

EBIC BACKGROUND PAPER

Natural polymers

EXECUTIVE SUMMARY

- The draft fertilising products regulation limits the use of polymers in CE-marked fertilising products; however, the regulation does not distinguish natural polymers (from polymerization processes that occur in nature and are thus subject to nature depolymerization/biodegradation) and derived from biological materials) from synthetic polymers (usually petrochemicals and of variable biodegradability depending on the specific polymer).
- Because they are subject to natural depolymerization (biodegradation), the use of natural polymers, especially when derived as secondary raw materials from other value chains, is fully consistent with the objectives and environmental concerns of the Circular Economy and the draft fertilising products regulation.
- Natural polymers are common ingredients of biostimulants (and other fertilising products). Excluding them from the scope of the draft fertilising products would prevent CE-marking of large numbers of products that precisely meet the objectives of the Circular Economy. Their exclusion thus runs absolutely contrary to what this regulation aims to achieve. Correcting what appears to be an inadvertent exclusion of natural polymers and distinguishing them from manufactured polymers/plastics would allow the future regulation to better promote the Circular Economy and bio-based products that are sustainable.
- **For that reason, EBIC makes recommendations below on small adjustments to the draft fertilising products regulation that could resolve the inadvertent exclusion:**
 - **Add a definition of polymer into Article 2**
 - **Modify CMC 1, point 1(e)**
 - **Amend CMC to accept the last part of EP amendment 228**
 - **Modify CMC 10 to include biostimulant effects**
 - **Ensure that protein hydrolysates from animal origin are included in CMC 11**
 - **Add a new CMC “Natural polymers”**

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I. NATURAL POLYMERS ARE DERIVED FROM BIOLOGICAL MATERIALS

There are many natural polymers (also called biogenic polymers) that are useful components of biostimulant products. The **European Chemical Agency (ECHA) defines a natural polymer as “the result of a polymerization process that has taken place in nature, independently of the extraction process.** 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.”¹ Natural polymers that are subject to further chemical processing are “chemically modified natural polymers”.

Natural polymers can be broken down into two main categories, polysaccharides (sugar-based polymers) and polypeptides (protein-based).

- Polysaccharides are polymers whose monomer units are carbohydrates (sugars). They are derived from plant and seaweeds, extracts and vegetal residues such as fermentation residues. Common examples used in biostimulants are **lignins** (incorporated into biostimulants as **lignosulfonates**, a chemically modified natural polymer which is a by-product of the paper industry), **starches**, and **chitosan** (found in the exoskeletons of insects and crustaceans). Other well-known polysaccharides include rubber and cotton.
- Proteins and polypeptides are complex chains of protein-based monomers (amino acids). Polypeptides include **protein hydrolysates** – mixtures of various amounts of **amino acids and their derivatives, peptides and/or polypeptides**. They are derived both from vegetal raw materials often as by-products from the food industry and as by-products like treated hides and skins. Some are primary products obtained through other methods such as fermentation. Some well-known polypeptides are keratin (found in your hair and fingernails) and collagen (in the skin, bones, cartilage, tendon and teeth).

The same ECHA guidance document explains that while Article 2.9 of REACH exempts all polymers (natural or not) meeting the criteria of Art. 3(5) from registration² because their monomers must be registered. This includes chemically modified natural polymers. The building block monomers (sugars or amino acids) of natural polymers (including chemically modified natural polymers) can also be considered “non-isolated intermediates” and are thus also exempt from REACH registration under article 2.1.c of REG (EC) 1907/2006. The guidance document is very clear that even chemically extracted modified natural polymers would be exempt from REACH registration if they continue to meet the criteria defining a polymer. In this case, the building block monomers of the original natural polymer would also benefit from a registration exemption. However, this exemption does not apply to the substance(s) used for the modification of the natural polymer.

II. NATURAL POLYMERS CAN BE DISTINGUISHED FROM MANUFACTURED POLYMERS THROUGH CHARACTERIZATION.

Natural polymers are analytically distinguishable from both synthesized organic and inorganic polymers, which allows for each type to be addressed in appropriate ways in the draft fertilizing products regulation.

According to ECHA, **natural polymers are substances that meet the following criteria:**

- They result from a polymerization process that has occurred in nature;
- Over 50% of the weight of the substance consists of **polymer molecules** (see definition below) and

¹ ECHA (April 2012). “Guidance for monomers and polymers”. Version 2.0. Section 3.2.1.3.

² Article 6.3 makes it clear that the registration exemption for polymers is the logical result of their component monomers being registered, so registration for polymers would result in a duplication of registration requirements. This situation does not apply to natural polymers; however, the 2012 ECHA guidance specifies that the building block monomers of natural polymers can also be considered non-isolated intermediates and are thus also exempt from REACH registration.

- The amount of polymer molecules presenting the same molecular weight must be less than 50% of the weight of the substance.³

A "polymer molecule" is a molecule that contains a sequence of at least 3 monomer units, which are covalently bound to at least one other monomer unit or other reactant. A "polymer molecule" is a molecule that contains a sequence of at least 3 monomer units, which are covalently bound to at least one other monomer unit or other reactant.

The **general definition of a polymer** in the REACH regulation⁴ is somewhat different:

"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 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;
- 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."

III. NATURAL POLYMERS ARE CURRENTLY EXCLUDED FROM THE DRAFT FERTILIZING PRODUCTS REGULATION

Natural polymers are common ingredients of biostimulants.

According to the draft fertilizing products regulation proposed by the European Commission in March 2016, polymers are excluded from fertilizing products unless they qualify for the Component Material Categories 9 and 10 (nutrient polymers and other polymers used to retain moisture in the soil). Neither of these categories include the natural polymers described above.

Polymers are explicitly excluded from CMC 1 (see point 1(e) of Annex II – Part II – CMC 1), with no distinction between the manufactured polymers covered by CMCs 9 and 10 and natural polymers. This means that natural polymers produced through fermentation and extracted by enzymatic processes, for example, would not be eligible for this CMC.

Since many natural polymers are derived from plants, CMC 2 offers some hope, but all the natural polymers modified by chemical and enzymatic hydrolysis (protein hydrolysates) are excluded by the proposed language of this category. Only the natural polymers modified by physical and mechanical processes may be included.

Some natural polymers of animal origin (for example protein hydrolysates deriving from treated hides and skins) may be included in the future regulation if they meet an endpoint listed in the CMC 11 (not yet defined).

The origin of this exclusion appears to be the Commission's intent to prevent fertilizing products from being a source of soil contamination by certain plastics and microplastics. However, natural polymers are formed in soils (and elsewhere in nature), so they have no role in soil pollution by plastics. There is therefore no scientific justification for a blanket omission. On the contrary, because many of these natural polymers are sourced as by-products from common agro-food production processes, their inclusion would support the Circular Economy ambitions of the draft text. Such natural polymers are commonly included in fertilizing products today, both those authorized at national levels and CE-marked fertilizers. However, when those

³ ECHA (April 2012). "Guidance for monomers and polymers". Version 2.0.

⁴ Article 3.5 of Regulation (EC) 1907/2006

substances are authorized for fertilizing products, they are rarely labelled as natural polymers (but as protein hydrolysates, polysaccharides, etc.), which may explain the lack of attention to this omission thus far.

IV. EBIC RECOMMENDATIONS

Several possible solutions exist (some of which could co-exist) to resolve the inadvertent exclusion of natural polymers from the draft fertilizing products regulation:

- I. **Add a definition of polymer into Article 2** of the draft regulation stipulating that for the purpose of this regulation, the term “polymer” refers to manufactured polymers and does not include natural polymers. (This would allow natural polymers to qualify for CMC 1 if they do not fit in another CMC.)
- II. **Modify CMC 1, point 1(e)** to specify that CMC 1 does not cover polymers with the exception of natural polymers as defined by ECHA. (This would allow natural polymers to qualify for CMC 1 if they do not fit in another CMC.)
- III. **Amend CMC 2 to accept the last part of EP amendment 228:** “...or any other preparation/processing that does not render the final substance subject to registration under Regulation (EC) No 1907/2006”. (This would allow for natural polymers of vegetal origin to be used under this category as long as the treatment chemicals are not contained in the ingredient used in the fertilizing product.)
- IV. **Modify CMC 10 “Other polymers”** to add a new para. 1(c): “(1)(c) positively influencing yield and/or quality through a biostimulant effect as described in the definition of PFC 6.”
- V. **Ensure that protein hydrolysates** from animal by-products (ABPs) **are included in the list of ABP endpoints** defined for CMC 11.
- VI. **Add a new CMC “Natural Polymers”** citing the ECHA definition and criteria above. (They would qualify for REACH exemption under either Annex IV and/or Annex V, points, 6, 7 8 or 9).