



Finding Essentiality Feasible: Challenges & Considerations

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Outline

- Defining Essential
- Essentiality Framework
- Challenges & Considerations

Disclaimer:

The views expressed are solely those of the presenter and not the HHS, NIH, or NIEHS.

Defining Essential



Defining Essentiality

- The two elements of an essential use are:
 - a use is “necessary for health or safety or for the functioning of society”

and

 - “there are no available technically and economically feasible alternatives”.

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The concept of essential use for determining when uses of PFASs can be phased out

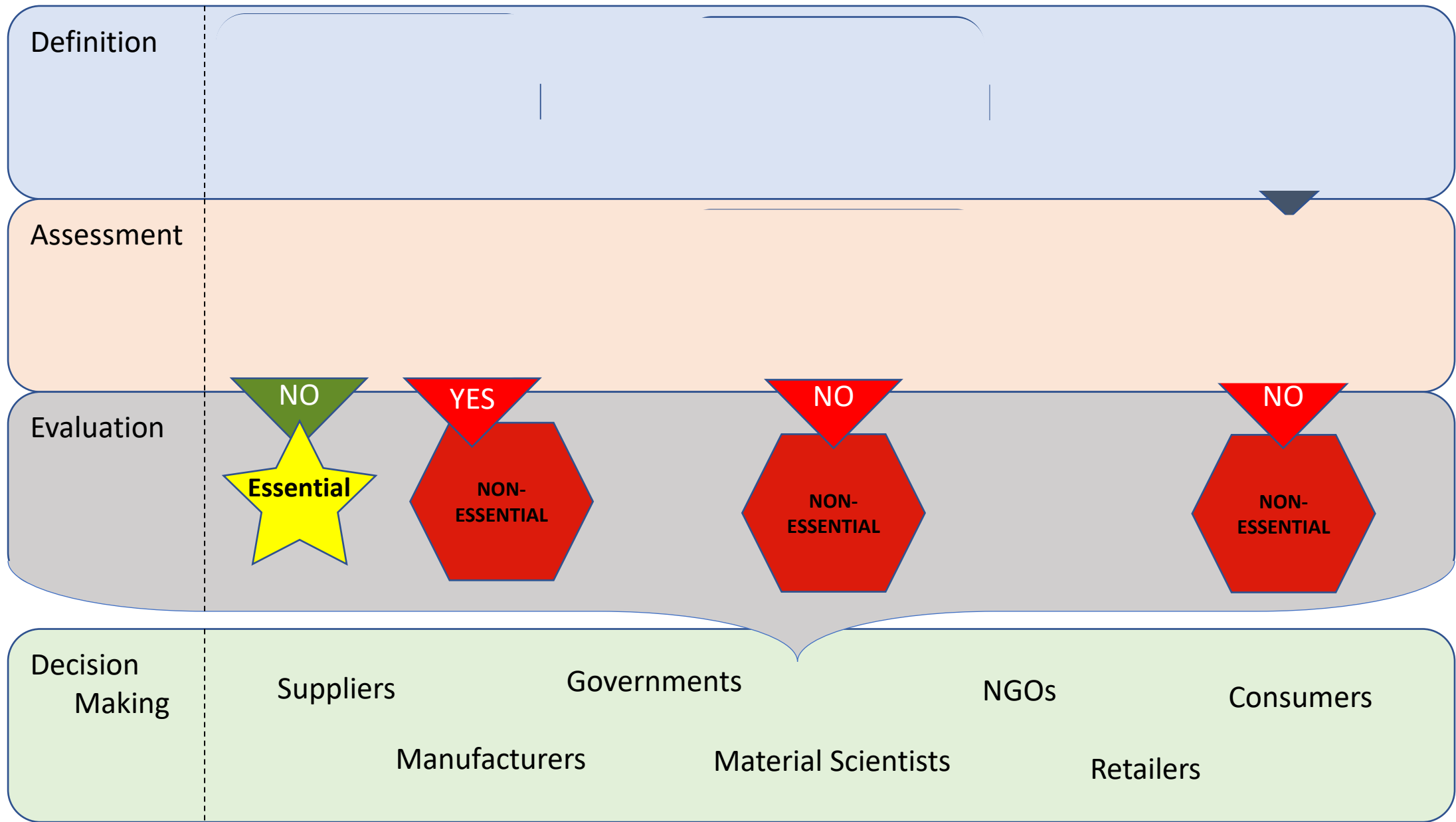
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Table 1.

Three essentiality categories to aid the phase out of non-essential uses of chemicals of concern, exemplified with PFAS uses.

Category	Definition	PFAS examples
1 “Non-essential”	Uses that are not essential for health and safety, and the functioning of society. The use of substances is driven primarily by market opportunity.	Dental floss, water repellent surfer shorts, ski waxes
2 “Substitutable”	Uses that have come to be regarded as essential by society because they perform important functions, but where alternatives to the substances have now been developed that have equivalent functionality and adequate performance, which makes those uses of the substances no longer essential.	Most uses of AFFFs, certain water-resistant textiles.
3 “Essential”	Uses considered essential by society because they are necessary for health or safety or other highly important purposes <i>and</i> for which alternatives are not yet established.*	Certain medical devices, occupational protective clothing.

* This essentiality should not be considered permanent; rather, a constant pressure is needed to search for alternatives in order to move these uses into Category 2 above.



Challenges











- What is a PFAS? What is a “Chemical(s) of Concern”? Is it appropriate to group?
 - The essential use concept allows us to move away from the single chemical approach
 - OECD Definition, fluorinated polymers, trifluoroacetic acid (TFA) and its salts, etc.

ORIGINAL RESEARCH article

Front. Environ. Sci., 05 April 2022 | <https://doi.org/10.3389/fenvs.2022.850019>



Assembly and Curation of Lists of Per- and Polyfluoroalkyl Substances (PFAS) to Support Environmental Science Research

 Antony J. Williams^{1*},  Linda G. T. Gaines²,  Christopher M. Grulke^{1†},  Charles N. Lowe¹,  Gabriel F. B. Sinclair³,  Vicente Samano⁴,  Inthirany Thillainadarajah⁴,  Bryan Meyer⁴,  Grace Patlewicz¹ and  Ann M. Richard¹

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Challenges

- What is necessary for the “Functioning of Society”?
 - “Essentiality” requires jurisdictional context and judgement
- Knowledge of the technical performance is required.
 - Partnership with manufacturers is needed. (CBI; Innovation)
- How does the technical performance relate to the product service?
 - What level of performance is *required* for the essential aspect of service?
 - Chemical, End-use, Service Function
- Chemical Alternatives Assessment is complex.
 - Avoiding regrettable substitutions

Challenges

- PFAS are intricately embedded in the global supply chain.
- Shear volume of PFAS and their uses require a phased and precautionary approach.
- Inability to test for PFAS in products, assess full lifecycle, consider recycled raw materials.
- Multi-component consumer products?
- Entire product lifecycle needs to be considered.



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The concept of essential use for determining when uses of PFASs can be phased out

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Finding essentiality feasible: common questions and misinterpretations concerning the “essential-use” concept

Ian T. Cousins,^{†*} Jamie C. De Witt,^b Juliane Glüge,^c Gretta Goldenman,^d Dorte Herzke,^e Rainer Lohmann,^f Mark Miller,^g Carla A. Ng,^h Sharyle Patton,ⁱ Martin Scheringer,^j Xenia Trier^k and Zhanyun Wang^l

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Feature

Addressing Urgent Questions for PFAS in the 21st Century

Carla Ng,^{*} Ian T. Cousins, Jamie C. DeWitt, Juliane Glüge, Gretta Goldenman, Dorte Herzke, Rainer Lohmann, Mark Miller, Sharyle Patton, Martin Scheringer, Xenia Trier, and Zhanyun Wang



Policy Analysis

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Advancing Safer Alternatives Through Functional Substitution

Joel A. Tickner,^{*,†} Jessica N. Schifano,[‡] Ann Blake,[§] Catherine Rudisill,^{||} and Martin J. Mulvihill[⊥]



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Article

Information Requirements under the Essential-Use Concept: PFAS Case Studies

Juliane Glüge,[▲] Rachel London,[▲] Ian T. Cousins, Jamie DeWitt, Gretta Goldenman, Dorte Herzke, Rainer Lohmann, Mark Miller, Carla A. Ng, Sharyle Patton, Xenia Trier, Zhanyun Wang, and Martin Scheringer^{*}

Cite This: <https://doi.org/10.1021/acs.est.1c03732>

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What is NOT essential?

- **Luxury, Convenience, and Decoration** are not considered essential
- **Performance above the bar** is not considered essential
- **Economics and Feasibility** are only considered for substitution not essential function
- **Poor skills** are not considered in essentiality
- **Product differentiation and marketing** are not considered essential

**A chemical cannot be deemed “Essential”,
Only a specific use-case can!**

Thank you





National Institute of
Environmental Health Sciences

Division of the National Toxicology Program





- Public health protective approach
 - Essential-use petitions provide the data needed for innovation
- Focus on the 256,