

# SUMMARY REPORT

Event **Expert Meeting on Plastics Definition under Directive 2019/904**

Date **13-12-19**

Location **European Commission – DG Environment, Brussels**

Participants

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## 1 OPENING/INTRODUCTION (European Commission)

In accordance with Article 12 of Directive 2019/904 on the reduction of the impact of certain plastic products on the environment (Single-Use Plastics Directive), the Commission is currently preparing **guidelines** on single-use plastic (SUP) products falling in the scope of the Directive. A significant number of questions from stakeholders and MS have been received on the definition of 'plastic' in the Directive (article 3(1)), on which further clarification is needed. The plastic definition will be covered by the guidelines under preparation.

In light of the above, DG ENV (ENV.B.3 Waste Management & Secondary Materials) organised a meeting with key stakeholders and ECHA, to further discuss the definition of plastic contained in the Directive. Stakeholders invited to attend the meeting included representatives and experts from industry, research bodies and NGOs, who have taken a particular interest in providing input and feedback to the Commission previously on this issue.

## 2 ECHA PRESENTATION ON PLASTIC DEFINITION IN THE SUP DIRECTIVE (DIRECTIVE (EU) 2019/904) – and relevant provisions in the REACH Regulation and ECHA Guidance (see attached presentation, annex 2)

### 2.1 Definition of plastic in the SUP Directive

ECHA recalled the definition of **plastic** in **article 3(1) of the SUPD**, as well as the rationale in **Recital 11 of the SUPD**, which refers to: *'plastic' 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*. ECHA highlighted that the SUPD defines a polymer according to Article 3(5) of REACH Regulation (EC) No 1907/2006.

### 2.2 'Natural polymers' vs. 'naturally occurring substances'

ECHA recalled that **Recital 11 of the SUP Directive** specifies: *"plastics manufactured with modified natural polymers, or plastics manufactured from bio-based, fossil or synthetic starting substances are not naturally occurring and should therefore be addressed by this Directive". Recital 11 also states that "the adapted definition of plastics should therefore cover polymer-based rubber items and bio-based and biodegradable plastics... ["]*.

Furthermore, it was noted that **Article 3(39)** defines **'naturally occurring substances'** as follows:

*'Naturally occurring substances': substances which occur in nature 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.*

However, ECHA noted that 'natural polymers' are not necessarily 'naturally occurring substances'. **ECHA Guidance on polymers and monomers** (section 3.2.1.3) provides the following definition of what is a 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 through 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. Natural polymers are a broader group because of the extraction methods allowed.

## 2.3 'Not chemically modified substance'

**SUPD:** Recital 11 of the SUP Directive defines a 'not chemically modified substance' with reference to **Article 3(40)** of the REACH Regulation.

**REACH:** Article 3(40) of REACH defines a 'not chemically modified substance' as: "*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*".

ECHA explained that processes intended solely to remove impurities are not considered to be a chemical modification, as long as the chemical structure of the molecule is not modified. In this context, ECHA noted that **no chemical modification** should occur **during the whole process** (even where the end result presents the same chemical structure as at the beginning of the process).

ECHA also provided additional guidance concerning the link with the **Micro-plastics Restriction** proposal in the context of REACH. Paragraph 3(a) of the Micro-plastics Restriction states that "*Natural polymers (as defined in REACH Guidance on monomers and polymers) that have not been chemically modified (as defined in REACH Article 3(40))*" are not considered to be micro-plastics. ECHA highlighted the importance of using the same terminology to the extent possible across relevant EU legislation.

## 3 DISCUSSION

The following paragraphs summarise the main questions/feedback raised by participants, following the presentation made by ECHA. It should be noted that the summary of main discussion points related to 'natural polymer' and 'chemical modification' are combined, as these specific topics were discussed in parallel during the meeting.

### 3.1 The notion of 'natural polymer' and 'chemical modification'.

**Stakeholders made the following comments:**

- Need to promote the use of **regenerated cellulose**, which is less detrimental to the environment compared to other materials such as cotton. However, one of the main difficulties associated with the use of cellulose I, is that it cannot be melted. Specific processes are used to change its form e.g. viscose process to spin it into fibres or dissolution for lyocell.
- The **degree of chemical modification** should be considered, otherwise many substances could be considered as polymers covered by the SUP Directive. Also consider policy applications for the use of these polymers in areas beyond plastic, such as the textile sector.
- **Fermentation** should be considered a natural process, which occurs in nature as part of the biochemical synthetic or break-down processes by the cells of living organisms in nature. Industrial fermentation makes this process faster and ensures that substances such as cellulose can be produced at commercial scale. This is particularly relevant in the case for **polyhydroxyalkanoates** (PHA), which could be an alternative to polypropylene due to its significant potential for marine biodegradability, but is produced through industrial fermentation. The inclusion of these polymers in the scope of the SUP Directive would create significant barriers to innovation and challenges for industry. Industry needs incentives to develop next generation materials that are beneficial to the environment. In the case of PHA, the industrial process required for fermentation should not be of importance if the end product is a sustainable alternative in view of the wider objective of reducing marine litter.
- Regulation (EC) 1334/2008 uses a similar approach as the SUP Directive in regard to defining '**natural flavouring substance**'. Regulation (EC) 1334/2008 defines a 'natural flavouring substance' as

"[...]substances that are naturally present and have been identified in nature."<sup>1</sup> The term 'natural' should be interpreted in the same way in both texts.

- **Chemical modification** should not automatically define a substance as plastic as there are many treatments that affect the structure of polymers and final end-products. If the SUPD definitions were applied to other materials e.g. cotton, wood pulp and paper, they would be considered as chemically modified polymers since they undergo processes that modify their chemical structure. If the scope of the directive includes certain fibres, such as lyocell, industry may turn towards fibres e.g. cotton that are worse for the environment, which would be counter-productive.
- **Crystalline changes** are not chemical changes, but physical changes, which also happen in nature. Changing the crystalline structure of a polymer through dissolution for example, is not a chemical change. In the case of cellulose, changing its molecular mass can occur via a number of natural processes e.g. hydrolysis. Crystalline changes, such as the transition between cellulose I and cellulose II, should not be considered as chemical modifications (but only changes in the three-dimensional structure of the polymer chains). Similarly, lignin is another example of a 'natural polymer' whose molecular mass changes constantly (chemical modifications occurring in nature) and which is very difficult to extract in similar weight.
- **Nonwoven fabrics** are made from fibres and used for wet wipes and sanitary items, which as such are not banned under the SUP Directive (contrary to other products e.g. straws, cutlery, etc.), but must comply with other requirements, such as marking, and extended producer responsibility. However, there is a strong negative public perception around the word "plastic", and a product labelled as 'containing plastic' would be detrimental to industry.
- Suggestion to include additional clarification on natural polymers by distinguishing those for which **synthesis is "spontaneous"** (naturally occurring/not chemically modified) and those that are **"induced"** (chemically modified). The guidelines should also propose **a list of substances** included and exempt from the scope of the plastic definition in the SUP Directive.

#### **Additional reflections and feedback from Commission/ECHA:**

- The objective of the SUP Directive is to prevent and reduce the impact of certain plastic products on the marine environment. It is based on the precautionary principle with limited scope for exemptions. The interpretation of what is a 'non-chemically modified natural polymer' should take a restrictive (precautionary) approach in accordance with REACH and ECHA Guidance.
- It is extremely difficult to determine whether polymers synthesised, or treated/modified in industrial settings have the exact same chemical structures as those which occur in nature, or. The Guidance for monomers and polymers and Article 3(40) of REACH therefore give a very straightforward view on 'natural polymer' and 'not chemically modified substances', respectively.
- Where changing crystalline structure modifies the physical properties of the polymer, but without changing its chemical structure, this process -in principle- would not constitute 'chemical modification'. If during the manufacturing process only hydrogen bonds are broken or formed, this would probably not constitute a chemical modification. However, in general, it may be very difficult to analytically compare the resulting material of manufacturing processes with that of the ingoing material, if during the synthesis functional groups are attached to molecules, which at the end of the process are removed. Therefore, the conversion rates of these processes should be considered. For example, is it possible to ensure - and verify - a 100 % conversion rate when regeneration is completed? How can one verify that all the functional groups added during side reactions have been removed? These and other questions will have to be assessed in more detail, in collaboration with ECHA.

<sup>1</sup> "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."

- With regard to biodegradability having been accepted as a condition for derogation from the Microplastics Restriction under REACH (and not in the SUPD), it was explained that the scope of the Microplastics Restriction proposal is wider than that of the SUP Directive and does not define 'intended use'. As such, it could provide more options for substitution. In addition, there is a clear difference between the biodegradation of small plastic particles (microplastics) and bigger plastic items, such as plates and cutlery.
- The SUP Directive will be evaluated in 2027, at which time its scope may be revised in light of solid scientific evidence. At the same time, the Commission will assess the scientific and technical progress concerning criteria for a standard for biodegradability in the marine environment applicable to single-use plastic products.

### 3.2 The notion of 'main structural component'

The plastic definition in the SUPD refers to '*a polymer..., which **can function as a main structural component** of final products...*'.

With regard to this concept, the Commission and ECHA made the following observations:

- The notion of 'main structural component' is currently not defined in EFSA guidance, except in relation to food contact: "materials need to meet functional and performance requirements to ensure that the safety and quality of the products are maintained". The objective of EFSA guidance on food contact materials is to make a distinction between polymers used as self-standing materials and those that are not self-standing materials (e.g. adhesives, coatings). Essentially, if the plastic has enough mechanical strength to provide structure and rigidity to a material, then it is considered as a main structural component.
- DG ENV summarised some of the questions raised by stakeholders in relation to 'can function as main structural component', notably in regard to plastic linings and coatings used in paper cups, plates and food containers. In the Commission's view, this should be interpreted by considering product functionality (can the products without the plastic component still fulfil its intended function/comply with necessary safety/hygiene standards?), as opposed to a 'threshold approach', as defended by part of industry, which considers a minimum percentage of plastic content, and/or other parameters such as recyclability, repulpability, etc.
- DG ENV reminded participants that in Recital 11 of the Directive, only paints, inks and adhesives are excluded from the SUP Directive and that plastic coatings and linings should in principle be covered, as the Directive explicitly refers to products 'wholly or partly made of plastic'.

## 4 CLOSURE OF THE WORKSHOP AND NEXT STEPS

The Commission thanked all participants for their attendance and valuable feedback. The next steps were also summarised:

- **Minutes** of the meeting will be drafted by the external contractors supporting the Commission with the preparation of the Guidelines. The minutes will be reviewed by the Commission and shared with participants, along with presentation made by ECHA;
- Commission to further assess the issues highlighted above in **collaboration with ECHA**;
- ECHA to consider developing a **list of natural polymers exempted** from the plastic definition in the Directive (list subject to periodic review).
- The Commission is working with external contractors to develop the guidelines. The first interim report is due in January 2020 and will set out a first approach of these guidelines. A workshop was organised in October 2019, to collect stakeholder feedback and viewpoints. **A follow-up workshop will be organised in March 2020** to present the draft guidelines to the stakeholders.

## 5 ANNEXES

### 5.1 Summary of relevant background documents and position papers

Author	Title of source	Key findings
Richard Blackburn	Definition of 'plastic' in relation to cellulose fibres	Cellulose II fibres (regenerated cellulose fibres) e.g. lyocell and viscose should not fall under the definition of 'plastic' under EU Directive 2019/904. These substances are based on natural biopolymers where their production process results in only a physical change. Cellulose II fibres are as biodegradable as cellulose I fibres in both terrestrial and marine environments. If cellulose II fibres are restricted or prejudiced in their use in products, there is a risk that manufacturers will move exclusively to the use of cellulose I fibres – primarily cotton, whose life-cycle is less sustainable and results in higher environmental impacts.
Nova-Institute	Which polymers are 'natural polymers' in the sense of the single-use plastic ban?	<p>Proposition of exemplary list of polymers that should be considered as natural polymers and those that should not in accordance with relevant definitions under the REACH Regulation and SUP Directive.</p> <ul style="list-style-type: none"> <li>Natural polymers (produced via biosynthesis in animals, plants, algae, fungi, bacteria...): agar agar, alginate, casein, cellulose (including rayon fibres, such as viscose and lyocell), chitin, chitosan, collagen, curdlan, cutin, dextran, gelatine, glycoproteins, hair, hyaluronic acid, inulin, keratin, levan, unmodified lignin, pectins, PHAs, polyphosphates, pullulan, silk, starch (amylopectin, amylose), suberin, xanthan, natural oligomers (ellagitannins, gallotannins, oligomeric proanthocyanidins, exophilin A)...</li> <li>Chemically modified natural polymers (chemically modified prior to use to obtain specific properties): cellulose (cellulose acetate, cellulose butyrate, other cellulose derivatives), lignin: (ligninsulfonate), starch (starch acetates and other starch derivatives), bioethanol (bio-based polyethylene), lactic acid (polylactic acid (PLA)), sebacic acid (polyamides (PA)), succinic acid, polybutylene succinate (PBS)</li> </ul>
Lenzing	Wood-based (regenerated) cellulose fibers in the context of the SUPD	Arguments supporting the view that cellulose in natural fibers (cotton and bast fibres) and regenerated cellulose fibres (viscose, modal, lyocell) have the same natural polymer and completely identical in their chemical structure. Accordingly, these substances should not be considered 'plastic' and fall outside the scope of the Directive.
Eastman Chemical Company	Single Use Plastic Directive Position Paper on Man-Made Cellulosic Fibres	Man-made cellulosic fibres (MMCFs) e.g. viscose, lyocell, cupro, cellulose acetate and cellulose triacetate do not meet the definition of 'not chemically modified' as per the REACH regulation and SUP Directive. MMCFs undergo chemical modification via solvent dissolution and further processing to reduce the natural polymer chain length, and hence the viscosity, which enables conversion to fibre through a mechanical spinning process. They would not be deemed a 'substance which occurs in nature' under REACH, and therefore, cannot be a natural polymer. Accordingly, all MMCFs should be subject to the Directive.

<p>Eunomia/ Eastman</p>	<p>Review of SUP Directive on Man-Made Cellulosic Fibres (Review for Eastman Chemical Company)</p>	<p>Differentiation between 'natural' and 'chemically modified' for man-made cellulosic fibres (viscose, lyocell and cellulose acetate).</p> <p>While man-made cellulosic fibres cannot be considered 'natural' according to definitions under REACH, this does not mean that any non-natural polymer by definition is 'chemically modified':</p> <ul style="list-style-type: none"> <li>• Man-made cellulosic fibres produced by modifying viscosity through depolymerisation should be considered as chemically modified e.g. cellulose acetate, viscose which undergoes a chemical change through acetylation in which new bonds are formed, and hydrolysis in which bonds are broken down. In the case of viscose, there is a clear consumption of hydrogen and breaking of the bonds.</li> <li>• Man-made cellulosic fibres that are formed using solvents to modify viscosity are not chemically modified e.g. lyocell which undergoes dissolution is not a chemical process, as no bonds are broken or formed, and no material is consumed. Viscosity reduction is caused by dissolving the material rather than breaking the hydrogen bonds. Hydrogen bonds are an intermolecular force rather than a chemical bond. This disruption is not a chemical change in the material. Lyocell could be considered a 'non-natural non-chemically modified polymer' and therefore should be exempt from the SUP Directive.</li> </ul>
<p>Edana</p>	<p>Technical note on non chemically modified cellulose fibres</p>	<p>Regenerated cellulose fibres e.g. viscose, modal, and lyocell have the same molecular structure as cellulose in natural fibres (cotton and bast fibres) and are not chemically modified. Regenerated cellulose fibres are produced through industrial processes for extraction (of the cellulose from plant material e.g. wood) dissolution and regeneration. Cellulose in both natural and regenerated cellulose fibres is biodegradable by the same enzyme systems of microorganisms.</p>
<p>Edana</p>	<p>Infographic on natural polymer: cellulose</p>	<p>Compared to the chemical structure of the natural polymer cellulose (e.g. cotton, wood), the difference between non-chemically and chemically modified cellulose is explained as follows:</p> <ul style="list-style-type: none"> <li>• Chemically modified cellulose e.g. cellulose-acetate – the chemical structure is different from cellulose as the OH-groups of native cellulose are partly replaced with functional groups, through a breakage and formation of covalent bonds; whereas</li> <li>• Non-chemically modified cellulose e.g. viscose, lyocell – the chemical structure is identical to cellulose, only the crystalline structure is different i.e. number of hydrogen bonds between the molecules of different polymer chains has changed; similar to water changes phase when freezing into ice.</li> </ul>
<p>Kaneka</p>	<p>PHAs and PHBHTMs qualifying as natural polymers that have not been chemically modified</p>	<p>Kaneka's biodegradable polymer PHBHTM (Poly ((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate)) is a PHA, i.e. a polymer that is produced in nature by numerous microorganisms. PHAs and PHBHTM should qualify as natural polymers that have not been chemically modified:</p> <ul style="list-style-type: none"> <li>• PHAs and PHBHTMs are not chemically modified: PHAs and PHBHTM are biosynthesized through fermentation technology, which does not change its structural chemical formula (except for a slight reduction of the molecular weight due to hydrolyzation). The fermentation process (even when controlled) should be seen as a process whereby polymerization occurs in nature.</li> <li>• PHA and PHBHTM qualify as natural polymers: PHAs and PHBHs occur in nature. PHAs are biosynthesized within living microorganisms. PHBHTM synthesized in micro-organisms cultivated in a well-controlled fermentation process (biotechnology) are similar</li> </ul>

		<p>to PHBHs synthesized in wild micro-organisms. For that reason, PHAs and its derivative PHBHs are 'naturally occurring substances'.</p> <p>Regulation (EC) 1334/2008 makes reference to substances that are naturally present in the environment. The wording 'natural' should be interpreted in the same way in both legislations for the purpose of consistency regarding the definitions and interpretations.</p> <p>Suggestion to define 'natural polymers' as used in the SUP Directive as "polymers obtained by appropriate physical, enzymatic or microbiological (i.e. fermentation) processes from material of vegetable, animal or microbiological origin as these polymers correspond to polymers that are naturally present and have been identified in nature."</p>
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## 5.2 Presentation ECHA (PPT slides)