SUSTAINABLE SURFACE PROTECTION BY GLASS-LIKE HYBRID AND BIOMATERIALS COATINGS

BIO-SUSHY

1st SSbD Training

Lignin Safety & Toxicity in Bio-based Food Packaging

November 26, 2024

Online

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Horizon's Europe GA number: 101091464

Agenda

09:30	Opening Remarks and Introduction	• Goal of the training and overview • BIO-SUSHY brief project intro (5 min)	Axia Innovation
09:40	SSbD Framework and Steps	• Explanation of SSbD framework (15 min)	ITENE
09:55	Lignin Types	• Different lignin types: full assessment and example (10 min)	Wood K plus
10:05	Safety Assessment	• Toxicity data from BIO-SUSHY (15 min) • Bio-sensor and release accelerator (20 min)	ITENE, University of Leeds
10:40	Break		
10:50	Practical Application Session	• How do we apply SSbD to certain compounds (15 min)	ITENE, Wood K plus, University of Leeds
11:05	Q&A	• Open Q&A with participants	ITENE, Wood K plus, University of Leeds
11:20	Closing remarks	• Summary of key takeaways • Closing remarks and acknowledgment	Axia Innovation, Materia Nova

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Introduction

You may have assumed PFAS without knowing it

PFAS, What?

PFAS (per and polyfluorinated alkyl substances) provide excellent water and oil repellency properties.

Why is it a problem?

PFAS are known as 'forever chemicals' due to their resistance, widespread, and linked to environmental and health problems like cancer and decreased fertility.

How?

Exposure could happen through eating, drinking, or using consumer products containing PFAS.

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Objective

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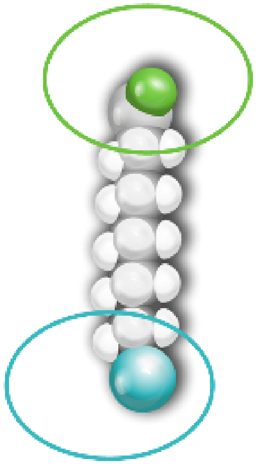
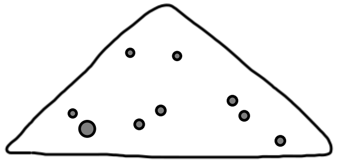
Develop 3 PFAS-free bio-based coatings

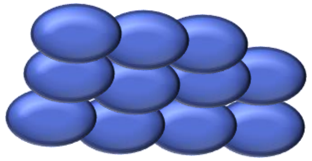


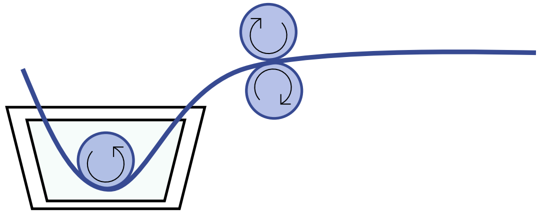
Hydro/oleophobic additives

Thermoplastic Bio-based powder

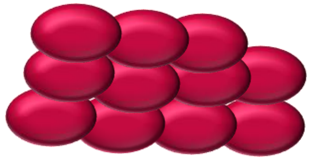


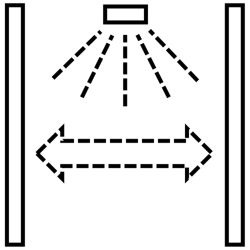
Water-based Hybrid sol-gel organic





Solvent-based Hybrid sol-gel inorganic





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BIO-SUSHY Methodology – Based on 3 pillars

R&I COATING DEVELOPMENT

- Development of 3 novel SSbD coatings materials with water and oil repellency
- Validation of coating materials with 3 case studies (cellulose food trays, textile, glass packaging)

MODELING

- Development of the BIO-SUSHY set of computation tools for SSbD of coatings
- Development of integrated approaches supported by the BIO-SUSHY HUB for effective data management and sharing

SAFE AND SUSTAINABLE BY DESIGN

- Development of an SSbD Framework applied to PFAs-free coatings (safe by material design, safe by process design, toxicological studies, LCA, LCC, SLCA)
- Standardisation roadmap

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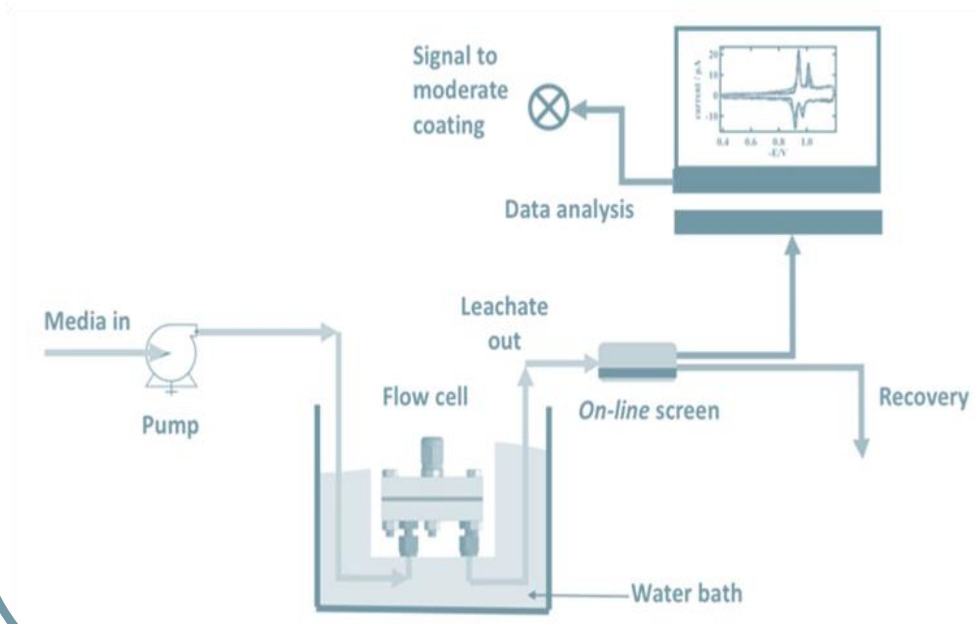
Unique value proposition

Coatings validated in 3 case studies

Textile	Food trays and packaging	Glass cosmetic packaging

Rapid coating and formulation screening



Standardisation & SSbD framework

- Standardisation of new coatings
- Definition of safety and sustainability criteria

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Impacts

Provide business opportunities to EU's SMEs

Boosting EU R. D. & I.

Reduction of PFAS in the environment

Enhance social acceptance

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Value Chain

Modelling and computational tools

Coating components and formulation

Scaling up/ validation

Standardisation, certification

Validation of use cases (end-users)

Social acceptance

Safe and sustainable by design

Characterization & ecotoxicity tests

S-Life cycle assessment

Exploitation, communication, and dissemination

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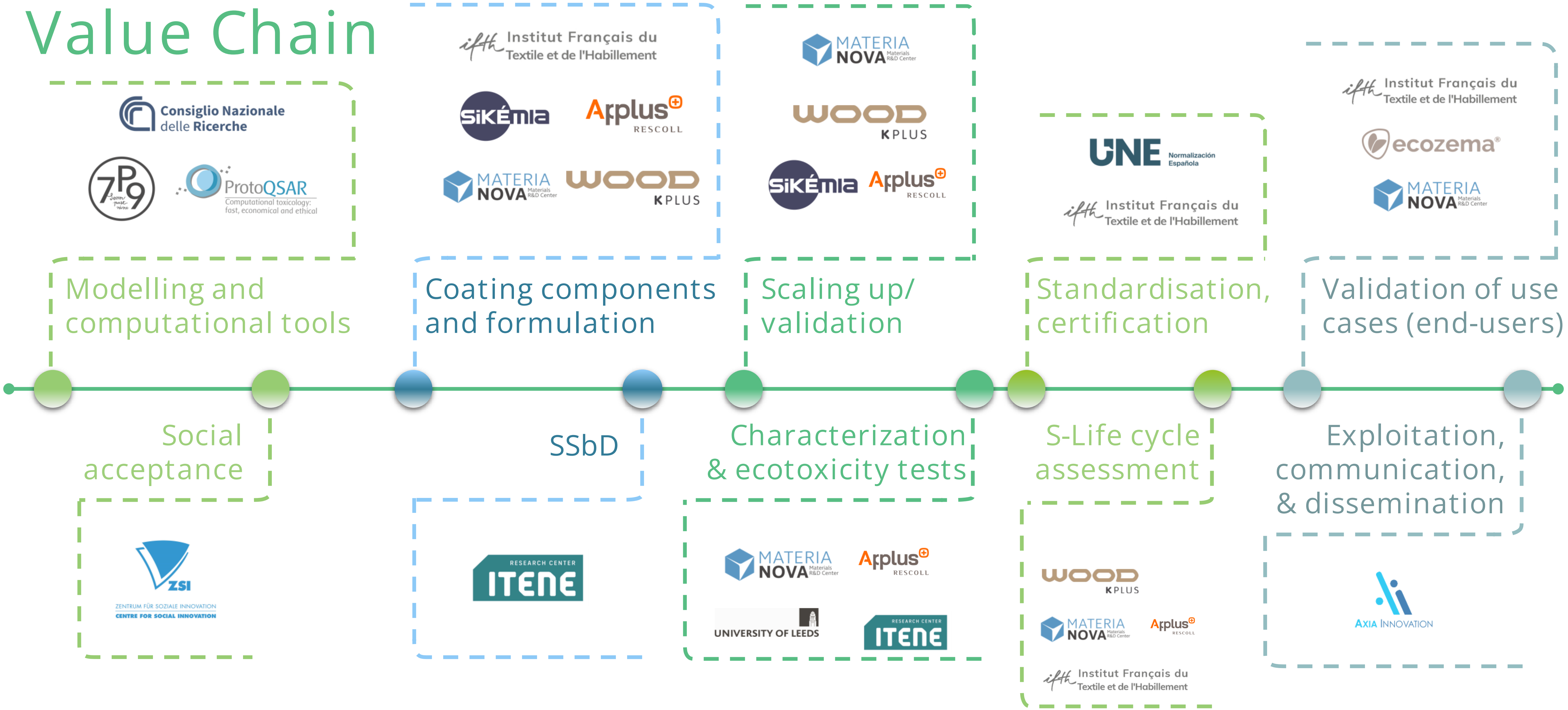
Value Chain



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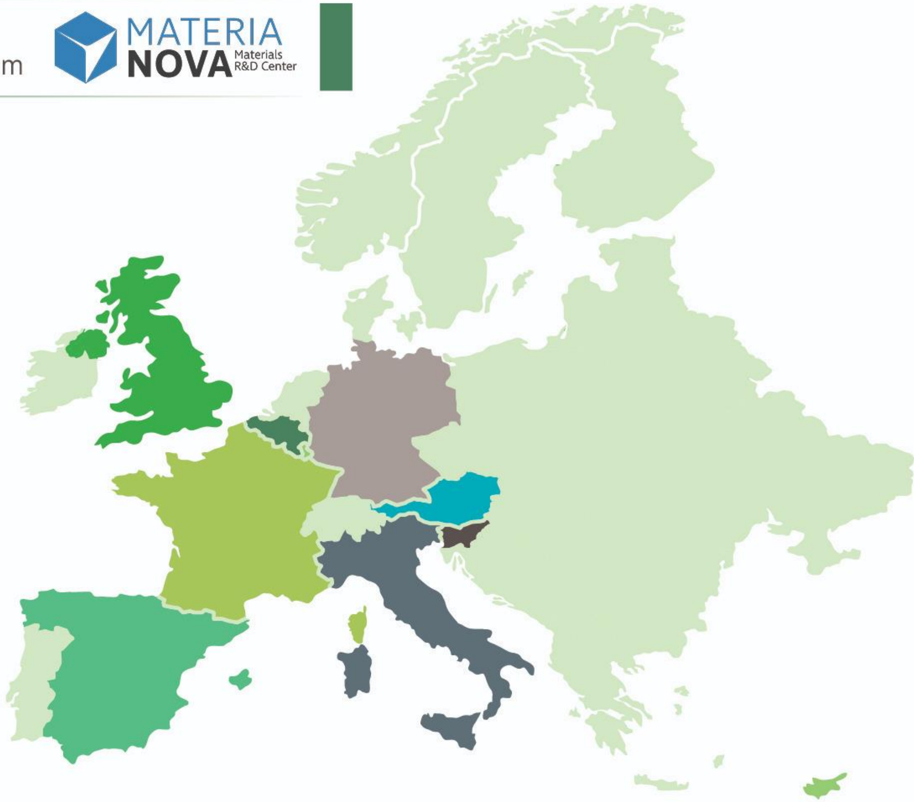
Team

The BIO-SUSHY project is a collaboration between 14 partners from 7 EU countries and 1 EU-associated country: 6 RTDs, 6 SMEs, 1 university, and 1 national association.

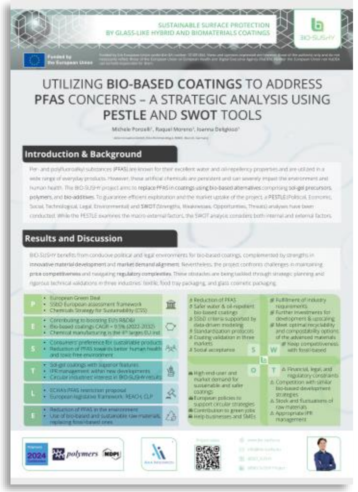
BIO-SUSHY COORDINATOR:
Materia Nova, Av. Nicolas Copernic 3, 7000 Mons, Belgium

MATERIA NOVA Materials R&D Center

- Consiglio Nazionale delle Ricerche
- AcumenIST smart Innovation, Science & Technology
- ecozema
- IFTH Institut Français du Textile et de l'Habillement
- Axia Innovation
- Applus+ RESCOLL
- University of Leeds
- SiKÉMIA
- 7P9
- ITENE Research Center
- WOOD K PLUS
- ProtoQSAR Computational toxicology: fast, economical and ethical
- ZSI
- UNE Normalización Española



Stay up to date with our progress



www.bio-sushy.eu

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@BIO-SUSHY Project

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Pau Camilleri

Project Manager of Processes and Products

Safety Unity

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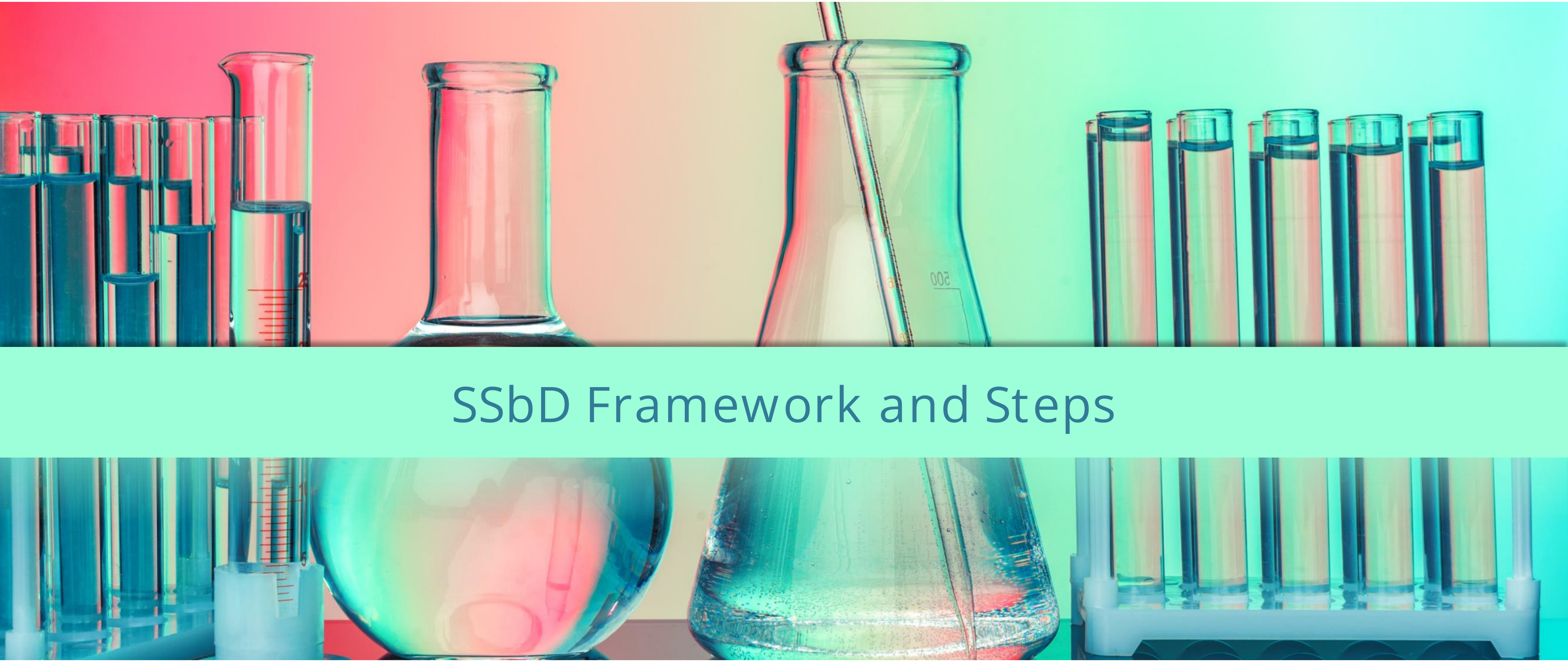

SSbD Framework and Steps

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BIO-SUSHY

INTRODUCTION

European Green Deal

European Green Deal: European Commission aims to transform the EU´s economy for a more sustainable future

CLIMATE

BIODIVERSITY

CIRCULARITY

HUMAN HEALTH

ENVIROMENT

ZERO POLLUTION ECONOMY

TOXIC FREE ENVIROMENT

To achieve these objectives, the Chemicals Strategy for Sustainability (CSS) calls for the transition to a Safe and Sustainable by Design (SSbD) approach for chemicals

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Introduction to the European SSbD framework

EC & JRC


Safe and Sustainable by Design chemicals and materials

Framework for the definition of criteria and evaluation procedure for chemicals and materials

Caldeira, C. Farcal, R., Garmendia Aguirre, I., Mancini, L., Tosches, D., Amelio, A., Rasmussen, K., Rauscher, H., Riego Sintes, J., Sala, S.

2022

Joint Research Centre

EUR 31100 EN


ISSN 1831-9424

European Commission

JRC Technical Report

Safe and Sustainable by Design chemicals and materials

Application of the SSbD framework to case studies

Caldeira, C., Garmendia Aguirre, I., Tosches, D., Mancini, L., Abbate, E., Farcal, R., Lipsa, D., Rasmussen, K., Rauscher, H., Riego Sintes, J., Sala, S.

2023

EUR 31528 EN

Joint Research Centre

SSbD Framework aims to identifying and minimizing, at an early phase of the innovation process, the impacts concerning human and environmental health.

Addresses the safety and sustainability of the material/ chemical/ product and associated processes along the whole life cycle, including all the steps of the research and development (R&D) phase, production, use, recycling and disposal.

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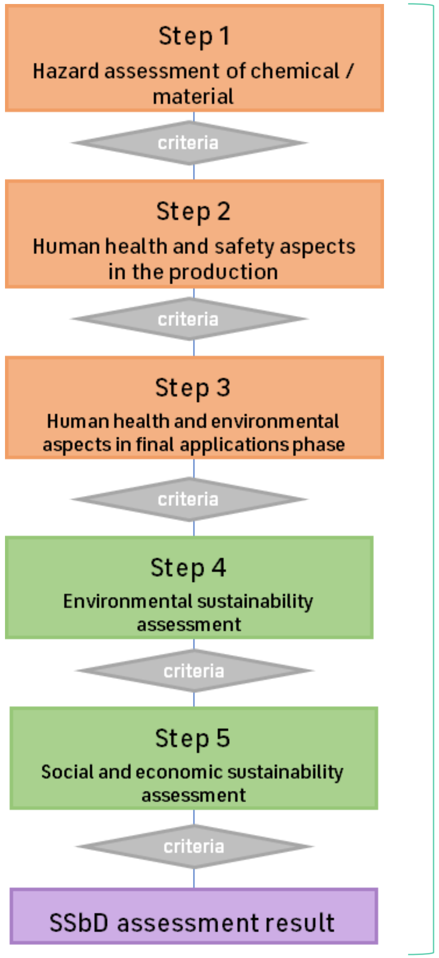
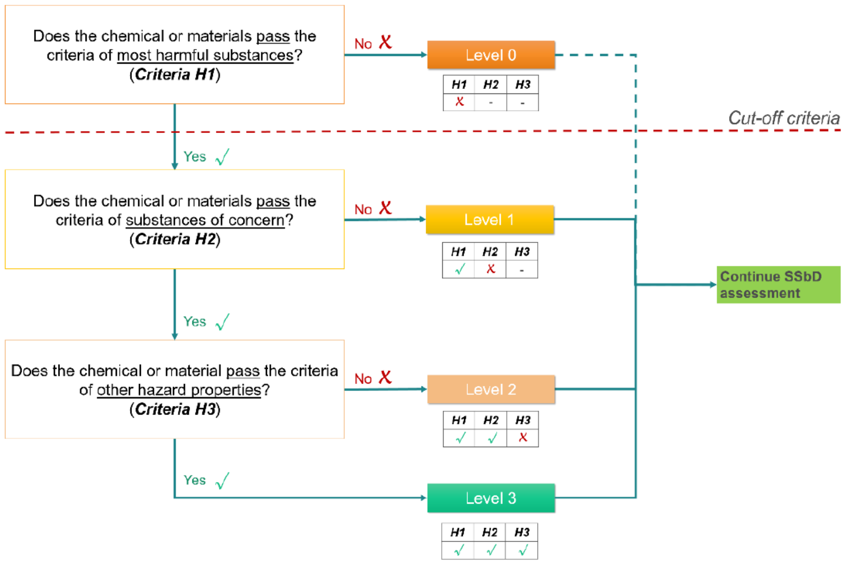
Introduction to the European SSbD framework

5-step methodology



Scoring system for each step (following decision trees and cut-off criteria) which allow to determine if the materials/products under development could be safer and more sustainable than current alternatives

TRANSITION TO GREENER AND SAFER MATERIALS AND PRODUCTS



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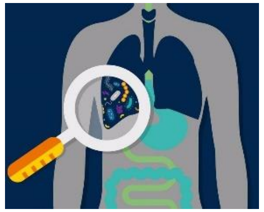
Introduction to the European SSbD framework

SAFETY



- Hazard assessment of new coatings and materials developed for human and environmental health (raw materials and substances, coatings and materials, final demonstration products)
  - Methods based on IATAs, NAMs
  - Experimental: *in vitro* tests & bioassays
  - *In silico* methods
  - Bibliographic
- Process hazard assessment
  - Occupational exposure

SUSTAINABILITY

- Assessment of the environmental impacts generated by products and processes throughout their life cycle:
  - Pollutant emissions,
  - Green House Gas Protocol
  - Contribution to Climate Change
  - Carbon Footprint
  - LCA
  - Circularity
- Socio-economic impacts
  - LCC
  - sLCA

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Introduction to the European SSbD framework

What do we understand by SSbD?

An approach that focuses on providing a functional materials/products, while avoiding damage to human health or the environment as a consequence of their fabrication process, use or disposal.

In essence, the SSbD approach aims to **identifying and minimizing,** at an early phase of the innovation process, **the impacts concerning safety and sustainability, minimizing the environmental footprint**, in particular regarding climate change and resource use and, protecting ecosystems and biodiversity, taking a lifecycle perspective.

The SSbD approach **addresses the safety and sustainability of the material/ chemical/ product and associated processes along the whole life cycle**, including all the steps of the research and development (R&D) phase, production, use, recycling and disposal.

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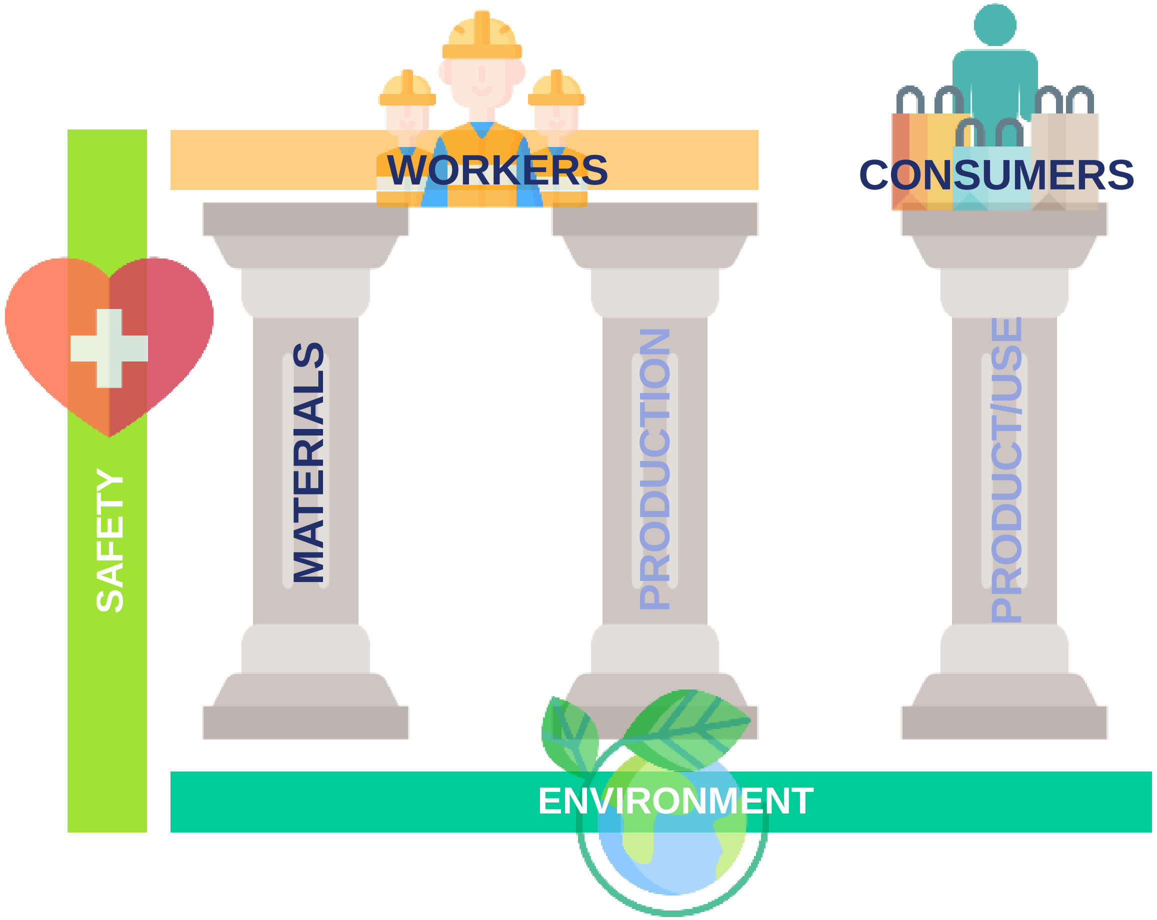
Introduction to the European SSbD framework

This strategy is based on three main pillars:

1st. Safe and Sustainable material/ product by design:

Minimizing, in the R&D phase, possible hazardous properties and sustainability issues (use of sustainable sources of raw materials/natural resources, minimizing resource consumption and sources, promoting social responsibility) of the designed material/product while maintaining its function.



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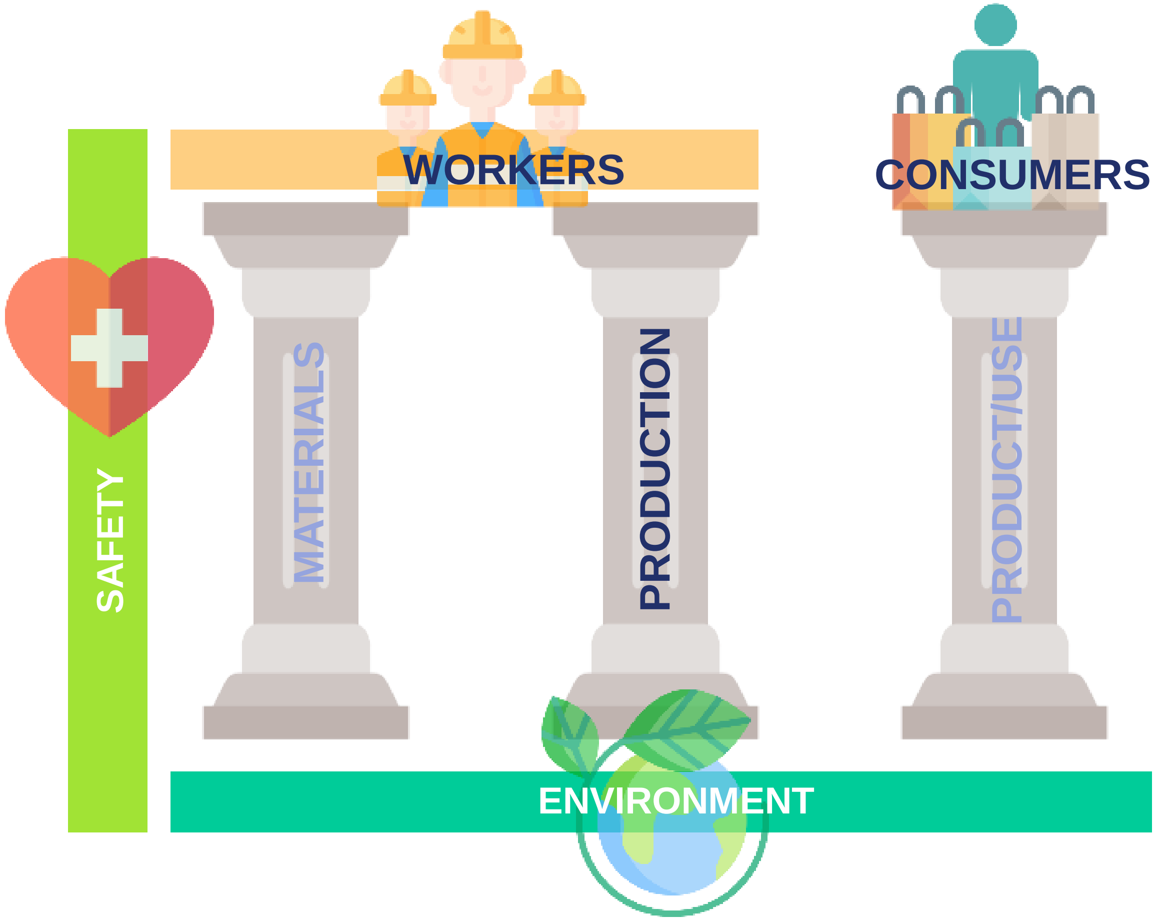
2nd. Safe and Sustainable production:

Ensuring industrial safety during the production of materials/ products, more specifically occupational, environmental and process safety aspects.

This pillar should also ensure sustainable processes during the production of materials/products, minimizing emissions (to air, water, and soil) and resource consumption (energy, water), and optimizing waste management.



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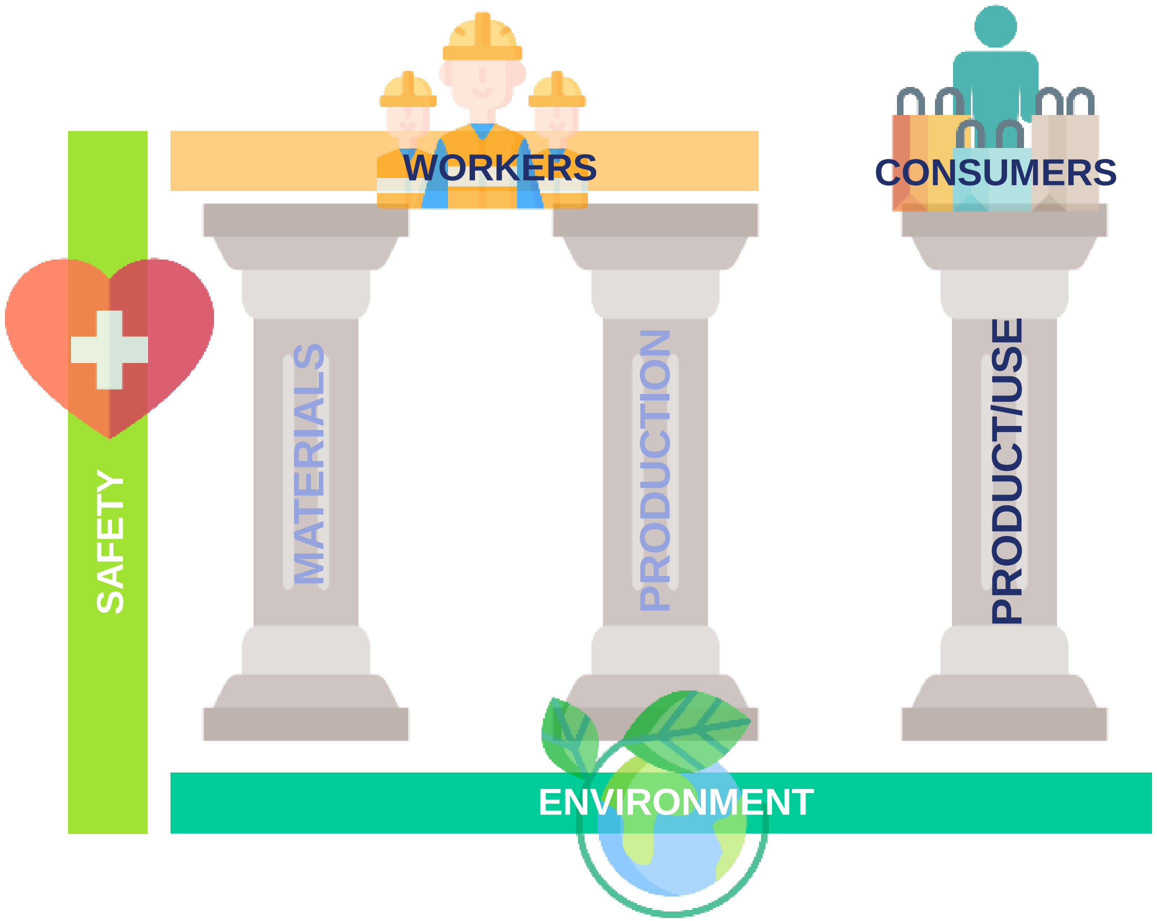
3rd: Safe and Sustainable use and end of life of the product:

Minimizing exposure and associated adverse effects through the entire use life, recycling and disposal of the material/ chemical/ product.

Materials should be designed in a way that the use of resources is minimized during use and recycling stages, and that the material or product supports the waste hierarchy and circular economy.



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SSbD methodology

Definition of the SSbD Criteria

- Definition of the criteria for every step

Information gathering

- Information about the materials and chemicals used is being gathered by communication with partners.

Step 1: Intrinsic Hazardous properties

- Assessment of the chemicals based on the ECHA, CLP and SDS.

Step 2: Occupational health safety.

- Estimation of the production and processing-related risks. Risk estimated as a combination of chemical and/or material hazards, exposure and risk management measures.

Step 3: Human Health and Environmental Aspects of the final application.

- Likelihood of exposure to the chemical or material, potential exposure routes and related toxicity impacts on human health and the environment.

Step 4: Environmental sustainability assessment.

- Environmental sustainabili ty aspects of the chemical or material.

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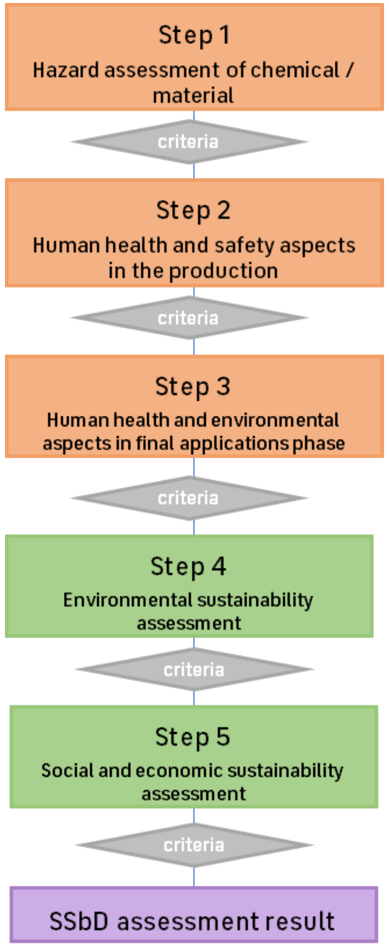

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MATERIA NOVA Materials R&D Center

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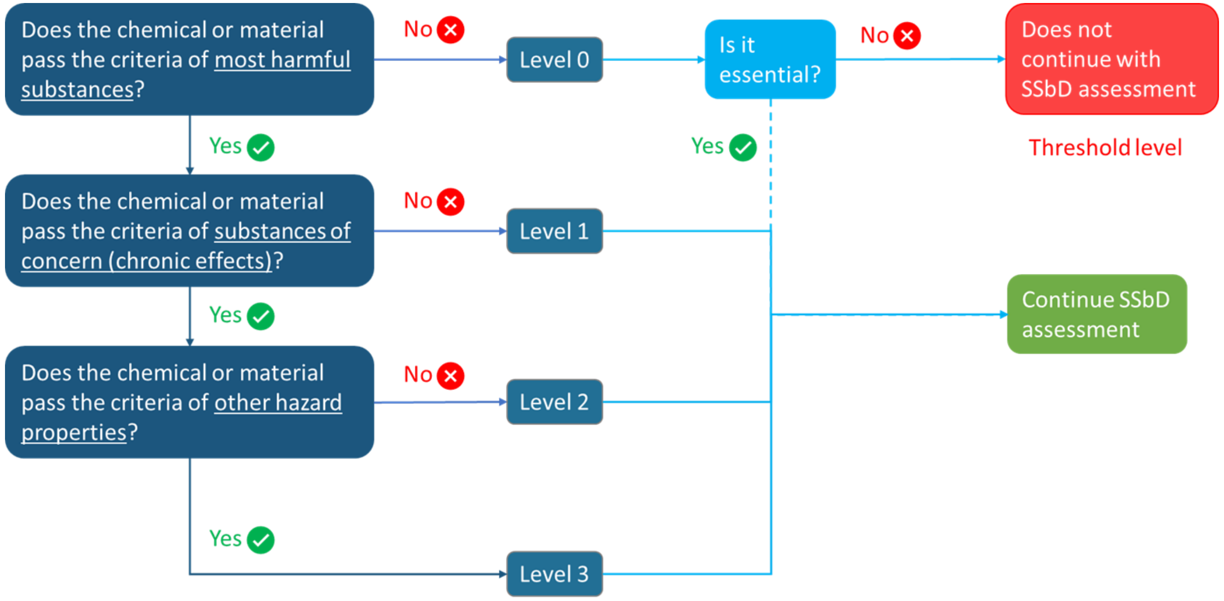
How is the framework being applied?
Step 1: Intrinsic hazardous properties

For Step 1, four levels are currently defined (*from 'Level 0' to 'Level 3'*) that will allow the assessor to rank a specific chemical based on these levels and further to integrate the results of the hazard-based evaluation to the overall SSbD assessment.



Level 0 – chemicals or materials considered most harmful substances (Group A) → Prioritized for substitution

Level 1 – chemicals or materials that induce chronic effects, part of the substances of concern (Group B) → Substituted as far as possible

Level 2 – chemicals or materials with other hazardous properties (not included in Group A and B) → Flagged for review and eventually reduce toxic effects

Level 3 – chemicals or materials that pass all safety criteria in Step 1.

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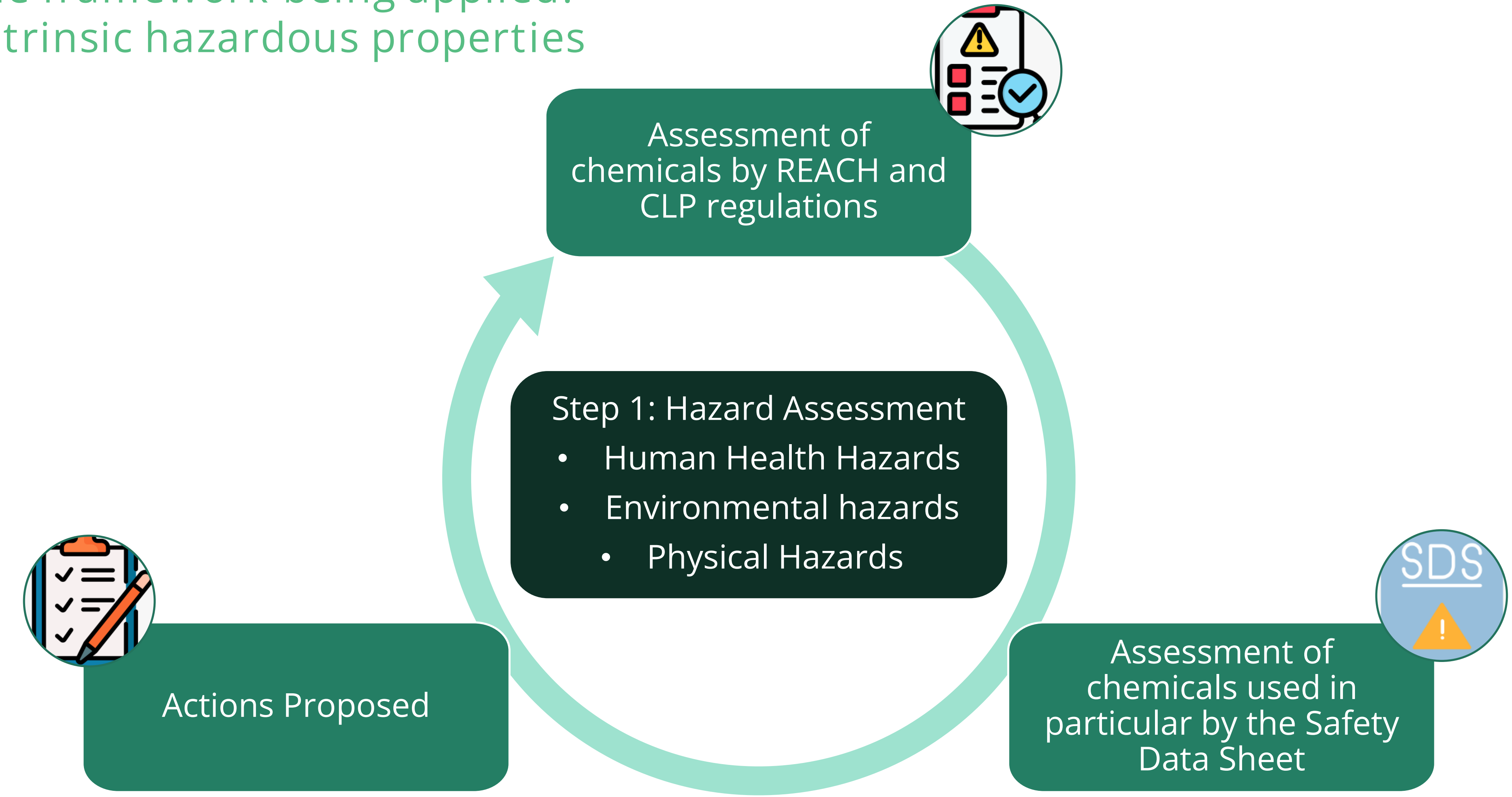

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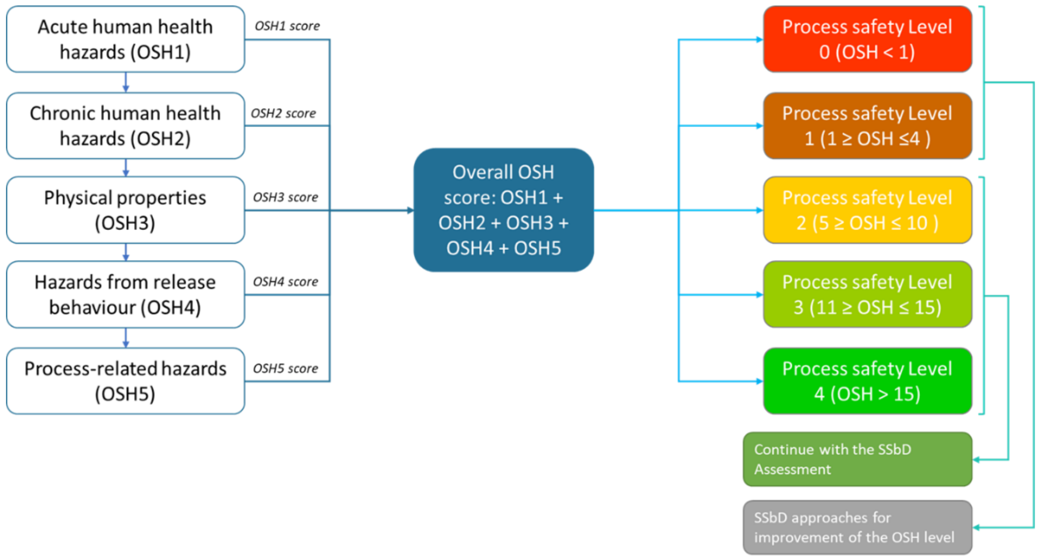
How is the framework being applied?
Step 2: Human Health and Safety aspects of Production and Processing



For Step 2, five levels are currently defined (from 'Level 0' to 'Level 4') that will allow to rank the production and processing-related risks levels and further to integrate the results of the hazard-based evaluation to the overall SSbD assessment.

Level 0 – production and processing-related risks considered most dangerous → Prioritized for modification/substitution

Level 1 – Prioritized for modification/substitution

Level 2 – Flagged for review and eventually reduce toxic effects

Level 3 – chemicals or materials that pass all safety criteria in Step 2.

Level 4 – chemicals or materials that pass all safety criteria in Step 2.

Risk level	Acute human heal th hazards	Chronic hu man health hazar ds	Physical pro perties	Hazards from release behaviour	Process-realted haza rds	Safety	
Very high-risk	0	0	0	0	0	0	Very high risk
High-risk	1	1	1	1	1	1-5	High risk
Medium-risk	2	2	2	2	2	6-10	Medium-risk
Low-risk	3	3	3	3	3	11-15	Low-risk
Neglible risk	4	4	4	4	4	16-20	Neglible risk

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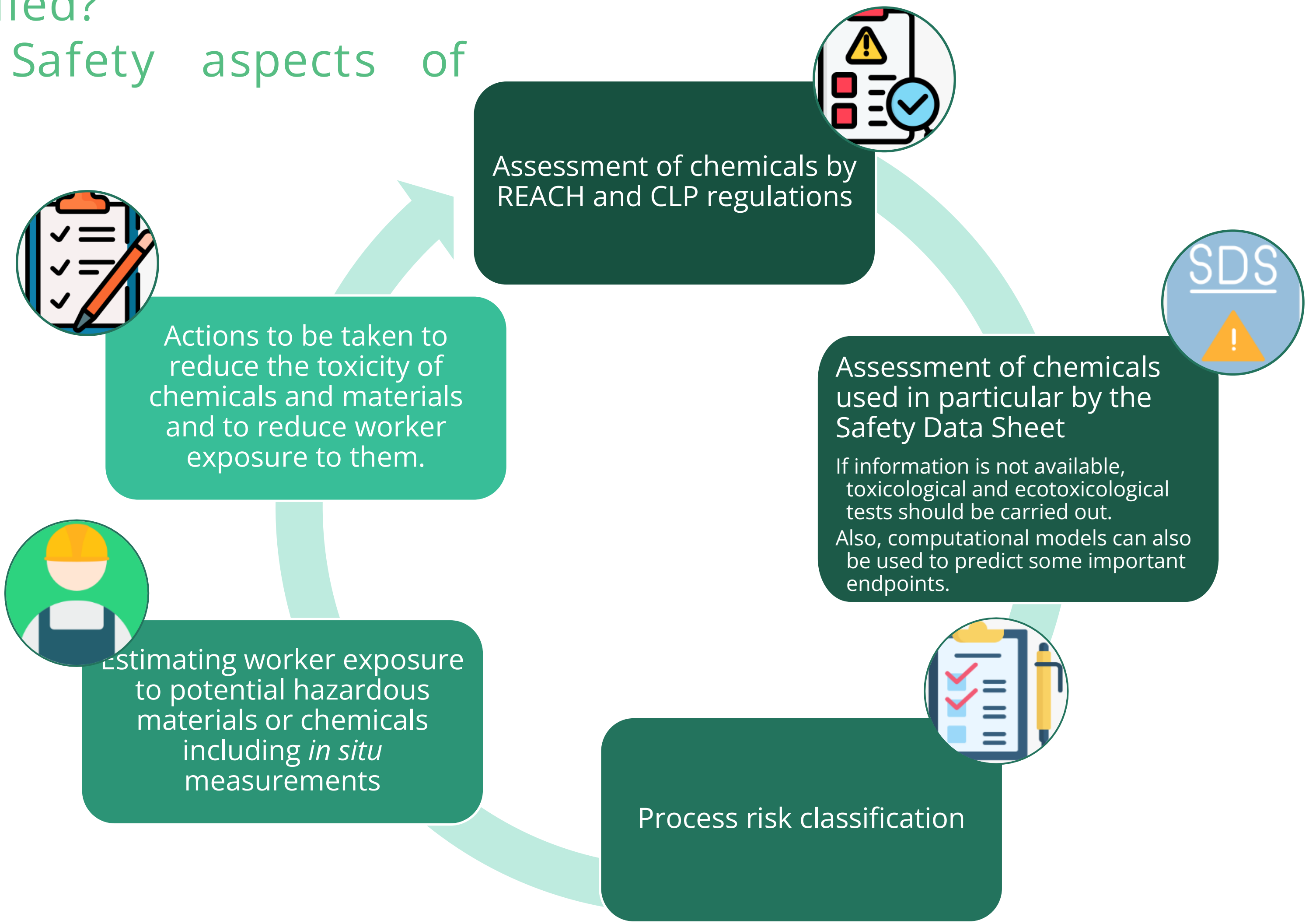
How is the framework being applied?
Step 2: Human Health and Safety aspects of Production and Processing

Step 2: Human health and safety aspects of production and processing.

Occupational health and safety during production and processing of a chemical



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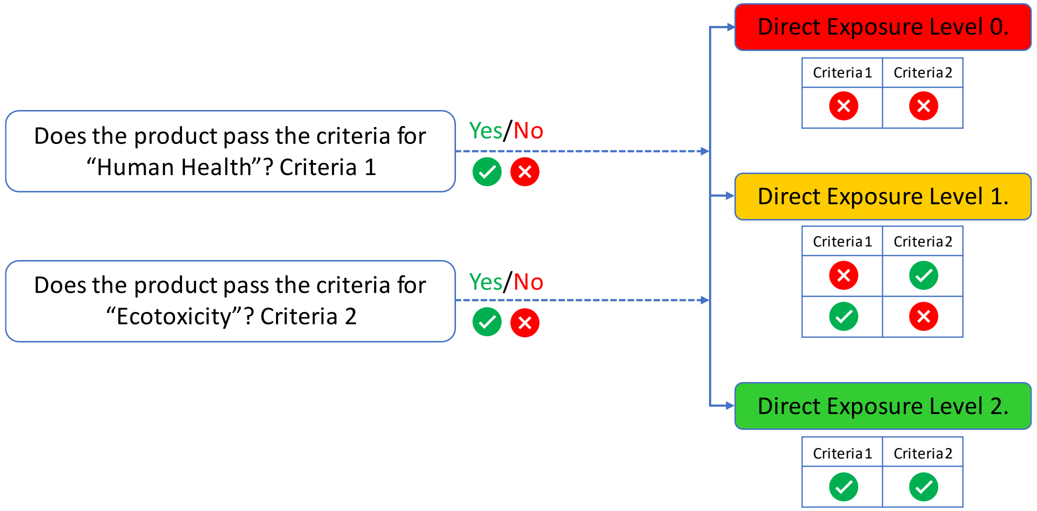
How is the framework being applied? Step 3. Human health and environmental aspects of the final application

For Step 3, three levels are currently defined (from 'Level 0' to 'Level 2') that will allow to rank the human health and environment impacts of the final application of the product and further to integrate the results of the hazard-based evaluation to the overall SSbD assessment.



Level 0 – The product generates a toxic exposure to humans or the environment above the tolerable limit → Actions to be taken

Level 1 – Flagged for review and eventually reduce toxic/ecotoxic effects

Level 2 – chemicals or materials that pass all safety criteria.

Position to safe level	Score	Color code	Criteria evaluation
> Safe level + 50%	0		Fail the criteria
> Safe level; < Safe level + 50%	1		
> Safe level - 25%; < Safe level	2		Pass the criteria
> Safe level - 50%; < Safe level - 25%	3		
< Safe level - 50%	4		

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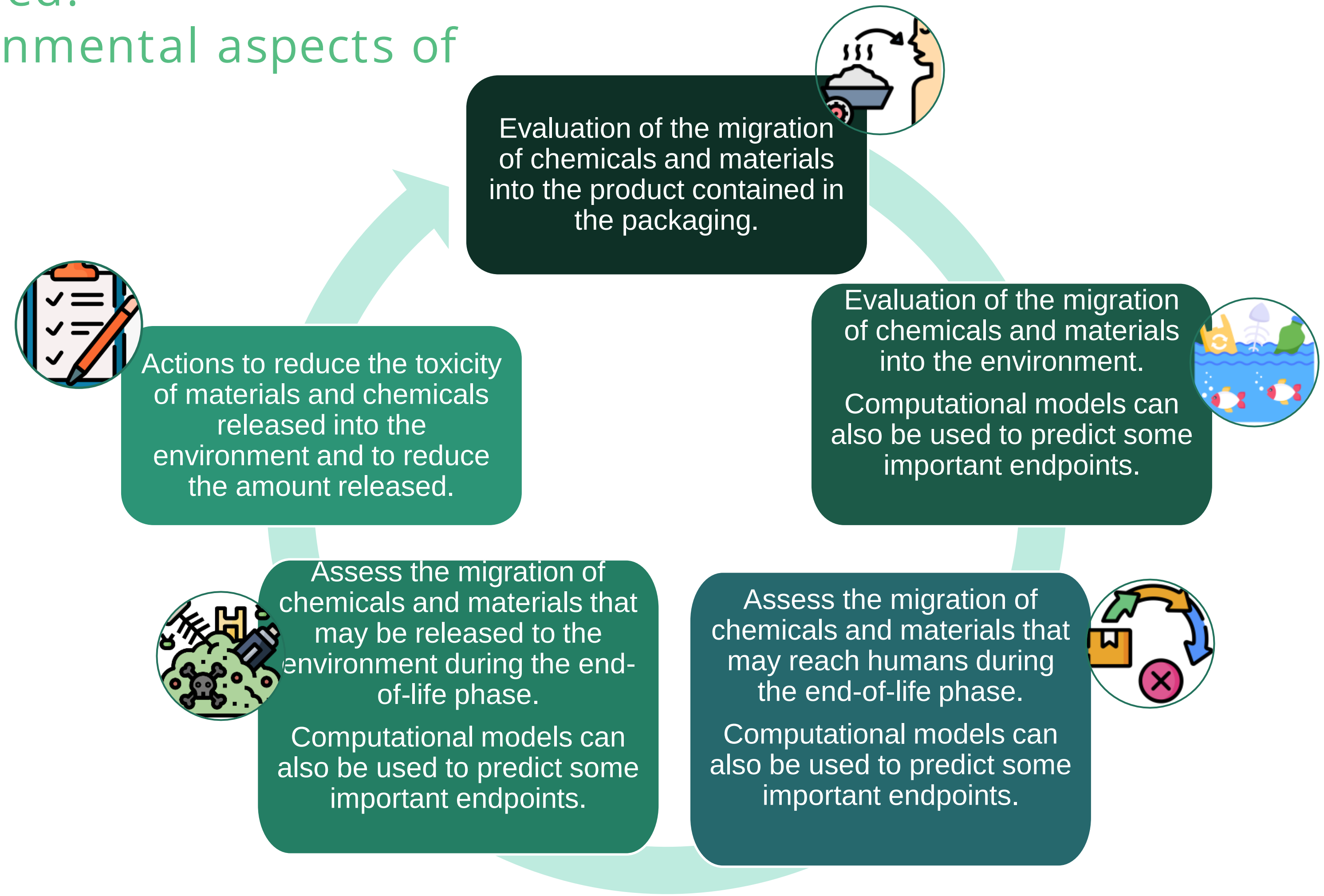
How is the framework being applied?
Step 3. Human health and environmental aspects of the final application

Step 3: Human health and environmental aspects of the final application.

Exposure to the chemical or material as well as the potential exposure routes and related toxicity impacts on toxicity on human health and the environment



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Agenda

09:30	Opening Remarks and Introduction	• Goal of the training and overview • BIO-SUSHY brief project intro (5 min)	Axia Innovation
09:40	SSbD Framework and Steps	• Explanation of SSbD framework (15 min)	ITENE
09:55	Lignin Types	• Different lignin types: full assessment and example (10 min)	Wood K plus
10:05	Safety Assessment	• Toxicity data from BIO-SUSHY (15 min) • Bio-sensor and release accelerator (20 min)	ITENE, University of Leeds
10:40	Break		
10:50	Practical Application Session	• How do we apply SSbD to certain compounds (15 min)	ITENE, Wood K plus, University of Leeds
11:05	Q&A	• Open Q&A with participants	ITENE, Wood K plus, University of Leeds
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BIO-SUSHY

Ivana Burzic

International Project Manager

Bio-based Composites and Processes (BCP) Team

WOOD KPLUS

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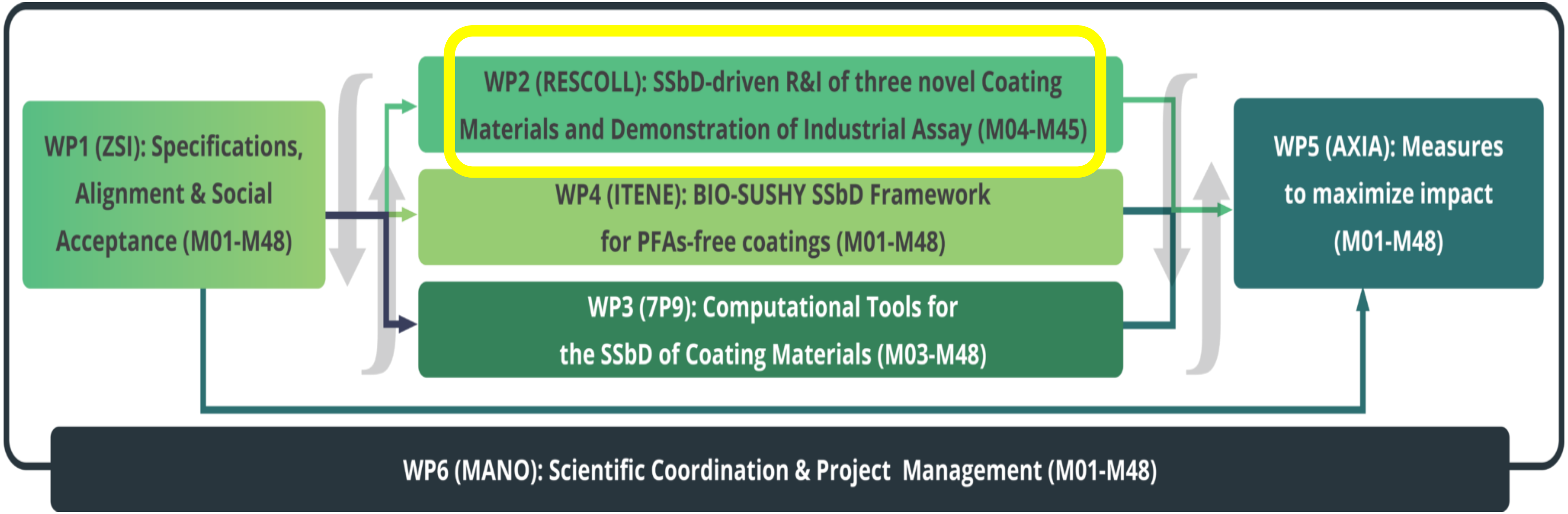
Outline

BIO-SUSHY

Wood K plus role in BIO-SUSHY



1. Development and validation of organic coating materials for spray coating applications on paper and cellulosic substrates for food packaging
2. Close cooperation with BIO-SUSHY partners dealing with SSbD Framework

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BIO-SUSHY

BIO-SUSHY Food Packaging case study

- PFAS free coating materials - PHA and/or PBS thermoplastic matrices with functionalized lignin
- Water repellence – water contact angle WCA >100° & water absorption test
- Grease resistance - according to KIT rating test TAPPI T559 oil contact angle
- Bio-based at least 80%
- Food contact tests according to EU regulation 10/2011 & 1935/2004
- Non-toxic and following SSbD approach
- Spray coating <100 µm thickness
- Film formation – hot press followed by thermoforming

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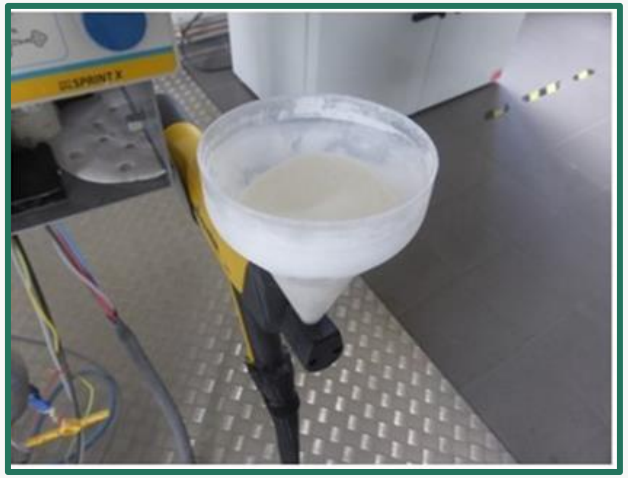
1st process step - Compounding

2nd process step - Grinding



3rd process step – Spray coating

4th process step – Hot pressing

Organic powder coating formulation development steps

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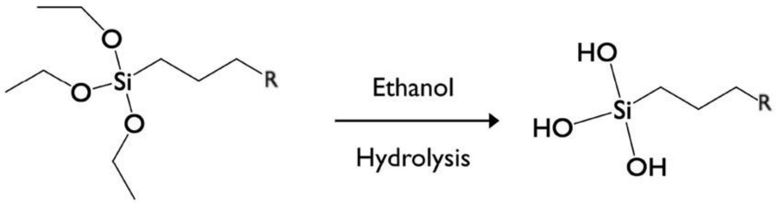
BIO-SUSHY

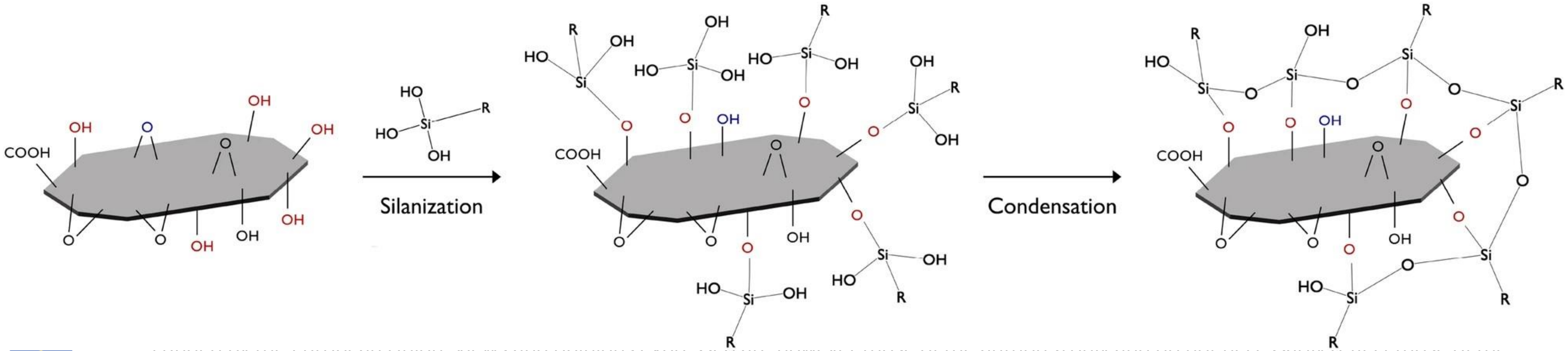
Potential of lignin as coating material (single component) and as an additive for coatings food trays application

- Kraft lignin UPM BioPiva have been selected and modified by alkoxysilane with a long alkyl chain has been chosen to chemically modify the lignin to provide water repellency.

- This modification also improves its compatibility with non-polar matrices.



Functionalization of Lignin with C8 Silane grafting function (n-octyltriethoxysilane)



Uncoated reference paper substrate

Powder-coated paper substrate using modified lignin

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Sample	Type of powder	Contact angle measurements									KIT (Grease)	Gurley-measurements					"Water repellency" (water droplet on an inclined surface - 45° to 60°)	Water absorption test "Cobb" 2h [g/m²]
		Water		Ethylene glycol		Diiodomethane		Total surface energy [mN/m]	Disperse part [mN/m]	Polar part [mN/m]								
		CA [°]	STD	CA [°]	STD	CA [°]	STD				Kit rating	1	2	3	4	5		
N_1888 Reference paper	Paper substrate 330gsm	117,91	3,68	83,06	7,89	70,94	1,40	23,69	23,54	0,15	1	22s	22s	23s	24s	24s	water penetration	143,9
N_1889	PBS	88,37	3,91	63,4	3,85	39,36	3,26	37,26	35,99	1,27	12	-*1)	-*1)	-*1)	-*1)	-*1)	moderate water repellent	23,4
N_1890	PHBV	79,45	0,79	59,5	3,80	48,01	4,88	35,82	31,17	4,66	12	-*1)	-*1)	-*1)	-*1)	-*1)	water repellent	55,3
N_1962	Modified Lignin modified UPM BioPiva 100	103,87	1,82	63,68	1,38	55,61	1,77	32,89	32,84	0,05	all 12 valuation solutions show changes	The measurement is not possible. It seems that the air can not go throught the sample!					water repellent	16,6
N_2061	PHB-PHHx	85,57	5,84	71,22	3,07	56,17	1,38	29,72	26,18	3,55	12	-*1)	-*1)	-*1)	-*1)	-*1)	moderate water repellent	3,5
N_2062	UPB BioPiva 100 (Lignin)	82,62	3,40	48,27	4,58	41,82	2,91	40,20	37,34	2,86	12	-*1)	-*1)	-*1)	-*1)	-*1)	moderate water repellent	85,7

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Toxicity and Safety Assessment

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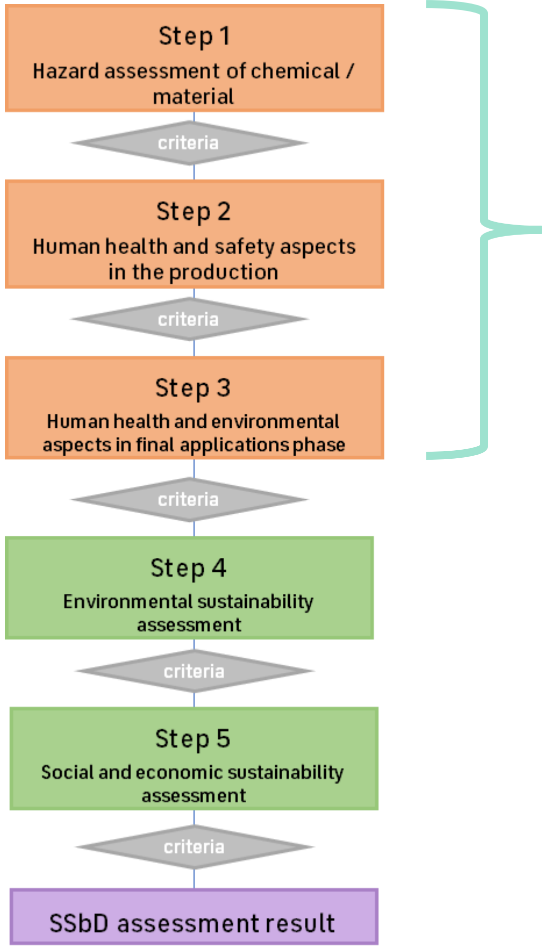
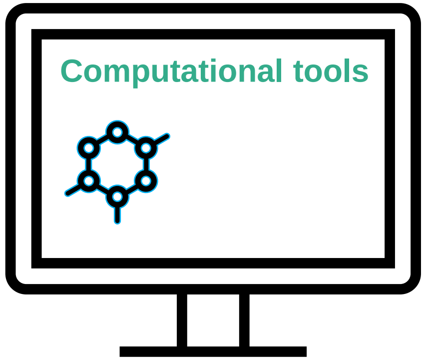
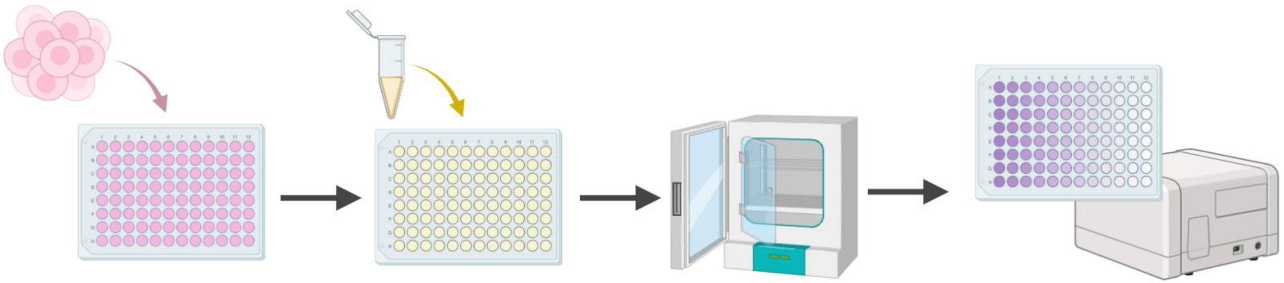
BIO-SUSHY

How can we evaluate the safety?







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BIO-SUSHY

Computational tools

When the information is not available, Computational tools can also be used to predict some important endpoints needed to perform the assessment following SSbD Framework.

SAR (Structure-Activity Relationship): SAR methods are based on the idea that the biological activity or chemical property of a molecule can be related to its chemical structure

When quantified, this relationship is known as QSAR (Quantitative Structure-Activity Relationship). QSAR is a mathematical relationship which correlates measurable and calculable descriptors to specific biological/pharmacological/toxicological activities in terms of an equation.

The OECD principles for QSAR validation

- A defined endpoint
- An unambiguous algorithm
- A defined domain of applicability
- Appropriate measures of goodness-of-fit, robustness and predictivity
- A mechanistic interpretation, if possible

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Step 1: Intrinsic hazardous properties

VEGA includes 112 QSAR models for regulatory purposes, that predict endpoints related to: human toxicity, eco-toxicity, environmental properties, phisico-chemical properties, toxicokinetics.

DANISH QSAR DATABASE: includes estimates from more than 200 (Q)SARs from free and comercial platforms and related to physicochemical properties, ecotoxicity, environmental fate, ADME and toxicity.

JANUS

Janus: prioritization of chemical substances for PBT, CMR and endocrine disrupting activity. New approach that combines P, B, aquaT, C, M, R, and ED. Provides experimental and predicted values used.

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Step 2: Human health & safety aspects in the production and processing phase

ProScale

A tool for a hazard and exposure-based quantitative scoring system for comparing direct chemical risks to workers, professionals and consumers associated with products in a life cycle perspective

ecetoc

A tier 1 screening exposure tool that estimates the risk of chemical exposure for workers, consumers, and the environment.

Stoffenmanager®

A risk banding tool used to prioritize risks for inhalation and dermal occupational exposure.

ART Advanced REACH Tool

A tier 2 occupational exposure assessment tool that estimates occupational inhalation exposure to dust, mist, and vapour.

INTEGRA

A unified computational platform that integrates environmental fate, exposure, and internal dose dynamically over time.

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Step 3: Human health & environmental aspects in the final application phase

A software system to support the risk assessment of chemicals intended to be used in plastic Food Contact Materials (FCM):

- Migration modelling of chemicals from FCM into food
- Predictions of toxicological endpoints using VEGA

A unified computational platform that integrates environmental fate, exposure, and internal dose dynamically over time:

- Multimedia environmental modelling
- Exposure modelling
- Internal dose modelling
- Exposure reconstruction

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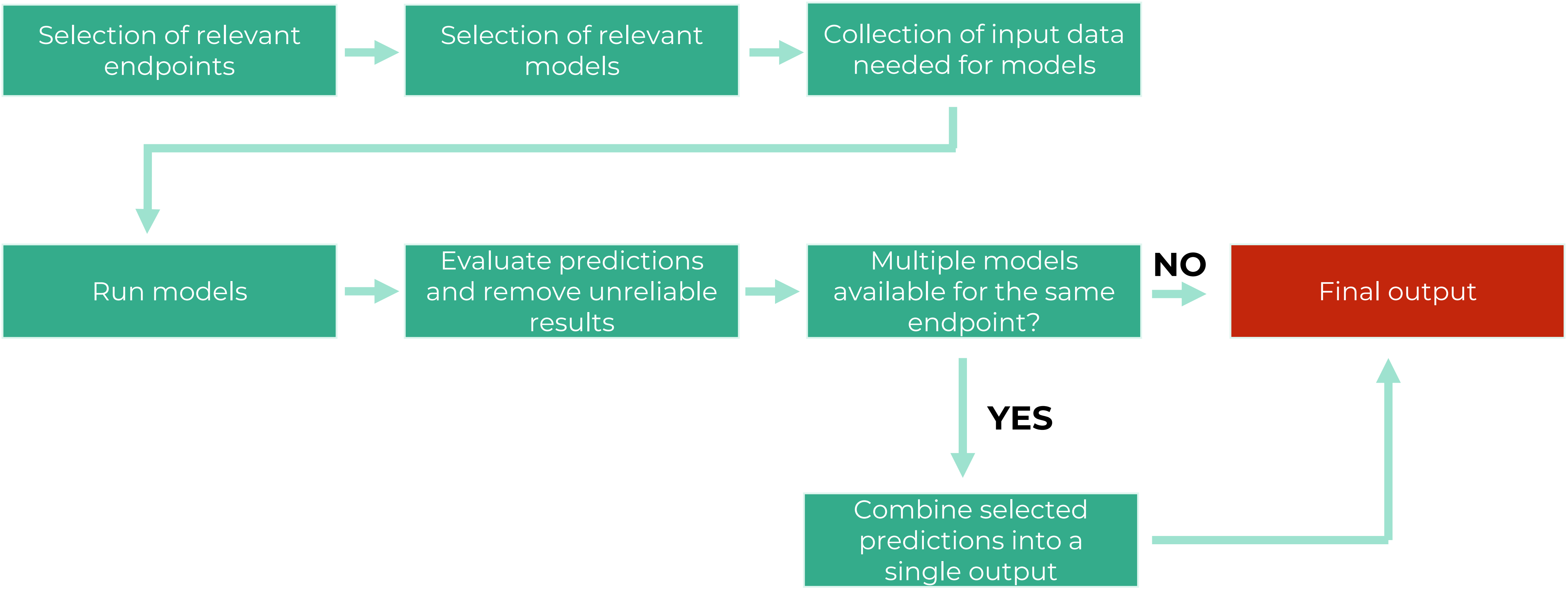

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Ashi Rashid

Research Fellow

School of Chemistry

UNIVERSITY OF LEEDS

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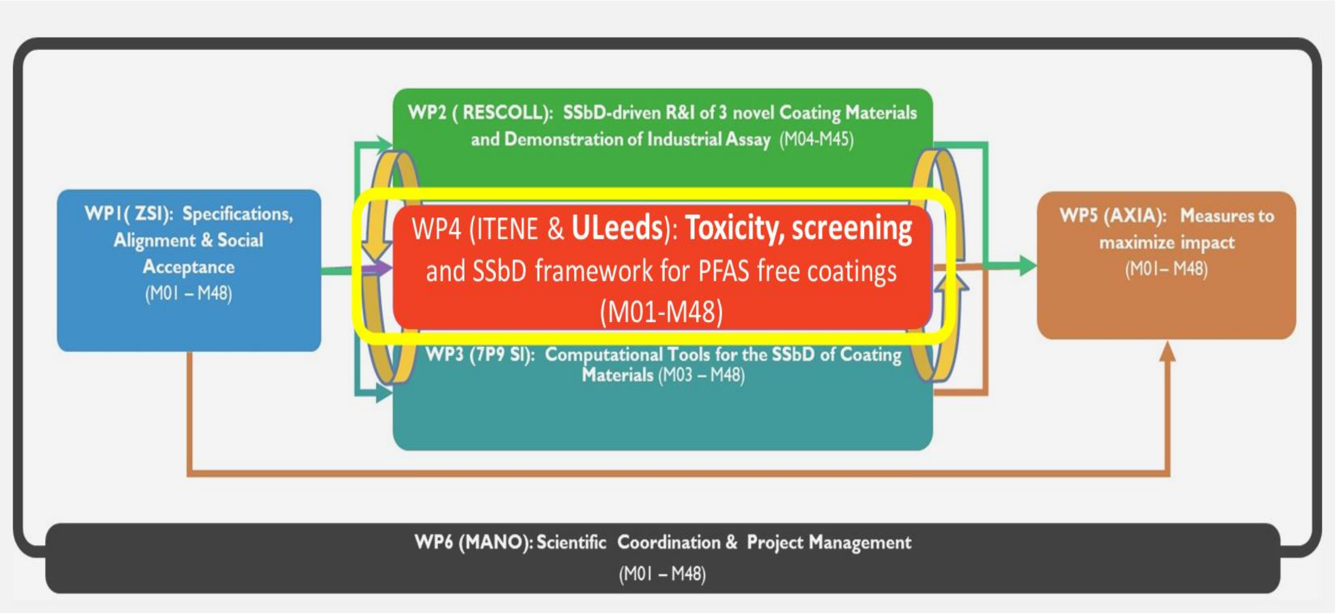
Outline

Our role at ULEEDS



1. Screening of coating materials and formulations
2. Screening of coating: release studies using release accelerator
3. To assess membrane interactions of coating materials

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Membrane disruption assessments of coating material & coatings

High throughput screening

Bio-membrane sensor

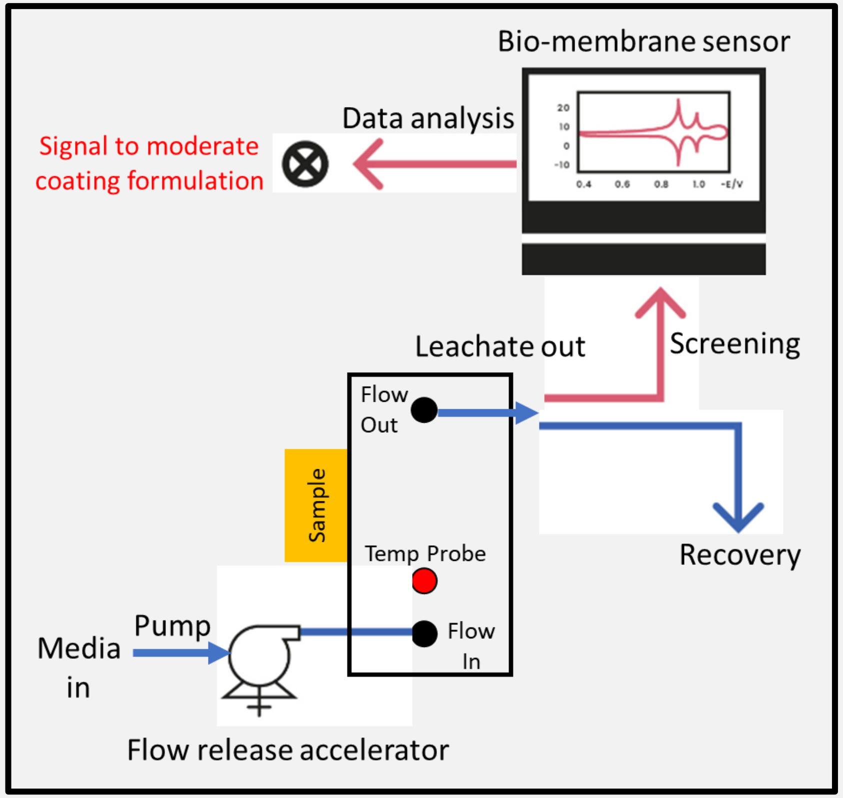
- **Polymers**
- **Nanomaterials**
- **Toxins**
- **Drugs**
- **Therapeutic agents**
- **Coating materials and formulations**

Coating release studies

Flow release accelerator

Coatings:

- **Paper, glass, textile, metal coatings**
- **Temperature, time, reagent**
- **Leachates**



Flow release accelerator coupled with Bio-membrane sensor using signal to moderate coating formulation

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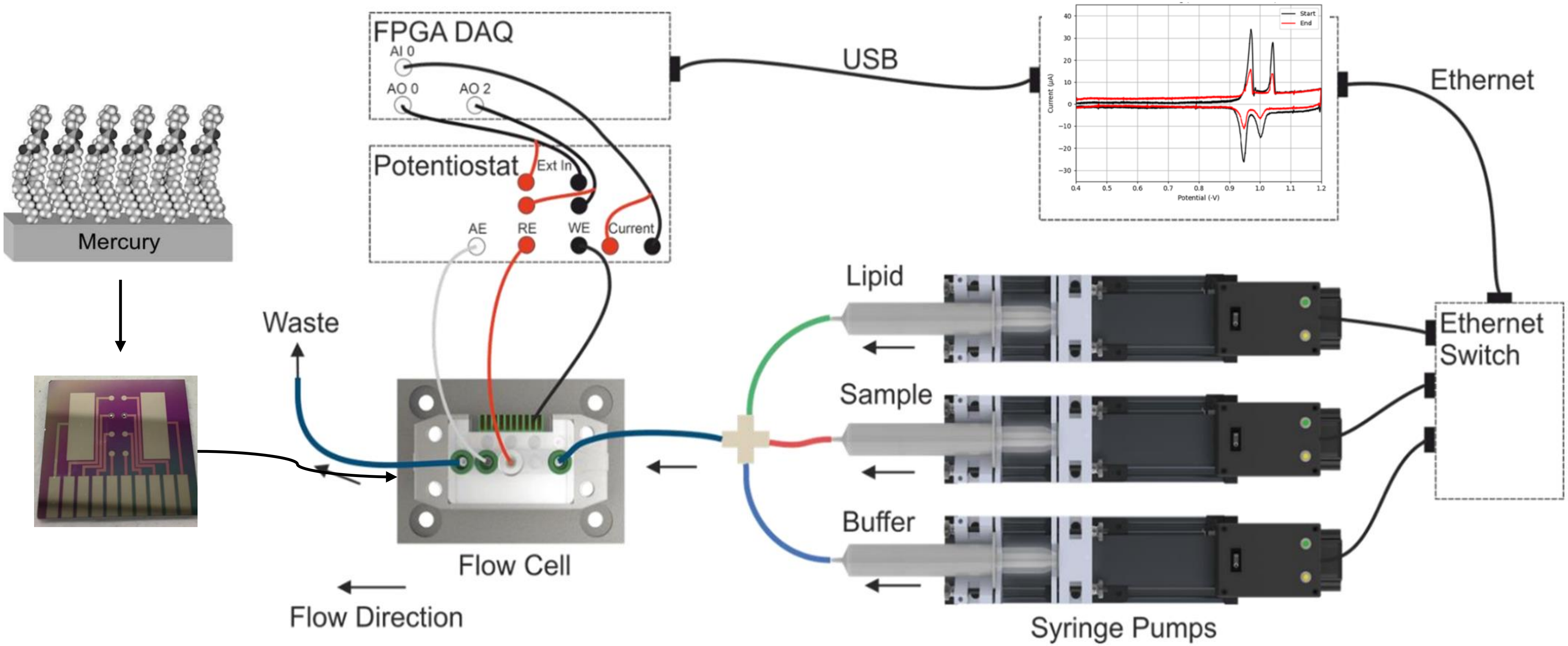
BIO-SUSHY

Bio-membrane sensor: Methodology



Electrical and fluidic components of bio-membrane sensor

A. Nelson et al, High-throughput electrochemical sensing platform for screening nanomaterial–biomembrane interactions, Rev. Sci. Instrum. 91, 025002 (2020).

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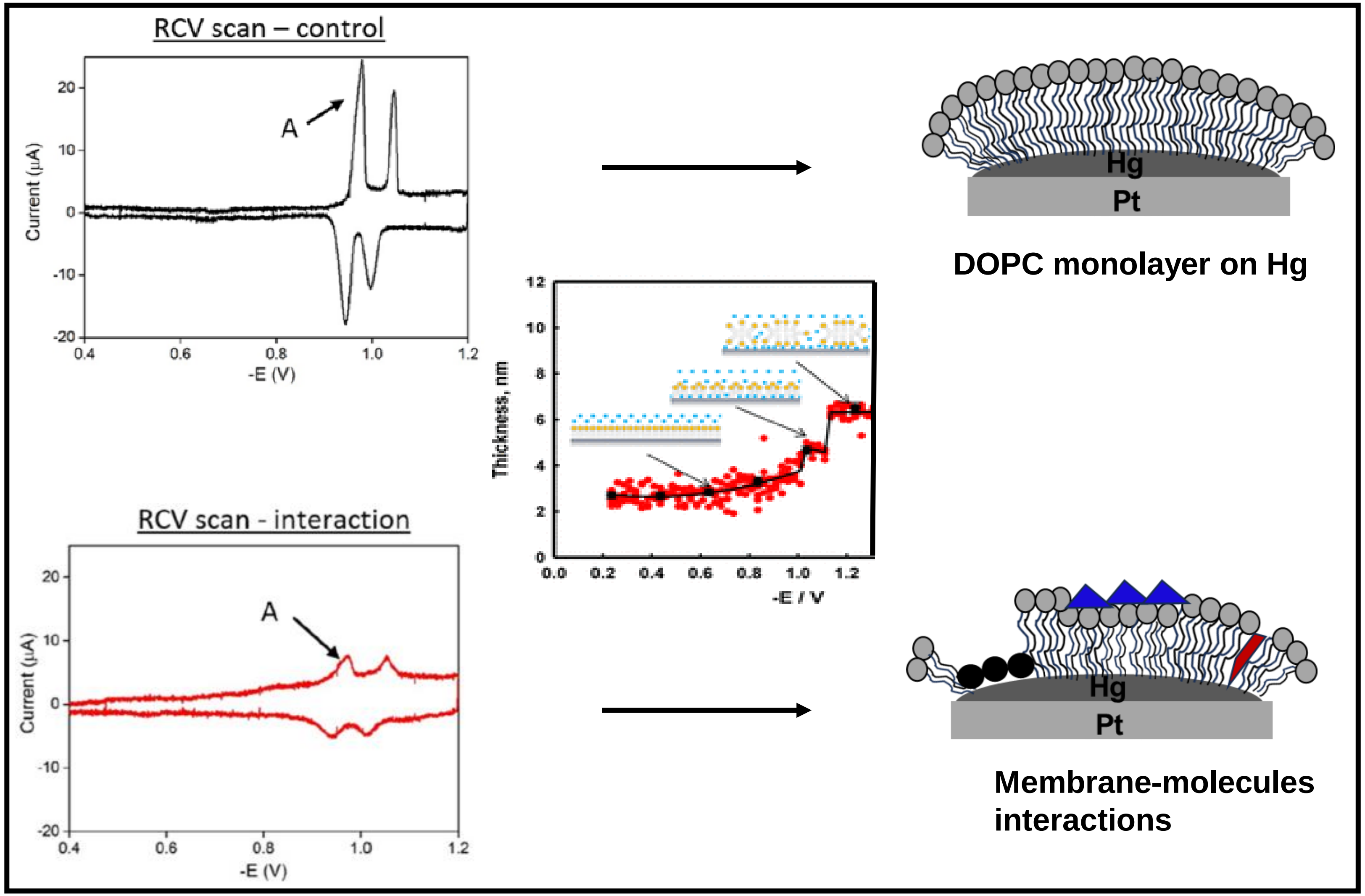

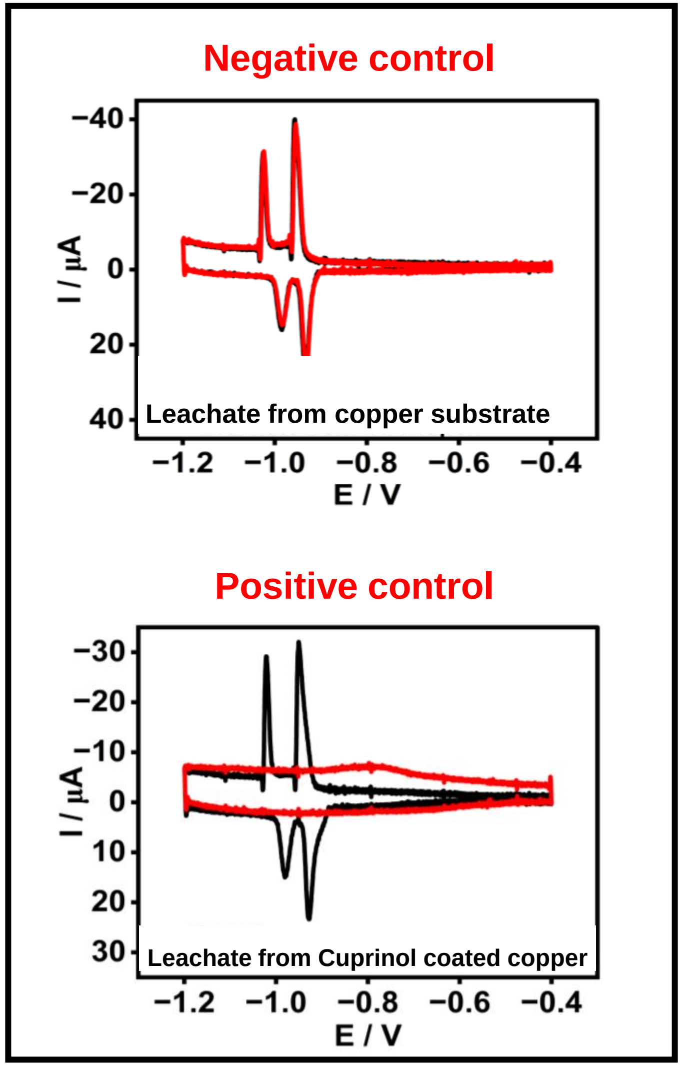

A. L. Nelson et al, Direct characterization of fluid lipid assemblies on mercury in electric Fields, ACS Nano, 2014, 8, 4, 3242–3250.

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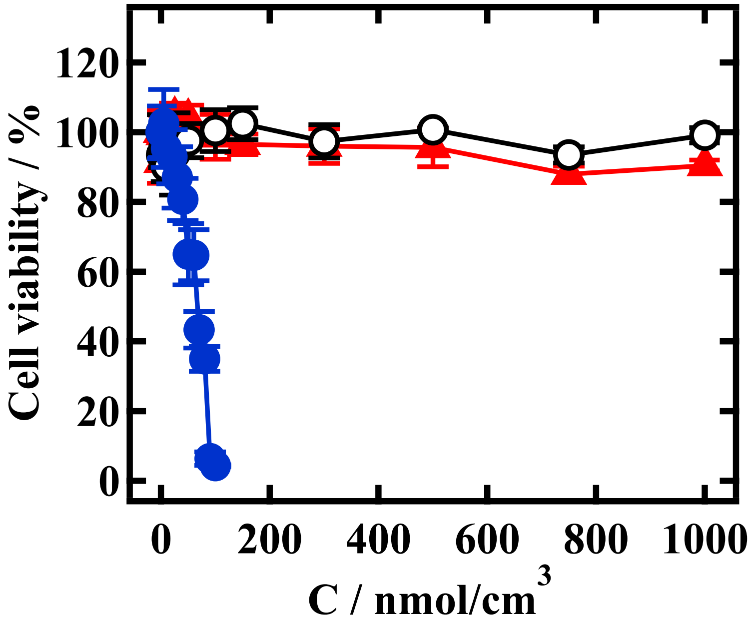
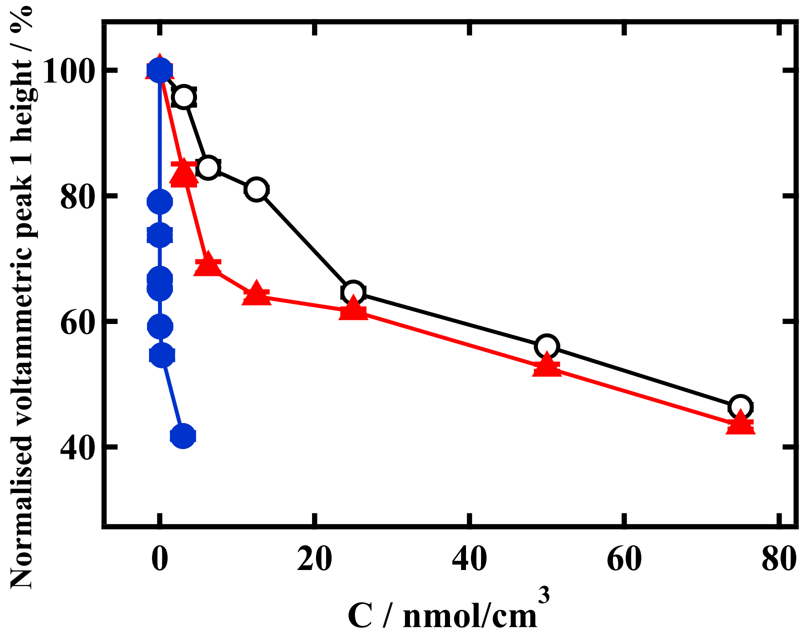
BIO-SUSHY

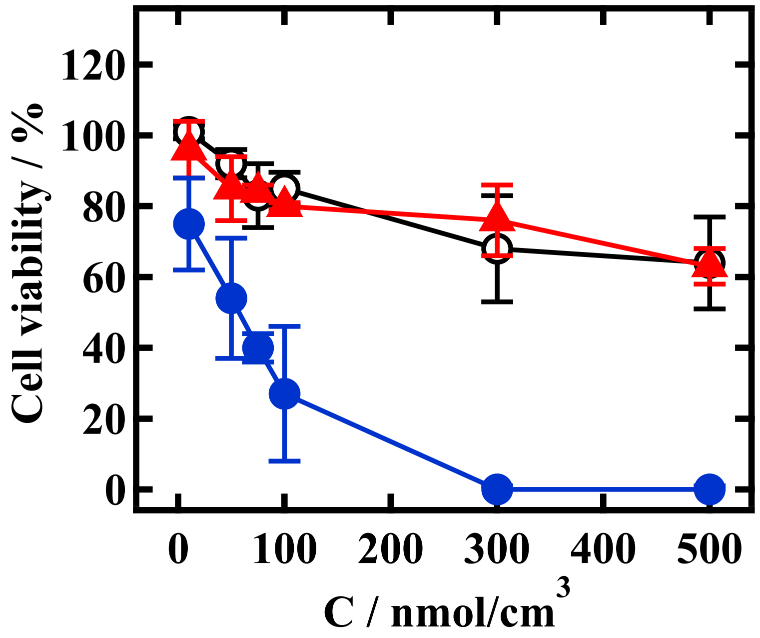
Bio-membrane sensor output equivalent to cytotoxicity assay



THP1 cell culture
(3 hrs exposure)



Bio-membrane sensor
(2 mins exposure)



Caco-2 TC7 cell culture
(3 hrs exposure)

- ○ **Colchicine**
- ▲ **Methyl methanesulphonate**
- ● **Chlorpromazine**

Biomembrane sensor: > 10 times more sensitive than *in vitro* cell viability tests

A. L. Nelson et al, Rapid identification of in vitro cell toxicity using an electrochemical membrane screening platform, Bioelectrochemistry 153 (2023) 108467.

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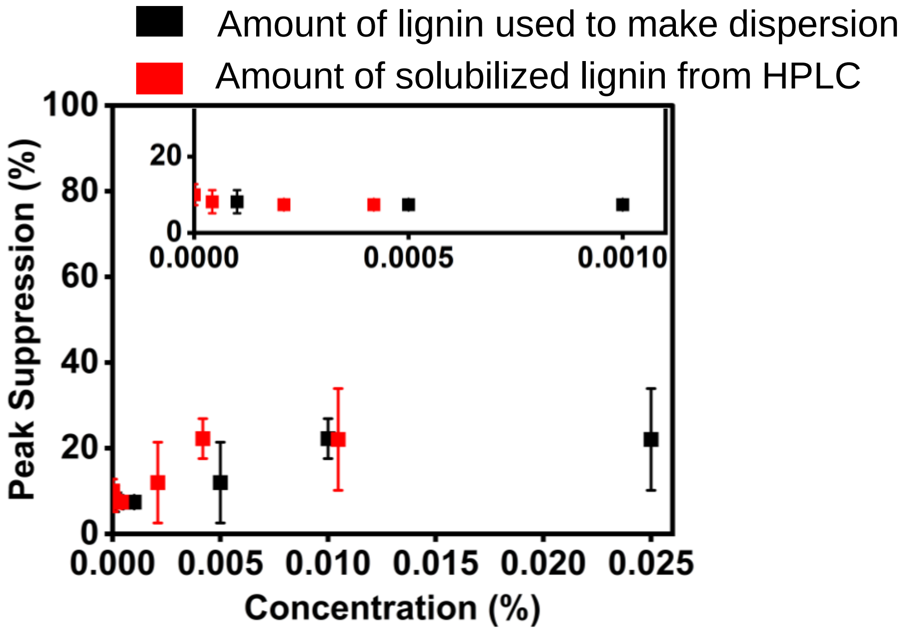
BIO-SUSHY

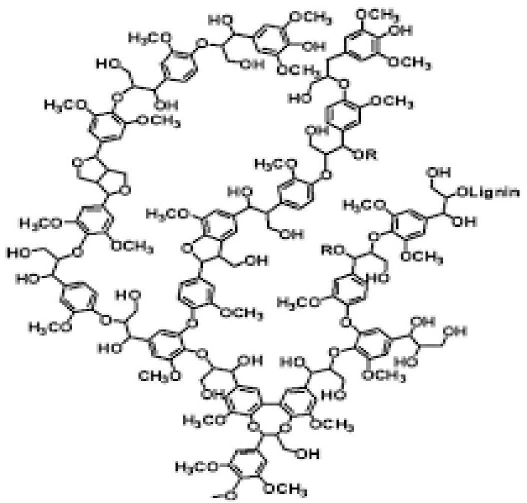
Lignin solubility & Dosing Challenge

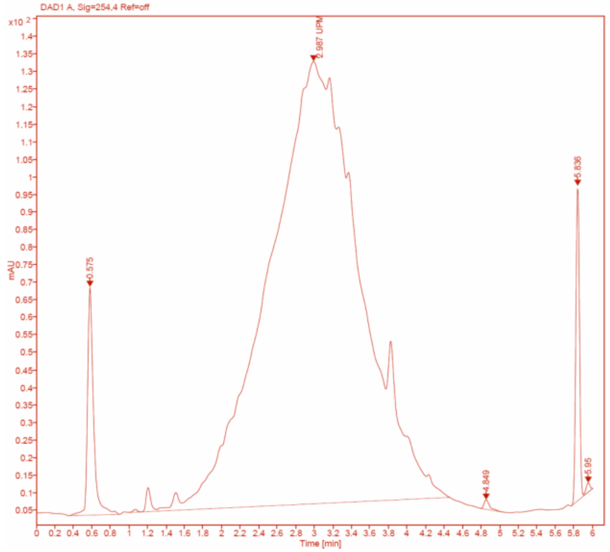
Highly hydrophobic and water insoluble

Heterogeneous water dispersions (Stock solution) → Sonication → Centrifugation → HPLC → Concentration from calibration curve

Centrifugation → Dilutions → Bio-membrane sensor → Concentration vs Peak suppression (%) plots







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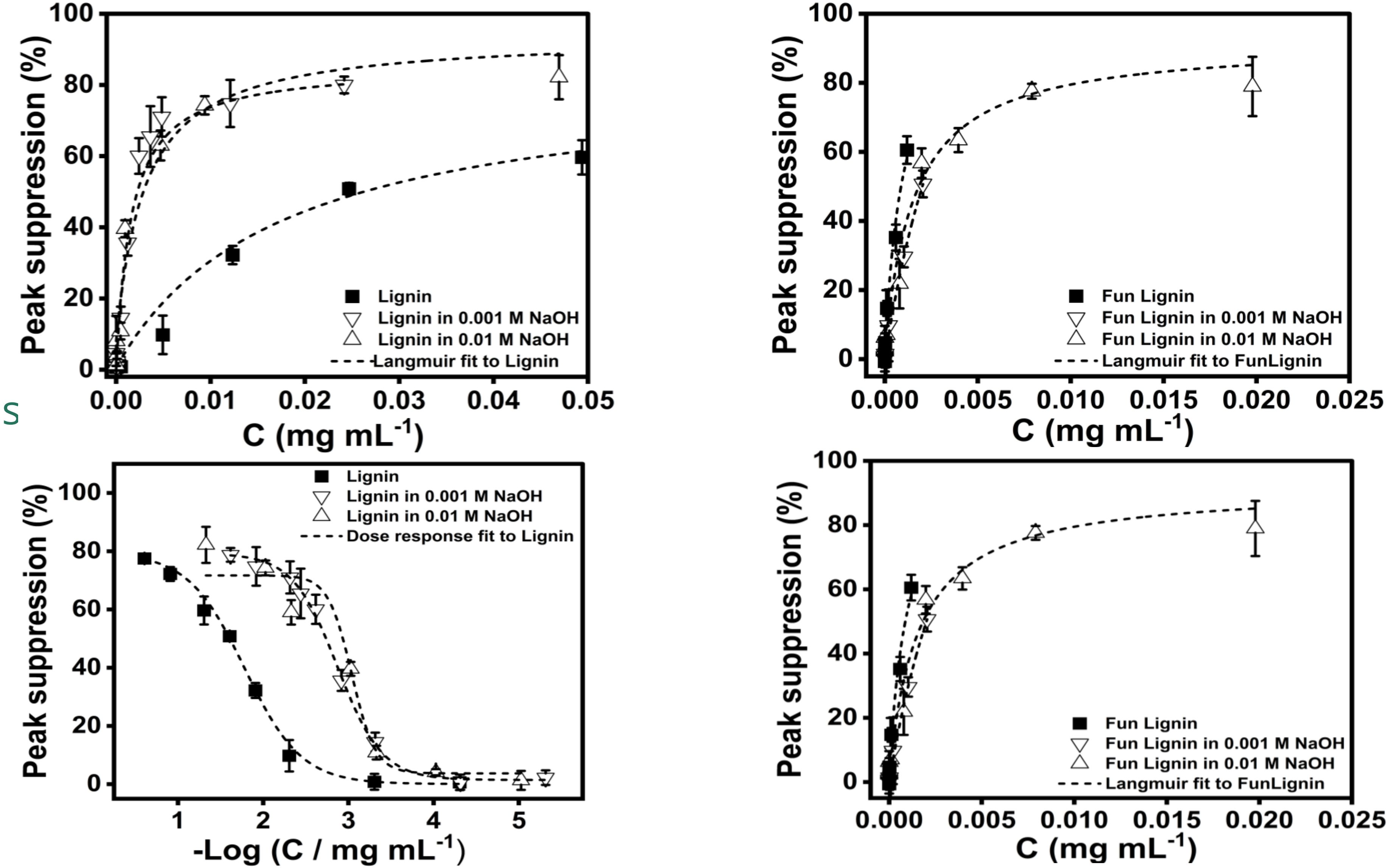
Membrane interactions of solubilized Lignin



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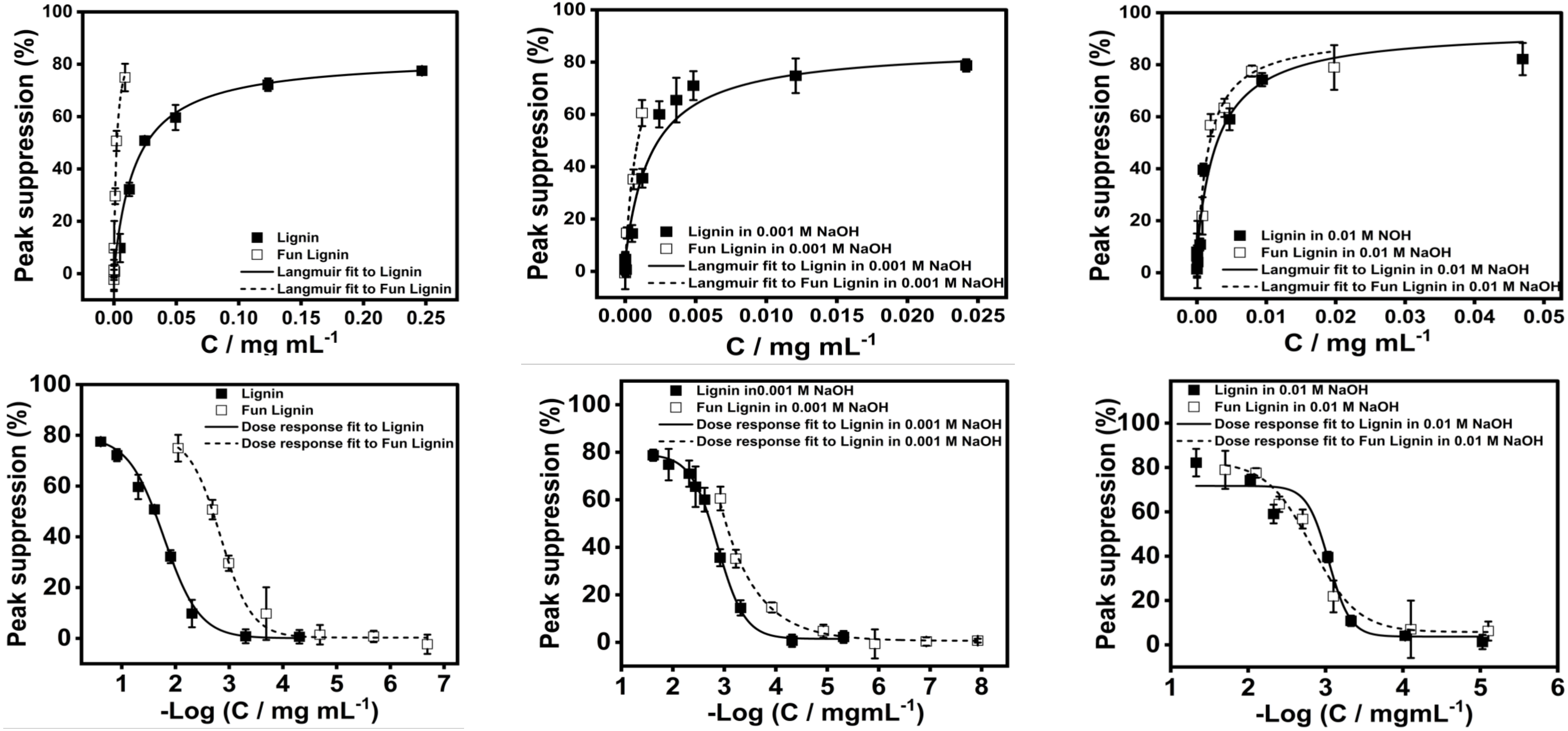

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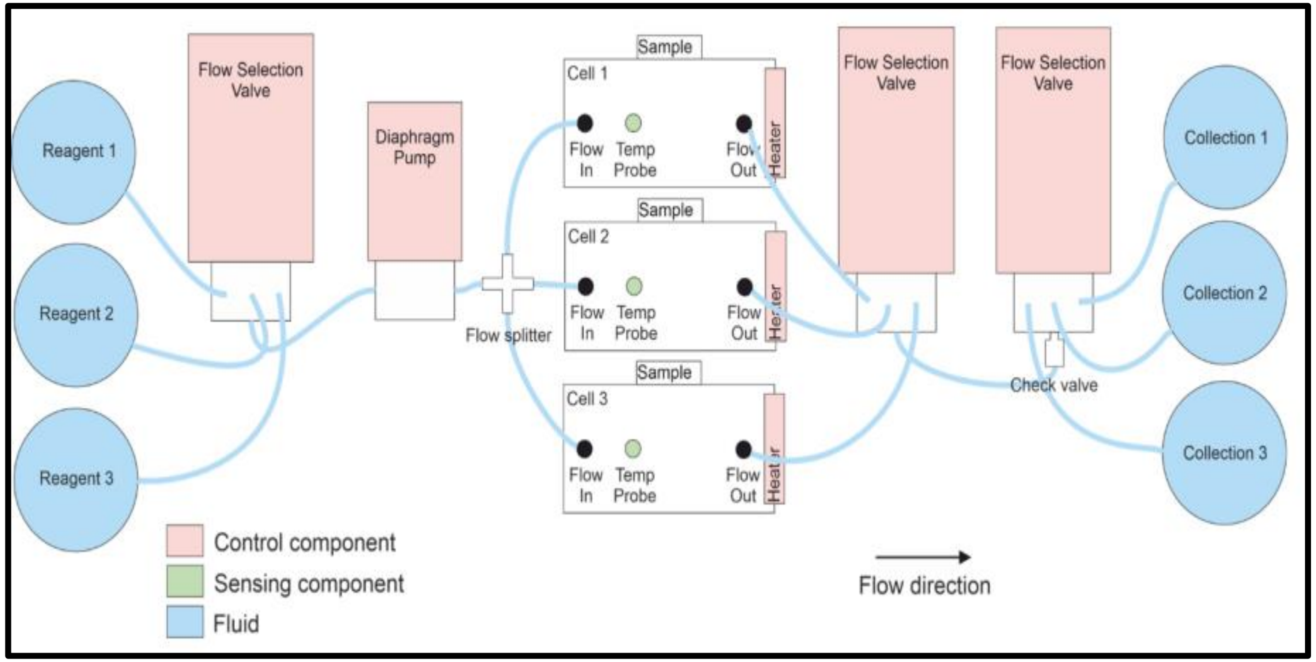
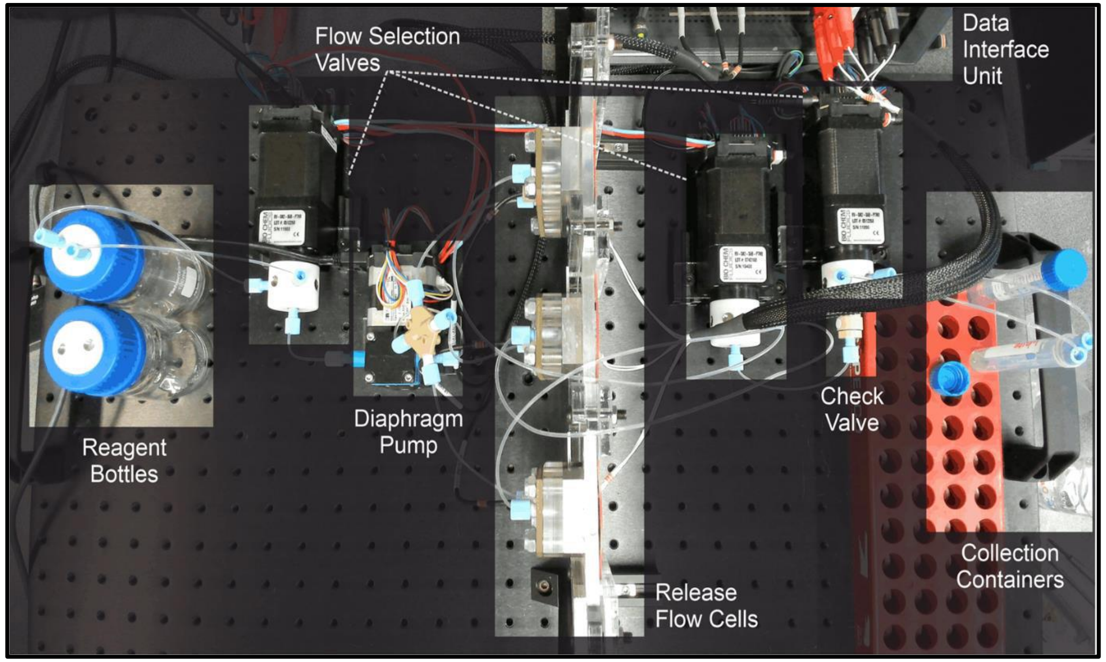
Coating release accelerator

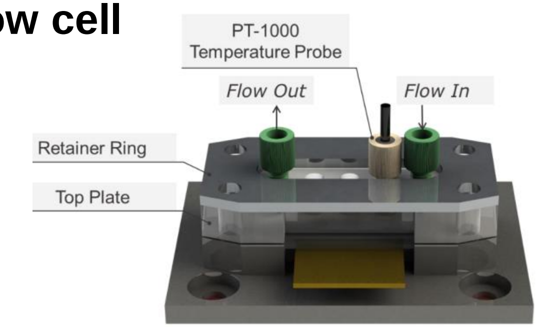


Electrical components and fluidic connections of mini-release accelerator platform

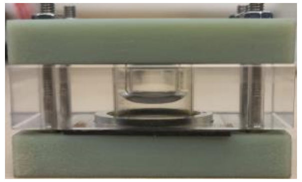


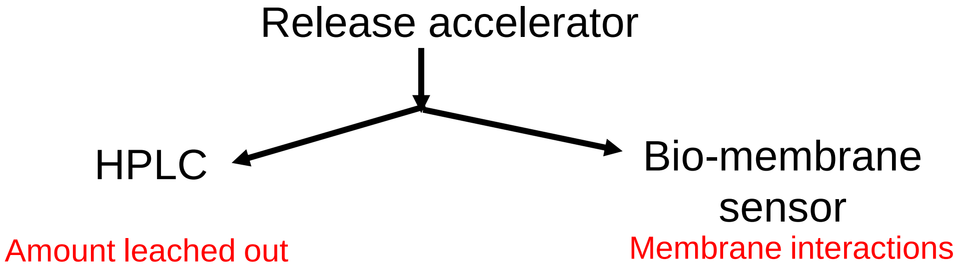
Top-down view of mini-release accelerator platform

Flow cell



Static cell





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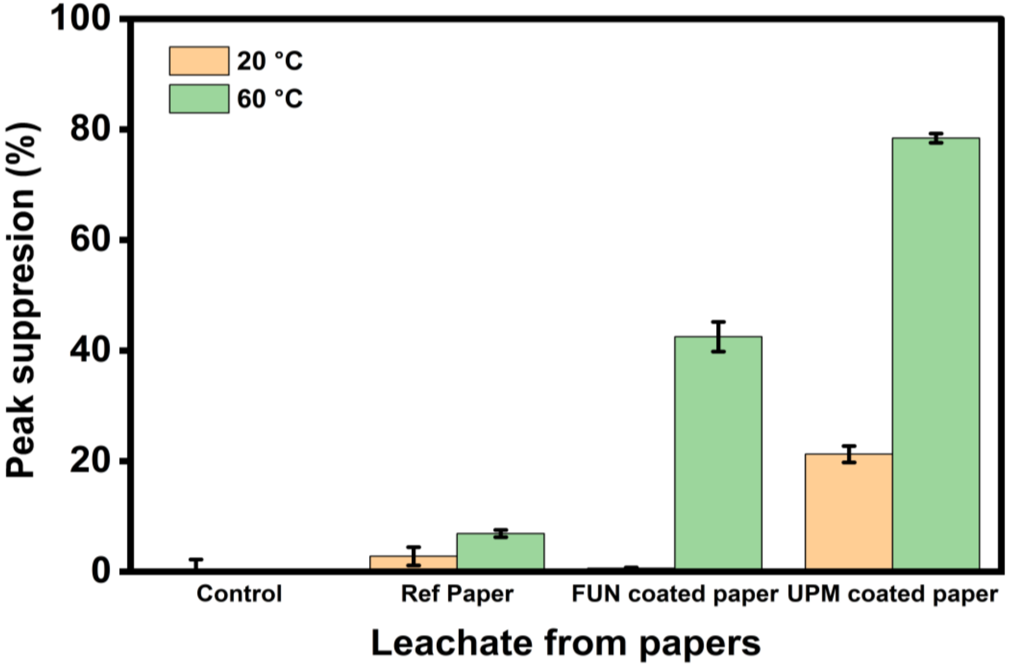
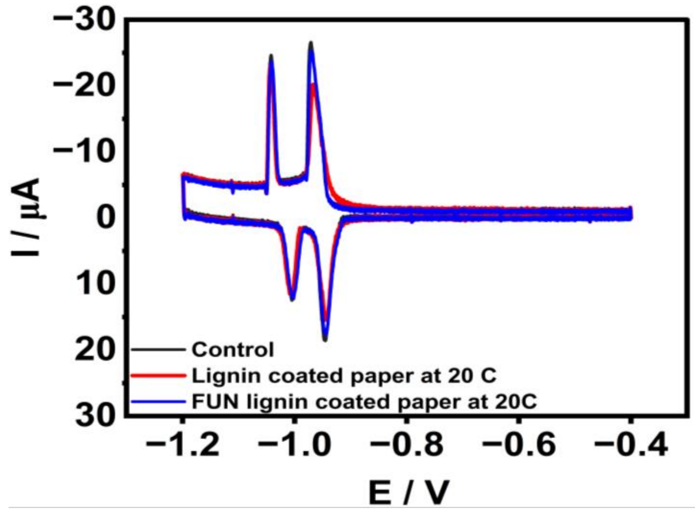
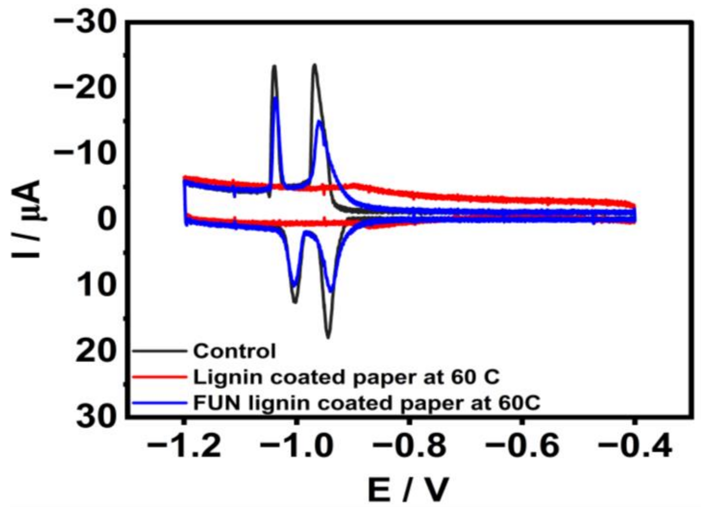


Membrane interactions of released Lignins





SSbD technology in action!

Coated paper	Amount released mg mL^{-1}	
	20 °C	60 °C
Lignin	0.0019	0.051
Functionalized Lignin	0 <?	0.0073

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BIO-SUSHY

Cytotoxicity of Lignin

- Lignin is ***released*** from coated papers.
- Lignin is ***bio-membrane active***.
- Different lignin types show different extent of interactions
- *Use of SSbD technology for feedback to modify material design*

Material	Cytotoxicity assessment	Outcome	Reference
Lignin	Tetrazolium salt assay using HEK293 and H460	More than 90% of cells dead (LC50: 0.021%)	https://doi.org/10.3390/ma13153365
Lignin NPs (152 nm)	Cytotoxicity using MCF-7, A-549 and HEK-293	74 % MCF-7, 38% A-549 and 15% HEK-293	https://doi.org/10.1016/j.ijbiomac.2020.02.311
Lignin coated cellulose nano fibrils (L-CNF)	LDH increase & Alamar blue assay using THP-1	<50 ug/ml	https://doi.org/10.1021/acs.biomac.6b00756
Lignin (Acacia Nilotica)	Cytotoxic using MCF-7	cytotoxic ($IC5_0$: 2-15 µg/ml)	https://doi.org/10.1016/j.ijbiomac.2016.01.109
Organosolv lignin	Cytotoxic using MSCs	Reduction in cell viability	https://doi.org/10.3390/biology11050696.

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BIO-SUSHY

Achievements

- ✓ Slow release of functionalized lignin
- ✓ Application of SSbD approach for *online* signaling to moderate the coating formulation

Future Plans

- ✓ Reduce leaching of lignin by chemical modification/compounding
- ✓ Identifying the exact chemical composition of leachate

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BIO-SUSHY

UNIVERSITY OF LEEDS

Supervisor: **Andrew Nelson** (University of Leeds)
Co-supervisor: **Nik Kapur** (University of Leeds)
Jeanine William (University of Leeds)
Will Stokes (University of Leeds)
Joshua Owen (University of Leeds)
All BIO-SUSHY consortium especially: **Ivana Burzik** (WOODKPLUS)
Christoph Jocham (WOODKPLUS)
Pau Camilleri Lledo (ITENE)
Javier Alcodori (ITENE)
Aude Mezy (SIKEMIA)

THANK YOU!

UK Research and Innovation

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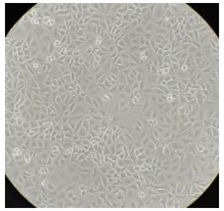
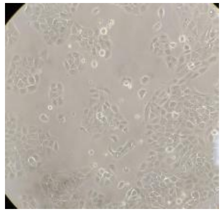
Toxicity assessment-SSbD STEPS 1-3

Exhibition routes

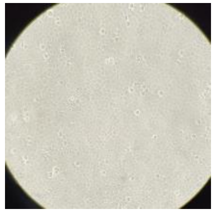
Cell culture



A549 cell line derived from alveolar wall epithelial cells



HaCaT cell line derived from adult skin keratinocytes



CaCo-2 cell line from colorectal epithelium

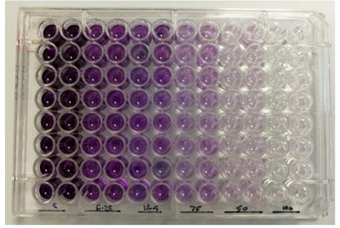
Effects studied

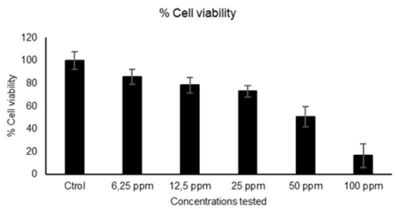
1 CYTOTOXICITY. Alteration of basic cellular functions: MTT assay.

Reduction

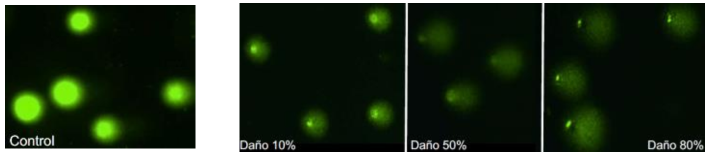
MTT → Formazan crystals

Example





2 GENOTOXICITY. Adverse biological effects on genetic material.



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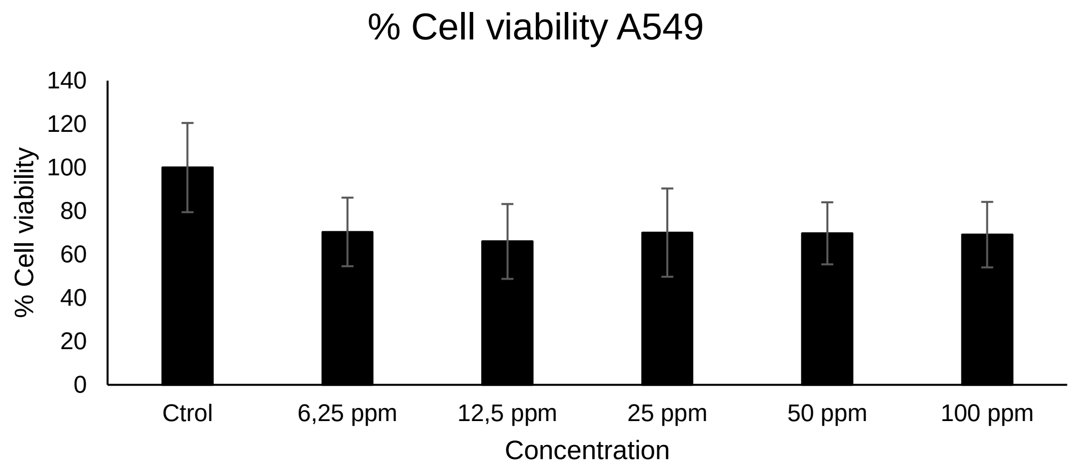
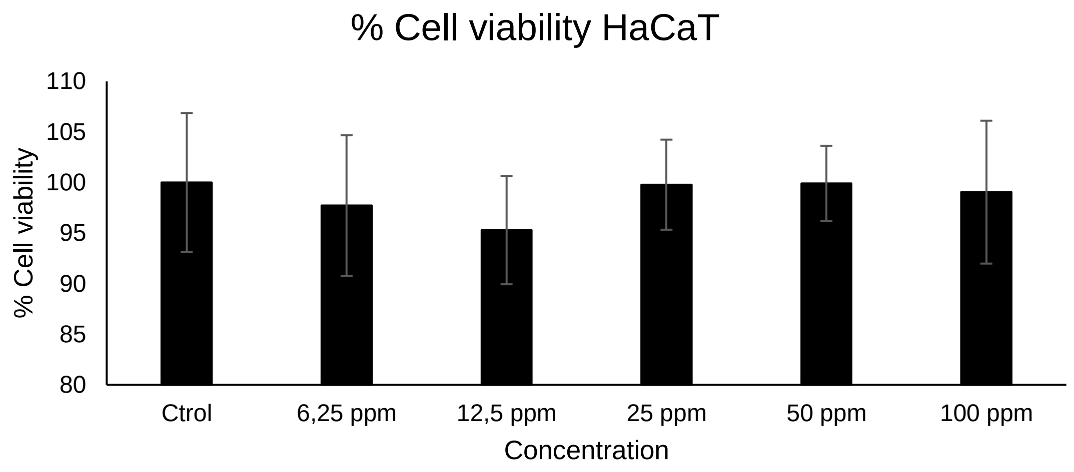
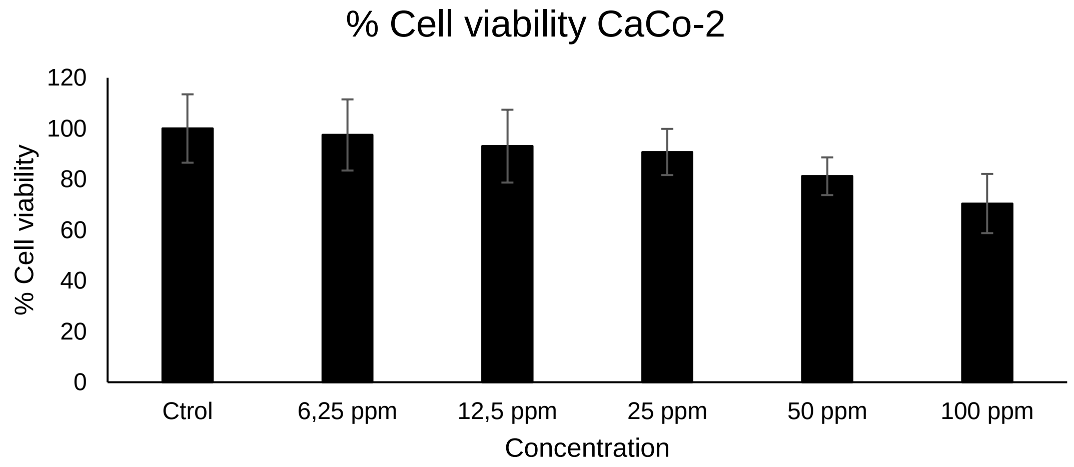
Toxicity assessment- Results







Cell viability	Sample	EC_{50}
A549	Lignin C8 Modified	>100 ppm
CaCo-2	Lignin C8 Modified	>100 ppm
HaCaT	Lignin C8 Modified	> 100 ppm

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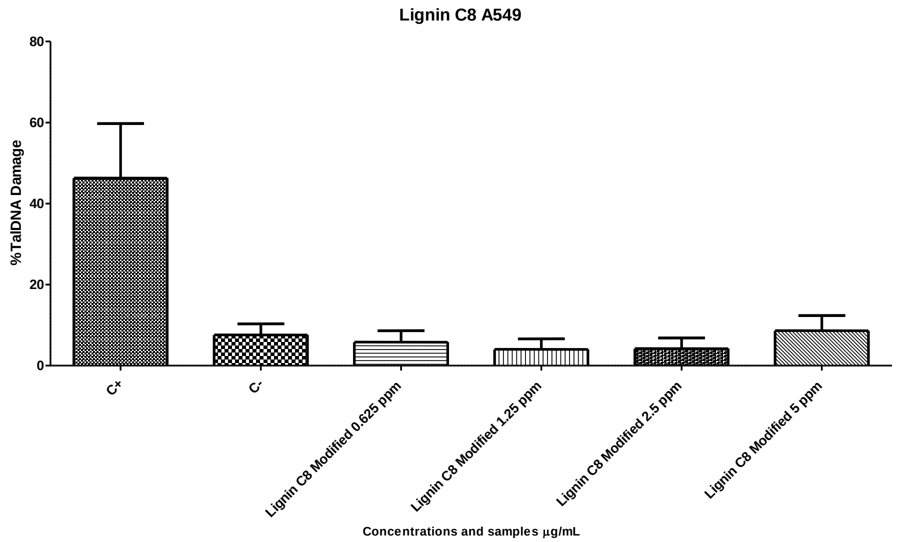
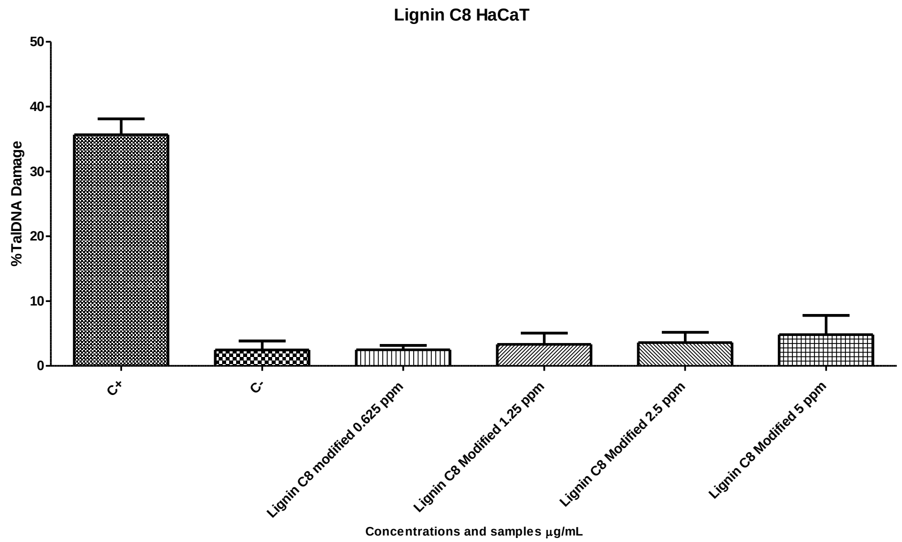
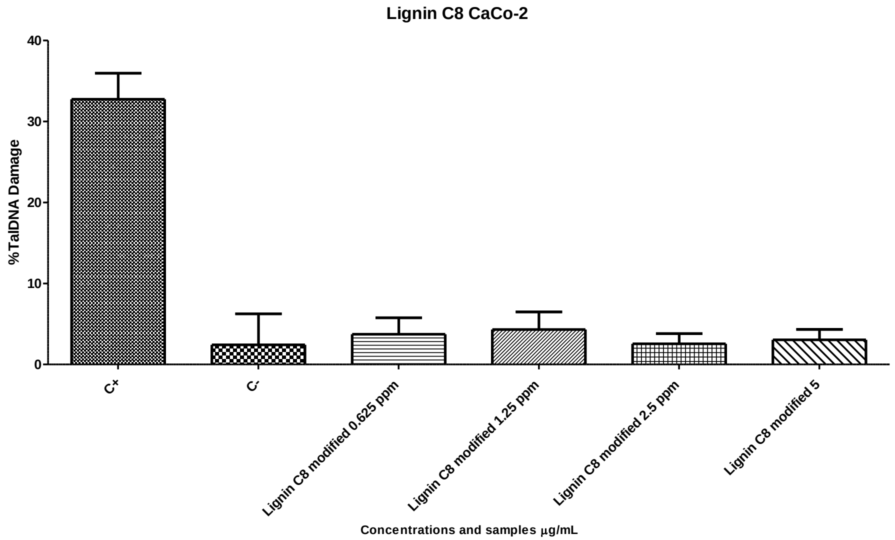
Toxicity assessment- Results







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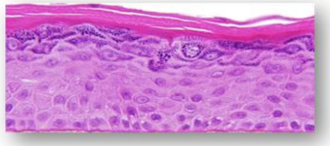
Toxicity assessment-SSbD STEPS 1-3

Exhibition routes

Cell culture

Effects studied



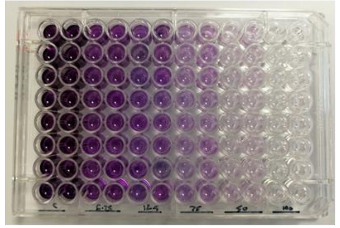
Reconstructed Human Epidermal Model

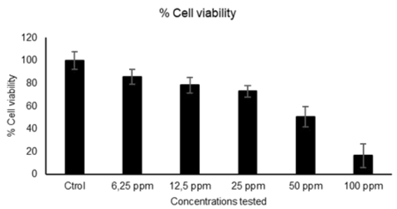
1 CYTOTOXICITY. Alteration of basic cellular functions: MTT assay.

Reduction

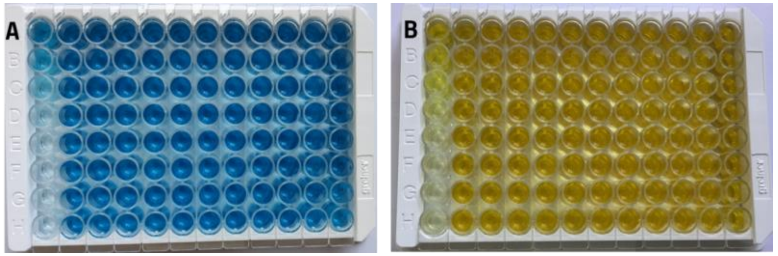
MTT → Formazan crystals

Example





2 INFLAMMATORY RESPONSES. Activation of IL6, 8 and 18



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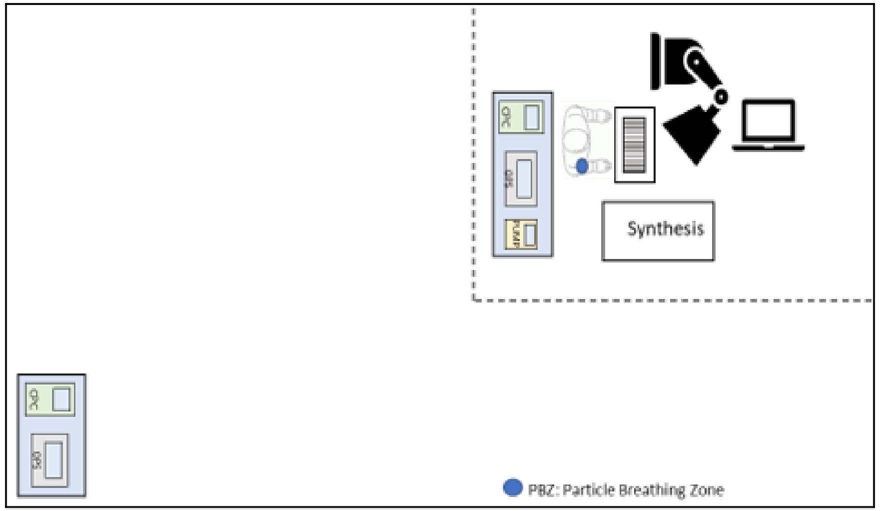
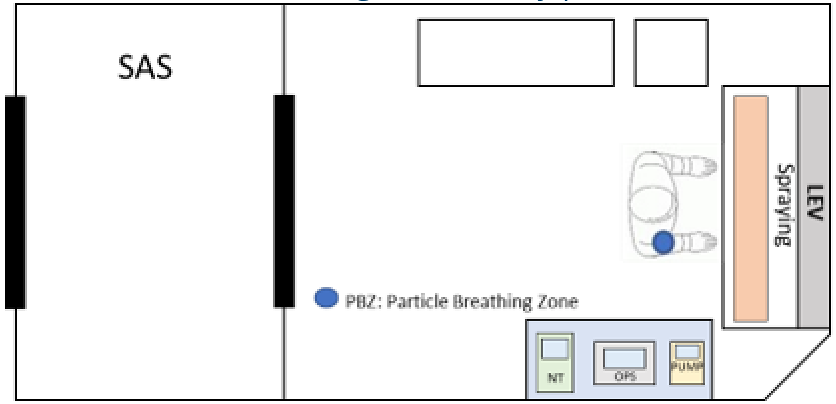
Occupational Monitoring

- Assessment of potential release and occupational exposure to nanoparticles and volatile compounds.
- 1st step: Virtual/Computational assessment. → Definition of occupational exposure scenarios through qualitative assessment using control banding tool Nanosafer.
- 2nd step: Experimental monitoring campaign. OCDE 2015: ENV/JM/MONO(2015)19 and EN17058

Far Field:
Measured during the period of activity



Background:
measured during non-activity period



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Occupational Monitoring

- Assessment of potential release and occupational exposure to nanoparticles and volatile compounds.
- 1st step: Virtual/Computational assessment. → Definition of occupational exposure scenarios through qualitative assessment using control banding tool Nanosafer.

Exposure Scenario	Intermediate Toxicity Compound and/or moderate exposure potential	High toxicity suspected and/or high exposure potential	Very high toxicity suspected and/or moderate to very high exposure	Very low toxicity and low exposure potential
	ES1	ES6	ES7	ES8
Estimated hazard level	0.56	1	1	0.2
Near-field Acute / Exposure Band	0.0000 EB1: Very low exposure potential	0.0020 EB1: Very low exposure potential	1.539 EB5: Very high exposure	0.0968 EB1: Very low exposure potential
Near-field Daily / Exposure Band	0.0000 EB1: Very low exposure potential	0.0006 EB1: Very low exposure potential	0.4844 EB3: Moderate exposure potential	0.0357 EB1: Very low exposure potential
Far-field Acute / Exposure Band	0.0000 EB1: Very low exposure potential	0.0008 EB1: Very low exposure potential	0.5737 EB4: High exposure potential	0.0577 EB1: Very low exposure potential
Far-field Daily / Exposure Band	0.0000 EB1: Very low exposure potential	0.0003 EB1: Very low exposure potential	0.2084 EB2: Low exposure potential	0.0245 EB1: Very low exposure potential
Risk Level	RL3	RL4	RL5	RL1

- Specific recommendations to every scenario
- Specific recommendations to every Risk Level
- Identification of the most interesting scenarios for on-site monitoring

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Occupational Monitoring

- Assessment of potential release and occupational exposure to nanoparticles and volatile compounds.
- 2nd step: Experimental monitoring campaign. OCDE 2015: ENV/JM/MONO(2015)19 and EN17058

Scenario	Type of Company	Process under study
1st scenario	Chemical formulating company	Modification of lignin
2nd scenario	Chemical formulating company	Formulation of different compounds to produce the coating
3rd scenario	Final Company	Application of the coating on the food packaging

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BIO-SUSHY

Agenda

09:30	Opening Remarks and Introduction	• Goal of the training and overview • BIO-SUSHY brief project intro (5 min)	Axia Innovation
09:40	SSbD Framework and Steps	• Explanation of SSbD framework (15 min)	ITENE
09:55	Lignin Types	• Different lignin types: full assessment and example (10 min)	Wood K Plus
10:05	Safety Assessment	• Toxicity data from BIO-SUSHY (15 min) • Bio-sensor and release accelerator (20 min)	ITENE, University of Leeds
10:40	Break		
10:50	**Practical Application Session**	• How do we apply SSbD to certain compounds (15 min)	ITENE, Wood K Plus, University of Leeds
11:05	Q&A	• Open Q&A with participants	ITENE, Wood K Plus, University of Leeds
11:20	Closing remarks	• Summary of key takeaways • Closing remarks and acknowledgment	Axia Innovation, Materia Nova

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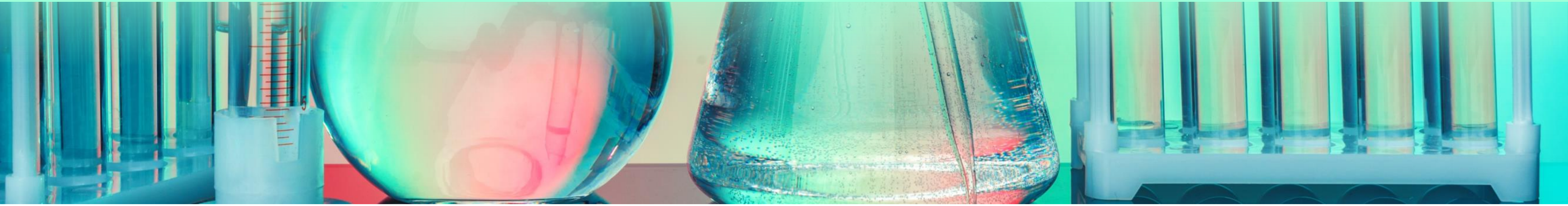
Practical Application Session



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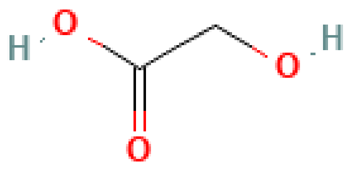
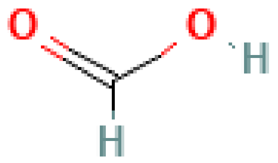
Case study: example



Chemical compound A



Chemical compound B

STEPS:

- ☐ Review information from ECHA and CLP
- ☐ Obtain SDS from supplier
- ☐ Compare both following SSbD Framework
- ☐ With the final score, decide which one is better

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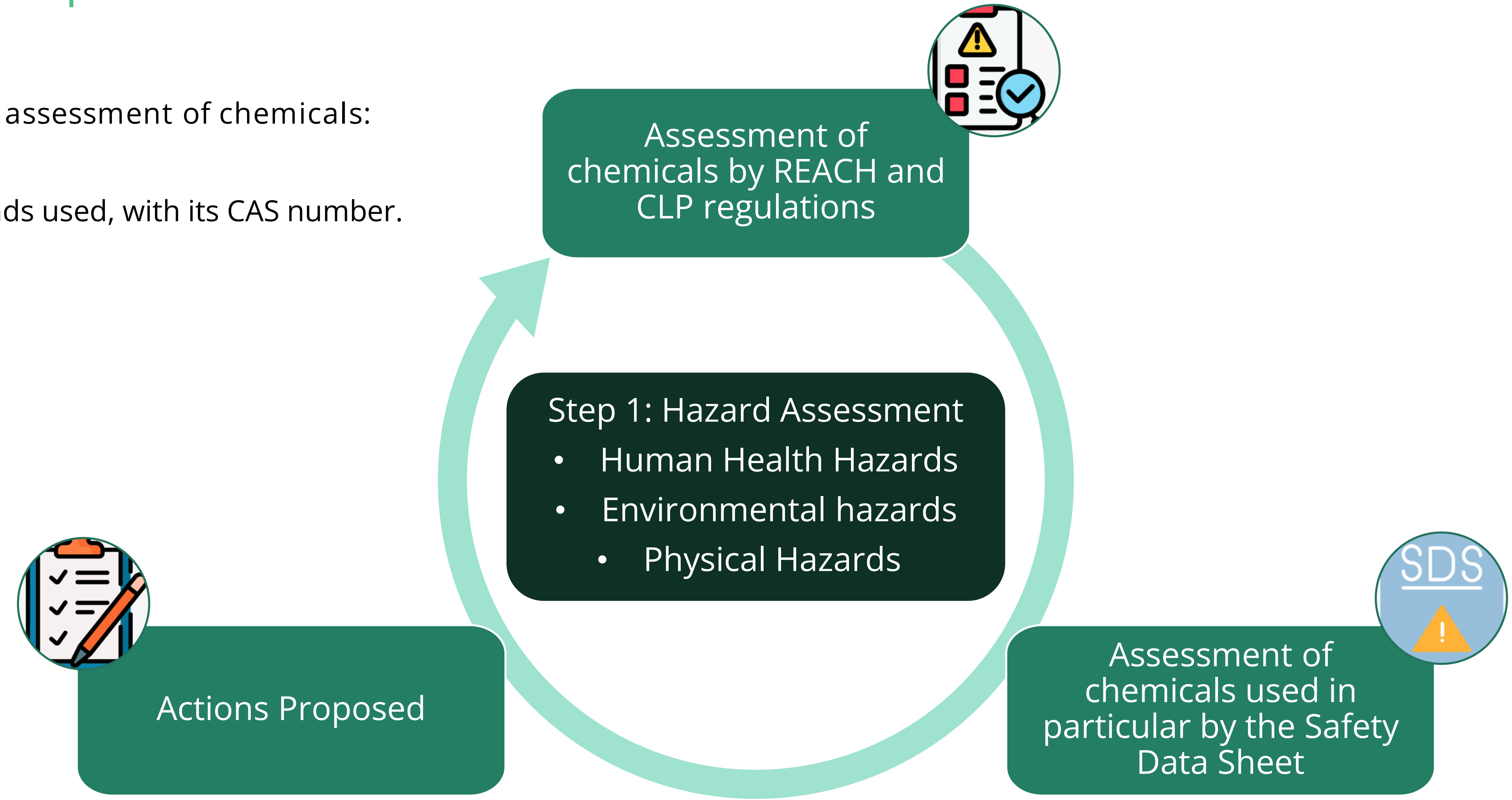
Case study: Step 1

Input needed for the assessment of chemicals:

- List of the compounds used, with its CAS number.
- SDS of the supplier



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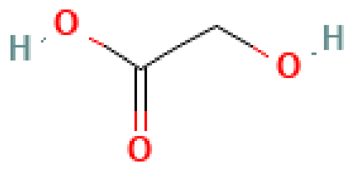
Case study: example Step 1



Chemical compound A

REACH & CLP Regulation:

- Not classified

SDS:

- H314 (Skin corrosion Sub-category 1B), H318 (Serious eye damage, Category 1), H332 (Acute toxicity, Inhalation Category 4)

Laboratory assessment:

- Confirming or testing chemicals and materials when information is not available

Classification:

- Human Health Hazards: Group C (Level 2)
- Environmental Hazards: Group D (Level 3)
- Physical Hazards: Group D (Level 3)

Level 2 → Flagged for review and eventually reduce toxic effects

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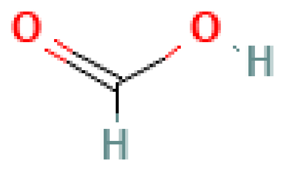
Case study: example Step 1



Chemical compound B

REACH & CLP Regulation:

- H314 (Skin Corrosion, Subcategory 1C)
- Endocrine disruption HH Cat 2
- Endocrine disruption ENV Cat 2

SDS:

- H302 (Acute toxicity, Category 4), H314 (Skin Corrosion, Subcategory 1C), H318 (Serious eye damage, Category 1), H331 (Acute toxicity, Category 3)
- H226 (Flammable liquids, Category 3)

Laboratory assessment:

- Confirming or testing chemicals and materials when information is not available

Classification:

- Human Health Hazards: Group B (Level 1)
- Environmental Hazards: Group B (Level 1)
- Physical Hazards : Group C (Level 2)

Level 1 → Substituted as far as possible

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Case study: example Step 1

$$SSbD\ Score\ Setp\ 1 = \frac{2+3+3}{9}$$

Chemical compound A

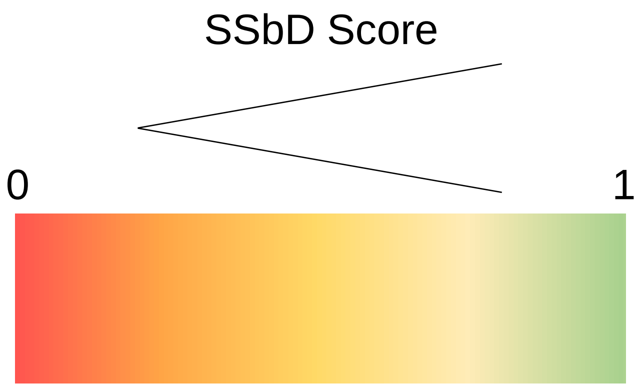
$$SSbD\ Score\ Setp\ 1 = \frac{HHH + EH + PH}{9}$$

$$SSbD\ Score\ Setp\ 1 = \frac{HHH + EH + PH}{9}$$

Chemical compound B

$$SSbD\ Score\ Setp\ 1 = \frac{2+3+3}{9}$$

$$SSbD\ Score\ Setp\ 1 = 0.89$$



$$SSbD\ Score\ Setp\ 1 = \frac{1+1+2}{9}$$

$$SSbD\ Score\ Setp\ 1 = 0.44$$

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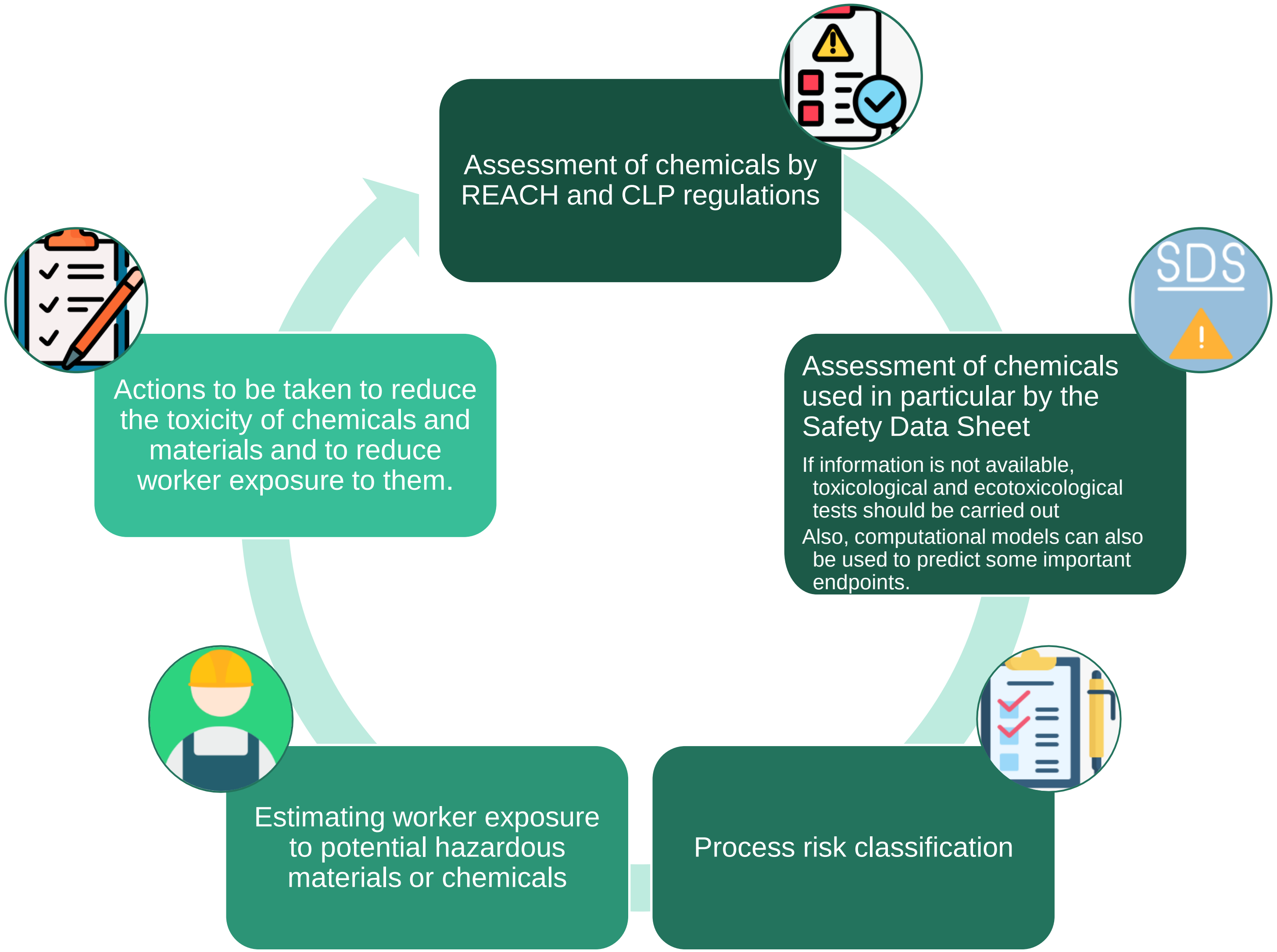
Case study: Step 2

Step 2: Human health and safety aspects of production and processing.

Occupational health and safety during production and processing of a chemical



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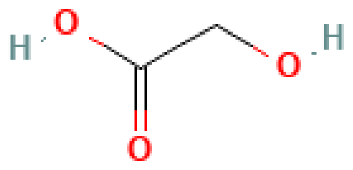
Case study: Step 2



Chemical compound A

REACH & CLP Regulation:

- Not classified

SDS:

- H314 (Skin corrosion Sub-category 1B), H318 (Serious eye damage, Category 1), H332 (Acute toxicity, Inhalation Category 4)

Laboratory assessment:

- Confirming or testing chemicals and materials when information is not available

Classification:

- Acute Human Health Hazards: Level 2
- Chronic Human Health Hazards: Level 2
- Physical Properties: Level 4
- Hazards from release behaviour: Level 4
- Process related hazards: Level 3

Level 2 → Flagged for review and eventually reduce toxic effects

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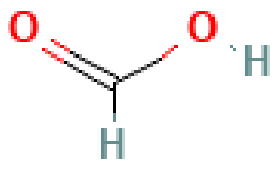
Case study: Step 2



Chemical compound B

REACH & CLP Regulation:

- H314 (Skin Corrosion, Subcategory 1C)
- Endocrine disruption HH Cat 2, Endocrine disruption ENV Cat 2

SDS:

- H302 (Acute toxicity, Category 4), H314 (Skin Corrosion, Subcategory 1C), H318 (Serious eye damage, Category 1), H331 (Acute toxicity, Category 3)
- H226 (Flammable liquids, Category 3)

Laboratory assessment:

- Confirming or testing chemicals and materials when information is not available

Classification:

- Acute Human Health Hazards: Level 1
- Chronic Human Health Hazards: Level 2
- Physical Properties: Level 2
- Hazards from release behaviour: Level 1
- Process related hazards: Level 4

Level 1 → Prioritized for modification/substitution

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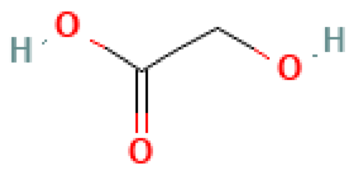
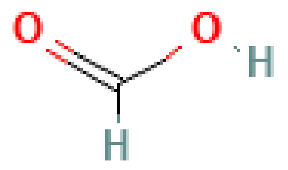
Case study: Step 2



Chemical compound A

$$SSbD\ Score\ Setp\ 2 = \frac{AHHH + CHHH + PP + HRB + PRR}{20}$$

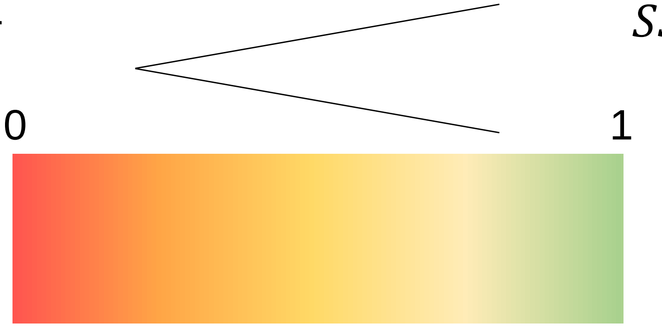


Chemical compound B

$$SSbD\ Score\ Setp\ 2 = \frac{2 + 2 + 4 + 4 + 3}{20}$$

$$SSbD\ Score\ Setp\ 2 = 0.75$$

SSbD Score



$$SSbD\ Score\ Setp\ 2 = \frac{1 + 2 + 2 + 1 + 4}{20}$$

$$SSbD\ Score\ Setp\ 2 = 0.50$$

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BIO-SUSHY

Case study: Step 3

Step 3: Human health and environmental aspects of the final application.

Exposure to the chemical or material as well as the potential exposure routes and related toxicity impacts on toxicity on human health and the environment

Evaluation of the migration of chemicals and materials into the product contained in the packaging.

Evaluation of the migratio of chemicals and materials into the environment.

Computational models can also be used to predict some important endpoints

Assess the migration of chemicals and materials that may reach humans during the end-of-life phase.

Computational models can also be used to predict some important endpoints

Assess the migration of chemicals and materials that may be released to the environment during the end-of-life phase.

Computational models can also be used to predict some important endpoints

Actions to reduce the toxicity of materials and chemicals released into the environment and to reduce the amount released.

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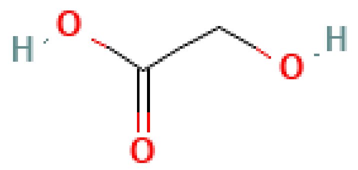
BIO-SUSHY

Case study: Step 3



Chemical compound A

Human Exposure

- Criteria for Tolerable Daily Intake (TDI), Specific Migration Limit of the chemical (SML), and Derived No-Effect Eevel (DNEL).
- Criteria and data stablished from REACH, CLP, and Laboratory Toxicity Data

Environmental Exposure

- Criteria for Release Factor and fate in different environments, Predicted Environmental Concentration & Predicted No-Effect Concentration
- Criteria and data stablished from REACH, CLP, and Laboratory Toxicity Data

> Safe level + 50%	0
> Safe level; < Safe level + 50%	1
> Safe level - 25%; < Safe level	2
> Safe level - 50%; < Safe level - 25%	3
< Safe level - 50%	4

Classification:

- Human Exposure: Level 3
- Environmental Exposure: Level 3

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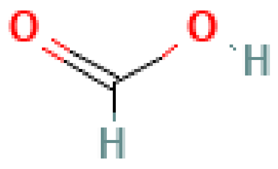
Case study: Step 3



Chemical compound B

Human Exposure

- Criteria for Tolerable Daily Intake (TDI), Specific Migration Limit of the chemical (SML), and Derived No-Effect Eevel (DNEL).
- Criteria and data stablished from REACH, CLP, and Laboratory Toxicity Data

Environmental Exposure

- Criteria for Release Factor and fate in different environments, Predicted Environmental Concentration & Predicted No-Effect Concentration
- Criteria and data stablished from REACH, CLP, and Laboratory Toxicity Data

> Safe level + 50%	0
> Safe level; < Safe level + 50%	1
> Safe level - 25%; < Safe level	2
> Safe level - 50%; < Safe level - 25%	3
< Safe level - 50%	4

Classification:

- Human Exposure: Level 2
- Environmental Exposure: Level 1

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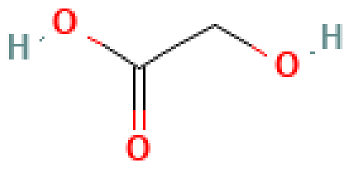
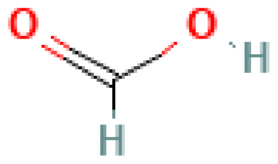
Case study: Step 3

$$SSbD\ Score\ Setp\ 3 = \frac{Human\ Exposure\ Level + Environmental\ Exposure\ Level}{8}$$



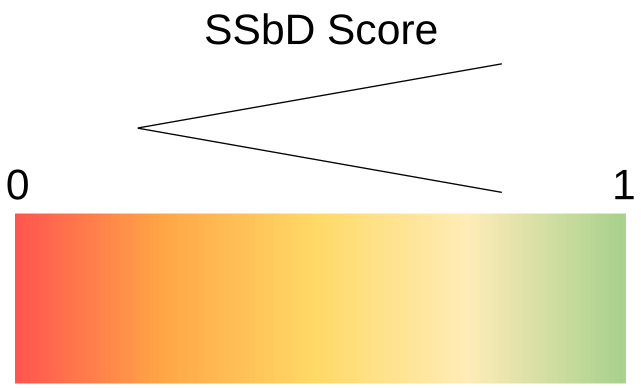
Chemical compound A



Chemical compound B

$$SSbD\ Score\ Setp\ 3 = \frac{3+3}{8}$$

$$SSbD\ Score\ Setp\ 3 = 0.75$$



$$SSbD\ Score\ Setp\ 3 = \frac{2+1}{8}$$

$$SSbD\ Score\ Setp\ 3 = 0.375$$

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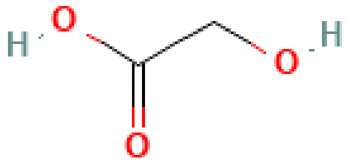
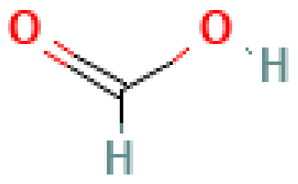
Case study: Final Result



Chemical compound A

- Step 1: 0.89
- Step 2: 0.75
- Step 3: 0.75



Chemical compound B

- Step 1: 0.44
- Step 2: 0.50
- Step 3: 0.375

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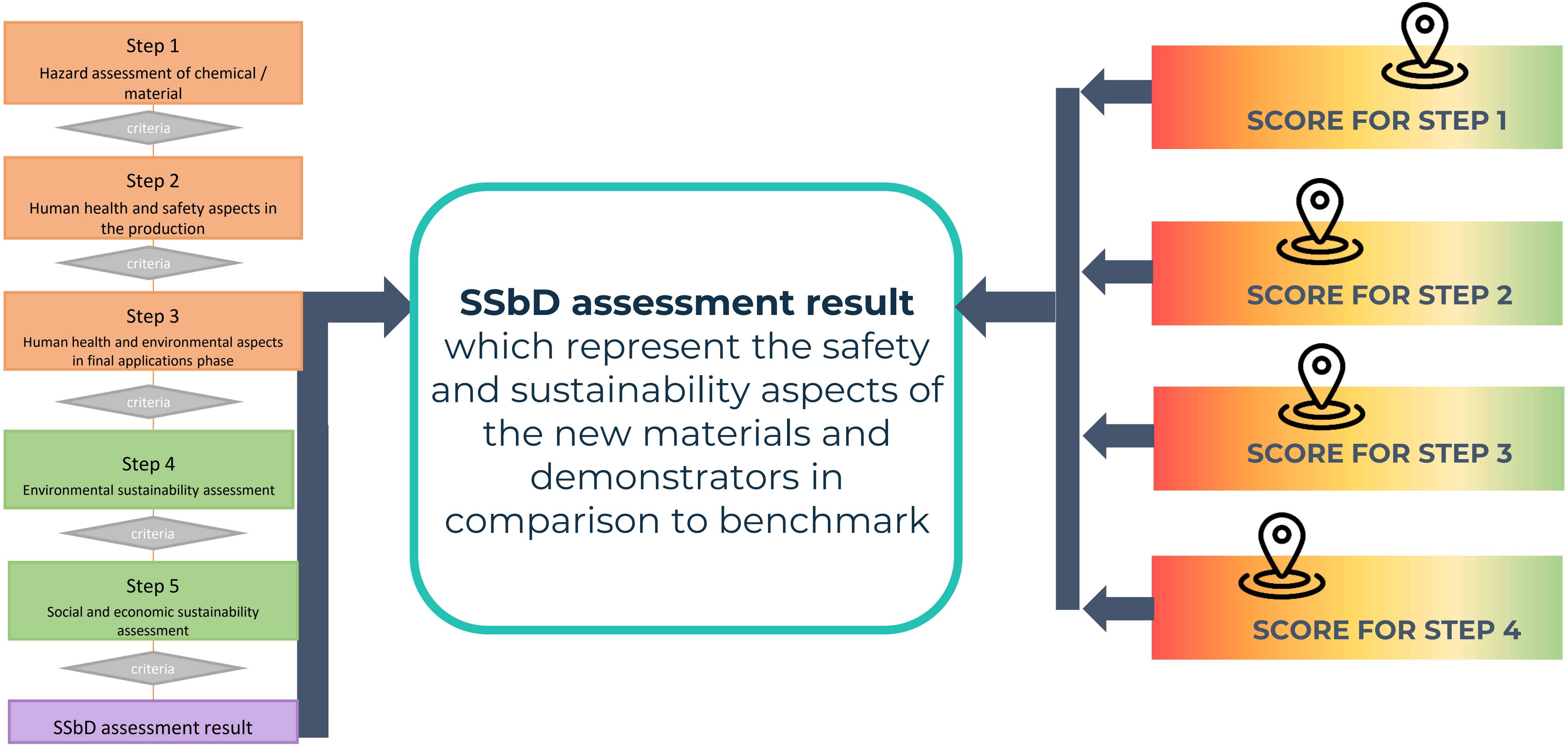
Case study: Final Result



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THANK YOU!

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