Microplastics: a perspective on the regulatory landscape for the cleaning products industry

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Abstract:
Insoluble polymeric microparticles that degrade very slowly and are practically impossible to clean up upon release into the environment have been the focus of legislation for the past few years. The estimate on the contribution of microplastics (intentionally added) from the cleaning products industry relative to the total estimated annual releases of microplastics emitted by (but not intentionally added to) products to EU surface waters is minor in magnitude yet still significant for developing regulations. We are now seeing the first wave of regulations on these microplastics being adopted with more to follow in associated fields such as packaging, personal care, home and fabric care, among others. This article attempts to capture the current state of the regulatory landscape for microplastics specifically as it applies to the cleaning products industry and explains some of the proposed derogations such as those for water-soluble and biodegradable polymers. Science-based argumentation and subsequent legislation is necessary to manage this ubiquitous issue of microplastics and the path is long but is clear it will be for the betterment of our environment.

Keywords:
- Microplastics
- Water-soluble
- Regulations
- Detergents
- PVA
- Regulation

WHAT ARE MICROPLASTICS?
Plastics are an essential part of our everyday lives primarily based on their properties of durability and ability to provide protection from the elements. However, these very properties also result in plastics resisting degradation if not properly disposed and lead to accumulation in the environment as pollutants. These larger plastic particles break down over time into smaller particles which are defined broadly as "microplastics". One such very visible pollutant affecting oceans, coastlines, waterways, and in a way all forms of our water supply is marine microplastic litter. Scientific evidence suggests that the vast majority of microplastics present in this litter in waterways is coming from the break-down of bigger plastic materials and this is appropriately being addressed through impactful actions globally (1). In Europe, the EU Commission has identified this risk to the environment from marine litter as part of the Strategy on Plastics in a Circular Economy (2).

So, what are microplastics? The most consistent definition of the term microplastics refers to small, usually microscopic, solid particles made of a synthetic polymer (or in some cases chemically-modified natural polymers) that are associated with long-term persistence in the environment if released, as they are very resistant to dissolution or (bio)degradation (3).

The regulatory scope of restricting microplastics, as applied to the cleaning products industry, is not based on addressing the use of plastics directly in cleaning applications (i.e., packaging) but instead focusing on the potential pathways for the release into the environment. The two sources of this uncontrolled release of microplastics can thus be classified as intentional released/added microplastics and unintentionally released microplastics. To explain further, intentionally added microplastics are typically seen as microbeads and similar additives in cosmetics, personal care products, and detergents. Unintentionally added microplastics occur from the breakdown of larger pieces of plastic by wear and tear e.g., washing of synthetic clothing or from debris of detergent packaging improperly disposed by the user.

REGULATORY LANDSCAPE: INTENTIONALLY ADDED MICROPLASTICS
In 2017, the European Parliament and the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) requested the European Chemical Agency (ECHA) to prepare a dossier on the possible restriction of microplastics that are intentionally present in products used in the European economic region (4). ECHA pursuant to Article 69(1) of Regulation (EC) No 1907/2006, published this dossier in 2019 designated as the Annex XV dossier (5, 6).

The dossier put an estimate on the amount of microplastics released to the environment at 42,000 metric tonnes per year (in the sectors assessed) and identified this release occurring by three pathways: down-the-drain, through municipal solid waste, or by direct release. The dossier proposed a complete ban on microplastics in sectors and applications where the releases were considered unavoidable, and a reporting requirement to obtain information on releases from uses excluded from the ban.

The 2019 draft restriction proposed prohibiting specifically the placing on the market of any solid polymer contained in microparticles, or microparticles which have a solid polymer surface coating, as a substance on their own or in a mixture in a concentration equal to or greater than 0.01 % by weight.

The restriction actions were focused on a group of polymers sharing the same intrinsic properties of size, dimension ratio, solid state, synthetic origin, and persistence in the environment. One of the key actions also proposed in the draft was exclusion of specific degradable and/or water-soluble polymers and natural polymers that have not been chemically modified, based on the lack of the same long-term persistence. Specifically, the derogations proposed in the draft were:

- Natural polymer without chemical modification or that are biodegradable
- Substances intended for industrial use or medicinal use or fertilizing products
- Substances whose containment or disposal is controlled (i.e. incineration), or physical properties are modified so it is no longer a microplastic

The draft dossier was reviewed in 2020 by ECHA's Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) Opinion (7,8). This review resulted in additional recommendations for removing the lower limit on particle size and adding more stringent criteria for degradation. The committee also recommended excluding non-carbon-based polymers from the restriction proposal as current tools to prove persistence were not suitable for such materials. The removal of the lower limit was recommended to avoid ways of circumventing the restriction by shifting to smaller particles which may lead to increased toxicity risks.

Following the usual procedural steps, the restriction proposal passed voting at the REACH committee in April 2023 with the recommendations by RAC and SEAC on exclusion of non-carbon-based polymers accepted and the other recommendations on lower limit and derogations included with a scientific analytical threshold added (9). This restriction was titled as Annex XVII and was published in September 2023 and is expected to be adopted by the Commission in late 2023 following the usual scrutiny steps of the European Parliament (10).

DEROGATIONS IN THE RESTRICTION (ANNEX XVII)

a) Dimensions: The Annex XVII restriction proposed the materials/substances having any dimensions larger than 0.1 um to be in scope of the restriction. This was accepted considering analytical constraints on smaller particles but allowed for lowering the limits in the future as new and improved methods become available.

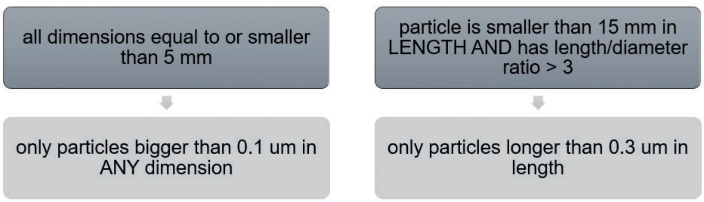

Figure 1. Criteria for consideration as polymeric microparticle as per Annex XVII.

b) Appendix X: Rules on proving degradability: Polymers which degrade in multiple environmental compartments were accepted to be excluded from the scope of the restriction. This process of biodegradation needs to be assessed by recognized screening test methods. These permitted test methods are organized into five groups and derogation is achieved by successfully meeting the pass criteria in ANY of the permitted test methods in groups 1 to 3. If group 4 or group 5 tests are used, the pass criteria need to be met in three environmental compartments of (1) fresh, estuarine, or marine water; (2) fresh, estuarine, or marine sediment; or fresh, estuarine, or marine water/sediment interface, or (3) soil.

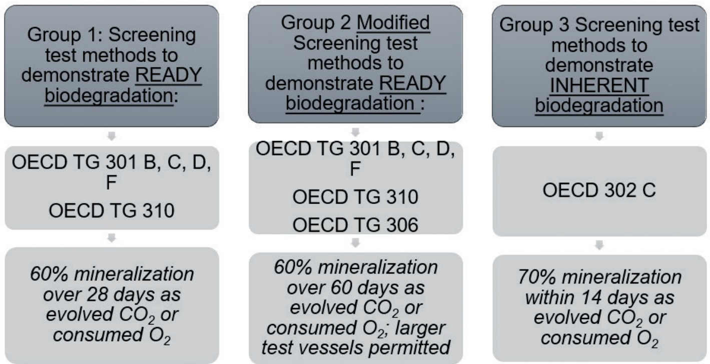

Figure 2. Test methods for derogation under biodegradability as per Annex XVII.

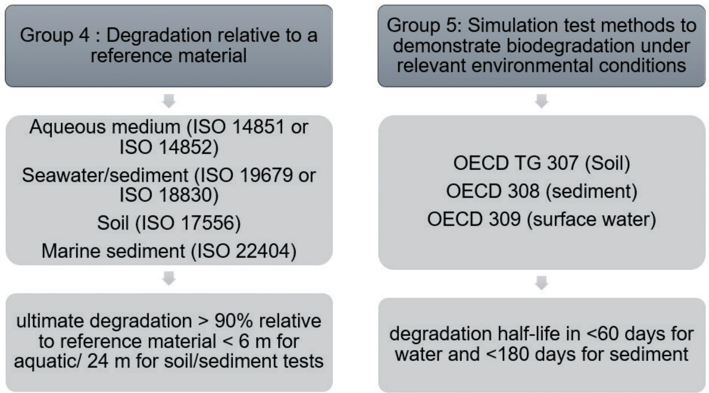

Figure 3. test methods for biodegradation in environmental compartments per Annex XVII.

c) Appendix Y: Water-soluble solid polymers lose their solid state after their release into the environment, and therefore do not contribute to the identified concern in scope. This derogation is to be proven above a value of 2 g/l using established test methods.

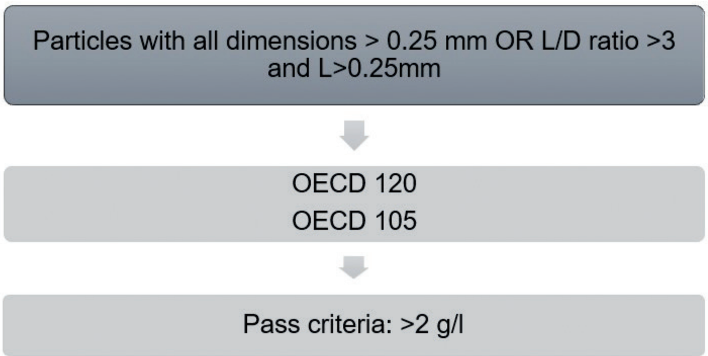

Figure 4. Criteria for solubility testing as per Annex XVII.

BIODEGRADATION DEROGATION: BACKGROUND AND EXPLANATION TO AVOID MISUNDERSTANDINGS

Biodegradation is an intrinsic property of carbon-based materials, and it is worthwhile to take a moment to fully understand the science behind the test and the interpretation of results.. Biodegradation can be simply described as the breaking down of complex carbon-hydrogen-oxygen-based structures into simpler and smaller molecules and eventually back into the building blocks that constitute them in the first place: carbon, oxygen, and hydrogen. A popular misconception is that only natural substances biodegrade which is incorrect; biobased polymers like Bio-Polyethylene terephthalate (PET) or Bio-polyethylene (made from sugarcane) do not biodegrade even though they are made from renewable resources. Biodegradation is simply dependent on the right chemistry and not on the origin, e.g., Polyvinyl alcohol (PVA) and polybutylene adipate terephthalate (PBAT) are two examples of synthetic molecules that undergo the same mechanistic biodegradation like natural cellulose or carbohydrate. Plant based plastics are often labelled as biodegradable. But if the right environmental factors are not present it might take just as long as regular plastics, an example is Polylactic Acid (PLA) that shows extremely slow biodegradation in marine systems and is designed primarily for industrial composting conditions.

Every carbon-based polymeric material can biodegrade under the right conditions with varying timelines and hence it is very important to define these conditions and timelines so as to demonstrate realistic end-of-life. To elaborate further, a common polymer like polyethylene can break down over thousands of years just sitting in the sun but that process will affect the environmental persistence at such a slow speed that it cannot be termed as being of any use while assessing the end-of-life of polyethylene. Hence it is very important to define "realistic" biodegradation in specific environmental compartments (i.e. waste-water, soil, compost, etc.) and within real-life timelines of days and months vs hundreds of years. In the context of biodegradation of plastics in the aquatic/marine environment, it is important to understand the development of the standard tests in this field.

Industry and society recognized the need to assess the biodegradability of substances entering the aquatic environment in the 1950/60s which led to significant scientific laboratory work on this topic that consequently led to the development of standard methods to assess biodegradation that further framed regulations. In 1973, Sturm published pioneering work in the field of testing for biodegradation of substances in aqueous media (11). This work was further refined and expanded by research conducted by numerous investigators that eventually resulted in the development of a set of six tests adopted by the Organization for Economic Cooperation and Development (OECD) in 1992 (12). These tests have become international standards for assessing the biodegradability of materials introduced into our waterways. Over the past several decades, these OECD standards are utilized in part of the tiered approach to evaluate and identify persistency of chemicals such as surfactants and other organic chemistries and are extending now to microplastics (see figure 2 above on group 1-3).

OECD 301 is the most commonly used test to model or predict biodegradation in aerobic aqueous medium, i.e. in a typical waste-water treatment plant where these materials are expected to end up after use. There are six tests in OECD 301 which assess the same outcome through different indicators; OECD 301A monitors the disappearance of organic carbon, OECD 301B quantifies the generation of carbon dioxide, OECD 301C, 301D, and 301F monitor oxygen uptake, and OECD 301E measures the disappearance of dissolved organic carbon.

These tests are by design highly stringent tests that provide very limited opportunity for biodegradation, the idea being that a material giving a favorable result in such a conservative test should biodegrade very rapidly in the environment. These tests use unacclimatized heterotrophic bacteria that consume the substance being evaluated for respiration and for cellular growth. All of these tests were developed as rapid screening tests that are performed under high-stress conditions so as to demonstrate the biodegradability of the test material under worst-case scenarios, e.g., using low amounts of microorganisms and high amounts of test material. For example, a typical OECD 301 test (shown below in Figure 5) uses inoculum from a well operated domestic wastewater treatment plant (WWTP) that has a diverse and robust microbial population (no pre-exposure to the test chemical is allowed) diluted to 30 mg/l microbe concentration (from a starting value of typically 3000-4000 mg/l) and is fed with the test specimen at concentration of 10-20 mg/l. This mixture is sealed in a test reactor with no active mixing kinetics (whereas the WWTP sees very active movement in and out of solids and solution)

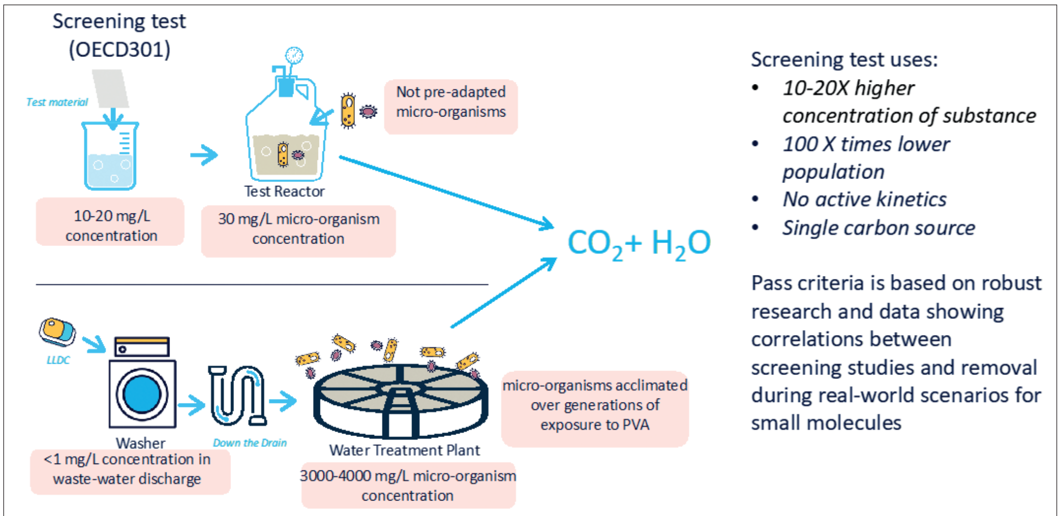

Figure 5. Differences between OECD 301 screening test and actual waste-water treatment plant conditions for Polyvinyl-alcohol based water-soluble films.

In each of the above tests, carbon-dioxide generation (or oxygen consumption) amounting to 60% of the test substrate's organic carbon is an indication of the complete consumption of the substrate, with the balance of the carbon (40%) being used for biomass creation. A common misunderstanding is that the 60 percent threshold means that only 60% of the test substrate degrades and the rest of the test substance remains behind as un-degraded test material which is incorrect; the rest of the material continues to be broken down and incorporated as body-mass by the microbes. Theoretical calculations show that heterotrophs, for each 100 grams of organic carbon in the substrate in a biodegradation test, will use a maximum of 42 grams as cellular biomass, and a minimum of 58% will convert to carbon dioxide due to cellular respiration (13). In the OECD screening tests, the test chemical is the only food source present for the microbial community with a high food to microorganism ratio (F/M) and low residual carbon. Thus, the pass criteria were set to 60% theoretical carbon dioxide evolution based on the knowledge of these typical bacterial trends supported by robust research and data showing correlations between screening studies and removal during real-world scenarios for small molecules (14).

Another misunderstanding of OECD test methods and results is that it is assumed special bacteria are needed for biodegradation as the test shows a delay (Figure 6) in the carbon dioxide evolution. The low levels of inoculum by design in these tests are meant to limit the microbial diversity which is unrealistic compared to actual environmental compartments. The test allocates for time needed for this microbial population to adapt to the test chemical as the sole food source to use and grow to rapidly degrade the high concentration of test substrate. This lag in time is not expected in the environment as the microbial community is either already acclimatized to a diversity of carbon sources and does not need to adapt or is expected to need much lesser time based on more favorable conditions than in a test vessel. For example, a material like PVA used in water-soluble unit-dose detergent packets has been through the waste-water streams of households for decades and hence the microorganisms are not required to adapt to a new material nor is there a need to introduce specially "trained" microorganisms into the system.

It is necessary to explain the science of biodegradation testing and also the interpretation of the results and data as it can be very misleading if misunderstood. One such atypical case of misunderstanding of the test data and its misinterpretation was used to petition the United States Environmental Protection Agency (US-EPA) about potential toxicity coming from high levels of un-degraded water-soluble films based on PVOH. The EPA's response, in the form of a published statement endorsing the current biodegradation screening tests and also the lack of toxicity of PVOH, serves to underline the necessity to develop better understanding of the tests than focus on developing new test protocols (15). EPA's response showed how the petition had misinterpreted literature-based OECD 301 data on PVOH and correlated the results to bioaccumulation and toxicity based on assuming the exact same conditions used in the screening test also exist in WWTP and hence incorrectly concluding that high amounts of PVOH remain and are discharged un-degraded to the environment. The EPA's scientifically substantiated argument conclusively endorsed the use of OECD test guidelines that have been the basis of decades of EPA studies on eco-toxicity and end-of-life scrutiny for degradable chemistries. This example serves to amplify the need for simple and understandable interpretations of test data vs any need to reinvent or develop new biodegradation test protocols.

REGULATORY LANDSCAPE: UN-INTENTIONALLY ADDED/ CREATED MICROPLASTICS

Microplastics coming from un-intentional means were identified as the second source for microparticles in the marine environment by the European Union Commission. This source does lack clarity as the main principle of being "un-intentionally" created makes it practically impossible to enforce any regulatory restrictions. These kinds of particles are also known as secondary microplastics are derived from fragmentation and weathering of larger plastic substrates due to a combination of mechanical wear/abrasion, solar/UV radiation, and biodegradation in the environment.

In 2021, EU Commission's Directorate-General of Environment (DG-ENV) engaged in a study to support work on possible restrictions on these secondary microplastics (16). The study focused on three sources: tyre abrasion, pre-production plastic pellets, and synthetic textiles.

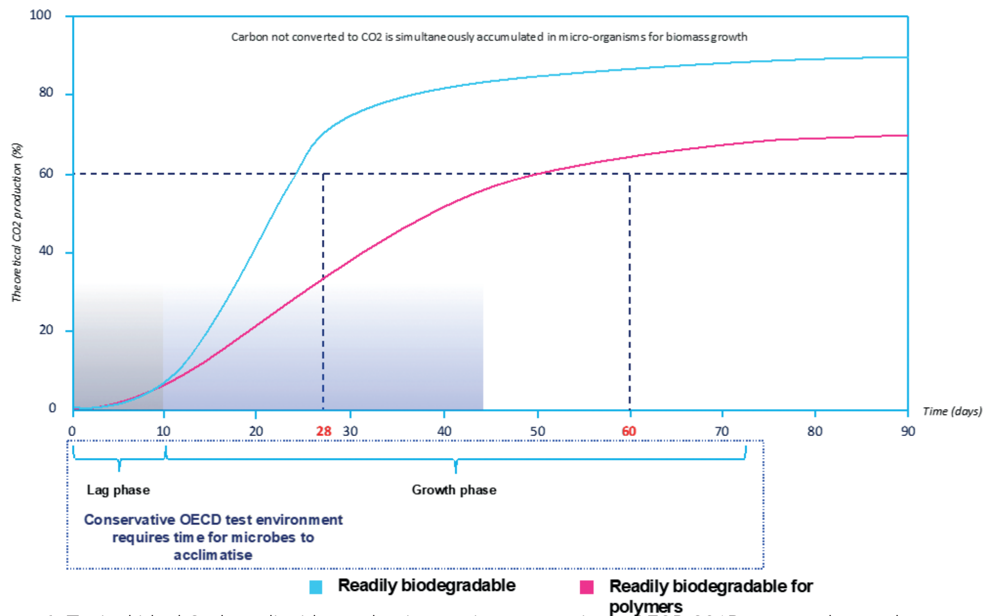

Figure 6. Typical ideal Carbon-dioxide production vs time curves in an OECD 301B test used to evaluate biodegradation.

After analysing other possible sources, three additional sources were added to the scope: paints, laundry and dishwasher capsules, and geotextiles (17). The study authors organized public workshops around each of these six areas that focussed on call for evidence and the results of the public consultation were published in October 2023 (18). The report's findings recommended prioritization on the issue of plastic pellets but did not specify any new measures for the other five categories. This may be attributed to other sources being studied under existing framework; for example, detergent capsules are already in scope under annex XVII above as related to the water-soluble films being derogated under solubility and biodegradation. Secondly, the public consultation did result in numerous industry and academic experts providing technical background and data in support of arguments for removing these sources from consideration.

Overall, the landscape for un-intentionally added/created microplastics is still very unclear and under-developed and will be undergoing a significant amount of investigation over the next few years as it begins to take some sort of shape or form.

WHAT'S NEXT?

Decades of diligent scientific research and development lie behind the current and next-generation products used in the cleaning products industry. These products will continue to be developed in the first place to delight the users with safety and sustainability built-in, within the scope of current and future regulations by relying on key principles of transparency, accountability, and stewardship. The near future will see regulations on intentionally added microplastics, in the context of cleaning products, progress through the final stages of adoption and implementation. These are not the only ones as multiple other regulatory initiatives are in different stages of development in relevant sectors such as packaging, cosmetics, wastewater treatment, etc. that will eventually also affect the cleaning products sector directly or indirectly. Innovation by the industry in developing solutions that enable the same consumer experience while still complying with the regulatory framework is really the key balancing act. This innovation and implementation cycle needs to be based on the thorough understanding and interpretation of the science behind the regulatory guidelines and not on misuse of the same for misleading the consumer.

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