

The European Light Stabilisers and Antioxidants Association (ELISANA), a Cefic sector group, takes the opportunity to provide feedback to the European Commission regarding the recent Draft Commission Implementing Decision related to the European Drinking Water Directive (EU) 2020/2184.

13 November 2023

Upon careful review of the Draft Commission Implementing Decision and the related Annexes, we noticed the proposed Maximum Tolerable Concentration at the tap ($MTC_{\text{tap, organics}}$) for the Substance 7,9-di-tert-butyl-1-oxaspiro[4,5]deca-6,9-diene-2,8-dione, also known as Arvin VIII, (EC Number 872-478-6, CAS Number 82304-66-3) of 2.5 $\mu\text{g/L}$ (Table 4 of Annex I 2.IA).

This organic substance is one of the well-known degradation products of stabilizers manufactured by our member companies, and in close communication with the German Umweltbundesamt, we commissioned several toxicological studies in research laboratories (according to OECD Testing Guidelines, compliant with GLP) to robustly assess the safety profile of this substance.

Additionally, bioaccumulation properties of the substance were assessed in a comprehensive weight of evidence approach.

An MTC of 2.5 $\mu\text{g/L}$ is usually set for substances for which only (negative) genotoxicity data are available. Thus, we are concerned that time constraints may have hampered to consider all available data.

Based on our understanding of the $MTC_{\text{tap, organics}}$, it seems that the new information on bioaccumulation properties and the subchronic toxicity study has not yet been considered in the derivation of the proposed limit value stated in the present Draft Commission Implementing Decision.

We sincerely ask the Commission to consider these data in the derivation of the Maximum Tolerable Concentration at the tap ($MTC_{\text{tap, organics}}$) for the substance.

According to the available toxicity data, the appropriate MTC_{tap} for Arvin VIII is **100 $\mu\text{g/L}$** .

Finally, regarding Art. 3., 2. IA, ELISANA suggests to keep the original Article 3 in this IA (May version) (point 1 below), and adding a new clause (point 2 below) in regards to Tables 3 and 4 of Annex I 2.IA:

- Point 1. For the purpose of including additional starting substances, compositions and organic cementitious constituents in the European positive lists or removing an entry from the European positive lists, an application shall be made to ECHA in accordance with the procedure established under Regulation [Article 11(5) Commission Regulation].
- Point 2. Without undue delay, a relevant competent authority or an economic operator may submit an application to update Tables 3 and 4 of Annex I, when the latest scientific developments are made available to them.