# Stablor® and reduction of visceral fat while maintaining lean mass: evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

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# Stablor® and reduction of visceral fat while maintaining lean mass: 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 Laboratoires Nutrition et Cardiométabolisme, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of France, 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 Stablor® and decrease in visceral fat while preserving lean mass. The food Stablor®, a drink preparation with defined macro- and micronutrient composition and a specific proportion of amino acids (tryptophan to neutral amino acids ratio) which is the subject of the health claim, is sufficiently characterised. The Panel considers that reduction of visceral fat while maintaining lean body mass in the context of an energy restricted diet is a beneficial physiological effect in overweight or obese subjects with abdominal fat and cardiometabolic risk factors. Four human studies were submitted by the applicant as pertinent to the claimed effect. In weighing the evidence, the Panel took into account that one human study from which conclusions could be drawn for scientific substantiation of the claimed effect did not show an effect of Stablor® on visceral fat mass in the context of an energy restricted diet. The Panel concludes that a cause and effect relationship has not been established between the consumption of Stablor® and reduction of visceral fat while maintaining lean body mass in the context of an energy restricted diet.



**Keywords:** Stablor®, visceral fat, lean body mass, health claim

**Requestor:** Competent Authority of France following an application by Laboratoires Nutrition et Cardiométabolisme

**Question number:** EFSA-Q-2016-00319

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## Summary

Following an application from Laboratoires Nutrition et Cardiométabolisme, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of France, 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 Stablor® and reduction of visceral fat while maintaining lean mass in overweight or obese subjects with abdominal fat and cardiometabolic risk factors.

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 general approach of the NDA Panel for the evaluation of health claims applications is outlined in the EFSA general guidance for stakeholders on health claim applications and the guidance on the scientific requirements for health claims related to appetite ratings, weight management and blood glucose concentrations.

The food that is the subject of the health claim is Stablor®. The Panel considers that Stablor®, a drink preparation with defined macro- and micronutrient composition and specific proportion of amino acids (tryptophan to neutral amino acids ratio), is sufficiently characterised.

The claimed effect proposed by the applicant is 'decrease in visceral fat while preserving lean mass'. The target population proposed by the applicant is 'overweight or obese subjects with abdominal fat and cardiometabolic risk factors'. The Panel considers that reduction of visceral fat while maintaining lean body mass in the context of an energy restricted diet is a beneficial physiological effect in the target population.

Four human studies were considered by the applicant as pertinent to the claimed effect. The Panel considers that no conclusions can be drawn from three uncontrolled studies for the scientific evaluation of the claim.

The Panel notes that one human intervention study does not show an effect of Stablor® on the primary outcome (reduction of visceral fat) in the primary (full analysis set (FAS)) analysis and that the per protocol (PP) analysis for the primary outcome is at risk of bias.

In the absence of evidence for an effect of Stablor® on reduction of visceral fat while maintaining lean body mass in efficacy studies in humans, the studies on the proposed mechanisms of action were not considered by the Panel for the scientific substantiation of the claim.

In weighing the evidence, the Panel took into account that one human study from which conclusions could be drawn for scientific substantiation of the claimed effect did not show an effect of Stablor® on reduction of visceral fat while maintaining lean body mass in the context of an energy restricted diet.

On the basis of data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of Stablor® and reduction of visceral fat while maintaining lean body mass in the context of an energy restricted diet.

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# 1. Introduction

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

Regulation (EC) No 1924/2006[1] 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).

## 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: Stablor® and decrease in visceral fat while maintaining lean mass in overweight or obese subjects with abdominal fat and cardiometabolic risk factors.

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of Stablor®, a positive assessment of its safety, nor a decision on whether Stablor® 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 Stablor®, a drink preparation containing a protein fraction with a specific proportion of amino acids, a patented ratio between tryptophan (Trp) and neutral amino acids (NAAs) as well as particular vitamin and mineral fractions. This preparation has to be mixed with water before consumption.

### Health relationship as claimed by the applicant

According to the applicant, the claimed effect relates to: 'a decrease visceral fat while preserving lean mass in overweight or obese subjects with abdominal fat and cardiometabolic risk factors', in the context of a well-balanced diet and a mild caloric restriction, to which the food is added.

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

According to the applicant, Stablor® works to counteract and normalise different metabolic disorders linked to excessive visceral fat, particularly dysregulation of the Trp metabolism and disturbances in the protein metabolism. The consumption of Stablor® also ensures a better balance of micronutrients intake in subjects that are known to have deficiencies. Stablor® has also potential action on microbiome modulation and intestinal epithelial barrier.

[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. OJ L 404, 30.12.2006, p. 9–25.

### Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: 'In the context of a well-balanced diet and a mild caloric restriction, the addition of Stablor® contributes to decrease visceral fat while preserving lean mass in overweight or obese subjects with abdominal fat and cardiometabolic risk factors'.

### Specific conditions of use as proposed by the applicant

According to the applicant, Stablor® has to be mixed with water before consumption as a drink.

The applicant advises to consume two sachets of Stablor® daily in the framework of a diet containing 50% carbohydrates, 35% fats and 15% proteins, with a low glycaemic load, together with a mild caloric restriction (−600 kcal/day) leading to a total daily intake of 1,750 kcal/day on average.

### Data provided by the applicant

Health claim application on consumption of Stablor® and reduction of visceral fat while maintaining lean mass in overweight or obese subjects with abdominal adiposity and cardiometabolic risk factors pursuant to Article 13.5 of Regulation 1924/2006, 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, 2017).

As outlined in the General guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016), it is the responsibility of the applicant to provide the totality of the available evidence.

This health claim application includes a request for the protection of proprietary data in accordance with Article 21 of Regulation (EC) No 1924/2006. Data claimed to be proprietary and confidential by the applicant include:

- the manufacturing process of the finished product;
- the manufacturing formula of the food. However, the information that calcium caseinate, wheat protein and mixed minerals and vitamins are used needs to be disclosed as this is essential information in relation to the claim;
- the detailed specifications of the food, including analytical methods used to ensure the quality of the product. However, information related to macronutrients content, caloric value of the product, vitamins and minerals content needs to be disclosed as this is essential information in relation to the claim;
- the clinical report of the unpublished human study (Clément and La Marche, 2014; – unpublished report) and of its ancillary study (Genoscreen Report, 2015 – unpublished report) However, information related to macronutrients content, caloric value of the product, vitamins and minerals content needs to be disclosed as this is essential information in relation to the claim. The detailed information related to comparator composition will be not disclosed. However, information related to macronutrients content and caloric value of the comparator needs to be disclosed as this is essential information in relation to the claim.

### Methodologies

The general approach of the NDA Panel for the evaluation of health claims 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).

## 3. Assessment

### 3.1. Characterisation of the food/constituent

The food that is proposed by the applicant as the subject of the health claim is Stablor®, a drink preparation containing a protein fraction with a specific proportion of amino acids (ratio between Trp and NAAs) and a fixed combination of vitamins and minerals. The preparation is offered in sachets and needs to be dissolved in around 200 mL of water before consumption. Three flavours are available: chocolate, coffee and vanilla-toffee.

The composition of three flavours of Stablor® has been provided. The list of ingredients is as follows: calcium caseinate, whey protein concentrate, whey protein hydrolysate, whey protein isolate, free amino acids mix (Gln, Leu, Arg, Trp and taurine), milk minerals concentrate, vitamins (B6, folic

acid, E and D), minerals (zinc gluconate, chromium chloride, trimagnesium citrate, potassium phosphate and acesulfame potassium) and soluble chicory fibres. The amounts of each of these components per 100 g, per sachet and per recommended dose (two sachets) have been provided.

The manufacturing process is claimed by the applicant as confidential.

The macronutrient composition of the finished product for each of the three flavours has been provided. The content of protein, carbohydrate, fat and fibre are 62.5–63.0 g/100 g, 8.5–13.0 g/100 g, 2.7–4.7 g/100 g and 6.9–9.1 g/100 g, respectively, depending on the flavour.

Technical datasheets for all the ingredients and specifications for the finished products are provided, along with reference methods for testing the components (including microbiological analyses).

Information related to stability and batch-to-batch variability was provided.

The Panel considers that the food Stablor®, a drink preparation with defined macro- and micronutrient composition and specific proportion of amino acids (tryptophan to neutral amino acids ratio), 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 'decrease in visceral fat while preserving lean mass'. The target population proposed by the applicant is 'overweight or obese subjects with abdominal fat and cardiometabolic risk factors'.

The scientific evidence for the substantiation of health claims related to the reduction of abdominal fat can be obtained from human intervention studies showing a reduction in abdominal fat by using methods with appropriate validity and precision (e.g. magnetic resonance imaging (MRI) and computed tomography (CT)). Surrogate measures of abdominal fat (e.g. waist circumference) could be used for the scientific substantiation of these claims if the reduction is sufficiently large so that it could not be attributed to a reduction in lean body mass/body water. The conditions in which the effect is achieved need to be specified (under energy-restriction, eating *ad libitum*, etc.). Evidence for a sustained effect with continuous consumption of the food/constituent over, for example, about 12 weeks, should also be provided (EFSA NDA Panel, 2012).

The scientific evidence for the substantiation of health claims on the increase/maintenance of lean body mass can be obtained from human intervention studies showing an increase (or reduced loss) in lean body mass which could not be attributed to an increase in body weight (i.e. an increase in lean body mass relative to body fat mass). Changes in lean body mass should be assessed using methods with appropriate validity and precision. Imaging techniques (e.g. dual energy x-ray absorptiometry (DXA), MRI and CT) are generally appropriate to assess changes in lean body mass in human intervention studies. Bioimpedance analysis (BIA) and air-displacement plethysmography (ADP) may not be appropriate to assess small changes in lean body mass when used alone, particularly in obese subjects and/or when significant changes in body water compartments occur. The conditions in which the effect is achieved need to be specified (e.g. training vs usual physical activity, eating *ad libitum* vs energy-restriction, etc.). Evidence for a sustained effect with continuous consumption of the food/constituent over, for example, about 12 weeks, should also be provided. Measurements of protein metabolism (e.g. synthesis and breakdown) may be used in support of a mechanism by which the food/constituent could exert the claimed effect (EFSA NDA Panel, 2012).

The Panel considers that reduction of visceral fat while maintaining lean body mass in the context of an energy restricted diet is a beneficial physiological effect in the target population.

## 3.3. Scientific substantiation of the claimed effect

The applicant performed a literature search in the PubMed, Science Direct and Google scholar databases using the following search terms: 'Stablor' AND (obese OR obesity OR weight OR waist OR abdominal fat OR lean mass). Papers published in English or French were selected. Additional hand searching was also performed.

**Human studies**

Four human studies (two published and two unpublished) were considered by the applicant as pertinent to the claim.

Three studies (Ranson, 2013, 2014; UCP Abridged Report, 2014, unpublished study report) investigated the effect of Stablor® on body weight and visceral fat-related outcomes in the context of an energy-restricted diet, but the lack of a control group does not allow conclusions on the effect of

Stablor® *per se* (i.e. independently of energy restriction) on the outcome variables. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

In a randomised, multicentre (two centres) two-arm, double-blind, parallel, controlled study, Clément and La Marche (2014) evaluated the effect of Stablor® on changes in visceral fat mass and other cardiometabolic risk factors in overweight and obese subjects meeting the criteria for metabolic syndrome according to International Diabetes Federation (IDF) standards for a European population.

The Panel considers that the study group (overweight and obese subjects with metabolic syndrome) is appropriate for a health claim on the reduction of visceral fat.

The study was performed in France (n = 54) and Canada (n = 53). A block randomisation was used taking into account study centre and gender (desired ratio male/female of 2/3). The participants were allocated to consume Stablor® (two sachets per day dissolved in water; n = 58) or a 'comparator' (n = 59) with the same appearance, flavour and similar energy content (control) for 16 weeks.

The Panel notes that subjects were independently randomised in the two centres with a similar number of subjects, gender distribution and treatment allocation in the two centres.

The study consisted of a screening period of 3 days to 4 weeks, followed by an intervention period of 12 weeks with an energy-restricted diet followed by a 4-week maintenance period. From the inclusion visit, all subjects were advised to follow a standardised energy-restricted diet for 12 weeks. The target daily energy intake was calculated for each individual as the resting energy expenditure (REE) × 1.3 for the physical activity level (PAL) minus 600 kcal (energy deficit). REE was calculated according to Harris and Benedict equation. The target macronutrient composition of the background diet was 50%E (energy) as carbohydrates, 35%E as fats and 15%E as proteins. For the next 4 weeks (weeks 13–16), a stabilisation diet with 20% more energy was prescribed. Dietary advice was given at the inclusion visit, and after 6, 12 and 16 weeks. A phone call initiated by the dietician was also performed weekly. Subjects were also instructed to maintain their habitual physical activity level.

Sample size calculation was based on the expected difference in change in the visceral fat area between the two study groups using one-sided Student t-test, with an estimated difference of 6 $cm^2$ between the two study groups, a common standard deviation of 9 $cm^2$, a first one-sided risk alpha of 2.5% and a 90% power. This calculation was based on the assumption that the mean visceral fat surface would be 150 $cm^2$ at baseline for both groups and will be reduced by 20% (30 $cm^2$) in the study group and by 16% (24 $cm^2$) in the comparator group. The estimated number of subjects required per group was 49. A total of 120 subjects were planned to be enrolled, assuming a 20% dropout rate.

The primary outcome of the study was the absolute change in abdominal visceral fat mass assessed by computed tomography (CT) in the full analysis set (FAS) population. Upon a request from EFSA, the applicant specified that the horizontal slide of the CT scan used to assess abdominal visceral fat mass was located 5 cm above the L4–L5 intervertebral disc, and that analysis of the scans was performed centrally by one group of radiologists with the use of automatic calculation of total fat area, visceral fat area and subcutaneous fat area, for both study sites.

Secondary outcomes were absolute changes in total fat mass, subcutaneous fat mass, visceral fat/subcutaneous fat ratio, visceral fat/body mass index (BMI) ratio, lean body mass, lean body mass/fat body mass ratio, blood pressure, waist circumference, glycaemic and lipid profiles, amino acids levels, and C-reactive protein (CRP).

Total body mass, fat mass and lean mass were assessed by DXA following the same procedure in both centres, although a different software was used in each centre. Upon a request from EFSA, the applicant clarified that the different versions of the software did not affect the measurement.

The energy content and macronutrient composition of the comparator used in the study was 190–197 kcal per sachet, 15%E as proteins, 49%E as carbohydrates, and 36%E as fats. The applicant claims that the main differences between Stablor® and the comparator were related to the aminogram (Trp/NAA ratio, the glutamic acid content and the leucine content).

The Panel notes that the protein content was > 4-fold higher in the Stablor® products (62.5–63.0 g/100 g) than in the comparator (15.2–15.3 g/100 g). After a request from EFSA to justify the appropriateness of the macronutrient composition of the comparator to test the effect of Stablor® on the primary outcome, the applicant argued that the comparator had to be 'isocaloric to Stablor® but comply with the macronutrient composition of the background diet (carbohydrate/fat/protein providing 50%, 35% and 15% of total energy)'.

In the statistical analysis of the results, multiple ANOVA models were used to compare absolute changes in visceral fat mass between the two groups adjusted for centre, age (in classes) and gender. The same analyses were conducted for the secondary outcome variables.

Upon a request from EFSA, the applicant clarified that corrections for multiple testing were not used in relation to the statistical analysis of the secondary outcomes.

Upon a request from EFSA, the applicant submitted a Reporting and Analysis Plan (RAP) describing the planned statistical analyses. The Panel notes that version 1.0 of RAP was dated 31 March 2014 while the study was finished on 21 February 2014, meaning that this document was not prepared *a priori*. The applicant argues, however, that the study was unblinded only after the completion of the RAP.

While 376 subjects were screened for inclusion, 118 subjects were recruited (59 in each group, mean age 47.9 years, mean BMI 32.3 kg/m$^2$, 44 men). The FAS was defined by the applicant as all subjects randomised who consumed at least one sachet of the study product and had one post-baseline CT scan (54 in the Stablor® group and 53 in comparator group). The per protocol (PP) analysis was based on all subjects in the FAS population who completed the study without any major protocol violation (49 in the treatment and 50 in the control group).

Reasons for major protocol violation were poor compliance (< 80%; two subjects on each group), inclusion criteria not met (two subjects in the Stablor® group and one in the comparator group), and ingestion of drugs listed in the exclusion criteria (one subject in Stablor® group). Upon a request from EFSA, the applicant clarified that three subjects who did not meet the inclusion criteria were incorrectly randomised and that this deviation was detected after completion of the study.

The absolute decrease in visceral fat area was significantly higher in the Stablor® group than in the comparator group in the PP analysis (–20.46 ± 23.14 cm$^2$ vs –12.56 ± 20.77 cm$^2$, p = 0.02), but not in the FAS (primary) analysis (–20.75 ± 23.24 cm$^2$ vs –14.55 ± 24.30 cm$^2$, p = 0.06).

Upon a request to discuss the observed differences between the FAS and PP analysis, the applicant explained that in the Stablor® group, 'the exclusion of five patients resulted in a –0.29 cm$^2$ (–1.4%) decrease of the area of visceral fat and a decrease of the variance of –10.5 cm$^2$ (0.5%) while in the comparator group the exclusion of three patients resulted in a –1.98 cm$^2$ (–13.7%) decrease of the mean of and a decrease of the variance of –3.53 cm$^2$ (–14.5%)'. The Panel notes that the exclusion of five subjects in the Stablor® group and of three subjects in the comparator groups from the FAS to the PP analysis resulted in an increased difference in fat loss between the groups, mainly due to a smaller decrease in visceral fat in the comparator group. The SD of the means also decreased accordingly. The mean decrease in visceral fat area in three subjects excluded from the comparator group was 47.7 cm$^2$, about 3.8-fold higher than the mean change observed in the remaining subjects (n = 50) in the comparator group. The Panel notes that the exclusion of the three non-compliant subjects from the analysis had a big impact on the results, particularly by decreasing the amount of visceral fat mass loss in the control group. The Panel considers that this study does not show an effect of Stablor® on the primary outcome in the primary (FAS) analysis and that the PP analysis for the primary outcome is at risk of bias.

The total fat area (measured by CT) significantly decreased in the Stablor® group vs the comparator group in the FAS (–46.64 ± 43.77 cm$^2$ vs –30.85 ± 48.31 cm$^2$, p = 0.023) and PP analysis (–44.62 ± 43.43 cm$^2$ vs –28.97 ± 43.42 cm$^2$, p = 0.016). No significant differences between groups were reported for other secondary outcomes, including changes in lean body mass, fat mass, blood pressure, glycaemic and lipid profiles, and CRP.

The Panel considers that this study does not show an effect of Stablor® on visceral fat mass in the context of an energy restricted diet.

### Mechanism by which the food/constituent could exert the claimed effect

The applicant indicated several mechanisms by which the Stablor® product could exert the claimed effect on visceral fat mass while retaining lean body mass, including: (a) regulation of tryptophan metabolism, (b) regulation of protein metabolism, (c) correction of micronutrient deficiencies, (d) improving the gut barrier dysfunction.

In the absence of evidence for an effect of Stablor® on the reduction of visceral fat mass while maintaining lean body mass in efficacy studies in humans, the studies provided by the applicant on the proposed mechanisms by which Stablor® could exert the claimed effect were not considered by the Panel for the scientific substantiation of the claim.

### Weighing of the evidence

In weighing the evidence, the Panel took into account that one human study from which conclusions could be drawn for scientific substantiation of the claimed effect did not show an effect of Stablor® on visceral fat mass in the context of an energy restricted diet.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Stablor® and reduction of visceral fat while maintaining lean body mass in the context of an energy restricted diet.

## 4. Conclusions

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

- The food/constituent, Stablor®, a drink preparation with defined macro- and micronutrient composition and specific proportion of amino acids (Trp to NAAs ratio), which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is 'decrease in visceral fat while preserving lean mass'. The target population proposed by the applicant is 'overweight or obese subjects with abdominal fat and cardiometabolic risk factors'. Reduction of visceral fat while maintaining lean body mass in the context of an energy restricted diet is a beneficial physiological effect in the target population.
- A cause and effect relationship has not been established between the consumption of Stablor® and reduction of visceral fat while maintaining lean body mass in the context of an energy restricted diet.

## Steps taken by EFSA

Health claim application on 'Stablor®' and 'reduction of visceral fat while maintaining lean mass' pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 000319_0448_FR). Submitted by Laboratoires Nutrition et Cardiométabolisme, 38 Cours Clémenceau, 33000 Bordeaux, France. This application was received by EFSA on 27/4/2016.

1) 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.
2) The scientific evaluation procedure started on 20/7/2016.
3) On 6/9/2016, 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 29/9/2016 and was restarted on 13/10/2016, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
4) On 13/10/2016, EFSA received the applicant's reply (which was made available to EFSA in electronic format on 13/10/2016).
5) On 16/11/2016, 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 22/12/2016 and was restarted on 6/1/2017, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
6) On 6/1/2017, EFSA received the applicant's reply (which was made available to EFSA in electronic format on 6/1/2017).

During its meeting on 31/1/2017, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to Stablor® and reduction of visceral fat while maintenance of lean body mass.

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## Abbreviations

| | |
|---|---|
| ADP | air-displacement plethysmography |
| ANOVA | analysis of variance |
| BIA | bioimpedance Analysis |
| BMI | body mass Index |
| CRP | C-reactive Protein |
| CT | computed tomography |
| DXA | dual energy X-ray absorptiometry |
| E | energy |
| FAS | full analysis set |
| IDF | International Diabetes Federation |
| NAA | neutral amino acids |
| MRI | magnetic resonance imaging |
| NDA | EFSA Panel on Dietetic Products, Nutrition and Allergies |
| PAL | physical activity level |
| PP | per protocol |
| RAP | Reporting and Analysis Plan |
| REE | Resting Energy Expenditure |
| SD | standard deviation |
| Trp | tryptophan |