Decision on how the European Commission deals with the labelling of foodstuff that contain probiotics as 'health claims' (case 2273/2023/MIK)

Decision

Case 2273/2023/MIK - **Opened on** 19/12/2023 - **Decision on** 20/12/2024 - **Institution concerned** European Commission (No maladministration found) |

The case concerned the European Commission's view that the word 'probiotics', when used in relation to foods, suggests to consumers that they will derive a health benefit from consuming these foods. However, under EU food legislation, such 'health claims' can be used only when authorised by the Commission based on a scientific assessment by the European Food Safety Authority (EFSA). So far, EFSA has given negative opinions on health claims concerning probiotics due to the absence of sufficient scientific evidence demonstrating their positive health effects.

The complainant, an association of producers of probiotics, argued that the Commission is wrong to consider the term 'probiotic' to be a 'health claim', and that it should rather consider this term to be a 'nutrition claim' or an objective descriptor provided to consumers to enable them to make informed choices about their foods.

The Ombudsman found that the Commission's interpretation of EU food legislation in relation to probiotics is reasonable and in line with the main goal of this legislation, which is to ensure a high level of consumer protection. The Ombudsman thus closed the case.

Background to the complaint

1. The complaint concerned how the European Commission interprets the term 'probiotics'[1] when used on food labelling and in communication concerning food, such as commercials. According to a Commission guidance document of 2007[2] ('Commission guidance of 2007'), the use of statements such as "*contains probiotics*" constitute 'health claims' under the EU regulation on nutrition and health claims on foods ('the Claims Regulation').[3]

2. Health claims cannot be used on food labels or in food advertising unless authorised by the Commission based on a scientific assessment by the European Food Safety Authority (EFSA).[4] So far, the Commission has rejected all applications for authorising health claims concerning probiotics due to negative scientific opinions by EFSA.

3. The complainant, an organisation representing the interests of the European probiotic industry, was dissatisfied with this situation. It argued that the position of the Commission results in a *de facto* ban on using the term 'probiotics' on food products in the EU, which is neither in the interest of the probiotic industry nor in the interest of consumers.

4. After many exchanges with the Commission on the matter, which did not lead to a change of the Commission's position, the complainant turned to the Ombudsman.

The inquiry

5. The Ombudsman opened an inquiry into the complaint.

6. In the course of the inquiry, the Ombudsman received the reply of the Commission on the complaint and, subsequently, the comments of the complainants in response to the Commission's reply.

Arguments presented to the Ombudsman

7. The **complainant** contended that the Commission is wrong to consider that using the term 'probiotics' on food labelling and in communication suggests a positive health effect stemming from the consumption of this food. Rather, the term conveys to consumers objective information about the ingredients of food products.

8. In the complainant's view, the Commission should therefore allow the use of statements such as "*contains probiotics*" as 'nutrition claims' under the Claims Regulation. Alternatively, the Commission could consider such statements to be neutral descriptors, that is, objective information provided to consumers under the Food Information Regulation[5] to help them make informed choices in relation to food.

9. The complainant also argued that the Commission's position creates legal uncertainty, as food operators are unsure whether they can state 'probiotics' on their products. At the same time, the Food Information Regulation requires clear information to be provided to consumers including the name of the food and the list of ingredients.[6]

10. The complainant further considered that the Commission's position is incompatible with guidance[7] issued by EFSA on that matter ('EFSA guidance on health claims'). According to this guidance, health claims must refer to benefits to a specific body function, whereas the term 'probiotics' does not contain such a reference. This means, in the complainant's view, that, although the Commission considers the term 'probiotics' to be a health claim, EFSA will never issue a favourable scientific opinion on it.

11. Moreover, the complainant argued that the position of the Commission leads to regulatory differences within the EU because some Member States have adopted their own guidelines, which may allow the use of the term 'probiotics'.

12. Overall, the complainant found that the Commission lacked willingness to engage with its arguments and to find a constructive solution.

13. In reply, **the Commission** confirmed its position that the term 'probiotics', although not defined in EU legislation, implies a positive effect on health. The Commission relied in this regard on the definition of the World Health Organisation (WHO), which refers to probiotics as "*live microorganisms which when administered in adequate amounts confer a* ***health benefit*** *on the host*" (emphasis added).

14. The Commission emphasised that this interpretation has been agreed among Member States, acknowledged by the practices of food business operators and consistently used since the publication of its guidance in 2007. The Commission further noted that none of the applications for authorisation of health claims concerning live microorganisms, 'probiotics' and similar terms submitted to date received a favourable scientific opinion of EFSA. This is mainly due to the absence of scientific evidence on the effects of probiotics on a healthy population, insufficient characterisation of the strains of microorganisms used in the relevant foods, the poor quality of studies, and undefined claims.

15. In this context, the Commission considered that, if industry was nonetheless allowed to market food labelled as 'probiotics', consumers might expect these foods to confer health benefits on them, be inclined to favour such foods over others, and might even be willing to pay a higher price. This would be contrary to the goals of the Claims Regulation and the Food Information Regulation, which aim at ensuring that consumers are well informed about the food products they purchase.

16. According to the Commission, the complainant is also wrong in saying that the term 'probiotics' could never be authorised as a health claim in view of the EFSA guidance on health claims. This guidance provides only examples of health claims previously assessed by EFSA in order to facilitate the preparation of future applications.

17. The Commission's guidance on the implementation of the Claims Regulation, which sets out the Commission's interpretation of the term 'probiotics' as a health claim, was endorsed by Member States in 2007 and, in the Commission's view, there is nothing to suggest that it is no longer up-to-date.

18. As regards the alleged regulatory differences among Member States, the Commission noted that national authorities are responsible for initial checks of applications for authorising health claims and that national authorities have accepted that statements concerning 'probiotics' are health claims and, as such, require authorisation.

19. As regards the complainant's proposal to consider the term 'probiotics' as a 'nutrition claim' rather than a 'health claim', the Commission argued that there is no link between probiotics and the nutritional qualities of foods. In any case, the Claims Regulation requires scientific evidence to substantiate any claims,[8] including nutrition claims, which is currently lacking.

20. As regards the complainant's proposal to consider the term 'probiotics' as a neutral descriptor, the Commission noted that the Food Information Regulation requires that food information is not misleading. Considering that the term 'probiotics' implies a health benefit, it may only be used if authorised in accordance with the Claims Regulation.

The Ombudsman's assessment

21. This case concerns the Commission's interpretation of the term 'probiotics' and in particular its position that the term implies health benefits on people consuming food containing probiotics. As a result, the Commission considers that the term 'probiotics' must be considered a 'health claim' under the Claims Regulation. In support of its position, the Commission relies on the WHO definition of 'probiotics', and the endorsement of its interpretation of the term by Member States via the adoption of the Commission guidance document of 2007.

22. The complainant disagrees with the Commission's interpretation and instead suggests an alternative interpretation that would allow the term 'probiotics' to be used on food labels and in advertising without necessarily demonstrating health benefits with scientific evidence. Importantly, the complainant does not contest the Commission's statement that, so far, applicants for the authorisation of health claims concerning probiotics have not been able scientifically to prove health benefits of probiotics on specific body functions.

23. The underlying complex factual question is therefore whether consumers expect the intake of 'probiotics' to have a positive effect on their health and, if so, to what extent the use of the term 'probiotics' on food labelling and in communication affects consumer choice.

24. The Ombudsman's role in cases involving divergent interpretations of legal frameworks is to examine whether the EU administration's interpretation of the relevant legal framework is reasonable and in line with the general aims and principles underpinning it.[9] Moreover, the Ombudsman can question the position of the EU administration on complex factual questions only if she finds manifest errors in the administration's assessment.

25. The Ombudsman considers that this inquiry did not bring to light a manifest error in the Commission's assessment that the term 'probiotics' suggests health benefits to consumers and may thus influence their choice of food and readiness to pay a higher price.

26. Based on this assessment, it is clear from the Commission's reply that its interpretation of the term 'probiotics' as a health claim is intended to give effect to the general aim of the Claims Regulation, which is to protect consumers from potentially misleading information about the food they purchase. The result of the Commission's interpretation is that food operators must prove health benefits of their products with scientific evidence before making such claims. The Ombudsman accepts that, in such cases, the Commission should rather err on the side of caution to protect consumers from potentially misleading information.[10]

27. As such, it is reasonable for the Commission to consider statements such as "*contains probiotics*" as 'health claims', which are defined as claims implying "*that a relationship exists between a food category... and health*". In this context, in the Ombudsman's view, nothing suggests that the Commission guidance of 2007 is no longer up-to-date.

28. Moreover, the Ombudsman accepts the Commission's explanation that the EFSA guidance on health claims is based on past cases and that it does not rule out submitting new applications to authorise health claims concerning 'probiotics' in the future if these are supported by scientific evidence demonstrating their health benefits.

29. The Ombudsman does not believe that the Commission's interpretation of the term 'probiotics' creates legal uncertainty. Legal uncertainty means that the applicable rules are unclear and, because of this, their addressees cannot ascertain which conduct is prohibited, required, or allowed. In this case, on the contrary, the Commission's position contributed to clarifying the legal framework.

30. It is not within the Ombudsman's mandate to determine whether some Member States allow a use of the term 'probiotics', which is not in line with the Claims Regulation. However, even if that were the case, this would not mean that the Commission is wrong, but rather that some Member States do not comply with EU law, which would be for the Commission to address in its capacity as guardian of the EU Treaties.

31. Moreover, the files reviewed within the scope of this inquiry show that the Commission has engaged with the concerns raised by the complainant and has consistently held a clear position on the matter, in line with the general aim of the Claims Regulation. The Ombudsman commends the Commission's approach in this regard.

Conclusion

Based on the inquiry, the Ombudsman closes this case with the following conclusion:

There was no maladministration by the European Commission.

The complainant and the Commission will be informed of this decision**.**

Emily O'Reilly
European Ombudsman

Strasbourg, 20/12/2024

[1] The complaint concerned also related terms such as 'prebiotics'.

[2] Guidance on the implementation of Regulation 1924/2006 on nutrition and health claims made on foods - Conclusions of the Standing Committee on the Food Chain and Animal Health (14 December 2007), https://food.ec.europa.eu/system/files/2016-10/labelling_nutrition_claim_reg-2006-124_guidance_en.pdf, p. 11.

[3] Regulation 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ L 404/9, https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32006R1924.

[4] Art. 10(1) and 16 of Regulation 1924/2006.

[5] Regulation 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, OJ L 304/18, https://eur-lex.europa.eu/eli/reg/2011/1169/oj.

[6] Art. 7 of Regulation 1169/2011.

[7] Guidance on the scientific requirements for health claims related to the immune system, the gastrointestinal

tract and defence against pathogenic microorganisms, EFSA Journal 2016;14(1):4369, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4369.

[8] Art. 6(1) of Regulation 1924/2006.

[9] See Decision of the European Ombudsman in case 2000/2015/ANA on the European Commission's compliance with the rules on the approval of plant protection products, https://www.ombudsman.europa.eu/en/decision/en/91579.

[10] See, decision 2000/2015/ANA (footnote 9 above), paragraph 22.