D4.4 - Safety and sustainability assessment of processes and materials I

make good decisions early on

Safe-by-Design has played an important role in developing new materials. Recently, the combination of safety with sustainability aspects, through implementing a Safe-and-Sustainable-by-Design (SSbD) concept extends these considerations. The SSbD approach is holistic, incorporating the safety dimension towards human health and environment as well as the social and economic dimensions. In this way, SSbD covers the safety towards the end-user of a product, occupational safety and hazards during the production process(es) while at the same time ensuring the lowest impact on the environment, in terms of environmental toxicity along the life cycle and at the end-of-life (EoL) like biodegradability or recyclability.

This report presents the safety and sustainability assessment I of materials developed in BreadCell project. Virtual and f2f meetings, on-site partner visits and desk research were performed to screen and conceptualize the safety assessment strategy and to identify potential safety concerns. Production and post-processing exposure routes, cytotoxicity and biodegradability was evaluated. Safety strategy and end-of-life considerations were designed. The sustainability of the BreadCell technology reflects the three pillars of sustainability, the economic, environmental and social dimensions, and the potential impact on the United Nations Sustainable development goals (UN SDGs) is highlighted.

BreadCell Safe-and-Sustainable-by-Design concept

1. Safety assessment of processes and materials I

1.1 Hazard assessment of chemicals and materials

1.2 Human health and safety aspects

2. Sustainability assessment of processes and materials I

2.1 Environmental sustainability assessment

2.2 Socio-economic sustainability

This assessment is divided into two key components: the **safety assessment**, which focuses on identifying and mitigating potential risks to human health and the environment associated with manufacturing processes and material properties; and the **sustainability assessment**, which evaluates the economic, environmental, and social dimensions of BreadCell material production. The aim is to enable timely decisions that comply to regulatory standards and minimize adverse effects on human health and the environment.

www.bnn.at

MEMBER OF BASQUE RESEARCH & TECHNOLOGY ALLIANCE

Funded by the European Union

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 964430

Safety assessment of processes and materials I

1.1 Hazard assessment of chemicals & materials

No hazards have been classified for *cellulose pulps, viscosifiers, traditional foaming agents and the other BreadCell additives*. Therefore, cytotoxicity screening tests were focused on the BreadCell foaming agents and foams of different characteristics developed in the project.

1.2 Human health and safety aspects

The dose response assay was used to quantify IC_{50} values. The *BreadCell foaming agents* **are not cytotoxic** compared to reference materials that are considered safe used in food contact materials.

Non-cytotoxic

A tailored safety testing strategy was defined for *BreadCell foams*. The work will focus on cytotoxicity mechanism, irritation tests and bacterial mutagenicity:

In vitro cytotoxicity

Evaluation of toxicity mechanisms by analyzing plasma membrane damage and activity of mitochondrial enzymes

In vitro skin irritation

Using 3D epidermal model

Skin irritant is predicted if the mean relative tissue viability of three individual tissues exposed to the test substance is <50% of the mean viability of the negative controls

In vitro ocular irritation

Using human cell constructs

If the test article-treated tissues viability is <60.0% relative to negative control, the test article is irritant

Bacterial mutagenicity

Ames test to identify substances that affect the structure of DNA

Biodegradability testing

The biodegradability of two BreadCell foams was investigated under controlled composting conditions according to

EN 13432:2001

The aim is to reach 90% biodegradation in comparison to microcrystalline cellulose, that usually degrades within 3 months.

BreadCell foams fulfil the criteria of biodegradability under controlled composting conditions as per EN 13432:2001 using the biodegradability testing apparatus.

BNN
www.bnn.at

tecnalia
MEMBER OF BASQUE RESEARCH & TECHNOLOGY ALLIANCE

Funded by the European Union

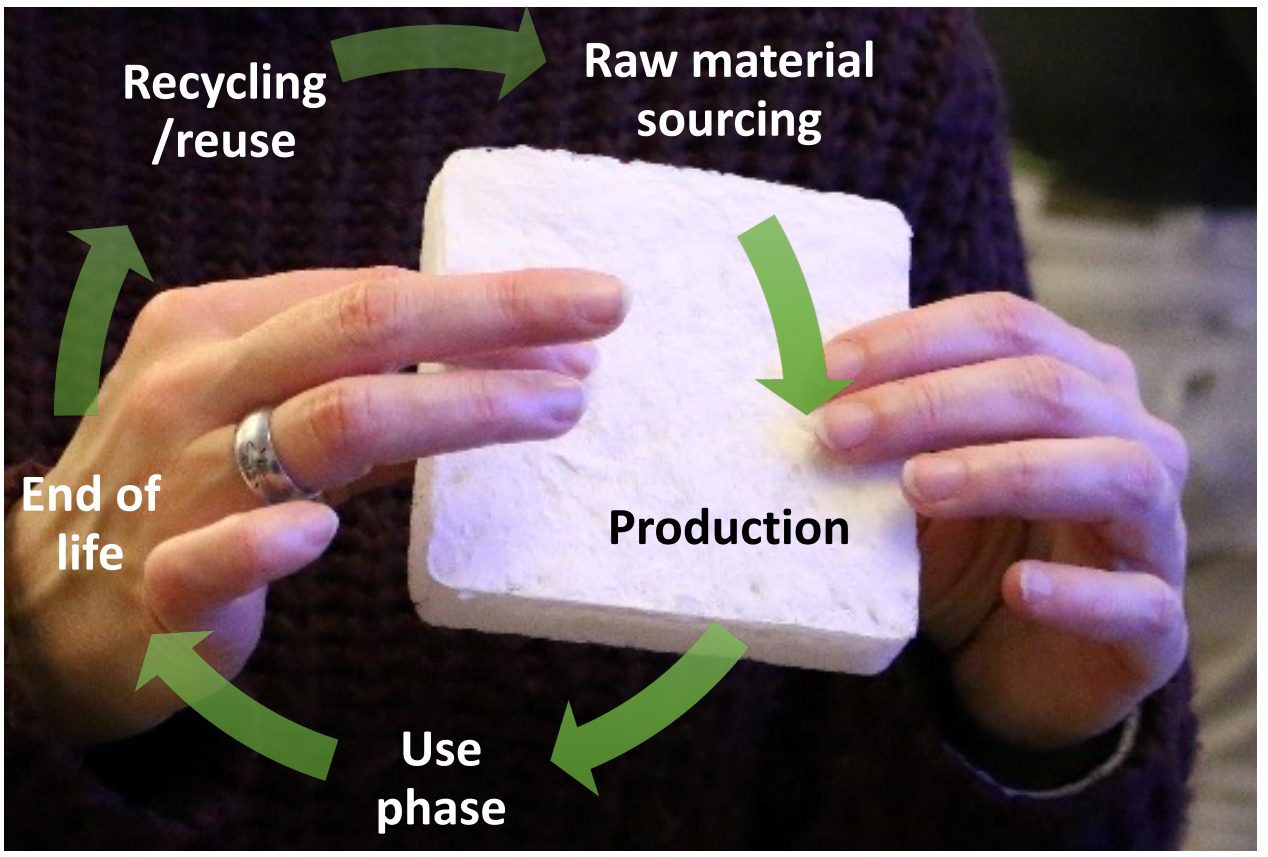
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 964430

Sustainability assessment of processes and materials I

2.1 Environmental sustainability assessment

Qualitative life cycle assessment (QLCA) approach

Utilize life cycle thinking at lab scale to understand comprehensive impacts



Raw material sourcing: The transition to biobased foams supports sustainability by reducing reliance on non-renewable resources. Promoting sustainable forestry practices is crucial.

Production: Pulping and bleaching phases are associated with emissions. Additionally, it is important to consider the CO_2 emissions from the foaming and drying processes.

Use phase: Energy consumption, emissions, and resource use can affect a product's environmental impact, along with impacts on human health and ecosystems. Expectation is that BreadCell foams overall environmental impact is low.

End of life: No major foreseen challenges in disposal and recycling; Biodegradable and can be recycled as paper. However, end of life routes are very use case specific.

Greenhouse gas emissions: Bio-based products can reduce greenhouse gas emissions compared to fossil-based counterparts. However, deforestation and land-use changes from biomass sourcing can compromise these benefits.

Eutrophication: Wastewater from pulp production can increase eutrophication impacts. Emphasis is on the importance of supply chain transparency.

Acidification, ozone depletion, ozone formation: Bio-based products perform similarly to fossil-based counterparts with only minor differences observed.

Interpretation and suggestions

Adopt **sustainable sourcing strategies** to combat forest degradation and protecting biodiversity

Emphasize **durability** in product design to **reduce waste**

Implement end-of-life approaches that **enhance recyclability and biodegradability** and take the use cases into consideration

www.bnn.at

MEMBER OF BASQUE RESEARCH & TECHNOLOGY ALLIANCE

Funded by the European Union

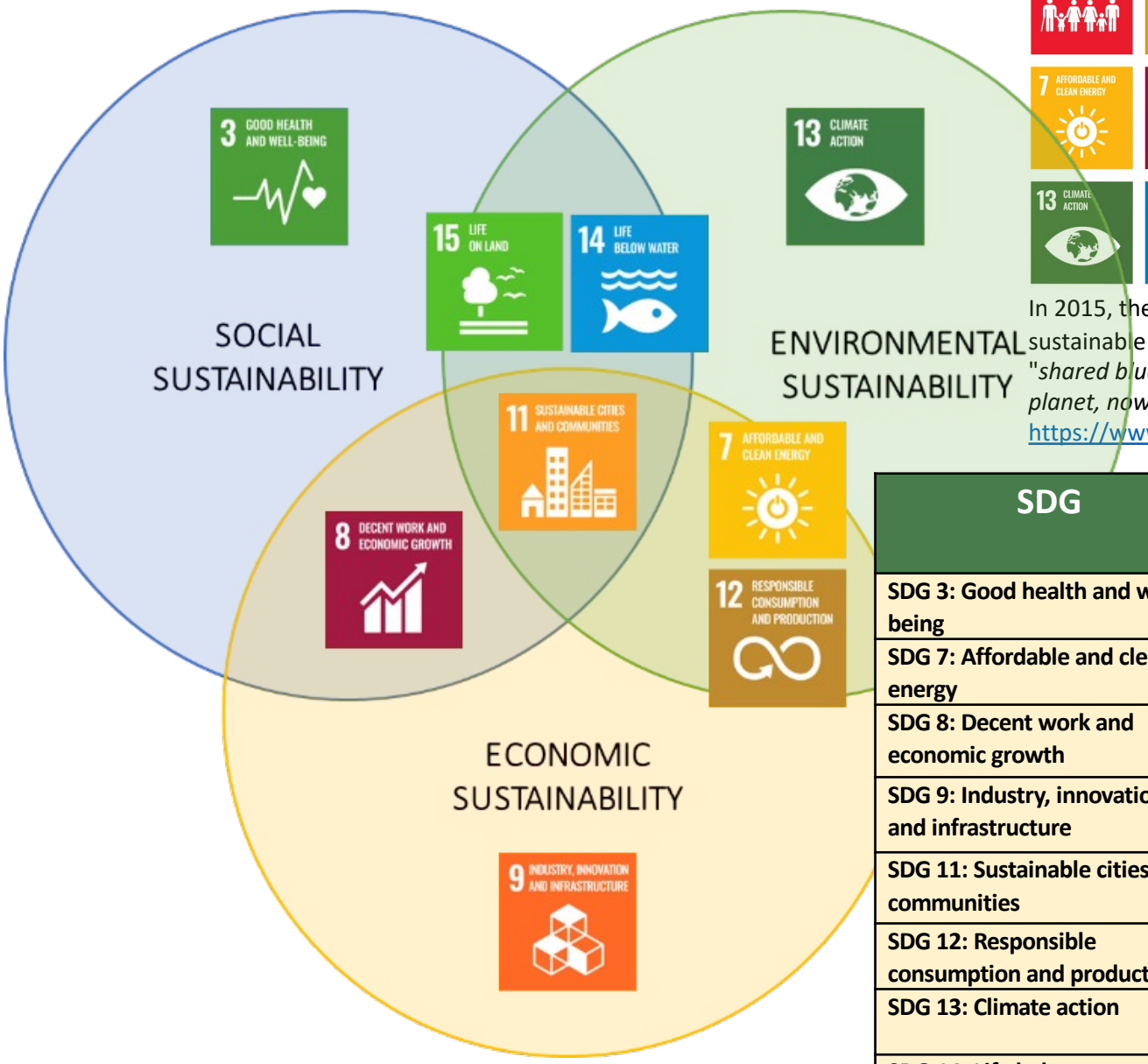
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 964430

Sustainability assessment of processes and materials I

2.2. Socio-economic sustainability

The sustainability of bio-based foams within the broader spectrum of bio-based products of the bioeconomy depends on their environmental, economic, and social impacts that intersect with United Nation's SDGs. Progress towards the SDGs in general has been slow, and **it is urgent to address critical challenges such as urban sustainability, fossil fuel subsidies, material consumption disparities, and climate change**. The role of bio-based products, including bio-foams, is pivotal in mitigating these challenges and advancing towards a fairer and greener world.

BreadCell can make a difference – Social impact and relation to UN SDGs



In 2015, the United Nations General Assembly developed 17 sustainable development goals (SDG), which are described as "*shared blueprint for peace and prosperity for people and the planet, now and into the future*".
https://www.un.org/sustainabledevelopment

SDG	Impact of bio-based products
SDG 3: Good health and well-being	Reduced pollution, health hazards minimized.
SDG 7: Affordable and clean energy	Reduced fossil fuel reliance.
SDG 8: Decent work and economic growth	Economic opportunities, rural job creation.
SDG 9: Industry, innovation, and infrastructure	Techno-economic viability, innovation.
SDG 11: Sustainable cities and communities	Enhanced urban waste management, rural development.
SDG 12: Responsible consumption and production	Biodegradability, compostability, circular economy.
SDG 13: Climate action	Greenhouse gas reduction, climate mitigation.
SDG 14: Life below water	Aquatic pollution reduction, particularly microplastics, possible negative impact of pre-treatment of pulp
SDG 15: Life on land	Sustainable forest management

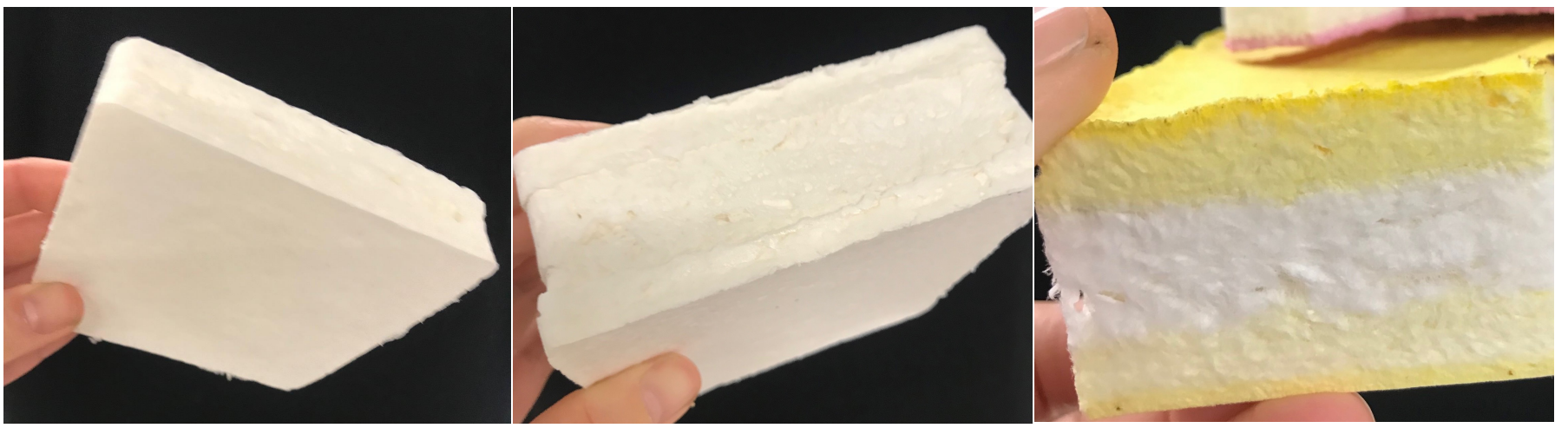
BNN
www.bnn.at

tecnalia
MEMBER OF BASQUE RESEARCH & TECHNOLOGY ALLIANCE

Funded by the European Union

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 964430

D4.4 - Safety and sustainability assessment of processes and materials I



BreadCell foam component materials are **non hazardous**
BreadCell foaming agents are **non-cytotoxic**
BreadCell foams can be **dispersed** back in water and components can be **reused**
BreadCell foams are **biodegradable**

Funded by the European Union

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 964430