



UK Nutrition & Health Claims Committee

SCIENTIFIC OPINION

Scientific Opinion on the modification of the authorisation of a health claim related to beta-glucan from oats or barley and the reduction of the blood glucose rise after a meal pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹ following a request in accordance with Article 19 of retained Regulation (EC) No 1924/2006¹, as amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020

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003UKNHCC

Requestor

PepsiCo International

UKNHCC members

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Declarations of interest

Read the [UKNHCC register of interests](#) containing all declarations of interests made by members.

UKNHCC secretariat

Adrienne Cullum, Jennifer Garry and Celia Sabry-Grant

¹ 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.

Official observers²

Sarah Clarke (Welsh Government), Chika Edeh (Food Standards Scotland), Elliott Dews (Food Standards Agency Northern Ireland) and Margie Van Dijk (Department of Health and Social Care)

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UKNHCC (United Kingdom Nutrition and Health Claims Committee) 2024. Scientific Opinion on the modification of the authorisation of a health claim related to beta-glucan from oats or barley and the reduction of the blood glucose rise after a meal pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹ following a request in accordance with Article 19 of retained Regulation (EC) No 1924/2006¹, as amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020.

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UKNHCC disclaimer

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of beta-glucan from oats or barley, a positive assessment of its safety, nor a decision on whether beta-glucan from oats or barley is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of retained Regulation (EC) No 1924/2006¹ as amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of retained Regulation (EC) No 1924/2006¹ as amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020.

Claim type

Article 19: Modification of an existing health claim authorisation

Process undertaken by the UKNHCC

- The application was received by the UK Nutrition and Health Claims Committee (UKNHCC) on 20 March 2024 at which point the scientific evaluation process started
- On 18 April 2024, the scientific evaluation was suspended following the ‘stop the clock’ process to request additional information from the applicant

² The [UKNHCC code of practice](#) states that Official observers attend UKNHCC meetings to provide updates from their respective nations on science and policy matters of relevance whilst respecting UKNHCC independence.

- On 8 May 2024, the UKNHCC received additional information and the scientific evaluation was restarted, in compliance with Article 16(1) of Regulation (EC) No 1924/2006¹
- During its meetings on 21 May and 10 June 2024, the UKNHCC evaluated the evidence submitted by the applicant
- During its meeting on 9 July 2024, the UKNHCC discussed the draft scientific opinion
- Following the meeting, the final scientific opinion was agreed via email correspondence and a drafting meeting held on 30 July 2024.

Summary

An application from PepsiCo International was submitted for authorisation of a health claim pursuant to Article 19 of retained Regulation (EC) No 1924/2006¹ as amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 via the Competent Authority of Great Britain. The United Kingdom Nutrition and Health Claims Committee (UKNHCC) was asked to deliver an opinion on the modification of the authorisation of a health claim related to “Consumption of beta-glucans from oats or barley contributes to the reduction of the glucose rise after a meal”, pursuant to Article 13(1) of Regulation (EC) No 1924/2006.

The scope of the application was proposed to fall under a modification of an existing authorised health claim.

The requested modification of the existing health claim was to lower the dose required to obtain the claimed effect from 4grams (g) to “at least 2g of beta-glucan from oats or barley for each 30g of available carbohydrates should be consumed per meal as part of a meal or as a food”.

The food that is the subject of the health claim is beta-glucans from either oat or barley naturally present in food or isolated beta-glucan. Beta-glucans are soluble cereal fibres found primarily in oats and barley. They comprise a heterogenous group of polymers found in soluble non-starch polysaccharides and are collectively referred to as beta-glucan.

The Committee considers that the food, beta-glucan from oat or barley from all sources, is sufficiently characterised in relation to the proposed claimed effect.

The claimed effect proposed by the applicant is the reduction of post-prandial glycaemic response. The target population is individuals who wish to reduce their post-prandial glycaemic responses.

The Committee assessed each of the 27 studies presented by the applicant as pertinent to the claim in relation to the following criteria: dose, suitability of comparator and outcomes. A risk of bias assessment was conducted on studies that the Committee considered pertinent to the claim. The Committee also considered meta-analyses identified by the applicant.

Sixteen of the 27 studies are considered pertinent, and the dose provided by these studies ranges from 0.89g to 1.92g beta-glucan per 30g available carbohydrate (avCHO). Eleven studies that used a dose of more than 2g beta-glucan per 30g avCHO were not considered further.

In weighing the evidence, the Committee notes there are no studies that have a low risk of bias, report an insulin response, and report consistent findings across outcome measures. Furthermore, there is insufficient evidence on the lack of adverse impact on insulin, which is stated as a requirement in the European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies (NDA) guidance (EFSA Panel on Dietetic Products & Allergies, 2012). The Committee concludes that the totality of evidence submitted is insufficient to show consistency and effectiveness at doses less than or equal to (\leq) 2g beta-glucan per 30g avCHO across different types and sources of beta-glucan (types such as instant or steel cut oats and sources such as barley isolate or concentrate).

Given the range of issues identified in the pertinent studies, the Committee agrees that the evidence is insufficient to demonstrate a cause-and-effect relationship between beta-glucan (across different types and sources) and reduction of post-prandial glycaemic response at doses \leq 2g per 30g avCHO.

Information provided by the applicant

Applicant name and address

PepsiCo International, 450 South Oak Way, RG2 6UW, Reading, United Kingdom

Food/constituent as stated by the applicant

“The food that is the subject of the health claim is beta-glucan from oats or barley naturally present in food and to isolated beta-glucan”

Health relationship as claimed by the applicant

According to the applicant, “In 2011, EFSA acknowledged that intervention studies in healthy subjects consistently show that oat and barley beta-glucans show an effect in decreasing post-prandial glycaemic responses, without disproportionately increasing post-prandial insulinaemic responses. In order to obtain the claimed effect, 4g of beta-glucans from oats or barley for each 30g of avCHO should be consumed per meal (EFSA Panel on Dietetic Products 2011), however, not at a lower dosage”.

Wording of the health claim as proposed by the applicant

“Consumption of beta-glucans from oats or barley contributes to the reduction of the glucose rise after a meal”.

Specific conditions of use as proposed by the applicant

“In order to obtain the claimed effect, at least 2g of beta-glucans from oats or barley for each 30g of available carbohydrates should be consumed per meal as part of a meal or as a food. The target population is individuals who wish to reduce their post-prandial glycaemic responses”.

Documentation provided

Health claim application for a modification of an existing claim on beta-glucans from oats or barley and reduced glucose rise after a meal pursuant to Article 19 of retained Regulation (EC) No 1924/2006¹, as amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020. Application ID: 003UKNHCC. Submitted by PepsiCo International.

Assessment

1. Characterisation of the food/constituent

- 1.1. Beta-glucans are soluble cereal fibres found primarily in oats and barley. They comprise a heterogeneous group of polymers found in soluble non-starch polysaccharides and are collectively referred to as beta-glucan.
- 1.2. Upon request from the UKNHCC, the applicant was asked to provide additional information via the stop the clock process on the characterisation of the food. The applicant confirmed that the food that is the subject of the claim is beta-glucan (single constituent) naturally present in food and isolated beta-glucan with a molecular weight from 50 to 3,000 kilodaltons.
- 1.3. The applicant provided a brief overview of the manufacturing process, however no quality system, such as, a good manufacturing process, was indicated.
- 1.4. The Committee considers that the food, beta-glucan from oats and barley, which are the subject of the health claim, are sufficiently characterised in relation to the proposed claimed effect.

2. Relevance of the claimed effect to human health

- 2.1. The claimed effect proposed by the applicant is the reduction of post-prandial glycaemic response. The target population proposed by the applicant is individuals who wish to reduce their post-prandial glycaemic responses.
- 2.2. The applicant proposed that at least 2g of beta-glucan from oats or barley per 30g available carbohydrates (avCHO) should be consumed to achieve the claimed effect.
- 2.3. The applicant noted that the European Food Safety Authority (EFSA) had previously stated that the reduction of post-prandial glycaemic response can be considered a beneficial physiological effect to subjects with, for example, impaired glucose tolerance which is common in the general adult population (EFSA Panel on Dietetic Products & Allergies, 2012).

- 2.4. The applicant noted relevant EFSA guidance that “the scientific evidence for the substantiation of health claims on the reduction of post-prandial blood glucose responses can be obtained from human intervention studies showing a decrease in blood glucose concentrations at different time points after consumption of the test food during an appropriate period of time and no increase in insulin concentrations in comparison to the reference food” (EFSA Panel on Dietetic Products & Allergies, 2012).
- 2.5. The applicant proposed changes in blood glucose concentrations at different time points (assessed using incremental area under the curve (iAUC) test vs reference meals) and no increase in insulin concentrations in comparison to the reference food, as the outcome measure for post-prandial glycaemic response, together with the incremental postprandial glycaemic peak.
- 2.6. The Committee considers a decrease in area under the curve (AUC) or iAUC for blood glucose, as well as peak blood glucose, with no increase in insulin concentration in comparison to the reference food as suitable outcome measures for the scientific substantiation of claims related to glucose response after a meal.
- 2.7. The Committee notes that a reduction of post-prandial glycaemic response (as long as post-prandial insulinaemic responses are not increased) is a beneficial physiological effect for the general population.

3. Scientific substantiation of the claimed effect

- 3.1. The scientific risk assessment was conducted in line with the [UKNHCC Framework for the evaluation of evidence submitted for the substantiation of nutrition and health claims](#) (UKNHCC, 2023).
- 3.2. Upon request from the UKNHCC, the applicant was asked to provide additional information via the stop the clock process on the following areas:
- characterisation of the food
 - clarity on the proposed wording to amend the existing claim and conditions of use
 - pertinent scientific data for the substantiation of the claim and conditions of use
- 3.3. In assessing the application, the Committee agreed that the claim relates to all preparations of beta-glucan from oats and barley, both naturally present and isolated beta-glucan.
- 3.4. The applicant performed literature searches in databases PubMed and the Cochrane Library. The date of the literature searches was not provided. The applicant used the following search terms and syntax:

- oat
- AND barley
- AND (beta-glucan OR b-glucan)
- AND (post-prandial OR postprandial)
- AND (glucose OR glyce^mi* OR glycaemi*).

The search was limited to studies undertaken in humans and articles published in English. The inclusion and exclusion criteria applied to select the pertinent publications were reported. The applicant included randomised controlled trials of acute duration that used oat and barley beta-glucan from a variety of sources. Outcome measures included postprandial glucose and insulin response reported as AUC. Peak glucose rise was also assessed as a secondary ‘parameter.’

- 3.5. The applicant identified a total of 27 publications as being pertinent to the proposed claim. The Committee assessed each of the 27 studies presented by the applicant as pertinent to the claim in relation to dose, suitability of comparator and outcomes. A risk of bias assessment was conducted on studies that the Committee assessed as pertinent to the claim.
- 3.6. The Committee reviewed the 8 meta-analyses identified by the applicant (AbuMweis et al, 2016, Henrion et al, 2019, Musa-Veloso et al, 2021, Noronha et al, 2023, Tiwari & Cummins, 2011, Tosh, 2013, Tosh & Bordenave, 2020, Zurbau et al, 2021), and the primary data on which they are based, to assess the pertinence to the claim of the included studies.
- 3.7. The applicant stated that “In order to obtain the claimed effect, at least 2g of beta-glucans from oats or barley for each 30g of available carbohydrates should be consumed”. Consequently, the Committee deemed that an effect should be shown in study arms with ≤ 2 g to be consistent with the proposed claim. To assess the scientific literature, this means that only studies reporting on intervention meals providing ≤ 2 g beta-glucan per 30g avCHO could be considered pertinent. As such, studies including intervention meals with greater than (>) 2g beta glucan per 30g avCHO were not considered pertinent.
- 3.8. The Committee agreed glucose was not a suitable comparator. The Committee agreed pertinent comparators were only those that contained similar levels of macronutrients to the test food, avCHO, fat and protein (where reported).
- 3.9. A reduction in post-prandial glycaemic response is considered a beneficial physiological effect. Suitable outcome measures were blood glucose concentrations at different time points or peak blood glucose. The Committee noted that:

- the response should be sufficient to demonstrate an effect on AUC or iAUC glucose response or peak glucose, and there should be a level of consistency when both are reported
- there should be no increase in insulin concentrations in comparison to the reference food or meal, which aligns with guidance on the scientific requirements for health claims on the reduction of post-prandial blood glucose concentrations (EFSA Panel on Dietetic Products & Allergies, 2012)

3.10. Risk of bias (ROB) analysis (based on Cochrane ROB2 for crossover trials) was undertaken for all studies which the Committee agreed as pertinent. The Committee took this into account and the assessment is included in the annex. The Committee considers 16 out of the 27 studies submitted as pertinent and a formal risk of bias analysis was undertaken on these (Cavallero et al, 2002; Östman et al, 2006; Poppitt et al, 2007; Granfeldt et al, 2008; Regand et al, 2009; Thondre & Henry, 2009; Chillo et al, 2011; Paquin et al, 2013; Lindström et al, 2015; Ekström et al, 2017; Wolever et al, 2018; Rieder et al, 2019; Wolever et al, 2019; Wolever et al, 2020; Zhu et al, 2020). The eleven remaining studies used a dose of >2g beta-glucan per 30g avCHO and were not considered further (Holm et al, 1992; Yokoyama et al, 1997; Casiraghi et al, 2006; Panahi et al, 2007; Alminger & Eklund-Jonsson, 2008; Granfeldt et al, 2008; Thondre & Henry, 2011; Finocchiaro et al, 2012; Kwong et al, 2013a; Kwong et al, 2013b; Hartvigsen et al, 2014).

3.11. The studies the Committee considered pertinent are shown in the annex. The Committee noted that without appropriate meta-analysis of these studies, the assessment of pertinent studies relied solely on the p values and confidence intervals (CI) reported for each of the individual studies.

3.12. The Committee took account of sample size together with risk of bias when weighing the evidence. Further details are provided in the annex. The Committee noted that 6 of the pertinent studies had a small sample size ($n \leq 10$ participants) and therefore were likely to have low power (as indicated by the wide CI). The Committee therefore found it difficult to draw conclusions from the findings of these small studies; one of these studies (Zhu et al, 2020) showed a significant effect for iAUC and peak glucose (at 1.86g beta-glucan per 30g avCHO), and the other 5 studies reported no effect. The Committee noted that 7 out of 16 studies included between 11 and 20 participants and the remainder (3 out of 16) included between 21 and 40 participants.

3.13. The Committee also noted that 9 of the 16 pertinent studies did not report on insulin response, limiting the evidence available by which to assess whether there was any increase in insulin responses in comparison to the reference food or meal, see annex.

- 3.14. The risk of bias assessment for pertinent studies is shown in the annex. None of the studies were identified as being at low risk of bias; most studies were identified as having ‘some concerns’ (13 out of 16) and the remaining studies at high risk of bias (3 out of 16), see annex.
- 3.15. There were issues with overall reporting of the pertinent studies, including method of randomisation, blinding, missing outcome data, and balance of the reference meal for other nutrients such as protein and fat, leading to uncertainty in the risk of bias of many of these studies, see annex.
- 3.16. There were no registered protocols or trial registration for 12 out of 16 pertinent studies (Cavallero et al, 2002; Östman et al, 2006; Poppitt et al, 2007; Granfeldt et al, 2008; Regand et al, 2009; Thondre & Henry, 2009; Chillo et al, 2011; Paquin et al, 2013; Lindström et al, 2015; Ekström et al, 2017; Rieder et al, 2019) and the Committee considers there was uncertainty whether other outcome measures or subgroups were included in the trials, but not reported, see annex.
- 3.17. The Committee also noted that the meta-analyses identified by the applicant provided insufficient evidence of consistency of the dose-response and minimum effective dose across different types and sources (with varying molecular weights) of beta-glucan (Tiwari & Cummins, 2011; Tosh, 2013; AbuMweis et al, 2016; Henrion et al, 2019; Tosh & Bordenave, 2020; Musa-Veloso et al, 2021; Zurbau et al, 2021; Noronha et al, 2023). The Committee therefore considers there to be insufficient evidence on the dose-response relationship and minimum effective dose of the food or food constituent that is required to obtain the claimed effect in order to establish conditions of use.
- 3.18. There were 12 study arms (across 8 studies) that reported statistically significant reductions in post-prandial glycaemic response versus the comparator. The Committee noted that the effect of beta-glucan on post-prandial glycaemic response was smaller with lower doses, see annex. The dose used in pertinent studies ranged from 0.89g to 1.92g per 30g avCHO (based on extrapolated values, the absolute dose in grams differed between studies based on the amount of avCHO).
- 3.19. Of the 10 pertinent studies that reported both iAUC and peak glucose, 5 studies found statistically significant reductions for iAUC in at least one study arm and 6 studies found statistically significant reductions for peak glucose in at least one study arm. Three studies reported statistically significant findings for both. Of these 10 studies, 8 were identified as having ‘some concerns’ with the risk of bias and 2 studies at high risk of bias, see annex.
- 3.20. The largest sample sizes were in the 3 studies undertaken by Wolever (Wolever et al, 2018; Wolever et al, 2019; Wolever et al, 2020). The Committee noted that in all 3 studies the comparator (cream of rice) differed from the test

food, having a lower protein content (1.3g vs between 3.6g and 4.3g) and slightly lower fat content (0g vs approximately 2g). In the first study (Wolever et al, 2018), beta-glucan reduced the peak glucose response when given with instant oatmeal at doses of 1.27, 1.48 and 1.70g beta-glucan per 30g avCHO, but there was no evidence of a change in iAUC. Oat bran was included in the second and third meal, respectively. In the second study (Wolever et al, 2019), beta-glucan reduced the peak glucose response at a dose of 1.69g beta-glucan per 30g avCHO when given with old fashioned oats, 1.71g beta-glucan per 30g avCHO with steel cut oats, but a dose of 1.75g beta-glucan per 30g avCHO given with instant oats had no effect. There was a reduction in iAUC with the steel cut oats test meal but not with any of the other meals. In the third study (Wolever et al, 2020), authors reported a significant reduction in peak glucose with 1.17g beta-glucan per 30g avCHO given with instant oatmeal and oat bran, but no change in iAUC. Study details are provided in the annex.

4. Weighing the evidence

- 4.1. In weighing the evidence, the Committee took account of 16 studies that were considered pertinent. Of these, there were no studies that had a low risk of bias, reported an insulin response, and reported consistent findings across outcome measures.

- 4.2. Given the range of issues identified in the pertinent studies (the effect of dose, the effect of the composition across different types and sources of beta-glucan (types such as instant or steel cut oats, sources such as barley isolate or concentrate) and the potential lack of power in small sample studies), the Committee considers that there is insufficient evidence to demonstrate a cause-and-effect relationship between different preparations of beta-glucan and reduction of post-prandial glycaemic response at doses ≤ 2 g per 30g avCHO.

Conclusions

On the basis of the data presented by the applicant, the Committee concludes that:

- the food, beta-glucan from oats and barley from all sources, which are the subject of the health claim, are sufficiently characterised in relation to the proposed claimed effect
- a reduction in post-prandial glycaemic response is a beneficial physiological effect for the general population
- the evidence is insufficient to demonstrate a cause-and-effect relationship between beta-glucan (across different types and sources) and reduction of post-prandial glycaemic response at doses ≤ 2 g per 30g available carbohydrate

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Abbreviations

AUC/iAUC	Area under the curve/incremental AUC
avCHO	Available carbohydrate
CI	Confidence Intervals
EC	European Commission
EFSA	European Food Safety Authority
NDA	Panel on Dietetic Products, Nutrition and Allergies
UKNHCC	United Kingdom Nutrition and Health Claims Committee