GO!PHA
Global Organization for PHA

Reactie op internet consultatie betreffende 'ontwerpbesluit single use plastics'

Amsterdam, 9 Augustus 2020

Het dagelijks bestuur van de Stichting Global Organization for PHA (GO!PHA) reageert in haar hoedanigheid als stakeholder en vertegenwoordiger van meer dan 40 organisaties (waaronder multinationals, SMEs, onderzoeksinstituten en universiteiten) in deze online consulatie op het Besluit kunststofproducten voor eenmalig gebruik en de bijbehorende wijzing van het Besluit beheer verpakkingen 2014. GO!PHA is een door leden aangestuurde organisatie zonder winstoogmerk met als doel het versnellen van de ontwikkeling van de Polyhydroxyalkanoate (PHA) industrie.

Doormiddel van deze consultatie willen wij onze steun betuigen aan het Besluit kunststoffen voor eenmalig gebruik. Milieuvervuiling veroorzaakt door kunststoffen is een alsmaar groter wordend probleem. Het moment is daar om op een juiste manier het probleem terug te dringen en te minimaliseren, zodat wij een schonere en duurzamere wereld kunnen overdragen aan toekomstige generaties. Het Single Use Plastics Directive (SUP) en het daaruit voortvloeiende Besluit kunststofproducten voor eenmalig gebruik zijn hier de spil in.

Een handelsverbod op kunststofproducten zal bedrijven stimuleren om verder te investeren in innovatieve productoplossingen voor eenmalig en meermalig gebruik. GO!PHA steunt deze aanpak en de nadruk op een innovatieve oplossing voor het huidige probleem. De oplossing ligt in het gebruik van nieuwe materialen zoals cellulose, hout en PHA die in de natuur voorkomen en daardoor, en door de toegepaste productieprocessen minder belastend zijn voor het milieu. De definitie gehanteerd in artikel 15a – "*kunststof is een materiaal, bestaande uit een polymeer, dat chemisch gewijzigd is en niet van nature voorko*mt" – biedt ruimte voor het gebruik van dit soort materialen en stimuleert het gebruik van innovatieve, duurzame en natuurlijke materialen.

GO!PHA vraagt uw steun om dit uitgangspunt ook uit te dragen binnen de Europese Unie. Op dit moment beschrijft de richtlijn van het SUP Directive nog materialen die in de natuur voorkomen, zoals PHA, toe binnen het verbod. Daarom vragen wij u om *"geproduceerde polymeren die het resultaat zijn van biosynthese via industriële fermentatieprocessen met dezelfde chemische identiteit als natuurlijk voorkomende polymeren te definiëren als natuurlijk polymeren"*. Innovatie en klimaatneutraliteit moeten de drijfveer blijven van zowel het Nederlands als Europees beleid. PHA en andere natuurlijke polymeren bieden hiervoor de geschikte oplossing. Laten we gezamenlijk zorgen dat de doelen uit het Besluit kunststofproducten verwezenlijkt kunnen worden.

Vriendelijke groet,

Mede namens alle leden van de Stichting Global Organization for PHA (GO!PHA),

Het dagelijks bestuur.

Bijlagen

18 September 2019 – NOVA Institut letter on natural polymers
7 Maart 2020 – GO!PHA response to SUP directive
16 April 2020 – GO!PHA response to SUP directive
19 Mei 2020 – GO!PHA response to SUP directive

Open Letter to DG Environment

Which polymers are “natural polymers” in the sense of the single-use plastic ban?

nova-Institute, Hürth, Germany, 18 September 2019

After a relatively short negotiation period, the new rules on single-use plastics to tackle marine litter were adopted and published in June 2019, in brief commonly known as the “single-use plastic ban” (Directive 2019/904) (European Parliament 2019). Items that fall under this ban include single-use products made of plastic to which alternatives exist on the market, such as cotton bud sticks, cutlery, plates, straws, stirrers, sticks for balloons, as well as cups, food and beverage containers made of expanded polystyrene and all products made of oxo-degradable plastic.

For the purpose of the Directive and its measures, a **plastic** is defined as a material consisting of a polymer 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** (Annex 3.1 Definition – Plastic).

This means that all previously named items made of plastics defined as such (Annex 3.1 Definition – Plastic) fall under the ban except those made from ‘natural polymers that have not been chemically modified’, in the sense of a **not chemically modified substance** (Annex 3.3 Definition – Not chemically modified substance).

However, within the Directive, it is not specified which polymers fall into the group of “natural polymers”. Also, the term “natural polymers” as such is not further defined within the proposal of the Directive.

For the definition of a **polymer** as a component of a plastic, the Directive refers to the REACH regulation (European Parliament 2007) (Annex 3.1 Definition – Plastic), here the terms **polymer** (Annex 3.2 Definition – Polymer) and the term **substances which occur in nature** are defined (Annex 3.4 Definition – Substances which occur in nature). By considering, delineating and interpreting these two definitions, the European Chemicals Agency (ECHA) implemented a definition for **natural polymers** in which they are explained **‘as polymers which are a result of a polymerisation process that has taken place in nature, independently of the extraction process with which they have been extracted’** (ECHA 2012) (Annex 3.5 Definition – Natural polymer). Furthermore, it is emphasised that natural polymers are not necessarily **substances which occur in nature** when extracted and assessed according to the **substances which occur in nature** definition (Annex 3.4 Definition – Substances which occur in nature).
Based on this definition of a natural polymer, the following shows a list of polymers that should be considered as natural and examples of those that should not.

1 Polymers to be considered as natural polymers

Polymerisation processes that take place in nature are those relying on the metabolism and biosynthesis of organisms and microorganisms such as animals, plants and algae, fungi and bacteria. The majority of these natural polymers are polysaccharides or proteins, but also other forms are possible as it is the case for lignin and polyhydroxyalkanoates (PHAs). In general, these natural polymers fulfil different functions within the organisms and/or microorganism as a texture-forming component (e.g. chitin), cellular interaction component (e.g. glycoproteins) or as energy storage material (e.g. polyhydroxyalkanoates (PHAs)). The biosynthesis either takes place in nature itself or is deliberately induced in artificial cultivation and fermentation processes.

The following chemically unmodified **polymers** are clustered according to their natural origin. They are produced via the explained biosynthesis and should be **considered as natural polymers:**

- **Natural polymers produced via biosynthesis in animals**
  - Polysaccharides and polymers based thereon: chitin, hyaluronic acid
  - Proteins and based thereon: casein, collagen, gelatine, hair, keratin, silk
  - Others: polyphosphates
- **Natural polymers produced via biosynthesis in plants and algae**
  - Polysaccharides and polymers based thereon: agar agar, alginate, cellulose, hemicellulose, inulin, pectins, starch, xanthan
  - Others: lignin, polyphosphates, suberin
  - Mixtures of natural polymers and other natural compounds: cotton, gluten, latex
- **Natural polymers produced via biosynthesis in fungi**
  - Polysaccharides and polymers based thereon: chitin, chitosan
  - Proteins and polymers based thereon: glycoproteins
  - Others: polymalat (PMLA), polyphosphates
- **Natural polymers produced via biosynthesis in bacteria**
  - Polysaccharides and polymers based thereon: alginate, bacterial cellulose, curdlan, dextran, pullulan, xanthan
  - Others: ε-poly-L-lysine, hyaluronic acid, poly-γ-glutamic acid, polyhydroxyalkanoates (PHAs), polyphosphates

Based on the definition of **polymers** in the REACH regulation (European Parliament 2007) (Annex 3.2 Definition – Polymer), also so-called oligomers (if the number of monomers > 2) fall under this definition and natural varieties of these have to be considered here. In principle, oligomers are intermediates between monomers and polymers, they are lower molecular weight variants of polymers and are systematically named according to the number of monomers involved: dimer (2), trimer (3), tetramer (4) etc.

- **Natural oligomers produced via biosynthesis plants and algae**
  - Secondary metabolites: ellagitannins, gallotannins, oligomeric proanthocyanidins
- **Natural oligomers produced via biosynthesis in fungi**
  - Fatty acid-based oligomers: exophilin A

2 Polymers not to be considered as natural polymers

Besides these natural polymers that can be and are used as such without any further modifications, also natural polymers exist that are **chemically modified** prior to use to obtain specific properties. These polymers should therefore **not be considered as natural polymers:**

- **Examples natural polymers that are chemically modified**
  - Cellulose: cellulose acetate, cellulose butyrate and other cellulose derivatives
  - Lignin: ligninsulfonate
  - Starch: starch acetates and other starch derivatives

As defined in Annex 3.2 Definition – Polymer, polymers in general are always consisting of the same or different monomers, also called building blocks. These building blocks can be produced by plants and algae, as well as fungi and bacteria from renewable feedstocks and are therefore from natural, bio-based origin.
Bio-based polymers that are made from these bio-based monomers are always synthesised by a polymerisation reaction outside the plant or microbial cell, which is a chemical modification. These bio-based polymers should therefore also **not be considered as natural polymers:**

- **Examples of bio-based monomers used for bio-based polymer production**
  - Bio-based monomers from plants and algae: bioethanol for bio-based polyethylene
  - Bio-based monomers from fungi and bacteria: lactic acid for polylactic acid (PLA), sebacic acid for polyamides (PA), succinic acid and 1,4-butanediol for polybutylenesuccinate (PBS)

Based on these scientific facts and the clear guidance given by REACH (European Parliament 2007) and ECHA (ECHA 2012), we request the European Commission to exempt the above named "natural polymers" from the measures outlined in Directive 2019/904 (European Parliament 2019).

Experts supporting this proposal:

Cologne, September 2019

- **Prof. Dr. Lars M. Blank**, Rheinisch-Westfälische Technische Hochschule Aachen (RWTH Aachen University), Institute of Applied Microbiology (iAMB), Germany
- **Prof. Dr. Christian Bonten**, Stuttgart University, Institut für Kunststofftechnik (IKT), Germany
- **Prof. Dr. George Guo-Qiang Chen**, Tsinghua University, Center for Synthetic & Systems Biology, China
- **Prof. Dr. Craig Criddle**, Stanford University, Environmental Biotechnology Group, United States
- **Prof. Dr. Bruce E. Dale**, Michigan State University (MSU), Michigan Biotechnology Institute, East Lansing, United States

- **Prof. Dr. Ludo Diels**, Flemish Institute for Technological Research (VITO), Mol and Antwerp University, Institute of Environment & Sustainable Development, Belgium
- **Prof. Dr. María Auxiliadora Prieto Jiménez**, Biological Research Center-Spanish National Research Council (CIB-CSIC), Polymer Biotechnology Group, Madrid, Spain
- **Ass.-Prof. Dr. Marina Kalyuzhnaya**, San Diego State University (SDSU), Cell & Molecular Biology Faculty, United States
- **Prof. Dr. Klaus Kümmerer**, Leuphana University Lüneburg, Chair for Sustainable Chemistry and Physical Resources, Germany
- **Prof. Dr. Kevin O'Connor**, University College Dublin (UCD), Biocatalysis Group, Ireland
- **Prof. Dr**. **Juliana Ramsay**, Queen's University, Department of Chemical Engineering, Kingston, Canada
- **Prof. Dr**. **Manfred Zinn**, University of Applied Sciences and Arts Western Switzerland – Valais (HES-SO Valais-Wallis), Institute of Life Technologies, Sion 2, Switzerland
- and the nova team: **Michael Carus, Dr. Pia Skoczinski, Lara Dammer** and **Achim Raschka**

3 Annex

3.1 Definition – Plastic

DIRECTIVE (EU) 2019/904 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 June 2019 on the reduction of the impact of certain plastic products on the environment

Article 3(1):
'plastic' means a material consisting of a polymer within the meaning of Article 3(5) 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;
(European Parliament 2019)

3.2 Definition – Polymer

Corrigendum to 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

Article 3(5):
'polymer' means a substance consisting of molecules characterized 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;
(European Parliament 2007)

3.3 Definition – Not chemically modified substance

Corrigendum to 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

Article 3(40):
'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;
(European Parliament 2007)

3.4 Definition – Substances which occur in nature

Corrigendum to 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

Article 3(39):
'substances which occur in nature' means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;
(European Parliament 2007)

3.5 Definition – Natural polymer

Guidance for monomers and polymers – Guidance for the implementation of REACH. Version 2.0

3.2.1.3 Case of a natural polymer or a chemically modified natural polymer

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.

Following Article 2(9) of REACH, any polymer meeting the criteria of Article 3(5), whether natural polymers or not, does not have to be registered. This exemption from registration includes natural polymers which are chemically modified (e.g. post-treatment of natural polymers).
Monomer substance(s) and other substance(s) ending up in the form of monomeric units and chemically bound substance(s) in natural polymers can, for practical reasons, be treated as "non-isolated intermediates" and do not have to be registered.

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 (within the meaning of Article 6(3)) used for the modification of the natural polymer and

meeting the provisions of Article 6(1) and 6(3) needs to be registered accordingly, unless it has been registered up the supply chain. These registration obligations apply provided the chemically modified natural polymer itself meets the Article 3(5) polymer definition.

Whenever it is not scientifically possible to identify and quantify the building blocks of a substance that is under consideration as to whether it is a natural polymer or not, this substance must instead of a natural polymer be regarded as a UVCB substance (see section 2.2 for further information) that therefore has to be registered.
(ECHA 2012)

4 References

ECHA (European Chemicals Agency) 2012. Guidance for monomers and polymers – Guidance for the implementation of REACH. Version 2.0. ECHA (Ed.), Helsinki, Finland, 2012-04. Download at https://echa.europa.eu/documents/10162/23036412/polymers_en.pdf/9a74545f-05be-4e10-8555-4d7cf051bbed

European Parliament 2007. Corrigendum to 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. Official Journal of the European Union (Ed.), 2007-05-29. Download at https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:EN:PDF

European Parliament 2019. DIRECTIVE (EU) 2019/904 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 June 2019 on the reduction of the impact of certain plastic products on the environment. Official Journal of the European Union (Ed.), Brussels, Belgium, 2019-06-12. Download at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.155.01.0001.01.ENG&toc=OJ:L:2019:155:TOC

GO!PHA
Global Organization for PHA

PHA (Polyhydroxyalkanoates) are a class of *Natural Polymers* that have *not been chemically modified*

7th March 2020

GO!PHA response to the Eunomia study on the plastics definition under the Directive (EU) on the reduction of the impact of certain plastic products on the environment

The SUP Directive [1] (P8-TA-2019_305) mentions in Article 3 (1) the definition of "*plastic*", "*natural polymer*" and "*chemically modified polymer*", in order to identify materials that would be subject to exclusions from the above-mentioned SUP Directive.

PHA is a *Natural Polymer*, which is *not chemically modified*. Additionally, they have excellent end of life biodegradability in all environments including marine environments and is produced from renewable substrates fit with the European Commission's own vision of a Circular Economy.

GO!PHA, an Industry Organization, representing the PHA Industry and its downstream market participants, requests the European Commission (hereafter Commission) to clarify that PHA produced via the cultivation of microorganisms, and having identical structures and chemical compositions as naturally occurring PHA, are classified as *Natural Polymers* within the scope of the SUP Directive.

Hereby we respectfully submit our comments and arguments in favour of our request for the EU to classify PHA as *Natural Polymers*.

The origin of the definitions of "*Plastics*", "*Polymers*", "*Natural Polymers*" and "*Chemically Modified Polymers*" are the ECHA guidelines of 2006 [2] and their subsequent revisions.

The ECHA guideline states:

"*Natural polymers are understood as polymers which are the result of a polymerization 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.*

Following Article 2(9) of REACH, any polymer meeting the criteria of Article 3(5), whether natural polymers or not, does not have to be registered. This exemption from

registration includes natural polymers which are chemically modified (e.g. post-treatment of natural polymers).”

The second sentence in the first paragraph in the above-mentioned quote on Natural Polymers outlines that *Natural Polymers* do not need to occur in nature on their own and clearly seen differently than *substances which occur in nature* as it is independent of the extraction process. Therefore, polymers can be called “natural” when made in a different setting, such as fermentation, which is a natural process that uses microorganisms except it is controlled in an industrial setting and produces polymers that are chemically and structurally identical to those found in a natural setting.

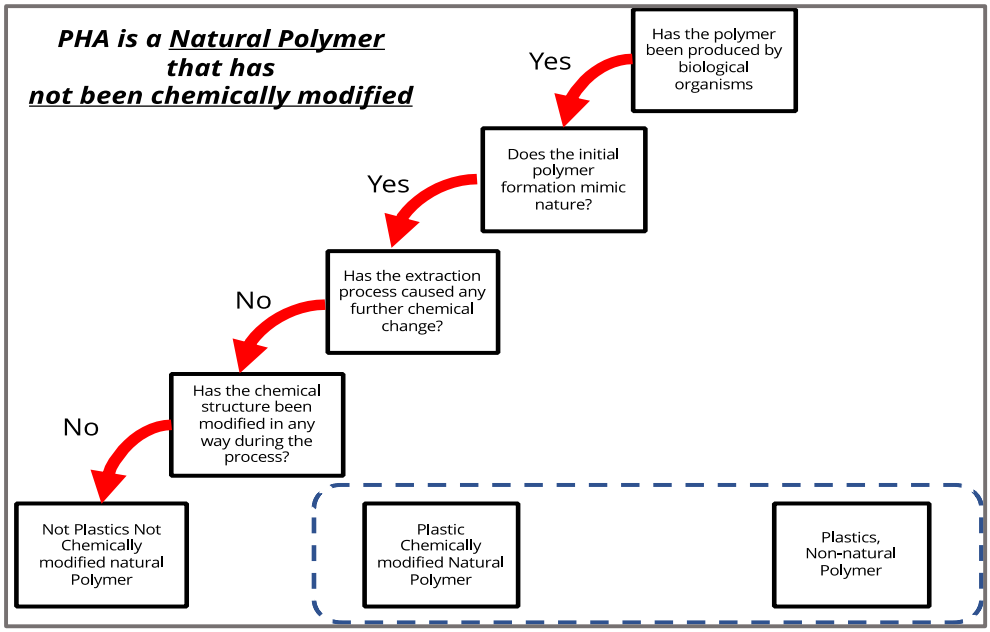
The definition of a *Natural Polymer* should also be seen via the definition of a “*Natural Substance*” as elaborated by ECHA Guidance for Exemptions from the obligation to register, Annex V, Version 1.1, November 2012 (pages 18-19)[3] which is defined as:

“Naturally occurring substances as such” means, substances obtained, for example, from plants, micro-organisms, animals, or certain inorganic matter such as minerals, ores and ore concentrates, or organic matter such as crude oil, coal, natural gas”.

The definition above and other parts there-of states that microorganisms are biological entities, same as plants or animals. Therefore, substances obtained by cultivating them via fermentation must be considered *Natural Substances*, similar to materials obtained from plants and animals that are harvested/cultivated/raised to obtain substances which are also considered *Natural Materials*.

Based on ECHA guidelines covering *Natural Polymers* and *Natural Substances* outlined above PHA is a *Natural Polymer, is not chemically modified* and a *Natural Substance*.

This is further illustrated using the methodology used in the January 21st Eunomia report “What is Plastic” [4]:



In addition, the Eunomia Report states the following with regard to PHA presented by Nova Institut[5] and 17 renowned experts in the field of plastics, molecular biology and microbiology:

"In an open letter to DG Environment, issued in September 2019, the Nova Institut [5] identified several other substances which they believe are "natural polymers" and should be exempt from the provisions of the SUP Directive. One notable polymer on this list was Polyhyroxyalkanoates (PHA), classed under "natural Polymers produced via biosynthesis in bacteria". The polymer is produced by bacteria (biological organisms), but the commercial production of the polymer does not take place in nature. As such, based on the ECHA guidance, it directly contradicts one of the conditions of being considered a natural polymer ('Did the initial polymer formation reaction occur in nature?'), and thus it appears that it could not be considered exempt from the SUP Directive. In addition, the production of PHA depends upon the nutrients added to the culture, reinforcing that the polymer is not being produced "in nature"."

Referring to multiple ECHA guidelines, the following important arguments against the Eunomia report's conclusion and recommendation arise:

a. *Natural Substances* made via microorganisms are considered natural as long as their structure and chemical composition mimics the same materials found in nature.
b. The definition of *Natural Polymers* is derived from that of *Natural Substances*; therefore, *Natural Polymers* do not need to exist on its own in nature and could be made in another setting as long as it mimics nature in structure and chemical composition.
c. Eunomia, in their decision tree to determine if a polymer is a plastic, asked, "Did the initial polymerization reaction occur in nature?" while the entire definition of *Natural Polymer* and *Natural Substance* does not stipulate the process of its manufacture, rather only whether their structure and chemical composition are identical to those found in nature. That requires the following question be asked; "Does the initial polymer formation mimic nature?". In the case of PHA the polymer formation occurs inside the microorganism, therefore, the answer to this question is in the affirmative.
d. Eunomia mentions that the use of nutrients in an industrial process make PHA unnatural. Microorganisms also use nutrients in nature to make PHA, hence the use of nutrients in fermentation using microorganisms is identical to the natural process.

Based on multiple ECHA guidelines and the definitions for *Natural Substances* and *Natural Polymers*, there is sufficient evidence to indicate that PHA are *Natural Polymers* and that Eunomia's conclusions are not based on all relevant ECHA guidelines.

In addition, the Eunomia Report mentions that a decrease in molecular weight is a form of chemical modification. This claim is scientifically incorrect. Reduction in molecular weight of polymers in general and in the example given in their report[4] (Figure 4: Viscose Production) decrease the physical properties of such polymers and have no impact on their, chemical composition, therefore reduction in molecular weight of a natural material does not make them unnatural. Furthermore, molecular weight reduction does not change recyclability, biodegradability or compostability, which are all important requirements for any litter that has been left in the environment.

In China[6] and in the United States, legislators are also working on regulations to ban Single Use Plastics. The main purpose of these bans, like in the EU, are to curb plastic waste and littering, to avoid their harmful effects to the environment even if such products are left in the environment, and to encourage designing products for circularity. Exempting only *Natural Polymers* or *Natural Substances* alone is not sufficient and wood, a *Natural Substance* which contains cellulose and lignin is a good example. In marine environments the cellulose will fully biodegrade, but the lignin will not, since lignin needs fungi to make it biodegrade, while fungi are not present in a marine environment.

These definitions were introduced as part of REACH registration in 2006 to ensure proper risk assessments of various man-made chemicals and polymers. These definitions were not created to control litter or to protect the environment from pollution, the primary objectives of the SUP Directive. Therefore, we strongly believe that the utilization of these definitions alone in the SUP Directive leaves room for subjectivity and halts the innovation of promising new materials.

The SUP Directive states that it should act *"to prevent and reduce the impact of certain plastic products on the environment, in particular the aquatic environment, and on human health, as well as to promote the transition to a circular economy with innovative and sustainable business models, products and materials, thus also contributing to the efficient functioning of the internal market."* The subjectivity of the definitions mentioned above do not propagate the intent and the spirit of the SUP Directive.

Four key elements defining materials for use in an effective SUP Directive in our opinion are:

1. Should not be harmful to the environment in any way when they are purposely or accidentally left in the environment. Therefore, they should:
   - Biodegrade into carbon dioxide and water when left in the environment.[6]
   - Be non-toxic and harmless if ingested by birds, animals, fish or marine mammals.
2. Should fit into current and future waste collection, recycling and incineration streams, such as be home and industrially compostable, recyclable when large streams of such materials become commercially available, or can be incinerated, if necessary.
3. Encourage the use of renewable raw materials that are readily available in the atmosphere (like CO_2 or CH_4), in the biosphere (renewable substrates) or in the Technosphere (recycled carbon), it also would benefit the environment through reduction of greenhouse gases.

4. Establish a regulatory and standards driven regime for biodegradability and compostability rooted in science to allow for the introduction of new and innovative materials.

Based on 40+ years of science and technology-based evidence, **PHA** is one such innovative ***Natural Polymer*** that has ***not been chemically modified*** with end of life properties that only nature can design – biodegrade in all natural environments, soil, fresh water and marine environment. We thank the Commission for giving GO!PHA's position due consideration and classifying PHA as *Natural Polymers* in the final SUP Directive. We are ready to meet and assist the Commission with further discussion, evidence and information in order to reach the goals of the SUP Directive.

REFERENCES

1. EU SUP Directive P8-TA-2019_305
2. ECHA Guidance for monomers and polymers, April 2012 Version 2, page 20
3. ECHA Guidance for Annex V, Exemptions from the obligation to register, Version 1.1, November 2012 (pages 18-19)
4. Eunomia Report of January 21, 2020 "What is Plastic"
5. Nova Institute, Open Letter to DG Environment, "Which polymers are "natural polymers" in the sense of the SUP Directive, Nova Institut, Hürth, Germany
6. Opinions of the Chinese National Development and Reform Commission and the Ministry of Ecology – Nova Institut, Hürth, Germany (included)
7. Biodegradable materials in various environments, Nova Institut, Hürth, Germany (included)

GO!PHA
Global Organization for PHA

Status of PHA (Polyhydroxyalkanoates) as a class of *Natural Polymers* that have *not been chemically modified*

17th April 2020

GO!PHA represents over 40 stakeholders in the PHA industry and their downstream markets. We had responded on March 9, 2020 on Article 3 (1) in the SUP Directive which represents the definition of "*plastic*", "*natural polymer*" and "*chemically modified polymer*", in order to elaborate our position on PHA.

In our response we demonstrated that PHA is a *Natural Polymer*, which is *not chemically modified*. Additionally, they have excellent end of life biodegradability in all environments including marine environments and is produced from renewable substrates fitting with the European Commission's vision of a Circular Economy.

GO!PHA, once again, requests the European Commission (hereafter Commission) to clarify that PHA produced via the cultivation of microorganisms, and having identical structures and chemical compositions as naturally occurring PHA be classified as *Natural Polymers* that have *not been chemically modified* within the scope of the SUP Directive.

Hereby we respectfully submit additional comments and arguments in favour of our request for the Commission to classify PHA as *Natural Polymers that are not chemically modified*.

1. **During the April 3, 2020 workshop, ECHA presented that PHA be defined as a Nature Identical Polymer and stated it to be different from a Natural Polymer:**

Nature Identical Polymer is not defined in any ECHA guidelines, and as has been stated in our prior communication to the Commission, ECHA's *Natural Polymer* definition was created for a completely different purpose, and not for the purpose of the SUP Directive. EU Regulation *(EC) No 1334/2008* [3] , on the other hand defines *Natural Compounds used as flavourings* as follows*:*

> *natural flavouring substance shall mean a flavouring substance obtained by appropriate physical, enzymatic or* ***microbiological processes*** *from material of vegetable, animal or* ***microbiological origin*** *either in the raw state or after processing for human consumption by one or more of the traditional food preparation processes listed in* ***Annex II****. Natural flavouring substances correspond to substances that are* ***naturally present*** *and have been* ***identified in nature****;*

Annex II of *(EC) No 1334/2008* further lists ***microbiological processes*** and ***fermentation*** as acceptable processes to produce flavourings. In addition, the above

definition refers to natural flavourings as those that are either ***naturally present*** or have been ***identified in nature***, without regard to their origin or their manufacturing process. Therefore, flavourings that are ***naturally present*** or ***identified in nature***, but are produced via ***fermentation*** or ***microbiological processes*** are considered to be natural flavourings.

Given the a) above precedence with *Natural Compounds* within European Union legislation, b) the lack of a definition of *Natural Polymers* within the SUP Directive, and c) ECHA's guiding definition for *Natural Polymers* having being set up for a completely different purpose; we believe that the Commission should include in its definition of *Natural Polymers* those polymers that *exist in nature* and are *produced via fermentation or microbiological processes* that have *not been chemically modified* in line with *(EC) No 1334/2008*. Such a definition would exempt PHA from the SUP Directive.

2. PHA is a Natural Polymer when the end point is considered:

ECHA, in their presentation on April 3rd argued that using the *have not been chemically modified* section of the definition viscose can be considered to be a *Natural Polymer that has not been chemically modified*. ECHA argued that since the chemical modification in viscose occurs unintentionally and due to the extraction process, one must look at the product produced *at the end point* of the extraction process. Considering the end point, ECHA argued, that the Commission can classify viscose to be a Natural Polymer and exempt it from the SUP Directive.

GO! PHA would like to take the *End Point* argument to the *Natural Polymer* part of the definition as well. PHA is produced via industrial fermentation using the same microorganisms that produce them in nature, using the same natural and renewable substrates. PHA thus produced have chemical structures identical to those found in nature. Therefore, if the production methods for PHA are excluded from consideration, and only the *end point* is considered, as argued by ECHA in the case of viscose, PHA is a *Natural Polymer*. PHA is present in nature, it is produced using exactly the same processes as in nature, using the same microorganisms and substrates. It also has the same chemical structure as those found in nature.

3. A Comprehensive Definition of materials that fulfil the objectives and intent of the SUP Directive must include biodegradability as a criterion:

The original intent of the SUP Directive is three part:

1) *to prevent and reduce the impact of certain plastic products on the environment, in particular the aquatic environment, and on human health,*

2) *to promote the transition to a circular economy with innovative and sustainable business models, products and materials*

3) *to contribute to the efficient functioning of the internal market.*

Eliminating litter completely is an extremely difficult task, however, eliminating damage from litter via the use of harmless and sustainable materials can be accomplished through this SUP Directive. Given the first two primary objectives of the SUP Directive, GO!PHA believes that any material with a natural character and

marine biodegradability must be the overriding criteria used to exempt materials from the SUP Directive. *Natural Polymers that have not been chemically modified* alone is a narrow and insufficient method for defining materials to fit the primary objectives of the SUP Directive. Not all natural materials biodegrade in all environments; case in point, Lignin and Chitin do not biodegrade in marine environments and yet they would be classified as *Natural Polymers* using the ECHA guidelines solely, while, PHA just like cellulose – Lyocell and viscose – are natural and biodegradable in all environments would be excluded from the SUP Directive.

4. The innovative nature of PHA, including in combination with other natural materials, can have far reaching positive consequences:

The innovations with PHA given their behavior as plastics and end of life characteristics are very well known. GO!PHA would also like to bring to the Commission's attention an additional innovative nature of PHA, their combination with cellulose. Both materials have similar biodegradation characteristics and together bring significant value in single use and multiple use applications while at the same time ensuring:

a. Recyclability within a well-organized paper recycling system without generating microplastics,

b. Allow for complete composting in home and industrial composting facilities,

c. Incinerate after collecting for energy generation, if no other uses can be found, coupled with a closed loop carbon dioxide capture and use, and

d. Not harm the environment, including the marine environment, if unintentionally littered.

Several of our members are working with industry leading partners in the cellulose industry to bring such innovations to the market. Therefore, to include PHA in the SUP Directive now would stifle such projects that currently employ large number of highly skilled researchers in Europe and would further stifle large number of manufacturing jobs when these projects are scaled and commercialized. In addition to that, other countries and regions are adopting single use plastics legislation that allows biodegradability to be a criterion for determining exemption from their directives, thus allowing PHA and innovative cellulose/PHA technologies to be commercialized in those regions at the expense of European Union innovations and jobs.

5. GO!PHA continues to believe that an effective SUP Directive must have the following four key elements that define materials:

1. They should not be harmful to the environment in any way when they are purposely or accidentally left in the environment. Therefore, they should:
   - Biodegrade into carbon dioxide and water when left in the environment.
   - Be non-toxic and harmless if ingested by birds, animals, fish or marine mammals.
   - The objective of biodegradability of materials to be used in has also been laid out in the European Union's new *Circular Economy Action Plan of March 2020*.

2. Should fit into current and future waste collection, recycling and incineration streams. Therefore, they must be home and industrially compostable, recyclable when large streams of such materials become commercially available or can be incinerated to generate energy/carbon dioxide capture/recycle/reuse, if necessary.
3. Encourage the use of renewable raw materials that are readily available in the atmosphere (like CO_2 or CH_4), in the biosphere (renewable substrates) or in the Technosphere (recycled carbon), thus also benefiting the environment through reduction of greenhouse gases, and fit into the overall vision of the European Union's new *Circular Economy Action Plan of March 2020*.
4. Establish a regulatory and standards driven regime for biodegradability and compostability rooted in science to allow for the introduction of new and innovative materials.

GO!PHA, on behalf of our members, therefore, requests the Commission to exempt PHA from the SUP Directive:

a. By classifying PHA as a *Natural Polymer* under the SUP Directive's current definition in line with *(EC) No 1334/2008*, or

b. Create a new definition for materials that would exempt biodegradable materials from the directive

Waiting 7 years, for the next revision of the SUP Directive, to exempt PHA would kill significant ongoing environmentally sustainable innovations (many of whom are EU sponsored) in materials that would otherwise allow EU citizens to continue to enjoy the benefits of plastics without harming the environment. Killing these innovative projects, risks sending future potential EU manufacturing jobs to other regions of the world.

We thank the Commission for giving GO!PHA's position due consideration and exempting PHA from the SUP Directive. We are ready to meet and assist the Commission with further discussion, evidence and information in order to achieve the objectives, intent and spirit of the SUP Directive.

Sincerely

REFERENCES (included, as noted below):

1. EU SUP Directive P8-TA-2019_305
2. GO! PHA Position Paper to DG Environment, March 9, 2020 (included)
3. EU Regulation (EC) No 1334/2008 on Flavouring

GO!PHA
Global Organization for PHA

19th May 2020

PHA (Polyhydroxyalkanoates) are a class of ***Natural Polymers*** that have ***not been chemically modified*** *within the SUP Directive P8-TA-2019_305.1*

GO!PHA is a member driven Foundation (not-for-profit) engaged in the proliferation of PHA (Polyhydroxyalkanoates), a class of natural materials abundantly produced by microorganisms as a carbon/energy storage material. PHAs biodegrade in all environments, including marine environments similar to cellulose – paper, Viscose®, Lyocell®, Tencent® etc., therefore giving them all end of life options – compost, incinerate, and recycle. In addition to the foregoing, PHAs have the beneficial properties of plastics and they can be processed like plastics; and hence represent the next generation of innovations in sustainable materials, packaging and consumer products that are also circular.

GO!PHA has already requested the European Commission to classify PHA as a natural polymer and therefore fall outside the scope of the above referenced SUP Directive via two position papers. We attach the two position papers for your review and comment. [1,2]

Natural Polymers is not defined in the SUP Directive and no reference to the ECHA guideline is made in the SUP Directive. The Commission requested ECHA recommend a definition and ECHA has proposed the definition from the guidelines on Monomer and Polymers under REACH. During the April 3, 2020 Workshop ECHA presented a case for an alternative definition of ***Natural Polymer***, however that would require the Commission to ***agree on the boundaries and develop a definition specifically for the SUP Directive or have an alternative reference to the Guidance definition***. [3] We urge the Commission to consider broadening the definition of ***Natural Polymers*** in line with ***Directive (EC) No 1334/2008 on flavoring,*** which already and rightfully classifies ***fermentation*** as a ***natural process and their output as natural materials.*** Indeed, fermentation is not different from growing a managed forest to harvest cellulose to manufacture paper, cellulose, lignin, etc.

PHAs are industrially produced via the cultivation of microorganisms (fermentation) that use natural and renewable substrates/raw materials such as sugars, fatty acids, food waste, and

other carbon rich biomass. PHAs thus produced have identical structures and chemical compositions as naturally occurring PHA.

The draft report of March 31, 2020 ECHA presented three possible interpretations to the ***have not been chemically modified*** portion of the definition of plastics. [4] They are as follows:

1. A strict interpretation where no modification is allowed even during the extraction process.
2. An interpretation that refers to a process in which no intentional change occurs in any stage of the manufacturing process. The changes which occur due to the extraction process are not considered as intentional changes and therefore not to affect the status of the extracted substance as a natural polymer.
3. An interpretation that refers to the end stage of the manufacturing process. The changes occurring during the manufacturing process are not considered relevant, the end product of the manufacturing should be considered when determining the status of the polymer.

The third interpretation, above, states that the manufacturing process is irrelevant, as long as the end product is the ***natural polymer***. Setting aside the fact that fermentation is already classified by the Commission as a natural process (*Directive (EC) No 1334/2008 on* flavorings), by simply rendering the manufacturing process irrelevant, PHAs produced would fit the definition of a natural polymer that has not been chemically modified, since they are identical to those found in nature. Therefore, PHAs are then exempt from the SUP Directive. Therefore, we urge the Commission to accept this (third) interpretation of the ***have not been modified*** part of the definition.

GO!PHA has identified over 91 projects on the development, production and applications testing of PHAs that have been sponsored by the EU over the last twenty years [5]. 34 of those projects alone have had a total budget of 134 Million Euros, out of which the EU has spent 110 Million Euros [3]. Most of these projects have focused on valorizing waste streams from human activity such as from cheese production, from wastewater treatment facilities, etc. to minimize waste generation and to promote a Circular Economy.

Several manufacturers have recently increased their production capacities and others have announced significant new investments in the order of hundreds of millions of Euros to produce PHA at commercial scale. They have done so on the basis of established scientific research that demonstrates the plastics like properties of PHA during use and their multiple end of life options such as recyclability, and biodegradability (and therefore industrial and home compostability).

Given the body of evidence on the:

a) Innovative nature, value and significance of PHA as a class of ***natural polymers***
b) Multiple end of life options - compost (home and industrial), recycle, incinerate
c) Their beneficial properties for use in single use applications,
d) The effort to industrialize PHA in the EU via sponsored research and development, and
e) Industrial activity and new investments surrounding PHA,

The Commission must not wait an additional 7 years to exempt PHA from the SUP Directive.

In addition, we have presented clear and convincing arguments in our two position papers and (above) in this paper to ensure that PHA can be classified as a ***Natural Polymers*** **that have** ***not been chemically modified*** within the scope of the SUP Directive

GO!PHA and our members are ready to meet for further discussion, evidence and information in order to fully achieve the objectives, the intent and the spirit of the SUP Directive.

REFERENCES

1. March 9, 2020 GO!PHA Response to SUP Directive
2. APRIL 16, 2020 GO!PHA Response to SUP Directive
3. Page 20 of SUPD Workshop ECHA Presentation (SUPD_W1_2nd Stakeholder webinar Part A B_Final)
4. Page 15 of Background information for the April 3, 2020 SUPD Workshop; Study to support the development of implementing acts and guidance under the Directive on the reduction of the impact of certain plastic products on the environment: IDENTIFYING AND DESCRIBING THE PRODUCTS COVERED BY THE SUP DIRECTIVE PARTS A, B, D DRAFT 31 March 2020 (Prepared by the European Commission DG ENV in cooperation with Ramboll, Deloitte, In Extenso, Prognos, European Institute of Environmental Policy)
5. Overview of PHA projects funded by the European Commission