BIO-PLASTICS EUROPE

Definition of the current EU bioplastic approach to standards defining biodegradability and safety.

Project Acronym	BIO-PLASTICS EUROPE
Work Package	6 – Safety Components
Deliverable	D6.1 Technical Report: Definition of the current EU bioplastic approach to standards defining biodegradability and safety
Deliverable Lead	MMU
Type	Report
Dissemination Level	Public
Contractual delivery date	31/10/2020 (M13)
Actual submission date	30/10/2020
Author(s)	Carly Fletcher, Craig Banks, Alan Dempsey (MMU), Pauline Moreau (NaturePlast), Elisabetta Arato and Stefano Gianazzi (TICASS).

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

Revision and history chart

Version	Date	Main author	Summary of Changes
0.1	24/09/2020	Carly Fletcher (MMU)	Initial draft
0.2	28/09/2020	Craig Banks (MMU) Alan Dempsey (MMU)	Internal Institution review (MMU) – Review and commenting of first draft
0.3	29/09/2020	Carly Fletcher (MMU)	Revised draft in light of comments, acceptance of track changes, addition of Figure 9, more detail regarding migration limits of harmful substances.
0.4	13/10/2020	Pauline Moreau (NaturePlast) Elisabetta Arato (TICASS) Stefano Gianazzi (TICASS)	Internal project review – Proof read and commented upon by WP6 project partners.
0.5	23/10/2020	Carly Fletcher (MMU)	Revised draft – Revised in light of comments, acceptance of track changes, inclusion of aquaculture products, list of abbreviations and acronyms completed, and report summary drafted.
0.6	26/10/2020	Carly Fletcher (MMU) Craig Banks (MMU) Alan Dempsey (MMU)	Final internal institutional review (MMU)
0.7	27/10/2020	Lars Gutow (AWI) Jelena Barbir (HAW) André Wolf (HWWI) Eleonora Foschi (UNIBO)	QCR check Pre-submission check Input from WP8 regarding LCA Input from WP7 regarding business communication
0.8	29/10/2020	Carly Fletcher (MMU)	Final version for submission
0.9	30/10/2020	Jelena Barbir (HAW)	Submission to the EU

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

Abstract

This document fulfils the requirements set out by the Project Handbook (Deliverable 2.3) to present a single technical report outlining the current EU approach to bio-based safety standards. It will highlight and synthesise all documents that are used to determine the safe use and end-of-life management of bio-based plastics, specifically for use in toys, packaging of foodstuffs, reusable cutlery, agricultural equipment and fisheries / aquaculture products. The report will also provide a comparison to other global standards.

Keywords

Bio-based and biodegradable plastics, safety, standardisation, regulations, bio-based products, EU approach, toys, reusable cutlery, food packaging, agriculture equipment, fisheries and aquaculture products.

Disclaimer

This document does not represent the opinion of the European Community, and the European Community is not responsible for any use that might be made of its content. This document may contain material which is the copyright of certain BIO-PLASTICS EUROPE consortium parties and may not be reproduced or copied without permission. All BIO-PLASTICS EUROPE consortium parties have agreed to full publication of this document. The commercial use of any information contained in this document may require a license from the proprietor of that information.

Neither the BIO-PLASTICS EUROPE consortium as a whole, nor a certain party of the BIO-PLASTICS EUROPE consortium warrant that the information contained in this document is capable of use, nor that use of the information is free from risk and does not accept any liability for loss or damage suffered by any person using this information.

Acknowledgement

This document is a deliverable of the BIO-PLASTICS EUROPE project. This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement № 860407.

Table of Contents

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

List of Abbreviations and Acronyms

Abbreviation	Meaning
^{14}C	Carbon-14 (Radioactive carbon)
ABS	Acrylonitrile Butadiene Styrene
AMS	Accelerator Mass Spectrometry
ASTM	American Society for Testing and Materials
BI	Beta Ionization
BSI	British Standards Institution
BT	Technical Board
CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardization
CO_2	Carbon Dioxide
EC	European Commission
ELCD	European Life Cycle Database
ETSI	European Telecommunication Standards Institute
EU	European Union
FCM	Food Contact Materials
GHG	Green House Gas
GPS	General Product Safety
HDPE	High Density Polyethylene
ILCD	International Reference Life Cycle Data System
IPCC	Intergovernmental Panel on Climate Change
IRMS	Isotope Ratio Mass Spectrometry
ISO	International Standards Organisation
LCA	Life Cycle Assessment
LCI	Life Cycle Inventory
LCIA	Life Cycle Impact Analysis
LSC	Liquid Scintillation-Counter method
OECD	Organisation for Economic Co-operation and Development
PBS	Polybutylene Succinate
PE	Polyethylene
PHBV	Poly(3-hydroxybutyrate-co-3-hydroxyvalerate)
PIM	Plastic Implementation Measure
PP	Polypropylene
PS	Polystyrene
Qu	Question
SC	Sub-Committee
TC	Technical Committee
TC	Total Carbon
TCMG	Technical Committee Management Group

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

TC-WG	Technical Committee Working Group
TOC	Total Organic Carbon
USA	United States of America
WP	Work Package
WRI	World Resources Institute

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

List of Figures

List of Tables

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

1 Executive Summary

This report, which provides a **definition of the current EU bioplastic approach to standards defining biodegradability and safety,** forms part of Work Package 6 – Safety Components (Task 6.1 Review and define the current EU approach to standards defining biodegradability and safety) of the project "Developing and Implementing Sustainability-Based Solutions for Bio-Based Plastic Production and Use to Preserve Land and Sea Environmental Quality in Europe (BIO-PLASTICS EUROPE)" under the H2020 Grant Agreement No. 860407.

The general objective of this report is to review and summarise the current EU approach to standards defining the safe use and end-of-life management (particularly biodegradability) of bio-based materials, with a specific focus on the following consumer products; toys, food packaging, cutlery, agriculture mulch films and fisheries / aquaculture equipment.

This document has been delivered to the European Commission in October 2020 (M13).

For any comments on this report, please contact the Project Coordinator:

Prof. Dr. Walter Leal
E-mail: walter.leal2@haw-hamburg.d

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

2 Introduction

Conventional plastics, which can be characterised as petroleum-based and non-biodegradable, have been the primary choice for many products as they are easy to process, cheap and highly resistant to chemical and mechanical stress. While the unique adaptability of plastic has seen the material used in a huge range of products (from simple packing materials to complex engineering components), their durability has raised questions concerning end-of-life disposal (Philp et al., 2013). From a waste management perspective, the dominant strategies for dealing with waste plastics are (preferably) mechanical recycling then incineration and landfill (Rigamonti et al., 2014). However, the quality and composition of the waste plastic has a huge bearing on the strategy employed. For example, waste streams that are source separated and include good quality plastics are more likely to be recycled than mixed waste streams, or waste streams that are contaminated with other materials. In the case of mixed/contaminated streams, incineration is often the preferred management option (Rigamonti et al., 2014). If neither of these optimal strategies are employed, then disposal to landfill is the likely alternative. Due to the invulnerability of plastic materials to microbial decomposition, they are unlikely to biodegrade within landfill and therefore occupy the space for an undetermined amount of time (Philp et al., 2013).

Replacing conventional plastics with bio-based plastics has been identified as a potential solution for two reasons. One, it will reduce the dependency on fossil fuels as a source of the initial feedstock, and two, in the case of biodegradable materials, could relieve the pressure on landfills as a means to manage complicated waste streams (Álvarez-Chávez et al., 2012; Philp et al., 2013). Bio-based plastics are materials that consist, partly or fully, of biomass (Endres and Siebert-Raths, 2011). While it is noted that "bioplastics" is a term to denote any plastic material that is either bio-based (that can be biodegradable or non-biodegradable) or petroleum-based that is bio-degradable (Nova-Institute, 2014), this study focuses primarily on bio-based plastics. At face value, the emergence of bioplastics, specifically those that are biodegradable, may offer solutions to the widespread and serious environmental concerns caused by conventional (petroleum-based) plastics (Philp et al., 2013). The major advantage of bio-based plastics is that the carbon contained within any GHG emitted (for example through incineration) is sourced from recent biological production rather than from fossil resources. However, uptake of bio-based plastics has been restricted by poor performance, high production costs, industry resistance and instances of green-washing (Philp et al., 2013).

That being said, the development and commercialisation of bio-based plastics for a variety of uses, particularly for more sophisticated applications, is of interest to manufacturers who are looking to use safer and more environmentally friendly materials (Philp et al., 2013). Bio-based materials are promising as an alternative due to the feedstock being renewable. In addition, some bio-based materials (those that are biodegradable) can theoretically be composted, while others can be recycled, and others have been shown to be more energy efficient than petroleum-based plastics in production and processing (Álvarez-Chávez et al., 2012). However, for bio-based plastics to be successful in replacing conventional plastics, they must be shown to be safe both during and after use (Álvarez-Chávez et al., 2012). On this subject, Philp et al (Philp et al., 2013) argues that while there is a plethora of standards concerning biodegradability, compost-ability,

Horizon 2020 This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

etc. the absence of international agreement and harmonisation on the application of these standards to bio-based plastics is lacking. Furthermore, without such harmonisation there is a danger that trade barriers will develop within import/export markets.

2.1 Aim

The aim of this document is **to review and summarise the current EU approach to standards defining the safe use and end-of-life management (particularly biodegradability) of bio-based materials**, with a specific focus on the following consumer products; toys, food packaging, cutlery, agriculture mulch films and fisheries / aquaculture equipment.

2.2 Approach

To address the aim of this document, a comprehensive literature review was undertaken. The following types of documents were included within the review;

- International and European standardisation documents,
- EU policy documents and reports,
- Academic literature.

Using these documents, the following research questions have been addressed;

(1) What is the function of standardisation, and how is it structured within Europe and internationally?

The intention of this report is to understand the function of standardisation to address safety and environmental issues related to the use of bio-based plastics. To begin with, this report will describe the role of standardisation, how it should function with respect to overcoming safety and environmental issues and how standardisation organisations are structured within the EU. This report will also briefly comment on international standardisation.

(2) To date, how has the standardisation of bio-based products developed in the EU?

This report will then take stock of how the standardisation of bio-based products within the EU has developed. It will follow, and make comment on, the reports, mandates and actions published by the European Commission and European standardisation agencies between 2007 and 2018.

(3) What standards for bio-based products already exist?

To provide an overview, this report provides a summary of the standards published in relation to bio-based products in light of the development work identified through Qu2.

(4) What standards are available to assess the biodegradability of materials (specifically, bio-based and/or plastics)?

This report summarises any standards related to biodegradability and/or compostability, specifically concerning either bio-based and/or plastic products.

Horizon 2020 This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

(5) How are standards used to ensure the safe use of products, specifically those within certain product groups?

To align with work completed across the Bio-plastics Europe project (particularly WP3 and 5), standards related to specific product groups are summarised. Product groups include; toys (hard plastic sand toys), packaging (rigid and flexible plastic food packaging), cutlery (reusable plastic), agricultural equipment (plastic mulch films) and fisheries / aquaculture products (fishing bait / lures, fish transport crates and marine geomaterials).

(6) How do international standards compare to the above?

For the standards summarised above to address Questions 3-5, this report will comment either on how they have adopted international standards or how they compare with their international counterparts.

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

3 Findings

3.1 The role of standardisation

With a range of motivations, standardisation can be used to ensure compatibility across network externalities, reduce (often negative) environmental impacts and/or overcome information asymmetry between producers and consumers in light of safety aspects (Berti and Falvey, 2018).

A standard is a technical document that is designed to be used as a voluntary set of rules or guidelines, unless incorporated within a piece of legislation where it may become mandatory (CEN-CENELEC, 2020b). They can also be used to provide a definition or outline a specific methodological approach. Standards can be specific to a certain product, system or process, or as an 'umbrella standard' can cover a subject horizontally, with sub-parts that address specific details and methods (CEN, 2010b).

The development of a standard is based on a voluntary process where consensus amongst different economic actors is sought (CEN-CENELEC, 2020b). However, as many standards start out as voluntary industry initiatives or are heavily reliant on information provided by the private sector, over-representation of producers' interests has been noted (Berti and Falvey, 2018).

To be successful, Zielczynski (Zielczynski, 2007) argues that standards should be: unambiguous, testable, clear, correct, understandable, feasible, independent, atomic, necessary, abstract, consistent, nonredundant and complete (as described in Table 1).

Table 1: Characteristics of successful standards (Zielczynski, 2007).

CHARACTERISTIC	DESCRIPTION
Unambiguous	Cannot be interpreted differently.
Testable	Should be able to verify implementation.
Clear	Information should be concise, simple and precise.
Correct	Facts should be true.
Understandable	Grammatically correct and consistent.
Feasible	Should be realistic within existing constraints.
Independent	Knowledge of another standard should not be necessary.
Atomic	Should contain a single traceable element.
Necessary	It is key to the system and needed by stakeholders.
Abstract	Should not contain information regarding specific design / implementation criteria.
Consistent	No conflicts should be present between standards.
Nonredundant	Should be expressed only once and not overlap with other standards.
Complete	Specification should be included for all conditions that could occur.

For many products, it has been acknowledged that the use of standards can be an essential element to aggregate initial market demand (CEN, 2011). Conversely, a lack of standardisation

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

can act as a barrier and limit the uptake of the products within consumer markets and in public procurement (CEN, 2011).

3.2 Standardisation within the EU

European standards are seen as a key component of the Single European market and are critical in facilitating trade. Traditionally, standards have been created for technical reasons, for example to codify best practice and state-of-the-art technical solutions. More recently, standards have also become enablers for greater social inclusiveness and engagement, creating areas of convergence within growing markets across different industries (CEN, 2020a).

In a nut shell, standards have been used within Europe to; enhance the safety of products, encourage economics of scale, enable manufacturers to comply with EU legislation, promote the interoperability of products and services, facilitate market uptake of innovation, encourage greater competition, facilitate trade, support environmental sustainability, reflect outcomes of R&D, and promote a common understanding (CEN, 2010a).

At the European level, the standardisation of processes and products is managed by three organisations; European Committee for Standardisation (CEN), European Committee for Electrotechnical Standardization (CENELEC) and European Telecommunication Standards Institute (ETSI).

CEN is responsible for developing and defining voluntary standards at the European level. The CEN remit covers activities in a range of fields and sectors such as air and space, chemicals, construction, consumer products, defence and security, energy, the environment, food and feed, health and safety, healthcare, ICT, machinery, materials, pressure equipment, services, smart living, transport and packaging (CEN, 2020a).

CEN is structured across several interconnected levels (CEN, 2020b) as shown by Figure 1. When establishing and reviewing standards, overall control lies with the Technical Board (BT). In turn, the BT relies on the Technical Committee Management Group (TCMG) and the Technical Committee (TC) to oversee the management and establishment/undertaking of work programmes, respectively. The TC may then establish a number of Subcommittees (SC) or Technical Committee Working Groups (TC-WG) to undertake the work programme in accordance with an agreed business plan (CEN, 2020b). For each step down the organisational level, the specificity of the scope and/or task increases. For example, a TC-WG will work on a specific task related to the scope of the project being led by its parent TC or SC. In the case of TC-WG, tasks may include the provision of technical advice and information, the development of rules and procedures, or the completion of an individual study (CEN, 2020b).

Horizon 2020 This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

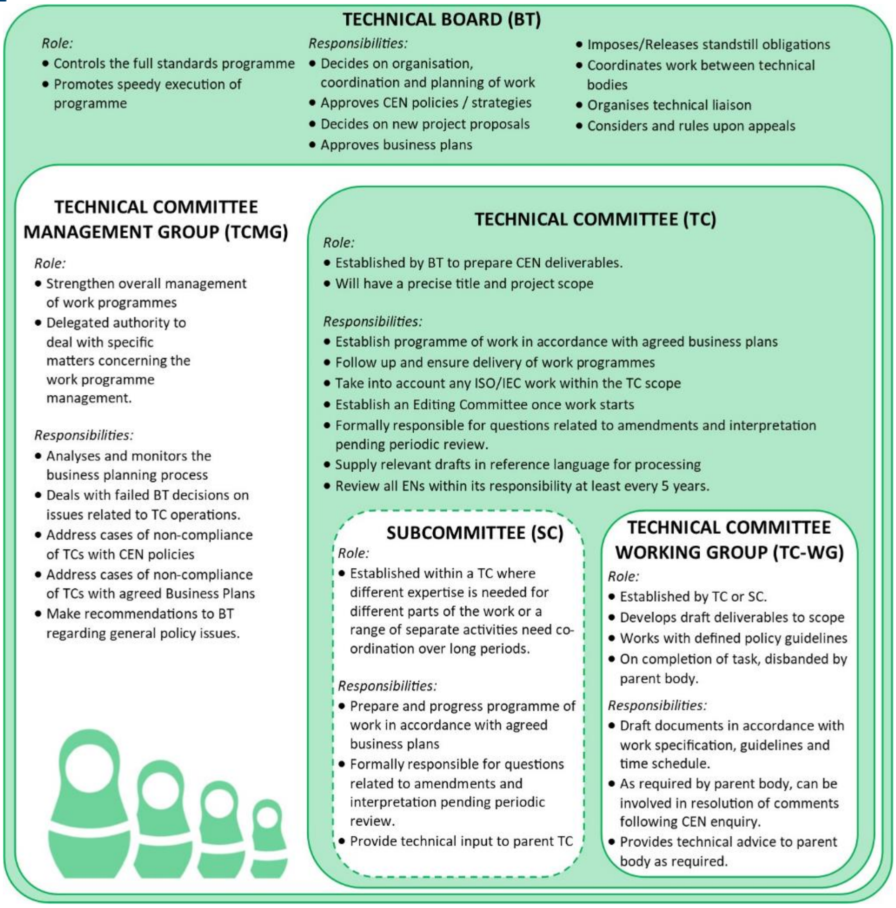

Figure 1: Technical structure of CEN, with role and responsibilities for each level shown.

CENELEC is responsible for standardisation within the electrotechnical engineering field. In general, within its field it prepares voluntary standards that help facilitate trade between countries, creates new markets and cuts compliance costs (CENELEC, 2020). As the responsibilities of CENELEC are outside the overall scope of this report, no further comment will be made on this organisation.

ETSI is responsible for standardisation within telecommunications, broadcasting and other electronic communication networks. Within this field, it provides services to fulfil European and global market needs (ETSI, 2020). As the responsibilities of ESTI are outside the overall scope of this report, no further comment will be made on this organisation.

With regards to the EU member states, 34 national standards bodies, such as the British Standards Institution (BSI), represent national interests. Within the standardisation process, the national bodies engage with International organisations, such as ISO (details of which are available in the next section) as well as the three European Standards Organisations previously mentioned (CEN, CENELEC and ETSI). A key role of the BSI, and the other national standards bodies, is to publish

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

European and International standards in the language native to each nation on behalf of the overarching organisation (BSI, 2020).

3.3 Standardisation outside the EU

The EU has been identified as one of the 'regulators of the world' and is widely regarded as having some of the world's most stringent regulations in areas such as public health, the environment, data privacy and financial services (Young, 2014). Another 'regulatory superpower' noted by Young (Young, 2014) is the United States of America (USA). Within the USA, ASTM, formally known as the American Society for Testing and Materials, is the international standards organisation (equivalent to CEN) that develops and publishes voluntary standards for a range of materials, products, systems and services (ASTM, 2020).

A key issue to consider when discussing safety standards, is the influence of a globally interconnected economy, where the integration of global trade in safe goods needs comparable implementation of pertinent regulations (Larson and Jordan, 2018). To address this issue, the use of a meta-regulatory space of regulating regulation has been proposed (Scott, 2003). One such international regulatory body that has already created a meta-regulatory regulation space is the International Organisation for Standardisation (ISO). At this international level, ISO creates documents that provide requirements, specifications, guidelines and / or characteristics to ensure the consistent and purposeful use of materials, products, processes and services (ISO, 2020).

The European Standardisation Organisations (CEN, CENELEC, etc.) have a dedicated agreement with ISO, the Vienna Agreement, that aims to promote collaboration between the organisations and to prevent duplication of effort. As a result, joint standards projects are planned and carried out with appropriate priority given to meeting European legislation and market requirements. This helps promote the benefits international standards in terms of internal trade and market harmonisation (CEN-CENELEC, 2020a).

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

3.4 Development of bio-based product standards (EU)

Leading the field in innovation, the EU holds the largest share of industrial patents applied to bio-based products. However, in comparison to international competitors such as the USA, Brazil and South-East Asia, the EU has not been successful in the commercialisation of such products (Bell et al., 2018). Indeed, Mengal et al. (2018), notes the lack of a distinct and/or coherent bio-based industry sector within Europe leading to fragmentation and inefficiency.

Acknowledging that the European market remains fragmented and is not always innovation-friendly, the development of the bio-based market has been promoted by the European Commission, most significantly within the EU Bioeconomy Strategy (EC, 2018).

The overall objectives of the EU Bioeconomy Strategy (EC, 2018) are to ensure food security, to move away from a fossil-based economy and to unlock the potential of the blue economy (i.e. biomass from marine sources). The strategy aims to promote long term sustainable development by considering natural resource management, encouraging market-based jobs and growth, increasing global sustainability with responsible development and addressing climate change.

The strategy (EC, 2018) is based on three key priorities;

(1) strengthen and scale up the bio-based sectors, unlocking investments and markets,
(2) rapidly deploy bioeconomy strategies both locally and across Europe, and,
(3) understand the ecological boundaries of the bioeconomy.

A challenge recognised by the EU Bioeconomy Strategy is the appropriateness of the regulatory framework in which the bioeconomy operates, and the impact this has on business models, investments, waste legislation and product standards (Bell et al., 2018). Here, it is important that a long-term, stable and transparent policy and incentive framework is developed that facilitates collaboration, supports development and stimulates market demand (De Besi and McCormick, 2015; Dupont-Inglis and Borg, 2018). **In developing standards for bio-based products, the European Commission acknowledged that initial focus should be placed on the determination of bio-based content, product functionality and biodegradability (CEN, 2011)**.

Furthermore, it was noted that efforts should be made to evaluate and communicate the environmental impact of bio-based products (CEN, 2011; Testa et al., 2015). A particularly pertinent issue, where the communication and marketing of bio-based products as an alternative to fossil-based materials is often based on environmental credentials.

3.4.1 2007: Analysis of the existing bio-based market

In 2007, the European Commission published the report "Accelerating the Development of the Market for Bio-based Products in Europe" (EC, 2007). This report provides a broad analysis of the existing and emerging markets for bio-based products.

Figure 2 presents a summary of the report contents. Overall, the taskforce report (EC, 2007) recognised the many societal benefits of bio-based products. For example, in addition to

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

substituting fossil-based products on a like-for-like basis, bio-based products could also offer new functionalities and higher quality products.

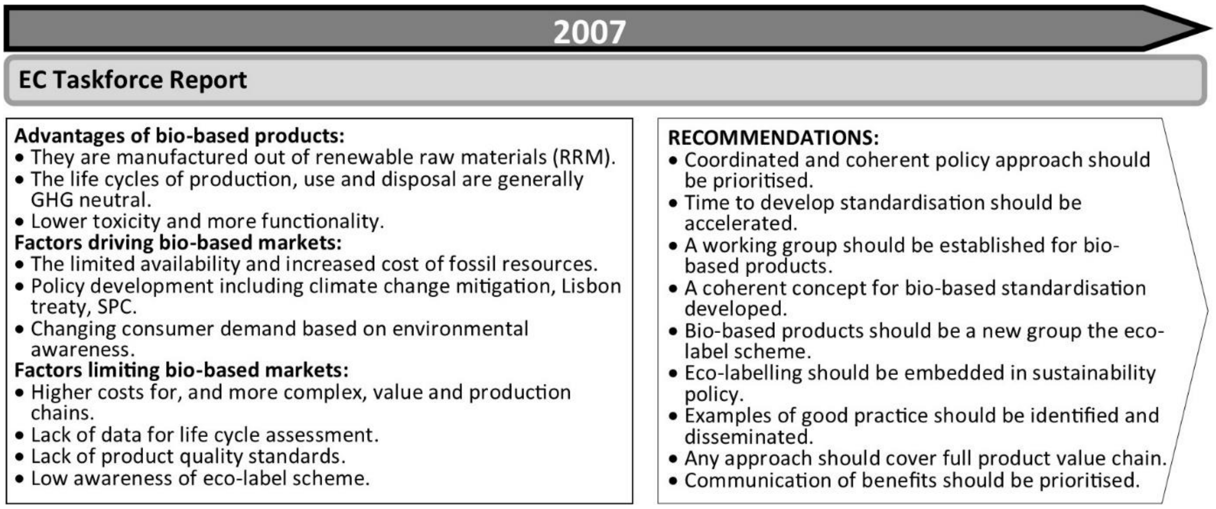

Figure 2: Summary of the taskforce report - "Accelerating the Development of the Market for Bio-based Products in Europe".

Recommendations were also made regarding policy coordination and demand-side measures such as standardisation, labelling, public procurement, regulatory initiatives and end-user communication. Some key points from this report are detailed below.

3.4.1.1 KEY POINT 1: COHERENT POLICY APPROACH

A range of existing EU policies, in policy areas such as agriculture, environment and energy, are likely to have a considerable impact on the development of the bio-based product market. Therefore, requiring a strategic approach, policy development concerning the bio-based product market will need to consider the numerous stages of production and consumption, from the creation of the renewable raw material to the final consumer product.

To do this, utilising dynamic interactions between demand and supply is recommended by the taskforce (EC, 2007). It is thought that demand-side measures (e.g. international harmonisation, engaged public procurement and better communication) would complement supply-side measures such as greater access to finance and improved availability of raw feed stock.

3.4.1.2 KEY POINT 2: HARMONISATION OF INTERNATIONAL STANDARDS

The harmonisation of international quality standards was also recognised as vital by the taskforce report. Ensuring that the production of raw biomass is completed in a sustainable manner that maximises the societal benefits (EC, 2007). This raises a particular issue concerning exported goods and the implementation / enforcement of standards internationally.

Indeed, Philp et al. (2013) highlights that most biomass producers are found outside OECD countries, while the majority of actors that consume biomass in manufacture or as the end-user

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

are found within. In turn, this may create global infrastructure issues concerning ethical, economic and technical aspects (Philp et al., 2013).

3.4.1.3 KEY POINT 3: USE OF A LABELLING / CERTIFICATION SCHEME

To promote the use of quality standards, the use of the existing EU Eco-label scheme has been suggested (EC, 2007). Here, the objective of a label would be to inform consumers of the best performing products, which in turn would reward the producers of that product to maintain and improve its sustainability (EC, 2020).

It is argued that the use of ecolabels can provide easily digestible and ubiquitous messaging to consumers, which in turn can drive more sustainable decisions. However, care must be taken not to overload the market with conflicting or overlapping labelling schemes. Furthermore, to avoid the erosion of positive feeling towards labelling schemes, care should be taken to eliminate the presence of 'green washing' (which refers to misleading claims, symbols or the use of colour that suggests a more environmentally sustainable product) (Wedding, 2010).

3.4.1.4 KEY POINT 4: APPLICATION OF LIFE CYCLE ASSESSMENT

To a large extent, sustainability standards and eco-labels are heavily reliant on harmonised and in-depth Life Cycle Assessments (LCA) (EC, 2007). To determine the environmental impact of bio-based products, an extensive LCA that covers the whole value chain is required (Philp et al., 2013).

To avoid reinventing the wheel, the taskforce report suggests that practitioners make use of existing standards such as the ISO 14040 series, as well as those under development, specifically those that concern the use of recycled materials and products (EC, 2007).

Despite the standardisation of LCA methodology through the ISO 14040 series, Philp et al. (2013) argues that significant degrees of freedom can lead to variations in results. Furthermore, in considering the use of LCA for bio-based products, such as bioplastics, the contentious issue of carbon neutrality, unique nature of the different types of bioplastic and increased number of recovery options need to be considered (Philp et al., 2013).

3.4.1.5 KEY POINT 5: REPORT RECOMMENDATIONS

The taskforce report set out a range of recommendations to address the key issues noted above.

Starting with the raw bio-based resource, the taskforce suggests that thorough cradle-to-grave LCA should be employed to ascertain the environmental impact. Specifically, the net impact on GHG emissions should be considered and applied to systems that create both specific intermediary materials and the final end-user product (EC, 2007).

As bio-based products are produced in an agricultural-manufacturing-industrial system, an integrated approach is required to ensure any detrimental repercussions to any part of the system are avoided [9]. In response to this potential issue, the taskforce report suggested that targeted support should be given to nations that grow and produce the initial feedstock, especially in light of development status and with specific focus on rural development (EC, 2007).

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

Lastly, in order to get buy-in from all relevant societal groups and market actors, it is important to communicate the benefits of bio-based products to consumers and the general public (Sijtsema et al., 2016). Indeed, the taskforce report suggests that communication efforts should have a "lighthouse" function that steers both producers and consumers towards the bio-based market (EC, 2007). As such, communication aspects should be a priority within policy recommendations.

Furthermore, as purchasing behaviours are increasingly based on ethical and environmental concerns, these aspects should be promoted within product communication channels. For example, the promotion of "green" qualities such as bio-degradability and compostability are already influencing consumer behaviour, where consumers are showing a willingness to pay a premium for more sustainable or environmentally friendly products (Sijtsema et al., 2016).

3.4.2 2008: Release of Mandates M429 and M430

Following the publication of the taskforce report (EC, 2007), the European Commission published two mandates in October 2008, Mandates M429 and M430 (EC, 2008a, b). As with all commission derived mandates, they were addressed to the three standards organisations of the EU; CEN, CENELEC and ETSI.

Mandate M429 was launched by the Commission to explore the potential for a set of EU-wide bio-based product standards (EC, 2008a). On the other hand, M430 was more specific, highlighting bio-polymers and bio-lubricants as avenues to explore (EC, 2008b). The contents of both mandates are summarised in Figure 3.

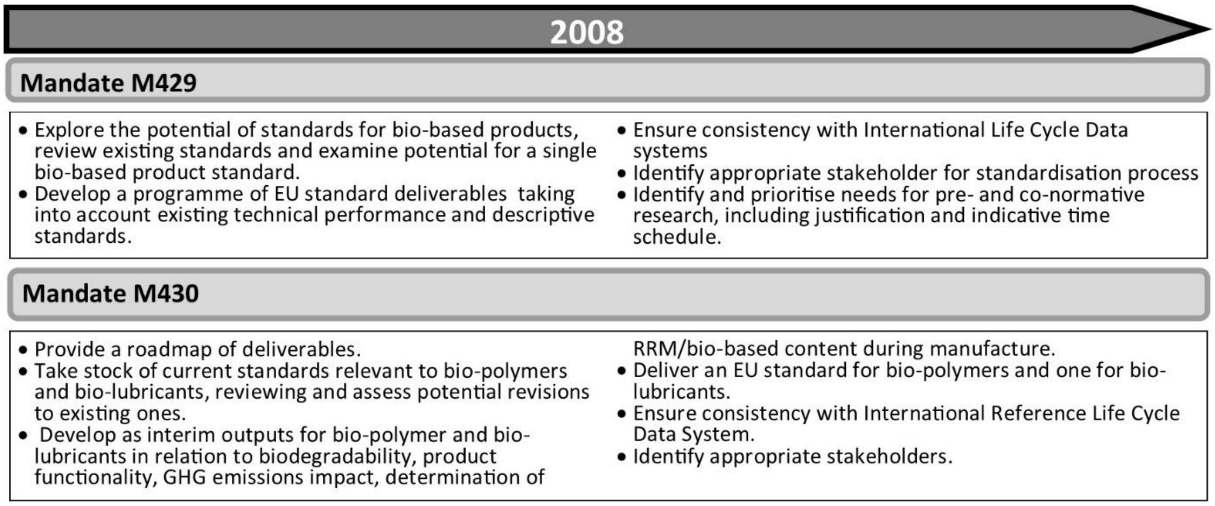

Figure 3: Summary of Mandate M429 and M430

In brief, the three EU standards organisations were instructed to develop a programme of work and execute appropriate tasks to promote the bio-based product lead market. Tasks included the

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

exploration of existing standards, development of new standards, recommendations for LCA and the identification of special stakeholders (EC, 2008a).

3.4.3 2009: CEN report on bio-based products

The working group named: “Bio-based Products” (CEN/BT/WG 209), was established for the execution of M429/430. The main output from this working group was a CEN report titled: “Bio-based products” (CEN, 2010b).

As highlighted in Figure 4, the report identified a wide range of interested groups including; raw material suppliers, producers and manufacturers (both of intermediate materials and final products), purchasers and consumers, waste managers, legislators, researchers and controlling bodies (certification, testing, etc.).

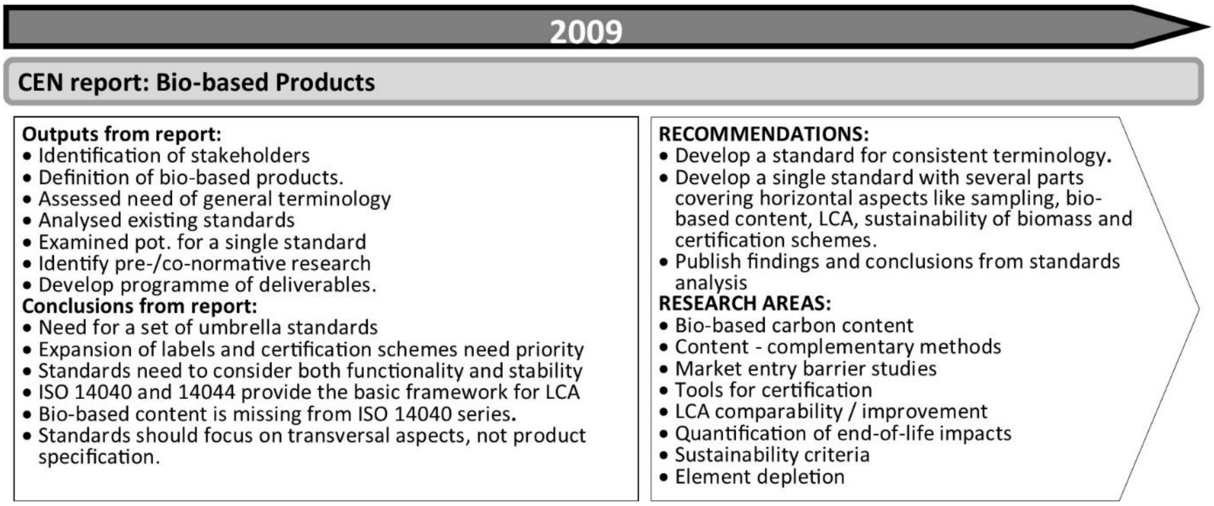

Figure 4: Summary of CEN report "Bio-based products"

This report focused on the status of existing standards, methods to determine bio-based content, product functionality, end-of-life / sustainability aspects and finally, research needs.

It also provided definitions for the terms; “Bio-based”, “Biomass” and “Bio-based product”, as detailed in Table 2, and highlighted a lack of general terminology for bio-based products. Here, the (mis)allocation of the term bio-plastic was specifically identified, where three different iterations of bio-plastic were found to be in use; (1) materials that are bio-based, as defined by Table 2, (2) materials that are biodegradable, but not necessarily bio-based, and (3) materials that are biocompatible and therefore not harmful to living tissue, e.g. dissolvable stitches (CEN, 2010b).

Horizon 2020
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No. 860407

Table 2: Terms and definitions identified in the "Bio-based products" report (CEN, 2010b).

TERM	DEFINITION
Bio-based	Materials that are derived from biomass.
Biomass	Material of biological origin excluding material embedded in geological formations and/or fossilized. This definition refers to the well-known short-cycle of carbon (i.e. the life cycle of biological materials) and includes materials from plants, algae, marine organisms, forestry, micro-organisms, animals, and biological waste from households, agriculture, animals and food/feed production.
Bio-based product	Product wholly or partly bio-based, where a bio-based product is normally characterised by the bio-based content.

In general, the "bio-based products" report concluded that barriers to market uptake are created when only functionality is incorporated within product standards. Furthermore, it acknowledged that LCA should be used to determine, and thus communicate, the benefits of using bio-based products (CEN, 2010b). Current methods used to complete an LCA, such as the ISO 14040 series, that generally include end-of-life as a major product life stage, does not at the moment consider aspects that are specific to bio-based content (ISO, 2006). Furthermore, aspects that are related to social and economic criteria are limited and thus require further development (CEN, 2010b; ISO, 2006).

A key recommendation from the final "bio-based products" report was to publish the findings of a standards analysis completed by the WG-BT 209. In May 2011, the technical report: CEN/TR 16208, was published, which analysed relevant standards, documents and other appropriate reports related to bio-based products (BSI., 2011).

The results of these analyses, specific to general bio-based products and bio-based plastics, are presented in Table 3. Here the scope of each document reviewed within the standards analysis as well as evaluation notes from the technical committee are summarised. In brief, the evaluation of these documents highlighted the need to develop consistent terminology and a standardised method to determine biomass content, as well as a lack of bio-based specific references within existing standards regarding LCA and end of life management (biodegradability, compostability, anaerobic digestion, etc.).

Table 3: Summary of standards, documents and reports evaluated by WG-BT 209 (CEN, 2010b).

DOCUMENTS REVIEWED	SCOPE	EVALUATION
Vocabulary		
ANSI / ASABE S593	Provides uniform terminology and definitions concerning biomass production and use.	Definitions are generally related to either energy or production. Biomass definition excludes material from animal products. Greenhouse Gas terminology differs from ISO 14064 definition.
CEN/TR	Recommends bioplastic and	Based on stakeholder discussions of commonly used terms. Focus on application to plastics, but with some wider

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

15932	biopolymer related terminology	applicability. Biomass definition excludes material from geological formation or fossilisation.
Life Cycle Assessment		
ILCD / ELCD	Provides methodological and data basis for LCA.	Based on LCA framework established in ISO 14020 and ISO 14040. Comparability relies on the expansion of the database.
CR 13910	Best practice guidelines for undertaking LCA specific to packaging and distribution systems.	Based on LCA framework established in ISO 14040. No specific reference to bio-based products.
ASTM D7075-04	Defines implementation of ISO 14040 applied to bio-based products within US.	Based on LCA framework established in ISO 14040. No equivalent at European or International level.
VDI 4431	Provides guidance to industrial businesses for plant-specific life-cycle management systems.	Provides tools that focus on the efficient use of reconditioned or reused components / materials in order to reduce waste. Focus on reuse and recycling. No specific reference to bio-based products.
ISO 14064	Provides a general framework for inventories of GHG emissions and sinks.	GHG sinks refer to IPCC and WRI reports. No specific reference to bio-based products.
ISO 14067-1	Provides the methodology to calculate and communicate carbon footprint.	Under development - will be interesting to see whether bio-mass and bio-based products are included.
NTA 8080	Dutch technical agreement to determine sustainable use of biomass in energy.	Based on Directive 2009/28/EC and Dutch “Cramer criteria”. Lists criteria for sustainable biomass use. Lacks measurement methods and social criteria.
BEES	US decision-making tool to evaluate the environmental and cost performance of products.	Based on LCA framework established in ISO 14040. A methodology already used to evaluate bio-based products. Distinguishes between environmental, economic and social effects.
ASTM D6852-02	Process to determine bio-based content, total resource consumption, and environmental profile.	Outdated - referring to ISO 14043 (replaced by ISO 14040). Not “cradle-to-grave”. No equivalent at European or International level. Could be useful as an umbrella standard.
CEN/TC 383	Deals with the subject of sustainability criteria.	Drafted prEN 16214-3 applicable to the production, cultivation, and harvesting of biomass for biofuels and bioliquids production.
ISO/DIS 26000	Provides guidance on social responsibility.	Provides a broad definition of social responsibility. No specific reference to bio-based products. Could be underlying standard for social sustainability criteria.
ISO 14025	Principles and procedures for developing Type III environmental declaration programmes.	Forms a basis when developing labels and certification schemes. No specific reference to bio-based products.
BP X30-323	Good practice guide defining the principles and procedures for developing environmental declarations for consumer information.	Environmental communication is based on scientific knowledge. Can be applied to all products currently on the market, irrespective of distribution. Covers environmental impacts, but not other sustainable development issues.
ISO 14040	Presents the principles and framework for completing an LCA.	Applicable to all products and services. No specific reference to bio-based products, bio-content, biodegradability or

Horizon 2020
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No. 860407

		compostability. Forms a basis to monitor performance over time.
ISO 14044	Presents the requirements and guidelines for completing an LCA.	See above (ISO 14040).
PAS 2050	Specifies requirements for the assessment of the life cycle GHG emissions.	Presents LCA generics similar to ISO 14040. Acknowledges that bio-based products can form a bio-based carbon sink result in LCA.
Bio-based content		
ASTM D6866	Determines bio-based content using Radiocarbon and IRMS Analysis.	European and International versions are under development. This remains the most reliable method. Precision on mean bio-based carbon content +/- 3%.
ASTM D 7026	Brief guide and method for sample collection in collaboration with ASTM D6866.	Highlights the importance of representative sampling. States that any existing product-specific sampling methods should be used. Only refers to homogeneous materials, or large representative sample sizes.
CEN/TC 249	Specifies one test method to determine biomass fraction in biopolymers.	Based on ^{14}C content measurements. Applies to any organic carbon containing polymers. Under draft, when finished should be an alternative to ASTM D6866. Current aimed at biopolymers but could be adapted for other materials.
EN 15440	Specifies three test methods to determine biomass fraction in solid recovered fuel.	Aimed at solid biofuels only but could be adapted for other bio-based materials and products. Based on ^{14}C content measurements.
Material specific – Plastics		
EN 14995	Procedures to determine compostability or anaerobic treatability of plastic materials.	Requirements specific to end of life option for plastics. Not material specific, applicable to any type of plastic, regardless of origin. Derived from EN 13432.
EN 13432	Procedures to determine compostability or anaerobic treatability of packaging materials.	Requirements specific to end of life option for packaging. Not material specific, applicable to any type of packaging, regardless of origin. Does not address compostability of residual contents. Application can be extended to other materials or products.
ISO 14855	Test method for biodegradability and composting of plastic materials.	Based on carbon dioxide evolution. Not specific for materials of biological origin. Only relevant for solid materials. Specified for plastic materials, where application could be extended to any type of solid materials.
CEN/TR 15822	Technical report summarising current state of knowledge regarding biodegradable plastics.	Focuses on biodegradable plastics which are used on, or end up in, soil. Addresses links between use, disposal, degradation and the environment.
NF U 52-001	Characterisation of mulching products made from biodegradable materials.	French standard specifying test methods regarding biodegradability and ecotoxicity. Also, requirements for packaging, identification and marking. Based on life expectancy on the soil.
NF 082	Regulations applicable to plastic waste bags.	French standard, applicable to non-biodegradable bags for collection of HH waste, biodegradable bags for collection of organic waste going to composting facilities and bags for soft infection-risk generating waste.

Notes: ILCD - International Reference Life Cycle Data System; ELCD - European Life Cycle Database; GHG - Green House Gas; IPCC - Intergovernmental Panel on Climate Change; WRI - World Resources Institute; IRMS - Isotope Ratio Mass Spectrometry.

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

Evaluating each document on its applicability to bio-based product standards, the technical committee concluded that there is **a need for a set of umbrella standards that can be applied to any bio-based material or product**.

Where reference to bio-based materials and products is missing from existing product standards, the committee also recommended that relevant sections should be introduced or elaborated on. It was also recommended that using an umbrella standard format, the development of standards for bio-based products should focus on the following;

- Sampling.
- Determination of bio-based content.
    - The committee recommended that an alternative method to determine bio-based content, independent of carbon, should also be developed.
- Application of LCA specifically to bio-based materials and products.
- Sustainability of biomass used.

The analysis highlighted a plethora of documents concerning the application of LCA. However, for specific application to bio-based products, the committee recommended that a data collection exercise among relevant industries was needed to update the databases used in LCA (BSI., 2011).

Another major issue identified by this report, concerns the use of labels and certification regarding bio-based content, environmental friendliness and end of life management (i.e. biodegradation and/or compostability) (BSI., 2011).

Concerning the last point, confusion regarding the best option for the disposal when a bio-based product is no longer required has been identified, i.e. should the end-user use a home composting system, recycling service or municipal green waste service to dispose of a bio-based product (Boesen et al., 2019). In turn, this may create further barriers to the bio-based product market as the products do not seem to live up to expectations and thus creating higher levels of scepticism and hesitation by consumers (Brockhaus et al., 2016). Furthermore, Boz et al. (2020) argue that misinterpretation of on-label claims, bias and 'green-washing' may create a barrier to market in the future.

To overcome this particular issue, the report compiled by WG-BT 209 (CEN, 2010b) recommended that the use of existing labels and certificates such as the EU Ecolabel, the Blue Angel label and the Cradle-to-Cradle certification programme could be explored and, if necessary, expanded.

The technical committee were keen to emphasise that any product-specific standards should be based wholly on the technical performance of that product. Furthermore, to create consistency within the market, **standards should not include any undue discrimination in favour or against the use of bio-based, fossil-based, virgin or recycled materials (BSI., 2011)**.

3.4.4 2011: Release of Mandate M492

Following on from the "Bio-based products" report (CEN, 2010b), the commission published Mandate M492 in March 2011 (EC, 2011b). The aim of M492 was to promote the bio-based

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

product lead market by establishing a committee for bio-based products. Taking into account CEN/TR 16208 (which was published after this mandate), the scope of this committee was to standardise terminology, methods, criteria, guidance, and tools applicable to bio-based products (more detail is given in Figure 5). In this mandate, it was assumed that short-term deliverables would be in the form of descriptive standards and/or test methods.

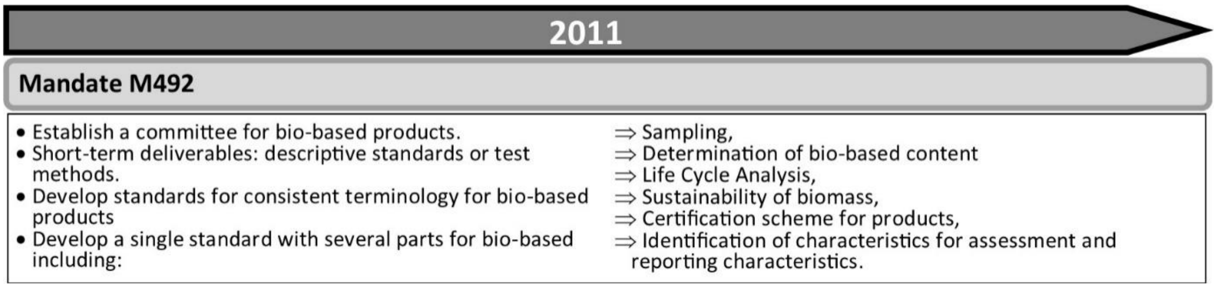

Figure 5: Summary of Mandate M492

3.4.5 2011–2018: Work programme of Technical Committee 411

In response to Mandate M492, considering the "Bio-based products" report (CEN, 2010b) and in coordination with CEN/TR 16208 (BSI., 2011), Technical Committee 411 (TC-411) published a programme of work (CEN, 2011) (Figure 6).

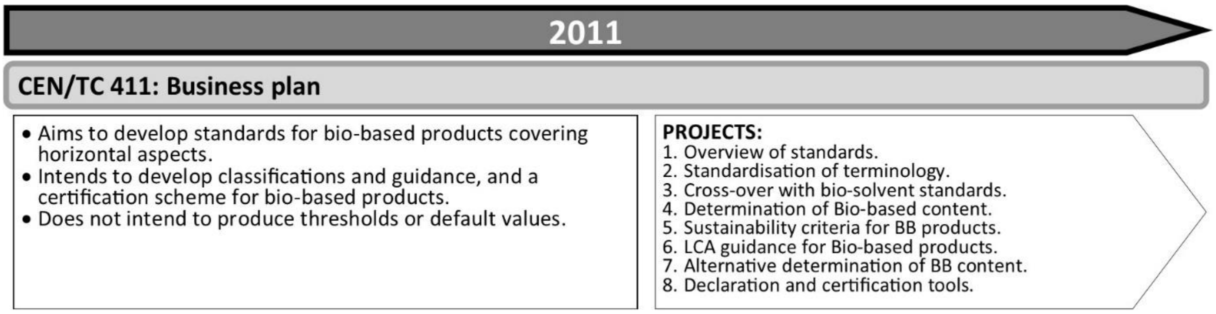

Figure 6: Summary of CEN/TC 411 Business plan

The objectives of TC-411 were to provide a consistent terminology for bio-based products, develop a range of standards that cover sampling methods, determination of bio-based content, application of (bio-based specific) LCA and sustainability aspects as well as guidance on the use of existing standards for end of life options. The TC would also develop a certification scheme for bio-based products to identify which characteristics can/should be assessed and how they should be reported. To do this, TC-411 set out a business plan that included eight distinct projects, as detailed in Table 4.

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

Table 4: Aims and outputs from sub-projects within the Technical Committee 411 work programme for "Bio-based Products", highlighting which report recommendation or mandate has been addressed.

SUB-PROJECTS AND AIMS	RECOMMENDATION / MANDATE
(1) Overview of standards Based on input from Members, update the list of standards in CEN/TR 16208 and establish a base document for the working groups.	*CEN Report:* Publish findings and conclusions from standards analysis (as CEN/TR 16208)
(2) Standardisation of terminology Accelerate the development of the EU market for bio-based products by developing a consistent terminology for bio-based products.	*M492 - Work item 1:* Standardisation of general terminology applicable to bio-based products.
(3) Cross-over with bio-solvent standards In parallel, technical specifications and technical reports for bio-solvents will be developed.	*M491* - check horizontal standards'' aspects with bio-solvents
(4) Determination of Bio-based content Develop a standardised method to determine bio-based content, based on the carbon content of products, using existing standardised methods.	*M492 - Work item 2:* Standardisation of a method determining the bio-based carbon content of products. Also, another method, non-carbon based.
(5) Sustainability criteria for bio-based products Develop a standardised sustainability criterion applicable for bio-based products.	*M492 - Work item 3:* Standardisation of sustainability criteria.
(6) LCA guidance for bio-based products Develop standardised life cycle analysis guidance applicable for bio-based products.	*M492 - Work item 4:* Standardisation of life cycle analysis guidance applicable to bio-based products.
(7) Alternative determination of bio-based content Develop a standardised method to determine bio-based content, not based on the carbon content of products, using existing standardised methods.	*M492 - Work item 2:* Standardisation of a method determining the bio-based carbon content of products. Also, another method, non-carbon based.
(8) Declaration and certification tools. Develop certification scheme(s) for bio-based products, identifying which characteristics can/should be assessed and how to report.	*M492 - Work item 5:* Standardisation of declaration and certification tools applicable to bio-based products.

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

3.5 Bio-based product standards

The overall outcome of these work programmes was the development of ten bio-based product specific standards. As a brief overview, these bio-based specific standards seek to provide information regarding terminology and definitions, methods to determine bio-based content, environmental sustainability and life cycle assessment and the means of communication to provide the information collected (i.e. on bio-based content, sustainability etc.) between businesses and to the end-user. The aim/scope, approach and delivery of each are described below.

3.5.1 EN 16575:2014 Bio-based products – Vocabulary

This standard provides the following terms, as defined by Table 5.

Table 5: Bio-based product vocabulary and definitions, as described by EN 16575:2014

Term	Definition
Bio-based	Derived from biomass
Bio-based carbon / biogenic carbon	Carbon derived from biomass
Bio-based carbon content	Fraction of carbon derived from biomass in a product
Bio-based content	Fraction of a product that is derived from biomass
Bio-based product	Product wholly or partly derived from biomass
Biodegradation	Degradation caused by a biological activity, e.g. by enzymatic action, leading to a significant change in the chemical structure of a product
Biomass	Material of biological origin excluding material embedded in geological formations and/or fossilized
Biomass content	See bio-based content.
Co-product	Any of two or more products coming from the same unit process or product system
Degradation	Irreversible process leading to a significant change in the structure of a product, typically characterized by a change of properties (e.g. integrity, molecular mass or structure, mechanical strength) and/or by fragmentation, affected by environmental conditions, proceeding over a period of time and comprising one or more steps
Durability	Ability for a product to retain the values of its properties under specified condition
Life Cycle Assessment (LCA)	Compilation and evaluation of the inputs, outputs and the potential environmental impacts of a product system throughout its life cycle
Mass balance	Relation between input and output of a specific substance within a system in which the output from the system cannot exceed the input into the system
Product	Substance, mixture of substances, material or object resulting from a production process
Renewable material	Materials that is composed of biomass and that can be continually replenished
Sustainable Development	Development that meets the needs of the present without compromising the ability of future generations to meet their own needs
Total carbon (TC)	Quantity of carbon present in a product in the form of organic, inorganic and elemental carbon

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

Total organic carbon (TOC)	Quantity of organic carbon present in a product
Waste	Any substance, mixture of substances, materials or object which the holder discards or intends or is required to discard

To enable the correct use of these terms, this document also provides several term-specific notes.

Perhaps the most substantial is the use of **"bio-based" vs. the prefix "bio".** While the document acknowledges that the use of the prefix "bio" frequently appears in everyday language and has been used within the industry, the standard encourages the use of "bio-based" to ensure transparent and non-misleading information. Indeed, the document notes that the use of the prefix "bio" has been used as a marketing tool across several products such as detergents and plastics that would not meet the defined terms contained within this standard. As such the use of the prefix "bio" could lead to unsubstantiated, and therefore deceptive, claims concerning the sustainability of these products.

The document also **expands on the definition for "product",** whereby this can include an intermediate, material, semi-finished or final product resulting from different degrees of transformation. Transformation can include simple physical or mechanical processes, materials resulting from fractionation and/or extraction, intermediates from chemical, physical, or biological processes and semi-finished / final products such as biopolymers, biocomposites and bio-lubricants.

This standard also highlights the cross-linkages with other international standards. For example, definitions for degradation and biodegradation are adapted from ISO 472:2013, and definitions for co-product, LCA and waste are adapted from ISO 14040:2006.

3.5.2 EN 16766:2017 Bio-based solvents - Requirements and test methods

The aim of this standard is to provide a **set of requirements for bio-based solvents to determine bio-based content, technical performance properties and test methods**. As it is not relevant to the overall objective of this report (i.e. standardisation approach to bio-based *plastics*), this standard will not be considered further.

3.5.3 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

The scope of this standard is to provide a **method to determine the bio-based content** of a product, using radiocarbon analysis and elemental analysis. This does not describe a direct analytical determination method, as that was deemed unfeasible, but instead requires the collation of specific data by the producer, which is then compared against radiocarbon and elemental analysis results. This method is not needed for natural products that are wholly derived

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

from biomass. Where natural products are used to produce, or are a constituent of, a product then this standard must be followed.

For the purpose of this standard, **products are categorised into two groups** depending on whether they are obtained through chemical or biological reaction (Group I) or without chemical or biological reaction (Group II).

Delivery of this standard requires the production of a test report that includes; a reference to this standard, identification of the material or product tested, group of the product, calculated value of bio-based carbon content and bio-based content, validated value of the bio-based content, identification of the testing laboratory, any additional information and date of laboratory sample receipt and test date(s).

3.5.4 EN 16785-2:2018 Bio-based products - Bio-based content - Part 2: Determination of the bio-based content using the material balance method

The scope of this standard is to provide a method of **determining the bio-based content in products using the material balance approach** applied to a representative product batch in a production unit. To utilise this standard, the composition of a product, bio-based content for each input, output and loss should be known. Furthermore, the bio-based content of the product should be verifiable by analysis.

To calculate the bio-based content of a product;

1. **Establish the material balances (expressed in kilograms)** for the product corresponding to a defined time period and representative product batch. Where the sum of the inputs $(M_{in,i})$ should equal the sum of any losses $(M_{lo,j})$ plus output $(M_{t,out})$

$$\Sigma M_{in,i} = \Sigma M_{lo,j} + M_{t,out}$$

2. **Establish bio-based content (as a percentage)** material balances for the product corresponding to a defined time period and representative product batch. Where the bio-based content is determined as a percentage of bio-based content within the inputs $(m_{B,in,i})$, losses $(m_{B,lo,j})$ and outputs $(M_{B,out})$.

$$\Sigma M_{in,i} \times m_{B,in,i} = \Sigma M_{lo,j} \times m_{B,lo,j} + M_{B,out}$$

3. **Calculate the bio-based content** (m_B), expressed as a percentage, of the product for a representative product batch.

$$m_B = 100 \times \frac{M_{B,out}}{M_{t,out}}$$

Where

m_B is the bio-based content of the product, expressed as a percentage of the total mass of the dry matter of the product.

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

$M_{B,out}$ is the bio-based mass, expressed in kilograms, of the output leaving the production unit for the product batch.

$M_{t,out}$ is the total mass of the dry matter, expressed in kilograms, of the output leaving the production unit for the product batch.

Delivery of this standard requires the production of a test report that includes; a reference to this standard, identification of the material or product tested, identification of the testing laboratory, dry mass and bio-based content of each input, dry mass and bio-based content of each loss, total mass of dry matter under consideration, calculated value of bio-based content, any additional information and date of laboratory sample receipt and test date(s).

3.5.5 EN 16640:2017/AC:2017 Bio-based products - Bio-based carbon content - Determination of the bio-based carbon content using the radiocarbon method

The scope of this standard is to provide a method for the **determination of the bio-based carbon content** in a product, based on the ^{14}C content measurement. This standard is based on the principle that the ^{14}C present in products originates from recent atmospheric CO_2. Due to its radioactive decay, ^{14}C is almost absent from fossil-based products, and thus can be considered for use as a tracer of products recently synthesised from atmospheric CO_2, i.e. bio-based products.

Two primary tests methods are provided; (A) Liquid scintillation-counter method (LSC) and (B) Accelerator mass spectrometry (AMS). This standard also allows the use of a third method, (C) Beta ionization (BI). Bio-based carbon content is expressed by a fraction of sample mass or as a fraction of the total carbon content. This calculation method is applicable to any product containing carbon, including bio composites.

Sampling and conversion (of the carbon present for ^{14}C determination) methods should follow existing product-specific standards to provide a representative and suitable sample of the material or product where the quantity or mass is accurately reported.

Collected samples should be sent to specialised laboratories along with prepared blank samples, where one of the three test methods (A, B or C) should be used to determine ^{14}C content.

To calculate bio-based carbon content;

1. Determine **total carbon content of a sample** (x^{TC}), expressed as a percentage of the total dry mass.
2. Calculate **bio-based content by mass** (x_B), using the ^{14}C content value and applying correction factors. Determination of ^{14}C content will differ depending of choice of method (A, B or C).
3. Calculate **bio-based carbon content as a fraction of the total carbon content** (x_B^{TC})

Delivery of this standard requires the production of a test report that includes; a reference to this standard, identification of the material or product tested, identification of the testing laboratory,

Horizon 2020 This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

method of sample preparation, storage conditions, method used to determine ^{14}C, test results, method of carbon conversion, ^{14}C activity, total carbon content, x^{TC}, x_B, x_B^{TC}, any additional information and date of laboratory sample receipt and test date(s).

3.5.6 EN 17351:2020 Bio-based products - Determination of the oxygen content using an elemental analyser.

The scope of this standard is to provide a **direct method for the determination of the total oxygen content in bio-based products using an elemental analyser**. This standard can be used in the determination of bio-based content. While this method provides an alternative (non-carbon based) method to determine bio-based content, it does acknowledge that under the current state of the art, it is not possible to differentiate between oxygen originating from biomass and non-biomass (inorganic) components. It can also be used as a standalone standard to determine oxygen content in organic compounds.

In principle, the method described requires a dried sample (< 5% water content) to be pyrolyzed in an inert gas stream. The gaseous products from this pyrolysis are then exposed to reactants (either nickel activated carbon, carbon black or glassy carbon), where the oxygen present is transformed into carbon monoxide. Formed water is removed using magnesium perchlorate, and the carbon monoxide separated and measured using thermal conductivity.

Delivery of this standard requires the production of a test report that includes; a reference to this standard, identification of the material or product tested, identification of the testing laboratory, details regarding sample preparation, storage conditions, results of the test and total oxygen content (expressed as mass %), any additional information and date of laboratory sample receipt and test date(s).

3.5.7 EN 16751:2016 Bio-based products - Sustainability criteria

The scope of this standard is to provide **horizontal sustainability criteria** applicable to the bio-based part of all bio-based products covering all three sustainability pillars; environmental, social and economic.

This **standard can be used** to provide sustainability information about the biomass production or use of biomass throughout a supply chain (for the bio-based part of a wholly/partly bio-based product). Alternatively, it can used to set a framework to provide information on the management of sustainability aspects, for business-to-business communication or to develop product specific standards and certification schemes.

This **standard cannot be used** to make claims that operations or products are sustainable or to establish thresholds or limits.

General requirements of this standard include;

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

- The application of all criteria to biomass production, as well as other operations along the bio-based product supply chain.
- To address each criterion, a response to each indicator should be provided for each activity under the direct control of the economic operator.
    - Each indicator should be supported by quantitative metrics when relevant.
    - If indicators are not relevant / not applicable on objective grounds, or not possible to apply, then it shall be documented and justified in a transparent manner.
    - An indicator is relevant if it is part of, or affected by, the process within the reporting boundaries.
    - If no information is available, an explanation shall be provided to address an indicator.
    - An economic operator can be active within any part of the supply chain producing or selling the bio-based product.
- Reporting boundaries are defined by the position of the economic operator within the supply chain.
    - The reporting boundary should be justified and documented.
    - Any exclusion of a process or part of a process should be justified
    - Processes under direct control of the economic operator include activities that are conducted or subcontracted by the operator.
- The assessment of sustainability should cover a relevant time period, which needs to be documented and justified.
    - Time periods applied for one operation may vary depending on the indicators.
    - Time periods choice should consider potential bias of intra- and inter- annual variation.
    - For biomass production, the time period should cover the crop rotation period.
- The type and origin of biomass feedstock should be documented and include the type (species / waste stream), and origin (including location, land type, area codes).
- Data, information sources and assumption should be transparently documented and justified.
- Documentation regarding the procedures used to address indictors should be recorded.
- Transmission of information should take place through a chain-of-custody through the supply chain. Which chain-of-custody system is adopted should be disclosed by the economic operator and should be recognised and widely accepted internationally, regionally or nationally.
- The use of confidential data to demonstrate compliance with this standard should be clarified by the economic operator including responsibilities of receiving parties not to share received confidential data with third parties.
- Decisions should be preferably based on a natural science-based approach. Other scientific approaches e.g. from social or economic sciences, may also be used where it is not possible or adequate to use natural science approach. If no science approaches are available, decisions may be based on value (e.g. moral or ethical) choices. All choices must be documented and justified.

Horizon 2020 This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

To deliver this standard, economic operators should consider the following criterion and present responses to the indicators, as detailed in Figure 7. The level of response should be considered in the context of undue administrative or economic burden for the economic operator. In some cases, the response to an indicator may be “not relevant” or “not applicable”, e.g. a farmer with no employees would find indicators concerning labour rights, working conditions and living condition not applicable.

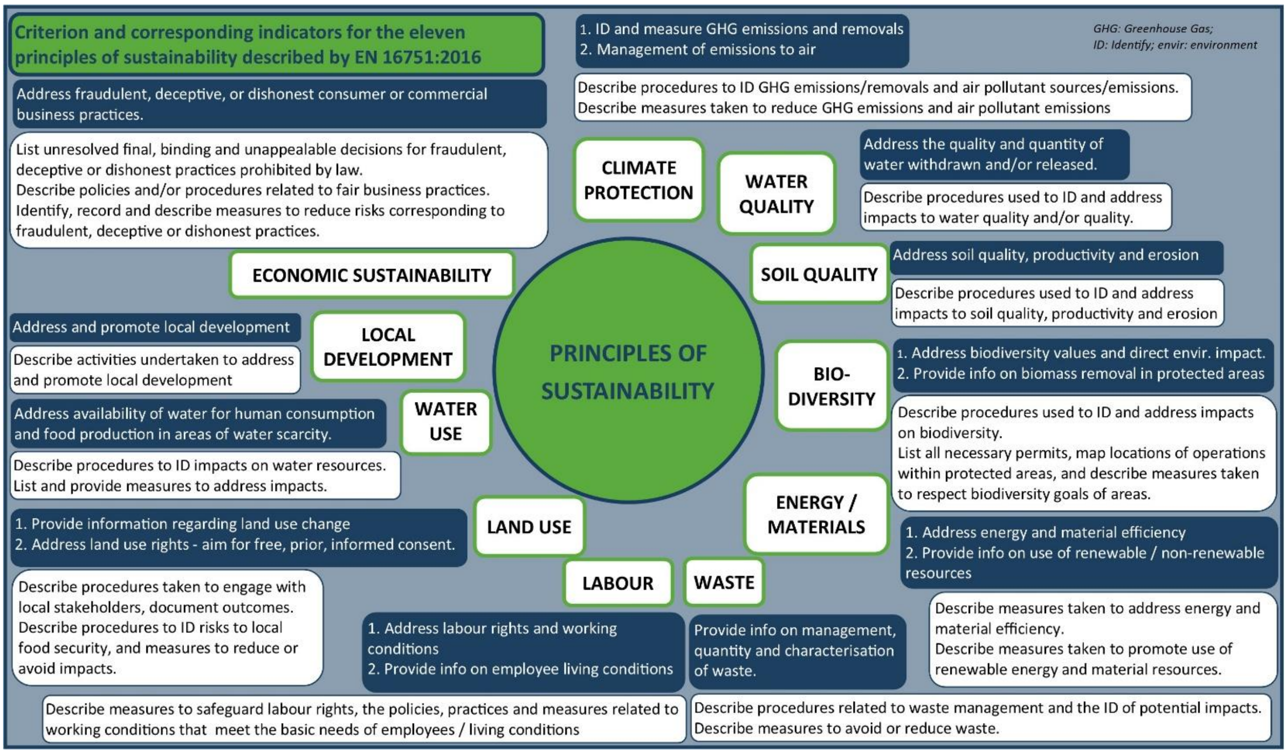

Figure 7: Principles of sustainability, based on EN 16751:2016

3.5.8 EN 16760:2015 Bio-based products - Life Cycle Assessment.

The scope of this standard is to provide **guidance and requirements concerning the impact assessment of bio-based products using life cycle assessment (LCA),** with a specific focus on how to handle the specificities of the bio-based part of a product.

This standard is based on the LCA requirements and guidance given in ISO 14040 and 14044. The LCA of a bio-product should cover the entire product (not just the bio-based part). This standard focuses on how to handle the specificities of bio-based product, i.e. the additional points that need consideration alongside the standard LCA method provided by ISO 14040 and 14044. Additional details with respect to the following LCA aspects: goal and scope, life cycle inventory

Horizon 2020
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No. 860407

(LCI), life cycle impact assessment (LCIA) and Interpretation and reporting, are presented in the Table 6.

Table 6: Additional details for LCA aspects (based on ISO 14040/14044 series), provided by EN 16760:2015

LCA aspects	Additional details
Goal	• No additional details, requirements of ISO 14040 (5.2.1) and ISO 14044 (4.2.2 and 4.2.3) shall apply.
Scope	• In addition to scope detailed in ISO 14044, limitations, assumptions, and methods to assess issues specific to bio-based products should be explained. • Any technical input to establish and manage the system producing the biomass is considered within the system boundary. • When determining function, functional units and reference flows, it is recommended in cases where bio-based products are intermediates or can provide several functions or services that a reference flow such as weight or volume is used. • The equivalence of the systems being compared should be evaluated before interpreting the results.
Life Cycle Inventory (LCI)	• Responsible sourcing and sustainable management practices can be found in the production of bio-based raw materials. • If biomass has been produced in conformance with a relevant standard this shall be considered in determining elementary flows and in impact assessment and interpretation. • For biomass production, the collection of data and modelling should consider the management regime and cropping, harvesting and crop rotation (including the positioning of the crop in the rotation), e.g. the effect of inter- and intra-annual variation and when possible, use values representing the selected period. • For bio-based products, the biogenic carbon content can be of key importance to determine GHG emissions. To track biogenic carbon in a value chain, allocation based on carbon content can be used. When allocating based on other relationships the modelled biogenic carbon flows might not reflect the actual physical content and flows. • The distinction between resource and raw material is decisive for biomass. Resources enter the system as elementary flows, while raw materials are intermediate flows within the system. Biomass that has been drawn from the environment without previous human transformation shall be inventoried as an elementary flow. • In LCI modelling for bio-based products it is necessary to further distinguish material use from the use of energy. (i.e. a resource can be used to provide the energy required to produce a product or used as a constituent of the product itself) • Land use is an important aspect of the life cycle of bio-based products. Land use has two aspects: land occupation and land transformation; these can both have positive or negative effects • When modelling land use in LCI, the following should be considered: area as a physical unit, distinction between transformation and occupation, identification of land use type and land use change in GHG accounting. • Water is of vital importance for the production of biomass and impacts on water quality and availability is of crucial importance for bio-based products. • Data related to water which represent elementary flows may be directly collected from unit processes or derived from data which represent material flows, e.g. ancillary material or waste for further processing. The water inventory should include inputs and

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

	outputs from each unit process being part of the system to be studied. Any discrepancies in the inventory balance shall be explained. • Agriculture can have positive and negative impacts on the environment. Agricultural goods and biochemical compounds extracted from these good can be used as raw materials in bio-based products. It is noted that agricultural field work is complex, and practices vary significantly across farms and regions. Many parameters influence LCA impacts of agriculture, including intensification and optimization of production practices. At the same time (resource-, energy-, emission-) efficiency and thus the resulting environmental interventions mirrored in LCA of agricultural production, vary significantly amongst the (a) type of crop cultivated (b) management regime (fertilizer, pesticide, mechanization, irrigation, tillage practices) (c) soil and climate characteristics (hence location and time), (d) farm practices for (potential) conservation and drying steps of harvest etc.
Life Cycle Impact Assessment (LCIA)	• This standard provides guidelines for specific impact indicators such as the treatment of biogenic and non-biogenic carbon in assessing climate change, land use impact on areas of protection, and the impact of water use. • To calculate life cycle impact assessments, all biogenic and non-biogenic carbon emissions and removals should be considered. Two main approaches may be applied for modelling CO_2 emissions and removals related to biomass: 1) the CO_2 sequestered in biomass during the growth phase is included in the model with negative values in the growth phase and positive values as it is emitted at end-of-life; or 2) the CO_2 sequestered in biomass during the growth phase is included in the model with a characterization factor of zero and emission of biogenic CO_2 correspondingly have a characterization factor of zero. • The biogenic carbon embedded in the bio-based products should also be equal to biogenic carbon released in case of end-of-life treatment of the product with complete oxidation. For this specific case, the net result, summing up the results over the whole life cycle of a product, of both approaches is identical, however contributions of different life cycle steps (e.g. biomass production) to global warming potential will be different.
Interpretation and reporting	• For bio-based products the interpretation phase allows also to consider qualitative information e.g. regarding management practices in the production and final disposal of bio-based products. • In comparison to traditional, existing products such as glass, paper and fossil-based materials, the new generation of bio-based products are often in a relatively early stage of development, and assumptions are needed to portray the life cycle. LCA studies revealing differences in maturity of products or production systems should also be addressed during the Interpretation phase. A thorough check of possible inconsistencies and/or different level of detail of inventories should always be performed in comparative studies between bio-based products and their alternatives.

To deliver this standard, a third-party report (which is mandatory for any type of LCA communication) when intended to be disclosed to the public should include sourcing aspects, treatment of biogenic carbon in the LCA and the treatment of technological maturity.

The only standardized approach to simplify the results out of an LCA is the Type III environmental declaration according to EN ISO 14025. In LCA, the standardized reporting tool is the third-party report. However, the outcome of both options is still often too complex in Business-to-Business and especially Business-to-Consumer communication.

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

3.5.9 EN 16848:2016 Bio-based products - Requirements for Business to Business communication of characteristics using a Data Sheet.

The scope of this standard is to provide the requirements necessary for the transparent and non-misleading **business-to-business communication of bio-based characteristics** by the means of a specific Data Sheet. It is intended as a tool to generate and transfer information in the value chain and/or as an input for product-specific technical standards (applicable to the materials and the final application) and certification schemes.

For the purpose of this standard, the terms "claim, label and declaration" are defined as a statement, symbol or graphic that indicates an aspect of a bio-based product that could be placed on a product or packaging label, in product literature, in technical bulletins, in advertising or in publicity, materials safety data sheets, etc.

To adhere with this standard, a declaration must be made through a Data Sheet that;

- Is in accordance with ISO 14020
- Clearly identifies whether the declaration concerns the packaging, packaging components, or the product.
    - Separate claims can be made on different components provided they can be separated (where information on how to separate the components is given when not self-evident)
- Includes product name, supplier name, bio-based (carbon) content (given as %), intended use, biomass type and origin, sustainability aspects, and end of life. As described in the Table 7.

Table 7: Details of the information required for business-to-business communication, as provided by EN 16848:2016

Required information	Details
Product name	Information to unequivocally identify the product, e.g. type, grade, batch code, reference, trade name/mark, IUPAC name, molecular formula, EC number etc.
Supplier name	Information to unequivocally identify the supplier, e.g. name, address and contact details.
Intended use	Indication of intended use e.g. industrial sector, one or more applications or processing technologies.
Biomass type	Type of biomass e.g. plants, trees, algae, marine organisms, etc. used to produce the bio-based product.
Biomass origin	Geographic origin of the biomass used
Bio-based (carbon) content	Clearly distinguish between the two approaches, i.e. is fraction of biomass determined from bio-based carbon content (e.g. EN 16785-1) or bio-based content (e.g. EN 16785-2). Both values should be declared.
Sustainability aspects	Present any statement of sustainability in correspondence to the biomass-based fraction only (i.e. not the whole product), based on aspects detailed in EN 16751. If any

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

	standards or certification systems are used, these should be stated, and proof of compliance provided.
End of Life	Information regarding characteristics that are used to assess the potential impact of different end of life options should be provided. When the end-user is known, the requirements for claims on end of life options in ISO 14021 should be followed where applicable.

3.5.10 EN 16935:2017 Bio-based products - Requirements for Business-to-Consumer communication and claims

The scope of this standard is to provide the requirements necessary for the transparent and non-misleading **business-to-consumer communication of bio-based characteristics** by the means of labelling and claims. It is intended as a tool to generate and transfer information to the consumer or as an input for product-specific standards and certification schemes.

For the purpose of this standard, the terms "claim, label and declaration" are defined as a statement, symbol or graphic that indicates an aspect of a bio-based product.

To adhere with this standard, communication should;

- Clarify whether the communication and/or claim concerns the packaging, packaging components or the product.
    - Separate claims can be made on different components provided they can be separated (where information on how to separate the components is given when not self-evident)
- Include the following information, where the claim "bio-based" is used - minimum bio-based content and recommended end of life strategy for the product (where the decision regarding disposal lies with the consumer). Information pertaining to sustainability aspects or additional information can also be included.
- Present the value for bio-based content as a minimum percentage of biomass content in relation to the total dry mass, as determined according to EN 16785-1. Th following format should be used: '*minimum X % bio-based*' or '*> X % bio-based*', where X is the value for bio-based content.
- Present any statement of sustainability in correspondence to the biomass-based fraction only (i.e. not the whole product), based on aspects detailed in EN 16751. If any standards or certification systems are used, these should be stated.
- Be readily available and other relevant information should be accessible.
    - Communications can be physically attached to or on the product and contain either physical or virtual information.
- Information that determines the end of life options for the product should be communicated, especially in cases where the disposal decision lies with the consumer.

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

- For products designed to undergo end of life within the environment (e.g. mulch films), a claim of biodegradability, based on a relevant internationally recognised standard or test methods should be included.

To deliver this standard, communication with the consumer should include the points raised above. Claims can be given as (any combination) of text, symbols and graphics, with display examples given below (Figure 8).

Bag	
bio-based content............	> 99%
biomass sustainability......	biomass sourced according to <name>, <reference>
disposal...............................	industrially compostable Check availability with your local authority

EN 16935

Bottle	
bio-based content............	> 30%
biomass sustainability......	biomass sourced according to <name>, <reference>
disposal...............................	plastic recycling Check availability with your local authority
Detergent	
additional information....	biodegradable in nature <reference>

EN 16935

Bio-based content		Disposal
Bag	Bag	Bag
> 99% bio-based content	*biomass sourced according to <name.>, <reference>*	*Seedling Logo* Industrially compostable *check availability with your local authority*

EN 16935

Figure 8: Examples of communication display, reproduced from EN 16935:2017

This standard provides a basic framework concerning the type of information that should be included within communication between business and consumers. It may be argued that the examples above oversimplify several aspects, for example more detail should be given regarding the product, i.e. “bag” should be replaced with shopping bags, fruit/vegetable bag, bio-waste bag etc. and “bottle” should be expanded to include the material such as rPET. Furthermore, the use of the phase “biodegradable in nature” may be misleading and could foster increased cases of intentional littering. Here, an alternative phrase could be “In cases of unintentional release, biodegrades in marine / soil / composting facilities” (as according to EN 13432:2002). It also relies on existing logos and certification schemes (such as the seedling logo), especially with reference to compostability and bio-degradability. The use of existing certification schemes is further explored in the next section (Section 3.6).

Horizon 2020

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No. 860407

3.6 Biodegradability standards (EU vs. International)

Degradation, as defined by ISO (2013), is

> *"an irreversible process leading to a significant change of the structure of a material, typically characterized by a loss of properties (e.g. integrity, molecular weight, structure or mechanical strength) and/or fragmentation."*

As shown by *Figure 9*: The two stages of degradation, adapted from Krzan et al. (2006) the degradation process is completed across two phases: disintegration and mineralisation, where these phases rely on a combination of various mechanisms and factors. Disintegration starts with noticeable fragmentation when plastics are exposed to an environment that results in the collapse of the macromolecular architecture. Key environmental factors that cause disintegration, and thereby degradation, include; heat (thermal-degradation), sunlight (photo-degradation), oxygen (oxidative-degradation), water (hydrolytic-degradation), physical stress (mechanical-degradation), and most importantly for this study, microorganisms (biodegradation). While the first phase sees the deterioration of physical properties, the second phase, mineralisation, completes the ultimate conversion of plastic fragments into their molecular components. This second phase also requires the presence of microorganisms to enable aerobic or anaerobic digestion (Krzan et al., 2006).

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

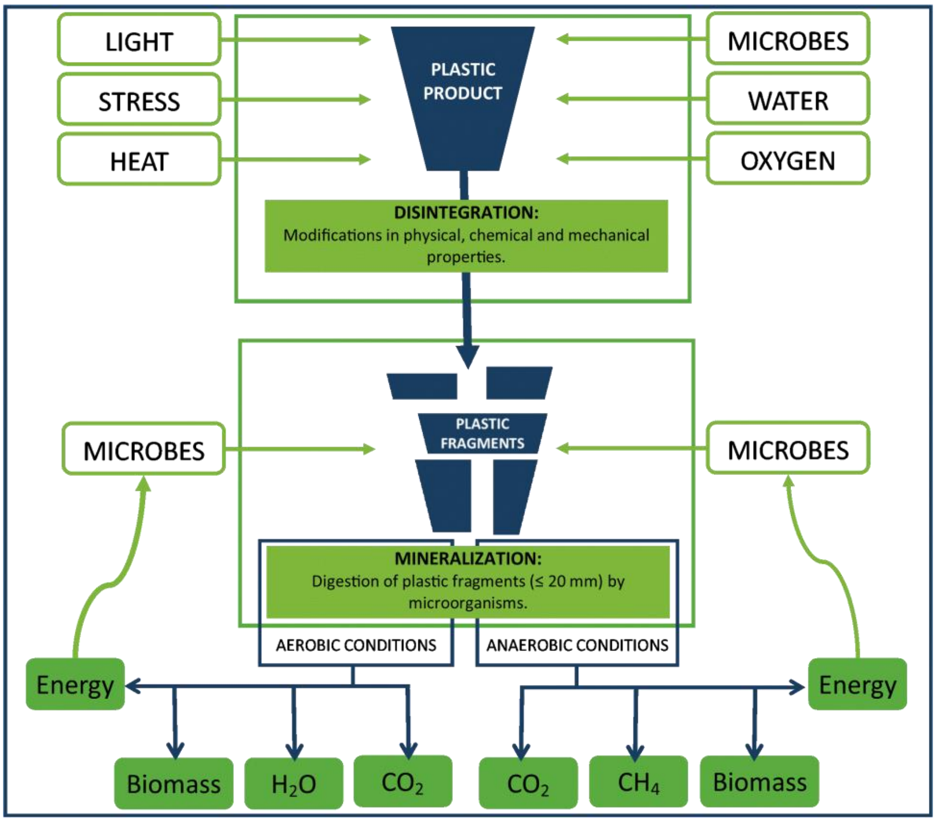

Figure 9: The two stages of degradation, adapted from Krzan et al. (2006)

The first standardised test methodology specifically for the biodegradability and compostability of plastic products was published by ASTM in 1999, although prior to this ISO had published several standards on the biodegradation of organic compounds (Krzan et al., 2006). More recently, a review completed by Philp et al. (2013), identified a considerable list of international standards concerning the biodegradation of plastics (both petroleum and bio-based) and highlighted a number of challenges for comparative assessment. Challenges include the influence of the test environment – is it anaerobic or aerobic, compost, soil, fresh or marine water etc., and the use of many different terms such as ready vs. inherent vs. complete biodegradation. To overcome these challenges, the environment in which the material ends-up after use should inform testing method. Consideration must also be given to differences in performance, i.e. laboratory-scale tests vs. real-life situations (Philp et al., 2013).

A key challenge is the one-directional relationship between (and claims of) biodegradability and compostability (Krzan et al., 2006). While a product must be able to biodegrade to be compostable, the reverse is not true – i.e. a biodegradable material does not have to degrade in the environment and timeframe specified for composting (Krzan et al., 2006). Therefore, correct claims concerning biodegradability and compostability are important. Furthermore, Philp et al. noted even if a material passes a biodegradability test in an aerobic environment, it is highly possibly that it would not biodegrade as well within a landfill. So, labelling a material or product

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

as biodegradable may be misleading if the local waste infrastructure cannot perform aerobic biodegradation (Philp et al., 2013).

Given the importance of composting, as an environmentally friendly waste management treatment method, many international standards concern aerobic degradation tests in composting conditions (Krzan et al., 2006). Biodegradability / compostability standards published by ISO, generally consider aerobic biodegradation within aqueous and composting environments, based on the amount of oxygen demanded by the system or the amount of CO_2 evolved from the reaction. Most of the testing methodologies are carried out either in controlled (composting) or under laboratory conditions. However, overall the ISO standards cover a range of circumstances including; aerobic composting (in soil and industrial compost facilities – as mentioned previously), anaerobic digestion, littering on marine sandy sediment or in a river of continuous flow, and in biogas production.

In addition to general biodegradability standards published by ISO, the EU has also published a range of standards specific to the *biodegradability of packaging materials*. The EU standards specific to the biodegradability of packaging focus mainly on compostability and anaerobic treatability. Testing methodologies are carried out in a variety of circumstances such as pilot-scale aerobic composting facilities, controlled laboratory-based conditions and under defined composting conditions.

Addressing one of the key challenges previously highlighted, labelling of products and materials to indicate its relative biodegradability and/or compostability could promote the correct use and proper end-of-life management. National labelling schemes such as those in the US, Germany, Belgium and Japan (Figure 10), show compliance with one or more of the following standards; ISO 14851, EN 13432 and ASTM D6400 (Krzan et al., 2006). Here, standards that determine the biodegradability and/or compostability of materials and products can be used as input into labelling and certification schemes to aid communication between businesses and end-users. Of course, these labels only indicate the potential of products and materials to be biodegradable / compostable, and do not reflect the availability of any local waste management infrastructure. Furthermore, as each country (and often separate companies) utilise their own logo to indicate that a product is bio-based, compostable or biodegradable, this may lead to duplicity of certification / logos and therefore may create confusion among consumers. Instead, the creation of a unique and harmonised logo, that identifies a product as bio-based and is based on the level of compostability / biodegradation within a given end-of-life scenario (e.g. in soil, marine water, composting facilities, etc.).

Horizon 2020 This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

USA

- Biodegradable Products Institute
- ASTM D6400 or D6868
- Product is compostable in an industrial facility

Germany

- International Biodegradable Polymers Association and Working Group
- EN 13432 or ASTM D6400
- Product will biodegrade in an industrial composting facility

Belgium

- AIB Vinçotte
- EN 13432 or ISO 14851
- Can differentiate between home/industrial composting, soil/marine environments and % bio-based content

Japan

- Biodegradable Plastics Society
- ISO 14851
- Product is biodegradable

Figure 10: National certification schemes for biodegradability

Horizon 2020 This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

3.7 Product Group 1: Toys

The first product group being considered within the Bio-plastics Europe project is toys, with a specific focus on beach/sand toys.

Sand toys are made from rigid plastic, generally acrylonitrile butadiene styrene (ABS) or polypropylene (PP) that is made to be durable during use. They are produced for use by children aged 3+ years old, under adult supervision.

Innovation within the Bio-plastics Europe project will investigate the use of bio-based plastic materials, namely a PHBV-based material (referred to as BPE-T-PHBV), which contains impact modifiers to enable the product to bio-degrade when lost or left behind.

This Photo by Unknown Author is licensed under CC BY-SA

3.7.1 Toy safety regulations

All toys, regardless of type, need to adhere to Directive 2009/48/EC (EU, 2009) on the safety of toys. This directive, as well as a comparable US policy - the US Consumer Product Safety Improvement Act of 2008, were developed after a series of violations of existing safety standards saw more than 19 million toys recalled worldwide in one year (Larson and Jordan, 2018).

The Toy Safety Directive (2009/48/EC) lays down provisions concerning assessment of conformity, CE marking and market surveillance for product entering the community market. It also provides obligations for manufacturers, importers and distributors (EU, 2009).

Essential safety requirements laid out by Directive 2009/48/EC states that;

- ➔ toys must not be placed on the market unless they comply with these requirements
- ➔ toys shall not jeopardise the safety or health of users, or third parties, when used in the way intended, bearing in mind the behaviour of children
- ➔ toys shall comply with these requirements during their foreseeable and normal period of use.

Before placing a toy on the market, analysis of any **chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards** that the toy may present, as well as an assessment of the potential exposure to such hazards, should be completed.

A further consequence of these policies was the emergence of a series of international safety standards, namely ISO 8124 series, ASTM F963 series and the EN-71 series (Larson and Jordan, 2018).

A key component of Directive 2009/48/EC is the use of the EC-label to highlight conformity and the use of appropriate warnings. Requirements of the EC-label states that any warning should be

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

clearly visible, easily legible and understandable, and accurate, attached either on an affixed label, on the toy itself or accompanying instructions (EU, 2009).

3.7.2 Safety components specific to beach/sand toys

According to Directive 2009/48/EC toys should be designed and manufactured in such a way as to meet hygiene and cleanliness requirements in order to avoid any risk of infection, sickness or contamination. Under the general requirements of EN 71-1:2014+A1:2018, sand toys must exhibit material cleanliness where it is visually clean (assessed by the unaided eye) and free from infestation. Furthermore, any accessible edges must not present an unreasonable risk of injury. To determine whether small parts, sharp edges or sharp points may become accessible during use, as well as suitability for children under 36 months, the following mechanical tests can be performed; the drop test, the impact test and the compression test.

As well as the physical and mechanical elements, consideration of the flammability, migration of certain toxic elements and other chemical compounds may be needed. As such, the use of EN 71-:2011+A1:2014 should be used to determine flammability, EN 71-9: 2005+A1:2007, EN 71:10:2005 and EN 71-11:2005 are used to determine migration and/or content or hazardous chemical compounds, and EN 71-3:2019 is used to determine migration of other toxic elements.

Horizon 2020

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No. 860407

3.8 Product Group 2: Packaging

The second product group being considered within the Bio-plastics Europe project is packaging, with a specific focus on rigid and soft food packaging.

Creator: curtoicurto | Credit: Getty Images/iStockphoto

Rigid food packaging, such as that used for cosmetic and drinks bottles, is generally made from high density polyethylene (HDPE), polypropylene (PP) and polystyrene (PS). Soft food packaging, such as that used for yoghurt pots are generally made from polyethylene (PE) and polypropylene (PP). The primary function of any type of packaging is to contain and protect the contents by providing a barrier to water, oxygen, leakage, contamination, etc.

Innovation within the Bio-plastics Europe project will investigate the use of bio-based plastic materials, namely a PBS-based material (referred to as BPE-SP-PBS) for use as soft packaging and a PLA-based material for rigid packaging (referred to as BPE-RP-PLA).

3.8.1 Food safety legislation

Food contact materials are ubiquitous in everyday life, particularly in the form of food packaging. When in contact with food, these materials may behave differently and transfer their constituents to the food. Some constituents, if in large enough quantities, may create a risk to human health or change the food itself, therefore these materials are subject to legally binding rules and regulations (Karamfilova, 2016).

Any material that comes into contact with food must adhere with food safety laws, namely the Regulations (EC) 1935/2004 and (EC) 2023/2006, which are applied to all materials, and Regulation (EU) 10/2011 that is focused on plastic materials and provides a revision known as the Plastic Implementation Measure (PIM).

n.b:. Where a 'Directive' sets out a result that each member state must achieve on a particular issue, it allows each member states to decide on the approach and methods taken. In comparison, a 'Regulation' provides both the result needed to be achieved as well as the approach/method to be taken.

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

In line with EU General Food Safety Law, Regulation (EC) 1935/2004 focuses on food contact materials. Key objectives of this directive are to ensure the effective functioning of the internal market and to secure a high level of human health and consumer protection. To do this, (EC) 1935/2004 sets out two main requirements; (1) all food contact material should be manufactured using 'Good Manufacturing Practices' (as defined by (EC) 2023/2006) so that under normal conditions and usage, they do not transfer their constituents to food in quantities that could endanger human health, bring about unacceptable changes in composition or causes deterioration of organoleptic characteristics (flavour, colour, texture, etc.), and, (2) any labelling, advertisement or presentation of the material should not mislead the consumer (EC, 2004). Suitability for food contact can be indicated through the words 'for food contact', reference to a specific use (e.g. wine bottle, soup spoon etc.) or by using the symbol shown in Figure 12.

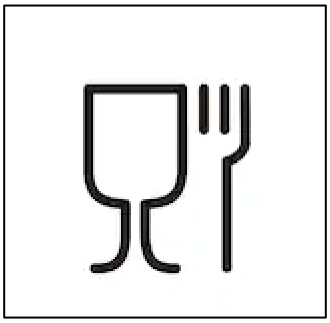

Figure 11: Food Grade symbol reproduced from Annex II Reg (EC) 1935/2004

'Good Manufacturing Practices' as defined by Regulation (EC) 2023/2006 obligate business operators in all stages of manufacture, processing and distribution, to establish, implement and adhere with quality assurance and quality control systems (EC, 2006).

Where the food contact material contains plastic (either exclusively or as part of a multi-layer material), regulation (EU) 10/2011 should be adhered to. This regulation applies to plastic materials and products intended to come into contact with food, already in contact with food or can reasonably be expected to come into contact with food. This regulation sets out specific and overall migration limits such that the plastic material or product should not transfer constituents to foods in quantities that are harmful to human health. Specific migration limits for Barium, Cobalt, Copper, Iron, Lithium, Manganese and Zinc are provided as well as a release limit for primary aromatic amines (Table 8). This regulation also provides a number of food simulants that should be used and assigns simulants to food categories to aid appropriate testing regimes (EC, 2011a).

Table 8: Analysis and migration limits for constituents of plastic material intended for use in contact with food, as detailed by Regulation (EU) 10/2011 (EC, 2011a).

Constituent	Test method	Migration limit
Any substance	Testing should be performed under standardised test conditions including testing time, temperature and test medium (food simulant) representing worst foreseeable conditions of use of the plastic material or article. • Generally, all materials and articles should be tested with food stimulants A (Ethanol 10% v/v), B (Acetic acid 3% v/v)	No more than 10 mg of total constituents released per 1 dm^2 of food contact surface area (mg/dm^2). Food intended for infants and young children, no more that 60mg of total constituents released per kg of food stimulant.
Barium		No more than 1 mg/kg of food or food stimulant.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

<table>
<tr><td>Cobalt</td><td rowspan="7">and D2 (Vegetable oil). Other stimulants may be appropriate depending on the food type intended to be contained.
Test conditions (time and temperature) depends on the envisioned contact time and temperature under the worst foreseeable conditions.
Analysis of migrating substances should be completed in accordance with Article 11 of Regulation (EC) No 882/2004, and should comply with relevant community rules, internationally recognised protocols (e.g. those accepted by CEN) or scientific protocols deemed fit for purpose.</td><td>No more than 0.05 mg/kg of food or food stimulant</td></tr>
<tr><td>Copper</td><td>No more than 5 mg/kg of food or food stimulant</td></tr>
<tr><td>Iron</td><td>No more than 48 mg/kg of food or food stimulant</td></tr>
<tr><td>Lithium</td><td>No more than 0.6 mg/kg of food or food stimulant</td></tr>
<tr><td>Manganese</td><td>No more than 0.6 mg/kg of food or food stimulant</td></tr>
<tr><td>Zinc</td><td>No more than 25 mg/kg of food or food stimulant</td></tr>
<tr><td>Primary aromatic amines</td><td>Sum of primary aromatic amines released shall not exceed the detection limit of 0.01mg/kg of food or food stimulant.</td></tr>
</table>

3.8.2 General Product Safety

In addition, any products (without specific safety regulations) should also conform with the General Product Safety Directive (92/59/EEC) that ensures any products placed on the European market are safe. Here, a "safe product" is defined as:

> *"any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons."*

This considers the characteristics of the product, its effect on other products, its presentation (including labelling, warnings and instructions for use) and categories of 'at risk' consumers. A product is presumed safe when they conform with European / nationally transposed safety standard, or in the absence of such; voluntary national standards, commission recommendations, sectoral codes of good practice, state of the art and technology and/or reasonable consumer expectations are adhered to.

3.8.3 Safety components specific for rigid vs. soft food packaging

To determine which test conditions and methods are to be used to analyse overall migration of substances from materials and articles in contact with food, EN 1186-1:2002 should be consulted. Not only does this standard set out the types of test that are applicable but also designates the most appropriate food stimulant. For example, in testing materials used for yogurt pots, the stimulant B, 3 % acetic acid (w/v) in aqueous solution, should be used. In light of the parameters laid down in this standards, the most suitable test methods in EN 1186-2 to EN 1186-9 would then be used. Where the product is likely to come into contact with low (refrigerator / freezer) or high (oven / microwave) temperatures, the following standards; EN 1186-12 and EN 1186-13, respectively, should also be considered.

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

3.9 Product Group 3: Cutlery

The third product group being considered within the Bio-plastics Europe project is reusable outdoor cutlery.

Reusable outdoor cutlery is generally made from polypropylene (PP), with rigid, durable characteristics, that allow for stability during use and heat-proof properties, for example when in contact with hot foods and/or dish-washer cycles.

Innovation within the Bio-plastics Europe project will investigate the use of bio-based plastic materials, namely a PLA-based material (referred to as BPE-C-PLA) that will enable the product to bio-degrade when lost or left behind.


This Photo by Unknown Author is licensed under CC BY

As with the packaging products highlighted above, reusable outdoor cutlery has to adhere with the rules and requirements concerning the Food Contact Materials (FCM) regulations and the General Product Safety (GPS) Directive.

3.9.1 Safety components specific for reusable cutlery

As well as ensuring that the materials used, and the design of these products, adhere with FCM regulations and GPS, it has been recommended that reusable plastic cutlery show heat-proof properties, specifically resistance to mechanical dish washing.

Testing the resistance of domestic articles, such as plastic cutlery, to mechanical dish washing, EN 12875-1:2015 provides a test method that incorporates the combined chemical, thermal and mechanical stresses expected in the use of domestic dishwashers. This standard defines dishwashing resistance as the “ability of the article to withstand a number of test cycles without significant change”. This standard does not, however, define the number of cycles any given product should be able to withstand, but it does require that at least 125 test cycles are completed during the test. After each cycle, the articles should be inspected for deviations from the original through a visual inspection.

Where the cutlery is intended for use by children aged up to 36 months, the standard EN 14372:2014 (Child use / cutlery and feeding utensils) should also be considered. General requirements of this standards include;

- When assembled for use, all components should be free from points and edges that are likely to cause injury (tested in accordance with EN 71-1). The product should also be free from splinters, burrs and flash. Smalls parts, finger traps (holes between 5.5 – 12mm), and removable decoration should also be avoided.
- When subjected to tensile strength, torque, tear resistance, strength/rigidity and drop tests, the product should not break, tear or become separated.

Horizon 2020
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No. 860407

- Products made from thermoplastics should be tested for migration of certain soluble elements (antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium), phthalate content, and when containing polycarbonate or polysulfone Bisphenol A release.
- When made from thermosetting plastics, products should be tested for migration of soluble elements and Formaldehyde release.
- Limits for soluble elements, phthalate content, Bisphenol A release and Formaldehyde release are given (Table 9).

Table 9: Migration limits and test methods for soluble elements, phthalate content, Formaldehyde release and Bisphenol A release, as detailed by EN 14372:2002

Constituent	Test Methods	Limits
Antimony	Soluble elements are extracted from the individual components of the cutlery and feeding utensils. Conditions which simulate contact with stomach acid shall be used. The concentrations of the soluble elements are described quantitatively. • Test shall be carried out according to EN 71-3	15 mg/kg
Arsenic		10 mg/kg
Barium		100 mg/kg
Cadmium		20 mg/kg
Lead		25 mg/kg
Chromium		10 mg/kg
Mercury		10 mg/kg
Selenium		100 mg/kg
Phthalate	The aim of the method is primarily to extract, identify and quantify monomeric phthalates contained in the samples. The extraction method uses Soxhlet extraction apparatus with diethyl ether. The total diethyl ether extractable plasticiser content is calculated by weight with Gas Chromatography-Mass Spectroscopy (GC-MS) detection to identify and quantify individual phthalates.	0.1% (m/m)
Formaldehyde	The levels of formaldehyde release from cutlery and feeding utensils shall be determined using the method outlined in EN ISO 4614.	15 mg Formaldehyde / kg migration liquid
Bisphenol A	BPA is extracted from the test articles into aqueous food simulant, identified and its level determined by high performance liquid chromatography (HPLC) with ultra violet diode array detection (UV-DAD) and fluorescence detection (FLD).	0.03 µg/ml into aqueous food simulant.

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

3.10 Product Group 4: Agriculture products

The next product group being considered within the Bio-plastics Europe project is agriculture products, specifically mulch films.

Mulch films are generally made from polyethylene (PE). The purpose of mulch films is to provide protection and/or to add fertilizer or fungicide to agricultural fields. They can be designed to be used and removed, where they are then disposed of or recycled. Others are designed to be left on the soil, where they biodegrade in a controlled fashion after a fixed period of time.

This Photo by Unknown Author is licensed under CC BY-SA

Innovation within the Bio-plastics Europe project will investigate the use of a PLA-based material (referred to as BPE-MF-PLA) for agricultural mulch films that enables the controlled biodegradation and the controlled release of fertilizer.

3.10.1 Technical standards for mulch films

CEN have developed several technical standards concerning the use of agricultural films. These standards cover silage bale wrapping, barrier (fungicide) films, recyclable silage/mulching films and other thermoplastic covering films. For the purpose of this report, only standard EN 17033:2018 has been evaluated to be within the scope of the overall Bio-plastics Europe project. The overall objective of this standard is to ensure that the film will biodegrade in soil without creating any adverse environmental impacts. It specifies test methods to determine the control of constituents, biodegradation, ecotoxicity, appearance and technical properties (for more detail see Table 10). It also provides the requirements for the packaging, identification and marking of films. This standard defines a classification of biodegradable mulch films according to their service life on soil and provides a good practice guide for the use of such films.

Table 10: Test methods and limits for biodegradable mulch films, as detailed by EN 17022:2018

Test aspect	Test Methods	Limits
Control of constituents	Concentration of regulated metals shall be tested in line with ISO 17294-2 / ISO 12846.	Concentration of regulated metals must not exceed: Cd – 0.5 mg/kg of dry matter Cr – 50 mg/kg of dry matter Cu – 50 mg/kg of dry matter Hg – 0.5 mg/kg of dry matter Ni – 25 mg/kg of dry matter Pb – 50 mg/kg of dry matter Zn – 150 mg/kg of dry matter

Horizon 2020 This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

		"Substances of Very High Concern" shall not exceed a conc. limit of 0.1% (by weight). Materials used to manufacture mulching products shall not contain less than 60% by mass volatile solids (largely excluding inert products)
Biodegradation	Test in accordance with ISO 17556	Samples should not be subjected to conditions and/or procedures designed to accelerate biodegradation. Over 24 months, 90% of the organic carbon shall be converted to CO_2, either in absolute terms or relative against a reference material.
Ecotoxicity	Test methods include; Acute toxicity plant growth test, Acute toxicity earthworm test, Chronic toxicity earthworm test and Nitrification inhibition test with soil microorganisms.	Investigate possible adverse effects caused by constituent materials or intermediate residues.
Appearance	Visual checks [1]Can be checked by unrolling at least 2m and examining it against the light.	Free edges of the roll shall be sealed with adhesive tape or by some other similar means to prevent unwinding. Sufficient tension to prevent layers of the roll from transversal slipping when handled. [1]Shall be homogeneous for the purpose of application
Technical properties	Determination of thickness: Test in accordance with ISO 4593. Determination of width: Test in accordance with ISO 4592. Determination of film length Determination of tensile characteristics: Test in accordance with ISO 527-1 and 527-3. Determination of impact resistance: Test in accordance with ISO 7765-1:2004.	Tolerance of nominal thickness ±10%, tolerance of single point thickness ±25% Width tolerance ±2% (or -1, +2 mm for mulching maize) Roll length tolerance ±2% Tensile stress at break (MD/TD) on unexposed film is; ≥16/16 MPa – nominal thickness is < 10µm ≥18/16 MPa – ≥10 - ≤15µm, ≥18/16 MPa – > 15µm Tensile strain at break (MD/TD) on unexposed film is; ≥100/250% - where the nominal thickness is < 10µm ≥150/300% - ≥10 - ≤15µm ≥200/350% - > 15µm Impact resistance; ≥60g - where the nominal thickness is < 10µm ≥80g - ≥10 - ≤15µm ≥100g - > 15µm

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

3.11 Product Group 5: Fisheries and aquaculture products

The final product group that is being considered within the Bio-plastics Europe project are fisheries and aquaculture products; namely fishing bait (as known as lures), fish transport crates and marine geomaterials.

This Photo by Unknown Author is licensed under CC BY

Plastic fishing bait, or lures, are mainly used in recreational angling and closely resemble, and therefore provide an alternative to, live bait. While there are hundreds of different types and brands of fishing lures, generally they are made from softened plastic such as polyvinyl chloride (PVC). Their durability and subsequent longevity, as a result of being composed of inert non-biodegradable synthetic polymers, means that they can be reused and thus, multiple fish can be caught during a lure's lifetime (Raison et al., 2014).

Fish transport crates are generally made from high density polyethylene (HDPE). They are used to store fresh fish and to aid transportation between fishing vessel and appropriate market place (i.e. retail, wholesale, etc.). They are designed to be durable so that they are resistant to high impacts and can be reused multiple times.

Marine geomaterials are one of many geotechnical engineering materials, also known as geosynthetics or geotextiles, which are generally made from polyethylene (PE), polypropylene (PP), polyester, and polyvinyl chloride (PVC). They are utilised in a range of geotechnical engineering applications, where they are used to (1) prevent the migration of liquids (and/or gases), (2) contain soils and sediments, (3) drain, collect and transport liquids, (4) filter fluids from soils, (5) prevent or reduce localised stress, (6) reinforce structures, (7) prevent intermixing of two dissimilar materials, (8) control surface erosion and/or (9) increase or reduce frictions across an interface (Müller and Saathoff, 2015). The marine geomaterials specifically considered within the Bio-plastics Europe project concern those used to contain and support embankments. While the geomaterials restrict the movement, and therefore loss, of soils and substrate, they also allow the growth of vegetation such as seagrass that in turn replace the binding structure given by the geomaterial.

For marine geomaterials, a PLA-based material (referred to as BPE-AM-PLA) that decomposes after final fixation of roots (e.g. of seagrass) will be investigated. For fishing bait, a PLA-based material (referred to as BPE-AM-PLA2) will be investigated. And finally, for the fish transport crates, a PHBV-based material (referred to as BPE-AM-PHBV) will be investigated.

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

3.11.1 Safety components specific to aquaculture products

The aquaculture products listed here must adhere with the General Product Safety (GPS) Directive to ensure that they are fit for purpose and are made of a suitable quality. Other issues, specific to the three product types, that may require further consideration are noted below.

Fishing bait / lures

A key issue raised by Raison et al. (Raison et al., 2014) regarding the use of plastic lures reflect the consequences of when a lure is lost, i.e. either ingested by the fish (immediately or through foraging) or lost to the environment. If a lure was to be ingested, it may act as a 'bezoar' (a non-digestible, non-degradable foreign object that obstructs the gastrointestinal tract) particularly if the lure contains porous plastic that swells when water is absorbed. The subsequent consequence of this may be a reduction in body condition and possibly anorexic behaviour. For those lost in the environment, due to their durability they do not degrade and thus remain in the environment for a prolonged time. Whilst settled on the bottom, this increases the risk of being digested by fish, especially those who forage on the bottom (Raison et al., 2014). While this highlights potential fish-welfare issues, it also raises another: what is the impact of ingested plastic lures on the food chain, especially when considering species included within the human diet? Specifically concerning the bioaccumulation of plastics across species and the migration of harmful/toxic substances through the food chain.

Fish transport crates

Similar to food packaging, fish transport crates must be shown to adhere with Food Contact Materials (FCM) regulations as they are used to store and transport food items. To determine which test conditions and methods are to be used to analyse overall migration of substances from materials and articles in contact with food, EN 1186-1:2002 should be consulted. Not only does this standard set out the types of test that are applicable but also designates the most appropriate food stimulant. In light of the parameters laid down in this standard, the most suitable test methods in EN 1186-2 to EN 1186-9 would then be used. As this product is very likely to be used within very cold temperatures (e.g. freezers), consideration of EN 1186-12 should be taken.

Marine geomaterials

A key issue raised by Müller and Saathoff (2015) regarding the use of marine geomaterials is the environmental impact of degradation products and the emission of additives. As these geomaterials age, they become more brittle and therefore more likely to rupture and disaggregate. However, as this would also cause the material itself to fail, it can be seen as a technical issue. As such maintenance schedules that would identify early aging effects are important. So too, is the material selection, where the geomaterials used must be fit for purpose during the entire envisaged service life (Müller and Saathoff, 2015).

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

4 Summary

The use of plastic products has become ubiquitous throughout our everyday lives. However, the production and disposal of plastic products are often damaging to the environment. For example, in addition to the environmental damage caused through the extraction and manipulation of fossil fuel feedstock, conventional plastic products, due to their non-biodegradability can accumulate and then persist in a variety of ecosystems, finding their way into localised food chains and smothering communities. Utilisation of bio-based and biodegradable plastics have been identified as a possible way to counteract the negative impacts of plastic use. However, for bio-based plastics to be successful in replacing conventional plastics, they must be shown to be safe both during and after use. This document by employing a comprehensive literature review, sought to summarise the current EU approach that ensures the safe use and end-of-life management (particularly biodegradability) of bio-based materials, with a specific focus on the following consumer products; toys, food packaging, cutlery, agricultural mulch films and aquaculture equipment.

As the trade of products and services are often based within a globally interconnected economy, robust and comparable methods are key to ensuring safety. The EU has been identified as one of the main international regulators: widely regarded as having some of the strictest public health and environmental safety regulations in the world. Within the EU, safety is ensured through the interconnected use of directives, regulations, standardisation and protocols. Directives and regulations provide the targets and limits that should be applied to products and materials to ensure their safety. Acting in a complementary role, standardisation documents can be used to ensure compatibility across network externalities, reduce (often negative) environmental impacts and/or overcome information asymmetry between producers and consumers in light of safety aspects. Practically they can contain a set of rules or guidelines, provide a definition or outline a specific methodological approach.

The use of standardisation also helps aid the development of emerging markets, where a lack of standardisation can act as a barrier and limit the uptake of products within consumer markets and in public procurement. Indeed, the use of standardisation has been promoted within the EU to increase the uptake of bio-based materials and products, aiming to overcome the historically fragmented and non-innovation friendly market. Starting with an initial report in 2007, a broad assessment of existing and emerging markets recognised the societal benefits of bio-based products. It also acknowledged the need for greater policy coordination and demand-side measures such as standardisation, labelling and end-user communication. Following the publication of two European mandates (M429 and M430), standardisation organisation, CEN took on the challenge of exploring the potential of setting EU-wide bio-based products standards. To address this challenge, the Bio-based Products Working Group (established by CEN) identified relevant stakeholders, provided basic definitions, assessed the need to standardise terminology and evaluated existing standards. They also identified the need to develop a set of umbrella standards, suggested the expansion of labels and certification schemes, and highlighted potential coordination with the ISO 14040 series to incorporate bio-based products into LCA frameworks.

Horizon 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

The work completed by CEN resulted in the publication of 10 standardisation documents, specifically focused on bio-based materials. The vocabulary standard defines a list of bio-based related terms. An important note here, is the frequent incorrect use of the prefix bio, for example in bioplastic, where the standard encourages the use of the term "bio-based" to ensure transparency and non-misleading information. Several standards that can be used to determine bio-based content based on different carbon-based and non-carbon-based methods (radiocarbon analysis, material balance and elemental analysis) were also published. The remainder of the standardisation documents published during this work programme concern the quantification and communication of desirable properties (e.g. renewable feedstock, degradability, compostability, etc.). Here, a standard was developed that would aid the provision of sustainability information on the following aspects; climate protection, water and soil quality, biodiversity, energy and waste, labour rights, land and water use rights, local development and economic sustainability. Under this standard, these sustainability aspects can be considered with respect to biomass production as well as the use of biomass/ bio-based materials throughout the supply chain. This standard also identified relevant indicators and metrics for each sustainability aspect. Another standard focused on the additional points that require consideration when handling bio-based materials within an LCA (based on the ISO 14040 methodology). Finally, two communication standards provide the requirements necessary for business-to-business and business-to-consumer communication. These are intended to be used as tools to generate and transfer information across the value chain and can be input into product-specific standards and certification schemes.

When it comes to ensuring the biodegradability of bio-based products, and indeed product safety aspects, non-specific / more general (i.e. not bio-based specific) standards, regulations and directives need to be considered. While there is a considerable list of international standards concerning the biodegradation of plastics (both petroleum and bio-based), a number of challenges for comparative assessment have been identified. Challenges include the influence of the test environment; for example, is it anaerobic or aerobic, compost, soil, fresh or marine water etc., and the use of many different terms such as ready vs. inherent vs. complete biodegradation. Another key challenge is the one-directional relationship between (and claims of) biodegradability and compostability, where a compostable product must be able to biodegrade, but a biodegradable product may not necessarily be compostable. This highlights the importance of the correct use of claims concerning biodegradability and compostability.

All products regardless of type or function must be shown to conform with the General Product Safety Directive (92/59/EEC). This means that they do not present any risks to human health / safety under normal, or reasonably foreseen, conditions. For products with a specific function or target consumer group (such as food packaging and toys), other safety rules and regulations also need to be considered. For example, any product that may come into contact with food, such as packaging, reusable cutlery and transport crates (e.g. for seafood) must adhere with food safety laws, namely the Regulations (EC) 1935/2004 and (EC) 2023/2006, which are applied to all materials, and Regulation (EU) 10/2011 that is focused on plastic materials. The Food Contact Materials Regulations ensure that all relevant materials (and subsequent products) are

Horizon 2020 This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

manufactured using Good Manufacturing Practices. Furthermore, under normal conditions/usage, materials do not transfer their constituents to the food contained in quantities that (1) could endanger human health, (2) bring about unacceptable changes in composition, or (3) causes organoleptic characteristics (flavour, colour, texture, etc.) to deteriorate. Toys and care articles (such as children's cutlery) are also subject to further safety provisions. In this case, products intended for use by children must adhere with the Toy Safety Directive (2009/48/EC). Essential safety requirements laid out by this directive ensure that during normal or foreseeable periods of use, these products do not jeopardise the safety or health of users, or third parties, especially when used in the way intended, bearing in mind the behaviour of children. Analysis and the potential risk of any chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards should be completed. Complementary to this directive, the EN-71 series of standards emerged to offer a set of standardised methods to complete these analyses.

4.1 Final remarks

Going forward, the key question is what difference to human health and environmental safety does the use of bio-based plastics have, if any? This could be asked at the level of product safety directives and regulations, i.e. are there any caveats required or particular challenges that need to be addressed for products made from bio-based plastic. For example, an additional issue that could be considered when comparing identical products made from bio-based and conventional plastics concerns durability and degradation. Here, desirable characteristics of the two different material types are in conflict, i.e. the biodegradability of some bio-based materials is a desirable property, whereas in the case of conventional plastics it is the durability of the product during the use phase that is favoured. Albeit, this characteristic of durability in the conventional plastic also provides the problem of persistence in the ecosystem when discarded. In addition, how materials are tested and evaluated, for example through the use of generic testing protocols and standards, should also consider the impact that the presence of bio-based materials may have on the accuracy and appropriateness of such methods. An additional issue of note that needs further consideration is the disparate use of certification schemes and logos in the communication of bio-based products. Under the current system, national and company-level certification schemes and logos are used to infer information regrading bio-based content, compostability and degradability, which in turn may lead to confusion and limited uptake by the end-user. Development of harmonised, international certification scheme (and accompanying logo) that differentiates between different end of life scenarios could help alleviate these issues.

Horizon 2020
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

5 References

Álvarez-Chávez, C. R., Edwards, S., Moure-Eraso, R. and Geiser, K. (2012) Sustainability of bio-based plastics: General comparative analysis and recommendations for improvement, Journal of Cleaner Production, 1 (23). pp.47-56. https://doi.org/10.1016/j.jclepro.2011.10.003

ASTM (2020) Detailed Overview. Retreived from https://www.astm.org/ABOUT/full_overview.html

Bell, J., Paula, L., Dodd, T., Németh, S., Nanou, C., Mega, V. and Campos, P. (2018) EU ambition to build the world's leading bioeconomy—Uncertain times demand innovative and sustainable solutions, New Biotechnology, Pt A (40). pp.25-30. https://doi.org/10.1016/j.nbt.2017.06.010

Berti, K. and Falvey, R. (2018) Does trade weaken product standards?, Review of International Economics, 4 (26). pp.852-868. https://doi.org/10.1111/roie.12345

Boesen, S., Bey, N. and Niero, M. (2019) Environmental sustainability of liquid food packaging: Is there a gap between Danish consumers' perception and learnings from life cycle assessment?, Journal of Cleaner Production, (210). pp.1193-1206. https://doi.org/10.1016/j.jclepro.2018.11.055

Boz, Z., Korhonen, V. and Sand, C. K. (2020) Consumer considerations for the implementation of sustainable packaging: A review, Sustainability (Switzerland), 6 (12). https://doi.org/10.3390/su12062192

Brockhaus, S., Petersen, M. and Kersten, W. (2016) A crossroads for bioplastics: exploring product developers' challenges to move beyond petroleum-based plastics, Journal of Cleaner Production, (127). pp.84-95. https://doi.org/10.1016/j.jclepro.2016.04.003

BSI (2020) UK national standards body. Retreived from https://www.bsigroup.com/en-GB/about-bsi/uk-national-standards-body/

BSI. (2011) PD CEN/TR 16208:2011 Biobased products - Overview of standards., Retreived from https://shop.bsigroup.com/ProductDetail?pid=000000000030235436

CEN-CENELEC (2020a) ISO & IEC. Retreived from https://www.cencenelec.eu/intcoop/StandardizationOrg/Pages/default.aspx#:~:text=CEN%20has%20an%20agreement%20for,Organization%20for%20Standardization%20(ISO).&text=As%20a%20result%2C%20new%20standards,planned%20between%20CEN%20and%20ISO.

CEN-CENELEC (2020b) What is a Standard. Retreived April 2020 from https://www.standardsbuildtrust.eu/what-is-a-standard

CEN (2010a) COMPASS, Retreived from https://www.cen.eu/news/brochures/brochures/Compass.pdf

CEN (2010b) Final Report of CEN/BT/WG 209 "Bio-based products", Retreived from https://www.biobasedeconomy.eu/wg-209-bio-based-products/

CEN (2011) Business Plan: CEN/TC 411 Bio-based products, Retreived from https://standards.cen.eu/dyn/www/f?p=204:7:0::::FSP_LANG_ID,FSP_ORG_ID:25,874780&cs=1BF58D5EAF35E439A7F6E73B274FBFDB8#1

CEN (2020a) European Standards. Retreived from https://www.cen.eu/work/products/ENs/Pages/default.aspx

CEN (2020b) Technical Board. Retreived from https://boss.cen.eu/TechnicalStructures/Pages/BT.aspx

Horizon 2020 This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

CENELEC (2020) About CENELEC: Who we are. Retreived from https://www.cenelec.eu/aboutcenelec/whoweare/index.html
De Besi, M. and McCormick, K. (2015) Towards a bioeconomy in Europe: National, regional and industrial strategies, Sustainability (Switzerland), 8 (7). pp.10461-10478. https://doi.org/10.3390/su70810461
Dupont-Inglis, J. and Borg, A. (2018) Destination bioeconomy – The path towards a smarter, more sustainable future, New Biotechnology, (40). pp.140-143. https://doi.org/10.1016/j.nbt.2017.05.010
EC (2004) REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC Retreived from https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32004R1935
EC (2006) COMMISSION REGULATION (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food Retreived from https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32006R2023
EC (2007) Accelerating the Development of the Market for Bio-based Products in Europe: Report of the Taskforce on Bio-based Products. Composed in preparation of the Communication "A lead market Imitative for Europe" {COM(2007)860 final}, Retreived from https://edepot.wur.nl/162176
EC (2008a) M/429 Mandate addressed to CEN, CENELEC and ETSI for the elaboration of a standardisation programme for Bio-based products., Retreived from https://ec.europa.eu/growth/tools-databases/mandates/index.cfm?fuseaction=search.detail&id=407
EC (2008b) M/430 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 product aspects., Retreived from https://ec.europa.eu/growth/tools-databases/mandates/index.cfm?fuseaction=search.detail&id=408#
EC (2011a) COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food Retreived from https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32011R0010
EC (2011b) M/492 Mandate addressed to CEN, CENELEC, and ETSI for the development of Horizontal European Standards and Other Standardisation Deliverables for Bio-based products., Retreived from https://ec.europa.eu/growth/tools-databases/mandates/index.cfm?fuseaction=search.detail&id=477
EC (2018) COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS A sustainable Bioeconomy for Europe: Strengthening the connection between economy, society and the environment. Retreived from https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52018DC0673
EC (2020) EU Ecolabel. Retreived April 2020 from https://ec.europa.eu/environment/ecolabel/
Endres, H.-J. and Siebert-Raths, A. (2011) Engineering biopolymers, Eng. Biopolym, (71148).
ETSI (2020) About ETSI. Retreived from https://www.etsi.org/about?jjj=1600699212760
EU (2009) DIRECTIVE 2009/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 June 2009 on the safety of toys Retreived from https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009L0048

Horizon 2020 This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

ISO (2006) ISO 14040:2006 Environmental management - Life cycle assessment - Principles and framework Retreived from https://www.iso.org/standard/37456.html
ISO (2013) ISO 472:2013 Plastics - Vocabulary Retreived from
ISO (2020) About us. Retreived from https://www.iso.org/about-us.html
Karamfilova, E. (2016) Food Contact Materials - Regulation (EC) 1935/2004: European Implementation Assessment, Retreived from https://www.europarl.europa.eu/RegData/etudes/STUD/2016/581411/EPRS_STU(2016)581411_EN.pdf
Krzan, A., Hemjinda, S., Miertus, S., Corti, A. and Chiellini, E. (2006) Standardization and certification in the area of environmentally degradable plastics, Polymer Degradation and Stability, 12 (91). pp.2819-2833. https://doi.org/10.1016/j.polymdegradstab.2006.04.034
Larson, D. B. and Jordan, S. R. (2018) Playing it safe: toy safety and conformity assessment in Europe and the United States, International Review of Administrative Sciences, 4 (85). pp.763-779. https://doi.org/10.1177/0020852317747370
Mengal, P., Wubbolts, M., Zika, E., Ruiz, A., Brigitta, D., Pieniadz, A. and Black, S. (2018) Bio-based Industries Joint Undertaking: The catalyst for sustainable bio-based economic growth in Europe, New Biotechnology, (40). pp.31-39. https://doi.org/10.1016/j.nbt.2017.06.002
Müller, W. W. and Saathoff, F. (2015) Geosynthetics in geoenvironmental engineering, Science and technology of advanced materials, 3 (16). pp.034605-034605. https://doi.org/10.1088/1468-6996/16/3/034605
Nova-Institute (2014) Annex V in Study on "Methodology framework for the bioeconomy observatory", Retreived from
Philp, J. C., Bartsev, A., Ritchie, R. J., Baucher, M.-A. and Guy, K. (2013) Bioplastics science from a policy vantage point, New Biotechnology, 6 (30). pp.635-646. https://doi.org/10.1016/j.nbt.2012.11.021
Raison, T., Nagrodski, A., Suski, C. D. and Cooke, S. J. (2014) Exploring the potential effects of lost or discarded soft plastic fishing lures on fish and the environment, Water, Air, & Soil Pollution, (225).
Rigamonti, L., Grosso, M., Møller, J., Martinez Sanchez, V., Magnani, S. and Christensen, T. H. (2014) Environmental evaluation of plastic waste management scenarios, Resources, Conservation and Recycling, (85). pp.42-53. https://doi.org/10.1016/j.resconrec.2013.12.012
Scott, C. (2003) Speaking Softly Without Big Sticks: Meta-Regulation and Public Sector Audit, Law & Policy, 3 (25). pp.203-219. https://doi.org/10.1111/j.1467-9930.2003.00148.x
Sijtsema, S. J., Onwezen, M. C., Reinders, M. J., Dagevos, H., Partanen, A. and Meeusen, M. (2016) Consumer perception of bio-based products—An exploratory study in 5 European countries, NJAS - Wageningen Journal of Life Sciences, (77). pp.61-69. https://doi.org/10.1016/j.njas.2016.03.007
Testa, F., Iraldo, F., Vaccari, A. and Ferrari, E. (2015) Why Eco-labels can be Effective Marketing Tools: Evidence from a Study on Italian Consumers, Business Strategy and the Environment, 4 (24). pp.252-265. https://doi.org/10.1002/bse.1821
Wedding, C. (2010) Toward greater ecological intelligence in the United States: Ten statements with statistics and commentary regarding ecolabels, Sustainability : science, practice, & policy, 1 (6). pp.39-44. https://doi.org/10.1080/15487733.2010.11908041

Horizon 2020 This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407

Young, A. R. (2014) Europe as a global regulator? The limits of EU influence in international food safety standards, Journal of European Public Policy, 6 (21). pp.904-922. https://doi.org/10.1080/13501763.2014.910871
Zielczynski, P. (2007) Characteristics of a Good Requirement. Retreived from

Horizon 2020 This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 860407