# Standards and Regulations for the Bio-based Industry STAR4BBI



Work Package 3

D3.2 Regulatory and Standardization needs in bio-based industries

# PUBLIC

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#### Acronyms

BBI JU: Bio-based Industries Joint Undertaking.

CEN: European Committee for Standardization.

CO2: Carbon dioxide.

CRISPR: Clustered regularly interspaced short palindromic repeats.

CPR: Construction Products Regulation.

DNA: Deoxyribonucleic acid.

EC: European Commission.

ECJ: European Court of Justice.

EIP: European innovation partnership.

EU: European Union.

FDCA: 2,5-Furandicarboxylic acid.

GHG: Greenhouse gas.

GMO: Genetically modified organism.

IAR: International Agricultural Research.

ICT: Information and communications technology.

ISO: International Organization for Standardization.

LCA: Life cycle assessment.

MOW: Municipal organic waste.

NGO: Non-governmental organization.

PEF: Polyethylenefuranoate.

PET: Polyethylene terephthalate.

PPP: Public-private partnership.

REACH: Registration, evaluation, authorization and restriction of chemical substances.

RED: Renewable energy directive.

R&D: Research and development.

SME: Small and medium-sized enterprises.

UBA: German Environment Agency – Umweltbundesamt.

WFD: Waste Framework directive.

### **Executive summary**

The STAR4BBI project will support adaption of the regulatory framework and relevant standards for selected existing value chains and for the development of new value chains based on biomass from forests, from agriculture and from organic waste.

For this purpose, a previous research was conducted on possible upcoming innovations in the next 10-15 years that would have positive impacts in terms of improving biomass availability and production processes in biorefineries. The results were published in March 2018 and are available in the D3.1 on "Identification of technological trends in selected value chains"<sup>1</sup>.

Conclusion thereof is that the following measures will play an important role in upscaling the bio-based industry in the studied timeframe:

- to establish a supportive regulatory framework for the bioeconomy;
- to adopt relevant principles of the cascading use of biomass;
- to use alternative innovative feedstock (e.g. food waste and industrial waste);
- to adopt digitalization in agriculture and forestry;
- to establish cooperation agreements with farmers and forest owners.

In addition, for project selected value chains (see table 1), the following three most promising potential drivers of change were identified (see table 2): gene-editing technologies, valorisation of lignin, as well as furan-based chemistry.

Table 1 STAR4BBI selected value chains. Available in the D2.1 on "Market entry barrier"<sup>2</sup>. Developed by the STAR4BBI project partners. 2018

Sugars from starch   Reverdia				
Sugars from starch		<	Biofoam	>
Starch, fibres			$\longrightarrow$	
Starch, oil 🗧 Matrica ——— Novamont ————————————————————————————————————				
Fatty acids from oils				
Crude tall oil Kraton				
Wood				
Feedstock Refinery production	(Bio)chemical conversion	Intermediates production	Consumer products manufacturing	Consumer markets

Identified technologies/innovations	
Gene-editing technologies	
Techniques for the valorisation of lignin	
Furan-based chemistry to produce 2,5-Furandicarboxylic acid (FDCA) from sugars	

In previous research (D2.1 and D3.1), special attention was paid to existing regulatory, standardization and investment barriers, which could delay or stop these technological and innovative developments. To this effect, a 2-round Delphi survey was conducted to identify needed updates of the regulatory and standardization framework for supporting a full deployment of innovation potentials and for unlocking investments in the bioeconomy.

This report summarizes the results of the 2-round Delphi survey and of different thematic focus groups that were organized on genome editing techniques, valorisation of lignin technologies, furan-chemistry from sugars and aquatic biomass to produce bio-based products. Table 3 (below) includes an overview of the main results of this research work. In the left column, previously identified features/elements (see D3.1) which represent *keystones* for the establishment of the future bioeconomy are indicated. In the right column, experts' suggestions and actions to be taken to fully deploy the potential and opportunities of the European bioeconomy are indicated and defined as *needed updates*.

These suggestions represent a summary of the view of the expert's interviewed and they do not necessarily represent the view of the partners of the consortium or of the EU.

Identified keystones	Identified needed updates			
Establish a supportive regulatory framework for the bioeconomy (see section 4.1)				
Supportive regulatory framework	<ul> <li>To adopt identified measures towards the creation of a stable and supportive regulatory framework, such as:         <ul> <li>To introduce a carbon tax for all products.</li> <li>To support the cascading use of biomass.</li> <li>To develop biomass related standards (e.g. quality, origin).</li> <li>To end subsidies for biofuels.</li> <li>To introduce effectively implemented preferred public procurement for bio-based products.</li> </ul> </li> <li>To establish long-term policies towards the establishment of a level playing field for bio-based products.</li> <li>To overcome regulatory requirements that imply additional costs.</li> <li>To carry out strong communication actions to inform consumers on the benefits of bio-based products.</li> <li>To support the creation of agro-industrial value chains based on the sustainable use of biomass.</li> </ul>			

Increase efficiency in biomass production and production processes (see section 4.2)			
Cascade use principles (see section 4.2.1)	<ul> <li>To identify cascading use principles to be included in a strategy for supporting the realization of cascading potentials.</li> <li>To strengthen the use of the cascading principles in regulation and standardization.</li> </ul>		
Waste as an alternative feedstock to produce bio-based products (see section 4.2.2)	<ul> <li>To clarify the terms "residues" and "side-streams".</li> <li>To clarify the articles 5 and 6 of the Waste Framework Directive.</li> <li>To update EU rules applicable to waste management, chemicals and products to achieve the circular economy goals.</li> <li>To harmonize chemicals policy and waste policy.</li> <li>To support the use of side-streams and municipal organic waste as feedstock to produce bio-based products.</li> </ul>		
Digitalization and Indus- try 4.0 in agriculture, forestry and bio-based industries (see section 4.2.3)	<ul> <li>To fill knowledge gaps of farmers and forest owners (e.g. through easy-to-use applications).</li> <li>To solve the problem of data ownership.</li> </ul>		
Cooperation agree- ments and networks (see section 4.2.4)	• To establish cooperation agreements and networks to promote a sustainable bioeconomy in Europe.		
Regulatory suggestions fo	r identified breakthrough technologies (see section 5)		
Gene-editing tech- niques (see section 5.1)	<ul> <li>To exclude new genome editing techniques (e.g. CRISPR-Cas) from the strict regulation of GMO, when applied to bio-based products.</li> <li>To set specific ruling for gene-editing techniques away from the GMO Directive.</li> </ul>		
Lignin valorisation tech- nologies (see section 5.2)	<ul> <li>To financially support the R&amp;D for the valorisation of lignin.</li> <li>To amend the European standards on biodegradability and compostability of products (e.g. EN 13432).</li> </ul>		
Furan-chemistry from sugars (see section 5.3)	• To set measures to support the technology-push of FDCA.		
Aquatic biomass to pro- duce bio-based products (see section 5.4)	<ul> <li>To increase investments in R&amp;D to valorise algae biomass into high- value products.</li> </ul>		

#### 1. Introduction

The STAR4BBI project supports the establishment of a coherent, well-coordinated and favourable regulatory framework towards the development of a cutting-edge bioeconomy for Europe. It proposes suggestions for the adaption of the regulatory framework and relevant standards for selected existing value chains and for the development of new value chains based on biomass from forests, from agriculture and from organic waste.

With this aim, a previous research was conducted in which experts' opinions were collected with regard to possible upcoming innovations in the next 10-15 years that would have positive impacts in terms of improving biomass availability and production processes in biorefineries. The results were published in March 2018 and are available in the D3.1 on "Identification of technological trends in selected value chains". According to the expert's opinions, the adoption of relevant principles of the cascading use of biomass, the alternative innovative feed-stocks (e.g. food waste and industrial waste), as well as, the digitalization and cooperation agreements with farmers and forest owners will play an important role in upscaling the biobased industry in the timeframe of 10 to 15 years. In addition, the following three most promising potential drivers of change were identified: gene-editing technologies, valorisation of lignin, as well as furan-based chemistry.

This report, presents the results of a 2-round Delphi survey implemented from March until December 2018, as well as, the results of four thematic focus groups organized from July until January 2019 on genome editing techniques, valorisation of lignin technologies, furan-chemistry from sugars and aquatic biomass to produce bio-based products. The objective of this research was to identify needed updates in the regulatory and standardization framework for supporting a full deployment of innovation potentials and for unlocking investments in the bioeconomy. Whereas in the first round of the Delphi survey experts' opinions were identified on which elements should be included in a supportive standardization and policy framework for promoting the culture of innovation, a second round was conducted aiming at recollecting expert's opinions to find out more about the relevance of these important elements of a supportive regulatory framework.

As part of the implementation of this project, recommendations for policy makers will be designed towards the establishment of an investment and regulatory friendly framework able to underpin the full deployment of the identified potential innovations.

The remainder of the report is structured as follows: section 2 describes the adopted methodology; section 3 includes a general description of the participants; sections 4 and 5 present identified needs and suggested regulatory and standardization updates; section 6 contains conclusions and next steps; and the Annexes include the templates for the 2-round Delphi survey and focus groups, as well as, the results of the first round of the Delphi survey which serve as a basis for the second round. The results of the second round are directly integrated in sections 4 and 5.

# 2. Methodology

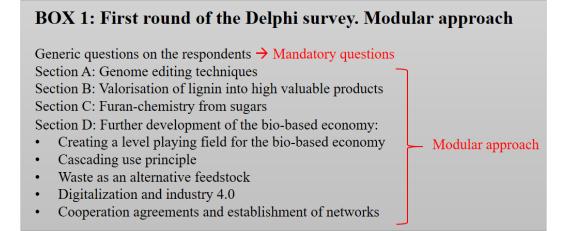
# 2.1 General description

A 2-round Delphi survey has been implemented from March until December 2018. The Delphi method is based on structural surveys and makes use of information from the experience and knowledge of the participants<sup>3</sup>, and aims to synthesize the collective expertise of the respondents<sup>4</sup>. It includes two or more rounds to validate and refine the results of the initial communication activity with the participants.

The aim of the first round of the Delphi was to identify experts' opinions on which elements should be included in a supportive standardization and policy framework for bio-based products. The second round aimed at recollecting expert's opinion on the relevance of the important features that a supportive regulatory framework should include, as well as, the relevance of other identified actions needed for establishing a level playing field for bio-based products. In order to gather more information, different focus groups webinars were organised between July and January 2019 on the following identified relevant topics: genome editing techniques, valorisation of lignin technologies, furan-chemistry from sugars and aquatic biomass to produce bio-based products.

# 2.2 Preparation of the questions

The preparation of the questions for the first round of the Delphi survey was based on the results of previous project activities, as well as, the knowledge of project partners. The last version of the questionnaire was agreed during a project meeting with the partners in Cologne (Germany) in February 2018. A modular approach was selected (see Box 1), in order to give the experts, the possibility to choose the set of questions they would like to answer (based on their expertise). So as not to guide the answers of the respondents, most of the questions included in the first round of the survey were open questions, and as a consequence, the needed time for responding was relatively high. However, the fact of having open questions led to the identification of various and different answers containing interesting elements, which served as a basis for the second round of the survey (see Annex I for the complete template of the first round of the survey):



The questionnaire of the second round of the Delphi, aimed at gathering experts' opinions on the importance of identified elements to be included in a supportive regulatory framework. It mostly included multiple choice questions, being much faster to answer compared to the first round. In addition, an open question was added to each section in case experts wanted to add further information. Box 2 includes an overview of the major components of the questionnaire of the second round (see Annex III for the complete template of the second round of the survey):

#### BOX 2: Second round of the Delphi survey

Section A: Level playing field Section B: Cascading use principle Section C: Waste as an alternative feedstock Section D: Cooperation agreements and networks Section E: Digitalization and industry 4.0 Section F: Genome editing techniques

To conclude, the questions of the focus groups were focused on the identified challenges to each specific topic (see Annex IV). Box 3 includes an overview of the main elements considered in each agenda of the focus group:

#### BOX 3: Agenda of the focus groups

- Welcome and introduction to STAR4BBI project.
- Presentation of previous results.
- Focus group activity: Identification of relevant challenges in terms of the technology itself, regulations and standards.
- Summary and conclusion.

# 2.3 Selection of the target audience

In order to reach the maximum number of experts for the first round of the Delphi the following two versions of the survey were created, both with the same questions:

- A closed version: relevant experts were identified and provided with tokens or identification numbers.
- An opened version: a link to the survey was disseminated in several newsletters and no tokens were provided.

For the closed version, a comprehensive list of experts that could add value to the project was prepared. With the help of all project partners, experts with a high expertise on the overall bioeconomy, on genome editing, on valorisation of lignin into high-value products and on furan-chemistry from sugars at the EU level were identified. A final list of 887 experts, including experts from academia, industry and NGOs, working in bioeconomy related projects and topics, advisory board members, experts that attended the Bio-economy submit 2018 conference and the 12th European Bioplastics Conference 2017, both in Berlin, were invited to respond to the survey.

For the open version of the survey, a link was disseminated to different newsletters, including:

• Nova-institute newsletter



• IAR – Le Pôle de la Bioéconomie (France):

# Participez au sondage de STAR4BBI, un projet dont IAR a intégré l'advisory board

Publié le **17 avril 2018** par **Stéphanie Clément** Participez au sondage de STAR4BBI, un projet dont IAR a intégré l'advisory board STAR4BBI "Standards and Regulations for the Bio-based Industry " « Normes et règlements pour l'industrie biosourcée » L'Université technique de Berlin, partenaire du projet STAR4BBI, lance un sondage dans … Continuer la lecture

Publié dans Informations

For the second round of the survey, only the experts that agreed to answer the second round were contacted, therefore, no link to an open version was distributed. According to the principles of the Delphi survey, the second round can only be responded by the experts that responded to the first round<sup>5</sup>.

For the focus groups, previously identified experts for the Delphi exercise and for interviews conducted in the framework of previous project activities were contacted. Among these participants, experts of other BBI projects, experts of related industries, research institutions, consultancies, standardization bodies, NGOs and association/networks can be found.

## 2.4 IT tools

For the Delphi survey, the open source online statistical tool LimeSurvey was used. As a web server-based software, it enables users using a web interface to develop and publish online surveys, collect responses, create statistics and export the resulting data to other applications (www.limesurvey.org).

The focus groups were carried out with the Adobe web conferencing software (<u>https://web-conf.vc.dfn.de</u>).

# 3. General description of the participants

# **3.1** First round of the survey

As indicated in section 2.3, 887 experts were invited to participate in the closed version of the survey, in addition to other experts reached by a mailing list. In total, 100 experts completed the survey. Figure 1 gives an overview of the generalities of the respondents. As shown in the figure, the majority of the respondents (45%) came from Germany, from both academia (36%) and industry (34%). In terms of expertise, most of them declared to be bioeconomy experts (70%).

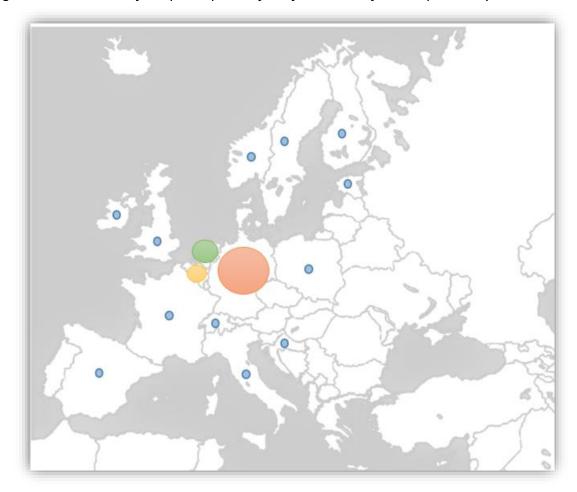
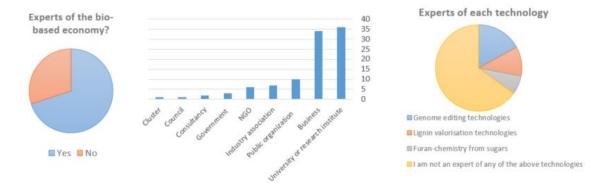


Figure 1 Generalities of the participants of the first round of the Delphi survey

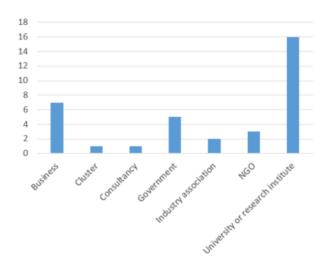


# 3.2 Second round of the survey

Figure 2 provides some generalities of the respondents of the second round of the survey, which was distributed only among the experts that claimed the wish to participate in a second round (99%). Finally, 35 experts completed the survey, more than half coming from Germany (54,3%). From them, most of the experts work in academia (45%) and industry (20%).

Figure 2 Generalities of the participants of the second round of the Delphi survey

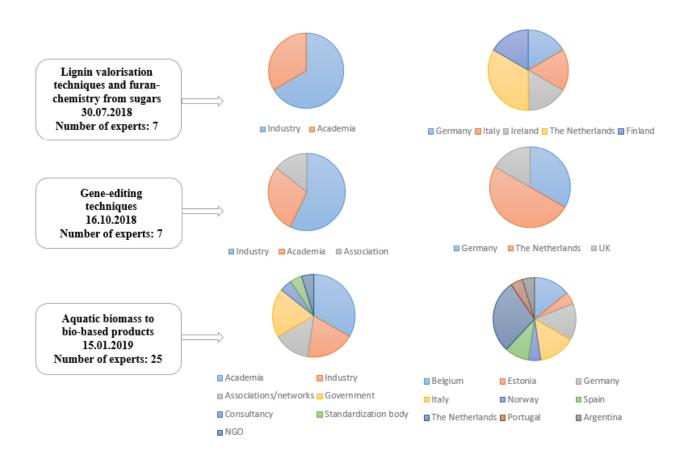




### 3.3 Focus groups

In figure 3, an overview of the participants of the conducted 3 focus groups is presented. In the first focus group on lignin valorisarion techniques and furan-chemistry from sugars, the majority of the experts represented the industry (72%), as well as, in the second focus group on gene-editing techniques (57%). In the contrary, most of the experts the participated in the focus group on aquatic biomass represented mostly academia (32%). Regarding the geographical localization, most of the experts in the 3 focus groups came from The Netherlands (29%, 43% and 32% of the participants respectively).

*Figure 3 Generalities of the participants of the focus groups* 



# 4. Needed regulatory updates/recommendations

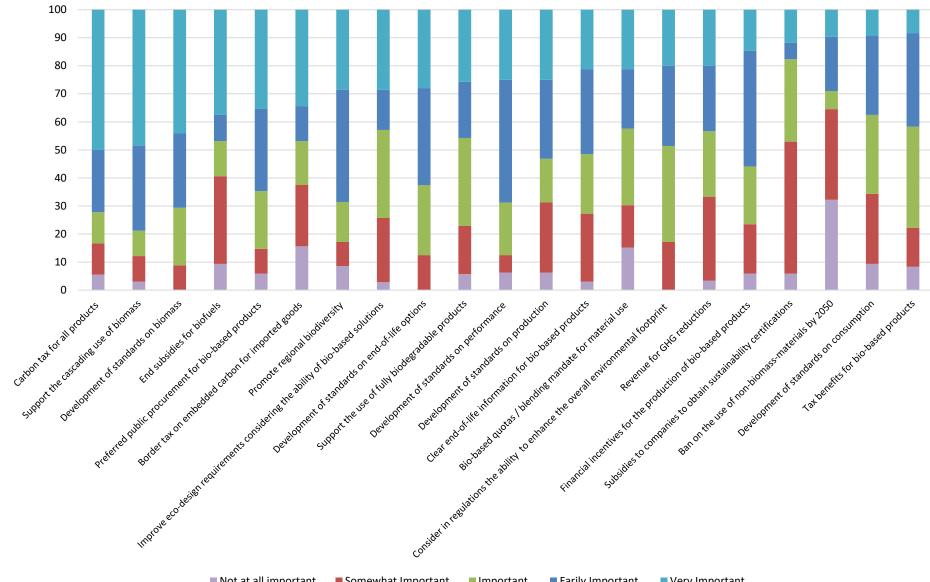
This section of the report summarizes needed regulatory updates towards the establishment of a supportive regulatory framework for the bioeconomy in Europe. The combined results of the conducted 2-round Delphi survey and focus groups are presented as follows. Firstly, recommendations for establishing a supportive regulatory framework for the bioeconomy are described. Subsequently, ideas for supporting efficiency in biomass production and bio-based production processes via regulations and standards are described. This includes specific suggestions for facilitating the cascading use of biomass, the use of waste as feedstock to produce bio-based products and the use of ICTs in agriculture, forestry and bio-based industries. For each section, **needed updates** are highlighted, followed by an explanation of possible solutions to be implemented in order to overcome the identified challenges.

# 4.1 Establish a supportive regulatory framework for the bioeconomy

Need: To adopt identified measures towards the creation of a stable and supportive regulatory framework (e.g. introduce a carbon tax for all products)

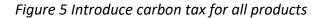
Figure 4 (below) provides an overview of the important features that according to the participants should be considered in order to achieve a stable and supportive regulatory framework for the bioeconomy. The different categories of features were derived from the answers of the first round of the survey. In the second round, the experts ranked the identified features, by adopting a five-level Likert items scale, from "not at all important" to "very important".

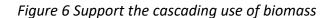
Figure 4 Needed features to achieve a stable and supportive regulatory framework for the bioeconomy



Not at all important Somewhat Important Important Farily Important Very Important

As shown in figure 4, and further analysed in figures 5 and 6, the majority of the experts consider that the introduction of a carbon tax for all products and the support of the cascading use of biomass are very important features to be considered in order to achieve a stable and supportive regulatory framework for the bio-based economy. It is worth mentioning that other relevant proposed measures include the development of biomass related standards (e.g. quality and availability) in order to increase consumers' confidence in biomass quality and therefore sustainability production; end subsidies for biofuels; as well as, introduce preferred public procurement for sustainable bio-based products.



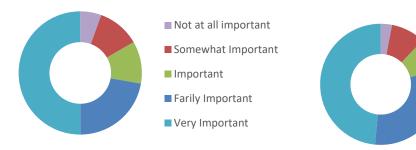


Not at all important

Important
 Farily Important

Very Important

Somewhat Important



18 experts, the 50% of the respondents, appointed that the establishment of a carbon tax for all products is very important



In addition to the given answers in the survey, experts were asked to indicate additional features that in their opinion are needed for achieving a stable and supportive regulatory and standardisation framework for the bioeconomy. Relevant answers in this regard recall the fact that sustainability should be demanded for all products. In this sense, it was suggested to adopt an umbrella sustainability standard applicable to all bio-based products, including energy products. In addition, it was mentioned that it is important to set clearer boundaries around sustainability and circular bioeconomy, helping to establish needed mechanisms such as policy documents, legislation, certification schemes, standards and labels.

# Need: To establish long-term policies towards the establishment of a level playing field for bio-based products

According to the experts, an important element towards the establishment of a level playing field for bio-based products is the implementation of long-term policies and policy instruments, which are independent of governmental changes and provide ambitious but realistic goals. The low fossil-based products prices and the existing blending mandate for biofuels, are not letting the industrial material use of biomass developing with the same opportunities. The adoption of long-term regulations will create needed trust for companies, therefore increasing their reliability on bio-based products and their willness to invest.

The policy framework should be scientifically robust, comprehensive and consistent across all related sectors (e.g. in agriculture in order to ensure a sustainable supply and cost-efficient feedstock). It should consider several environmental damaging factors (e.g. CO2 emissions,

impacts on biodiversity, land use and climate change) and related social impacts and costs. Besides, it should be focused on increasing public awareness for both companies and consumers. This could be done by organizing trainings and awareness campaigns focused on increasing the motivation of the consumer when choosing products. Information should be easy to be understood, as well as, functionality and sustainability issues should be communicated in a scientifically correct way without being misleading. In this sense, according to some experts, quality and performance standards could help citizens to guide their market choices.

A supportive regulatory framework should include demand support measures (e.g. green public procurement), as well as, incentives for R&D for the bio-based industry and academia. Legislative acts aiming at fostering the emergence on bio-based products and limiting the costs of environmental externalities, as well as, promoting the economy of circularity (e.g. through the application of specific fiscal measures) should be designed.

Although there were different opinions on whether these policies should be established at the national or international level, all experts agreed that they should be in any case aligned and applicable to all territories, monitoring their effectiveness and updating them at any time if required.

#### Need: To overcome the regulatory requirements that imply additional costs

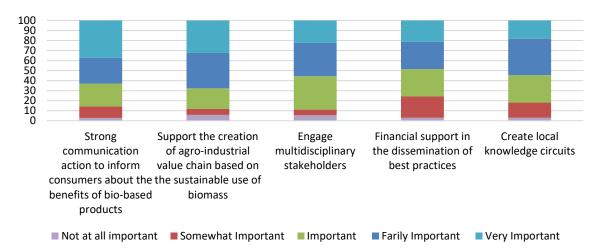
Several regulatory requirements imply additional costs and time expenditure for companies, and this may lead to delays in the market introduction of bio-based products. However, these requirements are necessary mechanisms to control the products that are entering the market, therefore, cannot be avoided. For example, the registration of new materials in the REACH regulation implies additional direct and indirect costs due to the adaptation of these materials to the requirements, as well as, the administrative process for entering new products is time consuming, since materials are not directly included in the regulation and must ensure compliance with the regulation. In this sense, several ways were proposed to overcome these hurdles, such as the simplification of administrative procedures, in the case of this example for registering new products in the REACH, as well as, the provision of subsidies for covering costs linked to the compliance with certification schemes requirements.

#### Need: To make bio-based products more competitive

Additionally, in order to make bio-based products more competitive, experts recommend carrying out strong communication actions in order to inform the public about the benefits of bio-based products and therefore, increase their awareness and willingness to buy them.

Experts also argued that the establishment of agro-industrial value chains based on the sustainable use of biomass are important measures for making bio-based products more competitive. Indeed this value chains play an important role in developing strategies that aim at promoting investments to agro-enterprises, facilitate knowledge sharing between them, and in general, for further expanding the role played by agriculture in the economic growth<sup>6</sup>.

All responses in this respect are shown in the figure 7:



#### Figure 7 Actions to make bio-based products more competitive

# 4.2 Increase efficiency in biomass production and production processes

#### 4.2.1 Cascade use principle

# Need: To identify cascading use principles to be included in a strategy for supporting the realization of cascading potentials

The cascading use approach to biomass utilization is seeing by the respondents as a way to maximise resource efficiency and to reduce negative environmental impacts of the production of bio-based products. According to the EC, cascading use can be defined as the efficient utilisation of resources by using residues and recycled materials to extend total biomass availability within a given system<sup>7</sup>. Another approach differentiates between "cascading use" in terms of a vertical use hierarchy (a product is manufactured and after its end of life a new product is made from it through e.g. recycling) and "co-production" in terms of a horizontal use hierarchy, which means the utilisation of side streams and residues<sup>8</sup>. In addition, the German Environmental Agency (UBA) defines cascading use as the approach of using biomass, that has been already processed, at least one more time for material or energy purposes. Within this definition a distinction is made between, single-stage cascade, when the biobased product is used for energy at the end of its life, as well as, multi-stage cascade, when the biobased product is used one more time as material<sup>9</sup>.

Currently, the realization of cascading potential is still minor and industries rarely implement it at the operational level. In this sense, there is a need to identify the cascading principles to be included in a common strategy for supporting the implementation of the cascading use of biomass and the full deployment of cascading potentials. Identifying clear principles for the operationalisation of the cascading use would help companies in considering cascading use not only as a policy guidance indicator for sustainability. In addition, a common understanding would help establishing a basis for a coherent regulatory framework, developing quality labels and standards, making data comparable (e.g. for LCA), and improving communication among stakeholders, as well as, increasing consumer awareness. Taking into account all the stated above, a consistent definition of the term cascading use is lacking across all sectors and its integration into existing legislature differs widely among MS<sup>10</sup>. According to the interviewed experts, a common strategy for supporting the operationalization of the term "cascading use of biomass", should embrace the following elements:

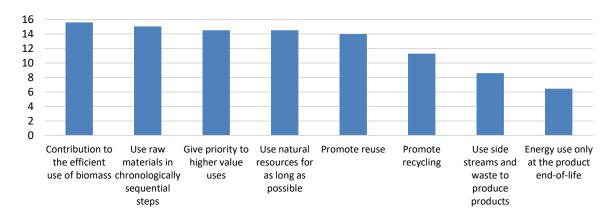


Figure 8 Elements to be included in a strategy for promoting cascading use of biomass

Experts argue that these principles should be integrated in relevant regulations (e.g. Circular economy package, Construction Products Regulation (CPR), cosmetic products legislation, eco-design directive, Food packaging regulation, etc.) and should be developed by the EC together with the relevant stakeholders (government, academia, industry and NGOs) and standardization bodies (e.g. CEN, ISO). In this sense, several experts see it as a priority to create a European bioeconomy council that would be in charge of supporting the implementation of these actions.

In addition, experts were asked to suggest possible needed actions for supporting the implementation of cascading use of biomass. Results are shown in figure 9:

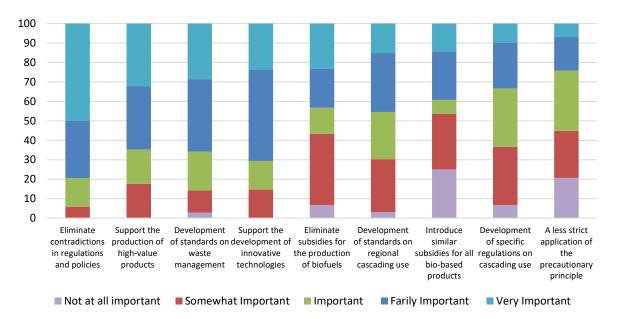


Figure 9 Actions for supporting the implementation of cascading use of biomass

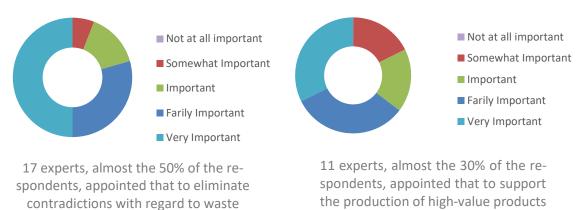
As indicated in figure 9, and further analysed in figures 10 and 11, to eliminate contradictions in regulations and policies with regard to the treatment of waste will support a cascading use of biomass. In addition, in this regards it is also relevant to find strategies to financially support the industries to produce first high value products from biomass:

Figure 10 To eliminate contradictions in regulation and policies with regard to the treatment of waste

management is very important

Figure 11 To support the production of high-value products from biomass

from biomass is very important



Need: To strengthen the use of the cascading principles in regulation and standardization

In addition, in order to strengthen the use of cascading principle in regulation and standardization, experts commented that there is a need to support zero waste principles by developing standards on waste collection and treatment and by defining when residues are waste or as by-product (see section 4.2.2 on waste as alternative feedstock to produce bio-based products). Some experts highlighted that these standards should be developed at the EU level in order to be harmonized, however, other experts believe that they should be developed at national/local level in order to support local resources and land use efficiency depending on the specific conditions of each region.

To conclude, to establish measures such as incentives for using waste as feedstock instead of using fossil-based resources (e.g. by establishing higher recycling quotas and if this is not possible, supporting the use of this waste for producing bio-based products), as well as, to increase the financial support to the R&D on cascading use of biomass (e.g. in order to reinforce the production of high value products from biomass), are actions that should be promoted according to the interviewed experts.

#### 4.2.2 Waste as an alternative feedstock to produce bio-based products

#### Need: To clarify the terms "residues" and "side-streams"

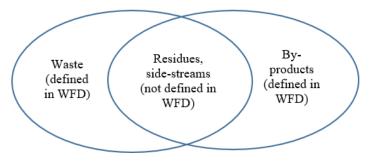
The Waste Framework Directive (2008/98/EC) sets basic concepts and definitions related to waste management (e.g. waste, recycling, recovery, etc.). It also explains when waste ceases to be waste and becomes a secondary raw material, as well as, how to distinguish between waste and by-products or side-stream. However, the clarification of the terms "residues" and "side-streams" is seemingly not sufficient for the needs of the bioeconomy, which can be seen

from some of the comments uttered by experts in the interviews. A lot of the confusion seems to stem from the mixed-up use of the terms "residues" and "side-streams", which are quite usual in the bio-based industry in addition to the terms "waste" and "by-product".

The terms "residues" and "side-streams" are not defined by the WFD, meaning that there is no legal status assigned to these terms. In the bio-based industry, they are often used for a variety of secondary resources, for example 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. Some experts mixed up the terms "side-streams" and "by-products" during the interviews, which happens quite frequently. For maximum clarity, project partners noted:

- Only the terms "waste" and "by-product" have the status of legal concepts.
- All other terms are not defined and can be assigned to any resource, whether they are "wastes" or "by-products" from a legal perspective.

Figure 12 Waste, residues, side-streams and by-products according to the WFD. Develop by project partners. 2019



#### Need: To clarify the articles 5 and 6 of the WFD

As reported by the experts interviewed in the first round, when they were asked about the biggest hurdles in legislation and standards in order to use residues to produce bio-based products, the complexity to determine whether residues are defined as waste or as by-product in the existing European legislation is the biggest issue. In this sense, the complexity of the article 5 of the WFD<sup>11</sup>, where the specifications that a product must meet in order to be considered by-product are explained, are impeding the use of waste to produce bio-based products.

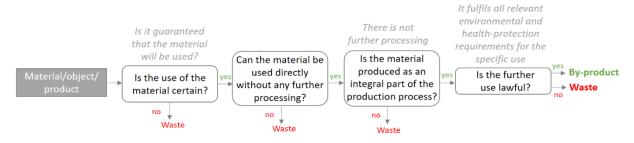
#### Waste Framework Directive (2008/98/EC)

According to Art.5 of the WFD, there are several conditions to be met in order to define waste (any substance or object, which the holder discards or intends or is, required to discard) as by-product. These four conditions are cumulative, meaning that all must be met:

- further use of the substance or object is certain;
- the substance or object can be used directly without any further processing other than normal industrial practice;
- the substance or object is produced as an integral part of a production process;
- further use is lawful, i.e. the substance or object fulfils all relevant product, environmental and health protection requirements for the specific use and will not lead to overall adverse environmental or human health impacts.

In figure 13, a graphical representation of the article 5 of the WFD explained above is shown. In the figure, the requirements that a product, object or material should meet in order to be considered a by-product are presented:

#### Figure 13 The requirements that a product, object or material should meet in order to be considered a by-product. Updated from the Communication on waste and by- products of the European Commission (21.2.2007). 2018



#### In addition, article 6 of the Directive specifies when waste shall cease to be waste:

<u>Waste Framework Directive (2008/98/EC)</u>
The Art.6 on end-of-waste status, certain specified waste 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:</u>
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;

•the use of the substance or object will not lead to overall adverse environmental or human health impacts.

According to this article, as long as the criteria have not been set at Community level, MS may decide on the status of the waste in a case by case basis, or in other words, MS have the right to decide whether certain waste has ceased to be waste. This leads to a situation where MS developed their own criteria failing to have an EU harmonized legal framework. For example, according to the article 184 of the Italian Legislative Decree 152/2006 (Environmental Protection Code), a production residue could be again used in the next production process without any other treatment. This issue should be clarified and harmonised it at the European level.

# Need: To update EU rules applicable to waste management, chemicals and products to achieve the circular economy goals

EU rules applicable to waste management, chemicals and products should be updated in order to achieve the circular economy goals, which are (see Circular Economy Package<sup>12</sup>):

- 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 substituting substances of concern and, where this is not possible, reducing their presence and improving their tracking.

One objective could impede the fulfilment of the other objective. According to the first objective, the maximization of the use of resources (including waste) must be allowed, however,

according to the second objective, the substances of concern must be avoided. Looking to the future, waste may contain substances that are no longer allowed in new products.

#### Need: To harmonize chemicals policy and waste policy

Another concern is the conflict between chemicals policy and the waste policy. As a matter of principle, both policies have the same objective, which is waste prevention, eliminating or at least minimising the use of very high concern substances. However, there is a difference between the "product not-allowed substances" and the "waste not-allowed substances", produced due to the contamination of waste by the presence of legacy substances. These last ones 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. The existence of these legacy substances and how to deal with them when contained in products (produced before the regulator control, represent a relevant hurdle. The problem is linked to the fact that there is a time difference between the lifetime of a product (defined here, as the time a product needs to reach its end-of-life) and the time a substance (that might be contained in the product) takes to be classify as "legacy substances".

Furthermore, according to the experts, harmonization with regard to limit values for pollutants and their possible adverse environmental effects should be addressed. These criteria have not been set at the European level, and therefore, MS have the right to decide case by case whether certain waste has ceased to be waste. Consequently, each MS has developed its own different criteria.

All the stated above demonstrates the lack of harmonization in what refers to end-of-waste rules, making it uncertain when and how waste becomes a by-product, and vice-versa. Consequently, many products or materials are used without an established end-of-waste criteria and therefore under unclear legal circumstances and without transparency.

#### Need: To support the use of side-streams as feedstock to produce bio-based products

In the following graph, the most important measures that according to the respondents should be taken in order to support the use of side-streams as feedstock for the production of bio-based products are shown:

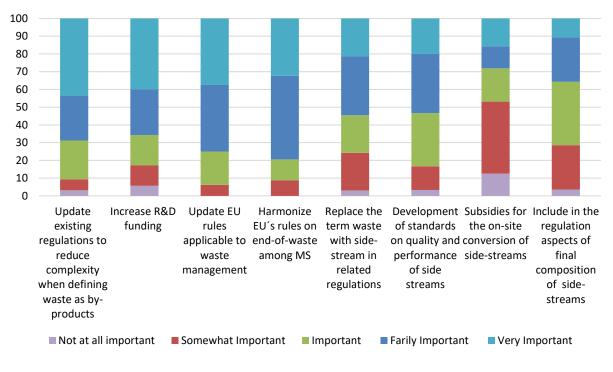
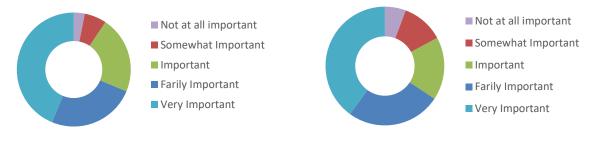


Figure 14 Measures to support the use of side-streams as feedstock in the production of biobased products

As shows in figure 14, and further analysed in figures 15 and 16, updating the existing regulations to reduce complexity when defining waste and by-products (e.g. articles 5 and 6 of the WFD), and increasingR&D funding in order to support the development of innovative technologies, are the actions that have the most urgency to be taken:

Figure 15 To update existing regulations to reduce complexity when defining waste as by-products

*Figure 16 To increase R&D funding (e.g. to de-velop innovative technologies)* 



14 experts, the 39% of the respondents, appointed that to update the existing regulations to reduce complexity when defining waste as by-products is very important 14 experts, the 39% of the respondents, appointed that to increase the R&D funding (e.g. to develop innovative technologies) is very important

#### Need: To support the use of MOW as feedstock to produce bio-based products

Experts were asked about the necessary measures for supporting the use of Municipal Organic Waste (MOW) in the production of bio-based products and the following measures were suggested:

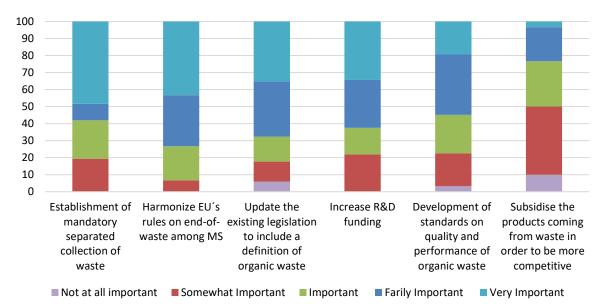
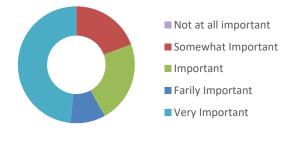


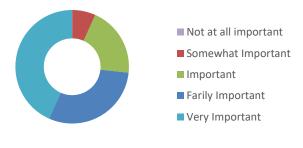
Figure 17 Measures to support the use of MOW a feedstock in the production of bio-based products

According to figure 17, and further analysed in figures 18 and 19, the establishment of mandatory separated collection of waste, as well as, the harmonization of EU rules on end-ofwaste among MS are the most important measures that should be carried out for supporting the use of MOW as feedstock for bio-based products:

*Figure 18 To establish mandatory separated collection of waste* 



15 experts, the 42% of the respondents, appointed that the establishment of mandatory separated collection of waste is very important Figure 19 To harmonize EU's rules on endof-waste among MS (in particular the socalled 'end-of-waste criteria')



13 experts, the 36% of the respondents, appointed that to harmonize the EU rules on end-of-waste among MS is very important

### 4.2.3 Digitalization and Industry 4.0 in agriculture and forestry

#### Need: To fill knowledge gaps of the farmers and forest owners

Taken into account the innovative character of using ICTs in agriculture and forestry, the importance of identifying and filling the knowledge gaps of the farmers and forest owners was commented. For that, there is a necessity to develop better easy-to use life-long training programs, focused on local needs. More specifically, the experts suggested the following actions to support the use of digital innovations by farmers and forest owners:

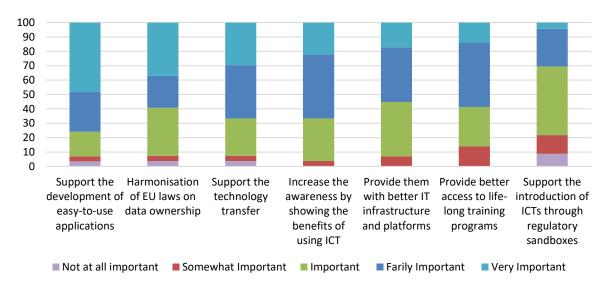
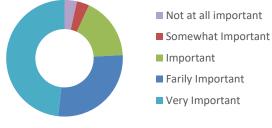


Figure 20 Actions to support the use of digital innovations by farmers and forest owners

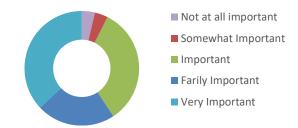
In the figures 21 and 22, the two most imminent actions in view of the experts are shown:

Figure 21 To support the development of easyto-use



14 experts, the 39% of the respondents, appointed that to support the development of easy-to-use applications is very important

Figure 22 To harmonise of EU laws on data ownership



10 experts, the 28% of the respondents, appointed that to harmonisation of EU laws on data ownership and data security is very important

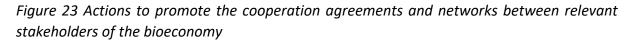
#### Need: To solve the problem of data ownership

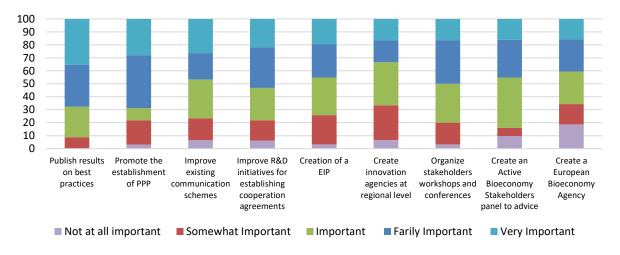
To conclude, data ownership represents a huge problem. A high magnitude of data is correlated with a possible loss of privacy and an illicit collection of confidential information. Several experts believe that this information should be of public domain, by establishing user agreements and securing the transparency in data handling.

#### 4.2.4 Establish cooperation agreements and networks

#### Need: To establish cooperation agreements and networks to promote a sustainable bioeconomy in Europe

According to the majority of the experts, cooperation agreements between farmers or forest owners, agroindustry and bio-based industry are extremely important in order to promote a sustainable bioeconomy in Europe. More specifically, these agreements will help increase the knowledge and skills of biomass producers and ensure an adequate participation of all value chain stakeholders in final revenue. Experts endorse the creation of networks and partnerships between major bioeconomy stakeholders and they provided various suggestions in order to facilitate them:





Among the proposed measures to support the creation of networks, to publish results on best practices to serve as a model for future network establishments, as well as, to promote the establishment of PPP, sharing the risk and creating innovative and long-term networks for public and private sectors, were selected as the most important measures:

Figure 24 To publish the results on best practices Figure 25 To promote the establishment of PPP



# 5. Regulatory suggestions for identified breakthrough technologies

From the ex-ante analysis executed under the STAR4BBI project, the following three innovations were identified by the experts as potential drivers of change for the future of the European bioeconomy (see D3.1).

- 1) gene-editing technologies;
- 2) techniques for the valorisation of lignin into high value products; and
- 3) furan-based chemistry from sugars to produce FDCA.

The capacity for innovation and future development of these three breakthrough innovations/technologies depend on favourable regulatory and investments conditions. More specifically, and further explained in the D3.1, concerning gene-editing technologies, updates in the current European regulatory framework were considered extremely important to fully deploy the potential and opportunities of this technological breakthrough. With regard to lignin valorisation, the majority of the interviewed experts mentioned fast pyrolysis and catalytic conversion of lignin to produce aromatics as the most promising future developments. Most of the identified challenges that are preventing from fully exploiting the potential of this technology are related to technical challenges, e.g. difficulty to deal with the heterogeneous structure of lignin, the lack of knowledge regarding its structure and the necessity of new pretreatment methods in order to preserve the lignin fraction. In respect to furan-chemistry to produce FDCA from sugars, companies such as Corbion are already producing high purity FDCA, however the still unacceptable price represents an important challenge that is hampering its fully employment. This technology cannot yet compete with the low price of fossilbased plastics.

In addition, bio-based products produced from algae or aquatic biomass were assessed for their potential to be drivers of change for the future European bio-based economy. In this sense, focus groups were organised in order to capture expert's opinion on possible challenges linked to regulations and standards that may be hampering their development.

The results obtained in the 2-round Delphi survey, as well as, in the organized focus groups are presented in this chapter.

## 5.1 Gene-editing techniques

# Need: To exclude new genome editing techniques from the strict regulation of GMO, when applied to bio-based products

#### Current regulatory situation in Europe

On the 25<sup>th</sup> of July 2018, right after the first round of the survey, the European Court of Justice (ECJ) adopted a radically different opinion as the advocacy General and decided that organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive<sup>13</sup>. According to the EU, the techniques and methods of mutagenesis (set of techniques, which make it possible to alter the genome of a living species without the insertion of foreign DNA. Mutagenesis techniques have made it possible to develop seed varieties which are resistant to selective herbicides) alter the genetic material of an organism in a way that does not occur naturally. The Court considers that direct modification of the genetic material of an organism through mutagenesis makes it possible to obtain the same effects as the introduction of a foreign gene into the organism (transgenesis). The ECJ believes that the fact of excluding these 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.

The decision to include gene-editing techniques within GMO regulations was unexpected since just a few months before, on the 18<sup>th</sup> of January 2018, the Advocate General Michal Bobek communicated that organisms obtained by mutagenesis are, in principle, exempted from the obligation in the GMO Directive<sup>14</sup>. In the communication, Mr. Bobek stated that unlike transgenesis, mutagenesis does not entail the introduction of a foreign DNA into living organisms. This announcement came up since the French agricultural union Confédération Paysanne together with eight other associations, argued that the use of herbicide resistant seed varieties obtained by mutagenesis carries a risk to the environment and to the human and animal health. The objective of these organizations was to answer French regulators in regards to the transposition of the French GMO regulation. In order to clarify it, the Advocacy General was invited to the French Conseil d'Etat.

The surprising verdict generated mixed reactions. For example, the German Research minister Anja Karliczek said that this decision should be based in a "research-friendly judgment", since these new plant breeding methods are necessary to meet the challenges of climate change<sup>15</sup>.

#### Experts in accordance with the new ruling of the ECJ

Only few interviewed experts support the new ruling and argue that this decision is absolutely in line with the precautionary principle. They also believe that more research is needed in order to verify long-term effects and possible trade-offs in terms of sustainability, biodiversity and human health of the application of these new breading techniques.

#### Experts out of accord with the new ruling of the ECJ

Most of the interviewed experts in the Delphi survey disagree with the new ruling of the ECJ. According to them, gene-edited plants should not be considered as transgenic organisms, and therefore, they should be exempted from the European regulations governing GMOs. Experts mentioned that this ruling is not scientifically justified. According to them, the introduction of genetic alterations that could also be the result of classical breeding techniques cannot be considered GMO. In fact, modern genome editing technologies has allowed far more efficient gene modification and can be used in different application sectors related to the bioeconomy, including:

• Plant breeding, by 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 biofuels, pharmaceuticals and other high-value chemicals.
- Synthetic biology by improving the creation of strains.
- 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).

In addition, on the 16<sup>th</sup> of October 2018 right after the decision of the court, a focus group exercise was organised with experts on gene-editing techniques, and their opinion on the decision of the court was requested. The majority of the experts agreed that the new ruling will have negative impacts in the future of the European bio-based industry. Worldwide developments in this area are very fast, and in this sense, other countries might gain technological leadership, complicating the path for European companies to develop and use these innovative techniques. Especially for many smaller biotech companies that are working towards bringing new plant varieties to the market, this judgment could be detrimental. Experts also argue that the new ruling will result in additional costs and long administrative procedures especially for SMEs. In addition, it was mentioned that the new ruling would support the non-acceptance of consumers, demotivating the industry and therefore slowing down the innovation potential of the bio-based economy.

According to these experts, the focus of the regulation should be on the end-product and the regulation should not affect in the same way the edited crops to be used exclusively for the production of bio-based products (e.g. bioplastics) on the same way as edited crops for the production of food and feed. In this sense, a quick proposed solution would be to update the Annex IB of the Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms<sup>16</sup>. In the Annex IB, different methods that can be excluded from the Directive are listed. Methods such as CRISPR-Cas, previously proving that they have been used safely for a long time, should be included.

#### Need: To set specific ruling for gene-editing techniques away from the GMO Directive

Experts were also asked whether gene-edited plants should be regulated, and there was no consensus in this respect. On the one hand, the experts that answered that gene-edited plants should not be regulated, appointed that since genome editing does not involve the introduction of DNA from another organism it is also nearly impossible to detect whether a living thing's DNA has been edited or not, and therefore, since changes are indistinguishable from naturally occurring mutations, no new regulations are needed. On the other hand, the experts who answered that gene-edited plants should be regulated appointed, that due to the possibility of off-target effects (edits in the wrong place) and mosaicism (some cells carry the edit but others do not), a regulation which contains the following features is of primary concern:

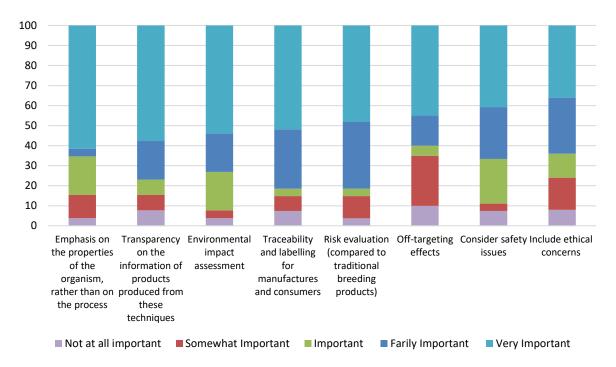
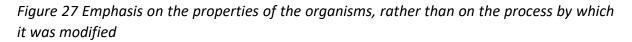


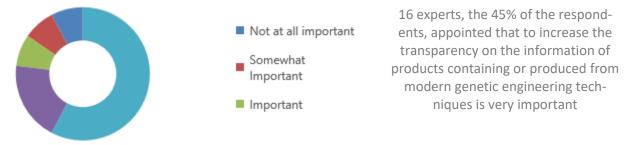
Figure 26 Features to include in the regulation for gene-editing techniques

As can be observed in figure 26, and further analysed in figures 27 and 28, to put an emphasis on the properties of the organism, and this means that regulation should be focused on the product rather than on the process, is the most important action to be taken according to the experts. In addition, the transparency on the information of products containing or produced from modern genetic engineering techniques should be increased in order to enhance industry and consumers awareness.





*Figure 28 Transparency on the information of products containing or produced from modern genetic engineering techniques* 



# 5.2 Lignin valorisation into high valuable products

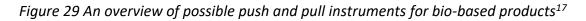
#### Need: To financially support the R&D for the valorisation of lignin

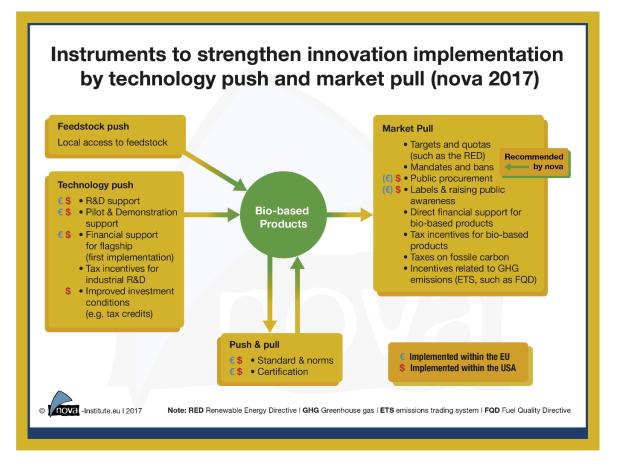
In order to support the use of lignin as feedstock to produce bio-based products, the need of a clear definition that provides information about its specific fractions was considered by the experts as extremely important. This definition should engage different actors such as potential customers and industries, especially big brands who have the power to commercialize and develop production processes. However, the structure of lignin is heterogeneous and there are many types of lignin, making it impossible to define all components, and therefore, according to most of the experts, it would be very complex to develop a standardized definition of lignin which is valid for all lignin streams.

In this sense, one possible solution would be to define lignin properties, which depend on the source and extraction process, for each application of lignin, and for example, to develop a supply chain map based on the properties needed for the different applications. For that, different applications for lignin should be defined and industries should provide the needed technical description for each application. Evidence of all this is that Borregaard - assessed value chain on the project and global supplier of lignin-based binding and dispersing agents for decades – only uses one type of lignin. In addition, several European Networks are already working on the lignin characterization, defining the structure-function relationship with specific proportions for each application.

As reported by the experts, cross-sectoral partnerships between the forest-based sector, agro sector and frontrunners of the chemical industry are extremely important to support the valorisation of lignin. In order for these partnerships to be established, all actors should be involved, particularly farmers. Farmers are usually the most difficult participants to get involved, requiring investments of all actors. A way to bring relevant players together would be through research projects (e.g. BBI) and regional support organizations.

In addition, the development of policies, which support private parties' investments, a review of the RED in order to promote the cascading use of wood, as well as, to support the use of lignin through green public procurement are other measures, that according to the experts need to be taken in order to support the valorisation of lignin. Several experts commented that the use of lignin to produce bio-based products should be supported through incentives. Other experts highlighted that the interest for bio-based products should be increased only by providing market pull. In this respect, in the following figure, several instruments to strengthen the implementation by technology push and market pull are shown.





#### Need: To amend the European standards on biodegradability and compostability of products (e.g. EN 13432)

Another important issue in respect to lignin valorisation is that the European standards on biodegradability and compostability of products (e.g. EN 13432) are demanding degradation to CO2, water, methane, biomass and minerals within a certain time (typically 90% within 6 months). These requirements cannot be met by products (partially) made out of lignin, since lignin is a recalcitrant biopolymer, meaning that it resists to degradation (attack by microbes). A possible solution for this problem could be to update the standards and exclude lignin from the compostability and biodegradability requirements. Other experts commented that since the main function of lignin in nature is to resist to biodegradation, industry could benefit from this attribute and use lignin for applications that require high durability and resistance to biodegradability and compostability. In this case, new standards for (non-biodegradable) products containing lignin should be developed.

# 5.3 Furan-chemistry from sugars

## Need: To set measures to support the technology-push of FDCA

Although companies such as Corbion are already producing high purity FDCA, the still unacceptable price represents an important challenge that is hampering the fully employment of this technology.

According to several experts, the future development of this innovation depends on the consumers' willingness to pay a higher price. In this sense, a key point is to show the extra functionalities that FDCA products. Research conducted by the industry (such as Avantium and Corbion) has proven that apart from obtaining a strong reduction of the carbon footprint of their supply chains, PEF bottles outperform PET bottles in several areas: barrier properties (gas permeability), ability to seal out oxygen (lasting longer carbonated drinks), better packaging coatings (to keep drinks more fresh), ability to withstand heat (glass transition temperature or Tg) and process-ability at lower temperatures (melting temperature or Tm).

In addition, according to the experts, the following measures (among others) could be taken in order to support the market uptake of products obtained from furan-chemistry (experts did not provide with any specific measure for furan-chemistry):

- Establishment of a blending mandate for bio-based products.
- Incentives to support technological innovation.
- Increase NGOs know-how on bio-based products since they highly influence politics, slowing down the development of the bio-based industries.
- Reward environmental positive externalities.
- Green public procurement.

To conclude, the creation of an initiative at European level such as the American BioPreferred Program, would be extremely important in order to support the production of bio-based products in general and FDCA in particular. The Biopreferred program aims at increasing the purchase and use of bio-based products, in order to encourage the economic development, create new jobs and provide new markets for farm commodities. The program has two different parts: it establishes a mandatory green public procurement for federal agencies and their contractors, and it sets a voluntary labelling initiative for bio-based products.

# 5.4 Algae and aquatic biomass to produce bio-based products

Over the last decade, great efforts have been made in order to identify sustainable and economically-viable solutions regarding the valorisation of biomass into high-value products. Since bio-based products from algae or aquatic biomass have emerged as particularly promising, the EC requested to further analyse them and for this reason it was later added to the project. Aquatic biomass is an interesting feedstock, it is abundantly available and could potentially meet quantitatively the demand requirements for fuels and materials, as well as, it does not directly interact with food for human consumption.

Algae basically can be divided in two major types.

- Microalgae, emerged as particularly promising since they can be grown on land with saltwater instead of valuable fresh water resources, and will provide oils, proteins, carbohydrates and valuable specialties.
- Macroalgae or seaweed, used for food and (fish) feed since they contain low calories but which are rich in vitamins, minerals, proteins, polysaccharides, steroids and dietary fibre.

Algae is currently being used for the following applications: mainly pharmaceuticals (e.g. antiinflammatory and antioxidant), cosmetics and food. The future aim is to valorise the algae or aquatic biomass into high-value products (e.g. chemicals). There is a huge demand for microalgae for cosmetics, but the problem is the lack for regulations (e.g. regarding the safety of the product) and its high price. Some experts stated that algae-based fuels are considered the only renewable energy resource with the capacity to meet the global demand for fuels in the long-term. Other experts commented that algae have a potential source to produce bio-based plastics, an interesting future market and application.

## Need: To increase investments in R&D to valorise algae biomass into high-value products

Although many efforts are being made in this respect, there is still a need for huge investments to upgrade the technologies to valorise algae biomass into high-value products from pilot-phase to industrial level.

This lack of research goes together with a lack of regulatory harmonisation. For example, regulations on the spatial planning in oceans and seas are not harmonised, as well as, different processes to treat aquatic biomass (e.g. harvesting) differs per country. In this sense, a harmonisation of the existing legislation would support the use of aquatic biomass, however, the industry is very small and such topics are not on top of the agenda of national governments. All this makes the move towards the development of aquatic cultivation at an affordable price a very slow process.

# 6. Conclusion and next steps

This report provides an overview of the existing regulatory and standardization needs that should be overcome to support the development of a cutting-edge bioeconomy in Europe. It is based on experts' opinion collected through interviews, the implementation of a 2-round Delphi survey and the organization of different thematic focus groups.

The findings are presented starting with the description of proposed needs to be addressed for **establishing a supporting regulatory and standardization framework for the bioeconomy and for levelling the playing field between both, bio-based products and biofuels, as well as, bio-based products and fossil-based products**. In this regards, relevant suggestions refer to the adoption of specific measures towards the creation of a stable and supportive regulatory framework (e.g. introduction of carbon tax for all products), and to the establishment of long-term policies towards a level playing field for bio-based products, independent of governmental changes, creating trust and wiliness to invest among companies. In addition, all regulatory requirements that follow create bureaucratic paths and imply additional costs for relevant actors should be simplified. It is also important to adopt strategies and actions directed at increasing the competitiveness of bio-based products, such as strong communication actions to inform consumers about the benefits of bio-based products.

For increasing the efficiency in biomass production and production processes, several initiatives were suggested. Primarily, there is a need to identify principles to be included in an implementation strategy for supporting the cascading use of biomass. Furthermore, in order to support the use of waste as a feedstock, several clarifications and updates of the existing regulatory framework, should be proposed (e.g. there is a need to update articles 5 and 6 of the WFD to determine whether residues are waste or by-product). A key contribution will also be provided by the adoption of new ICTs in the production of biomass. In this regards, there is a need, for example, to fill knowledge gaps of farmers and forest owners (e.g. through easyto-use applications). To conclude, the establishment of cooperation agreements and networks to promote a sustainable bio-based economy in Europe is considered of great importance.

In addition, experts identified different needs that are preventing the capacity for innovation of the potential drivers of changes of the European bioeconomy. In regards to **genome editing techniques** there is a concern about the new ruling of the ECJ and its consequences for the further development of the bio-based industry. For supporting the **valorisation of lignin** for producing high value added products, there is a need to amend the European standards on biodegradability and compostability, which currently includes requirements that cannot be met by products containing lignin.

As part of the implementation of this project, recommendations for policy makers including possible solutions for the identified needs will be designed. The main overall objective is to support the establishment of an investment and regulatory friendly framework for the bioeconomy, enabler to underpin the full deployment of upcoming innovations. These recommendations will be published in August 2019 and will be included in the next report D3.3 "Policy Paper on strategy for development of an RCS framework".

# Annex I: First round survey template

Dear Sir/Madam,

We would like to kindly ask you to participate in the following survey, aimed at identifying current and future regulatory and standardization needs for the bioeconomy. The survey results will provide the basis for developing proposals for updating current regulations and standards in anticipation of expected and desired technology and industry developments.

The survey is part of the BBI-JU financed project "STAR4BBI", which seeks to establish a coherent, well-coordinated and favourable regulatory framework that helps develop a cutting-edge bioeconomy for Europe (for more information: <u>www.bbi-europe-eu/projects/star4bbi</u>).

The anonymized survey results will be available to all interested participants for validation in a second survey round. If you would like to receive these results, please enter your email:

If you have any question or experience technical difficulties, please do not hesitate to contact us.

With kind regards,

Luana Ladu Tel.: +49(0)30314-76858 luana.ladu@tu-berlin.de



Janire Clavell Tel.: +49(0)30314-73996 j.clavell@tu-berlin.de



#### What kind of organization do you work?

□ Business □ NGO □ Industry □ Public organization □ University or research institute

other (please indicate): \_\_\_\_\_

In which country do you work? \_\_\_\_

#### How many employees does your organization have?

□ Less than 10 □ 10-49 □ 50-249 □ 250-5000 □ More than 5000

Do you consider yourself an expert in the field of bio-based products?

□ Yes □ Somewhat □ No

#### Are you an expert in the following areas?

- □ Genome editing technologies
- □ Lignin valorisation technologies
- □ Furan-chemistry from sugars
- □ I am not an expert of any of the above technologies (please, go directly to section D).

If you are an expert on any of the above-indicated technologies, please answer the related questions:

Section A for: Genome editing technologies Section B for: Lignin valorisation technologies Section C for: Furan-chemistry from sugars

We would be very grateful if you could additionally answer general questions on further development of the bioeconomy. If you are interested, please answer the questions in section D.

SECTION A: GENOME EDITING TECHNOLOGIES	
Question 1: Should gene-edited plants (resulting from ne	w breeding techniques) be considered as GMO?
□ Yes	□ No
Question 2: Should modern genetic engineering techni	ques be exempted from the European regulations
governing GMOs?	
□ Yes	□ No
Question 3: Should new plant breeding techniques (NBTs	) be regulated?
□ Yes	□ No
If yes: which issues should be considered in the regula-	If no: why do you think that regulation is not nec-
tion (e.g. safety issues; ethical issues)? Please be as spe-	essary, referring to the precautionary principle?
cific as possible	
If yes: which regulation (if any) would be applicable to	
(products arising from) NBTs such as CRISPR/Cas 9?	
Question 4: Is there a need to develop a clear and harm	
techniques? Or should the regulation be at the global lev	el?
EU regulation	
Regulation at the global level	
I am not sure	
Other:	
Question 5: If regulations on genome editing technique	s are introduced, now should these regulations be
designed?	anoma Editing/EACAC Depart 21 an Constra Editing
https://www.easac.eu/fileadmin/PDF_s/reports_statements/G pdf	enome_Editing/EASAC_Report_31_on_Genome_Editing.
<ul> <li>Regulation should focus on the technology itself (genore)</li> </ul>	me editing technique)
<ul> <li>Regulation should focus on the specific sector of applic</li> </ul>	
□ I am not sure	ation (as recommended by LASAC)
□ Other:	
l'Other.	
Question 6: What should a new regulation on new bread	ing technologies (NRTs) he hased on?
□ Based on a closed list of particular technologies	
<ul> <li>Based on a closed list of particular technologies</li> <li>Be flexible and able to be applied to existing or forecor</li> </ul>	aing technologies
□ I am not sure	
□ Other:	
SECTION B: LIGNIN VALORISATION TECHNOLOG	SIES
Question 1: Should the existing European standards on b	
EN13432, EN14995, EN14046, ISO18644, ISO14855) be	updated in order to facilitate the use of lignin as a
feedstock?	
If yes: which aspects should be included in an updated ve	ersion of the standards?
Question 2: Would it be feasible to create a standardized	definition of lignin (structure and properties)?

🗆 Yes	□ No
If yes: who should be responsible for developing such a	standardized definition?

Question 3: Would the creation of cross-sectoral partnerships between the forest-based sector, agro sector and the frontrunners of the chemical industry support the valorisation of lignin?

□ No

Question 4: What type of policy, regulatory or standardization-related measures would be the most effective in promoting technologies for converting lignin into high-value added products?

#### SECTION C: FURAN-CHEMISTRY FROM SUGARS

 $\Box$  Yes

Question 1: How could the technology-push of FDCA be supported? Note: The difficulties of producing high purity FDCA make the price unacceptable

#### SECTION D: FURTHER DEVELOPMENT OF THE BIOECONOMY

Creating a level-playing field for bioeconomy

Question 1: In your opinion, what would be the most important features of stable and supportive regulatory environment for the bioeconomy? Please indicate at least two important features.

Question 2: In your opinion, what measures should be taken to promote and ensure a level playing field between energy and material use of biomass?

Question 3: In your opinion, what measures should be taken to promote and ensure a level playing field between bio-based products and fossil-based products?

Question 4: Some regulatory requirements, such as the registration of new products under REACH, imply significant additional costs for companies. In your opinion, which regulatory requirements impose the highest financial burden on firms in the bioeconomy?

Question 5: How could the additional costs incurred by regulation be reduced?

#### Cascading use principle

Question 1: What is your understanding of cascading use?

□ Vertical use hierarchy (a product is manufactured and after its end of life, a new product is made from it, e.g. through recycling)

□ 'Coupled or co-production' in terms of a horizontal use hierarchy, which means the utilisation of side streams and residues

□ Both of the listed above

□ Other:

Question 2: Do you think that a common definition of the term cascading use would be useful?					
□ Yes	□ No				
If yes, what would the definition be useful for?					

If yes, and who should be in charge of developing such a definition?

Question 3: What do you think are the biggest hurdles / inconsistencies in European and national legislation that hamper the implementation of the cascading use of biomass?

Question 4: How can the cascading principle be strengthened in regulation and standardisation? Please give specific examples of particular parts of European, national and even regional legislation and standards that could be amended to boost cascading use

#### Waste as alternative feedstock

*Question 1: What are the biggest hurdles / inconsistencies in legislation and/or standards hampering the utilisation of agricultural residues for producing bio-based products?* 

Question 2: How can the use of agricultural residues be supported through legislation or standards? Please be as specific as possible, indicating concrete pieces of European or national legislation or standards and how they could be amended.

*Question 3: What are the biggest inconsistencies in legislation and/or standards hampering the utilisation of organic waste for producing bio-based products?* 

Question 4: How can the use of organic waste be supported through legislation or standards? Please be as specific as possible, indicating concrete pieces of European or national legislation or standards and how they could be amended.

*Question 5: Would the current Draft Waste Framework Directive published by the European Commission on DATE adequately support the use of waste as feedstock?* 

 $\Box No$ 

If yes, how could it be improved?

 $\Box$  Yes

Question 6: Which quality aspects need to be considered in the collection / use of waste wood to guarantee that it is safe for humans and the environment?

#### **Digitalization and Industry 4.0**

*Question 1: How could investments linked to the use of new digital developments by farmers and forest owners be supported?* 

*Question 2: How could investments linked to the use of new digital developments by industries producing bio-based products be supported?* 

Question 3: How could the development of new skills and competences of farmers and forest owners be supported in order to take advantage of the opportunities provided by the adoption of new digital developments?

*Question 4: How can data ownership and data security for the agricultural sector be guaranteed?* 

#### Cooperation agreements and establishment of networks

*Question 1: How important are cooperation agreements between farmers or forest owners, agroindustry and bio-based industry for:* 

	Important	Neutral	Not important
Promoting a sustainable bioeconomy in Eu-			
rope			
Increasing the knowledge and skills of biomass			
producers			
Ensuring an adequate participation of all value			
chain stakeholders in final revenue			
Question 2: How could the establishment of these	e agreements be fac	ilitated/ promoted /	'supported?

*Question 3: How important is the creation of networks and partnerships between different bioeconomy stakeholders in Europe in promoting a sustainable bioeconomy in Europe?* 

Very important	□Neutral	Not important

Question 4: How could the establishment of these networks be facilitated/ promoted /supported?

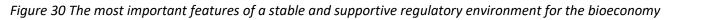
## WHAT IS NEXT?

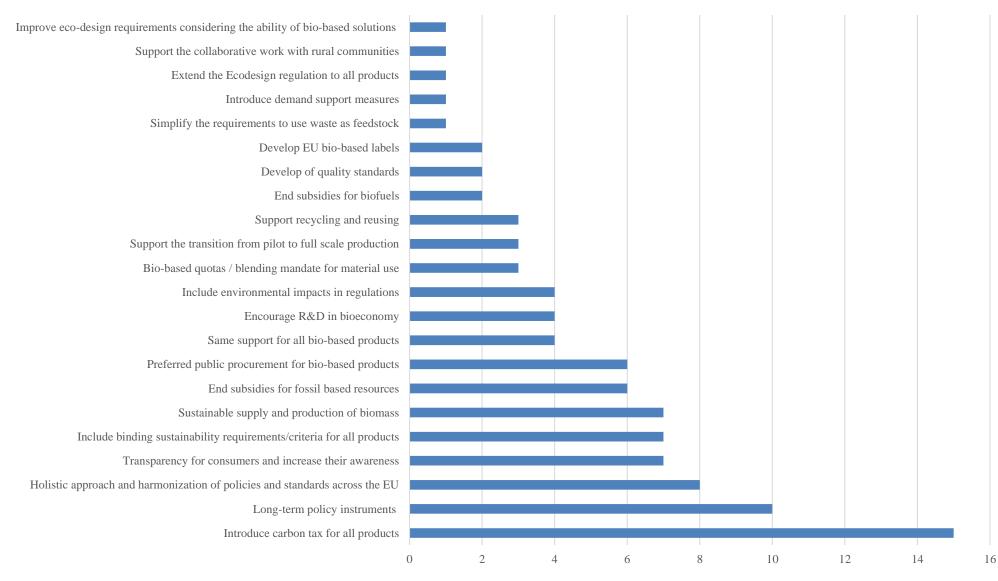
In a second survey round, you will be given the chance to provide us with your feedback on recommendations for improving regulations and standards. For this purpose, we would appreciate it very much if you could confirm your interest in participating in the second round of the survey by providing us with your email in the box below:

# Annex II: Statistics of the first round of the survey

### Creating a level-playing field

<u>Question 1:</u> In your opinion, what would be the most important features of a stable and supportive regulatory environment for the bioeconomy? Please indicate at least two important features: (The numerous answers have been classified into major categories, as indicated in the figure below).

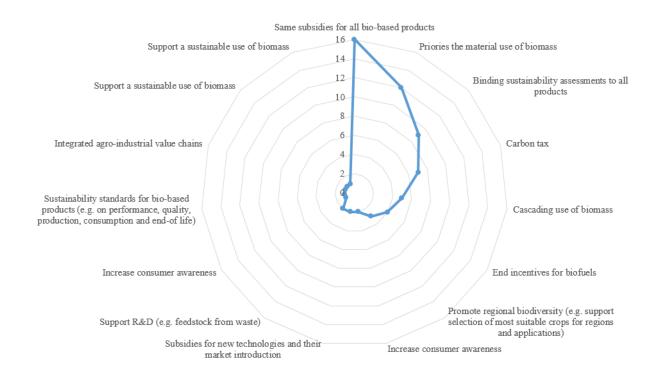




### Work Package 3: Foresight activity on regulations, standards and investments

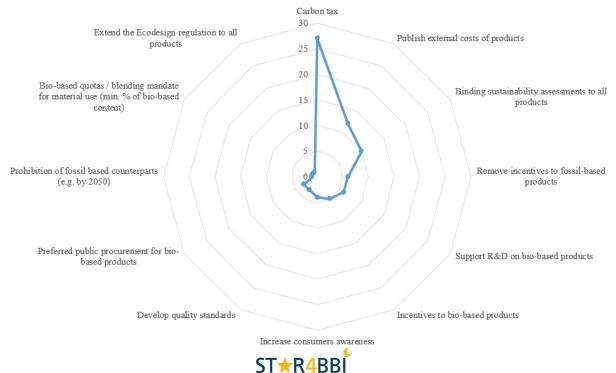
<u>Question 2:</u> In your opinion, what measures should be taken to promote and ensure a level playing field between energy and material use of biomass?

Figure 31 Measures to promote and ensure a level playing field between energy and material use of biomass



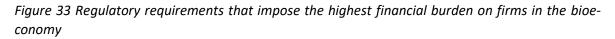
<u>Question 3:</u> In your opinion, what measures should be taken to promote and ensure a level playing field between bio-based products and fossil-based products?

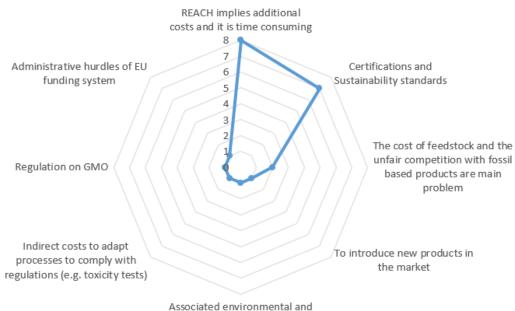
Figure 32 Measures to promote and ensure a level playing field between bio-based products and fossil-based products



## Work Package 3: Foresight activity on regulations, standards and investments

<u>Question 4:</u> Some regulatory requirements, such as the registration of new products under REACH, imply significant additional costs for companies. In your opinion, which regulatory requirements impose the highest financial burden on firms in the bioeconomy?

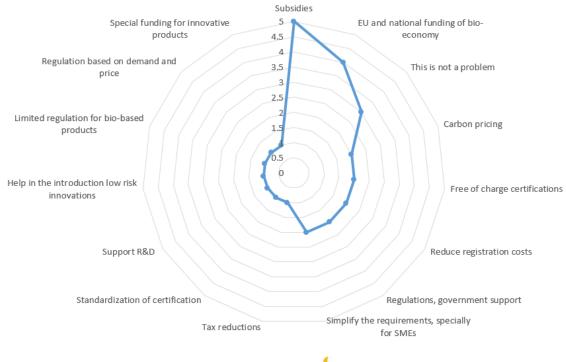




social costs

Question 5: How could the additional costs incurred by regulation be reduced?

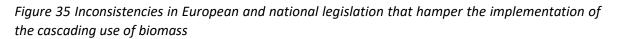
Figure 34 Measures to reduce additional costs incurred by regulation

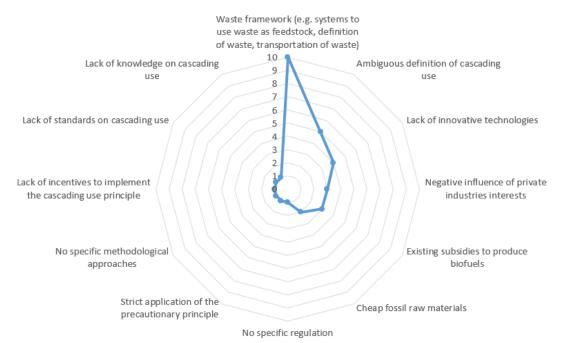


### Work Package 3: Foresight activity on regulations, standards and investments

#### **Cascading Use Principle**

<u>Question 3:</u> What do you think are the biggest hurdles / inconsistencies in European and national legislation that hamper the implementation of the cascading use of biomass?





<u>Question 4:</u> How can the cascading principle be strengthened in regulation and standardisation? Please give specific examples of particular parts of European, national and even regional legislation and standards that could be amended to boost cascading use.

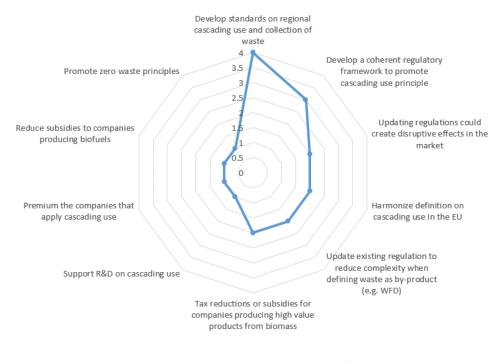


Figure 36 Measures to strength the cascading principle in regulation and standardisation

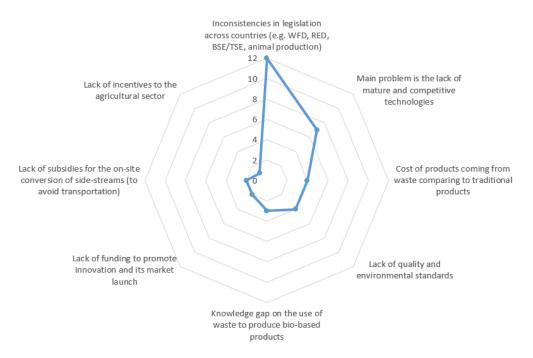


#### Work Package 3: Foresight activity on regulations, standards and investments

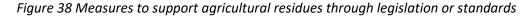
#### Waste As Alternative Feedstock

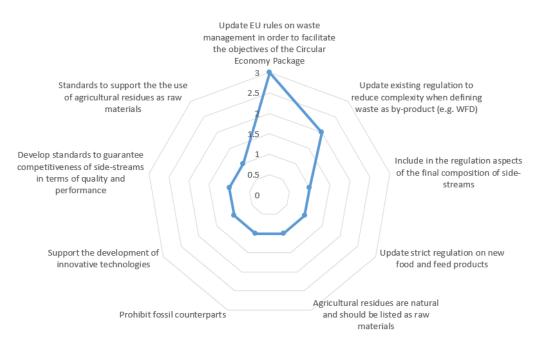
<u>Question 1:</u> What are the biggest hurdles / inconsistencies in legislation and/or standards hampering the utilisation of agricultural residues for producing bio-based products?

*Figure 37 Inconsistencies in legislation and/or standards hampering the utilisation of agricultural residues for producing bio-based products* 



<u>Question 2:</u> How can the use of agricultural residues be supported through legislation or standards? Please be as specific as possible, indicating concrete pieces of European or national legislation or standards and how they could be amended



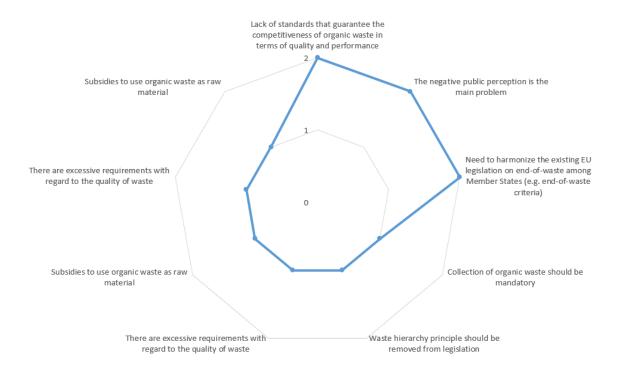




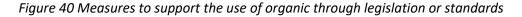
### Work Package 3: Foresight activity on regulations, standards and investments

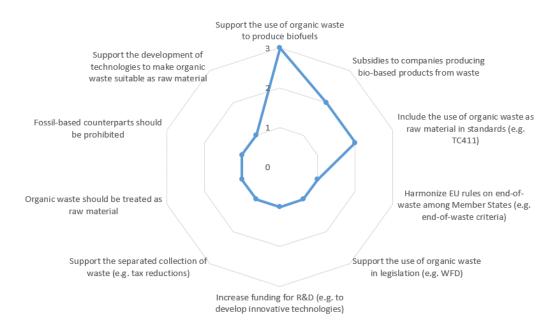
<u>Question 3:</u> What are the biggest inconsistencies in legislation and/or standards hampering the utilisation of organic waste for producing bio-based products?

Figure 39 The biggest inconsistencies in legislation and/or standards hampering the utilisation of organic waste for producing bio-based products



<u>Question 4:</u> How can the use of organic waste be supported through legislation or standards? Please be as specific as possible, indicating concrete pieces of European or national legislation or standards and how they could be amended

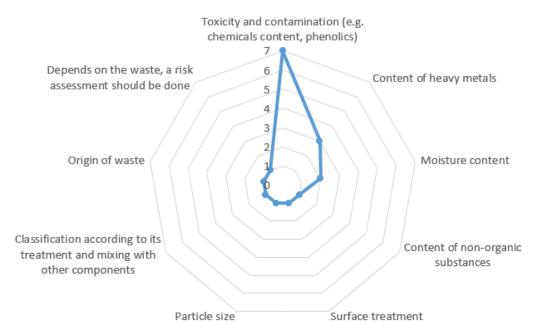




## Work Package 3: Foresight activity on regulations, standards and investments

<u>Question 6:</u> Which quality aspects need to be considered in the collection / use of waste wood to guarantee that it is safe for humans and the environment?

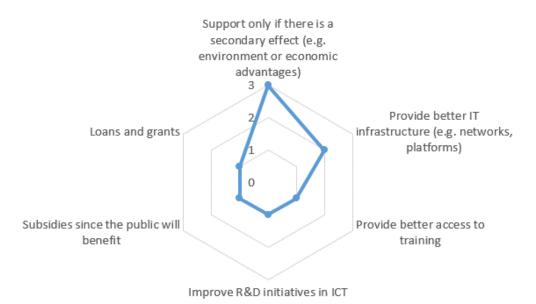
Figure 41 Quality aspects that need to be considered in the collection / use of waste wood to guarantee that it is safe for humans and the environment



### Digitalization and Industry 4.0

<u>Question 1:</u> How could investments linked to the use of new digital developments by farmers and forest owners be supported?

Figure 42 Measures to support the investments linked to the use of new digital developments by farmers and forest owners

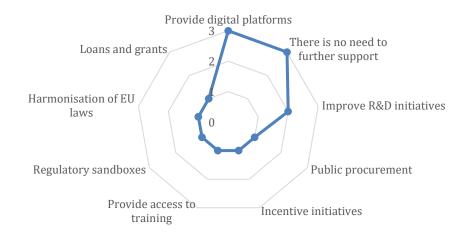




## Work Package 3: Foresight activity on regulations, standards and investments

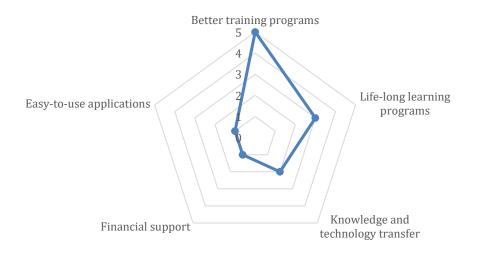
<u>Question 2:</u> How could investments linked to the use of new digital developments by industries producing bio-based products be supported?

Figure 43 Measures to support the investments linked to the use of new digital developments by industries producing bio-based products



<u>Question 3:</u> How could the development of new skills and competences of farmers and forest owners be supported in order to take advantage of the opportunities provided by the adoption of new digital developments?

Figure 44 Measures to support the development of new skills and competences of farmers and forest owners

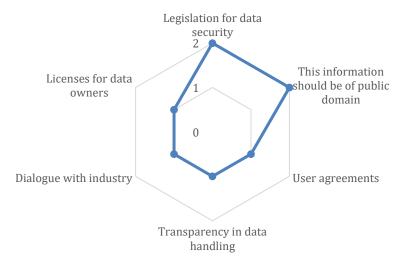




### Work Package 3: Foresight activity on regulations, standards and investments

Question 4: How can data ownership and data security for the agricultural sector be guaranteed?

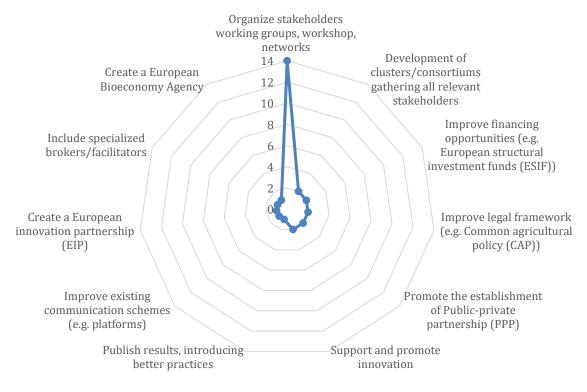
Figure 45 Measures to guarantee data ownership and data security for the agricultural sector



#### **Cooperation Agreements and Networks**

<u>Question 2:</u> How could the establishment of these agreements be facilitated/ promoted /supported?

Figure 46 Measures to support the establishment of cooperation agreements between farmers, forest owners, agroindustry and bio-based industry

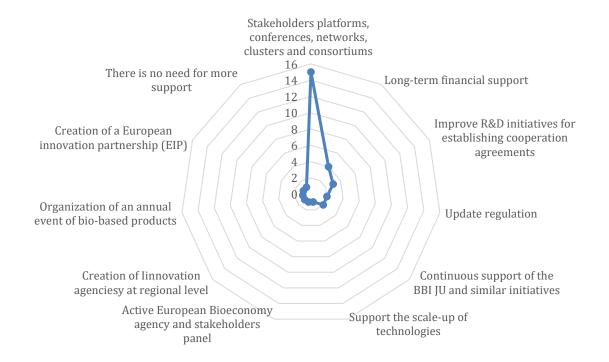




## Work Package 3: Foresight activity on regulations, standards and investments

Question 4: How could the establishment of these networks be facilitated/ promoted /supported?

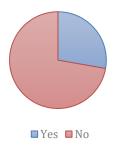
Figure 47 Measures to support the establishment of cooperation agreements between different bioeconomy stakeholders in Europe in promoting a sustainable bioeconomy in Europe



### **Genome Editing Technologies**

<u>Question 1:</u> Should gene-edited plants (resulting from new breeding techniques) be considered as GMO?

Figure 48 Should gene-edited plants (resulting from new breeding techniques) be considered as GMO?

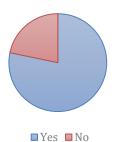


<u>Question 2:</u> Should modern genetic engineering techniques be exempted from the European regulations governing GMOs?

*Figure 49 Should modern genetic engineering techniques be exempted from the European regulations governing GMOs* 

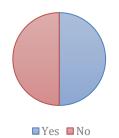


Work Package 3: Foresight activity on regulations, standards and investments

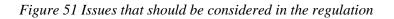


Question 3: Should modern genetic engineering techniques be regulated?

Figure 50 Should modern genetic engineering techniques be regulated?



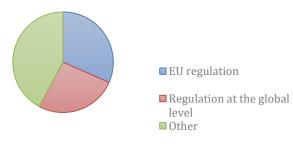
If yes: Which issues should be considered in the regulation (e.g. safety issues; ethical issues)? Please be as specific as possible





<u>Question 4:</u> Is there a need to develop a clear and harmonized EU regulation on the use of genome editing techniques? Or should the regulation be at the global level?

Figure 52Is there a need to develop a clear and harmonized regulation on the use of genome editing techniques

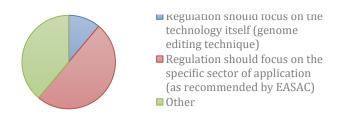




Work Package 3: Foresight activity on regulations, standards and investments

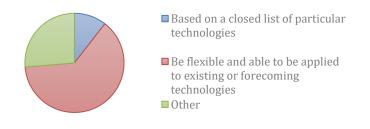
<u>Question 5:</u> If regulations on modern genetic engineering are introduced, how should these regulations be designed?

Figure 53 How should regulations on modern genetic engineering be designed?



<u>Question 6:</u> What should a new regulation on modern genetic engineering techniques be based on?

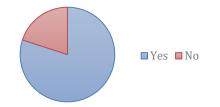
Figure 54 What should a new regulation on modern genetic engineering techniques be based on?



#### **Lignin Valorisation Technologies**

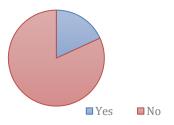
<u>Question 1:</u> Should the existing European standards on biodegradability and compostability of products (e.g. EN13432, EN14995, EN14046, ISO18644, ISO14855) be updated in order to facilitate the use of lignin as a feedstock?

Figure 55 Should the existing European standards on biodegradability and compostability of products be updated in order to facilitate the use of lignin as a feedstock?



<u>Question 2:</u> Would it be feasible to create a standardized definition of lignin (structure and properties)?

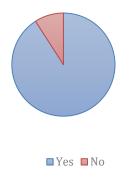
Figure 56 Would it be feasible to create a standardized definition of lignin?



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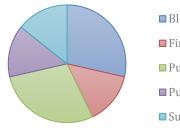
<u>Question 3:</u> Would the creation of cross-sectoral partnerships between the forest-based sector, agro sector and the frontrunners of the chemical industry support the valorisation of lignin?

Figure 57 Would the creation of cross-sectoral partnerships between the forest-based sector, agro sector and the frontrunners of the chemical industry support the valorisation of lignin?



## **Furan-Chemistry From Sugars** <u>Question 1:</u> How could the technology-push of FDCA be supported?

Figure 58 Measures to support the technology-push of FDCA



- Blending mandate for bio-based products
- Financial support of technological innovation
- Public awareness
- Publish postive externalities
- Support the market take-up



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# Annex III: Second round survey template

Dear Sir/Madam,

Thank you very much for participating earlier in the first round of the survey aimed at identifying current and future regulatory and standardization needs for the bioeconomy.

In this second round of the survey you will be asked to rate the outcomes derived from the first round. Completing the survey will take approximately 20 minutes.

If you have any question or experience technical difficulties, please do not hesitate to contact us. With kind regards,

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The survey is part of the BBI-JU financed project "STAR4BBI", which seeks to establish a coherent, well-coordinated and favourable regulatory framework that helps develop a cutting-edge bioeconomy for Europe (for more information: www.bbi-europe-eu/projects/star4bbi).

### Level playing field

For ensuring a level-playing field for the bioeconomy vis-à-vis fossil-based a supportive regulatory and standardization framework should be established.

<u>Question 1:</u> For each of the following features, please rate their relevance (in your opinion) for achieving a stable and supportive regulatory and standardisation framework for the bioeconomy:

0 (not important) - 5 (very important)	0	1	2	3	4	5
Taxation:						
Introduce a carbon tax for all products						
Tax benefits for bio-based products (e.g. VAT or other)						
Border tax on embedded carbon for imported goods from regions						
outside of the EU where there are weak environmental controls						
Revenue for GHG reductions						
Financial incentives for the production of bio-based products (e.g.						
support R&D and production incentives)						
End subsidies for biofuels						
Bio-based quotas / blending mandate for material use (min. % of bio-						
based content)						
Preferred public procurement for bio-based products						
Ban on the use of biomass for energy production by 2050						
Ban on the use of non-biomass-materials by 2050						
Support the cascading use of biomass (food, feed, material use and						
energy before landfill)						
Consider in regulations the ability of bio-based solutions and compo-						
nents to enhance the overall environmental footprint						
Clear end-of-life information for bio-based products						
Support the use of fully biodegradable products						
Promote regional biodiversity (support selection of most suitable			1			
crops for regions and applications)						



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Support standardization activities for bio-based products (e.g. further develop European standards						
that give legal conformity indications)						

On performance			
<ul> <li>On biomass (quality, sustainability, origin, etc.)</li> </ul>			
On production			
On consumption			
On end-of-life options			
Subsidies to companies to obtain sustainability certifications for bio-			
based products			
Improve eco-design requirements considering the ability of bio-based			
solutions and components to enhance the overall environmental foot-			
print of products and materials			

Other (please indicate):

<u>Question 2</u>: For each of the following actions, please rate their relevance (in your opinion) for supporting the development of the bioeconomy:

0 (not important) - 5 (very important)	0	1	2	3	4	5
Strong communication action to inform consumers about the benefits						
of bio-based products						
Financial support in the dissemination of best practices						
Create local knowledge circuits						
Engage multidisciplinary stakeholders						
Support the creation of agro-industrial value chain based on the sus-						
tainable use of biomass						

### Cascading use principle

According to earlier investigations, a common understanding of the term "cascading use" would avoid ambiguity and misinterpretations. In this second round, we would like to know your opinion on the definition that should be adopted, as well as the relevance of the identified features for supporting the implementation of the cascading use principle.

<u>Question 3:</u> Please indicate (in your opinion) which of the following features should be included in the definition of cascading use? You can select more than one feature:

Contribution to the efficient use of biomass	
Use raw materials in chronologically sequential steps	
Give priority to higher value uses	
Use natural resources for as long as possible	
Promote reuse	
Promote recycling	
Use side streams and waste to produce products	
Energy use only at the product end-of-life	

Please, write down other important features that in your opinion should be considered in the definition of the cascading use of biomass:



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<u>Question 4</u>: Please rate the importance (in your opinion) of the following features for supporting the implementation of the cascading use of biomass:

0 (not important) - 5 (very important)	0	1	2	3	4	5
Development of specific regulations on cascading use						
Support the development of affordable innovative technologies to						
implement the cascading use						
Support the production of high-value products from biomass						
Eliminate subsidies for the production of biofuels						
Introduce similar subsidies for all bio-based products						
Development of standards on regional cascading use						
Development of standards on waste management						
Eliminate contradictions in regulations and policies with regard to						
the treatment of waste						
A less strict application of the precautionary principle						

<u>Question 5:</u> In your opinion, is there any existing regulation (at national or European level) that should be updated in order to support the cascading use principle?

#### Waste as an alternative feedstock

As reported by the experts interviewed in the first round, the complexity to determine whether residues are defined as waste or as by-product in the existing European legislation is an issue. In addition, the lack of waste or secondary raw materials quality and performance standards and the existing knowledge gap on the use of waste as a feedstock have been identified as major problems. In this second round, you would be asked to rate the importance of identified measures for supporting the use of side streams and municipal organic waste as feedstock.

<u>Question 6:</u> Please, rate the importance (in your opinion) of the following measures for supporting the use of side-streams (e.g. agricultural residues) as feedstock:

0 (not important) - 5 (very important)	0	1	2	3	4	5
Update existing regulations to reduce complexity when defining						
waste as by-products (e.g. Waste Framework directive)						
Replace the term waste with side-stream in related regulations (im-						
portant for increasing the consumer acceptance)						
Harmonize EU's rules on end-of-waste among Member States (in						
particular the so-called 'end-of-waste criteria')						
Update EU rules applicable to waste management in order to facili-						
tate the achievement of the objectives of the Circular economy						
package						
Include in the regulation aspects of final composition of side-						
streams						
Development of standards to guarantee competitiveness of side						
streams (recovered materials) in terms of quality and performance						
Subsidies for the on-site conversion of side-streams (to avoid trans-						
portation)						
Increase R&D funding (e.g. to develop innovative technologies)						



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<u>Question 7:</u> In your opinion, is there any existing regulation (e.g. national or international) that should be updated in order to support the use of side-streams as an alternative feedstock?

<u>Question 8:</u> Please, rate the importance of the following measures (in your opinion) for supporting the use of municipal organic waste as feedstock:

0 (not important) - 5 (very important)	0	1	2	3	4	5
Update the existing legislation to include a definition of organic						
waste						
Harmonize EU's rules on end-of-waste among Member States (in						
particular the so-called 'end-of-waste criteria')						
Development of standards to guarantee competitiveness of organic						
waste in terms of quality and performance						
Establishment of mandatory separated collection of waste						
Subsidise the products coming from waste in order to be competi-						
tive with traditional products						
Increase R&D funding (e.g. to develop innovative technologies)						

<u>Question 9:</u> In your opinion, is there any existing regulation (e.g. national or international) that should be updated in order to support the use of municipal organic waste as an alternative feed-stock?

### **Cooperation agreements and networks**

Cooperation agreements between farmers or forest owners, agroindustry and bio-based industry are needed in order to increase the knowledge and skills of biomass producers and to ensure an adequate participation of all value chain stakeholders in final revenues. We would like to know your opinion on the importance of the identified measures to facilitate the establishment of these cooperation agreements.

<u>Question 10:</u> Please, rate the importance (in your opinion) of the following measures for establishing cooperation agreements and networks between different European stakeholders of the bioeconomy:

0 (not important) - 5 (very important)	0	1	2	3	4	5
Promote the establishment of Public-private partnership (PPP)						
Creation of a European innovation partnership (EIP)						
Create innovation agencies at regional level						
Create a European Bioeconomy Agency (in charge of piloting and						
coordinating all the Bioeconomy initiatives at European and na-						
tional level)						
Create an Active Bioeconomy Stakeholders panel that advices on						
actions to be taken (forward)						
Improve R&D initiatives for establishing cooperation agreements						
Publish results on best practices						
Improve existing communication schemes (e.g. platforms)						
Organize stakeholders workshops and conferences						

### **Digitalization and Industry 4.0**

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The experts interviewed in the first round of the survey highlighted the need to bridge the existing knowledge gap of farmers and forest owners regarding the use of ICTs. Data security also represents one of the main problems, since loss of privacy and therefore illicit collection of confidential information could take place. We would like to know your opinion on the importance of the identified measures to support the use of ICT by farmers and forest owners

<u>Question 11:</u> Please, rate the importance (in your opinion) of the following measures for supporting the use of new digital developments by farmers and forest owners:

0 (not important) - 5 (very important)	0	1	2	3	4	5
Provide them with better IT infrastructure and platforms						
Provide better access to life-long training programs						
Increase the awareness by showing the benefits of using ICT						
Support the introduction of ICTs through regulatory sandboxes						
Harmonisation of EU laws on data ownership and data security						
Support the technology transfer (technology dissemination from in-						
dustries with a large experience working with ICTs)						
Support the development of easy-to-use applications						

### Genome editing section

The majority of experts interviewed in the first round of this survey agreed that gene-edited plants resulting from NBT (new breeding techniques) should not be considered as GMO, and therefore, they should be exempted from the European regulations governing GMOs. However, their position on the need for a regulation on NBTs is controversial. Half of the experts believe that NBTs should be regulated, while the other half consider that there is no need for an additional regulation.

On the 25th of July 2018, the European Court of Justice published its decision on organisms obtained by mutagenesis. The court ruled that gene-edited crops are genetically modified organisms, and therefore, they must comply with the tough regulations that apply to plants made with genes from other species. In this second round, we would like to know your opinion on the decision of the court and on the importance of the identified factors to be included in a European regulation on NBTs.

<u>Question 12</u>: Do you agree with the decision of the court on ruling gene-edited crops as genetically modified organisms?

Yes	
No	

Why? Please indicate:

<u>Question 13:</u> What is, your opinion, the impact of this decision on the future development of the European bioeconomy?

<u>Question 14:</u> Please rate the importance (in your opinion) of including the following features in a supporting European regulation on modern genetic engineering (e.g. for plants and microorganisms):

0 (not important) - 5 (very important)	0	1	2	3	4	5
Transparency on the information of products containing or produced						
from modern genetic engineering techniques						
Traceability and labelling for manufactures and consumers						



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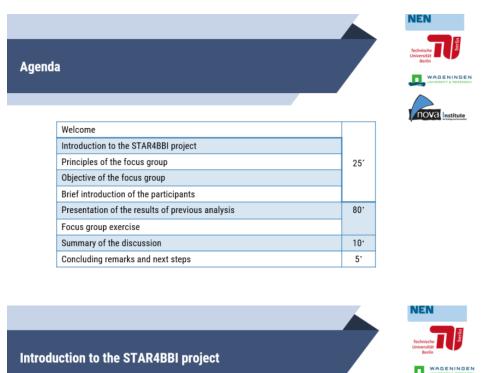
Include ethical concerns			
Risk evaluation (compared to traditional breeding products)			
Consider safety issues			
Environmental impact assessment			
Emphasis on the properties of the organisms, rather than on the pro-			
cess by which it was modified (product-based assessment rather than			
process-based)			
Off-targeting effects			

Please write down other important factors that in your opinion should be considered in the European regulation:



## STAR4BBI Work Package 3: Foresight activity on regulations, standards and investments

# Annex IV: Template of the focus groups



Project: STAR4BBI - Standards and Regulations for the bio-based economy (3 years)

Funding program: BBI JU program of the European Commission

Goal: To establish a coherent, well-coordinated and favourable regulatory framework to support the development of a cutting-edge bio-based economy for Europe, through the assessment of example bio-based product value chains, promoting a level playing field for bio-based products

More information at: www.star4bbi.eu



- We want to capture everything you have to say
- We do not identify anyone by name in our report. You will remain anonymous

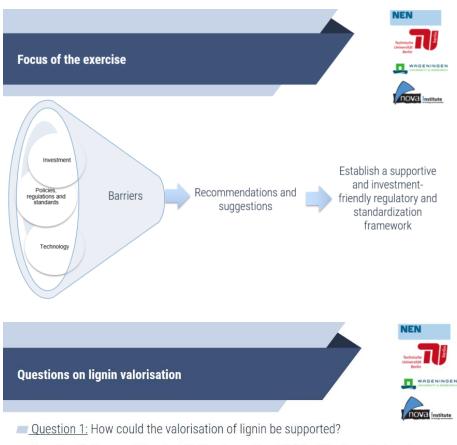




Work Package 3: Foresight activity on regulations, standards and investments



It aims at capturing the view of experts with regard to the existing challenges and proposing solutions for supporting the implementation of these technologies



<u>Question 2:</u> How could such definition be achieved? (Identification of steps for a possible roadmap)

<u>Question 3:</u> How could such cross-sectoral partnerships be facilitated or established?

<u>Question 4:</u> How could the existing European standards on biodegradability and compostability of products be adapted in order to facilitate the use of lignin in compostable/biodegradable products?

<u>Question 5:</u> How could the currently existing pre-treatment methods be developed in order to preserve the lignin fraction?



Work Package 3: Foresight activity on regulations, standards and investments



<u>Question 1:</u> Which measures should be taken in order to achieve high purity FDCA production at reasonable price?

<u>Question 2:</u> Which other hurdles you encounter today or expect in the (near) future?

<u>Question 3:</u> How would standards and regulations support the production of high purity FDCA?



<u>Question 1:</u> Do you agree with the decision of the court on ruling gene-edited crops (obtained by mutagenesis plant breeding techniques) as genetically modified organisms? Why?

<u>Question 2:</u> What is, according to you, the impact of this decision on the future development of the European bio-based economy?

<u>Question 3:</u> Is there any other challenge that in your opinion could prevent the fully deployment of gene-editing techniques?



<u>Question 1:</u> What do you expect for the medium (10 years) term future developments regarding aquatic biomass?

<u>Question 2:</u> Which hurdles regarding regulations and standards to you foresee? And what could be done to remove the hurdles?



Work Package 3: Foresight activity on regulations, standards and investments

# Contact

The Bio Based Industries Joint Undertaking under the European Union's Horizon 2020 research and innovation programme under grant agreement No 720685







Work Package 3: Foresight activity on regulations, standards and investments

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<sup>8</sup> Vis M., U. Mantau, B. Allen (2016) Study on the optimised cascading use of wood. No 394/PP/ENT/RCH/14/7689. Final report. 337 pages

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<sup>&</sup>lt;sup>1</sup> Full D3.1 accessible at: <u>http://www.biobasedeconomy.eu/app/uploads/sites/2/2018/09/Please-click-here-to-access-deliverable-3.1.pdf</u>

<sup>&</sup>lt;sup>2</sup> Full D2.1 accessible at: <u>http://www.biobasedeconomy.eu/app/uploads/sites/2/2018/09/Please-click-here-to-access-deliverable-2.1.pdf</u>

<sup>&</sup>lt;sup>3</sup> JRC, EC (2015) Delphi Survey. Available at: <u>http://forlearn.jrc.ec.europa.eu/guide/4\_methodol-ogy/meth\_delphi.htm</u>