
AIMPLAS
Excelencia en Plásticos

“Regulatory analysis: bottlenecks and regulatory barriers at EU level for nanomaterials and bio-based products”

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Índice

What is AIMPLAS?

A **technology centre** with more than 30 years' experience in the plastic sector.

Our Purpose

Add value to companies to generate **wealth** and create **employment**.

Add value to society to improve quality of life and ensure environmental sustainability.

More than **12,000 m²** of cutting-edge facilities

- Pilot plants (6,500 m²)
- Laboratories (4,500 m²)

REACH

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the **Registration, Evaluation, Authorisation and Restriction of Chemicals** (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Plastic

PLASTIC:

THERE ARE NOT A DEFINITION IN THIS DOCUMENT
BUT
MOST OF THE REGULATION ABOUT PLASTIC DEFINE IT LIKE

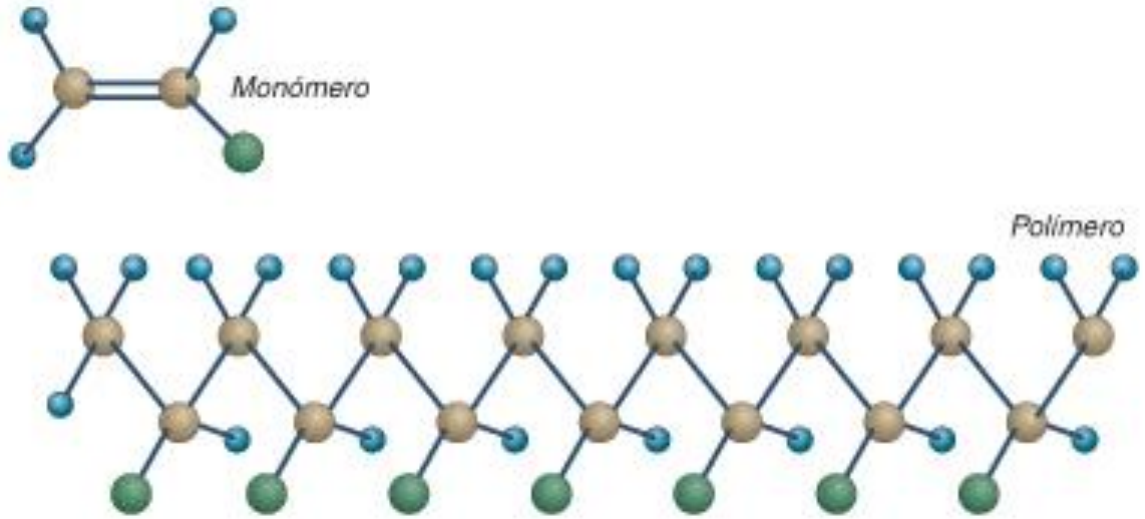
'plastic' means a material consisting of a **polymer** as defined in point 5 of Article 3 of Regulation (EC) No 1907/2006, to which additives or other substances may have been added, and which can function as a main structural component of final products, with the exception of natural polymers that have not been chemically modified;

Polymer: means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. 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. A polymer comprises the following:

(a) 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;

(b) less than a simple weight majority of molecules of the same molecular weight.

In the context of this definition a ‘monomer unit’ means the reacted form of a monomer substance in a polymer;.


Monómero
Polímero

What does means natural polymer not chemically modified?

Natural Polymers

Natural polymers

'Natural polymers are understood as **polymers which are the result of a polymerisation process that has 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" when assessed according to the criteria set out in Article 3(39) of the REACH Regulation.' [ECHA Guidance]

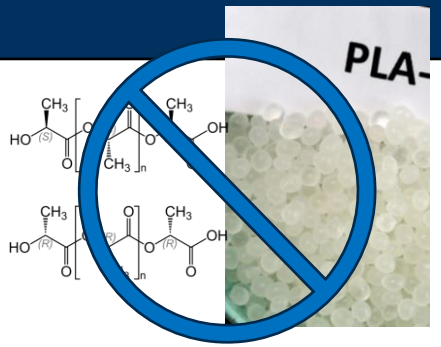
Natural polymer

EXTRACTION METHOD

The scope of the natural polymer refers to a broader group that is independent of the method used to extract the substance from nature.

A consequence of this distinction and applying the definition from the **ECHA Guidance** is, for example, that **cellulose** and **lignin extracted from wood** and **corn starch obtained via wet milling** meet the definition of natural polymer

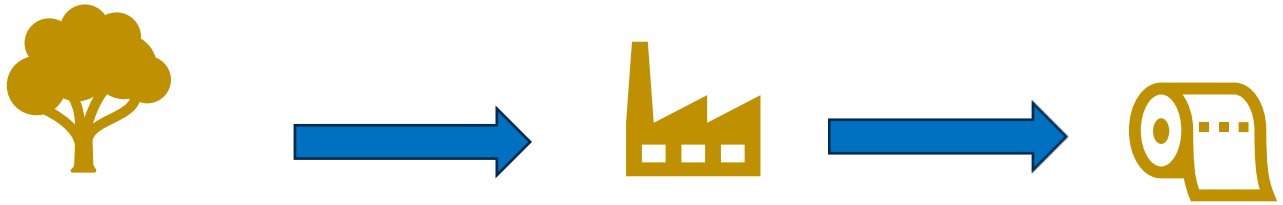
Natural polymer	No natural polymer
POLYMERISATION PROCESS	
The polymerisation process has taken place in nature	The polymerisation process is the result of an industrial process involving living organisms. Therefore, polymers resulting from biosynthesis through man-made cultivation and fermentation processes in industrial settings, por example: polyhydroxyalkanoates (PHA), are not considered natural polymers.



Not chemically modified

‘**not chemically modified substance** means 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.’ (REACH art. 3.40)

To take a decision whether a polymer has been chemically modified in its production or not, should **consider only the difference between the ingoing and the resulting polymer**, disregarding any modifications which might have taken place during production processes, as those are not relevant for the properties and the behavior of the polymer used and eventually potentially released into the environment



Where **changes** in the chemical structure of a polymer result from reactions that are only taking place during the **extraction process** of a natural polymer (e.g. wood pulping process to extract cellulose and lignin), **these are not considered to result in a chemical modification.**

Synthetic polymer nano-microparticles

Nanomaterial

"a **nanoform** is a form of a natural or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more **external dimensions is in the size range 1 nm-100 nm**, including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm."

As of 1 January 2020, **explicit legal requirements** under REACH apply for companies that manufacture or import nanoforms. These reporting obligations address **specific information requirements**, outlined in revised annexes to the REACH regulation:

-characterisation of nanoforms or sets of nanoforms covered by the registration (Annex VI);

-chemical safety assessment (Annex I);

-registration information requirements (Annexes III and VII-XI); and

-downstream user obligations (Annex XII).

COMMISSION REGULATION (EU) 2023/2055

of 25 September 2023

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards **synthetic polymer microparticles**

"**Shall not be placed on the market** as substances on their own or,

where the **synthetic polymer microparticles** are present to confer a

sought-after characteristic, in mixtures in a concentration equal to

or **greater than 0,01 % by weigh**"

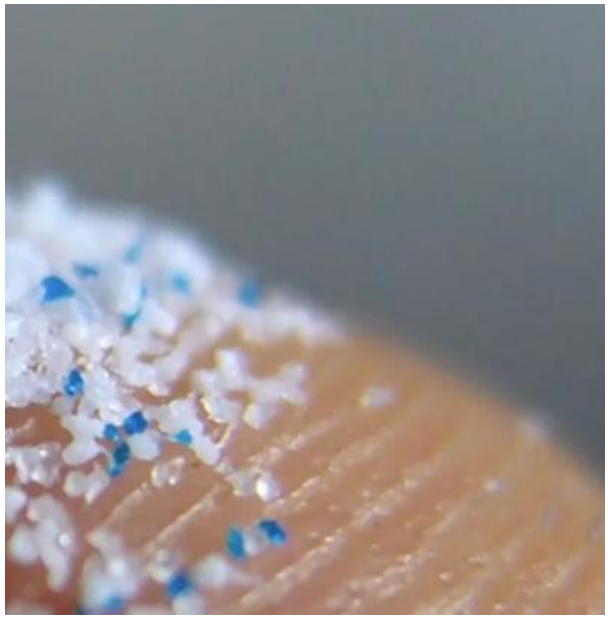
COMMISSION REGULATION (EU) 2023/2055

Synthetic polymer microparticles:

polymers that **are solid** and which fulfil both of the following conditions:

(a) are contained in particles and constitute at least **1 % by weight**

of those particles; or build a continuous surface coating on particles;

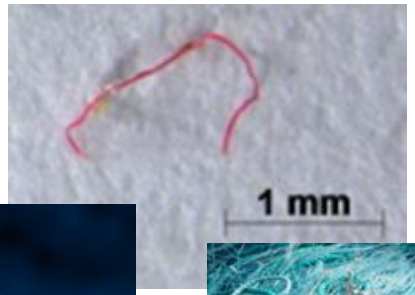


(b) at least 1 % by weight of the particles referred to in point (a) fulfil either of the following conditions:

(i) all **dimensions** of the particles are equal to or less than **5 mm**;

(ii) the **length** of the particles is equal to or less than **15 mm and**

their length to diameter ratio is greater than 3



Polymers excluded

(a) polymers that are the result of a polymerisation process that has taken place in nature, independently of the process through which they have been extracted, which are not chemically modified substances;

"natural polymers not chemically modified"

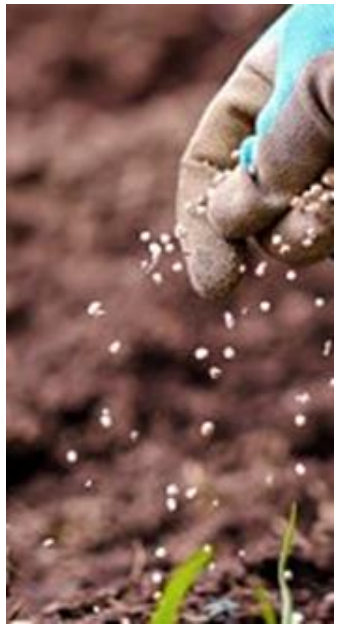
(b) polymers that are **degradable** as proved in accordance with Appendix 15;

These polymers must be tested and obtain a **final degradation ≥ 90%**

regarding the degradation of the reference material in:

-**six months** in **aquatic** tests; either

-**twenty-four months** in **soil,** sediment or water/sediment interface tests.



Polymers excluded

(c) polymers that have a **solubility greater than 2 g/L** as proved in accordance with Appendix 16;

Tests according to guides:
-OECD Guide No. 120
-OECD Guide No. 105

Likewise, you are expected to comply with this condition within 24 hours. reach a solubility of > 2 g/L.

(d) polymers that do **not contain carbon atoms in their chemical structure**.

Exceptions based on the uses of microplastic

The restriction will not apply to the placing on the market of:

a) synthetic polymer microparticles, as substances on their own or in mixtures, for use at industrial sites;

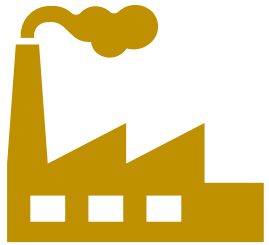
b) human and veterinary medicines

c) fertilizer products

d) food additives

e) in vitro diagnostic products

f) food and feed



Exceptions based on dispersion

The restriction will not apply to the placing on the market of:

a) synthetic polymer microparticles which **are contained by technical** means so that releases to the environment are prevented when used in accordance with the instructions for use during the intended end use;

(b) synthetic polymer microparticles the **physical properties**

of which are permanently modified during intended end use in such a way

that the polymer no longer falls within the scope of this entry;

(c) synthetic polymer microparticles which are **permanently incorporated into a solid matrix** during intended end use.

Circular Economy Action Plan for a cleaner and more competitive Europe

The document

What the European Commission do?

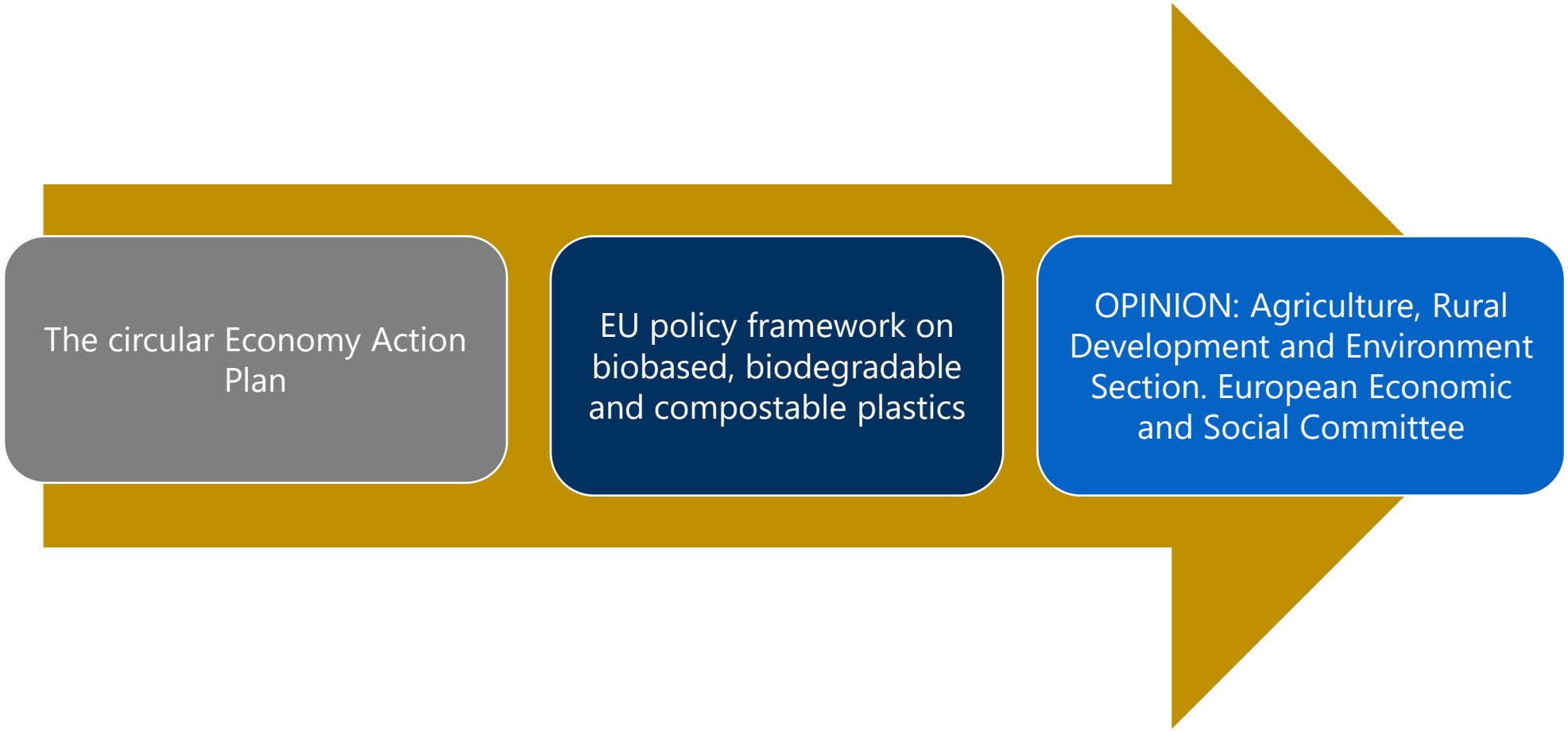
The Commission

-helps to shape the EU's overall strategy,

-**proposes new EU laws and policies**,

-monitors their implementation and manages the EU budget.

The Circular Economy Action Plan	
It´s a document to proposes policies and strategies to achieve some goals, in this case, related to environmental protection. It is a political document. 	It is not binding legislation. It is not a legal document applicable to specific case. 


The circular Economy Action Plan
EU policy framework on biobased, biodegradable and compostable plastics
OPINION: Agriculture, Rural Development and Environment Section. European Economic and Social Committee

Biobased plastic situation: challenge and opportunities

CHALLENGE

To fight greenwashing and avoid misleading consumer

Ensuring biodiversity and the responsible use of farmland

Increase knowledge on the circularity of bio-based plastics through life cycle analysis

Opportunities

-help meet climate neutrality targets: the organic waste used to produce biobased plastics can offer a partial decoupling from fossil resources finding

-new uses for bio-based plastics for long-life products

-to inform correctly about the management of bio-based plastic waste, in order to maximize its use.

DRAFT LEGISLATION

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on preventing plastic pellet losses to reduce microplastic pollution

Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on substantiation and communication of explicit environmental claims (Green Claims Directive)

Proposal for an international plastics treaty (UNEP)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