ECETOC Task Force “Additive Risk Assesment in a circular economy”

MARII Workshop, Madrid, 16. October 2025

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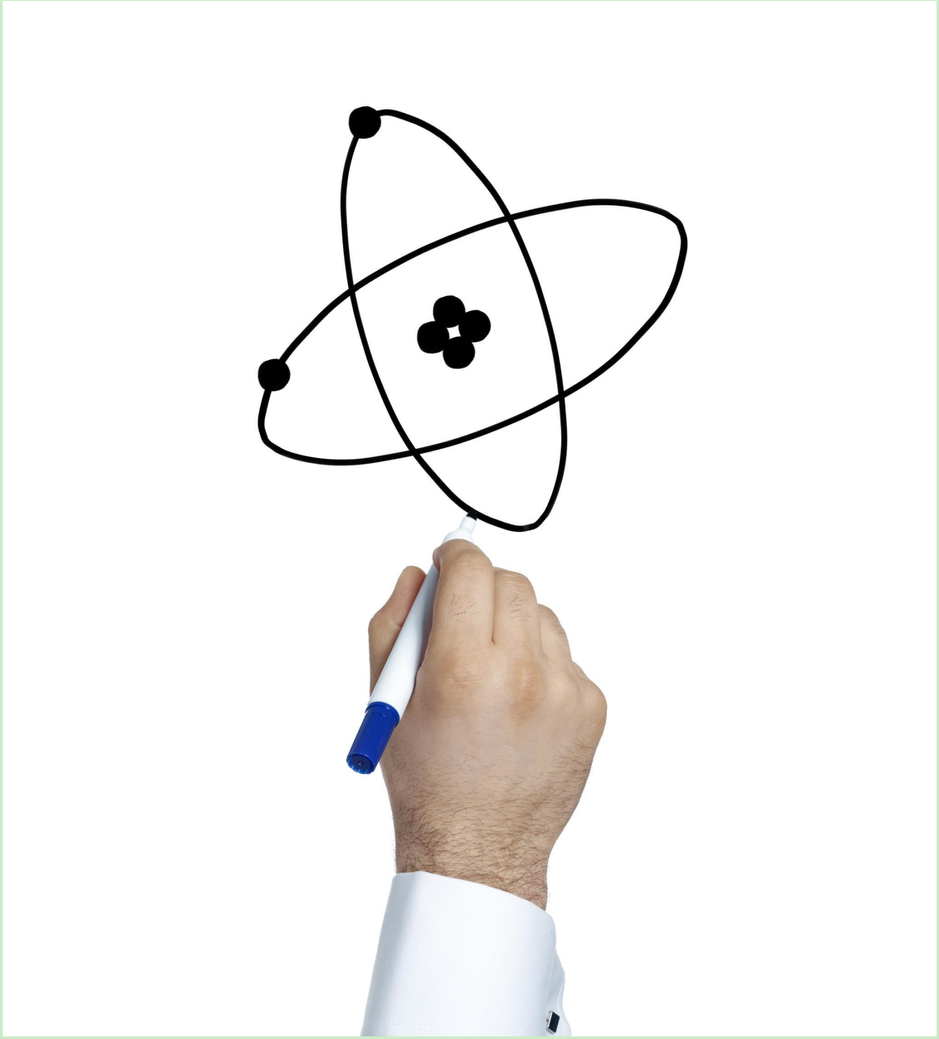
Understanding ECETOC:
A Collaborative Science Platform

- ECETOC is an industry sponsored think tank
- ECETOC aims to bring together scientists from academia, industry, and government sectors.
- Focus on advancing chemical safety through scientific research.
- The organization facilitates working groups and task forces on regulatory topics.
- ECETOC promotes sustainable chemical management globally.
- It provides trusted scientific advice for policymaking and industry practices.



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Background of the Task Force

Geopolitical background

- Discussion on UN Plastic Treaty since 2022 also puts chemicals associated with plastics on the spot.
- Global plastic production & (re)use are increasing
- Caveat: Existing risk assessment frameworks do not readily account yet for recycling and recycled feedstock

Objective of the Task Force

Generate a framework to pave the road for risk assessment of plastic additives in complex circular scenarios.

Goals:

- Guidance for relevant stakeholders
- Describe a risk-based approach for additives in circular uses
- Describe limitations and define areas for further work and research

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Focus on additives and their challenges in a circular economy

Additives in plastic applications

Additives are intentionally added substances that must be considered at different stages of the life cycle of plastics incl. possible breakdown products.

Legal requirements

Different regions have regulations in place for sensitive applications e.g. in food contact materials or medical devices (e.g. blood bags).

Complexity of risk assessment

Risk assessment becomes complex due to mixed plastics with different additives (incl. breakdown products) and recycling methods.

Predictions and assumptions

Assessment requires knowledge of degradation products* over the life cycle and under various stressors (e.g. light).

* The TF established the term “major known degradation products” to account for toxicological relevance and state-of-the-art analytical techniques

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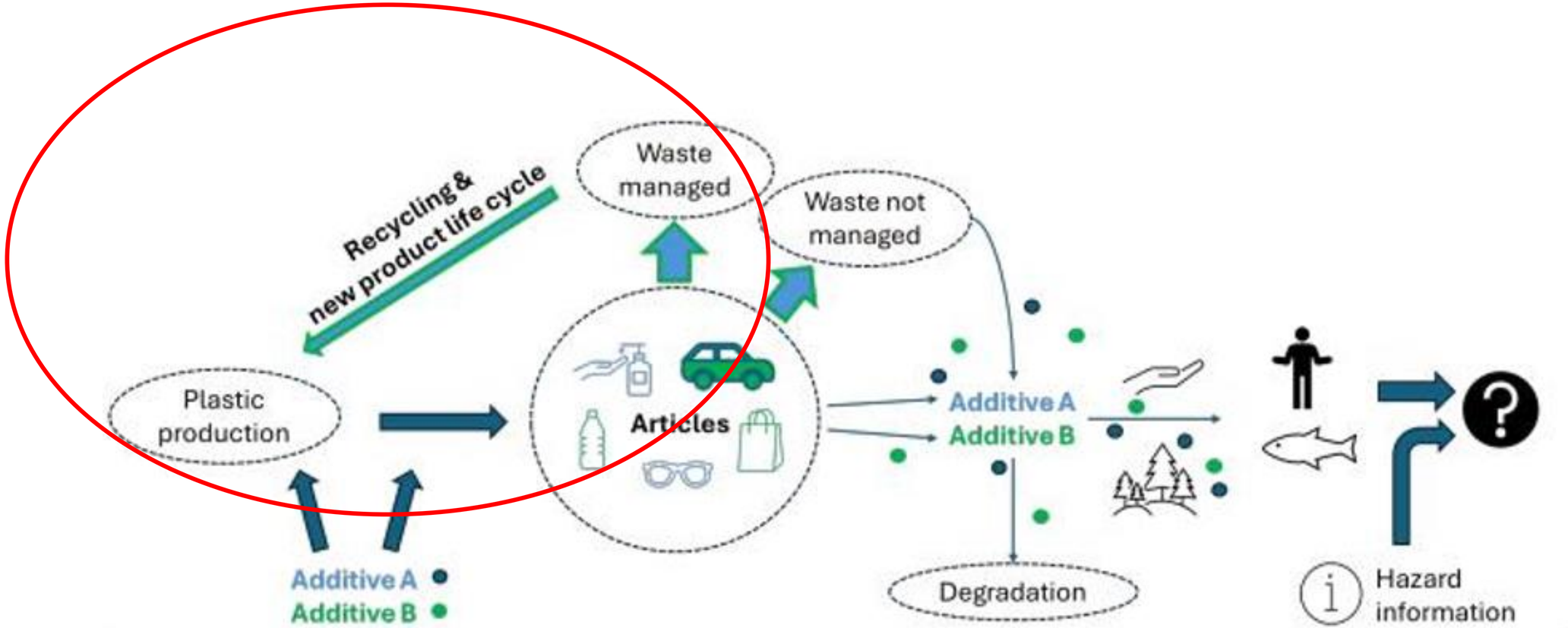
What is at stake?

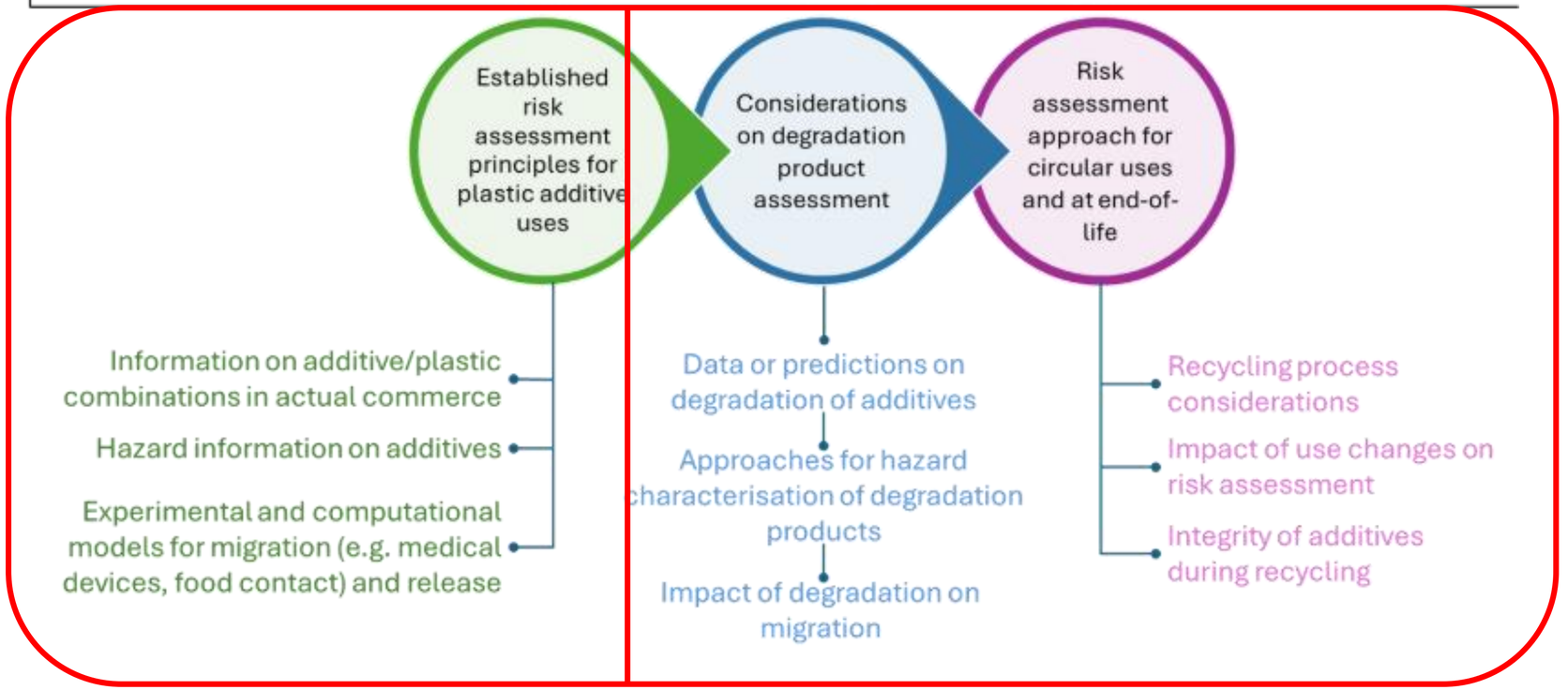


Intended use of additives	Migration, exposure	Risk
How is article used and discarded? Which additives and how much are in which plastic? How much additive remains in recycled materials? Research needs: What's in the material stream?	How much additive is released from the plastic? How does additive degrade? Who is exposed how much? Research needs: Which degradants?	Which combinations of additive, plastic and use would pose a concern?

Project Phases of the ECETOC Plastic Additives Task Force

1. How much of a plastic additive gets released how, where and when?
2. Where could risks occur and how could those be mitigated?
3. How do degradation and recycling impact the risk assessment?

The ECETOC TF includes experts in exposure sciences, material sciences, eco-/toxicology and environmental fate from academia, industry and regulatory bodies



Manuscript #1 **Manuscript #2**

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Focal issues to be tackled

How to assess risk in complex scenarios

Keep the effort within reasonable limits via a stepwise approach while not compromising on safety standards.

Release of additives

How much plastic additive is released when, where and how in order to evaluate risks.

Degradation and impacts on recycling and re-use

The impact of and recycling on risk is taken into account to enable sustainable solutions.

Identification and assessment of breakdown products

How can breakdown products be determined (analytics) and how can they be assessed in a meaningful and efficient way (e.g. grouping, modeling, potency etc.)

Focal issues to be tackled

Problem formulation & scope of assessment

Focus on relevant object of the assessment (e.g. a specific additive in a specific use) helps to set up the assessment accordingly.

No need to re-invent the wheel

Risk assessment is nothing new and useful tools and approaches exist already.

Set the right priorities

Decision matrix supports users to focus on the substances of highest concern (e.g. due to adverse effects and/or high exposure applications)

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Risk prioritisation matrix human health

Table 1: Prioritisation matrix informing on human health concern level

Level of concern	Criteria informing on hazard		Criteria informing on exposure		
	Hazard potential	**Hazard potency (expert judgement to determine critical effect)**	**Plastic use**	**Concentration [c]**	**Migration potential (plastic type, additive properties) [d]**
High	CMR, ED	e.g. mammalian NOAEL/C ≤ 10 mkd	Medical devices	> 10% (> 100,000 ppm)	Significant migration potential during use
Moderate	Sensitisation	e.g. mammalian NOAEL/C > 10 to ≤ 100 mkd	Food contact, toys (for children > 3 years)	0.1-10% (1,000-100,000 ppm)	Unknown migration potential
Low	No classification [a]	e.g. mammalian NOAEL/C > 100 to ≤ 1,000 mkd	Other consumer applications, professional uses	0.01% to < 0.1% (100 to < 1,000 ppm)	Low / slow migration
Very low	MW > 1,000 Da indicating limited systemic bioavailability [b]	e.g. mammalian NOAEL > 1,000 mkd	Industrial uses / rare contact	< 0.01% (< 100 ppm)	Negligible migration

Abbreviations: bw: body weight; CMR: carcinogenicity, mutagenicity, reproductive toxicity; ED: endocrine disruptor; mkd: mg/kg body weight/day; MW: molecular weight; NOAEL/C: no-observed adverse effect level / concentration.

Depending on the scope of the assessment, either full risk assessment can be done for all 'additive + use' combinations, or one or more of the above prioritisation criteria can be applied to exclude those additives/uses being of lower priority for the context. Note that a given 'additive + use' can be of low concern in one aspect and of high concern in another. Other criteria than mentioned here, e.g. to determine hazard potential, may be relevant for the given prioritisation exercise, further considering that prioritisation criteria are often driven by policy context.

[a] Conclusion on hazard concern not possible in (complete) absence of hazard data.

[b] Approximation for individual additive constituents.

[c] Indicative thresholds that may apply unless specific limits are in place.

Risk prioritisation matrix environment

Table 2: Prioritisation matrix informing on environmental concern level

Level of concern	Criteria informing on hazard		Criteria informing on exposure		
	Hazard potential	Hazard potency (reflected by chronic NOEC/EC_{10})	Plastic use [a]	Concentration [b]	Migration potential (plastic type, additive properties) [c]
High	Confirmed PBT / vPvB	≤ 0.1 mg/L (NRD) ≤ 0.01 mg/L (RD)	Environmental application with likelihood of long-lasting exposure (e.g. agricultural use)	> 10% (> 100,000 ppm)	Significant migration potential during intended use
Moderate	Chronic aquatic Cat. 1-3 Suspected PBT / vPvB	> 0.1 to ≤ 1 mg/L (NRD) > 0.01 to ≤ 0.1 mg/L (RD)	Wide-dispersive consumer use (e.g. single use plastic)	0.1-10% (1,000-100,000 ppm)	Unknown migration potential
Low	No classification [d]	> 0.1 to ≤ 1 mg/L (NRD)	Applications with defined recycling/waste stage (e.g. automotive applications) and low anticipated environmental exposure	0.01% to < 0.1% (100 to < 1,000 ppm)	Low / slow migration during intended use
Very low	MW > 1,000 Da indicating limited systemic bioavailability [e]	> 1 mg/L (NRD, RD)	Long-term environmental exposure unlikely (e.g. use in construction)	< 0.01% (< 100 ppm)	Negligible migration during intended use

Abbreviations: EC_{10}: 10% effect concentration; MW: molecular weight; NOEC: no-observed effect concentration; NRD: non-rapidly degradable ingredient (Table 4.1.2 in United Nations, 2023); PBT: persistent, bioaccumulative, toxic; RD: rapidly degradable ingredient (Table 4.1.2 in United Nations, 2023); vPvB: very persistent, very bioaccumulative.

Risk prioritisation example: α-tocopherol

"Additive + use" example	Criteria informing on hazard		Criteria informing on exposure			Human health priority score
	Hazard potential	Hazard potency	Plastic use	Additive concentration	Migration potential	
1a) Use of α-tocopherol at 100-300 ppm in PP for automotive applications, such as bumpers	Low priority (2)	Low priority (2)	Very low priority (1)	Low priority (2)	Low priority (2)	(2+2) x (1+2+2) = **20**
1b) Use of α-tocopherol at 100-300 ppm in PP for single-use kitchenware			Moderate priority (3)			(2+2) x (3+2+2) = **28**

"Additive + use" example	Criteria informing on hazard		Criteria informing on exposure			Environ. priority score
	Hazard potential	Hazard potency	Plastic use	Concen-tration	Migration potential	
1a) Use of α-tocopherol at 100-300 ppm in PP for automotive applications, such as bumpers	Low priority (2)	Very low priority (1)	Low priority (2)	Low priority (2)	Low priority (2)	(2+1) x (2+2+2) = **18**
1b) Use of α-tocopherol at 100-300 ppm in PP for single-use kitchenware			Moderate priority (3)			(2+1) x (3+2+2) = **21**

- **Prioritisation steps support an efficient workflow especially for complex scenarios**
- **Applicable to compare different uses for one substance or vice versa**

Outlook

Enable risk assessment in a circular economy as a standard process

Establish generic exposure scenarios for managed waste & recycling and expand the use descriptor map (PROCs, ERCs etc.)

Regulatory focus & prioritisation

Focus regulatory actions on risky uses while, increasing certainty around low risk opportunities

Transparency on use details

The better we know how actual uses contribute to emissions and exposure, the better we can assess risk and assess mitigation option.

Foster a safe circular economy as part of the solution

Expand accepted assessment approaches over the full polymer life cycle to increase trust of all stakeholders and remove barriers.


Thank you.
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