D5.1. Preliminary regulatory framework.

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List of Acronyms

Acronym	Definition
ABS	Access and Benefit Sharing
BDMs	Biodegradable plastic mulch films
CEAP	Circular Economy Action Plan
CLP	Classification, Labelling. Packaging
CMR	Carcinogenic, Mutagenic or toxic for Reproduction
CRFs	Controlled Release Fertilisers
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DPP	Digital Product Passport
EC	European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EoL	End of Life
EPR	Extended Producer Responsibility
EQS	Environmental Quality Standards
EQSD	Environmental Quality Standards Directive
ESPR	Ecodesign for Sustainable Products Regulation
ETS	Emissions Trading System
EU	European Union
EVA	Ethylene-Vinyl Acetate
FAO	Food and Agriculture Organization of the United Nations
FCMs	Food Contact Materials
FPR	Fertilising Products Regulation
GDP	Gross Domestic Product
GHG	Greenhouse Gases
GMOs	Genetically Modified Organisms
GPP	Green Public Procurement
GWD	Groundwater Directive
H&S	Health and Safety
IAS	Intentionally Added Substances
ICT	Information and communication technology
IED	Industrial Emission Directive
IPM	Integrated Pest Management
LCA	Life Cycle Assessment
LULUCF	Land use, land use change and forestry

MRL	Maximum Residue Levels
MS	Member States
NGO	Non-Governmental Organization
NIAS	Non-Intentionally Added Substances
OML	Overall Migration Limit
OSH	Occupational Safety and Health "Framework Directive"
PBAT	Polybutylene Adipate Terephthalate
PBT	Persistent, Bioaccumulative and Toxic
PE	Polyethylene
PFA	Perfluoroalkoxy
PHA	Polyhydroxyalkanoates
PHBV	Poly(3-hydroxybutyrate-co-3-hydroxyvalerate)
PLA	Polylactic acid
PoMs	Programmes of Measures
PPPs	Plant Protection Products
PPWR	Packaging and Packaging Waste Regulation
RBMPs	River Basin Management Plans
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SDGs	Sustainable Development Goals
SDS	Safety Data Sheet
S-LCA	Social-Life Cycle Assessment
SML	Specific Migration Limit
SSbD	Safe and Sustainable by Design
SUD	Sustainable Use of Pesticides Directive
SVHCs	Substances of Very High Concern
TPS	Thermoplastic starch
TRL	Technology Readiness Level
vPvB	very Persistent and very Bioaccumulative
WFD	Waste Framework Directive
WP	Work Package

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Keywords list

- Regulation
- Fertiliser
- End of life
- Validation
- Compliance

Disclaimer

Table of Contents

1. Executive summary

This Deliverable D5.1 provides the preliminary review of the Regulatory Framework related to the PHAntastic project to ensure the compliance of PHAntastic delivery systems with EU and national policies, including the protection of the human health and the environment against harmful substances, and assessing the safety of materials and products used and developed during the project.

PHAntastic tackles the reduction of agrochemicals and plastics pollution using polyhydroxyalkanoates (PHAs, a family of bio-based biodegradable polymers) in combination with safe active bioproducts. The general objective of the project is to develop and demonstrate in a relevant environment (TRL5-6) several innovative PHA- based delivery systems for active bioproducts (fertilisers, biocides, plant protection products) including:

- Biodegradable PHA-based mulching film for horticultural crops, incorporating active bioproducts (fertilisers, biocides) and microbiological cocktails, to support controlled product release and ensure product degradation at the end of its useful life.
- Biodegradable PHA-based growth foams for growth of tree seedlings, incorporating active bioproducts and plant growth promoting rhizobacteria guaranteeing a balanced soil microbiota and sustainable PHA biodegradation.
- Controlled release fertilisers consisting in different PHA-based formulations (e.g., encapsulated/coated granules).
- Controlled release PHA-based formulations of pesticides (e.g., encapsulation).

The approach will include the development of PHA-based delivery systems for active bioproducts as alternative to conventional agrochemicals resulting in less GHGs emissions, improved efficiency, improved toxicity and ecotoxicity profile and biodegradability. Furthermore, the development of risk, safety, and sustainability assessments of the resulting products in line with the Safe and Sustainable by Design framework, including regulatory considerations.

This Deliverable D5.1 is specifically addressed to the regulatory requirements for fertilizers (FPR), for food contact materials (EC Regulation No 1935/2004, Plastics Regulation (EU) No 10/2011) and H&S aspects and the relevant standardization and certification landscape for PHAntastic delivery systems at international, EU and national levels.

In detail, the most relevant regulations and guidelines include:

- Regulation EU No 2019/1009 on Fertilising Products (last update November 20th 2024),
- Regulation EU No 528/2012 on use of biocidal products (last update June 11th 2024),
- Directive 2009/128/EC on sustainable use of pesticides (last update July 26th 2019),
- Regulation EC No 1107/2009 on plant protection products (last update November 21st 2022),
- Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin (last update January 08th 2025),
- Regulation (EU) No 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (last update January 05th 2025),

- Regulation (EC) No 2022/2379 on statistics on agricultural input and output (last update November 23rd 2022),
- Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage (last update June 26th 2019),
- Regulation (EU) No 2018/841 on the inclusion of greenhouse gas emissions and removals from land use, land use change and forestry in the 2030 climate and energy framework (last update May 11th 2023),
- REACH Regulation No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (last update October 10th 2024),
- Safe and Sustainable by Design (SSbD) of chemicals and materials - Methodological Guidance,
- Regulation (EC) No 10/2011 on plastic materials and articles intended to come into contact with food (last update January 20th 2025),
- Directive 89/391 - OSH "Framework Directive" on Safety and Health at Work (last update December 11th 2008),
- Regulations and Standards on end-of-life scenarios and Certification schemes and labels to provide the compliance (EN 13432, OK biodegradable SOIL and Biodegradable in Soil according to EN 17033),
- European Green Deal, Farm to Fork strategy, Mission “A Soil Deal for Europe”, Zero Pollution Action Plan, Chemicals Strategy for Sustainability.

The overall objective of the Regulations review is to provide the most updated tool to assess and validate the compliance of PHAntastic delivery systems with EU and national policies, ensuring the high protection of the human health and the environment against harmful substances, assess the safety of chemical substances used in the project and in developed products.

2. Introduction

2.1. Context and challenges

2.1.1. Agrochemicals: widespread use and impacts

Agrochemicals are chemical products, mainly fertilizers and pesticides (Plant Protection Products – PPPs -, and biocides), used in agriculture to maintain and increase productivity. In 2021, 90.1% of EU agricultural lands relied on agrochemicals, with consumption of fertilizers reaching 10.9 million tons, and sales of pesticides, 350 million tons[1,2,3]. These agrochemicals are responsible for doubling crop yields over the last century. However, they cause multiple negative impacts on environmental and human health. To lessen their effects, the EU aims at reducing by 50% fertilizer losses and use of chemical pesticides by 2030 as part of the Farm to Fork and other key policies and strategies (Zero Pollution Action plan, the Chemicals Strategy for Sustainability and the EU Missions also support these goals. Controlled polymer-based delivery systems preventing agrochemical losses (e.g., lixiviation, volatilization) and resulting excessive inputs are available. However, they are based on non-biodegradable polymers and generate plastic pollution. Other agricultural plastics (mulch films and growth foams) are used to maintain a prosperous plant environment and prevent agrochemical wash-off, minimizing the quantities to be applied. However, they also result in significant amounts of non-biodegradable plastics being released into environment.

However, the excessive use of agrochemicals causes severe impacts, contaminating wildlife, water, food, and endangering human health, from agricultural workers to consumers. In Europe, 81% of marine water, 31% of coastal water, 36% of rivers and 32% of lakes have been reported as eutrophic because of the indiscriminate use of fertilizers, while 45% of the fruit and vegetables available at EU supermarkets are polluted with pesticide residues according to the European Food Safety Authority (EFSA)[4,5].

There is therefore a pressing need to reduce the use and impacts of these inputs to guarantee the sustainability of our food systems while supporting human health. In line with these concerns, the EU has set ambitious goals of decreasing nutrient losses by 50% by 2030 and reducing the use and risk of chemical pesticides by 50% as part of the Farm to Fork strategy. Other policies and strategies such as the Mission “A Soil Deal for Europe”, the Zero Pollution Action Plan, the Chemicals Strategy for Sustainability also support these ambitious goals.

2.1.2. Agrochemicals, delivery systems and agricultural plastics: a quest for sustainability

Conventional agrochemical application methods entail a range of physical, chemical, and biological processes (e.g., volatilization, leaching) resulting in product losses and reduced efficacy, what usually leads to their excessive use. As an example, it is estimated that 64% of the total nitrogen applied to agricultural crops is lost to the environment, while 98% of sprayed insecticides and 95% of herbicides reach a destination other than their target species[6,7].

Over the last decades, a considerable scientific effort has been made to develop delivery systems (e.g., controlled release fertilizers – CRFs, polymer coated pesticides) to modulate specific aspects of agrochemicals application (e.g., release rate, specificity). These systems enhance efficiency, contributing to reduce application volumes and associated harmful impacts. However, most of these solutions incorporate oil-based and non-biodegradable plastics (e.g., PE, EVA), resulting in additional impacts in the long term (e.g., CRFs alone contribute to 100,000 tons of plastic residues every year)[8,9]. In line with these concerns, the new EU Fertilising Products Regulation (FPR) has set the obligation to eliminate all non-biodegradable polymers in fertilizing products by 2026[10]. Current compostable/biodegradable polymer alternatives are generally blends of oil and bio-based polymers (e.g., PLA, TPS, PBAT) that do not always completely degrade in agricultural soil.

In addition to these polymer-based delivery systems for agrochemicals, other agricultural plastics, such as mulch films and growth foams, are widely used to increase agricultural production. They are also mostly made of oil-based or not completely biodegradable plastics, resulting in multiple environmental (e.g., plastic pollution) and socioeconomic impacts (e.g., public disapproval, economic costs of removal). According to FAO, every year, at least 12.5 million tons of agricultural plastics are used globally.

2.1.3. PHA as substitute for current polymer carriers

Polyhydroxyalkanoates (PHAs) are a family of bio-based polymers produced by microorganisms. Their demonstrated biodegradability in all environments (soil, aquatic, and compost), safety and modifiability make them an effective alternative to non-biodegradable polymers in agricultural applications, including agrochemical delivery systems and other agricultural plastics. However, their implementation still faces several challenges, such as high production costs and processing issues.

PHAntastic project aims to overcome these challenges by combining different copolymers from the PHAs family such as Poly-3-hydroxybutyrate-co-3-hydroxyvalerate (PHBV, produced from agrifood residues), Poly-3-hydroxybutyrate-co-3-hydrohexanoate (PHBH), Poly-3-hydroxybutyrate-4- hydroxybutyrate (P34HB).

2.2. PHAntastic project and its objectives

PHAntastic project aims to substitute widely used agricultural plastics (mulch films and growth foams) by bio-based and completely biodegradable versions based on PHBV obtained from agri-food residues blended with commercial PHA grades, that deliver active bioproducts (bio-based fertilizers and Plant Protection Products - PPPs) instead of synthetic fertilizers and pesticides. PHAntastic will reach the double objective of reducing both agrochemicals and plastic inputs in our agricultural systems while protecting environmental and human health. The project will develop and demonstrate innovative delivery systems in collaboration with horticultural and fruit tree producers in Spain and The Netherlands:

- *mulch films: Biodegradable PHA-based mulch films for horticultural crops (e.g., lettuce, broccoli) incorporating bio-based fertilizers and PPPs.*
- *growth foams: Biodegradable PHA-based foams for growth of tree seedlings (citrus and ornamental), containing the same active bioproducts described for PHAntastic mulch films (bio-based fertilizers and PPPs).*

Besides developing these delivery systems for biopolymers, PHAntastic will tackle their risk, safety, sustainability, social and economic assessment throughout the whole product development process, in line with the Safe and Sustainable by Design (SSbD) framework and relevant regulations.

2.3. Specific objectives on Regulatory compliance

To reach the overall objective in terms of Regulatory compliance, several specific objectives are presented below:

- *PHAntastic delivery systems will be produced according to existing relevant standards of production and risk assessment to guarantee compliance with the Safe and Sustainable by Design framework (SSbD).*
- *PHAntastic delivery systems will be laboratory tested, including efficacy and possible toxicity and ecotoxicity on plant and soil.*
- *Final outputs will be validated with 4 end-users of 2 European countries (ES and NL) to ensure suitability to different climates and agricultural practices.*
- *Safety, environmental benefits and positive social and economic impacts, of PHAntastic delivery systems will be assessed in line with the Safe and Sustainable by Design (SSbD) framework.*

A thoughtful review of European and National regulations is carried out to ensure the regulatory fit of PHAntastic's solutions and described in the next paragraphs.

In particular, considering the experimental activities and implementations as defined within the first WPs, in terms of the selection and adaptation of active bioproducts for PHAntastic delivery systems (WP1), the development of PHA-based blends and processes for PHAntastic delivery systems (WP2), the laboratory production and testing of PHAntastic delivery systems and related testing (WP3) and the demonstration and validation of PHAntastic delivery systems on real-life case studies (WP4), the main regulatory topics are strictly linked as summarised in the next Table 1.

	WP1	WP2	WP3	WP4
European Regulations and Framework on environmental topics	✓	✓	✓	✓
REACH Regulation – Regulation EC 1907/2006	✓	✓	✓	
Soil directive - Regulation (EU) 2023/839 for land use, forestry, and agriculture	✓	✓	✓	✓
Pesticides Regulations	✓			✓
End of life Regulation and regulatory specifications	✓	✓	✓	✓
Safety Regulations and guidelines	✓	✓	✓	✓
Food contact material Regulations		✓	✓	✓
OSH "Framework Directive" (Directive 89/391)	✓	✓	✓	✓

Table 1. Correlation among PHAntastic WPs and considered Regulations.

3. European Regulations and Framework on environmental topics

The main **environmental Directives and Regulations** at European level are:

- European Green Deal, Farm to Fork strategy, Mission "A Soil Deal for Europe", Zero Pollution Action Plan, Chemicals Strategy for Sustainability are more general strategies and framework provided by European Commission;
- EU Water Framework Directive, by alignment with the objective of protecting the EU's water resources and ecosystems and ensuring all Europeans have access to clean drinking and bathing water;
- European Climate Law, by contributing towards the objective of achieving climate neutrality in 2050;
- Fit for 55 Package, by demonstrating alternatives that reduces GHG emissions in agriculture and promotes soils' health;
- Circular Economy Action plan and Chemicals Strategy for Sustainability, by promoting a truly circular economy process and assessing the innovations (technological solutions) along the entire life cycle (LCA);
- Bioeconomy strategy, the Biodiversity, Soil, Blue economy and Industrial strategies, as materials, circularity, and industrial technologies will be combined to use local raw materials (biowaste streams such as agri-food residues) to produce sustainable fertilizers and reclaimed water;
- Regulation (EU) No 2018/841 on the inclusion of greenhouse gas emissions and removals from land use, land use change and forestry in the 2030 climate and energy framework (last update May 11th 2023);
- Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage (last update June 26th 2019);

PHAntastic solutions will enhance soil and oceans health, the blue economy and the agro-industrial ecosystem and will contribute to meet the objectives of +12 EU policies and strategy commitments such as the EU Green Deal and the Sustainable Development Goals (SDGs), specifically:

- SDG6 (Clean water and sanitation, targets 6.4, 6.5, 6.6, 6b),
- SDG12 (Responsible production and consumption, targets 12.2, 12.4, 12.5, 12.6, 12.8),
- SDG13 (Climate action, target 13.2),
- SDG14 (Life below water, target 14.1),
- SDG15 (Life on land, targets 15.3, 15.5).

The European Union has implemented a range of regulations and initiatives aimed at promoting sustainability across various sectors. Here are some key regulations and frameworks:

European Green Deal: Launched in December 2019, the European Green Deal is a comprehensive roadmap aimed at making Europe the first climate-neutral continent by 2050. It includes measures to reduce greenhouse gas emissions, promote sustainable industry, and protect biodiversity.

EU Climate Directive: This law sets a legally binding target for the EU to achieve climate neutrality by 2050 and establishes a framework for setting intermediate targets and monitoring progress.

Fit for 55 Package: Introduced in July 2021, this package aims to reduce net greenhouse gas emissions by at least 55% by 2030 compared to 1990 levels. It includes revisions to existing legislation, such as the EU Emissions Trading System (ETS), and introduces new measures in sectors like transport and energy.

EU Taxonomy Regulation: This regulation, which came into effect in July 2021, establishes a classification system for environmentally sustainable economic activities. It aims to guide investments towards sustainable projects and activities.

Circular Economy Action Plan: Part of the European Green Deal, this plan aims to promote sustainable product design, reduce waste, and encourage recycling and reuse of materials. It includes initiatives for various sectors, including textiles, plastics, and electronics.

Biodiversity Strategy for 2030: This strategy aims to protect and restore ecosystems and biodiversity in the EU. It includes commitments to increase protected areas and restore degraded ecosystems.

Farm to Fork Strategy: This strategy aims to make food systems fair, healthy, and environmentally friendly. It includes measures to promote sustainable agriculture, reduce the use of pesticides, and encourage organic farming.

REACH Regulation: The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation aims to protect human health and the environment from the risks posed by chemicals. It requires companies to register chemical substances and assess their safety.

Waste Framework Directive: This directive sets the basic concepts and definitions related to waste management, including recycling and recovery targets, to promote a circular economy.

These regulations and initiatives reflect the EU's commitment to sustainability and its goal of transitioning to a more sustainable economy. These Regulations and Directives are briefly described in the next Paragraphs.

3.1. European Green Deal[11]

In December 2019, the European Commission presented the European Green Deal – a roadmap for making the EU's economy sustainable by turning climate and environmental challenges into opportunities across all policy areas and making the transition just and inclusive for all.

The European Green Deal provides a roadmap with actions to boost the efficient use of resources by moving to a clean, circular economy and stop climate change, revert biodiversity loss and cut pollution. It outlines investments needed and financing tools available and explains how to ensure a just and inclusive transition.

The European Green Deal covers all sectors of the economy, notably transport, energy, agriculture, buildings, and industries such as steel, cement, ICT, textiles and chemicals.

Figure 1. The European Green Deal.

To set into legislation the political ambition of being the world's first climate neutral continent by 2050, the Commission presented the first 'European Climate Law'. To reach climate and environmental ambition, the Commission presented the Biodiversity Strategy for 2030, the new Industrial Strategy and Circular Economy Action Plan, the Farm to Fork Strategy for sustainable food and proposals for pollution-free Europe.

Meeting the objectives of the European Green Deal requires significant investment. Achieving the current 2030 climate and energy targets is estimated to require €260 billion of additional annual investment, representing about 1.5% of 2018 GDP. This investment needs the mobilisation of the public and private sectors. The Commission presented in early 2020 a Sustainable Europe Investment Plan to help meet investment needs. At least 25% of the EU's long-term budget should be dedicated to climate action, and the European Investment Bank, Europe's climate bank, provided further support. For the private sector to contribute to financing the green transition, the Commission presented a Green Financing Strategy in 2020.

Fighting climate change and environmental degradation is a common endeavour but not all regions and Member States (MS) start from the same point. A Just Transition Mechanism supports those regions that rely heavily on very carbon intensive activities. It supports the citizens most vulnerable to the transition, providing access to reskilling programmes and employment opportunities in new economic sectors. In March 2020, the Commission launched a 'Climate Pact' to give citizens a voice and role in designing new actions, sharing information, launching grassroots activities and show-casing solutions that others can follow.

The global challenges of climate change and environmental degradation require a global response. The EU continues to promote its environmental goals and standards in the UN's Biodiversity and Climate Conventions and reinforce its green

diplomacy. The G7, G20, international conventions, and bilateral relationships are and will be used to persuade others to step up their efforts. The EU also uses trade policy to ensure sustainability and it can build partnerships with its neighbours in the Balkans and Africa to help them with their own transitions.

3.2. Farm to Fork Strategy[12]

The Farm to Fork Strategy is at the heart of the European Green Deal aiming to make food systems fair, healthy and environmentally-friendly. Food systems cannot be resilient to crises such as the COVID-19 pandemic if they are not sustainable. We need to redesign our food systems which today account for nearly one-third of global GHG emissions, consume large amounts of natural resources, result in biodiversity loss and negative health impacts (due to both under- and over-nutrition) and do not allow fair economic returns and livelihoods for all actors, in particular for primary producers. Putting our food systems on a sustainable path also brings new opportunities for operators in the food value chain. New technologies and scientific discoveries, combined with increasing public awareness and demand for sustainable food, will benefit all stakeholders.

The Farm to Fork Strategy aims to accelerate our transition to a sustainable food system that should:

- *have a neutral or positive environmental impact,*
- *help to mitigate climate change and adapt to its impacts,*
- *reverse the loss of biodiversity,*
- *ensure food security, nutrition and public health, making sure that everyone has access to sufficient, safe, nutritious, sustainable food,*
- *preserve affordability of food while generating fairer economic returns, fostering competitiveness of the EU supply sector and promoting fair trade.*

Figure 2. Farm to fork strategy.

The strategy sets out both regulatory and non-regulatory initiatives, with the common agricultural and fisheries policies as key tools to support a just transition. To enable and accelerate the transition to a fair, healthy and environmentally-friendly food system, advisory services, financial instruments, but also research and innovation are instrumental as they can help resolve tensions, develop and test solutions, overcome barriers and uncover new market opportunities.

3.3. European Climate Directive - Regulation (EU) 2021/1119[13]

The European Climate Law writes into law the goal set out in the European Green Deal for Europe's economy and society to become climate-neutral by 2050. The law also sets the intermediate target of reducing net greenhouse gas emissions by at least 55% by 2030, compared to 1990 levels.

Climate neutrality by 2050 means achieving net zero greenhouse gas emissions for EU countries as a whole, mainly by cutting emissions, investing in green technologies and protecting the natural environment. The law aims to ensure that all EU policies contribute to this goal and that all sectors of the economy and society play their part.

The objectives are:

- *Set the long-term direction of travel for meeting the 2050 climate neutrality objective through all policies, in a socially fair and cost-efficient manner*
- *Set a more ambitious EU 2030 target, to set Europe on a responsible path to becoming climate-neutral by 2050*
- *Create a system for monitoring progress and take further action if needed*
- *Provide predictability for investors and other economic actors*
- *Ensure that the transition to climate neutrality is irreversible*

The European Climate Law sets a legally binding target of net zero greenhouse gas emissions by 2050. The EU Institutions and the MS are bound to take the necessary measures at EU and national level to meet the target, taking into account the importance of promoting fairness and solidarity among MS. The Climate Law includes measures to keep track of progress and adjust actions accordingly, based on existing systems such as the governance process for MS' national energy and climate plans, regular reports by the European Environment Agency, and the latest scientific evidence on climate change and its impacts.

The Climate Law also addresses the necessary steps to get to the 2050 target:

- *Based on a comprehensive impact assessment, the EU has set a new target for 2030 of reducing net greenhouse gas emissions by at least 55% compared to levels in 1990. The new EU 2030 target is included in the Law.*
- *In July 2021, the Commission adopted a series of proposals to revise all relevant policy instruments to deliver the additional emissions reductions for 2030.*
- *The Law also includes a process for setting a 2040 climate target.*

The Climate Law includes:

- *a legal objective for the Union to reach climate neutrality by 2050,*
- *an ambitious 2030 climate target of at least 55% reduction of net emissions of GHG as compared to 1990, with clarity on the contribution of emission reductions and removals,*

- *recognition of the need to enhance the EU's carbon sink through a more ambitious LULUCF regulation, for which the Commission made a proposal in July 2021 and which entered into force in May 2023,*
- *a process for setting a 2040 climate target, considering an indicative GHG budget for 2030-2050 to be published by EC,*
- *a commitment to negative emissions after 2050,*
- *the establishment of European Scientific Advisory Board on Climate Change, that will provide independent scientific advice,*
- *stronger provisions on adaptation to climate change,*
- *strong coherence across Union policies with the climate neutrality objective,*
- *a commitment to engage with sectors to prepare sector-specific roadmaps charting the path to climate neutrality in different areas of the economy.*

3.4. Fit for 55 Package[14]

Introduced in July 2021, the Commission welcomed two final pillars of its 'Fit for 55' legislative package for delivering the EU's 2030 climate targets. This complete package of legislation shows that Europe is delivering on its promises made to citizens and international partners to lead the way on climate action and shape the green transition for the benefit of citizens and industries. The overall package includes emissions reduction targets across a broad range of sectors, a target to boost natural carbon sinks, and an updated emissions trading system to cap emissions, put a price on pollution and generate investments in the green transition, and social support for citizens and small businesses. To ensure a level playing field for European companies, the Carbon Border Adjustment Mechanism ensures that imported goods pay an equivalent carbon price on targeted sectors. The EU now has updated targets on renewable energy and energy efficiency, and will phase out new polluting vehicles by 2035, while boosting charging infrastructure and the use of alternative fuels in road transport, shipping and aviation.

The 'Fit for 55' package responds to the requirements in the EU Climate Law to reduce Europe's net greenhouse gas emissions by at least 55% by 2030. It was updated when the Commission proposed increased ambition on renewable energy and energy efficiency in the REPowerEU plan to respond to Russia's invasion of Ukraine and boost Europe's energy security. The final legislative package is expected to reduce EU net greenhouse gas emissions by 57% by 2030. While this legislative package is a central part of the European Green Deal, work continues on other pending legislative files and proposals, and on the implementation of legislation in the MS. The Energy Taxation Directive, an integral part of the Fit for 55 Package, remains to be completed, and the Commission urges MS to conclude negotiations as soon as possible.

The Fit for 55 package is a set of proposals to revise and update EU legislation and to put in place new initiatives with the aim of ensuring that EU policies are into line with the climate goals agreed by the Council and the European Parliament. The package of proposals aims at providing a coherent and balanced framework for reaching the EU's climate objectives, which:

- *ensures a just and socially fair transition,*
- *maintains and strengthens innovation and competitiveness of EU industry while ensuring a level playing field vis-à-vis third country economic operators,*
- *underpins the EU's position as leading the way in the global fight against climate change.*

In particular dealing with the MS' **emissions reduction targets**, the effort sharing regulation, last amended in 2018, sets binding annual greenhouse gas emissions targets for MS in sectors that are not covered by the EU Emissions Trading System (EU ETS) or the regulation on Land Use, Land Use Change and Forestry (LULUCF). These sectors include:

- *road and domestic maritime transport,*
- *buildings,*
- *agriculture,*
- *waste,*
- *small industries.*

The new rules, as part of the Fit for 55 Package, will increase the EU-level greenhouse gas emissions reduction target for 2030 from 29% to 40%, compared with 2005, in the sectors concerned. They will also update the national targets accordingly.

Furthermore, dealing with **emissions and removals from land use, land use change and forestry**, the LULUCF regulation sets a binding commitment for the EU to reduce emissions and increase removals in the land use and forestry sectors. With the Fit for 55 Package, the provisions are made more ambitious. The new rules set an increased EU-level target of at least 310 million tons of CO2 equivalent net removals of greenhouse gases for 2030. Binding national targets are defined for each member state.

The Environment Council adopted a general approach on the revised LULUCF regulation on 29 June 2022. A provisional agreement was reached with the European Parliament in November 2022. The regulation was adopted by the Council in March 2023.

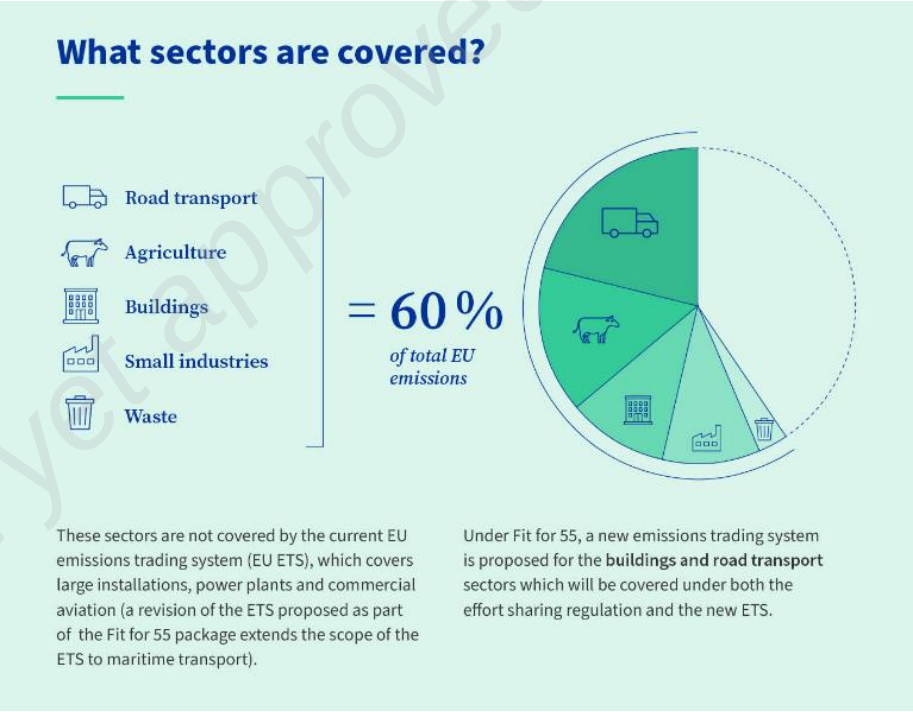

Figure 3. EU Emissions Trading System (EU ETS) and regulation on Land Use, Land Use Change and Forestry (LULUCF).

3.5. Circular Economy Action Plan[15]

The EU's new circular action plan paves the way for a cleaner and more competitive Europe; as part of the European Green Deal, this plan aims to promote sustainable product design, reduce waste, and encourage recycling and reuse of materials. It includes initiatives for various sectors, including textiles, plastics, and electronics.

The European Commission adopted the new Circular Economy Action Plan (CEAP) in March 2020. It is one of the main building blocks of the European Green Deal, Europe's new agenda for sustainable growth. The EU's transition to a circular economy will reduce pressure on natural resources and will create sustainable growth and jobs. It is also a prerequisite to achieve the EU's 2050 climate neutrality target and to halt biodiversity loss.

The action plan announces initiatives along the entire life cycle of products. It targets how products are designed, promotes circular economy processes, encourages sustainable consumption, and aims to ensure that waste is prevented and the resources used are kept in the EU economy for as long as possible. It introduces legislative and non-legislative measures targeting areas where action at the EU level brings real added value. Measures that will be introduced under the new action plan aim to:

- *make sustainable products the norm in the EU,*
- *empower consumers and public buyers,*
- *focus on the sectors that use most resources and where the potential for circularity is high such as: electronics and ICT, batteries and vehicles, packaging, plastics, textiles, construction and buildings, food, water and nutrients,*
- *ensure less waste,*
- *make circularity work for people, regions and cities,*
- *lead global efforts on circular economy.*

The Commission will implement all 35 actions listed in the action plan.

In 2023, the Commission revised the circular economy monitoring framework, previously adopted in 2018. The revision adds new indicators on

- *material footprint and resource productivity - to monitor material efficiency,*
- *consumption footprint – to monitor if EU consumption fits within planetary boundaries.*

The new framework supports the EU's circular economy and climate neutrality ambitions under the European Green Deal.

3.6. EU Taxonomy Regulation - Regulation (EU) 2020/852[16]

The Taxonomy Regulation entered into force on 12 July 2020. It establishes the basis for the EU taxonomy by setting out the 4 overarching conditions that an economic activity has to meet in order to qualify as environmentally sustainable. Under the Taxonomy Regulation, the Commission had to come up with the actual list of environmentally sustainable activities by defining technical screening criteria for each environmental objective through delegated and implementing acts.

1) **Climate change mitigation**: the proposed innovations will make a more efficient management of water in agricultural systems reducing the impact of water scarcity and decreasing the impact of erosion caused by runoffs and changes in hydrological patterns. Additionally, positive impacts on soils and water will contribute to food safety and security.

2) **Climate change adaptation**: PHAntastic has a strong focus on contributing to managing water resources at basin level and to reduce the use of synthetic fertilisers and landfilling of organic by-products which will reduce associated GHG emissions.

3) **The sustainable use of water and protection marine resources**: PHAntastic's approach will enhance the protection of water and marine resources through the promotion of practices and technologies related to efficient water management, fertigation, water retention and prevention tools that ensure water reservoirs protection and controlled use of fertilizers.

4) **The transition to a circular economy**: the project advocates for innovations and safe products that are locally sourced and that contribute to develop circular business models such as the bio-waste treatment as a resource, which is a key priority on the Circular Economy Action Plan.

5) **Pollution prevention and control**: PHAntastic promotes and integrates innovative technologies for fertigation, irrigation systems and alternative forms and supply of water with prevention tolls that will reduce leaching of nutrients to soil and water bodies, recovery of nutrients from agricultural waste and reduction in GHG emissions and pollutants transmission and accumulation to soil, water and ecosystems.

6) **The protection and restoration of biodiversity and ecosystems**: PHAntastic will have a positive impact on soil health and water status enhancing the restoration of degraded ecosystems and biodiversity. Harmful effects (e.g., eutrophication, nutrient losses) of synthetic chemicals affecting ecosystems and biodiversity will be reduced. Some innovations will enhance soil and crop biodiversity (e.g., compost bricks could create 'biodiversity islands' in the land).

3.7. Biodiversity Strategy for 2030[17]

The EU's biodiversity strategy for 2030 is a comprehensive, ambitious and long-term plan to protect nature and reverse the degradation of ecosystems. The strategy aims to put Europe's biodiversity on a path to recovery by 2030, and contains specific actions and commitments. It is the proposal for the EU's contribution to the upcoming international negotiations on the global post-2020 biodiversity framework. A core part of the European Green Deal, it will also support a green recovery following the Covid-19 pandemic.

The biodiversity strategy aims to put Europe's biodiversity on the path to recovery by 2030 for the benefit of people, climate and the planet. In the post-COVID-19 context, the strategy aims to build our societies' resilience to future threats such as:

- *the impacts of climate change*
- *forest fires*
- *food insecurity*
- *disease outbreaks - including by protecting wildlife and fighting illegal wildlife trade.*

The strategy contains specific commitments and actions to be delivered by 2030 such as launching an EU nature restoration plan, through concrete commitments and actions; the plan is for EU countries to put in place effective restoration measures to restore degraded ecosystems, in particular those with the most potential to capture and store carbon and to prevent and reduce the impact of natural disasters.

As part of this plan, the Commission proposed the EU's first ever Nature Restoration Law which includes an overarching restoration objective for the long-term recovery of nature in the EU's land and sea areas, with binding restoration targets for specific habitats and species.

Introducing measures to enable the necessary transformative change: the strategy highlights unlocking funding for biodiversity, and setting in motion a new, strengthened governance framework to:

- *ensure better implementation and track progress,*
- *improve knowledge, financing and investments,*
- *better respecting nature in public and business decision-making.*

Introducing measures to tackle the global biodiversity challenge: these measures will demonstrate that the EU is ready to lead by example to address the global biodiversity crisis. In particular, working towards the successful adoption of an ambitious global biodiversity framework under the Convention on Biological Diversity.

Two online tools track progress in implementing the strategy:

- *an online actions tracker provides up-to-date information on the state of implementation of the strategy's many actions,*
- *a targets dashboard shows progress to the quantified biodiversity targets set by the Strategy, at the EU level and in the MS.*

3.8. REACH Regulation – Regulation EC 1907/2006[18]

REACH establishes procedures for collecting and assessing information on the properties and hazards of substances. Companies need to register their substances and to do this they need to work together with other companies who are registering the same substance. ECHA receives and evaluates individual registrations for their compliance, and the EU MS evaluate selected substances to clarify initial concerns for human health or for the environment. Authorities and ECHA's scientific committees assess whether the risks of substances can be managed. Authorities can ban hazardous substances if their risks are unmanageable. They can also decide to restrict a use or make it subject to a prior authorisation.

Substance Identification: Substance identification is a process by which the identity of the substance is established. Accurate identification of a substance is a pre-requisite to most REACH, CLP and biocides processes. In particular, it enables joint REACH registrations to be prepared efficiently and correctly and ensures that test data is appropriate for the substance registered under REACH. This leads to a robust hazard and risk assessment of the registered substance.

Registration: companies are responsible for collecting information on the properties and uses of the substances they manufacture or import above one tonne a year. They also have to assess the hazards and potential risks presented by the substance. This information is communicated to ECHA through a registration dossier containing the hazard information and, where relevant, an assessment of the risks that the use of the substance may pose and how these risks should be controlled. Registration applies to substances on their own, substances in mixtures and certain cases of substances in articles. Registration is based on the "one substance, one registration" principle: this means that manufacturers and importers of the same substance have to submit their registration jointly. Potential manufacturers and importers of substances must submit an inquiry to ECHA and register the substance before they can manufacture or import the substance. REACH registration requires information on intrinsic properties of a substance. Companies manufacturing and importing chemicals are responsible for the safe use of their products. As registrants, they need to assess if their chemicals may cause adverse effects to human health and the environment. This is done based on reliable test results or by alternative information which is scientifically justified.

Chemical Safety Report (CSR) and Chemical Safety Assessment (CSA): a CSR is required for all substances subject to registration in quantities of 10 tons a year or more per registrant. The REACH Regulation requires registrants to prepare a registration dossier. This is composed of a technical dossier and, where relevant, a Chemical Safety Report (CSR), which summarises the results of a Chemical Safety Assessment (CSA). A CSR is only required if the registrant manufactures or imports a substance in quantities of 10 tons or more a year.

The CSR documents the CSA performed as part of the REACH registration process. The CSA results in the following outputs:

- *Assessment of any hazards,*
- *Identification of the conditions under which the risks from the manufacture and uses are under control, i.e. exposure scenarios,*
- *Documentation of relevant data, justifications and conclusions in a CSR,*
- *Communication down the supply chain,*
- *Information requirements for intermediates.*

Evaluation: given that registered substances are allowed to circulate freely on the internal market, companies must ensure that the information contained in their registration dossiers is correct at the time of registration and that any changes to this information are reported without delay. This stems from the principle of REACH that the registrants must ensure the substances used and placed on the market do not adversely affect human health or the environment. The REACH evaluation provisions give ECHA the responsibility to check whether registrations are in compliance with the requirements of this Regulation. ECHA and the MS evaluate the information submitted by companies to examine the quality of the registration dossiers and the testing proposals and to clarify if a given substance constitutes a risk to human health or the environment.

Evaluation under REACH focuses on three different areas: examination of testing proposals submitted by registrants, compliance check of the dossiers submitted by registrants and substance evaluation. Once the evaluation is done, registrants may be required to submit further information on the substance.

Authorisation:

- ***Substances of Very High Concern identification (SVHCs)****: The authorisation process aims to ensure that SVHCs are progressively replaced by less dangerous substances or technologies where technically and economically feasible alternatives are available. The route to authorisation starts when a Member State or ECHA, at the request of the Commission, proposes a substance to be identified as an SVHC. Substances with the following hazard properties may be identified as SVHCs:*
  - *Substances meeting the criteria for classification as Carcinogenic, Mutagenic or toxic for Reproduction (CMR) category 1A or 1B in accordance with the CLP Regulation.*
  - *Substances which are Persistent, Bioaccumulative and Toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH Annex XIII.*
  - *Substances on a case-by-case basis, that cause an equivalent level of concern as CMR or PBT/vPvB substances.*

  The SVHC identification process includes a 45-day consultation. Once a substance is identified as an SVHC, it is included in the Candidate List. The inclusion in the Candidate List brings immediate obligations for suppliers of the substance, such as: supplying a SDS, communicating on safe use, responding to consumer requests within 45 days and notifying ECHA if the article they produce contains an SVHC in quantities above one tonne per producer/importer per year and if the substance is present in those articles above a concentration of 0.1% (w/w).

- ***Adding SVHCs to the Candidate List****: the intention to propose a substance for identification as an SVHC is published in the registry of intentions before the proposal is submitted, to inform interested parties in advance of the submission. The proposal is prepared according to Annex XV to REACH and includes two main parts. The first one provides the data and justification for identifying the substance as an SVHC. The second part, examined during the follow-up steps after the identification, includes information on volumes on the EU market, the uses and possible alternatives to the substance.*

Restriction: restrictions are an instrument to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions are normally used to limit or ban the manufacture, placing on the market (including imports) or use of a substance, but can impose any relevant condition, such as requiring technical measures or specific labels. A restriction may apply to any substance on its own, in a mixture or in an article, including those that do not require registration, for example, substances manufactured or imported below one tonne per year or certain polymers. On-site isolated intermediates,

substances used in scientific research and development, and substances only posing risks to human health from their use in cosmetics are exempted from those substances to which REACH restriction applies.

3.9. Waste Framework Directive - amending Directive 2008_98_EC[19]

The Waste Framework Directive (see also Paragraph 5.1) sets the basic concepts and definitions related to waste management, including definitions of waste, recycling and recovery. It also regulates other important aspects such as when certain waste ceases to be waste and becomes a product, or a secondary raw material (end-of-waste criteria). It obliges the EU MS to separately collect textile waste as of January 2025. It also encourages MS to use Extended Producer Responsibility (EPR) schemes as an economic tool to achieve the objectives laid down in the Directive and it also provides some basic guidance on EPRs. In July 2023, the European Commission proposed a revision of the Regulation, including mandatory EPR for textiles and harmonisation in the management of textile waste.

The proposed directive sets binding targets on food waste reduction by 2030:

- *10% in processing and manufacturing,*
- *30% per capita in retail, restaurants, food services and households.*

The general approach agrees with the targets as proposed by the Commission and provides for the possibility to set targets for edible food waste by 31st December 2027, when the Commission will review the 2030 targets.

3.10. Water Framework Directive - Directive 2000/60/EC[20]

PHAntastic ensures compliance with the EU Water Framework Directive, which provides the suitable framework to address water scarcity and drought, as well as EU regulations such as the Regulation on minimum requirements for water reuse for agricultural irrigation, that establishes new rules to stimulate and facilitate water reuse in the EU, and the Recast of the EU Drinking Water Directive, that addresses leakage in the water supply networks.

Citizens, nature and industry all need healthy rivers and lakes, groundwater and bathing waters. The Regulation focuses on ensuring good qualitative and quantitative health, i.e. on reducing and removing pollution and on ensuring that there is enough water to support wildlife at the same time as human needs.

Since 2000, the Directive has been the main law for water protection in Europe. It applies to inland, transitional and coastal surface waters as well as groundwaters. It ensures an integrated approach to water management, respecting the integrity of whole ecosystems, including by regulating individual pollutants and setting corresponding regulatory standards. It is based on a river basin district approach to make sure that neighbouring countries cooperate to manage the rivers and other bodies of water they share.

The key objectives of the Directive are set out in Article 4 of the Directive. It requires MS to use their River Basin Management Plans (RBMPs) and Programmes of Measures (PoMs) to protect and, where necessary, restore water bodies in order to reach good status, and to prevent deterioration. Good status means both good chemical and good ecological status.

The Water Framework Directive is the primary legislation. It is supported by two so-called daughter directives on the quality and quantity of groundwater and on the quality of surface water. The Directive contains provisions regarding the deadlines for meeting the objectives of the Directive, as well as provisions on exemptions. The annexes to the Directive specify details as regards, for example, monitoring requirements, the criteria for assessing water body status, and the contents of the RBMPs.

At present, the Annex X includes the list of priority substances that MS must monitor in surface waters, but the standards for them are set in the Environmental Quality Standards Directive (EQSD) and must be met to achieve good surface water chemical status in accordance with WFD Article 4 and Annex V point 1.4.3. The Directive also requires MS to set and meet Environmental Quality Standards (EQS) for substances of national concern, i.e. river basin specific pollutants; the monitoring of which currently contributes to the assessment of ecological status. This list of priority substances needs to be reviewed, and updated, if necessary, every 6 years. Similarly, the list of pollutants and standards of EU-wide concern in Annex I to the Groundwater Directive (GWD) must also be reviewed every 6 years; these contribute to the assessment of chemical status in groundwater. That Directive also includes requirements as regards pollutant trends and quantitative status.

In December 2019, a Fitness Check concluded that the water legislation is broadly fit for purpose, with room for improvement related to investments, implementation, integrating water into other policies, chemical pollution, administrative simplification and digitalisation. The key findings show that the directives have led to a higher level of protection for water bodies and flood risk management than could have been expected without them. The objectives of the directives are as relevant now as they were at the time of the adoption, if not more. They contribute to achieving a range of sustainable development goals.

In October 2022, the Commission adopted a proposal to revise the lists of pollutants in surface water and groundwater. Some other amendments are also proposed.

3.11. Groundwater Directive (GWD) - Directive 2006/118/EC[21]

In order to meet demand and ensure sufficient quality for its use in human activities, groundwater needs to provide a safe and long-term sustainable source of water. As a finite resource, groundwater needs to be protected from pollution and over-exploitation. The EU legislation on protecting groundwater focuses on achieving good chemical status and good quantitative status. Measures must also be taken to prevent and limit the input of pollutants and reverse deteriorating trends in groundwater quality.

Groundwater is a precious resource hidden from sight, where pollution poses a serious threat. Over 95% of the world's freshwater, excluding glaciers and ice caps, is found underground. Groundwater provides the steady base flow of rivers and wetlands, being of utmost importance for these natural ecosystems, and it is at the same time the main source of water for human consumption, agriculture, industry and tourism. As groundwater moves slowly, the impact of human activities lasts for a relatively long time, meaning that pollution that occurred some decades ago is still threatening groundwater quality today.

The accumulation of some pollutants will continue for several generations to come. Remediation of groundwater to remove pollutants is very difficult, as is locating and measuring the presence and impacts of pollution on groundwater. This leads to a lack of awareness and evidence on its extent. Groundwater resources are also under increasing pressure from water abstraction and climate change. The EU's objectives include:

- *preventing and limiting groundwater pollution,*
- *ensuring that a sufficient quantity of good quality water is available for people's needs, the economy, and the environment,*
- *sustainably managing groundwater resources and preserving the natural ecosystems dependent on them,*
- *assessing groundwater bodies with the aim of achieving good chemical and quantitative status.*

The GWD provides the detailed procedures for meeting the Water Framework Directive's environmental objectives for groundwater quality. It sets EU-wide groundwater quality standards for a small number of pollutants in Annex I, requires MS to set threshold values for substances of national concern, including, where relevant, those listed in Annex II, and requires measures to be taken to prevent or limit the input of pollutants into groundwater. The GWD establishes quality criteria allowing further improvements to be made based on monitoring data and new scientific knowledge. It represents a proportionate and scientifically sound response to the requirements of the Water Framework Directive as it relates to assessments of chemical status of groundwater and the identification and reversal of significant and sustained upward trends in pollutant concentrations.

3.12. Environmental Quality Standards Directive (EQSD) - Directive 2008/105/EC[22]

Healthy surface water ecosystems are important for many reasons, not only for nature but also to ensure that citizens, agriculture and industry can access clean water. The health of surface waters is influenced by several factors including hydromorphology and pollution. The main legislation on inland, transitional and coastal surface waters focuses on achieving good ecological status and good chemical status.

The EU aims to ensure that all surface water bodies achieve good ecological and good chemical status. For the former, surface waters must respect certain minimum levels of so-called quality elements, including biological, hydromorphological, physic-chemical (including nutrients) and general quality elements. For good chemical status, surface waters must meet minimum quality standards for selected pollutants and must reduce or phase out the emissions of those substances to water.

MS must ensure that Environmental Quality Standards (EQS) set for the priority substances in the Directive are met in order to achieve good chemical status.

A Watch List mechanism was established in 2013 to improve the available information on identifying the substances of greatest concern. MS have to monitor the substances on the list at least once per year for up to four years. The watch list was established in 2015, updated in 2018 and 2020 and again in 2022.

In 2019, the Commission adopted a strategic approach to pharmaceuticals in the environment, a legal requirement of the Environmental Quality Standards Directive. It aims to counteract the negative effects of pharmaceuticals on the environment. It covers all phases of the lifecycle of pharmaceuticals, from design and production to use and disposal. It identifies over 30 actions in six areas, including:

- *raising awareness and promoting prudent use,*
- *improving training and environmental risk assessment,*
- *gathering monitoring data,*
- *promoting greener pharmaceutical design and manufacturing,*
- *reducing emissions from manufacturing,*
- *reducing waste and improve wastewater treatment.*

Good progress has been made in implementing these actions, as detailed in this 2020 overview. Some are already well advanced or even completed. Several Green Deal Initiatives and the Pharmaceutical Strategy will also help to achieve the objectives. The overview looks at the implementation as a whole and outlines how each action has been implemented so far, and any planned follow-up.

3.13. ABS Regulation - Regulation (EU) N. 511/2014[23]

Countries have sovereign rights over the genetic resources found on their territory. Genetic resources are any plant, animal or microbial materials that have value. They can be used in research and development for many different purposes, including in medical research or environmental innovation. Benefits can arise from research or development on genetic resources, including the commercial use of a developed product. These benefits should be shared fairly and equitably with the country providing these resources. This is the concept of "access and benefit sharing".

Objectives: in line with international agreements, the EU aims to ensure that benefits from genetic resources are shared fairly and equitably with the country providing these resources.

The Nagoya Protocol on "Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization" was adopted in 2010. It aims to establish a clear, legally binding framework determining how researchers and companies can obtain access to the genetic resources of a country and to the traditional knowledge associated with these resources. It also explains how the benefits arising from the use of these genetic resources and associated traditional knowledge will be shared. A video explains the access and benefit sharing concept in simple words.

The EU Access and Benefit Sharing (ABS) Regulation N. 511/2014 brings EU law into line with these international obligations and entered into force in 2014. These rules apply when genetic resources, and the traditional knowledge associated with them, are used in research and development for their genetic properties and/or biochemical composition, including through the application of biotechnology.

An Implementing Regulation (Commission Implementing Regulation (EU) 2015/1866, of 13 October 2015) contains measures on some specific aspects, as provided for in the EU ABS Regulation, in particular registered collections, best practices and

monitoring of user compliance. Currently there are three registered collections and one best practice recognised through a Commission Decision.

With regard to the monitoring of user compliance, a web-based application (DECLARE) was created to allow users to submit due diligence declarations online (see the user guide and audio-visual user's manual).

A guidance document on the scope of application and core obligations of the ABS Regulation was adopted in 2020. It incorporates and complements the previously adopted guidance document of 2016.

Designated Competent Authorities in EU MS are responsible for implementing the EU ABS Regulation. For information on possible access measures adopted by EU MS, please consult their country profile on the international ABS Clearing-House.

The Expert group on ABS under the Nagoya Protocol ensures a uniform implementation of the EU ABS Regulation across the EU and provides a platform for cooperation between the MS and with the European Commission. It shares information, best practices and lessons learnt and develops guidance for the users of genetic resources.

The Commission is also assisted by the ABS Consultation Forum, a group made of selected interested parties (mainly trade and business associations and NGOs) and the EU MS to provide advice and expertise to the Commission for the implementation of the EU ABS Regulation and its Implementing Regulation, and to facilitate coordination and cooperation with MS and stakeholders in that regard.

The Commission is required to submit a report on the application of the Regulation to the European Parliament and the Council, including an assessment of its effectiveness.

The first EU ABS Regulation Implementation Report was adopted on 24 January 2019. It covers the first three years of application of the Regulation (October 2014 - August 2017), which is reduced to two years of application for provisions concerning due diligence (Art. 4), monitoring of user compliance (Art. 7) and compliance checks (Art. 9).

It is based on information from the national reports submitted by all 28 MS to the Commission, as well as other information available. See MS' National Reports.

Precious tools for the implementation of the Nagoya Protocol are InforMEA, the United Nations Information Portal on Multilateral Environmental Agreements, and the Earth Negotiations Bulletin which provides a balanced and independent daily coverage at mainly UN-led sustainable development negotiations and events around the world.

3.14. Ecodesign for Sustainable Products Regulation (ESPR)[24]

The Ecodesign for Sustainable Products Regulation (ESPR), which entered into force on 18 July 2024, is the cornerstone of the Commission's approach to more environmentally sustainable and circular products. Products and the way we use them can significantly impact the environment. Consumption in the EU can, therefore, be a major cause of climate change and pollution. The ESPR is part of a package of measures that are central to achieving the aims of the 2020 Circular Economy Action Plan and

fostering the transition to a circular, sustainable, and competitive economy. It will contribute to helping the EU reach its environmental and climate goals, double its circularity rate of material use and achieve its energy efficiency targets by 2030.

The ESPR aims to significantly improve the sustainability of products placed on the EU market by improving their circularity, energy performance, recyclability and durability. It will also play a central role in developing a strong, well-functioning single market for sustainable products in the EU.

By doing so, a significant step will be taken towards better protecting our planet, fostering more sustainable business models and strengthening the overall competitiveness and resilience of the EU economy.

The ESPR replaces the Ecodesign Directive 2009/125/EC and establishes a framework for setting ecodesign requirements on specific product groups. It extends the Ecodesign Directive in two ways. Firstly, while the latter applies only to energy-related products, the ESPR extends this scope to cover virtually all physical products. Only a few exemptions apply, for example, for food and feed, and medicinal products. Secondly, the ESPR reinforces the range of ecodesign requirements that can be set for products, which can comprise requirements relating to durability, circularity and the overall reduction of the environmental and climate footprint of products, amongst many others.

This will strengthen the Single Market by avoiding diverging legislation in each Member State and create economic opportunities for innovation and job creation, notably in remanufacturing, maintenance, recycling and repair.

The ESPR enables the setting of performance and information rules – known as 'ecodesign requirements' – for almost all categories of physical goods, including:

- *Improving product durability, reusability, upgradability and reparability,*
- *Enhancing the possibility of product maintenance and refurbishment,*
- *Making products more energy and resource-efficient,*
- *Addressing the presence of substances that inhibit circularity,*
- *Increasing recycled content,*
- *Making products easier to remanufacture and recycle,*
- *Setting rules on carbon and environmental footprints,*
- *Limiting the generation of waste,*
- *Improving the availability of information on product sustainability.*

For groups of products that share enough common characteristics, the framework allows horizontal rules to be set.

The ESPR also contains a number of other new measures:

Digital Product Passport (DPP): The ESPR will introduce a Digital Product Passport, a digital identity card for products, components, and materials, which will store relevant information to support products' sustainability, promote their circularity and strengthen legal compliance. This information will be accessible electronically, making it easier for consumers, manufacturers, and authorities to make more informed decisions related to sustainability, circularity and regulatory compliance. It will also allow custom authorities to perform automatic checks on the existence and authenticity of the DPPs of

imported products. Information to be included in the DPP will be identified by the Commission, in close consultation with all relevant stakeholders, and will depend on the specific product in question. This information can include:

- *Product's technical performance,*
- *Materials and their origins,*
- *Repair activities,*
- *Recycling capabilities,*
- *Lifecycle environmental impacts,*
- *Rules to address destruction of unsold consumer products.*

Many unsold products in the EU are simply destroyed, a practice that wastes valuable resources. For the first time in the EU, the ESPR introduces measures to address this practice by introducing a ban on the destruction of unsold textiles and footwear, opening the way for similar bans in other sectors if evidence shows they are needed. It will also require large and eventually medium-sized companies across all product sectors to disclose annual information on unsold consumer products on their website, such as the number and weight of products they discard, as well as their reasons for doing so.

Green Public Procurement (GPP): Public authorities in the EU spend around €1.8 trillion purchasing works, goods and services. The ESPR will help steer these funds in a more sustainable direction by enabling mandatory GPP rules to be set for specific products. Under those rules, public authorities who purchase the products concerned will be required to purchase products that meet the highest levels of performance in terms of sustainability and circularity. This has the potential to significantly boost demand for sustainable products, in turn, further incentivising companies to invest in this area.

The ESPR is a type of framework legislation and lays the foundation for the subsequent adoption of concrete rules, either on a product-by-product basis or horizontally - on the basis of groups of products with similar characteristics. The process will begin with a prioritisation exercise. In the first half of 2025, the Commission will adopt the first ESPR working plan, setting out which products will be prioritised over the coming years. Development of product rules will then start, based on inclusive planning, detailed impact assessments and regular stakeholder consultation within a dedicated Ecodesign Forum.

3.15. Soil directive - Regulation (EU) 2023/839 for land use, forestry, and agriculture[25]

This Regulation makes amendments in Regulation (EU) 2018/841 and Regulation (EU) 2018/1999 in line with the ambition to increase net greenhouse gas removals to levels above 300 million tons of CO2 equivalent in the LULUCF sector by 2030. It extends the subject matter and its scope of the Regulation (EU) 2018/841 according to 2030 Union target for net greenhouse gas removals in the LULUCF sector. It also makes amendments regarding the commitments, national targets and flexibilities of the MS; land use mechanism for the period 2026 to 2030; and review of Regulation (EU) 2018/841 taking into account international developments, efforts undertaken to achieve the long-term objectives of the Paris Agreement, and Union law, including on nature restoration. Regulation (EU) 2023/839 has applied since 11th May 2023.

The land use sector encompasses the management of cropland, grassland, wetlands, forests, settlements, as well as changes in land use including afforestation (i.e., planting trees), deforestation, or draining of peatlands. With agricultural and forest lands covering more than three-quarters of the EU's territory, the land use sector offers significant carbon sequestration and emission reduction opportunities.

Land can serve as both a carbon sink, absorbing CO_2 from the atmosphere, and a carbon source, releasing CO_2 through activities such as deforestation. Sustainable land management practices, including afforestation and protection of existing carbon stocks, have great potential for carbon sequestration. Moreover, carbon can be stored in the long term in durable products made of sustainably sourced wood.

Climate change-related challenges – such as wildfires, windthrow, and pest vulnerabilities, as well as unsustainable management practices – are threatening the capacity of the land use sector to act as a net carbon sink, absorbing more CO_2 from the atmosphere than it emits. Climate change is also causing losses in agricultural production and reducing suitable areas for crop cultivation. These challenges are putting the livelihoods of those dependent on the sector in danger.

To address the above-mentioned challenges and leverage opportunities for climate action, the EU has implemented robust legislative frameworks. One of those is the revised Regulation on land use, land use change, and forestry (LULUCF), which aims to enhance governance, promote transparency, and strengthen the link between climate mitigation and environmental protection measures.

3.16. Directive 2004/35/EC on prevention and remedying of environmental damage (last update June 26th 2019)[26]

With a view to preventing and remedying environmental damage, the present Directive establishes a framework of environmental liability based on the "polluter-pays" principle. For the purposes of this Directive, environmental damage includes damage to protected species and natural habitats, water damage and land damage, as defined in Article 2. Article 3 defines the application scope, which encompasses the following: (a) environmental damage caused by any of the occupational activities listed in Annex III, and to any imminent threat of such damage occurring by reason of any of those activities; (b) damage to protected species and natural habitats caused by any occupational activities other than those listed in Annex III, and to any imminent threat of such damage occurring by reason of any of those activities, whenever the operator has been at fault or negligent. Articles 5 and 6 require MS to adopt internal provisions as regards preventive action and remedial action to be taken by operators. According to articles 7 and 8, the operators shall identify potential remedial measures in accordance with Annex II and bear the costs for the preventive and remedial actions taken pursuant to this Directive.

The natural or legal persons (a) affected or likely to be affected by environmental damage or (b) having a sufficient interest in environmental decision making relating to the damage or, alternatively, (c) alleging the impairment of a right, where administrative procedural law of a Member State requires this as a precondition, shall be entitled to submit to the competent authority any observations relating to instances of environmental damage or an imminent threat of such damage of which they are aware and shall be entitled to request the competent authority to take action under this Directive (Article 12). This Directive

sets out six annexes attached. Annex I lays down the criteria to be taken into consideration to assess the significance of adverse effects on protected species and natural habitats. Annex II sets out a common framework to be followed in order to choose the most appropriate measures to ensure the remediation of environmental damage.

3.17. Regulation (EU) No 2018/841 (last update May 11th 2023)[27]

This Regulation applies to emissions and removals of the greenhouse gases (as listed in Section A of Annex I) reported pursuant to article 7 of Regulation (EU) No. 525/2013 and that occur in any of the following land accounting categories on the territories of MS: afforested lands; deforested lands; managed cropland; managed grassland; managed forest land. The objective is to include agriculture and forestry into European climate mitigation efforts. This decision is a direct response to revise the accounting rules for GHG emissions and removals from forests and soils. It meets international standards by maintaining the voluntary nature of accounting for draining and rewetting of wetlands. The rules are intended to better recognise the efforts of farmers and forest owners to maintain carbon stored in soils and forests and to facilitate a more climate-friendly architecture (funds are available through the Common Agricultural Policy's Rural Development pillar), protecting water resources and biodiversity. It also contains reporting requirements for MS on their initiatives to decrease emissions from forestry and agriculture-related activities as well as increase the carbon sink.

On 19 April 2023, Regulation (EU) 2018/841 was amended by Regulation (EU) 2023/839 to simplify reporting and compliance rules and alter the expectations for setting 2030 emission removal targets to align with the EU's updated 55% reduction target.

4. Pesticides Regulations

In Europe, pesticide regulation is primarily governed by the European Union (EU), with key legislation focusing on the approval, use, and monitoring of pesticides. The regulations are designed to protect human health, the environment, and biodiversity. The European Union benefits from one of the most stringent systems in the world for authorising and controlling the use of pesticides. Pesticide Regulation in Europe is robust, with a focus on safety, transparency, sustainability, and reducing the environmental impact of pesticide use. Regulations are periodically updated to reflect new scientific evidence and societal concerns, with a long-term goal of reducing pesticide dependency in agriculture.

More specifically, the most relevant regulations related to **Fertilisers and Pesticides** include:

- Regulation EU No 2019/1009 on Fertilising Products (last update November 20th 2024),
- Regulation EU No 528/2012 on use of biocidal products (last update June 11th 2024),
- Directive 2009/128/EC on sustainable use of pesticides (last update July 26th 2019),
- Regulation EC No 1107/2009 on plant protection products (last update November 21st 2022),
- Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin (last update January 08th 2025),
- Regulation (EU) No 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (last update January 05th 2025),
- Regulation (EC) No 2022/2379 on statistics on agricultural input and output (last update November 23rd 2022).

Here below, a brief presentation of the main current Regulations is provided.

4.1. Fertilisers regulation (Reg. EU 2019/1009) – updated Nov. 20th 2024[28]

This Regulation lays down provisions on fertilizing products. The application scope does not include the following: (a) animal by-products or derived products which are subject to the requirements of Regulation (EC) No. 1069/2009 when made available on the market; (b) plant protection products covered by the scope of Regulation (EC) No. 1107/2009.

As a general rule, the Regulation promotes free movement of fertilizers: MS shall not impede, for reasons relating to composition, labelling or other aspects covered by this Regulation, the making available on the market of EU fertilising products which comply with these provisions. Product requirements are laid down under Annexes I, II and III. These requirements concern the relevant product function category, the relevant component material category or categories and labelling.

The Regulation establishes specific obligations of manufacturers, distributors and importers as regards requirements to be met by fertilizers placed on the market. Presumption of conformity is foreseen under article 13: EU fertilising products which are in conformity with harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements set out in Annexes I, II and III covered by those standards or parts thereof.

The Regulation is composed of the following Chapters: I) General provisions; II) Obligations of economic operators; III) Conformity of EU fertilising products; IV) Notification of conformity assessment bodies; V) Union market surveillance, control of EU fertilising products entering the Union market and Union safeguard procedure; VI) Delegated powers and Committee procedure; VII) Amendments; VIII) Transitional and final provisions.

4.2. Regulation EU No 528/2012 on use of biocidal products - updated June 11th 2024[29]

This Regulation lays down harmonized rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment. The provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to safeguard the health of humans, the health of animals and the environment. These rules concern in particular:

(a) the establishment at EU level of a list of active substances which may be used in biocidal products;

(b) the authorization of biocidal products;

(c) the mutual recognition of authorizations within the Union;

(d) the making available on the market and the use of biocidal products within one or more MS or the EU;

(e) the placing on the market of treated articles.

This Regulation sets out articles relating to the approval of active substances; general principles concerning the authorization of biocidal products; simplified authorisation procedure; national authorizations of biocidal products; authorization through mutual recognition; Union authorizations of biocidal products; cancellation, review and amendment of authorizations; parallel trade; technical equivalence; placing on the market of treated articles; monitoring, record keeping and reporting; establishment of the Register for biocidal products; the role of the Agency and the Biocidal Products Committee; and adaptation to scientific and technical progress.

4.3. Directive 2009/128/EC on the sustainable use of pesticides (SUD Regulation)[30]

Directive 2009/128/EC aims to achieve a sustainable use of pesticides in the EU by reducing the risks and impacts of pesticide use on human health and the environment and promoting the use of Integrated Pest Management (IPM) and of alternative approaches or techniques, such as non-chemical alternatives to pesticides. EU countries have drawn up National Action Plans to implement the range of actions set out in the Directive.

The SUD forms part of the EU legal framework covering pesticides and their use. By promoting the use of integrated pest management and of alternative approaches and techniques, such as non-chemical alternatives to pesticides, the SUD supports the achievement of the targets set out in the Farm to Fork Strategy for reducing the risks and use of pesticides.

Commission Staff Working Paper Accompanying the Proposal for a Directive of the European Parliament and of the Council establishing a framework for Community action to achieve a sustainable use of pesticides. The main actions relate to training of users, advisors and distributors of pesticides, inspection of pesticide application equipment, the prohibition of aerial spraying, limitation of pesticide use in sensitive areas, and information and awareness raising about pesticide risks. EU countries must also promote Integrated Pest Management, for which, general principles are laid down in Annex III to the Directive.

4.4. Regulation (EC) N. 1107/2009 on authorization of plant protection products[31]

This Regulation lays down rules for the authorization of plant protection products in commercial form and for their placing on the market, use and control within the European Union. It sets out, on the one hand, rules for the approval of active substances, safeners and synergists, which plant protection products contain or consist of, and, on the other hand, rules for adjuvants and co-formulants. The purpose of these provisions is to ensure a high level of protection of both human and animal health and

the environment and to improve the functioning of the internal market through the harmonization of the rules on the placing on the market of plant protection products, while improving agricultural production.

The Directive recalls the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, MS shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory.

Chapter II lays down detailed requirements and conditions for approval of active substances, safeners, synergists and co-formulants. Chapter III is devoted to plant protection products (requirements and content, authorization for use), whereas Chapter IV concerns adjuvants. Plant protection products shall be used properly. Proper use shall include the application of the principles of good plant protection practice and compliance with prescribed conditions. It shall also comply with the provisions of Directive 2009/128/EC and, in particular, with general principles of integrated pest management.

Chapter IX on emergency measures lays down the regulatory procedure to be taken immediately where it is clear that an approved active substance, safener, synergist or co-formulant or a plant protection product which has been authorized in accordance with this Regulation is likely to constitute a serious risk to human or animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State concerned.

This is the primary regulation for the approval of active substances and the placing of plant protection products (pesticides) on the market in the EU. It outlines:

- *Approval Process: Active substances must be approved by the European Commission before they can be included in plant protection products. The EFSA conducts risk assessments for active substances.*
- *Risk Assessment: Pesticides are assessed for their impact on human and animal health, as well as the environment (including soil, water, and non-target species).*
- *Market Authorization: Once active substances are approved, individual EU MS can authorize specific plant protection products for use within their jurisdictions.*

4.5. Regulation (EC) N. 396/2005 on maximum residue levels of pesticides[32]

With a view to ensuring a high level of consumer protection, the present Regulation lays down provisions relating to maximum levels of pesticide residues in or on food and feed of plant and animal origin. The Regulation is composed of the following Chapters:

(I) *Subject matter, scope and definitions;*
(II) *Procedure for application for MRLs;*
(III) *MRLs applicable to products of plant and animal origin;*
(IV) *Special provisions relating to the incorporation of existing MRLs into this Regulation;*

(V) Official controls, reports and sanctions;
(VI) Emergency measures;
(VII) Support measures relating to harmonized pesticide MRLs;
(VIII) Coordination of applications for MRLs;
(IX) Implementation;
(X) Final provisions.

As main information, this regulation sets Maximum Residue Levels (MRLs) for pesticide residues in food and feed products to protect consumers. MRLs are established based on safety assessments and are regularly reviewed:

- *MRLs ensure that pesticide residues in food products are within safe limits.*
- *MRLs can vary depending on the type of product and the pesticide used.*

4.6. Regulation (EU) N. 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products[33]

This Regulation lays down rules for: (a) the performance of official controls and other official activities by the competent authorities of the MS; (b) the financing of official controls; (c) the administrative assistance and cooperation between MS in view of the correct application of the rules; (d) the performance of controls by the Commission in MS and in third countries; (e) the adoption of conditions to be fulfilled with respect to animals and goods entering the European Union from a third country; (f) the establishment of a computerized information system to manage information and data in relation to official controls. The objective is to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products. Therefore this Regulation shall apply to the official controls performed for the verification of compliance with the rules, whether established at European Union level or by the MS, to apply European Union legislation, in the areas of: (a) food and food safety, integrity and wholesomeness at any stage of production, processing and distribution of food, including rules aimed at ensuring fair practices in trade and protecting consumer interests and information, and the manufacture and use of materials and articles intended to come into contact with food; (b) deliberate release into the environment of Genetically Modified Organisms (GMOs) for the purpose of food and feed production; (c) feed and feed safety at any stage of production, processing and distribution of feed and the use of feed, including rules aimed at ensuring fair practices in trade and protecting consumer health, interests and information; (d) animal health requirements; (e) prevention and minimisation of risks to human and animal health arising from animal by-products and derived products; (f) welfare requirements for animals; (g) protective measures against pests of plants; (h) requirements for the placing on the market and use of plant protection products and the sustainable use of pesticides, with the exception of pesticides application equipment; (i) organic production and labelling of organic products; (j) use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed.

4.7. Regulation (EU) 2022/2379 on statistics on agricultural input and output[34]

This Regulation establishes an integrated framework for aggregated European statistics relating to the input and output of agricultural activities, as well as the intermediate use of such output within agriculture and its collection and processing. Article 5 lays down the domains and topics statistics on animal production, crop production, agricultural price, nutrients, and plant protection products. The data shall be transmitted to the Commission (Eurostat) in the form of aggregated data sets. The MS shall take the necessary measures to ensure the quality of the data and metadata transmitted.

5. End of life Regulation and regulatory specifications

All main information on specific Regulations and details for the End of Life (EoL) are described in the following paragraphs.

The most relevant regulations related to **EoL scenarios** are:

- Waste Framework Directive - amending Directive 2008_98_EC
- Packaging and Packaging Waste Regulation 2025/40 (PPWR)
- Regulations and Standards on end-of-life scenarios (EN 13432, EN 17033)
- Certification schemes and labels to provide the compliance (OK biodegradable SOIL and Biodegradable in Soil)

The identified PHAntastic solutions will be evaluated according to the regulatory specifications and requirements, defined in these Standards and any other European and National regulations.

5.1. Waste Framework Directive, amending Directive 2008_98_EC[35]

The Waste Framework Directive sets the basic concepts and definitions related to waste management, including definitions of waste, recycling and recovery. It regulates other important aspects such as when certain waste ceases to be waste and becomes a product, or a secondary raw material (end-of-waste criteria). It obliges the EU MS to separately collect textile waste as of January 2025. It also encourages MS to use Extended Producer Responsibility (EPR) schemes as an economic tool to achieve the objectives laid down in the Directive and it also provides some basic guidance on EPRs. In July 2023, the European Commission proposed a revision of the Regulation, including mandatory EPR for textiles and harmonisation in the management of textile waste.

The proposed directive sets binding targets on food waste reduction by 2030:

- *10% in processing and manufacturing,*
- *30% per capita in retail, restaurants, food services and households.*

The general approach agrees with the targets as proposed by the Commission and provides for the possibility to set targets for edible food waste by 31 December 2027, when the Commission will review the 2030 targets.

The revised EU WFD establishes concepts and definitions related to waste management, including recycling and recovery. It outlines when waste should be considered a secondary raw material, allowing stakeholders to distinguish between waste and by-products. Additionally, it lays out waste management principles, requiring that waste be managed without endangering human health or the environment, with an emphasis on waste prevention. The main key features are:

- *Introduces binding waste reduction targets.*
- *Establishes a hierarchy for waste processing.*
- *Improves recycling systems within the EU.*
- *Facilitates waste recovery through decontamination.*
- *Outlines mandatory requirements for a centralized database containing information on Substances of Concern In articles, as such or in complex objects (Products).*

It outlines comprehensive measures for waste management across MS. It mandates the establishment of an integrated network of waste disposal and recovery installations, allowing states to regulate waste shipments to protect their networks and environment. MS must develop detailed waste management plans, which must include information on waste types, quantities, sources, projections, and existing disposal and recovery installations. These plans must also address special arrangements for hazardous waste and waste containing critical raw materials and assess future installation needs.

The directive's key focus is waste prevention promoting sustainable production and consumption models. It also encourages the design and manufacture of resource-efficient, durable, and reparable products, with particular attention to those containing critical raw materials.

The directive also promotes reuse and repair systems, especially for electronics, textiles, furniture, and construction materials. It emphasises the importance of making spare parts and repair information available and calls for waste reduction in industrial production and mineral extraction processes.

5.1.1. Proposal for a Targeted Revision of the Waste Framework Directive (2025)

On 19 February 2025, the Council of the EU and the European Parliament (the co-legislators) reached a provisional agreement on the targeted revision of the WFD. The agreement introduces mandatory Extender Producer Responsibility (EPR) schemes for textiles across all EU MS and includes a provision allowing MS to eco-modulate EPR fees based on extrinsic product durability.

5.1.2. Extended Producer Responsibility (EPR)

Many EU MS have implemented national laws and EPR schemes that require producers to take responsibility for the end-of-life management of their products, including biodegradable bioplastics. These schemes often incentivize the use of recyclable or compostable materials.

With the targeted revision of the WFD, each Member State will set up its own EPR scheme for textile and footwear products. Under such schemes, for instance, textile producers will contribute to the management of used and waste textiles.

5.2. Packaging and Packaging Waste Regulation 2025/40 (PPWR)[36]

The rules for packaging and packaging waste were first laid out in the Packaging and Packaging Waste Directive 94/62/EC (PPWD). The directive was repealed by the Packaging and Packaging Waste Regulation 2025/40 (PPWR), which entered into force on 11 February 2025. Its general date of application is 18 months after that. The PPWR regulates what kind of packaging can be placed on the EU market and packaging waste management and prevention measures. The regulation mandates that packaging must be designed for recyclability or compostability, aligning with circular economy principles: All packaging must comply with essential requirements related to its manufacturing, composition, and reusable or recoverable nature.

The key documents are the approved regulation and some more commentaries. The delegated acts linked to the Regulation will be implemented by 12 August 2026.

5.3. EN 13432:2000 – "Packaging - Requirements for packaging recoverable through composting and biodegradation - Test scheme and evaluation criteria for the final acceptance of packaging"[37]

The mandatory parameters and specific requirements for soil are:

Chemical characteristics: low levels of heavy metals concentrations, in particular for Arsenic, Cadmium, Chrome, Copper, Mercury, Molybdenum, Nickel, Lead, Selenium and Zinc, and Fluorine content have to comply with specified limit values defined in the European Standard EN 13432:2000.

Biodegradation (metabolic conversion of the plastic material to carbon dioxide): > 90% (absolute or relative) within 6 months. The preferred testing method is a compost biodegradation test according to ISO 14855.

Note. All constituents and their maximum concentrations as specified on the positive list (technical sheet ref. TS-OK10) are regarded as fulfilling the biodegradation requirements.

Disintegration (fragmentation below 2 mm size with no visible contamination): Disintegration requirements must be met according to EN-13432. At 12 weeks from the start of disintegration, the material must be fragmented, with no particles or fragments smaller than 2 mm x 2 mm.

Environmental safety (Ecotoxicity, no negative effects in compost): Germination rate > 90% and Biomass growth > 90% black compost sample.

Note. All constituents and their maximum concentrations as specified on the positive list (ref. TS-OK10) are regarded as fulfilling the compost quality requirements. All food additive approved ingredients are regarded as fulfilling the compost quality requirements. Constituents that appear on the (candidate) list of Substances of Very High Concern (Annex XIV or the REACH) are not accepted.

5.4. EN 17033:2018 - Plastics - Biodegradable mulch films for use in agriculture and horticulture - Requirements and test methods[38]

The standard was developed in January 2018 by the European Committee for Standardization, Technical Committee CEN/TC 249 Plastics and applies to all European Union countries. This standard regulates the requirements for biodegradable plastic mulch films (BDMs): their composition, biodegradability in soil, effect on the soil environment (ecotoxicity), mechanical and optical properties, and the test procedures for each of the listed categories.

Until the release of EN 17033, no standard existed that was issued by an international organization. This standard is an important achievement that will hopefully facilitate increased replacement of conventional polyethylene mulches by BDMs in the production of fruits, vegetables and other specialty crops. The EoL options for polyethylene mulches are undesirable: landfilling or recycling, stockpiling or illegal burning. Plastic fragments remaining in the field or formed from stockpiles are likely to be dispersed in the environment, where they are a hazard to biota. Fragmentation is exacerbated by sunlight and other environmental factors, leading to embrittlement. The fragments can further degrade into micro- and nano-plastics, which can lead to further harm.

EN 17033 requires laboratory testing and specific criteria associated with the tests are given in Table 2:

- *chemical composition (in particular for regulated metals and hazardous substances,*
- *biodegradation in soil,*
- *ecotoxicity (i.e., toxic effects on plants, invertebrates, microorganisms),*
- *selected physical characteristics (e.g., thickness, tensile stress, light transmission).*
    - *The major criterion of EN 17033 is the requirement of ≥90% biodegradation under aerobic conditions for the plastic (i.e., conversion of organic carbon into CO2) in a natural topsoil from an agricultural field or forest at 20 – 28°C conditions within 2 years using a standardized test to measure CO_2 respiration.*
    - *The ecotoxicity tests are more stringent than those of ASTM D6400, for instance, involving plants, invertebrates (earthworms), and microorganisms. The three levels of ecotoxicity tests pertain to different soil exposure pathways, i.e., soil solid material, pore water, and pore gases. Plants and microorganisms would experience toxicants mainly through contact and uptake of soil pore water, while earthworms would also be exposed to toxicants through ingestion of soil material and the soil's gas phase.*

	Criterion	Test Method	Defined requirements
Constituents	Heavy metals	EN 17294-2	Zn < 150 mg/kg Cd and Hg <0.5 mg/kg Cr, Cu, Pb <50 mg/kg Ni <25 mg/kg
	Hazardous substances of "very high concern"	/	< 0,1%
	Loss of ignition at 550°C	/	≥ 60%
Biodegradation	Operated at 20-28°C (25°C ± 2°C preferred)	ISO 17556	≥90% conversion of mulch's carbon into CO_2 within 2 years under ambient soil conditions
Ecotoxicity	No acute ecotoxicity to plants	OECD 208	≥90% of germination rate and plant growth achieved compared to mulch-free soil
	No acute ecotoxicity to invertebrates Earthworms (Eisenia fetida or E. andrei)	ISO 11268-1 & -2	<10% difference in mortality rate and biomass amount compared to mulch-free soil
	No acute toxicity to microorganisms (nitrification inhibition of bacteria))	ISO 15685	nitrification should be ≥80% of that achieved for BDM-free soil
Dimensional, mechanical, and optical properties	Tensile stress at break MD and TD refer to machine direction and transverse direction, respectively.	ISO 727-1 and -3	≥18 MPa (MD) ≥ 16 MPa (TD) Films of <10 µm must possess tensile stress of ≥16 mPa
	Light transmission	/	≤3% (only for black and opaque films)
Miscellaneous	Proper labelling; preparation of a test report by manufacturer	/	/
	Surface area	Annexes G and H of EN 17033	not decrease <10% during deployment

Table 2. Testing requirements and criteria for biodegradable plastic mulches, as outlined in EN 17033.

5.5. Certification schemes and labels

5.5.1. OK biodegradable SOIL (TÜV Austria's certification scheme)[39]

The "OK biodegradable SOIL" scheme of certification (developed by TÜV Austria) is considered for the biodegradability assessment and verification. This scheme can be applied on raw materials, components and constituents also known as intermediate products and finished products for horticultural and agricultural application that have a function in the same environment (soil) where they are meant to biodegrade. The mandatory parameters and specific requirements are:

Chemical characteristics: low levels of heavy metals concentrations, in particular for Arsenic, Cadmium, Chrome, Copper, Mercury, Molybdenum, Nickel, Lead, Selenium and Zinc, and Fluorine content have to comply with specified limit values defined in EN 13432.European Standard EN 13432:2000.

Note. All organic constituents on the positive list (ref. TS-OK-10) are regarded as fulfilling the chemical characteristics requirements. All inorganic constituents on the positive list (technical sheet ref. TS-OK-10) are regarded as fulfilling the chemical characteristics requirements except for the limitations of the elements Hg, Cd, Pb, Cu, Cr and Zn, which still have to be measured. All food additive approved ingredients are regarded as fulfilling the chemical characteristics requirements.

Biodegradation (metabolic conversion of the plastic material to carbon dioxide): > 90% (absolute or relative) within 2 years.

Note. The preferred type of biodegradation test is a soil biodegradation test according to ISO 17556.2, ISO 11266 or ASTM D.5988-96.

Disintegration (fragmentation below 2 mm size with no visible contamination): No disintegration requirements must be met. Nevertheless, materials or products containing constituents or components that include an evident risk of visual contamination are not accepted.

Environmental safety (Ecotoxicity, no negative effects on the final compost): Germination rate > 90% and Biomass growth > 90% compared with blank compost.

Note. All constituents and their maximum concentrations as specified on the positive list (ref. TS-OK10) are regarded as fulfilling the compost quality requirements. All food additive approved ingredients are regarded as fulfilling the compost quality requirements. Constituents that appear on the (candidate) list of Substances of Very High Concern (Annex XIV or the REACH) are not accepted.

5.5.2. Biodegradable in Soil (DIN CERTCO's Certification scheme)[40]

Compliance with the threshold values named in EN 17033 and in detail:

- *PFAs shall not be intentionally used.*
- *SVHC ≤ 0.1 % (by weight).*
- *≥ 60 % by mass of volatile solids.*

- *Ultimate biodegradability (ISO 17556) ≥ 90 % absolute, or 90 % with a suitable reference substrate not longer than 24 months at 20 - 28 °C ± 2 °C (preferably 25 °C).*
- *Organic constituents present in a concentration > 1 % (by weight) shall demonstrate ultimate biodegradability separately. Alternatively, ultimate biodegradability of the manufactured item can be demonstrated. The sum of organic constituents which do not need to show ultimate biodegradability shall not exceed 5 x 1 %.*
- *The germination rate and plant biomass of two plant types mentioned in OECD 208 grown on the soil using test substance must be higher than 90 % of the corresponding blank (without test material). Evidence must be demonstrated via a test according to the standards named under Annex B 3. (Remark: The ecotoxicity test shall be performed with soil prepared according EN 17033, Annex A.)*
- *The difference in the observed mortality as well as in the biomass of surviving adult earthworms between a soil exposed to the test material and the corresponding blank soil not exposed to the test material shall be less than 10 % of those from the corresponding blank soil. Evidence must be demonstrated via a test according to the standards named under Annex B 3. (Remark: The ecotoxicity test shall be carried out with soil prepared according EN 17033 Annex A.).*
- *The nitrite formation in soil exposed to the test material shall be more than 80 % of those from the corresponding blank soil not exposed to the test material. Evidence must be demonstrated via a test according to the standards named under Annex B 3. (Remark: The ecotoxicity test shall be carried out with soil prepared according EN 17033 Annex A.).*
- *Materials and additives or exposed to soil must not have any toxic effect on microorganisms in soil.*
- *Substances that may be exposed to the soil along with the product must not have any toxic effect on microorganisms in soil.*
- *Additional Requirements for biodegradable mulch films:*
    - *Biodegradable mulch films shall fulfil the requirements according to EN 17033, for dimensional, mechanical and optical properties.*
    - *Biodegradable mulch films shall be labelled and (optional) be marked according EN 17033.*

5.5.3. Other characterizations

Agronomic parameters i.e. pH, electrical conductivity, total organic matter, organic C, total macroelements (N, P, K, Ca, Mg) and microelements (Fe, Cu, Mn, Zn).

Hazardous parameters: heavy metals (Cd, Ni, Pb, Cr, Co, Hg), improper elements (glass, metals, plastics).

6. Safety Regulations and guidelines

The most relevant regulations and guidelines related to **Safety** are:

- Safe and Sustainable by Design (SSbD) of chemicals and materials - Methodological Guidance.
- Regulation (EC) No 10/2011 on plastic materials and articles intended to come into contact with food (last update January 20th 2025).
- Directive 89/391 - OSH "Framework Directive" on Safety and Health at Work (last update December 11th 2008).

6.1. Methodological Guidance on Safe and Sustainable by Design[41]

The 'safe and sustainable by design' (SSbD framework) is a voluntary approach to guide the innovation process for chemicals and materials, announced on 8 December 2022 in a Commission Recommendation. It aims to:

- *steer the innovation process towards the green and sustainable industrial transition,*
- *substitute or minimise the production and use of substances of concern, in line with, and beyond existing and upcoming regulatory obligations,*
- *minimise the impact on health, climate and the environment during sourcing, production, use and end-of-life of chemicals, materials and products.*

The framework is composed of a (re-)design phase and an assessment phase that are applied iteratively as data becomes available. The (re-)design phase consists of the application of guiding principles to steer the development process. The goal, the scope and the system boundaries – which will frame the assessment of the chemical or material – are defined in this phase.

The assessment phase comprises of 4 steps:

- *Hazard properties of chemical(s);*
- *Workers exposure during production;*
- *Exposure during use;*
- *Life-cycle assessment.*

The assessment can be carried out either on newly developed chemicals and/or materials, or on existing chemicals and/or materials to improve their safety and sustainability performance during production, use and/or end-of-life.

The Methodological Guidance clarifies some aspects of the voluntary application of the 'safe and sustainable by design' (SSbD) framework for chemicals and materials. It combines the disciplines of "Risk Assessment" (RA) and "Sustainability Assessment" (SA), which have different methodologies, framing and terminology. This Methodological Guidance explains the rationale of

the framework and replies to the feedback collected during several stakeholder consultations, which have contributed to its progressive refinement. It furthermore presents a method for scoping analysis and discusses why it is important to correctly frame the subsequent SSbD assessment. Following on, thematic chapters specifically address aspects of the framework: safety assessment, environmental sustainability assessment and also socio-economic assessment.

The SSbD Framework is a general approach to steer innovation towards safe and sustainable chemicals and materials throughout the entire life cycle. The framework can be applied to the development of new chemicals and materials or to the re-assessment of those already in existence.

The application of the SSbD Framework is voluntary. It combines established hazard and risk assessment approaches for chemicals and materials, with sustainability assessment techniques, such as Life Cycle Assessment (LCA) methods.

The SSbD Framework has been developed to promote the design, development, production and use of completely new safer and more sustainable chemicals and materials considering their entire life cycle, steering the substitution of hazardous and less sustainable chemicals and materials. The overall goal is to help in preventing pollution whilst also reducing society's environmental footprint.

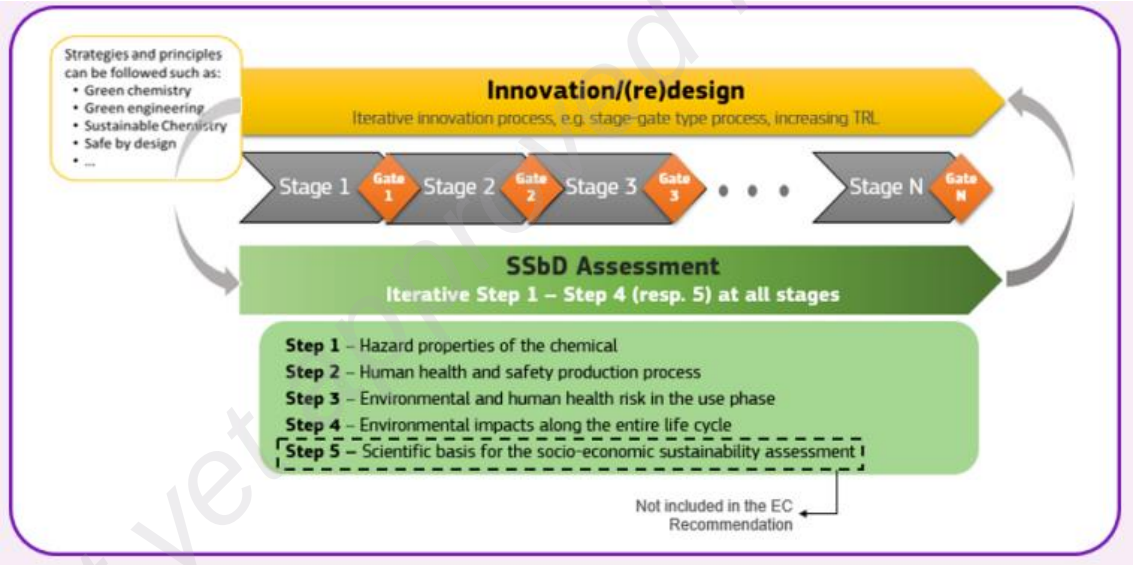

Figure 4. Overview of the SSbD framework.

6.1.1. Step 1 Hazard assessment of the chemical/material

- *Hazard identification: the approach for collection and generation of data for the hazard assessment and*
- *Hazard characterisation: the derivation of maximum exposure limits.*

The hazard assessment starts with gathering all relevant and available information. This is then followed by the hazard assessment per se of the available information, a process that comprises 3 elements which are part of the assessment in the following steps:

1. *Evaluation and integration of the available data,*
2. *Classification,*
3. *Derivation of the hazard thresholds for the specific assessment target.*

6.1.2. Step 2 and 3: Safety aspects in the chemical/material production, processing and final application

Understanding and estimating the exposure to a chemical/material is one of the fundamental requirements for safety assessment. Although it is not as extensively discussed as the hazard identification in the context of the SSbD framework, it is a key aspect in achieving both the CSS and the goals of the Green Deal related to strengthening the protection of human health and the environment. The assessment and the minimisation of the exposure to chemicals and materials plays a central role here. To understand and estimate the exposure it is important to specify the use in which the chemical/material is utilised or applied. Any activity for which there is a potential for human or environmental exposure to a chemical/material is defined under REACH as "use"[42]: use means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, and production of an article or any other utilisation. It provides:

- *Exposure identification and assessment,*
- *Risk characterisation,*
- *Available sources of information for the purpose of developing the exposure scenarios.*

In addition, products are defined as any physical goods that are placed on the market or put into service. Substance on their own, mixtures, materials, articles, or complex products used by consumers, industrial or professional users are considered final products.

Therefore, a chemical/material can be a final product, or it can be used to produce the final product (while not being present in the final product itself) and/or it can be contained in the final product.

However, the SSbD strives to make a difference between those "uses" that can be regulated – and therefore better known and more manageable (e.g. occupational) - and those "uses" that cannot be regulated, and which may only be managed to a certain extent. Industrial uses are regulated, for example, by occupational safety and health (OSH) legislation and/or the Industrial Emissions Directive (IED) (European Parliament and the Council, 2010, as amended, revised "ED 2.0" legislation published in 2024) which set known high effectiveness requirements in risk management measures such as closed systems, ventilation and training. On the other hand, the safe use of consumer applications relies on the instructions of use based on information on consumer habits and practises. This distinction also tries to differentiate between those more generic uses (covered in chemical horizontal legislation, such as REACH and CLP) and product-specific uses (covered in vertical and product specific legislation such as that related to plant protection products, biocides, cosmetics, human and veterinary medicines, food contact materials

(FCM), or toys, etc.). However, the line that separates these scenarios sometimes is diffuse, and it is not clear where a particular use should fall. In these cases, the assessor should make sure that the use is covered either in Step 2 or Step 3, and that all the relevant aspects for the safety assessment are covered.

6.1.3. Step 4: Environmental Sustainability Assessment

An introduction on performing Life Cycle Assessment (LCA) is provided with reference to the Technology Readiness Level (TRL) and associated level of data available. It guides the user on performing a tiered LCA according to the maturity of the innovation, including:

- *Narrowing the system boundaries (under specific conditions),*
- *Data generation and collection; and*
- *Interpretation of results to guide innovation.*

Adjustments to the LCA might occur over progressive refinements according to an iterative approach.

6.1.4. Socio-economic assessment (optional step)

Recommendations and approaches are suggested:

- *For the social assessment: assess social performances and risks along the life cycle using a Reference Scale method.*
- *For Critical Raw Materials (CRMs): flag the presence of CRMs by screening the life cycle inventories.*
- *For the economic assessment: apply monetisation factors to the results of the LCA.*

6.2. Food contact material Regulations (Regulation (EC) n. 1935/2004 and Regulation (EC) No 10/2011)

The legislative context for the packaging materials that come in contact with food is presented. Food industry has been conducting research and development activities on food packaging to increase shelf life, keep the food quality at optimum level, attract consumer interests, and reduce waste. A package material for any type of food should minimize aroma and flavour losses, constitute an excellent barrier for gas and water, provide a perfect hermetically sealed seam, as well as have good mechanical properties. Food contact materials including food packaging are generally based on paper, metal, ceramic, aluminium, lacquers and coating, and plastic. Food packaging is used to increase shelf life, to keep food quality at optimum level, to attract consumer interest, to facilitate the sale and distribution.

The degree of the final product quality and safety, and consumer expectations from the ergonomic features of the package affects the acceptance criteria of a package material. A package material for any type of foods should minimize aroma and

flavour losses, constitute an excellent barrier for gas and water, provide a perfect hermetically sealed seam, as well as have a good mechanical property and offer chemical and biological protection against contamination. Glasses, metals, paper, ceramic, and plastics are the most used materials for food packages. Glasses are inert packaging material and its shows heat resistance to thermal processing has advantages of providing good strength under compression and heat. Glasses as well as metals like steel and aluminium act a barrier to gases, water vapor and aromas. Paper based packaging materials produced from wood pulp, rags, and other waste have been reported to be used since the seventeenth century. Ceramic type packaging materials including glass and pottery are produced at high temperatures from non-metal inorganic material produced by high temperatures. Plastic packaging materials are made up from polymers by adding additives, processing aids, catalysts, and plasticizers.

Chemical components of packaging materials may migrate into foods when they contact with them. This type of transfer is called as chemical migration, which is a mass transfer operation. Diffusion the macroscopic movement of molecules from high to low concentration is the main mechanism in migration. The migrated chemicals from packaging materials can be originated from the substances used in their formulation and also from interactions between different ingredients, degradation products or from the presence of impurities in the raw materials. The duration of the contact between the material and food, temperature profile during interaction and the physicochemical behaviour of the packaging material are the main drives for the migration.

Keeping consumer health safe, components of food contact materials shall not migrate into the foods. Therefore, substances used in the manufacture of the packaging materials are regulated with maximum limits that may migrate into foodstuffs without causing any health concerns. To analyse migrated chemicals, food simulants are used to test migration in the scope of compliance with regulations. Sophisticated equipment such as liquid and gas chromatography equipped with mass spectrometry and inductively coupled plasma mass spectrometry have been used successfully for migration analysis so far.

Migration from packaging materials is a diffusion process that is subject to the normal laws of physics. Consequently, the conditions of use of polymers will influence the levels of migration that may be expected from them. Migration increases with increased time of contact, increased temperature of contact, intimacy of the contact and foodstuffs that interact strongly with the packaging and have a high solubility for the migrant(s).

Migration decreases with only indirect contact, low diffusivity (‘inert’) packaging materials, presence of an inert barrier layer.

6.2.1. Regulation (EC) n. 1935/2004[43]

This Regulation states that food contact materials shall be safe and shall not transfer their constituents into the food in quantities that could endanger human health, change the composition of the food in an unacceptable way or deteriorate the organoleptic properties of foodstuffs.

6.2.2. Regulation (EU) n. 10/2011[44]

This Regulation is a specific measure of Regulation (EC) n. 1935/2004 and establishes the specific rules for plastic materials and articles to be applied for their safe use. Annex I of Regulation (EU) n. 10/2011 contains the Union list of authorized monomers, additives, polymer production and other starting substances. These listed substances called as "Intentionally Added Substances (IAS)" can be used to manufacture plastic materials, with the restrictions and specifications established in the list.

The contamination of foods due to the release of chemicals from packaging materials can be originated from the substances used in their formulation (IAS) but also from interactions between different ingredients, degradation products or from the presence of impurities in the raw materials (so called "Non Intentionally Added Substances-NIAS").

The components from food contact materials must not migrate into the foods in unacceptable quantities. Therefore, substances used in the manufacture of FCMs are regulated with maximum limits that may migrate into foodstuffs without causing any health concerns.

The migration of the substances present in the packaging material must not exceed 2 different limits:

1. *the Overall Migration Limit (OML) is applicable to the total of migrant substances,*
2. *the Specific Migration Limit (SML) refers to individual substances or groups of substances.*

According to the Regulation, plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per dm^2 of food contact surface (mg/dm^2) as overall migration limit. SML are set for individual authorized substances based on toxicological evaluation.

The SML is a maximum permitted amount of a substance in food. This limit should ensure that the food contact material does not pose a risk to health. It should be ensured by the manufacturer that materials and articles not yet in contact with food will respect these limits when brought into contact with food under the worst foreseeable contact conditions. Therefore, compliance of materials and articles not yet in contact with food should be assessed and the rules for this testing should be set out.

Plastic materials and articles shall not transfer their constituents to foods in quantities exceeding the SMLs set out in Annex I of the Regulation 10/2011. Those SMLs are expressed in "mg of substance / kg of food". For substances for which no specific migration limit or other restrictions are provided in the same Annex I, a generic specific migration limit of 60 mg/kg shall apply.

The food simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with a single food or specific groups of foods are set out in point 3 of Annex III to Commission Regulation (EU) No 10/2011.

6.2.3. Requirements for safety profile by total migration of the plastic materials

Plastic materials can be put in contact with food and migration tests are carried out for the quantification of the total migration. For the experimental activity the general applied Standard method is EN 1186:2002 series (Materials and articles in contact

with foodstuffs – Plastics). All these methods deal with overall migration test, providing the main procedures and calculations to assess the total migration from each different simulant, temperature and contact time condition. Below the applied Standards are listed:

- *EN 1186-1:2002 Part 1: Guide to the Selection of Conditions and test methods for Overall Migration,*
- *EN 1186-3:2002 Part 3: Test methods for Overall Migration into Aqueous food Simulants by Total İmmersion,*
- *EN 1186-12:2002 Part 12: Test methods for Overall Migration at Low Temperatures,*
- *EN 1186-14:2002 Part 14: Test methods for 'Substitute tests' for Overall Migration from Plastics İntended to come into contact with Fatty Foodstuffs using test Media İso-Octane and 95% Ethanol.*

The EN 13130[45] series deals with specific migration (Materials and articles in contact with foodstuffs - Plastics substances subject to limitation - Guide to test methods for the specific migration of substances from plastics to foods and food simulants and the determination of substances in plastics and the selection of conditions of exposure to food simulants).

The guiding principle in the EC Directives on plastics, is that migration testing should mimic actual and foreseeable conditions of use, and this includes taking into account the physical state of the packaged food (or material) and the nature/extent of this contact.

Migration from packaging materials is a diffusion process that is subject to the normal laws of physics. Consequently, the conditions of use of biodegradable polymers and packaging will influence the levels of migration that may be expected from them, especially in terms of temperature and duration of the storage and the usage. The procedures used to bring and maintain the plastic in contact with the food simulant, procedures used for both overall migration and specific migration, are described in the EN 1186 series of standards.

Surface area calculation of test specimen: for the calculation of the surface area, the surface area can be seen as the sum of all the areas that make up the food contact surface of the article. Empirical methods can be used to calculate the surface area by placing the article on a piece of millimetric or plain paper of sufficient size. The paper is then wrapped around the contour of the article and cut to size. The contact area is then calculated by either counting the area based on millimetric measurements or by weighing the paper and converting the weight to the surface area.

Type of contact: total immersion or article filling: according to the type of article the test is performed by total immersion.

Single use article testing: according to the final type of usage of developed packaging (single use), one migration test is carried out.

Simulants: to determine migrated chemicals into food either for specific or total migration, analysis is performed in food simulants, not actual foodstuffs. Food simulants are used as substitutes for food due to the complexity and variety of foodstuffs, simplification of chemical analysis, and make comparable results between different laboratories. There are five simulants described in the legislation for plastic (EU 10/2011):

- *10% ethanol (v/v) in aqueous solution (simulant A),*
- *3% acetic acid (w/v) in aqueous solution (simulant B),*
- *20% ethanol (v/v) in aqueous solution (simulant C),*
- *50% ethanol (v/v) in aqueous solution (simulant D1),*

- *vegetable oil (simulant D2),*
- *poly(2,6-diphenyl-p-phenylene oxide, particle size 60-80 mesh, pore size 200 nm, commonly named as Tenax) (simulant E).*

The selection of the simulants for the specific final applications of the food packaging is performed according to the specifications provided by the Regulation:

- *Food simulants A, B and C are used for hydrophilic foods.*
- *Food simulant B is used for acidic foods with pH below 4.5.*
- *Food simulant C is used for alcoholic foods with an alcohol content of up to 20 %.*
- *Food simulants D1 and D2 are assigned for lipophilic foods.*
- *Food simulant D1, D2, and E are used for alcoholic foods with an alcohol content of above 20 %, for fatty foods, and for dry foods, respectively.*

Time-temperature exposure conditions: migration experiments must be conducted under standardized conditions of contact time and temperature to get the worst scenario for the labelling information on the maximum temperature of use. The foreseeable conditions of use as regard contact time and temperature are presented in the following tables. The Regulation affirmed that if it is found that carrying out the tests under the combination of contact conditions specified in the tables causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place. In addition, for contact times above 30 days at room temperature and below, the specimen has to be tested in an accelerated test at elevated temperature for a maximum of 10 days at 60 °C.

Contact time in worst foreseeable use	Test time
t ≤ 5 min	5 min
5 min < t ≤ 0,5 hour	0,5 hour
0,5 hours < t ≤ 1 hour	1 hour
1 hour < t ≤ 2 hours	2 hours
2 hours < t ≤ 6 hours	6 hours
6 hours < t ≤ 24 hours	24 hours
1 day < t ≤ 3 days	3 days
3 days < t ≤ 30 days	10 days
Above 30 days	See specific conditions

Table 3. Contact time of the overall migration test.

Conditions of contact in worst foreseeable use	Test conditions
Contact temperature	Test temperature
T ≤ 5 °C	5 °C
5 °C < T ≤ 20 °C	20 °C
20 °C < T ≤ 40 °C	40 °C
40 °C < T ≤ 70 °C	70 °C
70 °C < T ≤ 100 °C	100 °C or reflux temperature
100 °C < T ≤ 121 °C	121 °C (*)
121 °C < T ≤ 130 °C	130 °C (*)
130 °C < T ≤ 150 °C	150 °C (*)
150 °C < T < 175 °C	175 °C (*)
T > 175 °C	Adjust the temperature to the real temperature at the interface with the food (*)

(*) This temperature shall be used only for food simulants D2 and E. For applications heated under pressure migration testing under pressure at the relevant temperature may be performed. For food simulants A, B, C or D1 the test may be replaced by a test at 100 °C or at reflux temperature for duration of four times the time selected according to the conditions in Table 1.

Table 4. Contact temperature of the of the overall migration test.

For all migration tests, the final overall migration is reported as the mean of a minimum of three determinations on separate test specimens and compared with the Overall Migration Limit (OML), provided in the next table.

Parameters (Official standard method)	**Requirement**
Overall Migration Limit (OML) (EN 1186)	< 10 mg/dm^2

Table 5. Requirements for food contact compliance.

6.3. OSH "Framework Directive" (Directive 89/391)[46]

The present activity aims at providing Health & Safety (H&S) risk assessment on the developed processes. Risk assessment is performed for working environment and for workers according to regulations. The steps provided by ARCHA aim at:

- *Identifying hazards and exposure.*
- *Analysing or evaluating the risk associated with the identified hazard and exposure.*
- *Providing good practice procedures to eliminate, minimise and further control the risks.*

The validation, sampling and monitoring all most characterising parameters and chemical pollutants are assessed in terms of the compliance with European Regulation (Directive 89/391/EEC, the so-called Occupational Safety and Health (OSH) "Framework Directive").

Each company has a responsibility to ensure workplaces are safe and employees and contractors are protected from harm. Using risk assessments allow employers to effectively identify hazards, assess the level and likelihood of the risks they pose, and put control measures in place to reduce or, where possible, eliminate risks completely. Companies have the moral and legal responsibility to make sure all workers and members of the public are kept safe from any harm or ill-health that might occur as a result of the work operations. So, in every workplace, risks need to be identified and assessed so control measures can be implemented.

The process for risk assessments can help to identify hazards, consider the risks they pose and plan effective precautions to reduce or eliminate those risks. Risk assessment findings can then be discussed and communicated with staff and contractors, helping to ensure that workers know which risks they might face during work activities, and the control measures they should implement to minimise risks. Hazards can be anything from potentially dangerous activities (such as working at height, working with or around mobile plant, operating machinery or manual handling operations), to using hazardous substances, to psychological strain, such as stress.

Once hazards are identified, it's necessary to consider what risks they pose; how they could harm someone, who might be affected, and how likely the risk is. Then it's important to implement control measures proportionate to the severity and probability of risk. After the risk assessment is complete, it should be written up and made available to workers on all levels of the organisation.

The objective of the risk assessment is to allow the employer to take the control measures actually necessary to safeguard the safety and health of workers and therefore guarantee:

- *the prevention of occupational risks,*
- *information for workers,*
- *their professional training,*
- *the organization and means intended to implement the necessary measures.*

Even if the goal of risk assessment includes the prevention of occupational hazards - and this should always be its primary goal - this will not always be achievable in practice. In cases where risks cannot be eliminated, they must be minimized as far as possible and residual risks must be kept under control.

At a later stage, as part of the review program, residual risks will be re-assessed and further consideration will be given to eliminating or further reducing them, probably in the light of the new knowledge then acquired.

The risk assessment has been structured and implemented in such a way as to:

- *identify the dangers that exist in the workplace and assess the risks associated with them, to determine what measures must be taken to protect the health and safety of employees, in compliance with the law;*
- *assess the risks in order to make the selection as motivated as possible of the work equipment, of the chemical products and preparations used and of the equipment that are in the workplace, of the chemical products and preparations used and of the equipment that are found at the workplace, as well as the organization of the same;*
- *establish a list of priorities in terms of further preventive measures for the decreasing of the risks.*

6.3.1. General criteria for risk assessment

The criteria adopted for the assessment of risks in the activity in question refer to the aforementioned document of "Guidelines regarding the assessment of risks at work" issued by the European Community DG V / E / 2 EEC Medicine and Work Unit in order to provide MS of the Community “Guidelines for carrying out risk assessments at work" and in which "the steps to be taken to identify the most appropriate means to eliminate risks or apply control measures if necessary are described”.

It is important to pay attention to the definitions indicated by the document:

- *Hazard: intrinsic property or quality of a certain entity (e.g. materials or work equipment, work methods and practices) with the potential to cause harm.*
- *Risk: probability that the potential level of damage is reached in the conditions of use and / or exposure, as well as possible dimensions of the damage itself.*
- *Risk assessment: procedure for assessing the risks for the safety and health of workers, in the performance of their duties, deriving from the circumstances of the occurrence of a hazard in the workplace.*

The criteria adopted for risk assessment can be divided into the following operational phases:

- *Definition of the program,*
- *Identification of the sources of danger,*
- *Examination of work, maintenance and safety procedures,*
- *Regulatory examination for the definition of risk reduction levels,*
- *Risk assessment,*
- *Particular risks for which a specific assessment is required.*

Therefore, on the basis of the results of the examinations, identification of the sources of danger, examination of work, safety and maintenance procedures, examination of protection measures, examination of accident statistics, it will be possible to evaluate the risks by associating each one with a level of "attention" that can be defined in different ways also with reference to regulatory requirements.

N.	Category	Description	Reference
SAFETY RISKS			
A01	Workplaces	Working environment	Titolo II D.Lgs 81/08 e s.m.i.
A02	Equipment		Titolo III D.Lgs 81/08 e s.m.i.
A03	Technical installations		
A04	Handling machines		
A05	Storage and manipulation		
A06	Storage and manipulation for substances		Titolo IX D.Lgs 81/08 e s.m.i. – Reg. CLP
A07	Electricity		Titolo III D.Lgs 81/08 e s.m.i.
A08	Fire		DPR 151 del 1/8/2011 – DM 3/8/2015
A09	ATEX		Titolo XI D.Lgs 81/08 e s.m.i.
A10	Risks of Relevant Accidents		D.Lgs 334/99
HEALTH RISKS			
B01	Dangerous substances	Chemicals	Titolo IX D.Lgs 81/08 e s.m.i. – Reg. CLP
B02	Dangerous substances	Cancerogenics	Titolo IX D.Lgs 81/08 e s.m.i.
B03	Dangerous substances	Asbestos	Titolo IX D.Lgs 81/08 e s.m.i.
B04	Physical agents	Noise	Titolo VIII, II D.Lgs 81/08 e s.m.i.
B05	Physical agents	Vibration	Titolo VIII, III D.Lgs 81/08 e s.m.i.
B06	Physical agents	Electromagnetic radiations	Titolo VIII, IV D.Lgs 81/08 e s.m.i. - D.Lgs 1 agosto 2016, n. 159
B07	Physical agents	Ionizing radiation	
B08	Physical agents	Optical radiations	Titolo VIII, V D.Lgs 81/08 e s.m.i.
B09	Physical agents	Microclimate	D.Lgs 81/08 e s.m.i.
B10	Physical agents	Illumination	
B11	Biological agent		Titolo X D.Lgs 81/08 e s.m.i.
B12	Video-terminals		Titolo VII D.Lgs 81/08 e s.m.i.
B13	Manual handling loads	Lifting, pushing and towing	Titolo VI D.Lgs 81/08 e s.m.i.
B14	Manual handling loads	Repeated movements of the upper limbs	Titolo VI D.Lgs 81/08 e s.m.i.
PARTICULAR RISKS			
C01	Pregnant workers		D.Lgs 151/01
C02	Minors		D.Lgs 345/99
C03	Work-related stress		D.Lgs 81/08 - Accordo EU 2004
C04	Specific Risks		D.Lgs 81/08 e s.m.i.
C05	Risks associated with differences		D.Lgs 81/08 e s.m.i.
C06	Alcohol and Drugs Risk		D.Lgs 81/08 e s.m.i. Deliberazione 9 dicembre 2013, n. 1065
C07	Night job		
C08	Presence of confined spaces		DPR 14 settembre 2011 , n. 177
SERVICES and AIDS			
S01	Services and strippers		
S02	Signage		Titolo V D.Lgs 81/08 e s.m.i.
S03	Entrusting of works to companies or self-employed persons		Titolo I D.Lgs 81/08 e s.m.i.
S04	Accident and near-accident analysis		
S05	Personal protective equipment		Allegato VIII D.Lgs 81/08 e s.m.i.
S06	Procedures		
S07	Education and training		

Table 6. List of all risks in workplaces (Italian Regulation as reference, transpositions of European legislation).

7. Conclusions

Agrochemicals have significantly increased crop yields but also cause environmental and health issues. The EU aims to reduce fertilizer losses and chemical pesticide use by 50% by 2030. Existing polymer-based delivery systems help control agrochemical release but are non-biodegradable, contributing to plastic pollution.

The PHAntastic project addresses this issue by developing biodegradable PHA-based agrochemical delivery systems, including:

- Biodegradable PHA-based mulching film for horticultural crops, incorporating active bioproducts (fertilisers, biocides) and microbiological cocktails, to support controlled product release and ensure product degradation at the end of its useful life.
- Biodegradable PHA-based growth foams for growth of tree seedlings, incorporating active bioproducts and plant growth promoting rhizobacteria guaranteeing a balanced soil microbiota and sustainable PHA biodegradation
- Controlled release fertilisers consisting in different PHA-based formulations (e.g., encapsulated/coated granules).
- Controlled release PHA-based formulations of pesticides (e.g., encapsulation).

These innovations aim to reduce greenhouse gas emissions, improve efficiency and safety, and ensure sustainability, aligning with EU environmental goals.

This Deliverable D5.1 provides the preliminary review of the Regulatory Framework, specifically addressed to the regulatory requirements for fertilizers (FPR); safety aspects as for workers, processes, final products and food contact materials and the relevant certification schemes for PHAntastic systems.

The overall objective of the Regulations review is to provide the most updated tool to assess and validate the compliance of PHAntastic delivery systems with EU and national policies, ensuring the high protection of the human health and the environment against harmful substances, assess the safety of chemical substances used in the project and in developed products.

In particular, considering the experimental activities and implementations as defined within the first WPs, in terms of the selection and adaptation of active bioproducts for PHAntastic delivery systems (WP1), the development of PHA-based blends and processes for PHAntastic delivery systems (WP2), the laboratory production and testing of PHAntastic delivery systems and related testing (WP3) and the demonstration and validation of PHAntastic delivery systems on real-life case studies (WP4), the main regulatory topics are strictly linked as summarised in the next Table 7.

	WP1	WP2	WP3	WP4
European Regulations and Framework on environmental topics	✓	✓	✓	✓
REACH Regulation – Regulation EC 1907/2006	✓	✓	✓	
Soil directive - Regulation (EU) 2023/839 for land use, forestry, and agriculture	✓	✓	✓	✓
Pesticides Regulations	✓			✓
End of life Regulation and regulatory specifications	✓	✓	✓	✓
Safety Regulations and guidelines	✓	✓	✓	✓
Food contact material Regulations		✓	✓	✓
OSH "Framework Directive" (Directive 89/391)	✓	✓	✓	✓

Table 7. Correlation among PHAntastic WPs and considered Regulations.

Furthermore, this deliverable establishes the groundwork for the achievement of Milestone 5 “PHAntastic delivery system pass the assessments on SSbD, biodegradability, regulatory, environmental, economic and social acceptance” that will be provided at Month 46 with the planned deliverables D5.9, D5.10, D5.11, D5.12 and D5.13 and obtained results on PHAntastic delivery systems.

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