SAFER AND SUSTAINABLE INNOVATION APPROACH: CASE ON ADVANCED MATERIALS

Workshop on Agile Approaches for Governing Emerging Technologies
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BETTER POLICIES FOR BETTER LIVES

OECD WORK ON CHEMICAL SAFETY

Protect human health and the environment

Share burden and increase efficiency in developing standard methods

Harmonised instruments for the safety assessment of chemicals and GMOs

- Test Guidelines, Good Laboratory Practice => Mutual Acceptance of Data
- Tools for predicting the effects of chemicals (non-animal methods)
- Guidance for Hazard and Exposure Assessment
- Guidelines and tools for exchanging information

Industry, regulators, researchers

Safe use of chemicals

avoid non-tariff trade barriers; shorten time to market; savings of 309 MEUR/y for industry and governments

Behaviour and toxicity may be different compared to 'simple' nanomaterials and soluble chemicals

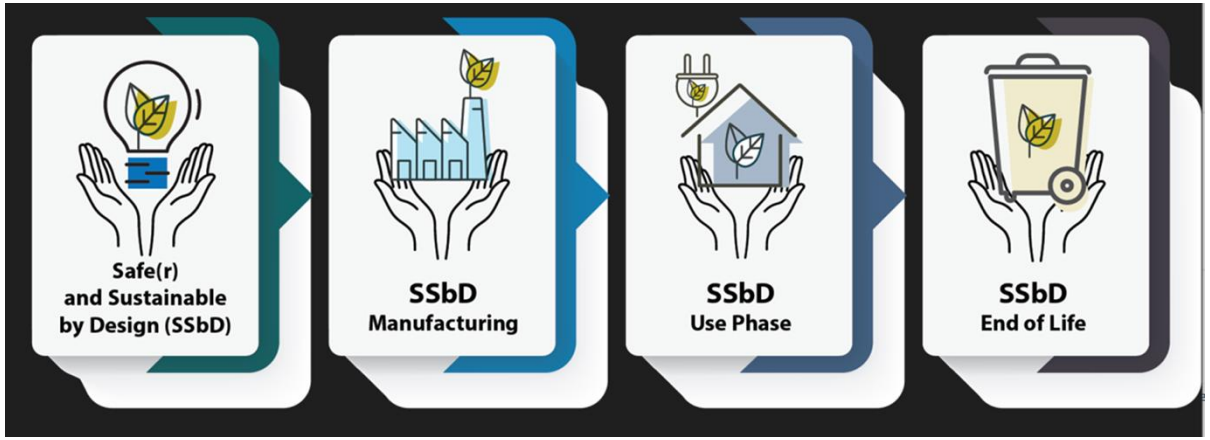
Applicability of existing regulation (Regulatory Preparedness)

Are adaptations to legislation/regulation/test methods for nanomaterials sufficient?

Policy ambitions to promote innovation that is SSbD How to address and consider both safety and sustainability

Safer and Sustainable Innovation Approach (SSIA) - Framework

1- Proposing a cultural change of mindset & Identifying Barriers and Constraints

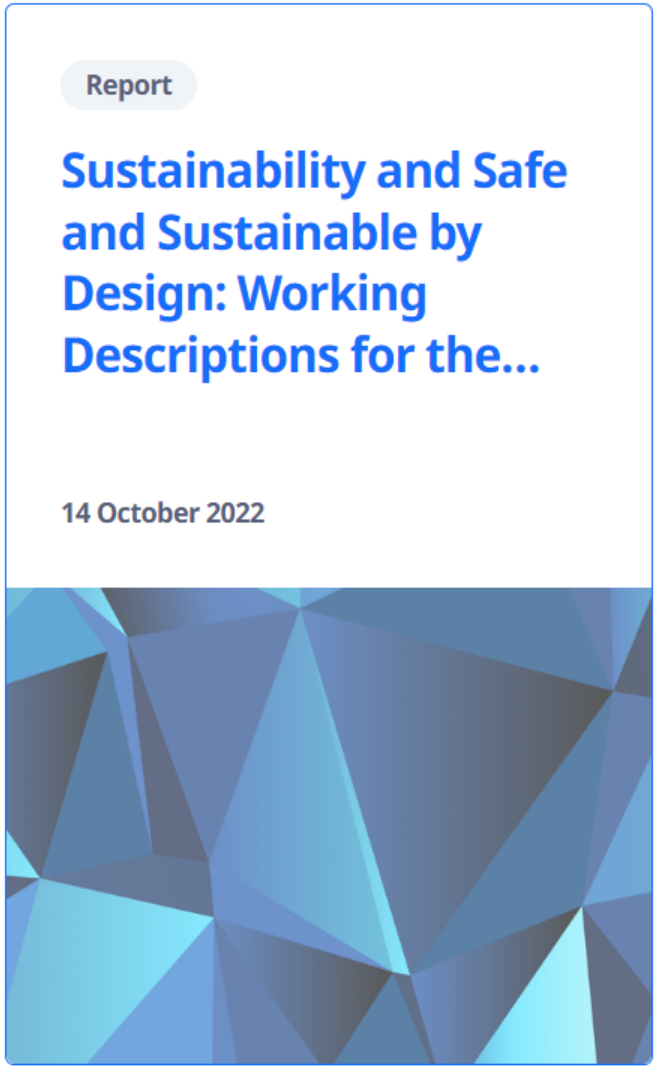


SSbD
safety and sustainability would be more effective and less costly for companies if it is incorporated earlier into the innovation process and throughout.

RP
Better anticipate and adapt governance to keep up with the pace of knowledge generation and innovation of nanomaterials, advanced materials and nano-enabled products.
Capacity to anticipate the regulatory safety and sustainability challenges posed by emerging technologies.

TE
Is a physical or virtual space in which industry, innovators and governmental institutions (other) can share and exchange knowledge, information and views on new technologies. Need to be aware of innovations sufficiently early to take appropriate action to modify or develop regulatory tools, when applicable (**RP**)

Safer and Sustainable Innovation Approach (SSIA) - Framework



2- Having a common understanding and identify the elements to be considered: Working Descriptions on Sustainability and SSbD

- Safety + Sustainability
  - Resource use
  - Circularity
  - Recyclability
  - Waste generation
  - Traceability

3- Developing Tools for practical implementation of SSIA - foresight systems

- SbD systems aiming to estimate hazard/ exposure/ risk to humans and the environment/ indicators considered to assess sustainability

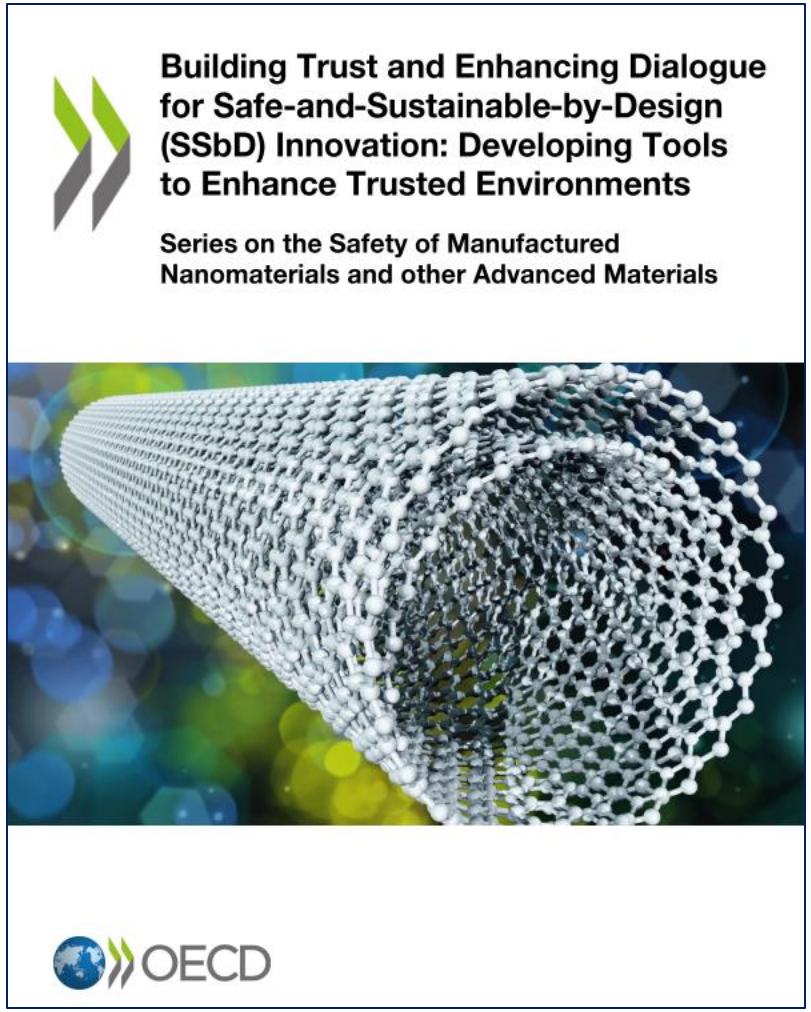
Name	State of development	Design aspects	Life Cycle Considerations	Human Health Risk Assessment	Environmental Risk Assessment	Environmental sustainability aspects			Economic sustainability aspects	Social sustainability aspects
						Use of resources	Circularity	Climate Change		
Tools										
ASINA Expert System	Available	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
BAM, Benefit Assessment Matrix	Available	Yes	Yes	No	No	Yes	No	No	Yes	No
DIAGONAL	Not Available	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
HARMLESS	Not Available	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
LICARA nanoSCAN	Available		Yes	Yes	Yes	Yes	No	No	Yes	Yes
SUNDS	Available	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No
SUNSHINE	Available	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Integrative Systems										
Early4AdMa	Available	No	Yes	Yes	Yes	Yes	Yes	No	No	No
Portfolio Sustainability Assessment	Available	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Platforms										
NanoSolveit	Available	Yes	No	Yes	Yes	No	No	No	No	No
CompSafeNano	Available	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes
SAbyNA/ SbD4nano	Not Available	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No

Inventory of frameworks, methods, aspects/parameters, and tools/toolboxes for SSbD and RP

Information needs to identify hot spots relevant for SSbD [Stage Gate Functionality/ HH and Env Safety/ Sustainability]

TRL Stage Gate	FUNCTIONALITY	HUMAN AND ENVIRONMENTAL SAFETY	ENVIRONMENTAL SUSTAINABILITY
STAGE 1 BUSINESS IDEA TRL1	**NM use orientated properties** Potential applications	**Material restrictions and product specific legislation** (national & other regions) **Apply design principles**: avoid properties known to be linked to toxicity endpoints	**Are critical raw materials used? Apply design principles** to optimize raw materials extraction, production, recyclability, and circulatory.
STAGE 2 BUSINESS CONCEPT	**NM identity/PC characteristics** Physical form & amounts required. Does it need functionalization? composition/ size/shape/surface/ perfection) crystallinity How is the NM **synthesized**?	**PC relevant for human hazard including physical hazards**: dissolution rate in physiological relevant media; high/enhanced reactivity; release of toxic ions in human body; causes frustrated phagocytosis, crystallinity: flammability, explosiveness, etc **Based on the comparison with a similar material of known toxicology:** is there any indication of **increased toxicity** (carcinogenicity, mutagenicity, reprotoxicity immune toxicity)? or **change in kinetics** (translocation blood-brain barrier, blood-testis barrier or placenta? **PC relevant for human exposure**: form of exposure, dustiness **Intended use:** exposure routes, releases to environmental compartments, vulnerable exposed groups, **Fate**: Bioaccumulation and persistency in environmental compartments, mobility between compartments **Uptake by plants or animals:**	**Process characteristics relevant for sustainability** (resources used: energy, water, raw materials and potential emissions to air, water, soil, sediments, waste generated, does waste contains toxic substances) **Product characteristics relevant for sustainability**: recyclability, emissions during use, waste produced and resources during used, durability. **End of life**: is the material biodegradable? can be recycled from the product? Energy and resources associated to the end-of life processes.
STAGE 3 PROTOTYPE	Does the prototype fulfil the **requirements specified for functionality**? Is it suitable for the application? What modifications are required to improve safety and sustainability? How it compares with benchmark material?	**Perform PC characterization Kinetics:** indication of uptake into the body, translocation across the brain and, blood-testis barrier or placenta, persistency in tissues? **Release and exposure scenarios throughout the lifecycle:** identify hot spots and form of exposure along the lifecycle **Transformations of the NM throughout the life cycle** (changes in dissolution, aggregation, agglomeration, surface chemistry compared to the pristine material) **Acute and chronic human and environmental toxicity (in vitro assays)**	**Release rate to the different environmental compartments Release rate during use** Durability, performance, reparability, recyclability testing
STAGE 4 PILOT SCALED	Is the real functionality still compelling? Have all **functionality tests**, including indicators for robustness, transformation, and durability been performed? Do the results indicate that the requirements are fulfilled?	**Update data on release & exposure** to the workplace, consumers and environmental compartments **Testing for compliance with legislation** Measured workers exposure and compared to OELs when available	Update release rates based on pilot production
STAGE 5 MARKET LAUNCH		Periodic occupational exposure assessments Health surveillance of workers Epidemiological studies in workers and consumers if relevant Study of effect biomarkers for long term exposure	Update data with production volume

Developing Tools for practical implementation of SSIA principles: TE, Barriers & Constraints



Enhance Industry-policy dialogues (trusted environments)

Learning from industrial good practices by collecting observations and lessons learned from SbD/SSbD case studies, projects for reflection at the tool level (for SSbD) and the process and organizational infrastructure level (to inform the governance of TE).

- Develop pilots for TE (e.g. identify new risks, need for test methods, dealing with trade-offs)

Early Awareness and Action System for AdMa (Early4AdMa)

- Tool in **anticipatory risk governance** approach to allow for **timely decision-making**
  - Identify potential **safety** (both environmental and human), **sustainability** and **regulatory issues** for AdMa at an early stage
    - Including applicability of test methods, suitability of sample preparation
  - Identify potential **follow-up actions**
    - Guidance development, research needs, steer towards SSbD
- Relies on **existing data** and **expert assessment**
- Step-wise approach: in two tiers and seven steps

Functionality :

- To help answer the sets of questions in a manner that is relevant to the case (e.g. by considering the material or the AdMa-enabled product, the relevant compartment(s) and anticipated form(s) of release)
- To provide the context for identifying signals, as relevant, and the weight of the signal.

EARLY4AdMa

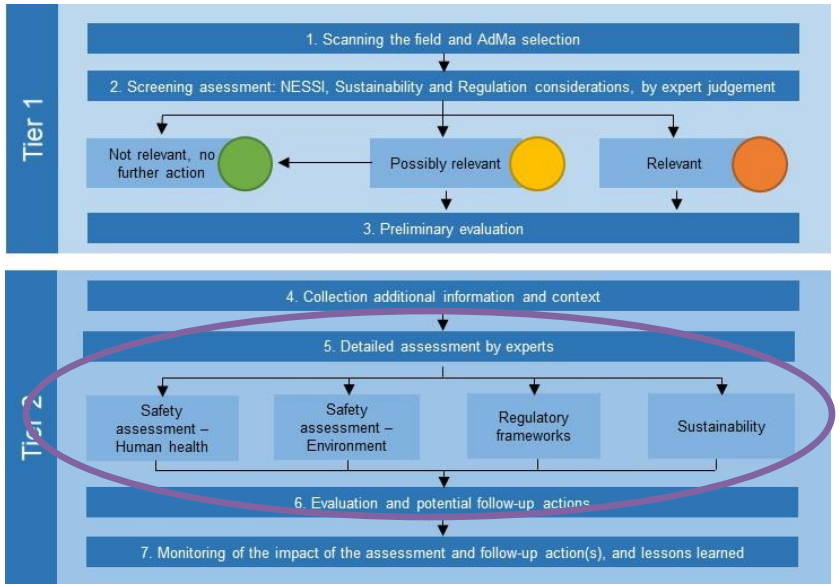
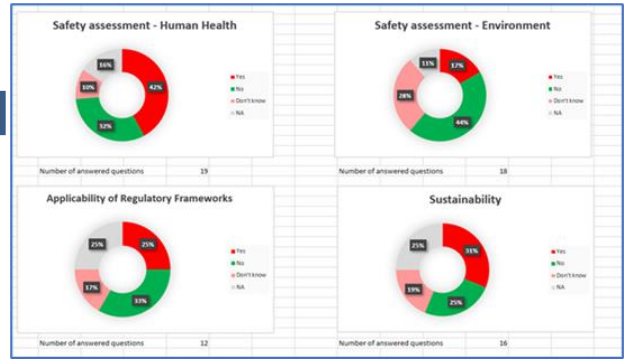


Table 2. Overview of potential follow-up actions related to topics as can be identified in step 5. Note: the list of potential actions are merely examples and is not exhaustive.

Topic	Some suggestions for follow-up actions
Safety assessment (human health and environment)	• Reduce uncertainties by generating additional (safety) data. • Consider substitution of materials of concern and/or regulatory action. • Consider risk management measures, e.g., to reduce exposure or release.
Applicability of regulatory frameworks	• Share knowledge with the involved Institutions, Regulatory Agencies, Ministries, Authorities and Committees to allow timely consideration whether/ which current regulatory frameworks need adaptations. • Develop guidance and best practices. • Encourage research to underpin the development of suitable (standardised) test methods and improve assessment strategies. • Encourage development of suitable (standardised) test methods or improve assessment strategies.
Sustainability	• Encourage improved sustainability based on identified areas of most relevance, e.g. ○ Minimalization of critical raw material use ○ Reduction of global warming potential ○ Minimalization of energy, water and land consumption ○ Reduction of environmental footprint ○ Effective recyclability and reusability
Other	• Encourage safe-and-sustainable-by-design in further material/product development, encourage substitution. • Facilitate interaction between relevant stakeholders. • Regularly monitor developments of innovations.

Graphical summary



Relies on **existing data** and **expert assessment (Trusted Environments)**

Table 1. An overview of major topics and sub-topics that are part of step 5. Questions related to each subtopic can be found in '**Early4AdMa assessment system (details on step 5)**'.

Topic	Sub-topic
Safety assessment for human health	Physico-chemical properties Hazard Kinetics Exposure
Safety assessment for the environment	Physico-chemical properties Hazard Fate Exposure/environmental release
Applicability of regulatory frameworks	Sample preparation and analytics Applicability regulatory frameworks
Sustainability	Raw materials and resources Manufacturing, production, transport and use End-of life (recyclability and reusability)

Table 5. Questions to assess potential issues related to 'Applicability of Regulatory Frameworks'. When a question is not applicable for the advanced material under investigation, this can be indicated in the '**NA**' column. '**?**' indicates unknown. Any relevant consideration may be provided in the comments section. For some questions, additional guidance on how to answer the question is provided in **Annex 1**. This is indicated by '**→Guidance**'.

Sub-topic	Question	Yes	No	?	NA	Comment/ clarification
Sample preparation and analytics	Are there issues expected with the analysis of the characteristics of AdMa as pristine material? → **Guidance**					
	Are there issues with sample preparation for determination of physicochemical properties, hazard, toxicokinetics, fate or exposure assessment of the specific material likely, e.g. due to the absence of guidance, protocols or existing protocols are not adequate? → **Guidance**					
	Are there issues expected with the analysis of the AdMa in complex matrices in view of exposure, environmental fate or toxicokinetic analysis? → **Guidance**					
Applicability Regulatory Frameworks	Is the material(s) or application(s) of the material outside of the scope of current chemical or sector specific legislation(s)?					
	If the material(s) or its application(s) falls within the scope of relevant (possibly sector-specific) legislation do the information requirements for substance identification **lack** provisions that **explicitly address** the nano/multicomponent/advanced character of the material? → **Guidance**					
	If the answer to the previous question is "yes": If the material(s) or its application(s) falls within the scope of relevant (possibly sector-specific) legislation do the information requirements for substance identification **lack** provisions that **allow addressing** the nano/multicomponent/advanced character of the material?					
	If the material(s) or its application(s) falls within the scope of relevant (possibly sector-specific) legislation, do the information requirements lack provisions that cover the potential **human health** safety issues (section 3.2) for the AdMa?					
	If the material(s) or its application(s) falls within the scope of relevant (possibly sector-specific) legislation, do the information requirements lack provisions that cover the potential **environmental** safety issues (section 3.3) for the AdMa?					

- Address uncertainty among regulators, industry, SMEs, and the public, regarding potential risks and impacts of new technologies/ materials.
- Pragmatic and science-based standards for strong and innovative economy (relevant, reliable and transferable methods)
- Move ahead and avoid paralysis by analysis (data-generation).
  - Not all the data is needed for decision making
  - Use existing knowledge to anticipate potential effects. materials
- Multidisciplinary! TE including dif. Experts/ stakeholders
- Need a change of mindset: prevention rather than risk management
- Regulatory preparedness to manage quick and responsible uptake of innovative materials and solutions
- Good regulation to increase trust. Moving to a trusted environment to increase Regulatory preparedness

More information

- Websites: http://www.oecd.org/chemicalsafety/; https://www.oecd.org/science/nanosafety/
- https://www.oecd.org/chemicalsafety/safer-and-sustainable-innovation-approach/
- EHS Newsletters: http://www.oecd.org/chemicalsafety/environment-health-safety-news.htm

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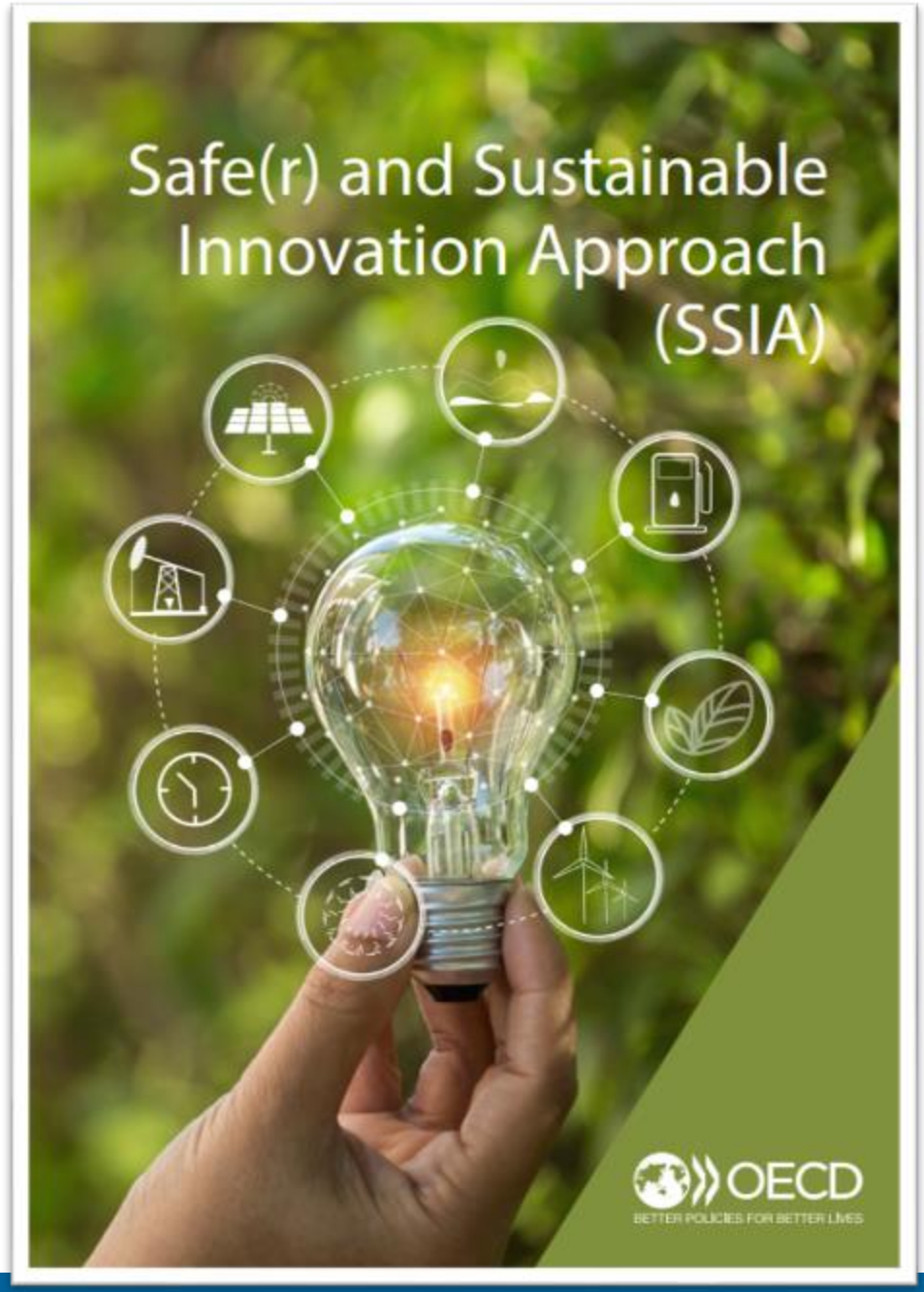

Thank you

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