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Beta-glucans from oats and/or barley in a ready-to-eat cereal manufactured *via* pressure cooking and reduction of blood-glucose rise after consumption: evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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Abstract

Following an application from Nestlé S.A. submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 *via* the Competent Authority of Belgium, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to beta-glucans from oats and/or barley in a ready-to-eat cereal manufactured *via* pressure cooking and reduction of blood glucose rise after consumption. The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The food proposed is 'beta-glucans from oats and/or barley incorporated into ready-to-eat breakfast cereals manufactured *via* pressure cooking'. The applicant proposed that at least 1.3 g of beta-glucans/ 25 g of available carbohydrates in ready-to-eat breakfast cereals manufactured *via* pressure cooking should be consumed. Beta-glucans from oats, barley or any combination thereof incorporated into ready-to-eat cereals manufactured by pressure cooking, are sufficiently characterised. The claimed effect proposed is 'reduction of the blood glucose rise after the meal'. The reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect. One human intervention study showed an effect of beta-glucans from oats and/or barley, incorporated into breakfast cereals manufactured *via* pressure cooking at a level of at least 1.2 g/25 g available carbohydrates, on decreasing post-prandial glycaemic responses without disproportionally increasing insulinaemic responses. Dose-response relationships were not tested, and no evidence has been provided that beta-glucans incorporated into cereals processed using pressure cooking would exert a higher effect on post-prandial glucose responses than beta-glucans added to other carbohydrate containing foods. Whereas the effect of beta-glucans in reducing post-prandial blood glucose responses is well established, the evidence provided is insufficient to establish such an effect at doses of 1.3 g beta-glucans per 25 g of available carbohydrate incorporated into ready-to-eat breakfast cereals manufactured *via* pressure cooking (i.e. either batch cooking or extrusion).

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1924/2006 harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health), which are based on newly developed scientific evidence or include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3). According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

1.2. Interpretation of the Terms of Reference

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: beta-glucans from oats and/or barley in a ready-to-eat breakfast cereal contribute to a reduction of the blood glucose rise after that meal.

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of beta-glucans from oats and/or barley in a ready-to-eat breakfast cereal, a positive assessment of its safety, nor a decision on whether beta-glucans from oats and/or barley in a ready-to-eat breakfast cereal is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

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 Regulation (EC) No 1924/2006.

2. Data and methodologies

2.1. Data

Information provided by the applicant

Food/constituent as stated by the applicant

According to the applicant, the food for which the health claim is made is 'beta-glucans sourced from oats and/or barley, incorporated into ready-to-eat breakfast cereals manufactured *via* pressure cooking (i.e. either by batch cooking or extrusion), and present at a level of at least 1.3 g per 25 g available carbohydrate in the ready-to-eat cereal'.

Health relationship as claimed by the applicant

According to the applicant, the health effect is related to 'reduction of the blood glucose rise after the meal'.

Mechanism by which the food/constituent could exert the claimed effect as proposed by the applicant

The applicant claims that 'the mechanism by which beta-glucans from oats or barley could exert the claimed effect is well established and relates to the increased viscosity of the meal bolus when beta-glucans are added. When the meal bolus reaches the small intestine, a high viscosity delays the rate of absorption of nutrients, including glucose. Ready-to-eat cereals that are manufactured *via* pressurised batch cooking or extrusion, and containing oat or barley beta-glucans, are associated with increased beta-glucan extractability and increased viscosity, both of which are postulated to have a

greater effect on lowering the postprandial glucose response than the oat or barley ingredients themselves (i.e. not incorporated into the batch-cooked or extruded cereals).'

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: 'consumption of beta-glucans from oats and/or barley in a ready-to-eat breakfast cereal contributes to a reduction of the blood glucose rise after that meal'.

Specific conditions of use as proposed by the applicant

According to the applicant, the target population for the intended health claim is the general population. The quantity of at least 1.3 g per 25 g available carbohydrates is recommended. The quantity of beta-glucans can easily be integrated into one breakfast cereal serving. One serving of cereal generally falls within the range of between 30 and 45 g.

Data provided by the applicant

The health claim application pursuant to Article 13.5 of Regulation 1924/2006 was presented in a common and structured format as outlined in the Scientific and technical guidance for the preparation and presentation of applications for authorisation of health claims (EFSA NDA Panel, 2016).

As outlined in the General guidance for stakeholders on health claim applications, it is the responsibility of the applicant to provide the totality of the available evidence.

2.2. Methodologies

The general approach of the NDA Panel for the evaluation of health claim applications is outlined in the EFSA General guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016).

The scientific requirements for health claims related to appetite ratings, weight management and blood glucose concentrations are outlined in a specific EFSA guidance (EFSA NDA Panel, 2012).

The data claimed as proprietary are: unpublished clinical Study Reports: SUGiRS, 2018 (unpublished) and SUGiRS, 2019 (unpublished), and unpublished In Vitro Study Report Hyytiäinen-Pabst et al., 2019 (unpublished).

The data claimed as confidential are: In SUGiRS, (2018 unpublished) study report: table 1 p.6, Results pp. 11-20, conclusions pp. 21-22; Appendices B-F. In SUGiRS (2019, unpublished) study report: table 1 p. 5; results pp. 11-15; interpretation of findings p. 16; Appendices B-F; Report #1912a: Table 1 p. 5; Results pp. 11-15; Interpretation of findings p. 16; Appendices B-F. EFSA has issued its Decision on Confidentiality on 17/12/2020.

3. Assessment

The approach used by the NDA Panel for the evaluation of health claims is explained in the General scientific guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016). In assessing each specific food/health relationship, which forms the basis of a health claim the NDA Panel considers the following key questions:

- i) the food/constituent is defined and characterised;
- ii) the claimed effect is based on the essentiality of a nutrient; or the claimed effect is defined and is a beneficial physiological effect for the target population and can be measured *in vivo* in humans;
- iii) a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use).

Each of these three questions needs to be assessed by the NDA Panel with a favourable outcome for a claim to be substantiated. In addition, an unfavourable outcome of the assessment of questions (i) and/or (ii) precludes the scientific assessment of question (iii).

3.1. Characterisation of the food/constituent

The food/constituent proposed by the applicant as the subject of the health claim is 'beta-glucans sourced from oats and/or barley, incorporated into ready-to-eat breakfast cereals manufactured *via* pressure cooking (i.e. either by batch cooking or extrusion), and present at a level of at least 1.3 g per 25 g available carbohydrate in the ready-to-eat cereal'.

Beta-glucans are non-starch polysaccharides composed of glucose molecules in long linear glucose polymers with mixed β -(1 $\rightarrow$ 4) and β -(1 $\rightarrow$ 3) links. Their molecular weight varies from 50 to 2,000 kDa. Beta-glucans occur naturally in the bran of cereal grasses such as barley (ca. 7%), oats (ca. 5%), rye and wheat (1–2%), and are measurable in foods by established methods. The mixed linkages are important for their physical properties, such as solubility and viscosity. Their viscosity is a function of the concentration of dissolved beta-glucans, of their molecular weight (Wood et al., 2000), and further depends on differences in raw materials, processing and methods of determination.

In 2011, the EFSA NDA Panel evaluated a health claim on beta-glucans from oats and barley and reduction of post-prandial glycaemic responses pursuant to Article 13(1) of Regulation (EC) No 1924/2006 with a favourable outcome (EFSA NDA Panel, 2011). The Panel considered that, in order to obtain the claimed effect, 4 g of beta-glucans from oats or barley for each 30 g of available carbohydrate should be consumed per meal.

In the present application, the applicant proposes that at least 1.3 g of beta-glucans per 25 g of available carbohydrates in ready-to-eat breakfast cereals manufactured via pressure cooking (i.e. either by batch cooking or extrusion) should be consumed in order to obtain the claimed effect. The applicant claims that the reason for the lower amount of beta-glucans needed to exert the claimed effect relative to the amount of available carbohydrates consumed is due to the manufacturing process (i.e. the pressure cooking) of these ready-to-eat breakfast cereals.

Regarding the manufacturing process of the ready-to-eat breakfast cereals, batch cooking involves the application of steam injected into a closed, pressurised vessel. Depending on the type of cereal, the cooking time can range from 30 min to 2 h. Once the grains are cooked, the dough mixture is shaped, dried and toasted to produce the finished cereal product. In contrast, for cereals prepared by extrusion, the mixed ingredients are forced through a die and then cut into specific shapes; thus, extrusion cooking involves subjecting the grain mixture to high pressure and high shear conditions, at high temperature for just a short period of time. An overview of the manufacturing process and information regarding stability of batches was provided by the applicant.

Upon a request from EFSA, the applicant clarified that the food constituent proposed as the subject of the claim is beta-glucans from oats, barley or any combination thereof.

The Panel considers that the food constituent, beta-glucans from oats, barley or any combination thereof, incorporated into ready-to-eat cereals manufactured by pressure cooking, which is the subject of the health claim, is sufficiently characterised.

3.2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is 'reduction of the blood glucose rise after the meal'. The proposed target population is the general population.

Claims on the reduction of post-prandial blood glucose responses refer to the ability of a food/constituent to reduce the blood glucose rise after consumption of a food or meal rich in digestible carbohydrates (i.e. in comparison to a reference food or meal). This ability may be considered a beneficial physiological effect (e.g. for subjects with impaired glucose tolerance) as long as insulin responses are not disproportionally increased.

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 (i.e. at least 2 h) and no increase in insulin concentrations in comparison to the reference food (EFSA NDA Panel, 2012).

The Panel considers that the reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.

3.3. Scientific substantiation of the claimed effect

The applicant performed a literature search on 29 April 2019 in the following databases: Adis Clinical Trials Insight, Allied & Complementary Medicine[™], BIOSIS Previews[®], CAB ABSTRACTS, Embase[®], Foodline[®]: Science, FSTA[®], MEDLINE[®] and NTIS: National Technical Information Service. Keywords used for the exposure were 'oat* or barley or beta-glucan or beta glucan or β -glucan or β glucan' and terms related to outcome were 'glycemi* or glycaemi* or glucose or post-prandial or post prandial or postprandial or post-meal or post meal'. The main exclusion criteria were: the food

constituent studied was not beta-glucans derived from oats and/or barley; the investigational product was not administered orally (i.e. it was not consumed); the amount of beta-glucans administered was not reported and could not be calculated from information provided in the manuscript; the amount of beta-glucans administered in the test meal was greater than or equal to 4 g per 30 g available carbohydrates; the food matrix was not a ready-to-eat breakfast cereal manufactured *via* pressure cooking (i.e. either batch cooking or extrusion); the outcome measures were not related to post-prandial glucose and insulin responses; the independent effects of the oat or barley beta-glucans could not be determined; and the amount of available carbohydrates in the active and control test meals differed by more than 15% or was not reported.

No limitations were placed on the literature search with respect to the publication date or language.

No pertinent human intervention studies were retrieved by the search. The applicant submitted two unpublished human intervention studies as pertinent to the health claim (SUGiRS, 2018 unpublished and SUGiRS, 2019, unpublished). Both studies were conducted by the same research group in Australia at the Sydney University's Glycaemic Index Research Service (SUGiRS).

In a one-centre, randomised, double-blind, cross-over, placebo-controlled, positive-controlled study (SUGiRS 2018, unpublished and claimed as proprietary by the applicant), post-prandial blood glucose and insulin concentrations were measured over a 2-h period in 15 subjects. The study was conducted using an internationally recognised glycaemic index methodology (Joint FAO/WHO Report, 1998, International Standard[®]; ISO/FDIS 26642:2010). Upon a request from EFSA on the reasons for the enrolment of 15 participants in the study rather than 10, a number usually used in glycaemic index studies, the applicant clarified that a higher number of participants were recruited to account for the inter- and intra-individual variability in glucose responses and attrition.

Non-smoking subjects with normal body mass index (BMI; 18–25 kg/m²) of both sexes, aged 25–60 years were recruited from the staff and student population of the research centre. Non-inclusion criteria were dieting, impaired glucose tolerance, suffering from any illness or food allergy and regular use of prescription medication other than standard contraceptive medication.

Six batch-cooked and two extruded products were tested. These included six batch-cooked ready-to-eat breakfast cereals with no or added beta-glucans from oats ($n = 3$; at doses of 0, 1.2 and 1.6 g of added beta-glucans per 25 g of available carbohydrates) or barley ($n = 3$; at doses of 0.8, 0.9 and 1.4 g of added beta-glucans per 25 g of available carbohydrates). In addition, two extruded breakfast cereals with beta-glucans from oats at doses of 0 and 1.2 g per 25 g of available carbohydrates, respectively, were tested. All products were consumed with 250 mL of water. Pure glucose (25.7 g) dissolved in water was used as the reference food and was consumed by each participant on three separate occasions.

Participants were assigned a randomisation number in chronological order of inclusion from the randomisation list.

Glucose was consumed on the first, sixth and 11th test sessions, and the eight breakfast cereals were consumed in random order in between. Each test session was completed on a separate morning with at least one day between sessions. The applicant was asked to clarify whether the washout period between two consecutive tests was adequate to minimise the impact of the previous test session on the results of the next session. In response, the applicant submitted the study by Mettler et al. (2009) showing that the incremental areas under the curve (iAUC)_{0-120min} of blood glucose concentrations did not differ significantly between the short and long intervals (consecutive days and 5- to 10-day intervals, respectively) and that the variability of the blood glucose iAUC_{0-120min} was not influenced by the time span between the tests.

Study participants and investigators were blinded to the composition of the test products throughout the study (including data collection and analysis). Within a given study, test foods had almost identical appearance, so it was not possible for participants or investigators to detect differences between the test products by sight. Upon a request from EFSA, the applicant clarified that researchers preparing the test portions were blinded to the composition of the test products and the potential differences between the cereals. The applicant also clarified that even if the participants could detect differences in textures and taste between the test products, this should not have influenced the results as the order of the visits was randomised and the endpoints measured were assessed using objective methods.

During each test session, blood glucose and insulin concentrations were measured eight times over 2 h (twice at baseline, and once at 15, 30, 45, 60, 90 and 120 min) after consuming the meals. Blood glucose concentrations were analysed in duplicate using a glucose hexokinase enzymatic assay and an automatic centrifugal spectrophotometric clinical chemistry analyser. Serum insulin concentrations were

analysed using a commercial insulin sandwich type enzyme-linked immunoassay. The iAUC of plasma glucose and insulin responses were calculated, with fasting levels as baselines. Dietary, exercise, medication and lifestyle habits of the participants were assessed at each study visit to ensure that participants maintained their usual dietary and lifestyle habits throughout the study duration.

The primary outcome of the study was to establish the glycaemic index (GI) and the insulinaemic index (II) of the eight breakfast cereals tested using glucose as reference. The secondary objective was to compare the glycaemic and insulinaemic responses (iAUC) to the consumption of the eight breakfast cereals differing in the manufacturing process and in the amount of beta-glucans added. Additionally, peak plasma glucose ($C_{\max}$) and maximum glucose concentration time ($T_{\max}$) were measured.

For the statistical analyses of the glycaemic and insulinaemic responses (iAUC), two different data sets were created. The first included data for batch-cooked cereals (containing 0, 0.8, 0.9, 1.2, 1.4 and 1.6 g of beta-glucans) and for the glucose solution. The second included data for the two extruded breakfast cereals (containing 0 and 1.2 g of beta-glucans) and for the glucose solution. Paired t-tests comparing the study endpoints for each type of cereal containing beta-glucans against the same type of cereal without beta-glucans and against the glucose solution were performed. No adjustment for multiple comparisons was presented in the study report. Upon a request from EFSA, the applicant provided a re-analysis adjusting the results for multiple comparisons using the Benjamini–Hochberg procedure controlling for the false discovery rate. The main analysis was performed on a per protocol (PP) basis. The PP set featured all subjects who tested all products and who were not considered as outliers for the glucose or insulin iAUC for any of the tested products. Outlier response was defined as a value more than $\pm$ two standard deviations (SD) from the group mean value.

All 15 participants recruited (age 33.8 years, range: 25.2–53.8 years, BMI 23.2 kg/m², 18.5–24.9 kg/m²) completed the study. For batch-cooked cereals, the results for one participant regarding glucose response at the test with 0.9 g of beta-glucans per 25 g of available carbohydrates was classified as an outlier (i.e. had a glucose response $\pm$ 2 SD from the mean). For extruded cereals, the results of another participant regarding the insulin response to the extruded cereal without added beta-glucans was classified as outlier (i.e. had an insulin response $> +2$ SD from the mean). These subjects were not considered in the PP analysis. Hence, the PP population included 14 participants for the analyses on batch-cooked cereals and 14 participants for the analyses on extruded cereals for all outcomes (i.e. glucose and insulin iAUC).

The results adjusted for multiple comparisons showed significantly lower blood glucose and insulin concentrations (iAUC) following consumption of the two types of breakfast cereals with added beta-glucans as compared to the same type of breakfast cereals with no added beta-glucans. Exceptions were the batch-cooked cereal with 0.9 g beta-glucans for glucose iAUC and the batch-cooked cereal with 0.8 g beta-glucans for insulin iAUC. The Panel notes that, although the study was planned as dose–response study at least in relation to the content of beta-glucans in batch-cooked breakfast cereals, dose–response relationships were not assessed.

The Panel considers that this study shows an effect of beta-glucans from oats and/or barley incorporated into ready-to-eat breakfast cereals manufactured *via* pressure cooking at a level of at least 1.2 g per 25 g of available carbohydrates on decreasing post-prandial glycaemic responses, without disproportionately increasing post-prandial insulinaemic responses. The Panel notes that the effect was not consistent at doses of beta-glucans < 1.2 g per 25 g of available carbohydrates and that dose–response relationships between the intake of beta-glucans and post-prandial glycaemic responses were not tested.

SUGiRS (2019, unpublished and claimed as proprietary by the applicant) is a one-centre, randomised, double-blind, cross-over, placebo-controlled, positive-controlled study, which investigated the effects of four ready-to-eat breakfast cereals with oat beta-glucans on post-prandial blood glucose and insulinaemic responses over a 2-h period. The study was carried out in the same research centre as the previous study (SUGiRS, 2018, unpublished) and had a similar design, including the same inclusion and non-inclusion criteria for participation and the same methods used for the measurements of glucose and insulin concentrations in blood.

Three batch-cooked and three extruded ready-to-eat breakfast cereals, were tested with 125 mL of milk and each meal contained 0g, 1.0g and 1.3g of oat beta-glucans per 25g of total available carbohydrate. All foods were consumed with 250 mL of water on eight separate sessions: four with the cereals with added beta-glucans and four with the cereals with no added beta-glucans.

The applicant provided data in relation to the content of available carbohydrates in all the cereal meals (breakfast cereals plus 125 mL of low-fat milk) tested. The amount of available carbohydrates was 28.9 g, 26.9 g and 25.6 g in the batch-cooked cereals containing 0 g, 1.0 g and 1.3 g of beta-glucans, respectively, and 28.2 g, 25.6 g and 24.9 g in the extruded cereals containing 0 g, 1.0 g and 1.3 g of beta-glucans, respectively. The Panel notes that the amount of available carbohydrates in the cereals is inversely proportional to the amount of beta-glucans they contain. Thus, it is not possible to assess whether differences in glucose and insulin responses following the consumption of the cereals could be attributed to differences in the content of beta-glucans, to differences in the amount of available carbohydrates, or to a combination of these.

Upon a request from EFSA, the applicant also clarified that randomisation considered only the cereals containing beta-glucans, but not the cereals without beta-glucans, which were tested twice each (i.e. at the beginning and end of each study period).

The Panel considers that no conclusions can be drawn from this study with respect to the dose of beta-glucans in breakfast cereals manufactured *via* pressure cooking (i.e. either batch cooking or extrusion) that is required to exert the claimed effect for a given amount of available carbohydrates. This is because it is not possible to assess whether differences in glucose and insulin responses following consumption of the ready-to-eat breakfast cereals could be attributed to differences in the content of beta-glucans, to differences in the amount of available carbohydrates or to a combination of these, and to which extent. The Panel also notes that the order in which control foods were tested was not randomised.

The Panel considers that one human intervention study (SUGiRS, 2018, unpublished) shows an effect of beta-glucans from oats and/or barley, incorporated into ready-to-eat breakfast cereals manufactured *via* pressure cooking (i.e. either batch cooking or extrusion) at a level of at least 1.2 g per 25 g available carbohydrate, on decreasing post-prandial glycaemic responses without disproportionately increasing post-prandial insulinaemic responses. The Panel notes that the results of the study by SUGiRS (2018, unpublished) have not been confirmed by other research groups.

Mechanism of action proposed

The applicant claims that the physiological effects of beta-glucans have largely been attributed to their viscosity generating properties within the gastrointestinal tract and that the manufacturing processes and cooking techniques can induce structural changes to beta-glucans and alter their viscosity properties, which in turn could influence their effects on the glycaemic response (Henrion et al., 2019).

The applicant provided a report (Hyytiäinen-Pabst et al., 2019 unpublished, claimed as proprietary by the applicant) in which an *in vitro* model of the upper gastrointestinal tract was used to investigate the physico-chemical properties of beta-glucans in processed cereal samples and in raw materials used in the manufacture of these processed cereals. The processed cereals tested included the batch-cooked and extruded cereals investigated in the SUGiRS 2018 study, but also porridges and granola-type cereals. The Panel notes that the total amount of beta-glucans in the test samples varied widely across raw materials and processed cereals. To produce 'physiological extracts', samples were incubated in simulated salivary fluid (pH 7.0) (oral phase), followed by simulated gastric fluid (pH 3.0) together with pepsin (gastric phase) and lastly in simulated intestinal fluid (pH 7.0) with porcine bile extract, pancreatin and additional lipase from porcine pancreas (duodenal phase). The percentage of beta-glucans that could be extracted from processed cereal products of all types into the 'physiological extract' was higher than the percentage of extractable beta-glucans from their non-processed raw materials. Viscosity of the 'physiological extracts' obtained from the processed cereals with added oats or barley beta-glucans was measured after removing insoluble particles by centrifugation in the supernatant and compared with the viscosity of 'physiological extracts' obtained from the same processed cereals without added beta-glucans. The viscosity in the supernatant was higher for the batch-cooked and extruded cereals with added oats or barley beta-glucans than for the ones without beta-glucans. The viscosity in the supernatant from the granola-type cereal with oat beta-glucans was higher than the one from granola-type cereal without beta-glucans; the difference was less pronounced for barley beta-glucans. There was no difference in the viscosity in the supernatants of porridge produced with and without beta-glucans.

The Panel considers that this study does not provide evidence that beta-glucans incorporated into ready-to-eat cereals processed using batch cooking or extrusion would exert a greater effect on the reduction of post-prandial glucose responses than beta-glucans added to other foods not manufactured *via* pressure cooking and containing similar amounts of available carbohydrate.

Weighing the evidence

In weighing the evidence, the Panel took into account that one human intervention study showed an effect of beta-glucans from oats and/or barley, incorporated into ready-to-eat breakfast cereals manufactured *via* pressure cooking (i.e. either batch cooking or extrusion) at a level of at least 1.2 g per 25 g available carbohydrate, on decreasing post-prandial glycaemic responses without disproportionally increasing post-prandial insulinaemic responses. However, the Panel also considered that only one study from which conclusions could be drawn is available, and that dose-response relationships between the concentration of beta-glucans in ready-to-eat breakfast cereals and post-prandial glucose responses were not tested. No evidence has been provided that beta-glucans incorporated into ready-to-eat cereals processed using pressure cooking would exert a higher effect on the reduction of post-prandial glucose responses than beta-glucans added to other carbohydrate containing foods (i.e. and thus that the dose of beta-glucans required to exert the claim effect per a given amount of digestible carbohydrates would be lower).

The Panel concludes that, whereas the effect of beta-glucans in reducing post-prandial blood glucose responses is well established, the evidence provided is insufficient to establish such an effect at doses of 1.3 g beta-glucans per 25 g of available carbohydrate incorporated into ready-to-eat breakfast cereals manufactured *via* pressure cooking (i.e. either batch cooking or extrusion), as requested by the applicant.

Conclusions

On the basis of the data presented, the Panel concludes that:

- The food/constituent, beta-glucans from oats, barley or any combination thereof, incorporated into ready-to-eat cereals manufactured by pressure cooking, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is 'reduction of the blood glucose rise after the meal'. The target population proposed by the applicant is the general population. Reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.
- The effect of beta-glucans in reducing post-prandial blood glucose responses is well established. However, the evidence provided is insufficient to establish an effect on reduction of post-prandial glycaemic responses at doses of 1.3 g beta-glucans per 25 g of available carbohydrate incorporated into ready-to-eat breakfast cereals manufactured by pressure cooking (i.e. either batch cooking or extrusion), as requested by the applicant.

Documentation as provided to EFSA

Health claim application on beta-glucans from oats and/or barley in a ready-to-eat cereal manufactured *via* pressure cooking and reduction of blood glucose rise pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0497_BE). Submitted by Nestlé S.A., Avenue Nestlé 55 CH-1800 Vevey, Switzerland.

Steps taken by EFSA

- 1) This application was received by EFSA on 10/06/2020.
- 2) The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- 3) The scientific evaluation procedure started on 21/09/2020.
- 4) On 8/10/2020, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application. The scientific evaluation was suspended on 27/10/2020 and was restarted on 11/11/2020, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- 5) During its meeting on 25/02/2021, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to the consumption of beta-glucans from oats and/or barley in a ready-to-eat cereal manufactured *via* pressure cooking and reduction of blood glucose rise.

References

- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2011. Scientific Opinion on the substantiation of health claims related to beta-glucans from oats and barley and maintenance of normal blood LDL-cholesterol concentrations (ID 1236, 1299), increase in satiety leading to a reduction in energy intake (ID 851, 852), reduction of post-prandial glycaemic responses (ID 821, 824), and "digestive function" (ID 850) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2207, 21 pp. <https://doi.org/10.2903/j.efsa.2011.2207>
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2012. Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations. EFSA Journal 2012;10(3):2604, 11 pp. <https://doi.org/10.2903/j.efsa.2012.2604>
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016. General scientific guidance for stakeholders on health claim applications. EFSA Journal 2016;14(1):4367, 38 pp. <https://doi.org/10.2903/j.efsa.2016.4367>
- Henrion M, Francey C, Lê KA and Lamothe L, 2019. Cereal B-glucans: the impact of processing and how it affects physiological responses. *Nutrients*, 11, 1729–1742. <https://doi.org/10.3390/nu11081729>
- Hyytiäinen-Pabst T, Holopainen-Mantila U, Lille M and Mikkelsen A, 2019 [unpublished]. Dated: 6 November 2019. Prepared by VTT Technical Research Centre of Finland, Prilly Switz. Cereal Partners Worldwide (CPW S.A.), Prilly, Switz. Study Title: Physico-chemical characterization of beta glucans in raw and processed cereal samples. Customer Report: [Proprietary]. (VTT-CR-00803-19).
- International Standard®; ISO/FDIS 26642:2010. Food products – Determination of the glycaemic index (GI) and recommendation for food classification.
- Joint FAO/WHO Report. Carbohydrates in Human Nutrition. FAO Food and Nutrition, Paper 66. Rome: FAO, 1998.
- Mettler S, Steiner K and Colombani PC, 2009. Influence of test interval length on the variability of glycemic response tests. *European Journal of Clinical Nutrition*, 63, 1452–1454.
- SUGiRS, 2018 unpublished. Dated: May 2018. Prepared by University of Sydney, Sydney University's Glycemic Index Research Service (SUGiRS), Sydney, Australia for Cereal Partners Worldwide (CPW) [Nestlé, etc.], Lausanne, Switz. Study Title: A study to measure the glycemic index and insulinemic index values of eight breakfast cereal products: [Proprietary]. (Glycemic Index Research Report #1820a).
- SUGiRS, 2019 unpublished. Dated: February & March 2019. Prepared by University of Sydney, Sydney University's Glycemic Index Research Service (SUGiRS), Sydney, Australia for Cereal Partners Worldwide (CPW) [Nestlé, etc.], Lausanne, Switz. Study Title: A study to measure the postprandial glucose and insulin responses to three cereal with milk test meals: [Proprietary]. (Glycemic Index Research Reports #1904a, #1912a).
- Wood PJ, Beer MU and Butler G, 2000. Evaluation of role of concentration and molecular weight of oat beta-glucan in determining effect of viscosity on plasma glucose and insulin following an oral glucose load. *British Journal of Nutrition*, 84, 19–23.

Abbreviations

BMI	Body Mass Index
Cmax	peak plasma glucose
FAO	Food and Agriculture Organization of the United Nations
FDIS	Final Draft International Standard
GI	Glycaemic Index
iAUC	incremental Area Under the Curve
II	Insulinaemic Index
ISO	International Organization for Standardization
NDA	Panel on Nutrition, Novel Foods and Food Allergens
NTIS	National Technical Information Service
PP	Per Protocol
SD	Standard Deviation
SUGiRS	Sydney University's Glycaemic Index Research Service
Tmax	maximum glucose concentration time
WHO	World Health Organization