**European Parliament**
2019-2024

*Committee on Petitions*

18.1.2021

# NOTICE TO MEMBERS

**Subject: Petition No 0745/2020 by K.B. (Polish) on wrongful interpretation of Regulation 1925/2006 on the addition of vitamins and minerals in case of aloe vera**

## 1. Summary of petition

The petitioner complains that wrongful interpretation by the Commission of Regulation 1925/2006 of 20 December 2006 on the addition of vitamins and minerals and some other substances to food will lead to a prohibition of the use of many popular dietary supplement ingredients in the European Union, including plant materials. In particular, he refers to botanical species containing hydroxyanthracene derivatives, including aloe vera leaves. He calls for: 1) the correct interpretation of the provision of Article 8 of Regulation 1925/2006, and 2) not publishing the Commission Regulation amending Annex III to the Regulation as regards botanical species containing hydroxyanthracene derivatives to include extracts from aloe vera leaves (Annex III, Part A).

## 2. Admissibility

Declared admissible on 22 October 2020. Information requested from Commission under Rule 227(6).

## 3. **Commission reply**, received on 18 January 2021

In accordance with Commission Implementing Regulation (EU) No 307/2012[1] establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006[2], the

[1] Commission Implementing Regulation (EU) No 307/2012 of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods, *OJ L 102, 12.4.2012, p. 2–4.*
[2] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods, *OJ L 404, 30.12.2006, p. 26–38.*

procedure under Article 8 is only launched, at the request of Member States or of the Commission, if a preliminary assessment of the actual conditions of use and of consumption of the substance shows a potential risk to consumers.

Regarding hydroxyanthracene derivatives (HADs), in its opinion of 9 October 2013[3] adopted in the context of the Claims Regulation[4], the European Food Safety Authority (EFSA) listed a number of contraindications and restrictions related to stimulant laxatives, which originated from scientific documents of the committee on herbal medicinal products. Given the possible safety concerns highlighted in the EFSA opinion and that HADs are widely used in foods in a number of Member States, it was considered appropriate to initiate the Article 8 procedure for these substances.

In its scientific opinion of 23 January 2018[5], EFSA concluded that certain HADs (such as aloe-emodin, emodin and danthron) as well as aloe extracts containing HADs, irrespective of whether the extracts originate from the leaf fillet or from the rest of the aloe vera leaf, are genotoxic and can cause cancer in the intestine, based on the data obtained from *in vitro* and *in vivo* clinical studies. The EFSA panel further considered that there is a safety concern for certain extracts containing HADs (such as rheum, cassia and rhamnus extracts) although scientific uncertainty persists.

According to Article 8 of the Regulation (EC) No 1925/2006[6], if a harmful effect on health has been identified in respect to certain substances, those substances should be prohibited or allowed under specified conditions of use. If the possibility of a harmful effect has been identified relating to certain substances but scientific uncertainty persists, those substances should be placed under Union scrutiny with a view of further evaluation within four years subject to which such substances might be generally allowed, allowed under conditions of use or prohibited.

In line with the safety assessment of EFSA and the procedure provided for in Article 8 of Regulation (EC) No 1925/2006, which must be followed if a substance and/or the ingredient containing the substance added to food represents a potential risk to consumers, the Commission proposed to prohibit the use of those substances in food, and all preparations containing them, that were considered by EFSA genotoxic and carcinogenic, without scientific uncertainty,. Substances for which scientific uncertainties remain according to the EFSA opinion were proposed to be placed under Union scrutiny, during which interested parties will have the possibility to submit data demonstrating the genuine safety of the substances in question.

Considering that the EFSA panel noted that there was some evidence of genotoxic effects of aloe extracts depleted of HADs, and that it could not advise on a daily intake of HADs that does not give rise to concerns for human health, no safety limit could be set in the measure to distinguish between the different botanical preparations, including aloe preparations, with a range of HAD levels. Indeed, Article 8 allows placing a substance in part B of Annex III of

[3] https://www.efsa.europa.eu/en/efsajournal/pub/3412
[4] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ L 404, 30.12.2006, p. 9.
[5] https://www.efsa.europa.eu/en/efsajournal/pub/5090
[6] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods, OJ L 404, 30.12.2006, p. 26.

Regulation (EC) No 1925/2006 and to set up conditions of use, such as a safety limit or a warning statement, when it is justified from a safety point of view. However, based on EFSA's conclusion that HADs are genotoxic and carcinogenic, allowing the use of HADs in foods subject to conditions of use would not adequately protect adequately consumers' health.

Considering that it is possible during manufacturing to remove HADs from the botanical preparations, but impurities of these substances may still be present, the EU Reference Laboratory (EURL) on mycotoxins and plant toxins was asked for assistance in establishing a validated analytical method and its limits of quantification for HADs in different botanical preparations, including aloe preparations. On the basis of the EURL's report on the available analytical methods for the quantification of HADs, the Standing Committee on Plants, Animals, Food and Feed (PAFF), agreed on harmonised limits of quantification (LOQs) for HADs to address the industry's concerns regarding impurities of HADs. The Committee also agreed that the PAFF meeting minutes would include the mentioned LOQs so as to ensure harmonisation of control activities. The PAFF Committee was consulted by written procedure in order to deliver an opinion on the draft measure. The measure received a favourable opinion by the Committee.

Conclusion

Article 8 of Regulation (EC) No 1925/2006 aims to address a situation where a substance represents a potential risk to consumers. The Commission considers that this Article has been implemented in line with its original intention.

In accordance with the Article 8 procedure of Regulation (EC) No 1925/2006 and the General Food law[7], which establishes that only safe food can be placed on the Union market, appropriate measures need to be taken by the Commission when a potential risk of harmful effect on health is identified. In this context, the Commission's measure in question aims at ensuring a high level of consumer protection, taking into account the advice of EFSA.

[7] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1.