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INTRODUCTION

- The SSbD concept aims to integrate human health, environmental safety and sustainability considerations into product design processes.
- Several SSbD implementation frameworks are explicitly aligned to the (pre) regulatory context, predominantly in Europe. We focussed on key elements of the most comprehensive frameworks and guidance (Figure 1).
- We reviewed published and grey literature to identify common framework elements and key conceptual and implementation challenges.

SSbD FRAMEWORKS AND GUIDANCE AT A GLANCE

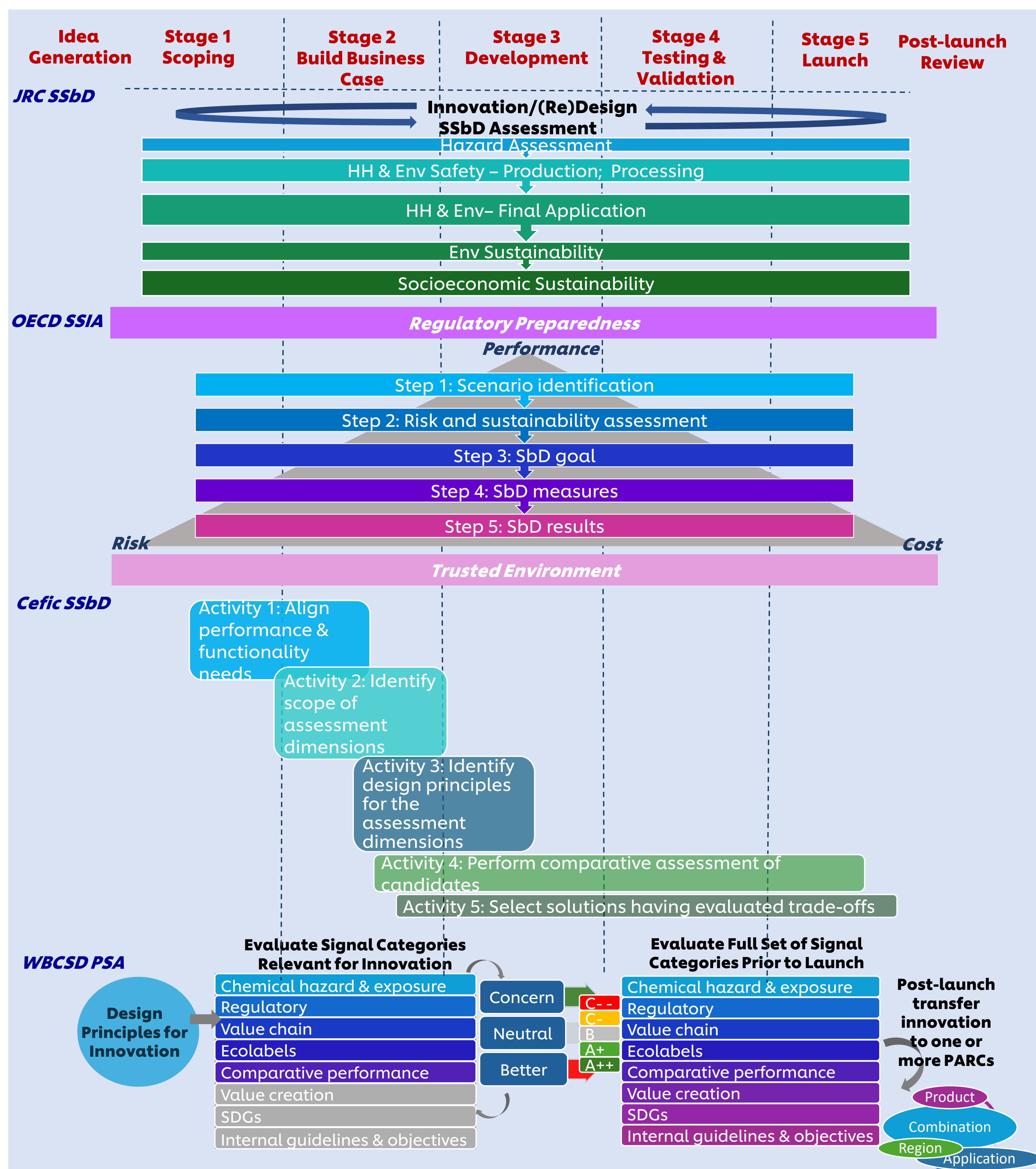


Figure 1. Key assessment steps of the JRC, OECD, CEFIC and WBCSD SSbD frameworks applied to innovation process. Stage 1 – 5 as per Robert Cooper's Stage-Gate™ process¹ for innovation HH-Human Health; Env-Environment; SSIA-Safe(r) and Sustainable Innovation Approach; SbD-Safe by Design; PSA-Portfolio Sustainability Assessment

The four frameworks and guidance:

- Define innovation process in a broadly similar way
- Key characteristics (Table 1), assessment steps (Figure 1) and information required differ

Table 1. Key characteristics of the JRC, OECD, CEFIC and WBCSD SSbD frameworks

	JRC SSbD Framework	OECD SSIA Approach	CEFIC SSbD Guidance	WBCSD PSA Framework
Scope	Chemicals and materials in EU	Nanomaterials, NEPs, advanced materials, current efforts concentrated in EU	EU chemical industry	Goods and services globally
Guidance on applying to innovation process	Through scoping analysis, system boundaries, iterative and tiered assessment	Through case studies	Through assessment dimensions & design principles	Provided in principle on using specific PSA elements
Regulatory context	To enable EGD's CSS	To enable regulatory preparedness for advanced materials & NEPs	To enable EGD's CSS	To stay ahead of market specific regulatory changes
Absolute safety	Forms the conceptual basis	Not limited by absolute safety	Key to the initial steps of assessment	Not limited by absolute safety
Hazard-based cut-offs	Yes	No	Yes, but there is also provision for trade-offs	No
Risk-based considerations	Secondary to hazard-based cut-offs	Risk is a key element of SbD	Enabled through trade-offs	Provision for consideration of safe use
Absolute sustainability	Ultimate goal	Move towards safe operating space	Move towards safe operating space	No
Environmental sustainability	Yes	Yes	Yes	Yes
Socioeconomic sustainability	Optional assessment	Included within Step 2 of SbD assessment	Optional assessment	Integral element within signal categories
Coherence with future regulations	Focussed on current regulations	Enabled through regulatory preparedness	Focussed on current regulations	Enabled through specific signal category
Use of new science approaches	None or limited to early stages of innovation	None or limited to early stages of innovation	None or limited to early stages of innovation	None or limited to early stages of innovation
Data requirements	Extensive data requirements with limitations in data availability			
Consideration of trade-offs	No provision	Provision exists with little guidance	Provision exists & demonstrated through examples	No provision
Use of a scoring system	Yes	Not included	Not included	Yes
Guidance on tools for SSbD	Yes	Yes	Minimal	Minimal

NEPs-Nano-enabled products; EGD-European Green Deal; CSS-Chemical Strategy for Sustainability; SbD-Safe by Design; PB-Planetary Boundaries

KEY REFLECTIONS AND RECOMMENDATIONS

Conceptual basis of SSbD frameworks

- Absolute safety: Hazard-focus will significantly curtail future chemical and material innovation
- Absolute sustainability: Major implementation challenges

Recommendations:

- Application of 'safe use' instead of 'absolute safety'
- Development of a comprehensive research agenda on absolute sustainability

Scientific methods and approaches

- Lack of modern scientific methods, e.g. New Approach Methods (NAMs) and Next Generation Risk Assessment (NGRA)
- Varying method robustness for environmental impact categories

Recommendations:

- Support regulatory use of NAMs, exposure information, and computational modelling (incl. AI) to ensure alignment with ongoing transition to NGRA approaches
- Support standardised environmental LCA and develop early-stage assessment approaches

Data requirements

- Inadequate data availability to meet requirements

Recommendations:

- Drive coherence across (pre) regulatory requirements & acceptance of NAMs
- Global data ecosystem to support data availability
- Findable Accessible Interoperable Reusable (FAIR) data principles
- Resolve confidentiality concerns

Identifying and handling trade-offs

- Assumption that trade-offs can be avoided
- Inadequate guidance / approaches to handle trade-offs

Recommendations:

- Acknowledge the existence of trade-offs
- Develop approaches to identify & handle trade-offs

Tools, guidance and training for uptake of SSbD

- Absence of tools, training and guidance to facilitate widespread adoption of SSbD

Recommendations:

- Digital infrastructure, guidance and training for SSbD assessment
- More sector- & technology-specific case studies



1. Cooper, R.G. (2010) **The Stage-Gate Idea to Launch System**, In: Wiley International Encyclopedia of Marketing <https://doi.org/10.1002/9781444316568.wiem05014>