

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to non-digestible carbohydrates and a reduction of post-prandial glycaemic responses pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

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ABSTRACT

Following an application from Beneo-Orafti SA, Sensus BV and Cosucra-Groupe Warcoing SA, 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 Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to fructo-oligosaccharides (FOS) from inulin and a reduction of post-prandial glycaemic responses. Non-digestible carbohydrates including FOS are resistant to hydrolysis and absorption in the small intestine and do not contribute to post-prandial glycaemia. This opinion applies to non-digestible carbohydrates (e.g. non-starch polysaccharides, resistant oligosaccharides and resistant starch) which should replace sugars in foods or beverages in order to obtain the claimed effect. The Panel considers that the food constituent, non-digestible carbohydrates, which is the subject of the health claim, and the food constituent (i.e. sugars) that non-digestible carbohydrates should replace in foods or beverages, are both sufficiently characterised in relation to the claimed effect. The Panel considers that a reduction of post-prandial glycaemic responses might be a beneficial physiological effect. In weighing the evidence, the Panel took into account that consumption of non-digestible carbohydrates results in reduced post-prandial blood glucose (and insulinaemic) responses compared with the consumption of sugars on a weight-by-weight basis owing to the non-digestibility in the small intestine and to a decrease in the amount of available carbohydrates, and that the consumption of foods/drinks in which non-digestible carbohydrates replaced sugars induced lower post-prandial glycaemic and insulinaemic responses than sugar-containing foods/drinks. The Panel concludes that a cause and effect relationship has been established between the consumption of foods/beverages containing non-digestible carbohydrates instead of sugar and a reduction of post-prandial glycaemic responses as compared to sugar-containing foods/beverages.

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KEY WORDS

non-digestible carbohydrates, post-prandial glycaemic responses, health claims

¹ On request from the Competent Authority of Belgium following an application by Beneo-Orafti SA, Sensus BV and Cosucra-Groupe Warcoing SA, Question No EFSA-Q-2013-00615, adopted on 11 December 2013.

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SUMMARY

Following an application from Beneo-Orafti SA, Sensus BV and Cosucra-Groupe Warcoing SA, 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 Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to fructo-oligosaccharides (FOS) from inulin and a reduction of post-prandial glycaemic responses.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application included a request for the protection of proprietary data.

The food that is the subject of the health claim is fructo-oligosaccharides (FOS, oligofructose) obtained from chicory (*Cichorium intybus* L.) inulin, which should replace sugars (i.e. monosaccharides and disaccharides) in foods or beverages in order to obtain the claimed effect (i.e. reduction of post-prandial glycaemic responses). The Panel notes that the characteristic which is most relevant to the claimed effect is not unique to FOS but common to other non-digestible carbohydrates (e.g. non-starch polysaccharides, resistant oligosaccharides, resistant starch) because, similar to FOS, non-digestible carbohydrates are resistant to hydrolysis and absorption in the small intestine and do not contribute to post-prandial glycaemia. This opinion applies to non-digestible carbohydrates (e.g. non-starch polysaccharides, resistant oligosaccharides and resistant starch) which should replace sugars in foods or beverages in order to obtain the claimed effect. The Panel considers that the food constituent, non-digestible carbohydrates, which is the subject of the health claim, and the food constituent (i.e. sugars) that non-digestible carbohydrates should replace in foods or beverages, are both sufficiently characterised in relation to the claimed effect.

The claimed effect proposed by the applicant relates to the reduction of post-prandial blood glucose responses. The target population proposed by the applicant is the general population. The Panel considers that a reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) might be a beneficial physiological effect.

The applicant identified a total of three human intervention studies and three human mechanistic studies as being pertinent to the health claim.

One cross-over trial assessed the effects of test ice creams where the sucrose content was replaced by various sugar replacers on post-prandial blood glucose responses relative to a control ice-cream which contained sucrose. Consumption of the test ice creams elicited significantly lower glucose incremental area under the curve (iAUC) (with the exception of maltitol and maltitol/resistant dextrin containing ice-creams) than the sucrose-containing control ice cream.

A randomised cross-over trial assessed post-prandial glycaemic responses following consumption of a long chain inulin, “native” inulin, and two FOS-containing products. Relative to the glucose containing drink, glycaemic responses were significantly lower after consumption of long-chain inulin, “native” inulin and the two FOS-containing products.

One double-blind, randomised, cross-over study was carried out with a yoghurt with 20 % of the sucrose replaced by FOS derived from chicory inulin. Compared with the reference yoghurt, the glucose iAUC was significantly decreased following consumption of the sugar-reduced yoghurt. There was also a significant reduction in the peak blood glucose values and the insulin iAUC values, whereas no differences were reported for the peak insulin responses.

The three mechanistic studies addressed the non-digestibility of FOS in the human small intestine, which, according to the applicant, constitutes the underlying mechanism for the claimed effect.

It is well established that sugars increase post-prandial glycaemia. Non-digestible carbohydrates including FOS are resistant to hydrolysis and absorption in the small intestine and do not contribute to post-prandial glycaemia. The Panel considers that replacing sugars by any non-digestible carbohydrate (e.g. non-starch polysaccharides, resistant oligosaccharides and resistant starch) would contribute to the claimed effect, i.e. a reduction of post-prandial glycaemic responses.

In weighing the evidence, the Panel took into account that consumption of non-digestible carbohydrates results in reduced post-prandial blood glucose (and insulinaemic) responses compared with the consumption of sugars on a weight-by-weight basis owing to the non-digestibility in the small intestine and to a decrease in the amount of available carbohydrates, and that the consumption of foods/drinks in which non-digestible carbohydrates replaced sugars induced lower post-prandial glycaemic and insulinaemic responses than sugar-containing foods/drinks.

The Panel concludes that a cause and effect relationship has been established between the consumption of foods/beverages containing non-digestible carbohydrates instead of sugars and reduction of post-prandial glycaemic responses as compared to sugar-containing foods/beverages.

The following wording reflects the scientific evidence: “Consumption of foods/drinks containing non-digestible carbohydrates instead of sugars induces a lower blood glucose rise after meals compared to sugar-containing foods/drinks”.

The Panel considers that in order to bear the claim sugars (i.e. monosaccharides and disaccharides) should be replaced in foods or drinks by non-digestible carbohydrates so that foods or drinks contain reduced amounts of sugars as per Annex of Regulation (EC) No 1924/2006 and in accordance with the Guidance on the implementation of Regulation (EC) No 1924/2006 of the Standing Committee on the Food Chain and Animal Health for comparative nutrition claims made on foods. The target population is individuals who wish to reduce their post-prandial blood glucose responses.

TABLE OF CONTENTS

Abstract	1
Summary	2
Table of contents	4
Background	5
Terms of reference	5
EFSA Disclaimer.....	5
Information provided by the applicant	7
Assessment	7
1. Characterisation of the food/constituent	7
2. Relevance of the claimed effect to human health.....	8
3. Scientific substantiation of the claimed effect	8
4. Panel’s comments on the proposed wording	10
5. Conditions and restrictions of use	10
Conclusions	11
Documentation provided to EFSA	11
References	11
Abbreviations	13

BACKGROUND

Regulation (EC) No 1924/2006⁴ 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 which 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).

STEPS TAKEN BY EFSA

- The application was received on 18/06/2013.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application included a request for the protection of proprietary data.
- The scientific evaluation procedure started on 08/08/2013.
- On 26/09/2013, 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 and the clock was stopped on 09/10/2013, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 18/10/2013, EFSA received the requested information and the clock was restarted, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- During its meeting on 11/12/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to non-digestible carbohydrates and reduction of post-prandial glycaemic responses.

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: non-digestible carbohydrates and a reduction of post-prandial glycaemic responses.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of non-digestible carbohydrates, a positive assessment of their safety, nor a decision on whether non-digestible carbohydrates are, or are 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.

⁴ 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. OJ L 404, 30.12.2006, p. 9–25.

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.

INFORMATION PROVIDED BY THE APPLICANT

Applicants' names and addresses: Beneo-Orafti SA, Rue L. Maréchal 1, B-4360 Oreye, Belgium. Sensus BV, Borchwerf 3, 4704 RG Roosendaal, The Netherlands. Cosucra-Groupe Warcoing SA, 1, Rue de la Sucrierie, B-7740 Warcoing, Belgium.

The application includes a request for the protection of proprietary data for one unpublished study (Thondre and Lightowler, 2012), in accordance with Article 21 of Regulation (EC) No 1924/2006.

Food/constituent as stated by the applicant

According to the applicant, the food that is the subject of the health claim is fructo-oligosaccharides (FOS, oligofructose) obtained from chicory (*Cichorium intybus* L.) inulin.

Health relationship as claimed by the applicant

According to the applicant, the consumption of foods/drinks containing FOS from chicory instead of sugars leads to a reduced blood glucose rise. The applicant claimed that this effect is owing to the non-digestibility of FOS in the small intestine of humans.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "Consumption of foods/drinks containing oligofructose from chicory instead of sugars induces a lower blood glucose rise".

The following alternative wordings were proposed: "Foods/drinks containing oligofructose from chicory instead of sugars:

- induce a lower blood glucose rise after their consumption".
- attenuates post-prandial blood glucose response/glycaemia".
- contributes to a reduction of post-prandial blood glucose responses".
- supports a lower post-prandial blood glucose response".
- helps to reduce/lower post-prandial blood glucose response".
- helps to maintain a lower post-prandial blood glucose response".

Specific conditions of use as proposed by the applicant

According to the applicant, the claimed effect can be obtained with a single intake of a food in which sugars have been partially (at least 20 %) or completely replaced by FOS from chicory on a weight-by-weight basis.

The target population proposed by the applicant is the general population.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is fructo-oligosaccharides (FOS, oligofructose) obtained from chicory (*Cichorium intybus* L.) inulin, which should replace sugars in foods or beverages in order to obtain the claimed effect (i.e. reduction of post-prandial glycaemic responses).

The FOS which was proposed by the applicant as the food which is the subject of the health claim is obtained from inulin extracted from chicory (*Cichorium intybus* L.) roots. An overview of the manufacturing process, stability data and batch-to-batch variability were provided.

The applicant proposes to replace sugars with FOS from chicory inulin in a variety of food products (e.g. dairy products, edible ices, confectionery, cereal products, bakery wares, soups and sauces, beverages, savouries, snacks, desserts, food supplements and other processed foods).

From the information provided, the Panel notes that the main characteristic of FOS from chicory inulin which contributes to the claimed effect is the non-digestibility of FOS in the small intestine, and that replacing digestible (glycaemic) carbohydrates (e.g. sugars) by any non-digestible carbohydrate would contribute to the claimed effect. The applicant was requested to indicate the characteristics or properties of FOS from chicory inulin which make it unique as compared to other non-digestible carbohydrates in relation to the claimed effect. In reply, the applicant stated that the claim should be restricted to FOS from chicory because “this was the scientific basis of the dossier”. The applicant also commented on regulatory issues but did not provide scientific arguments/evidence for an effect of FOS from chicory on the reduction of post-prandial blood glucose concentrations when replacing sugars in foods beyond what could be expected by the replacement of digestible (glycaemic) carbohydrates by non-digestible carbohydrates.

The Panel notes that the characteristic which is most relevant to the claimed effect (i.e. reduction of post-prandial glycaemic responses by replacing sugars in foods and beverages) is not unique to FOS but common to other non-digestible carbohydrates (e.g. non-starch polysaccharides, resistant oligosaccharides, resistant starch) because, similar to FOS, non-digestible carbohydrates are resistant to hydrolysis and absorption in the small intestine and therefore do not contribute to post-prandial glycaemia.

This opinion applies to non-digestible carbohydrates (e.g. non-starch polysaccharides, resistant oligosaccharides and resistant starch; EFSA NDA Panel, 2010) which should replace sugars (i.e. monosaccharides and disaccharides) in foods or beverages in order to obtain the claimed effect. The Panel notes that non-digestible carbohydrates have a neutral taste and cannot substitute for the sweet taste of sugars.

The Panel considers that the food constituent, non-digestible carbohydrates, which is the subject of the health claim, and the food constituent (i.e. sugars) that non-digestible carbohydrates should replace in foods or beverages, are both sufficiently characterised in relation to the claimed effect.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant relates to the reduction of post-prandial blood glucose responses. The target population proposed by the applicant is the general population.

The elevation of blood glucose concentrations after consumption of a food and/or meal, i.e. post-prandial glycaemia, is a normal physiological response which varies in magnitude and duration, and which may be influenced by the chemical and physical nature of the food or meal consumed, as well as by individual factors (Venn and Green, 2007). Decreasing post-prandial glycaemic responses may, for example, be beneficial to individuals with impaired glucose tolerance, as long as post-prandial insulinaemic responses are not disproportionately increased. Impaired glucose tolerance is common in the general population of adults.

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

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in Medline, EMBASE and CAPLUS using the search terms “fructan” or “fructane” or “fructans” or “FOS” or “fructooligosaccharide*” or “fructo-oligosacch*” or “inulin” or “inulin-type fructan” or “oligofructose” or “oligo-fructose” or “fructose cont*.”

oligosaccharide*” AND “glycem*” or “glycaem*” or “hyperglycem*” or “hyperglycaem*” or “hyperglycem*” or “hyper-glycaem*” OR “blood glucose*” or “bloodglucose*” or “blutglukose” or “blutglucose*” or “blood sugar*” or “blutzucker” or “blood dextrose*” or “blooddextrose*”. The only limits set in the search strategy were the exclusion of patents and duplicates. The search was carried out on 7 November 2012, with an update on 25 April 2013. In addition to the literature search in the databases mentioned above, alternative search strategies (e.g. internet, Pubmed) were performed to identify further possibly pertinent studies. Studies were included if they contained primary data of post-prandial blood glucose response tests (oral intake) of FOS used as a sugar replacer in comparison with reference products containing traditional glycaemic sugars and determined in humans under equal conditions; if the duration of the blood glucose response test was at least 120 minutes; and if the subjects were healthy without regular medication with potential effects on blood glucose response, not diabetic and not pregnant or lactating. Studies were excluded if they used FOS not to replace sugars but in addition to normal sugar content (e.g. as a fat replacer); if they used other fructans than FOS from chicory (e.g. inulin from chicory or fructans derived from Jerusalem artichoke or short-chain fructo-oligosaccharides derived from sucrose); or if they used FOS from chicory in combination with probiotics or other fructans or fibres.

The applicant identified a total of three human intervention studies (Hull et al., 2005, unpublished; Meyer, 2007; Thondre and Lightowler, 2012, unpublished) and three human mechanistic studies (Ellegård et al., 1997; Rumessen and Gudmand-Høyer, 1998; Teuri et al., 1999) as being pertinent to the health claim.

One cross-over trial (Hull et al., 2005, unpublished) in 12 subjects assessed the effects of test ice creams, where the sucrose content was replaced by various sugar replacers (mostly polyols, but also FOS), on post-prandial blood glucose responses relative to a control ice cream (15 % sucrose). Consumption of the test ice creams elicited a significantly lower glucose incremental area under the curve (iAUC) (with the exception of maltitol and maltitol/resistant dextrin containing ice-creams) than the sucrose-containing ice cream.

A randomised cross-over trial (Meyer, 2007) assessed post-prandial glycaemic responses following consumption of a long-chain inulin (degree of polymerisation (DP) 23, mono- and disaccharide content less than 0.5 %), “native” inulin (DP 9-10, 8 % mono- and disaccharides), and two FOS-containing products with varying percentages of mono- and disaccharides (i.e. 15 % and 40 %, respectively). Study subjects received 25 g glucose or 25 g of the above test products dissolved in water. Relative to the glucose-containing drink, glycaemic responses were significantly lower after consumption of long-chain inulin (5 ± 2 % of the glucose drink), native inulin (14 ± 3 % of the glucose drink) and the two FOS-containing products (20 ± 5 % and 48 ± 6 %, respectively, of the glucose drink).

One double-blind, randomised, cross-over study (Thondre and Lightowler, 2012, unpublished, claimed as proprietary by the applicant) in 40 subjects was carried out with a yoghurt with 20 % of the sucrose replaced (on a weight-by-weight basis) by FOS derived from chicory inulin. Compared with the reference yoghurt, the glucose iAUC was significantly reduced following consumption of the sugar-reduced yoghurt. There was also a significant reduction in the peak blood glucose values and the insulin iAUC values, whereas no differences were reported for the peak insulin responses.

The three mechanistic studies (Ellegård et al., 1997; Rumessen and Gudmand-Høyer, 1998; Teuri et al., 1999) addressed the non-digestibility of FOS in the human small intestine which, according to the applicant, constitutes the underlying mechanism for the claimed effect.

It is well established that sugars increase post-prandial glycaemia. Non-digestible carbohydrates including FOS are resistant to hydrolysis and absorption in the small intestine and do not contribute to post-prandial glycaemia. The Panel considers that replacing sugars by any non-digestible carbohydrate (e.g. non-starch polysaccharides, resistant oligosaccharides and resistant starch; EFSA NDA Panel, 2010) would contribute to the claimed effect, i.e. a reduction of post-prandial glycaemic responses.

A claim related to sugar replacers and reduction of post-prandial glycaemic responses has already been assessed by the Panel with a favourable outcome (EFSA NDA Panel, 2011). The scientific substantiation of the claim was based on the reduced post-prandial blood glucose (or insulinaemic) responses induced by sugar replacers compared with sugars on a weight-by-weight basis owing to their reduced/delayed digestion/absorption and/or to a decrease in the amount of available carbohydrates, and on the lower post-prandial glycaemic and insulinaemic responses induced by foods/drinks containing sugar replacers compared with sugar-containing foods/drinks.

In weighing the evidence, the Panel took into account that consumption of non-digestible carbohydrates results in reduced post-prandial blood glucose (and insulinaemic) responses compared with the consumption of sugars on a weight-by-weight basis owing to non digestibility in the small intestine and to a decrease in the amount of available carbohydrates, and that the consumption of foods/drinks in which non-digestible carbohydrates replaced sugars induced lower post-prandial glycaemic and insulinaemic responses than sugar-containing foods/drinks.

The Panel concludes that a cause and effect relationship has been established between the consumption of foods/beverages containing non-digestible carbohydrates instead of sugars and a reduction of post-prandial glycaemic responses as compared to sugar-containing foods/beverages.

The Panel could have reached this conclusion without the human study (Thondre and Lightowler, 2012, unpublished) claimed as proprietary by the applicant.

4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: "Consumption of foods/drinks containing non-digestible carbohydrates instead of sugars induces a lower blood glucose rise after meals compared to sugar-containing foods/drinks".

5. Conditions and restrictions of use

The Panel considers that, in order to bear the claim, sugars (i.e. monosaccharides and disaccharides) should be replaced in foods or drinks by non-digestible carbohydrates so that foods or drinks contain reduced amounts of sugars as per Annex of Regulation (EC) No 1924/2006 and in accordance with the Guidance on the implementation of Regulation (EC) No 1924/2006 of the Standing Committee on the Food Chain and Animal Health for comparative nutrition claims made on foods⁵.

The target population is individuals who wish to reduce their post-prandial blood glucose responses.

The Panel notes that non-digestible carbohydrates have a neutral taste and cannot substitute for the sweet taste of sugars.

⁵ Guidance on the implementation of Regulation (EC) No 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.

CONCLUSIONS

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

- The food constituent, non-digestible carbohydrates, which is the subject of the health claim, and the food constituent (i.e. sugars) that non-digestible carbohydrates should replace in foods or beverages, are both sufficiently characterised in relation to the claimed effect.
- The claimed effect proposed by the applicant relates to the reduction of post-prandial blood glucose responses. 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 disproportionately increased) might be a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of foods/beverages containing non-digestible carbohydrates instead of sugars and a reduction of post-prandial glycaemic responses as compared to sugar-containing foods/beverages.
- The following wording reflects the scientific evidence: “Consumption of foods/drinks containing non-digestible carbohydrates instead of sugars induces a lower blood glucose rise after meals compared to sugar-containing foods/drinks”.
- In order to bear the claim, sugars should be replaced in foods or drinks by non-digestible carbohydrates so that foods or drinks contain reduced amounts of sugars as per Annex of Regulation (EC) No 1924/2006 and in accordance with the Guidance on the implementation of Regulation (EC) No 1924/2006 of the Standing Committee on the Food Chain and Animal Health for comparative nutrition claims made on foods⁵. The target population is individuals who wish to reduce their post-prandial blood glucose responses.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on fructo-oligosaccharides (FOS) from inulin and reduction of post-prandial glycaemic responses pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0390_BE). June 2013. Submitted by Beneo-Orafti SA, Sensus BV and Cosucra-Groupe Warcoing SA.

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ABBREVIATIONS

iAUC incremental area under the curve

DP degree of polymerisation

FOS fructo-oligosaccharides