

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.*

## WORKING DOCUMENT

02/06/2022

### **Removal of metatartaric acid (E 353) from the Union list of authorised food additives**

#### **Background**

In 2020, the safety of the permitted food additive metatartaric acid (E 353) was re-evaluated by EFSA<sup>1</sup> in the context of the programme for the re-evaluation of approved food additives required by Regulation No 1333/2008. EFSA concluded that metatartaric acid should be included in the group acceptable daily intake (ADI) of 240 mg/kg body weight per day, expressed as tartaric acid and that there is no safety concern for the use of metatartaric acid at the reported uses and use levels. However, EFSA made several recommendations concerning the specifications for metatartaric acid (E 353) in Regulation No 231/2012, including the need to lower maximum limits for toxic elements (arsenic, cadmium, lead and mercury). The latter recommendation was based on the consideration that contamination at the current maximum limits could have a significant impact on the exposure to these toxic elements, which are already close to the health based guidance values or benchmark doses (lower confidence limits) established by EFSA.

#### **Follow-up to the re-evaluation**

In line with the approach<sup>2</sup> agreed for the follow-up of such inconclusive scientific opinions, SANTE E2 organised a call for data (published 19 January 2021) requesting business operators to submit the technical data needed to address the issues identified by EFSA by the specified deadline (19 July 2021), ([http://ec.europa.eu/food/safety/food\\_improvement\\_agents/additives/re-evaluation\\_en](http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en)).

However, no interest to submit data was expressed and consequently no data were received by the given deadline.

Therefore it is concluded that there is no interest that metatartaric acid (E 353) remains permitted in the EU and the current authorisation for the use of metatartaric acid (E 353) as a food additive should be terminated (this substance should be removed from the list of authorised food additives).

Metatartaric acid (E 353) is authorised for use as stabilising agent in accordance with Regulation No 934/2019. However, it has been noted that potassium hydrogen tartrate (E 336i) and tartaric acid D,L or its neutral salt of potassium are also authorised for use as stabilising agent in accordance with Regulation No 934/2019. In addition, E 353 is authorised

---

<sup>1</sup> EFSA Journal 2020;18(3):6031 (<https://www.efsa.europa.eu/en/efsajournal/pub/6031>)

<sup>2</sup> [https://ec.europa.eu/food/system/files/2022-01/fs\\_food-improvement-agents\\_reeval\\_approach.pdf](https://ec.europa.eu/food/system/files/2022-01/fs_food-improvement-agents_reeval_approach.pdf)

as a food additive in two food categories<sup>3</sup> in accordance with Annex II to Regulation No 1333/2008. In these food categories, also group I additives (including E334-7, E 354) are authorised. Consequently, the removal of its authorisation as a food additive would not be expected to have a major/significant economic impact for food additive/food producers, in general. The impact on food supply/availability for consumers would be expected to be very limited, if any. No environmental impact is expected.

---

<sup>3</sup> Fruit wine and made wine (14.2.4) and other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol (14.2.8)