



3.6.2022

NOTICE TO MEMBERS

Subject: Petition No 1109/2020 by K.W. (German) on labelling of food additive carrageenan

1. Summary of petition

The petitioner calls for labelling food additive carrageenan (E407) in all products containing this additive and for studying the impact of this additive on human health.

2. Admissibility

Declared admissible on 21 January 2021. Information requested from Commission under Rule 227(6).

3. Commission reply, received on 20 May 2021

According to the applicable legislation, the indication of the list of ingredients of the food is mandatory.¹ Food additives are food ingredients² and therefore they must be included in the list of ingredients. Product labels must designate food additives by the name of the category (e.g. thickener) followed by their specific name (e.g. carrageenan) or, if appropriate, by E-number (e.g. E 407), so that the consumer is appropriately informed about the presence and function of food additives in foods.

Omission from the list of ingredients is possible only for (i) food additives whose presence in a given food is solely due to the fact that they were contained in one or more ingredients of that food, (ii) food additives, which are used as processing aids, and (iii) food additives used as carriers. In those cases, food additives are typically present in very small quantities. Such

¹ See Article 9(1)(b) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers (OJ L 304, 22.11.2011, p. 18).

² See Article 2(2)(f) of Regulation (EU) No 1169/2011.

omission is only possible if these food additives do not cause allergies or intolerances³ and they do not serve any technological function in the finished product.

All food additives are subject to a pre-marketing authorisation and only those included in an European Union list may be placed on the market as such and used in foods under the conditions of use specified therein. Food additives may only be authorised if their use does not pose a safety concern to the health of the consumer at the level of use proposed, on the basis of the scientific evidence available. Prior to the authorisation, their safety is assessed by the European Food Safety Authority (EFSA). In addition, the European Commission set up a programme for the re-evaluation of the safety of food additives that were already permitted in the EU before 20 January 2009⁴. For this re-evaluation EFSA takes into account any relevant new scientific and technical information available. When needed, the Commission takes appropriate risk management measures based on the outcomes of the EFSA scientific assessment. Permitted additives are also kept under continuous observation and their safety is re-evaluated whenever necessary in light of the changing conditions of use and new scientific information.

The safety of carrageenan (E 407) when used as a food additive was re-evaluated by EFSA in 2018⁵. In its scientific opinion, EFSA noted that no adverse effects have been detected in chronic toxicity studies with carrageenan in rats at levels up to 7,500 mg/kg bw per day, the highest dose tested and that there was also no concern with respect to genotoxicity or carcinogenicity. However, EFSA noted uncertainties as regards the chemistry, the exposure assessment and biological and toxicological data and thus concluded that the existing health based guidance value (i.e. acceptable daily intake value – ADI) should be considered temporary, while the database should be improved within 5 years. This EFSA opinion has been followed up by a call for data⁶ to address the remaining uncertainties in order to complete the safety re-evaluation of carrageenan (E 407).

Conclusion

The EU legislation assures the safe use of food additives, enables consumers to make informed choices and protects their interests. It requires that food additives remain under continuous scrutiny and that their safety is re-evaluated when necessary. The most recent safety re-evaluation of carrageenan (E 407) does not provide any grounds for more stringent labelling requirements, which would go beyond the general labelling provisions applicable to food additives. Following the call, new data are being generated to address the uncertainties identified in the latest EFSA opinion on carrageenan. The Commission closely follows this process and will consider appropriate risk management measures, if needed, based on the next EFSA opinion, after the requested data will have been made available.

4. Commission reply (Rev I), received on 03 June 2022

In reply to petition 1109/2020, the Commission stressed that food additives are food ingredients

³ Food additives that cause allergies and intolerances are listed in Annex III to Regulation (EU) No 1169/2011.

⁴ Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a program for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (OJ L 80, 26.3.2010, p. 19).

⁵ <https://www.efsa.europa.eu/en/efsajournal/pub/5238>

⁶ https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en

and, therefore, their indication in the list of ingredients is mandatory⁷. The reply also explained the specific conditions under which the applicable legislation allows for the omission of food additives from the list of ingredients and that there are strict conditions concerning safety assessment prior to the authorisation as well as the obligation to keep food additives under continuous observation and re-evaluate their safety whenever necessary. The reply clarified that currently there are no grounds for more stringent labelling requirements for carrageenan (E 407). However, the Commission will consider appropriate risk management measures, if needed, based on the next opinion of the European Food Safety Authority (EFSA) that will address the uncertainties identified in the latest EFSA opinion on carrageenan⁸.

In the email of 30 March 2022, the petitioner raised two specific questions and requested clear answers.

Is it correct that carrageenan is still not subject to declaration in all foods? Yes, this is correct as exceptions from declaration apply.

As explained in the previous Commission's reply, those exceptions are limited to (i) food additives whose presence in a given food is solely due to the fact that they were contained in one or more ingredients of that food (e.g. use of an additive in sauce, which is present in a compound food), (ii) food additives, which are used as processing aids (e.g. to facilitate realising (tour out) of a foodstuffs out of a tin), and (iii) food additives used as carriers (e.g. to disperse or otherwise physically modify other food additive, nutrient or flavouring in order to facilitate its handling, application or use).

In all those cases, food additives are typically present in very small quantities and omission from declaration is only possible if these food additives do not cause allergies or intolerances⁹ and they do not serve any technological function in the finished product.

There will be no investigation into intolerance to carrageenan? No specific assessment of hypersensitivity, allergenicity and food intolerance is expected, as EFSA in 2018 noted that no reports of significant allergic and/or anaphylactic reactions after ingestion of foods containing carrageenan were identified in the available literature. However, the EFSA opinion noted uncertainties as regards the chemistry, the exposure assessment and biological and toxicological data and indicated that the database should be improved within 5 years in order to complete the assessment. The follow-up open call for data¹⁰ sets the deadline to submit the information to address the remaining uncertainties at 31 December 2022, before EFSA can assess these. Any interested party is invited to submit the relevant information to EFSA so that it is taken into account in the next EFSA opinion.

Conclusion

⁷ See Articles 2(2)(f) and 9(1)(b) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, OJ L 304, 22.11.2011, p. 18.

⁸ <https://www.efsa.europa.eu/en/efsajournal/pub/5238>

⁹ Food additives that cause allergies and intolerances are listed in Annex III to Regulation (EU) No 1169/2011.

¹⁰ <https://www.efsa.europa.eu/en/consultations/call/call-technical-and-toxicological-data-carrageenan-e-407-uses-foods>

Carrageenan (E 407) is subject to the general rules and exceptions for the declaration of food additives in the list of ingredients. The most recent safety re-evaluation of carrageenan (E 407) does not provide grounds for more stringent labelling requirements. Any interested party may still submit the information relevant to the safety of carrageenan in reply to the open call for data issued by EFSA. The Commission will thereafter consider appropriate risk management measures, if needed, based on the next EFSA opinion.