

Brussels, 23 April 2019

To:



DG Santé
European Commission
Rue de la Loi / Wetstraat 200
1049 Brussels

Impact assessment of a potential ban of the use of E171 for food supplements

Dear



Dear ,

Following our telephone conversation of last week, we have the pleasure of sharing with you an impact assessment of the economic consequences of an EU-wide ban of the use of the food additive titanium dioxide (TiO₂ – E171) for the food supplements sector.

As you are well aware, France has announced that it will enact a ban of the use of this food additive from 1 January 2020 and is expected to shortly notify the Commission of this decision. This ban allegedly would be based on uncertainties of the safety of E171 following an update of a report relating to the safety published by ANSES earlier last week. However, this report does not bring new elements on the table than what EFSA has already considered when it assessed the safety of TiO₂ mid last year and concluded that there were no reasons to reconsider its earlier opinion. In addition, EFSA is carrying out further work on E171, the outcome of which is soon to be expected.

We are very committed to safety and consumer protection. However, we believe that measures as drastic as what is envisaged by France should be based on thorough safety assessment. A ban is, in the light of the current knowledge of the safety of E171 not justified and we would support the Commission in not accepting such a measure, when it will be notified.

To help assess the impact of a ban, we carried out an impact assessment among our membership.

Characteristics of the survey:

- The survey was carried out between 21 March and 13 April 2019.
- We received detailed input from 26 Member Associations and Company's, covering 12 EU countries.
- The survey covers food supplements sold in all EU Member States, Switzerland and Norway. Values for export are not included.

We believe the survey is sufficiently representative to make an estimation of the economic impact.



Results:

1. Technological need:

E171 has an established technological need for food supplements. Its use is confirmed by the users as colouring agent, with a concomitant opacifying effect.

The technological features of E171 are unique

- In coatings of food supplements, it has excellent light-scattering properties, white opacity and brightness and absorbance of UV light characteristics, protecting the content of tablets and capsules against the intrusion of light that otherwise would degrade light-sensitive vitamins and other substances.
- It also has an even and bright white aspect that is capable of masking the normal unlovely colour of tablets and capsules, that would deter consumption. This white aspect is not only important for white tablets but also serves as ground layer for other colours that can be applied.

Because of these unique properties, it is not possible at this stage to apply substances that are equally effective as E171.

2. Value:

E171 is widely used in food supplements, given the normal unlovely colour of a tablet and because of the opacifying properties.

It is estimated that it is used by nearly all food supplements manufacturers in the EU producing tablet food supplement forms.

The sample from our survey covered a total of 236 Million units sold annually (base on sales 2018) amounting to a value of € 504 Million.

To put this in perspective, the total value of the food supplements market in Europe was estimated by Statista (using data from Euromonitor) to € 7.2 Billion in 2015, growing to € 7.9 Billion in 2020.¹

This comprises all forms of food supplements, also those in which E171 is not used (e.g. powders, liquids, capsules, etc).

Assuming that half of food supplements sold in Europe are of the tablet and capsule formats and that the distribution of users across Europe is the same as in the countries that were covered by our survey, the total value of products affected by a ban on TiO₂ based on our survey alone would be over € 1 Billion or nearly 30% of the total market of tablet and capsule form food supplements.

This is likely to be an underestimation.

The value of affected products per company ranges from € 20,000 for the smaller companies to € 148,000,000 for the bigger companies. The median value of affected products per company is € 3,000,000.

Assuming that there are about 2000 food supplement companies active in the EU and that about half of these companies have products that use E171, this would result in a total value of products covered of € 3 Billion.

¹ <https://www.statista.com/statistics/589374/dietary-supplements-market-value-europe/>

A ban would have two immediate consequences:

- The sales of the products would cease, leading to an immediate loss of revenue of that value of the products.
- All these products would require reformulation, which, our respondents confirm, is difficult.

Some of the companies have already engaged in the search for suitable alternatives, given the situation in France and confirm that it is extremely difficult to find suitable alternatives with the same efficacy. It would require at least 1-1.5 years to develop the reformulated products and carry out the required shelf life testing for stability. The resources required for this work are important and beyond the possibilities of many SMEs (over 95 % of companies in the food supplements sector are SMEs).

In summary, a ban of the currently authorised use of E171 would have devastating consequences for the food supplements sector, estimated to affect products worth € 1 up to € 3 Billion, depending of the above scenarios, covering nearly 30-50% of the current market of food supplements in Europe.

Such a measure can only be enacted based on the outcome of a robust risk assessment. Given the EFSA has not considered the use of E171 as a concern for safety, after having assessed the data that France has put forward as basis for its measure, we strongly believe that there is no justification for France to unilaterally ban the use of E171 based on the precautionary principle.

We would therefore call upon the European Commission to firmly oppose and safeguard the EU safety-based authorisation of E171 as food additive.

Do not hesitate to come back should you require further information,

Yours sincerely,

