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

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among **FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD**

Environment Directorate
ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT
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Foreword

1. Technological innovations such as nanotechnology and/or biotechnology are being developed at such a rapid pace that they present a challenge to health and environmental risk assessment. Because of this rapid rate of innovation, a gap can arise between technological innovations and the development of suitable risk assessment tools and frameworks. A way to minimise this gap is (a) for industry to try to reduce uncertainties and risks to human and environmental safety, starting at an early phase of the innovation process and covering the whole innovation value chain (or life cycle for product development) (the 'Safe(r)-by-Design' concept, SbD); and (b) for regulators to anticipate the regulatory challenges posed by innovations such as innovative nanomaterials (NMs) and nano-enabled products, their applications and potential safety issues (Regulatory Preparedness, RP). These two distinct components together form a 'Safe(r) Innovation Approach' (OECD, 2020).

2. We are currently in a world that faces various transitions. Climate change and environmental degradation are an existential threat to the world (EC, 2021). While the current (legislative, regulatory and/or policy) systems work to protect humans and the environment, there is a need for further improvements in order to keep up with the high levels of production and industrial use of chemicals and other substances as these are growing rapidly and are expected to double in 2030 (UNEP, 2019). Scholars concluded that we have surpassed local no-effect boundaries, and argue that we have passed the various planetary boundaries[1]; of an estimated 8 million animal and plant species (75 per cent of which are insects), around 1 million are threatened with extinction (IPBES, 2019); there are dramatic rates of decline in insect populations that may lead to the extinction of 40% of the world's insect species over the next few decades (Sánchez-Bayo, F. and K.A.G. Wyckhuys, 2019). The Living Planet Index, which looks at trends in vertebrate populations, shows that species have declined rapidly since 1970, with reductions of 40% for terrestrial species, 84% for freshwater species and 35% for marine species (WWF, 2021). Urgent actions are needed to tackle chemical pollution and protect ecosystems (UNEP, 2019; Steinhäuser, K.G., et al, 2022). Novel entities is one of the nine planetary boundaries, which consists of new chemical substances, new forms of existing substances and modified and new life forms (Steffen, W., et al., 2015). Technological innovations such as nanotechnology fall in this category. There is sufficient evidence for chemical impacts on environmental and human health on local to global scales (Diamond, M.L., et al., 2015), even if their quantification is sometimes challenged due to complexity (Persson, L.M., et al., 2013; MacLeod, M., et al., 2014). The reality remains that the rate of increase of chemical production and use is alarming and exceeds that of most other indicators including population growth rate, emissions of carbon dioxide and agricultural land use (Bernhardt, E.S., et al., 2017; Brack, W., et al., 2022). Therefore, innovative approaches such as SbD need to transition to include other sustainability dimensions such as environmental, social and economic impacts and move towards Safe-and-Sustainable-by-Design (SSbD) and Safe-and-Sustainable-Innovation Approach (SSIA) in order to ensure we stay within a safe operating space within the planetary boundaries.

3. SbD was developed as a response to observations that NM safety would be more effective and less costly for companies if it was incorporated earlier into the innovation process and throughout. Expanding SbD to SSbD can be beneficial for industry as it might

[1] Planetary boundaries - Stockholm Resilience Centre

lead to price incentives (less energy, less resource use, etc.), consumer acceptance and shorter time to market; in addition to contributing to a safe operating space within the planetary boundaries. SbD and SSbD presents collaborative opportunities for industry and regulators.

4. RP was developed as a response to observation that regulators need to better anticipate and adapt governance to keep up with the pace of knowledge generation and innovation of NMs and nano-enabled products. For regulators, the benefit of SSbD is that it provides an integral view and an assessment that includes opportunity to have non-traditional information for a holistic assessment of the effects and/or impacts if the substance as well as an integral view and assessment to include all the sustainability dimensions (safety, environmental, social and economic impacts) for better decision-making, and based on comprehensive information.

5. When facing ‘emerging risks’ of innovations in nanotechnology, biotechnology, bio- and nano-enabled products, the challenge is to make appropriate product development and risk assessment / risk management decisions in the context of uncertainties. These uncertainties can be reduced by using appropriate frameworks and the development and use of suitable OECD Test Guidelines and other hazard/risk assessment tools. Thus, for the identification of potential emerging risks of NMs and nano-enabled products, there is the need to support the development of suitable Test Guidelines, as well as relevant risk assessment tools and frameworks to implement SIA. This is similar for the other sustainability dimensions (environmental, social and economic) where an inventory of appropriate frameworks and tools is needed; particularly those integrating all the sustainability dimensions.

6. Chemical safety is considered a necessary element of sustainability, which as described e.g., by the United Nations Sustainable Development Goals, is a wider concept. A first step towards SSbD and SSIA is the development of working descriptions for sustainability and SSbD in order to have a common understanding and facilitate the practical application and operationalization of SSbD and ensure that NMs and nano-enabled products are produced and used safely and within the planetary boundaries.

Background

7. In 2020, the OECD Working Party on Manufactured Nanomaterials (hereafter WPMN) published the report "***Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled Products***" (OECD, 2020). The report reviews the state-of-the-art vis-a-vis the 'Safe(r)-by-Design' concept; and identifies regulatory challenges posed by innovations such as innovative nanomaterials (NMs) and nano-enabled products, their applications and potential safety issues (Regulatory Preparedness[2]). The interaction between Safe by Design (SdB) and Regulatory Preparedness (RP), form a 'Safe(r) Innovation Approach'. The 2020 report focused on Safe(r) by Design (SbD) and Sustainability was not specifically addressed. Nevertheless, some tools pertaining to sustainability assessment, such as Life Cycle Analysis (LCA) and Socio-Economic Analysis (SEA), were already included in the Safe(r) Innovation Approach.

8. The WPMN agreed on the need to integrate sustainability and to move from a Safer Innovation Approach (SIA) to a Safer and Sustainable Innovation Approach (SSIA). As a first step, the WPMN developed two working descriptions for Sustainability and on Safe-and-Sustainable-by-Design (hereafter SSbD), that will complement those presented in the 2020 report on Safe by Design (SbD), Regulatory Preparedness (RP) and Trusted Environment (TE) (OECD, 2020).

Working Descriptions

9. These **working descriptions** will be used for the further development of the OECD Safer Innovation Approach (SIA) and the implementation of the concept of Safe and Sustainable by Design (SSbD) for nanomaterials and advanced materials (OECD, 2022)[3] in the context of the work of the OECD WPMN:

1. To support innovation and to ensure that nanomaterials and advanced materials are developed in a safe and sustainable way supported by a circular economy.

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[2] Regulatory Preparedness "refers to the capacity of regulators, including policymakers, to anticipate the regulatory challenges posed by emerging technologies such as nanotechnology, particularly human and environmental safety challenges. This requires that regulators become aware of and understand innovations sufficiently early to take appropriate action, and that appropriate regulatory tools are modified or developed as needed. Regulatory Preparedness helps to ensure that innovative materials and products undergo suitable (and if appropriate, adapted) safety assessment before entering the market.

Regulatory Preparedness requires dialogue and knowledge-sharing among regulators and between regulators and innovators, industry and other stakeholders. This communication and interaction help regulators to anticipate the need for new or modified regulatory tools, and reduce the uncertainties for innovators and industry associated with the future development of the safety legislation and regulations applicable to emerging technologies." OECD (2020) OECD, Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled Products. Series on the Safety of Manufactured Nanomaterials, 2020. 96 [ENV/JM/MONO(2020)36/REV1]

[3] A working description for ***Advanced Materials*** was developed by the OECD's Working Party on Manufactured Nanomaterials and made publicly available in document ENV/CBC/MONO(2022)29].

2. To support a dynamic process for identifying and prioritizing the elements to be considered for safety and sustainability. This requires continuous dialogue and/or collaboration between regulators and innovators, and other relevant stakeholders.

Working Description: Sustainability

Sustainability supports societal, economical, and environmental UN Sustainable Development Goals (SDG's) for our planet and for present and future generations. It refers to the use of the biosphere by present generations while maintaining its potential yield (benefit) for future generations. The safety concept for humans and the environment is transversal to all sustainability dimensions (environmental, social and economic).

Sustainability relates to / is about minimizing the environmental footprint, in particular regarding climate change, pollution and resource use, protecting ecosystems and biodiversity. It entails a lifecycle perspective (from raw material extraction, production, use, and end of life) where research and development (R&D) is aligned to a holistic approach by integrating human and environmental safety and taking advantage of and promoting circularity and innovation.

Sustainability should prevent waste in the first place (zero waste) and include material loops and processes that support the "waste hierarchy" which ranks waste management options according to what is best for the environment, giving top priority to durability and repairability. When a material, product or process is developed, efforts should be made for re-use, recycling, recovery, waste reduction, and lastly ensure minimal disposal. Circular economy and industrial responsibility are means that contribute to sustainability

Sustainability has three main aspects, all of them overlapping and cross linked by safety:

a Planet/Biosphere/Environment:

- Remaining within the planetary boundaries by preserving the environment and natural resources and ensuring biological quality in order to enable them to provide ecosystem services to society for the present and future generations (maintenance of ecosystem services for humanity).
- Aiming at using green and sustainable chemistry principles[4] to minimize the toxicity and environmental footprint, in particular regarding climate change, pollution and resource use.

b People/Society:

- Ensuring beneficial social impact as e.g. social welfare, human health safety, and respect of human rights, including equality and education

c Prosperity/Economy*:*

- Ensuring economic growth and innovation within the planetary boundaries.

In summary, sustainability could be described as the ability of a material or chemical to provide products/services with desired functionalities without exceeding planetary boundaries, while ensuring wellbeing and other socio-economic benefits.

[4] UNEP The Green and Sustainable Chemistry: Framework Manual

Working Description: Safe and Sustainable by Design (SSbD)

Safe and sustainable by design (**SSbD**) can be described as an approach that focuses on providing a function (or service), while avoiding onerous environmental footprints and chemical properties that may be harmful to human health or the environment.

In essence, the SSbD approach aims to identifying and minimizing, at an early phase of the innovation process, the impacts concerning safety for humans and the environment and for 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.

For **safe and sustainable by design** in nanotechnology, three pillars of design can be specified:

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

II. ***Safe and Sustainable production***: ensuring industrial safety during the production of materials/ chemicals/ products, more specifically occupational, environmental and process safety aspects. The pillar should also ensure processes for the production of materials /chemical/ products minimize emissions (to air, water and soil) and resource consumption (e.g. energy, water), and optimizing waste management; and

III. ***Safe and Sustainable use and end-of-life:*** minimizing exposure and associated adverse effects through the entire use life, recycling and disposal of the material/ chemical/ product. Materials/chemicals/products should be designed in a way that demand of resources is minimized during the use phase as well as during recycling, and that the material/ chemical/ product supports the waste hierarchy and circular economy.

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