INVESTNL

ecomatters

Biopolymers from a regulatory perspective

A study on the relevant European and Dutch legislation impacting the production and use of biopolymers

ecomatters

Version: 1.0

Date: 04-11-2021

Authors: M. Mense and W. van Kootwijk

Editor: E. van IJken

Organisation: Ecomatters B.V.

Contactdetails: info@ecomatters.nl

Website: www.ecomatters.nl

Commissioner: Invest-NL

Contactdetails: info@invest-nl.nl

Website: https://www.invest-nl.nl

ecomatters

Contents

1. Introduction

1.1 Context

Companies are increasingly looking at biopolymers or bio-plastics as the solution for reducing resource use, climate impact and littering. As a result, there is a growing variety of bio-plastics on the market today. There are bio-plastic alternatives for almost every conventional plastic material and application.

The properties of bio-plastics have been improving over the last decade and can more often compete with conventional plastics on characteristics such as flexibility, transparency, heat resistance, and gloss. Biobased or partially biobased non-biodegradable plastics can even be technically equivalent to their fossil-based counterparts, and are therefore also known as drop-in plastics.

Although biopolymers may pose lower environmental burdens compared to their conventional equivalents, it should be carefully considered that the high-volume replacement with biobased polymers will not lead to new serious environmental problems or human health issues. Within the EU frameworks this is often called preventing “regretful substitutions”.

In order to prevent these so-called regretful substitutions, existing as well as new legislation is increasingly focusing on the manufacturing, use, and waste processing of these new types of biopolymer products (either as substances or as articles). These regulations aim both at environmental impact reduction as well as chemical safety for human and environment. Not only do these regulations pose restrictions and lay down (data) requirements, but also do they offer exemptions and regulatory incentives to drive the EU economy towards a less fossil driven society.

1.2 Scope

In this report, we take a regulatory perspective on the full life-cycle of biopolymer products. As such, we identify the most prominent and relevant sets of EU and Dutch regulation for biopolymers concerning the raw materials, production (of the substance), application/use (of the article), and End-of-Life scenarios.

In the diagram on the next page (Figure 1), the life-cycle of biopolymers is presented from this perspective. Manufacturers (or importers) who place biopolymers on the European market are most directly impacted by the regulatory requirements of their feedstock (raw material) as well as by legislation regarding the human and environmental safety of their substance (polymer). We identify this as direct (regulatory) impacts.

When a biopolymer is marketed for certain applications, such as packaging or agricultural use, additional application specific regulations often apply to guarantee its applicability and safety. As these regulations often target the downstream actors placing an article on the market, we call these indirect (regulatory) impacts. It is important to note that compliance with these regulations always involves the upstream manufacturers just as much.

The same applies for End-of-Life. Biodegradability or recyclability claims for example are usually assessed at article level, but manufactures of polymers have to be able to substantiate the End-of-life claims of their polymer to support article producers adhering to relevant regulations.

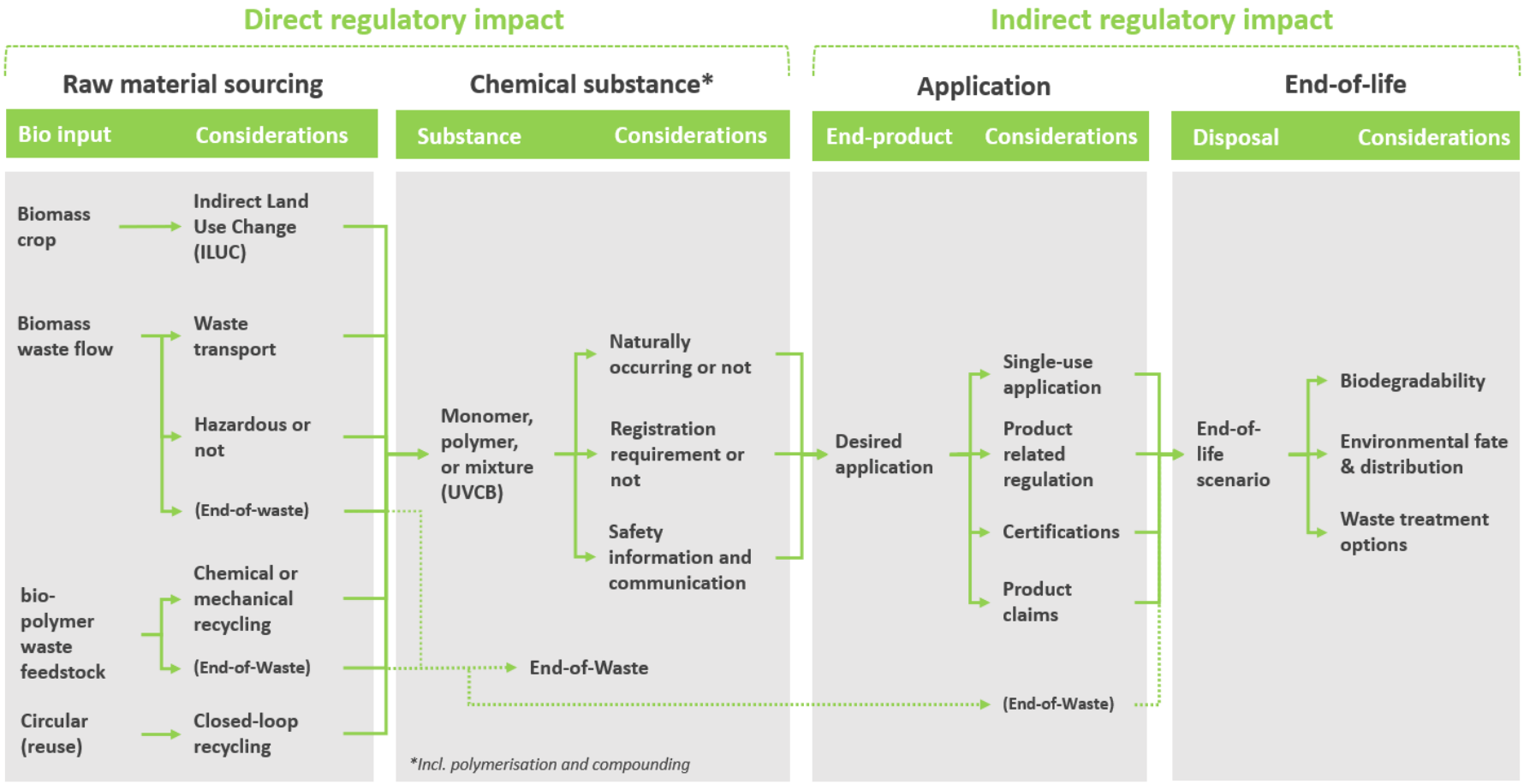

Figure 1 Framework for the regulatory perspective on the full life-cycle of biopolymer products

2. What can you find in this report?

The report discusses the relevant regulatory implications for the successful market introduction of biobased polymers.

Similar to Life-Cycle-Assessment (LCA), where the complete life-cycle of a product or process is assessed (from Gradle to Grave) for environmental impact such as global warming potential, there are sets of regulations for each step in the life-cycle of biobased substances, materials and articles.

In the next chapter we start with an explanation and discussion on several concepts such as “biobased”, “Natural substances and Polymers”, and “Biodegradability”. Additionally, we have included several definitions of important subjects often re-occurring in this report.

From there in chapter 4, we give a bird’s eye view on objectives, strategies and action programs on biopolymers for both the EU as the Dutch national government. Although these strategies do not lay down any specific requirements, they give valuable insight in the direction where the EU and the Dutch government are moving with regards to fossil-based polymer reduction and their substitution by (biodegradable) biopolymers.

In chapter 5, a full overview of the identified legislation is presented for both direct and indirect regulatory impacts. Each set of legislation is qualitatively scored for its impact on the market introduction of a biopolymer.

In chapter 6 and 7 we take a close look at the identified legislation with regard to the Direct impacts. These include the rules with respect to biomass input material (sourcing), waste or recycled input flows and highly extensive regulations such as REACH and its applicability on polymers and biopolymers.

In chapter 8 we discuss the rules specifically for biopolymer applications. In this chapter we focus among other on single use application, ECHA`s proposal for the restriction of microplastics, agricultural uses, and (food)packaging.

In chapter 9, we have come to the End-of-life phase of the polymeric materials. Here we discus relevant regulations with regard to the End-of-life of the material most notably the Waste Framework Directive and adopted waste hierarchy, but also the Dutch ‘Landelijk Afvalbeheerplan’.

The report is concluded with a summary chapter at the end (chapter 10). This chapter compiles the relevant conclusions per chapter in a condensed table. The table follows the report structure to allow for easy navigation of conclusion. Apart from providing a snapshot of all relevant regulatory findings and providing a readable summary of the discussed regulation, it will be useful as a guide for future reference.

A list of abbreviations that are used throughout the report is provided in Annex I.

3. Basic concepts explained

3.1 Basic concepts regarding biopolymers and degradability

Although the term biopolymer, or biobased polymer, includes the biological origin of the materials (instead of fossil based), it is important to be aware that this term includes a broad variety of polymers (see Figure 2).

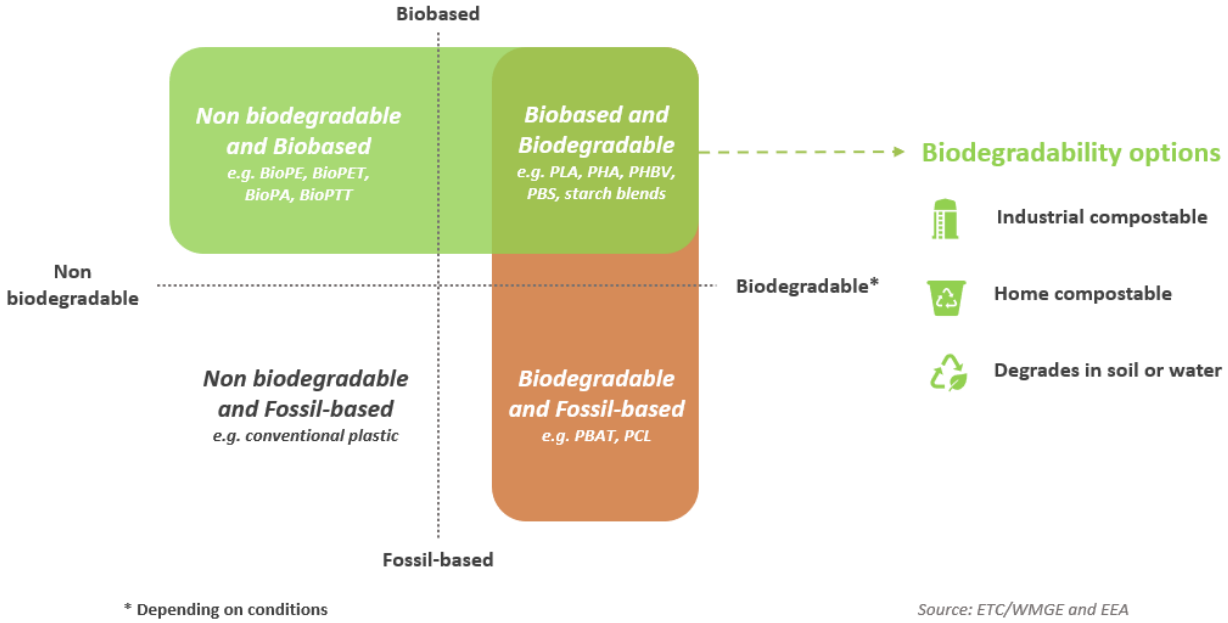

Figure 2 Overview of biopolymer variety (incl. biodegradability options)

Often biopolymers are assumed to be biodegradable as well. Many types however, are specifically produced with similar inert specifications as their petroleum counterparts to serve as drop-in material. Others types are indeed "designed" to be more easily degradable in industrials digestion plants or even in home compost bins. Additionally, certain biobased polymers are manufactured with are intended to degrade rapidly in the natural environment such as in natural soils, surface waters, and the marine environments.

As we will discuss later in this chapter, great care should be given in using the term biodegradable. This term carries no regulatory meaning by itself.

In order to better understand these concepts and avoid confusion we continue this chapter first with an introduction of the relevant terms and concepts. Here we explain the regulatory concepts and difference between substances, polymers and articles. Additionally, we explain the concepts of naturally occurring substance, natural polymer, and chemically unmodified, as these concepts form a common thread in several EU regulations relevant for production and use of biopolymers.

3.1.1 Selection of applied definitions:

As is often the case, for many concepts more than one definition exists. Regarding the production, marketing and use of biopolymers, the EU chemicals legislation (REACH) regulation offers comprehensive definitions for the concepts relevant for the current topic. Not only are these definitions applicable under

the REACH regulation itself, often they are applied to other sets of (environmental) regulations introduced after REACH.

Similarly, the European Waste Framework Directive, lays down several definitions for terms and concepts in this paper with regard to waste, waste prevention and recovery of waste.

Definitions

A substance: is a chemical element (and its compounds) in its natural state or the result of a manufacturing process. In a manufacturing process, a chemical reaction is usually needed to form a substance. The following substance types can be discerned:

Mixtures: A mixture is a mix or solution of two or more substances. Under REACH legislation, mixtures are not considered substances.

Articles: Under REACH an article is an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition does. Examples of articles are plastic packaging or clothing. There are also **Complex objects** which may be made of several individual articles. This can be something as complex as an e-bike consisting of hundreds of different articles (frame, battery, electronics, tyres etc).

Substance types

Mono-constituent substance: You have a mono-constituent substance when one main constituent makes up at least 80% of the substance. A mono-constituent substance is named after the main constituent. Its impurities do not need to be mentioned in the name.

Multi-constituent substance: You have a multi-constituent substance if your substance consists of several main constituents. Each of these main constituents will be present at a concentration of between 10% and 80% in the substance. A multi-constituent substance is named as a "reaction mass of the main constituents" present in the substance. Note that this is different than a mixture.

UVCB substance: UVCB stands for unknown or variable composition, complex reaction products or of biological materials. If you have a UVCB substance, your substance has many different constituents, some of which may be unknown. The composition can be variable or difficult to predict. UVCB substances are often not fully identifiable and therefore you need to provide a description of the manufacturing process and other types of information, such as a boiling range. In general, the name of a UVCB substance is usually a combination of the starting materials

Monomer: a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer forming reaction used for the particular process[1].

Polymer: The Organisation of Economic Co-operation and Development (OECD) defines a polymer as follows: “A 'POLYMER' means a substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight[2].”

Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. By this definition, many

[1] https://www.oecd.org/env/ehs/oecddefinitionofpolymer.htm
[2] https://www.oecd.org/env/ehs/oecddefinitionofpolymer.htm

low molecular weight substances, oligomeric reaction products, dimmers or trimers cannot be called polymer.

More simply put, a polymer must meet the following three criteria:

- molecules must be distributed over a range of molecular weights;
- the weight percentage of molecules containing three monomer units or above should exceed 50%;
- the weight percentage of any molecule of the same molecular weight shall not exceed 50%.

In REACH regulation, some more terms can be distinguished that allow further classification of the variety in polymers and are also important regarding the applicability of regulation, throughout the report. These terms are:

- natural polymers;
- unmodified natural polymers;
- substances which occur in nature.

The applicability of these terms depends on the polymerisation process, extraction process and whether chemical modification took place. Figure 3 to the right presents an overview of how these elements determine which term is applicable. After Figure 3, regulatory definitions for these terms are provided.

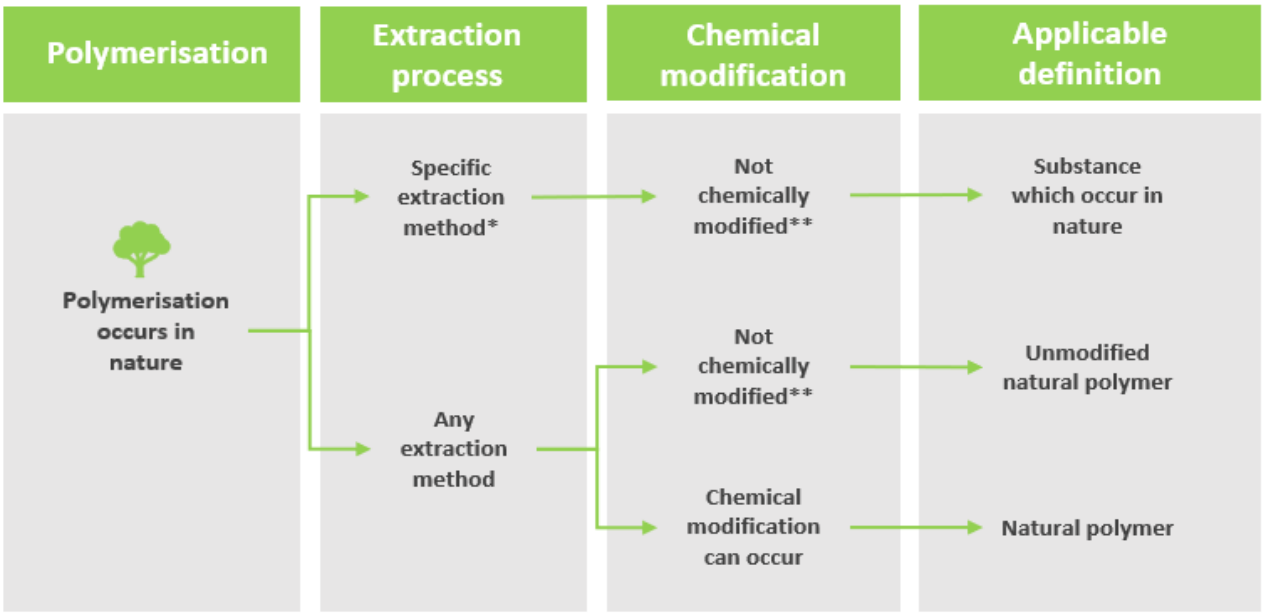

Figure 3 Regulatory definitions on natural occurrence and natural polymers

Natural polymer: Polymers which are the result of a polymerisation process that has taken place in nature. The polymerisation process is considered independently of the extraction process with which they have been extracted. *This means that natural polymers are not necessarily 'substances which occur in nature' when assessed according to the criteria set out in Article 3(39) of the REACH Regulation.*

Substances which occur in nature: Living or dead material occurring in nature as such, which is chemically unprocessed, or which is extracted from air by any means or physically processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation or by heating solely to remove water.

Substances which occur in nature are substances obtained, for example, from plants, micro-organisms, animals, or certain inorganic matter such as minerals, ores and ore concentrates, crude oil, coal, natural gas.

It should be noted that whole living or dead organisms (e.g. yeast, freeze-dried bacteria) or parts thereof (e.g. body parts, branches, leaves, flowers etc.) are not considered as substances, preparations or articles in the sense of REACH and are therefore outside of the scope of the REACH regulation. The latter would also be the case if these 'organisms' have undergone digestion or decomposition resulting in waste as defined in Waste Framework Directive. This is also the case if, under certain circumstances, these might be seen as recovered materials.

Substances which occur in nature are considered to be:

- unprocessed naturally occurring substances: no treatment at all of the substance takes place, or;
- processed only by manual, mechanical or gravitational means: parts of the substance as such may for instance be removed by hand or by machine (e.g. by centrifugation), e.g. by grinding, sieving, centrifugation, flotation, etc. Applicable processing techniques are:
    - by dissolution in water: the only solvent which can be used is water. The dissolution by any other solvent or mixture of solvents or mixture of water with other solvents disqualifies the substance as naturally occurring;
    - by flotation: physical separation process taking place in water/liquid without chemical reaction;
    - by extraction with water: separation process which is based on the different distribution of a certain constituent or constituents from a material by using water only;
    - by steam distillation: distillation of naturally occurring substances with water vapour as carrier for the separation of certain constituent(s) without chemical reaction;
    - heating solely to remove water: purification or concentration of a substance by removing water by heat while no chemical reaction occurs;
    - extracted from air by any means: substances which occur naturally in air, extracted by applying any methods and solvents as far as no chemical reaction occurs.

Not chemically modified substance: 'a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities'.

Waste: 'any substance or object which the holder discards or intends or is required to discard'. Any substance or object is either waste or non-waste.

End-of-Waste: To stimulate the re-use of waste into new raw materials, the EU frameworks regarding waste and substances make it possible for waste to cease being waste. When a recycled product receives the status of end-of-waste, users of this product no longer have to comply to waste regulations. To judge if and when something ceases to be waste, End-of-waste criteria have to be considered and met.

3.2 Biodegradability

The term biodegradable plastic in itself is not considered a useful term. Nor should it be used as a claim on substances or (intermediate) articles with regard to End-of-life or environmental fate.

Biodegradability always needs to be communicated in combination with:

- degradation conditions such as temperature, available enzymes, soil type, moisture level, etc); and
- timeframe (how long until x% is degraded); and
- resulting degradation products and residues.

The criteria above determine if the biodegradability properties of the substance or article are indeed matching with the expected conditions for its intended use. Only when it is certain that the conditions are matching, the potential environmental benefits can honestly be claimed.

Currently, harmonised international standards on biodegradable plastics dealing with biodegradability is considered inadequate. This is especially the case for plastics (un)intentionally released in the natural environment.

As will be further discussed in the relevant chapters, several sets of legislation have adapted the REACH definition for natural polymers as a differentiator for considering in- or exclusion of biodegradable bioplastics under rules or restrictions in the applicable legislations.

The REACH definition for natural polymer as presented in the previous section (and in Figure 3), does not focus on biodegradability in itself, but solely on the natural origin (polymerisation) of the polymer. In chapter 8.1 on the Single Use Plastics (SUP) directive we will go deeper into the applicability of this definition as well as its consequences.

3.2.1 Relevant Standards

Industrial Composting

Industrial composting is an established process with commonly agreed requirements concerning temperature and timeframe for biodegradable waste to metabolise to stable, sanitised products (biomass) to be used in agriculture (humus/fertiliser). This process takes place in industrial or municipal composting plants. These plants provide controlled conditions, i.e. controlled temperatures, humidity, aeration, etc. for a quick and safe composting process.

Within the EU, EN 13432 for plastic packaging and EN 14995 for non-packaging items are the available standards for industrial composting claims. When the requirements are proven to be met, articles can be labelled for industrial composability.

EN 13432: Specifies requirements and procedures to determine the composability and anaerobic treatability of **packaging and packaging materials** by addressing four characteristics:

1) biodegradability (including conditions, timeframe, and degradation products);
2) disintegration during biological treatment;
3) effect on the biological treatment process; and
4) effect on the quality of the resulting compost.

Additionally, EN 13432 requires the compostable plastics to disintegrate after 12 weeks and be completely biodegrade after six months. That means that afterwards 90% or more of the plastic material will have been converted to CO_2. The remaining share is converted into water and biomass (i.e. valuable compost). Materials and products complying with this standard can be certified and labelled accordingly.

EN 13432 certified compostable products are labelled with the 'Seedling logo' (Dutch: Kiemplantlogo), to ensure that compostable products can be distinguished from visually similar non-compostable products. The Seedling logo is owned by European Bioplastics.

Compositing realities

In a publication from STAR4BBI (a biobased Industries Joint Undertaking) it was discovered that in the Netherlands industrial composters run their process in less time than the prescribed 12 weeks from the standard. The Dutch Waste Management Association (VA) stated that composting time is around 2-3 weeks and sometimes even shorter between 5 and 18 days. As a result, the compostable products might not be fully composted. As compost cannot be sold with visible 'non soil' parts, such as plastic residues, the composters sieve out all plastics (compostable and fossil) before the composting cycles start. Due to this reason, most compostable plastics currently end up in the incineration facilities.

source: https://edepot.wur.nl/511292#page=28&zoom=100,109,536

EN 14995: This European Standard specifies requirements and procedures to determine the composability or anaerobic treatability of plastic materials by addressing the same four characteristics as included in EN 13432.

Home Compostable

There is currently no international standard specifying the conditions for home composting of biodegradable plastics. However, there are several national standards, such as the Australian norm **AS 5810** "Biodegradable plastics – biodegradable plastics suitable for home composting". Belgian certifier TÜV Austria Belgium had developed the **OK compost** home certification scheme, requiring at least 90% degradation in 12 months at ambient temperature. Based on this scheme, the French standard **NF T 51-800** **"**Plastics — Specifications for plastics suitable for home composting" was developed, specifying the very same requirements for certification.

It should be noted that meeting the standards for home composting does not exclude a polymer for any restriction or requirement imposed by other EU legislation, such as the Single Use Plastics directive or Bio-stimulant and Fertilizer regulation.

Agricultural biodegradability standards

NEN-EN 17033: This standard specifies the requirements for biodegradable films, manufactured from thermoplastic materials, to be used for mulch applications in agriculture and horticulture. This document is applicable to films intended to biodegrade in soil without creating any adverse impact on the environment. It also specifies the test methods to assess these requirements as well as requirements for the packaging, identification and marking of films. For information purposes, it defines a classification of biodegradable mulch films according to their service life on soil and gives a good practice guide for the use of the films.

Please note that with the introduction of the new Bio-stimulant and Fertilizer regulation (EU) 2019/1009 additional or other degradation and residue requirements may apply. See chapter 8.3 for a more information on the use of bioplastics in agricultural applications.

Degradability in the marine environment

Degradability test standards for the marine environment include ISO 23977[3], ASTM D6691[4] and ASTM D7081 (no longer supported), which can give valuable insight in the degradation properties of a polymer. However, currently there agreed technical standards available including pass or fail criteria to certify that a specific plastic product is properly biodegradable in the marine environment in a certain timeframe (and without causing harm to the environment).

However, the European Chemicals Agency (ECHA) is currently investigating whether any of the existing standard methods for determining the (bio)degradation of chemicals in the environment (such as OECD 301[5] / OECD 306[6]) and their associated thresholds and guidance could be meaningfully applied to (micro)plastic materials in the marine environment

Biodegradable polymer (substance) in articles

When a polymer is determined to be biodegradable under certain conditions, it does not automatically mean than the article produced with this polymer is still compliant with the relevant standards or definitions.

Many biopolymers used in articles contain additives and polymerization aids to adjust the technical qualities of the materials (such as crosslinkers, anti-oxidants, fillers etc). Additionally the polymer may be compounded with other polymer materials.

These adaptations can have a tremendous impact on the degradability potential. Therefore, most biodegradability standards require the biodegradability testing of the final article. Proving readily and safe degradation in the natural environment is however the responsibility of the whole value chain. Starting with the raw material supplies and manufacturers and including formulators and article manufacturers.

---

[3] https://www.iso.org/standard/77499.html

[4] ASTM D6691-17, Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials in the Marine Environment by a Defined Microbial Consortium or Natural Sea Water Inoculum, ASTM International, West Conshohocken, PA, 2017, www.astm.org

[5] https://www.oecd-ilibrary.org/environment/test-no-301-ready-biodegradability_9789264070349-en

[6] https://www.oecd-ilibrary.org/environment/test-no-306-biodegradability-in-seawater_9789264070486-en

Other standardized test protocols

The above-mentioned biodegradability standards are a not exhaustive list. For upcoming rules, restrictions and exemptions, several other testing standards are currently being evaluated for application within regulatory frameworks.

Examples are:

- ISO 14855-1:2012 Determination of the ultimate aerobic biodegradability of plastic materials under controlled composting conditions – Method by analysis of evolved carbon dioxide – Part 1: General method;
- ISO 15985:2014 Plastics – Determination of the ultimate anaerobic biodegradation under high-solids anaerobic digestion conditions – Method by analysis of released biogas;
- ISO 17556:2012 Plastics – Determination of the ultimate aerobic biodegradability of plastic materials in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved.

It is important to note that the above ISO methods often do not include "pass or fail" criteria for the tested materials.

3.3 Definitions of the terms we use in this report

SoC: Substances of Concern. An overarching group of substances with harmful properties, including ZZS, pharmaceutical residues, pesticides and pathogens.

SVHC: Substances of very High Concern. An SVHC is a chemical substance (or part of a group of chemical substances) for which it has been proposed that use within the European Union should be subject to authorisation under the REACH regulation. A substance may be considered to be an SVHC if it meets one or more of the following criteria: it is carcinogenic; it is mutagenic; it is toxic for reproduction; it is persistent, bio accumulative and toxic (PBT substances); it is very persistent and very bio accumulative (vPvB substances); there is "scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern"; such substances are identified on a case-by-case basis.

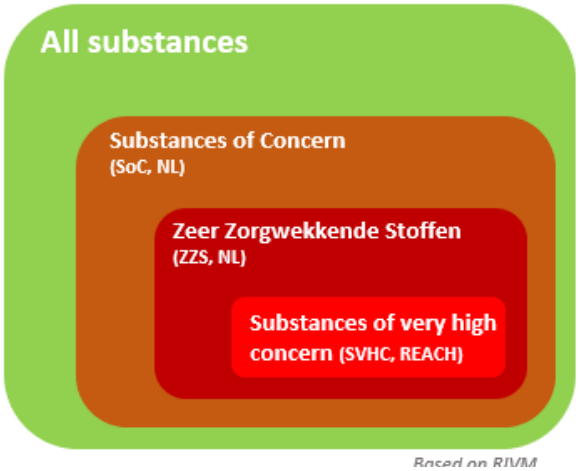

Figure 4 Substances of concern hierarchy

The list containing the selected SVCH under REACH is called "The candidate list for Substances of Very High Concern" and can be accessed via https://echa.europa.eu/candidate-list-table. It is called "candidate" list because the SVHC are candidates for REACH Authorization and Restriction (see chapter 7.2.1)

ZZS: Zeer Zorgwekkende Stoffen as implemented by the RIVM, the Dutch national institute for public health and the environment. Similar to SVHC, ZZS are substances that are dangerous for people and the environment because they, for example, hinder reproduction, are carcinogenic or accumulate in the food chain. The ZZS also need to meet the criteria used for SVHCs but are coming from a wider range of sources (e.g. also POPs and hazardous substances from the Water Framework Directive). This makes the list of ZZS broader than the list of SVHC. Dutch government policy on ZZS is laid down in the regulations included in the Activities Decree (Activititeitenbesluit Milieubeheer). This obliges companies, subject to the law on environmental conservation (Wet mileubeheer), to prevent their discharges and emissions of ZZS to air and water. If this is not feasible, the emissions must be limited as much as possible (minimization obligation). As of 1 January 2016, this minimization obligation applies to all ZZS.

The list of ZZS can be found here: https://rvszoeksysteem.rivm.nl/ZZSlijst/TotaleLijst

EU Strategy: The EU's overall political goals developed collectively by its institutions.

Directive: A "directive" is a legislative act that sets out a goal that all EU countries must achieve. However, it is up to the individual countries to devise their own laws on how to reach these goals **Regulation:** A "regulation" is a binding legislative act. It must be applied in its entirety across the EU. This definition is used in the report unless it is explicitly stated that the regulation concerns a regulation enacted by the government of the Netherlands.

4. EU and Dutch objectives, strategies and action programs

This chapter includes sections on the EU and Dutch government's long-term objectives in regards to biopolymers. These objectives translate into strategies and direct-action plans, which in turn result in regulation. This chapter mostly serves to provide context on future developments, and it therefore does not contain specifics on regulation, as these are included in chapter 6 to 9 of this report. Additionally the overview in this chapter tries to summarise the most relevant developments. It does not, however, aim to provide a full-scale overview of all strategic actions on the EU and Dutch national level that could potentially be impactful on biopolymers.

4.1 EU objectives, and environmental action programs

The EU has recognized biopolymers and their applications as an important contributor in the transition towards sustainable and circular economies. Therefore, many action plans and strategy documents from the European Commission (EC) include policy implications and prospected policy changes regarding the production, use and End-of-life of biopolymers. This section is the result of an analysis and extraction of information specifically relevant to biopolymers, from relevant EU action plans and strategies. Although, these action plans and strategies do not provide clear regulatory guidance for the production and marketing of biopolymers, they do give valuable insight in the value proposition of these materials in the larger EU ambition for a carbon neutral and circular economy.

In Figure 5, an overview is presented of the EU action plans and strategy documents that are discussed in this chapter.

Figure 5 European policy areas, action plans and strategies

4.2 EU Green Deal policy areas

The European Green Deal[7], first presented on 11 December 2019, is a blueprint for the large sustainability transformation that Europe needs to make. Its main goal is to make Europe the first climate neutral continent by 2050. To achieve this, on 14 July 2021, the EC proposed a new reduction target for CO_2 emissions of 55% in 2030 compared to 1990.[8] The European Green Deal not only concerns climate change, but also covers many other sustainability topics.

The European Green Deal has 11 policy areas. Two policy areas are particularly relevant for biopolymers, the substances from which they are produced, are used in, or the waste they generate:

1. Transition to a circular economy
2. Zero pollution

For each of these policy areas an action plan has been developed or recently revised from previous action plans. Action plans provide a vision for Europe until 2030 or beyond and contain concrete objectives to develop policy on a more granulated level. These action plans will be discussed in the next section.

4.3 EU Action plans

4.3.1 Zero Pollution for Air, Water and Soil

The EU Action Plan: 'Towards a Zero Pollution for Air, Water and Soil'[9] is one of the key deliverables of the European Green Deal. It was officially adopted by the EC on 12 May 2021. This action plan can be considered as a toxic free vision for 2050. By this year all air, water and soil pollution should be eliminated or diminished to safe levels for health and natural ecosystems. Key targets for 2030 have been formulated, and are in some cases related to biopolymers. For example:

- *"Improving water quality by reducing waste, plastic litter at sea (by 50%) and microplastics released into the environment (by 30%)."*

This target should be achieved through a combination of measures to reduce plastics use and waste, together with measures to promote a circular and clean economy. Such measures will take a legislative shape in the Single Use Plastics Directive, Marine Strategy Framework Directive and REACH.

4.3.2 Circular Economy Action Plan (CEAP)

The Circular Economy Action Plan (CEAP)[10] was adopted by the EC in March 2020. As one of the key pillars of the European Green Deal, CEAP aims to reduce pressure on natural resources and boost sustainable growth. Two objectives of CEAP that are specifically related to biopolymers are:

- focus on sectors that use most resources and where the potential for circularity is high, such as plastics;

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1588580774040&uri=CELEX:52019DC0640
[8] https://ec.europa.eu/commission/presscorner/detail/nl/ip_21_3541
[9] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0400&qid=1623311742827
[10] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1583933814386&uri=COM:2020:98:FIN

- ensure less waste.

The CEAP sets out 35 actions[11]. 15 of these entail future policy implications related to biopolymers or their applications, and are listed below. It should be mentioned that all of these actions have yet to be worked out in the future, hence the years referring to the expected date of delivery have been included.

A sustainable product policy framework:

- legislative proposal for a sustainable product policy initiative (2021);
- legislative proposal on substantiating green claims (2021).

Focus on key product value chains:

- review to reinforce the essential requirements for **packaging** and reduce (over)packaging and packaging waste (2021);
- mandatory requirements on **recycled plastic content** and **plastic waste reduction** measures for key products such as packaging, construction materials and vehicles (2021/2022);
- restriction of intentionally added microplastics and measures on **unintentional release of microplastics** (2021);
- **policy framework** for **biobased plastics** and **biodegradable** or **compostable plastics** (2021);
- strategy for a Sustainable **Built Environment** (2021);
- initiative to **substitute single-use packaging, tableware and cutlery** by reusable products in food services (2021).

Ensure less waste, more value:

- waste reduction targets for specific streams and other measures on waste prevention (2022);
- EU-wide harmonised model for **separate collection of waste and labelling** to facilitate separate collection (2022);
- **methodologies** to track and minimise the presence of **substances of concern in recycled** materials and articles made thereof (2021);
- harmonised **information systems** for the presence of **Substances of Concern** (2021);
- scoping the development of further EU-wide **end-of waste** and **by-product** criteria (2021);
- revision of the rules on **waste shipments** (2021).

Leading efforts at global level:

- leading efforts towards reaching a **global agreement on plastics** (ongoing).

4.4 EU Strategies

Several European sustainability strategies contribute to the action plans from the Green deal. The strategies make the action plans operational by giving a clear perspective of what needs to be done in the future to achieve the outlined sustainability targets. Three strategies (Table 1) are discussed in this section, because they are relevant to biopolymers.

[11] https://ec.europa.eu/environment/pdf/circular-economy/implementation_tracking_table.pdf

Table 1: EU Strategies

Strategy	Contributing to
Chemical Strategy (4.4.1)	Zero Pollution Action Plan (4.3.1)
Plastics in a Circular Economy Strategy (4.4.2)	Circular Economy Action Plan (4.3.2)
Bio-economy Strategy (4.4.3)	

4.4.1 Chemical Strategy

The Chemical Strategy[12] for sustainability was adopted by the EC at 14 October 2020. It contributes to the zero-pollution ambition as announced in the Green Deal. The Strategy wants to support innovation for safe and sustainable chemicals, while ensuring the protection of human health and the environment against hazardous chemicals. Such protection also involves restricting and prohibiting the use of harmful chemicals in consumer products. The elements in this strategy are categorized in 5 key subjects:

1) innovating for safe and sustainable EU chemicals;
2) stronger EU legal framework to address pressing environmental and health concerns;
3) simplifying and consolidating the legal framework;
4) a comprehensive knowledge base on chemicals;
5) setting the example for a global sound management of chemicals.

For each of these key subjects, only the elements relevant to (development) of biopolymers and applications are presented in the remainder of this section.

Key subject 1: Innovating for safe and sustainable EU chemicals

Move towards safe and sustainable-by-design chemicals:

- move to sustainable biobased chemicals, and investing in searching alternatives to substances of concern;
- the commission will develop EU safe and sustainable-by-design criteria for chemicals.

Non-toxic material cycles:

- minimise substances of concern in products by introducing requirements. (part of Sustainable Product Policy Initiative);
- improve availability of information about chemical content and safe use;
- ensure justification of authorisations and derogations from restrictions for recycled materials under REACH;
- invest in sustainable innovations that aim for decontamination of waste streams, safe recycling and reduction of (plastic) waste;
- further develop chemical risk assessment methodologies looking at complete life-cycle of substances, materials and products.

[12] https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

Innovating industrial production:

- Finance R&D in low-environmental impact chemical/material production processes, innovative business models, advanced materials for applications in energy, construction, mobility, health, agriculture and electronics sectors.

Key subject 2: Stronger EU legal framework

REACH and Classification, Labelling and Packaging (CLP) regulations need to be the basis for the regulation of chemicals. Other approaches for the assessment and management of chemicals in existing sectorial legislation (especially those for consumer products) should be complementary to REACH and CLP.

Chemical protection:

- protection against harmful chemicals, with a specific focus on consumer products.

Mixtures:

- REACH: introduce mixture assessment factors for the chemical safety assessment of substances;
- investigate how combination effects can be taken in to account in relevant legislation on applications, food contact materials.

Chemical pollution in natural environment:

- potentially propose new hazard classes and criteria in the CLP Regulation to fully address environmental toxicity, persistency, mobility and bioaccumulation.

Key subject 3: Simplifying and consolidating the legal framework

Coordinate and simplify actions across EU chemical legislation:

- Introducing the 'One substance, one assessment'[13] approach to avoid redundancy and make assessment procedures simpler and more transparent; *Currently, risk assessment and risk management of the same chemical is carried out at different times for different uses by different bodies, under different legislation, often using different data and potentially leading to seemingly different outcomes. The EU Commission intends to look at how to simplify and strengthen the legal framework and review how to use the EU's agencies and scientific bodies can move towards 'one substance – one assessment' and thus reduces potential for conflicting outcomes.*
- The shift towards a 'one substance, one assessment' approach will be supported by several coordination and monitoring initiatives.

[13] One substance, one assessment: https://echa.europa.eu/documents/10162/21877836/efsa-echa-position-paper-osoa_en.pdf/74b1ae31-290b-a608-85e9-05b340840b34#:~:text=We%20propose%20that%20%E2%80%9Cone%20substance,built%20around%20three%20main%20principles%3A&text=%2D%20Better%20coordination%20on%20or%20distribution,uses%20of%20the%20same%20chemical.

Zero tolerance for non-compliance:

- the principles of 'no data, no market' and the 'polluter-pays' will be strengthened under REACH. In practice this will mean a mandatory compliance of all registration dossiers and a repeal of registration numbers in case of non-compliance (see chapter 7.2.1 for details on registration under REACH).

Key subject 4: A comprehensive knowledge basis

Information requirements:

- extend the duty of registration under REACH to certain polymers of concern;
- investigate the introduction of information requirements under REACH on the overall environmental footprint of substances;
- change REACH information requirements to enable identification of dangerous substances.

Key subject 5: Global leadership

Strengthen international standards:

- increase the implementation of the Globally Harmonized System of Classification and Labelling of Chemicals (UN GHS).

4.4.2 Plastics in a Circular Economy strategy

The European Strategy for Plastics in a Circular Economy[14] was already adopted in 2018, and is now part of the CEAP. The strategy is an important step in protecting humans and the environment from plastic pollution problems and microplastics.

To strengthen the role of science in plastics policy, experts from across the plastics value chain have given recommendations on different aspects of the transition towards a CE for plastics. There are 2 'independent expert reports' developed by a group of scientific advisors:

- environmental and health risks of microplastics[15];
- biodegradability of plastics in the open environment[16].

Biodegradable and biobased plastics within this strategy

In the strategy there is relatively little attention for plastics produced from a biobased feedstock. The main argument for biobased plastics is the reduction of climate impact and lower dependency on fossil resources,

[14] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1516265440535&uri=COM:2018:28:FIN
[15] https://op.europa.eu/en/publication-detail/-/publication/f235d1e3-7c4d-11e9-9f05-01aa75ed71a1/language-en/format-PDF/source-108645429
[16] https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/0c0d6267-433a-11eb-b27b-01aa75ed71a1

but the strategy does not focus on this specifically. Plastics with biodegradable properties do have a more prominent role in the strategy.

Upcoming biodegradable plastics can bring societal opportunities and/ or environmental benefits in specific applications, their marketization should be treated with care. A lack of distinctive labelling and marking or functioning waste collection and treatment systems can make plastic pollution worse or lead to issues for mechanical recycling. To avoid such negative effects, the strategy includes a dedicated part to the prospected establishment of a clear regulatory framework for plastics with biodegradable properties. The most important elements are listed below.

General highlights:

- biodegradable plastics have been investigated and developed as a solution to the high level of plastic pollution in the environment and harmful effects to biodiversity such as entanglement and ingestion;
- biodegradable and compostable plastics have proven to be environmentally superior for targeted applications, such as plastic bags for organic waste;
- most biodegradable plastics still pose environmental harm because they only degrade under specific conditions. Especially biodegradation in marine environments is problematic.
- 'compostable' does not equal home composting compatibility;
- mixing compostable and conventional plastics can influence quality of resulting recyclates;
- well-functioning separate collection systems and clear consumer information are crucial.

Future regulatory developments:

- the commission will implement measures to stimulate innovation and steer market developments for the applications of biodegradable plastics where can be identified that environmental benefits are clear;
- the process of defining and labelling compostable and biodegradable plastics requires a set of harmonised rules. The Commission will suggest such rules to improve sorting and prevent false claims;
- LCA will be used by the Commission to identify the conditions under which the application of biodegradable or compostable plastic products is environmentally preferable;
- restrict the use of so-called bio-degradable oxo-plastics in the EU, via REACH, because of its lack of benefits over conventional plastics and its rapid fragmentation into microplastics.

Future promotion of innovation for biodegradable and biobased plastics:

- there is specific attention from the Commission on driving innovation for materials that are completely biodegrade in marine environments and freshwater and are harmless for the environment and ecosystems;
- if scientific research substantiates it, the Commission will grasp opportunities to support developments of alternative feedstocks, such as biomass, within plastic production processes. For that purpose, life-cycle impacts of alternative feedstocks are being investigated.

4.4.3 Bioeconomy Strategy

The Bioeconomy strategy[17] was first presented in 2012 and updated in 2018. Although it was published before the EU Green Deal, it contributes to many of the same objectives[18]. The overall goal of the strategy is ''the partial replacement of non-renewable products by more sustainable biobased ones''. This strategy thus has a direct link with biopolymers, since they are an example of turning biomass feedstock (or biomass waste streams), into valuable products and can be a substitute for fossil-based materials. Using biobased and biodegradable polymers, as an alternative to fossil-based plastics, is already promoted by the European Environmental Agency[19] in cases where the risk of dispersion into the ecosystem is high, for example as lubricants, materials subject to wear and tear, or disposable products.

The bioeconomy strategy contains 14 concrete actions[20] divided over three main action areas:

1. strengthen and scale up the biobased sectors, unlock investments and markets;
2. deploy local bio economies rapidly across the whole of Europe;
3. understand the ecological boundaries of the bioeconomy.

Specific action on biobased and biodegradable plastics:

The first action area includes a concrete action on biobased and biodegradable (plastics): "*Research and innovation investments for the development of substitutes to fossil-based materials that are biobased, recyclable and marine biodegradable, and of bio-remediation methods by mobilising the key actors in the relevant value chains including the plastics value chain and to contribute to plastic-free, healthy and productive European seas and oceans*." This action will ensure to:

- support research and innovation to establish European (CEN) standards for biodegradability in the marine environment, in particular pre- and co-normative research;
- support development of functional substitutes that are at the same time biobased, recyclable and marine biodegradable;
- provide clear synergies regarding the variety of actions on this topic related to the CEAP, the Single Use Plastics legislation, the Marine Strategy Framework Directive, the Plastics Strategy and international cooperation schemes and activities.

Other important elements from the strategy:

- the bioeconomy strategy points out that further regulation and legislation is required regarding biodegradability, and refers to future revisions of the SUP (see chapter 8.1);
- there is a need to develop standards, market-based incentives, and labels that are applicable to biobased products. Reliable and comparable data on environmental performance is foundational here;
- the strategy recognizes biodegradable waste (or biowaste) as an important source of biomass, but also acknowledges a lack of standardised definitions to assess waste volumes;

[17] https://op.europa.eu/en/publication-detail/-/publication/edace3e3-e189-11e8-b690-01aa75ed71a1/language-en/format-PDF/source-149755478
[18] https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/66722c8d-2e03-11eb-b27b-01aa75ed71a1
[19] https://www.eea.europa.eu/publications/circular-economy-and-bioeconomy
[20] https://op.europa.eu/en/publication-detail/-/publication/775a2dc7-2a8b-11e9-8d04-01aa75ed71a1

- there is a need to address limitations of impact assessment methods, for example regarding the inclusion of biodegradability and littering.

4.5 Dutch objectives, strategies and action programmes

In 2016 the Dutch cabinet published a circularity programme '**Nederland Circulair in 2050**'[21], in which a vision and ambition is shaped to achieve a circular economy by 2050 in the Netherlands.

As a follow-up in 2017, a broad group of interest organisations, business actors and governmental bodies have set up a Raw Material Agreement (Dutch: **Grondstoffenakkoord**)[22]. This plan served as a basis for formulating five transition agenda's (Dutch: **Transitieagenda's**) for prioritized themes, in 2018:

1. biomass and food;
2. plastics;
3. production industry;
4. construction;
5. consumer goods.

A transition agenda covers several aspects:

- development directions for 2021, 2025 and 2030;
- action agenda (selected innovation projects for short and long term with focus on impact);
- knowledge agenda (research topics crucial for accelerating transition);
- social agenda (market effects and socially responsible circular business models);
- investment agenda (financial barriers and interventions to resolve them).

In 2019 an execution programme (**Uitvoeringsprogramma Circulaire Economie**) was set up in which the five transition agendas were translated into concrete actions and projects for the period 2019-2023. This programme was later updated for the period 2020-2023[23].

In the following subsections, only the 'Transition Agenda Plastics'[24] and the 'Uitvoeringsprogramma Circulaire Economie 2020-2023' will be shortly discussed because they contain relevant policy implications regarding biobased plastics.

4.5.1 Transition Agenda Plastics

Current situation

In 2015/2016, the total annual amount of consumed plastic in the Netherlands was 2.000 kilo tonne (kt), of which 20 kt is biobased, 1.700 kt is virgin fossil-based and 250-300 kt is recycled. From the 2.000 kt of

[21] https://www.rijksoverheid.nl/onderwerpen/circulaire-economie/nederland-circulair-in-2050
[22] https://www.rijksoverheid.nl/onderwerpen/circulaire-economie/documenten/rapporten/2017/01/24/grondstoffenakkoord-intentieovereenkomst-om-te-komen-tot-transitieagenda-s-voor-de-circulaire-economie
[23] https://www.rijksoverheid.nl/documenten/rapporten/2020/09/25/uitvoeringsprogramma-2020-2023
[24] https://www.rijksoverheid.nl/documenten/rapporten/2018/01/15/bijlage-3-transitieagenda-kunststoffen

annually consumed plastic, 1700 kt is discarded. The largest share of these discarded plastics is still incinerated.

Ambitions for 2050

In 2050 the Dutch plastic chain should be 100% circular. Plastics have low environmental footprints, high quality and are produced from recycled or biobased materials.

Ambitions for 2030

- reduce incineration with -44% from (1.313 kton to 740 kton);
- reduce share of virgin fossil plastics with -36% (from 1.700 kton to 1090 kton). This requires investments in mechanical and chemical recycling capacity and production of biobased plastics.

To achieve the ambitions for 2030, capacity expansion is needed in accordance with the values in Table 2.

Table 2: Required capacity expansion 2030

	2016 (kt)	2030 (kt)	Expansion capacity (kt)
Collection ('milieustraten')	874	1.760	886
Sorting	874	1.760	886
Mechanical recycling	250-300	750	450-500
Chemical recycling	0	250	250
Biobased plastics	20	370	350

The transition agenda proposes four development directions:

1. prevention (More with less, and less leakage);
2. more demand and supply of renewable (biobased) plastics;
3. higher quality, more environmental return;
4. strategic (cross-chain) collaboration.

More details on the action agenda, knowledge agenda, social agenda and investment agenda can be found in the transition agenda report. No significant regulatory changes are foreseen as a result of the strategy for biopolymers.

For biodegradable plastics is mentioned that:

- the choice for biodegradable materials is more obvious for applications where the risk of leakage to the environment is high, such as agriculture;
- biodegradable plastics should always comply with required degradability conditions, such as ISO 17556 for biodegradation in soil;
- further investigation is required to find environmentally beneficial applications for biodegradable plastics.

4.5.2 Uitvoeringsprogramma Circulaire Economie 2020 - 2023

In this 'Uitvoeringsprogramma Circulaire Economie' several plastic-related projects have been included that contribute to the development directions from the Transition Agenda Plastics. The most important information on these projects is summarized in the Table 3. Details can be found in the programme report.

Table 3: Summary plastic related projects from 'Uitvoeringsprogramma Circulaire Economie'

Project	Leading Actor	Activities	Effects	Period
1. Plastic Pact NL	Ministry I&W	- Agreements cross-chain collaboration - Product & material innovation - Knowledge sharing	- Less material use - More recycling - More application of recycled plastic	2019-2025
2. Microplastics	Ministry I&W	- EU wide ban on intentionally added microplastics - Adjustment EU norm car tires - Measuring and waste removal methods	- Less microplastic pollution in soil, water, air - Knowledge on human health effects	2020-2022
3. Reuse plastics	Ministry I&W, NRK and foundations	- Pilots to test effectiveness and acceptability of reusable products	- Less material use - CO_2 reduction - Less pollution	2020-2025
4. Chemical Recycling	Topsector Chemie, Ministry I&W and EZK	- At least 10% chemical recycling in 2030 - Action plan/roadmap - Innovation strategy - R&D programme - Chemical recycling within LAP3	- Increase reuse - Less incineration - Less virgin plastics - CO_2 reduction	2020-2030
5. Biobased Plastics	Total-Corbion	- Framework for production, financial support and applications - Green list for bio-degradables in LAP	- Less virgin plastics - CO_2 reduction - 370 kton biobased plastics in 2030	2020-2030
6. More and better mechanical recycling	Suez	- Exploration additional sorting capacity - Exploration technical opportunities separation/sorting - National test centre	- Less incineration - More capacity - More supply for sorting - Higher quality sorted steams - Approach for mixed stream	2020-2025

7. Application recycled plastics in new products and packaging	NRK, PSP and Province Overijssel	- Inventory market demand recycled plastics - Set up a Green Deal for legitimate claims - Uniform EU standards for recycled plastics	- Market transparency - Increased production and use of recycled plastics	2019-2025

5. Overview of identified relevant rules and regulations

As mentioned previously, the market for biopolymers has increased significantly over recent years, and received a considerable amount of attention in the regulation. As with any substance or polymeric article covered under regulation, the aim is to assure safe use for man and environment.

Section 5.1 and 5.2 provide a cursory overview of the relevant regulations and protocols governing each phase in the life-cycle of a biopolymer (Figure 6). For each included regulation an assessment of its relevance is provided and a brief description of the impact is given.

Figure 6 Life-cycle of a biopolymer

In the concurrent chapters the regulations and protocols are covered in more detail. The regulations will be covered per step in the Life-cycle, but please keep in mind that some regulations might cover multiple steps in the cycle. In such cases, it will be discussed under the step where the regulatory impacts are the most considerable and references will be included in the other steps.

5.1 Direct impacts

An overview of the identified regulations that have direct impact on producers or importers of biopolymers is presented in Table 4.

Table 4 Overview of regulations with direct impact

Life cycle Stage	Regulation	Relevance	Most important Impact
Raw material sourcing	Renewable Energy Directive	Medium	Sustainability criteria for biofuels may be used as blueprint for bio-materials.
Raw material sourcing	Regulation on the Shipment of Waste (RSW)	Limited	Different procedures for shipping non-hazardous waste (green list) or hazardous waste (amber list) with in the European Economic Area (EEA).
Raw material sourcing	Basel Convention	Limited	Convention governing international transport of waste (only relevant for plastic waste transport outside of the EEA).
Chemical substance	REACH	High	Data requirements proving safe use.
Chemical substance	Classification, labelling and Packaging (CLP) regulation	Medium	Defines hazard classes with corresponding communication and labelling requirements.
Chemical substance	Persistent Organic Pollutants (POP) regulation	High	Defines a list of Persistent Organic Pollutants that are not allowed in biopolymers.
Chemical substance	Minamata Convention	Limited	Biopolymers should not be contaminated with mercury.
Chemical substance	Montreal Protocol	Limited	Biopolymers should not be contaminated with ozone depleting substances.

5.2 Indirect impacts

An overview of the identified regulations that have indirect impact on producers or importers of biopolymers is presented in Table 5.

Table 5 Overview of regulations with indirect impact

Life cycle Stage	Regulation	Relevance	Most important Impact
Application (article)	Single Use Plastics Directive (SUP)	High	Biobased polymers and polymers with biodegradability claims do not get exempted from the imposed restriction on single use articles.
Application (article) & End-of-life	Microplastics restriction	High	Adding polymers, other than naturally occurring polymers, as microplastics might become prohibited depending on the outcome of a restriction proposal by ECHA.
Application (article)	Bio-stimulant and fertilizer regulation	High	Biopolymers are only allowed in fertilizing products if the polymer has a certain purpose (as identified in regulation) and passes tests regarding negative effects on environment.
Application (article) & End-of-life	Packaging and Packaging waste directive	Medium	Defines rules for packaging design and packaging waste management. No specifics on biobased packaging. EU targets for reusability/recycling of plastics are relevant.
Application (article)	Food Contact Material	High	Defines requirements for materials that are intended to come in contact with food. For biobased plastics the same rules apply as for conventional plastics. A declaration of compliance is mandatory for plastics.
Application (article)	Construction Products Regulation	Limited	Defines basic standards for any construction products, including those produced with biopolymers.
Application (article)	Cosmetics products regulation	Limited	Regulation governing safe-use and labelling of substances in cosmetic applications. Restrictions in place on the use of certain substances.
Application (article)	Eco-design directive	Limited	Sets energy performance requirements for manufacturers. Very limited impact on biopolymers.
Application (article)	Certification and Product claims	Optional	Not strictly speaking regulation, but can be impactful in regards to placing an application on the market. The associated standards generally require insight on the applications expect environmental impact.
End-of-life	Waste Framework Directive (WFD)	High	Defines when something is a waste and defines End-of-waste options. Has been implemented in the Netherlands through the Landelijk Afval Plan (LAP) 3.0

6. Raw materials sourcing for biopolymers

This chapter discusses the rules and regulations relevant to biomass input material (sourcing), (bio)waste or recycled input flows, and chemical safety regulations such as REACH and its applicability on polymers and biopolymers for the production of substances and articles.

6.1 Rules regarding raw input materials production

Driven by sustainable policies and public opinion the market for biobased materials has been steadily growing over the last years. However, considering the enormous potential for biobased replacements there is a challenge for policy makers and industry because the production of biobased input materials requires land and is typically associated with adverse environmental effects such as indirect land-use change (ILUC).

Regulation

Currently there is no legislation identified regulating the production of certain biomass for use in the materials sector. However, in order to make the desired contribution to the transition to a biobased economy, biomass input material must be produced and used as sustainably as possible.

Transition to a biobased economy should generally contribute to the following sustainability themes:

1. cut carbon emissions compared to current fossil-based products to contribute to the transition towards a climate neutral society;
2. contribute to a circular economy, where resources are preserved for re-use and recovery;
3. contribute to a safe non-toxic environment;
4. does not lead to adverse competition with natural land-use or land-use for food production.

To meet the above criteria as a producer of biopolymers, the choice of raw materials as well as the source of these materials is highly relevant.

The choice of raw materials is one of the most critical elements (in addition to the End-of-life treatment, see chapter 9) to take into account when determining the environmental impact of bio-plastics compared to fossil-based plastics.

For example; Bio-plastics made from fermentable sugars, like sugar cane and sugar beet are often preferable to cereal crops, like maize. Mainly because for sugars, by-products or product waste can be used and there is no competition with food production.

This is also the case for other waste types, like used cooking oil as a basis for the bioplastic. In the raw material choice, care should also be given to maintain the soil quality at a sustainable level during biomass production.

6.1.1 Renewable Energy directive (outlook)

We have not identified legislation focusing on the requirements of raw biomass-based materials for biopolymers. However, in terms of energy production and fuels the European Union has laid the foundations for legally binding sustainability criteria for the production of and trade in biobased raw materials from inside and outside Europe in the form of Renewable Energy Directives: RED and RED II.

The main sustainability criteria for biofuels out of the RED are that the biofuels need to prove minimal greenhouse gas savings in comparison to fossil fuels, and that the biomass cannot be grown on high carbon stock land such as wetlands, forests or land with high biodiversity such as primary forest or highly biodiverse grasslands.

As mentioned, the RED legislation focuses solely on the production of biofuels. However, these criteria (in adapted form) may be easily translatable to apply to bio-materials as well.

Currently, well known certification schemes, such as REDcert[25], have adaption programs for biomass certification for materials based on the criteria laid down in the RED II.

6.1.2 Biomass waste flows for biopolymer production

Beyond using biomass it can be often advantageous to aim for the use of biomass waste-flows as input mass for biopolymer production. This is because it prevents competition with food production, prevents ILUC and contributes to a more circular economic system.

However, the use of certain waste streams can also introduce certain risks with regard to the chemical safety of the materials and articles when they reach the use stage.

To quote ECHA's Executive Director Bjorn Hanse:

"Chemicals are fundamental to the circular economy – they are used in products and will either be recycled or discarded as waste. A circular economy cannot be discussed without looking into the legislation on chemicals and what is happening with hazardous substances in the entire chain of events. A smooth transition to a circular economy involves "finding the balance" between materials that have a value and need to be recycled, and the hazardous substances in them that should be eliminated."[26].

Generally waste streams used as input for the production of biopolymers should be screened for the presence of hazardous substances and the potential migration of these substances of concern (SoC) into the biobased polymer. If the occurrence of SoC in the recycled polymer cannot be 100% excluded, the use applications of the polymer should be restricted to the uses where exposure to humans and environment can be prevented.

Legislation

For dealing with the biomass waste flows, the End-of-Waste Criteria (as part of the Waste Framework Directive) and REACH are applicable. The End-of-Waste Criteria are used to assesses the transition from

[25] https://www.redcert.org/en/redcert-systems/material-purposes.html

[26] from: Chemicals are at the core of the circular economy and Europe's future, ECHA newsletter September 2016, issue 3

waste bask to non-waste, while REACH manages the safe introduction and use of chemicals. These two extensive sets of EU rules are discussed in chapter 7.1 End-of-Waste Criteria and chapter 7.2 REACH.

6.2 Regulation on the shipment of waste

The Regulation on the Shipments of Waste (EC) No 1013/2006 (RSW)[27] is directly applicable to Member States. It regulates the cross-border transport of waste from, to and within the EU. The regulation includes a green list of waste types that, in case they have the purpose of recovery, may be transported to certain countries within Europe using a simple procedure. There is also an amber list of hazardous wastes for which a notification procedure must be followed, and for which all countries (sender, transit and receiver) must provide authorization.

According to the RSW, if one country in the EU qualifies a stream as waste, another country in the EU should also consider it as waste. Importing waste products from countries outside Europe to Europe is difficult. Here, the regulation states that the sender of waste (in this case the country is outside Europe) has to make the first choice, namely on which list the materials or products should be placed.

A barrier for the smooth cross-border transport of waste is the unclear definition of waste. More information on waste definition is covered in chapter 7. Despite the fact that the Waste Framework Directive (EC) 2008/98 provides conditions to clarify whether something is waste or not, Member States of the EU have different interpretations of the definition of waste. Due to this, companies trading internationally might have to follow different procedures with many administrative actions, even if their own country qualifies the stream as End-of-Waste or by-product.

6.3 The Basel Convention

The Basel Convention on the Control of Transboundary Movements of hazardous Wastes and their Disposal is an international treaty adopted in 1989. It came into force in 1992 and with 188 parties currently joining the convention, it has nearly universal membership[28]. The Convention mainly aims to:

- reduce movements of hazardous waste between nationals and specifically from developed to developing countries;
- minimize rate and toxicity of waste generated;
- ensure environmentally sound waste treatment at source of generation, and assist developing countries in doing so.

For years, large quantities of mixed toxic plastic waste were transported from developed countries towards developing countries where they were supposed to be recycled. Instead, the majority of this contaminated plastics were landfilled, burned or littered. To tackle this problem and make the global trade of plastic waste more transparent and regulated, the convention was amended in 2019 by including plastic waste in the legally binding framework. In practice, the changes in the convention mean that only clean and separated single stream plastics or certain clean mixtures can move under 'green light' controls from January 2021. All other plastics require 'prior informed consent' before export. The EC has decided to not amend the RSW,

[27] https://eur-lex.europa.eu/legal-content/NL/ALL/?uri=CELEX%3A32006R1013
[28] http://www.basel.int/Countries/StatusofRatifications/PartiesSignatories/tabid/4499/Default.aspx

but created dedicated codes to facilitate understanding around these types of plastic waste streams within the EEA[29].

Biopolymers are not specifically mentioned in the convention.

[29] https://www.ilent.nl/onderwerpen/afvaltransport-evoa/wijziging-classificatie-kunststofafval-per-1-januari-2021

7. Rules regarding the placing on the market of biopolymers

7.1 End-of-Waste Criteria

As mentioned in the previous chapter, when using waste streams for the production of biopolymers, extensive land use or competition with food production can be prevented. However, when something has been discarded, care should be taken when these waste streams are re-introduced onto the market as raw materials or articles. In this chapter we describe the process and regulatory (data)requirements which are applicable when waste ceases to be waste.

When something is thrown away it becomes waste. More specifically, the EU Waste Framework Directive (WFD) defines waste as 'any substance or object which the holder discards or intends or is required to discard'. Therefore, any substance or object is either waste or non-waste.

When a company wants to do something with this waste such as sorting, incinerating, composting, etc., specific waste regulation applies to protect people and the environment. However, currently, economies are starting to transform into a more circular system, and thus increasing emphasis is placed on utilising waste streams. This means that we try to generate less waste by either re-using products or waste is re-cycled into new products instead of being incinerated.

For polymer manufacturers who intend to use biowaste as feedstock, it is highly important to know exactly when they deal with waste and when not. They need to establish whether their 'raw materials' are waste within the meaning of the WFD or possibly remain substances, mixtures or articles within the meaning of REACH (see also chapter 7.2).

To stimulate the utilisation of waste into as raw material, the WFD makes it possible for waste to cease being waste. When a recycled substance or article receives the status of End-of-Waste, users of this substance or article no longer have to comply to waste regulations. These End-of-Waste rules have recently been amended by the revision of the main European waste directive in 2018 and were largely implemented in July 2020 by Member States.

To judge if and when something ceases to be waste, End-of-Waste criteria are currently being developed for specific product groups. However in general, a given waste may only cease to be a waste if:

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

7.1.1 End-of-Waste assessment as a toxicological safety net

Although everyone is in favour of a higher degree of recycling, in practice it is not that simple. One of the big issues, that is often overlooked, is that that there are many (restricted) SoC currently present in our waste streams. When these streams are recycled, the SoC may remain unidentified and are re-introduced on the market in various recycled products.

For a circular economy to be successful in the long-term it is essential that customers are confident (and remain so) in the quality and safety of the recycled materials. If, due to lack of information on hazardous chemicals or due to the absence of clear regulatory control, this confidence is removed it is likely that the market demand will shift back to virgin materials and the progress towards a circular economy will be seriously hampered.

Unfortunately, in recent years this was the case. Several “scandals” have reached the mainstream media reporting of potentially unsafe levels of hazardous substances as a result of overlooking the hazard profile of the recycled materials.

A well-known example are the rubber pellets used on artificial turfs made from recycled car tires. When the rubber granulate was introduced, it was presented as a very environmentally friendly solution for the staggering number of waste-tires. However, in October 2016 the Dutch television program Zembla reported on the risk of potential health effects due to the presence of hazardous substances in these types of rubber. Although it was well known that these substances are present in car tires, the potential exposures during this new use (dermal contact on the football field) were inadequately assessed before this new type of use had become widespread.

Other examples include the presence of Substances of Very High concern (SVHC) in pizza boxes made from recycled cardboard and the presence of hazardous flame retardants, which were once used in electronics, and have found to be re-introduced on the market in plastic toys for children.

Although in many of these cases, the risk of detrimental effects on humans or the environment were found to be minimal after further investigation, the reputational damage was considerable.

In order to stimulate the European transition towards a circular economy, REACH does not apply the same level of scrutiny to recycled materials as that it does on virgin materials. For example, Cadmium is exempted under REACH for the use in certain applications of recycled PVC, and recyclers can benefit from recycling privileges such as the exemption from registration when they put their recycled product on the market. However, given the nature of regulation governing the use of waste and the desire for establishing a consistent regulatory framework supporting the circular economy, it is clear that it is a hot topic for political debate. Any future regulation will therefore be subject to considerable scrutiny, and will take time to develop.

Until other regulation comes into force, the End-of-Waste assessment plays an important role in assuring the safety of recycled materials in our society. For a primary raw material, the risk assessment and registration according to the REACH regulation is sufficient before placing the substance on the market. When assessing an End-of-Waste status, a REACH registration alone is not sufficient, but additional risk assessments are requested. Such as for drug residues, pathogens, potential SoC and ZZS that are not regulated by the REACH and POP regulation.

7.1.2 Quick scan to determine of the substance/article has reached End-of-Waste

To assess if a material meets criteria for End-of-Waste status, the flow diagram (Figure 7) on this page can be applied as a first assessment. The diagram below is based on the translation of the WFD End-of-Waste criteria in the Netherlands as part of the law on environmental conservation "Wet milieubeheer". The questions posed is a representation of data tool developed by the government and serve as a guideline and can in certain cases be interpreted more broadly. For more specific details please consult the next section.

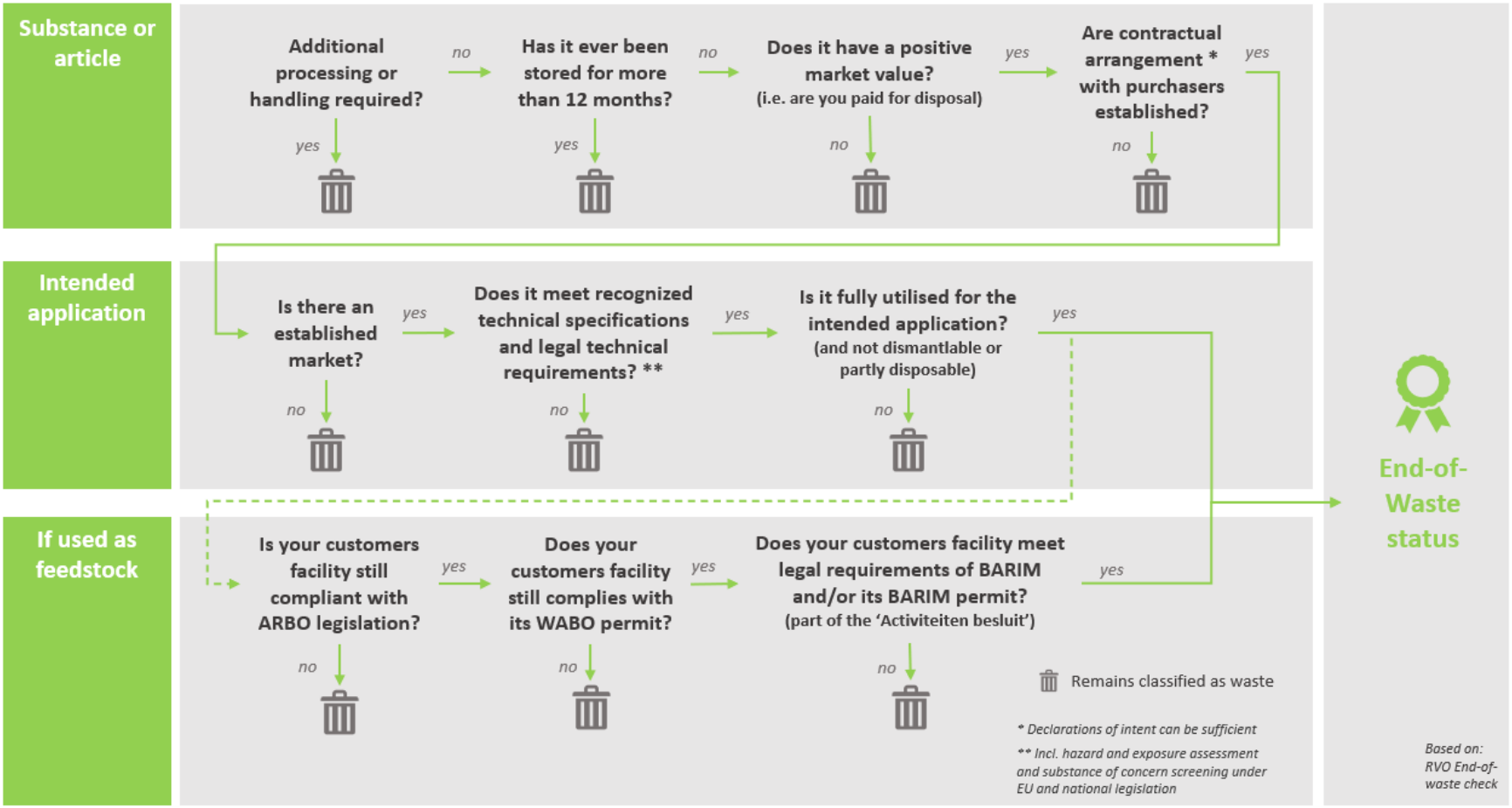

Figure 7 End-of-waste quick scan

7.1.3 Information requirements to show End-of-Waste status.

There are clear data requirement to prove to clients as well as authorities that the recycled/ recovered raw material[30] (waste), which is used for a newly produced substance or article, has reached End-of-Waste status.

To do so the following data requirements need to be met:

- available description of the recycling process and process description of how the produced article or substance came into being;
- detailed overview of waste and non-waste feedstocks (including EWC-Stat numbers[31]);
- documentation on potential presence of substances of concern in the feedstock (see also chapter 7.2.6 on SVHC screening);
- detailed chemical composition of the recycled raw material or substance, based on similar is analytical data as required for REACH registration purposes, consisting of:
  - physical-chemical composition;
  - content of impurities;
  - physical size and shape;
  - homogeneity, i.e. the variation within the given specification;
  - grading and classification of consignments.
- overview of phys-chemical characteristics;
- description of the intended use/application of the produced substance or article;
- documentation proving a solid market for the substance or article and that it has a positive market value (such as signed contracts with buyers);
- description of currently common article or substance it intends to replace;
- documentation proving that the article or substance meets recognized technical specifications and legal technical requirements applicable to the intended application;
- a description of the customer's requirements for the application of the article or substance;
- a study report or other information showing which adverse effects on humans and the environment (if any) may occur and how these are avoided in the application of the article or substance;
- documentation indicating how obligations and licensing requirements laid down in permits and environmental legislation are met, and describing how this is operationally guaranteed.

The process in practice

To compile all necessary information requirements companies (in NL) can submit their information via the portal of the Directorate-General for Public Works and Water Management (RWS).

The portal can be accessed via https://www.afvalcirculair.nl/onderwerpen/afval/toetsing-afval/

Requesting a ruling is currently not possible in most cases!

You can complete the questionnaire and compile all necessary data online, but it is not possible to request a ruling in most cases. At the moment, no new requests for a legal opinion are being processed by RWS.

[30] Can also consists of recycled substances in case of mechanical recycling.

[31] https://ec.europa.eu/eurostat/documents/342366/351806/Guidance-on-EWCStat-categories-2010.pdf/0e7cd3fc-c05c-47a7-818f-1c2421e55604

Due to the large number of requests that have been submitted, there is not enough capacity to process new requests. In some cases it is possible to request a ruling from the competent local authority or The Dutch Human Environment and Transport Inspectorate (ILT).

As a EoW ruling is not a legal necessity in the Netherlands. The recycler of a substance or article is allowed to assess whether a substance has reached End-of-Waste or not. However, recycling companies need to have data readily available to support the End-of-Waste status of their recycled/ recovered raw materials to relevant authorities (and their clients). Although not legally binding, by completing the online dossier, they ensure themselves to have available all information and data demonstrating that their substance or article has reached End-of-Waste.

International trade of substances or articles with national End-of-Waste ruling

Unfortunately a Dutch End-of-Waste ruling is not automatically valid in other European Member States. As a result of different sets of national legislations, compliancy with technical and legal requirements at national level of other EU Member States for certain uses cannot be assured based on Dutch rules only.

Especially for recycling processes for which harmonised criteria have not been developed yet; this creates obstacles for international market access. When a recycled product is intended for market in other Member States, it should minimally be assured that the country specific rules for the intended use are met.

Waste or by-product as input material?

Via End-of-Waste assessment recyclers have a regulatory basis for the possibility of turning waste into raw materials. However, where an End-of-Waste declaration states that a waste is no longer classified as waste and again becomes a raw material, it is also possible to prevent waste from becoming waste in the first place. This is the case when the it involves a by-product of a production process, most likely a production residue. Such a production residue can be seen as a by-product instead of a waste, provided the residue meets certain conditions. These conditions are stated in Article 5 of the Waste Framework Directive (WFD).

Whether a production residue can be classified as a by-product is the responsibility of the producer. It must be considered whether the following four conditions are met:

- it is certain that the substance or object will be used;
- the substance or article can be used immediately without further handling other than normal production;
- the substance or object is produced as an integral part of a production process; and
- further use is lawful, i.e. the substance or object complies with all product, environmental and health protection regulations for the specific use and will not lead to adverse effects on the environment or human health.

This European directive has been transposed into Dutch legislation through Article 1.1, paragraph 6 of the Environmental Management Act “Wet milieubeheer”. When meeting these conditions, the production residue can be seen as a by-product and therefore never enters the waste phase (i.e. being disposed). The consequence of this is that the resulting substance or article does not have to “go through” an EoW

assessment since the input materials where never waste. However, please keep in mind that producers of substances (using these by-products) are not recyclers themselves and cannot claim recycling privileges under REACH for example (see chapter 7.2.4).

Similar to EoW assessment the by-product producer should evaluate and document how the conditions (as laid down in the WFD for being a by-product) are met. Additionally, it is important to realise, that similar to EoW assessment, there must be an assessment for every individual application (in case the by-product is considered for multiple production applications).

Outlook

Currently only for scrap metal, glass cullet, and copper scrap detailed criteria have been developed and published.

For recycled plastic, there are only technical proposals from the Joint Research Centre (JRC 2014) on End-of-Waste criteria for waste plastic for conversion available[32]. These proposals so far mainly include requirement for the quality (purity) of the feedstock of plastic waste.

However, there are a couple of proposals which can become relevant for plastic production out of waste from biological origin.

Most notably:

- bio-waste (note that this only concerns plastic to plastic mechanical recycling), health care waste, and used products of personal hygiene shall not be used as input;
- End-of-Waste plastic should contain a maximum of 2% of non-plastic impurities and have no hazardous properties or come into contact with contaminants during processing;
- hazardous waste shall not be used as an input, except where proof is provided that the processes and techniques (as criteria to remove all hazardous properties specified in Section 3 of the regulation text) have been applied.

Furthermore, with regard to the restrictions of input materials two main options are formulated: a negative list, and a positive list approach. A negative list approach for input material criteria would limit the inputs or input sources that pose a specific environmental, health or quality concern if not treated adequately. The positive list approach consists of referring to the types of input materials that are preferred because their origin ensures absence or minimisation of risks, e.g. a requirement that only selective collection sources are accepted for End-of-Waste status[33].

It is important to note, that the proposals dating from 2014 do not include any mention of the production of biobased plastics from biological feedstock (PHA, PLA, Bio-PET, etc). The sole focus of these proposals lies on the plastic-to-plastic recovery and recycling. For biobased polymers manufactured from biobased waste streams the EoW assessment will likely continue to be on a case-by-case basis, depending on input materials and intended uses.

[32] https://publications.jrc.ec.europa.eu/repository/handle/JRC91637
[33] https://publications.jrc.ec.europa.eu/repository/handle/JRC91637

Management systems

Additionally, as similar systems have been implemented for glass and metals, it is not unlikely that the proposed requirements on management system are to be implemented for biobased recycling as well.

The management system shall likely include a set of documented procedures concerning each of the following aspects[34]:

- monitoring of the quality of waste plastic resulting from the recovery operation (including sampling and analysis);
- monitoring of the treatment processes and techniques;
- acceptance control of waste used as input for the recovery operation;
- feedback from customers concerning the product quality;
- record keeping of the results of monitoring conducted of above points
- review and improvement of the management system;
- training of staff. The management system shall also prescribe the specific monitoring requirements set out for each criterion.

The management system of the supplier shall be certified by an accredited conformity assessment body or by an accredited environmental verification body.

7.2 REACH

Registration, Evaluation, Authorisation and restriction of Chemicals (REACH) is an EU regulation dating from December 2006. REACH Regulation (EC) 1907/2006[35] addresses the production and use of chemical substances, and their potential impacts on both human health and the environment. It is the strictest law to date regulating chemical substances affecting industries throughout the world. The regulation also established the European Chemicals Agency (ECHA), which manages the technical, scientific and administrative aspects of REACH. The regulation covers a large spectrum of chemicals, but for the purpose of this report we will focus only on the parts of the REACH regulation that deal with polymers.

Summary of REACH requirements for (natural)polymers:

- under REACH all polymers are excluded from registration (all other REACH requirements apply). The monomers do need to be registered however
- registering a monomer most often means joining an existing registration. Compiling a new dossier is only necessary if the monomers have not been registered before by other actors;
- almost all newly developed biobased polymers, intended to be an alternative for conventional petroleum-based polymers (PE, PP, PET), do not fall under the definition of natural polymer (regardless of biodegradability profile);
- in case of recovery or recycling operations, registration of the monomers can be exempted if sameness of substance with the already registered monomeric substance can be proven. All other REACH obligations do still need to be fulfilled;

[34] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52010PC0576&from=EN
[35] https://eur-lex.europa.eu/eli/reg/2006/1907/2014-04-10

- a main obligation for (recycled) polymers under REACH (as well as for the WFD and End-of-Life) is the Substance of Concern assessment. The testing of Substances of Very High Concern (SVHC, see also chapter 7.2.6) provides business, consumers, and end-users with the assurance that tested products and materials do not contain a detrimental amount of chemicals that are hazardous to human health and the environment. The EU regulates the presence of SVHCs in consumer goods through REACH as well.

What information does the manufacturer of a (bio)polymer need to generate in order to demonstrate REACH compliance?

- Full chemical identity of substance placed on the market:
  - Analytical report containing minimally 2 analytical tests for substance identification and 2 tests for substance quantification.
- Substance of Very High Concern screening needs to be performed. The following data can be used for the screening:
  - certificates from raw material suppliers;
  - expert assessment on potentially present SVHCs;
  - analytical testing.
- Classification and labelling from the CLP regulation;
- Hazard and safety information and communication thereof to downstream users (SDS).

Future Outlook

The EC has stated its commitment to publish a proposal by 2022 to bring "at least some" polymers under the REACH registration requirement. Parallel to this, it will run a pilot project to assess findings from voluntary registrations of polymers. This commitment has been included in the in Chemical Strategy from the commission.

These ongoing initiatives are partly a result of ECHA witnessing unprecedented levels of interest in its proposed restriction for intentionally-added microplastics (see chapter 8.2).

7.2.1 REACH requirements in detail

Registration

Under REACH, companies are responsible for collecting information on the properties and uses of the substances they manufacture or import above 1 ton per year. They also have to assess the hazards and potential risks presented by the substance.

This information needs to be communicated to ECHA in the form of a registration dossier containing the hazard information and, where relevant, an assessment of the risks that the use of the substance may pose and how these risks should be controlled.

Registration applies to substances on their own, substances in mixtures, and certain cases of substances in articles. Chemical substances that are already regulated by other legislations such as medicines, or radioactive substances are partially or completely exempted from REACH requirements.

Registration is based on the "one substance, one registration" principle. This means that manufacturers and importers of the same substance have to submit their registration jointly. The analytical and spectral information provided should be consistent and sufficient to confirm the substance identity.

Company obligations

As the deadline for registration for existing substances passed in 2018, only for new substances a registration-dossier have to be compiled from the start. Currently, newly starting manufactures (or importers) of existing substances only need to join the existing registration for their substance. They do this by demonstrating “sameness of substance” using analytical studies suitable for substance identification and quantification (e.g. UV-VIS, LC-MS, GC, etc). In order to ensure fair competition, new registrants of an existing substance buy a Letter of Access to gain access to the existing registration. This way, they retroactively pay their fair share in the original registration cost of the substance.

In chapter 7.2.3 we discuss company obligations with regard to (natural) polymers in more detail.

Evaluation

Evaluation provides a means for the authorities to require registrants, and in very limited cases downstream users (e.g. article manufacturers), to provide further information. There are two types of evaluation that can occur, namely a dossier evaluation or a substance evaluation.

Company obligations

The process of Evaluation is performed by ECHA. At this step no specific company obligations apply unless the competent authority requests additional information.

Authorisation & Restriction

REACH Annex XIV is also referred to as the REACH Authorization List. It contains a list of substances that require authorization under REACH regulations. The first step in the procedure for authorisation or restriction of use of a chemical is the classification of a substance as a Substance of Very High Concern (SVHC) by ECHA. The Candidate List of substances of very high concern (usually simply called SVHC list), contains substances that meet certain criteria– such as being carcinogenic, toxic for reproduction, or persistent in the environment (see chapter 7.2.6 on the company requirements on SVHC screening)

Substances included in Annex XIV for Authorization cannot be placed on the market or used after a certain date ("sunset date"), unless an exception is granted for their specific use or the use is exempted from authorization requirements.

This authorisation requirement attempts to ensure that risks from the use of such substances are either adequately controlled or justified by socio-economic grounds, having taken into account the available information on alternative substances or processes.

Additionally, when the use of a substance poses an unacceptable risk to human health or the environment, a substance may be subject to a restriction (REACH annex XVII). The Annex XVII of REACH includes a list of certain hazardous substances, mixtures or articles (including those that do not require registration) for which use restrictions apply for putting them on the market.

For example, the use of Mercury compounds is listed in Annex XVII and shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use:

(a) to prevent the fouling by micro-organisms, plants or animals of:
    - the hulls of boats;
    - cages, floats, nets and any other appliances or equipment used for fish or shellfish; farming,
    - any totally or partly submerged appliances or equipment.
(b) in the preservation of wood;
(c) in the impregnation of heavy-duty industrial textiles and yarn intended for their manufacture;
(d) in the treatment of industrial waters, irrespective of their use.

The list is often known as REACH restricted substances list or simply as REACH annex XVII.

REACH enables restrictions of use to be introduced across the Member States where this is shown to be necessary. Member States or the Commission are the authorities that may prepare such proposals.

Company obligations

The main obligations for companies placing substances, mixtures or articles on the market is to have in-depth knowledge on the composition of their product and be aware of SVHC (from the candidate list. Annex XIV or Annex XVII) in their product.

Ideally, no such substances are present in the substances or articles. Otherwise the use of these substances (intentionally added or not) should be phased out as soon as possible. However, at a minimum companies need to ensure that the use of the substance is both allowed (Authorised) for its intended use and is NOT specifically restricted for the intended use (e.g. listed in Annex XVII).

In practice REACH requires a mandatory screening for SVHC substances as well as a screening for Annex XIV and Annex XVII substances, mixtures and articles at the 0.1% content level.

Exemptions under REACH

As mentioned previously there are substances or uses that are (partially) exempted. These are listed here:

Substances completely excluded from REACH

- radio-active substances;
- substances under customs supervision;
- substances used in the interest of defence and covered by national exemptions;
- waste;
- non-isolated intermediates (see 7.2.5)

Substances exempted from REACH registration:

- substances used in food applications;
- medicinal products;
- substances included in Annex IV of the REACH Regulation (68 substances known to be safe such as Nitrogen, Corn Oil);

- substances covered by Annex V[36] of the REACH Regulation. For example, by-products and hydrates.
- substances which occur in nature, if they are not chemically modified. Minerals, ores, ore concentrates, cement clinker, natural gas, liquefied petroleum gas, natural gas condensate, process gases and components thereof, crude oil, coal, coke;
- substances occurring in nature other than those listed under Annex IV or Annex V, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC. Examples include beeswax and some fibres;
- polymers (however, the monomer should still be registered);
- recycled or recovered substance already registered (See 7.2.4);
- re-imported substance;
- substances used for the purposes of product and process-oriented research and development (PPORD). Note: a PPORD notification should be submitted instead.

7.2.2 Polymers under REACH

As mentioned previously, the premise in REACH in regards to polymers are that they all **are exempt from registration and evaluation.** However, any manufacturer or importer of a polymer still needs to submit a registration to ECHA for the monomer substance(s) and/ or any other bound substance(s), that have not already been registered by an upstream supply chain actor, if both the following conditions are met:

(a) the polymer consists of 2% weight by weight (w/w) or more of such monomer substance (s), or other substance(s) in the form of monomeric units and chemically bound substance(s);
(b) the total quantity imported or used of the monomer substance(s) or other substance(s) makes up to 1 tonne or more per year.

For chemical intermediates - "a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance"- reduced data requirements apply under REACH. This is because these intermediates are not reaching the market as such and no exposure to these substances occur.

Although a monomer is by definition an intermediate when used for polymer production, the limited data requirements for the registration of intermediates under REACH **do not** apply to monomers for polymer production. However, additives used to preserve the stability of the polymer and impurities are regarded as being part of the polymer and therefore do not need to be registered separately. If other additives have been added to improve the performance of the polymer (for example, flame retardants), those additives should still be registered separately, if the concentration of such additives are above 2% w/w and the annual quantity of such additives are above 1 ton per year. When a given substance can be used both for preserving the stability of the polymer and for improving its performance (e.g. if the substance acts as a light stabiliser and a flame retardant), it is good practice to consider only the quantities necessary to preserve the stability of the polymer substance. The quantity of the substance that is not necessary to preserve the stability of the polymer cannot be regarded a part of the polymeric substance. It should be considered as another substance within a mixture. As such it may need to be registered. Polymers and used additives may also be subject to authorization and restriction under REACH, when they are listed in Annex XIV or Annex XVII. Additionally, polymers are not exempt from CLP regulation (see chapter 7.3). A polymer is a substance and

it must be notified to ECHA if it fulfils the criteria for classification as hazardous and it has been placed on the market.

7.2.3 Natural polymers

The regulatory perspective on polymers in REACH is relatively straightforward. Albeit, these rules do not specifically look at biopolymers, ECHA does specifically establish what natural polymers are in their guidance documents. This starts from the perspective that the polymerisation has to occur (has taken place) in nature instead of in an industrial process that mimics this natural occurrence. Therefore, it is not possible to claim that biopolymers that are created with an industrial process can be considered natural, even if the same polymer can be obtained from nature. So, please keep in mind that the (perceived) sameness of substance is not supported in the regulatory framework. For instance, polymers resulting from industrial synthesis or fermentation processes are not considered as natural polymers. To elaborate on this point, Figure 8 provides an overview of the different, and sometimes partly overlapping, definitions used around natural occurrence regarding polymers in REACH and adjoining regulations. This figure uses the definitions outlined in chapter 3.

To be specific, in REACH regulation natural polymers are understood as polymers, which are the result of a polymerisation process that has occurred (or taken place) in nature, independently of the extraction process with which they have been extracted. This means that natural polymers are not necessarily 'substances which occur in nature' due to the extraction criteria set out in Article 3(39) of the REACH regulation.

Company obligations

The exemption from registration for polymers extends to natural polymers which are chemically modified (i.e. post-treatment of natural polymers), unmodified natural polymers which are not chemically modified, for chemically unmodified substances that occur in nature, but also for industrially produced polymers (that mimic natural processes). Please note that exemption from registration is not an exemption from other obligation under REACH.

7.2.4 Recycled or recovered substance already registered

Under certain conditions, ECHA offers recyclers an exemption from the obligation to register substances from recycling processes. This exemption is laid down in Article 2(7) of REACH.

The main conditions for this exemption are:

- feedstock comes from EU;
- conformity of the identity of the recovered substance with a (already) registered substance can be demonstrated;
- availability of relevant information about the registered substance (e.g., for the preparation of an SDS and exposure scenarios);
- although this exemption was explicitly implemented by ECHA to accelerate the transition to a more circular economy, these recycling privileges are still relatively unknown within the chemical industry.

7.2.5 Non-isolated chemical intermediates

A non-isolated intermediate is defined as an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place.

As discussed in section 7.2.2, the monomers used for polymer production need to be registered. However, in some cases the monomeric building blocks are not isolated during manufacturing. A common example of this is the production of polymeric substances by organisms using fermentation processes. At no point in the “biomanufacturing” within the organism the monomeric building-blocks can be isolated.

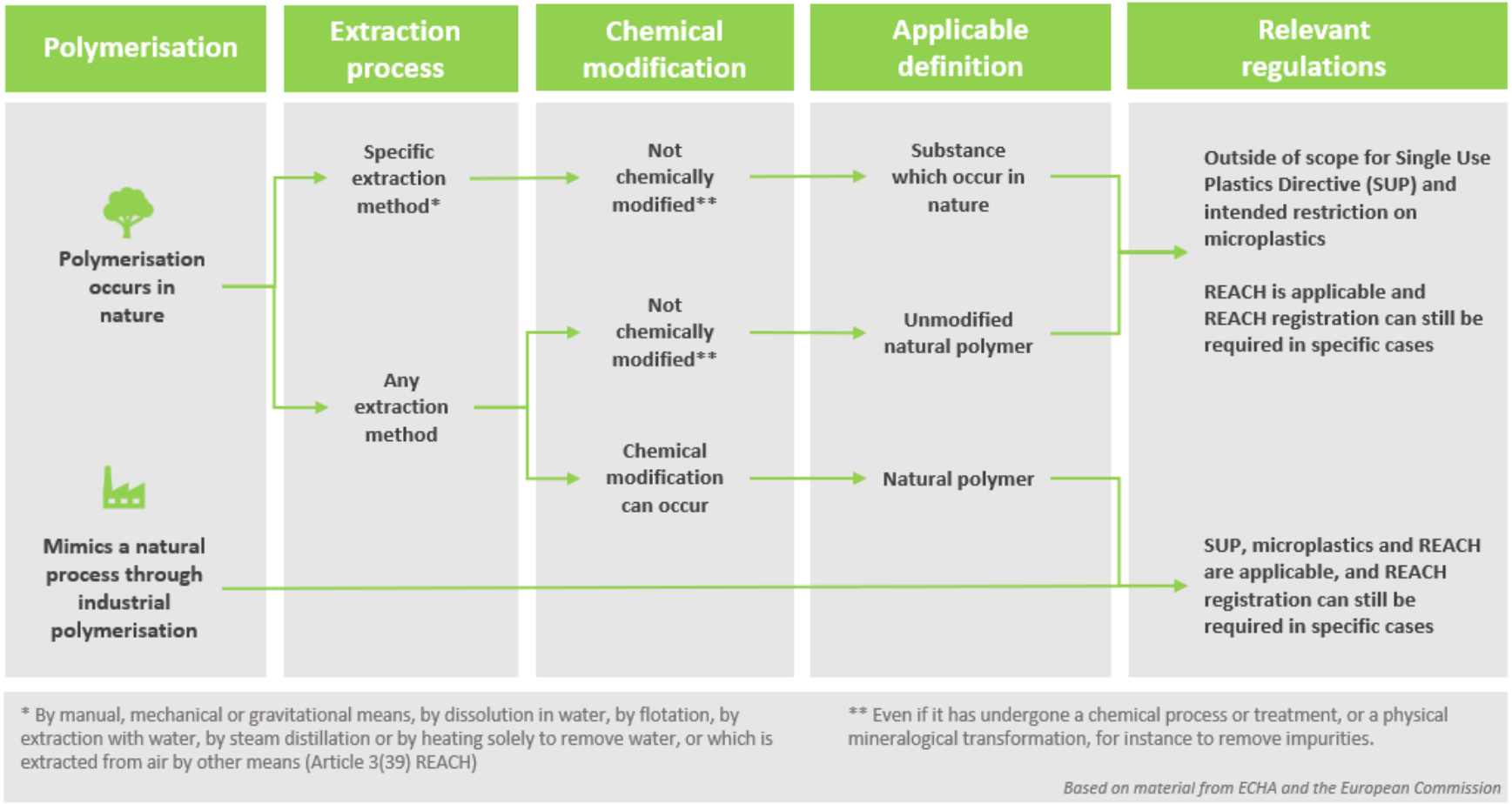

Figure 8 Regulatory definitions on natural occurrence and natural polymers and the relevant regulations

Note on definitions:

The REACH definitions for natural occurring substance and unmodified natural polymer have also been used within the SUP (see chapter 8.1) and the proposed restriction for intentionally occurring microplastics (see chapter 8.2). These terms define what constitutes as 'natural' within both regulations, and these definitions are used when assessing the regulatory implications of these regulations for biopolymers. For the REACH the distinction matters less, as polymers do not need to be registered. However, in some cases the monomers are also exempted from registration when the polymerisation occurs in nature in instead of in an industrial process.

In the case of natural polymers that are not chemically modified:

- the building block monomer substance(s) and other substance(s) in the form of monomeric units and chemically bound substance(s) with a similar origin as the natural polymers, can be treated as "non-isolated intermediates" and do not have to be registered.

In the case of natural polymers that are chemically modified:

- in the case of chemically modified natural polymers, the building block monomer substance(s) and other substance(s) in the form of monomeric units and chemically bound substance(s) similarly originating from the natural polymers can also, for practical reasons, be treated as "non-isolated intermediates" and do not have to be registered;
- however, any monomer substance or any other substance used for the chemical modification of the natural polymer needs to be registered accordingly, unless it has been registered by an upstream supply chain actor.

In case of substances that occur in nature:

- Substances occurring in nature are exempt from registration, evaluation and other downstream user obligations only if they are not chemically modified or classified as dangerous, according to the Directive on Dangerous Substances 67/548/EEC.

7.2.6 SVHC screenings and communication requirements

Chemical substances that meet certain REACH criteria– such as being carcinogenic, toxic for reproduction, or persistent in the environment- may be proposed as SVHC (substance of very high concern). As previously discussed, the listing of a substance as an SVHC by the European Chemicals Agency (ECHA) is the first step in the procedure for authorisation or restriction of use of a chemical.

Although these high concern substances can be considered unwanted due to their hazardous nature, they are used (and in the past in large quantities) due to their flame retardant, stabilizing, or other functional properties in plastics, furniture, building materials, and electronics.

Currently manufacturers or suppliers have to comply with REACH and must identify and monitor SVHC substances in their products. In addition to identifying potential SVHC substances, companies must check whether applied substances appear on the REACH list of restrictions (Annex XVII) and / or the REACH authorization list (Annex XIV).

To avoid SVHC substances from ending up in toys, agriculture, clothes or food packaging made from recycled feedstock it is important that these chemicals can be tracked from manufacturing to waste. In doing so, the waste processors and secondary manufactures (recyclers) know if a waste product contains one or more of these substances and how to safely extract them from the waste streams.

Company obligations

If you are an EU article supplier and your product contains SVHC > 0.1% w/w, you must communicate information on it along the supply chain. As a minimum, the name of the SVHC has to be passed on. If requested by a consumer you must supply them with the SVHC safe use information within 45 days.

In addition to the communication responsibility, EU article producers and importers have to notify ECHA if the total quantity of SVHC in articles is greater than 1 tonne per year.

Additionally, manufacturers need to pay attention of the growing number of SVHC substances on the Annex XIV list for authorization. Manufacturers without authorization for a specific substance use must carefully watch the latest application and sunset dates to comply with REACH requirements on allowed SVHC use.

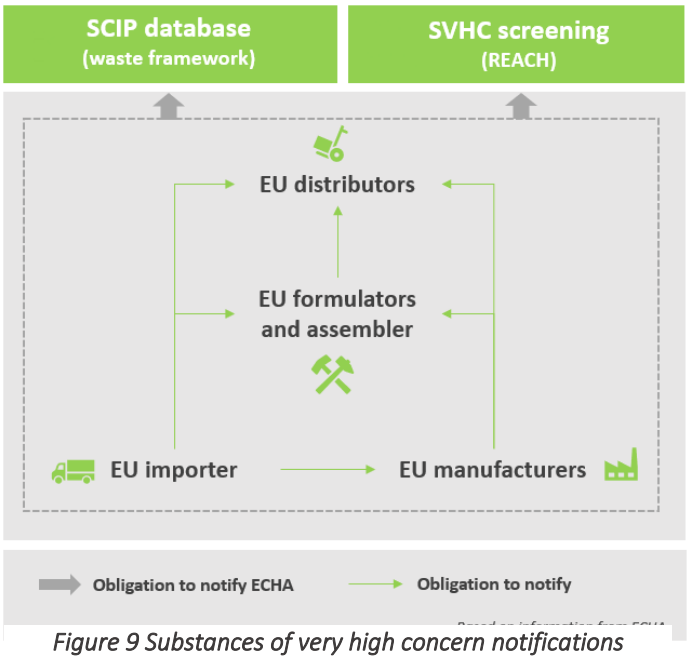

Figure 9 Substances of very high concern notifications

If you are an EU supplier of mixtures for consumers, you may need to provide a Safety Data Sheet if the mixture contains a SVHC ≥ 0.1% w/w, upon request by downstream users or distributors. This requirement is in addition to the obligations in accordance to the dangerous preparation Directive (EC) 1999/45C and the CLP Regulation (EC) 1272/2008/

Importance for polymer manufacturers

Although the SVHC requirements are formulated mainly for article suppliers under REACH, all members of the supply chain are obliged to complete some actions relating to SVHC.

As can be observed from the diagram (Figure 9) not only under REACH but also under the WFD, there are mandatory requirements around screening and communication of SVHC substances notifications. For the WFD this relates to the SCIP database (see chapter 9.1.2 for additional information).

Only when the presence of the substances is tracked from raw material to its End-of-life, a safe and efficient circular economy can be realised.

7.3 Classification, Labelling and Packaging (CLP) Regulation

Mandatory End-of-Waste assessments and/ or REACH requirements make sure that producers have enough data on the potential hazards and risks of their substances and articles. Based on this information substances or formulations must often be labelled to uniformly communicated hazard and safety information.

CLP stands for the Regulation (EC) 1272/2008 on the Classification, Labelling and Packaging of substances and mixtures. CLP introduces the United Nations globally harmonized system (UN GHS) for classification and labelling of chemicals into Europe. CLP entered into force on 20th January 2009.

In contrast to REACH, CLP applies to all substances irrespective of the annual tonnage. Furthermore, CLP is applicable to all industrial sectors. Manufacturers, importers or downstream users of substances or mixtures to need to classify, label and package their hazardous chemicals appropriately before placing them on the market.

One of the main aims of CLP is to determine whether a substance or mixture displays properties that point towards classification as hazardous. If so, the CLP-classification is the starting point for hazard communication on the associated dangers.

When relevant information (e.g. toxicological data) on a substance or mixture meets the classification criteria in CLP, the hazards of a substance or mixture are identified by assigning a certain hazard class and category. The hazard classes in CLP cover physical, health, environmental and additional hazards, and the list with substance can be found here: https://echa.europa.eu/en/information-on-chemicals/cl-inventory-database.

Once a substance or mixture is classified, the identified hazards must be communicated to other actors in the supply chain, including consumers. Hazard labelling allows the hazard classification, with labels and safety data sheets, to be communicated to the user of a substance or mixture, to alert them about the presence of a hazard and the need to manage the associated risks[37].

CLP and REACH overlap

The CLP and REACH regulations partly overlap, and this overlap constitutes:

- both regulations contain hazard communication tools. The labelling rules are set out in CLP regulation, while the Safety Data Sheet (SDS) rules are set out in REACH regulation. So for practical purposes a CLP label must always be used together with SDS;
- the classification of a substance is one mandatory part of REACH registration dossier, whereas the necessary classification criteria are included in CLP regulation.

<u>Company obligations</u>

Classification & Labelling Inventory (C&L):

- the notification obligation under CLP requires manufacturers and importers to submit classification and labelling information for the substances they are placing on the market to the C&L Inventory held by ECHA[38].

Poison centres:

- in 2017 the CLP Regulation, implemented harmonised information requirements for notifications for hazardous formulations. Hazard and safe use information is submitted to the appointed bodies in the Member State and is used for emergency health response (the Poison Centres). The Dutch

[37] https://echa.europa.eu/regulations/clp/understanding-clp
[38] https://echa.europa.eu/en/information-on-chemicals/cl-inventory-database

poison notification center is the University Medical Center Utrecht. The full list of national appointed bodies can be found at https://poisoncentres.echa.europa.eu/appointed-bodies.

- From January 1st 2021 the notification of product information to the individual national poison centers has been harmonized across the member states. Notification of the product information needs to be submitted to the ECHA submission portal and ECHA makes the information available to the national poisons center.
- Annex VIII[39] to the CLP regulation defines a unique formula identifier (UFI), which is now required on the label of the mixture, creating an unambiguous link between a mixture placed on the market and the information made available to emergency health response.

7.4 Persistent Organic Pollutants (POP) regulation and Stockholm Convention

Persistent Organic Pollutants (POP) are substances that pose serious risks to human health and the environment. They remain intact in the environment for long time periods and accumulate in the fatty tissue of organisms. Exposure to POPs could lead to cancer, birth defects, increased disease susceptibility and damage to immune, reproductive and nervous systems. Since these substances are transboundary travellers, meaning that they are widely distributed geographically, the existence of POPs should be tackled on a global scale. Therefore, POPs are globally regulated by the Stockholm Convention adopted in 2001, building on the Aarhus Protocol adopted in 1998. In the EU, these legislative pieces are implemented by the Persistent Organic Pollutants regulation (EC) 2019/1021[40](EU POP). Organisations operating in the EU should follow this regulation.

The EU POP Regulation has the objective to protect the environment and human health from the risks posed by POPs. To ensure this protection, specific control measures are in place:

- strong restrictions or entirely prohibit POP market introduction and use;
- minimise release of POP to environment when they are formed as by products in industry;
- ensure safe management of stockpiles of restricted POPs;
- waste with POPs follows environmentally sound disposal.

Examples of POPs are:

- pesticides, such as DDT;
- industrial chemicals, such as PCBs;
- unintentional by-products from industrial processes, degradation or combustion, such as dioxins.

Company Obligations

Bioplastics need to be screened on the existence of POPs. Also, additives which could be necessary for producing final products could be considered as POPs under the EU POP. For example, hexabromobiphenyl is an additive used for reducing flammability, which could be useful for construction applications. However, this additive has an endocrine disrupting effect and should therefore be eliminated according to the

[39] https://echa.europa.eu/documents/10162/13643/guidance_on_annex_viii_to_clp_en.pdf/412c5874-f8ec-cf52-fe1e-2fbe08fe2d11

[40] https://eur-lex.europa.eu/legal-content/NL/TXT/?uri=CELEX%3A32019R1021

Stockholm convention and EU POP regulation. Recent research also found indications that the presence of POPs could alter the biodegradability of a certain biopolymer.[41]

Specific attention should be given when using potentially polluted feedstock in the production of biopolymers (for instance while using raw materials obtained from recycling processes). In these circumstances the occurrence of POPs in the polymers may not be intentional but the results of migration from the waste feedstock into the polymer. Even when using relatively clean waste streams, it can still be contaminated by contact with processing equipment or containers used for processing other waste streams. Regulatory guidance in the form on End-of-Waste assessment and mandatory SVHC screenings are in place to avoid to accidental marketing of polluted material (see chapter 7.1 and chapter 7.2.6).

A common understanding paper[42] by the EC can be consulted for information on the relationship between POP regulation and REACH, regarding restrictions and authorisation requirements.

Outlook

Although currently not recognised from a regulatory perspective, a publication[43] by the working group of Regional Centres of the Stockholm and Basel[44] Conventions stated that marine plastics litter and its chemical components should be classified as persistent pollutants, and have called for immediate preventive measures to reduce plastics pollution.

In the publication it is noted that the degradation of persistent plastics into microplastic and nano-plastic fragments facilitate their uptake by marine biota, likely resulting in the accumulation in the food chain. Additionally, some polymers contain chemical additives and contaminants that are known for their endocrine disrupting properties and these "may be harmful at extremely low concentrations for marine biota, thus posing potential risks to marine ecosystems, biodiversity and food availability."

Although most of these chemicals "may not qualify as 'persistent' under the strict criteria of the Stockholm Convention", the authors claim that "they may be potentially as harmful as officially recognized POPs in terms of behaviour and consequences in the marine environment". This is because of the "continuous flow of 'fresh' plastic waste," enhanced persistence in marine systems because of "their adsorption to microplastics, combined with the harsher environmental conditions of low temperature and salinity, combined also with low light and low oxygen content in subsurface waters and sediments," along with further inhibition of degradation due to "sorption of contaminants in nanopores of plastics."[45]

Currently there is no strong indication that plastics are going to be regulated under the EU POP regulations. However, the concern over plastics and microplastics in the (marine) environment are clearly being recognised by international authorities. Most notable the SUP (chapter 8.1), ECHA`s proposal on the ban on intentionally added microplastics (chapter 8.2) and the new EU Bio-stimulant and fertiliser regulation (chapter 8.3).

---

[41] https://qaehs.centre.uq.edu.au/event/session/2917
[42] https://ec.europa.eu/docsroom/documents/5805/attachments/1/translations/en/renditions/native
[43] https://enveurope.springeropen.com/articles/10.1186/s12302-018-0139-z
[44] The objective of the Basel Convention is to protect human health and the environment against the adverse effects of hazardous wastes.
[45] Adapted from https://www.foodpackagingforum.org/news/chemicals-in-marine-plastics-as-persistent-pollutants

7.5 Minamata Convention on Mercury

The Minamata Convention on Mercury is a global treaty to protect human health and the environment from the negative effects of mercury. This treaty was ratified by the EU in 2017. As long as biopolymers do not contain or are contaminated with mercury, and mercury is not used for industrial processes, the Minamata Convention is not relevant for biopolymers. Of course, when particular waste streams are used as raw materials for biopolymer production, specific care should be taken if migration of i.e. heavy metals from waste is possible.

7.6 Montreal Protocol

The Montreal protocol aim to reduce and phase-out the consumption and production of ozone depleting substances (ODS). Such chemicals damage the stratospheric ozone layer when released in the atmosphere, thereby undermining the earth's protection against harmful ultraviolet solar radiation. As long as biopolymers do not contain or are contaminated with ODS, the Minamata Convention is not relevant for biopolymers.

8. Rules regarding the use and application of biopolymers

In the previous chapter we discussed the rules that impact the manufacturing and market entry of biopolymer substances, such as REACH. However, already in the design and manufacturing stage of your substance, the intended uses or fields of application should be considered for the final article. For many applications there are specific rules and regulations that might apply. As a producer of a biopolymer substance this might not seem directly relevant, but if your customers need to adhere to specific application regulations it will impact what they expect from your substance. In this respect, the rules and conditions regarding biodegradability in articles are most notable and relevant here.

8.1 Single Use Plastics Directive

As a part of the EU Plastic Strategy, European Parliament created a Single Use Plastics Directive (SUP) to tackle marine litter coming from single-use plastic products most often found on European beaches, together with fishing gear and oxo-degradable plastics.

In addition to combating plastic marine litter SUP strongly promotes circular approaches that give priority to sustainable and non-toxic re-usable products and re-use systems, aiming to reduce the quantity of waste generated and to assure circular life-cycle for plastics.

For which types of products does it exactly apply?

The SUP applies to **plastic products** that are meant to be **used only once** and disposed afterwards.

The 10 items being addressed by the Directive are:

- cotton bud sticks;
- cutlery, plates, straws and stirrers;
- balloons and sticks for balloons;
- food containers;
- cups for beverages;
- beverage containers;
- cigarette butts;
- plastic bags;
- packets and wrappers;
- wet-wipes and sanitary items.

Depending on existence of suitable alternatives, the use of single-use plastics should be reduced or placing them on the market should be prohibited.

The use of products without suitable alternatives should be reduced such as:

- **cups for beverages**, including their covers and lids;

- **food containers** (for example boxes).

Placing on the market should be prohibited for single-use products that have suitable, affordable alternatives such as:

- **cutlery** (forks, knives, spoons, chopsticks);
- **plates**, **straws**, **beverage stirrers**, sticks attached to balloons (except for industrial or other professional uses), **food containers made of expanded polystyrene**;
- **beverage containers and cups for beverages made of expanded polystyrene**, including their caps and lids.

Specific considerations:

- plastics manufactured from **biobased** substances or **biodegradable** plastics are also within the scope of this Directive (see section 8.1.1);
- paints, inks and adhesives as polymeric materials, are excluded from the scope of the SUP and not considered to fall under the definition of plastic in this directive.

Other topics:

- clear marking is required when putting the product on the market (informing of appropriate disposal and negative impact of littering);
- additional requirements for article producers: recycled content in PET bottles, collection rates for plastic bottles, extended producer responsibility for covering costs of awareness-raising measures and waste collection (of single-use packaging).

8.1.1 Biobased or Biodegradable alternatives and the SUP

As mentioned in the previous section, biobased polymers and polymers with biodegradability claims do not get exempted from the imposed restriction on single-use articles.

In theory, polymers that do readily degrade in the various natural environments may contribute less to the littering problems on land and in the oceans. However, the second important goal of the SUP is the reduction of generated waste as the result of single-use articles and aim for increasing the uptake of reusable articles. In some cases, biodegradable polymers might have favourable End-of-life options compared to conventional polymers. But in general switching from conventional polymers to biobased/ biodegradable polymers for single-use plastic articles does not reduce the amount of waste or (natural) resources lost. Also, the risks that littered plastics pose to biodiversity (e.g., ingestion) is often not (fully) diminished by using biodegradable plastics, because their degradation time is still relatively long due to conditions or material properties.

Unmodified natural polymers and naturally occurring substances are exempted

Unmodified natural polymers/ naturally occurring polymers (substances), such as silk, wool, cellulose, are outside the scope of the SUP[46]. The SUP uses the definition "unmodified natural polymer" from the REACH regulation to assess if a polymer is considered to be so too. The exemption is also in place for naturally occurring substances (that are polymers). A consequence is that for example cellulose and lignin, extracted from wood and corn starch obtained via wet milling, meet the definition of unmodified natural polymer.

If however, a chemical modification of the substance is involved it still falls under the SUP regulation. So, chemically modified natural polymers are not exempted. However, this is not the case, when the substance has gone through a chemical process or treatment, or a physical mineralogical transformation that **does not alter** the chemical composition.

As outlined in chapter 7.2.3 (and Figure 8), **unmodified natural polymer** and **naturally occurring substance** are both to be considered chemically unmodified. A key distinction between them relates to the extraction methods that are used. The definition used for unmodified natural polymer is independent of the method used to extract the substance from nature, while naturally occurring substances are only extracted using certain extraction methods (see figure 8). However, these specific extraction methods from article 3 (39) are not directly referred to in the SUP and therefore the regulation is applicable to both situations.

Outlook

As discussed, biodegradable/ biobased plastics are considered to be plastic under the SUP directive. One of the main reasons is that there are currently no widely agreed technical standards available to certify that a specific plastic product is properly biodegradable in the marine environment in a short timeframe and without causing harm to the environment.

However, the proposed review of the Directive in 2027 is planned to include an assessment of the scientific and technical progress concerning criteria or a standard for biodegradability in the marine environment applicable to single-use plastic products. In the context of the new CEAP, the Commission plans to develop in 2021 a policy framework on the use of biodegradable or compostable plastics, based on an assessment of the applications where such use can be beneficial to the environment, and of the criteria for such applications[47].

8.2 Uses as microplastic

8.2.1 Restriction of intentionally added microplastics

What are microplastics?

When plastics are not properly disposed of or recycled, they may end up in the environment where they stay for centuries and degrade into smaller and smaller pieces. These small pieces (typically smaller than 5mm) are called **microplastics** and they are of concern.

Microplastics are solid plastic particles composed of mixtures of polymers and functional additives. They may also contain residual impurities. Microplastics can be **unintentionally formed** when larger pieces of

[46] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0607(03)&from=EN
[47] https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_2709

plastic, like car tyres or synthetic textiles, wear and tear. But they are also **deliberately manufactured and added** to products for specific purposes, such as exfoliating beads in facial or body scrubs.

Why are they a problem

Each year around 42 000 tonnes of microplastics end up in the environment when products containing them are used. The largest single source of pollution is the granular infill material used on artificial turf pitches, with releases of up to 16 000 tonnes. In addition, the release of unintentionally formed microplastics (when larger pieces of plastic wear and tear) to the European surface waters is estimated to be around 176.000 tonnes a year[48].

Microplastics have been found in marine, freshwater and terrestrial ecosystems as well as in food and drinking water. Their continued release contributes to permanent pollution of our ecosystems and food chains. Exposure to microplastics in laboratory studies has been linked to a range of negative (eco)toxic and physical effects on living organisms.

The European Food Safety Authority (EFSA) has in 2016 reviewed the available evidence on microplastics and nano-plastics in food in 2016. Experts identified the need to generate more data on their occurrence levels in food and on their potential effects on human health. To that end, EFSA is holding a scientific colloquium in 2021 to discuss the current state of play and ongoing research in this field[49].

ECHA's proposed restriction

Within the REACH framework substances can be subject to certain restrictions when the use of a substance poses an unacceptable risk to human health or the environment. In chapter 7.2 we describe the regulatory context of these restrictions, but in summary, restrictions are applied to restrict (or even prohibit) the manufacturing, placing on the market (including importing) or use of a substance, but can also impose relevant conditions such as requiring technical measures or specific labels.

As a result of increasing concerns over plastic leaching into the environment and potential migration into the food chain EU Member States have already enacted or proposed national bans on intentional uses of microplastics in consumer products. Current restrictions mainly have main focus on the application of scrubbing microbeads in cosmetics. These beads are rinsed off after use, and migrate to sewage treatment plant and surface waters.

As part of its plastics strategy and sustainable development goals, the EC asked the ECHA to complete a restrictions proposal (a so-called Annex XV report) for intentionally added microplastics used in products that are placed on the market in European Union/European Economic Area (EU/EEA). The proposal (from January 2019) aims to ban microplastics in products such as cosmetics, detergents, fertilisers and more. According to ECHA, the ban of microplastics would prevent the release of 500.000 tonnes of microplastics into the environment over a 20-year period[50].

[48] https://www.echa.europa.eu/documents/10162/28801697/qa_intentionally_added_microplastics_restriction_en.pdf/5f3caa33-c51f-869e-81c8-7e1852a4171c

[49] https://www.efsa.europa.eu/en/news/microplastics-and-nanoplastics-food-emerging-issue

[50] https://echa.europa.eu/nl/hot-topics/microplastics

The proposal intends to ban products that contain microplastics from the EU/EEA market if these microplastics are inevitably released to our environment when the products are used. The EC's proposal, to amend the list of substance restrictions (included in Annex XVII of the REACH regulation) with microplastics, will be put to a vote before the EU Member States in the REACH Committee in the second half of 2021.

Examples of such products are cosmetics, cleaning and laundry products, fertilisers, plant protection products and seed coatings. Other products, such as paints and inks, may also contain microplastics, but their use does not inevitably lead to environmental releases. For example, when a paint dries, the microplastic particles of the paint join together and form a film. These uses are not proposed to be banned.

However, the proposal requires companies to give instructions on how users can prevent or minimise any residual releases of microplastics to the environment. For example, instructions for paints that contain microplastics would need to describe how to clean paint residues from brushes and rollers without rinsing them into wastewater systems. Companies also need to report these microplastic uses and releases to ECHA to ensure that residual releases are monitored and, if necessary, controlled in the future.

Additionally, the proposal outlines two options to control the releases of microplastic infill from artificial turf sports pitches: a ban on placing them on the market or the mandatory use of risk management measures. These options have different costs to society, but also different effectiveness in preventing releases. Upcoming regulatory changes regarding artificial grass infill are relevant for producers and users of biodegradable infill granulates. Only polymeric materials meeting extensive biodegradability testing and pass levels (such as OECD and or ISO testing) may be allowed when the restriction becomes enforced. Within the restriction proposal exact criteria for biodegradability are not yet available.

Which polymers are covered?

The proposed restriction does not cover all polymers – it concerns only those that are consistent with the microplastic definition and relevant to the concern: less than 5 mm in size, solid, particulate, insoluble and non-biodegradable. Unfortunately, within the restriction proposal exact criteria for biodegradability are not yet available.

It should also be noted that the proposal does not concern microplastics that are formed unintentionally in the environment (also called secondary microplastics). Examples of secondary microplastics are releases from car tyres while driving or from the degradation of plastic litter. The EC is considering measures to tackle these secondary sources as part of the EU's Plastics Strategy and CEAP[51].

8.2.2 Impact on Biopolymer and biodegradable polymer markets

The current 'working definition' (as outlined in the call for evidence[52]) for microplastic particles is:

[51] https://chemicalwatch.com/167171/european-commission-publishes-radical-wide-ranging-chemicals-strategy
[52] https://echa.europa.eu/previous-calls-for-comments-and-evidence/-/substance-rev/31325/del/50/col/staticField_-104/type/asc/pre/1/view

- 'any polymer[53], or polymer-containing, solid or semi-solid particle having a size of 5mm or less in at least one external dimension'.

The ECHA working definition within the restriction proposal did originally not distinguish between synthetic (i.e. artificial), naturally occurring or modified/ unmodified natural polymers or between water soluble and water insoluble polymers. However, these elements are currently being recognized to be important for risk assessment and information on these aspects was specifically requested in the call for evidence (Stakeholders responded to ECHA's call for evidence for this restriction proposal on the basis of a 'working definition' for microplastic).

Based on ECHA's more recent *Note on substance identification and the potential scope of a restriction on uses of 'microplastics'* [54] it is noted that polymers that occur in nature can, by default, be considered to be inherently (bio)degradable in the environment. Therefore, ECHA`s current view is that they **should not be** considered microplastics. So, substances that occur in nature and/ or chemically unmodified natural polymers are inherently biodegradable and are not considered microplastics according to ECHA.

This approach is consistent with Article 2(7)(a) and 2(7)(b) of REACH regulation (as elaborated in Annexes IV and V). However, polymers that occur in nature that have been chemically modified in some respect (e.g. cross-linked) or are industrially polymerised **should be** considered to be microplastics, where they also meet the microplastic criteria for physical state, morphology and dimensions. The relevance of these polymers to the scope of a restriction will depend on whether they are released to the environment through their use and on their (bio)degradability in the environment.

Clear criteria for (bio)degradability in the environment have not been proposed yet. However, ECHA is currently investigating whether any of the existing standard methods for determining the (bio)degradation of chemicals in the environment materials (such as OECD 301[55] / OECD 306[56]) and their associated thresholds and guidance could be meaningfully applied to microplastic materials.

In general, degradation is followed by the determination of parameters such as dissolved organic carbon (DOC), CO_2 production and oxygen uptake.

Potential scope of the restriction

In ECHA`s note on substance identification and the potential scope of a restriction on uses of 'microplastics', 17 uses have been indicated as being within the scope of the proposed restriction.[57] In Annex II of this report the list of uses as identified by ECHA is included.

As these uses cover a broad array of applications, the use of biopolymers can be affected in both positive as negative way. Although most biopolymers will not be excluded from the scope based on the "unmodified

[53] According to Article 3(5) of REACH

[54] https://echa.europa.eu/documents/10162/13641/note_on_substance_identification_potential_scope_en.pdf/6f26697e-70b5-9ebe-6b59-2e11085de791

[55] https://www.oecd-ilibrary.org/environment/test-no-301-ready-biodegradability_9789264070349-en

[56] https://www.oecd-ilibrary.org/environment/test-no-306-biodegradability-in-seawater_9789264070486-en

[57] https://echa.europa.eu/documents/10162/17233/note_on_substance_identification_potential_scope_en.pdf/6f26697e-70b5-9ebe-6b59-2e11085de791

natural polymer" definition, proven degradable polymers may likely be considered as a favourable substitute for conventional polymers.

8.3 Agricultural use

8.3.1 Bio-stimulant and Fertilizer regulation

This section dives into the Bio-stimulant and Fertilizer regulation (EC) 2019/1009[58]. The regulation will come into force on 16 July 2022. The regulation lays down rules about putting fertilising products onto the EU market. From a (bio)polymer perspective that can be either as a separate application for instance as a coating agent. It can also be part of the fertiliser to improve the fertilisers wettability or acts a binding material. Additionally, please keep in mind Member States can also have their own (existing) fertiliser regulations to govern market access within their own borders.

The Bio-stimulant and Fertilizer regulation prescribes several Component Material Categories (CMC) of which a fertilising product shall solely consist. For each of these CMCs, a set of requirements are determined to avoid any environmental problems or harm to plant, animal or human health.

Figure 10 presents a visual timeline of the relevant regulatory considerations in the present and future from a (bio)polymer perspective, and contains the most important aspects discussed in this section.

Polymers have been placed in a separate CMC, more specifically CMC 8 (Nutrient polymers) and CMC 9 (Polymers other than nutrient polymers). This is discussed in more detail below.

Polymers other than nutrient polymers

One of the categories with allowed materials is CMC9: 'Polymers other than nutrient polymers. In the requirements related to this CMC it is stated that a fertilising product in the EU can contain polymers (other than nutrient polymers) only if the purpose of the polymer is:

a) *"to control the water penetration into nutrient particles and thus the release of nutrients (in which case the polymer is commonly referred to as a 'coating agent')*
b) *to increase the water retention capacity or wettability of the fertilising product*
c) *to bind material in a fertilising product with a growing medium functionality."*

Another requirement for CMC9 is that the polymers with purpose (a) and (b), nor its by-products after degradation, should not create any overall adverse effect on animal or plant health, or on the environment, under reasonably foreseeable conditions.

To prove compliancy with this requirement the polymer must pass three tests:

- Plant growth acute toxicity test: The test makes a comparison between the plant growth in soil exposed to test material and growth in a blank soil (control soil). The test is passed if the germination rate and the biomass of the plant species grown exposed soil is more than 90 % in comparison to the plant growing on the control soil.

[58] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1009&from=EN

- **Earthworm acute toxicity test:** In this test a comparison is made between earthworm survival in soil exposed to test material and survival in control soil. The test is passed if the difference in mortality and biomass of surviving earthworms in the exposed soil is smaller than 10% in comparison to earthworms in the control soil.
- **Nitrification inhibition test with soil micro-organisms:** The test compares nitrite formation in exposed soil and formation in control soil. The test is passed if the nitrite formation in soil exposed to test material is more than 90% in comparison to nitrite formation in the control soil.

For each of these three tests there are some additional requirements that need to be met to validate a pass of the test. More details about these requirements can be found on page 66 of the regulation.

Using polymers under other CMCs

In a recent technical update[59] of the regulation, the EC adjusted the regulation to allow for some polymers to be used under other CMCs, namely CMC1 (virgin material) and CMC11 (by-products). This adjustment of the regulation was made because some polymer-based technical additives are already used frequently to fulfil some important functions that are not mentioned in CMC9, but do ensure efficiency and safe use (such as anti-caking and anti-dust). The allowance of polymers in CMC1 and CMC11 applies to the polymers that cause no environmental harm. For determining whether polymers cause environmental harm, there is reference to the scientific opinions[60] issued by two ECHA committees on intentionally added microplastic particles. Surprisingly, in paragraph 13 of the technical update it is mentioned that "those polymers will be registered under Regulation (EC) No 1907/2006 (REACH) with a dossier including a safety report for their use as a fertilizing product". Please note that this is in contrast with the current exclusion of registration for polymers under REACH as described in 7.2.2 of this report.

[59] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12135-Fertilising-products-technical-update_en

[60] https://echa.europa.eu/nl/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

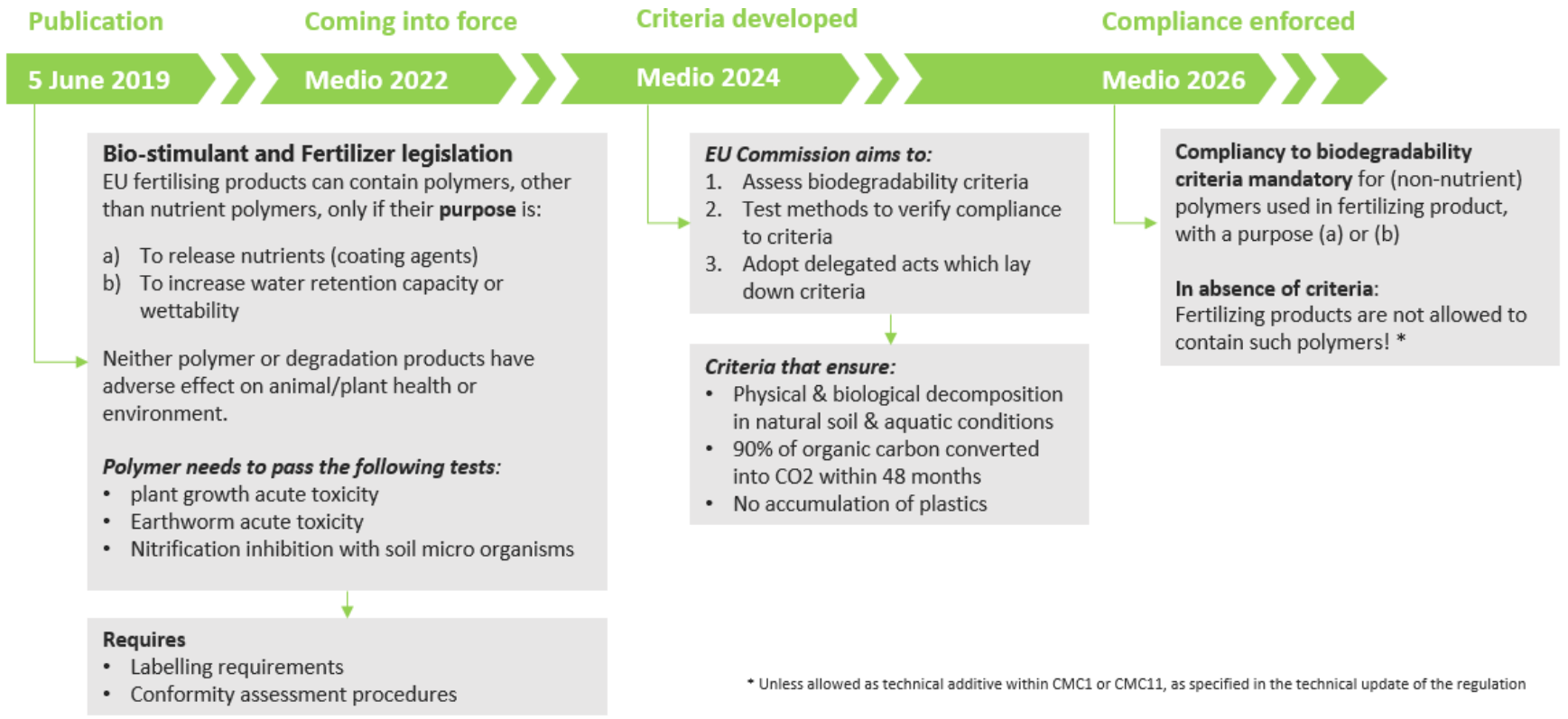

Figure 10 Timeline regulatory considerations regulation (EU) 2019/1009

Labelling requirements

The regulation also lists some generic labelling requirements, to ensure that sufficient information is provided to the user. One of those requirements is specifically dedicated to the CMC of polymers (other than nutrient polymers).

Fertilizing products with such polymers need to be provided with information on the functionality period. This is the time period following use during which the nutrient release is being controlled or the water retention capacity is being increased. The functionality period shall not be longer than the period between two applications as indicated in the use instructions. These use instructions shall include: Instructions for intended use, including application rates, timing and frequency, and target plants or mushrooms. In cases where the fertilizing product contains a polymer with purpose (c), users must be informed not to use the product in contact with soil, and make sure of a sound disposal of the products after end of use, in collaboration with the manufacturer.

The regulation also includes product specific labelling requirements. For example, regarding coated solid inorganic macronutrient fertilisers, the label must indicate the name of the coating agents and the percentage of fertiliser coated by each coating agent, followed by a specific marking:

- for polymer coated solid inorganic macronutrient fertilisers, the following marking: “The rate of nutrient releases can vary according to the temperature of the substrate. An adjustment of fertilisation may be necessary”;
- for sulphur coated solid inorganic macronutrient fertilisers and sulphur/polymer coated solid inorganic macronutrient fertilisers, the following marking: “The rate of nutrient release can vary according to the temperature of the substrate and the biological activity. An adjustment of fertilisation may be necessary.”

The Bio-stimulant and fertilizer regulation can be consulted for a complete list of generic labelling requirements (Annex III, part I) and product-specific labelling requirements (Annex III, part II).

Conformity assessment procedures

Fertilising products need to be subjected to so-called ‘conformity assessment procedures’ in order to assess whether the product complies with requirements from this regulation and to ensure that such assessment is performed in a standardised way. Such a procedure can for example include product tests (on technical design of the product) or production process test. If a product contains polymers (other than nutrient polymers), Module B followed by Module C should be used for conducting the test. More information about these modules can be found in Annex IV part II of the regulation.

Biodegradability requirements

The regulation acknowledges that it should be possible for innovative applications containing polymers to enter the market. Yet, criteria for their biodegradability still need to be developed, to ensure that after use these polymers are able to physically and biologically decompose. The criteria will be developed by 2024

The criteria must ensure that:

- that the polymer is able to **physical and biological decompose in natural soil conditions and aquatic environments** across the Union. Carbon dioxide, biomass and water should be the only product left after decomposition;
- the conversion of **organic carbon into carbon dioxide should be at least 90% in a maximum period of 48 months** after the end of the indicated functionality period of the EU fertilising product, and as compared to an appropriate standard in the biodegradation test;
- the use of polymers does **not result in accumulation of plastics** in the environment.

After a transitional period, per 16 July 2026 these criteria will be enforced and polymers not compliant to the criteria will be prohibited.

It should be noted that all of the requirements from this regulation that are applicable for polymers (other than nutrient polymers), also apply to fertilizing products (articles) that contains such polymers. In some case it might be that a polymer on its own might comply to the regulatory requirements, but the fertilizer product that contains the polymer might not.

8.4 Packaging and Packaging waste directive

As packaging is a very likely field of application for biopolymers, we identified the EU packaging and packaging waste directive[61] as a directive laying down potentially important sets of rules or restrictions. However, this directive does not mention the application of biobased polymers in its regulatory texts.

It is important to note however, that EU targets for the reusability or recycling of plastic packaging will include the use biobased plastics. The packaging directive defines a recycling target (by weight) for plastic packaging of 50% and 55%, for 2025 and 2030 respectively.

It is important to note, that although a biodegradable packaging can increase recycling potential (e.g. through composting), uncareful substitution can also hamper established recycling schemes for conventional polymers such as PET recycling. This also relates to the aim of keeping high value materials in the economy as long as possible, as is further discussed in chapter 9.1 about the Waste Framework Directive.

EU rules on packaging and packaging waste cover both packaging design and packaging waste management. They aim to deal with the increasing quantities of packaging waste, which cause environmental problems. They also aim to remove barriers in the internal market which are caused by EU countries adopting different rules on packaging design.

[61] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01994L0062-20150526

8.5 Food contact materials

During production, transport, and consumption, food comes into contact with all kinds of materials. For example, think of conveyor belts, filters, all kinds of (plastic) packaging materials and the coffee machine at your office. Overall, these materials are called: Food Contact Materials (FCMs).

The responsibility for the food safety of materials falls to the business operators who are putting them on the market. Specifically, the safety of materials relies on ensuring that there is no migration of chemical substances in unsafe levels from material (packaging) to food. Therefore, producers and importers must check and document that their food contact materials meet this and other legislative requirements.

8.5.1 EU Food contact legislation

As a result, the European Food Safety Authority (EFSA) regulates the safety of food contact materials. At EFSA's website, you can search for opinions on substances to be used in food contact materials.

Overall, the Regulation (EC) 1935/2004[62] is applicable for all food contact materials in the EU. In short, this framework of regulations states that materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable condition of use, they do not transfer their constituents to food in quantities which could:

- endanger human health;
- bring about a large change in composition;
- bring about deterioration of the organoleptic characteristics.

In the EU 17 materials for FCM have been identified. However, Harmonised EU legislation only exists for 4 of them. The most well-known set of harmonised EU legislation is Regulation (EC) No 10/2011 on Plastic Materials and Articles. For other materials such as coatings, adhesives, and paper, national legislation applies (i.e. the Dutch Packaging and Consumer Items (Commodities Act) regulation).

Specifically for plastics Regulation (EU) No 10/2011 (3) lays down the requirements for plastic packaging and consumables. This regulation includes a list of permitted substances for making the packaging. However, the list of substances for polymerization aids is not exhaustive. Therefore, Chapter I of Annex Part A of this Regulation contains an additional list of substances authorized at national level, resulting in a complete list of permitted substances for the manufacture food contact materials.

In the EU, a declaration of compliance (DoC) is mandatory for food contact plastics (including recycled plastics), active and intelligent materials, ceramics and regenerated cellulose film. For other types of food contact materials (i.e., paper, inks), a DoC is currently not mandatory. However, it is common for actors up the value chain to request one.

Biobased polymers

The packaging market is influenced heavily by strong market and consumer-driven preferences. For example, the increasingly bad reputation of single-use plastics forces manufacturers to consider more biodegradable, biobased and/or recyclable alternatives. However, while these alternatives have a beneficial

[62] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32004R1935

effect on the natural environment, they do not necessarily guarantee food safety. As a result, in some cases, the biodegradable properties or recycled content can even be at odds with the principle of inertness and traceability requirements stipulated in the EU framework regulation.

For biobased plastics the same rules apply as for conventional plastics. Within FCM regulation the following definition is laid down in article 3 on polymers.

A 'polymer' means any macromolecular substance obtained by:

- a polymerisation process such as polyaddition or polycondensation, or by any other similar process of joining monomers and other starting substances; or
- chemical modification of natural or synthetic macromolecules; or
- microbial fermentation.

With regard to the monomeric starting substances the following applies:

- a substance undergoing any type of polymerisation process to manufacture polymers; or
- a natural or synthetic macromolecular substance used in the manufacture of modified macromolecules; or
- a substance used to modify existing natural or synthetic macromolecules.

For plastics intended to come in contact with food, regulation (EU) 10/2011 lays down the safety requirements for plastic materials and articles intended to come into contact with food[63].

In addition to Food Contact Materials (FCM) consisting exclusively of plastics the regulations apply to:

- plastic multi-layer materials and articles held together by adhesives;
- materials that can be printed or covered by a coating;
- plastic layers or plastic coatings, forming gaskets in caps and closures;
- plastic layers in multi-material and multi-layer materials and articles.

Company Obligations

The following requirements result from regulation regarding food contact materials:

- fully understand the composition. Companies must collect the complete and full composition of their article (including all additives and polymer production aids). Only substances that are positive-listed in Annex I of the Regulation (EU) 10/2011 may be intentionally used in the manufacture of plastic materials and articles;
- check for specific provisions for several categories of plastic materials such as caps and closures and multi-layer plastic materials or multi-material multilayers;

[63] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011R0010-20200923&from=EN

- follow the testing requirements. There are specific requirements that need to be followed for testing of overall and specific migration, including comprehensive guidance on selecting simulants and conditions for testing;
- risk assessment requirements. The assessment of Non-Intentionally Added Substances (NIAS) and their risk is required from manufacturers of plastic food contact materials and articles;
- obtain a Declaration of Compliance (DoC). A DoC is required **at all stages of production and marketing** (excluding the retail stage) and it needs to be supported by appropriate underlying documentation. Figure 11 contains a brief overview of what to consider in regards to getting a DoC.

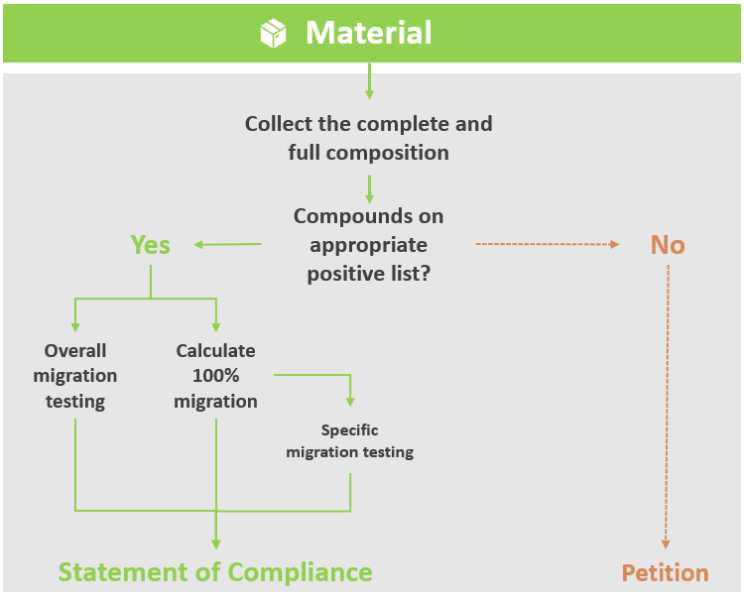

Figure 11 Material testing process

Examples of biobased (starting monomers) positive-listed in the 10/2011 regulation

There are several biobased (monomeric) starting substances already present in the positive substance list of the 10/2011 regulations for plastic materials for food contact.

Based on their origin different purity and migrations limits may apply. Additionally, specific manufacturing conditions are specified as well. To demonstrate we shortly cover the biobased substances, Lactic Acid, 3-hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer, and Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate).

FCM substance No 99: Lactic Acid,

Conditions:

- only overall migration limits apply.

FCM substance No 744: 3-hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer

Conditions:

- overall migration limits apply;
- specific migration limit of: 0.05 mg/kg foodstuff (expressed as crotonic acid);
- the copolymers are produced by the controlled fermentation of Alcaligenes eutrophus using mixtures of glucose and propanoic acid as carbon sources. The organism used has not been genetically engineered and has been derived from a single wildtype organism Alcaligenes eutrophus strain (H16 NCIMB 10442). Master stocks of the organism are stored as freeze-dried ampoules. A submaster/working stock is prepared from the master stock and stored in liquid nitrogen and used to prepare inocula for the fermenter. Fermenter samples will be examined daily both

microscopically and for any changes in colonial morphology on a variety of agars at different temperatures. The copolymers are isolated from heat treatment bacteria by controlled digestion of the other cellular components, washing and drying. These copolymers are normally offered as formulated, melt formed granules containing additives such as nucleating agents, plasticisers, fillers, stabilisers and pigments which all conform to the general and individual specifications;

- more specification on production and purity requirements for FCM 744 are laid down in Table 4 of Annex I of the 10/2011 regulation.

FCM substance No 1059: Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate)

conditions:

- produced by fermentation of palm oil using a genetically modified microorganism (Cupriavidus necator);
- only to be used either alone or blended with other polymers in contact with all foods under contact conditions of up to 6 months and/or 6 months and more, at room temperature or below, including hot fill or a short heating up phase. The migration of all oligomers with a molecular weight below 1.000 Da shall not exceed 5,0 mg/kg food;
- when a final material or article containing this substance is placed on the market, a well described method to determine whether the oligomer migration complies with the restrictions specified above shall form part of the supporting documentation as referred to in the 10/2011. This method shall be suitable for use by a competent authority (such as the Dutch NVWA to verify compliance. If an adequate method is publicly available, reference shall be made to that method. If the method requires a calibration sample, a sufficient sample shall be supplied to the competent authority on its request.

8.5.2 Recycled materials and FCM

The previously mentioned Regulation (EC) No 10/2011 sets out criteria for the composition of new plastic materials. However, after these materials have been used, they do not comply anymore to requirements regarding safety from the plastic Regulation, as they may have been contaminated with other substances. Therefore, a separate regulation exists to control the recycling processes. This is Regulation (EC) No 282/2008[64] on recycled plastic materials and articles intended to come into contact with foods.

The key point of the requirements for recycled materials are as follows:

- The 282/2008 regulation does not apply to previously unused offcuts, or polymers which have been chemically broken down into monomers, for example, removing their quality of plasticity;
- The materials and articles covered here are **also** subject to Regulation (EC) No 10/2011 on plastic materials intended for food packaging;
- The recycled plastic used for the manufacture of materials and articles covered by this Regulation must come from an **authorised recycling process** (e.g. mandated by the EC), managed according to rules set out in the Annex of Regulation (EC) 2023/2006 on good practice for materials and articles intended to come into contact with food.

[64] https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32008R0282

Authorisation may be granted if recycling processes comply with the following:

- The recycling input must be quality controlled;
- the input must originate from plastic materials made in accordance with EU legislation on plastic materials and articles intended for contact with food;
- the process must guarantee that there is no risk of contamination or that it is at a level posing no risk to health;
- the finished article must not release substances into food in a quantity likely to endanger human health or cause an unacceptable change in the composition of the food, or a deterioration in its appearance, smell or texture;
- the EC keeps a public register of authorised recycling processes, as well as a register of recycling sites in EU and non-EU countries;
- (optional): voluntary declaration on the recycled content in recycled plastic materials and articles that follow the rules set out in ISO 14021:1999.

In addition to meeting the other requirements of Regulation (EC) 10/2011, the Declaration of Compliance must confirm that:

- an authorised recycling process was used, and state its EC registration number,
- the plastic input, the recycling process and the recycled plastic meet the specifications for which the authorisation has been granted; and
- a quality assurance system is in place.

A detailed guidance document which specifies the administrative and technical data that applicants should submit for the safety assessment of a plastic recycling process from EFSA can be found here: https://www.efsa.europa.eu/en/topics/topic/plastics-and-plastic-recyclingx

8.6 Construction

According to Plastics Europe, the building and construction sector in Europe consumes around 10 million tonnes of plastics each year (20% of total European plastics consumption), making it the second largest application for plastics after packaging. Plastic pipes, for instance, account for the majority of all new pipe installations, with well over 50% of the annual tonnage. And this share continues to grow[65]

Biobased plastics are becoming increasingly advanced and could pose a real alternative to virgin plastic in the construction industry. Off course, the suitability of biobased plastics depends on the requirements of the application.

Basic standards that construction products need to comply with are covered in the EU Construction Products Regulation (EC) 2011/305[66] (CPR), which is valid for all products. Such quality standards include stability properties, mechanical strength and low flammability. Most polymers including biopolymers are for example easily flammable, and should therefore be adjusted to improve their protection against flaming, before being used in interior or exterior parts of a building.

[65] https://www.plasticseurope.org/en/about-plastics/building-construction
[66] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011R0305

Before new building products are introduced on the market, there must be proof of their application suitability. New or (as of yet) non-regulated building products and bioplastic facade claddings for example should demonstrate usability at EU level with a so-called European Technical Assessment (ETA).[67] Manufacturers of building products can request these ETAs, if a harmonized European norm is lacking.

Outlook

As became clear from the EC goals outlined in chapter 4, any construction product or application ideally should contribute to a safe, low carbon, and circular economy.

The CPR lays down harmonized rules for the marketing of construction products in the single market. This means that construction products all have to adhere to the same (minimum) standards in order to guarantee quality (and safety) of these products within the EU. This makes it possible to compare products from different manufacturers. Under the CPR, national authorities can set performance requirements using the harmonized European standards. The CPR has been identified as one of the regulations which can be revised in order to boost the uptake of recycled content in construction products and enhance the circular economy. This has been mentioned both in the Green Deal and the 2020 CEAP.[68]

8.7 Cosmetics

For chemical manufacturers in the modern day, the cosmetics industry represents a lucrative target market. Globally, cosmetics account for billions of dollars in revenue, and with new products constantly being developed and hitting the market, the scope for development and innovation is high.

As the general public is becoming more "environmentally aware" and synthetic chemicals are more often perceived as unhealthy, an increase in the application of bio(based) ingredients in cosmetics can be observed.

Of course, the fact that something is of natural origin does not tell us anything from a toxicological or general health perspective. As with any other ingredient the safety should (among other) have been evaluated under the Regulation (EC) 1223/2009[69] on Cosmetics Products.

This regulation requires that manufacturers or importers of certain kinds of cosmetic products abide by the required manufacturing practice, content requirement, and the labelling requirements, and ensure the safety and quality of the cosmetic products, which should not pose harm to human health.

Manufacturers should prepare a report that contains information about the cosmetic product. The report is divided into two parts – A and B.

Part A of the Cosmetic Product Safety Report shall include:

- the composition of the cosmetic product;
- the physical and chemical characteristics of the product;

[67] https://ec.europa.eu/growth/sectors/construction/product-regulation/european-assessment_en
[68] https://www.zeeland.nl/sites/zl-zeeland/files/final_-eu_public_procurement_and_circular_biobased_construction_report_digitoegankelijk.pdf
[69] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R1223

- usage instructions;
- packaging material information;
- information on side-effects.

Importers should also include information concerning the microbiological quality, chemical identity of the substances, and other technical information regarding the product materials and packaging materials.

Part B of the Cosmetic Product Safety Report shall include:

- the assessment conclusion;
- labelled warnings and information on how to use the product;
- explanation on how the conclusion was reached (based on Part A);
- the assessor's credentials and approval.

Specific Requirements on ingredients

Regulation (EC) 1223/2009 sets aside several sections specifically explaining the permissible and banned substances that could be used in cosmetic products. Users can refer to Annex II, and Annex III in the regulation for the lists of banned and restricted substances, and to Annex IV, Annex V, and Annex VI for allowed substances and preservatives.

The complete list of permissible and banned substances can be accessed via ec.europe.eu, and can be found here: https://ec.europa.eu/growth/sectors/cosmetics/cosing_en

Outlook

With regard to biopolymers in cosmetics, the most important use that should be noted, is the use of biopolymers in the form of micro-plastics. Already in 2015 Cosmetics Europe called for an out phasing of the use of micro-plastic (limited to microbeads) in cosmetics. Although the use has decreased in recent years and public awareness on the environmental impact increased, there is currently no legislation in force limiting the use of microplastics in cosmetics.

However, a European ban is expected in 2022 as a result of the more general proposal on the restriction of intentionally added microplastics (see chapter 8.2) for a full description on the proposed ban.

8.8 Eco-design directive

Directive 2009/125/EC[70] of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of eco-design requirements for energy-related products. The Directive provides consistent set of rules for improving the environmental performance of products across the EU. The rules cover applications like household appliances, information and communication technologies or engineering. The rules set out minimum mandatory requirements for the energy efficiency of these products that

[70] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32009L0125

manufactures have to meet. This helps prevent creation of barriers to trade, improve product quality and environmental protection.

The regulation also identifies environmental aspects related to each phase of a product's life cycle (from raw material sourcing to end-of-life) that should be taken into account during product design. One of these aspects is the ease for reuse and recycling. An example that influences this aspect is the use of component and material coding standards for the identification of components and materials suitable for reuse and recycling (including plastic parts according to ISO standards). Another important environmental aspect identified in the Directive is the avoidance of technical solutions detrimental to reuse and recycling of components and whole appliances. Such environmental aspects should be taken into account when a biopolymer (or any other material) is chosen for product development.

Bio(polymers) are not specifically mentioned in the regulatory texts of this Directive. However, biobased polymers and articles manufactured from them do need the comply with the rules laid down in this directive.

8.9 Certifications and Product Claims

As the interest in environmentally friendly products (articles) increases, more and more companies decide to communicate about the environmental performance of their products. This is generally done on a voluntary basis, but it can help to build a case on the environmental benefits of an article (or substance) through third-party acknowledgement. However, please keep in mind that this does not provide any regulatory exemptions or leeway from regulatory authorities, but it might be beneficial for marketing to end-users or for creating a competitive advantage over competitors.

Claims

It is becoming more and more common to make sustainability claims, or environmental claims, to show how a product or its packaging has improved its environmental footprint. Claims like: 'CO_2 emissions decreased by 10%' or '20% less plastic used' are more often seen. As a result, the correctness of sustainability claims becomes the subject of more scrutiny.

In May 2021 the Dutch Authority for Consumers and Markets (ACM) announced the start of an investigation on the sustainability claims of 170 companies in the energy, textiles and dairy sectors. From an online investigation led by ACM together with other European regulators, it already became clear that claims often contain false, vague or misleading information. It makes it difficult for consumers to judge which product is actually the more sustainable option.

Guidelines for Sustainability Claims

There are various guidelines for making sustainability claims for companies, aimed to contribute to consumer's confidence in sustainable products. Plus, as a result markets for sustainable products and services can develop better. A number of the key guidelines are provided below.

Sustainability claims according to ACM:

In addition to their research, ACM published guidelines for sustainability claims that companies can use. With these guidelines, ACM aims to achieve that companies provide consumers with true and complete information about sustainability of their products and services. ACM's five rules of thumb for fair sustainability claims are:

- make clear which advantages the product offers: Sustainability claims are only of use to consumers if these are clearly phrased and easy to understand, they should be specific about the product's sustainability benefit.
- substantiate your sustainability claims with facts, and keep them up-to-date: proof of the claim is required and will need to be checked regularly to make sure it still holds up.
- comparisons with other products, services, or companies must be fair: ensure that comparisons with other products or companies will not lead to any misunderstandings among consumers.
- be honest and specific about your company's efforts with regard to sustainability: distinguish between general information about your company's efforts with regard to sustainability, and specific information about the benefits of an individual product.
- make sure that visual claims and labels are useful for consumers, not confusing: use only clear symbols, pictograms or labels that directly support the claim and do not give a false impression about sustainability.

Sustainability claims according to ISO 14021:2016

According to ISO 14020 standards family, "an environmental claim is defined as a statement, symbol or graphic that indicates an environmental aspect of a product, a component or packaging". These claims may refer to any stage of the life cycle stage of a product, such as manufacturing, packaging, transport, use or consumption and disposal. ISO has classified environmental claims in three types:

- Type I environmental claims (ISO 14024:2018 Type I environmental labelling): environmental product claims that meet a set of requirements either set by a governmental body or a private organisation. Such environmental claims can be seen in different types of products in the form of logos or symbols showing criteria compliance. Examples are the EU Ecolabel and FSC.
- Type II environmental claims (ISO 14021:2016 Self-declared environmental claims): these are voluntary claims made by manufacturers and businesses, thus "self-declared". The aim of such claims is to stimulate the demand and supply of products and services causing less strain on the environment by communicating verifiable and accurate environmental product aspects. These types of claims do not mandate an LCA study but do require the consideration of relevant life cycle stages of a product to identify the impacts along the value chain (i.e. LCA screening).
- Type III environmental claims (ISO 14025:2006 Type III environmental declarations): these claims present environmental information on the life cycle of a product and are based on ISO 14040/ISO14044 LCA standards. They require an in-depth LCA, with 3rd party verification and certification. Environmental Product Declarations (EPD) belong to these types of environmental claims.

Scrutiny on sustainability claims in the EU

The EU is increasing it scrutiny on environmental claim. The Unfair Commercial Practices Directive 2005/29/EC is the primary regulation on unfair business practices in the EU law, and is applicable from this context. In particular, it focuses on misleading advertising, including environmental claims, that could potentially harm consumers' economic interests or distort their economic behaviour. In this directive, two main categories are distinguished: claims which are deceiving either objectively (i.e. presenting fake information), or subjectively (i.e. information is truthful but the way of presenting may misguide the consumer).

9. End-of-life

After its useful life a biopolymer-based article will be discarded. This is the moment in its life-cycle we call the End-of-life stage. During End-of-life the article can be reused, the materials can be recycled and composted, or the discarded items can be incinerated or landfilled.

As with all other life-cycle stages, there is specific regulation concerning the safe and efficient handling and recovery of waste materials. Although it is the End-of-life phase of a product, the regulatory requirements are highly relevant for manufacturers bringing a biopolymer to the market. The reason is two-fold. Firstly, the public awareness around the End-of-life of products is growing and secondly the emphasis on fostering circularity is strongly supported by the EC and the Member States. Given these developments this chapter focuses on the regulatory aspects associated with the End-of-life. However, as closing the loop plays an important role, there is logically an overlap with regulation discussed in the End-of-Waste section (7.1) of this report.

9.1 Waste Framework Directive:

The Waste Framework Directive (EC) 2008/98[71] (WFD) sets the basic concepts and definitions related to waste management, including definitions on waste, recycling and recovery.

From an overarching perspective the directive requires waste to be managed under the following criteria:

- not endangering human health or harming the environment;
- without risk to water, air, soil, plants or animals;
- without causing a nuisance through noise or odours;
- and without adversely affecting the countryside or places of special interest.

[71] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008L0098

9.1.3 Waste Hierarchy

The foundation of EU waste management is the "waste hierarchy"[72], established in the WFD (adapted from Dutch ladder van Lansink, see figure 12). It establishes an order of preference for managing and disposing of waste.

Based on this hierarchy it should be noted that regardless of material origin (fossil or bio) and regardless of its degradability profile, loss of material after its service life should be prevented. Meaning that even the use of articles based on biobased polymers should be minimized or designed to be re-used as much as possible. However, for certain plastic applications this is unfeasible, and in those cases recycling of the polymer is the preferred option for end-of-life.

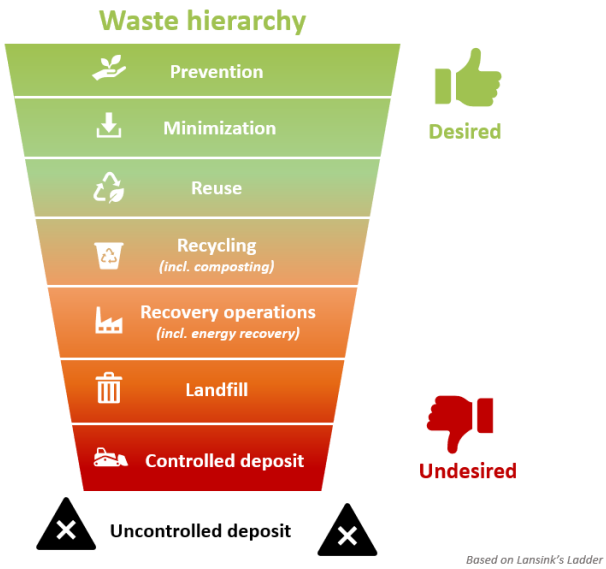

Figure 12 European Waste Hierarchy

Composting is also considered recycling within the WFD. Here it is important to note however, that from a resource use perspective this is not necessarily the preferred option for the EC. Most of the biopolymers will degrade mostly into CO_2 instead of usable compost. And although this CO_2 is of biogenic origin, it can be argued that, from a resource conservation point of view, composting may lead to unnecessary land-use for biomass production.

Considerations regarding resource use:

- the loss of (useful) materials should be prevented, regardless of the material origin and/ or biodegradability profile;
- prevention, minimization and reuse are preferred waste handling options, even for bioplastics;
- compositing is considered recycling, but note that most biopolymers degrade into +/- 90% CO_2 instead into reusable biomass. Therefore, don't deliver on the promise during their end-of-life.

Considerations regarding hazardous waste:

- the WFD provides additional labelling, record keeping, monitoring and control obligations from the "Cradle-to-Grave", in other words from the waste production to the final disposal or recovery of hazardous waste;
- it also bans the mixing of hazardous waste with other categories of hazardous waste, and with non-hazardous waste.

Considerations regarding By-products:

- in addition to waste the WFD also includes by-products as a substance or object, resulting from a production process, the primary aim of which is not the production of that item. By-products can come from a wide range of business sectors, and can have very different environmental impacts. It

[72] https://ec.europa.eu/environment/topics/waste-and-recycling/waste-framework-directive_en

is important to classify by-products correctly to avoid environmental damage or unnecessary costs for business.

9.1.2 The SCIP database

Chemical substances that meet certain REACH criteria – such as being carcinogenic, toxic for reproduction, or persistent in the environment – may be proposed as SVHC (substance of very high concern). We discussed them in detail in chapter 7.2.6)

To avoid SVHC substances from ending up in toys, clothes, or food packaging made from recycled feedstock, these chemicals need to be tracked from manufacturing to waste. In doing so, waste processors and secondary manufactures (recyclers) know if a waste product contains one or more of these substances and how to safely extract them from the waste streams.

The SCIP database

The new SCIP database, to be launched by ECHA this year (2021), is intended to contain information on Substances of Concern in articles, as such, or in complex objects (products). The aim is to promote the substitution of hazardous chemicals and transition towards a safer circular economy. This way it is ensured that the information is available throughout the whole life-cycle of raw materials, substances and articles, including their waste stage.

<u>Company Obligations</u>

When an SVHC on the Candidate List is present in an article in a concentration above 0.1 % to trigger the submission requirement, the following suppliers of articles (or substances) will need to submit information to the SCIP database:

- EU producers and assemblers;
- EU importers; and
- EU distributors of articles and other actors who place articles on the market.
- Retailers and other actors supplying articles directly to consumers do not need to submit information to ECHA.

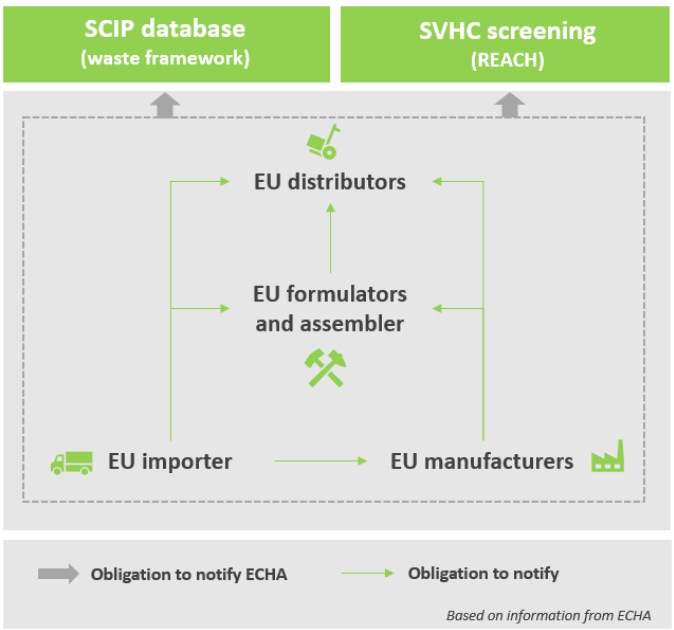

Figure 13 Substances of very high concern notifications

Producers and distributors of articles, that have been produced outside of the EU, do not have direct obligations under the WFD. However, they should support their EU customers (importers) by providing them with the necessary information on SVHCs in articles.

9.1.3 End-Of-Waste rules

End-of-waste criteria specify when certain waste ceases to be waste and becomes a product, or a secondary raw material.

According to Article 6 (1) and (2) of the WFD, certain specified waste types cease to be waste when it has undergone a recovery operation (including recycling) and complies with specific criteria, in particular when:

- the substance or object is commonly used for specific purposes;
- there is an existing market or demand for the substance or object;
- the use is lawful (substance or object fulfils the technical requirements for the specific purposes and meets the existing legislation and standards applicable to products);
- the use will not lead to overall adverse environmental or human health impacts.

This criteria for specific materials are set by the EC through the "comitology"[73] procedure. A mandate to set End-of-waste criteria was introduced to provide a high level of environmental protection and an environmental and economic benefit. They aim to further encourage recycling in the EU by creating legal certainty and a level playing field as well as removing unnecessary administrative burden.

When a waste stream is recycled into a non-waste substance or article the life-cycle is completed. Although the concept of End-Of-Wate is laid down in the WFD we discussed this topic including recyclers requirements in chapter 7.1 in full.

9.1.4 Implementation in the Dutch Landelijk Afvalbeheer Plan (LAP3)

Landelijke Afvalbeheer Plan (LAP3)

The WFD obliges nations to form a national waste management plan. In the Netherlands this is the 'Landelijk Afvalbeheer Plan' (LAP3), effective from 21 March 2021.

The LAP3 describes:

- a sector plan for 85 different waste streams that can be collected separately or separated after collection;
- which recycling methods are allowed and whether ZZS presence is allowed in a waste stream;
- a 'minimum standard' which gives an indication of how a specific waste material may be processed to ensure that processing is done at a sufficiently high level;
- the definition of the waste hierarchy. In general, high-quality processing is desirable. The prevention of waste is therefore preferred over recycling. Recycling is then preferred over energy recovery. Energy recovery is then preferred over disposal landfill;
- a standard maximum price for high-quality waste processing (including recycling) of €205 euro per tonne. This price is equal for waste streams with and without ZZS. However, since waste containing ZZS is a burden, a higher maximum price for processing such streams could be defendable. Especially because a guidance on risk analysis of ZZS in waste (Rijkswaterstaat, 2018) prescribes that ZZS should always be removed from a waste stream if it is technically/economically feasible;

[73] https://eur-lex.europa.eu/summary/glossary/comitology.html

- in 2023 the LAP3 will be replaced by a Circular Material Plan (CMP1). Where the scope of LAP3 is on only waste treatment (end of chain), the CMP extends the scope to include high value recycling in order to promote circular economy innovation and improve the minimum standard.

Biodegradable and non-biodegradable biopolymers under LAP3

LAP3 has a separate sector plan for packaging waste, including plastic packaging. Packaging made from non-biodegradable bioplastics can be collected a treated according to this sector plan. There might be changes in the sector plans because a policy position is currently under development regarding "the use and treatment of bioplastics, biodegradable plastics and oxo-degradable plastics."[74]

As mentioned in 3.2.1. biodegradable polymers certified according to composting standard EN13432 are in reality rarely composted in composting facilities. This is because the composting facilities often do not accept compostable plastic products (except for compostable bags with the seedling logo because they are essential to collect organic waste)[75]. This refusal is due to severely shortened composting-cycles, different degradability properties of bioplastics, and the risk that consumers confuse different types of plastics, thereby contaminating organic waste streams. Accordingly, LAP3 stipulates that all biodegradable plastics should be disposed as general household waste (sectorplan 1) instead of organic waste (sectorplan 6)[76].

This is very important to consider as a producer of biodegradable plastics, because it makes the recyclability potential of the material much more relevant and important. Without recycling, biodegradable plastics would be incinerated together with general household waste.

Substance classifications

The Netherlands applies a list of substances of concern (SoC) and 'Zeer Zorgwekkende Stoffen' (ZZS) but these include more substances than the list of SVHC by ECHA. The difference between SoC, ZZS and SVHC is visualized in Figure 14. The list of ZZS[77] contains 1.564 substances by January 2021 (of which 211 were also SVHC from REACH) and this list is updated twice a year. As Figure 14 indicates, there are other SoCs besides ZZS for which environmental quality standards have been set. Examples are pharmaceutical residues, pesticides and metals such as zinc and copper. These SoCs can be relevant for assessing waste treatment options.

Balance between SoC minimisation and recycling maximisation in a circular economy

To achieve a circular economy, three main challenges regarding SoCs are:

1. share information about substances and SoC across product chain;

[74] Sectorplan 41: https://lap3.nl/sectorplannen/sectorplannen/verpakkingen
[75] https://keurmerkenwijzer.nl/keurmerken/kiemplantlogo/
[76] https://lap3.nl/sectorplannen/sectorplannen/gft/
[77] Zeer Zorgwekkende Stoffen: https://rvs.rivm.nl/onderwerpen/zeer-zorgwekkende-stoffen

2. ensure safe re-usability of products by all actors in the chain;
3. all actors should deal responsibly with products containing SoCs for which there is no alternative.

In a circular economy, the ambition to maximise recycling an minimise SoC does not always go hand in hand. Restricting SoCs can hamper recycling and recycling can keep SoCs in the loop. Therefore, according to the LAP3:

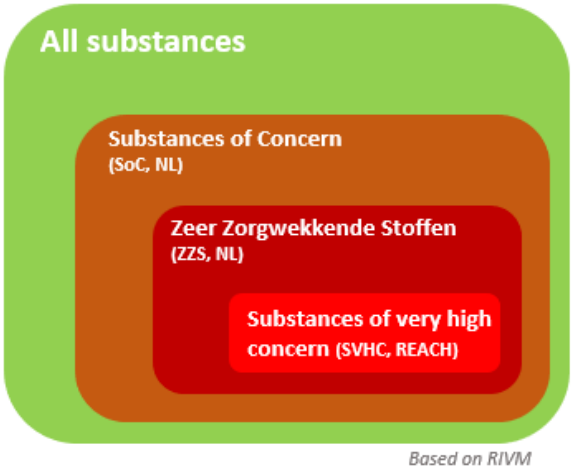

Figure 14 Substances of concern hierarchy

"*a balance must be found between promoting recycling on the one hand and reducing the number of hazardous substances in the economy on the other. In the European discussion on recycling of materials containing ZZS, the Netherlands believes that a methodology must be formulated at the European level to determine the best option*."

Legislation on handling SoC in waste streams

The goals of setting limit values for SoC are to minimise risks to humans and the environment. There are two main approaches for this effort, namely a hazard-based and a risk-based approach. A hazard-based approach is taken in the EU REACH legislation by identifying harmful substances and focussing their specific properties related to exposure. A risk-based approach is followed by the EU waste policy and Dutch environmental policy. In this risk-based approach, not only the properties of the substance, but also the acceptability of specific uses is taken in to account.

The LAP3 also implements a risk-based approach to determine in which cases the recovery/ reuse/ recycling of waste containing ZZS may be permitted. Yet, when it is possible to remove ZZS from waste streams, this should always be done. Section B14 and Annex F11 of LAP3[78] contains a detailed description on how waste streams containing ZZS should be handled, and how ZZS in waste or recycled materials should be dealt with.

The LAP3 dictates that a risk analysis is required in cases where the ZZS in a material exceeds the generic limit concentration of 0.1% (or other specific limit values for the foreseen application). The goal of this risk analysis is to find out whether the ZZS would hinder the granting of a permit for the foreseen application and whether uncertainty could be resolved with an experimentation phase. This experimentation can be part of the permit granted but when measurements indicate that risks are unacceptable, the permit is withdrawn and the recycled materials need to be destroyed. A guidance document on the risk analysis for ZZS in waste has been developed by Rijkswaterstaat (2018)[79].

Risks can differentiate waste treatment solutions. In finding the right solution, the focus needs to be on the foreseen application. In the context of ZZS and applications, three categories can be distinguished:

[78] Beleidskader - LAP3: https://lap3.nl/beleidskader/
[79] Handreiking risicoanalyse ZZS in afvalstoffen (https://lap3.nl/nieuws/nieuws-2018/handreiking/)

1. low/no risk applications (no or very little ZZS): Possibly set generic or specific product rules;
2. medium risk: requires specific product rules or management conditions in LAP or in the permit;
3. high risk: identification and control of risks and possibly phasing out through the LAP.

With the ambition of scaling up to a circular economy, a circularity perspective should be taken by ministries and branch organisations when selecting main waste streams, their risks and their potential applications. In low and medium risk categories, existing options to promote circularity can and should be implemented more extensively, such as setting limit values for secondary materials. Human health and environmental safety should however never be put at stake.

10. Summary table

This chapter provides a summary (Table 7) containing a condensed overview of the most important information from each of the previous chapters. There is a distinction between informational elements, regulatory requirements and recommendations/ consideration, each marked with a specific symbol (Table 6).

Table 6: Legend of symbols

Symbol legend	
	informational
	regulatory requirement
	Recommendation/ consideration

Table 7: Summary of chapters

CHAPTER 3	**Definitions**	
		Biopolymers do not equal biodegradable polymers. The biological origin of materials does not mean that it is biodegradable in reasonable timeframe and under natural conditions.
		The applicability of the terms 'natural polymer, unmodified natural polymer or substance which occurs in nature' depends on information on the polymerisation process, extraction process and whether chemical modification took place
		Natural polymers are the result of a polymerisation process that has taken place in nature. Therefore biopolymers which are chemically/ industrially produced (with or without bio-degradability claims) are not qualified as natural polymers.
		Several sets of legislation have adopted the REACH definition for natural polymers as a differentiator for in- or exclusion of biopolymers under the rules and restrictions.
		Biodegradability is only meaningful if communicated in combination with conditions, timeframe and degradation products/residues.
		There are several EU standards for industrial composting and agricultural biodegradability, and some national standards for home composting. There are currently no harmonized standards (including pass/fail criteria based on regulatory programs) for marine degradability.
		Biodegradability should be tested on the intended application(article) and not only on the polymer (substance) it is produced with, because additives and polymerization aids can alter degradability potential.
	EU and Dutch strategy & action plans	
		The EU green deal is aiming for Europe to be the first carbon neutral continent in 2050 and lays out action plans to facilitate the transition to a circular economy and pollution-free environment.
		Biobased and biodegradable plastics are recognized as important part of this transition.

CHAPTER 4		Take note of the proposed policy changes from the Chemicals Strategy, which are considered to have direct impact on producers of biopolymers, since these proposals are mostly related to the production, contents and safety of chemical substances.
		Take note of the proposed policy changes from the Plastics in a Circular Economy Strategy, which are considered to have an indirect on producers of biopolymers, since these proposals are mostly related to the biodegradability and composting of specific applications.
		Take note of the proposed policy changes from the Bioeconomy Strategy, which are considered to have both direct and indirect on producers of biopolymers. These proposals are related to the substitution fossil-based materials with biobased materials, as well as the stimulation of biodegradable applications and biodegradability regulation development.
		For 2050, The Transition Agenda Plastics aims to achieve a 100% circular Dutch plastic chain. For 2030, the goal is to reduce incineration and the share of virgin plastics with -44% and -36%, respectively, which requires significant expansion of capacity in mechanical and chemical recycling and production of biobased plastics.
Direct impact: raw materials		
CHAPTER 6		Although there is currently no legislation governing the use of biomass for biopolymer production, the criteria from the renewable energy directives, which are set out criteria for biomass production for biofuel, could also be applied to biomaterials, may it be in adjusted form.
		When choosing biomass feedstock as raw material, it is important to avoid adverse effects such as (un)intended land use change and competition with food production. Such adverse effects can be prevented when biopolymers are produced from biomass waste streams.
		Using biomass waste as raw material brings a risk of contaminating the biopolymer with hazardous substances, resulting in possible restrictions depending on the intended use.
		The regulation on the Shipments of Waste regulates the cross-border transport of waste from, to and within the EU by imposing a 'green list' and 'amber list' of wastes with complementary procedures to follow.
		The international transport of waste may nevertheless be practically complex, due to divergent interpretations of (end-of-) waste across different EU member-states.
Direct impact: chemical substances		
	End-of-Waste (EoW) criteria	
CHAPTER 7		The EU Waste Framework Directive (WFD) defines waste as 'any substance or object which the holder discards or intends or is required to discard'. Any substance or object is therefore either waste or non-waste.
		For polymer manufacturers using biowaste as feedstock it is highly important to know whether their 'raw materials' are waste within the meaning of the WFD or possibly remain substances, mixtures or articles (following the definitions used in REACH and the WFD).
		EoW criteria need to be met for something to cease being waste and to obtain an EoW status. Only then, waste regulations do no longer have to be followed for further processing and handling. Currently a Dutch EoW ruling is not automatically valid in other member states.

	When assessing the potential to get an EoW status, a REACH registration alone is not sufficient, but additional risk assessments are required. Such as for drug residues, pathogens, potential SoC and ZZS that are not regulated by the REACH and POP18 (Persistent Organic Substances) Regulation.
	The quick scan (figure 6 in this report) can be used to identify if the substance or application can get an EoW status, and also what is required if it is used as a feedstock material instead.
	To prove an EoW status to clients and authorities, multiple data requirements need to be fulfilled and data need to be submitted through the portal of the Ministry of Infrastructure and Water Management.
	Although no specific EoW criteria currently exist for plastic recycling, the JRC has made some proposals regarding plastic-to-plastic recovery and recycling.
	A mandatory management system for biobased recycling could be introduced based on JRCs proposals. This will cover similar requirements as currently applicable for management systems taking care of glass and metals recycling. Additionally, such a recycling system would require certification.
REACH	
	All polymers are excluded from REACH registration. The monomers do need to be registered however!
	Additional exemptions to registration of monomers in natural polymers apply. Yet almost all newly developed biobased polymers do not fall under the definition of natural polymer (regardless of biodegradability profile), because the industrial polymerization process mimics nature instead of taking place in nature.
	REACH registration: One substance, one registration principle: if a monomer has already been registered, an actor can join this existing registration dossier and retroactively pay a fair share of registration costs. A sameness of substance analysis is required. Additionally, to promote circular solutions, recyclers are exempt from registration when the recycled substance is already registered by other market parties.
	Information requirements to comply with REACH: • Full chemical identity of substance (Analytical report with 2 substance identification tests and 2 substance quantification tests) • Substance of Very High Concern (SVHC) screening. • Identify and monitor SVHC substances in product. Check whether applied substances appear on the REACH list of restrictions (Annex XVII) and / or the REACH authorization list (Annex XIV). For SVHC screening provide: ▪ certificates from raw material suppliers; ▪ expert assessment on potentially present SVHCs; ▪ analytical testing. • Classification and labelling requirements from the CLP regulation apply too; ▪ hazard and safety information and communication through Safety Data Sheets, while using CLP labelling criteria
Classification Labelling and Packaging (CLP)	
	According to CLP regulation (EC) 1272/2008, Manufacturers, importers or downstream users of substances or mixtures to need to classify, label and package their hazardous chemicals appropriately before placing them on the market. This applies to all industrial sectors and is irrespective of annual tonnage.

	Submit classification and labelling (C&L) information to the C&L Inventory held by ECHA.
	Meet the harmonised information requirements for notifications for hazardous formulations.
	According to Annex VIII of the CLP regulation the label of a mixture requires a unique formula identifier (UFI), which serves as a link between the mixture and its hazard information.
Persistent Organic Pollutants (POP) regulation	
	Biopolymers (substances) need to be screened on the existence of POPs, especially if they are produced with potentially polluted feedstocks.
	Applications (articles) should be screened on POPs (since additives, needed to produce final products, could fall under POP regulation).
Indirect impact: application (article)	
Single Use Plastics (SUP) directive	
	The SUP applies to plastic products that are meant to be used only once and disposed afterwards.
	Depending on existence of suitable alternatives, the use of single-use plastics should be reduced or placing them on the market is prohibited.
	Unmodified natural polymers (in accordance to the REACH definition) are outside the scope of the SUP.
	Polymers created via synthetic route or through cultivation and fermentation processes in industrial settings are not the result of a polymerisation process that has taken place in nature, and thus not considered as unmodified natural polymers. Therefore, plastics manufactured from biobased materials or biodegradable plastics are also within the scope of the SUP.
	Although no accepted standards for marine biodegradability currently exist, take note of the proposed review of the SUP (2027) and a prospected policy framework (2021) from the EC, both concerning biodegradability regulation.
Microplastics	
	As a result of increasing concerns over plastic leaching into the environment and potentially migration into the food chain EU Member States have already enacted or proposed national bans on intentional uses of microplastics in consumer products.
	The EC asked ECHA to complete a restrictions proposal (Annex XV report) for intentionally-added microplastics.
	The proposal intends to ban products that contain microplastics if these microplastics are inevitably released to our environment when the products are used.
	If microplastics are present in products but not inevitably released during use, the proposal still requires instructions on prevention/minimisation of residual microplastic releases.
	The proposal only covers polymers that meet the microplastic definition: less than 5 mm in size, solid, particulate, insoluble and non-biodegradable. Unintentionally formed microplastics (by wear & tear) are outside the scope.
	ECHA: substances that occur in nature and chemically unmodified natural polymers are considered inherently biodegradable and harmless are not considered microplastics. Polymers that have been chemically modified are considered microplastics.

	Criteria for biodegradability are not yet available. For microplastic material, ECHA is currently investigating the applicability of existing biodegradability standard methods (such as OECD 301 / OECD 306) and their associated thresholds and guidance.
	Interpretation of microplastic proposal: • most biopolymers not excluded based on the "substances that occur in nature or chemically unmodified natural polymer" definitions; • additionally, proven biodegradable polymers of chemically modified nature could still be considered favourable substitutes for existing fossil-based plastics.
Agricultural (bio-stimulant and fertilizing products regulation)	
	Fertilising products are allowed to contain polymers (other than nutrient polymers) only if the purpose of the polymer is to release of nutrients or increase water retention capacity or wettability of product.
	The polymer needs to pass three tests to be allowed: plant growth acute toxicity, earthworm acute toxicity, nitrification inhibition with soil micro-organisms.
	There are mandatory labelling requirements and conformity assessment procedures for polymers other than nutrient polymers.
	• Note that medio 2024 the EC will assess, test compliancy and adopt acts on, biodegradability criteria; • note that medio 2026 compliancy to these criteria will be mandatory; • note that in absence of criteria polymers (other than nutrient polymers) are not allowed in fertilizing products (exception described in next point).
	According to a technical update by the EC, some polymer based technical additives will be allowed in fertilizing products (as virgin materials or by-products) if they ensure efficient or safe use and do not cause environmental concern.
Packaging	
	The packaging directive lays down rules or restrictions for packaging but does not mention the application of biobased polymers in its regulatory texts.
	Note that the EU targets for reusability or recycling of packaging and packaging waste include biopolymers.
Food contact materials	
	Materials and articles (including active and intelligent materials and articles) shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable condition of use, they do not transfer their constituents to food in quantities which could endanger human health, bring about a large change in composition, bring about deterioration of the organoleptic characteristics.
	For biobased plastics the same rules apply as for conventional plastics. Biopolymers used as FCM need to comply with Regulation (EU) 10/2011 on Plastic Materials and Articles.
	(EU) 10/2011: • a declaration of compliance (DOC) for food contact plastics (including recycled plastics) is mandatory at all stages of production and marketing; • meet compositional requirements, testing requirements and risk assessment requirements. There are several biobased monomeric starting substances already listed as positive substance in the regulation.

CHAPTER 9		Complementary (!) to (EU) 10/2011 there is a separate regulation on recycled plastic materials and articles intended to come into contact with foods, (EC) 282/2008. These additional rules expect; • recycling happens through an authorised recycling process and must be quality controlled; • process must guarantee that there is no risk of contamination or that the finished article release substances into the food or alter its composition or deterioration in any way.
		Take note of the detailed guidance document on the EFSA website, specifying which administrative and technical data applicants should submit for the safety assessment of a plastic recycling process.
	Construction	
		Construction products need to comply with basic standards covered in the EU Construction Products Regulation (CPR) (2011/305/EU), which is valid for all products, including biopolymers.
	Cosmetics	
		(Biobased) cosmetics products should comply with Regulation (EC) No. 1223/2009 on Cosmetics Products, which obliges manufacturers/importers to compose a report with information on manufacturing practice, content requirements, labelling requirements, and safety and quality of the cosmetic products.
		There is currently no EU legislation to restrict the use of (biopolymer) microplastics in cosmetics, but such a ban is expected in 2022.
	Certifications and product claims	
		When making a sustainability claim for your products, it is important to support it with an eco-label; for instance with a third-party label (type I), self-declaration label (type II), or LCA-based labels (type III).
		Eco-labels do not provide any regulatory exemptions or leeway from regulatory authorities.
Indirect impact: End-of-life		
	Waste Framework Directive (WFD)	
		The waste hierarchy from the WFD states that regardless of material origin (fossil vs bio) and regardless of its degradability profile, loss of material after its service life should be prevented. Prevention, minimization, reuse or (and to a lesser extend) recycling are preferred waste handling options, also for biopolymers.
		The transition to a circular economy involves finding a balance between maximising recycling and minimising SoC presence.
		The WFD bans the mixing of hazardous waste with other categories of hazardous waste, and with non-hazardous waste.
		The SCIP database is in place to track (SVHC) substances, and ensure that waste processors and secondary manufactures (recyclers) know if a waste product contains one or more of these substances and how to safely extract them from the waste streams.
		Different types of article suppliers have the obligation notify other organisations in the supply chain about SVHCs and/or notify ECHA (submit info to the SCIP database and perform SVHC screening.

	LAP3 entails the Dutch implementation of the WFD. LAP3 stipulates that all biodegradable and non-biodegradable plastics should be disposed as general household waste instead of organic waste.
	A detailed description of how waste streams/recycled materials containing ZZS should be handled, is addressed in Section B14 and Annex F11 of LAP3.
	Note that the LAP3 will be replaced by a Circular Material Plan CMP1 in 2023.
	Note that LAP3 might be changed because a policy position on bioplastics, biodegradable plastics and oxo-degradable plastics is currently under development.

Annex I Abbreviation list

CEAP:	Circular Economy Action Plan
CLP:	Classification Labelling Packaging (regulation)
CMC:	Component Material Category
CO2:	Carbon dioxide
CPR:	Construction Products Regulation
DoC:	Declaration of Compliance
DOC:	Dissolved Organic Carbon
EC:	European Commission
ECHA:	European Chemicals Agency
EEA:	European Economic Area
EFSA:	European Food Safety Authority
ETA:	European Technical Assessment
EU:	European Union
FCM:	Food Contact Material
ILUC:	Indirect Land Use Change
ISO:	International Standards Organisation
JRC:	Joint Research Centre
LAP3:	Landelijk Afvalbeheer Plan 3.0
LCA:	Life Cycle Assessment/Analysis
OECD:	The Organisation of Economic Co-operation and Development
PHA:	Polyhydroxyalkanoates
POP:	Persistent Organic Pollutants
PPORD:	Product and Process-Oriented Research and Development
REACH:	Registration Evaluation Authorisation and Restriction of Chemicals
RED:	Renewable Energy Directive
RSW:	Regulation on the Shipment of Waste
SCIP:	Database for information on Substances of Concern In articles as such or in complex objects (Products) established under the Waste Framework Directive (WFD).
SoC:	Substance of Concern
SUP:	Single Use Plastics Directive
SVHC:	Substance of Very High Concern
UN GHS:	UN Globally Harmonized System of Classification and Labelling of Chemicals
UVCB:	Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials
WFD:	Waste Framework Directive
ZZS:	Zeer Zorgwekkende Stoffen

Annex II List of uses within the scope of microplastic restriction (ECHA)

Note from ECHA on substance identification and the potential scope of a restriction on uses of 'microplastics'.

The table included in this annex "*provides an illustration of how the microplastic identification criteria can be interpreted alongside the complementary risk-based criteria used to establish whether an indicative use can be considered to be relevant to the scope of a potential restriction. It is important to note that only intentional uses of microplastics are considered here. Accidental releases to the environment or the formation of secondary microplastics in the environment are outside of the scope of this restriction by default as the regulation of these sources is being considered elsewhere. The examples in individual rows are based on the information received in the call for evidence and this interpretation should be considered as indicative and preliminary only; further uses will also be considered. Additional information (denoted with '?') will be required prior to concluding whether a use is relevant to the potential scope of a restriction. This information will be obtained by the Agency through targeted consultation with respective stakeholders*".[80]

Application of microplastic identification criteria to indicative uses of polymers alongside risk-related criteria for identifying 'relevance to the restriction scope' (source: ECHA)

Indicative use	**'Microplastic' definition**				**Microplastic?**	**Relevance to the restriction scope ('microplastic' concern)**			**Of potential concern / relevant for further assessment?**
	Synthetic polymer (2.3.1)	**Solid** (2.3.2)	**Particle** (2.3.3)	**Size / dimensions** (2.3.4)	**yes/no** (all four criteria to be met for yes)	**Microplastic at point of use** (3.1.1)	**Microplastic released during use (or subsequent life-cycle step)** (3.1.2)	**Microplastic persistent in environment** (3.1.3)	**yes/no[81]** (all three criteria to be met for yes)
Polyethylene 'microbead' in rinse-off cosmetic products	✓	✓	✓	✓	Yes	✓	✓ via wastewater	✓	Yes
Polyethylene-based glitter in leave on cosmetic products	✓	✓	✓	✓	Yes	✓	✓ via wastewater	✓	Yes
Polymer encapsulation systems for fertilisers and plant protection products	✓	✓	✓	✓	Yes	✓	✓ via direct release	✓	Yes

[80] https://echa.europa.eu/documents/10162/17233/note_on_substance_identification_potential_scope_en.pdf/6f26697e-70b5-9ebe-6b59-2e11085de791

[81] In addition to the 'screening criteria' applied here. The scope of any proposed restriction will be based on all of the criteria in Annex XV of REACH.

Anti-caking additives in fertilisers for agricultural use	✓	✓	✓	✓	Yes	✓	✓ via direct release	✓	Yes
Microfibres or microspheres in paints for consumer use	✓	✓	✓	✓	Yes	✓	✓ via washing of brushes etc; releases during service life to be further assessed	✓	Yes
Polymer-based fragrance encapsulation systems in detergents or other household products	✓	✓	✓	✓	Yes	✓	✓ via wastewater	✓	Yes
Polyacrylonitrile fibres as fillers in construction material	✓	✓	✓	✓	Yes	✓	? Possibly only released unintentionally via accidental release to be further assessed	✓	?
Polymer-based seed coatings	✓	✓	?	?	?	✓	✓ via direct release	✓	?
Synthetic polymer solution for sealing cement used in oil wells	✓	✓	✓	✓ (some >5mm)	Yes	✓	? Possibly only released unintentionally via accidental release to be further assessed	✓	?
Polymers used for water and wastewater treatment	?	?	?	?	?	?	?	?	?
Articles containing super absorbent polymers for medical / consumer use	✓	?	?	✓	?	?	?	?	?
Use of super absorbent polymers for agricultural use	✓	?	?	✓	?	?	✓ via direct release	?	?
The use of polymer pellets (nurdles) for the production of articles by extrusion or similar 'melt' process that forms a matrix	✓	✓	✓	✓ (some >5mm)	Yes	✓	× Completely consumed	× No release	No
Chemically-modified naturally occurring polymers used as media in ion-exchange columns (no loss)	✓	✓	✓	✓	Yes	✓	× No release	× No release	No

Cellulose, or other naturally occurring polymer, in wash-off cosmetic product (not chemically modified)	× Naturally occurring polymer	✓	✓	✓	No	×	×	× (bio)degradable	No
Silica bead for exfoliating in wash-off cosmetic product	×	✓	✓	✓	No	×	×	×	No
Consumer/professional products (including detergents and cosmetics) containing water soluble polymers (soluble in the product and remains dissolved in the environment)	✓	×	×	×	No	×	×	× Appropriate criteria / standards required	No