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

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on nutrition and health claims made on foods**]**

[[X1]THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) An increasing number of foods labelled and advertised in the Community bear nutrition and health claims. In order to ensure a high level of protection for consumers and to facilitate their choice, products put on the market, including imported products, should be safe and adequately labelled. A varied and balanced diet is a prerequisite for good health and single products have a relative importance in the context of the total diet.

(2) Differences between national provisions relating to such claims may impede the free movement of foods and create unequal conditions of competition. They thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on the use of nutrition and health claims on foods.

(3) General labelling provisions are contained in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs[(3)]. Directive 2000/13/EC generally prohibits the use of information that would mislead the purchaser or attribute medicinal properties to food. This Regulation should complement the general principles in Directive 2000/13/EC and lay down specific provisions concerning the use of nutrition and health claims concerning foods to be delivered as such to the consumer.

(4) This Regulation should apply to all nutrition and health claims made in commercial communications, including inter alia generic advertising of food and promotional campaigns, such as those supported in whole or in part by public authorities. It should not apply to claims which are made in non-commercial communications, such as dietary guidelines or advice issued by public health authorities and bodies, or non-commercial communications and information in the press and in scientific publications.

This Regulation should also apply to trade marks and other brand names which may be construed as nutrition or health claims.

(5) Generic descriptors (denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on human health, such as 'digestive' or 'cough drops', should be exempted from the application of this Regulation.

(6) Non-beneficial nutrition claims are not covered by the scope of this Regulation; Member States intending to introduce national schemes relating to non-beneficial nutrition claims should notify such schemes to the Commission and to other Member States in accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services[(4)].

(7) At international level the Codex Alimentarius has adopted General Guidelines on Claims in 1991 and Guidelines for the Use of Nutrition Claims in 1997. An amendment to the latter has been adopted by the Codex Alimentarius Commission in 2004. That amendment concerns the inclusion of health claims in the 1997 Guidelines. Due consideration is given to the definitions and conditions set in the Codex Guidelines.

(8) The possibility of using the claim 'low fat' for spreadable fats provided for in Council Regulation (EC) No 2991/94 of 5 December 1994 laying down standards for spreadable fats[(5)] should be adapted to the provisions of this Regulation as soon as possible. In the meantime, Regulation (EC) No 2991/94 applies for the products it covers.

(9) There is a wide range of nutrients and other substances including, but not limited to, vitamins, minerals including trace elements, amino-acids, essential fatty acids, fibre, various plants and herbal extracts with a nutritional or physiological effect that might be present in a food and be the subject of a claim. Therefore, general principles applicable to all claims made on foods should be established in order to ensure a high level of consumer protection, give the consumer the necessary information to make choices in full knowledge of the facts, as well as creating equal conditions of competition for the food industry.

(10) Foods promoted with claims may be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products to which such nutrients and other substances are not added. This may encourage consumers to make choices which directly influence their total intake of individual nutrients or other substances in a way which would run counter to scientific advice. To address this potential undesirable effect, it is appropriate to impose certain restrictions as regards the products bearing claims. In this context, factors such as the presence of certain substances, or the nutrient profile of a product, are appropriate criteria for determining whether the product can bear claims. The use of such criteria at national level, whilst justified for the purpose of allowing consumers to make informed nutritional choices, is likely to result in barriers to intra-Community trade and should therefore be harmonised at Community level. Health information and communication supporting

national authority or Community messages about the dangers of misuse of alcohol should not fall under the scope of this Regulation.

(11) The application of nutrient profiles as a criterion would aim to avoid a situation where nutrition or health claims mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet. Nutrient profiles as provided for in this Regulation should be intended for the sole purpose of governing the circumstances in which claims may be made. They should be based on generally accepted scientific evidence relative to the relationship between diet and health. However, profiles should also allow for product innovation and should take into account the variability of dietary habits and traditions, and the fact that individual products may have an important role in the context of an overall diet.

(12) The establishment of nutrient profiles should take into account the content of different nutrients and substances with a nutritional or physiological effect, in particular those such as fat, saturated fat, trans-fatty acids, salt/sodium and sugars, excessive intakes of which in the overall diet are not recommended, as well as poly- and mono-unsaturated fats, available carbohydrates other than sugars, vitamins, minerals, protein and fibre. When setting the nutrient profiles, the different categories of foods and the place and role of these foods in the overall diet should be taken into account and due regard should be given to the various dietary habits and consumption patterns existing in the Member States. Exemptions from the requirement to respect established nutrient profiles may be necessary for certain foods or categories of foods depending on their role and importance in the diet of the population. These would be complex technical tasks and the adoption of the relevant measures should be entrusted to the Commission, taking into account the advice of the European Food Safety Authority.

(13) Food supplements as defined in 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[(6)] presented in a liquid form and containing more than 1,2 % by volume of alcohol are not considered as beverages under this Regulation.

(14) There is a wide variety of claims currently used in the labelling and advertising of foods in some Member States relating to substances that have not been shown to be beneficial or for which at present there is not sufficient scientific agreement. It is necessary to ensure that the substances for which a claim is made have been shown to have a beneficial nutritional or physiological effect.

(15) In order to ensure that the claims made are truthful, it is necessary that the substance that is the subject of the claim is present in the final product in quantities that are sufficient, or that the substance is absent or present in suitably reduced quantities, to produce the nutritional or physiological effect claimed. The substance should also be available to be used by the body. In addition, and where appropriate, a significant amount of the substance producing the claimed nutritional or physiological effect should be provided by a quantity of the food that can reasonably be expected to be consumed.

(16) It is important that claims on foods can be understood by the consumer and it is appropriate to protect all consumers from misleading claims. However, since the enactment of Council Directive 84/450/EEC of 10 September 1984 concerning

misleading and comparative advertising[7], the Court of Justice of the European Communities has found it necessary in adjudicating on advertising cases to examine the effect on a notional, typical consumer. In line with the principle of proportionality, and to enable the effective application of the protective measures contained in it, this Regulation takes as a benchmark the average consumer, who is reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors, as interpreted by the Court of Justice, but makes provision to prevent the exploitation of consumers whose characteristics make them particularly vulnerable to misleading claims. Where a claim is specifically aimed at a particular group of consumers, such as children, it is desirable that the impact of the claim be assessed from the perspective of the average member of that group. The average consumer test is not a statistical test. National courts and authorities will have to exercise their own faculty of judgment, having regard to the case-law of the Court of Justice, to determine the typical reaction of the average consumer in a given case.

(17) Scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims and the food business operators using claims should justify them. A claim should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence.

(18) A nutrition or health claim should not be made if it is inconsistent with generally accepted nutrition and health principles or if it encourages or condones excessive consumption of any food or disparages good dietary practice.

(19) Given the positive image conferred on foods bearing nutrition and health claims and the potential impact these foods may have on dietary habits and overall nutrient intakes, the consumer should be able to evaluate their global nutritional quality. Therefore, nutrition labelling should be compulsory and should be extensive on all foods bearing health claims.

(20) General nutritional labelling provisions are contained in Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs[8]. According to that Directive, where a nutrition claim appears on labelling, in presentation or in advertising, with the exclusion of generic advertising, nutrition labelling should be compulsory. Where a nutrition claim is made for sugars, saturates, fibre or sodium, the information to be given should be that of Group 2 as defined in Article 4(1) of Directive 90/496/EEC. In order to achieve a high level of consumer protection, this obligation to provide the information of Group 2 should apply mutatis mutandis where any health claim is made, with the exception of generic advertising.

(21) A list of permitted nutrition claims and their specific conditions of use should also be created based on the conditions for the use of such claims that have been agreed at national or international level and laid down in Community legislation. Any claim considered to have the same meaning for consumers as a nutrition claim included in the abovementioned list should be subject to the same conditions of use indicated therein. For example, claims related to the addition of vitamins and minerals such as ‘with …’, ‘restored …’, ‘added …’, or ‘enriched …’ should be subject to the conditions set for the claim ‘source of …’. The list should be regularly updated in order to take into account

scientific and technological developments. Furthermore, for comparative claims it is necessary that the products being compared be clearly identified to the final consumer.

(22) Conditions for claims such as 'lactose-free' or 'gluten-free', addressed to a group of consumers with specific disorders, should be dealt with in Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses[(9)]. In addition, that Directive provides the possibility that foodstuffs for normal consumption can indicate their suitability for use by these groups of consumers if they fulfil the conditions for such statement. Until the conditions for such statements are set at Community level, Member States may maintain or adopt relevant national measures.

(23) Health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard. In order to ensure harmonised scientific assessment of these claims, the European Food Safety Authority should carry out such assessments. Upon request the applicant should be able to have access to his file to check the state of the procedure.

(24) There are many factors, other than dietary ones, that can influence psychological and behavioural functions. Communication on these functions is thus very complex and it is difficult to convey a comprehensive, truthful and meaningful message in a short claim to be used in the labelling and advertising of foods. Therefore, it is appropriate, when using psychological and behavioural claims, to require scientific substantiation.

(25) In the light of Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction[(10)] which prohibits, in the labelling, presentation and advertising of products covered by that Directive, any reference to the rate or amount of weight loss which may result from their use, it is considered appropriate to extend this restriction to all foods.

(26) Health claims other than those referring to the reduction of disease risk and to children's development and health, based on generally accepted scientific evidence, should undergo a different type of assessment and authorisation. It is therefore necessary to adopt a Community list of such permitted claims after consulting the European Food Safety Authority. Furthermore, in order to stimulate innovation, those health claims which are based on newly developed scientific evidence should undergo an accelerated type of authorisation.

(27) In order to keep up with scientific and technological developments, the list referred to above should be revised promptly whenever necessary. Such revisions are implementing measures of a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.

(28) Diet is one of the many factors influencing the onset of certain human diseases. Other factors such as age, genetic predisposition, the level of physical activity, the consumption of tobacco and other drugs, environmental exposure and stress may all influence the onset of human diseases. Specific labelling requirements should therefore apply in respect of claims relating to the reduction of a disease risk.