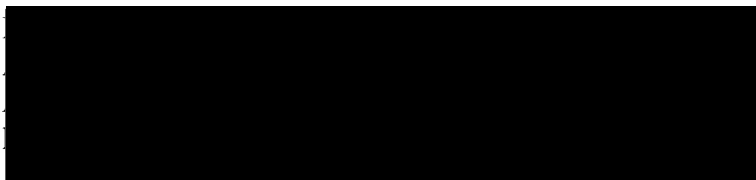


Date: 14th of April 2020

To:



Re: Response to the stakeholder webinar of Friday April 3, 2020, on the guidance identifying and describing the products covered by the Single-Use Plastics Directive (WP 1) under Directive (EU) 2019/904 (SUP Directive).

Dear,

As Kaneka we had the opportunity to attend this webinar, and to take part with other stakeholders in the discussion on the “guidance document” following the presentations submitted by the Consultants on the implementing acts and the guidance, and by ECHA on “elements of the plastic definition”.

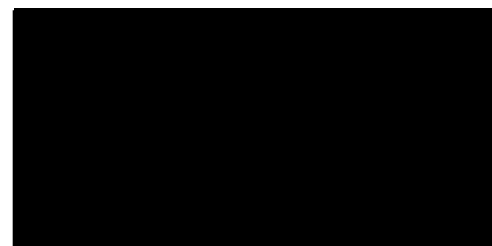
We can happily state that these presentations were very helpful and positive. Even with the core issues related to the definition of natural polymers the Consultants and ECHA showed some flexibility including the possibility of an alternative definition.

We wish to express our appreciation to the Commission for its openness and transparency to all stakeholders. This consultation process is of a paramount importance for industry to create legal certainty and will – hopefully – lead to a balanced yet forward looking “guidance document” by the EU Commission, with a view to promoting further research and innovation as a pre-requisite for the realization of a circular economy.

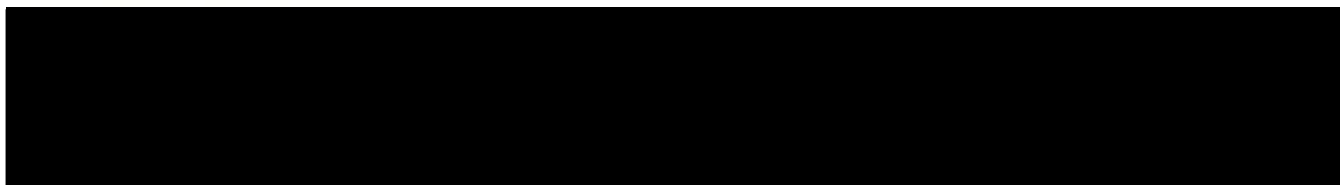
Since we did not have an opportunity to intervene in the webinar due to time constraint, we would like to highlight Kaneka’s key issues laid out in Kaneka’s position paper as attached which has been duly acknowledged by the DG Environment and ECHA: that polymers such as Kaneka PHBHTM should be classified as “not chemically modified natural polymers”, hence, falling outside the scope of SUPD.

Having said this, and with the hope of further clarification of the essential points in Kaneka’s position, we like to emphasize three elements coming out of the stakeholder webinar, which for us are of key importance in the discussion on the “guidance document”.

Sincerely Yours,



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1. Implication of “Natural Polymer”

It has been debated that polymers resulting from biosynthesis through artificial cultivation and fermentation processes manufactured in industrial settings, e.g. polyhydroxyalkanoates (PHA), may or may not be considered natural polymers which have resulted from a ‘*polymerization process that has taken place in nature*’.

Polyhydroxyalkanoates (PHAs), including poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate) (PHBH), occur in nature and are part of the metabolism of the micro-organisms. Kaneka PHBHTM “polymerization” process within Kaneka’s strain in fermentation, has been confirmed to be exactly the same as the PHBH “polymerization” process in wild strain occurring in nature (see Annex 1 to Kaneka’s position paper). There is no question that Kaneka’s PHBHTM is the result of a polymerization process that happens in nature; which accordingly results in the same chemical identity, composition and structure as other PHBH polymers present in the natural environment. Spectrographic analyses show that Kaneka PHBHTM is the same in chemical identity, composition and structure as other PHBH present in the natural environment (see Annex 2 to Kaneka’s position paper).

Therefore, Kaneka expects that the EU Commission will accept “Polymers resulting from fermentation process with the same chemical identity as polymers present in nature” to be considered natural polymers”.

Kaneka wishes to support an alternative definition of natural polymer as follows:

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, including polymers resulting from biosynthesis through artificial cultivation and fermentation processes manufactured in industrial settings with the same chemical identity as polymers present in nature.

2. Implication of “Not chemically modified”

While Paragraph 11 of the Recital of the SUPD describes that “unmodified natural polymers” should not be covered by this Directive as they occur naturally in the environment”, the term “*not chemically modified*” (SUP Directive, Article 3(1)), can, with regard to natural polymers, be interpreted in different ways which ECHA has shown as “potential options”. Note that whichever option is taken, Kaneka PHBHTM is recognized as “not chemically modified”, as no modifications take place in the manufacturing processes of Kaneka PHBHTM. The verified fact on the chemical identity between Kaneka PHBHTM and PHBH in nature proves that no chemical modification takes place (see annex).

However, according to Kaneka’s interpretation, changes occurring during the manufacturing process are not considered relevant in respect to the scope of the SUPD. The end product of the manufacturing should be considered when determining the status of the polymer.

Kaneka is in favour of the interpretation that refers to the end stage of the manufacturing process.

3. Contribution to Circular Economy

Kaneka appreciates the steps taken towards the Circular Economy; and supports the EU plastic strategy and the SUP Directive. The objectives of this SUP Directive are to: *“...(1) 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 (2) to promote the transition to a circular economy with innovative and sustainable business models, products and materials, thus also contributing (3) to the efficient functioning of the internal market.”*

We wish to emphasize that PHBH is an innovative and sustainable product and material, a safe and sustainable alternative to plastics which are persistent and harmful in the marine and other environments. To exclude or rule out the use of PHBH is tantamount to threaten the transition to a circular economy.

The above mentioned objectives will be achieved if and when these types of innovative and sustainable materials such as Kaneka’s PHBHTM polymers, are accepted by the EU Commission as “not chemically modified natural polymers”.
