Enabling Safe and Sustainable Innovation using NAMs: Biosurfactant case study

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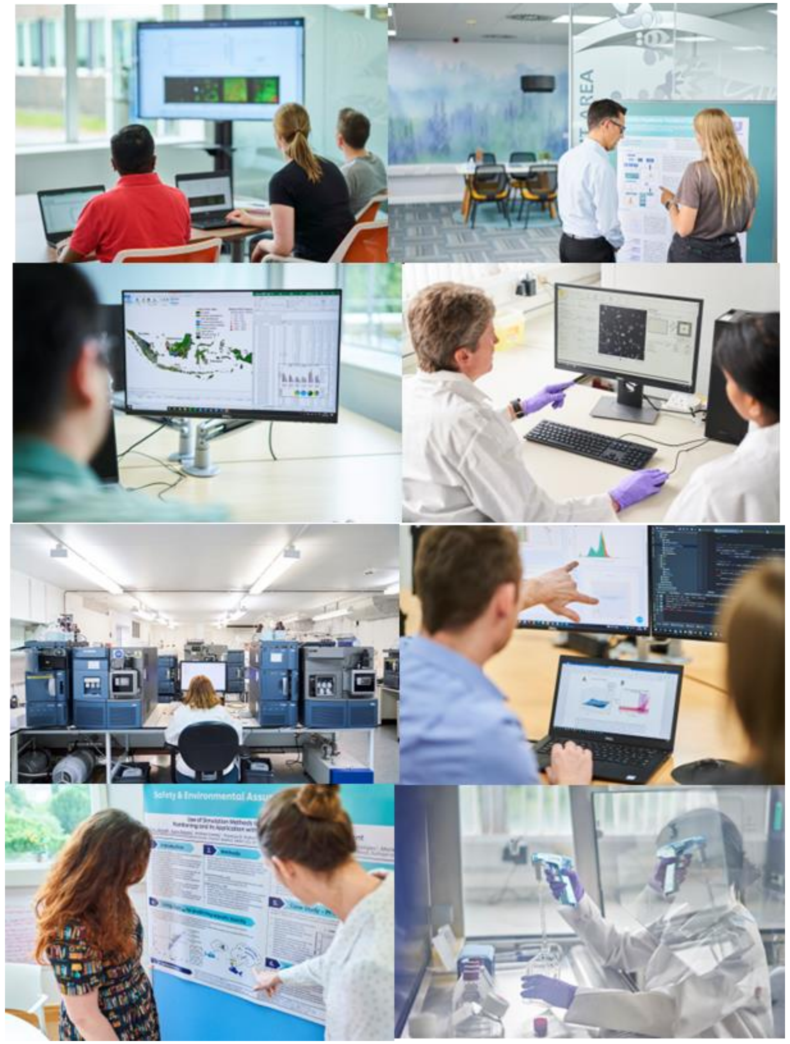

Conflict of Interest Statement

- Dr Maria Baltazar is an employee of Unilever (www.unilever.com)

Presentation Outline




1. Unilever’s approach to safe and sustainable by design (SSbD) without animal testing
2. Consumer Goods Product Innovation case study: use of a novel biosurfactant in a hand dish wash product
3. Our evaluation of the utility of published SSbD frameworks for consumer goods product innovation

Safe and Sustainable by Design (SSbD): building safety & sustainability into product innovation




- We ensure that our products are safe for consumers and workers and help minimise their environmental impacts
- Unilever Safety, Environmental & Regulatory Science (SERS) experts provide input at every stage of a product's life:
  - New discover and design new concepts
  - New technologies in product innovations
  - Anticipate product use & disposal scenarios
- By being involved throughout the innovation process, SERS experts help design safety and sustainability into our products

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Safe & Sustainable Products without Animal Testing

What we believe

- **Every Unilever product must be safe for people and our environment**
- **Animal testing is not needed to assess ingredient & product safety** –wide range of non-animal approaches available
- **We work to accelerate the global adoption of animal-free cosmetic safety assessment approaches**

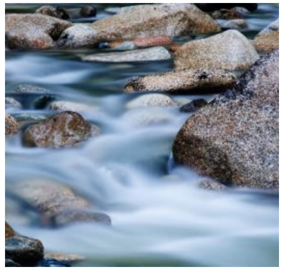
How we do it

40+ years of developing non-animal safety science

90+ collaborations

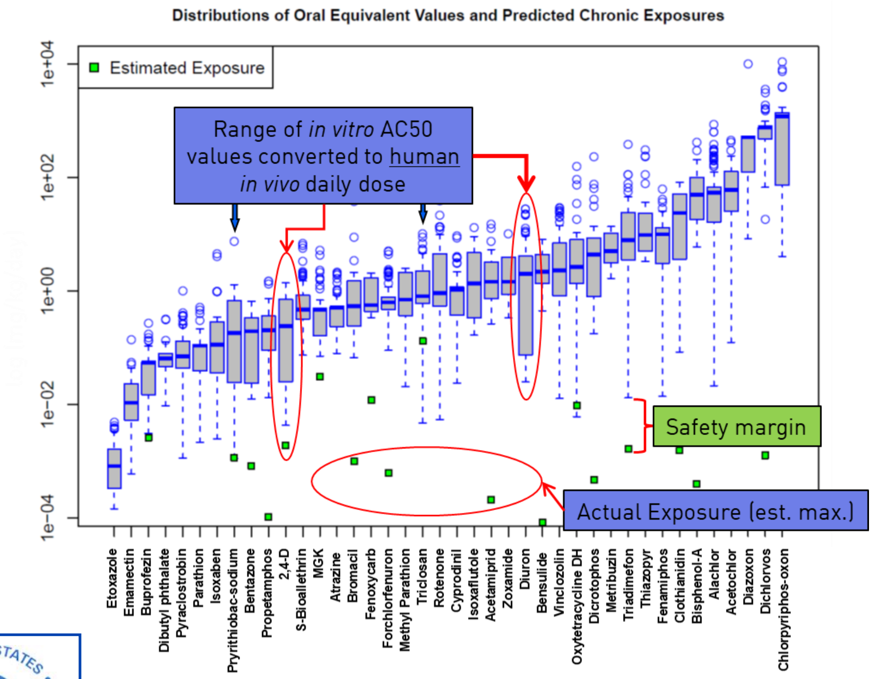
600+ publications





Safety without animal testing - Next Generation Risk Assessment (NGRA)

NGRA is defined as ***an exposure-led, hypothesis-driven*** *risk assessment approach that* ***integrates New Approach Methodologies (NAMs)*** *to assure* ***safety without the use of animal testing***

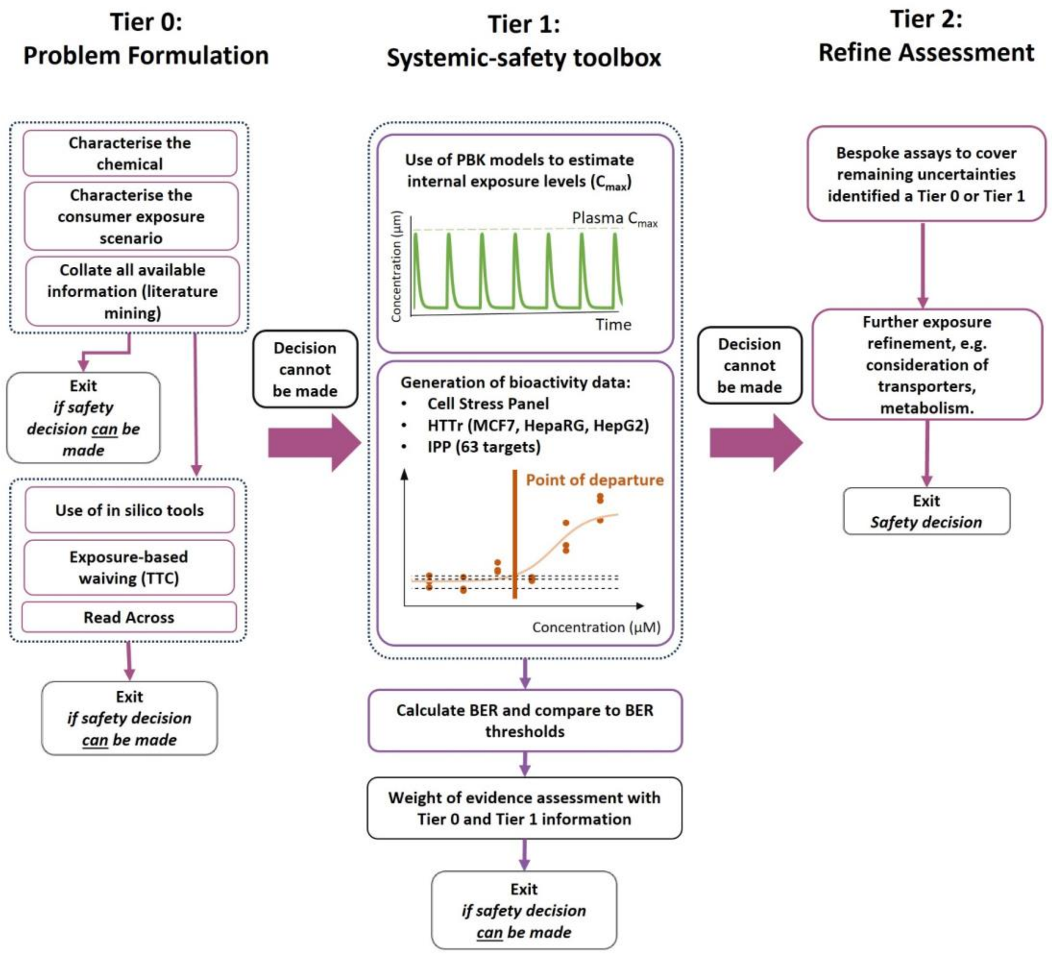


Slide from Dr Rusty Thomas, EPA, with thanks

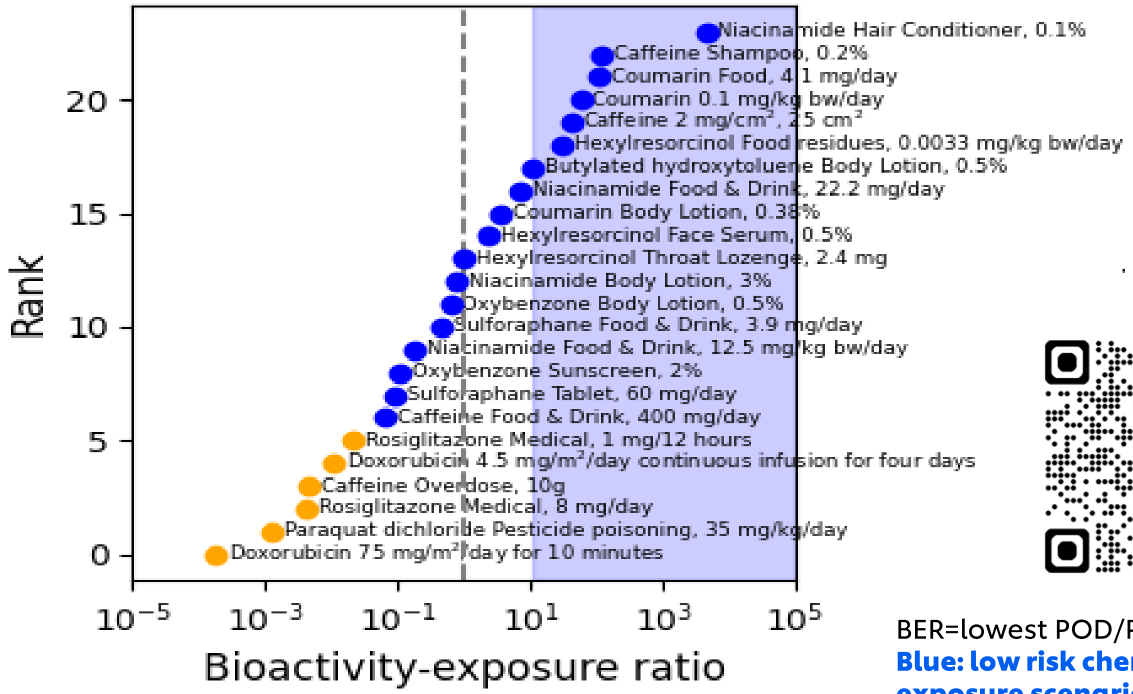
Rotroff, *et al.* Tox.Sci 2010
DOI:10.1093/toxsci/kfq220

The hypothesis underpinning this type of NGRA is that **if there is no bioactivity observed at consumer-relevant concentrations, there can be no adverse health effects.**

Our tiered, exposure-driven approach to next generation risk assessment
example: Human Health Systemic Safety NAM toolbox & workflow



NAM Systemic toolbox provides similar level of protection as traditional approaches for a total of 48 chemicals and 100 chemical exposure scenario



BER=lowest POD/Plasma Cmax

Blue: low risk chemical-exposure scenario

Yellow: high risk chemical-exposure scenario

Blue shaded region BER> 11

Cable S et al., (2024). https://doi.org/10.1093/toxsci/kfae159; Middleton et al., 2022. https://doi.org/10.1093/toxsci/kfac068

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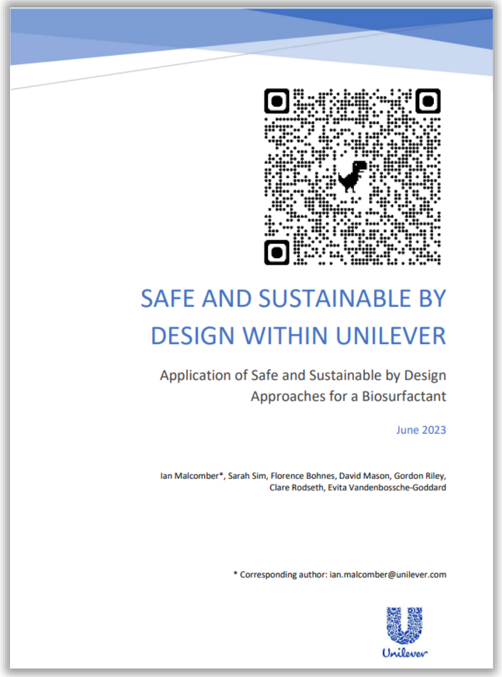
Novel Biosurfactant -case study

- Real consumer product innovation example using SSbD principles
- Renewable, biodegradable biosurfactant for inclusion in a hand dishwash product
- Novel, non-animal Next Generation Risk Assessment (NGRA) approach used to assess safety across consumer, occupational, environmental and sustainability
- Environmental impact of novel biosurfactant assessed against existing hand dishwash surfactant ingredients.


SAFE AND SUSTAINABLE BY DESIGN WITHIN UNILEVER

Application of Safe and Sustainable by Design Approaches for a Biosurfactant

June 2023

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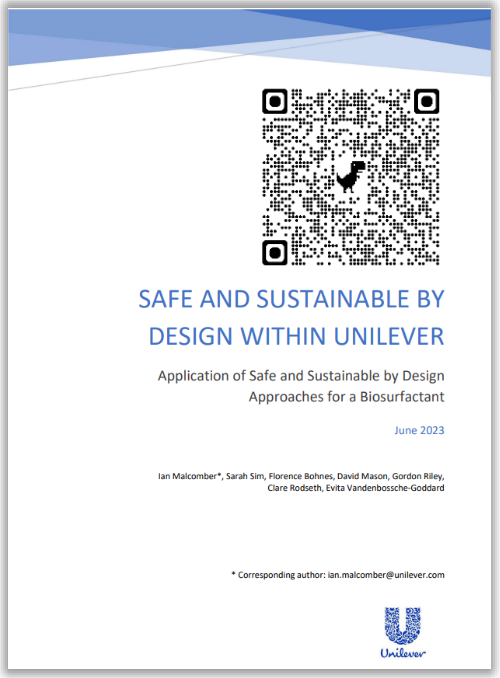
Novel Biosurfactant / Hand Dishwash case study: our SSbD framework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Ingredient Discovery	Ingredient Evaluation	Development & Testing	Production & Launch
Several ingredient options - early-stage supplier information	**One or few ingredient options** - quantitative material and process data (ingredient pilot plant)	**Commercial specification of ingredient & product formulation** (product pilot plant)	**Full-scale production of final formulation** with markets & volume targets
• Evaluation of ingredient options • Preliminary prognosis & screening assessment • Limited safety & sustainability data	• Evaluation of lead ingredient option • Identification of significant risks and impacts • Data generation on ingredient performance, safety & sustainability	• Refined evaluation of lead ingredient option in formulation • Implementation of safety strategy • Data gap filling	• Final evaluation of lead ingredient in formulation • Safety & sustainability assessments support market launch • Integration of info & insights from all stages

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Novel Biosurfactant / Hand Dishwash case study: consumer safety

	Ingredient Discovery	Ingredient Evaluation	Development & Testing	Production & Launch
Consumer Safety Assessment	<u>Data</u> - Surfactant class read-across - Literature: potential immune effects - Production strain information <u>Approach</u> - In silico predictions of potential health effects based on expected consumer exposure - Identification of potential contaminants of concern	<u>Data</u> - Literature: read across data - chemical characterisation - In vitro data for genotox. & skin sens. - In silico metabolite predictions <u>Approach</u> - Higher-tier in silico predictions based on refined consumer exposure - Targeted in vitro testing - Risk Assess expected contaminants of concern	<u>Data</u> - In vitro data for genotox.,skin sens, skin absorption & immune effects - Critical micelle concentration for biosurfactant <u>Approach</u> - Exposure-led, hypothesis-driven safety strategy for local & systemic toxicity - Characterisation of systemic exposure & health effects - Safety hypothesis testing to establish Bioactivity-Exposure ratio (BER)	<u>Data</u> - Commercial scale composition and consumer exposure - Full in vitro data package, including re-testing of commercial spec. <u>Approach</u> - Exposure-led hypothesis-driven safety strategy for commercial specification

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Novel Biosurfactant / Hand Dishwash case study: occupational safety

	Ingredient Discovery	Ingredient Evaluation	Development & Testing	Production & Launch
Occupational Safety Assessment	<u>Data</u> - Form & concentration - Surfactant class – read-across - Production process - Literature: physical properties (e.g. flammability) <u>Approach</u> - Assess for highly hazardous properties - In silico predictions of potential health effects based on expected worker exposure - Potential contaminants of concern	<u>Data</u> - Early stage process design - Initial tox. info. from consumer safety assessment - Chemical characterisation - Preliminary supplier safety data sheets/info <u>Approach</u> - Assessment to support process development and design requirements - Potential contaminants / residues of concern	<u>Data</u> - Specific form/conc. of ingredient - Chem. / biological characterisation data - Existing product manufacturing facility & processes data - Residual hazard info - Complete supplier safety data sheets <u>Approach</u> - Application of inherent safety approaches - Risk assessment for handling ingredient & formulated product - Basis of safety to manage residual risks throughout	<u>Data</u> - All hazardous properties defined - Consumer safety data - Handling processes & methods - Inherent safety principles & control measures <u>Approach</u> - Detailed review of the entire process, potential exposures & controls - Consider manufacturing steps & other workplace activities

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Novel Biosurfactant / Hand Dishwash case study: environmental safety

	Ingredient Discovery	Ingredient Evaluation	Development & Testing	Production & Launch
Environmental Safety Assessment	<u>Data</u> - Surfactant class – read across - Biodegradability data from supplier <u>Approach</u> - Environmental fate & effects - Estimates of environmental exposure for markets & volumes	<u>Data</u> - Expected market volumes - Fate & effects data <u>Approach</u> - Daphnia & algal acute studies - In silico predictions for fish toxicity (e.g. read-across, weight of evidence approaches based on MoA) - LogK_{OW} and LogK_{IAM} approaches to estimate bioaccumulation	<u>Data</u> - Incremental volume adjustments for ingredients in the product that are already used within Unilever's portfolio and have been demonstrated to be safe <u>Approach</u> - Data generation and prospective safety assessments for all ingredients in the product taking a 'Total Tonnage' approach	<u>Data</u> - Changes in market volumes (prospective / retrospective) <u>Approach</u> - Annual post-launch monitoring of safety of all ingredients – total tonnage approach - Refinements to the conservative assessments where safety margins are narrowing

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Novel Biosurfactant / Hand Dishwash case study: env. sustainability

	Ingredient Discovery	Ingredient Evaluation	Development & Testing	Production & Launch
Environmental Sustainability Assessment	<u>Data</u> - Life cycle stages / production process for material - Feedstock options - Supplier environmental performance claims <u>Approach</u> - Construct process flow - 'Rule of thumb' principles / heuristics for qualitative hotspot identification – impacts & life cycle stages - Identify potential risks / benefits and improvement potential	<u>Data</u> - Pilot plant production data for ingredient – energy & material use - Life cycle inventories / assessments for comparative surfactants <u>Approach</u> - Quantitative screening LCA assessment of ingredient – limited impact categories - Identify key drivers of impacts, possible environmental trade-offs and improvement potential	<u>Data</u> - Formulation data - Value chain process flow information - Life cycle inventories for product ingredients & processes - Spatial land cover data - Production scale-up scenarios <u>Approach</u> - Comparative Life Cycle Analysis (LCA) - Land Use Change Improved (LUCI) LCA - GHGs, soil erosion, biodiversity loss, nutrient pollution	<u>Data</u> - Data refinements for markets of interest <u>Approach</u> - Full LCA for claims substantiation & ongoing maintenance of claims – tailored to specific markets *Note: Environmental benefits were not communicated to consumer in this instance, so these steps were not completed*

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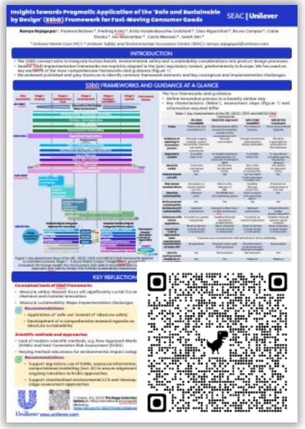
Insights from evaluation of available SSbD frameworks for consumer goods

- Our aim was to evaluate published SSbD frameworks & concepts to understand their utility for consumer goods product innovation
- For today, I'll focus on the two most mature approaches:
    1. European Commission DG JRC SSbD framework & guidance
    2. OECD Safe(r) and Sustainable Innovation Approach (SSiA)




European Commission

JRC TECHNICAL REPORT

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

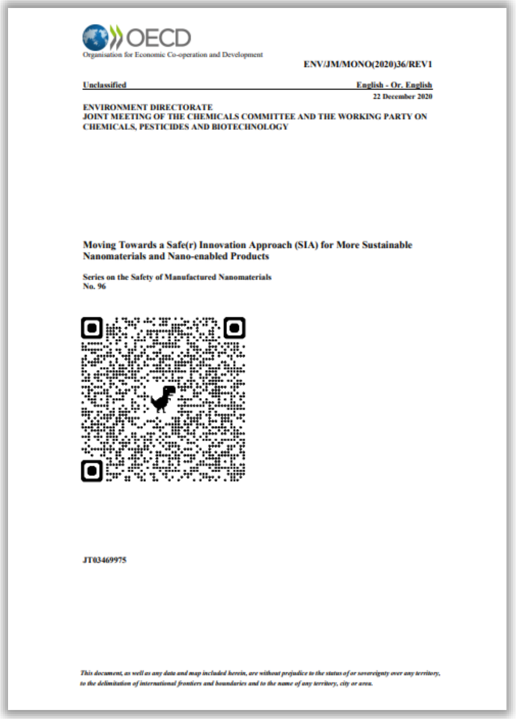

ISSN 1831-9424

European Commission

Safe and Sustainable by Design chemicals and materials - Methodological Guidance

Abbate, E., Garmendia Aguirre, I., Bracalente, G., Mancini, L., Tosches, D., Rasmussen, K., Bennett, M.J., Rauscher, H., Sala, S.

2024


OECD Organisation for Economic Co-operation and Development

ENV/JM/MONO(2020)36/REV1

Unclassified English - Or. English

22 December 2020

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled Products

Series on the Safety of Manufactured Nanomaterials
No. 96

JT03469975

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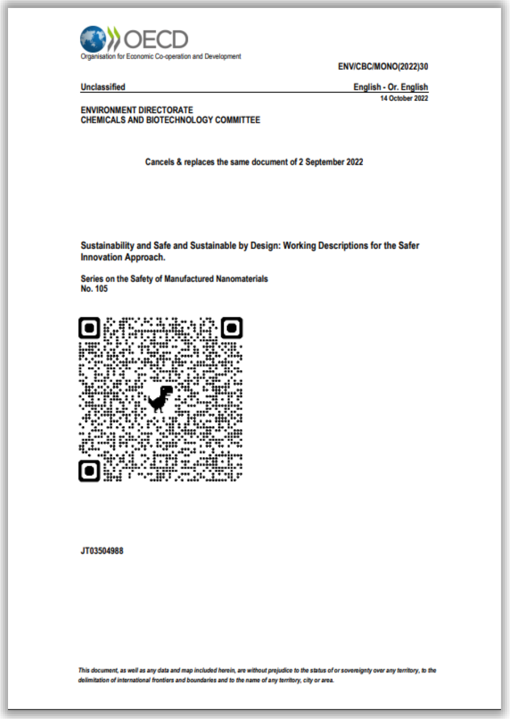
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ENV/CBC/MONO(2022)30

Unclassified English - Or. English

14 October 2022

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CHEMICALS AND BIOTECHNOLOGY COMMITTEE

Cancels & replaces the same document of 2 September 2022

Sustainability and Safe and Sustainable by Design: Working Descriptions for the Safer Innovation Approach.

Series on the Safety of Manufactured Nanomaterials
No. 105

JT03504988

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Comparison of JRC SSbD & OECD SSiA framework key characteristics

	European Commission Safe & Sustainable by Design (SSbD)	OECD Safe(r) and Sustainable Innovation Approach (SSiA)
Scope / Regulatory context	European Green Deal & Chemical Strategy for Sustainability	Nanomaterials, Nano-enabled Products (NEPs) and advanced materials
Absolute safety	Forms the conceptual basis	Not limited by absolute safety
Hazard-based cut-offs	Yes	No
Risk-based considerations	Secondary to hazard-based cut-offs	Risk is a key element
Absolute sustainability	Ultimate goal	Move towards safe operating space
Enable use of latest science	None or limited to early stages of innovation	None or limited to early stages of innovation
Data requirements	Extensive data requirements throughout the innovation process	
Consideration of trade-offs	No provision	Provision exists with little guidance

Recommendations to evolve SSbD frameworks to better support safe & sustainable consumer product innovation

1. Enable risk-based approaches & exposure assessment
2. Support use of latest non-animal safety & sustainability science
3. Explicitly address & manage trade-offs


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Recommendations to accelerate adoption of SSbD frameworks

1. Build global data ecosystem & digital infrastructure
2. Develop more sector- and technology-specific case studies
3. Create additional guidance & training for SSbD assessment


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Safe and Sustainable by Design chemicals and materials


Safe and Sustainable by Design chemicals and materials - Methodological Guidance

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- Sarah Sim
- Evita Vandenbossche-Goddard

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