

Standards and Regulations for the Bio-based Industry STAR4BBI



Work Package 3

D3.3 Policy paper on strategy for development of an RCS framework

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Acronyms

ASTA: American Seed Trade Association

B2B: Business-to-business

CBD: Convention on Biological Diversity

CCCA: Climate Change Centre Austria

CCU: Carbon capture and utilization

CEN: Comité Européen de Normalisation

CRISPR: Clustered regularly interspaced short palindromic repeats

DNA: Deoxyribonucleic acid

DSI: Digital Sequence information

EC: European Commission

ECJ: European Court of Justice

EN: European Standard

EOL: End-of-life

EP: European Parliament

ETS: Emissions Trading System

EuRIC: European Recycling Industries' Confederation

EU: European Union

GDP: Gross domestic product

GenTG: German Genetic Engineering Act

GHG: Greenhouse gas

GMO: Genetically modified organism

GMM: Genetically modified microorganism

IED: Industrial emissions Directive

ISCC: International Sustainability Carbon Certification

ISO: International Organization for Standardization

IPPC: Integrated pollution prevention and control

JRC: Joint Research Centre

KrWG: Kreislaufwirtschaftsgesetz (German Closed-loop waste Management Act)

LCA: Life-cycle assessment

LCI: Life Cycle Inventory

LMO: Living modified organism

MEP: Member of the European Parliament

MS: Member State

MSW: Municipal solid waste

NBT: New Breeding Technique

NGO: Non-governmental organization

NVRD: Koninklijke Nederlandse Vereniging voor Reinigings- en Afvalmanagement (Royal Dutch association for cleaning and waste management)

PEF: Product Environmental Footprint

SDG: Sustainable development goal

SDS: Sustainable Development Strategy

SIRA: Strategic Innovation and Research Agenda

SME: Small and medium-sized enterprise

VANG: Van-Afval-Naar-Grondstof (From Waste to Raw Material)

VCI: Verband der Chemischen Industrie (German chemical industry association)

WEEE: Waste electrical and electronic equipment

WFD: Waste Framework directive

WTO: World Trade Organisation

ZKBS: Zentrale Kommission für die Biologische Sicherheit (Central Committee for Biological Safety)

Executive summary

Moving towards a low carbon economy and reducing dependence on fossil-based resources are two priorities for the EU. In this transition process, the bioeconomy plays a crucial role. However, establishing a cutting-edge bioeconomy in Europe requires a favourable regulatory and standardization framework. In order to achieve this, there is a need to update certain regulations that are currently in place, as well as develop new “rules of the game” that apply equally to bio-based products, their fossil-based counterparts and biofuels.

Over the past three years, the STAR4BBI project has studied policy and standardisation hurdles that bio-based industries face. Based on the results of previous research conducted within the project, this report presents a set of different measures to support enabling environment for bio-based industries. A summary of the proposed measures is shown in Table 1:

Table 1 Overview of identified topics and proposed measures

Identified topics	Proposed measures
Introduction of a fossil carbon tax for all products	Measure and tax the carbon content of fossil resources extracted in the EU at the extraction point
	Measure and tax the fossil carbon content of imported fossil resources and products at EU Customs
	Reimburse the fossil carbon tax on the exports of EU producers
Development of a Sustainability Certification for all products	Introduce sustainability labels via the EU Ecolabel for consumers (for all different product groups) that span the whole life-cycle
	Create default values for the different sustainability criteria
	Change the EU Ecolabel’s rigid pass-or-fail system to a multi-level label
	Introduce new EU Ecolabel product groups for products that are not an end-product
Establish a favourable regulatory framework for genome editing techniques in the EU	Change the GMO definition in the GMO Directive (2001/18/EC) to align it with the Cartagena Protocol
	Update Annex 1B of the GMO Directive
	Change the risk assessment methodology of the GMO Directive
Update the existing Waste Framework Directive (WFD)	Eliminate overlapping concepts of “waste” and “by-products”
	Provide clear harmonized criteria to distinguish between waste and waste which ceases to be waste
	Update and extend the WFD’s waste hierarchy to explicitly address degradation, fermentation and composting as part of recycling and to include transformation
	Conduct required tests, in particular on ecotoxicity, to classify waste where appropriate
	Harmonize the WFD and Circular Economy Package

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	Provide guidance on preferred EOL options and the specific conditions/criteria to be developed at European (CEN) level
	Harmonize the waste classifications in the EU and consider waste of bio-based products appropriately

This report represents the basis for developing a strategy for updating and further developing a supportive and investment-friendly regulatory and standardization framework for the selected value chains.

1. Introduction

Evident consequences of current production and consumption patterns (e.g. climate and land use change and ecosystem degradation) coupled with global societal challenges (e.g. population growth and limited natural resources) represent the drivers of numerous sustainability strategies and related action plans adopted in recent years at global, national and regional levels. The aim of these policies, such as the European Bioeconomy Strategy, is to accompany and facilitate the shift towards a more sustainable and innovative low carbon economy. Indeed, the aim of the 2012 Bioeconomy Strategy¹ is to pave "the way to a more innovative, resource efficient and competitive society that reconciles food security with the sustainable use of renewable resources for industrial purposes, while ensuring environmental protection".

However, a favourable regulatory and standardization framework is a prerequisite for establishing a cutting-edge bioeconomy in Europe. To achieve this, certain regulations and standards that are currently in place must be updated and other solutions must be developed in order to create a level playing field for bio-based products, their fossil-based counterparts and biofuels. Over the past three years, the STAR4BBI project has studied policy and standardisation hurdles that bio-based industries face.

This deliverable proposes a set of different measures to achieve better policies and standards for bio-based industries. Some are intended to level the playing field for bio-based products in relation to their fossil-based counterparts by introducing a fossil carbon tax, mandatory sustainability criteria for all products or by regulating at the design of products and related end-of-life (EOL) routes at the EU level. Other proposed measures are intended to stimulate an increased production capacity and market share for bio-based products by establishing a supportive policy framework for bio-based materials similar to that which already exists for biofuels and bioenergy. Figure 1 provides an overview of the selected topics for which suggestions/recommendations are provided:

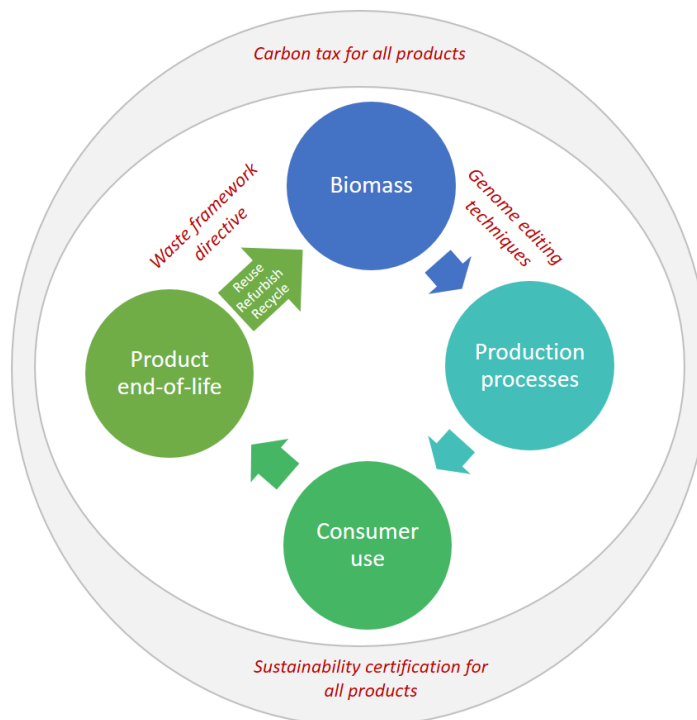


Figure 1 Selected topics for which measures are proposed

As shown in Figure 1, the proposed introduction of a **fossil carbon tax for fossil-based resources and products** and the establishment of a **harmonised sustainability certification for all products** aim to achieve a stable and supportive regulatory framework for the bioeconomy as a whole (entire value chain). Recommendations for establishing a supportive regulatory framework for the use of **genome-editing techniques** in Europe are proposed with the overall objective to improve efficiency in biomass production (e.g. biomass disease resistance) and production processes (e.g. biotechnology processes). To conclude, measures to update the **WFD** are proposed in order to overcome existing gaps that are hampering the use of waste to produce bio-based products.

The remainder of the report is structured as follows: section 2 describes the adopted methodology, and section 3 includes a general description of the topics and proposed suggestions to improve regulations for each of the identified topics. More specifically, section 3.1 presents specific measures to implement an EU wide fossil carbon tax for all products, section 3.2 presents suggestions centred on how to develop sustainability certifications for all products, section 3.3 contains proposals to support the safe use of genome-editing techniques in Europe, and section 3.4 includes specific proposals to update the current WFD. Finally, the conclusions are presented in section 4.

2. Methodology

Results of previous research carried out within the STAR4BBI project have served as a basis for this report and are the first step of the methodology presented in Figure 2 below. Specific outcomes of the following deliverables have been analysed and translated into suggestions for the establishment of a supportive and investment-friendly regulatory and standardization framework that will adapt to the rapid technological changes of the bioeconomy:

- Deliverable 2.1: Market entry barriers report²
- Deliverable 2.2: Elimination of hurdles in standards and regulation³
- Deliverable 3.1: Identification of technological trends in selected value chains⁴
- Deliverable 3.2: Regulatory and standardization needs in bio-based industry⁵

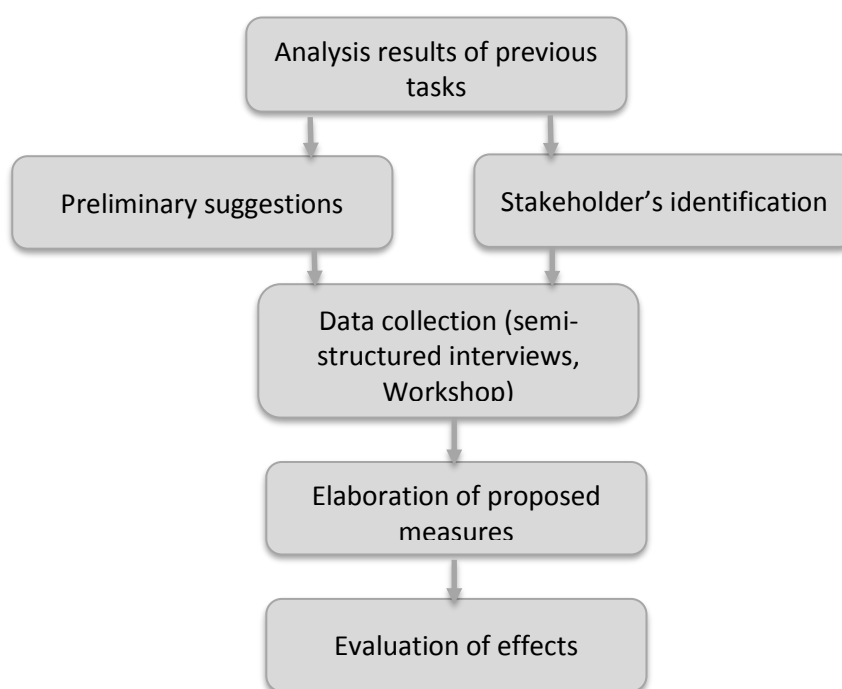


Figure 2 Methodology

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Firstly, results of previous tasks were analysed and translated into preliminary suggestions for the establishment of a supportive and investment-friendly regulatory and standardization framework. This list of preliminary suggestions served as a basis for the development of the questions for conducting semi-structured interviews with relevant stakeholders at the EU level. The semi-structured interviews were conducted from March until May 2019.

Further interactions with stakeholders for identifying and discussing proposed solutions were undertaken during the workshop “Assessing Bio-based Product Value Chains. How Better Regulation and Standardisation Can Promote a Level Playing Field” held in Cologne in May 2019.

After collecting data from experts, final recommendations were developed and are presented in this report.

3. Towards of supportive and investment-friendly regulatory and standardization framework

3.1 Fossil carbon tax for all products

Recently, an active discussion concerning the integration of a CO₂ tax has been taking place by a number of EU Member States (MS) as this mechanism will significantly reduce greenhouse gas (GHG) emissions and will help the MS reach their climate goals. Discussion is primarily on levying taxes on the CO₂ emissions of products and fuels. In other words, such a tax would target downstream products and fuels.

An issue with the implementation of a CO₂ tax is that, if it is applied only in the EU, there is a risk of industrial loss in the EU since industries would relocate their facilities to other countries where no CO₂ tax is charged. Additionally, if such a tax were to be implemented comprehensively, all products would require Life Cycle Assessment (LCA) so that the tax could be applied to products according to their CO₂ emissions. LCA studies are expensive, require significant time and effort and the existing, flexible methodology creates possibilities for subjective evaluation. Mandatory LCA studies are especially an issue for SMEs, as they usually lack the funds to pay for an LCA. If they are forced to provide an LCA, small companies are impacted much more than large companies.

One of the proposed measures for a supportive framework for a bio-based economy is the establishment of a fossil carbon tax, which instead of being levied on the emissions, will be levied on the fossil carbon in fossil resources and products.

The here proposed fossil carbon tax would provide more effective implementation mechanisms than a CO₂ tax. This tax would be levied on the carbon content of fossil resources. In other words, the tax would target upstream products and the increased costs would then be passed on through the value chain. CO₂ emissions released from fossil resources are proportional to their carbon content; therefore, by putting a tax on the carbon content of fossil resources, emissions at the end of life are expected to decrease similarly to what would occur in the case of a CO₂ tax. If the tax is applied at a rate that balances the prices of renewable carbon feedstocks¹ with fossil-based feedstocks, industries are expected to regularly choose renewable resources.

¹ There are three sources of renewable carbon:

- Renewable carbon from recycling of already existing plastics and other organic chemistry products (mechanical and chemical recycling).
- Renewable carbon gained from all types of biomass.

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Our proposed fossil carbon tax is levied on all fossil resources in proportion to their carbon content at the early stages of the value chain by measuring the carbon content of the fossil feedstocks, for example:

- at the coal mine
- where the crude oil is extracted
- at the gas pipeline

If fossil fuels are imported, duty or tax must be paid at the EU border. This is also applicable to products containing fossil fuels, though these fees can be waived in the case of renewable carbon (provided that proof is given).

The implementation of the fossil tax mechanism will be a driver for reducing the extraction of fossil resources and consequentially relying more on renewable carbon sources. Thus, this mechanism will serve two objectives: transitioning from fossil-based resources towards a more bio-based industry and achieving CO₂ savings because of this transition.

It is important to clarify that, in the case of a CO₂ tax, the tax is levied against CO₂ emissions, not carbon content, although it is often called a “carbon tax”. This can create confusion with a fossil carbon tax. In order to avoid misunderstanding of terms, we propose to use the term “fossil carbon tax” when referring to the here suggested taxation of the fossil carbon content of products or resources and “CO₂ tax” when referring to the taxing of emissions.

In the case of a fossil carbon tax, when products or fuels are imported into the EU, taxes will be levied against the importing company at the EU border in proportion to the fossil-carbon content of products or fuels imported. This can be done by radiocarbon dating (by measuring the carbon-14 isotope), which has been used for many years in certification tests of bio-based products to verify the bio-based content of products. Additionally, the energy used for producing a product outside of the EU needs to be taxed when imported into the EU. This is an important component of this mechanism, as otherwise production of energy intense products will become expensive in the EU due to high energy and fossil carbon taxes. If similar products are produced in other countries where fossil energy is not taxed accordingly and if those products are then imported to EU markets, a non-level playing field will occur between local and imported products. This will be prevented by import duties. However, it is important to consider the fulfillment of the proposed energy duty for the imported products to the World Trade Organisation (WTO) regulations. A more detailed analysis of WTO rules on border tax adjustment should be carried out for the actual implementation of the fossil carbon tax.

If it is unknown whether the product was produced using renewable energies, the renewable energy mix of their country (where the product was produced) will be considered and taxes will be levied on the fraction of energy produced using fossil resources. This way, when the products are imported to the EU, the fossil resources used for the production processes as well as the fossil feedstock used for the importing product will be taxed.

This mechanism will create equal conditions for EU producers and importing companies, since EU producers will pay a similar tax on the fossil feedstocks they use. Additionally, fossil energy used in production processes in the EU will be taxed as well, since all the fossil resources on the market will be taxed from the upstream at extraction point, or at the border for imports.

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- Renewable carbon from direct CO₂ utilisation of fossil point sources (while they still exist) as well as from permanently biogenous point sources and direct air capture.

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When exporting products, EU product producers can be reimbursed for the tax. If the products contain recycled fossil carbon, a certification should be provided to confirm the amount. In this case, the tax would be reduced by the percentage of recycled fossil carbon in the product. Consequently, EU product producers relying on grid energy mix for their production processes will have comparably higher production costs since the fraction of fossil-based energy will be taxed (additional to energy taxes, also the fossil carbon tax will be applied) and, if the product is exported, the tax paid for the fossil energy required in production processes will not be reimbursed. However, the exporters will receive back the taxes they have paid for the fossil-based carbon contained in their product. This will create more initiative to invest in renewable energies thus to avoid the increased prices of fossil-based energies.

Therefore, the integration of fossil carbon tax in the EU will not be associated with a loss of industrial activities since all fossil-based products entering the EU market will be taxed and will have a comparable price to locally produced products. Local producers thus have a fair competition with imported products in the EU market and will remain operating in the EU. This allows to apply the tax at EU level only and counters the regular argument that such a tax requires a global framework.

CO₂ is responsible for 60 % of the human contribution to climate change, while methane (CH₄) and nitrous oxide (N₂O) contribute 15-20% and 20%⁶, respectively. The EU Emission Trading System (ETS) covers the emissions of nitrous oxide (N₂O) from production of nitric, adipic and glyoxylic acids and glyoxal⁷. Some EU countries tax these emissions under additional taxation systems, which are however not covered by the CO₂ tax. For example, Sweden implements a NO_x tax (NO_x abatement often gives rise to increased emissions of other pollutants, like carbon oxide (CO), nitrous oxide (N₂O) and ammonia (NH₃), as by-products of the incomplete break-down of NO_x)⁸.

Given that this is a policy paper for strategy development, details about implementation mechanisms of fossil carbon tax will not be discussed in this report. Details will be presented in Deliverable 4.4 and will be available for on the STAR4BBI project website⁹.

Stakeholders were interviewed with a goal of either verifying the fossil carbon tax mechanism itself, or for clarifying issues and questions for the development of the proposals. The opinions of the stakeholders are presented in chapter 0.

3.1.1 Main contributions of fossil carbon tax to the bioeconomy

The lack of a level playing field of bio-based products against their fossil-based counterparts and biofuels is one of the major hurdles identified within this project.

Integration of a fossil carbon tax on products, if implemented at a relatively high rate, will lead to a price increase of these products in the EU, which in turn will lead to harmonised market conditions for fossil-based and bio-based products. Generally, the high price of bio-based products is a key issue hindering their market uptake. Price parity between bio-based and conventional fossil-based products is expected to increase the market uptake of bio-based products, since consumers are expected to choose greener choices. Therefore, the level of the fossil carbon tax will be crucial to achieve the desired level-playing field between fossil-based and bio-based products. A level playing field is expected to create more incentives for investment in this industry and to hasten innovations and technology development within the bioeconomy.

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However, in order to be able to make predictions on the investment and technology development of the bio-based industry, and how a carbon tax would influence the investment climate, it is important to identify the factors that have had an influence on the investment situation to date.

L. Dammer and M. Carus (2014)¹⁰ studied the investment climate in bio-based industries in the Netherlands and the other EU countries. The results showed that willingness to invest in the bio-based industries was very low and that an important underlying issue was related to the missing political will to support this field of businesses.

Therefore, the integration of a carbon tax will lead to harmonising the economic balance between fossil-based and bio-based products, which will provide better market conditions for the latter. However, to achieve the full potential of bio-based industries, additional political tools for supporting these should be coupled with the fossil carbon tax. In Deliverable 4.4 of the STAR4BBI project, a proposal for the integration of a new policy specific to bio-based materials is made, which would provide political support for bio-based products. Also, while the fossil carbon tax would have positive effects on the bio-based industries, the main motivation of the discussions around this tax are related to the urgent action needs to reach climate goals set by the EU.

A number of hurdles identified during the STAR4BBI project were related to a lack of policy dedicated to bio-based products, which is often related to the quantity of bio-based products circulated in the market – they are rather niche than mainstream. Achieving higher production rates of bio-based products (an expected result of harmonised price conditions between fossil-based and bio-based products) will lead to urgent necessity for implementing solutions for other policy and standardisation issues around bio-based products, such as the EOL, certification, etc. This in turn will enhance the investment in the field and support further development of bio-based products.

3.1.2 Related existing regulations

Currently there is no EU policy to regulate a fossil carbon or an EU-wide CO₂ taxing system. The fossil carbon tax proposed in this document has not yet been implemented either within or outside of the EU. A more commonly discussed taxing system is the CO₂ tax, where the tax is levied on the emissions of downstream products and fuels. However, it is important to note that for a CO₂ tax, even if the emissions are being taxed, the calculation of emissions is in number of countries carried out based on the carbon content of fossil resources.

The advantages of the implementation of the fossil carbon tax over a CO₂ tax have been already discussed in the introduction to this document.

The taxing systems where a CO₂ tax has been implemented focus primarily on the taxation of emissions from different sectors. In the examples given in tables 2 through 7 (see pages 15, 16 and 17), it is clear that the taxation rate is set for sectoral emissions from different sectors and that fossil resources in products are not covered by the tax, thereby not providing an effective mechanism for pushing the chemical sector towards renewable resources.

To elaborate the taxation system for one of the EU countries, implementing a CO₂ tax, the example of Denmark will be discussed below, as the implementation mechanisms in other EU countries are very similar.

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In Table 2 through Table 7 the sectors which are being taxed in the EU countries that implement a CO₂ tax are given. Under each sector different fuel products are being taxed, such as diesel, gasoline, oil products, natural gas, coal, etc. Below the columns of the Table 2 through Table 7 will be elaborated to illustrate the taxation system in the mentioned countries (see the tables below):

- “CO₂ emissions by sector” presents the amount of emissions occurring in the 6 sectors listed in the tables below.
- “Average price” introduces the taxation rate per ton of CO₂ for different sectors. Therefore, as suggested in the table, different sectors are taxed at different rates.
- “Share of emissions priced” illustrates the share of emissions that are being priced under the CO₂ taxation. Therefore, in the case of Denmark, apart from Electricity, all other sectors are taxed partially at the shares given in this column.
- “Average price” of ETS is the price per ton of CO₂ in EU ETS system in 2014.
- “Share of emissions priced” are the share of emissions that is covered and priced by the EU ETS system.
- Overlap of tax and ETS illustrates the shares of different sectors that are covered by both the CO₂ tax and the EU ETS system.
- “Emissions not priced by tax or ETS” shows the fraction of emissions within each sector that are not priced neither under CO₂ tax, nor the EU ETS system.

In the row “Total” corresponding to the column “Emissions not priced by tax or ETS” exhibits that that for example in the case of Denmark around 1/3 of the emissions are not being taxed neither by the CO₂ tax, nor are these covered under the EU ETS system. Similarly, in other countries implementing a CO₂ tax, the share of unpriced emissions differs from 11% to 55% dependent on the country.

It is important to note, that the “Total” of emissions given in the tables below only accounts for emissions stemming from energy use in any of the sectors and not for embedded carbon in products which is set free at the end of life. This is one of the weakest points of this mechanism, that is already being implemented by the countries mentioned below and which is being largely discussed by the EU MS.

Contrary to the presented CO₂ taxes that are currently in place, under a fossil carbon tax, all fossil carbon will be taxed independent of the sectors it will be used in further along the value chain. Additionally, the fossil carbon in products will be similarly taxed.

Table 2 Share of emissions priced and average price signals from tax & ETS, Denmark ¹¹

	CO ₂ emissions by sector (in t CO ₂)	Tax		ETS		Overlap of tax and ETS ⁵	Emissions not priced by tax or ETS
		Average price (in EUR/tCO ₂)	Share of emissions priced	Average price (in EUR/tCO ₂)	Share of emissions priced		
Agriculture & Fishing	2 121	128.7	71%	7.2	2%	2%	28%
Electricity	6 697	104.6	100%	7.2	77%	77%	0%
Industry	20 707	50.4	18%	7.2	40%	8%	51%
Offroad transport	917	162.6	85%	7.2	10%	8%	14%
Residential & Commercial	7 375	153.8	43%	7.2	0%	0%	57%
Road transport	11 136	202.4	94%	0.0	0%	0%	6%
Total¹	48 952	77.9	54%	2.0	28%	14%	33%

Table 3 Share of emissions priced and average price signals from tax & ETS, Finland ¹²

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	CO ₂ emissions by sector (in t CO ₂)	Tax		ETS		Overlap of tax and ETS ⁵	Emissions not priced by tax or ETS
		Average price (in EUR/tCO ₂)	Share of emissions priced	Average price (in EUR/tCO ₂)	Share of emissions priced		
Agriculture & Fishing	2 234	19.2	69%	7.2	1%	1%	31%
Electricity	12 320	37.6	100%	7.2	66%	66%	0%
Industry	52 741	63.8	27%	7.2	35%	13%	51%
Offroad transport	814	237.6	40%	7.2	24%	10%	46%
Residential & Commercial	10 170	59.2	30%	7.2	0%	0%	70%
Road transport	11 749	216.1	100%	0.0	0%	0%	0%
Total⁴	90 027	46.7	48%	2.1	30%	17%	39%

Table 4 Share of emissions priced and average price signals from tax & ETS, France ¹³

	CO ₂ emissions by sector (in t CO ₂)	Tax		ETS		Overlap of tax and ETS ⁵	Emissions not priced by tax or ETS
		Average price (in EUR/tCO ₂)	Share of emissions priced	Average price (in EUR/tCO ₂)	Share of emissions priced		
Agriculture & Fishing	11 394	24.4	89%	7.2	0%	0%	11%
Electricity	27 113	12.4	100%	7.2	96%	96%	0%
Industry	102 676	8.3	55%	7.2	59%	36%	22%
Offroad transport	4 798	21.3	11%	7.2	60%	7%	35%
Residential & Commercial	114 853	18.7	38%	7.2	1%	0%	62%
Road transport	127 112	180.2	100%	0.0	0%	0%	0%
Total⁴	387 945	63.7	68%	1.7	23%	17%	25%

Table 5 Share of emissions priced and average price signals from tax & ETS, Ireland¹⁴

	CO ₂ emissions by sector (in t CO ₂)	Tax		ETS		Overlap of tax and ETS ⁵	Emissions not priced by tax or ETS
		Average price (in EUR/tCO ₂)	Share of emissions priced	Average price (in EUR/tCO ₂)	Share of emissions priced		
Agriculture & Fishing	600	182.5	100%	0.0	0%	0%	0%
Electricity	12 135	2.3	95%	7.2	96%	95%	4%
Industry	6 228	33.9	65%	7.2	60%	49%	24%
Offroad transport	216	176.8	60%	7.2	16%	9%	34%
Residential & Commercial	8 363	25.3	74%	7.2	0%	0%	26%
Road transport	10 368	210.6	100%	0.0	0%	0%	0%
Total⁴	37 910	69.6	87%	3.0	41%	39%	11%

Table 6 Share of emissions priced and average price signals from tax & ETS, Sweden¹⁵

	CO ₂ emissions by sector (in t CO ₂)	Tax		ETS		Overlap of tax and ETS ⁵	Emissions not priced by tax or ETS
		Average price (in EUR/tCO ₂)	Share of emissions priced	Average price (in EUR/tCO ₂)	Share of emissions priced		
Agriculture & Fishing	1 501	77.4	33%	0.0	0%	0%	67%
Electricity	5 246	193.1	100%	7.2	24%	24%	0%
Industry	60 176	62.2	24%	7.2	23%	14%	67%
Offroad transport	719	112.4	10%	7.2	68%	7%	29%
Residential & Commercial	7 484	159.4	21%	7.2	0%	0%	79%
Road transport	21 241	226.6	91%	0.0	0%	0%	9%
Total⁴	96 367	68.3	42%	1.2	16%	10%	51%

Table 7 Share of emissions priced and average price signals from tax & ETS, United Kingdom¹⁶

	CO ₂ emissions by sector (in t CO ₂)	Tax		ETS		Overlap of tax and ETS ⁵	Emissions not priced by tax or ETS
		Average price (in EUR/tCO ₂)	Share of emissions priced	Average price (in EUR/tCO ₂)	Share of emissions priced		
Agriculture & Fishing	1 680	27.4	66%	7.2	10%	10%	34%
Electricity	160 840	10.9	100%	7.2	96%	96%	0%
Industry	117 473	18.1	57%	7.2	56%	29%	16%
Offroad transport	5 120	50.5	39%	7.2	40%	16%	36%
Residential & Commercial	93 937	23.2	32%	7.2	1%	0%	67%
Road transport	111 359	280.6	100%	0.0	0%	0%	0%
Total^d	490 411	71.5	76%	3.3	45%	39%	17%

At the EU level, the EU ETS is already regulated under Directive 2003/87/EC. Additionally, energy products are regulated and taxed under Directive 2003/96/EC on the taxation of energy products. Whether the fossil carbon tax and the EU ETS should be combined or if they should operate separately is an administrative issue, which has to be decided by the European Commission.

3.1.3 Debate, discussion and public opinion on the topic

Deeper discussion of a fossil carbon tax levied on the carbon content of fossil resources, as suggested in this document, has not yet occurred as this was newly suggested by nova-Institute GmbH as a project partner of STAR4BBI. However, the stakeholders that participated in the discussion surrounding the implementation of a CO₂ tax are also relevant stakeholders for the fossil carbon tax suggested by this project. Below, the points of views of different stakeholders, concerning CO₂ tax are presented; it is assumed that the stakeholders participating in the CO₂ taxing mechanism discussion have similar interests concerning the fossil carbon tax. Additionally, during the interviews with stakeholders, the opinion that pricing of carbon at a relatively high rate is the central necessity and the concrete implementation mechanisms should be subject to discussion was often expressed. This confirms the assumption that the stakeholders listed below support the pricing of carbon and will not oppose to the fossil carbon taxation mechanism.

Table 8 Stakeholder's views

Stakeholders	Stakeholders' views concerning the carbon tax
The European Green Party	<p>As advocates of environmental protection through political action, the European Greens are highly interested in tools and mechanisms that can lead to cutting CO₂ emissions. Ten priority measures¹⁷ were identified by the Greens to protect our climate. The third measure on this list is on putting a fair price on carbon by revising the ETS, implementing a carbon tax and by border adjustment for imported emissions so that they may be taxed similarly as emissions generated within the EU.</p> <p>While countries that are already implementing the CO₂ tax do not consider the taxation of imported products for their emissions, this suggestion by the European Greens will be much easier to implement by the fossil carbon tax than by the CO₂ tax. This is because measuring the fossil carbon content of the fossil products is simpler than measuring the CO₂ emissions of products (an LCA study would be necessary).</p>

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Academia	<p>Among scientists there is agreement that a carbon tax is a strong instrument for reaching EU climate goals. Interviews and the Delphi study carried out in the previous phases of the STAR4BBI project show that scientists see a need for pricing of carbon.</p> <p>Out of 36 total respondents of the Delphi study, 17 were from academia; 10 respondents described the carbon tax as very important and 5 described it as fairly important for achieving a level-playing field for bio-based industries. Additionally, Climate Change Centre Austria (CCCA), an association combining 25 scientific institutions in Austria, confirmed that the association and their members share the position on the importance of carbon pricing during an interview.</p>
Bio-based industry	<p>Bio-based industry is one of the main advocates for the integration of a carbon tax since this will lead to increasing prices of fossil-based products and will create a level playing field for the bio-based products.</p>
Industry	<p>Opinions on a carbon tax in industry are diverse. Some of the largest companies, such as General Motors Co. and four major oil and gas companies (Exxon Mobil Corp., BP PLC, Shell and Total SA) support the integration of a carbon tax¹⁸. They claim to be aware of the impacts of climate change, and would prefer to implement a carbon tax sooner with a rate that would allow industry to adjust to it rather than later with a relatively high rate.</p> <p>In a Delphi study carried out in the BEPASO project funded by the German government, industry's response concerning the integration of a carbon tax was also positive.</p> <p>However, BusinessEurope suggests that the EU has to implement a carbon border adjustment for imported products to create a level playing field between local and imported products.¹⁹ Considering this requirement, it is clear that, even if industry supports integration of carbon tax, before its implementation at the EU level, carbon border adjustment will be of central importance for the industry. This is an additional argument highlighting the advantage of the fossil carbon tax, which will allow achieving of the carbon border adjustment much easier than the CO₂ tax.</p>
Society	<p>The social acceptance of the carbon tax is also an important issue to be considered in order to evaluate the feasibility of this mechanism.</p> <p>According to Mercator Research Institute on Global Commons and Climate Change, the poorer sector of society spends a large portion of its income on carbon-intensive goods. However, the wealthier segment has overall higher carbon footprint. A carbon tax could intensify the social inequality and reduce its social acceptance²⁰.</p> <p>Society is aware of climate change impacts; however, demonstrations in France in response to the increasing CO₂ tax showed, that when the taxes create too high of a burden on people, there must be a mechanism to return these taxes to citizens.</p>

Stakeholders' opinions concerning the effects of a fossil carbon tax on the bio-based industries

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There is general agreement among the stakeholders interviewed that a tax on fossil carbon is a valid idea and that it would have a positive impact on the bioeconomy as a whole. A number of stakeholders mentioned that the rate of the tax plays an important role in the effectiveness of this mechanism. In Deliverable 4.4, the different approaches concerning the carbon tax rate are addressed. Other issues, questions and concerns that were raised are presented below with appropriate comments:

- Novel bio-based production processes might be less energy efficient, so a carbon tax (and thus increasing energy prices for the current energy mix) could hinder the use of such processes more than the existing streamlined petrochemical alternatives.
 - *Comment by STAR4BBI team:* This concern seems too general, since bio-based industries are already operating efficiently, which was confirmed by bio-based industry representatives during the workshop. Additionally, the increased fossil energy prices will also lead to bio-based industries (as well as other industries) choosing renewable energy sources for their production processes to avoid paying higher prices for fossil energies.
- The introduction of a fossil carbon tax according to the mechanism suggested by STAR4BBI would have a rather high impact on fossil resources in general, but the impact on the chemical sector in the EU would be less certain because most chemicals produced in the EU are exported, meaning that the tax would be refunded.
 - *Comment by STAR4BBI team:* According to EUROSTAT data, in 2017, the production value of chemicals in the EU was around € 500 billion; from this overall production capacity around € 155 billion worth of chemicals were exported from the EU and additionally € 107 billion worth of chemicals were imported into the EU^{21, 22}. Considering that the imported chemicals will be taxed according to their fossil carbon content and for exported chemicals the tax will be reimbursed; around € 155 worth chemicals will be freed from taxation while overall € 452 worth chemicals will be taxed by the fossil carbon tax. Instead of putting the financial burden of a fossil carbon tax only on local European producers, this mechanism creates a setting where industries outside of the EU also carry the responsibility for the fossil carbon used in their products, similar to the industries operating in the EU.

3.1.4 Stakeholders participating in the study

For this topic, two experts were interviewed on the phone to verify and discuss the concepts suggested and six experts were contacted via e-mail to verify specific issues concerning the mechanism. Among them, two worked in an intergovernmental organisation, two of them in academia and two were policy makers.

In addition, eight participants took part in the discussion regarding a fossil carbon tax and provided their feedback concerning the mechanism during the “Assessing Bio-based Product Value Chains. How Better Regulation and Standardisation Can Promote a Level Playing Field” stakeholder workshop held in Cologne in May 2019. The group participating in the fossil carbon tax discussion during the workshop was comprised of four participants representing the industry and four participants representing research institutes.

The inputs, questions and issues raised by the stakeholders has been used to refine and improve the initial proposals of the project presented in the text.

3.1.5 Conclusion

As shown by the above report, a fossil carbon tax would serve the dual purpose of promoting bio-economy and climate change mitigation while at the same time not hampering the European industry. It has a number of advantages compared to the more commonly discussed CO₂ tax. A number of questions concerning the implementation of the fossil carbon tax arise that are outside of the scope of this deliverable and are not discussed in this document; however, these issues have been discussed in detail in the Deliverable 4.4 of the STAR4BBI project. Below, the central issues regarding the favourable conditions of the fossil carbon tax provides as compared to a CO₂ tax and how the implementation of this tax will influence the bio-based industries are presented:

- The implementation of a CO₂ tax is very complex to realise for the chemicals, materials and products sector; taxing the fossil carbon in products and fossil resources simplifies this challenge and provides an elegant solution.
- By putting the tax at the beginning of the value chain (upstream), the complete value chain is taxed.
- All imported products will be taxed according to their fossil carbon content in addition to fossil resources produced and used in the EU due to a relatively easy measurement system.
- Imported products will be additionally taxed for the energy that has been used for producing these products. Default tax rates will be set for different product groups based on the energy taxes that the product producers pay in the importing countries.
- For exported products, the tax will be reimbursed to EU producers according to the tax paid (in proportion to fossil carbon content).
- Fossil-based products produced in or imported to the EU will become more expensive, which will create a level playing field for bio-based products.
- A fossil carbon tax coupled with other political instruments (such as the integration of a policy specific for bio-based materials, as proposed in the Deliverable 4.4) is expected to boost investment in bio-based industries.

3.2 Sustainability certification for all products

3.2.1 Sustainability criteria

The development of sustainability criteria for all products throughout the entire value chain is essential to ensure a level playing field for all products. With these criteria in place, a fair comparison and choice concerning externalities can be made between materials/products.

There are some starting points for the successful development of a sustainability certification scheme for all products:

- The three main pillars for sustainability criteria are Environmental, Social and Economic.
- Impacts should cover the whole life-cycle of the product.
- The same assumptions and calculations must be made for all products with the same function to support comparability of environmental performance claims (LCA and Product Environmental Footprint (PEF)).
- There must be clear rating and labelling of products based on their environmental performance, e.g. in a similar way with the EU Energy Label (label shows energy efficiency with a grade from A to G).

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Sustainability criteria/requirements have been captured in several documents, such as *EN 16751:2016 Bio-based products - Sustainability criteria*, which sets horizontal sustainability criteria applicable to the bio-based part of all bio-based products. In addition, the Renewable Energy Directive sets out sustainability criteria for biofuels to ensure that they are produced in a sustainable and environmentally friendly manner. ISO 13065 presents several criteria and indicators regarding biomass for bioenergy purposes that underline the principles of sustainability. *EN 16760:2015 Bio-based products - Life Cycle Assessment* provides specific life cycle assessment requirements for bio-based products. Furthermore, CEN Guide 4, a guide for addressing environmental issues in product standards, contains an Environmental Checklist as a reference tool for standards writers to include environmental aspects in standards (see the 2014 NOVA paper on Proposals for a Reform of the Renewable Energy Directive to a Renewable Energy and Materials Directive, for an overview on Sustainability Criteria for Renewable and Fossil Feedstocks in Different Applications According to Different Legal Frameworks).²³

Based on these documents, when developing sustainability criteria for all products, the following criteria should be taken into account:

Environmental criteria

- *Climate protection and air quality - promotion of good air quality and reduction of GHG emissions:*

Throughout the life cycle of a product, GHGs are emitted primarily in the form of CO₂ for fossil-based products and N₂O for bio-based products (as a result of fertiliser use). Conversely, plants sequester atmospheric CO₂ during their growth. It is therefore important to take into account how GHG emissions and removals related to their operations are managed during the whole life cycle of a product.

Micro- and Nano-particles have always occurred in nature, but over the centuries their concentration in the air has increased strongly as a result of the combustion of fossil fuels. Small dust particles can penetrate deep into the lungs and, if they cannot solve or disintegrate, can accumulate in the body and inflict damage²⁴. The decay of plastics can cause the formation of Micro-/Nano-plastics, which are harmful for both aquatic wildlife and humans. For bio-based plastics, this problem usually does not occur. Identification of contamination risks is important.²⁵

- *Biodiversity:*

Agriculture is responsible for the 70% of projected losses in terrestrial biodiversity due to widespread land conversion, pollution and soil degradation. However, increased yields through more intensive production practices and the expansion of agriculture area have been key to enabling improved food security over the past century. Fortunately, there is a growing understanding of the environmental impacts of different agricultural practices, which has in turn given rise to “best practices” for agricultural production. One of the rapidly expanding ways by which these best practices are being developed, promoted and implemented is through a system of voluntary sustainability standards operating across multiple agricultural sectors. As these initiatives grow in popularity, it becomes increasingly important to understand how and where they may contribute to biodiversity protection. Average coverage of biodiversity impact indicators includes Habitat Conservation, Water Use and Quality, Soil Fertility and Climate Change.²⁶

➤ *Water usage:*

This criterion focuses on the usage of fresh water (quality and quantity during the product's life cycle). It is important to track the source and amount of the water used during feedstock production, conversion, and end-use, as well as the impact it has on the local environment. Indicators are water conservation, management of fresh water as a sustainable resource, quality of water released and impact to water sources.

➤ *Soil usage:*

It is important to be aware of how soil quality, productivity and erosion are addressed. In agriculture, crop rotation is an important factor to report on related to soil productivity. Typically, oil platforms (land or sea) are used to obtain resources for fossil-based products. Although most have been around for a long time, their effects on geological formation, such as seismic activity and wildlife population, should be noted.²⁷ For bio-based products, large patches of land are needed in order to farm the needed resources. As such, it is important to list the origin of this land to determine if it was obtained fairly or by means of deforestation or exploitation of local farmers and families through the legal purchase of the land at an unfairly low price, thus leading local economies into distress.²⁸

➤ *Environmental burdens/waste:*

The environmental burden and waste caused by extractions of crude oil and natural gas should be taken into account. Contamination risks during the lifetime of products are mostly caused by littering, therefore the biodegradation of materials should be considered. Through degradation, chemicals can be brought into the environment. As such, burdens caused by extractions, depletion, decay time and the use of chemicals should be accounted for. EOL strategies are important for both biodegradable and fossil-based materials; economic sustainability can be promoted by the use of various strategies for the optimal use of existing resources. Some plastics can be recycled. However, recycling often does not take place in the country of origin, meaning that, in addition to recycling emissions, shipping emissions must also be accounted for. For bio-based products, EOL strategies can also vary (e.g. composting to create fertilizers and biofuel). Therefore, it is important to take into account EOL emissions (both positive and negative), landfill impacts and the regeneration of energy.²⁹

➤ *Energy and material resources:*

It is important to carry out an overall assessment of the amount of energy and material resources needed for the whole life-cycle of the product, including determining how much of this energy is renewable.

Social criteria

➤ *Labour rights and job creation:*

Key factors include how labour rights (e.g. freedom of association, abolition of child labour, discrimination) are protected, how working/living conditions are addressed, the amount of

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jobs that are sustained by the producers for the whole life cycle, and the work quality. When assessing jobs, criteria such as employee safety, minimum wages and maximum hours of work per day should be considered.

➤ *Local development:*

Effects on local communities can be positive (e.g. growth of local economy, local awareness) or negative (e.g. local air pollution, exploitation of local resources). Therefore, it is important to note the effects that companies have on local community development and ensure that local traditions and culture are respected.

➤ *Land use rights and land use change:*

Land use rights should be respected. Additionally, possible effects on local food security should be noted.

➤ *Water use rights:*

This includes respecting water use rights and determining impacts on local water resources.

Economic criteria

➤ *Sustainable production:*

Promoting resource and energy efficiency, and sustainable infrastructure are key factors within this criterium. Its implementation helps to reduce future economic costs and strengthen economic competitiveness.³⁰

Proposed indicators for comparison

In order to make a fair comparison between products based on the criteria listed above, clear indicators need to be developed and proposed. Fortunately, many indicators are already available, for example in the documents mentioned in section 3.2.4. Thresholds or limits can be established for the indicators. A table with an example of criteria and indicators is presented below.

Table 9 Example of criteria and indicators

Criteria	Indicators
GHG emissions during life cycle	<ul style="list-style-type: none"> • Production GHG (kg CO₂eq)
Soil	<ul style="list-style-type: none"> • Soil quality index (Dimensionless, pt) • Biotic production (kg biotic production) • Erosion resistance (kg soil) • Mechanical filtration (m³ water) • Groundwater replenishment (m³ groundwater)
Energy input during life-cycle	<ul style="list-style-type: none"> • Total energy input (kWh)

Job Creation/ Sustainability	<ul style="list-style-type: none"> • Amount of jobs (number) • Probability of growth (%) • Working conditions (e.g. good, toxic, long hours, low wage)
Water usage during life-cycle	<ul style="list-style-type: none"> • Usage (metric tonnes) • Source (e.g. no local threat, medium local threat, high local threat)
Effect on Local Communities	<ul style="list-style-type: none"> • Positive effects (categorised as low, medium or high impact) • Negative effects (categorised as low, medium or high impact)

3.2.2 Sustainability certification scheme

Based upon the criteria previously described, a certification scheme could be developed to provide clear guidance on how to make effective, trustworthy claims to consumers, on product-related sustainability information. This scheme is ideally applicable to all regions and companies of all sizes. Ultimately, certification would aim to empower consumers to make informed sustainable choices.³¹ Although it is not to be expected that bio-based products will have a superior performance on all criteria compared to their fossil-based counterparts, this will mostly indeed be the case for some important ones (e.g. GHG emissions). This is also the outcome of a Braskem study in which, based on an LCA-methodology, a comparison is made between a bio-based polyethylene film (made using a sugar cane-based polyethylene resin) and fossil-based polyethylene resin.³²

Today, a good example of the impact of sustainability certification can be seen in the cocoa industry. Organizations like UTZ, a certification for sustainable farming, increase pressure on the cocoa industry to eliminate illegal child labour and modern slavery, have an open and transparent value chain with traceable cocoa beans, and paying a higher price for the product to allow farmers earn a living wage. Anonymity also disappears from the chain since it is known who harvests the cocoa beans and under which conditions. This is supported by global standardization and certification initiatives.³³ Recently, Barry Callebaut, the largest chocolate maker in the world, has joined the alliance to make the cocoa value chain open and transparent. Therefore, the sustainability criteria/certification of the cocoa value chain plays a very important role in providing for a level playing field for, in this case, the cocoa industry.

Another good example of sustainability certification is the EU Ecolabel Scheme. The EC has presented a series of proposals on sustainable consumption and production that contribute to improving the environmental performance of products and increase the demand for more sustainable goods and production technologies. The building blocks of the European Union's policy on sustainable consumption and production are an integral part of the European Union's renewed Sustainable Development Strategy (EU SDS). One of the building blocks is the EU Ecolabel Scheme, a voluntary scheme designed to encourage businesses to market products and services that are more beneficial to the environment and allow European consumers, including public and private purchasers, to easily identify them.³⁴

3.2.3 Implementation of sustainability criteria/scheme

In the last decades, certification - an independent seal showing that a product, process, system or service satisfies a certain standard or quality - has become an important tool for governments and companies to demonstrate their sustainability performance. Currently there are certification schemes available for almost every product and service (e.g. forest, food, fair trade, agriculture and energy). However, a harmonized product sustainability certification for business-to-consumer transactions is difficult to set up. This is because the user phase of the value chain is difficult to check. Product use and disposal differs between cultures and countries, though the most significant overall sustainability effect may be regional or local consumption patterns steered by policies and subsidies. A harmonized sustainability certification scheme for business-to-business (B2B) would be a more feasible option to implement. Global companies and organizations could assist in this effort by implementing transparent, secure and efficient platforms for sustainable value chains, for example by using emerging technologies like blockchain.

To be able to make an optimal comparison between different products, a sustainability certification scheme would ideally be set up in a similar way as the EU Energy Label. The EU Energy Label shows how the appliances are ranked on a scale from A to G according to its energy consumption; Class A (green) is the most energy efficient and Class G (red) the least. With such a scheme, a gradual sustainable range that develops over time would become possible. In this case, fossil-based products could also be compared amongst each other and producers would not be forced to transition exclusively to bio-based products (i.e. level playing field). This will allow for progress and development over time.

Implementation of sustainability criteria for all products in society can take place through several routes: public procurement, regulation and communication.

Public procurement

Public procurement is the procurement of goods, services and construction on behalf of a public authority, such as a government agency. With 10% to 20% of gross domestic product (GDP), government procurement accounts for a substantial part of the global economy.³⁵ Procurers prefer labels (or certification schemes) because they are relatively easy to use in procurement procedures, such as green public procurement, to make sure the products bought meet the requirements.

It is very difficult, if not impossible, to introduce one harmonised label for all products because the focus should be on the stages where the product has the highest environmental impact, which differs from product to product. Therefore, a more feasible, longer-term option for implementation would be to introduce labels for all the different product groups. In the meantime, examples like the Bioplastics Europe Database, which contains comparisons and alternatives for more sustainable products, could be further developed.

A promising label is the EU Ecolabel. The EU Ecolabel is a label of environmental excellence that is awarded to products and services that meet high environmental standards throughout their life-cycle: from raw material extraction, to production, distribution and disposal. It promotes the circular economy by encouraging producers to generate less waste and CO₂ during the manufacturing process. The EU Ecolabel criteria also encourage companies to develop products that are durable and easy to repair and recycle.³⁶

Under the EU Procurement Directives (2004/18/EC and Directive 2004/17/EC), ecolabels may be used in public procurement, providing a number of conditions are met³⁷:

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- Procurers are not allowed to demand that a product carries an ecolabel, but may only indicate that the criteria underpinning a certain ecolabel must be met and that the ecolabel may be used as one form of proof of compliance.
- Procurers may only use ecolabel criteria that refer to characteristics of the product or service itself or production processes, not those relating to the general management of the company.
- Procurers may only refer to ecolabels that meet a number of requirements (the Type I or ISO 14024 ecolabels, such as the EU Ecolabel, meet these requirements).
- The requirements for the label are based on scientific evidence.
- The ecolabels are adopted with the participation of all stakeholders, such as government bodies, consumers, manufacturers, distributors and environmental organisations.
- The ecolabels are accessible to all interested parties.

Different sets of criteria are established for each product or service group covered by the scheme.³⁸ These criteria will normally define the environmental performance that the product must reach. There is a clear overlap with the sustainability criteria listed in section 3.2.1. For example, EU Ecolabel criteria for paper products include recyclability, emissions, waste and energy. Furthermore, criteria for textiles include treatment of emissions to air and water and fundamental principles and rights at work. Finally, criteria for gardening include energy consumption and CO₂ emissions. Implementation of the EU Ecolabel has been a success; for example for the product group ‘paints and varnishes’ more than 37,500 products have been awarded with the EU Ecolabel licence.³⁹ The EU Ecolabel also encourages sustainable production; for example, only lubricants that are made of at least 50% renewable natural resources, are biodegradable and minimize CO₂ emissions are eligible for the EU Ecolabel. However, for small organisations with limited funds it is difficult to start the process of certifying their products. To counter this, the EU Ecolabel has special discounts for SMEs, micro-enterprises and applicants from developing economies in order to facilitate their compliance.

Because the EU Ecolabel spans the whole life cycle of a product, it is compatible with *EN 16760: 2015 Bio-based products - Life Cycle Assessment*, which covers the LCA of the whole product, not only its bio-based part. *CEN/TR 16957:2016 Bio-based products - Guidelines for Life Cycle Inventory (LCI)* for the EOL phase can be used to provide guidance on how to compile an inventory for the EOL phase in a LCA of bio-based products. In general, this phase is the same for both bio-based and non-bio-based products: recycling (mechanical/organic), recovery, incineration, landfill and wastewater treatment.⁴⁰

An important issue with the current EU Ecolabel scheme is that it uses a rigid pass-or-fail-system, set out in the EC Regulation No 66/2010 on the EU Ecolabel. This means that the label can only be obtained when all criteria are met. Ideally, the EU Ecolabel would use a similar scheme as the earlier mentioned EU Energy Label, which awards a grade from A to G. This idea has been suggested by participants of the STAR4BBI workshop in Cologne on 14 May 2019 as well as in the Open-Bio project, by stakeholders in a recent consultation held by the Joint Research Centre (JRC) on EU Ecolabel criteria for financial products and in proposals for revision of EU Ecolabel criteria for Hard Coverings.⁴¹ A multi-level EU Ecolabel provides more transparency for relevant stakeholders in knowing whether a product is, for example 60, 80 or 90 percent sustainable. This concept with bandwidths offers more options of choice and gives niche products the opportunity to stand out from products that deliver lower sustainability percentages. At the same time, products that are for example 70 percent sustainable can still qualify for the label.⁴² In addition, a label with multiple gradations

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could give producers an idea of how close they are to a higher grade of the EU Ecolabel and encourage them to identify ways in which they could achieve this⁴³.

For the implementation of the sustainability scheme (EU Ecolabel) a product group to start with on the short term could be toys. This is an interesting option due to its volumes and accessibility to consumers. Large toy companies like LEGO® have already started producing a range of sustainable LEGO elements made from bio-based plastics sourced from sugarcane. For the toys group, the sustainability criteria mentioned in paragraph 3.2.1 could be implemented. When a product complies with the criteria, it would be eligible to receive the EU Ecolabel. This would be further deployed through procurement. From start to finish, the process of setting up a new product group in the EU Ecolabel takes on average 2 years.

During the workshop in Cologne, several matters were raised regarding the implementation of sustainability criteria via the EU Ecolabel. Notably, it can be costly to prove the sustainability criteria for the smaller companies. Therefore, default values should be made available to give SME's the opportunity to participate. As mentioned previously, the EU Ecolabel already has special discounts for SMEs to facilitate compliance. The feasibility of having valid criteria defined for all products was discussed; EOL options and criteria are especially difficult to include. It was suggested to have overarching sustainability criteria that can be used for all the product groups and then some specific criteria that are product specific. For example, biodegradability is only a characteristic of certain product categories.

Another topic discussed was the textiles product group since well-developed Ecolabel criteria already exist for this product group. Product groups where sustainability criteria should be further developed within the EU Ecolabel should either be consumer driven or have high production volumes. It was determined during the workshop that the EU Ecolabel is a good vehicle to further develop criteria for the indicators laid down in the CEN standard. Moreover, good labelling is essential for sustainability.

When considering a current EU Ecolabel, e.g. for Clothing and Textiles, the opportunity already exists to communicate compliance (in %) with criteria on the packaging (see figure 3 below). Therefore, it would take a relatively small adjustment to communicate whether a product is, for example, 60, 80 or 90 % sustainable (such as by assigning a grade from A to G).

Text that may appear alongside the Ecolabel depending on product content

Fibres used	Production specification	Text that may be displayed
Cotton fibres	Organic content of more than 50 %	Made with xx % organic cotton
	Organic content of more than 95 %	Made with organic cotton
	IPM content of more than 70 %	Cotton grown with reduced pesticides
Man-made cellulose fibres	Certified sustainable pulp of more than 25 %	Made using xx % wood from sustainable forests
	Certified sustainable pulp of more than 95 %	Made using wood from sustainable forests
Polyamide	Recycled content of more than 20 %	Made with xx % recycled nylon
	Recycled content of more than 95 %	Made with recycled nylon
Polyester	Recycled content of more than 50 %	Made with xx % recycled polyester
	Recycled content of more than 95 %	Made with recycled polyester

Assessment and verification: the applicant shall provide a sample of the product packaging showing the label, together with a declaration of compliance with this criterion.

Figure 3 Text opportunities alongside current Ecolabel for Clothing and Textiles on production specification

Regulation

In the past, the EC has made recommendations to member states on the development of sustainability schemes for the bio-energy sector. The EC has also reported on whether these schemes have sufficiently and appropriately addressed the sustainability criteria and whether these schemes have led to barriers to trade and the development of the bio-energy sector. Approved recognised schemes by the EC include International Sustainability Carbon Certification (ISCC), RRSB EU RED, 2BSVs and Better Biomass.⁴⁴

It also has considered if additional measures such as common sustainability criteria at EU level would be appropriate. Recently, the EC has classified most palm oil fuels as unsustainable and there is discussion on introducing carbon taxes. Although GHG emissions are only one of the criteria for sustainability certification listed above, this could be the right moment to address the topic of regulations for the introduction of harmonized sustainability criteria for products. The introduction of sustainability criteria for all products fits well into the current European Union's policy on sustainable consumption and production as an integral part of the European Union's renewed EU SDS.⁴⁵ Ultimately, certain unsustainable products could be banned in the EU.

Communication

Raising consumer awareness about sustainability issues is crucial. Consumers might even not be aware that certain products are derived from fossil-based feedstock. The implications of their product choices should become clearer. Therefore, a label should be easy to recognise and reliable. With an estimated 455 ecolabels, it is difficult for consumers to choose and know what to trust. Very few of these labels give consumers meaningful guidance in choosing environmentally superior products.⁴⁶

Studies show that consumers care about the source of the label and the quality of information it contains. They prefer detailed labels that contain information about the sustainability claims being

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made rather than simple icons that lack substance. These studies also tested if the source of a sustainability label (public/private) affect consumers' evaluations. Consumers are more likely to trust labels that come from governments because they are more transparent and avoid the risk of a conflict of interest.⁴⁷ Therefore, in communicating on the introduction of sustainable criteria for all products these points should be taken into account so consumers can make meaningful, well-informed and low threshold decisions when choosing what products to buy. As a result, the implications of their product choice should become clearer. Clear sustainability certification and labelling could help achieve this.

3.2.4 Related regulations and standards

ISO 13065:2015 Sustainability criteria for bioenergy specifies principles, criteria and indicators for the bioenergy supply chain to facilitate assessment of environmental, social and economic aspects of sustainability. It is applicable to the whole supply chain, parts of a supply chain or a single process in the supply chain. However, it does not determine the sustainability of processes or products. It is intended to facilitate comparability of various bioenergy processes or products and can also be used to facilitate comparability of bioenergy and other energy options.

EN 16751:2016 Bio-based products - Sustainability criteria sets horizontal sustainability criteria applicable to the bio-based part of all bio-based products, excluding food, feed and energy. These criteria cover all three pillars of sustainability: environmental, social and economic. If the product is partly bio-based, this standard can only be used for the bio-based part since it does not address non-bio-based (fossil, mineral) parts of a product. The standard can be used for two applications: to provide sustainability information about the biomass production only and to provide sustainability information in the supply chain for the bio-based part of the bio-based product. This standard sets a framework to provide information on management of sustainability aspects, but cannot be used to make claims that operations or products are sustainable since it does not establish thresholds or limits. However, it can be used for B2B communication or for developing product specific standards and certification schemes.

EN 16760: 2015 Bio-based products - Life Cycle Assessment provides specific LCA requirements and guidance for bio-based products, excluding food, feed and energy, based on EN ISO 14040 and EN ISO 14044. This standard covers bio-based products derived wholly or partly from biomass. It provides guidance and specifies requirements to assess the life-cycle impact of bio-based products with a focus on the bio-based part of the product. The applications of LCA as such are outside the scope of this European Standard.

CEN/TR 16957:2016 Bio-based products - Guidelines for LCI for the EOL phase provides guidance on how to compile an inventory for the EOL phase in LCA of bio-based products.

The Renewable Energy Directive establishes an overall policy for the production and promotion of energy from renewable sources in the EU. It requires the EU to meet at least 20% of its total energy needs with renewables by 2020 by means of achieving individual national targets. All EU countries must also ensure that at least 10% of their transport fuels come from renewable sources by 2020. The Directive sets out sustainability criteria for all biofuels produced or consumed in the EU to ensure that they are produced in a sustainable and environmentally friendly manner. Companies can show they comply with the sustainability criteria through national systems or so-called voluntary schemes recognised by the European Commission.

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EC Regulation No 66/2010 on the EU Ecolabel concerns the European Union Ecolabel, which is a voluntary environmental labelling scheme that enables consumers to make conscious choices without compromising on the quality of the products.

CEN Guide 4: 2008 Guide for addressing environmental issues in product standards contains an Environmental Checklist that can be used as a reference tool for standards writers to include environmental aspects in standards.

3.2.5 Debate, discussion and public opinion on the topic

Table 10: Stakeholder's views

Stakeholders	Stakeholders' views
EU-policy makers	Sustainability is on consumers' radar. Raising these sustainability criteria to all products fits well into the current EU policy on sustainable consumption and production. The EU already has applicable experience in the biofuels field.
Bio-based material producers	Claim that their footprint is lower than for fossil-based material producers. However, this will depend on the LCA. An example of a valid claim is made in the earlier mentioned Braskem study in which, based on an LCA-methodology, a comparison is made between a bio-based polyethylene film (made using a sugar cane-based polyethylene resin) and fossil-based polyethylene resin.
Fossil-based product producers	It likely depends on the LCA of a specific product whether or not a bio-based product will score better in sustainability criteria.
Certification bodies	There is a need to introduce a sustainability certification scheme for all products that is based on environmental, social and economic performance in a similar way as the EU Energy Label.
Standardization organizations	There is a need for harmonized LCAs.
End users/Consumers	There is uncertainty regarding the ability of standardized environmental performance rating/labelling to bring trust to consumers as well as whether consumers will be willing/able to pay more (green premium price) for a better rating.
Research institutions	Default values must be created for criteria that are difficult to calculate or prove. Blockchain could provide trustworthiness of sustainability claims.

3.2.6 Stakeholders participating in the study

To identify and analyse the suggestions (see section 3.2.7) to support the development of a sustainable certification for all products, 3 experts were interviewed. The experts represented industry, a

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national coordination institution for R&D and a sustainability platform that also certifies the EU Ecolabel in the Netherlands

In addition, during the workshop “Assessing Bio-based Product Value Chains. How Better Regulation and Standardisation Can Promote a Level Playing Field” held in May 2019, a discussion was conducted with stakeholders to validate the suggestions. 4 experts from industry and 1 expert from academia participated in the discussion.

3.2.7 Suggestions for improvement

There are several suggestions for the current EU Ecolabel to improve its applicability:

1. Create default values

The EC can decide that voluntary schemes or bilateral and multilateral agreements concluded by the Union contain accurate data regarding the sustainability criteria by means of “default values”. Market parties can use these default values to demonstrate that a certain sustainability criterion is met. This should reduce the administrative burden for market parties because companies can opt for these predetermined values instead of calculating an actual value. The default values are set at a conservative level, so that it is unlikely that market parties, by choosing the default values, can claim values that are better than the actual values. The default values can be adjusted to technical and scientific progress.⁴⁸

2. A multi-level EU Ecolabel

A multi-level EU Ecolabel provides more transparency for relevant stakeholders in knowing whether a product is, for example, 60, 70 or 80 percent sustainable. A minimum level to attain the label of course must be set. This scheme already works very well with the EU Energy Label. It gives consumers the opportunity to make even more conscious choices, gives producers clarity about where they stand and what improvements are needed, and provides a scope to set conditions in public procurement (to prevent it from becoming a niche market).

3. Make it possible to propose new EU Ecolabel product groups that are not an end-product (e.g. packaging, which is an important product group for the bio-based industry)

With the current EC Regulation No 66/2010 on the EU Ecolabel it is only possible to propose new product groups for end-products. However, there will be a new EC elected in 2019, which also means new opportunities to propose adjustments to the current EC Regulation on the EU Ecolabel. The sense of urgency (sustainability agenda, energy transition and circular economy) and social interest of the EU population currently exists to support this change. The challenge with sustainability criteria/certification is to find balance in the input and the outcomes. It will be challenging for producers to gather data for all sustainability criteria. The challenge is to ensure that it is simple and accessible for all producers while also keeping the costs down. Another challenge is to ensure that it is understandable for consumers. It would be relatively easy to start with, for example, the GHG reduction (environmental impact) and add more sophisticated sustainability levelling (social and economic) later on. Creating default values would be an important step. Additionally, special discounts for SMEs to facilitate compliance, as is already possible with the EU Ecolabel, seems to be a requirement not to remain a niche market.

Although it is a long-term effort, fortunately there are already good examples in practice to build on. There are possibilities to address these issues at different levels and at different stages to ensure that sustainability criteria/certification for all products is simple, transparent and accessible.

3.3 Genome editing techniques

3.3.1 Background

In order to overcome crucial global societal challenges, such as food security, sustainability and climate change, there is a need to increase agricultural productivity. The European plant-breeding sector is working to develop innovative and sustainable solutions to overcome these challenges⁴⁹. These solutions include developing efficient crops that are resistant to pests, disease and other stresses by using techniques such as genome editing.

Breeding techniques can be classified into three main categories:

- Conventional breeding techniques (e.g. mutagenesis): alteration of the genome of a living species without the insertion of foreign deoxyribonucleic acid (DNA).
- Genetic modification techniques (e.g. transgenesis): alteration of the genome of a living species by the insertion of foreign DNA.
- New breeding techniques (NBTs) (e.g. clustered regularly interspaced short palindromic repeats (CRISPR)/Cas9): alteration of a selected DNA sequence in a cell by modifying a DNA molecule at a selected point. Genome editing is a type of NBTs.

Compared to conventional breeding techniques and genetic modification techniques, NBTs are precise and less time consuming, and can be used to introduce specific characteristics in a wide variety of crops. As such, NBTs have become important in plant breeding innovations because they allow for the creation of additional genetic variations by making precise changes to the existing crop's genome.

Researchers worldwide have embraced genome-editing techniques due to their precision and effectiveness, and because they offer a wide range of opportunities to develop new and improve existing products. Genome-editing techniques show great potential in the fields of medicine (e.g. diagnostic agents, vaccines), the bioeconomy (e.g. bio-fuels) and agriculture (e.g. nutrient-enriched and stress-resilient crops to address food waste and food insufficiency).⁵⁰ In addition, they can provide solutions for existing global societal challenges, such as growing population, climate change, economic inequity and insecurity, and food security⁵¹.

Specific to the bioeconomy, experts indicated that the utilization of gene-editing techniques can potentially revolutionize the future production of bio-based products. Modern genome editing technologies have allowed far more efficient gene modification and can be used in different application sectors related to the bioeconomy, including:

- Plant breeding: increasing the production, composition, yield and disease resistance of agricultural crops.
- Industrial biotechnology processes: industrial microbial biotechnology and genome editing in microorganisms, bacteria and yeast to generate feedstocks for biofuels, pharmaceuticals and other high-value chemicals.
- Photosynthesis of plants: by modifying the genome of the plant, it is possible to improve the efficiency of the conversion of light into crop mass (currently, photosynthesis in plants is still relatively inefficient).

The continuous development of genome editing techniques is essential for Europe to continue as a global leader in science, innovation and competitiveness. However, current EU regulations applicable to genome editing techniques restricts their application⁵². In response, researchers working

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with novel plant genome editing techniques are calling for updated EU regulations applicable to genome-edited plants that match the scientific progress in this area. This report proposes some measures that could be adopted towards the establishment of a supportive policy and regulatory framework able to foster innovations (such as the use of genome editing) while ensuring safety standards for human health and the environment.

3.3.2 Related regulations/decisions/rulings

3.3.2.1 European level

Judgment of the European Court of Justice (ECJ) in case C528/16 (25 July 2018)⁵³:

At the EU level, the most recent ruling affecting genome editing techniques is the judgment of the European Court of Justice (ECJ) in case C528/16 (25 July 2018). The ECJ ruled that organisms obtained by mutagenesis² are genetically modified organisms (GMOs) and are, in principle, subject to the obligations laid down by the GMO Directive (Directive 2001/18/EC). Mutagenesis techniques with a proven history of safe application are exempt from these obligations. According to the ECJ, new mutagenesis techniques (including precise genome editing technologies such as CRISPR/Cas9) alter the genetic material of an organism in a way that does not occur naturally as they make it possible to obtain the same effects as what would be obtained with the introduction of a foreign gene into the organism (transgenesis). The ECJ believes that excluding genome-edited organisms from the scope of the GMO Directive would compromise its main purpose, which is to avoid possible adverse effects on human health and the environment, and would fail to respect the precautionary principle.

This surprising ruling came after the January 2018 decision of the advocacy general (Advocate General's Opinion in Case C-528/16⁵⁴) that the GMO Directive does not apply to organisms obtained through certain techniques of genetic modification, such as mutagenesis. The justification for the exemption of mutagenesis in this decision was that it does not entail the insertion of foreign DNA into a living organism.

Directive 2001/18/EC on the deliberate release into the environment of GMOs (12 March 2001)⁵⁵:

In accordance with the precautionary principle, the objective of this Directive is to protect human health and the environment when deliberately releasing GMOs into the environment for non-market purposes and when placing GMOs on the market. A case-by-case environmental risk assessment is required for a release to the environment. To this aim, MS and the Commission will share information regarding managing risks related to the release and the placing on the market of GMOs. MS are responsible for implementing emergency measures and informing the public if an incident occurs. The methodology for the risk assessment according to Directive 2001/18/EC is presented in Figure 4:

² Mutagenesis: a set of techniques that make it possible to alter the genome of a living species without the insertion of foreign DNA which have made it possible to develop seed varieties resistant to selective herbicides²

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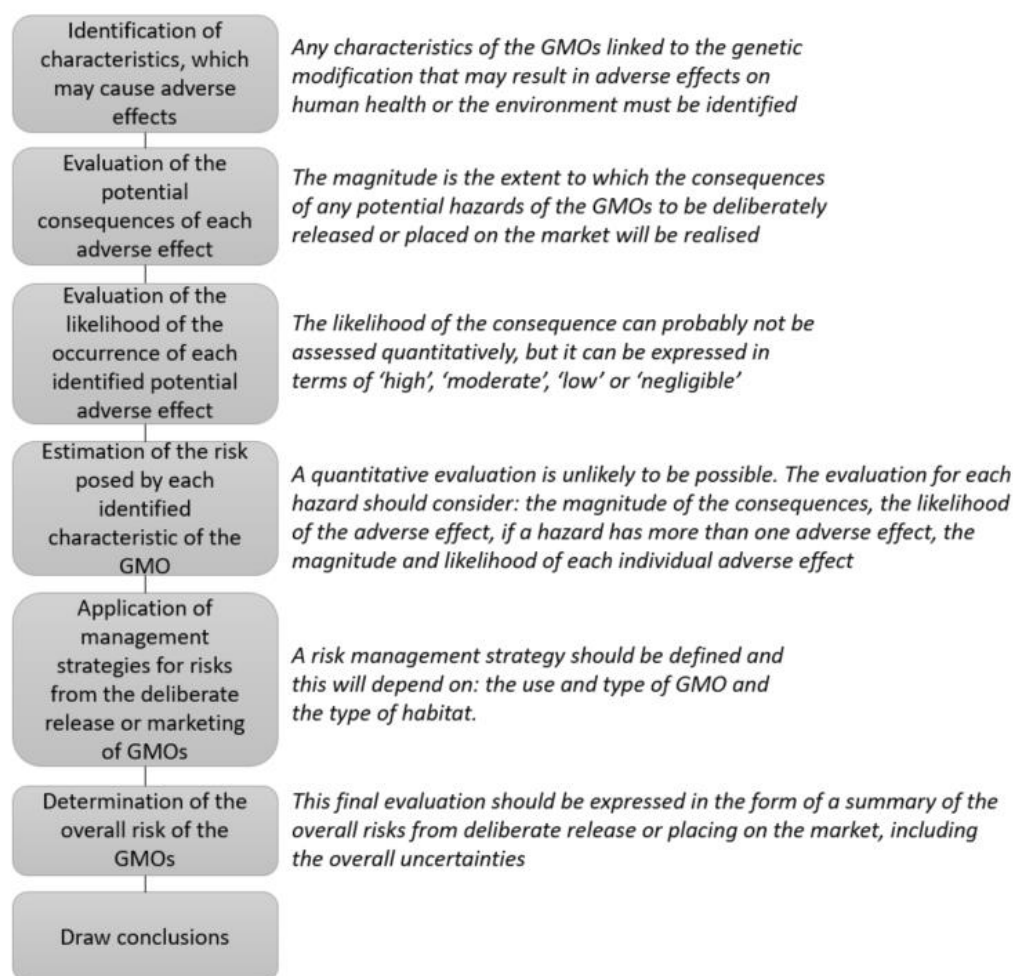


Figure 4 Methodology for an environmental risk assessment according to the Directive 2001/18/EC Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory (11 March 2015)⁵⁶:

This Directive establishes a comprehensive legal framework for the authorisation of GMOs. This framework is applicable throughout the EU to GMOs to be used for cultivation purposes. Under the framework, GMOs to be used for such purposes must undergo an individual risk assessment before being authorised to be placed on the EU market.

Directive 2009/41/EC on the contained use of genetically modified micro-organisms (6 May 2009):

This Directive lays down common measures for the contained use of genetically modified microorganisms (GMMs) in order to protect human health and the environment. To this aim, the user is responsible for assessing the contained uses of the GMMs and considering any potential harmful effects resulting from this use. Such effects can be for example, causing diseases to humans (including allergenic or toxic effects), diseases to animals or plants, deleterious effects due to the impossibility of treating a disease or providing an effective prophylaxis, deleterious effects due to establishment and dissemination in the environment and deleterious effects due to the natural transfer of inserted genetic material to other organisms. For the assessment, the identification of any potentially harmful effects, characteristics of the activity, the severity of the potentially harmful effects and the likelihood of the potentially harmful effects being realised should be noted.

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Regulation (EC) 1829/2003 on genetically modified food and feed (22 September 2003)⁵⁷:

This Regulation provides the basis for ensuring a high level of protection of human life and health, animal health and welfare, the environment and consumer interests in relation to genetically modified food and feed while facilitating the effective functioning of the internal market. In the case of GMOs or food containing or consisting of GMOs, the application must also be accompanied by the complete technical dossier supplying the information required in Directive 2001/18/EC and information and conclusions about the risk assessment carried out in accordance with the principles set out in Directive 2001/18/EC.

Within this regulation, it is recognised that, in some cases, a scientific risk assessment alone cannot provide all the information on which a risk management decision should be based. In these cases, other legitimate factors relevant to the matter under consideration may be taken into account.

Regulation (EC) 1830/2003 amending Directive 2001/18/EC concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs (22 September 2003)⁵⁸:

Directive 2001/18/EC requires MS to take measures to ensure traceability and labelling of authorised GMOs at all stages of their placement on the market. MS must ensure those inspections and other control measures, including sample checks and testing (qualitative and quantitative), have been completed. Guidance on sampling and detection should be developed in accordance with Article 23 of Directive 2001/18/EC in order to facilitate a coordinated approach for control and inspection, and to provide legal certainty for operators.

According to Article 23 of Directive 2001/18/EC, MS and the Commission will meet regularly and exchange information on the experience acquired with regard to the prevention of risks related to the release and the placement of GMO's on the market. This information exchange will also cover experience gained from the implementation of the risk assessment.

3.3.2.2 National level (Germany)

The two government bodies responsible for genome editing technology in Germany are the Central Committee for Biological Safety (ZKBS) and the Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit - BVL). The ZKBS participates in approval proceedings, advises the government on policy and monitors safety, while the BVL approves scientific trials and is responsible for all GMO-related activities, such as the import and export of GMO crops.

Gesetz zur Regelung der Gentechnik (Gentechnikgesetz - GenTG⁵⁹) (Law on the Regulation of Genetic Engineering), originally passed in 1990, implements the provisions of the EU Directive 2001/18/EC in Germany. Within the limits of EU law, this regulation is characterized by restrictiveness, complexity and rigorous requirements⁶⁰. GenTG operates within the framework of EU law and has three main objectives:

- To protect the life and health of human beings, animals, plants, tangible assets and the environment from any possible risks emanating from GMOs by taking appropriate precautions.
- To guarantee that GMOs can be grown, produced and marketed in coexistence with non-GMOs. This goal was introduced in 2005 in compliance with the common-market orientation of Directive 2001/18/EC.
- To provide the legal framework for the research, development, use and promotion of the scientific, technological and economic possibilities of GMOs.

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The GenTG law applies to⁶¹:

- genetic engineering facilities;
- genetic engineering works;
- releases of genetically modified organisms; and
- placing GMOs, or products that contain or consist of GMOs, on the market.

GenTG reaffirms that, according to Directive 2001/18/EC, the operator is responsible for conducting a proper risk assessment when releasing GMOs to the environment or placing them on the market. Compliance is achieved through reporting and internal monitoring.

3.3.2.3 National level (The Netherlands)

In the Netherlands, there are two legislative texts that regulate GMOs. Both texts exist within the framework of Wet Milieubeheer⁶², the governing environmental legislation in the Netherlands:

- Besluit genetisch gemodificeerde organismen milieubeheer 2013⁶³: a resolution made 1 April 2014 that establishes the rules with regard to the contained use and deliberate release into the environment of GMOs.
- Regeling genetisch gemodificeerde organismen milieubeheer 2013⁶⁴: a regulation of the Secretary of State for Infrastructure and the Environment.

As a result of Judgment of the ECJ in case C528/16, in which the ECJ ruled that NBTs fall under the GMO Directive, NBTs also fall under the two pieces of Dutch legislation described above.

In April 2019, the Dutch Ministry of Infrastructure and Public Works initiated the necessary steps to modernize the safety policy in the field of biotechnology⁶⁵ with the goal of improving the opportunities that biotechnology can offer society while also ensuring safety for both people and the environment. Intensive consultations were held with relevant stakeholders (business community, professional associations, interest groups, ethicists, knowledge institutions, NGOs, governments and civil society organizations) in 2017 to gain insight into their wishes and preferences for policy modernization. Identified relevant topics for the above-mentioned stakeholders were, among others, optimizing the implementation practice of biotechnology licensing and ensuring the freedom of choice of citizens and professional users with regard to products that may or may not contain GMOs. To date, the main conclusions of the study are as follows:

- Participants made a clear distinction between different applications.
- Participants sometimes adopted a principled attitude, but more often adopted a balanced attitude in which the various benefits and consequences of a specific application were compared with each other.
- If there is a clear benefit, such as addressing disease and hunger, applications are more likely to be approved. Similarly, if profit or pleasure is the main objective of an application, participants were critical.
- Guaranteeing safety is seen as crucial; strict supervision and international agreements are expected. As such, participants attached great importance to robust research into short- and long-term consequences prior to societal applications of biotechnology.

The Dutch Ministry of Infrastructure and Public Works believes it is urgent to update European GMO legislation and, if necessary, adjust it in response to advancing biotechnological developments. An evaluation of the GMO Environmental Management Decree 2013 is currently taking place with the publication of the results anticipated for summer 2019.

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In addition, the Ministry of Infrastructure and Water Management presented the Biotechnology and Safety research program in March 2016. The aim of this program is to gain scientific knowledge about the risks and uncertainties of biotechnological innovations and how measures can be built in from the start to guarantee safety.

To conclude, the Netherlands Commission on Genetic Modification (COGEM) advises the Government on environmental risks associated with European license applications for GMOs. The RIKILT Institute of Food Safety carries out a brief risk assessment.

3.4 Impact of these regulations on the European bioeconomy

Many experts (see sections 3.3.4 and 3.3.5) disagree with the ruling of the ECJ in case C528/16. The European Academies Science Advisory Council (EASAC) comments that it is important to ensure that regulations are evidence-based, proportionate and sufficiently flexible to cope with future advances. A number of experts mentioned that this ruling is not scientifically justified and argue that an organism that has undergone genetic alterations that could also be the result of classical breeding techniques cannot be considered a GMO.

In this respect, according to the experts, even if the precautionary principle was established to offer guidance in situations in which a new technology might pose risks to human health or the environment, it cannot be automatically assumed that genome-editing techniques are dangerous. In other words, precaution and innovation cannot be framed as opposite⁶⁶. The strict application of the precautionary principle might have the negative effect of slowing down innovation, rather than embrace its potential to benefit society.

A majority of the experts agreed that the new ruling would have negative impacts for the future development of the European bio-based industry. Worldwide developments in this field are fast-paced, meaning that other countries might gain technological leadership while European companies cannot readily develop and use these innovative techniques. This judgement could be detrimental, especially for smaller biotechnology companies that are working to bring new plant varieties to market.

Experts also argue that the new ruling will result in additional costs and long procedures. NBTs are currently ruled under the Directive 2001/18/EC and must undergo a risk assessment prior to market authorisation in the EU. These procedures (e.g. administrative procedures, pre-market evaluations) are lengthy processes and incur additional costs.

The obligations imposed by the GMO regulation on traceability and labelling of GMOs entering the European market are difficult to implement and control. Currently, modifications in plants can be detected analytically; however, the used methodology for genome editing cannot be identified. Therefore, all products that have been edited/modified genetically are subject to the obligations laid down by the GMO Directive, although this edition/modification may have occurred naturally. This issue becomes more prevalent when companies import products from different countries.

Furthermore, this new ruling will support the non-acceptance of consumers. One of the major problems regarding consumer acceptance on GMOs is the possibility that their transgenes could have adverse effects on the environment and human health⁶⁷. According to the new ruling, NBTs are now considered GMOs and this will expand the existing concern of consumers on GMOs, to NBTs. The non-acceptance of consumers will consequentially demotivate the industry to make investments in products obtained using genome-editing techniques.

3.5 Debate, discussion and public opinion on the topic

As previously commented, there is currently widespread discussion in Europe surrounding the applicability of Directive 2001/18/EC to NBTs. Opinions of some experts and organizations in favour and against the new ruling are summarized in table 9 below:

Table 11 Opinions of experts and organizations in response to the ruling of the ECJ in case C528/16

<i>In favour of the new ruling</i>	<i>Against the new ruling</i>
<p>The Confédération paysanne (French agricultural union) argues that the use of herbicide-resistant seed varieties carries a risk of significant harm to the environment and the health of both humans and animals similar to the risk posed by GMOs obtained by transgenesis.</p>	<p>On 18 January 2018, the Advocate General Michal Bobek communicated that organisms obtained by mutagenesis are exempted from the obligations of the GMO Directive because, unlike transgenesis, mutagenesis does not entail the introduction of a foreign DNA into living organisms.</p>
<p>Some NGOs expressed that impacts are uncertain and that regulation cannot keep pace with the speed of technological innovation. Dana Perls, the senior food and agriculture campaigner at Friends of the Earth, pointed to CRISPR/Cas9 and other forms of genome editing missing their targets and accidentally altering other stretches of DNA in an organism.</p>	<p>EuropaBio's highlights industry's concerns about the new ruling of the ECJ. According to him, Europe could miss out on significant benefits of certain applications of genome editing. He states, "in addition to providing consumer and environmental benefits, such as enhanced nutrition, improved health or a more circular economy, innovations made possible by genome editing hold enormous promise to keep Europe at the forefront of socio-economic development, continuing to generate jobs and growth in the EU".</p>
<p>Bart Staes, the Member of the European Parliament (MEP) of the Greens/EFA group, also applauded the decision, stating "Just because the industry has come up with new ways to modify organisms does not mean that these techniques should be exempt from existing EU standards on GMOs".</p>	<p>Many scientists responded to the decision with dismay, predicting that countries in the developing world would follow Europe's lead and block useful genome-edited crops from reaching farms and marketplaces. The ruling may also curtail imports from the USA, which has taken a more lenient view of genome-edited foods. Since the agricultural revolution 10,000 years ago, all crop breeding has come down to altering the genetic composition of plants. In addition, according to many scientists, there is not a strong scientific reason to consider genome-edited plants to be GMOs.</p> <p>The German chemical industry association (VCI), which represents companies such as Bayer, BASF and Merck KGaA, stated that the court's ruling was "backward looking and hostile to progress".</p> <p>The National Academy of Sciences in the USA has found no evidence to confirm that these crops are any more dangerous than conventionally bred ones.</p>

3.5.1 Stakeholders participating in the study

To identify and analyse the suggestions (see section 3.3.6) to support the development of genome editing techniques, eight experts were interviewed. The experts represented academia, industry, NGOs, consumer organizations and EU associations, as shown in Figure 5 below:

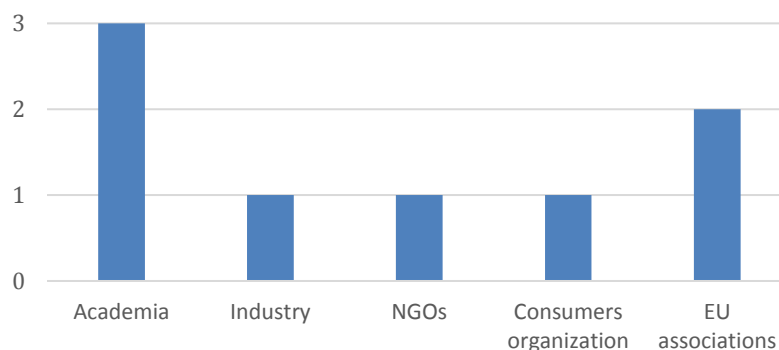


Figure 5 Professional background of interviewed experts for the genome editing techniques

In addition, during the workshop “Assessing Bio-based Product Value Chains. How Better Regulation and Standardisation Can Promote a Level Playing Field” held in May 2019, a discussion was conducted with stakeholders in to validate the suggestions made by STAR4BBI project. Four experts from industry and one expert from academia participated in the discussion.

In the following section, the suggestions to support the development of genome editing techniques resulting from research, conducted interviews and discussions during the stakeholder workshop are presented.

3.6 Proposed measures for establishing a supportive regulatory framework

Thanks to genetic engineering, scientists now have the ability to do precise genetic modification of crops⁶⁸. The EU should not apply the GMO Directive to NBTs in order to give strength and recognition to the competitiveness of the European plant-breeding sector⁶⁹. In this sense, several suggestions to support the development of these techniques are presented in Figure 7 below. Interactions with stakeholders, in the form of semi-structured interviews and a discussion with experts at the stakeholder’s workshop that took place in May 2019, have served as a basis for collecting their opinions on the suggestions made as well as for identifying new proposals from them and discussing solutions.

In Figure 6, an overview of the suggestions for supporting genome editing techniques is presented. Firstly, suggestions related to regulations have been identified. Updating the GMO definition stated in Directive 2001/18/EC to focus on the process and not the end product is the most important and urgent proposal to be carried out. In the case that the GMO definition is not updated, Annex 1B, which lists the different methods that can be excluded from the Directive, should be updated to include NBTs. If the definition of GMO is updated, Annex 1B could be deleted. A follow-up step would be to update the risk assessment methodology under the Directive 2001/18/EC, which is currently considered to be complicated, costly and time-consuming. Among the suggestions related to technological development, supporting the development of detection and identification systems and plant breeder rights, as well as improving the approach of Digital Sequence Information (DSI)

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of the Nagoya Protocol have been identified as necessary strategies to improve the efficiency of genome editing techniques. To increase public awareness and support knowledge sharing among stakeholders were identified as being critical steps towards acceptance and support for the development of genome editing techniques.

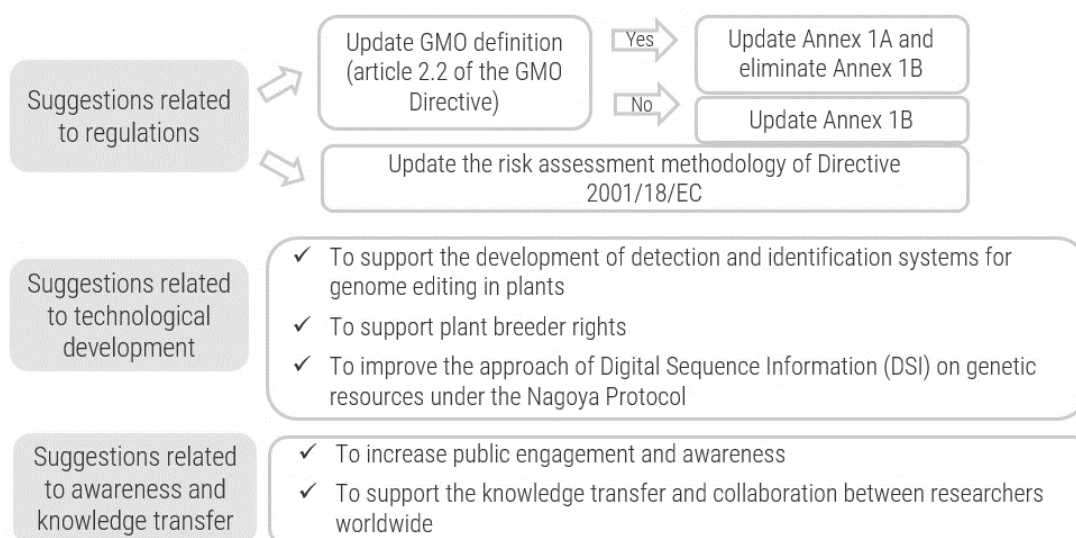


Figure 6 Overview of the suggestions for genome editing techniques

3.6.1.1 Suggestions related to regulations

1. Medium-term solution: change the GMO definition (article 2.2 of the Directive 2001/18/EC) to align with the Cartagena Protocol

Directive 2001/18/EC defines a GMO as an organism “in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination” and genetic modification techniques as “recombinant nucleic acid techniques involving the formation of new combinations of genetic material”. The definition of a GMO in Directive 2001/18/EC was not changed during the revision of previous governing legislation (Directive 90/220/EC)⁷⁰. Despite the process- and product-related terms contained in Directive 2001/18/EC, it is interpreted as strictly process-based legislation⁷¹. This fact becomes controversial when genome-edited products are indistinguishable from the products developed by classical breeding techniques⁷².

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity Protocol (adopted on 29 January 2000 and entered into force on 11 September 2003) is an international treaty governing the movements of living modified organisms (LMOs) resulting from modern biotechnology from one country to another. According to the Protocol, a LMO is “any living organism that possesses a novel combination of genetic material obtained using modern biotechnology”; this definition captures both the end-product (living organism with a novel combination of genetic material) and the used technique (use of modern biotechnology).

In 2000, during the negotiations of the Cartagena Protocol, EU member countries accepted the LMO definition in the negotiated text and interpreted this definition to be in accordance with the definition of a GMO in Directive 90/220/EC. However, there was no update of the definition in Directive 2001/18/EC after these negotiations.

The Directive should distinguish between different uses of the same product, such as edited crops to be used exclusively for the production of either bio-based products (e.g. bioplastics) or food and

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feed. This means that the regulation should be both a product- and process-based approach. In other words, if the end-product obtained from genome editing techniques is indistinguishable from the end-product obtained from classical breeding techniques, the assessment methodology should be the same.

Currently, Canada regulates the introduction of novel traits into crops. Its biotechnology regulatory framework does not assess the use of a certain technology, but the novelty of the final plant product⁷³. However, according to one expert, Canada is not a good example. The Canadian regulation on GMO is focused only on the end-product and they are having problems to register new products, since registration processes are very intensive. One good example is Argentina, which in 2012 initiated discussions with regulators and policy-makers, and the resulting gene-editing regulatory approach was developed to be consistent with the Cartagena Protocol on Biosafety. According to the Argentinian regulatory system, if there is no new combination of genetic material the product is non-GM⁷⁴. Basically, if the final product is free of the transgene, this product is classified as non-GM. The result is a flexible and dynamic regulatory framework that relies on case-by-case risk assessment. In this sense, according to the experts, the flexibility in regulations is very important mechanism for future innovations and techniques be supported in regulation.

Changing the GMO definition would be the easiest and quickest way to support the application of genome editing techniques in the EU. If this is carried out, Annex 1B will not be needed, since all the listed techniques would be included in such a definition (e.g. mutagenesis).

2. Long-term solution: To update the Annex 1B of the Directive 2001/18/EC

In Annex 1B of Directive 2001/18/EC, the different techniques that can be excluded from the Directive are listed. These techniques are based on their long safety record:

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are: (1) mutagenesis; (2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

According to the EC, mutagenesis is defined as a set of techniques that make it possible to alter the genome of a living species without the insertion of foreign DNA. Several experts consider that, accounting for the definition of mutagenesis, methods such as CRISPR/Cas9 should be included in Annex 1B to avoid unnecessary costs related to authorisation procedures.

To this aim, the Dutch Government presented a discussion paper to the EC and permanent representatives of the MS in September 2017 on how products derived from NBTs could be regulated⁷⁵. This paper proposed that plants resulting from NBTs that are equally safe as plants derived by traditional plant breeding should fall under Annex 1B and be exempt from the Directive and that criteria should be set based on the final product rather than the technique used to obtain it. Under this proposal, not all products would necessarily be exempted. The Dutch Government is also aware that revising the Annex could take many years to negotiate.

As stated by the experts, the main problem is deciding which techniques should be either exempted or included in Annex 1B. Varieties of mutations occur in NBTs, which are markedly different from

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conventional techniques. In this sense, it will be challenging from a technical point of view to decide which new techniques should or should not be included the Annex.

Another challenge is that, in the case of an intention of amending Annex 1B, a procedure needs to be initiated since Annex 1B is not included in Article 27 of Directive 2001/18/EC (where the annexes that can be modified according to technical progress are listed). Annex 1B has not been updated to account for the technical progress made since its establishment in 2001.

3. Long-term solution: To change the risk assessment methodology of Directive 2001/18/EC

A follow-up step to be completed after an update of the GMO definition as previously described is to update and simplify the risk assessment methodology under Directive 2001/18/EC. According to several experts, the methodology is complicated and time consuming, and should be modified based on, for example, the risk assessment methodology developed under the Cartagena Protocol, which is presented in Figure 7:

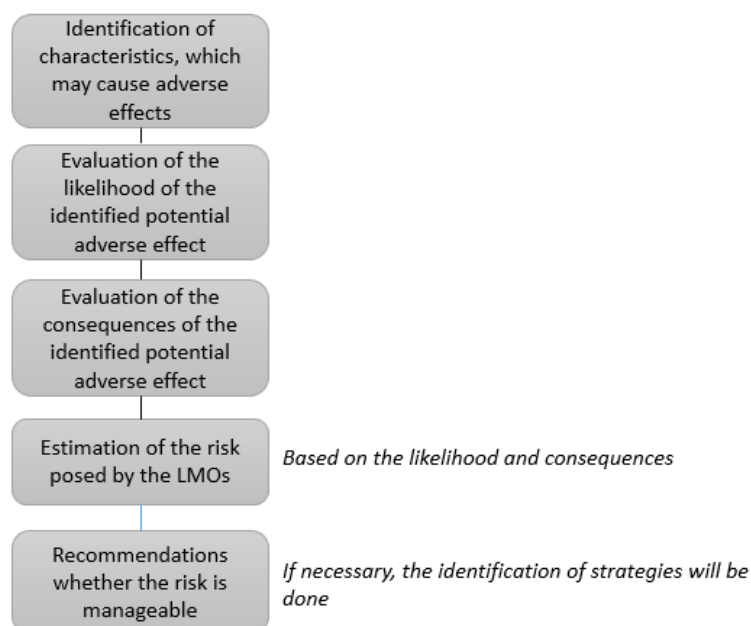


Figure 7 Methodology for an environmental risk assessment according to the Cartagena Protocol

The risk assessment methodology under the Cartagena Protocol seeks to identify and evaluate the potential adverse effects of LMOs on the conservation and sustainable use of biological diversity in the potential receiving environment, while also accounting for risks to human health⁷⁶. If there exists uncertainty regarding the level of risk following the completion of the risk assessment, it may be addressed by requesting further information, implementing risk management strategies or by monitoring the GMO.

This long-term solution is intended to be a follow-up solution implemented after the update of the GMO definition. The aim of this proposal is to facilitate the introduction of genome-edited products into the market.

Note on the above-mentioned suggestions: The above-mentioned suggestions could be implemented by updating the existing regulation on GMO (Directive 2001/18/EC) or by creating a completely new directive. In any case, this approach should be flexible and be updated if needed in the following 4-5 years, since the rapid development of new technologies entails the creation of flexible legislation.

3.6.1.2 Further suggestions

Following further suggestions related to the technological development of genome editing techniques as well as to public awareness and knowledge sharing are presented in Table 10 below. These suggestions are not related to the regulatory context of genome editing techniques; however, they have been identified as providing critical support for their development:

Table 12 Further suggestions related to technological development, and public awareness and knowledge sharing

Suggestions related to technological development	
Support the development of detection and identification systems for genome editing in plants	<p>Genome-edited crops could become indistinguishable from naturally occurring crop variants because sometimes the changes made through genome editing techniques may be the same as those, which may be derived from random mutations⁷⁷. This offers great opportunities, but also creates regulatory challenges.</p> <p>Currently, genome-editing techniques are regulated according to the GMO Directive simply because recombinant nucleic acid techniques are involved. This means that the GMO Directive is based on the used technique and not on the end-product.</p> <p>At present, modifications in plants can be detected analytically; however, the used methodology for genome editing cannot be identified. Therefore, all imported products that have been edited/modified genetically are subject to the obligations laid down by the GMO Directive, although this edit/modification may have occurred naturally.</p> <p>Currently, this is affecting many products that are not allowed to enter the EU. There is therefore a need to be able to identify the methodology for genome editing and this way support the import of such products.</p>
Support plant breeder rights	<p>Naturally occurring mutation techniques from essentially biological processes³ cannot be patented.</p> <p>This is a problem for NBTs since sometimes the obtained genome-edited product is indistinguishable from the product developed by classical breeding techniques (no edited genes can be detected).</p> <p>There is a need to support the establishment of patents for these innovative processes.</p>

³ Essentially biological processes for the production of plants are processes for the production of plants based on the sexual crossing of whole genomes and on the subsequent selection of plants, which are excluded from patentability based on being essentially biological. Currently, non-essentially biological processes and products are only patentable when inventive, novel, etc.

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<p>Improve the DSI on genetic resources under the Nagoya Protocol</p>	<p>The Nagoya Protocol⁴ sets out core obligations for its contracting parties to take measures in relation to access to genetic resources, benefit sharing and compliance. According to it, the countries of origin of the materials on which the DSI was based have sovereign rights on the data and can claim benefit sharing on their use, which could restrict data exchange and use. This is still under debate in the CBD since many parties seem to prioritize benefit sharing over unrestricted research</p> <p>Besides, on paper, the Nagoya Protocol supports the exchange of information on genetic resources, but the bureaucracy behind the Protocol is so intensive that it is disturbing the system.</p> <p>In addition, several experts commented that there exists a problem related to the availability of information, which is restricting the use of genetic resources data. On one hand, the DSI is only sequence information and does not contain all information on the DNA, while on the other hand, in most cases, valuable and necessary information is not available (e.g. country of origin).</p>
<p>Suggestions related to public awareness and knowledge sharing</p>	
<p>Increase public engagement and awareness</p>	<p>Aggressive and unscientific propaganda against genetic engineering is hindering research and innovation and creating a negative public image⁷⁸. In this sense, there is a need to increase public awareness, which could be done by communicating the benefits of using genome-editing techniques. Stakeholders (such as farmers, consumers and NGOs) need to be involved in discussions about the risks and benefits of genome editing techniques⁷⁹⁸⁰.</p>
<p>Support knowledge transfer and collaboration between researchers worldwide</p>	<p>Relevant European stakeholders should continue working towards the enhancement of genome editing techniques while strictly complying with existing ethical codes for conducting responsible research. Decision-makers should also promote awareness by communicating the benefits of using these techniques and providing appropriate regulatory advice.</p> <p>This could be done by creating a platform that allows sharing trust and information.⁸¹ To this aim, several proposals are being made for creating a Global Genome Editing Observatory⁸²⁸³. In addition, according to the German Bioeconomy Council, a biodiversity monitoring programme could be created in order to analyse long-term changes in biodiversity and establish the necessary policy measures to control possible adverse impacts⁸⁴.</p>

⁴ The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (CBD), also known as the Nagoya Protocol on Access and Benefit Sharing (ABS), is a 2010 supplementary agreement to the 1992 CBD. Its aim is the implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity.

3.7 Updates of the Waste framework directive

3.7.1 From waste to bio-based products

The use of waste as feedstock was identified in previous STAR4BBI (D3.1⁸⁵ and D3.2⁸⁶) as one of the main innovations that will play an important role in upscaling the European bio-based industry in the timeframe of 10 to 15 years. An advantage of using waste biomass, especially agricultural and food waste, is the non-interference with food production and land use. Consequently, it represents a potential solution to the food security challenge and presents an attractive and viable option as a potential substitute feedstock for fossil fuels⁸⁷. In addition, the use of waste as feedstock will provide a solution to the increasing generation of solid waste⁸⁸, a major challenges currently faced by the EU. Indeed, in the EU alone, more than 2.5 billion tonnes of waste is produced every year⁸⁹, of which around 88 tonnes is food-waste (equivalent to 173 kilos of food waste per person annually with an associated cost of € 143 billion⁹⁰). Food losses occur throughout the entire supply chain, from agricultural primary production to consumption⁹¹, and the social, economic and environmental impacts of this food wastage are enormous.

Valorising food waste within the bioeconomy offers a high potential for regional innovation and new productive investments^{92,93}. The Strategic Innovation and Research Agenda (SIRA)⁹⁴ of BBI JU, adopted in 2013 and updated in 2017, recognized the use of waste as feedstock as very important strategy for increasing resource and energy efficiency while lowering environmental impacts. BBI JU is committed in leveraging the potential use of waste as feedstock by financing projects with the objectives of fostering a sustainable biomass supply to feed existing and new value chains, optimising efficient processing through R&D and pilot biorefineries, developing innovative products, and speeding up market uptake of bio-based products.

In addition, food waste prevention is an integral part of the EC's Circular Economy Package to stimulate Europe's transition towards a circular economy, which will boost global competitiveness, foster sustainable growth and generate new jobs⁹⁵. Circular economy is a model of production and consumption that involves sharing, leasing, reusing, repairing, refurbishing and recycling existing materials and products as long as possible in order to extend the life cycle of products. In this regard, Europe's bio-based industries also need to make a sustainable, resource-efficient and waste-free use of renewable materials in order to play an important role in spurring sustainable growth and boost Europe's competitiveness.

However, realising the potential of waste as biomass (in particular food waste) depends on the level of investment in constructing bio-refineries capable of processing biomass and bio-waste for different end-uses. At the moment, the EU market for secondary raw materials is small due to technical and non-technical barriers such as uncertainty of the quality of the materials, fragmented waste management regulation at national and regional level, and the absence of EU-wide waste management standards⁹⁶. Therefore, in order to unlock the potential of waste as a feedstock for the bioeconomy, existing challenges must be addressed. These challenges exist mostly in the areas of policy, and social and techno-economical realms.

Above all, a supportive regulatory framework is needed.; existing gaps and misalignments within the WFD and between the WFD and other EU regulations are hampering the use of waste to produce bio-based products. The WFD (Directive 2008/98/EC on waste) provides the general framework for waste management at the European level. As an example, the WFD defines waste as "any substance or object, which the holder discards or intends or is required to discard". This definition embodied in this legislation can be an obstacle and could certainly make waste difficult to reuse.

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Another challenge is the waste hierarchy. According to the WFD, waste prevention is the preferred option, followed by reuse, recycling, recovery (including energy recovery), and, as a last resort, safe disposal. However, new concepts are emerging that seek to achieve a more resource efficient use of materials, such as the cascading use concept⁹⁷, which need to be considered.

As a key issue unveiled by the interview series is that the updated WFD still does not appropriately meet the various needs of the bio-based circular economy. In addition, it was highlighted that reducing waste has to be a priority along with the development of a supportive framework for using waste as feedstock. Considering this, updating the existing European regulatory framework on waste is key to further developing of the European bioeconomy and fostering the contribution of bioeconomy to circular economy⁹⁸. The present report (see section 3.4.5) proposes suggestions for a new framework that can realize the potential for the circularity of waste.

Following summaries of the WFD and related regulations at European and national levels (in Germany and in the Netherlands), suggestions for updating the WFD are proposed and discussed. These solutions are based on different stakeholders' categories (see section 3.4.4) that are particularly relevant to the use of waste as a feedstock, including companies, waste collectors and the public sector.

3.8 Waste framework directive and related regulations

3.8.1.1 European level

At the European level, the general framework for waste management is provided by Directive 2008/98/EC⁹⁹ on waste, which was later amended by Directive (EU) 2018/851¹⁰⁰. The WFD aims to reduce environmental and health impacts of waste generation and management as well as encourage resource efficiency through reuse, recycling and recovery. To accomplish this, the Directive establishes rules on how waste should be managed in the EU and provides general principles to achieve this (e.g. waste hierarchy, end-of-waste criteria, polluter pays principle and extended producer responsibility). The WFD stipulates that at least 50 % of the municipal waste (e.g. paper, glass, metals and plastics) must be recycled and prepared for reuse in all European MS by 2020.



Figure 8 Waste hierarchy of the WFD. EC. 2008

In addition, the WFD presents the concepts of life-cycle thinking and end-of-waste criteria, which specifies when certain waste ceases to be waste and obtains a status of a product or a secondary raw material. In addition, the terms "polluter pays principle" and the "extended producer responsibility" are used in order to give more responsibility to producers with respect to waste management¹⁰¹.

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In 2018, the European Parliament approved a package to update existing EU waste legislation (Directive 2018/851). It requires MS to improve their waste management systems to ensure that waste is valued as a resource. This Directive makes amendments in order to remove substances intended for animal feed from the scope of Directive 2008/98/EC, add a number of new definitions, change “cease to be waste” conditions and requirements, set out exemptions for separation of waste collection, establish bio-waste separation, establish household hazardous waste collection and update record keeping requirements. In Box 1, the new targets set by the directive are presented.

BOX 1

New targets proposed by the Directive:

- Reuse and the recycling of municipal waste ≥55% by weight (2025).
- Reuse and the recycling of municipal waste ≥50% by weight (2030).
- Reuse and the recycling of municipal waste ≥65% by weight (2035).

The following documents are related to the European WFD:

Communication on waste and by-products (COM(2007) 59)¹⁰² seeks to guide competent authorities in making case by case judgments on whether a given material is a waste or a by-product (article 5 of the WFD is based on this communication).

Decision (EU) No 2014/955/EU¹⁰³ amending Decision 2000/532/EC¹⁰⁴ establishes a list of wastes that defines a classification system for waste, including a distinction between hazardous and non-hazardous wastes. It is closely linked to the list of the main characteristics which render waste as hazardous contained in Annex III of the WFD (this Annex was updated by the Regulation (EU) No 1357/2014¹⁰⁵ on 18 of December 2014).

Among regulations that influence the WFD and the potential use of waste as feedstock, it is important to mention the Circular Economy Package (COM/2018/032)¹⁰⁶, which was adopted in December 2015 by the EU. The aim of the package is to help European businesses and consumers to make the transition to a stronger and more circular economy where resources are used in a more sustainable way. The proposed actions contribute to "closing the loop" of product lifecycles through greater recycling and re-use to the benefit of both the environment and the economy.

In addition, the UN Sustainable Development Goals (SDG) also set specific targets with respect to waste in Goal 12, which seeks to ensure sustainable consumption and production patterns in the EU¹⁰⁷. In Box 2, the specific objectives of Goal 12 are described:

BOX 2

Goal 12.3: By 2030, halve per capita global food waste at the retail and consumer levels and reduce food losses along production and supply chains, including post-harvest losses.

Goal 12.4: By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment.

Goal 12.5: By 2030, substantially reduce waste generation through prevention, reduction, recycling and reuse

To conclude, in order to provide guidance to ensure that products and services consistently meet existing regulatory requirements, the European Committee for Standardization (CEN, has developed the standards presented below:

- CEN/TR 16110:2010 (WI=00444023): Characterization of waste - Guidance on the use of ecotoxicity tests applied to waste.
- CEN/TR 16130:2011 (WI=00292061): Characterization of waste - On-site verification.

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- CEN/TS 16010:2013 (WI=00249795): Plastics - Recycled plastics - Sampling procedures for testing plastics waste and recyclates.

3.8.1.2 National level (Germany)

According to the National Bioeconomy Policy Strategy of Germany¹⁰⁸, and more specifically according to its strategic approach B1 on “expansion of information on the bioeconomy and strengthening the dialogue between society as a whole and the stakeholders in the bioeconomy”, the Federal Ministry of Food and Agriculture is engaging with consumers with the aim of reducing waste in Germany.

In Germany, the Closed-loop Waste Management Act, or Kreislaufwirtschaftsgesetz (KrWG), adopted on 1 June 2012 is the main law concerning waste management. It transposes the European Directive 2008/98/EC into German law. It is intended to promote low-residue, closed-loop waste management in order to conserve natural resources and to protect people and the environment. The Act granted waste management authorities a monopoly on the collection of household waste.

In addition, the National Waste-avoidance Programme (German Resource Efficiency Programme [ProgRes])¹⁰⁹ aims to promote the implementation of the KrWG and includes measures to reduce levels of discarded food and food waste.

Germany’s Waste Prevention Program is based on the scientific and technical findings of a study titled “Substantive implementation of Article 29 of Directive 2008/98/EC¹¹⁰” conducted by the German Environment Agency through in-depth investigations of selected federal, regional and municipal waste prevention instruments. It sets out an approach for preventing waste in the public sector by recommending specific instruments and measures. It also pursues the objective of supporting agreements between relevant stakeholders to minimise food waste. This programme will be revised and updated in 2019¹¹¹.

3.8.1.3 National level (The Netherlands)

In the Netherlands, Waste to Resource, or Van Afval naar Grondstof (VANG), was a program carried out between 2014 and 2016 to stimulate the transition towards a circular economy. It built upon the Waste Prevention Programme established by the Netherlands under the European WFD. Following VANG, in 2016, a government-wide programme for a circular economy was launched with the aim of developing a circular economy in the Netherlands by 2050.

The Implementation Act of the European WFD (12th of December 2013) is the implementation of Directive 2008/98/EC in the Netherlands. The overall objective is to decouple waste generation from economic growth as well as improve material and resource efficiency. An explicit objective to shift towards a circular economy is also mentioned.

The National Waste Management Plan (Landelijk Afvalbeheerplan)¹¹² is a waste management plan covering the period of 2017 to 2023 and looking ahead to the period up to 2029. It sets out the policy for waste management in the Netherlands and is part of the Dutch Circular Economy Plan. It contains 85 sector plans for specific categories of waste. It states that 77% of waste is currently recycled and the residual waste is mostly used for energy production. Landfilling reduced to 2.2% in 2016¹¹³.

Is it waste too!¹¹⁴ is a web-based tool that has been developed for businesses to assess whether their material or object is a by-product (article 5 of the WFD) or if it has end-of-waste status (article 6 of the WFD).

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A Circular Economy in the Netherlands by 2050 aims to accelerate the transition to a circular economy. The government will be developing transition agendas in which the five following chains and sectors have the highest priority: biomass and food, plastics, manufacturing, construction, and consumer goods. These agendas will be jointly implemented with the goal of making the sectors circular by 2050. The two strategic paths, as mentioned in A Circular Economy in the Netherlands by 2050, are:

- Raw materials in existing supply chains are utilised in an efficient and high-quality manner. In cases in which new raw materials are needed, fossil-based, critical and non-sustainably produced raw materials are replaced by sustainably produced, renewable and generally available raw materials when possible.
- New production methods and products will be designed for a circular economy. Sectors will be reorganised and new ways of consumption will be promoted in order to give an extra boost to the desired reduction, replacement and utilisation of raw materials for strengthening the economy.

The bioeconomy is linked with the five priority chains and sectors identified. There is a clear link between the bioeconomy and biomass and food concerning using renewable sources. Additionally, it is linked with plastics since bio-based plastics are an alternative to fossil-based plastics. The aim is that in 2050, 100% renewable plastics (recycled and biobased) will be used. There is also consideration of the benefits of biodegradable plastics. The bioeconomy is also linked with manufacturing, construction and consumer goods because bio-based materials can be used in these sectors.

3.8.2 Stakeholders participating in the study

Based on our research and a joint selection process within the project, 11 stakeholders representing academia, industry, NGOs and EU Associations were interviewed in order to determine their opinion regarding the preliminary suggestions for improvement as identified in previous STAR4BBI tasks. The background of the interviewed experts is shown in Figure 9 below:

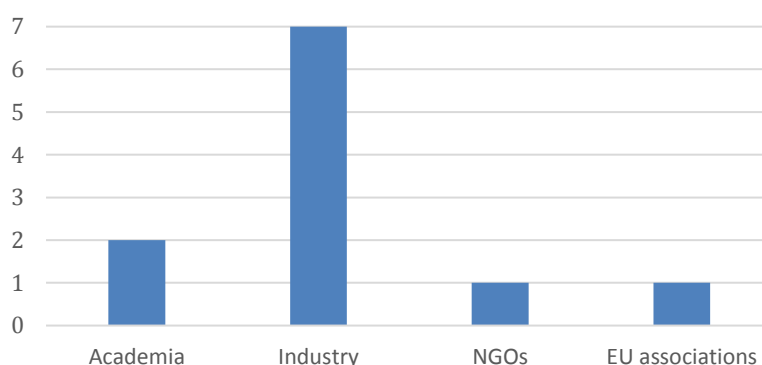


Figure 9 Professional background of interviewed experts for the WFD

In addition to this, a discussion on the suggestions for improvement of the WFD was conducted during the STAR4BBI Workshop “Assessing Bio-based Product Value Chains. How Better Regulation and Standardisation Can Promote a Level Playing Field” in held Cologne in May 2019. Identified suggestions presented in section 3.4.4 were discussed with 1 expert from academia, 6 experts from industry and 1 expert from a governmental organization.

3.9 Suggestions for updating the Waste Framework Directive

This section describes different suggestions proposed for updating the WFD and challenges linked to regulation that are hindering the development of bio-based products derived from waste.

The first suggestion is linked to the definitions provided in the WFD. According to the WFD, “waste” and “by-products” have a legal status, while “residues” and “side-streams” do not. However, all these terms are currently being used in bio-based industry, which is causing confusion among experts. The second and third suggestions are related to specific articles of the Directive that need to be updated since they are hampering the use of waste as feedstock. To conclude, other suggestions related to specific issues such as needed ecotoxicity test to classify waste and needed guidance on preferred EOL options are presented.

1. Eliminate overlapping concepts

The WFD sets basic concepts and definitions related to waste management (e.g. definition of waste, by-products recycling, etc.). Nevertheless, the terms “residues” and “side-streams” are not defined by the WFD, meaning that there is no legal status assigned to these terms (see Figure 10):

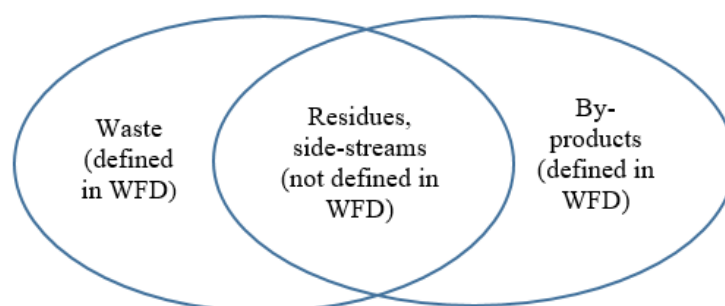


Figure 10 Waste, residues, side-streams and by-products according to the WFD

However, in the bio-based industry, the terms “residues” and “side-streams” are often used for a variety of secondary resources (e.g. for agricultural residues left on the field after harvest, for certain materials extracted from a feedstock during a production process in the food industry, wood chips left after wood processing, etc.).

Taking into account that only the terms “waste” and “by-product” have a legal status, unlike “residues” and “side-streams”, it is suggested by the experts only to use only the terms “waste” and “by-product” in order to avoid confusion.

2. To update the article 6 of the WFD by providing clear harmonized criteria to distinguish between waste and waste which ceases to be waste:

Article 6 of the Directive specifies when waste shall cease to be waste:

Definition of End-of-Waste status according to the article 6 of the WFD

Waste that shall cease to be waste when it has undergone a recovery, including recycling, operation and complies with specific criteria to be developed in accordance with the following conditions:

- *the substance or object is commonly used for specific purposes;*
- *a market or demand exists for such a substance or object;*
- *the substance or object fulfils the technical requirements for the specific purposes and meets the existing legislation and standards applicable to products; and*
- *the use of the substance or object will not lead to overall adverse environmental or human health impacts.*

According to article 6, as long as the criteria for waste have not been set at European level, MS may decide on the status of the waste in a case-by-case basis. In other words, MS have the right to decide whether certain waste has ceased to be waste or not. This has led to a situation where MS developed their own criteria, which is impeding the use of waste to produce bio-based products. In this sense, the EU should support the overall harmonization of end-of-waste, provide guidance for selecting the criteria and support the implementation of the criteria.

However, experts mentioned that the same material could have different characteristics in different MS (e.g. different climate and agricultural conditions imply different characteristics of the harvested feedstock). Concerning this, experts noted that developing an EU harmonised end-of-waste decree for all EU countries is almost impossible.

A potential solution would be to identify the fields in which common criteria are not possible and national criteria are needed. In this regard, the EU could develop an EU harmonized horizontal standard on end-of-waste, and each MS should develop a decree with criteria for specific products and specify when waste ceases to be waste.

In addition, accomplishing the two following issues is of specific importance:

- The EU must set the timing for the approval stage and support timely applications in order to support bio-based circular economy.
- MS must support and recognise other MS' decrees on end-of-waste. In this respect, the EU should provide guidelines and solutions to facilitate the multilateral recognition of national approaches among MS.

As an example, to prove the importance of the two previously stated issues, one Italian company that produces bio-based products out of used diapers cannot commercialise their product since the end-of-waste decree for hygienic materials published by the Italian ministry in 2018 is still under EU approval. In addition, even if the EU approves the request of the Italian government, when importing the product, the destination country should also support the decree and accept the end-of-waste criteria established by the country of origin. In this respect and as previously commented, the EU should facilitate recognizing the decrees of the MS by other MS.

3. To update the article 4 of the WFD and extend the WFD's waste hierarchy

According to article 4 of the WFD, the waste hierarchy specifies the order of priority in waste prevention and management legislation and policy as: (1) prevention, (2) preparing for re-use, (3) recycling, (4) other recovery (e.g. energy recovery) and (5) disposal. The WFD uses this hierarchy as a guiding principle.

However, various EOL options, in particular those of interest for bio-based products, are not considered appropriately. The STAR-ProBio project states in this regard: “(t)his hierarchy does not explicitly address biodegradation or composting, although they are captured by the ‘recycling’ element.”¹¹⁵ Although these two EOL options do not characterize bio-based products exclusively, they are of specific importance for them, which should be reflected in the waste hierarchy. A specific contribution of Directive (EU) 2018/851 is that it allows biodegradable and compostable packaging to be collected together with the bio-waste and to be recycled in industrial composting and anaerobic digestion¹¹⁶. This means that MS may allow waste with similar biodegradability and compostability properties that comply with relevant European standards or any equivalent national standards for packaging to be collected together with bio-waste.

Interviewees also suggested including the following additional elements:

- Fermentation as part of the recycling element.
- Transformation as a separate element in the hierarchy.

Taking this into account, article 4 should be updated to include a more detailed classification of EOL options and a more detailed waste hierarchy in order to provide clarity. However, it should be noted that the main challenge of implementing this suggestion is that multiple classes of EOL options would lead to a greater complexity.

4. To conduct required tests, in particular on ecotoxicity to classify waste where appropriate

On the one hand, the European Recycling Industries' Confederation (EuRIC) recommends conducting specific ecotoxicity tests, as stated in the following quote: “Bioavailability and bio-accessibility need to be taken into account when classifying waste. Waste is usually a complex blend, and chemical analysis is not suited to fully characterize its properties. Our view is that tests, notably on the ecotoxicity, give a more accurate evaluation of the risks”¹¹⁷.

On the other hand, among the interviewed experts, different views existed regarding ecotoxicity tests. Several experts agreed that targeted analyses should be recommended when ecotoxicity tests are beneficial to classify waste. These analyses should also consider the burdens these tests impose on industry, notably the high costs, and work to keep them as low as possible. However, other experts highlighted that even if the costs are high, ecotoxicity tests are of great importance in specific sectors, such as the construction sector. In this sense, industry sector categories for which the ecotoxicity tests are needed, could be developed.

With regard to waste to produce bio-based products, there are specific cases in which this waste is not toxic, but toxicity can be an issue as a result of additives in the final product. For example, bio-based plastic waste is not toxic, but additives may be an issue in the final product. In these cases, this waste should be tested.

To conclude, other relevant environmental issues besides toxicity were highlighted, that are addressed by, for example, the European emission standards or the standards and guidelines on the

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quality of compost. In this sense, and in order to broaden the focus of this suggestion, it was recommended to conduct risk assessment analysis instead of just ecotoxicity tests.

5. To harmonize the WFD and Circular Economy Package

The vision for the circular economy is linked with two specific goals (Circular Economy Package ¹¹⁸):

- (1) enabling recycling and improving the uptake of secondary raw materials by limiting unnecessary burdens and facilitating the cross-border circulation of secondary raw materials to ensure that they can be traded easily across the EU; and
- (2) substituting substances of concern and, where this is not possible, reducing their presence and improving their tracking.

According to the first objective, the maximization of the use of resources (including waste) must be allowed, however, according to the second objective, “substances of concern” must be avoided. There is a difference between “product not-allowed substances” and “waste not-allowed substances” produced due to the contamination of waste by the presence of legacy substances. Legacy substances are defined as substances whose use was lawful in products at the time of their production but which have subsequently been subjected to regulatory control by the time these products become waste.

There are multiple examples of problems associated with legacy substances. For instance, certain brominated flame-retardants that are persistent, bio-accumulative and toxic have been reported to be found in recycled plastic products including toys and kitchen utensils. In another case, the use of certain substances that were originally added to PVC to soften it are now regulated, meaning that recycled PVC containing those substances above specific quantities should not be used or placed on the market in the EU¹¹⁹.

The existence of legacy substances and how to deal with them they are present in products produced before regulatory control was implemented is a significant problem. The problem is linked to the fact that there is a time difference between the lifetime of a product (defined as the time a product needs to reach its EOL) and the time it takes for a substance (that might be contained in the product) to be classified as a legacy substance. This means that looking to the future, waste may contain substances that are no longer allowed in new products. The need to handle this issue appropriately is stressed by the EC already in COM(2018) 32 final¹²⁰.

According to EuRIC¹²¹, since legacy substances are not intentionally added, a higher concentration of regulated chemicals in recycled materials than in primary materials shall be allowed in the following cases:

- the substance does not pose a risk for the human health or the environment and traceability is ensured, and
- the articles/products in which this recycled material is included are properly disposed of at EOL.

Several interviewees highlighted the importance of setting upper limits for the content of legacy substances and that this value must be determined for each specific substance. From a methodological point of view, conducting risk assessments and developing appropriate criteria was suggested. In this respect, it would be possible to decide for which applications a higher concentration of chemicals is allowed, or which toxic substances under the REACH regulation, which do not comply with the established criteria, cannot be reused. For this reason, a list of exemptions within the

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Circular Economy Package could be developed that would allow “legacy substances” in suitable contexts.

Challenges to implement these suggestions are traceability concerning the use of waste coming from outside Europe and products that will be in contact with food. Concerning this last issue, an expert commented that more research is needed in this area.

6. To provide guidance on preferred EOL options

The project STAR-ProBio suggests more harmonized guidance regarding preferred EOL options. Little product-specific legislation addresses EOL management preferences since these depend on the product application. Some pieces of legislation tend to favor mechanical recycling (packaging related legislation), others tend to promote preparation for reuse and mechanical recycling (WEEE Directive) and some combine the promotion of waste prevention and organic recycling (such as Directive 2015/720/EU on plastic carrier bags).

According to the experts, there is a need to create a European guidance document or add a specific annex to the WFD that contains the following points:

- Specify preferred EOL options under specific conditions, bearing in mind that, for some products, specific EOL options are important whereas this may not be the case for other products. For example, a requirement for biodegradability for is important for biodegradable bags to collect bio-waste and fruit stickers, but not for the packaging of cosmetic products.
- Provide an overview of already defined preferable EOL options for main product categories.
- Include suggestions for waste collection (e.g. home compostable bags can be collected in bio tones).

Criteria should be developed at the European level, otherwise companies in countries with stricter rules may have disadvantages compared with companies in other EU countries. However, according to one expert, in some cases (e.g. wheat straw), the different conditions of the MS determine whether a specific EOL option is possible or not (e.g. in the specific case of the wheat straw, the expert referred to the valorisation option). Therefore, guidelines at national level tailored to their specific situation might provide specific advantages.

The project STAR-ProBio highlighted that the different characteristics that bio-based products and traditional products may have in the recycling stage, frequently lead to separate appropriately the bio-based parts before further treatment. Besides this, there are also bio-based and fossil-based products, materials, etc. which can be recycled together. In this respect, interviewed experts confirmed that recycling of bio-based and the fossil-based materials together is possible, for example, in the case of bio-based and fossil-based PE. The bio-based content of the recycled products may vary due to the specific material mix in the recycling process but the key characteristics of the resulting products are in line with the fundamental circular economy goals.

Experts highlighted that current existing EOL guidelines refer only to traditional streams and do not considered bio-based counterparts. In this direction, further analysis of the EOL stage of mixed waste is needed to provide guidance on appropriate combinations of bio-based and fossil-based materials. Further analysis of this topic is presented in the Deliverable 4.4 on Regulation action plan in section 3.4 on EOL.

7. To harmonize the waste classifications in the EU and consider waste of bio-based products appropriately

According to the EuRIC, an “absolute priority should be to reduce and ultimately annul the different interpretations of waste classification rules throughout the EU, leading to different classifications of the same waste stream between MS, and sometimes within a MS”¹²².

In addition, in accordance with the interviewed experts, there is a need to align the EU waste classification rules in order to avoid conflicting approaches between MS to cover more waste streams. To this end, the EC declared that plastics, construction products and electronic products must be prioritized due to their volume and high environmental impact¹²³.

In line with the second suggestion on the waste hierarchy, the waste of bio-based products shall be considered appropriately. It was especially stressed to include EOL options such as “biodegradable,” “compostable” and “not compostable” in the hierarchy.

4. Conclusion and next steps

This report provides specific suggestions for policy makers in order to establish a supportive and investment-friendly regulatory and standardization framework for the bioeconomy, enabling the full deployment of future innovations. Conclusions on each of the selected topics are presented as follows.

Integration of a **fossil carbon tax** will allow taxation of fossil carbon in chemicals, materials and products, which would be considerably complex when implementing a CO₂ tax. Not only the products produced in the EU will be taxed according to their fossil carbon content, but also imported products will be taxed at the EU Customs by measuring their carbon content. This will create a situation where all materials, products and fuels on the EU market are taxed according to their fossil carbon content, thus fair competition conditions will be made for local and importing companies. For the bio-based industries, this trend will create a level playing field on the economic dimension by creating similar price range for fossil-based and bio-based products. It is expected that customers will then choose the bio-based products as better alternatives when the price range is harmonised. This in turn will lead to larger profit of bio-based industry and larger investments in development of new technologies for producing new bio-based materials.

In addition, in order to create a level playing field between fossil-based and bio-based products, the introduction of **sustainability certification for all products** is needed. Public procurement accounts for a substantial part of the global economy. Ecolabels may be used in public procurement, and promising label for sustainability certification for all products is the EU Ecolabel where different sets of criteria are established for each product group covered by the scheme. A product group to start with on the short term could be toys, which is an interesting option due to its variety of products and it is close to consumers. It would be relatively easy to start with, for example, the GHG reduction (environmental impact) and add more sophisticated sustainability leveling (social and economic) later on. An important issue with the current EU Ecolabel scheme is that it uses a rigid pass-or-fail-system. Instead of this system, a multi-level EU Ecolabel provides more transparency for relevant stakeholders in knowing how sustainable their product is. This already works very well with the EU Energy label. It can be costly to prove the sustainability criteria for the smaller companies, therefore, default values should be made available. In addition, it should be made possible to propose new EU Ecolabel product groups that are not an end-product, e.g. packaging, which is an important product group for the bio-based industry. With the current EC Regulation No 66/2010 on the EU Ecolabel it is only possible to propose new EU ecolabel product groups for end-products. The election of a new European Commission in 2019 could introduce new opportunities to propose these needed adjustments to the current EC Regulation on the EU Ecolabel.

With regard to **genome-editing techniques**, measures are suggested in order to update the existing EU regulation (Directive 2001/18/EC), since, according to the last judgment of the ECJ, genome-editing techniques are now subject to the obligations laid down by the GMO Directive. In this sense, it is suggested to change the GMO definition (article 2.2) and align it with the definition of the Cartagena Protocol in order to capture both the end-product and the used technique. Consequentially, alterations produced by means of NBT that could also be the result of classical breeding techniques will not be considered GMO. Linked to that, the risk assessment methodology included in the directive should be aligned with the methodology included in the same protocol in order to make the process easier and less time-consuming. To conclude, Annex 1B, where the different methods that can be excluded from the directive are listed, should be extended. Considering the definition of mutagenesis, NBTs should be included in Annex 1B in order to avoid unnecessary costs

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related to authorisation procedures. All these suggestions present an opportunity for policy makers to support genome-editing techniques, which represent a promising next step in research towards beneficial uses in medicine, agriculture and the bioeconomy.

Updating the existing **European regulatory framework on waste** is a key challenge to overcome in order to unlock the potential of waste as a feedstock, thereby contributing to the development of the European bioeconomy. Currently, existing gaps and misalignments within the WFD are hampering the use of waste to produce bio-based products. Proposed solutions are linked to the need to adhere to the definitions that have legal status in the WFD; only the terms “waste” and “by-products” provided by the directive would be used. Article 6 should also be updated in order to provide clear, harmonized criteria to distinguish between waste and waste which ceases to be waste. Additionally, Article 4 on waste hierarchy should be updated to appropriately consider various EOL options, in particular those of interest for bio-based products. Other suggestions include conducting ecotoxicity tests and conducting risk assessment analysis, where appropriate, to classify waste; harmonizing the WFD and the Circular Economy Package to facilitate optimal resource use (including waste), providing harmonized European guidance on preferred EOL options and harmonizing the waste classifications in the EU to appropriately consider the waste of bio-based products.

This report seeks to be the basis for developing a strategy for the further development of standards and regulations in selected value chains in order to support investments in bio-based industries.

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