critical evaluation to ensure robustness and validity before they are used in policy-making.

Retrospective risk assessment
Generally, the approach is particularly well-suited to retrospective risk assessment, the objective of which is to evaluate the risks associated with existing environmental microplastic pollution. This is, in fact, how the approach has been applied in the scientific literature so far. However, it is important to note that, by design, the Koelmans approach does not cover all potential effect types. For example, it does not include effects of plastic-associated chemicals, or pathogen-related effects (see Figure 1). Furthermore, human health risks are often critical in chemical regulation. Although the principles of the approach can also be applied to human health risk assessments (Koelmans et al., 2020; Mohammed Nor et al., 2021), so far, due to limitations in available data on human health (World Health Organization, 2022), the approach has only been applied to assessing impacts of microplastics on ecosystems. Thus, this gap of knowledge on human health effects and exposure to microplastics prevents making policy decisions regarding microplastics on the basis of human health risks.

Nonetheless, local environmental managers who have access to measurement data should be able to use the Koelmans approach to estimate whether local ecosystems are at risk from the particle effects of microplastics, provided that exposure data is fit for purpose (e.g. based on particle number data, in addition to other criteria, see Chapter 4.2 for further elaborations). Note that the implementation (e.g. various alignments steps) does require expert knowledge, which may restrict the practical applicability by non-experts.

Prospective risk assessment
Due to the diversity in size, shapes, and weathering status and to the changes they undergo over time, it is challenging to derive generic risk limits for microplastics and/or to derive model-based PECs. Indeed, the distributions of microplastics vary significantly depending on their environment. For instance, the slopes of power law distributions describing microplastic concentrations may differ across aquatic compartments (Kooi et al., 2021) or per source of microplastics in soils (Redondo-Hasselerharm et al., 2024).

Thus, in order to apply this approach in prospective risk assessment, it would be necessary to define an expected distribution of microplastics across the environment a priori and use it as the basis for aligning exposure and effect data. There may be various options to resolve this. One option could assume a single generic distribution of microplastics, or, alternatively, define multiple environment-specific distributions that could be adjusted to be more or less conservative, with the addition of safety factors, where necessary, to account for uncertainties. Existing applications of the Koelmans approach (e.g. Redondo-Hasselerharm et al., 2024 and Kooi et al., 2021) provide a basis for setting such a default expected distribution. In their work, the authors define distribution parameters for four soil types on the basis of four likely sources of microplastics in the environment. These distributions were then applied to other soils of the same soil type to derive risk estimates (Redondo-Hasselerharm et al., 2024). If default distributions of microplastics are to be used in prospective risk assessment, it is essential to carefully consider how to implement them. Such default values should avoid being overly conservative, or too lenient for that matter, and should take practical applications and considerations into account. Additionally, it is important to clearly identify and understand where uncertainties lie.

In some cases of prospective risk assessment, practical challenges may also arise when applying the Koelmans approach. For instance, in the Netherlands, the relocation of soil and dredge materials is regulated by ‘Besluit Bodemkwaliteit’ en ‘Regeling bodemkwaliteit’, which is based on environmental quality standards set for various applications. These environmental quality standards are particularly important in the Netherlands, where large volumes of dredged materials are relocated every year. The contamination levels of these materials determine where they can be moved, and under what conditions, and in that sense, they can be considered prospective risk assessments. Even if default thresholds based on generic assumptions of microplastic distributions were available, it would be necessary to perform site-specific exposure assessments to make a meaningful comparison to the set thresholds. Given the number of cases, the vast volume of dredge, soils and other materials being moved each year, this may present practical challenges to environmental managers.

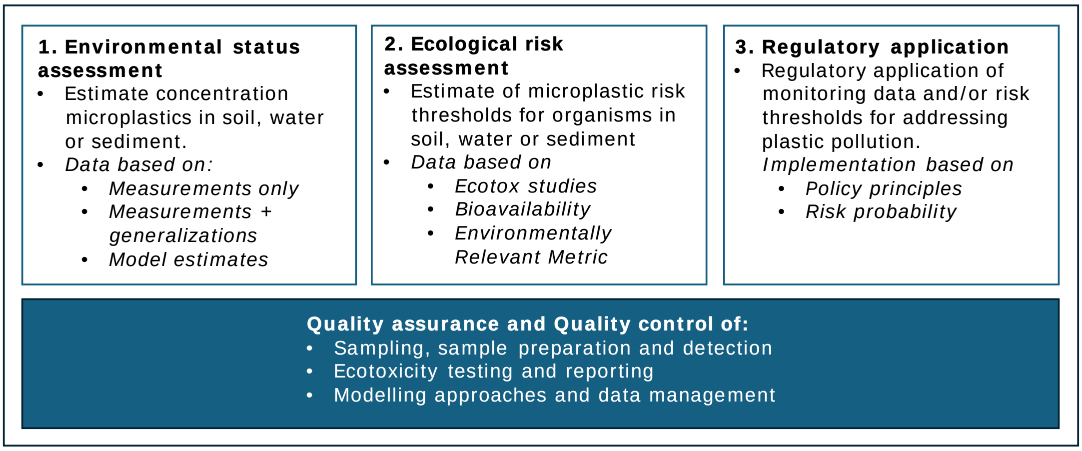
In summary, the Koelmans approach aligns with established risk assessment methods. It is particularly suited to retrospective risk assessment of existing microplastic pollution. However, due to the lack of human health-relevant data for microplastics, at present, risk assessments can only be based on ecosystem impacts. Furthermore, its use requires specific expertise, which, for the moment, may restrict its practical applicability. For prospective risk assessments, challenges arise from the diversity and variability of microplastics in size, shape, and distribution across environments. Implementation of the approach for this purpose requires defining default microplastic distributions. Existing studies provide a basis for such approaches, although further particular development is required.

4 Framework for ecological risk assessment of microplastics for regulatory purposes

In subchapter 4.1, we outline a framework for applying ecological risk assessment of microplastics in the policy domain. In the next subchapter (4.2), we discuss several key developmental needs relating to the implementation of the framework in a policy context.

4.1 Ecological risk assessment in support of microplastics policy

Figure 7 Illustration of the three steps that would make up a framework for linking regulatory action to risk assessment of microplastics in the environment.



1. Environmental status assessment
- Estimate concentration microplastics in soil, water or sediment.
- *Data based on:*
  - *Measurements only*
  - *Measurements + generalizations*
  - *Model estimates*

2. Ecological risk assessment
- Estimate of microplastic risk thresholds for organisms in soil, water or sediment
- *Data based on*
  - *Ecotox studies*
  - *Bioavailability*
  - *Environmentally Relevant Metric*

3. Regulatory application
- Regulatory application of monitoring data and/or risk thresholds for addressing plastic pollution.

Implementation based on
  - *Policy principles*
  - *Risk probability*

Quality assurance and Quality control of:
- Sampling, sample preparation and detection
- Ecotoxicity testing and reporting
- Modelling approaches and data management

This chapter proposes a framework for regulatory action on the basis of ecological risk assessment of microplastics. The scope of this framework is based on the particle-related effects of microplastics. Further efforts are required to broaden the framework to encompass the chemical and microbiological risks of microplastics and human health risks, should such an expansion be deemed desirable. It can also be argued that assessing human health risks and ecological risks of plastic-associated chemicals or microbiological hazards can be carried out in parallel, using existing policy instruments designed to address chemical pollution or microbiological hazards.

This framework consists of three parts (Figure 7):
1. Assessment of the environmental status based on estimating environmental concentrations of microplastics.
2. Ecological risk assessment in order to quantify the environmental impact of microplastics.
3. Regulatory applications of assessments based on specific policy principles and risk probabilities.

Because conducting these three steps for microplastics is relatively novel, specific attention is required to understanding the quality of the data being used. As such, the approach would only work if data were acquired using sufficient quality assurance and control measures.

4.1.1 *Environmental status – estimating microplastic concentration*

A first step towards risk assessment supporting regulatory action is assessing the general environmental status (e.g. of the Netherlands, or of a specific region or location). Depending on the purpose of the assessment, this environmental status is based solely on measured microplastic concentrations in soil, sediment or water[6] or combined with model estimates. For the purpose of risk assessment (step 2), these concentrations are used to assess the exposure on the basis of measured or predicted environment concentrations (MECs/PECs).

For deriving MECs/PECs, first, a clear definition of microplastic is needed to ensure a standardised, comparable quantification. This could be based on the definition used for polymer microparticles, as defined under the REACH restriction (EC, 2023b). As microplastics consist of several polymers and materials, it is important to clearly state the scope of the assessment, for example, which part of the microplastics domain is covered by the measurements.

Environmental concentrations of microplastics can be estimated using concentrations on the basis of (i) particle number measurements (counting) where one also determines shape and polymer type, (ii) mass measurements combined with measurements or estimates of the particle size distribution, shape and density or (iii) model estimates using emission, and fate modelling.

The Koelmans approach allows for the assessment of risk based on microplastic particle number concentrations. Using mass and emission-based concentrations may be feasible, but this would require additional methodological development in order to align such measurements to the Koelmans approach and to demonstrate the robustness of the resulting risk assessment (see also 4.2.1).

Part of assessing the environmental status is to identify which sites to assess (i.e. where to monitor or predict?). If one wants assessment of the nationwide status of the environment with regard to microplastic contamination, this would require a stratified sampling approach that covers most relevant soil types and land uses. One could also choose to focus environmental status assessment on expected (local) hotspots of microplastic pollution.

Currently, the environmental status, as relevant for risk assessment using the Koelmans approach, can be assessed using particle number measurements for particles with a length and width larger than 1 µm. Other extensions of the approach require further testing and method development (Table 3 and 4.2.1).

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[6] Air is only excluded because ecological thresholds are not commonly derived for the air compartment.

Table 3 The state of the art and further needs per component of proposed ecological risk assessment framework for microplastics for use in policy.

Component	State of the art	What needs development?
Environmental status assessment	- Measure particle number concentrations for alignment, e.g. using FTIR. - Apply to microplastics larger than 1 µm in any one dimension of different shapes.	- Extension to particles smaller than 1 µm. - Approach for aligning mass-based concentration measurements, e.g. using pyrolysis-GC-MS. - Model approach to link aligned risk limit to emission estimates.
Ecological Risk Assessment	- Use of ecotoxicity data, mostly of lower quality (monodisperse size distributions and limited variability in polymer types and shapes), from databases available already (e.g. ToMEx). - Align environmental concentrations to SSD-based risk thresholds on the basis of the Koelmans approach.	- Creating overview of the minimum data requirements and related assumptions and choices in deriving the aligned risk thresholds for linking to risk management options (e.g. sensitivity analysis). - Further consensus building based on deriving (indicative) thresholds for specific environmental regulations. - Updating thresholds on the basis of new ecotoxicity data based on assessment of quality.
Regulatory application	- Create overview of the probability that environmental concentrations exceed risk thresholds in order to support further policy development. This should be done retrospectively on the basis of measurement data and prospectively, e.g. based on the future estimates.	- Deriving risk limits for microplastics in soil, sediment and water for use in existing policies and regulations. - Creating an approach to derive emission limits on the basis of risk thresholds, as required by existing environmental policies and regulations.
Quality assurance and Quality control	- Provide QA/QC screening results of applied data and protocols on the basis of e.g. Brander et al. 2020; De Ruijter et al. 2020; Redondo-Hasselerharm et al., 2024. - Expand curated data sets to include more high-quality studies (performing studies and curating studies).	- Creating standardised test guidelines (e.g. within OECD, ISO, NEN, relevant scientific societies). - Creating guidance documents for exposure, effect and risk assessment of microplastics.

ISO, International Standardization Organization; OECD, Organisation for Economic Cooperation and Development; NEN, Stichting Koninklijk Nederlands Normalisatie Instituut.

4.1.2 Ecological risk assessment

A next step would be the ecological risk assessment of microplastics based on the Koelmans approach, following the steps as described in Chapter 3.3 and Appendix 2.1. The approach can be applied to measured environmental concentrations in soil, sediment and water, and it can be applied at local scale to inform local policy decisions. The approach can also be applied at a larger scale (e.g. nationwide) to assess the overall distribution of microplastic risks across different locations and environmental compartments.

Effect data

For an accurate ecological risk assessment, one needs high-quality ecotoxicity studies to derive a species sensitivity distribution which can be used to derive a risk limit. A curated set of effect studies is made available by the ToMEx tool[7] (Thornton Hampton et al., 2022b). However, most data from past ecotoxicity studies does not match all the quality criteria deemed relevant for ecological risk assessment (De Ruijter et al., 2020; Redondo-Hasselerharm et al., 2024). This leaves two options: either exclude studies of limited quality, which may result in inability to derive a risk estimate, or include studies of limited quality to derive a risk estimate and accept that the use of such data may reduce the accuracy of the outcome. Which option one chooses depends on the reason behind conducting a risk assessment.

As more effect studies take into account these criteria, it is expected that a sufficient number of high-quality studies will become available in the years to come. This should allow for an accurate estimation of ecological risks in multiple environmental compartments. In the near future, it is expected that more data will be available as part of the forthcoming 2.0 update of the ToMEx tool.

Alignment

The eventual aligned risk assessment can be conducted on the basis of deriving the aligned risk threshold using the size and shape distribution of the estimated environmental microplastic concentration as representative of the environmental status (Step 1 in Figure 7). This means that a location- or case-specific threshold can be derived using size and shape data from the environmental status assessment. Further work is needed in order to derive a general threshold that would be protective of all locations and microplastic sources.

As this encompasses several interconnected choices regarding, for instance, applied size distributions, size ranges based on measurement technique, and organism bioavailability characteristics, an overview of the relative impact of each choice on risk thresholds needs to be made. This overview can then be used to develop and gather support for an approach used for deriving more generalised thresholds, which can be more easily used in specific environmental policies and regulations. One example of such standardised thresholds based on ecological risk assessment using the Koelmans approach is presented in Mehinto et al. (2022) and forms part of ongoing work. In the paper by Mehinto and co-workers, a tiered approach is suggested, proposing four separate thresholds on the basis of an increasing level of confidence in potential ecological effects. This cannot be directly translated into other environmental regulations in place in, for instance, the Netherlands, because thresholds for microplastics should reflect the desired protection level which may differ across various policy frameworks.

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[7] https://sccwrp.shinyapps.io/aq_mp_tox_shiny/

Currently ecological risk assessments can be conducted using ecotoxicity data from the past, which has limited quality, but is still relevant because of the several assumptions and alignments that are part of the Koelmans approach. Further work is needed in order to derive more generalised risk thresholds and gather ecotoxicity data of higher quality (see Table 3 and section 4.2.2).

4.1.3 Regulatory application

The policymakers' needs identified in this study (see Chapter 2.1 and Appendix 1.1) make it is clear that each indicated need requires a different type of implementation of the environmental risk assessment approach. In part, this stems from the different applications of ecological risk assessment in different regulations. The basic application of ecological risk assessment is to assess the probability that environmental concentrations of a pollutant exceed risk thresholds for that pollutant. Such an application of ecological risk assessment based on the Koelmans approach is already possible (Table 3). This type of assessment can be used to prioritise certain mitigation measures and to get an overview of the degree of microplastic pollution in the Netherlands and Europe, now and in the future. To this end, the ecological risk assessment using the Koelmans approach can be applied retrospectively on the basis of existing microplastic measurements, and prospectively on the basis of estimates of future microplastic concentrations, making use of different policy scenarios.

For other environmental regulations that are based on environmental quality standards, additional work is needed in order to accommodate microplastics. For instance, in the Dutch 'Soil Quality Decree' ('Besluit bodemkwaliteit' in Dutch), thresholds are used to decide on safety for various (soil) applications. There are thresholds for various substances, which are set on the basis of standardised approaches for human and ecological risk assessment. For example, in the Netherlands, a generic methodology for setting (indicate) risk limits for emerging substances without environmental quality standards and little exposure and toxicity information is in development (in Dutch: Algemene Methodiek voor Niet-genormeerde Stoffen, AMNS) (IenW, 2023b). While the general ecological risk assessment of microplastics using the Koelmans approach can be standardised on the basis of some further analysis, it is a policy decision whether environmental quality standards for specific regulations should be derived. In future, it will be possible to derive and apply environmental quality standards for microplastics for specific regulations (e.g. soil/water), provided the above-mentioned approaches as described under step 2 are developed and sufficient data is available (Table 3).

To derive environmental quality standards, existing tools and models can be extended to take microplastics (direct particle effects, Figure 1) into account. Existing tools used for assessing emissions or deriving emission limits need to be extended to accommodate the specifics of microplastic fate and behaviour in the environment, such as the models on which the Dutch 'Immissietoets' (IenW, 2019) is based, for example, using approaches from SimpleBox4Plastics (Quik et al., 2023). Other tools commonly applied in operationalisations of environmental policies should also be extended to accommodate the specifics of assessing microplastics, such as the '*risicotoolbox bodem*'[8] and others.

4.1.4 *Quality assurance and quality control*

One current shortcoming of many microplastic studies is the lack of insight into their robustness and quality. In part, this related to the lack of clear quality criteria and standardised approaches to estimate environmental concentrations, perform ecotoxicity studies, or perform risk assessments. As such, experts are relatively confident of the environmental risk assessment based on the Koelmans approach, but less so about the actually derived threshold values (Mehinto et al., 2022).

Currently, quality criteria are being proposed for performing effect studies (de Ruijter et al., 2020) and measuring environmental concentrations (Brander et al., 2020; Koelmans et al., 2019; Redondo-Hasselerharm et al., 2024), which can already be applied to at least reports on the quality of studies included in an environmental risk assessment.

Another important aspect that can facilitate and speed up derivation of risk-based thresholds is the development of curated and accessible databases, such as the ToMEx database. Extending these databases to include (high quality) studies when they become available should remain a priority for researchers and regulatory agencies worldwide. However, efficient and relevant data collection also requires the use of standardised and widely accepted protocols. For this reason, organisations such as OECD, ISO and CEN/NEN, as well as dedicated scientific societies (such as the Society of Environmental Toxicology and Chemistry) have developed a wide range of specific test guidelines and guidance documents for the environmental risk assessment domain. For microplastics, it is clear that adaptations to existing guidance documents are needed due to the unique characteristics of these materials compared to conventional chemicals. Lessons can be learned from similar efforts in nanomaterial risk assessment. In recent years, significant progress has been made in adapting test guidelines and guidance documents for nanomaterials (Bleeker et al., 2023; Quik et al., 2020). There is a need for similar initiatives focusing on protocol standardisation and harmonisation for microplastics to support science-based policy action addressing microplastic pollution.

4.2 Further scientific needs

Building on the above framework in this chapter, we would like to discuss three aspects that require further (scientific) development going forward to regulatory action on microplastic pollution. These are specific needs for improving exposure and effect data and understanding and communicating uncertainties.

4.2.1 *Exposure data*

In our view, ecological risk assessment of microplastics should ideally be based on methods that can capture particle number and shape distributions. This is feasible through µ-FTIR or SEM-EDX methods,

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[8] https://www.risicotoolboxbodem.nl/

which can provide information on particle size morphology as well as determine polymer types. However, the downside of this approach is that it is relatively time-consuming where detecting smaller particle sizes is concerned. Alternatively, microplastic concentrations may be estimated using mass-based approaches (e.g. pyrolysis-GC-MS-based), which are indirect techniques detecting polymer breakdown products. The challenge regarding mass-based data for risk assessment is that it does not capture the full variability of microplastic characteristics relevant to alignment, such as size and shape. Mass-based quantification methods are still under development and may lead to over- or underestimation of microplastic concentrations (Brits et al., 2024). However, it should be noted that similar over- or underestimation may occur when using FTIR, for instance, albeit for different reasons.

While it is technically possible to convert mass-based data into particle number data (as done by, among others, Tunali et al., 2023), such conversions introduce additional uncertainties due to the assumptions made about particle size, shape, and density distributions. We argue that mass-based data should only be used when accompanied by some form of size binning, such as size fractionation of microplastics. Furthermore, as holds true for any analysis method, it should be demonstrated that sampling methods , sample preparation and detection/quantification are robust and limitations are clearly reported (e.g. demonstrated absences of polymer contamination and of interferences from other molecules/materials present in the matrix). These steps are essential to ensuring the ecological relevance and reliability of the data for risk assessment.

Next, regarding exposure data for nanoplastics, it is clear that, compared to microplastics, data about the presence, distribution, fate and transport of nanoplastics is significantly more limited. This can be attributed to the technical challenges regarding detecting and characterising particles at such small scales (SAPEA, 2019). Broadly speaking, there are two ways of handling a lack of data: one could either exclude nano-scale data altogether or use models to estimate missing size ranges. However, both options may introduce additional and unknown uncertainties to the risk assessment. In existing applications of the Koelmans approach, nano-size ranges were excluded. This is a defensible approach, provided that the limited scope of the assessment is stated clearly. Nanoplastics may not contribute much to the total volume of micro- and nanoplastics in any given sample, although they would contribute to the total surface area or particle number. Thus, when volume is used as an ecologically relevant metric, excluding nanoplastics may have a relatively limited impact on the risk estimate. However, this may be different when surface area is used as the ecologically relevant metric. As particles decrease in size, the surface area-to-volume ratio increases. Consequently, the ecological risk estimate based on surface area may be more significantly affected by the inclusion of nanoplastics. Furthermore, material physico-chemical analyses show that formation of nanosized fragments might be limited, showing an optimum microplastic formation size between 0.3 to 200 µm, based on polymer type and formation mechanism (Boersma et al., 2023; Grigoriadi et al., 2023). This supports the applicability of the current approach as applied to microplastics larger than 1 µm in length. In either case, there is a clear need to fill gaps in knowledge on presence in and size distribution of nanoplastics across the environment. Filling this gap will help refine and strengthen risk assessments relating to these small (< 1 µm) yet potentially impactful particles.

4.2.2 *Effect data*

Next, we would like to briefly discuss two topics relating to effect data that, in our view, are important to consider in the light of increasing the relevance and reliability of ecological risk assessments: 1) the use of higher than (>) NOEC data; and 2) the use of environmentally relevant microplastics and weathered microplastics in ecotoxicity testing.
We acknowledge that there are many other issues relating to the reliability and relevance of effect (and exposure) data. These have been addressed in other publications (e.g. de Ruijter et al., 2020).

First, microplastics are generally not highly toxic to organisms, and in many ecotoxicological studies, it takes high concentrations (sometimes exceeding 1% m/m) to see adverse effects. As a result, many studies fail to identify a significant effect even at the highest tested concentration. For example, nineteen out of fifty effect thresholds in Redondo-Hasselerharm et al. (2024) are >NOEC values. This presents a challenge for the ecological risk assessment. To address this, existing ecological risk assessments have used the highest tested concentrations at which no effects have been observed (i.e. the >NOEC value). Ideally, these values should only be used when no other data on a given species is available (RIVM, 2024). Relying on >NOEC values as proxies for effect thresholds results in ecological risk assessment being conservative, i.e. the predicted risks may be higher than the actual risks. Whilst this may not pose an issue if the risk assessment predicts no ecological risks, it becomes problematic when risks are predicted: in such cases, it remains unclear whether populations are truly at risk from exposure or truly protected. To improve the reliability of ecological risk assessments, ecotoxicological tests should (aim to) include test concentrations that are expected to cause adverse effects. This data, showing clear effect thresholds, is the most relevant for ecological risk assessments.

Second, the need for alignment of exposure and effect arises from the fact that most ecotoxicity studies have been conducted using monodisperse microplastics, typically involving only a few polymer types (Cui et al., 2024). There has been a growing effort to address this issue by conducting ecotoxicological tests that use a more environmentally relevant mixture of different sizes, shapes and types of microplastics (e.g. De Ruijter et al., 2023; Martínez-Pérez et al., 2024). While these studies are an important step forward, the particles used in these experiments may still not perfectly reflect the full complexity of environmental microplastics. Consequently, alignment of exposure and effect data is still required. Using more realistic mixtures may, however, reduce uncertainties in the alignment step.

Furthermore, ecotoxicological studies to date have used pristine, non-weathered microplastics (Alimi et al., 2022). These pristine microplastics often include additional chemicals, apart from the base polymers. Notably, studies have demonstrated that the leachate from pristine microplastics can induce toxicity (Boháčková and Cajthaml, 2024; Martínez-Pérez et al., 2024). On the other hand, laboratory-produced microplastics used in ecotoxicity tests may lack many of the functional additives, such as flame retardants and UV filters, that are incorporated into real-world plastic products. As such, the goal is to distinguish between the effects of plastic-associated chemicals and the direct particle effects. It should also be noted that organisms in the environment are primarily exposed to weathered microplastics, from which chemical additives have (partly) leached.

Nevertheless, in ecotoxicity studies using pristine microplastics, the observed toxicity may be (partly) driven by chemical additives. This could result in overly conservative effect thresholds. Indeed, studies show that the predicted no effect concentration of weathered microplastics in aquatic organisms may be eighty times higher than with pristine microplastics, which means that weathered microplastics are much less toxic than pristine microplastics (Cui et al., 2024). Similar to the use of >NOEC values, this may not be an issue if a risk assessment predicts no ecological risk. However, when risks are predicted, it remains unclear whether populations are truly at risk from exposure to microplastics or adequately protected.

To achieve more accurate risk estimates, one approach could be to exclude studies that did not include a leaching step. Such exclusion was done in the ecological risk assessment for sediments by Redondo-Hasselerharm et al. (2023) following the QA/QC procedure from De Ruijter et al. (2020). However, the feasibility of this approach depends on the availability of reliable and relevant data. For instance, in their ecological risk assessment of microplastics in terrestrial environments, Redondo-Hasselerharm and colleagues only excluded studies when it was explicitly demonstrated that the observed effects of microplastics were entirely attributed to chemical leaching rather than to the physical particle properties. This less-selective approach was necessary due to the limited availability of suitable data for comparison purposes.

Using more relevant microplastic mixtures, in terms of sizes, shapes, polymer types and weathering state, is likely to yield more reliable effect thresholds. We would like to stress the need for more studies that use these environmentally relevant particles to improve the relevance and reliability of ecological risk assessments (Alimi et al., 2022; De Ruijter et al., 2025a, 2025b).

4.2.3 *Understanding uncertainties*

One of the aims of this study was to assess the applicability of the Koelmans approach for ecological risk assessment of microplastics. As the approach includes many parameters and assumptions for coping with limitations of available data, there is a need for a better understanding of the minimum data requirements. This can be achieved by conducting a sensitivity and uncertainty analysis. Mehinto and colleagues conducted a sensitivity analysis to assess the impact of the alignment method, selected endpoints and individual studies on the effect threshold values (Mehinto et al., 2022). The study by Mehinto and co-workers demonstrates that some parameters (e.g. assumptions on bioavailability and parameters for estimating environmental microplastic polydispersity distribution) can have moderate impacts on the outcomes of the assessment. Choices surrounding the estimation of these parameters should be clear and based on scientific consensus, especially when the approach is used to inform policy decisions. Follow-up studies are needed to further the consensus building for specifics in the application of the Koelmans approach in regulatory context. In addition to further uncertainty and sensitivity analysis, this includes the applicability of probabilistic risk assessment outcomes and quality control and assurance of the risk assessment itself.

5 Conclusions and recommendations

This study aimed (i) to evaluate the applicability of the Koelmans approach for environmental risk assessment of microplastics for regulatory purposes, (ii) to assess the support for this approach among the scientific community, and (iii) to describe a framework for using ecological risk assessment of microplastics within the Dutch policy context. This study is a first step towards including particle effects from microplastics in reducing environmental pollution. In this chapter, the main conclusions from this report are presented followed by scientific and policy recommendations to develop and apply ecological risk assessment for regulatory purposes.

5.1 Conclusions

Currently, the Koelmans approach (Koelmans et al., 2020) is the best available method for the ecological risk assessment of particle effects of microplastics. This approach effectively addresses some of the main challenges to ecological risk assessment: the lack of exposure data and the non-alignment of effect and exposure data. Expert consultation conducted during this study indicated that the approach is generally supported by the scientific community, which is consistent with findings from previous studies (Mehinto et al., 2022).

The Koelmans approach is particularly well-suited to retrospective ecological risk assessment, i.e. the assessment of ecological risks of existing pollution in a specific environment. However, its current application requires relatively complex mathematical conversions and specialised expertise. This may pose limitations for the practical applicability outside of academic research. We recognise the potential of the approach to be adapted into a user-friendly tool for risk managers and decisionmakers, but this would require further development and should be considered a medium-term goal. The framework presented in Chapter 4.2 outlines the key developments required to expand its usability for this purpose.

Beyond the assessment of risks in specific environments, the Koelmans approach may also help define indicative environmental quality standards or risk limits. Such standards and limits are the basis for many chemical regulations in the Netherlands, for example, in managing soil, construction materials and dredge material. However, the current application of the approach, as described in the scientific literature, needs to be streamlined and tailored to practical application. Furthermore, developing pragmatic and broadly applicable thresholds will require further research (see the recommendations below), which we view as a medium- to long-term goal. In the short term, the Koelmans approach can be applied to conducting retrospective environmental risk assessments of microplastics in water, sediment and soil, providing insights into the extent to which risks occur at the current concentrations.

As mentioned above, applying the Koelmans approach involves making various assumptions and methodological choices, for instance relating to bioavailable size ranges, or coping with a lack of data, which can influence the outcomes of ecological risk assessments. Note that every risk assessment or models used to predict effects of or exposure to chemicals in the environment relies on certain assumptions. In this regard, applying the Koelmans approach is no exception. Generally speaking, however, it is crucial to clearly understand the basis of modelling assumptions and to determine whether the models' outcome provide a realistic worst-case estimate of risks and are not overly conservative. Moving forward, the uncertainties of the Koelmans approach need to be understood, clearly communicated, and carefully managed. Doing so will enhance scientific acceptance of the method and help clarify the scope of its applicability. A next step could be the development of guidance documents that clearly outline how to apply the approach.

By design, the Koelmans approach is focused on the particle effects of microplastics. It is important to highlight that the impacts of plastics in general goes beyond the particle effects of microplastics (Landrigan et al., 2023). This is also shown in Figure 1, which presents a simplified scheme of possible routes through which plastics may affect organisms along the degradation pathway. These other impacts include entanglement (e.g. animals trapped in plastic packaging), effects relating to changing the physical environment (e.g. soil parameters), effects due to association of pathogens to microplastics, and effects relating to releases of plastic-associated chemicals along the degradation pathway. We would like to emphasise that in addressing plastic pollution, the impacts of plastics on the environment, ecology, and human health cannot be limited to a single aspect, for example, only on the particle effects of microplastics or only involving the impacts of macroplastic debris. Also, the scientific consultation highlighted the urgency for ecological risk assessment of the plastic-associated chemicals. However, such assessments should account for all exposure routes and should not be restricted to chemicals associated with microplastics. To comprehensively assess and mitigate impacts of plastics and their alternatives, a systems approach is essential. Generally, a broader framework encompassing multiple assessments is required to address the full scope of the plastic pollution problem effectively.

5.2 Recommendations

On the basis of internal discussion, expert consultation, literature studies, and discussions with policymakers, we provide the following scientific and policy recommendations to develop and apply ecological risk assessment of microplastics.

General recommendations:

- In policy frameworks, we recommend implementing ecological risk assessment of particle effects of microplastics on the basis of the Koelmans approach (Koelmans et al., 2020).
- Specific chemical or biological risks may be associated with (micro)plastics, but they should be considered separately. The

challenges to ecological risk assessment of plastic-associated chemicals (e.g. mixture toxicity, lack of data) should be addressed within existing chemical frameworks.
- Within existing chemicals regulations (e.g. REACH) we recommend an increased focus and strengthening of guidance and methodologies on the use, exposure and environmental (and human health) risk assessment of plastics-associated chemicals in all life cycle stages. For instance, account for the fate and behaviour of microplastics in the assessment of plastic-associated chemicals.
- All forms of microplastic assessments supporting policy decisions should ideally be done on the basis of scientifically robust methods and approaches laid down in technical guidance documents (e.g. in Technical Guidance Documents) and described in detail to make the outcomes reproducible and comparable

Policy-related recommendations:
- The Koelmans approach can be applied to retrospective ecological risk assessments of microplastics in surface waters, sediments and soils in order to quantify the degree of microplastic pollution. This requires more monitoring data.
- Environmental quality standards or risk limits may be derived using the Koelmans approach. This requires further development (see the recommendation regarding knowledge gaps). Such standards or limits for microplastics may be useful for emission permissions and for the movement of construction materials, soils, and dredge materials. The impacts on human health may eventually also be included in the derivation of risk limits.
- For both retrospective and prospective risk assessment, the need for and relevance of a tiered assessment system can be explored. Such an approach could involve a trigger value (which should ideally be relatively easy to measure) that, once exceeded, requires a detailed assessment that fully considers size and shape variability of the site according to latest scientific developments.
- Ultimately, an accessible tool may be required that non-scientific experts can use to assess impacts of microplastics. For instance, within ‘risicotoolboxbodem’.[9] This would require substantial developmental work. Note that the growing body of data on occurrence and abundance of microplastics in the various environmental compartments may require some degree of interpretation of potential for ecological risks.

Filling knowledge gaps:
- Impact of assumptions and approaches when applying the Koelmans approach should be further investigated, for example, when dealing with data scarcity and bioavailable size ranges. This can be achieved by conducting a sensitivity and uncertainty analysis on the outcome of an environmental risk assessment.
- There is currently a lack of data on measured environmental concentrations in the Netherlands. This knowledge gap should be

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[9] https://www.risicotoolboxbodem.nl/

resolved to assess the current environmental status in the Netherlands with regard to microplastic pollution.

- Environmental measuring campaigns should be aimed at measuring particle numbers in order to be fit for ecological risk assessment using the Koelmans approach. It should be assessed whether mass-based measurements can also be applied and if so, under which conditions.
- It is recommended to gain a better understanding of the mechanism of toxicity of microplastics, in particular for soil organisms
- Uncertainties regarding effect levels should be reduced by conducting ecotoxicity tests using environmentally relevant, polydisperse and weathered microplastics.
- Exposure and effect studies should report particle size and shape distributions for them to be relevant for ecological risk assessment.
- More data on particle distributions as well as ecotoxicological data on the smallest microplastics (in particularly sub-micron microplastics) is needed.

International collaboration

- Developing test guidelines or guidance documents for effect studies, environmental analysis and reporting of microplastics (e.g. OECD Test Guidelines, a Guidance Document, or similar).
- Developing guidance for conducting ecological risk assessment using the Koelmans approach, including for dealing with data requirements.
- Further developing a database for effect data, which includes quality screening (e.g. supporting further development of ToMEx database).
- Creating a shared code base for scientists regarding ecological risk assessment using the Koelmans approach in order to perform comparable analysis. This should be based on scientific consensus on model quality and features, in time even resulting in a harmonised approach.

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CRediT author statement: Conceptualisation: Conceptualization: JQ, ES, AK; Methodology: ES, JQ, AK, PvB; Software: PvB; Formal analysis: PvB; Investigation: ES, JQ, PvB; Resources: AK; Data Curation: PvB; Writing – Original Draft: ES, PvB, JQ; Writing – Review & Editing: ES, JQ, PvB, AK; Visualisation: ES, PvB; Supervision: ES, JQ; Project administration: JQ; Funding acquisition: JQ.

AK served as an external advisor for the project, providing essential knowledge and input that was crucial for its successful completion. As a result, AK is included as a co-author of the report. Being the developer of the Koelmans approach, AK did not join the expert workshop where the approach was discussed and evaluated. The initial draft of the report was written by ES, PvB, and JQ (all RIVM) and subsequently reviewed by AK.

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References

Adam, V., Von Wyl, A., Nowack, B., 2021. Probabilistic environmental risk assessment of microplastics in marine habitats. Aquat. Toxicol. 230, 105689. https://doi.org/10.1016/j.aquatox.2020.105689

Alimi, O.S., Claveau-Mallet, D., Kurusu, R.S., Lapointe, M., Bayen, S., Tufenkji, N., 2022. Weathering pathways and protocols for environmentally relevant microplastics and nanoplastics: What are we missing? J. Hazard. Mater. 423, 126955. https://doi.org/10.1016/j.jhazmat.2021.126955

Bleeker, E.A.J., Swart, E., Braakhuis, H., Fernández Cruz, M.L., Friedrichs, S., Gosens, I., Herzberg, F., Jensen, K.A., Von Der Kammer, F., Kettelarij, J.A.B., Navas, J.M., Rasmussen, K., Schwirn, K., Visser, M., 2023. Towards harmonisation of testing of nanomaterials for EU regulatory requirements on chemical safety – A proposal for further actions. Regul. Toxicol. Pharmacol. 139, 105360. https://doi.org/10.1016/j.yrtph.2023.105360

Boersma, A., Grigoriadi, K., Nooijens, M.G.A., Henke, S., Kooter, I.M., Parker, L.A., Dortmans, A., Urbanus, J.H., 2023. Microplastic Index—How to Predict Microplastics Formation? Polymers 15, 2185. https://doi.org/10.3390/polym15092185

Boháčková, J., Cajthaml, T., 2024. Contribution of chemical toxicity to the overall toxicity of microplastic particles: A review. Sci. Total Environ. 957, 177611. https://doi.org/10.1016/j.scitotenv.2024.177611

Brander, S.M., Renick, V.C., Foley, M.M., Steele, C., Woo, M., Lusher, A., Carr, S., Helm, P., Box, C., Cherniak, S., Andrews, R.C., Rochman, C.M., 2020. Sampling and Quality Assurance and Quality Control: A Guide for Scientists Investigating the Occurrence of Microplastics Across Matrices. Appl. Spectrosc. 74, 1099–1125. https://doi.org/10.1177/0003702820945713

Brits, M., Van Poelgeest, B., Nijenhuis, W., Van Velzen, M.J.M., Béen, F.M., Gruter, G.J.M., Brandsma, S.H., Lamoree, M.H., 2024. Quantitation of polystyrene by pyrolysis-GC-MS: The impact of polymer standards on micro and nanoplastic analysis. Polym. Test. 137, 108511. https://doi.org/10.1016/j.polymertesting.2024.108511

Buonassissi, C.J., Dierssen, H.M., 2010. A regional comparison of particle size distributions and the power law approximation in oceanic and estuarine surface waters. J. Geophys. Res. Oceans 115. https://doi.org/10.1029/2010JC006256

Catarino, A.I., Kramm, J., Völker, C., Henry, T.B., Everaert, G., 2021. Risk posed by microplastics: Scientific evidence and public perception. Curr. Opin. Green Sustain. Chem. 29, 100467. https://doi.org/10.1016/j.cogsc.2021.100467

Chamas, A., Moon, H., Zheng, J., Qiu, Y., Tabassum, T., Jang, J.H., Abu-Omar, M., Scott, S.L., Suh, S., 2020. Degradation Rates of Plastics in the Environment. ACS Sustain. Chem. Eng. 8, 3494–3511. https://doi.org/10.1021/acssuschemeng.9b06635

Coffin, S., Bouwmeester, H., Brander, S., Damdimopoulou, P., Gouin, T., Hermabessiere, L., Khan, E., Koelmans, A.A., Lemieux, C.L., Teerds, K., Wagner, M., Weisberg, S.B., Wright, S., 2022a. Development and application of a health-based framework for informing regulatory action in relation to exposure of microplastic particles in California drinking water. Microplast Nanoplast 2, 12. https://doi.org/10.1186/s43591-022-00030-6

Coffin, S., Weisberg, S.B., Rochman, C., Kooi, M., Koelmans, A.A., 2022b. Risk characterization of microplastics in San Francisco Bay, California. Microplastics Nanoplastics 2, 19. https://doi.org/10.1186/s43591-022-00037-z

Cui, X., Yang, T., Li, Z., Nowack, B., 2024. Meta-analysis of the hazards of microplastics in freshwaters using species sensitivity distributions. J. Hazard. Mater. 463, 132919. https://doi.org/10.1016/j.jhazmat.2023.132919

De Ruijter, V.N., Hof, M., Kotorou, P., Van Leeuwen, J., Van Den Heuvel-Greve, M.J., Roessink, I., Koelmans, A.A., 2023. Microplastic Effect Tests Should Use a Standard Heterogeneous Mixture: Multifarious Impacts among 16 Benthic Invertebrate Species Detected under Ecologically Relevant Test Conditions. Environ. Sci. Technol. 57, 19430–19441. https://doi.org/10.1021/acs.est.3c06829

de Ruijter, V.N., Redondo Hasselerharm, P.E., Gouin, T., Koelmans, A.A., 2020. Quality criteria for microplastic effect studies in the context of risk assessment: A critical review. Env. Sci Technol. https://doi.org/10.1021/acs.est.0c03057

De Ruijter, V.N., Redondo-Hasselerharm, P.E., Koelmans, A.A., 2025a. A brief history of microplastics effect testing: Guidance and prospect. Environ. Pollut. 368, 125711. https://doi.org/10.1016/j.envpol.2025.125711

De Ruijter, V.N., Xie, X., Koelmans, A.A., 2025b. Microplastics versus natural mineral particles. How to create and test them while maintaining environmental relevance. J. Hazard. Mater. 481, 136538. https://doi.org/10.1016/j.jhazmat.2024.136538

EC, 2023a. Preliminary analysis of the main sources of microplastic emissions, ANNEX 15 of the IMPACT ASSESSMENT REPORT on Combatting microplastics pollution in the Eurpean Union.

EC, 2023b. Commission Regulation (EU) 2023/2055 of 25 September 2023 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles (Text with EEA relevance), OJ L.

EC, 2023c. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on preventing plastic pellet losses to reduce microplastic pollution.

Freriks, I., Oversteeg van, C., Zemmelink, H., 2023. Op weg naar microplastics monitoring in rivieren - Deel 3: Pilotmetingen microplastics in oppervlaktewater, waterbodem en rivieroevers. Rijkswaterstaat, Centrale Informatievoorziening. https://open.overheid.nl/documenten/ronl-fc3cde3f818a2bc233d013133a224af0ada07344/pdf

Gouin, T., Ellis-Hutchings, R., Thornton Hampton, L.M., Lemieux, C.L., Wright, S.L., 2022. Screening and prioritization of nano- and microplastic particle toxicity studies for evaluating human health risks – development and application of a toxicity study assessment tool. Microplastics Nanoplastics 2, 2. https://doi.org/10.1186/s43591-021-00023-x

Gouin, T., Roche, N., Lohmann, R., Hodges, G., 2011. A Thermodynamic Approach for Assessing the Environmental Exposure of Chemicals Absorbed to Microplastic. Environ. Sci. Technol. 45, 1466–1472. https://doi.org/10.1021/es1032025

Grigoriadi, K., Nooijens, M.G.A., Taşlı, A.E., Vanhouttem, M.M.C., Henke, S., Parker, L.A., Urbanus, J.H., Boersma, A., 2023. Experimental Validation of the Microplastic Index—Two Approaches to Understanding Microplastic Formation. Microplastics 2, 350–370. https://doi.org/10.3390/microplastics2040027

Groh, K.J., Arp, H.P.H., MacLeod, M., Wang, Z., 2023. Assessing and managing environmental hazards of polymers: historical development, science advances and policy options. Environ. Sci. Process. Impacts 25, 10–25. https://doi.org/10.1039/D2EM00386D

Hartmann, N.B., Hüffer, T., Thompson, R.C., Hassellöv, M., Verschoor, A., Daugaard, A.E., Rist, S., Karlsson, T., Brennholt, N., Cole, M., Herrling, M.P., Hess, M.C., Ivleva, N.P., Lusher, A.L., Wagner, M., 2019. Are We Speaking the Same Language? Recommendations for a Definition and Categorization Framework for Plastic Debris. Environ. Sci. Technol. 53, 1039–1047. https://doi.org/10.1021/acs.est.8b05297

Hermsen, E., Mintenig, S.M., Besseling, E., Koelmans, A.A., 2018. Quality Criteria for the Analysis of Microplastic in Biota Samples: A Critical Review. Environ. Sci. Technol. 52, 10230–10240. https://doi.org/10.1021/acs.est.8b01611

Herzke, D., Anker-Nilssen, T., Nøst, T.H., Götsch, A., Christensen-Dalsgaard, S., Langset, M., Fangel, K., Koelmans, A.A., 2016. Negligible Impact of Ingested Microplastics on Tissue Concentrations of Persistent Organic Pollutants in Northern Fulmars off Coastal Norway. Environ. Sci. Technol. 50, 1924–1933. https://doi.org/10.1021/acs.est.5b04663

Ho, K.T., Bjorkland, R., Burgess, R.M., 2024. Comparing the definitions of microplastics based on size range: Scientific and policy implications. Mar. Pollut. Bull. 207, 116907. https://doi.org/10.1016/j.marpolbul.2024.116907

Hua, J., Vijver, M.G., Chen, G., Richardson, M.K., Peijnenburg, W.J.G.M., 2016. Dose metrics assessment for differently shaped and sized metal-based nanoparticles. Environ. Toxicol. Chem. 35, 2466–2473. https://doi.org/10.1002/etc.3414

Huo, Y., Dijkstra, F.A., Possell, M., Singh, B., 2022. Ecotoxicological effects of plastics on plants, soil fauna and microorganisms: A meta-analysis. Environ. Pollut. 310, 119892. https://doi.org/10.1016/j.envpol.2022.119892

IenW, 2023a. National Circular Economy Programme 2023-2030.

IenW, 2023b. Verzamelbrief bodem en ondergrond.

IenW, 2020. Besluit tot invoering van statiegeld op kleine plastic flessen en uitvoering moties blikjes.

IenW, 2019. Handboek Immissietoets. Ministerie van Infrastructuur en Waterstaat.

Jacques, O., Prosser, R.S., 2021. A probabilistic risk assessment of microplastics in soil ecosystems. Sci. Total Environ. 757, 143987. https://doi.org/10.1016/j.scitotenv.2020.143987

Kim, S.W., Rillig, M.C., 2022. Research trends of microplastics in the soil environment: Comprehensive screening of effects. Soil Ecol. Lett. 4, 109–118. https://doi.org/10.1007/s42832-021-0077-3

Klimisch, H.-J., Andreae, M., Tillmann, U., 1997. A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data. Regul. Toxicol. Pharmacol. 25, 1–5. https://doi.org/10.1006/rtph.1996.1076

Koelmans, A.A., Bakir, A., Burton, G.A., Janssen, C.R., 2016. Microplastic as a Vector for Chemicals in the Aquatic Environment: Critical Review and Model-Supported Reinterpretation of Empirical Studies. Environ. Sci. Technol. 50, 3315–3326. https://doi.org/10.1021/acs.est.5b06069

Koelmans, A.A., Besseling, E., Wegner, A., Foekema, E.M., 2013. Plastic as a Carrier of POPs to Aquatic Organisms: A Model Analysis. Environ. Sci. Technol. 47, 7812–7820. https://doi.org/10.1021/es401169n

Koelmans, A.A., Diepens, N.J., Mohamed Nor, N.H., 2022. Weight of Evidence for the Microplastic Vector Effect in the Context of Chemical Risk Assessment, in: Bank, M.S. (Ed.), Microplastic in the Environment: Pattern and Process. Springer International Publishing, Cham, pp. 155–197. https://doi.org/10.1007/978-3-030-78627-4_6

Koelmans, A.A., Mohamed Nor, N.H., Hermsen, E., Kooi, M., Mintenig, S.M., De France, J., 2019. Microplastics in freshwaters and drinking water: Critical review and assessment of data quality. Water Res. 155, 410–422. https://doi.org/10.1016/j.watres.2019.02.054

Koelmans, A.A., Redondo-Hasselerharm, P.E., Mohamed Nor, N.H., Gouin, T., 2023. On the probability of ecological risks from microplastics in the Laurentian Great lakes. Environ. Pollut. 325, 121445. https://doi.org/10.1016/j.envpol.2023.121445

Koelmans, A.A., Redondo-Hasselerharm, P.E., Mohamed Nor, N.H., Kooi, M., 2020. Solving the Nonalignment of Methods and Approaches Used in Microplastic Research to Consistently Characterize Risk. Env. Sci Technol 54, 12307–12315. https://doi.org/10.1021/acs.est.0c02982

Kögel, T., Bjorøy, Ø., Toto, B., Bienfait, A.M., Sanden, M., 2020. Micro- and nanoplastic toxicity on aquatic life: Determining factors. Sci. Total Environ. 709, 136050. https://doi.org/10.1016/j.scitotenv.2019.136050

Kooi, M., Koelmans, A.A., 2019. Simplifying Microplastic via Continuous Probability Distributions for Size, Shape, and Density. Environ. Sci. Technol. Lett. 6, 551–557. https://doi.org/10.1021/acs.estlett.9b00379

Kooi, M., Primpke, S., Mintenig, S.M., Lorenz, C., Gerdts, G., Koelmans, A.A., 2021. Characterizing the multidimensionality of microplastics across environmental compartments. Water Res. https://doi.org/10.1016/j.watres.2021.117429

Kramm, J., Steinhoff, S., Werschmöller, S., Völker, B., Völker, C., 2022. Explaining risk perception of microplastics: Results from a representative survey in Germany. Glob. Environ. Change 73, 102485. https://doi.org/10.1016/j.gloenvcha.2022.102485

Landrigan, P.J., Raps, H., Cropper, M., Bald, C., Brunner, M., Canonizado, E.M., Charles, D., Chiles, T.C., Donohue, M.J., Enck, J., Fenichel, P., Fleming, L.E., Ferrier-Pages, C., Fordham, R., Gozt, A., Griffin, C., Hahn, M.E., Haryanto, B., Hixson, R., Ianelli, H., James, B.D., Kumar, P., Laborde, A., Law, K.L., Martin, K., Mu, J., Mulders, Y., Mustapha, A., Niu, J., Pahl, S., Park, Y., Pedrotti, M.-L., Pitt, J.A., Ruchirawat, M., Seewoo, B.J., Spring, M., Stegeman, J.J., Suk, W., Symeonides, C., Takada, H., Thompson, R.C., Vicini, A., Wang, Z., Whitman, E., Wirth, D., Wolff, M., Yousuf, A.K., Dunlop, S., 2023. The Minderoo-Monaco Commission on Plastics and Human Health. Ann. Glob. Health 89, 23. https://doi.org/10.5334/aogh.4056

Lau, W.W.Y., Shiran, Y., Bailey, R.M., Cook, E., Stuchtey, M.R., Koskella, J., Velis, C.A., Godfrey, L., Boucher, J., Murphy, M.B., Thompson, R.C., Jankowska, E., Castillo Castillo, A., Pilditch, T.D., Dixon, B., Koerselman, L., Kosior, E., Favoino, E., Gutberlet, J., Baulch, S., Atreya, M.E., Fischer, D., He, K.K., Petit, M.M., Sumaila, U.R., Neil, E., Bernhofen, M.V., Lawrence, K., Palardy, J.E., 2020. Evaluating scenarios toward zero plastic pollution. Science 369, 1455–1461. https://doi.org/10.1126/science.aba9475

Liu, Z., Huang, Q., Wang, H., Zhang, S., 2022. An enhanced risk assessment framework for microplastics occurring in the Westerscheldt estuary. Sci. Total Environ. 817, 153006. https://doi.org/10.1016/j.scitotenv.2022.153006

Martínez-Pérez, S., Schell, T., Franco, D., Rosal, R., Redondo-Hasselerharm, P.E., Martínez-Hernández, V., Rico, A., 2024. Fate and effects of an environmentally relevant mixture of microplastics in simple freshwater microcosms. Aquat. Toxicol. 276, 107104. https://doi.org/10.1016/j.aquatox.2024.107104

Mehinto, A.C., Coffin, S., Koelmans, A.A., Brander, S.M., Wagner, M., Thornton Hampton, L.M., Burton, A.G., Miller, E., Gouin, T., Weisberg, S.B., Rochman, C.M., 2022. Risk-based management framework for microplastics in aquatic ecosystems. Microplastics Nanoplastics 2. https://doi.org/10.1186/s43591-022-00033-3

Merrington, G., Nowell, L.H., Peck, C., 2024. An introduction to Criteria for Reporting and Evaluating Exposure Datasets (CREED) for use in environmental assessments. Integr. Environ. Assess. Manag. 20, 975–980. https://doi.org/10.1002/ieam.4899

Mintenig, S.M., Kooi, M., Erich, M.W., Primpke, S., Redondo-Hasselerharm, P.E., Dekker, S.C., Koelmans, A.A., van Wezel, A.P., 2020. A systems approach to understand microplastic occurrence and variability in Dutch riverine surface waters. Water Res 176, 115723. https://doi.org/10.1016/j.watres.2020.115723

Moermond, C.T.A., Kase, R., Korkaric, M., Ågerstrand, M., 2015. CRED: Criteria for reporting and evaluating ecotoxicity data. Environ. Toxicol. Chem. 35, 1297–1309. https://doi.org/10.1002/etc.3259

Mohamed Nor, N.H., Niu, Z., Hennebelle, M., Koelmans, A.A., 2023. How Digestive Processes Can Affect the Bioavailability of PCBs Associated with Microplastics: A Modeling Study Supported by Empirical Data. Environ. Sci. Technol. 57, 11452–11464. https://doi.org/10.1021/acs.est.3c02129

MSFD Technical Group on Marine Litter, 2023. Guidance on the monitoring of marine litter in European seas: an update to improve the harmonised monitoring of marine litter under the Marine Strategy Framework Directive. Publications Office of the European Union, LU.

OECD, 2022. Global Plastics Outlook: Economic Drivers, Environmental Impacts and Policy Options. OECD. https://doi.org/10.1787/de747aef-en

OSPAR, 2024. CEMP Guidelines for the monitoring of microlitter (including microplastics) in seafloor sediments for the OSPAR maritime area. https://www.ospar.org/documents?d=57834

Parker, B., Britton, J.R., Green, I.D., Jackson, M.C., Andreou, D., 2024. Microplastic-stressor responses are rarely synergistic in freshwater fishes: A meta-analysis. Sci. Total Environ. 947, 174566. https://doi.org/10.1016/j.scitotenv.2024.174566

Pfohl, P., Santizo, K., Sipe, J., Wiesner, M., Harrison, S., Svendsen, C., Wohlleben, W., 2025. Environmental degradation and fragmentation of microplastics: dependence on polymer type, humidity, UV dose and temperature. Microplastics Nanoplastics 5, 7. https://doi.org/10.1186/s43591-025-00118-9

Qiu, Y., Zhou, S., Zhang, C., Qin, W., Lv, C., 2023. A framework for systematic microplastic ecological risk assessment at a national scale. Environ. Pollut. 327, 121631. https://doi.org/10.1016/j.envpol.2023.121631

Quik, J.T.K., Hids, A.R., Steenmeijer, M.A., Mellink, Y., van Bruggen, A., 2024. Emission of Microplastics to Water, Soil, and Air. What can we do about it? (RIVM report No. 2024– 0106). Rijksinstituut voor Volksgezondheid en Milieu RIVM, Bilthoven, The Netherlands. https://doi.org/10.21945/RIVM-2024-0106

Quik, J.T.K., Meesters, J.A.J., Koelmans, A.A., 2023. A multimedia model to estimate environmental fate of microplastic particles. Sci. Total Environ. 163437. https://doi.org/10.1016/j.scitotenv.2023.163437

Quik, J.T.K., Meesters, J.A.J., Peijnenburg, W.J.G.M., Brand, W., Bleeker, E.A.J., 2020. Environmental Risk Assessment (ERA) of the application of nanoscience and nanotechnology in the food and feed chain. EFSA Support. Publ. 17, 1948E. https://doi.org/10.2903/sp.efsa.2020.EN-1948

R Core Team, 2024. R: A Language and Environment for Statistical Computing. R Foundation for Statistical Computing.

Redondo-Hasselerharm, P.E., Rico, A., Huerta Lwanga, E., van Gestel, C.A.M., Koelmans, A.A., 2024. Source-specific probabilistic risk assessment of microplastics in soils applying quality criteria and data alignment methods. J. Hazard. Mater. 467, 133732. https://doi.org/10.1016/j.jhazmat.2024.133732

Redondo-Hasselerharm, P.E., Rico, A., Koelmans, A.A., 2023. Risk assessment of microplastics in freshwater sediments guided by strict quality criteria and data alignment methods. J Hazard Mater 441, 129814. https://doi.org/10.1016/j.jhazmat.2022.129814

Rillig, M.C., Kim, S.W., Kim, T.-Y., Waldman, W.R., 2021. The Global Plastic Toxicity Debt. Environ. Sci. Technol. 55, 2717–2719. https://doi.org/10.1021/acs.est.0c07781

RIVM, 2024. Handleiding voor de afleiding van indicatieve milieurisicogrenzen Deel 4. Ecotoxiciteit: verzameling, selectie en rapportage van gegevens. versie 1.1.

Rutgers, M., Faber, M., Waaijers-van der Loop, S., Quik, J., 2022. Microplastics in soil systems, from source to path to protection goals. State of knowledge on microplastics in soil. Rijksinstituut voor Volksgezondheid en Milieu RIVM. https://doi.org/10.21945/RIVM-2021-0224

SAPEA, 2019. A Scientific Perspective on Microplastics in Nature and Society: Evidence review report (1.1). https://doi.org/10.26356/microplastics

Schmid, O., Stoeger, T., 2016. Surface area is the biologically most effective dose metric for acute nanoparticle toxicity in the lung. J. Aerosol Sci. 99, 133–143. https://doi.org/10.1016/j.jaerosci.2015.12.006

Shi, C., Wang, M., Wang, Z., Qu, G., Jiang, W., Pan, X., Fang, M., 2023. Oligomers from the Synthetic Polymers: Another Potential Iceberg of New Pollutants. Environ. Health 1, 228–235. https://doi.org/10.1021/envhealth.3c00086

Špela, Ž., Damjana, D., Matej, H., Matic, N., Marina, P., 2025. Soil water repellency of two disturbed soils contaminated with different agricultural microplastics tested under controlled laboratory conditions. Geoderma 453, 117124. https://doi.org/10.1016/j.geoderma.2024.117124

Stunnenberg, M., de Roda Husman, A.M., 2024. It’s a matter of microbes: a perspective on the microbiological aspects of micro- and nanoplastics in human health. Front. Nanotechnol. 6. https://doi.org/10.3389/fnano.2024.1368437

Tavşanoğlu, Ü.N., Akca, G., Pekmez, T., Başaran Kankılıç, G., Çırak, T., Çağan, A.S., Özkan Kotiloğlu, S., Grossart, H.-P., 2025. Increasing microplastics pollution: An emerging vector for potentially pathogenic bacteria in the environment. Water Res. 274, 123142. https://doi.org/10.1016/j.watres.2025.123142

Thornton Hampton, L.M., Brander, S.M., Coffin, S., Cole, M., Hermabessiere, L., Koelmans, A.A., Rochman, C.M., 2022a. Characterizing microplastic hazards: which concentration metrics and particle characteristics are most informative for understanding toxicity in aquatic organisms? Microplastics Nanoplastics 2, 20. https://doi.org/10.1186/s43591-022-00040-4

Thornton Hampton, L.M., Lowman, H., Coffin, S., Darin, E., De Frond, H., Hermabessiere, L., Miller, E., De Ruijter, V.N., Faltynkova, A., Kotar, S., Monclús, L., Siddiqui, S., Völker, J., Brander, S., Koelmans, A.A., Rochman, C.M., Wagner, M., Mehinto, A.C., 2022b. A living tool for the continued exploration of microplastic toxicity. Microplastics Nanoplastics 2, 13. https://doi.org/10.1186/s43591-022-00032-4

Tromp, P., Esveld, J., 2023. Results from Monitoring TWP (results from selective field measurements) in different environmental compartments) [WWW Document]. LEON-T Deliv. 32. URL https://www.leont-project.eu/wp-content/uploads/2025/01/D3.2_public.pdf

Tunali, M., Adam, V., Nowack, B., 2023. Probabilistic environmental risk assessment of microplastics in soils. Geoderma 430, 116315. https://doi.org/10.1016/j.geoderma.2022.116315

UNEP, 2022. UNEA Resolution 5/14 entitled "End plastic pollution: Towards an international legally binding instrument." https://digitallibrary.un.org/record/3999257?ln=en&v=pdf

Urbanus, J.H., Brunner, A., Boersma, A., Henke, S., Kooter, I., Lensen, S., Parker, L., Schwarz, A., Imhof, P., Dortmans, A., Wijngaard, M., 2022. Autobanden, verpakkingen en landbouwfolie zijn in Nederland de grootste bronnen van microplastics. TNO. https://publications.tno.nl/publication/34640141/cVUarS/TNO-2022-microplastics-nl.pdf

Vethaak, A.D., Legler, J., 2021. Microplastics and human health. Science 371, 672–674. https://doi.org/10.1126/science.abe5041

Wagner, M., Monclús, L., Arp, H.P.H., Groh, K.J., Løseth, M.E., Muncke, J., Wang, Z., Wolf, R., Zimmermann, L., 2024. State of the science on plastic chemicals - Identifying and addressing chemicals and polymers of concern. Zenodo. https://doi.org/10.5281/zenodo.10701706

Wang, M., Li, Q., Shi, C., Lv, J., Xu, Y., Yang, J., Chua, S.L., Jia, L., Chen, H., Liu, Q., Huang, C., Huang, Y., Chen, J., Fang, M., 2023. Oligomer nanoparticle release from polylactic acid plastics catalysed by gut enzymes triggers acute inflammation. Nat. Nanotechnol. 18, 403–411. https://doi.org/10.1038/s41565-023-01329-y

World Health Organization, 2022. Dietary and inhalation exposure to nano- and microplastic particles and potential implications for human health. https://www.who.int/publications/i/item/9789240054608

World Health Organization, 2019. Microplastics in drinking-water. https://iris.who.int/bitstream/handle/10665/326499/9789241516198-eng.pdf?sequence=5

Yang, T., Xu, Y., Liu, G., Nowack, B., 2024. Oligomers are a major fraction of the submicrometre particles released during washing of polyester textiles. Nat. Water 2, 151–160. https://doi.org/10.1038/s44221-023-00191-5

Yuan, Z., Nag, R., Cummins, E., 2022. Ranking of potential hazards from microplastics polymers in the marine environment. J. Hazard. Mater. 429, 128399. https://doi.org/10.1016/j.jhazmat.2022.128399

Zantis, L.J., Borchi, C., Vijver, M.G., Peijnenburg, W., Di Lonardo, S., Bosker, T., 2023. Nano- and microplastics commonly cause adverse impacts on plants at environmentally relevant levels: A systematic review. Sci. Total Environ. 867, 161211. https://doi.org/10.1016/j.scitotenv.2022.161211

Zhang, D., Ng, E.L., Hu, W., Wang, H., Galaviz, P., Yang, H., Sun, W., Li, C., Ma, X., Fu, B., Zhao, P., Zhang, F., Jin, S., Zhou, M., Du, L., Peng, C., Zhang, X., Xu, Z., Xi, B., Liu, X., Sun, S., Cheng, Z., Jiang, L., Wang, Y., Gong, L., Kou, C., Li, Y., Ma, Y., Huang, D., Zhu, J., Yao, J., Lin, C., Qin, S., Zhou, L., He, B., Chen, D., Li, H., Zhai, L., Lei, Q., Wu, S., Zhang, Y., Pan, J., Gu, B., Liu, H., 2020. Plastic pollution in croplands threatens long-term food security. Glob. Change Biol. 26, 3356–3367. https://doi.org/10.1111/gcb.15043

Zhang, Y., Paul, T., Brehm, J., Völkl, M., Jérôme, V., Freitag, R., Laforsch, C., Greiner, A., 2023. Role of Residual Monomers in the Manifestation of (Cyto)toxicity by Polystyrene Microplastic Model Particles. Environ. Sci. Technol. 57, 9925–9933. https://doi.org/10.1021/acs.est.3c01134

Appendix 1

Appendix 1.1 Policymakers workshop report (in Dutch only)

RIVM en IenW organiseerden op 16/09/2024 een workshop voor Rijksbeleidsmedewerkers over de risicobeoordeling van microplastics in het milieu. De genodigden waren beleidsmedewerkers bij IenW, Rijkswaterstaat (RWS) en LVVN. LVVN nam niet deel aan de workshop. Doel van de workshop was om op te halen wat de behoeften zijn vanuit beleid betreffende een risicobeoordeling voor microplastics, en om te onderzoeken of een aanpak die is ontwikkeld door de Bart Koelmans (WUR) aansluit bij die behoeften. Onderstaande tabellen laten de agenda van de workshop (Table A1.1) en het aantal deelnemers per (deel)organisatie zien (Table A2.2). Hierna volgt een samenvatting van de workshop.

Table A1.1 Agenda beleidsmedewerkers workshop

Wat	Wie	Duur
Inloop		
Introductie workshop: welkom en doelen	IenW	10 min
Het belang van risicobeoordeling voor beleid: presentatie en discussie	RIVM	30 min
Wat je wel of niet kan met een risicobeoordeling en omgaan met onzekerheden: presentatie en discussie	RIVM + WUR	30 min
Pauze		10 min
Hoe nu verder? Presentatie en discussie	RIVM	30 min
Afsluiting	IenW	10 min
Einde		

Table A1.2 Aantal deelnemers per (deel)organisatie

(Deel)organisatie	Aantal deelnemers
IenW - DGWB	7
IenW – DGMI	2
RWS	3
WUR	1
RIVM	4

Samenvatting workshop:

Belangrijkste opgehaalde perspectieven:

Het belang van een risicobeoordeling werd breed onderschreven. Verschillende behoeften/gebruikswensen voor een risicobeoordeling werden genoemd: ‘hotspots’ van vervuiling identificeren, draagvlak voor beleid creëren, normeringen, bijdrage aan bronaanpak, richting geven aan product- en materiaalkeuzes, monitoring van de status van leefomgeving, identificeren van ‘knoppen om aan te draaien’. Het belang van handelingsperspectief van de uitkomsten van risicobeoordeling werd breed erkend. Daarnaast was er zorg over of bewustzijn betreffende mogelijke neveneffecten van bijvoorbeeld normeringen, of in het algemeen ‘uitkomsten’ van een risicobeoordeling zonder handelingsperspectief. Een terugkomende wens onder de beleidsmedewerkers was dat risicobeoordeling een zekere specificiteit dient te hebben (dus niet alleen generiek voor alle plastic toegepast kan worden). Daarbij gaat het er bijvoorbeeld om dat de beoordeling inzicht geeft in risico's van specifieke deeltjes, polymeertypes, toepassingen etcetera.

Hieronder volgen meer gedetailleerde samenvattingen van de workshop-onderdelen. Ieder hoofddeel bestond uit een presentatie gevolgd door een open discussie. Discussiepunten worden hier alleen op hoofdlijnen gerapporteerd.

Het belang van risicobeoordeling voor beleid (agenda-item 2)
Het RIVM presenteerde de achtergrond van het huidige project over microplastics in de bodem in het kader van opkomende stoffen. De spreker introduceerde basisconcepten van de risicobeoordeling, en benoemde waar je als beleidsmaker kan inzetten op beleid in de keten van bron tot risico's relaterend aan de kennisagenda microplastics in het milieu. Uit een eerdere beleidsworkshop uit 2022 kwam naar voren dat inzicht in bronnen, effecten en risico's van belang is voor beleidsmakers. Dit is vervolgens opgepakt in diverse, door I&W gefinancierde projecten. Daarnaast werd een korte samenvatting gegeven van de bevindingen van een workshop uit maart 2024 waarin een gemengde groep mensen (vanuit beleid, academie, consultancy) input gaf op hoe of waarom je een risicobeoordeling kan gebruiken voor beleid.

Vervolgens werd aan de deelnemers van de workshop gevraagd hoe belangrijk zij een risicobeoordeling vinden voor hun beleid. Daarbij werd hun gevraagd om in de ruimte langs een as te gaan staan waarbij de ene kant van de zaal “heel erg belangrijk” en de andere kan van de zaal “niet belangrijk” representeerde. Alle deelnemers stonden in meer of mindere mate aan de “belangrijke” kant van de zaal. Daarna volgde een open discussie met de vraag: waarom staan de deelnemers waar ze staan/waarom is het dan belangrijk? De volgende discussiepunten kunnen worden herkend:

- Twijfel over nut van een risicobeoordeling: voor sommige deelnemers speelde mee of je iets kan met de uitkomsten van een risicobeoordeling die laat zien dat er een probleem (een risico) is. Als (micro)plastics in de praktijk niet uit de bodem te halen zijn, is het niet per se duidelijk wat je met de nieuwe informatie moet. Daarnaast heeft bronaanpak vanuit de doelstelling om emissies te reduceren geen risicobeoordeling nodig. Tegelijkertijd zou een risicobeoordeling wel kunnen helpen om ervoor te zorgen dat het probleem niet erger wordt.
- Een risicobeoordeling werd nuttig geacht vanuit zorgen voor drinkwater, waarbij veiligheid voor mens en milieu relevant geacht werd. Het belang van zoeken naar ‘*knoppen om aan te draaien’* die het grootste effect hebben.
- Verder werd genoemd dat een risicobeoordeling kan bijdragen aan het creëren van draagvlak voor beleid. Veel mensen weten weliswaar dat het een mogelijk probleem is, maar niet goed hoe erg het probleem is. Een risicoboordeling kan bijdragen aan bewustwording. Als je het probleem kan duiden, kan je meer mensen meekrijgen in beleidsmaatregelen. Daarbij wordt mogelijk de schadelijkheid voor de mens van groter belang

geacht. Ook in gesprek met de industrie kan een risicobeoordeling nuttig zijn om het gewicht van het probleem te kunnen duiden. En het is daarbij goed om te weten wanneer het een probleem is, en waar.
- Een breder discussiepunt dat werd genoemd betrof de uitdagingen vanuit de circulaire economie, waarbij er steeds meer secundair plastic met onbekende samenstelling in omloop is.
- Ook de mogelijke neveneffecten van een risicobeoordeling (of het vaststellen van risicogrenzen) werd besproken: stoppen van andere activiteiten, zoals de woningbouw.

Wat je wel of niet kan met een risicobeoordeling en omgaan met onzekerheden (agenda-item 3)
Het RIVM gaf een presentatie over de risicobeoordeling van microplastics met aandacht voor de microplastic-specifieke uitdagingen. Daarnaast werd de aanpak van de WUR (Koelmans et al. 2020) gepresenteerd, en benoemd hoe die omgaat met de genoemde uitdagingen. Daarnaast volgde een open discussie waarbij het ging om de centrale vraag: Welke factoren zijn van belang voor beleid en de beleidsdossiers waar je aan werkt?
In de discussie die volgde zijn de volgende discussiepunten te herkennen:
- Het belang van een wetenschappelijk gedragen aanpak werd onderschreven.
- De mogelijkheid om onderscheid te maken tussen typen polymeren en bronnen van microplastics omdat dit vaak direct de beleidsopties raakt. Het gaat hier bijvoorbeeld over onderscheid tussen bio-afbreekbare versus persistente plastics. *In hoeverre is afbreekbaarheid onderdeel van de risicobeoordelingsaanpak? Hoeveel draagt een bepaalde bron bij? Zijn er hotspots te identificeren? Is het mogelijk in te zoomen en weer uit te zoomen met een dergelijke risicobeoordelingsaanpak? Kan de aanpak helpen om bijvoorbeeld voor te schrijven welke plastics beter voor het milieu zijn (bijv. bio-afbreekbare, polymeertype, plasticsadditieven)?* Linken eigenschappen aan veiligheids-/duurzaamheidsaspecten, in het kader van Safe-and-Sustainable-by-Design?
- Een risicobeoordeling staat of valt met de kwaliteit van de gebruikte data. Een goede meetmethode (valide/robuust) voor metingen van concentraties in bodem (en water) is nodig, net als voor het meten van de (eco-)toxiciteit van microplastics. *Wat is de huidige stand van zaken op methodeontwikkeling in relatie tot benodigdheden risicobeoordelingsaanpak?*
- De wens om zonder grenswaarden een beeld te krijgen van de problematiek werd benoemd.
- Ook genoemd werd behoefte aan nuance ten opzichte van andere stoffen; plastics hebben een fundamentele rol in de economie.
- Er was verder nog behoefte aan duiding van de mate van zekerheid, niet alleen nu, maar ook in de toekomst. *Wanneer weten we het (wel) zeker? Is het mogelijk een tijdslijn te schetsen?*

Daarna werd er in vier kleinere groepjes gesproken over de afbakening van de risicobeoordelingsaanpak voor microplastics en het nut en de noodzaak hiervan en wat verder nog van belang is. De vraag was daarbij: wat zit er nu nog niet in de risicobeoordelingsaanpak dat wel voor beleid belangrijk is? Daarbij werden vooraf door de presentator de volgende mogelijk aspecten benoemd:

- Chemische effecten;
- Microbiologische effecten;
- Polymeertypen;
- Deeltjes buiten bandbreedte 1 µm – 5 mm;
- Selectie of weging kwaliteit studies (door beperkte kwaliteit beschikbare studies);
- Humane gezondheidseffecten.

In het algemeen zijn alle bovengenoemde aspecten (nog) niet meegenomen maar wel als relevant benoemd door ten minste een deelnemer. Maar ook is benoemd dat een milieurisicobeoordeling van alleen de fysieke aspecten (zoals bij de huidige aanpak het geval is) bijdraagt/nut heeft voor beleid. In de discussie en terugkoppeling daarvan kwamen de volgende punten naar voren:

- Ook de humane gezondheidseffecten zijn van (groot) belang en mogelijk doorslaggevend voor het voeren van beleid. Hiervoor moet ander onderzoek de basis leggen voor het beoordelen van gezondheidseffecten.
- Chemische effecten zijn ook relevant, mede omdat er al bestaande aanpakken liggen voor het beoordelen hiervan. Dit gaat vooral om chemische stoffen die in/aan de plastics zitten en eraf komen of uitlogen. Niet de chemische identiteit van het plastic deeltje.
- Microbiologische effecten zijn nuttig omdat het microbioom van de bodem een belangrijke component is van een vitale bodem.
- Wat is precies de functie van een risicobeoordeling? Hierbij werden de volgende opties genoemd: bronnen achterhalen, product- en materiaaleisen, normering, monitoring.

Additionele genoemde punten/aspecten van een risicobeoordeling die relevant zijn voor beleid waren:

- Het kunnen meenemen van nanoplastics en opgeloste polymeren;
- Verspreidingsgedrag en mobiliteit van plastic deeltjes.

Hoe nu verder? (agendapunt 4)
Het RIVM presenteerde (de achtergrond tot) de algemene methodiek niet-genormeerde stoffen (AMNS) met onder andere uitdagingen en kansen. Daarnaast werd een samenvatting gegeven van een monitoringsaanpak waar op dit moment aan wordt gewerkt en waarmee je onder andere achtergrondwaarden voor chemische stoffen kan bepalen. Op dit moment is er nog geen specifiek plan om plastics te meten maar er wordt grond ingevroren om latere analyse mogelijk te maken. Ook werd kort geïntroduceerd wat verschillende beschermdoelen zijn voor diverse bodemgebruiken. Vervolgens werd gevraagd aan de deelnemers wat zij nodig hebben voor hun beleid, bijvoorbeeld achtergrondwaarden, risicogrenswaarden en duiding humane effecten. De volgende discussiepunten kwamen ter sprake:

- Belang van gevoel krijgen voor omvang van het probleem.
- Een eerste stap in toepassen AMNS raamwerk is het vaststellen van achtergrondwaarden.
- Het belang van mengselbenadering werd benoemd.
- Voorkomen dat het nog meer toeneemt, waar gaan we naar toe als we niks doen: ‘over 100 jaar een probleem?’ *Kunnen metingen een prognose geven van trends voor ophoping in het milieu?*
- Hotspots identificeren om bijvoorbeeld lokale maatregelen te nemen.
- Koppeling met handelingsperspectief werd genoemd
- Er is wel maatschappelijke behoefte aan grenzen, of bijvoorbeeld in vergunningverlening. Tegelijkertijd is er mogelijk een angst voor normen zonder handelingsperspectief.
- Vanuit het mariene beleid is er wel behoefte aan risicogrenzen; dat heeft ermee te maken dat dat gevraagd wordt vanuit de Kaderrichtlijn Marien (EU). In andere kaders (KWR, bodemkaderrichtlijn) zijn die eisen er niet per se en is de beleidsbehoefte dus mogelijk ook anders. De internationale/EU inbedding van beleid (bijv. bodem vs. water vs. marien) bepaalt mogelijk ook de nationale beleidsbehoeften.
- Er werd voorgesteld om in een volgende vergadering/workshop verder te spreken over grenswaarden.

Appendix 1.2 Questionnaire on risk assessment of microplastics

The questionnaire consisted of thirty questions, which were a mixture of closed and open questions. The questions have been divided into three main parts:

- Introduction to the questionnaire and opening questions;
- Questions on environmental risk assessment of micro- and nanoplastics;
- Questions on the Koelmans et al. (2020) approach to environmental risk assessment.

Part 1: Introduction to the questionnaire and opening questions

Background to the study

Micro- and nanoplastics are ubiquitous in the environment and pose a hazard to organisms. However, risks of microplastics remain uncertain. In part, this uncertainty relates to the limitations in quality ofavailable scientific data. Furthermore, the uncertainty also relates to the extent in which risk assessment approaches can deal with the complexity of microplastics pollution, i.e,., the diversity of particles, physical, chemical and microbiological effects.

Thus far, several scientists have proposed approaches to environmental risk assessment of MNPs and used sethese to estimate the risks to the environment. Pragmatic choices have been made to deal with uncertainties and the complexity of microplastics pollution. One of these studies is Koelmans et al. (2020). This publication describes an approach to conduct an environmental risk assessment which was subsequently further developed and applied to several compartments in different publications (e.g. Kooi et al. 2021; Koelmans et al. 2023; Redondo-Hasselerharm et al. 2023; Redondo-Hasselerharm et al. 2024).

The Netherlands Ministry of Infrastructure and Water Management (I&W) has commissioned the Netherlands National Institute of Public Health and Environment (RIVM) to:

1. assess whether the approach by Koelmans et al. (2020) fits the needs of Dutch policy on MNPs and,
2. to identify perspectives of the international scientific community on environmental risk assessment of MNP in general and specifically the approach of Koelmans et al. (2020) for use policy

In the questionnaire we address the second aim of the study. Later this year we will organise a workshop to further discuss the findings with a group of experts. Through this study we hope to get a feeling from the scientific community on how environmental risks of MNP should be determined, and which aspects of the Koelmans et al. (2020) are broadly accepted and which not. Accordingly, we hope that this study can contribute to better science-based policy on MNPs in the environment.

Collaborators of the study

Prof. Dr. Albert A. Koelmans is hired as an external adviser in this project to better understand the approach outlined in Koelmans et al. (2020) and related papers. External experts from a Dutch university provided kindly input on the first draft of the questions.

How participants' input is used
We intend to publish the results of this questionnaire and the following workshop in an open-access RIVM report (in English) (due mid 2025) and at various international conferences. In addition we may further reflect on our findings and views on environmental risk assessment of MNP in perspective paper or similar.

In any case and in all reporting your name and affiliation will not be linked to specific responses. Individual responses will only be seen by researchers from the RIVM and will not be shared with external collaborators. The first four questions are related to personal information (country of your affiliation, position etc.). The responses to these questions will be reported in aggregate form only to ensure individual anonymity and confidentiality.

Focus of the study
This study is on the environmental risk assessment of MNPs. Here the focus is on ecotoxicological effects and exposure of the more traditional ecotoxicological species, i.e. plants,, invertebrates. Aquatic and terrestrial risk assessment is considered equally relevant.

We acknowledge the complexity of MNP pollution, MNP research, the interpretation of research findings, and conducting a hazard, exposure and risk assessment. Consequently, some questions are phrased generally and do not address the full complexity. We kindly ask participants to answer the questions as they apply to most cases. Please note that the findings will not be considered as the consensus view of the scientific community. Instead, our goal is to map perspectives to further science-based policy.

Definitions
We define MNPs as plastic particles between 5 mm to 1 nm in size. When we talk about environmental MNPs we mean the complex mixture of shapes, sizes, weathering states, and polymer types of plastic particles in the size range 5 um – 1nm as they can be found in the environment. Primary MNPs are defined as intentionally manufactured micro- or nano sized particles designed for commercial use.

The following sections show the questions of the questionnaire and the (aggregated) responses provided to the participants. For closed questions the responses are provided in brackets behind each option.

Question 1: In which country is your primary affiliation based? Responses are shown in Table A1.3.

Table A1.3 Aggregated responses to question 1 of the questionnaire

Country	**Count**
Switzerland	2
Canada	1
USA	2
Belgium	1
United Kingdom	1

Country	**Count**
Slovenia	2
The Netherlands	4
Spain	1
Norway	1

Question 2: Which sector does your primary affiliation belong to?
- Industry (0);
- Research organisation (3)
- University (10)
- Regulatory body (0)
- Government (2)
- Non-governmental organisation (0)
- Other, please specify (0)

Question 3: What is your current position?
- PhD student (2)
- Postdoctoral Researcher (2)
- Assistant or Associate Professor (5)
- Full professor (1)
- Technical/Support Staff (0)
- Researcher (1)
- Senior Researcher (2)
- Other, please specify (2):
    - Group leader;
    - Emeritus professor.

Question 4: What is/are your main expertise(s)? Please select all that apply.
- Soil science/ecology/ecotoxicology (8)
- Aquatic ecology/ecotoxicology (12)
- Ecotoxicological effect testing (10)
- Environmental exposure characterisation (5)
- Environmental transport and fate (4)
- Environmental risk assessment (7)
- Environmental regulation (3)
- Modelling (2)
- Other, please specify (1):
    - Ecological engineering.

Part 2: Perspectives on environmental risk(s) (assessment) of microplastics

Question 5: Which of these effects typically contribute the most to the environmental hazard of a given exposure concentration of environmental MNPs? Please rank them from the highest to the lowest contribution.

Score (between brackets) is the sum of ranking points of each participant where rank 1 = 3 points, rank 2 = 2 points, rank 3 = 1 point.
- Chemical effects (36)
- Particle effects (35)
- Microbiological effects (19)

Introduction to question 6: Primary MNPs are intentionally manufactured micro- or nano-sized particles designed for commercial use.

Question 6: For primary MNPs, do you think the ranking is different? If so, how are they different? Responses are shown in Table A1.4.

Table A1.4 Responses to question 6 of the questionnaire

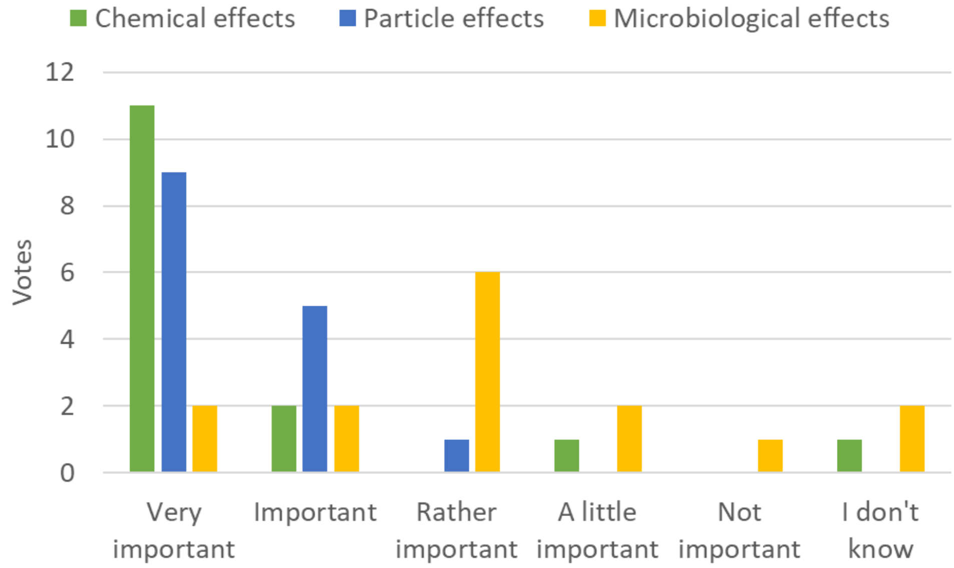
Responses
No (or variations thereof) (9 responses)
Probably more chemical effects (from leachates) and less microbiological effects.
I don't think that the ranking depends so much on whether the particles are pristine or not, but on the particle properties (chemical composition, size, shape, etc.). For tire particles, chemical effects have been found to be more important than particle effects. However, for other microplastics, particle effects are generally more relevant than chemical effects in the environment. In laboratory toxicity studies, chemical effects may also have a more important role than particle effects due to the small test systems, but this is not that relevant in outdoor mesocosm studies.
I think it is difficult to rank particle and chemical induced effects, because they act in combination. Pristine particles may leach less chemicals as they are not subjected to weathering yet, so perhaps particle effects may have higher role here.
It is the same (but depends on plastics food grade packaging do not contain as many additives as e.g. agricultural plastics.
Relative contribution of chemicals is most likely higher, as less has previously leaked from the particles.
Chemical toxicity may play a more important role than particle toxicity.

Question 7: How crucial is it to take into consideration the following effects in an environmental risk assessment for MNPs?

Participants could score the following options with a score of 1 (not important) to 5 (very important) or ‘I don’t know’. Results are shown in Figure A1.1.

- Chemical effects
- Particle effects
- Microbiological effects

Figure A1.1 Results of question 7.



Y-axis shows the total number of votes per option split by the three effect types: chemical effects (green), particle effects (blue), and microbiological effects (yellow).

Question 8: Which dose/exposure metric(s) do you think correlates best with observed effects of MNPs in organisms in a dose-response context?

- Volume (4)
- Mass (2)
- Surface area (2)
- Particle numbers (4)
- Mass of (a specific group of) plastic-associated chemicals (0)
- I don't know (9)
- Other, please specify (3):
  - Depends on the size of the organism and the uptake probability;
  - Probably a combination of particle numbers, size and shape;
  - Tricky, as strongly linked to particle size. I think both mass and particle number.

Question 9: In an environmental risk assessment, should different dose/exposure metrics be used for different types of MNPs (e.g. different size ranges, disfferent biological species)?

- Yes (10)
- No (1)
- I don't know (1)
- It depends on (3):
  - Depends on the objectives of the risk assessment;
  - Mass or volume will be relevant for chemical toxicity, while surface area or volume are relevant for particle toxicity. Both should be considered;
  - (One participants who selected 'It depends' did not provided further information).

Question 10: Among others, the following mechanisms of toxicity have been reported in the literature for environmental organisms. How would you rate the evidence base of these mechanisms?

Participants could score the following option with a score of 1 (very low confidence – evidence is weak or lacking), 2 (low confidence – evidence is limited or inconsistent), 3 (moderate confidence – evidence is reasonable but not conclusive); 4 (high confidence – evidence is strong and consistent), 5 (very high confidence – evidence is robust and well-established) or 'I don't know'. Responses are shown in Table A1.5.

- Food dilution in terrestrial invertebrates;
- Food dilution in aquatic invertebrates;
- Pore blockage in terrestrial plants;
- Oxidative stress;
- Internal physical damage;
- External physical damage;
- Effects from leached chemicals;
- Microbiome changes;
- Immunological effects.

Table A1.5 Responses to question 10 of the questionnaire.

	No evidence	Weak evidence	Moderate evidence	Strong evidence	Very strong evidence	I don' t know
Food dilution in terrestrial invertebrates	0	3	6	2	1	3
Food dilution in aquatic invertebrates	0	1	7	3	4	3
Pore blockage in terrestrial plants	0	3	2	4	0	3
Oxidative stress	0	0	4	7	4	3
Internal physical damage	0	1	5	8	1	3
External physical damage	0	4	5	6	0	3
Effects from leached chemicals	0	5	4	3	3	3
Microbiome changes	0	3	4	3	2	3
Immunological effects	0	3	3	3	3	3

Question 11: Is an important mechanism of toxicity missing (from question 10)? If so, what mechanism, and how would you rate the evidence base? Responses are shown in Table A6.

Table A1.6 Responses to question 11

Responses
Endocrine Disruption – moderate evidence.
Inflammation – moderate evidence.
Bioenergetic changes in the cells – evidence is only moderately present in current literature.
Effects from sorbed chemicals – moderate.
Changes in environment, e.g. changes in soil physico-chemical properties, such as pH and WHC. The level of evidence of these changes is rising, but

Responses
currently moderate evidence of correlation between habitat changes and toxicity.
The trojan horse mechanism provides strong evidence that it could contribute to toxicity of MNPs in an indirect manner.
There are several indirect effects reported in the literature. For instance, changes in the soil pH, or water holding capacity, which indirectly affect soil organisms. The level of evidence is low.
I think many of the above are not mechanisms of action in the strict sense but rather downstream effects. Goes in line with the fact that we do not understand the MoAs of MNPs very well.

Introduction to question 12: Environmental MNPs are a mixture of sizes, shapes, weathering states, and polymers and other plastic-associated chemicals.

Question 12:
Please, rank the following characteristics of environmental MNPs in order of their importance for inclusion in an environmental risk assessment.

The participants were provided with the below options, which they were asked to rank from most important to least important. The highest rank received 5 points, the lowest rank 1 point. In brackets, the sum of the ranking points per option:

- Size (64)
- Polymer type (45)
- Plastic associate chemicals (41)
- Shape (44)
- Weathering type (31)

Question 13: What criteria did you use to determine the above ranking (i.e. in question 12)? Please select all that apply:

- Availability of data (7)
- Ease of using the characteristic in a risk assessment (2)
- Relevance of the characteristic to the risks of MNPs (10)
- Other, please specify (1)
  - Tricky question to rank this. The combinations make for endless options. For example, I think plastic-associated chemicals are very important, but there are so many, impossible to test for all.

Question 14: Are any relevant characteristics missing [from question 12] and how relevant for the environmental risk assessment would any characteristic be? Responses are shown in Table A1.7.

Table A1.7 Responses to question 14.

Responses
Texture may matter – e.g. something hard and sharp may cause more harm to a small animal than something soft and rubbery. This should still be assessed.
Eco-corona (e.g. zeta potential, protein modifications, etc.) – potentially quite relevant.
Biofilm/ protein corona present.

Responses
Be careful to distinguish plastic-derived chemicals (internal, added at manufacture and can leach out) from plastic-associated chemicals (externally sorbed; interactions/associations happen once in the environment).

Introduction to question 15: When measuring MNPs in the complex media, measuring of all present plastic particles represents a major challenge. For example, through filtering only some size fractions are included, or some analytical techniques cannot measure dark-coloured particles or particles below a certain size. Accordingly, measurements may be an underestimation of the true plastic content of a sample.

Question 15: For environmental risk assessment purposes, is it acceptable to leave out part of the relevant particles?

- Yes (1)
- No (7)
- I don't know (0)
- It depends, please specify (7):
    - This is appropriate if you are able to extrapolate to the other size fractions and if you take a representative subsample of the chemistries and morphologies – there is literature on this;
    - If a relatively reasonable estimate of the magnitude of the missing fraction can be reported;
    - If we would have empirical knowledge on what the plastic pollution looks like in the fraction that is missing, we could use modelling approaches to fill the gaps, but there is a huge complexity that makes this extrapolation difficult at this time;
    - On the size fraction and the type of polymer you are missing;
    - As long as you model or account for the total, I think this is fine, and feasible;
    - When using the best possible method yes, this is likely the case in most risk assessments. But it should not be a reason to accept inferior methods and use data we know is far from the true environmental situation;
    - (One participants who selected 'It depends' did not provided further information).

Question 16: For environmental risk assessment purposes, is it acceptable to use extrapolation to include unmeasured fractions?

- Yes (11)
- No (0)
- I don't know (0)
- It depends, please specify (4):
    - See before;
    - If there are known biases that can be quantified and scaled;
    - It depends on how big and how relevant the fraction is that is not covered; but it also depends on the reliability (or uncertainty) of the available extrapolation method. It is hard to extrapolate to fractions that cannot be measured;
    - Validation of this is needed, but then fine.

Part 3: Koelmans et al. (2020) approach to environmental risk assessment of micro- and nanoplastics

The following introduction to Part 3 was provided:

As detailed at the start of this questionnaire, one of the aims of our study is to identify perspectives in the scientific community on the approach developed by Koelmans et al. (2020) and applied in several environmental compartments. Through this study, we hope to forward science-based MNP policy-making in the Netherlands.

The basics of the Koelmans et al (2020) approach are as follows:

1. Screening of quality of studies using Quality Assurance/Quality Control (QA/QC) criteria
2. Determination of ecologically relevant metric based on a given mechanism of toxicity (volume for food dilution, surface area for translocation-related effects)
3. Estimation of the “true” environmental concentrations of microplastics through alignments based on probability density functions (PDFs), e.g., application of power-law slopes
4. Alignment of effect concentrations to the ecologically relevant metric for environmentally relevant microplastic mixtures.
5. Assessment of uncertainty through probabilistic modelling

The following questions are about the risk assessment approach as originally described in Koelmans et al. (2020) and later applied by, among others, Redondo-Hasserlerharm et al. (2023, 2024) and Koelmans et al. (2023) to various environmental compartments.

Question17: Which statement below best reflects your understanding of the risk assessment approach outlined in Koelmans et al. (2020)?

- I don’t know it (0)
- I have heard of it (1)
- I have read the paper or related papers and have a basic understanding of the approach (8)
- I have read the paper or related papers and have a good understanding of the approach (3)
- I can apply the approach myself (3)

Introduction to question 18: Koelmans et al. (2020) and Redondo-Hasselerharm et al. (2024) use power law slopes to estimate the total concentrations of microplastics (from 5000 to 1 µm) in MNP exposure data.

Question 18: Do you agree with using this specific approach to estimate total concentrations of MNPs in a given sample?

- Strongly disagree (0)
- Disagree (0)
- Neutral (3)
- Agree (9)
- Strongly agree (3)
- I don’t know (0)

Question 19: Why or why not? Responses are shown in Table A1.8.

Table A1.8 Responses to question 19

Responses
There is evidence from some samples in nature that this works. I think we need more samples from different ecosystems in different areas to see if we can use generic values, but I think the method is a good idea and the best available.
Not familiar with the criteria used to select the power law as the estimation approach. However, I trust the author's selection process.
Across many environmental datasets, the power slope fitting approach always has a strong fit for the data with respect to size.
It is a good approach in the absence of measured data, but of course, it is only a best estimate.
It seems (too) simplistic, but I also appreciate that modelling and risk assessment require simplification. It seems hard to bring this out of a theoretical basis into practice, but I would need to become more familiar with the approach and application to be swayed more clearly one way or the other.
Considering the complexity of MNPs in the environment I have doubts about being able to estimate the MNPs in samples.
I guess it currently is the best way, considering our present-day knowledge.
Still hard to measure very small particles, I think that is an important step: validate whether this is correct. I think it will be, but good to ensure this.
It seems a good approach as the available methodologies on sampling are not providing information about the smallest fractions of microplastics, which are of high importance.
I think it approaches well what can be found in the field, however I expect it greatly depends on what the major source of MNPs is in a particular matrix, and for how long this has been the major source, whether this power law slope correctly describes the situation at that particular point in time.

Introduction to question 19: Redondo-Hasselerharm et al.(2024) assume food dilution and translocation-mediated effects to be mechanisms of toxicity and use volume and surface area as metrics for these mechanisms, respectively.

Question 20: Do you agree with volume as a metric for food dilution effects?
- Yes (12)
- No (0)
- Don’t know (2)
- It depends, please specify (1):
    - It depends on what medium you are investigating.

Question 21: Do you agree with using surface area as a metric for translocation-mediated effects
- Yes (6)
- No (1)
- Don’t know (6)
- It depends, please specify (2):

  - Surface area gives an indication of particle size, but I would say a minor dimension (Feret diameter) would be a better measure to determine possibility of translocation;
  - The size and charge may be more important. The translocation is most probable through damaged surface. Properties that induce this may be more appropriate.

Introduction to question 22: Many effect studies use monodisperse particles. Koelmans et al. (2020) and Redondo-Hasselerharm et al.(2024) re-calculate effect levels of such monodisperse particles to the defined ecologically relevant metric. Put briefly, they calculate the volume or surface area of particles (depending on the mechanism of toxicity) in the effect study, and then determine the number of particles that such a total volume or surface area would equate to if the MNPs of that study would have been a realistic polydisperse mixture of environmental MNPs. By doing so, exposure and effect levels are aligned, i.e. have the same ‘currency’.

Question 22: To what extent do you think that aligning effect and exposure concentrations is important for environmental risk assessments?

- Not important at all (0)
- Not very important (0)
- Somewhat important (1)
- Quite important (5)
- Very important (9)

Question 23: Do you have any specific thoughts on the alignment approach as developed by Koelmans et al. (2020) and Redondo-Hasselerharm et al. (2024) that you are willing to share? Responses are shown in Table A1.9.

Table A1.9 Responses to question 23.

Responses
I think they are elegant and useful as a best available method for a complex issue.
This is a very good approach. The Redondo-Hasselerharm et al. (2024) approach attempts to better quantify uncertainty of the alignments through Monte Carlo modelling of the alpha value, however additional parameters could be accounted for to more accurately estimate the uncertainty.

Question 24: The estimation of the risks using the approach by Koelmans et al. (2020) and Redondo-Hasselerharm et al.(2024) is:

- Very uncertain (0)
- Uncertain (2)
- Average (5)
- Certain (4)
- Very certain (0)
- I don’t know (3)

Question 25: Which factors contribute the most to the uncertainty?

- Uncertainty in the exposure data (2)
- Uncertainty in the effect data (4)

- Extrapolation of exposure concentrations to unmeasured fraction (4)
- Alignment of effect and exposure concentrations to the ecologically relevant metric (4)
- I don’t know (0)
- Other, please specify (1):
- A combination of the uncertainties listed above.

Question 26: Overall, do you think the method by Koelmans et al. (2020) and Redondo-Hasselerharm et al. (2024)results in an underestimation or an overestimation of the actual risks of MNPs?

- Large underestimation (0)
- Small underestimation (4)
- Accurate estimation (1)
- Small overestimation (3)
- Large overestimation (0)
- I don’t know (7)

Question 27: For which uses do you think the approach by Koelmans et al. (2020) and Redondo-Hasselerharm et al.(2024) is fit? Please select all that apply:

- Setting of environmental standards/risk limits (7)
- Identifying areas at most risks from MNP exposure (7)
- Supporting policy decisions on (plastic) use restrictions (8)
- Monitoring of environmental impacts over time (5)
- Enhancing public awareness and education (7)
- Purely academic purposes (3)
- I don’t think the approach should be used (3)
- I don’t know (1)
- Other (1)

Question 28: Following from the previous questions, what is still missing or needs to be further developed before the approach by Koelmans et al. (2020) should be used for the setting of formal environmental standards/risk limits? Please select all that apply.

- The approach can be used for this purpose (2)
- The approach can be used but it needs better exposure data (5)
- The approach can be used but it needs better effect data (7)
- More evidence for validity of using power slopes to estimate total concentrations (7)
- More proof of principle for method to align effect and exposure data (6)
- Better understanding of the true mechanism of toxicity of MNPs (12)
- It should consider polymer types (3)
- I don’t know (1)
- Other (1)

Question 29: Do you have any other perspectives on the Koelmans et al. (2020) and Redondo-Hasselerharm et al.(2024) approach that you would like to share?

No responses from participants

Question 30: Do you have suggestions (specific or general ideas) for alternative approaches to the risk assessment of MNPs? Table A1.10 shows the response(s).

Table A1.10 Response (1) to question 30.

Response
No, actually, it is really difficult to think of risk assessment for microplastics due to their extreme variability, but also the lack of good data is really complicating the situation. So, I think the approach by Koelmans and Redondo-Hasselerharm is the best we have now.

Appendix 1.3 Scientific expert workshop report

Background

The National Institute for Public Health and the Environment (RIVM) hosted an online workshop via MS Teams with a group of invited scientific experts on the topic on ecological risk assessment (ERA) of microplastics on 25 November 2024. The goal of this workshop was to gather perspectives on ERA of microplastics in general, but specifically on the approach to ERA of microplastics developed by researchers from the Wageningen University & Research led by Prof. Dr. Bart Koelmans and described in several publications. This document is a summary of the discussions during the workshop that was held under the Chatham house Rule.

Please note that, in this report, the responses to questions that were provided in text (e.g. via the MS Teams chat function) are mostly presented as they were submitted by the participants, with minor edits made for readability. These responses were provided within restricted time, and, as a result, some are relatively brief and may not fully capture the participants' perspectives. Open (verbal) discussions have been summarised and aggregated where relevant. Table A11 presents the agenda of the workshop.

Table A1.11 Agenda of the scientific expert workshop

Time (CET)	**What**
16:00–16:15	Welcome, workshop goals, introduction participants (RIVM)
16:15–16:25	Background project (RIVM)
16:25–16:30	Koelmans et al. approach to environmental risk assessment of microplastics
16:30-17:15	Discussion round 1 – Chemical vs. particle effects
Break (15 min)	
17:30–18:15	Discussion round 2 – Mechanism of toxicity and ecologically relevant metric
18:15–18:55	Discussion round 3 – Other aspects, moving forward
18:55–19:00	Closing, next steps (RIVM)
End of workshop (19:00 CET)	

Opening, project background, and Koelmans et al. approach to environmental risk assessment of microplastics

The chair welcomed the participants and explained the purpose and rules of the workshop. The workshop took place under the Chatham House Rule, which means that participants can share what they have heard, but not who attended or who said what. It was also explained that Bart Koelmans is involved in the project as an external advisor and that he will learn about the findings under the Chatham House Rule. Following the introduction, all participants briefly introduced themselves followed by a presentation by the organising team involving background information on the project, information on work done on microplastics by RIVM, and specific goals of this meeting. Finally, slides were presented on some of the challenges of environmental risk assessment of microplastics, introducing the Koelmans et al. approach and on how this approach deals with said challenges.

Subsequently, the workshop discussions started, which were organised in three rounds that addressed the following topics: 1) chemical vs. particle effects; 2) Mechanisms of toxicity and ecologically relevant metric; 3) Other aspects (see agenda, Table 1). The following sections provide details of the input collected during these discussion rounds.

Discussion round 1: Chemical and particle effects
The first round of discussion was about how to consider chemical and particle effects. In the documents circulated prior to the meeting and in the workshop presentation slides, the term ‘physical effects’ was used instead of ‘particle effects’. This led to confusion about what are physical effects and what are not. It was decided that, during the meeting, where ‘physical effects’ was mentioned, experts should read ‘particle effects’, which was a more clear/more appropriate term to the experts.

An organising team member presented some findings from a questionnaire that was sent out in the summer of 2024 to scientific experts in the field of ERA of microplastics. From the questionnaire it became clear that among the respondents of the questionnaire, particle and chemical effects were considered equally important to explaining the effects of microplastics in the environment, and that, accordingly, both aspects should be considered in a ERA of microplastics.
Using Mentimeter, the experts were asked to respond to the following (closed) question:

- **Question 1.1**: How to deal with physical and chemical effects [of microplastics] in environmental risk assessment?

Five options were provided:

1. Environmental risk assessment for chemicals should consider microplastics;
2. Microplastic environmental risk assessment should consider only (plastic-associated) chemical effects;
3. Microplastic environmental risk assessment should only include particle effects of microplastics;
4. Microplastic environmental risk assessment should consider both (plastic-associated) chemical and particle effects;
5. Other.

All experts chose option 4: ‘Microplastic environmental risk assessment should consider both (plastic-associated) chemical and particle effects’.

In the open discussion, the experts were then asked to explain their answer. During the discussion the following topics were discussed:

- **Importance of understanding fate:** It was argued that chemicals are generally important to consider in the risk assessment of plastics. Plastics (e.g. debris) released to the environment will degrade over time to form mesoplastics, macroplastics, microplastics and/or nanoplastics. Chemicals are released along this degradation route. The importance of considering whether to include chemicals or not depends on where along this route chemicals are released. The relative

contribution by chemical vs. particle effects may change. It was stated that the fate of chemicals in plastics is not well understood.
- **Mixture effects:** Mixture effects may also be relevant, which could be a reason to also consider chemicals in an environmental risk assessment. Mixture effects are also partly fate issues because chemicals may also affect each other’s bioavailability.
- **Towards Safe-and-Sustainable-by-Design plastics:** New generations of plastics will also require chemicals to achieve a specific functionality. Thus, including chemicals in the risk assessment of (micro)plastics is important to the development of Safe-by-Design plastics.
- **Excluding chemicals a priori:** In response to a follow-up question by one of the organising team members on the contribution of microplastics to the total exposure of microplastic-associated chemicals in the environment, it was brought up that any decision to exclude chemicals should be a result of an environmental risk assessment, rather than an priori decision. When a risk assessment shows chemicals are not relevant, they may be excluded. Whether this is the case may be situation-dependent.
- **Considering effects other than food dilution-related:** It was stated that chemicals have effects on organisms through other mechanisms than food dilution that could be relevant to include.
- **Feasibility of chemical risk assessment for microplastics:** It was acknowledged that we generally know how to conduct risk assessments for chemicals. The question for microplastics is, do we know which chemicals to assess, given the fact there are more than ten thousand potential chemicals in plastics? If we know the most important chemicals, their effects could be assessed separately. Doubts were expressed about the feasibility of also including also adsorbed chemicals in an ERA.
- **Case-specificity of relevance to including chemicals**: It was argued that, given the diversity in characteristics of microplastics, there may not be a one-size-fits-all answer as to whether chemical effects are relevant or not. Whether or not chemical effects are relevant may depend on size ranges (e.g. meso-, macro-, micro- and nanoplastics). How plastics enter the environment may also matter. For example, use of films in agriculture may directly result in release of microplastics to soil. However, due to presence of relatively pristine plastic films on agricultural soil, chemical release may be more relevant compared to the release of microplastics.

Subsequently, the participants were asked to respond to the following question:
- **Question 1.2**: To what extent do you support an environmental risk assessment that only considers particle effects?

Experts were asked to provide their response in the chat function of MS Teams. Table A1.12 shows the responses of the experts to question 1.2.

Table A1.12 Responses by experts to question 1.2.

Responses
Particle effects are the ‘novel’ effects that are an addition to chemical effects (which are already covered), so focusing on them makes sense.
I think a risk assessment focused on particles can be supported as this is the current gap in our risk assessment. Combined effects (mixtures) are already a challenge chemical [risk assessment] is grappling with. But it is the approach that is needed later if we can understand both separately.
I support it if it is the best we can do at the moment.
It is a step forward but it would contain uncertainty, which should be taken into account and be included.
[I] do support particle-oriented risk assessment, but chemical-related effects should [not] be excluded, or the contribution of chemicals to microplastics hazard and levels released to soil should be investigated more before making this decision.
If the intent of the risk assessment is to address total potential risk, only considering particle effects may underestimate that total risk (i.e. miss risks relating to chemicals). It would be important to specify that such an assessment is looking at particle effects only.
For microplastics, particle effects may predominate chemical effects Chemical effects can be covered separately, and perhaps be combined with particle effects using mixture toxicity approaches at a later stage.
I would support such an ERA under one of two conditions: 1) an ERA that considers chemical-induced effects is infeasible due to data/method limitations, and therefore a particle-based ERA is performed as a tentative/first-pass approach; or 2) a chemical-based ERA has already been performed for worse-case scenarios similar/relevant to the ERA of interest, and has been shown to be negligible. In this case, one might consider a multi-tiered ERA approach, with higher data needs for higher tiers, etc.

In the discussion that followed, the following additional points were discussed:

- **Uncertainty**: It was argued that there are uncertainties relating to mixture toxicity effects and the gap between an ERA outcome and what really happens in the environment.
- **Potential for underestimation**: By considering particles only, you run the risk of underestimating the risks from chemicals.
- **Reporting of the scope:** There was broad consensus among participants that if an ERA is based on particles only, this should be clearly stated and communicated to, for instance, policymakers.
- **Worst-case scenario**: It was shared that chemical risk assessment could also be performed on the basis of a worst-case scenario. For example, like the first-pass approach by the World Health Organization, where they assumed the most toxic chemicals in plastics would be aborted 100%.
- **Urgency to move forward**: It was stated that if one is to wait for an approach that can deal with the full complexity of (micro)plastic pollution (i.e. all chemical and particle effects), this may postpone conducting an ERA for use in policy-making, which may be undesirable.

Discussion round 2: Mechanisms of toxicity and ecologically relevant metric

Elmer Swart introduced the next discussion round on mechanisms of toxicity and ecologically relevant metrics. During this introduction, results from the questionnaire were shared, including a graph showing the level of evidence for a given list of mechanisms of toxicity for microplastics, and what is still missing or requires further development for setting environmental quality standards/risk limits for use in policy.

The experts were then asked to go to Menti.com and respond to the following question:

- **Question 2.1** How important is it to gain more knowledge on the mechanisms of toxicity before the approach can be used for formal environmental quality standards/risk limits for microplastics?

The following five options were provided:

1. Not important;
2. A little important;
3. Somewhat important;
4. Important;
5. Very important.

The options ‘Important’ and ‘Very important’ were each selected by four participants (n=8). The participants were then asked to briefly explain their response in an open question on the Menti.com platform. Table A1.13 shows the input collected.

Table A1.13 Responses from participants to the question ‘Please explain why?’ in relation to the responses provided in Question 2.1.

Responses
If [the mechanism of toxicity is] not only food dilution, completely different methods to align lab and field [data] would be needed.
[A] better mechanistic understanding can better define the applicability domain or the most relevant exposure of concern.
We might overlook important mechanisms of toxicity, thereby underestimating risk.
Knowing [the mechanism of toxicity] would allow [a] better understanding of adverse outcomes but might also help extrapolation between particles. There is already a lot of information [available on the mechanism of toxicity] so we already have a clue for a first step. Again, underestimation [of risks]/missing [relevant effects] might happen. But before we will know everything, might take more than five years.
[It is important to gain more knowledge on the mechanism of toxicity] because the Koelmans approach is an endpoint (MoA)-oriented approach.
Ideally, we would completely understand the mechanisms of toxicity. But in actual applications of risk assessments, there are many uncertainties. Again, [it is] very important to communicate that uncertainty.
We see uptake of microplastics in biota, but [we] don't know what [the] mechanism is, or what the route of uptake is. We know several possible mechanisms of toxicity of particles, but [we] have no idea of their relative importance in soil organisms.

Responses
The Koelmans approach requires an empirical linkage between the toxic effect and the ERM. A true MoA is not needed – just a linkage.

In the open discussion that followed, the following additional points were discussed:

- **Relevance of understanding the mechanism of toxicity:** It was argued that there is still much we don't know about the mechanisms of toxicity of microplastics. In addition to food dilution and translocation-related effects, there are also other relevant mechanisms of toxicity that are not being considered. The relative importance of these mechanisms of toxicity are not clear. New or other mechanisms could change which metric is relevant. In scientific papers, there is a lot of conjecture about what the mechanisms of toxicity are, but often they are not explored further. Microplastics can cause effects in other ways than one specific mechanism of toxicity. By choosing a certain mechanism of toxicity, those other effects are ignored. For example, fibre toxicity cannot be described by volume. It was argued that if a certain mechanism of toxicity is chosen as a basis for an ERA, there needs to be strong confidence that this is the most relevant mechanism of toxicity. It was also argued that a requirement to know the full mechanism of toxicity or the adverse outcome pathway will restrict our ability to conduct ERA and that even limited understanding of the linkage between a metric and effect would be sufficient, without needing to know what exactly happens at every stage of the adverse outcome pathway.
- **Lack of evidence for terrestrial system**: It was stated that the available evidence for the mechanism of toxicity for terrestrial organisms is not very strong. Indirect effects in soils may be more important. For plants, doubts were expressed as to whether pore-blockage is the most relevant mechanism of toxicity.
- **Use in policy-making**: During this discussion, some other perspectives were vented on the use of the approach in policy-making. Several participants argued that it can be used, albeit with clear communication of its uncertainties, and the acknowledgement that there is a risk of missing relevant aspects/toxicities. Others argued that in this stage it would be premature to conduct an ERA in a regulatory context. It was also stated that acknowledgement is needed that – due to the complexity of microplastic pollution and because microplastics are so different from conventional chemicals – a(n) (single) ERA, that is 100% fit for purpose, may not be possible. Moreover, it was argued that there is a big difference between what is needed for science and what is needed for policy-making. For use in policies, ERA cannot be changed every year, and communicating uncertainties is challenging.
- **Use of particle numbers**: It was noted that, especially in the terrestrial scientific field, many studies are using mass instead of particle numbers. This has to do with the ease of measuring mass. It was acknowledged that, given the fact that size is important for toxicity, particle number should be considered.

When particle distributions are known, it is relatively easy to calculate particle number concentrations and interchange between metrics.

Next the participants were asked to reflect on the following question:

- **Question 2.2:** What are the implications for choosing/continuing with this approach when the mechanism of toxicity is not clear enough?

In the open discussion that followed, the following additional points were discussed:

- **Scope of the approach to ERA:** It was argued that one should expect criticism if one uses an approach that only addresses one specific aspect of plastics, and that it would be worthwhile to not only focus on a single approach. Again, the need for transparency was raised.
- **Mechanism of toxicity:** Doubts were expressed as to whether food dilution is relevant in real environmental conditions at expected environmental concentrations. If this is a relevant mechanism, this would also apply to natural particles such as sand or silt. At environmental concentrations, other metrics may be more relevant and therefore, other metrics may apply. Furthermore, food dilution may not be relevant to all soil organisms, especially the ones that do not ingest soil for feeding, and thus, considering ingestion for those organisms is not relevant. For effects on soils organisms, effects on soil properties may be more important. It was argued that finding a single mechanism of toxicity may not be possible, and that the mechanism of toxicity may be dependent on specific environment, application, source etcetera.
- **Dealing with uncertainty and evolving insights**: It was stated that deriving a number is better than having no number, and that data requirements should not get in the way of assessing risks. If studies show that volume is the most sensitive ecologically relevant metric (ERM), this means that you are already on the safe side when using that ERM. You could consider all ERM and choose the lowest if needed. The question was raised as to whether we are being overly cautious and/or require more from a ERA of microplastics than what we from for a typical ERA. For most other chemicals, we don’t always know what the exact mechanism is, either. Also, safety factors can be applied if needed. When knowledge evolves, the soil quality threshold or ERA approach can be updated, although it was acknowledged that updating such policies is typically slow.

Next the participants were asked to reflect on the following question:

- **Question 2.3:** Is it acceptable to use size and shape as characteristics in the environmental risk assessment of microplastics (for use in policy)? Why or why not?

In the open discussion that followed, the following additional points were discussed:

- **Considering (polymer) type:** It was stated that when it comes to certain types of plastics, for example, biodegradable plastics and tyre wear particles, you cannot ignore polymer type. Especially tyre wear particles are very different from other polymer types, where chemical effects may be much more important and thus have to be considered in ERA. It was argued to be mindful of this, also in the light of industry and political push towards biodegradable plastics. It was stated that ongoing analyses have shown that size and shape are typically the best predictors for toxicity, whereas polymer type is usually not an important feature, although the underlying data did not contain much tyre wear data.

- **Other features**: It was argued that surface functionalisation and interaction with micro-organisms and proteins may be important to the effect microplastics have.

Discussion round 3: Any other aspects
In the last round of discussion, the participants were asked to go to the Mural.com platform and use the whiteboard that had been prepared to supply additional input on any aspect of the Koelmans et al. approach to ERA of microplastics, see Figure A1.2.

The participants were asked to add input on these questions:

- What is missing/needs further work for use in policy?
- Are there any further aspects of the approach/perspectives you would like to talk about/share?

Figure A1.2 Empty whiteboard that was made available via Mural.com, which participants could use to add additional reflections on the Koelmans et al. approach or, more generally, on environmental risk assessment of microplastics

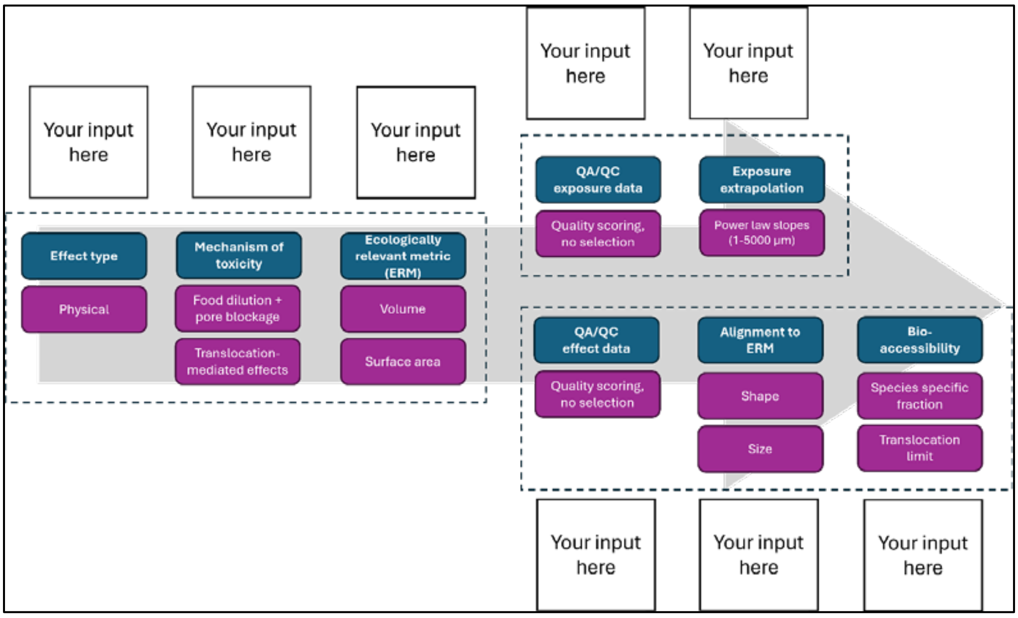


Table A1.14 shows the collected input categorised by ERA component : general input, effect type, mechanism of toxicity, ecologically relevant metrics, QA/QC exposure data, exposure alignment, QA/QC effect data, alignment to ERM and bio-assessable fraction.

Table A1.14 Input collected in a whiteboard in Mural.com.

General

Input	Input
The Koelmans approach is definitely the most advanced ERA for microplastics – so [it's] a good starting point. But for a regulatory ERA, it needs to be further developed, in particular by including other mechanisms of toxicity.	Further extending on my comment towards the end: tyre wear particles as a special group of microplastics need to be included in the ERA – but [tyre wear particles] probably require an approach of their own and should not be mixed with other microplastics.
I would recommend that ERAs be performed using site-specific monitoring data whenever possible to account for differences between particle distributions, and most importantly, uncertainties associated with those monitoring data.	A formal and quantitative approach to propagate uncertainties from alignments is needed, with some guidance regarding acceptable uncertainty bounds.
For each question discussed today [there is a] balance between moving forward with uncertainty OR don't do risk assessment yet.	We talked about mixture toxicity when referring to chemical+particle toxicity but [it] might also be valuable to see plastic-particle effects as a mixture (captured in the microplastome concept).
RA should be applicable for [the] current problem and it should be fit-for-future.	As there is no clear definition on [microplastics] and [nanoplastics], I don't know how to make the lower size cutoff.
Ecocorona of MPs.	Chemicals associated with MPs.
Dynamics of MPs in soil (from small to smaller?).	Nanoplastics
Fate of plastics and associated chemicals in soil.	Lack of data on effects of mixture of particles.
Consider what policy interventions can be done. For example, we can take action on mulching films, but maybe not on secondary plastics.	Build in a process to update [input] data, the approach itself, and the output data. For example, evaluate every 5 years, given the novelty of microplastics.
Hazard assessment approaches for microplastics are using chemical approaches. Does this need to be evaluated more critically? Apical responses require high concentrations, but more ecologically relevant responses could potentially be more insightful for chronic exposure.	It feels like some focus on this would help in terms of specific exposure scenarios that can build evidence towards particular hazard concerns relating to specific exposure scenarios. The terrestrial plastic projects @ EU level seem quite suited to helping with some sort of assessment like this. Tyre wear is another [issue] that would be a case study to explore. Site-specific RA seems like [something] where we could potentially learn more about how best to proceed.

Input	Input
Be clear on what types of plastics you are targeting (conventional vs biodegradable?)	

Effect type

Input	Input
I wonder about the significance of absorbed contaminants. If risk assessments are performed on relatively clean soils, will there be much chance for contamination by PCBs, PAHs, dioxins and other contaminants?	Group similar mechanisms of toxicity across multiple stressors (e.g. oxidative stress from particles and other chemicals). Also, consider synergistic toxicity of pathogens.
Surface reactivity	Add assessment/uncertainty factor for chemical-related effects.

Mechanism of toxicity

Input	Input
Surface properties (e.g. cationic charge)	Food dilution is a starting point as long as the uncertainties about other endpoints is communicated.
We need more knowledge on the link between particle characteristics and their effect/MoA to make a good selection of ERM.	Food dilution as an endpoint does not work for all terrestrial organisms (not those that do not use soil as food).
Indirect effects on soil properties should be considered.	Is poor blockage the right mechanism of toxicity for plants?
For soils, I think other modes of action should be considered, particularly where effects are observed for plants. Can indirect effects be included?	
Ecologically relevant metric	
Volume is very oriented towards food dilution as an endpoint. Particle size and shape should be considered.	How to consider dose-independent effects?

QA/QC exposure

Input	Input
Might be needed in the future.	Focus especially on options where you have the potential to do policy interventions.
Was there really no selection of relevant studies used? Why, then, was quality scoring done?	

Exposure alignment

Input	Input
Which power law exponent to take? Particularly in a specific local situation, it may deviate from an average value.	Power law data for particles <1 um are needed to validate this approach below those sizes. Also, a standardised approach is needed to determine what data is usable (e.g. establish lower size limits of detection).
Do the power law slopes also work for fibres? Or is there another way they fragment?	You might not always have all necessary data to do exposure extrapolation
Uncertainty about alignments below detection limits	1-5000 um is a very large size range. It does not consider that smaller particles might have different bio-accessibility and effects.

QA/QC effects

Input	Input
A set of minimum criteria should be established in lieu of using data that meets all De Ruijter criteria (currently just one? Study in literature).	To get a high quality score makes testing more expensive – particularly for soils where validation of test concentrations is time-consuming.

Alignment to ERM

Input	Input
Alignments should be performed probabilistically for specific site characteristics.	Maybe more validation of the alignment might be necessary.

Bio-accessible fraction

Input	Input
What about unicellular organisms?	Bioaccumulation and bio-accessibility at sensitive life stages may also be considered in future frameworks.
Biological considerations (e.g. life-stage specific aspects)	There are acknowledged inconsistencies around sensitive species (for example, Lemna are very sensitive although they don't fit the food dilution paradigm). These inconsistencies leave doubt around the approach.

The texts in brackets were added by authors of this publications to improve clarity. The additions have been checked for correctness by the scientific experts. Collected input has been organised by main topic (in bold).

In the last open discussion, the following points were brought up:

- **Other aspects relevant to consider**: The need to include nanoplastics (somehow) was brought up. This was thought to be particularly relevant since toxicities may increase as particles become smaller. Also, the issue of dealing with effects that are not dose-dependent was raised. Furthermore, there may be interactive effects between the particle-induced toxicities in the presence of pathogens, which may be an additional aspect to consider. It was also argued that in contaminated environments, there is an increased chance that microplastics can adsorb other contaminants. This could be considered in ERA.

- **Guidance**: It was suggested that there is a need to establish guidelines for what sizes to use in ERA. For example, to establish what is the lower size limit to use. Changing the size ranges used for species sensitivity distribution can strongly impact uncertainty and, to some extent, the final outcome of ERA. It was suggested to adjust the effect thresholds on a site-specific basis.
- **Mechanistic studies:** It was stated that performing studies according to available quality standards is challenging and costly. This could be a reason to focus on mechanistic studies, for which dose series are less important.

Appendix 2

Appendix 2.1 Details of the Koelmans approach

This appendix provides an detailed overview of the required inputs, the steps, and the formulas used in the Koelmans approach. First, we provide a brief overview of the inputs, followed by details of three main steps (effect alignment, exposure alignment and the risk assessment) followed by details of the used formulas, including a numerical example.

Required inputs:
The basic inputs required to perform an aligned risk assessment based on the Koelmans et al. (2020) approach are:

- Exposure data:
    - A microplastic environmental exposure concentration with a known size distribution suitable for fitting a model (e.g. for a power law distribution, the slope (alpha) should be known).
    - The measured minimum and maximum size of the particles making up the exposure concentration.
- Effect data:
    - An effect concentration of monodisperse particles, or an effect concentration with a known or assumed size distribution of polydisperse particles.
    - The minimum and maximum size of particles making up the effect concentration.
    - The maximum bioavailable particle size for the studied organism.
- One or multiple ecologically relevant metric(s) (ERM). Alignments can be performed for multiple ecologically relevant metrics.

Effect alignment:

1. Correct the effect concentration for bioavailability.
   When polydisperse particles are used in the effect study, any particles that are larger than the maximum bioavailable size of the tested organism should be discarded. This correction step decreases the reported effect concentration using the correction factor from equation A2.1.
2. Calculate the mean ecologically relevant metric (ERM) (e.g. volume) of particles in the effect study.
    a. For monodisperse particles, the mean ERM can be calculated directly from the given particle shape.
    b. For polydisperse particles, the mean ERM can be calculated by combining the ERM of the smallest and largest particles with the power law slope for the particles used in the test. If the latter is not known, an assumption needs to be made on which slope to use.
3. Calculate the mean ERM (e.g. volume) of particles in the environment.
   Similar to step 2, the mean volume of particles is calculated from the volume of the smallest (1 µm) and largest (5000 µm) particles in the environment, and using the power law slope reported in the exposure measurement.

4. Calculate the polydisperse effect concentration.
   In this step, the effect concentration from step 1 is corrected for the ERM differences (e.g. particle volume) between the environment and the effect study.
5. Calculate the aligned effect concentration.
   The effect concentration from step 4 was calculated for the bioavailable size range. In this step, the effect concentration is extrapolated to encompass the full environmental range of microplastics (1-5000 µm) in order to be able to directly compare the effect concentration to the exposure concentration.

Exposure alignment:

6. Calculate the aligned environmental concentration.
   Microplastics in the environment are often not measured in the complete 1-5000 µm range. In this step, the measured concentration is extrapolated to encompass the entire environmental microplastic range.

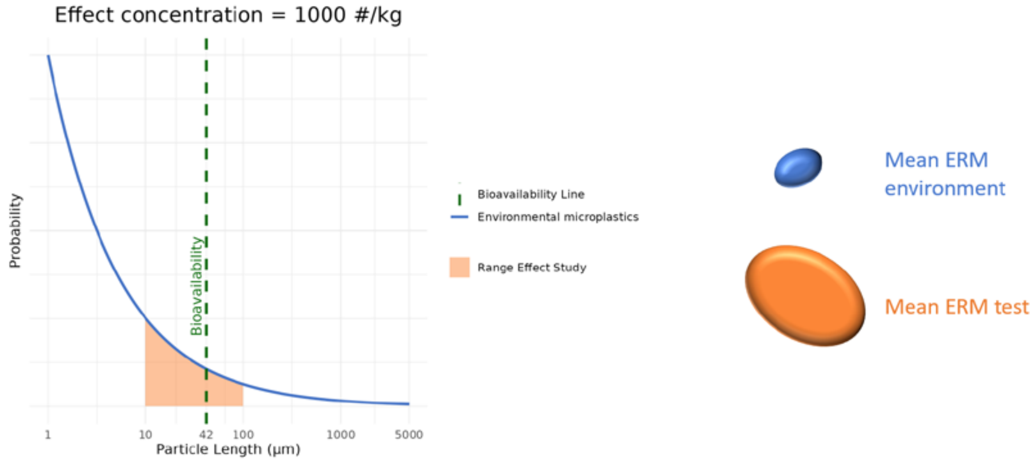
Risk assessment:

7. Derive the Hazardous Concentration on the basis of Species Sensitivity Distribution (SSD).
   By applying steps 1-5 on a set of effect concentrations a dataset can be created from which an SSD can be derived. The resulting HC_5 and HC_{50} values can be used in the subsequent risk assessment.
8. Calculate the Risk Characterisation Ratio (RCR).
   Divide the environmental concentration from step 7 by the HC_5 or HC_{50} concentration from step 6. The risk characterisation score quantifies whether a risk limit (such as the HC_5 or HC_{50} derived in step 6) is exceeded. A score greater than one means the chosen risk limit is exceeded.

Details on formulas and numerical example:
In this section, we will work through the steps listed above using a numerical example. We restrict this section to the effect and exposure alignment since the derivation of the SSD and HC_5 concentrations is the same as for chemicals.

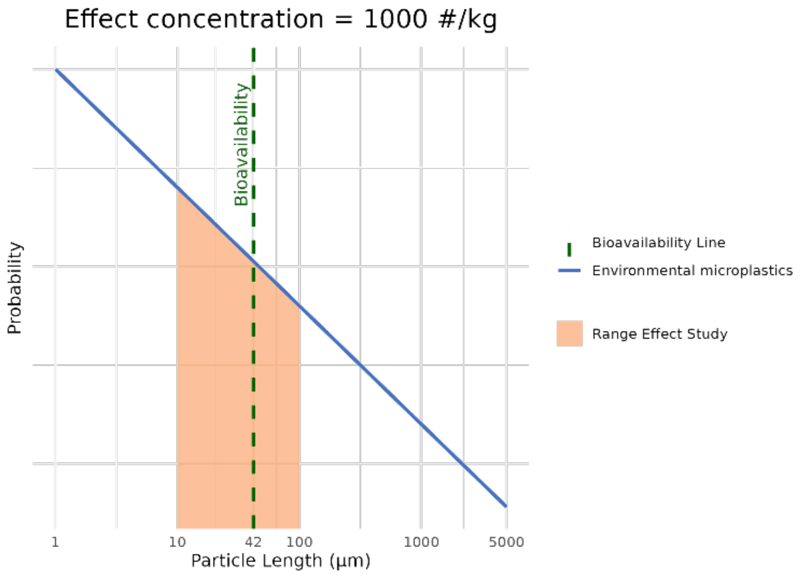
We introduce a hypothetical example regarding a reported effect concentration of 1000 particles/kg soil. This hypothetical effect study used microplastics with a size range from 10 – 100 µm, with particles shaped as fragments. The distribution of the effect size range is unknown, so we assume the power law slope α is 2.5 for particle length similar to Redondo-Hasselerharm (2024). For this example, we also use a power law slope α for volume of 1.86, which is the mean alpha for volume in compost from Redondo-Hasselerharm (2024). The figures will show a visualisation of the alignment steps, depicting the power law size distribution in the test and the environment, as well as the effect concentration after each step in the Koelmans alignment approach. Note that the shape of the power law distribution and the ratio of the particle sizes are for illustration purposes only. Figure A2.1 shows the starting situation before alignment. Figure A2.2 shows the log-log transformed power law depicted in Figure A2.1.

Figure A2.1 Illustration of a power law size distribution representing environmental microplastics in size range 1 to 5000 µm (blue line) and the size range used in an effect study (orange shading).



Ellipsoids on the right-hand side represent the average size of particles used in the test (orange) and as present in the environment (blue). Note that the X-axis is on a log scale.

Figure A2.2 Illustration of power law size distribution representing environmental microplastics in size range 1 to 5000 µm (blue line) and the size range used in an effect study (orange shading).



Note that axes are log-log transformed.

Step 1. Correct the effect concentration for bioavailability.
For this step, a correction factor for the calculated bioavailability is applied using Equation A2.1. Bioavailability is corrected by multiplying the effect concentration by this correction factor. The correction factor is applied to the length of microplastic particles, calculating what the effect concentration would be if only particles of bioavailable size were used in the effect study.

$$CF = \frac{X_{UL,D}^{1-\alpha} - X_{LL,D}^{1-\alpha}}{X_{UL,M}^{1-\alpha} - X_{LL,M}^{1-\alpha}}$$

Equation A2.1 Generic formula for the correction factor from Koelmans et al. (2020) where:

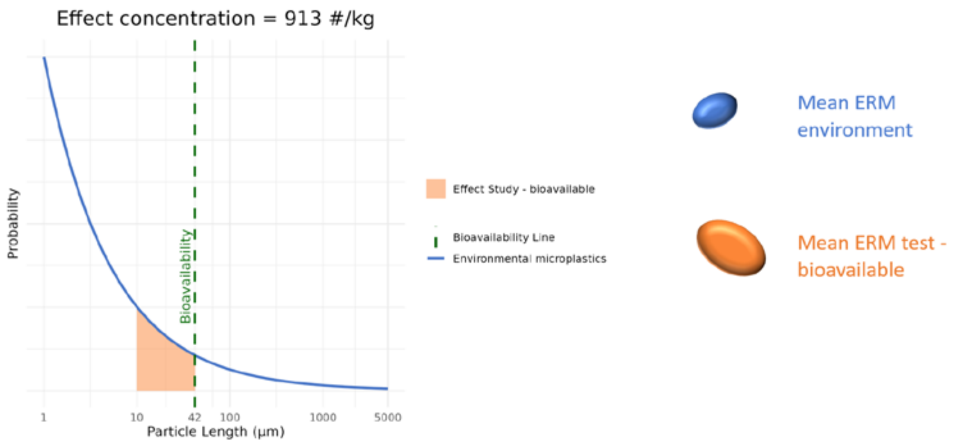
X: The ERM
UL: The upper limit
LL: The lower limit
α: The power law slope
M: The range for which data is available (the range to be corrected)
D: The default size range (the range that M is corrected to)

Using the numbers example, this would result in a correction factor for bioavailability (CF_{bio}) of 0.913, as is shown in the equation below:

$$CF_{\,bio} = \frac{42^{1-2.5} - 10^{1-2.5}}{100^{1-2.5} - 10^{1-2.5}} = 0.913$$

The effect concentration corrected for the bioavailable range then becomes 913 particles/kg soil. Figure A2.3 depicts the progress at this stage of the alignment.

Figure A2.3 Illustration of power law size distribution representing environmental microplastics in size range 1 to 5000 µm (blue line) and the size range used in an effect study (orange shading).



Ellipsoids to the right-hand side represent the average size of particle used in the test and as present in the environment. Note that the x-axis is on a log scale. This figure shows the progress of the alignment at step 1.

Steps 2 & 3. Calculating the mean ecologically relevant metric for the effect study and the environment.

The mean ERM (e.g. volume) is calculated from known or assumed particle dimensions and shapes based on the lower and upper limits of the size distribution. When effect studies are performed, the use of monodisperse microplastics estimating the upper and lower limits of the ERM can be skipped, as monodisperse microplastics have only one size/volume/surface. Various geometric formulas can be used to calculate the upper and lower limits when the shape of particles is reported. However, Redondo-Hasselerharm in accordance with Koelmans et al. (2020), assumed that the ERM, volume in their example, for most shapes of microplastic particles can be calculated as if particles were shaped like an ellipsoid.

Assumptions on the size and shape of the largest bioavailable particle as well as the size and shape of the smallest particle can have an effect on the upper and lower limits and mean ERM calculated. In fact, calculation and measurements of the volume and surface area of microplastic particles is an ever evolving field. Methods are dependent on the reported information on dimensions and shapes of microplastics, as well as the analytical equipment used. Here, we show the equations for volume (Eq. A2.2) and surface area (Eq. A2.3) as used in Redondo-Hasselerharm et al. (2024). Subsequently, we also assume the ratio between length:width and width:height to be 0.77 and 0.67, respectively, based on Kooi et al. (2021).

$$V = \frac{4}{3} * \pi * a * b * c$$

Equation A2.2 The volume of an ellipsoid where a, b and c are the semi-axis of the ellipsoid.

$$A = 4\pi * \sqrt[p]{\frac{(ab)^p * (ac)^p * (bc)^p}{3}}$$

Equation A2.3 The surface area of an ellipsoid using the Thomsen's approximation.
Where a, b and c are the semi-axis of the ellipsoid, p is a constant with a typical value of 1.6075.

In the example, the upper and lower limits for the effect study and the environment are presented in Table A2.1. For the upper limit in the environment (and the effect study), the values of the semi-axis are $a = 42 * \frac{1}{0.77}$; $b = 42$; $c = 42 * 0.67$.

In this example, we use the ratio $\frac{1}{0.77}$ to calculate the length (a) of the largest bioavailable particle with an average shape in environment (an ellipsoid). However, other approaches are possible where, instead, the length is set at the maximum bioavailability (Mehinto et al. 2022) or the maximum reported length in the effect study (Koelmans 2020, Redondo-Hasselerharm 2024), illustrating the difference in choices that can be made when implementing the Koelmans approach. In this example, similar to Redondo-Hasselerharm et al. (2024), the lower limit ERM in the environment and effect study were calculated using ratios of 1:1 between length:width and 1:0.67 between width and height.

Table A2.1 Particle volumes for the upper and lower size limits for microplastic particles in the environment and the effect study, indicated in µm3.

	Environment (µm³)	**Effect study (µm³)**
Upper limit	33,754.41	33,754.41
Lower limit	0.3508	350.8

On the basis of the upper and lower size limits of the ERM, the mean ERM for the effect study and the environment can be calculated. Assuming the distribution of particles is best described by a power law, the mean ERM can be calculated using Equation A2.4. For this equation, the power law slope used is the slope of the fitted ERM (volume in this example). For this example, a power law slope for volume in the environment of 1.86 is used. For the effect study, no power law slope for volume was reported. Therefore, the power law slope for volume in the effect study was approximated using the approach described in Redondo-Hasselerharm (2024) by using the ratios between slopes for length, volume and surface area. The power law slope for volume in the effect study was calculated as $2.5 * 1.776 = 1.408$. Table A2.2 shows the calculated mean volumes for the environment and effect study.

$$\mu_x = \frac{1-\alpha_x}{2-\alpha_x} * \frac{X_{UL}^{2-\alpha_x} - X_{LL}^{2-\alpha_x}}{X_{UL}^{1-\alpha_x} - X_{LL}^{1-\alpha_x}}$$

Equation A2.4 Calculating the mean ecologically relevant metric using the upper and lower limits and the power law slope (Kooi et al, 2021).
Where:
x: The ERM
α: Power law slope of ERM
UL: upper limit of the ERM
LL: lower limit of the ERM

Table A2.2 Calculated mean volume for environment and effect study.

	Environment (µm^3)	**Effect study (µm^3)**
Mean volume	8.588	3986.84

Step 4. Calculating the polydisperse effect concentration

The mean ERM will likely differ between the effect study and the environment. This difference represents the misalignment for this ERM between the particles in the effect study and the environment. By using Equation A2.5, the effect concentration from step 1 can be corrected for this misalignment. The resulting effect concentration is after this point corrected for both bioavailability (step 1) and differences in the mean ERM.

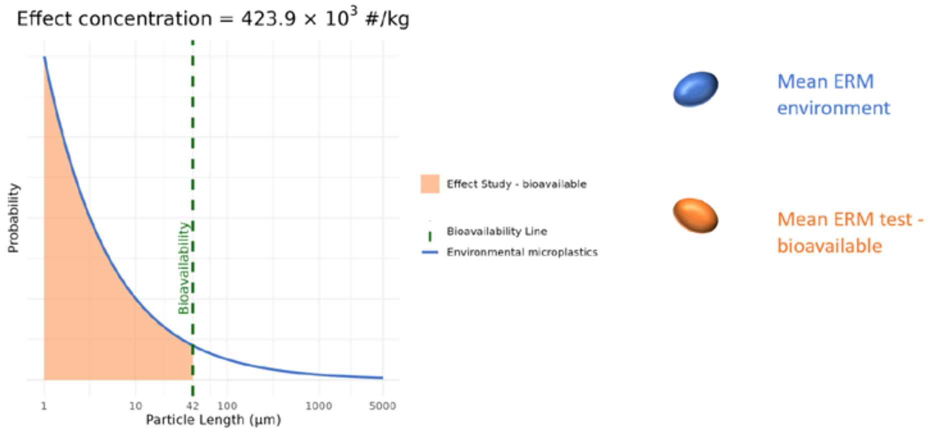
$$EC_{poly}^{bio} = EC^{bio} * \frac{\mu_x^{test}}{\mu_x^{env}}$$

Equation A2.5 Calculating the polydisperse bioavailable effect concentration for microplastics (Redondo-Hasselerharm et al. 2024).
Where:
EC^{bio}: *The effect concentration corrected for bioavailability (step 1)*
μ_x^{test}: *The mean ecologically relevant metric for the effect study*
μ_x^{env}: *The mean ecologically relevant metric for the environment*

Continuing the example using Eq. A2.5, the corrected bioavailable effect concentration then becomes 423.9 *10^3 #/kg, as illustrated below and in Figure A2.4.

$$EC_{poly}^{bio} = 913 * \frac{3986.84}{8.588} = 423.9 * 10^3 \ \#/\text{kg}$$

Figure A2.4 Illustration of power law size distribution representing environmental microplastics in size range 1 to 5000 µm (blue line) and the size range used in an effect study (orange shading).



Ellipsoids to the right-hand side represent average size of the particle used in the test and as present in the environment. Note that the x-axis is on a log scale. This figure shows the progress of the alignment in step 4.

Step 5. Calculate the aligned effect concentration.
The effect concentration calculated in step 4 describes the particles up to the largest bioavailable size. However, microplastics in the environment cover a larger size range. In this step, the bioavailable effect concentration is corrected to one that covers the entire environmental microplastics range (defined as lengths of 1-5000 µm). This correction can be performed using Equation A2.1, as shown in the equation below:

$$CF_{test,env} = \frac{X_{UL,D}^{1-\alpha} - X_{LL,D}^{1-\alpha}}{X_{UL,M}^{1-\alpha} - X_{LL,M}^{1-\alpha}} = \frac{5000^{1-2.5} - 1^{1-2.5}}{42^{1-2.5} - 1^{1-2.5}} = 1.0037$$

The aligned effect concentration for the environment can then be calculated using Equation A2.6:

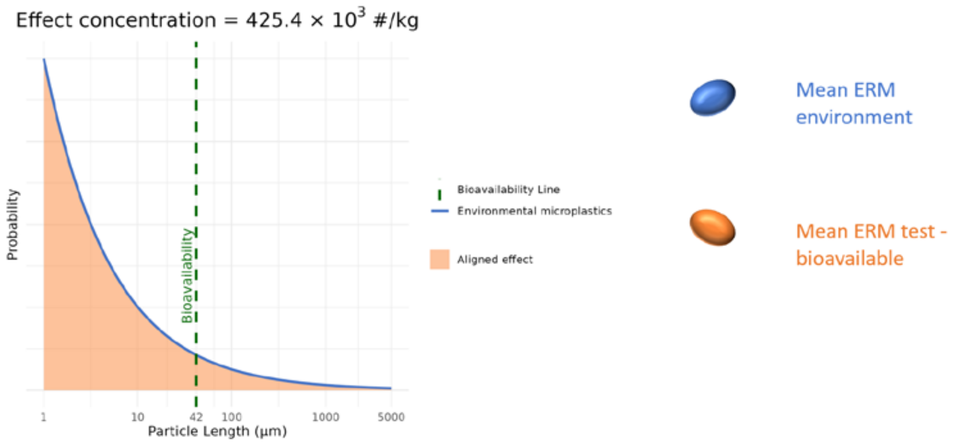
$$EC_{poly}^{env} = EC_{poly}^{bio} * CF_{test,env}$$

Equation A2.6 Where:
EC^{bio}_{poly}: *The effect concentration corrected for bioavailability (step 4)*
$CF_{test,env}$: *The correction factor ($CF_{test,env}$) for the bioavailable size (M) range in the effect study to the environmental size range (D) of microplastics*

Using Equation A2.6, the fully aligned effect concentration (see Figure A2.5) for this example is calculated as:

$$EC_{env} = 423.9 * 10^3 * 1.0037 = 425.4 * 10^3$$

Figure A2.5 Illustration of power law size distribution representing environmental microplastics in size range 1 to 5000 um (blue line) and the size range used in an effect study (orange shading).



Ellipsoids to the right-hand side represent average size of the particle used in the test and as present in the environment. x-axis is log scale. This figure shows the fully aligned effect concentration after step 5.

Step 6. Calculate the aligned environmental concentration

Measurements of microplastic concentrations in environmental samples using µ-FTIR often have a lower size detection limit of 20 µm. Additionally, depending on the cleanup and preparation of the sample, the upper size limit may be lower than the defined upper size of the microplastic size distribution under consideration (e.g. 5000 µm for microplastic fragments). As the range of microplastics within the scope of the environmental risk assessment is defined as between 1 and 5000 µm for fragments, the measured environmental concentration should be aligned to this size range. This alignment can be performed using Equation A2.1.

For example, the measurement of a sample using µ-FTIR with a fitted power law slope of 2.5 and size detection range between 20-5000 µm (M) will have a correction factor of 31.6 to environmental microplastics in range between 1-5000 µm (D) following Eq. A2.1:

$$CF = \frac{X_{UL,D}^{1-\alpha} - X_{LL,D}^{1-\alpha}}{X_{UL,M}^{1-\alpha} - X_{LL,M}^{1-\alpha}} = \frac{5000^{1-2.5} - 1^{1-2.5}}{5000^{1-2.5} - 20^{1-2.5}} = 31.626$$

Step 7. Derive the Hazardous Concentration from Species Sensitivity Distribution.

By repeating the alignment from steps 1-5 for reported effect concentrations for various species and taxa, a set of concentrations is created to which a Species Sensitivity Distribution (SSD) can be fitted following approaches common in the field of ecological risk assessment. From this SSD, Hazardous Concentrations (e.g. HC_5 or HC_{50}) can be derived to be used in the next step. Depending on the needs in the regulatory framework, a certain percentile, x, of the distribution of HCs should be used (HC_x).

Step 8. Calculate the Risk Characterisation Ratio

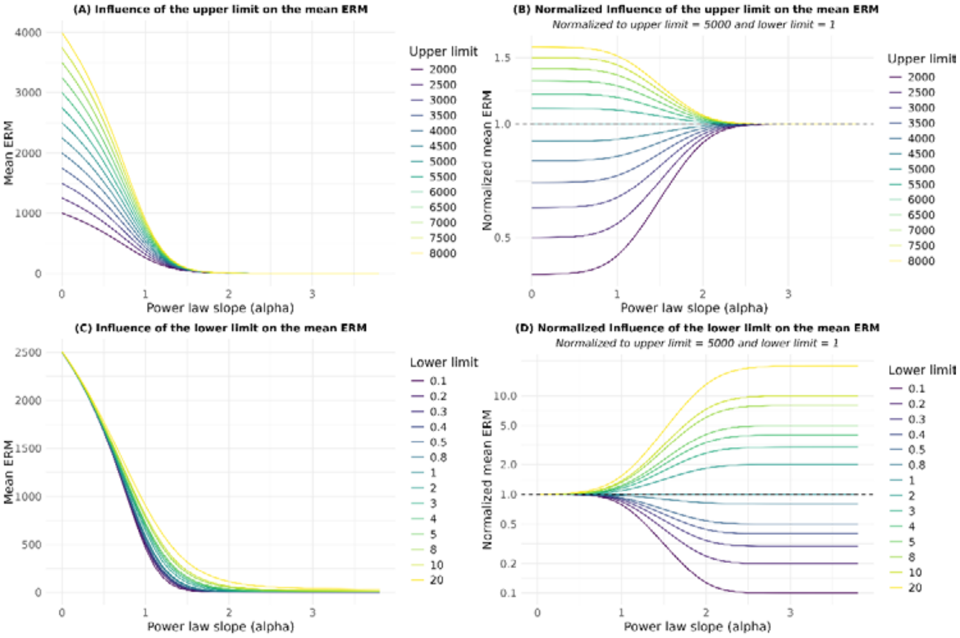
The Risk Characterisation Ratio (RCR) can be calculated using the HC_x value from the previous step, and the aligned measured concentration from step 6, using Equation A2.8. When the RCR value is greater than 1, the measured concentration of microplastics exceeds the hazardous concentration, which is an indication of potential for adverse ecological effects occurring.

$$RCR = \frac{Environmental\ Concentration}{HC_x}$$

Equation A2.8 Calculation of the Risk Characterisation Ratio from the aligned environmental concentration and the hazard concentration (HCx) based on aligned effect concentrations.

Appendix 2.2 Observations from applying the Koelmans approach

Figure A2.6 Illustration of the effect of variation in power law slope (alpha) of measurements with different upper or lower limits of the mean ERM as calculated using Equation A2.4.



Figures show the change in mean ERM (Panel A and Panel C) or the normalised mean ERM (Panel B and D) relative to a case with 10 µm and 5000 µm as lower and upper size limit, respectively. Panel A and B show this for selected upper size limits and Panel C and D show this for selected lower size limits.

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