

November 2010

EFLA/AEDA Interpretation Notes on Regulation EC n^o 1924/2006 on nutrition and health claims made on foods

N.B.: These notes do not cover issues that have been covered by the "Guidance on the implementation of Regulation EC n° 1924/2006 on nutrition and health claims made on foods", approved by the Standing Committee on the Food Chain and Animal Health on 14 December 2007.

The present document is the result of a collective work undertaken by EFLA members who have put together their personal views on how some provisions of Regulation 1924/2006 should be interpreted. This document has no formal legal status, can be amended continuously in the light of new ideas expressed and discussed among EFLA members or in the light of their respective experience, and can in no way be considered as a legal opinion delivered by EFLA or by its members. Therefore, neither EFLA nor any of its members can be deemed responsible for any of the views expressed in this document and the way it can used or quoted.



Article	Provision	The EFLA Interpretation
1(2)	This Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer.	Directive 2006/123/EC on services in the internal market defines, in its Article 4(12), 'commercial communication' as "any form of communication designed to promote, directly or indirectly, the goods, services or image of an undertaking, organisation or person engaged in commercial, industrial or craft activity or practising a regulated profession. The following do not in themselves constitute commercial communications: (a) information enabling direct access to the activity of the undertaking, organisation or person, including in particular a domain name or an electronic-mailing address;
		(b) communications relating to the goods, services or image of the undertaking, organisation or person, compiled in an independent manner, particularly when provided for no financial consideration."
		Within the context of Regulation 1924/2006, the expression "commercial communications" should therefore be understood as referring to any direct and/or indirect initiative aiming at promoting, selling or supplying a food product. This would include product labels, in-store displays, television, radio, internet and press advertisements, billboards, leaflets, etc.
		 Article 1(2) specifies that the Regulation applies to nutrition and health claims made in "commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer." The interpretation of this article is equivocal, particularly in the English version of the text, as it can be interpreted in two different ways: 1) The Regulation applies to all nutrition and health claims made in commercial communications delivered as such to the final consumer (i.e. where the commercial communications are delivered as such to the final consumer (i.e. where the commercial communications are delivered as such to the final consumer (i.e. where the commercial communications reference to the final consumer (i.e. where the communications reference to food products that are available on the market to the final consumer). However, the French version of the text is clearer and corresponds to the latter interpretation: "Le présent règlement s'applique aux allégations nutritionnelles et de santé formulées dans les communications à caractère commercial, qu'elles apparaissent dans l'étiquetage ou la présentation des denrées alimentaires ou la publicité faite à leur égard, dès lors que les denrées alimentaires en question sont destinées à être fournies en tant que telles au consommateur final."
		 The ambiguity of the English version of the text, and possibly also other language versions, will inevitably have an impact on the way the different national enforcement bodies will apply the Regulation in their respective markets. This difference of interpretation is particularly relevant to determine whether communications from food business operators to health professionals need to comply with the Regulation: 1) If interpretation 1) above is applied, communications to health professionals are excluded from the scope of the Regulation as the health professionals are not the final consumers of the product; 2) However, if interpretation 2) is applied, such communications to health professionals would have to comply with the Regulation if they refer to specific branded "foods to be delivered as such to the final consumer" i.e. if they refer to specific branded products that consumers can buy. They would not be covered by the scope of the Regulation if no specific branded foods – to be delivered as



		 such to the final consumer – are promoted (only a category of foods/substances). In our view, the two interpretations are valid, depending on which language version of the text one is using. Therefore, EFLA urges the European Commission to propose an amendment to the Regulation to clarify the original intention of the legislator. However, business-to-business communications are not covered by the scope of the Regulation, irrespective of which interpretation is applied: B-to-B communications are not communications delivered to the final consumer; B-to-B communications normally do not refer to "foods to be delivered as such to the final consumer" but to specific ingredients that will not be delivered as such to the final consumer. For example, communications from an ingredient supplier (e.g. vitamin C) to the manufacturer of the final product that will be sold to consumers (e.g. food supplement with different vitamins) are not covered by the scope of the Regulation. The websites of ingredient suppliers that do not sell any final products to consumers all necessary information to allow them to abide by the Regulation. Therefore, suppliers remain responsible for providing to its customers all necessary information to allow them to abide by the Regulation, as the commercial nature of such comply with the Regulation, as the commercial nature of such communications cannot be questioned and the products belonging to that category are available on the market. Article 1(2) further clarifies that the Regulation also applies in respect of foods intended for supply to mass caterers such as restaurants, canteens, hospitals, etc.
1(3)	A trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim may be used without undergoing the authorisation procedures provided for in this Regulation, provided that it is accompanied by a related nutrition or health claim in that labelling, presentation or advertising which complies with the provisions of this Regulation.	Trade marks, brand names and fancy names which can be understood as a nutrition or health claim will not need to undergo the applicable authorisation procedures if they are accompanied by a related and authorised nutrition or health claim. If this is not the case, they will then need to be authorised as such or they may be able to benefit from the applicable transition period referred to in Article 28(2). A "related" claim is to be understood as a claim that clearly expresses the beneficial nutritional property of the product (nutrition claim) or its specific effect on health (health claim) as was meant and/or implied in the respective trade mark, brand name or fancy name. The accompanying nutrition or health claim must comply with the provisions of the Regulation i.e. it must be an authorised nutrition or health claim or a nutrition or health claim covered by the respective transitional measures laid down in Article 28 of the Regulation. For example, a trade mark, brand name or fancy name may be accompanied by an Article 13(1)(a) health claim covered by the transition period laid down in Article 28(5) until the adoption of the Community list.
1(4)	For generic descriptors (denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an	Generic descriptors or denominations such as 'cough drops', 'digestive biscuits', 'tonic water', which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on health, may be exempted from having to be accompanied by a related and authorised nutrition or health claim.



	effect on human health, a	
	derogation from paragraph 3 may be adopted in accordance with the procedure referred to in Article 25(2), on application by the food business operators concerned. The application shall be sent to the	To obtain such derogation, an application must be submitted to a national competent authority which will forward it to the Commission. If no derogation is sought, such generic descriptors implying an effect on health will need to either be authorised as such or be accompanied by a related and authorised nutrition or health claim.
	national competent authority of a Member State which will forward it to the Commission without delay. The Commission shall adopt and make public the rules for food business operators according to which such applications shall be made, so as to ensure that the	Article 28 does not lay down any specific transition period for such generic descriptors. Hence, the general transition period would be applicable. Products bearing such denominations and labelled or placed on the EU market before 1 July 2007, which did not comply with the Regulation – i.e. bearing a generic descriptor that was not accompanied by a related nutrition or health claim – were authorised to be marketed until their expiry date, but not later than 31 July 2009.
	application is dealt with transparently and within a reasonable time.	 Generic descriptors which: were not submitted for approval as such, or did not apply for the derogation laid down in Article 1(4); and are not accompanied by a related nutrition or health claim are illegal since 1 August 2009.
		If generic descriptors were submitted for approval as an Article 13 health claim or applied for the derogation laid down in Article 1(4), it is understood that such descriptors will remain legal until a final decision is taken on them.
2(2)(1)	'claim' means any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics;	The definition of a 'claim' excludes any statement and/or representation that are mandatory under Community or national legislation. For example, statements indicating the particular nutritional characteristics of foodstuffs intended for particular nutritional uses are mandatory under Directive 2009/39/EC on foodstuffs intended for particular nutritional uses. These statements are therefore not covered by the scope of the claims Regulation.
		"Pictorial, graphic and symbolic representations, in any form, which state, suggest or imply that a food has particular characteristics" is to be regarded as a claim. Therefore, symbols and logos such as the Swedish Keyhole, the Healthy Choice logo, the UK Traffic Lights system and any other similar graphic representations, which imply that the products bearing them have particular nutritional characteristics, must also comply with the provisions of the Regulation.
		For example, the UK Traffic Lights logo comprises a number of clear nutrition claims which are represented by the green "dots" – low fat, low saturated fat, low sugars, low salt – which means the products using this labelling scheme must comply with the claims Regulation, including the nutrient profiles to be developed by the Commission. This will be problematic because products with two nutrients that do not comply with the nutrient profiles will not be able to include any "green dots" on their labels.
5(1)(b)(i)	General conditions 1. The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled: (b) the nutrient or other substance for which the claim is made: (i) is contained in the final product in a significant quantity as defined in Community legislation or, where	In certain cases, the "significant quantity" of the nutrient or other substance – for which the claim is made – which must be present in the final product is clearly defined in Community legislation. For example, in the case of certain nutrition claims (source of fibre, high protein, etc.), the significant amount is mentioned in the conditions applicable to these nutrition claims as laid down in the Annex to the Regulation. Also, in the case of vitamins and minerals, the significant amounts are defined in the Annex to Directive 90/496/EEC on nutrition labelling. In the case of health claims, the significant amounts are likely to be defined in the applicable conditions of use for such claims.

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	such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence; or ()	In cases where the significant quantity is not defined in Community legislation, it is the responsibility of the food manufacturer to ensure that the quantity contained in the final product will produce the claimed effect or is nutritionally relevant based on available scientific evidence.
6(3)	The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce all relevant elements and data establishing compliance with this Regulation.	A food business operator making a nutrition or health claim on a particular product must be able to provide the necessary data, upon request by national competent authorities, demonstrating that the claim made on the product complies with all the relevant provisions of the Regulation. This would include for example, evidence demonstrating that the nutrient/substance for which the claim is made is bio-available, data showing that the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the nutrient/substance to which the claim relates, that the substance present in the final product making the claim is indeed the same for which the health claim in question has been authorised, etc.
9	Comparative claims 1. Without prejudice to Directive 84/450/EEC, a comparison may only be made between foods of the same category, taking into consideration a range of foods of that category. The difference in the quantity of a nutrient and/or the energy value shall be stated and the comparison shall relate to the same quantity of food. 2. Comparative nutrition claims shall compare the composition of the food in question with a range of foods of the same category, which do not have a composition which allows them to bear a claim, including foods of other brands.	The Regulation includes specific provisions on comparative nutrition claims but none regarding comparative health claims. It is understood that comparative health claims are permitted provided they comply with the provisions of the Regulation, among which the need to be authorised under the applicable procedure and the need to indicate the difference in the quantity of the relevant nutrient on which the claim is made. In order to compare the nutrient quantity or energy value among a number of products belonging to the same category, the comparison must relate to the same amount of each food product, for example 100g. A comparison "per portion" (per bag, sachet or pack, per piece) would not be acceptable if the portions of each product being compared would have different weights.
10(2)	Health claims shall only be permitted if the following information is included in the labelling, or if no such labelling exists, in the presentation and advertising: (a) a statement indicating the importance of a varied and balanced diet and a healthy lifestyle; (b) the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect; (c) where appropriate, a statement addressed to persons who should avoid using the food; and (d) an appropriate warning for products that are likely to present	The additional mandatory labelling requirements referred to in Article 10(2) must be indicated when health claims are made, including during the transition period laid down in Article 28(5) for health claims as referred to in Article 13(1)(a). They are not necessary when only nutrition claims are made. This information must be displayed on-pack, except if no such pack exists, in which case it must be displayed in the presentation and advertising for the product in question. If the information is already included on the label, it is not necessary to mention it in the presentation and/or advertising for the product in question. The exact wordings of the required statements are under the responsibility of the food business operator.



	a health risk if consumed to excess.	
10(3)	Reference to general, non-specific benefits of the nutrient or food for overall good health or health- related well-being may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14.	General and non-specific references to the benefits of the product or substance for overall good health are only permitted if accompanied by a specific health claim included in the Community list or approved via the Article 14 procedure. However, this requirement can only be enforced when the Community list of permitted health claims will be published (Article 13 claims), unless the generic statement refers to a claim that has already been authorised (Article 13(5) claims or Article 14 claims).
11	In the absence of specific Community rules concerning recommendations of or endorsements by national associations of medical, nutrition or dietetic professionals and health-related charities, relevant national rules may apply in compliance with the provisions of the Treaty.	Article 11 refers specifically to " national associations ()". Therefore, a strict interpretation of the Regulation would restrict the scope of Article 11 to national associations only, excluding thereby European and international associations of medical, nutrition or dietetic professionals and health-related charities. However, as there are no a priori clear legal or scientific reasons to treat European or international associations in a different way as national associations, it is expected that this provisions will also apply to these. This interpretation has been reinforced by an informal agreement by Member State experts – reached at the 5 th of June 2008 meeting of the Commissions Claims Work Group – according to which it would be acceptable to treat International and European health related associations and charities in the same way as national associations. However, this remains an informal agreement with no legal status and could potentially be challenged in court. An amendment to Article 11 to clarify its scope would be necessary to ensure legal certainty. As long as there are no Community rules on recommendations of or endorsements by national associations of medical, nutrition or dietetic professionals and health-related charities, any existing national rules would be applicable. In the case where specific rules on this matter would not exist at the national level and that, therefore, no prohibition exists at national level, it is understood that such recommendations and/or endorsement would be permitted. However, this provision should be read in conjunction with Article 12(c) (se below).
12(b)	The following health claims shall not be allowed: () (b) claims which make reference to the rate or amount of weight loss;	The Regulation prohibits any claims referring to the "amount of weight loss" such as "lose 10 kg", "lose 3 inches from your waist" or "reduce fat deposit by X%". It also prohibits any claims referring to the "rate of weight loss" such as "lose 5 kg in two weeks" or "effective in 15 days". It is our understanding that words such as "fast", "instant" or "express" also imply a "rate of weight loss" and weight loss claims using them would therefore be prohibited ("instant weight loss", "fast method to get slim"). The specific case of "before & after weight loss pictures" is more complex. Considering that " <i>any message or representation</i> , () <i>including pictorial, graphic or symbolic representation, in any form,</i> <i>which states, suggests or implies that a food has particular</i> <i>characteristics</i> " should be regarded as a claim; Considering also that " <i>any claim that states, suggests or implies that a relationship exists</i> <i>between a food category, a food or one of its constituents and health</i> " should be regarded as a health claim; It must therefore be concluded that before & after weight loss pictures must be regarded as health claims as they are pictorial representations implying that a food product has an effect on one's health i.e. weight reduction. Also, although these pictorial representations may not necessarily literally mention any specific amount of weight loss or rate of weight loss, they do imply a "visible" reduction in weight that can potentially be evaluated (e.g.



		through differences in the clothing sizes). Hence, it is our understanding
		these before & after pictures are covered by the meaning of Article 12(b) and are therefore prohibited.
12(c)	The following health claims shall not be allowed: () (c) claims which make reference to recommendations of individual doctors or health professionals and other associations not referred to in Article 11.	Any health claims making reference to recommendations of individual doctors or health professionals and other associations not referred to in Article 11 are prohibited in commercial communications. This prohibition includes any health claims, in commercial communications, referring to recommendations by "individual doctors ()" such as: "Doctor John Doe recommends product X to help you maintain a healthy cholesterol level". It also prohibits more general endorsement or recommends by "individual doctors ()" such as "Doctor John Doe recommends by "individual doctors ()" such as "Doctor John Doe recommends by "individual doctors ()" such as "doctor/health professional would recommend a food product for other reasons than its beneficial impact on health.
13(4)	Any changes to the list referred to in paragraph 3, based on generally accepted scientific evidence and designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3), after consulting the Authority, on the Commission's own initiative or following a request by a Member State.	Once the Community list will be established, it will be possible to make changes to its content via the regulatory procedure with scrutiny. However, these changes would be limited, for example, to the conditions of use applicable to certain health claims, to take into account any new and relevant scientific developments, to remove certain claims from the list. This procedure is, in principle, not intended for the addition of new health claims to the Community list, which can only be made through the procedure laid down in Article 18. N.B. : The Commission and Member States are currently discussing whether the Article 13(4) procedure could also be used to add certain new claims to the list – for example, this procedure could be used to resubmit an application dossier for an Article 13 health claim which has been submitted for approval by end January 2008, but has since been
		withdrawn by the applicant – via a Member State – in order to re-submit a dossier containing additional information. It is also being discussed whether this procedure could be used to re-introduce an application for a claim negatively evaluated by EFSA but for which the applicant would like to submit complementary data. However, it remains unclear how this procedure will work, until when can dossiers be submitted, what should these dossiers contain, etc.
13(5)	Any additions of claims to the list referred to in paragraph 3 based on newly developed scientific evidence and/or which include a request for the protection of proprietary data shall be adopted following the procedure laid down in Article 18, except claims referring to children's development	Article 13(5) health claims, to be approved under the procedure laid down in Article 18, include all health claims which are not 'reduction of disease risk claims' or 'claims referring to children's development and health' and which have not been submitted for approval under the procedure laid down in Article 13(2) and 13(3). Article 13.5 health claims are therefore all "new" health claims – i.e. not previously submitted for evaluation by 31 January 2008 via a Member State list –, for which an authorisation is sought, with or without a
	and health, which shall be authorised in accordance with the procedure laid down in Articles 15, 16, 17 and 19.	request for the protection of proprietary data. Since 31 January 2008, all new additions to the Community list of permitted health claims must follow the Article 18 procedure. N.B.: The Commission and Member States are currently discussing
		whether the Article 13(4) procedure could also be used to add certain new claims to the list – for example, this procedure could be used to re- submit an application dossier for an Article 13 health claim which has been submitted for approval by end January 2008, but has since been withdrawn by the applicant – via a Member State – in order to re-submit



		a dossier containing additional information. It is also being discussed whether this procedure could be used to re-introduce an application for a claim negatively evaluated by EFSA but for which the applicant would like to submit complementary data. However, it remains unclear how this procedure will work, until when can dossiers be submitted, what should these dossiers contain, etc.
21	Data protection 1. The scientific data and other information in the application required under Article 15(3) may not be used for the benefit of a subsequent applicant for a period of five years from the date of authorisation, unless the subsequent applicant has agreed with the prior applicant that such data and information may be used, where: (a) the scientific data and other information has been designated as proprietary by the prior applicant at the time the prior application was made; and (b) the prior applicant had exclusive right of reference to the proprietary data at the time the prior application was made; and (c) the health claim could not have been authorised without the submission of the proprietary data by the prior applicant. 2. Until the end of the five-year period specified in paragraph 1, no subsequent applicant shall have the right to refer to data designated as proprietary by a prior applicant unless and until the Commission takes a decision on whether a claim could be or could have been included in the list provided for in Article 14 or, where appropriatery by the prior applicant.	The protection of proprietary data granted in Article 21 does not allow subsequent applicants to refer to such data for a period of five years to substantiate their own applications for the authorisation of the same or other health claims. A subsequent applicant can nevertheless submit a dossier for the authorisation of the same claim but it will need to provide its own different data to substantiate the claim. This provision allows the protection of data substantiating a claim, but the claim itself is not protected/reserved, provided a subsequent applicant is able to also obtain an authorisation for the same claim on the basis of other substantiating data (proprietary or not).
28(2)	Products bearing trade marks or brand names existing before 1 January 2005 which do not comply with this Regulation may continue to be marketed until 19 January 2022 after which time the provisions of this Regulation shall apply.	Trade marks and brand names which have been used in the EU, i.e. in any of the Member States, before 1 January 2005 and which do not comply with the Regulation may continue to be marketed, in any of the Member States, until 19 January 2022. The Regulation does not require that the trade mark or brand name must be officially registered. Its simple use/presence in the EU market, i.e. in any of the Member States, before 19 January 2005 is enough for it to be covered by this transitional measure. The use of a trade mark or brand name before 1 January 2005 in at least one EU Member State is a sufficient condition to allow its use until 19 January 2022 across all EU markets, even if it will be subsequently used for the first time in another Member State after 1 January 2005. This transitional measure applies to the trade marks or brand names themselves, not to the products bearing them. The same trade mark or



		brand name, existing before 1 January 2005, can be used after that
		date in new products and across other EU markets.
		Trade marks or brand names, existing before 1 January 2005, which are accompanied by health claims covered by the transitional measures referred to in Articles 28(5) and 28(6) in compliance with Article 1(3), will still be permitted until 19 January 2022 even if the accompanying health claims will not be included in the final Community list. In such cases, the health claims will have to be removed at the end of the transition period applicable to them, but the trade mark or brand name itself will still be covered by this transitional measure and can remain on the market until 19 January 2022.
28(3)	Nutrition claims which have been used in a Member State before 1 January 2006 in compliance with national provisions applicable to them and which are not included in the Annex, may continue to be used until 19 January 2010 under the responsibility of food business operators and without prejudice to the adoption of safeguard measures as referred to in Article 24.	Since 19 January 2010, only the nutrition claims mentioned in the Annex to the Regulation and complying with the conditions set therein are permitted in the EU.
28(5)	Health claims as referred to in Article 13(1)(a) may be made from the date of entry into force of this Regulation until the adoption of the list referred to in Article 13(3), under the responsibility of food business operators provided that they comply with this Regulation and with existing national provisions applicable to them, and without prejudice to the adoption of safeguard measures as referred to in Article 24.	Health claims describing or referring to the role of a nutrient or other substance in growth, development and the functions of the body which comply with relevant general provisions of the Regulation as well as with any applicable national legislation (if any) may be made until the establishment of the Community list of permitted health claims. In case there is no specific national legislation/guideline applicable to such claims, they would be permitted provided the national authorities accept them in line with the national principles they applied before the Regulation came into force and, provided also that they comply with the relevant provisions of the Regulation, such as the general principles (Article 3) and conditions (Article 5) applicable to claims, the additional labelling requirements (Article 10), etc.
28(6)	Health claims other than those referred to in Articles 13 (1)(a) and 14(1)(a), which have been used in compliance with national provisions before the date of entry into force of this Regulation, shall be subject to the following: (a) health claims which have been	 The following health claims are subject to the transitional measures referred to in this article: Health claims describing or referring to: psychological and behavioural functions (Article 13(1)(b)); 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 (Article 13(1)(c)); claims referring to children's development and health (Article 14(1)(b)).

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the subject of evaluation and authorisation in a Member State shall be authorised as follows: (i) Member States shall communicate to the Commission, by 31 January 2008 at the latest, such claims accompanied by a report evaluating the scientific data in support of the claim; (ii) after consulting the Authority, the Commission shall, in accordance with the regulatory procedure with scrutiny referred to in Article 25(3), adopt a decision concerning the health claims authorised in this way and designed to amend non-essential elements of this Regulation by supplementing it. Health claims not authorised under this procedure may continue to be used for six months following the adoption of the Decision; (b) health claims which have not been the subject of evaluation and authorisation in a Member State: such claims may continue to be used provided an application is made pursuant to this Regulation before 19 January 2008; health claims not authorised under this procedure may continue to be used for six months after a decision is taken pursuant to Article 17(3).	 These health claims had to be submitted, by January 2008, by/via a Member State for evaluation under the relevant procedure: The Article 13(3) procedure or the Article 18 procedure for claims referring to psychological and behavioural functions (Article 13(1)(b)) and claims referring to 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 (Article 13(1)(c)); The Article 14 procedure for claims referring to children's development and health (Article 14(1)(b)). These health claims are only permitted in the EU if they have indeed been submitted for approval under one of the procedures mentioned above. For example, any claims referring to psychological functions or weight control, which have not been submitted for approval by January 2008 are now illegal.
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