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LRI-ECO64: IMPROVING LABORATORY BASED POLYMER BIODEGRADATION EVALUATIONS

Background

Currently, the ECHA persistence schema includes a biodegradation screening evaluation with the option of moving to higher-tier simulation tests. All these tests were designed for low molecular weight, soluble test materials but some have been applied to non-soluble and poorly soluble chemicals and polymers (modifications are needed for some methods and some polymer classes). Due to ECHA's renewed interest in the evaluation of polymeric materials, there is much discussion about the applicability of standardized biodegradation test methods to polymers. ECETOC 133-2, *Applicability of Analytical Tools, Test Methods and Models for Polymer Risk Assessment*, conceptualized a tiered approach to polymer persistence assessment using many standard screening and simulation test methods but theorized that some methods may need to be modified to accommodate polymer test materials. Menzies et al 2023 recently showed that biodegradation screening methods (OECD 301 and 302) could be applied to water-soluble polymers, but method modifications were needed for some test substances.

This research aims to evaluate the appropriateness of standard biodegradation screening and simulation methods and the necessary modifications needed to accurately quantify polymer biodegradation. This research also seeks to quantify relationships between screening and simulation studies. *Research on environmental simulation studies is a particular focus due to the lack of polymer biodegradation data in these types of tests.* In addition, there is a need for polymeric reference materials to be identified and evaluated in simulation and screening studies for future use in biodegradation assessments.

Objectives

The project's objectives are to:

- Identify and synthesize polymeric-labeled test substances and reference materials and/or specific analytical methods that can be used for polymer biodegradation simulation studies. Identify analytical methods that can be used to identify metabolites.
- Conduct simulation studies using labeled substances (stable or radiolabeled) or specific analytical in a variety of relevant environmental fate compartments (e.g., OECD 307, 308, 309, and 314, particularly 314B). Include method modifications as necessary to accurately assess the biodegradability of each polymer. Apply specific analytical methods to identify metabolites.
- 3. Conduct screening tests (e.g., OECD 301, 310) to evaluate the biodegradation of the test substances evaluated in simulation studies.4.
- 4. Leverage work done in Cefic LRI ECO 52 & ECO 55 as well as relevant literature, to identify polymeric reference substances (natural or synthetic) that could be used to better asses the viability of the inocula and test methods for polymeric test substances and utilize these reference materials throughout the research studies.5.
- 5. Assimilate the results by looking for trends in modifications needed in tests and results between screening and simulation studies and between environmental compartments.6.
- 6. Publish results including recommendations on how to best conduct biodegradation studies for soluble and poorly soluble polymeric materials.

Scope

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Polymers vary widely by molecular weight, solubility, backbone, and charge density. Thus, any investigation into the applicability of existing tests for persistence assessment needs to consider polymers from a variety of classes with a variety of expected biodegradation profiles. The goal of this research is to understand from a few surrogates how the test methods apply across different polymer categories. Given the amount of research currently focusing on solid polymer materials (e.g., microplastics and articles) this proposal is designed to focus on soluble and poorly soluble

polymer classes and not on solid polymeric materials. It will be important that polymers being considered for evaluation are aligned with the industry steering team at project initiation to leverage ongoing research in this space.

Out of scope (optional)

Solid polymeric materials such as microplastics and articles as test substances (as stated above).

Deliverables

The final report shall contain an executive summary (2 pages max), a main part (max. 50 pages), and a detailed bibliography. It is expected that the findings will be developed into at least one peer-reviewed publication, following poster(s) and presentation(s) at a suitable scientific conference(s).

Partnering / Co-funding

Applicants should provide an indication of additional partners and funding opportunities that can be appropriately leveraged as part of their proposal. Partners can include, but are not limited to industry, government/regulatory organizations, research institutes, etc. Statements from potential partners should be included in the proposal package.

Fit with LRI objectives / Possible regulatory and policy impact involvements / Dissemination

Applicants should provide information on the fit of their proposal with LRI objectives and an indication on how and where they could play a role in the regulatory and policy areas. Dissemination plans should also be laid down.

References

Menzies, Wilcox, Casteel, McDonough. 2023. Water soluble polymer biodegradation evaluation using standard and experimental methods. Sci Tot Environ. 858 (3).

DEADLINE FOR SUBMISSIONS: September 1st, 2023 at 11:59 PM.

Timing: Start in QI 2024, 3 years

LRI funding: €400,000 - 500,000

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