



**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to iron and maintenance of normal hair growth pursuant to Article 13(5) of Regulation (EC) No 1924/2006**

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## SCIENTIFIC OPINION

### Scientific Opinion on the substantiation of a health claim related to iron and maintenance of normal hair growth pursuant to Article 13(5) of Regulation (EC) No 1924/2006<sup>1</sup>

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2, 3</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### ABSTRACT

Following an application from Pierre Fabre Dermo-Cosmétique, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of France, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim based on newly developed scientific evidence related to iron and maintenance of normal hair growth. Iron is sufficiently characterised. The claimed effect is “reduction of excessive hair loss”. The target population proposed by the applicant is non-menopausal women, aged between 19 and 49 years, presenting with excessive hair loss. The Panel considers that maintenance of normal hair growth is a beneficial physiological effect. The applicant identified a total of five observational studies and one review as pertinent to the claim. The narrative review contained no primary data. In two observational studies no tests were performed to exclude individuals with raised serum ferritin owing to inflammation/infection. No conclusions could be drawn from these studies for the scientific substantiation of the claim. Two further observational studies provided no evidence for a relationship between iron status and hair loss while a third study showed an association between low iron status and hair loss. In weighing the evidence, the Panel took into account that two observational studies showed no relationship of iron status with hair loss and that one observational study showed an association. The Panel notes that these studies were not controlled for environmental and physiological factors which might have influenced iron status besides iron intake, or for factors other than iron status which might have influenced hair loss. The Panel concludes that a cause and effect relationship has not been established between the intake of iron and maintenance of normal hair growth. © European Food Safety Authority, 2012

#### KEY WORDS

Iron, hair growth, ferritin, health claims.

<sup>1</sup> On request from the Competent Authority of France following an application by Pierre Fabre Dermo-Cosmétique, Question No EFSA-Q-2012-00059, adopted on 29 February 2012.

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## SUMMARY

Following an application from Pierre Fabre Dermo-Cosmétique, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of France, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to iron and maintenance of normal hair growth.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.

The food constituent that is the subject of the health claim is iron, formulated as ferrous sulphate. This evaluation applies to iron naturally present in foods and those forms authorised for addition to foods. The Panel considers that the food constituent, iron, which is the subject of the health claim, is sufficiently characterised.

The claimed effect is “reduction of excessive hair loss”. The target population proposed by the applicant is non-menopausal women, aged between 19 and 49 years, presenting with excessive hair loss. From the information provided, the Panel notes that the claimed effect relates to the maintenance of normal hair growth (i.e. reduced hair loss). The Panel considers that maintenance of normal hair growth is a beneficial physiological effect.

The applicant identified a total of five observational studies and one review as pertinent to the claim.

The narrative review contained no primary data and no conclusions could be drawn from this review for the scientific substantiation of the claim.

Five observational studies were presented; these investigated the relationship between low iron status in women and hair loss. It is noted that, while iron intake was not measured in those studies, iron status can be improved by increasing the intake of iron.

In two of the five observational studies, no tests were performed to exclude individuals with raised serum ferritin owing to inflammation/infection. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

In a cross-sectional observational study, hair loss (measured by trichogram) and serum ferritin concentrations were measured in 418 women aged 13-81 years. Individuals with abnormal biochemical results were excluded. The total number of women diagnosed with telogen effluvium was 135 and the mean ferritin concentration was 55.3 µg/L (range 2-304). No correlation was found between serum ferritin >10 µg/L and telogen hair loss rates. The Panel notes that this study provides no evidence for a relationship between iron status as measured by serum ferritin and hair loss.

In another cross-sectional observational study, serum ferritin and haemoglobin concentrations were measured in 30 women with telogen effluvium (aged 18-71 years) and compared with 11 women (aged 24-52 years) with no reported hair loss. Women with elevated erythrocyte sedimentation rate were excluded. The ferritin and haemoglobin concentrations in patients with telogen effluvium were not significantly lower than in controls. The Panel notes that this study provides no evidence for a relationship between iron deficiency and hair loss.

In a case-control study, serum ferritin concentrations of 30 women (aged 15-45 years) with diffuse telogen hair loss were compared with 30 women without hair loss (aged 15-45 years). Women with elevated erythrocyte sedimentation rate were excluded. Mean serum ferritin concentrations and transferrin saturation were significantly lower ( $p<0.001$  and  $p=0.006$ , respectively) and total iron binding capacity was significantly higher ( $p=0.004$ ) in the patients with telogen hair loss than controls. The odds ratio of having telogen hair loss was significantly higher in anaemic women

(Hb <120 g/L) (10.5, 95 % CI 1.2-90.7,  $p=0.013$ ) and in women with serum ferritin  $\leq 30$  ng/mL (21.0, 95 % CI 4.2-105.0,  $p<0.001$ ). The Panel notes that this study shows an association between low iron status and hair loss. However, the Panel also notes that this cross-sectional study was not controlled for environmental and physiological factors which might have influenced iron status besides iron intake, or for factors other than iron status which might have influenced hair loss.

In weighing the evidence, the Panel took into account that two observational studies showed no relationship of iron status with hair loss and that one observational study showed an association. None of these studies was controlled for environmental and physiological factors which might have influenced iron status besides iron intake, or for factors other than iron status which might have influenced hair loss.

The Panel concludes that a cause and effect relationship has not been established between the intake of iron and maintenance of normal hair growth.

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## BACKGROUND

Regulation (EC) No 1924/2006<sup>4</sup> 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 Art 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 30/12/2011.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- The scientific evaluation procedure started on 20/01/2012.
- During its meeting on 29/02/2012, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to iron and maintenance of normal hair growth.

## 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: iron and maintenance of normal hair growth.

## EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of iron, a positive assessment of its safety, nor a decision on whether iron 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.

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<sup>4</sup> 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.

## INFORMATION PROVIDED BY THE APPLICANT

**Applicant's name and address:** Pierre Fabre Dermo-Cosmétique, Service Affaires Réglementaires, Hôtel Dieu - Toulouse, 2 rue Viguerie - BP 3071, 31025 Toulouse, France.

### Food/constituent as stated by the applicant

According to the applicant, iron in the form of ferrous sulphate, as authorised for addition to foods and food supplements (Annex II of Regulation (EC) No 1925/2006 and Annex II of Directive 2002/46/EC).

### Health relationship as claimed by the applicant

According to the applicant, iron is contained in porphyrins and particularly in haemoglobin, which transports oxygen to the tissues, including the hair follicles where oxygen is required for mitotic activity. The applicant further states that iron is an essential cofactor for ribonuclease reductase, which is involved in DNA synthesis. Thus, according to the applicant, iron deficiency might reduce the proliferation of hair follicle matrix cells, which might lead to an impaired hair growth and to an accelerated hair loss.

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

The applicant has proposed the following wording for the health claim: “excessive hair loss in non-menopausal women”.

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

The applicant has proposed a daily intake of 14 mg iron formulated as ferrous sulphate. The target population proposed by the applicant is non-menopausal women, aged between 19 and 49 years, presenting with excessive hair loss.

## ASSESSMENT

### 1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is iron, formulated as ferrous sulphate.

Iron occurs naturally in foodstuffs in different oxidation states. The primarily occurring oxidation states in biological systems are +2 (ferrous state) and +3 (ferric state).

Different forms of iron, including ferrous sulphate, are authorised for addition to foods (Annex II of Regulation (EC) No 1925/2006<sup>5</sup> and Annex II of Directive 2002/46/EC<sup>6</sup>). This evaluation applies to iron naturally present in foods and those forms authorised for addition to foods (Annex II of the Regulation (EC) No 1925/2006 and Annex II of Directive 2002/46/EC).

The Panel considers that the food constituent, iron, which is the subject of the health claim, is sufficiently characterised.

<sup>5</sup> Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26–38.

<sup>6</sup> Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51–57.

## 2. Relevance of the claimed effect to human health

The claimed effect is “reduction of excessive hair loss”. The target population proposed by the applicant is non-menopausal women, aged between 19 and 49 years, presenting with excessive hair loss.

From the information provided, the Panel notes that the claimed effect relates to the maintenance of normal hair growth (i.e. reduced hair loss).

The Panel considers that maintenance of normal hair growth is a beneficial physiological effect.

## 3. Scientific substantiation of the claimed effect

The applicant performed a literature search in Pubmed/Medline, Science Direct, IBIDS, Scirus, and Google Scholar, using the search terms “iron” or “ferrous sulphate/sulfate” or “iron sulphate/sulfate” and “hair” or “hair loss” or “hair follicle” or “hair shedding” or “hair density” or “trichogram”. Publications were included if they addressed the relationship between iron status and hair loss in women, comprising study populations presenting with telogen hair loss. Studies were excluded if they evaluated the effect of supplementation with iron combined with another substance, were carried out in women under 18 years or in people with alopecia areata and/or androgenic alopecia, or had a poor methodology (no study protocol, no information on iron dosage or study duration, small number of subjects). Review publications which did not provide any additional data were also excluded.

The applicant identified a total of five observational studies and one review as pertinent to the claim.

The narrative review (Troost et al., 2006) contained no primary data and no conclusions could be drawn from this review for the scientific substantiation of the claim.

Five observational studies were presented; these investigated the relationship between low iron status in women and hair loss. It is noted that, while iron intake was not measured in those studies, iron status can be improved by increasing the intake of iron.

In a case-control study, serum ferritin concentrations were measured in 72 women with chronic telogen effluvium hair loss and compared with 30 healthy controls (Obaidat et al., 2005). This comparison was followed by an intervention where the subjects with hair loss were given iron supplements but there was no control group in the intervention. In a cross-sectional study, serum ferritin was measured in 5110 women and hair loss was evaluated using a questionnaire (Deloche et al., 2007). Ferritin is an acute phase reactant; therefore serum concentrations increase in the presence of inflammation or infection and under these conditions serum ferritin cannot be used to measure iron status. No tests were performed in the above studies to exclude individuals with inflammation/infection. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

In a cross-sectional observational study (Brégy and Trüeb, 2008), hair loss (measured by trichogram) and serum ferritin concentrations were measured in 418 women (aged 13-81 years, mean 42). Individuals with abnormal biochemical results (e.g. C-reactive protein, thyroid function tests) were excluded. For the trichogram, at least 50 hairs were removed from two sampling sites and evaluation of different hair roots carried out based on morphological characteristics relating to the hair cycle. The total number of women diagnosed with telogen effluvium (with or without female pattern hair loss) was 135 and the mean ferritin concentration was 55.3 µg/L (range 2-304). No correlation was found between serum ferritin >10 µg/L and telogen hair loss rates. The Panel notes that this study provides no evidence for a relationship between iron status as measured by serum ferritin and hair loss.



In another cross-sectional observational study, 30 women with telogen effluvium (aged 18-71 years, mean 48) were recruited consecutively at a clinic, and serum ferritin and haemoglobin concentrations were measured and compared with 11 women (aged 24-52 years, mean 42) with no reported hair loss (Kantor et al., 2003). Women with elevated erythrocyte sedimentation rate, indicating non-specific inflammation that could increase serum ferritin, were excluded. The ferritin and haemoglobin concentrations in patients with telogen effluvium were not significantly different from the controls. The Panel notes that this study provides no evidence for a relationship between iron deficiency and hair loss.

In a case-control study, serum ferritin concentrations of 30 women (aged 15-45 years, mean 28) with diffuse telogen hair loss who attended a clinic between February 2005 and March 2006 were compared with 30 women without hair loss (aged 15-45 years, mean 29), recruited from the same clinic (Moeinvaziri et al., 2009). Women with elevated erythrocyte sedimentation rate were excluded. The women with hair loss were recruited consecutively but no details were given on how the control women were selected, apart from the fact that they had other (unspecified) dermatological problems. Patients were evaluated by a dermatologist to diagnose telogen hair loss by history (more than 100 hairs/day) and physical examination (more than 2 telogen hairs shed in light pull test). Mean serum ferritin concentration and transferrin saturation were significantly lower ( $p < 0.001$  and  $p = 0.006$ , respectively) and total iron binding capacity was significantly higher ( $p = 0.004$ ) in the patients with telogen hair loss than controls. The odds ratio of having telogen hair loss was significantly higher in anaemic women (Hb  $< 120$  g/L) (10.5, 95 % CI 1.2-90.7,  $p = 0.013$ ) and in women with serum ferritin  $\leq 30$  ng/mL (21.0, 95 % CI 4.2-105.0,  $p < 0.001$ ). The Panel notes that this study shows an association between low iron status and hair loss. However, the Panel also notes that this cross-sectional study was not controlled for environmental and physiological factors which might have influenced iron status besides iron intake, or for factors other than iron status which might have influenced hair loss.

In weighing the evidence, the Panel took into account that two observational studies showed no relationship of iron status with hair loss and that one observational study showed an association. None of these studies was controlled for environmental and physiological factors which might have influenced iron status besides iron intake, or for factors other than iron status which might have influenced hair loss.

The Panel concludes that a cause and effect relationship has not been established between the intake of iron and maintenance of normal hair growth.

## CONCLUSIONS

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

- The food constituent, iron, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is “reduction of excessive hair loss”. The target population proposed by the applicant is non-menopausal women, aged between 19 and 49 years, presenting with excessive hair loss. Maintenance of normal hair growth is a beneficial physiological effect.
- A cause and effect relationship has not been established between the intake of iron and maintenance of normal hair growth.

## DOCUMENTATION PROVIDED TO EFSA

Health claim application on iron and maintenance of normal hair growth pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0320\_FR). December 2011. Submitted by Pierre Fabre Dermo-Cosmétique.

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