GO!PHA
Global Organization for PHA

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January 15, 2021

Mr. Mattia Pellegrini
Head of Unit B.3, Waste Management & Secondary Materials
Director General – Environment
The European Commission
Avenue de Beaulieu 9 – 5/111
B-1049 Brussels, Belgium

Dear Mr. Pellegrini,

I am writing on behalf of **GO!**PHA[1], the Global organization for Polyhydroxyalkanoates (PHA), and our members to express our most serious concerns on the latest version of the "draft guidelines" to Directive (EU) 2019/904. We wish to bring forward the following inconsistencies in the draft guidelines.

1. The Commission has brought PHA "within" the Directive.

Section 2.1.3 page 8 states: *"Based on the current implementation of the REACH Regulation and the ECHA Guidance, "polymers produced via an industrial fermentation process are not considered 'natural polymers' since polymerization has not taken place in nature"*

GO!PHA would like to state that industrial fermentation uses "*living organisms*" to biosynthesize materials or products, many of which are food and related products. Fermentation is a process that exists in nature. Industrial fermentation to produce PHA, food and beverages merely mimic the natural fermentation process and uses the same microorganisms that produce the same products that are found in nature. Therefore, commercially available PHA polymers produced using fermentation in an industrial setting merely makes the natural fermentation process economically viable. **The industrial fermentation process does not change the characteristics of the PHA Polymers relative to those found in nature starting from the use of renewable raw materials in their manufacture to their end-of-life profile.**

The recently concluded study on the *'Biodegradability of plastics in the open environments, SAPEA, December 18, 2020*' clearly mentions that biodegradable polymers:

" is a rapidly evolving and high-tech field, policy should avoid placing barriers to future developments and innovations."

[1] https://www.gopha.org/

2. The Commission has exempted paper- and board-based materials from this Directive.

Section 2.1.3, Page 9 states: "…paper without a plastic lining or coating is not included in the Directive as it (the paper) has not been chemically modified."
(Section 2.1.3, Page 9) and "Paper- and board-based single use products made up of only paper- and board-based material would, in light of the considerations above, as such not be considered as single-use plastic products in the meaning of the Directive."

GO!PHA would like to highlight the inconsistency in the Commission's choice of including and excluding materials under this Directive. The process of producing paper from cellulose modifies the cellulose fibers by forming covalent bonds with the polymers/chemicals that are added during their manufacture, thereby chemically modifying the cellulose extracted from nature. Cellulose could not function as paper without the presence of naturally occurring (but chemically modified) and/or synthetic chemicals and polymers, which therefore, form the main structural components of paper. Appendix B refers to scientific evidence that paper is indeed chemically modified cellulose.

Despite the chemical modification paper is known to biodegrade in the environment. Biodegradation has not been used a criterion to include or exempt materials from this Directive, however, the example of excluding paper and the reason(s) to include or exclude other materials clearly demonstrate that the criteria used in this Directive are unable to serve as distinguishing features for the purpose for which this Directive was intended. A similar argument can be made on paints, inks and adhesives which are also excluded from this Directive. Their mere presence, whether or not they constitute the main structural component of the final article, can be harmful to the environment, whose prevention is one of the primary inspirations behind this Directive.

3. The Commission categorizes cellulose/paper as "**sustainable or more sustainable**":

Section 2.1.2, Page 6: "More specifically, paper- and board-based products have been specifically assessed for their potential to serve as a sustainable alternative to single-use plastic products in the preparation of the legislative proposal for the Directive."
Section 2.1.2, Page 7 states: 'In the Impact Assessment for the Directive, paper-based products without plastic lining or coating have been identified as being an available and more sustainable alternative to single-use plastics"

In this Directive and guidelines and in the Impact Assessment SWD (2018) 254, no definition of "*sustainable alternatives*" are given and no reference to *sustainability* is made or even implied. This Directive rests on the definitions of plastic, polymer and natural polymer. The Commission even includes biobased and biodegradable polymers in this Directive. If the Commission wishes that alternative single use products and their packaging are "*sustainable*" the Commission needs to provide appropriate definitions, appropriate interpretations and a relevant impact assessment of *sustainability* of paper and other materials such as PHA in order to include or exempt them in this Directive and guidelines.

We agree with the Commission that "*sustainable alternatives*" must be exempted from this Directive. Biodegradable polymers, such as cellulose and PHA are "*sustainable alternatives*" to single use plastics, they complement each other well, and exhibit similar end-of-life profile, therefore **PHA Polymers fall in the same category of sustainable alternatives as cellulose.**

These inconsistencies create an unfair playing field for competing materials. We urge the Commission that in order to be consistent regarding ***"sustainable alternatives***", that are based on the European ***Green Deal Objectives*** following the ***Innovation Principle*** and minimizing ***Market and Trade Distortions*** to take the following measures:

1. Revise the definitions used in Section 2.1 of the Directive to exempt ***<u>sustainable alternatives</u>*** to single use plastics, including PHA.

2. Ensure that the guidelines reflect that polymers that are the result of a fermentation process and having the same chemical identity as polymers present in nature are considered to be 'natural polymers' within the Single-use plastic Directive (EU) 2019/904.

3. Ensure that the guidelines of the Directive (EU) 2019/904 do not harm market potential of high-tech and naturally found PHA in a manner that would seriously damage the investments made and planned through EU and national funds, as well as by companies that have already invested or have committed to invest in these innovative technologies and products.

We have proposed a modified guideline, on natural polymers produced from fermentation and which are also found nature, in Appendix A for the Commission to consider and implement.

In the interim, we and our members call on you to meet with us urgently to discuss this Directive and its draft guidelines.

Sincerely yours

Anindya Mukherjee

CC: Mrs Florika Fink-Hooijer, Director General Environment
Mr. Kestutis Sadaukas, Director DG Environment
Mrs. Anna Bobo Remijn, Policy Officer – Single Use Plastics
Mr. Rana Pant, Policy Officer – Single Use Plastics
Mr. Jan Ahlskog, FIPRA
GO!PHA Members

APPENDIX A: PROPOSAL FOR AMMENDING THE GUIDELINE TO REFLECT EQUITABLE RESOLUTION

We understand that the latest version of the draft guidelines states that:

> *"Based on REACH Regulation and ECHA guidance, under the registration obligations under REACH, polymers biosynthesized via industrial fermentation process are not considered 'natural polymers'. In order to align the implementation of the SUP Directive, the interpretation of the term 'natural polymer' should be adapted. Therefore, polymers resulting from biosynthesis through artificial cultivation and fermentation processes manufactured in industrial settings, e.g., <u>Polyhydroxyalkanoates (PHA)</u>, should not be considered natural polymers which have resulted from a <u>'polymerization process that has taken place in nature'</u>."*

In the above statement REACH Legislation is referenced with respect to Fermentation. However, EFSA is the EU agency that is knowledgeable and responsible for Fermentation as a process and the numerous products thereof, since Food, Animal Feed and Flavourings are the areas that are predominantly served through Fermentation and other microbial processes. Fermentation is relatively new to polymers and therefore ECHA's guidance and advice in this respect are insufficient and incomplete. As an alternative, our members and **GO!**PHA suggest modification that is in line with the original mandate from the European Parliament and renders the guidelines compatible with past legislation that regulate Fermentation as a process.

We suggest that the latest version of the draft guidelines be amended to state:

> *~~"Based on REACH Regulation and ECHA guidance, under the registration obligations under REACH, polymers biosynthesized via industrial fermentation process are not considered 'natural polymers'. In order to align the implementation of the SUP Directive, the interpretation of the term 'natural polymer' should be adapted. Therefore~~ For the purpose of the SUP Directive, polymers resulting from biosynthesis ~~through artificial cultivation~~ and fermentation processes manufactured in industrial settings, should only be considered 'natural polymers' which have resulted from ~~a 'polymerization process~~ biosynthesis that has taken place in nature' if the* ***chemical structure of the end polymers is indistinguishable from the chemical structure of a polymer prevalent in nature."***

APPENDIX B: MODIFICATION OF CELLULOSE FIBER DURING PAPER MANUFACTURE

1. Section 2.1.2 Can function as a main structural component of final products

"*In the production of many materials polymers are used to achieve specific material properties as well as higher process efficiencies. Those polymeric materials are usually synthetic chemical additives. Such polymeric materials used e.g. as retention agents or binders and processing aids in the production of materials which are by themselves not 'plastic' are as such not considered to meet the criterion of being able to function as a main structural component of a final product. More specifically, paper- and board-based products have been specifically assessed for their potential to serve as a sustainable alternative to single-use plastic products in the preparation of the legislative proposal for the Directive5. Paper- and board-based single use products made up of only paper- and board-based material would, in light of the considerations above, as such not be considered as single-use plastic products in the meaning of the Directive. However, where a plastic coating or lining is applied to the surface of paper-/board material to provide resistance against water or fat, the criterion of being able to function as a main structural component is met. Such plastic coating or lining provides the necessary water or fat resistance to paper-based products for the consumption of beverages (cups) or moist and fat from food (food containers, plates). Plastic coating or lining of otherwise paper- or board-based products for the purpose of the Directive results in multi-layered products. Hence, single use paper- or board-based products with plastic coating or lining fall within the scope of the Directive. The legislative process undergone by the Directive also documents this reading: The exemption for coatings originally included in Recital 8 of the Commission proposal6 no longer appears in the corresponding Recital 11 of the final text of the Directive.*"

Two commonly used "sizing" agent in papermaking, added to the pulp before paper web formation, are alkenylsuccinic anhydride (ASA) and alkylketene dimer (AKD). AKD and ASA provide hydrophobization of paper, especially when made under alkaline or neutral pH conditions – most common papermaking chemistries today. ASA imparts hydrophobicity to paper due to formation of covalent ester bonds between ASA and cellulose after paper drying[1]. ASA is a synthetically made chemical; the active ingredient is an oily monomer. For purposes of papermaking, the most important components of this monomer are a five-membered anhydride ring and a linear chain having between 14 and 20 -CH2- groups (often 18)[2]. The reactive ring can be at various positions relative to the chain, and most commercial ASA consists of a mixture of these isomers. The product is almost always delivered as a light amber oil that must be kept very dry until emulsification. ASA is added to the furnish in the form of an aqueous emulsion, in which the stabilizer is usually cationic starch or another cationic, hydrophilic polyelectrolyte. Some suppliers also add a very small amount of surfactant to aid in emulsification. Likely contaminants include linear saturated oils, linear mono-unsaturated oils, and ASA hydrolysis products. ASA is especially used in cases where full cure is desired before the size press and where it is important to maintain a high frictional coefficient in the paper product. ASA can improve paper machine runnability and preserve paper's dimensional stability by limiting penetration of size-press solution into the sheet. Holding the size-press starch out nearer to the paper surface also can make the surface-applied additives more effective for such purposes as promoting surface strength, reducing dusting, reducing picking of vessel segments during offset printing, and even improving the performance of hydrophobic polyelectrolytes added with the size-press starch solution. Examples include styrene-maleic anhydride (SMA), styrene acrylates (SA), alkylated urethane copolymers, and certain emulsion products having chemistries related to SMA or SA. Key goals in using ASA are (a) avoid hydrolysis, (b) distribute it well in the furnish, and (c) retain it efficiently. Hydrolysis is minimized by preparing the emulsion as late as possible - usually only seconds before the material is added to the thin stock. The cationic starch solution used in preparing the emulsion may be reduced in pH with the addition of such materials as adipic acid or alum, and it is usually cooled to some degree relative to its cooking temperature. A net ratio of about 3 to 5 parts cationic starch per part of ASA oil usually yields the most efficient sizing. To avoid excessive molecular chain cleavage of this starch, only a part of it is passed through the high shear zone of the emulsifier. Microscopic images (or other methods) can show whether one has achieved the desired narrow size distribution of droplets, usually with an average size near or below one micrometer. The recommended point of addition is after the hydrocyclone cleaners. Although the cationic starch sheath around each ASA droplet has some effect in attaching the size to cellulosic materials, a good retention aid system is needed to achieve a relatively high first-pass retention. Otherwise, a lot of the ASA will follow the white-water circuit, giving it time to decompose. Deposit problems usually can be minimized by such practices as limiting the dosage (often to within 2.5 lb/ton in the case of virgin bleached kraft furnish), having alum or PAC present somewhere in the system, turning off the ASA flow during wet breaks, and maintaining good retention.

AKD is an alkaline sizing agent synthesized from fatty acids. The most common form was a waxy solid material dispersed as small particles in a solution that contained a stabilizer. The stabilizer could be cationic starch or another cationic polyelectrolyte. Hercules Corp. (now Solenis) patented the use of unsaturated fatty acids to make a liquid form of AKD. Though slightly less efficient as a sizing agent than the waxy form, the unsaturated product does not make the paper as slippery[3]. AKD is much less reactive than ASA, and there is no consensus between researchers as to how much of it ever forms covalent ester bonds with cellulose or starch when paper is dried. AKD is widely used for liquid containers, ink-jet printing papers, and many other grades of paper and paperboard. AKD is especially favored for products that need to resist water over a long period of time. Because AKD is received at the papermill as a ready-made, milky emulsion, it can be a very convenient product to use. Also, the lower reactivity of AKD, compared to ASA, means that the papermaker has more flexibility on where to add it. For example, many users of AKD add it to the thick (pulp) stock; this practice tends to get the AKD to the fiber surfaces. In contrast, adding a sizing agent to the diluted (pulp) furnish in the thin stock loop can be expected to concentrate more of the size onto the fines fraction. Paper made with high levels of AKD is likely to be slippery, and it may cause problems in precision cutting and register during conversion, or in stacking during high-speed xerographic copying. These effects can be minimized by limiting the dosage (perhaps supplementing the sizing effect with surface hydrophobes added to the size-press starch), or by use of alkenylketene dimer (unsaturated form) in place of the more usual AKD.

2. Section 2.1.3 Natural polymers that have not been chemically modified **, paragraph 15, p.8:**

Paragraph 15, page 8 reads "*….paper without a plastic lining or coating is not included in the Directive as it has not been chemically modified…"* is not consistent with the term "chemically modified". Paper for single-use packaging is manufactured with cellulose fibers and additives, including sizing agents like ASA or AKD. Even uncoated, not-lined paper used for single-use packaging contains chemicals, therefore it is chemically modified. Additionally, such paper contains modified starches (which themselves are natural polymers that have been chemically modified) to impart strength integrity, stiffness and increase the efficiency of the sizing additives. Such starches are ethoxylated, oxidized or cationized. Natural pearl starch is seldom used in modern papermaking.

References

[1] (PDF) Anchorage of ASA on cellulose fibers in sizing ...www.researchgate.net › publication › 289995989_Ancho… ,
[2] https://projects.ncsu.edu/project/hubbepaperchem/ASA.htm
[3] https://projects.ncsu.edu/project/hubbepaperchem/AKD.htm