



Fecc
EUROPEAN ASSOCIATION OF
CHEMICAL DISTRIBUTORS

EU Consultation: Food safety - clearer information on food additives

European Association of Chemical Distributors (Fecc)

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Fecc acknowledges the consultation to amend Regulation (EU) No 307/2012 considering the EU Transparency Regulation on risk assessment in the food chain. In this consultation we would like to raise the following points:

1. On data submission and access - To prepare for the renewal of the authorisation and in line with new [Transparency Regulation \(EU\) No 1381/2019](#), the European Food Safety Authority (EFSA) has received a mandate from the Commission to review its scientific Guidance Document (GD) on the EU Safety Assessment on the application of flavourings on primary products, particularly for smoke flavourings.

According to the revised transparency legislation which entered into force on 27 March 2021, the scientific guidance for the preparation of applications on smoke flavouring primary products clearly mentioned the necessity to comply with [Regulation EU 2019/1981](#) for new dossier re-authorization, which leads to an additional complexity for business operators.

However, despite requests from various business operators and value chain partners, access into the EFSA system has only been granted on 31 March 2021, which may pose challenges for those who would need to submit their re-authorisation requests in a timely manner. We request that EFSA continues to make the request for additional information well in advance for better alignment between EFSA, business operators, the Commission and other concerned parties.

2. On EFSA pre-submission procedures - Fecc supports the Article (4) of the amendments. However, we encourage the Commission to take into account that the amendments to [Regulation \(EC\) No 178/2002](#) introduced new provisions concerning general pre-submission advice at the request of a potential applicant. The obligation to notify studies commissioned or carried out by business operators to support an application also falls under the remit of the authorities. This is to prevent cases of non-compliance with that obligation and to ensure that the documentation provided by applicants are vetted and satisfactory. Business operators, especially SMEs, must be supported to ensure that compliance to the EFSA transparency register is facilitated.

3. On Commission compliance with the Union list of approved food additives - We reiterate our position from the previous consultation on food additives ([link](#)) which states that EFSA must provide a reasonable transition period in the following scenarios:

- When a food additive must be removed in the Union list of approved food additives.
- When a non- food additive substance (enzyme, colourant, carrier) is classified as a food additive under the European Commission MEMO/11/783 definition of the term.
- When a food additive is already available on the market prior to an EFSA safety assessment, and provided that the safety assessment concludes no significant risks.

The third clause includes those of smoke flavourings. The current timeline set by EFSA would require applicants to submit dossiers by 30 June 2022, in line with the 18th months before expiry requirement (as stipulated in Art. 12 of Regulation 2065/2003). In its current timeline, it would be challenging for applicants to both comply with the requirements to conduct the scientific and GLP-regulated studies and submit the dossiers in time.

In addition, there is no guarantee that EFSA will be able to complete the safety assessment of all primary products for which new dossiers will be submitted, in time for their renewals, which puts the pressure on the business operators who do not have control over the limited transition period.

As the association that represents food and food ingredient distributors, most of which are SMEs, we believe that food safety and a sound, consistent regulatory framework go hand-in-hand. We would be happy to engage further with the Commission in the pursuit of sustainable, future-oriented and transparent solutions in this area.

To access the Fecc's response on the EU Commission's website, please [click here](#).