SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to chromium and contribution to normal macronutrient metabolism (ID 260, 401, 4665, 4666, 4667), maintenance of normal blood glucose concentrations (ID 262, 4667), contribution to the maintenance or achievement of a normal body weight (ID 339, 4665, 4666), and reduction of tiredness and fatigue (ID 261) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to chromium and contribution to normal macronutrient metabolism, maintenance of normal blood glucose concentrations, contribution to the maintenance or achievement of a normal body weight and reduction of tiredness and fatigue. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is trivalent chromium. The Panel considers that trivalent chromium is sufficiently characterised.

[1] On request from the European Commission, Question No EFSA-Q-2008-1047, EFSA-Q-2008-1048, EFSA-Q-2008-1049, EFSA-Q-2008-1126, EFSA-Q-2008-1188, EFSA-Q-2010-00618, EFSA-Q-2010-00619, EFSA-Q-2010-00620, adopted on 09 July 2010.

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Contribution to normal macronutrient metabolism

The claimed effects are "chromium has been shown to potentiate insulin action and thereby influences carbohydrate, lipid and protein metabolism", "chromium is part of enzymes of the carbohydrate and lipid metabolism", "promotes carbohydrates catabolism by potentiating insulin action and thereby influencing carbohydrates metabolism", "promotes fat catabolism by potentiating insulin action and thereby influencing lipid metabolism", and "glucose metabolism". The target population is assumed to be the general population. The Panel assumes that the claimed effect refers to macronutrient metabolism. The Panel considers that contribution to normal macronutrient metabolism is a beneficial physiological effect.

A common feature in all cases of chromium depletion reported in humans is an impaired glucose tolerance and glucose utilisation probably resulting from an increased resistance to the action of insulin. Although there is no consensus about the mechanism by which chromium could exert these effects, consensus opinions from authoritative bodies are generally in agreement that chromium facilitates the action of insulin, thus contributing to macronutrient metabolism.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of chromium and contribution to normal macronutrient metabolism. However, the evidence provided does not establish that inadequate intake of chromium leading to impaired macronutrient metabolism occurs in the general EU population.

Maintenance of normal blood glucose concentrations

The claimed effects are "to fulfil increased need during pregnancy and lactation" and "glucose metabolism". The target population is assumed to be the general population. In the context of the wordings and clarification provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal blood glucose concentrations. The Panel considers that long-term maintenance of normal blood glucose concentrations is a beneficial physiological effect.

Hyperglycaemia is a common feature of chromium depletion in humans, which is reversed by the administration of chromium.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of chromium and the maintenance of normal blood glucose concentrations. However, the evidence provided does not establish that intake of chromium inadequate for the maintenance of normal blood glucose concentrations occurs in the general EU population.

Contribution to the maintenance or achievement of a normal body weight

The claimed effects are "weight control", "promotes carbohydrates catabolism by potentiating insulin action and thereby influencing carbohydrates metabolism", and "promotes fat catabolism by potentiating insulin action and thereby influencing lipid metabolism". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the contribution to the maintenance or achievement of a normal body weight. The Panel considers that contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that results from the meta-analysis which assessed the effects of chromium picolinate on body weight were not robust and were possibly clouded by publication bias, that results from the largest intervention studies on the effects of chromium on body weight were inconsistent, that two studies showed a statistically significant effect of chromium on body weight, that three studies showed no effect and that no evidence of a

biologically plausible mechanism by which chromium could exert the claimed effect has been provided.

On the basis of the data presented, the Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the dietary intake of chromium and the contribution to the maintenance or achievement of a normal body weight.

Reduction of tiredness and fatigue

The claimed effect is "vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status". The target population is assumed to be the general population. The Panel considers that reduction of tiredness and fatigue is a beneficial physiological effect.

No references have been provided from which conclusions could be drawn for the scientific substantiation of the claimed effect. Also, tiredness and fatigue are not among the symptoms observed in the few cases of chromium depletion reported and referred to in the references provided.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the dietary intake of chromium and reduction of tiredness and fatigue.

Conditions and possible restrictions of use

The Panel considers that in order to bear the claims, a food should be at least a source of trivalent chromium as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

KEY WORDS

Chromium, macronutrient metabolism, blood glucose, body weight, tiredness, fatigue, health claims.

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[4] submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out[5]. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is trivalent chromium Cr(III), which is a well recognised nutrient and is measurable in foods by established methods. Trivalent chromium occurs naturally in foods in many forms and approximately 0.5-2 % is absorbed to be utilised by the body. Different forms of Cr(III) are authorised for addition to foods and for use in food supplements (Annex II of the Regulation (EC) No 1925/2006[6] and Annex II of Directive 2002/46/EC[7]). This evaluation applies to Cr(III) naturally present in foods and those forms authorised for addition to foods and for use in food supplements (Annex II of the Regulation (EC) No 1925/2006 and Annex II of Directive 2002/46/EC).

The Panel considers that the food constituent, trivalent chromium, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Contribution to normal macronutrient metabolism (ID 260, 401, 4665, 4666, 4667)

The claimed effects are "chromium has been shown to potentiate insulin action and thereby influences carbohydrate, lipid and protein metabolism", "chromium is part of enzymes of the carbohydrate and lipid metabolism", "promotes carbohydrates catabolism by potentiating insulin action and thereby influencing carbohydrates metabolism", "promotes fat catabolism by potentiating insulin action and thereby influencing lipid metabolism", and "glucose metabolism". The Panel assumes that the target population is the general population.

The Panel assumes that the claimed effect refers to macronutrient metabolism.

[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.
[5] Briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims: http://www.efsa.europa.eu/en/ndameetings/docs/nda100601-ax01.pdf
[6] 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.
[7] 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.

The Panel considers that contribution to normal macronutrient metabolism is a beneficial physiological effect.

2.2. Maintenance of normal blood glucose concentrations (ID 262, 4667)

The claimed effects are "to fulfil increased need during pregnancy and lactation" and "glucose metabolism". The Panel assumes that the target population is the general population.

In the context of the clarification provided by Member States for ID 262 and in the context of the proposed wordings for ID 4667, the Panel assumes that the claimed effect refers to the maintenance of normal blood glucose concentrations.

The Panel considers that long-term maintenance of normal blood glucose concentrations is a beneficial physiological effect.

2.3. Contribution to the maintenance or achievement of a normal body weight (ID 339, 4665, 4666)

The claimed effects are "weight control", "promotes carbohydrates catabolism by potentiating insulin action and thereby influencing carbohydrates metabolism", and "promotes fat catabolism by potentiating insulin action and thereby influencing lipid metabolism". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to body weight control.

Weight control can be interpreted as the contribution to maintenance of a normal body weight. In this context, weight loss in overweight subjects without achieving a normal body weight is considered to be a beneficial physiological effect.

The Panel considers that contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.

2.4. Reduction of tiredness and fatigue (ID 261)

The claimed effect is "vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status". The Panel assumes that the target population is the general population.

The Panel considers that reduction of tiredness and fatigue is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

Chromium depletion that responds to chromium supplementation has been reported in humans receiving long-term total parenteral nutrition (TPN) with TPN solutions low in or free of chromium (Jeejeebhoy et al., 1977; Freund et al., 1979; Brown et al., 1986). Jeejeebhoy et al. (1977) reported on a female receiving long-term parenteral nutrition for three and a half years, who exhibited impaired glucose tolerance and glucose utilisation, weight loss, neuropathy, elevated plasma fatty acids, depressed respiratory quotient and abnormalities in nitrogen metabolism. A patient receiving total parenteral nutrition low in chromium for five months after complete bowel resection developed severe glucose intolerance, weight loss and a metabolic encephalopathy-like confusional state (Freund et al., 1979). Both syndromes were reversed by chromium supplementation. Brown et al. (1986) reported that chromium supplementation reversed the development of unexplained hyperglycaemia and

glycosuria in a 63-year-old female during administration of a TPN regime of several months duration. Glucose intolerance was the only clinical manifestation of depletion in this patient.

Impaired glucose tolerance of malnourished infants has been reported to respond to an oral dose of chromium chloride (Hopkins and Majaj, 1967; Hopkins et al., 1968; IoM, 2001). Also, chromium appears to potentiate the action of insulin *in vivo* and *in vitro*, and restores glucose tolerance in rats (IoM, 2001; EVM, 2002).

3.1. Contribution to normal macronutrient metabolism (ID 260, 401, 4665, 4666, 4667)

A common feature in all cases of chromium depletion reported in humans is an impaired glucose tolerance and glucose utilisation probably resulting from an increased resistance to the action of insulin (Jeejeebhoy et al., 1977; Freund et al., 1979; Brown et al., 1986). As reported by Jeejeebhoy et al. (1977), these lead to elevated plasma concentrations of fatty acids, increased utilisation of fatty acids as a source of energy, and possibly to abnormalities in nitrogen metabolism, as nitrogen retention increased with the administration of chromium chloride.

Although there is no consensus about the mechanism by which chromium could exert these effects, consensus opinions from authoritative bodies are generally in agreement that chromium facilitates the action of insulin, thus contributing to macronutrient metabolism (SCF, 1993; IoM, 2001; EVM, 2002).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of chromium and contribution to normal macronutrient metabolism. However, the evidence provided does not establish that inadequate intake of chromium leading to impaired macronutrient metabolism occurs in the general EU population.

3.2. Maintenance of normal blood glucose concentrations (ID 262, 4667)

Hyperglycaemia is a common feature of chromium depletion in humans, which is reversed by the administration of chromium (Jeejeebhoy et al., 1977; Freund et al., 1979; Brown et al., 1986; SCF, 1993; IoM, 2001; EVM, 2002).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of chromium and the maintenance of normal blood glucose concentrations. However, the evidence provided does not establish that intake of chromium inadequate for the maintenance of normal blood glucose concentrations occurs in the general EU population.

3.3. Contribution to the maintenance or achievement of a normal body weight (ID 339, 4665, 4666)

Weight loss has been described in one case as a result of chromium depletion in long-term total parenteral nutrition (TPN), which was reversed by the administration of chromium (Jeejeebhoy et al., 1977; Freund et al., 1979; SCF, 1993). However, body weight changes have not been described as a common feature of chromium deficiency.

Among the references provided for the scientific substantiation of this claim, a meta-analysis of double-blind, randomised controlled trials (Pittler et al., 2003) and five intervention studies in humans (Anderson et al., 1983; Grant et al., 1997; Bahadori et al., 1997; Crawford et al., 1999, Rabinovitz et al., 2004) have investigated the effects of different forms of chromium on body weight. The study of Rabinovitz et al., (2004) was uncontrolled (all subjects received 200 μg chromium picolinate (CrPic) twice daily) and therefore the Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claimed effect.

The meta-analysis by Pittler et al. (2003) investigated the effects of chromium picolinate (CrPic) on body weight by searching and pooling available double-blind, placebo-controlled, randomised trials in humans reporting on body weight, even if body weight was not the primary outcome. Ten trials met the inclusion criteria (Volpe et al., 2001; Kaats et al., 1996; Kaats et al., 1998; Walker et al., 1998; Livolsi et al., 2001; Campbell et al., 1999; Joseph et al., 1999; Hasten et al., 1992; Hallmark et al., 1996; Grant et al., 1997). Fourteen studies were excluded because they were either not randomised, double-blind and placebo controlled, did not test a mono-preparation of CrPic, did not report on body weight or were published in duplicate. Seven other studies reported in six publications (Lee and Reasner, 1994; Anderson et al., 1997; Clancy et al., 1994; Press et al., 1990; Bahadori et al., 1997; Evans, 1989) were also considered but reported data that the authors of the meta-analysis found not suitable for statistical pooling. Doses of CrPic used in these studies ranged from 188 to 924 μg per day, and study duration was from 6 to 12 weeks. No data were available to calculate body mass index (BMI) in five of the studies.

The result of the meta-analysis for body weight suggests a significant reduction in body weight in subjects receiving CrPic compared with subjects receiving placebo (weighted mean difference: -1.1 kg; 95 % CI: -1.8 to -0.4 kg, n = 489). When the six trials (Volpe et al., 2001; Kaats et al., 1996, 1998; Campbell et al., 1999; Joseph et al., 1999; Grant et al., 1997) which included overweight or obese subjects for treatment periods ranging between 6 to 13 weeks were assessed separately, similar results were obtained (weighted mean difference: -1.1 kg; 95 % CI: -1.8 to -0.4 kg, n = 385). Sensitivity analyses performed to test the robustness of the main analysis showed that removing the data of one trial (Kaats et al., 1996) which accounted for 58 % of the overall effect, would alter the direction of the result. The meta-analysis of the remaining nine studies showed no significant effect of CrPic compared to placebo on body weight (weighted mean difference: -0.9 kg; 95 % CI: -2.0 to 0.2 kg, n = 335).

A funnel plot of the mean difference in body weight reduction against trial sample size was consistent with some degree of publication bias.

An additional human intervention study using CrPic and reporting on body weight changes which was published after the meta-analysis by Pittler et al. (2003) was provided in the consolidated list (Rabinovitz et al., 2004). However, this study lacked a control group (all subjects received 200 μg CrPic twice daily) and therefore the Panel considers that no conclusions can be drawn for the scientific substantiation of the claimed effect.

Two additional human intervention studies using CrPic and reporting on body weight with sample sizes of more than 80 subjects, and which were published after the meta-analysis by Pittler et al. (2003), have been identified by the Panel (Lukaski et al., 2007; Yazaki et al., 2010).

In the double-blind, placebo controlled intervention study by Lukaski et al. (2007), 83 women were randomly assigned to consume CrPic (200 μg Cr per day, n = 27), an equivalent amount of picolinic acid (1720 μg, n = 27) or placebo (n = 29) for 12 weeks. All three groups received nutritionally balanced diets controlled for energy and nutrients. No significant differences between groups were observed in body weight changes during the study, suggesting no effect of Cr as CrPic on body weight.

In the randomised, double-blind, placebo-controlled trial by Yazaki et al. (2010), 80 overweight or obese subjects (40 female) were randomly assigned to consume 1000 μg per day of CrPic or placebo (1630 mg per day of dicalcium phosphate) for six months. During the first three months, all subjects were asked to continue with their usual dietary habits and physical activity level, whereas a low-intensity nutrition education and weight loss programme was prescribed to both groups for the remaining three months. Only statistical analyses in completers were performed. Data were available for 67 subjects (35 in the treatment group) at three months and for 58 subjects at six months (30 in the

treatment group). No significant differences between groups were observed in body weight changes (expressed as BMI) during the study at any time point.

The remaining three intervention studies in humans provided in the consolidated list which reported on body weight changes used other forms of chromium, such as chromium chloride (Anderson et al., 1983) or niacin-bound chromium (i.e., chromium nicotinate) (Grant et al., 1997; Crawford et al., 1999).

In a randomised, double-blind cross-over study (Anderson et al., 1983), 76 normal, free-living subjects (28 females) received supplements of 200 μg per day chromium (Cr) in the form of chromium chloride and placebo for three months each in random order. No other dietary or lifestyle changes were advised. No significant differences between chromium and placebo in body weight changes were observed during the study.

Crawford et al. (1999) designed a randomised, double-blinded, placebo-controlled, crossover pilot study to assess the effects of 600 μg per day of niacin-bound chromium on body weight in 20 overweight African-American women undergoing a modest dietary and exercise programme. Placebo and Cr (n=10 verum first) periods were each two months in duration. No significant differences between chromium and placebo in body weight changes were observed during the study. The Panel notes the small number of subjects recruited in this study.

No evidence of a biologically plausible mechanism by which chromium could exert the claimed effect has been provided

In weighing the evidence, the Panel took into account that results from the meta-analysis which assessed the effects of chromium picolinate on body weight were not robust and were possibly clouded by publication bias, that results from the largest intervention studies on the effects of chromium on body weight were inconsistent, that two studies showed a statistically significant effect of chromium on body weight (Kaats et al., 1996, 1998), that three studies (Anderson et al., 1983; Lukaski et al., 2007; Yazaki et al., 2010) showed no effect and that no evidence of a biologically plausible mechanism by which chromium could exert the claimed effect has been provided.

The Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the dietary intake of chromium and the contribution to the maintenance or achievement of a normal body weight.

3.4. Reduction of tiredness and fatigue (ID 261)

Five references were provided for the scientific substantiation of this claim. These included two nutrition text books, a consensus opinion on dietary reference intakes for several vitamins and minerals including chromium (IoM, 2001), a general review on the potential effects of chromium including toxicity and an intervention study on the effects of acute chromium supplementation to male runners on a number of biochemical variables but which did not include fatigue as an outcome (Anderson et al., 1984).

Tiredness and fatigue are not among the symptoms observed in the few cases of chromium depletion reported and referred to in the references provided.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of chromium and reduction of tiredness and fatigue.

4. Panel's comments on the proposed wording

4.1. Contribution to normal macronutrient metabolism (ID 260, 401, 4665, 4666, 4667)

The Panel considers that the following wording reflects the scientific evidence: "Chromium contributes to normal macronutrient metabolism".

4.2. Maintenance of normal blood glucose concentrations (ID 262, 4667)

The Panel considers that the following wording reflects the scientific evidence: "Chromium contributes to the maintenance of normal blood glucose levels".

5. Conditions and restrictions of use

The Panel considers that in order to bear the claims, a food should be at least a source of trivalent chromium as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

CONCLUSIONS

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

- The food constituent, trivalent chromium, which is the subject of the health claims, is sufficiently characterised.

Contribution to normal macronutrient metabolism (ID 260, 401, 4665, 4666, 4667)

- The claimed effects are "chromium has been shown to potentiate insulin action and thereby influences carbohydrate, lipid and protein metabolism", chromium is part of enzymes of the carbohydrate and lipid metabolism", "promotes carbohydrates catabolism by potentiating insulin action and thereby influencing carbohydrates metabolism", "promotes fat catabolism by potentiating insulin action and thereby influencing lipid metabolism", and "glucose metabolism". The target population is assumed to be the general population. Contribution to normal macronutrient metabolism is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of chromium and contribution to normal macronutrient metabolism.
- The evidence provided does not establish that inadequate intake of chromium leading to impaired macronutrient metabolism occurs in the general EU population.
- The following wording reflects the scientific evidence: "Chromium contributes to normal macronutrient metabolism".

Maintenance of normal blood glucose concentrations (ID 262, 4667)

- The claimed effects are "to fulfil increased need during pregnancy and lactation" and "glucose metabolism". The target population is assumed to be the general population. Maintenance of normal blood glucose concentrations is a beneficial physiological effect.
- A cause and effect relationship has been established between the dietary intake of chromium and the maintenance of normal blood glucose concentrations.
- The evidence provided does not establish that intake of chromium inadequate for the maintenance of normal blood glucose concentrations occurs in the general EU population.

- The following wording reflects the scientific evidence: "Chromium contributes to the maintenance of normal blood glucose levels".

Contribution to the maintenance or achievement of a normal body weight (ID 339, 4665, 4666)

- The claimed effects are "weight control", "promotes carbohydrates catabolism by potentiating insulin action and thereby influencing carbohydrates metabolism", and "promotes fat catabolism by potentiating insulin action and thereby influencing lipid metabolism". The target population is assumed to be the general population. Contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.
- The evidence provided is insufficient to establish a cause and effect relationship between the dietary intake of chromium and the contribution to the maintenance or achievement of a normal body weight.

Reduction of tiredness and fatigue (ID 261)

- The claimed effect is "vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status". The target population is assumed to be the general population. Reduction of tiredness and fatigue is a beneficial physiological effect.
- A cause and effect relationship has not been established between the dietary intake of chromium and reduction of tiredness and fatigue.

Conditions and possible restrictions of use

In order to bear the claims, a food should be at least a source of trivalent chromium as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1047, EFSA-Q-2008-1048, EFSA-Q-2008-1049, EFSA-Q-2008-1126, EFSA-Q-2008-1188, EFSA-Q-2010-00618, EFSA-Q-2010-00619, EFSA-Q-2010-00620). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: http://www.efsa.europa.eu/panels/nda/claims/article13.htm.

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods[8] (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

a) the role of a nutrient or other substance in growth, development and the functions of the body; or

b) psychological and behavioural functions; or

c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD[9]

Foods are commonly involved in many different functions[10] of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

[8] OJ L12, 18/01/2007
[9] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[10] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

(a) the claimed effect of the food is beneficial for human health,

(b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),

(c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,

(d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.

- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.

- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. 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 wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to chromium, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
260	Chromium	Chromium has been shown to potentiate insulin action and thereby influences carbohydrate, lipid and protein metabolism.	Chromium is important for blood glucose level, glucose tolerance, chromium is important for insulin function, chromium is important for normal carbohydrate, lipid and protein metabolism.
	Conditions of use - Guidance level is 10mcg/day or less from supplements (FSA). Diabetic patients taking supplementary chromium may require adjustment of insulin dosage Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006. - Food supplement with 50 µg of chromium in the daily dose. - 200 mg/d minimally for 5 weeks. - 10-45 mcg Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006. - COMA calcuted and adequate level of intake of 25 ug chromium per day for adults. The product must contain at least 15% of COMA value = 3.75 ug. - Erwachsene im üblichen µg-Bereich - Erwachsene: 20 µg, upper limit: 40 µg - Sportler. - Chromium salt, From 25 µg to 200 µg per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
261	Chromium (III)	Vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status. <u>Clarification provided</u> Reduce fatigue and tiredness, particularly in situations of inadequate micronutrient status, due to role in influencing macronutrient metabolism.	Supplementation with B-vitamins, iron, magnesium as well as vitamin C can reduce fatigue and tiredness in situations of inadequate micro-nutrient status.
	Conditions of use - Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]," as per Annex to Regulation 1924/2006.		

ID	Food or Food constituent	Health Relationship	Proposed wording
262	Chromium	To fulfil increased need during pregnancy and lactation. Clarification provided To fulfil increased chromium needs during pregnancy and lactation for a proper metabolism to maintain normal blood glucose levels.	To fulfil increased chromium needed during pregnancy and lactation.
	Conditions of use - 10 - 45 mcg. Must meet minimum requirements for use of the claim "source of [name of vitamin/s] and/or [name of mineral/s]" as per Annex to Regulation 1924/2006.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
339	Chromium	Weight control.	Promotes metabolism. Supports weight control physiologically.
	Conditions of use - 200 µg chromium a day. - Food supplement with 50 µg of chromium in the daily dose.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
401	Gemüse / Spargel / Chrom Clarification provided asparagus as vegetable: chrome content	Bestandteil von Enzymen, Kohlenhydrat- und Fettstoffwechsel / Chrom Clarification provided Chrome is part of enzymes of the carbohydrate and lipmetabolism	[In german :] Das Spurenelement Chrom ist Bestandteil wichtiger Enzyme und wird unter anderem im Kohlenhydrat- und Fettstoffwechsel benötigt. Clarification provided The micronutrient chrome is part of enzymes required for carbohydrate and lipometabolism.
	Conditions of use - Es werden nur die Nährstoffe beworben, die lt. Nährwertkennzeichnungs-verordnung (Anlage 1) mindestens 15 Prozent der empfohlenen Tagesdosis in 100 g oder 100 ml enthalten.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4665	Chromium	Promotes carbohydrates catabolism by potentiating insulin action and thereby influencing carbohydrates metabolism.	Promotes carbohydrates catabolism, helping in body weight maintaining.
	Conditions of use - 30 µg / day as chromium chloride.		

ID	Food or Food constituent	Health Relationship	Proposed wording
4666	Chromium	Promote fat catabolism by potentiating insulin action and thereby influencing lipid metabolism.	Promotes lipid catabolism, helping in body weight maintaining.
	Conditions of use - 30 µg / day as chromium chloride.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4667	Chromium	Glucose Metabolism	Help to maintain a normal blood glucose level as part of a healthy lifestyle. / Contributes to normal glucose – insulin metabolism. / Can delay increased level of blood glucose.
	Conditions of use - Capsule, solution/ / equivalent at maximum of 0,3 mg chromium/ day, or as per individual conditions of use, during two weeks.		

GLOSSARY AND ABBREVIATIONS

BMI	Body mass index
CI	Confidence interval
Cr(III)	Trivalent chromium
CrPic	Chromium picolinate
TPN	Total parenteral nutrition