Regulatory assessment

Deliverable 6.4

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Table of Contents

List of Abbreviations

Acronyms	Description
BAT	Best Available Techniques
BPR	Biocidal Product Regulation
C2C	Cradle to Cradle
CEN	European Committee for Standardization
D	Deliverable
DIN	Deutsches Institut für Normung e.V.
EC	European Commission
EN	European Standard
EoW	End-of-waste
EPR	Extended Producer Responsibility
EU	European Union
GA	Grant Agreement
ISO	International Organisation for Standardization
LCA	Life Cycle Analysis
LCSA	Life Cycle Sustainability Analysis
P-CFP	Process Carbon Footprint
PHA	Polyhydroxyalkanoates
PHB	Polyhydroxybutyrate
PLA	Polylactic Acid
PPWD	Packaging and Packaging Waste Directive
PPWR	Packaging and Packaging Waste Regulation
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SC	Subcommittee
SFDR	Sustainable Finance Disclosures Regulation
SVHC	Substances of Very High Concern
TC	Technical Committee
TG	Technical Group
W2BC	**Waste2BioComp**
WG	Working Group
WP	Work Package

1. Introduction

This report presents the outcomes of Task 6.4, focused on the regulatory assessment of bio-based materials and components developed under the **W2BC** project. Regulatory compliance is a critical factor in the development of sustainable, market-ready bio-based products. This assessment specifically addresses the legal and safety considerations surrounding new biopolymers and additives, including pigments, bioactive components, nanoparticles, and nanocapsules.

The report provides an in-depth review of key regulatory frameworks, with particular emphasis on the REACH Regulation (EC) No 1907/2006. It evaluates compliance with the Candidate List of Substances of Very High Concern (SVHC), as well as the restrictions and authorization requirements outlined in Annexes XIV and XVII. Additionally, the Biocidal Products Regulation (BPR) (EU) No 528/2012 is considered, along with sector-specific legislation relevant to textile, footwear, and packaging applications. Moreover, the report addresses waste management and recycling regulations to ensure that innovations developed through the project are aligned with circular economy principles.

Overall, this regulatory assessment ensures that the **W2BC** project's outcomes not only demonstrate technical and environmental innovation but also meet the stringent regulatory requirements of the European market.

This task is part if WP6 - Toxicity and sustainability assessment – where the study of toxicity and sustainability (biodegradability and LCSA) aspects were studied for the **W2BC** materials.

2. Work carried out in Task 6.4

The project partners were attentive to current and emerging standards or regulations that have some correlation with the project developments, so that **W2BC** results were in line with the standardization landscape, namely in relation to:

- Bio-based materials (for the textile, packaging, and footwear value chains)
- Biodegradability and compostability tests
- Quantification of bio-based content in different materials
- Nanomaterials
- Chemical safety
- Wastes and by-products manipulation
- Recycling and re-use of recycled contents

The participation of IVW in the Deutsches Institut für Normung e.V. (DIN, German Institute for Standardization) and its active work in the field of composite standardization, and interchanged information in the fields of plastics & environmental aspects, biodegradable plastics, recycling of plastics in the circular economy, etc., will facilitate the contribution of **W2BC** results to future standardization activities.

Furthermore, CITEVE is participating in several subcommittees and working groups on ISO/TC38 – Textiles, and in different Technical Working Groups of the ECOSYSTEX initiative,[1] namely in TG4 - Renewable Materials & Standards, which also contributes to a close follow-up on the existing and emerging standards in this field.

The report "Overview of standardisation Committees, published and under development standards, and gap analysis for renewable materials/ textiles" published by ECOSYSTEX TG4, to which CITEVE has contributed under this task, contains a special focus on textiles and plastics.[2]

Throughout the project, the consortium maintained a continuous watch over new and evolving legislation, standards, and regulations that may influence the project outcomes or the future market integration of its results. This monitoring process ensured that the commercial implementation of new bio-based products remains viable and in compliance with international standards and regulation. An "international standards first" strategy has been adopted to guide the development of bio-based products, ensuring that these products meet globally recognized standards.

2.1. Bio-based materials (for the textile, packaging, and footwear VCs)

This section covers some regulations and standards related with bio-based materials, particularly those for the textile, packaging and footwear value-chains.

Below are some of the regulations and communications of the EC related with bioeconomy and different sustainability aspects, to which the products developed in **W2BC** have some relation:

- Sustainable Finance Disclosures Regulation (SFDR)
- COMM A sustainable Bioeconomy for Europe
- COMM EU policy framework on biobased, biodegradable and compostable plastics
- COMM Sustainable Carbon Cycles
- COMM Industrial carbon management
- COMM Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU

[1] https://textile-platform.eu/ecosystex

[2] https://static1.squarespace.com/static/666b018c0edddc61de8d4e7c/t/6720a9f01bcdf30180925782/1730193906356/ECOSYSTEX_TG4_1.pdf

Special attention should be given to prEN 18027 "Biobased Products – Life Cycle Assessment Additional requirements and guidelines for comparing the life cycles of biobased products with their fossil based equivalents" as this affects all he development related with any bio-based product.

Below are described some standards which aim to provide manufacturers, retailers, and consumers with clear guidelines and requirements for the use of bio-based materials in textiles, plastics, and footwear products. By standardizing testing methods, performance criteria, and labelling requirements, these standards facilitate the development and adoption of bio-based materials in various industries, supporting sustainability objectives and reducing dependence on fossil fuels.

2.1.1. Packaging VC

Plastic packaging producers in the EU must adhere to a range of regulations aimed at sustainability, waste reduction, and circular economy practices. The key legislative frameworks include the European Union according to the Single-Use Plastics Directive (EU) 2019/904, the Packaging and Packaging Waste Directive (PPWD), and the Circular Economy Action Plan:

1. **Single-Use Plastics Directive (EU) 2019/904:** This directive aims to reduce the environmental impact of single-use plastics, including packaging made from bio-based plastics.
    - Reduction Targets: Producers are subject to reduction targets for certain single-use plastic products, such as plastic straws, cutlery, plates, and cotton buds.
    - Extended Producer Responsibility (EPR): Producers are required to cover the costs of waste management, cleanup, and awareness-raising measures for certain single-use plastic products, as well as fishing gear.
    - Labelling Requirements: Producers must ensure that single-use plastic products are labelled with appropriate information on waste management options and the presence of plastics.
    - Application: Bio-based packaging, such as PLA-based containers and compostable packaging, is promoted as an alternative to single-use plastic packaging.
2. **Packaging and Packaging Waste Directive (PPWD):** Replaced the Packaging and Packaging Waste Directive (94/62/EC) on February 11, 2025.
    - Essential Requirements: Producers must ensure that packaging materials meet essential requirements for packaging design and composition, including minimizing the use of hazardous substances and ensuring the packaging is suitable for recovery, recycling, and reuse.
    - Recycling Targets: Producers are subject to recycling targets for packaging materials, including plastic packaging. They are required to take measures to achieve these targets and report on progress. By 2030, all packaging placed on the EU market must be recyclable. This includes the development and adherence to design-for-recycling criteria to ensure materials can be effectively processed and reused
    - Extended Producer Responsibility (EPR): Producers are responsible for financing the recovery and recycling of packaging waste. They may be required to join collective schemes or establish their own systems for meeting these obligations.
3. **Circular Economy Action Plan:** Is a central pillar of the EU's Green Deal and its strategy for sustainable growth. It aims to transition the EU economy from a linear model—where resources are used and discarded—to a circular model that prioritizes resource efficiency, waste reduction, and sustainability.
    - Eco-design Requirements: Producers are encouraged to design packaging materials in a way that minimizes environmental impact throughout their lifecycle, including using recyclable or biodegradable materials and reducing packaging waste.
    - Innovation and Research: Producers are encouraged to invest in research and innovation to develop new packaging materials and technologies that are more sustainable and environmentally friendly.
    - Voluntary Agreements: Producers may be encouraged to enter into voluntary agreements or commitments to improve the sustainability of their packaging materials and practices.
    - These requirements aim to promote the transition to a more sustainable and circular economy by reducing plastic waste, promoting recycling, and encouraging the use of environmentally friendly packaging materials and practices. Producers should ensure compliance with these

regulations to meet their legal obligations and contribute to environmental protection efforts in the EU.

4. **European Commission's Bioplastics Action Plan (2021)**: The Bioplastics Action Plan outlines the EU's commitment to enhance the use of bio-based and biodegradable plastics, including for packaging. It focuses on reducing the dependency on petroleum-based plastics and shifting towards more sustainable materials. Key provisions:
    - Promotes the development of advanced bio-based polymers such as Polylactic Acid (PLA) and Polyhydroxyalkanoates (PHA), which are derived from renewable resources through microbial fermentation.
    - Supports research into biodegradable plastics that can decompose in industrial composting facilities or natural environments.
    - Aims to reduce plastic waste and promote the use of renewable resources in packaging production.
    - Application: Industry stakeholders in the packaging sector are encouraged to adopt bio-based materials such as PLA, PHA, and other bioplastics to comply with emerging EU sustainability goals.
5. **UN Plastics Treaty**: is an international initiative aimed at addressing plastic pollution across its entire lifecycle—from production to disposal. Despite significant progress, negotiations remain ongoing, with the treaty yet to be finalized. Key objectives of the treaty:
    - Reduce Plastic Pollution: The treaty aims to curb the impact of plastic pollution by addressing the entire life cycle of plastic, from production to disposal.
    - Promote Circular Economy: Encourages recycling, reusing, and reducing plastic production to minimize waste and foster a sustainable approach.
    - Limit Plastic Production: Set global limits on plastic production, focusing on phasing out non-recyclable plastics and promoting the use of bio-based and biodegradable alternatives.
    - Increase Responsibility for Producers: Manufacturers of plastic products will be held accountable for managing the entire life cycle of their products, from production to disposal.

The UN Plastics Treaty is particularly relevant to the bio-based materials sector. By encouraging the use of bio-based and biodegradable plastics, the treaty aims to shift the packaging and plastics industries toward more sustainable alternatives.

In terms of test methods, the work under development of the technical committees *CEN TC411 Bio-based products*, *ISO/TC 61/SC 14/WG 3 Plastics - Environmental aspects - Biobased plastics*, and *ISO/TC 61/SC 14/WG 2 Plastics - Environmental aspects - Biodegradability* should be followed, as this can directly affect the implementation of the **W2BC** results, and the possibility of participating in some of the working groups will be assessed.

In particular ISO/TC 61/SC 14 subcommittee is dedicated to developing standards for bio-based plastics. Standards under development may include methods for quantifying the bio-based content of plastic materials, testing the mechanical and thermal properties of bio-based plastics, and guidelines for the biodegradability and compostability of bio-based plastics.

Special attention will be given to:

- prEN 18027 "Biobased Products – Life Cycle Assessment Additional requirements and guidelines for comparing the life cycles of biobased products with their fossil-based equivalents"
- ISO 16620 Plastics — Biobased content
- EN ISO 20200 Plastics — Determination of the degree of disintegration of plastic materials under simulated composting conditions in a laboratory-scale test
- EN 13432: Specifies requirements for compostable and biodegradable packaging materials
- EN 16785-1: Defines methods for quantifying bio-based content using radiocarbon (Carbon-14) analysis
- ISO 18606: Covers compostability and organic recycling of packaging materials
- ISO 22526 Series: Provides guidelines for assessing the carbon footprint and environmental impact of bio-based plastics used in packaging

- ISO 22526-4 Plastics — Carbon and environmental footprint of biobased plastics — Part 4: Environmental (total) footprint (Life Cycle Assessment)

2.1.2. Textile VC

Bio-based materials in the textile industry are managed by a combination of regulations, standards, and certifications to ensure sustainability, transparency, and compliance with environmental goals. Below is a summary of key frameworks:

1. **EU Strategy for Sustainable and Circular Textiles:** establishes a goal to transform the textile industry by 2030 to enhance durability, repairability, recyclability, and the use of bio-based fibres.
   - Circularity and Recyclability: Encourages textile producers to design bio-based materials that are recyclable or biodegradable.
   - Eco-design Requirements: Focuses on product lifecycle, ensuring that textiles are designed for durability, reuse, and easy recycling.
   - Chemical Restrictions: Restricts the use of harmful chemicals in textile production, which is relevant for bio-based materials to ensure they are safe for human health and the environment. Promote bio-based fibres like biopolyester, biopolyamides (nylon), and man-made cellulosic fibres (e.g., viscose).
2. **EU Ecolabel for Textiles (Regulation (EC) No. 66/2010)**: is a certification awarded to textiles meeting high environmental standards, including those made from bio-based materials. To qualify, bio-based textiles must meet criteria related to sustainability, including the reduction of toxic chemicals, efficient use of resources, and end-of-life disposal. The label applies to a wide range of textile products, including clothing, accessories, interior textiles, and intermediate products like yarn and fabric, provided they consist of at least 80% textile fibres.
   - Criteria: sustainable fibre production, efficient use of resources and energy during manufacturing, and the reduction of hazardous substances.
   - Prohibitions: certain practices, such as manual or mechanical sandblasting for denim finishes, and imposes strict limits on hazardous substances like formaldehyde and biocides.
3. **EU Waste Framework Directive (2008/98/EC):** is the basis of waste management legislation in the European Union, laying out essential principles, definitions, and targets to ensure sustainable waste handling while protecting human health and environment. Recent revisions have strengthened its focus on textiles, requiring separate collection of textile waste from January 2025 and harmonized EPR schemes to fund waste management costs. These updates aim to reduce fast fashion practices, promote durable designs, and develop infrastructure for sorting, reuse, and recycling. By aligning with the EU Strategy for Sustainable and Circular Textiles, the directive seeks to transform textiles into a circular economy model, reducing environmental impacts while boosting innovation and competitiveness in the sector.

In terms of test methods, there are some methods already implemented for textiles:

- ISO 16620 Series: Biobased Content Determination
  - ISO 16620-1: General principles for quantifying biobased carbon content using radiocarbon analysis.
  - ISO 16620-2: Specifies methods for calculating the biobased carbon content in monomers, polymers, and textile materials.
  - ISO 16620-4: Details methods for determining the biobased mass content in synthetic polymers used in textiles.
- ISO 22526 Series: Carbon and Environmental Footprint: Provides guidelines for assessing the carbon footprint and environmental impact of bio-based materials used in textiles.
  - ISO 22526-1: Establishes general principles for assessing the carbon and environmental footprint of biobased plastics used in textiles. Provides guidance on system boundaries and life cycle assessment (LCA) methodologies.

- ISO 22526-3: Focuses on quantifying and reporting the process carbon footprint (P-CFP) of biobased plastics. Aligns with ISO 14067 (carbon footprint quantification) and ISO 14040/14044 (LCA principles).

- ISO 18606: Compostability: Covers requirements for compostable materials, including textiles made from biobased plastics
- EN 16785-1: Specifies methods for quantifying bio-based content using radiocarbon analysis (also used for plastics and other materials).
- ISO/TC 38: This ISO technical group is responsible for developing standards related to textiles, where bio-based textiles are included. Its scope includes the standardization of methods, specifications, terminology, and definitions related to microplastics from textiles, traceability and responsible sourcing of animal fibres, and ethical and environmental issues in the textile supply chain. This subcommittee contributes to developing international standards that address sustainability challenges in the textile industry, including reducing microplastic pollution and ensuring ethical practices in sourcing raw materials. Standards under development may cover various aspects such as the determination of bio-based content in textiles, testing methods for assessing the performance and durability of bio-based fibres, and guidelines for labelling and certification of bio-based textile products.

Recently, standards and legislation have appeared related with microplastics, this being a problematic that was being studied for some time. The following standards have been published:

- ISO 4484-1:2023 Textiles and textile products — Microplastics from textile sources — Part 1: Determination of material loss from fabrics during washing, published 2023-02-10
- ISO 4484-3:2023 Textiles and textile products — Microplastics from textile sources — Part 3: Measurement of collected material mass released from textile end products by domestic washing method, published 2023-05-05

CITEVE is already working with these standards and trying to implement the methods therein described.

2.1.3. Footwear VC

The footwear industry is increasingly focusing on sustainability and the use of bio-based materials, driven by environmental concerns and the growing demand for eco-friendly products. Key aspects of footwear regulations and labels regarding bio-based materials include:

1. **Cradle to Cradle (C2C) Certification:** The C2C certification focuses on designing products for continuous cycles of reuse or recycling. Footwear certified with C2C ensures that all materials are safe for human health and the environment, and that products can be easily recycled at the end of their life. This certification evaluates material health, material reutilization, renewable energy, and water stewardship.
2. **EU Waste Framework Directive (2008/98/EC):** already described in section 2.1.2.
3. **Fair Labor and Ethical Manufacturing Standards:** Ethical sourcing and fair labour practices are critical components of sustainability. Many footwear companies are adhering to labour standards and ensuring fair working conditions across their supply chains.
4. **EU Ecolabel:** The EU Ecolabel is a voluntary label awarded to products meeting high environmental standards. Footwear made with biobased materials could be eligible for this certification, provided it meets specific environmental criteria such as energy efficiency, waste reduction, and responsible sourcing.
5. **Circular Economy Action Plan (2020):** already described in section 2.1.1.

In terms of test methods, there are several methods implemented for footwear, and some other for bio-based materials that may be applied to footwear:

- ISO 17088 (Compostable Materials): This standard is relevant for footwear that incorporates bio-based and biodegradable materials. It outlines the requirements for determining whether a material is compostable under industrial composting conditions.

- ISO 14021 (Environmental Labels and Declarations): This standard outlines how companies can declare their use of bio-based materials in their products. It includes guidelines on how to label products to indicate the use of renewable, bio-based resources, which is particularly important for the marketing of eco-friendly footwear.
- EN 16785-1: This standard defines methods for quantifying the bio-based content of materials through radiocarbon analysis. This standard can be applied to footwear materials to provide verification that they meet the required bio-based content.
- ISO 14067: Carbon Footprint of Products: Provides a standardized method to quantify the carbon footprint of products, including footwear. By following this standard, manufacturers can assess the greenhouse gas emissions associated with producing a specific footwear product, from materials sourcing to manufacturing and distribution.
- ISO 14040/14044: LCA: LCA is a systematic process for assessing the environmental impact of a product throughout its life cycle. Footwear manufacturers can use ISO 14040/14044 to assess their products' environmental impact, such as the energy consumption, water usage, emissions, and waste generation associated with production, use, and disposal.
- ISO 17709: Footwear – Test Methods for Footwear Soles: This standard focuses on the testing methods for soles to ensure that they provide adequate traction, durability, and shock absorption. It is especially relevant for performance footwear (e.g., hiking boots, running shoes, etc.).
- ISO 22647: Footwear – Fitting of Footwear: This standard provides guidelines for the fit of footwear, addressing how shoes should accommodate different foot shapes, sizes, and comfort levels. It includes recommendations for shoes last design and insole construction to enhance overall comfort.
- ISO/TR 20882: Addresses performance requirements for footwear components, including linings and in socks, which may incorporate biobased materials.
- ISO/TC 216: This ISO working group focuses on developing standards for bio-based materials in footwear. Standards under development may address the use of bio-based materials in shoe soles, insoles, and other footwear components, including testing methods for assessing the performance, durability, and environmental impact of bio-based materials in footwear applications.

2.2. Biodegradability and compostability tests

Bio-based materials are increasingly tested for biodegradability and compostability to ensure their environmental safety and compliance with international standards. These tests evaluate the decomposition of materials under specific conditions, such as soil burial, composting, or anaerobic digestion. Below are listed the standardized tests implemented in the EU, from which EN ISO 17556:2019 was used in **W2BC**:

- ISO 17088:2012: this standard specifies the requirements for biodegradable plastics and defines the requirements for compostable plastics. It outlines the methods to evaluate biodegradability and includes the conditions required for materials to be considered compostable under industrial condition
- ISO 16929:2021: test method for determining the degree of disintegration of plastic materials under pilot-scale aerobic composting conditions. It is part of the broader framework for evaluating industrial compostability, as defined in ISO 17088.
- ISO 14855 Series: Aerobic Biodegradability
    - ISO 14855-1: measures the aerobic biodegradability of materials under controlled composting conditions. Focuses on CO_2 evolution during decomposition.
    - ISO 14855-2: alternative methods for assessing biodegradation rates under thermophilic composting conditions.
- ISO 17556:2019: this ISO standard provides methods for testing the biodegradation of plastic materials under controlled laboratory conditions, particularly focused on bio-based materials in industrial composting conditions.
- ISO 20200:2023: this standard defines the test methods for determining the disintegration of plastic materials under simulated composting conditions. This is particularly relevant to packaging and textile industries using bio-based plastics and biodegradable materials.

- ISO 18606:2013: specifies criteria for organic recycling compatibility, focusing on biodegradation, disintegration, and ecotoxicity. Follow up of ISO/PWI 17952 Test method for determination of degradation rate of textile materials under simulated composting conditions in a laboratory-scale test.
- ISO 11721-1: assesses the resistance of cellulosic textiles to microorganisms present in soil. The test measures the relative reduction in tensile strength between buried and unburied specimens, providing insights into the material's durability and biodegradability when exposed to soil conditions.
- ISO 15985: evaluate the ultimate anaerobic biodegradability of plastics under high-solids anaerobic digestion conditions. This standard is designed to simulate the anaerobic digestion process commonly used in biogasification plants for the organic fraction of municipal solid waste.
- EN 13432: defines the requirements for packaging materials to be considered compostable in industrial composting facilities. It ensures that materials decompose into natural elements, such as carbon dioxide (CO_2), water, and biomass, without leaving harmful residues.
- EN 14995: defines the requirements and testing methods for determining the compostability of plastic materials. It is closely related to EN 13432, which focuses on packaging materials, but EN 14995 applies to all types of plastics, including non-packaging items.
- EN 14046: specifies a method for assessing the ultimate aerobic biodegradability of packaging materials under controlled composting conditions. It is closely aligned with ISO 14855 and focuses on simulating industrial composting processes to measure the biodegradation of organic materials.
- ISO/PWI 17952: test method for determination of degradation rate of textile materials under simulated composting conditions in a laboratory-scale test.
- ISO/AWI 25304: method for determining the degree of ultimate anaerobic biodegradability and disintegration of plastic materials when exposed to high-solids mesophilic or thermophilic anaerobic digestion conditions. This method simulates typical anaerobic digestion environments, such as those used for processing the organic fraction of mixed municipal solid waste.
- ISO/AWI 17952: methods for assessing the physical degradation of textile materials under simulated composting conditions in a laboratory setting. The standard focuses on evaluating degradation rates based on changes in mechanical properties and surface area loss of textiles. It does not cover degradation caused by heat (thermo-degradation) or light exposure (photo-degradation), making it specifically tailored to composting environments.

2.3. Quantification of bio-based content in different materials

Several standards exist for the determination of bio-based content, providing methodologies and criteria for assessing the proportion of renewable materials in a product. Some of the widely recognized standards include:

- ISO 16620 series: includes methods for the quantification of bio-based content in products derived from biomass. ISO 16620-2 covers the determination of bio-based carbon content using radiocarbon analysis, while and ISO 16620-4 cover the determination of biomass content using radiocarbon analysis and elemental analysis.
- EN 16785: provides a method to determine the total bio-based content in materials using radiocarbon analysis combined with elemental analysis. This standard is widely used for certification and labelling of bio-based products in Europe.
- DIN EN ISO 16640: This standard, published by the German Institute for Standardization (DIN) and adopted as an ISO standard, provides guidelines for the determination of bio-based carbon content in plastics and polymer materials using elemental analysis.

These standards offer reliable methods for quantifying the bio-based content of products, facilitating transparency and comparability in the bio-based industry. They are widely used across industries for certifying bio-based products such as textiles, plastics, coatings, and fuels. Certification programs like OK Biobased, BioPreferred®, and others rely on these standards to validate claims about renewable content. Manufacturers and regulators often refer to these standards to ensure consistency and accuracy in bio-based content claims.

2.4. Nanomaterials

Due to their unique properties at the nanoscale, nanomaterials require specific regulatory attention to ensure responsible production and use. In response, the EU and the ISO have established frameworks and standards to define, assess, and manage the potential risks associated with nanomaterials.

1. **European Commission's Recommendation 2011/696/EU** (update in 2022, C(2022)3689): Defines a nanomaterial as: "A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or agglomerate, where **50% or more of the particles... have one or more external dimensions in the size range 1 nm - 100 nm**." The 2022 update refined this definition by introducing explicit criteria for particle shapes (e.g., rods, plates, fibres) and removing exemptions based on surface area or adjustable thresholds. It also expanded the scope to include materials with internal or surface nanostructures, such as nanocomposites, ensuring broader applicability in sectors like chemicals, textiles, and consumer goods.
2. **Regulation (EC) No 1907/2006 (REACH)**: The REACH regulation is the primary legislation in the EU governing chemicals, including nanomaterials. Nanomaterials are covered under REACH through specific provisions, including:
    - Definition: A nanomaterial is defined as a material containing particles with at least one dimension in the range of 1 to 100 nm.
    - Registration Requirements: Manufacturers must register nanomaterials before they can be placed on the market, providing details on their properties, risks, and safe usage.
    - Safety Data: Companies must submit information on the potential toxicity, environmental impact, and human health risks associated with nanomaterials.
3. **Regulation (EC) 1935/2004 – Food Contact Materials:** To ensure the safety and quality of materials used for packaging, storing, and transporting food, ensuring that they do not release harmful substances into food. If nanomaterials are used in Food Contact Materials (e.g., nanoparticles in food packaging), they must comply with specific regulations under this framework.

There are also some standards related with definition and characterization of nanomaterials:

- ISO/TS 80004-1:2015: Defines general terms such as nanomaterial, nanoparticle, nanofiber. Establishes standardized definitions for foundational terms in nanotechnology — replacing ISO/TS 27687:2008. Clarifies concepts such as nano-object, nano-aggregate, and nano-dispersion.
- ISO/TR 13014:2012 – Guidance on Physico-Chemical Characterization: Provides guidance on the physico-chemical characterization of engineered nanomaterials that are used for toxicological assessments. This standard offers guidelines to help manufacturers, researchers, and regulatory bodies obtain the necessary physical and chemical data required to evaluate the toxicity and safety of engineered nanoscale materials.
- ISO 22412:2017 – Dynamic Light Scattering (DLS): To provide a reliable method for measuring particle size distributions of nanomaterials, particularly in liquid suspensions, by using DLS. To ensure the method provides consistent results that are reproducible, accurate, and appropriate for both scientific and regulatory purposes
- ISO/TR 13121:2011 – Nanomaterial Risk Evaluation: Provides guidance on evaluating the risks associated with nanomaterials. It aims to assist stakeholders—such as regulators, manufacturers, and researchers—in assessing the potential hazards, exposures, and risks that engineered nanomaterials might pose to human health, safety, and the environment.
- ISO/TR 18637:2016 – Nanomaterial Toxicity Testing: Outlines toxicological testing strategies, including *in vitro* and *in vivo* methods.

As the microparticles and nanocapsules developed within **W2BC** have a size greater than 100 nm (this was pre-established as a requirement in the proposal phase), they do not fall under the nanomaterial definition, as above described.

2.5. Chemical safety

Regarding chemical safety, the major regulation in the European Union is REACH Regulation (EC) 1907/2006, which "was adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry."[3]

Another important regulation, which also affects the developments of **W2BC**, namely the antimicrobial particles, is the BPR Regulation (EU) 528/2012, applicable to biocidal products fabricated and/or commercialized in the EU.

A major update in the REACH Regulation made during the timeline of the project and that directly affects its results is the new entry to Annex XVII (restricted substances):

- **Entry 78: synthetic polymer microparticles:** This includes any synthetic polymer, including those extracted from nature but that have undergone chemical modifications. As the PHA or PHB microparticles, nanocapsules and PHA flakes/pellets (which, due to their size can be considered microparticles) from **W2BC** fall under this entry, these particles will have to be tested as for their: i) degradability according with Appendix 15 of the REACH Regulation, and/or ii) solubility according with Appendix 16 of the REACH Regulation. If the particles do not pass the criteria in one of these Appendixes, they cannot be used in mixtures in a concentration above 0.01% by weight. However, as they are intended only for industrial applications, they can still be used above the indicated concentration, if the required information is passed on to the users.

The chemical substances and mixtures used along the project to produce the new bio-based materials were analysed, as some are identified in REACH as hazardous. This analysis is described in Deliverable D6.1 Toxicity evaluation of the bio-based materials.

As for the BPR, the antimicrobial microparticles/NCs developed in the project will have to be approved as active substances before being placed on the market.

2.6. Wastes and by-products manipulation

The management of waste and by-products is achieved by a combination of EU regulations and ISO standards, which aim to promote sustainability, ensure environmental protection, and support the circular economy. Below is an overview of the key regulatory frameworks relevant to waste and by-products manipulation:

1. **Waste Framework Directive** (2008/98/EC, amended by 2018/851): (also described in section 2.1.2) Defines waste, by-products, and end-of-waste (EoW) criteria. Sets the basic concepts and definitions related to waste, such as:
   - Waste hierarchy: Prevention, reuse, recycling, recovery, disposal.
   - By-product: Defines conditions under which substances can be classified as by-products rather than waste, promoting reuse in industrial processes.
   - End-of-waste criteria: Specifies when waste ceases to be waste and becomes a secondary raw material. Criteria include lawful use, existing market demand, and no adverse environmental or health impacts.

   The key Principle of this directive is "Polluter pays and extended producer responsibility (EPR)".
2. **Directive on the Landfill of Waste** (1999/31/EC, amended by 2018/850/EU): Limits biodegradable waste in landfills to reduce environmental impact. Encourages minimizing landfilling by valorising organic waste (e.g., converting to bio-based materials or bioplastics). Sets strict operational conditions for waste landfills.
3. **Industrial Emissions Directive** (2010/75/EU): Regulates waste treatment facilities to minimize emissions. Introduces Best Available Techniques (BAT) for industrial waste management.

[3] https://echa.europa.eu/regulations/reach/understanding-reach

4. **Circular Economy Action Plan (2020):** already described in section 2.1.1
5. **Packaging and Packaging Waste Regulation (PPWR) (EU 2025/40):** already described in section 2.1.1

Below is an overview of the key ISO standards relevant to waste and by-products manipulation:

- ISO 14001: Environmental Management Systems. Focuses on implementing effective environmental management practices, including waste reduction, reuse, and recycling. It emphasizes compliance with legal requirements and continuous improvement in environmental performance.
- ISO 24161:2022: Waste Collection and Transportation Management Vocabulary. Standardizes terminology, technology, and performance requirements for managing solid and liquid waste.

Key Considerations:

- By-Products vs. Waste: The distinction between by-products and waste depends on legal definitions under Article 5 of the Waste Framework Directive. Proper classification allows manufacturers to reuse materials without being subject to strict waste regulations.
- End-of-Waste Criteria: Materials that meet EoW criteria are no longer regulated as waste but must comply with product-specific legislation such as REACH.

2.7. Recycling and re-use of recycled contents

Bio-based materials are regulated and standardized to ensure their sustainability, traceability, and environmental compatibility. Below is a detailed overview of relevant regulations and ISO standards for recycling and reuse of bio-based materials, as applicable to the recycling.

1. **Waste Framework Directive** (2008/98/EC & Amendments - 2018/851/EU): Establishes the waste hierarchy: Prevention > Reuse > Recycling > Recovery > Disposal. Defines end-of-waste criteria, allowing recycled materials to be classified as non-waste when they meet specific quality standards. Introduces EPR, requiring producers to manage the recycling and disposal of their products.
2. **Packaging and Packaging Waste Regulation** (PPWR) (Replacing 94/62/EC): Sets minimum recycled content targets for plastic packaging:
   - 2025: 25% minimum recycled content for PET bottles.
   - 2030: 30% minimum recycled content for all plastic packaging.

   Requires improved design-for-recycling to ensure all packaging is recyclable by 2030. Introduces a harmonized labelling system to improve sorting and recycling.
3. **Standards on Recycling & Environmental Management**
   - ISO 14021: Environmental labels and declarations for products with recycled content.
   - ISO 14024: Environmental labelling certification for sustainable products.
   - ISO 14040/ ISO 14044: LCA to measure environmental impact.
4. **Standards for Recycled Content Quantification**
   - ISO 14067: Carbon footprint assessment, including recycled content analysis.
   - ISO 21930: Sustainability in building materials, incorporating recycled content.
5. **Recycling Standards for Specific Materials**
   - Plastic & Packaging:
     - EN 15343: Traceability of recycled plastics.
     - ISO 18604: Recycling of packaging materials.
   - Textiles:
     - ISO 20706-1: Fiber content analysis for recycled textiles.
   - Footwear & Rubber:
     - ISO 16186: Recycled material testing in footwear.
     - ISO 17709: Quality and safety requirements for footwear containing recycled materials.

3. Conclusions

In conclusion, Task 6.4 demonstrates the **W2BC** project's proactive approach to aligning with current and emerging standardization and regulatory landscapes.

The project partners have carefully tracked developments related to bio-based materials, biodegradability, chemical safety, and waste management across the textile, packaging, and footwear value chains. Some key aspects have been identified in the follow up of the developed products, before they enter the market.

By actively participating in key standardization bodies such as DIN and ISO/TC38, and closely monitoring initiatives like ECOSYSTEX, the project ensures that its results contribute to and are informed by the latest standards. The "international standards first" strategy, coupled with ongoing monitoring of relevant legislation, positions the project to facilitate the seamless integration of its innovative products into the market, promoting sustainable and responsible development in the bio-based sector. Furthermore, the potential for IVW to propose amendments to existing standards or initiate new DIN SPEC Business Plans, underscores the project's commitment to driving standardization efforts and supporting the broader transition towards a circular economy.

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