# ECOS response to Public Consultation

## EU fertilising products – biodegradability criteria for polymers and other technical amendments

Brussels, 5 April 2024

ECOS welcomes this opportunity to contribute to the public consultation on the biodegradability criteria for polymers in several different types of fertilisers used in the EU. As an Annex III organisation, we have been contributing in standardisation technical working groups at the CEN and ISO levels on plastic biodegradability. Our aim in contributing to this public consultation is ensuring scientific accuracy, alignment with standards, and above all, the reduction of plastics, microplastics, and polymers in the environment. It is imperative that the limits proposed in these amendments provide for the reduction of polymers in the environment.

We previously engaged in policy work related to the Fertiliser Product Regulation and are currently following the Soil Monitoring Law proposal. We work on reducing the impact of plastics in the environment from efforts to limit production via the ongoing Plastic Treaty negotiations, to advocating for reuse requirements in the Packaging and Packaging Waste Regulation, and in technical work such as biodegradability criteria. In 2023, we sent comments to REACH Committee members regarding the intentionally added microplastics restriction proposed derogation regarding biodegradable polymers. In that letter, we emphasised that polymers move easily from one environmental compartment to another, and that derogations for agricultural or horticultural applications represent an even higher risk of leakage to the environment.[1]

[1] https://ecostandard.org/wp-content/uploads/2023/04/ECOS-letter-against-biodegradable-polymer-derogation-REACH-microplastics-restriction-April-2023.pdf

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Overall, **the proposed delegated regulations should be improved in technical accuracy and specificity. Some assumptions are made that do not necessarily hold up in real world conditions.** We find that some requirements are not applied to all products being regulated (toxicity). We also find that some of the pass criteria are too low.

Recommendations:

- Improve specificity and references in noted areas.
- Remove assumptions regarding timelines and biodegradation; if something can be proven or referenced, please include a reference.
- Apply toxicity testing to coating agents as well as mulch films.
- Ensure pass criteria align with other regulations and standards.

We have divided our comments into the different sections below.

## Draft delegated regulation - 3a delegated regulation coating agents

Relevant for:
1. Coating agents (= polymers to control the release of nutrients) [production of controlled release fertilizers]
2. Water retention polymers (= polymers to increase the water retention capacity or wettability)
3. Binding materials

Background: Regulation (EU) 2019/1009 sets out an obligation for the Commission to assess by 16 July 2024 the biodegradability criteria for coating agents and water retention polymers used as component materials in EU fertilising products.

*Biodegradation criteria:*

*1. Soil environment (= main compartment, where products are applied)*

*a. Only polymers which can reach the ultimate degradation or mineralisation within 48 months after the functionality period should be allowed as component materials.*

*b. Accelerated test method at 37°C should be introduced as an alternative option to demonstrate 90% ultimate degradation or mineralisation.*

*1. Aquatic environment (= in case of leaching or other accidental presence in water surface)*

*a. Function of the polymer (6-9 months in average)*

*b. Test methods for biodegradability in water (reliable for 12 months)*

*i. Stringent criteria for aquatic environment as set out in Delegated Regulation (EU) 2023/2055 would negatively affect the primary function of soil-biodegradable coating agents and water retention polymers. Therefore, biodegradability in aquatic environments should be set out at a lower level during the testing period but still high enough to ensure that there would not be an accumulation of polymers in aquatic environments. It is assumed that the biodegradation process will continue after the 12-month testing period and will reach the 90 % within 48 months after the functionality period.*

## ECOS comments

About **usage** and **assumptions**: we are concerned that assumptions regarding degradation in soil due to factors like erosion and ultraviolet radiation, as mentioned in point 9 in "3a delegated regulation for coating agents" cannot be adequately proven. The same recital also mentions a "labelling requirement" to warn end-users "not to use the product close to surface water bodies and to maintain buffer strips." This is not adequately protective, as it relies upon individuals following instructions that lack specificity and risks the polymers entering aquatic environments.

In the **soil environment**: the accelerated testing rate of 37°C may give results that cannot be achieved in real-life conditions. Due to the fact that a temperature of 37°C is still in the mesophilic temperature range (just like the temperature as prescribed by ISO 17556, below), it can be assumed that the same level of biodegradation will be reached in a test at 25°C and in a test at 37°C. The main difference will be the duration of the test, as the 90% pass level will be reached earlier at the higher test temperature.

Additionally, this **higher temperature** is not aligned with other standards or policies regarding synthetic microplastics.

- A temperature of 37°C is high when compared to the testing temperature as prescribed by ISO 17556:2019 "Plastics — Determination of the ultimate aerobic biodegradability of plastic materials in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved". This standard says that a temperature constant to within ±2 °C in the range between 20 °C and 28 °C, preferably 25 °C, should be used.
- Such high testing temperature is not allowed by Commission Regulation (EU) 2023/2055 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.

In the **aquatic environment:** first, we urge the Commission to recognize that the presence of these polymers in the aquatic environment is more likely to occur than not. It is not realistic to only say "they are not supposed to reach aquatic environments" without proving that they will not. Because of this assumption that the polymers will not reach the aquatic environment, it seems like regulation has set a lower pass level, which is not in line with any other existing documents related to the issue (for example, ISO 22403:2020 "Plastics — Assessment of the intrinsic biodegradability of materials exposed to marine inocula under mesophilic aerobic laboratory conditions — Test methods and requirements"). Moreover, assuming that the biodegradation will continue if a certain biodegradation percentage is reached does not guarantee that no residuals will remain present. It is possible that certain polymers will reach a plateau at certain biodegradation percentage (for example 60%) and that no further biodegradation is observed, resulting in synthetic microplastics persistence in water.

## Annex - 3b ANNEX coating agents

This document describes the biodegradability criteria for polymers referred to in section CMC9.

*Two testing compartments are described:*

*1. Soil*

*a. Test criteria:*

*i. ultimate degradation of at least 90 % relative to the degradation of the reference material within 48 months plus the functionality period (FP) as indicated on the label; or*

*ii. mineralisation of at least 90 %, measured as evolved CO2, over a maximum of 48 months plus the functionality period (FP) as indicated on the label.*

*b. Test methods: ISO 17556 or ASTM D5988*

*c. Adjustment for products with no phase transition between 25°C and 37°C*

*i. Testing temperature can be adjusted to 37°C*

*ii. Test criteria are changed:*

1. *45% absolute biodegradation at 25°C after 20 months (plateau not yet reached / biodegradation remains progressing) + 90% relative or absolute biodegradation within 20 months + FP*

*2. Fresh, estuarine or marine water*

*a. Minimum relative biodegradation after 12 months depending on the functionality period (copied below).*

| **Criterion assessed** | **Pass criterion (FP=0)** | **Pass criterion (FP=1 month)** | **Pass criterion (FP=2 months)** | **Pass criterion (FP=3 months)** | **Pass criterion (FP≥6 months)** | ~~**Pass criterion (FP=9 months)**~~ |
|---|---|---|---|---|---|---|
| Minimum target degradation after 12 months | ≥ 43,8 % | ≥ 41,0 % | ≥ 38,1 % | ≥ 35,1 % | ≥ 25,0 % | ~~≥ 13,4~~ |

*b. Test methods: ISO 14851/ISO 14852/ASTM D6691*

*Three different reference materials are mentioned:*

1. *micro-crystalline cellulose*
2. *powder, ashless cellulose filters*
3. *poly-β-hydroxybutyrate*

### ECOS comments

On **soil testing:** There is a lack of clarity here regarding temperatures of testing. Point 4(a) in the document refers to 25°C, but there is no temperature specified in points 4(b) and 4(c). We assume that it is accelerated at 37°C but this should be specified.

The phrase “degradation or mineralization shall be progressing” in point 4(a) is not well defined. We would like to see a specific minimum biodegradation rate, aligned with existing standards and policies regarding synthetic microplastics (see comments above), to prevent differing interpretations.

On **water testing:** the pass criteria for the water environment are too low. The pass levels for fresh, estuarine or marine water are neither in line with 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, nor in line with any existing standard specifications for materials that are biodegradable in the marine environment.
If the Functional Period is 0 months, only 43.8% relative biodegradation should be reached after 12 months (while 90% relative biodegradation should be reached after 6 months according to 2023/2055). This pass level is too low in order to be able to guarantee that no polymer residuals will remain present in the environment.

Regarding the test methods listed, we recommend adding additional marine test methods of 2023/2055 to be complete:

1.4.1. Permitted test methods in group 4:

T5. "Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium – Method by analysis of evolved carbon dioxide." (EN ISO 14852:2021);

T6. "Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium – Method by measuring the oxygen demand in a closed respirometer." (EN ISO 14851:2019);

T7. "Plastics – Determination of aerobic biodegradation of non-floating plastic materials in seawater/ sediment interface – Method by analysis of evolved carbon dioxide" (EN ISO 19679:2020);

T8. "Plastics – Determination of aerobic biodegradation of non-floating plastic materials in seawater/sandy sediment interface – Method by measuring the oxygen demand in closed respirometer" (EN ISO 18830:2016);

T9. "Plastics – Determination of the ultimate aerobic biodegradability of plastic materials in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved" (EN ISO 17556:2019);

T10. "Plastics – Determination of the aerobic biodegradation of non-floating materials exposed to marine sediment – Method by analysis of evolved carbon dioxide" (ISO 22404:2019).

Additionally, the following test methods could also be included:

- ISO 23977-1, Plastics — Determination of the aerobic biodegradation of plastic materials exposed to seawater — Part 1: Method by analysis of evolved carbon dioxide,
- ISO 23977-2, Plastics — Determination of the aerobic biodegradation of plastic materials exposed to seawater — Part 2: Method by measuring the oxygen demand in closed respirometer].

Finally, the types of reference materials should be more specified because different types of poly-β-hydroxybutyrate exist which would give varying results.

## Draft delegated regulation - 3a delegated Regulation mulch films

*Criteria for mulch films:*

1. *Biodegradation*
    a. *Soil environment:*
        i. *Biodegradation should be proven within maximum 24 months.*
        ii. *Accelerated biodegradation method at 37°C is considered acceptable.*
    b. *Aquatic environment:*
        i. *Function: FP = 12 months in average*
        ii. *Test methods = reliable for 12 months*
            1. *Conflict between duration FP and duration reliability of test method. Therefore, it is assumed that biodegradation process will continue after 12-month testing period and will reach 90% biodegradation within 24 months after the PF.*

2. *Environmental safety for polymers in CMC9*
    a. *Plant growth acute toxicity test*
    b. *Earthworm acute toxicity test*
    c. *Nitrification inhibition test with soil micro-organisms*

*Polymers in mulch films should also be tested according to the above mentioned tests and additionally also a chronic toxicity test should be performed.*

### ECOS comments

On **biodegradation in the aquatic environment,** making assumptions about the biodegradation process is not normally done in standards that specify this process. While it is possible that biodegradation continues after the test continues, it is not accurate to say that it will reach a specified level without fully testing and observing that process. The biodegradation could continue but then plateau at a level below 90%, resulting in synthetic microplastics persistence in water.

On **environmental safety testing,** we note a lack of information and references to testing methods and how to conduct the tests. The document does not reference the test methods. We also did not find reference to test methods in REGULATION (EU) 2019/1009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003.

We recommend including a reference to test methods to follow. If a document already exists that specifies the test methods, then that could also be referenced. But it is important to clarify and specify the exact test methods to be followed.

## Annex - 3b ANNEX mulch films

In this document, it is mentioned how the earthworm chronic toxicity testing is evaluated. Moreover, the validity criteria are defined.

Additionally also the biodegradation criteria for mulch film are defined in detail:
*"Criteria for mulch films:*

1. *Biodegradation*
    a. *Soil environment:*
        i. *Criteria:*
            1. *Minimum 90% relative or absolute biodegradation within maximum 24 months + FP.*
            2. *Accelerated biodegradation method at 37°C is considered acceptable if there is no phase transition between 25°C and 37°C. (Modified criteria: 45% absolute biodegradation at 25°C after 10 months (plateau not yet reached / biodegradation remains progressing) + 90% relative or absolute biodegradation within 10 months + FP)*
        ii. *Test methods: ISO 17556, ISO CD/23517 / ASTM D5988*
    b. *Fresh, estuarine or marine water, or water sediment interface*
        i. *At least 30% relative biodegradation after 12 months.*
        ii. *Test methods: ISO 14851, ISO 14852, ASTM D6691, ISO 19679 and ISO 18830*

*Allowed reference materials:*

- micro-crystalline cellulose
- powder, ashless cellulose filters
- oly-β-hydroxybutyrate"

### ECOS comments

We note in this annex that some **aspects are missing**:

1. Lack of clarity about how the testing should be performed on the polymer (for instance, either performed on the polymer (as such) or on the polymer after an incubation period in soil.
2. Test item concentration.
3. Test methodology to be followed (perhaps the reference was inadvertently not included)

Regarding a test methodology to produce soil for subsequent toxicity testing, the Annex A of EN 17033 goes into detail about this process. We recommend including this as a reference.

The **validity criterion for the earthworm chronic toxicity testing** is not clear and does not align with other standardised test methods (we refer to ISO 11268-2 and OECD 222). We recommend amending the validity criterion as regards to chronic earthworm toxicity to align with recognized standards.

Regarding the biodegradation testing criteria for mulch films in **soil**, we have similar notes as above for coating agents. The temperatures must be better specified in tests (b) and (c); and the phrase "degradation or mineralization shall be progressing" should be defined through a specific minimum biodegradation rate, aligned with existing standards and policies regarding synthetic microplastics, to prevent differing interpretations.

On the point referencing test methods, ISO CD/23517 is not an appropriate reference here and should be removed. It is a standard specification with criteria for soil biodegradable mulch film and is not a test method to determine biodegradation in soil.

Regarding testing in **aquatic environments**, we again stress that the pass level is too low. 30% is not in line with other requirements and is much too low to guarantee that no polymer residuals remain in the environment. In other documents, a pass level of 90% is applied.

Regarding test methods referenced, we recommend including the following marine biodegradation test methods:

- ISO 23977-1, Plastics — Determination of the aerobic biodegradation of plastic materials exposed to seawater — Part 1: Method by analysis of evolved carbon dioxide.
- ISO 23977-2, Plastics — Determination of the aerobic biodegradation of plastic materials exposed to seawater — Part 2: Method by measuring the oxygen demand in closed respirometer.

Finally, we again note that the types of reference materials should be more specified because different types of poly-β-hydroxybutyrate exist which would give varying results.