



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Brussels
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Dear [REDACTED]

I would like to thank you for your email¹ of 22 November 2021 on the maximum limits for sodium nitrite and potassium nitrate in organic meat products.

As you mention, Section A1, Part A, of Annex V to Regulation (EU) 2021/1165² provides that the maximum ingoing amounts for the additives E250 (sodium nitrite) and E252 (potassium nitrate) are 80 mg/kg. These levels have been set as indicative since 24 May 2006 by Regulation (EC) No 780/2006³ with a limitation that *“these additives can only be used if it has been demonstrated to the satisfaction of the competent authority that no technological alternative giving the same sanitary guarantees and/or allowing to maintain the specific features of the product, is available”*. At that time, the term ‘indicative’ was also used in Directive No 95/2⁴ for the maximum amounts of E250 and E252 in conventional food.

However, Directive No 2006/52/EC⁵ of 5 July 2006 modified Directive No 95/2/EC, in particular, by removing the term ‘indicative’ on the basis of an opinion of the European Food Safety Authority (EFSA) recommending that the levels of nitrite and nitrate are set in the legislation as ‘added amount’.

On 5 July 2007, the Group of Independent Experts on Food Additives and Processing Aids Permitted in Processing of Organic Food of Plant and Animal Origin concluded⁶ on E252 and E250 in particular the following: *“Other preservation techniques such as higher salt concentrations, smoking or cooling can replace nitrate if all hygienic standards are fulfilled all the time...It is possible to have the acceptance in the market.*

¹ ARES(2021)7167044

² [Commission Implementing Regulation \(EU\) 2021/1165 of 15 July 2021 authorising certain products and substances for use in organic production and establishing their lists \(OJ L 253, 16.7.2021, p. 13\)](#)

³ [Commission Regulation \(EC\) No 780/2006 of 24 May 2006 amending Annex VI to Council Regulation \(EEC\) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs \(OJ L 137, 25.5.2006, p. 9\)](#)

⁴ [European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners \(OJ L 061, 18.03.1995, p. 1\)](#)

⁵ [Directive 2006/52/EC of the European Parliament and of the Council of 5 July 2006 amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs \(OJ L 204, 26.7.2006, p. 10\)](#)

⁶ Conclusions from Group of Independent Experts on Food Additives and Processing Aids Permitted in Processing of Organic Food of Plant and Animal Origin. (https://ec.europa.eu/info/sites/default/files/food-farming-fisheries/farming/documents/conclusions_food_additives_2007_en.pdf)



An example: In Denmark, where nitrite has not been used for organic meat products for more than 10 years, development of cured, organic meat products of good quality saw a rapidly increasing market...the group recommends that nitrate and nitrite within a reasonable time scale should be eliminated from organic meat products. In order to avoid harm to people, this should be done after a general and efficient education programme in alternative processing methods and hygiene to organic meat manufacturers. Addition of nitrite and nitrate should be kept as low as possible if not eliminated. The added amounts should be regulated, not the residual amounts.”

On this basis, Regulation (EC) No 123/2008⁷ introduced the following provisions in Annex VI to Regulation (EEC) No 2092/91⁸ :

“The use of the following substances shall be re-examined before 31 December 2010:

— Sodium nitrite and potassium nitrate in Sub-section A.1 with a view to withdrawing these additives;”

This provision has been reaffirmed in Article 27(3) of Regulation (EC) No 889/2008⁹.

The preparatory work for Regulation (EU) 2021/1165 started in early 2020. A draft text with the term ‘indicative’ struckthrough in the provisions regarding nitrite and nitrate was presented to the Member States’ representatives in April 2020. In the absence of opposition, the term ‘indicative’ was removed from the version of 25 September 2020.

The draft act has been subject to the feedback mechanism from 26 March 2021 to 23 April 2021¹⁰; 220 replies were received and none of them were related to nitrite or nitrate.

Any modification of the provisions laid down in Regulation (EU) 2021/1165 would have to be done in accordance with Article 24(7) of Regulation (EU) 2018/848: “*where a Member State considers that the specifications of use referred to in the production rules should be amended, it shall ensure that a dossier giving the reasons for.... amendments is officially sent to the Commission and to the other Member States...*”

⁷ Commission Regulation (EC) No 123/2008 of 12 February 2008 amending and correcting Annex VI to Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs

⁸ [Council Regulation \(EEC\) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs \(OJ L 198, 22.7.1991, p. 1\)](#)

⁹ [Commission Regulation \(EC\) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation \(EC\) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control \(OJ L 250, 18.9.2008, p. 1\)](#)

¹⁰ <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12377-Organic-farming-list-of-products-&-substances-authorized-in-organic-production-update- en>

The present opinion is provided on the basis of the facts as set out in your email of 22 November 2021 and expresses the view of the Commission services and does not commit the European Commission. In the event of a dispute involving Union law it is, under the Treaty on the Functioning of the European Union, ultimately for the European Court of Justice to provide a definitive interpretation of the applicable Union law.

Yours sincerely,

