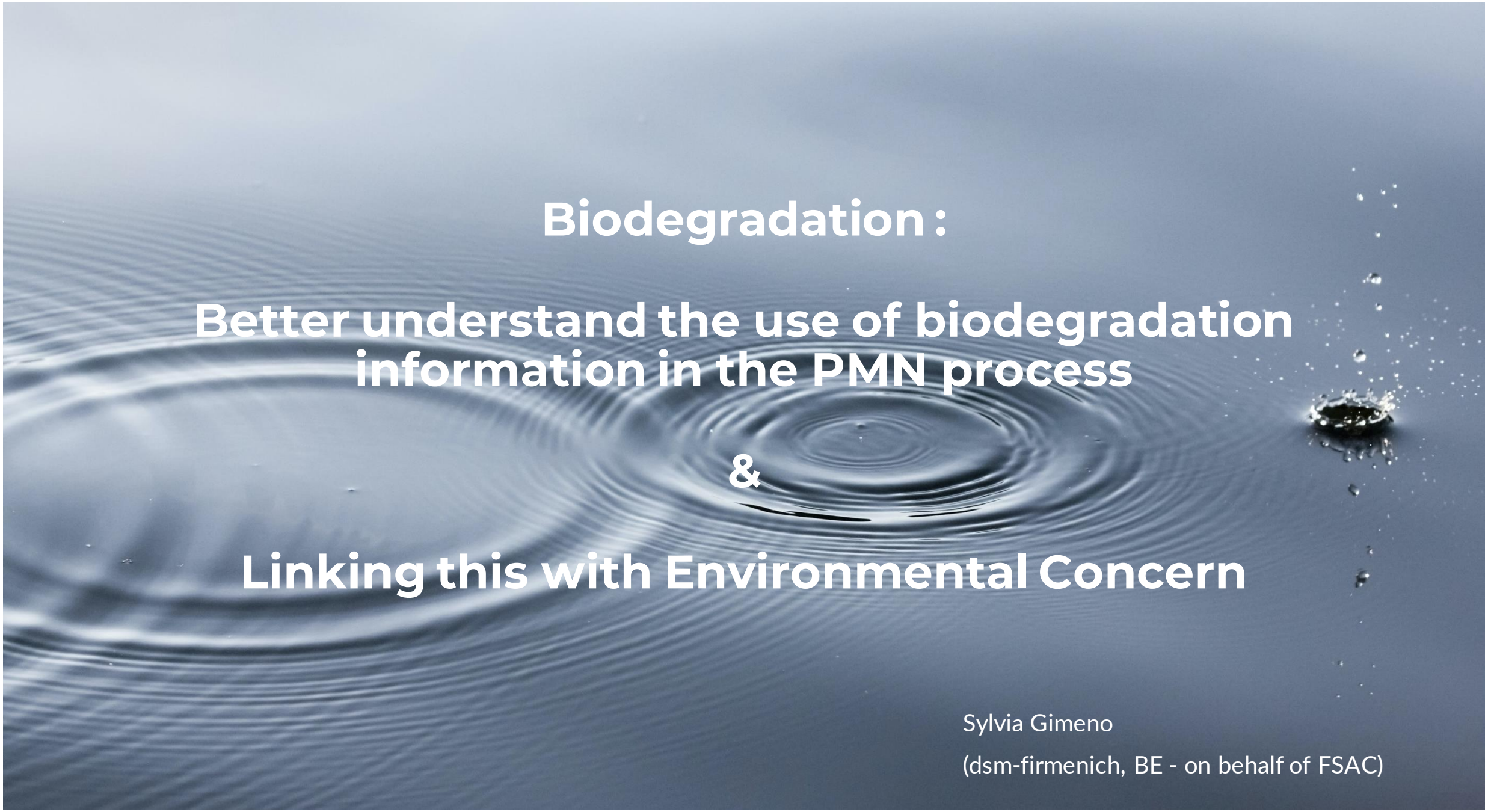
U.S. EPA Fragrance Technical Expert Meeting

Day 2

Understanding Biodegradation & Evaluating Environmental Toxicity

Session 2 : Biodegradation



Biodegradation :

Better understand the use of biodegradation information in the PMN process

&

Linking this with Environmental Concern

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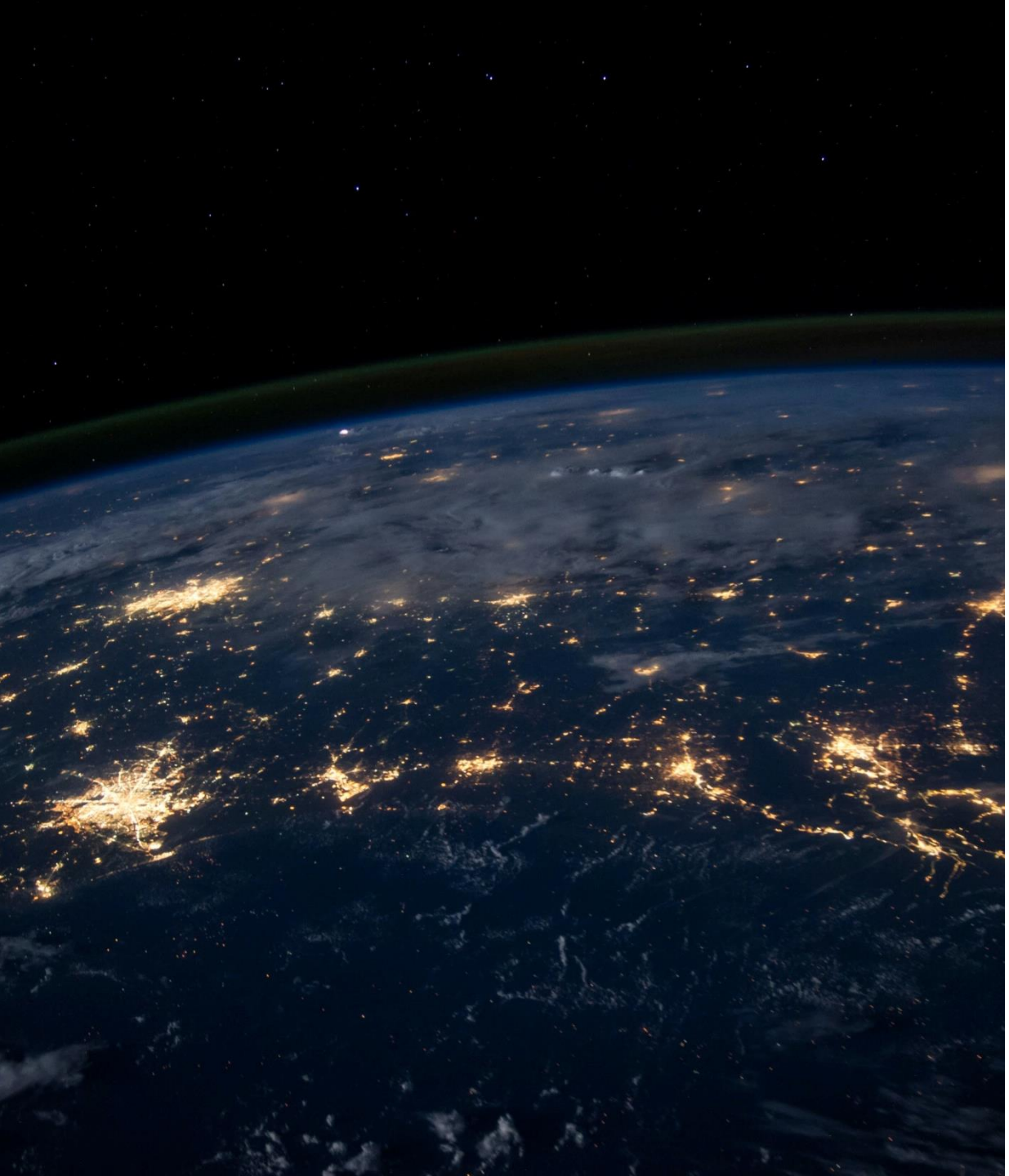

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Major role of fragrances in consumer products

Biodegradation is a key property for fragrances

01. Major role in consumer products, while small contribution volume-wise

- Fragrances are a very minor component of the Detergents and Household products
- But with a major role in consumers' acceptance and satisfaction of those products

02. Widespread use of Fragrances

- After use of Detergents and HouseHold products, incl Fragrances, they are released in the environment via the sewer
- Biodegradation minimizes their impact to the environment, since they will decompose into inert products (water, biomass and CO_2)

03. Biodegradability is a key property for fragrances both from a sustainable and ethical point of view

- Suppliers' commitment to Environmental Sustainability Goals
- Clients'demands, for claim support
- Regulatory purposes (Environmental hazard and risk assessment)

Most fragrances are biodegradable

Biodegradability => lower risk to the environment

Use in the PMN

Derive the WTP removal

Estimate the SWC (Surface Water Concentration) via E-FAST

Prediction on the # of days exceeding the chronic COC, and

Finally conclude on the chronic aquatic risk on the manufacture, processing, distribution in commerce, use, or disposal of the NCS

01. Biodegradation is important for fragrances

- Fragrances are developed based on solid principles of DfE
- Most new fragrances are readily/inherently biodegradable (except few fragrances with specific properties)
- All Fragrances NCS possess measured biodegradable data
- IFRA survey conducted in 2019 (8 major Fragrances Houses, >2300 formulations) -> average % w/w of confirmed biodegradable fragrance formulations used in finished products
  - 71-86% in laundry care products
  - 76-94% in dishwasher products

0.2 Ready and inherent biodegradability profiles

- ensure that the substance will completely degrade in the WWTP/river water
- Half-lives of 1-3h, typical retention time in WWTP is 12h or > industrial ones)
- 99.9% of the parent is removed in the WWTP, accounted for in E-FAST
- Biodegradable chemicals are unlikely able to cause any harm/exert toxic effect in aquatic organisms

03. High removal rate ensures

- A low SWC
- Low # of days the SWC exceeds the Ch COC, most often 0d
- Conclusion : no Risk for the receiving Environment

New Fragrance NCS have measured biodegradation data

Most Fragrance NCS are biodegradable and no ENV is identified

How are Consent Orders determined, when no environmental risk has been identified ?

01. Agency'feedback on many Fragrances' PMNs,

" in the absence of sufficient information to make a reasonable evaluation of the environmental effects of the New Chemical Substance, the manufacture, processing, distribution in commerce, use, or disposal of the NCS may present an unreasonable risk or injury to the environment."

02. From our POV, this is not comprehensible/justified

- Measured biodegradability data are available, are to be integrated in E-FAST
- Favorable biodegradation profile ➔ no Env risk is identified
  - All manufacturers/ formulators sites are linked to an on-site and/or POTW
  - Extremely low emissions of valuable Fragrances/formulated products on-site
  - Of which >99% will be removed in the WTP
  - What is the rationale for EPA to impose a water release restriction as a mitigation of a negligeable risk ?

03. How are regulatory actions taken ? How can we support the Agency decision process ?

- Do measured biodeg data have a positive impact on the Agency decision ?
- What information is needed, when no risk is identified, to conclude Not Likely determination

Thanks

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