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GO!PHA letter to the European Commission
Directorate-General for Environment
Department for Waste Management and Secondary Materials

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I am writing on behalf of **GO!**PHA[1], the Global organization for Polyhydroxyalkanoates (PHA), and our members to express our serious concerns because in the latest version of the "draft Guidelines" to Directive (EU) 2019/904, PHA would be brought "within" the Directive in a manner seriously hampering market potential of PHA in the EU.

We believe that this inclusion of PHA in the Guideline seriously undermines the potential of PHA to become a sustainable substitute for many single use applications where fossil fuel-based plastics are currently used. This not only contradicts several EU policy objectives and principles but would also distort trade in violation of WTO rules and put into jeopardy investments made in PHA development and commercialization through various EU and national funds.

The Innovation Principle: PHA is one of the most innovative and versatile materials known to man that is naturally found, uses renewable sources including waste carbon sources for their production, biodegrades in soil, fresh water and in marine environment, just like cellulose which is exempt from the Guidelines. The EU has sponsored over 110 Million Euros worth of research and innovation projects to valorise waste carbon sources into PHA for packaging including single use plastics (see Annex C). Significant public investment has also been made via various Member State Funds. The **EU Innovation Principle** strives to ensure that legislation is designed to create conditions conducive for **innovation** to flourish and to achieve a balance between predictability of the regulatory environment and adaptability to scientific and technological progress. This unfortunately will not be the case for PHA as per the current Guideline.

Green Deal Objectives: Recently the EU has announced a major push into more sustainable and a circular economy through the Green Deal. Some of its guiding principles include the use of renewable resources, valorising waste, biodegradable materials and waste reduction. New technologies, sustainable solutions and disruptive innovation are highlighted as "critical" to achieve the objectives of the European Green Deal. Bringing PHA, a renewable, sustainable and biodegradable material within the Directive goes against these objectives and the green oath to 'do no harm'. There is a great potential to use biowaste as a raw material for PHA.

Apart from the Green Deal push, restricting PHA contradicts other EU initiatives. The latest Circular Economy Action Plan pledged to address emerging sustainability challenges by developing a policy framework on the use of biodegradable or compostable plastics where they can be beneficial to the environment. Moreover, in its 2018 Plastics Strategy the Commission pointed at the opportunities offered by alternative feedstocks such as bio-based plastics and welcomed innovation efforts in biodegradable plastics. The inclusion of PHA hampers the effectiveness of these initiatives.

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

Market Distortion: By including PHA in the Guideline and exempting cellulose, the market for new and innovative materials will be distorted. Both products have similar properties in use as well at end of life, they can act as substitutes for each other and they both complement each other in numerous ways in many uses in single use plastic products and elsewhere.

Trade Distortion: Including PHA within the scope of Directive (EU) 2019/904 would violate Article III(4) of the WTO's General Agreement on Tariffs and Trade ("GATT") and Article 2(1) of the Agreement on Technical Barriers to Trade ("TBT Agreement"). Moreover, as there is no legitimate basis to treat PHA as more environmentally damaging than cellulose products, the less favourable treatment of PHA would also not be justifiable under the exemption for environmental protection under Article XX of the GATT or the "legitimate regulatory distinction" test of the WTO's TBT jurisprudence.

For all the reasons outlined above, we strongly believe that the Guidelines as currently drafted do not fit within the intent and the spirit of the Directive (EU) 2019/904. We also believe that the Guideline as written would breach fundamental policy objectives and principles of EU and WTO rules. Therefore, we request that the Commission take the following measures regarding the Guidelines:

1. Ensure that the Guideline 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

2. Ensure that the Guideline of the Directive (EU) 2019/904 do not harm market potential of PHA in manner that would seriously damage the investments made and planned through EU and national funds

We have proposed a modified guideline in Appendix A for the Commission to consider and implement and in Annex B you will find more information on the technical merits of PHA, and in Annex C we have listed European Union funded PHA projects. In the interim, we and our members would be happy to discuss any of the above further with you, should that be useful.

Sincerely yours,

Anindya Mukherjee

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., Polyhydroxyalkanoates (PHA), should not be considered natural polymers which have resulted from a 'polymerization process that has taken place in nature'."*

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 guideline compatible with past legislation that regulate Fermentation as a process.

We suggest that the latest version of the Draft Guideline 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: FURTHER EXPLANATION ON THE TECHNICAL MERITS OF THE PROPOSED CHANGES IN APPENDIX A

In effect, the draft Guideline uses Fermentation process to exclude PHA from the concept of "natural polymer" and subject it to the requirements of the Directive 2019/904. However, the Flavourings Regulation [2] clearly classifies Fermentation (also referred to as microbial processes) as producing natural products. Therefore, the guideline as currently stated would lead to an interpretation of the Directive that would render it contrary to the EU's own laws.

In addition, there is precedence in EU rulings where products produced through biotechnology (fermentation or microbial processes) that are identical to those found in nature could get the same EINICS number, thus acknowledging them to be identical.[3]

We would also like to clarify that the draft Guidelines confuse the terms "occurs naturally in the environment" with that of "substances which occur in nature," when they state that "*it is essential to underline that the terms 'natural polymer' and 'naturally occurring substance' are two distinct terms and should not be confused. The key distinction relates to the extraction methods allowed. The scope of the former (natural polymers) refers to a broader group, independent of the extraction method used to extract the substance from nature*." A close reading of Article 3(39) of the REACH Regulation, which the Directive states that the Guidelines should follow, makes clear that this Article defines "substances which occur in nature" as the group of substances that are characterized by their extraction method, and not the broader category of "naturally occurring substances." Thus, natural polymers are polymers that "occur naturally in the environment" (*i.e.*, naturally occurring substances), independently of the extraction process used. They are thus a broader group than "substances which occur in nature."

The key criterion to assess whether polymers are natural is whether they "occur naturally in the environment," not whether their "polymerization process has taken place in nature." This is made clear in recital 11 of Directive 2019/904, as it states that "*[u]nmodified natural polymers, within the meaning of the definition of 'not chemically modified substances' [under the REACH Regulation], should not be covered by this Directive as they occur naturally in the environment;*" and that the Directive should cover substances that are "not naturally occurring".

Polymers that "occur naturally in the environment" or that are "naturally occurring" are a much broader category of substances than polymers whose polymerization process "has taken place in nature." This is made clear by the definition of "substances which occur in nature" of Article 3(39) of the REACH Regulation, mentioned above, and by the European Chemicals Agency's own guidance on Annex V to the REACH Regulation. That guidance states that a substance that occurs naturally in the environment, or a naturally occurring substance, is one "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" (emphasis added), independently of the extraction or processing method used."[4] We fail to understand why the Commission has decided that the reasoning of the draft Guidelines should follow statements from only one ECHA guidance, but not others.

[2] European Parliament and the European Council, Flavourings Regulation No 1334/2008, 16 December 2018, p. L 354/38 art. 3(c)

[3] European Commission, Manual of Decisions for Implementation of the Sixth and Seventh Amendments to Directive 67/547/EEC on Dangerous Substances, 21 October 2002, p. 99

[4] ECHA, Guidance for Annex V Exemptions from the Obligation to Register (Version 1.1 November 2012), p. 19.

The reality is that neither Directive 2019/904 nor the REACH Regulation alone can provide any basis to exclude from the general concept of "substances that occur naturally in the environment" those substances that are demonstrated to occur naturally in the environment, solely because the same process is reproduced in an industrial and controlled environment to scale the production of exactly the same substance. In this respect prior EU Legislation and rulings and EFSA guidance, the body most intimately involved with fermentation as a process should also be taken into account. Similarly, the Directive and the Regulation do not provide any basis to exclude any substances from the general concept of "substances that occur naturally in the environment" simply because their commercial production requires a fermentation process to increase the number of bacteria that will produce the naturally occurring material.

PHAs are naturally occurring, non-chemically modified biopolymers produced by microorganisms as an energy reserve.[5] This process happens naturally in non-controlled environments and can for example be observed when some bacteria are exposed to natural nutrient-variable soils or water.

The production of PHA in controlled settings simply reproduces its occurrence in nature, but at a larger scale. PHA produced in a controlled setting is not chemically modified: its chemical structure is identical to those that occur in nature. In a controlled setting, an industrial fermentation procedure is used solely to scale up the bacteria and create the environment needed for them to thrive and produce the PHA. The PHA production takes place entirely inside the bacterial cells, and occurs identically to how it would occur naturally in the environment.

Materials made of PHA are biodegradable in soil, fresh water, marine and soil environments, and in both home and industrial compost settings.[6] In effect, microorganisms naturally found in marine water, fresh water, soil, landfills, compost and anaerobic sludge utilize the PHA as a food source. Any waste materials made from PHA that do not end in waste collection schemes will therefore biodegrade safely to their chemical components in both aerobic and anaerobic conditions. This also ensures that discarded PHA materials do not release microplastics into the environment. This behaviour of PHA is comparable to cellulose.

GO!PHA and our members are not requesting exception for renewable or biodegradable plastics under this directive. We are requesting that the Commission ensure that polymers that are the result of a fermentation process and have the same chemical identity as polymers present in nature are considered to be 'natural polymers' within this directive.

In fact, PHA is known to have similar or even better environmental impact to those materials that the draft Guidelines would consider to be natural polymers, such as reconstituted cellulose. One of our members have carried our life cycle analysis ("LCA") assessing a complete set of environmental metrics in accordance with the international standard ISO 14044, and they showed positive and promising results on carbon footprint in comparison to regenerated cellulose. Our members would be pleased to share such and other related information on this topic with the Commission

Including PHA within the scope of Directive 2019/904, in contrast with the exclusion of other substances that also occur naturally in the environment, such as regenerated cellulose, *is contrary* "*to promote the transition to a circular economy,*" as we find that there is no objective reason that may justify treating PHA differently in comparison to other materials such as regenerated cellulose. Just like regenerated cellulose, PHA occurs naturally in the environment, is recyclable, does not

[5] 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; Updated version 8 October 2019.

[6] This has been certified by TÜV Austria under standard S0720: see https://www.tuv-at.be/green-marks/certifications/ok-biodegradable/.

persist in nature and biodegrades fully. Therefore, we find that there is no legitimate basis to treat PHA as more environmentally damaging than cellulose products.

APPENDIX C: EUROPEAN UNION FUNDED PROJECTS ON PHA

List of Research Projects approved and funded within the European Union						
Grant agreement ID	**Funded under**	**Project name**	**Start/End date**	**Country**	**Overall budget**	**EU contribution**
745586	H2020-EU.3.2.6.	BioBarr	1-6-2017/31-5-2021	Italy	€3,784,375.00	€3,253,437.50
730349	H2020-EU.3.2.4.3. and H2020-EU.3.2.4.1.	RESURBIS	1-1-2017/31-12-2019	Italy	€3,377,915.00	€2,996,688.75
870294	H2020-EU.2.1.4.	MIX-UP	1-1-20/31-12-23	Germany	€7,365,335.00	€5,465,335.00
817788	H2020-EU.3.2.4.1. and H2020-EU.3.2.2.1.	SCALIBUR	1-10-18/31-12-22	Spain	€12,005,922.50	€9,999,391.39
862910	H2020-EU.3.2.5.3	SEALIVE	1-10-19/30-9-23	Spain	€10,281,120.49	€8,527,315.22
745791	H2020-EU.3.2.6.	REFUCOAT	1-6-19/31-5-20	Spain	€3,234,338.50	€2,300,735.30
773872	H2020-EU.3.2.2.3.	YPACK	1-11-17/31-10-20	Spain	€7,277,671.25	€5,996,591.02
720777	H2020-EU.2.1.4.	VOLATILE	1-12-16/30-11-20	Spain	€6,565,926.25	€6,565,926.25
88338	H2020-EU.3.2. and H2020-EU.3.5.4.	NoAW	1-10-16/30-9-20	France	€7,816,232.50	€6,887,570.00
690323	H2020-EU.3.5.4.	SMART-Plant	1-6-16/31-5-20	Italy	€9,768,806.09	€7,536,300.02
838120	H2020-EU.2.1.4. and H2020-EU.3.2.6.	INGREEN	1-6-19/30-11-22	United Kingdom	€8,775,678.83	€6,323,919.56
750126	H2020-EU.1.3.2.	CH4BioVal	18-9-17/17-9-19	Spain	€170,121.60	€170,121.60
679050	H2020-EU.3.2.	CELBICON	1-3-16/30-11-19	Italy	€6,211,040.25	€5,429,201.50
888704	H2020-EU.3., H2020-EU.2.3. and H2020-EU	VEnvirotech	1-11-19/29-2-20	Spain	€71,429.00	€50,000.00
633962	H2020-EU.2.1.4.	P4SB	1-4-15/31-3-19	Germany	€7,056,968.75	€7,056,968.75
760994	H2020-EU.2.1.4.	ENGICOIN	1-1-18/31-12-21	Italy	€6,986,910.00	€6,986,910.00
311933	FP7-KBBE	WATER4CROPS	1-8-12/31-7-16	Italy	€7,696,538.99	€5,973,689.00
245084	FP7-KBBE	ANIMPOL	1-1-10/31-12-12	Austria	€3,754,375.00	€2,895,660.00
213068	FP7-KBBE	LIPOYEASTS	1-8-8/31-7-11	Belgium	€1,201,481.00	€911,111.00
735158	H2020-EU.3.5. and H2020-EU.2.3.1.	PAPER-P	1-9-16/1-11-16	Italy	€71,429.00	€50,000.00
718097	H2020-EU.2.3.1. and H2020-EU.3.2.	EggPlant	1-2-16/31-5-16	Italy	€71,429.00	€50,000.00
669046	H2020-EU.3.5. and H2020-EU.2.3.1.	SCALEPHA	1-5-15/31-10-15	Italy	€71,429.00	€50,000.00
812602	H2020-EU.3., H2020-EU.2.3. and H2020-EU	POLIPO	1-6-18/30-11-18	Italy	€71,429.00	€50,000.00
867437	H2020-EU.4.	BterBioPlastics	1-5-19/30-4-21	Portugal	€147,815.04	€147,815.04
318931	FP7-PEOPLE	BIOASSORT	30-7-12/29-7-16	Italy	€296,100.00	€296,100.00
606548	FP7-SME	BIOACTIVELAYER	1-9-13/30-9-15	Greece	€1,252,494.80	€940,000.00
625774	FP7-PEOPLE	SIMPHASRLS	1-6-14/31-5-16	Portugal	€147,210.00	€147,210.00
273515	FP7-PEOPLE	NanoBioComp	1-9-11/31-8-13	Spain	€166,565.60	€166,565.60
280604	FP7-NMP	OLI-PHA	1-6-12/31-5-15	Spain	€3,983,608.60	€3,009,976.00
604770	FP7-SME	EUROPHA	1-10-13/30-9-16	Spain	€2,093,640.80	€1,572,902.10
613667	FP7-KBBE	GRAIL	1-11-13/30-10-2017	Spain	€7,867,807.49	€5,954,479.00
32967	FP6-SME	POLYVER	15-9-6/14-12-8	Italy	€939,218.00	€600,949.00
G5RD-CT-2001-00591	FP5-GROWTH	WHEYPOL	1-12-1/30-11-4	Austria	€1,666,582.00	€1,268,682.00
FAIR961780	FP4-FAIR	PHASTICS	1-1-97/31-12-99	Netherlands	€1,335,000.00	€800,000.00
				Total Funding	**€133,583,944.33**	**€110,431,550.60**