Validation of an industrial process to manufacture isosorbide bis(methyl carbonate) at pilot level

Deliverable 7.8

European and local legal and non-legal limitations, barriers and standards for VIPRISCAR products (I)

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EXECUTIVE SUMMARY

WP7 aims at providing insights and recommendations concerning the sustainability and technical feasibility of the project so that potential environmental, economic and legislative barriers can be identified and anticipated. This Deliverable 7.8 is assessing the relevant legislation, regulations and standards with respect to constraints concerning Vipriscar process and products. Indeed, within Vipriscar project, relevant European legal perspectives are the main support for the development of the innovative processes and uptake of the new bio-based products and chemicals on the market. Therefore, EU legislation (such as directives and regulations) will be analysed, along with all related documentations that could be of importance during the development of the project.

First, a review of common legislation and standards applying to bio-based products has been done by identifying EU policies related to the project, as well as CEN standards and ecolabels for bio-based materials. Indeed, one of the outputs of the project could be labelling of IBMC or bio-based polymers in order to optimize the product launch. Finally, the potential regulations affecting Vipriscar process have been identified and listed for further analysis, reviewing the current status of chemicals used in the process.

In conclusion, the present document is providing a preliminary analysis of the legislation in order to fulfil the objectives of the Work Package, namely identifying barriers, limitations, regulatory/legislation aspects, and product safety issues, which could affect the market entrance and exploitation of VIPRISCAR products. Considering the analysis made for this report, it is safe to conclude that there are no specific legal limitations for the proper development of the project, but there are legal precautions that should be addressed during the execution, especially regarding the upcoming development of the technology. For this reason, the report will be updated along the project in Deliverables 7.9 and 7.10.

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ABBREVIATIONS AND ACRONYMS

CEN: European Committee for Standardization

CENELEC: European Committee for Electrotechnical Standardization

CLP: Classification, Labelling and Packaging - Regulation (EU) No 1272/2008

CWA: CEN Workshop Agreements

EN: European Standard

GPP: Green Public Procurement

LCA: Life Cycle Assessment

OSH: Occupational Safety and Health

PBT: Persistent, bioaccumulative and toxic substances

PIC: Prior Informed Consent Regulation

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals - Regulation (EC) No 1907/2006

RRM: Renewable Raw Material

RSB: Roundtable on Sustainable Biomaterials

TR: Technical Report

TS: Technical Specification

vPvB: very Persistent and very Bioaccumulative substances

1. Introduction

The present deliverable is a preliminary analysis of the European and local legal and non-legal limitations, barriers and standards for VIPRISCAR products. It is the first version of the report related with Task 7.5 whose objective is to identify the legal limitations that could affect the market entrance and exploitation of VIPRISCAR products.

As stated before, the purpose of this task is to identify the upcoming legal challenges that might appear along the project´s execution and provide the participants with the relevant legal information. Nonetheless, the legal limitations studied in this document may have some variations during the project and afterwards. Therefore, a periodic follow up on the legal requirements and compliance is recommended to the interested partners.

A dedicated research was carried out to provide documentary support for the task. Hence, relevant documents to the specific aim of the VIPRISCAR project have been identified and listed. They provide an overall understanding of legal limitations and risks, along with insights regarding the main topics of interest. Actually, legal issues could affect the outcome of the project in several ways. Therefore, it is necessary to examine how the National and EU legislation could affect the process as a whole unit by realizing further studies on the limitations and restrictions that could be generated within the project's development.

Eventually, the objective of a well-directed legal analysis is to provide to the project a general overview of the prospected legal outcomes. Hence, the focus of this report is mainly directed towards the study of the most important legislation and how a legal framework could be implemented and adapted throughout the development of the VIPRISCAR project.

2. General overview

VIPRISCAR Project (Validation of an industrial process to manufacture isosorbide bis(methyl carbonate at pilot level) is, according to its own statements, a project that aims to improve production methods and demonstrate, through proof of process, the added value it can bring in three existing high-volume sector: automotive and furniture, hot melt adhesives and biomedical applications.

According to the Project´s Grant Agreement, there are two main objectives to achieve within the VIPRISCAR project. The first one is to validate a more sustainable production process for the manufacturing of Isosorbide bis(Methyl Carbonate) from Isosorbide at pilot scale in an industrially relevant environment (TRL 5). The second one is to demonstrate a proof of principle for the added value that IBMC brings to the market by showing the usefulness of derived polymers thereof in 3 specific market sectors: industrial coating, hot-melt adhesives and biomedical applications (antithrombotic-antimicrobial catheters). In particular, the principal raw material of VIPRISCAR process is isosorbide, which is a bio-based chemical with the potential to be used in the manufacturing of a range of different products, many of which currently rely on fossil-based raw material.

In order to analyse the legislation related to the implementation of the technology, the study will concentrate on the innovative processes and chemicals involved within the development of the project. Therefore, this report focuses on three important but not exclusive topics of interest as an intent to address the relevant limitations and barriers that could be faced during the project´s execution regarding legal aspects. In particular EU policies, standards and certification as well as regulations potentially affecting Vipriscar process will be analysed and mentioned as part of the task.

3. Common legislation and standards applying to bio-based products.

According to the European Committee for Standardization (CEN), a recognized European Union body (EU Regulation 1025/2012), bio-based products represent an important part of the bio-economy, which is seen as a major source of economic growth and employment for Europe in the 21st Century.

The CEN defines bio-based products as "*… products that are wholly or partly derived from biomass: material of biological origin, such as from trees, plants or animals. The biomass may have undergone some kind of physical, chemical or biological treatment before being turned into a product. Bio-based products can be either material, intermediate, semi-finished or final products. Specific examples of bio-based products include disposable tableware (cups, plates, bowls, etc), cleaning products (detergents, softeners, etc), personal hygiene products (soaps, shampoos, etc), solvents and paints, plastics, lubricants and floor coverings.*"[1]

The legislation and standards applying to the IBMC monomer and bio-based polymers produced by the VIPRISCAR technology are assessed in this section, regardless of the final application, focusing on their classification as bio-products.

3.1 EU Policies

The bio-based products market has been identified as a lead market by the EC, which is committed to support its market entrance and rollout through new policies, regulations, standards, public procurements, among others. The EU Bio-Economy Strategy, published in 2012, includes several recommendations to unlock the potential of bio-based products markets. Nonetheless, according to organizations with wide experience in the sector, such as Nova Institute (Nova-Institute, 2015), the European legislative network is clearly disfavouring the material applications of biomass and benefits the energy valorization (e.g. electricity production, biofuels production). However, the EU and Member States strategies on bio-economy aim to address the untapped potential of biomass material valorization.

3.1.1 EU's industrial policy

The EU intends to increase the industrial contribution to EU GDP from 15 to 20% by 2020, and the bio-based products are considered as a Key Enabling Technology to achieve this objective. The EC outlined a renewed industrial policy strategy in 2017, which is supported in the low-carbon, circular and resource efficient economy as one of its main pillars (European

[1] https://www.cen.eu/news/brochures/brochures/CEN_Bio-based-products_2014.pdf

Commission, 2017a). These supporting efforts are translated to initiatives, such as the Circular Economy Package.

3.1.2 Circular Economy Package

The Vipriscar process is completely embedded in the Circular Economy strategy of the EU, since it is: i) substituting fossil-based materials by bio-renewable ones; ii) creating at least 1 new cross-sector interconnection in bio-based economy clusters, and; iii) contributing to the circular economy by setting the basis for at least 1 new bio-based value chain and 1 new bio-based material.

The Circular Economy Package is funded with €650 million from Horizon 2020, €5.5 billion from structural funds for waste managements; ESIF funding and the different national budgets devoted. The bio-based materials are seen as a strong alternative for the current business-as-usual fossil-based materials. The Bio-Economy strategy is established as one instrument to achieve the circular economy objectives on the bio-based products and bio-energy production sectors; the ambitious objectives on waste management are also expected to boost the sector.

3.1.3 Bio-economy strategy

In 2012, the EU Bio-economy Strategy (European Commission, 2017b) was launched as a result of the Flagship Initiatives “Resource-efficient Europe” and “Innovation Union” of the EU2020 Industrial strategy. It has been further reviewed in 2017 to analyze its contribution to the Circular Economy Package. It acts on three pillars: i) investment in research, innovation and skills; ii) reinforced policy interaction and stakeholder engagement, and; iii) enhancement of markets and competitiveness.

Summarizing, all the previous information about EU policies affecting the bio-based products, the Bio-Economy Strategy and the Circular Economy Action plans are final instrument throughout the EU implements concrete actions.

First pillar. Investments in research, innovation and skills. Instruments such as the H2020 Work Programme, creation of European Innovation Partnerships like EIP-AGRI and the growth in capacity building programmes are being successfully implemented.

Second pillar. Reinforced Policy Interaction and Stakeholder Engagement. A set of actions were established, such as the creation of a Bio-economy Panel, a Bio-economy Observatory, supporting the development of national and regional Bio-economy strategies and international cooperation R&I initiatives.

Third pillar. Enhancement of markets and competitiveness in bio-economy. The EU efforts in this area are comprised by actions such as: providing a knowledge-base for sustainable intensification of primary production, supporting the development of bio- refineries and cascade use of biomass and waste streams (the PPP BBI JU[2] is an essential component of this action), supporting the expansion of new markets through standards and other relevant schemes and developing science-based approaches to inform consumers.

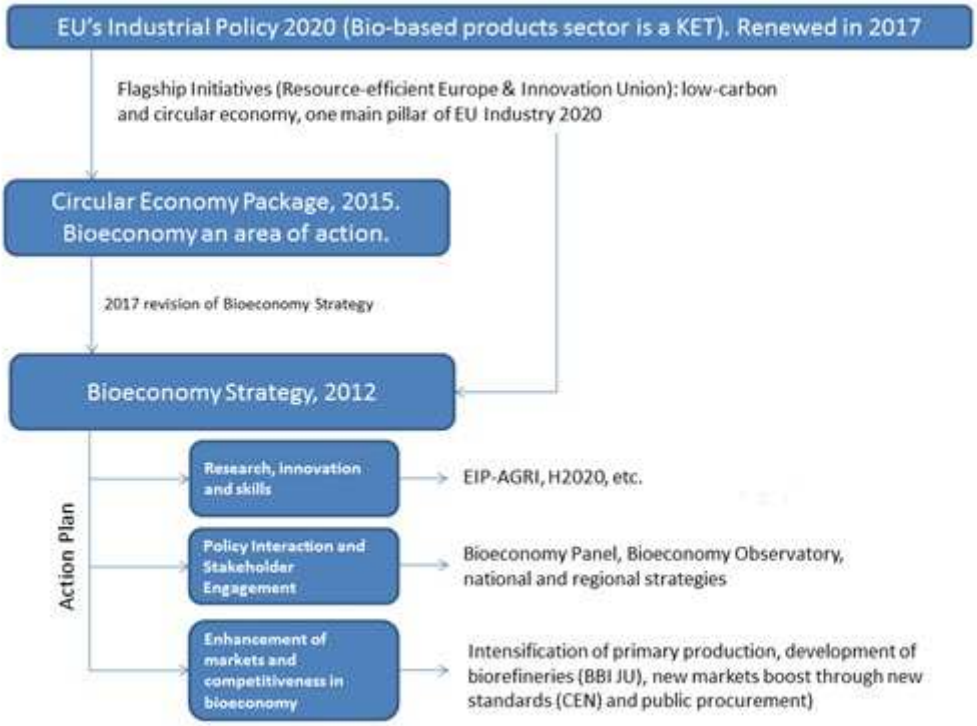

FIGURE 1 BIO-BASED PRODUCTS EU POLICY FRAMEWORK

The main limitation up to the date in the implementation of the Bio-economy Strategy has been the issue of establishing a **regulatory framework** to boost the bio-based products market. The progress is slow, although the Circular Economy Package action plan contains measures, such as modifying the EU waste legislation and measures to facilitate industrial symbiosis. **Investments** in biorefineries remain untapped. Within the 2017 review of the Bio-economy Strategy, it can be noticed that the EC is relying mainly on the commercial success of R&I post-projects fostered by R&D investments to contribute to the EU bio-based sector market uptake (with the policy and standardization framework almost fully implemented). The sector claims the need for greater EU funding instruments regarding high risks

[2] https://www.bbi-europe.eu/

investments as biorefineries implementation apart from the ones available through the H2020 Programme, the BBI JU and the ESIF funds (European Investment Bank, 2017).

There is still uncertainty regarding the **coherence and integration** of the different EU policies, although steps in certification, labelling and public procurement have been already taken (e.g. the proposed amendments on the EU Waste legislation, envisage measures targeting quality biowaste for recycling and targeting industrial symbiosis for feed materials). There are **no EU policy tools** supporting novel bio-based markets, such as in the United State: the US Bio-preferred Programme (Golden et al., 2015). All these uncertainties are hampering the private investments in the sector.

Although the CEN activities in the field of **standardization** are important to establish a long-term market for bio-based products, right now they are not helping enough in the **daily market competition** between bio-based and fossil-based products. The main market pull could be found in economically attractive bio-based products, and even making them mandatory for the industry (e.g. targets, quotas, tax incentives, bans, mandates, EU Emission Trading System, among other) (Nova-Institut, 2015). An example of EU successful intervention is the EU Renewable Energy Directive, which has created artificial demand on bioenergy and biofuels strongly boosting the sector; however, the EU cohesion and sustainable implementation of the changes are still a weakness in such policy instruments. This Directive is, at the same time, one of the main obstacles to develop a market of high added-value bio-based products: it is hampering the use of biomass in material applications in benefit of the energy valorization. The EU Parliament is aware of the problem, which reformed the Directive in 2015. Nonetheless, the bio-based products market is not taking off.

According to the "Commission Expert Group on Bio-based Products, 2017", it is a lost opportunity that the Public Procurement Directive passed in 2014 without reference to bio-based products. Administrations can develop **Public Procurement** policies, which support the bio-economy and act as a market pull mechanisms for bio-based products, but it is still a rare phenomenon. This can be due to public procurement issues that:

- has to confront complex legal requirements when preparing tenders;
- concerns about market distortion;
- lacks capacity to spend time on market exploration activities;
- avoids taking risks in terms of applying innovative procedures or new tender specifications.

This is not the only obstacle for bio-based products in public tenders. Indeed, bio-based products do not necessarily fulfil the requirements of these innovative environmentally

friendly tenders, even if Green Procurement schemes have been boosted. For example, LCA are many times required in these tenders, but complex value-chains and methodological gaps related to LCA of bio-based products make the process difficult (especially for SMEs with less resources). Nevertheless, recommendations for the development of commonly accepted sustainability criteria, labels and certification schemes to facilitate the inclusion of bio-based products in public procurement has been produced (European Commission, 2017b).

3.2 Standards and certifications schemes

3.2.1 CEN Standards

In alignment with the Bio-Economy Strategy, the EU is building up a set of standards to provide common reference framework for bio-based products in the market (e.g. biodegradability, bio-based content, recyclability, sustainability). Since the EU has detected a lack of European standards, the CEN has the mandate to develop bio-based products standards in four lines (CEN and CENELEC, 2018):

- Mandate (M/492) on Horizontal European standards and other standardization deliverables for bio-based products (European Commission, 2011a). The overall objective of this mandate is to create standards that cover horizontal aspects, such as terminology, certification tools, bio-based content, LCA application, sustainability criteria for the biomass feedstock and end-products, and further harmonization aspects. The CEN/TC 411 oversees fulfilling this mandate. In 2014, the EN 16575:2014 on "Bio- based products: vocabulary" was launched as the first step to establish common terminology. For the determination of bio-based content of products (EN 16785- 1:2015, EN 16640:2017/AC:2017, CEN/TR 16721:2014), sustainability of biomass feedstocks (EN 16760:2015, EN 16751:2016, CEN/TR 16957:2016) and on B2B and B2C communication (EN 16848:2016 and EN 16935:2017, respectively).

- Mandate (M/429) for the elaboration of a standardization programme for bio-based products. In 2011, the CEN published CEN/TR 16208:2011 "Bio-based products - Overview of standards". The mandate is dated on 2008 (European Commission, 2008), and was further developed by M/491 and M/492.

- Mandate (M/430) on bio-polymer and bio-lubricants: "This mandate concerns the development for bio-lubricants and bio-polymers of European standards together with CEN Workshop Agreements (CWAs) as interim outputs. The standards and the CWAs shall relate to the biodegradability (for bio-lubricants, only), product functionality, impact on greenhouse gas emissions, and the amount of different renewable raw

materials (RRMs) and/or different bio-based contents used during the manufacturing of such bio-lubricants and biopolymers."[3]

Table 1 lists the CEN standards, technical reports and specifications that can be applied to IBMC and IBMC-based polymers. The way standards could be affecting the products or materials to be used in VIPRISCAR project, will be further analyzed in the coming deliverables. As a reminder, it is important to underline that European Standard are voluntary and developed through a process of consensus, based on input from industry and other relevant stakeholders, including a public commenting period (enquiry) that is open to all interested parties. Once a European Standard has been formally adopted by CEN, it must be published as an identical national standard by CEN Members in 33 countries, and any conflicting national standard must be withdrawn. A *Technical Specification (TS)*, is developed when there is no immediate need or not enough consensus for an EN, or where technology is not mature enough and the subject matter is still under technical development, while a *Technical Report (TR)*, is a document containing information in relation to a particular topic, which is not suitable for publication as an EN or a TS.

TABLE 1. PRELIMINARY LIST OF CEN STANDARDS, TECHNICAL REPORTS (TR) AND TECHNICAL SPECIFICATIONS (TS) AFFECTING IBMC-BASED BIOPOLYMERS.

EN 16575:2014	Bio-based products: vocabulary
EN 16785-1:2015	Bio-based products - Bio-based content - Part 1: Determination of the bio-based content using the radiocarbon analysis and elemental analysis
EN 16640:2017/AC:2017	Bio-based products - Bio-based carbon content - Determination of the bio-based carbon content using the radiocarbon method
CEN/TR 16721:2014	Bio-based products - Overview of methods to determine the bio-based content
EN 16640:2017	Bio-based products - Bio-based carbon content - Determination of the bio-based carbon content using the radiocarbon method
EN 16760:2015	Bio-based products - Life Cycle Assessment
EN 16751:2016	Bio-based products - Sustainability criteria
CEN/TR 16957:2016	Bio-based products - Guidelines for Life Cycle Inventory (LCI) for the End-of-life phase
EN 16848:2016	Bio-based products - Requirements for Business to Business communication of characteristics using a Data Sheet
EN 16935:2017	Bio-based products - Requirements for Business-to-Consumer communication and claims
CEN/TR 16208:2011	Bio-based products - Overview of standards

[3] Mandate addressed to CEN for the development of European standards and CEN workshop agreements for Bio-polymers and Bio-lubricants in relation to Bio-based products aspects.

According to the CEN/TR 16721:2014, claimed bio-based products such as IBMC-based biopolymers could fall into three different categories:

1. "Bio-based product" certified through the C radiocarbon test ASTM D6866;
2. Products that have different bio-based content than the one that is claimed, but still above a minimum, also called bio-based products;
3. Products with claimed bio-based contents, which can potentially be near zero and that cannot be called as bio-based products.

3.2.2 Ecolabels and standards for bio-based materials

Other than CEN standards and TS or TR there are also several ecolabel systems worldwide (e.g. Europe's Ecolabel and Germany's Blauer Engel) that can be more or less dedicated to certifying bio-based materials. Indeed, some of these schemes such as RSB[4], ISCC+ and "Better Biomass" [5] are certifying the source of the biomass. In this regards, the European Funded project *Open-Bio* FP7[6] reported as one of its main output that a single label for certifying bio-based content of a product/material would not be of much use for consumers due to the complexity and variety of those products in the market. *Open-Bio* therefore proposed to modify the already existing EU Ecolabel to consider the criteria of the sustainable source of biomass. In the same line, the dedicated bio-based label launched in 2011 in the US by the *Biopreferred Programme*[7] has supported the public and private bio-procurement US programs specifying criteria for about 110 different product categories. The general process for certification and labelling that IBMC would require is depicted on Figure 2.

FIGURE 2 GENERAL PROCESS FOR CERTIFICATION AND LABELLING

The EU Ecolabel (European Commission, 2009) requires bio-based products to perform LCA in order to proof their better environmental performance in certain impact categories.

4 https://rsb.org/certification/

5 Report "Knowledge Based Bio-based Products' Pre-Standardization", nova-Institut GmbH, 2015. Available on http://www.biobasedeconomy.eu/app/uploads/sites/2/2017/03/Green-label-report.pdf

[6] https://cordis.europa.eu/project/rcn/110950/brief/en

[7] https://www.biopreferred.gov/BioPreferred/faces/pages/AboutBioPreferred.xhtml

Nonetheless, the lacking reviewed LCA literature and the heterogeneity of bio-based products represent obstacles to obtain the EU Ecolabel.

According to (Bioplastics MAGAZINE, 2014), bio-products manufacturers are likely to use a Voluntary Sustainability Standard such as the Roundtable on Sustainable Biomaterials (RSB) in order to promote the bio-based content of their products.
The RSB labelling requires a minimum of 25% of bio-based content to be provided. The content of IBMC-based polymers in final end-products is potentially very high and this would make possible to obtain that labelling. The certifications would allow the producers to make appropriate claims in their reference market avoiding the risk of greenwashing.

3.2.3 Conclusion

It shall be considered that these standards and certification schemes apply to the end-products (adhesives, coatings, catheters, etc.) containing IBMC-based biopolymers, and these are focusing on proving through several tests the actual bio-based content and its sustainable sourcing. An important aspect to underline is that one of the main obstacles for bio-based products standards is their novelty: the work to achieve a widespread acceptance and application is still ongoing. Further source of uncertainty is the lack of a minimum bio-based content or minimum sustainability performance required. A detailed assessment on certification, if needed, will be carried out in next deliverables in order to discuss when is advisable or not to obtain standards, eco-labels, etc. and which one will suit the potential markets of the IBMC-based polymers commercialization. More information will be needed to define better the actual end uses (products) of the IBMC-based polymers.

4. Regulations potentially affecting Vipriscar processes and products

The EU regulations and standards that may affect Vipriscar technology are the ones dealing with the emissions of the process, health and safety conditions at work and chemicals registration (REACH).

4.1 Health and Safety regulations

The following list of legislations and regulations are highlighted as of potential interest for the project. Further evaluations shall be carried out in next months, when more information on the developing of the IBMC process will be available.

- **Directive 89/391 of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work** - "Framework Directive". In 2004 the European Commission issued a Communication (COM [2004] 62) on the practical implementation of the provisions of same of the directives, namely 89/391 EEC (framework directive), 89/654 EEC (workplaces), 89/655 EEC (work equipment), 89/656 EEC (personal protective equipment), 90/269 EEC (manual handling of loads) and 90/270 EEC (display screen equipment)]. This Communication stated that there was evidence of the positive influence of EU legislation on national standards for occupational safety and health made up of both national implementing legislation and practical application in enterprises and public-sector institutions.

- OSH directives on workplaces, equipment, signs, personal protective equipment:

    - **Directive 2009/104/EC – use of work equipment** of 16 September 2009 concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC).
    - **Directive 99/92/EC - risks from explosive atmospheres** of 16 December 1999 on the minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres (15th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC).
    - **Directive 92/58/EEC - safety and/or health signs** of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work (ninth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC).
    - **Directive 89/656/EEC - use of personal protective equipment** of 30 November 1989 on the minimum health and safety requirements for the use by workers

of personal protective equipment at the workplace (third individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC).

- **Directive 89/654/EEC - workplace requirements** of 30 November 1989 concerning the minimum safety and health requirements for the workplace (first individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC).
- **Regulation (EU) 2016/425 on personal protective equipment** of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

- OSH directives on exposure to chemical agents and chemical safety.

  - **Directive 98/24/EC - risks related to chemical agents at work** of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC). The Directive provides for the drawing up of indicative and binding occupational exposure limit values as well as biological limit values at Community level. The employer must determine whether any hazardous chemical agents are present at the workplace and assess any risk to the safety and health arising from their presence. The employer must be in possession of an assessment of the risk in accordance with Article 9 of Directive 89/391/EEC. This assessment shall be kept up-to-date, particularly if there have been significant changes or if the results of health surveillance show it to be necessary.
  - **Directive 2017/164/EU - indicative occupational exposure limit values** of 31 January 2017 establishing a fourth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC, and amending Commission Directives 91/322/EEC, 2000/39/EC and 2009/161/EU.

4.2 Regulations for the market uptake of the products

Some regulations will have to be checked when trying to put the IBMC-based biopolymers in the market, such as:

- **Regulation (EC) No 1907/2006 – REACH of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency**. The purpose of this regulation is to ensure a high level of protection of human health and environment. It shall apply without prejudice to Community workplace and environmental legislation. There are

exemptions on medical, veterinary, alimentary and cosmetic products, polymers and some on-site isolated intermediates. The IBMC monomer and the IBMC-based polymers should:

- Identify if they are subject to these regulations. Indeed, the substances in mixtures or in articles[8] that are i) produced in quantities of **one ton or more per year** and ii) intended to be released under normal or reasonably foreseeable conditions of use shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions.
- Without prejudice to Article 4 of Directive 98/24/EC, a chemical safety assessment shall be performed, and a chemical safety report completed for all substances subject to registration in quantities of 10 tons or more per year per registrant. A chemical safety assessment of a substance shall include the following steps: human health hazard assessment, physicochemical hazard assessment, environmental hazard assessment, persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment. Any registrant shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies.
- There are other provisions for the supplier of substances which are dangerous, pose human health or environmental hazards, such as PBT or vPvB. These substances are included in the candidate list compiled by the Agency or for which there are Community workplace exposure limits.

- **Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures**, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. The Classification, Labelling and Packaging (CLP) Regulation purpose is to ensure a high level of protection of health and the environment, as well as the free movement of substances, mixtures and articles. CLP is legally binding across the Member States and directly applicable to all industrial sectors. It requires manufacturers, importers or downstream users of substances or

[8] "Article: means an object which during production is given a special shape, suface or design which determines its function to a greater degree than does its chemical composition" (Article 3(3) REACH)

mixtures to classify, label and package their hazardous chemicals appropriately before placing them on the market.

  - Classification is the starting point for hazard communication. When relevant information (e.g. toxicological data) on a substance or mixture meets the classification criteria in CLP, the hazards of a substance or mixture are identified by assigning a certain hazard class and category. The hazard classes in CLP cover physical, health, environmental and additional hazards.
  - Once a substance or mixture is classified, the identified hazards must be communicated to other actors in the supply chain, including consumers. Hazard labelling allows the hazard classification, with labels and safety data sheets, to be communicated to the user of a substance or mixture, to alert them about the presence of a hazard and the need to manage the associated risks.

- The **Prior Informed Consent Regulation (PIC, Regulation (EU) 649/2012)** administers the import and export of certain hazardous chemicals and places obligations on companies who wish to export these chemicals to non-EU countries. It aims to promote shared responsibility and cooperation in the international trade of hazardous chemicals, and to protect human health and the environment by providing developing countries with information on how to store, transport, use and dispose of hazardous chemicals safely.

Regarding REACH, there are some criteria for which Vipriscar final and intermediate products could be exempted. Indeed, as stated before, naturally occurring substances are exempted from REACH registration. These substances are materials or chemicals occurring in nature such as minerals, ores and any type of ore concentrates that are not chemically modified (see *Annex V of REACH*[9]). Since the IBMC-based polymers are obtained through chemical modification, it is foreseen that this exemption will not apply.

Polymers are also exempted from registration according to Title II of REACH *(Article 2(9)).* Therefore, polymer producers are not required to provide any kind of information about the properties of their polymers to the Agency except if the objective is a classification or a labelling[10]. This statement implies to evaluate if IBMC-based final products comply with the REACH definition of polymers. In accordance with REACH regulation on its (Article 3(5)), a polymer is defined as a substance that meets two specific criteria:

[9] https://echa.europa.eu/fr/support/getting-started/am-i-exempt
[10] https://echa.europa.eu/documents/10162/23036412/polymers_en.pdf

(a) Over 50 percent of the weight for that substance consists of polymer molecules;

(b) *The amount of polymer molecules presenting the same molecular weight must be less than 50 weight percent of the substance* (REACH, 2018).

Therefore, Vipriscar final products should normally comply with the definition of this Article. However, IBMC monomer might be considered differently. Indeed, according to the registration obligation laid down in Article 6 of REACH, monomers cannot be registered in accordance with the provisions which normally apply to onsite or transported isolated intermediates (Article 6(2)). However, Articles 17 and 18 (on intermediates) do apply for the other substances to be transformed into the manufactured polymer, provided those other substances meet the conditions specified in Articles 17 and 18. In this sense, IBMC monomer should imply the same REACH obligations for the manufacturer or the importer as any other substance. The requirements include general rules on restriction, information down the supply chain and classification and labelling. [11] In conclusion, the registration obligations of the different actors of the monomer and polymer supply chains are depicted on Figure 3.

Regarding the rest of the directives and regulations, a more detailed analysis will be offered in next deliverables, establishing which ones apply to Vipriscar process and involved substances.

[11] https://echa.europa.eu/documents/10162/23036412/polymers_en.pdf

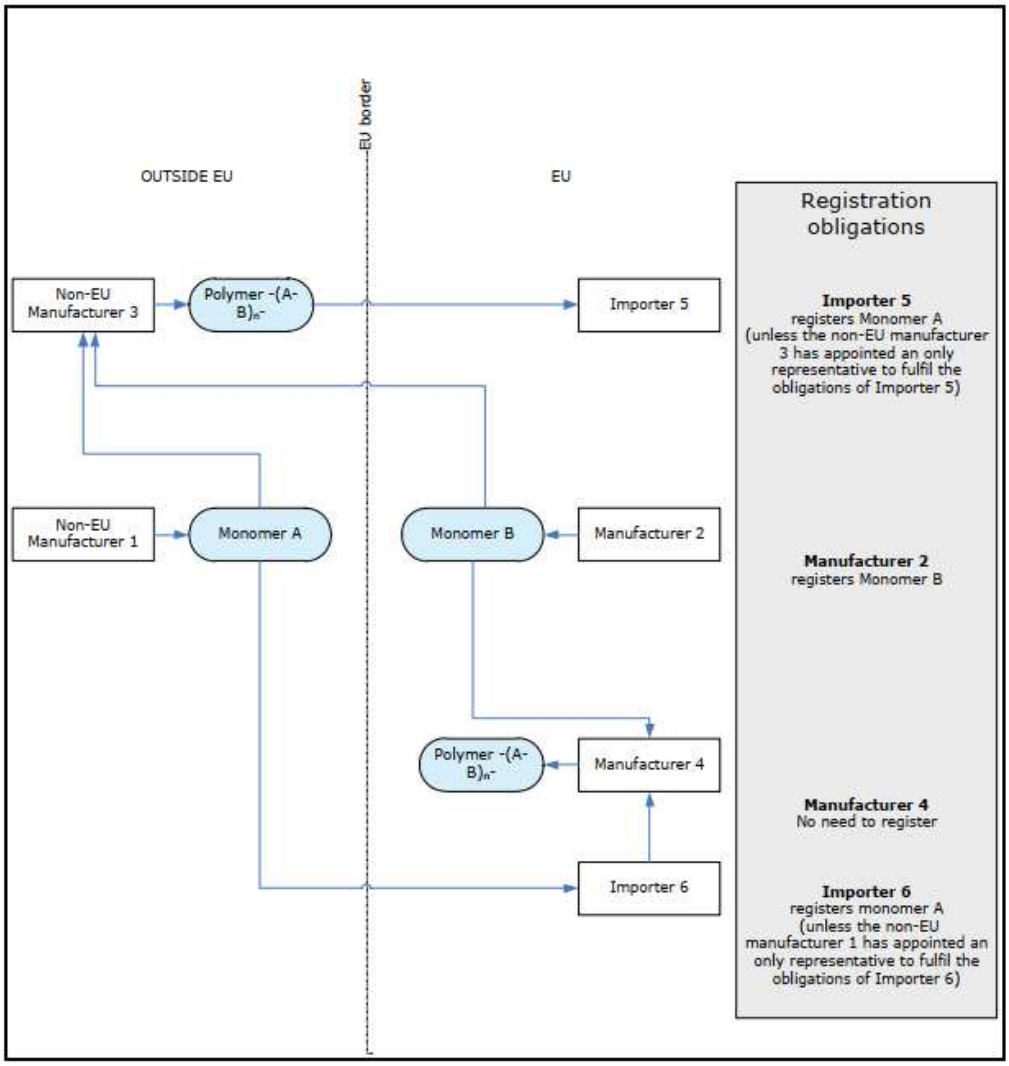

FIGURE 3 REGISTRATION OBLIGATIONS OF THE DIFFERENT ACTORS OF THE MONOMER AND POLYMER SUPPLY CHAINS (SOURCE REACH 2008)

4.3 Current status of the main chemicals used in Vipriscar process

Based on the simplified description of the IBMC monomer production and subsequent polymerization to PC and or PU the following chemicals are checked against REACH obligations (Table 2).

TABLE 2 - SUMMARY OF THE MAIN COMPONENTS STATUS

Chemical Name	CAS number	Hazard classification & labelling	Production-Import Volume [ton]	Candidate List (checked on May 2019)
IS: Isosorbide	652-67-5	According to the notifications provided by companies to ECHA in REACH registrations no hazards have been classified.	1.000 -10.000	False
DMC: dimethyl carbonate	616-38-6	Danger! According to the harmonised classification and labelling (CLP00) approved by the European Union, this substance is a highly flammable liquid and vapour.	100.000 – 1.000.000	False
IMMC: Isosorbide mono(methyl carbonate)	n.a.			
IBMC: isosorbide bis(methyl carbonate)	n.a.			
1,4 Butanediol	110-63-4	Warning! According to the classification provided by companies to ECHA in REACH registrations this substance is harmful if swallowed and may cause drowsiness or dizziness.	100.000 – 1.000.000	False

The DMC results as under "Compliance Check Evaluation"[12] and further information have been requested to the registrants. The decision was made on the 11/04/2019 with the deadline 20/04/2020[13].

[12] "*ECHA may examine any registration dossier to verify if the information submitted by registrants is compliant with the legal requirements. Compliance checks evaluate the substance identity description and the safety information in the dossier including the chemical safety report or specific parts of the dossier, for example the information related to the protection of human health*" https://echa.europa.eu/regulations/reach/evaluation/compliance-checks

[13] https://echa.europa.eu/information-on-chemicals/dossier-evaluation-status/-/dislist/substance/100.009.527

5. Limitation and barriers for the application of IBMC-based polymers

As the process and materials will be developed further analysis, review and justification from the legal point of view will be addressed. At the moment no detailed application are foreseen except for the medical one (catheters). The chapter is reporting the legislation that applies to the "medical devices" to which two pieces of legislative documents could be mentioned.

1. **Council Directive 93/42/EEC of 14 June 1993** concerning Medical Devices and subsequent modifications,

   For the purposes of this Directive, the following definitions shall apply:
   The medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
   - diagnosis, prevention, monitoring, treatment or alleviation of disease,
   - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
   - investigation, replacement or modification of the anatomy or of a physiological process,
   - control of conception,
   and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such mean;

2. **Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices**, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

   This Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products.

These EU legislative pieces of information will be properly addressed, studied, analysed and confronted in the upcoming reports. Eventually, EU legislation regarding essential topics like adhesives and coating will be studied as well.

6. CONCLUSIONS

The legal documents analysed in this report represent an overall picture of the current situation, but the analysis should be revisited regularly. Every day new criteria are met, and the legal context grows as the technologies are developed, consolidating into a framework that could affect the outcome of any project.

Directives, regulations, articles and other documents were analysed in order to provide a legal framework for the execution of Vipriscar project. Legal implications and safety standards could affect the development scenarios of the project. Indeed, industrialisation of Vipriscar process should comply with regulation on health and safety of the workers as well as directives concerning OSH about workplaces, equipment, signs, personal protective equipment but also exposure to chemical agents and chemical safety. The market uptake of IBMC should normally start by a registration to REACH and CLP. On the contrary, final bio-based polymer (PC and PU) should be exempted from this requirement. Finally, it might be interesting for a future commercialization of IBMC-based polymers to obtain an ecolabel, but this will be further investigated in next deliverable.

Considering the analysis made on this report, it is safe to conclude that there are no specific legal limitations for the proper development of the project, but there are legal precautions that should be addressed during the execution, especially regarding the upcoming development of the technology.

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