

# Procedure file

Basic information	
<p>COD - Ordinary legislative procedure (ex-codecision procedure) Regulation</p> <p>2003/0165(COD)</p>	Procedure completed
<p>Nutrition and health claims made on foods</p> <p>Amending Directive 2000/13/EC <a href="#">1999/0090(COD)</a> Amended by <a href="#">2006/0195(COD)</a> Amended by <a href="#">2007/0128(COD)</a> Amended by <a href="#">2008/0028(COD)</a> See also <a href="#">2011/2549(RPS)</a> See also <a href="#">2013/2726(RPS)</a> See also <a href="#">2018/2940(RPS)</a></p> <p>Subject</p> <p>3.10.10 Foodstuffs, foodstuffs legislation 4.20.05 Health legislation and policy 4.60.02 Consumer information, advertising, labelling</p>	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	<b>ENVI</b> Environment, Public Health and Food Safety		21/09/2004
		UEN <a href="#">POLI BORTONE Adriana</a>	
	Former committee responsible		
	<b>ENVI</b> Environment, Public Health and Food Safety		21/09/2004
		UEN <a href="#">POLI BORTONE Adriana</a>	
	<b>ENVI</b> Environment, Public Health, Consumer Policy		09/09/2003
		UEN <a href="#">NOBILIA Mauro</a>	
	Former committee for opinion		
	<b>IMCO</b> Internal Market and Consumer Protection (Associated committee)		31/08/2004
	PPE-DE <a href="#">STUBB Alexander</a>		
<b>JURI</b> Legal Affairs and Internal Market (Associated committee)		18/02/2004	
	ELDR <a href="#">WALLIS Diana</a>		
<b>ITRE</b> Industry, Research and Energy		31/08/2004	
	PPE-DE <a href="#">NIEBLER Angelika</a>		
<b>JURI</b> Legal Affairs and Internal Market		11/09/2003	
	PPE-DE <a href="#">KAUPPI Piia-Noora</a>		
<b>ITRE</b> Industry, External Trade, Research, Energy			
Council of the European Union	Council configuration	Meeting	Date
	<a href="#">Transport, Telecommunications and Energy</a>	<a href="#">2754</a>	12/10/2006
	<a href="#">Employment, Social Policy, Health and Consumer Affairs2733</a>		01/06/2006
	<a href="#">Employment, Social Policy, Health and Consumer Affairs2699</a>		08/12/2005
	<a href="#">Employment, Social Policy, Health and Consumer Affairs2663</a>		02/06/2005
	<a href="#">Agriculture and Fisheries</a>	<a href="#">2643</a>	28/02/2005
	<a href="#">Employment, Social Policy, Health and Consumer Affairs2627</a>		06/12/2004

## Key events

15/07/2003	Legislative proposal published	<a href="#">COM(2003)0424</a>	
01/09/2003	Committee referral announced in Parliament, 1st reading		
01/12/2003	Debate in Council	<a href="#">2549</a>	
01/06/2004	Debate in Council	<a href="#">2586</a>	
16/09/2004	Committee referral announced in Parliament, 1st reading		
06/12/2004	Debate in Council	<a href="#">2627</a>	Summary
28/02/2005	Debate in Council	<a href="#">2643</a>	Summary
21/04/2005	Vote in committee, 1st reading		Summary
02/05/2005	Committee report tabled for plenary, 1st reading		
12/05/2005	Committee report tabled for plenary, 1st reading	<a href="#">A6-0128/2005</a>	
25/05/2005	Debate in Parliament		
26/05/2005	Decision by Parliament, 1st reading	<a href="#">T6-0201/2005</a>	Summary
07/12/2005	Council position published	<a href="#">09858/3/2005</a>	Summary
19/01/2006	Committee referral announced in Parliament, 2nd reading		
21/03/2006	Vote in committee, 2nd reading		Summary
29/03/2006	Committee recommendation tabled for plenary, 2nd reading	<a href="#">A6-0122/2006</a>	
15/05/2006	Debate in Parliament		
16/05/2006	Results of vote in Parliament		
16/05/2006	Decision by Parliament, 2nd reading	<a href="#">T6-0198/2006</a>	Summary
01/06/2006	Debate in Council	<a href="#">2733</a>	
12/10/2006	Act approved by Council, 2nd reading		
20/12/2006	Final act signed		
20/12/2006	End of procedure in Parliament		
30/12/2006	Final act published in Official Journal		

## Technical information

Procedure reference

2003/0165(COD)

Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Directive 2000/13/EC <a href="#">1999/0090(COD)</a> Amended by <a href="#">2006/0195(COD)</a> Amended by <a href="#">2007/0128(COD)</a> Amended by <a href="#">2008/0028(COD)</a> See also <a href="#">2011/2549(RPS)</a> See also <a href="#">2013/2726(RPS)</a> See also <a href="#">2018/2940(RPS)</a>
Legal basis	EC Treaty (after Amsterdam) EC 095; Rules of Procedure EP 57
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/32906

## Documentation gateway

For information		<a href="#">COM(2003)0424</a>	16/07/2003	EC	Summary
Economic and Social Committee: opinion, report		<a href="#">CES0308/2004</a> <a href="#">OJ C 110 30.04.2004, p. 0018-0021</a>	25/02/2004	ESC	
Committee draft report		PE353.302	17/01/2005	EP	
Amendments tabled in committee		PE353.660	22/02/2005	EP	
Amendments tabled in committee		PE355.577	17/03/2005	EP	
Committee opinion	<b>ITRE</b>	<a href="#">PE349.832</a>	18/03/2005	EP	
Committee opinion	<b>IMCO</b>	<a href="#">PE353.538</a>	25/04/2005	EP	
Committee report tabled for plenary, 1st reading/single reading		<a href="#">A6-0128/2005</a>	12/05/2005	EP	
Text adopted by Parliament, 1st reading/single reading		<a href="#">T6-0201/2005</a> <a href="#">OJ C 117 18.05.2006, p. 0023-0186 E</a>	26/05/2005	EP	Summary
Council statement on its position		<a href="#">14795/2005</a>	23/11/2005	CSL	
Council position		<a href="#">09858/3/2005</a> OJ C 080 04.04.2006, p. 0043-0066 E	08/12/2005	CSL	Summary
Commission communication on Council's position		<a href="#">COM(2006)0002</a>	13/01/2006	EC	Summary
Committee draft report		<a href="#">PE367.861</a>	19/01/2006	EP	
Amendments tabled in committee		<a href="#">PE370.023</a>	01/03/2006	EP	
Amendments tabled in committee		<a href="#">PE371.744</a>	14/03/2006	EP	
Amendments tabled in committee		PE371.771	16/03/2006	EP	
Committee recommendation tabled for plenary, 2nd reading		<a href="#">A6-0122/2006</a>	29/03/2006	EP	
Text adopted by Parliament, 2nd reading		<a href="#">T6-0198/2006</a>	16/05/2006	EP	Summary

Commission opinion on Parliament's position at 2nd reading	<a href="#">COM(2006)0368</a>	12/07/2006	EC	Summary
Draft final act	<a href="#">03616/9/2006</a>	20/12/2006	CSL	
Follow-up document	SWD(2020)0095	20/05/2020	EC	
Follow-up document	SWD(2020)0096	20/05/2020	EC	

### Additional information

National parliaments	<a href="#">IPEX</a>
European Commission	<a href="#">EUR-Lex</a>

### Final act

[Regulation 2006/1924](#)  
[OJ L 404 30.12.2006, p. 0009](#) Summary

## Nutrition and health claims made on foods

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Pending the European Parliament's opinion, the Council took note of a progress report on the state of play of the examination carried out until now on the Commission's proposal for a Regulation on nutrition and health claims made on foods.

The Council held an exchange of views aimed at giving guidance for future work, in particular focusing on :

- the role of regulatory and other Community measures in ensuring proper information that enables the consumer to make healthy food choices, in the context of the overall community strategy to fight public health threats such as obesity and overweight;
- the concept of "nutrient profiles" as an instrument to helping the consumer at making healthy food choices.

## Nutrition and health claims made on foods

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The German delegation, supported by the Italian, French, Irish, Finnish and Portuguese delegations, drew the attention of the Council and the Commission to the fact that, in its opinion, current Community rules on food labelling did not go far enough in requiring information on the place of origin or provenance of pre-packaged foodstuffs; consumers' information needs were not being given due weight. In this context, the Commission was accordingly requested to submit a progress report on its efforts to improve information on provenance. These delegations argued that information on provenance should not be confined to processed food: it should also cover agricultural products, as with current beef labelling rules.

The Swedish delegation, welcoming the review of the marketing rules for foodstuffs and supporting the German delegation's request for encouragement of husbandry methods which are especially sensitive to animal welfare and the environment, said that it would look favourably on any initiative aiming at applying the same labelling rules to all foodstuffs.

The Spanish delegation emphasised the complex nature of food labelling and suggested that an evaluation of the true extent of consumer demand in this area was needed and that the outcome of the negotiations in progress within the Codex Alimentarius should be awaited before undertaking any review.

Commissioner Kyprianou said that since his area of responsibility covered horizontal provisions on product labelling, review of Community legislation in this field was at present under discussion by his department with a view to the Commission's adoption of new legislation by the end of 2006.

With this in mind, he stressed the need to analyse needs by consulting citizens. He reminded delegations of the principle that the labelling requirement was justified only where its absence would mislead the consumer.

Commissioner Fischer Boel, whose area of competence included the vertical provisions governing certain agricultural products, said that, while she recognised that labelling provided the consumer with better information and that a statement of origin was compatible with WTO rules, the matter required more detailed discussion; she would examine the matter as soon as possible.

## Nutrition and health claims made on foods

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The committee adopted the report by Adriana POLI BORTONE (UEN, IT) amending the proposal under the 1st reading of the codecision procedure:

- MEPs voted to delete Article 4 (restrictions on the use of nutrition and health claims) on the grounds that establishing specific nutrient profiles

which products must respect in order to bear nutrition or health claims could discriminate against individual products, which would be classified as "good" or "bad". They argued that it is not so much the composition of the product that matters as the use made of it and above all the balance of a person's diet;

- although the committee was in favour of tougher scientific requirements for nutritional and health claims, it wanted the authorisation procedure proposed by the Commission to be replaced by a less onerous notification procedure. In other words, rather than going through a lengthy authorisation procedure, manufacturers or importers would inform the authorities if they planned to start selling a product making nutritional claims. It would then be up to the authorities to object or issue a ban within a nine month period. MEPs also said that modern communication methods, including e-mail, should be used in the notification procedure in order to simplify matters administratively;

- although the Commission wanted to ban certain health claims explicitly, MEPs would be less restrictive. They wanted to allow claims about weight (slimming or appetite control, energy values, etc.) and about the advice of health professionals, provided these are scientifically substantiated and notified in accordance with the regulation. However, they introduced a new clause banning claims targeted directly at children;

- as regards the scope of the regulation, the committee would explicitly exclude wine, natural mineral water and publicity campaigns for agricultural products, which are already covered by other legislation, as well as trade marks;

- the committee introduced a new article tightening up data protection. If producers have to reveal industrial secrets to comply with the scientific requirements, they will be protected by intellectual property law;

- to ensure that small and medium-sized businesses are not penalised by the new system, they should be granted special aid to help in preparing the documentation;

- the regulation should be reviewed three years after its adoption, rather than six years as proposed by the Commission, and its impact on public health should also be evaluated;

- lastly, there should be an 18-month transitional period, rather than 6 months as proposed by the Commission, so that food placed on the market prior to the regulation's entry into force can continue to be sold until the end of its shelf life.

## Nutrition and health claims made on foods

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The European Parliament adopted a resolution based on the report drafted by Adriana POLI BORTONE (UEN, IT) and confirmed many of the amendments which were voted through in committee. (Please see the document dated 21/04/2005.) In particular, Parliament voted to delete Article 4 on nutrient profiles. The resolution was adopted by 458 votes in favour, 116 against and 15 abstentions. The amendment deleting the compulsory nutrient profiles was adopted by 303 votes in favour, 286 against and 10 abstentions. The following should be noted:

- a new recital states that "a varied, balanced diet is a prerequisite for good health. Products taken separately are only of relative importance compared to diet as a whole and diet is only one among many factors which influence the development of certain diseases in humans. Other factors such as age, genetic predisposition, the level of physical activity, use of tobacco and other drugs, environmental exposure and stress can also play a role in triggering human diseases. These factors must all be taken into account in the recommendations drawn up by the European Union in the area of health;

- a further recital states that the needs of the European food industry, and in particular those of SMEs, should be taken into account in order to ensure that innovation and competitiveness are not undermined;

- Parliament states that the Regulation will not apply to foods which are presented and sold loose, that is, without packaging, and shall not apply to fruit and vegetables (fresh produce);

- Parliament deleted a clause in the Commission's text stating that the use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim;

- Parliament changed the procedure for authorisation to a notification procedure, where manufacturers or importers would only have to inform the authorities if they plan to start selling a product making nutritional claims. It would then be up to the authorities to object or issue a ban;

- notification will be made by normal post or, preferably, using modern communication techniques (including e-mail), by the manufacturer when the product is first placed on the market or, in the case of a product manufactured in a third country, by the importer.

- a new clause on intellectual property rights is added;- the regulation should be reviewed three years after its adoption, rather than six years as proposed by the Commission, and its impact on public health should also be evaluated;

- application of the Regulation should not occur until 18 months after its entry into force, rather than six;
- finally, Parliament added particular points to the draft regulation concerning small and medium size enterprises and children. Nutrition and health claims, unless scientifically substantiated, may not be exclusively directed at children.

## Nutrition and health claims made on foods

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The common position on nutrition and health claims on foods was adopted unanimously by the Council. The Council's common position conforms to the objectives of the Commission proposal while introducing a certain number of modifications among which:

**Commercial brand names or trademarks:** a new provision introduced by the Council allows brand-names or trademarks to be used without undergoing an authorisation procedure, provided that they are accompanied by a related nutrition or health claim in the labelling, presentation or advertising, which complies with the provisions of this Regulation. In order to accommodate concerns regarding the application of the Regulation to existing trademarks and brand-names, a ten year transitional period has been introduced for brand-names or trademarks in use before the 1st of January 2005, after which they should comply with the Regulation.

**Nutrient profiles:** the Council maintained the concept of nutrient profiles as an important element to ensure the efficient application of the Regulation in relation to nutrition and health claims. The original proposal was considerably developed to focus more closely on the purpose and the scope of the nutrient profiles, and the procedure to be followed to elaborate them. Adequate safeguards were introduced to accommodate concerns regarding their scientific objectivity, the preservation of different dietary habits and national traditions, and the involvement of stakeholders in the process.

**Health claims:** the original Commission proposal envisaged the prohibition of several categories of health claims. The Council maintained the ban of some of these claims and, for others, stipulated that they could be used under certain conditions. The common position foresees that a list of certain health claims (which do not refer to disease reduction) will be adopted by the Commission within 3 years from the adoption of the Regulation, based on suggestions by the Member States. The scope of this Article has been widened and now includes claims referring to psychological and behavioural functions and slimming and weight control. Moreover, an authorisation procedure may be used for adding health claims to the list which are based on newly developed scientific data and/or include a request for the protection of proprietary data. As regards recommendations of or endorsements by national medical associations and health-related charities, a new Article is foreseen, according to which national legislation may continue to apply in compliance with the provisions of the Treaty until such time as Community rules are adopted.

**Scope of nutrition claims:** while the original proposal did not foresee the use of symbols/signposting as nutrition claims, the Council has examined this question in detail, being confronted with growing demands regarding the use of both positive and negative signposting on the nutritional status of a food (to be placed, for example, on supermarket shelves). As a result, the common position clarifies that the proposed Regulation only applies to beneficial claims, while claims referring to a nonbeneficial effect of the food will not be covered. In this respect, it is stated that Member States intending to introduce national schemes relating to non-beneficial claims should notify these schemes to the Commission and to Member States in accordance with Directive 98/34/EC. Furthermore, in order to take account of certain nutrition claims in pictorial, graphic or symbolic form used in several Member States, a transitional arrangement has been introduced in Article 27(4), which provides that national rules and criteria for the use of logos and symbols shall be authorised, if complying with the general principles of the Regulation.

**Alcoholic beverages:** the general prohibition in the use of claims in the case of alcoholic beverages, with the exception of claims that refer to a reduction in alcohol or in energy content, has been maintained. In addition, in the absence of specific Community rules on nutrition claims referring to the reduction or absence of alcohol or energy, it is clarified that national rules may apply in compliance with the Treaty. A new recital excludes food supplements in liquid form containing more than 1.2% of alcohol from the scope of these restrictions, as the alcohol quantity provided by the consumption of such foodstuffs is negligible. The Council, supported by the Commission, made several modifications to the annex taking notably account of recent scientific advances, and inserted a new recital stating that claims such as 'lactose free' or 'gluten free' should be dealt with in Directive 89/398/EEC.

In its common position, the Council included 35 of the 75 amendments adopted by the European Parliament at first reading. In particular, it includes the amendments concerning the following issues:

**Scope and definitions:** the amendments states that non-commercial communications are not covered in the Regulation; the Regulation shall apply without prejudice to Directive 89/398/EEC on foods intended for particular nutritional uses and Directives adopted on the basis thereof, Directive 80/777/EEC on natural mineral waters, and Directive 98/83/EC on water intended for human consumption. Moreover, existing Community definitions are added, such as the definition of food supplements (Directive 2002/46/EC) and the definition of labelling (Directive 2000/13/EC), and the definition of 'claim' is clarified.

**General principles:** amendments are introduced to clarify and complete the general principles for all claims; provide that claims shall not mask the overall nutritional status of a food; clarify the way the nutrient profiles will be set and used; state that the Authority should advise the Commission for the

setting of the nutrient profiles.

**Nutrition claims:** the common position states that the positive list of nutrition claims shall be revised in order to take account scientific and technological developments.

**Health claims:** the Council incorporates the amendment proposing to allow all the claims that were prohibited in the article 11 of the original proposal, provided they are scientifically substantiated. Reference to general, non-specific benefit for the overall good health or health related well being may be made if accompanied by a specific health claim complying with the Regulation. Only the claims which suggest that health could be affected by not consuming the food, the claims which make reference to recommendations of individual doctors or non-recognised health professionals and other associations, and the claims referring to the rate or amount of weight loss remain prohibited.

Other amendments partially accepted by the Council refer to the participation of organisations representing the food industry and consumers to establish the initial list of function claims as proposed in one amendment was supported by the Commission. Another amendment asks for

consultation of stakeholders and comitology for the adoption of guidelines for the implementation of the article 11 of the original proposal. An amendment is partially maintained in the common position that states that the applicant may make comments to the Commission on the opinion of the Authority within 30 days of its publication.

General and final provisions: the common position clarifies that the Register should be updated and available to the public and that transitional measures are needed in order to ensure a smooth transition for the economic operators. Different transition periods for various provisions of the Regulation are also provided in the common position.

Lastly, it should be noted that the Council rejected the amendments concerning the following issues :

the need to preserve the competitiveness of the food industry; on information campaigns on nutrition to be developed; on the involvement of a consumer panel to evaluate the claims; on the comparative claims between foods belonging to different food categories; on the submission of a food packaging sample to the Authority; on the substantial aid given to SMEs; on the Authority verification of the claims wording; on the time given to the Commission to examine the opinion of the Authority and on the time given to the Commission to release a report on the application of the Regulation.

## Nutrition and health claims made on foods

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[The Commission welcomes the common position adopted unanimously by the Council, as it maintains the general principles of the proposal of the Commission, especially regarding the requirement that foods meet a certain nutrient profile in order to make claims, and the requirement for certain health claim to go through an authorisation procedure. Numerous amendments proposed by the European Parliament are introduced by the Council in the final text that can be fully supported by the Commission.](#)

Following the invitation of the Council the Commission agrees, in the context of amendments to the Annex, to examine possible clarifications of the claim "source of [name of vitamin/s] and or [name of mineral/s]."

## Nutrition and health claims made on foods

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The committee adopted the report by Adriana POLI BORTONE (UEN, IT) amending the Council's common position under the 2nd reading of the codecision procedure. It reinstated a number of amendments (sometimes in modified form) that had been adopted by Parliament at 1st reading but had not been taken up by the Council. These sought to: restrict health claims which are exclusively directed at children, as well as health claims referring to weight loss or to recommendations of individual doctors or health professionals, unless scientifically substantiated; take account of the needs of SMEs; ensure that trade marks are not included within the scope of the regulation, on the grounds that this would cause major legal uncertainty and put existing brand-mark owners at a disadvantage; draw attention to the importance of Europe's gastronomic culture; introduce a new clause on intellectual property rights; ensure that the Commission's assessment report looks at the impact of the regulation on public health; and exclude from the regulation "foods which are offered for sale to the final consumer unpacked or packed only at the point of sale (fresh products such as fruit, vegetables or bread)".

On the contentious issue of nutrient profiles, the committee attempted to reach a compromise with the Council, which was reinstating, with modifications, Article 4 of the Commission's proposal (establishing specific nutrient profiles which products must comply with in order to bear nutrition or health claims) which Parliament had deleted at 1st reading. Rather than again proposing that the article be deleted, MEPs in the committee tabled a number of amendments to it designed to ensure that, when nutrient profiles are established, due account is taken of factors such as daily intake of the food in question as well as the dietary habits and consumption patterns in the various Member States. Moreover, when consulting with interested parties in the food industry, the Commission should pay "particular attention" to SMEs.

The committee also tried to find a solution to another contentious point, namely, the authorisation procedure for new claims which Parliament had rejected at 1st reading and which had been broadly reintroduced by the Council. MEPs now proposed a third path between the original authorisation procedure and the simpler notification procedure which Parliament had wanted to put in its place. To simplify the lives of companies in the food industry while not neglecting the interests of consumers, the committee introduced a new article providing for a quicker (6-month) and more flexible registration procedure for health claims which do not refer to the reduction of disease risk or to children's development and health. But the authorisation procedure would still be required for products which do make such claims or where the European Food Safety Agency, which is involved in the procedure, objects to a new registration.

## Nutrition and health claims made on foods

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The European Parliament adopted a resolution drafted by Adriana POLI BORTONE (UEN, IT) and made several amendments to the common position. The compromise text was agreed by Parliament, Council and Commission. The resolution was adopted by 614 votes to 8 with 16 abstentions. The key issues were as follows:

Nutritional profiles: the European Commission's original 2003 proposal intended to ban all health claims on products which are rich in sugar, fat or salt. The compromise text has reintroduced the controversial concept of "nutritional profiles" which indicate appropriate ratios of salt, sugar and fat in any given product. Rejected on first reading, the amended text now authorises health claims on products with high sugar, fat or salt levels where a single nutrient exceeds the nutrient profile, and provided that a statement about the specific nutrient appears in close proximity to, on the same side and with the same prominence as the claim. In other words, cereals with high sugar content may continue to boast of being "high in vitamins and minerals" on condition that they are also clearly marked as being "high in sugar content".

It will be the Commission's duty to set salt, sugar and fat ratios for all new products sold on the EU market, which it will do based on information provided by the European Food Safety Authority (EFSA) and in close consultation with industry and consumer groups.

Alcohol: as far as nutrition claims are concerned, only nutrition claims referring to low alcohol levels, or the reduction of the alcohol content, or the reduction of the energy content for beverages containing more than 1,2 % by volume of alcohol, shall be permitted. Drinks containing over

1.2% alcohol may not give as their only health claim the descriptions "reduction of energy content" or "low alcohol levels". In the absence of specific Community rules regarding nutrition claims referring to "low alcohol levels" or "the reduction or absence of alcohol" or "energy content", relevant national rules may apply.

Register: a register of health claims authorised so far is to be compiled, allowing manufacturers who wish to introduce a product with a particular health claim to consult the register in order to know the rules to be observed and not to have to go through the authorisation process itself. When a producer lodges an application, EFSA must give its opinion within 5 months. If the Authority demands further information from the applicant, a further one month is allowed. Where the Authority, following scientific assessment, issues an opinion in support of the inclusion of the claim in the Register, the Commission must take a decision on the application, taking into account the opinion of the Authority, any relevant provision of Community law and other legitimate factors relevant to the matter under consideration, after having consulted the Member States and within two months of receiving the opinion of the Authority. The scientific data and other information in the application may not be used for the benefit of a subsequent applicant for a period of five years (rather than seven years, as proposed by the Commission) from the date of authorisation

Trade marks: Parliament made a point of protecting existing trade marks which have been given fifteen years (rather than ten) to comply with the requirements of the new Regulation. Parliament also stated that 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", will be exempted from the application of the Regulation.

SMEs: to help food business operators, in particular SMEs, in the preparation of the application for scientific assessment, the Commission, in close cooperation with the Authority, shall make available appropriate technical guidance and tools to assist them in the preparation and the presentation of the application for authorisation.

Children: products for children will be subject to the "authorisation" procedure.

Report: the Commission must submit a report on the Parliament and Council within six years of entry into force of the Regulation. The report must also include an evaluation of the impact of the Regulation on dietary choices and the potential impact on obesity and non-communicable diseases.

Further points of the compromise: fresh food such as fruit, vegetables and bread are excluded from the regulation; national rules will apply until (and if) Community standards are adopted. Finally, foods used in a Member State before 1 January 2006 which are not included in the annex can continue to be used for 3 years after the regulation enters into force.

## Nutrition and health claims made on foods

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The Commission can accept all the amendments adopted by the European Parliament. The amendments adjusting the scope of the Regulation have been accepted. Those concerning the nutrient profiles that foods will have to meet in order to bear claims have also been adopted as well as those dealing with the authorisation procedures for health claims and extending the transition periods. These amendments are the result of a compromise agreement reached between the European Parliament, Council and Commission during the second reading. The amendments are in line with the Commission's objectives for the proposal and maintain the balance of interests achieved in the common position.

## Nutrition and health claims made on foods

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PURPOSE: to adopt Community rules on the use of nutrition and health claims on foods.

LEGISLATIVE ACT: Regulation 1924/2006/EC of the European Parliament and of the Council on nutrition and health claims made on foods.

CONTENT: the Council adopted, with a qualified majority, a Regulation concerning the addition of vitamins and mineral substances to certain types of food, having approved all of the amendments adopted by Parliament at second reading. The Swedish and Danish delegations voted against the Regulation with the Irish and Dutch delegations abstaining.

An increasing number of foods labelled and advertised in the Community bear nutrition and health claims. In order to ensure a high level of consumer protection and in order to facilitate consumer choice, products put on the market need to be safe as well as properly labelled. Differences between national provisions relating to such claims may impede the free movement of foods and create unequal conditions of competition. The purpose of the present Regulation, therefore, is to adopt rules on the use of nutrition and health claims on foods.

It does so by harmonising the provisions laid down by law, regulation or administrative action in the Member States relating to nutrition and health claims. It applies to nutrition and health claims made in commercial communications, whether the labelling presentation or advertising of foods be delivered as such to the final consumer and it includes foods which are placed on the market unpacked or supplied in bulk. Food intended for restaurants, hospitals, schools, canteens and similar mass caterers will similarly be covered by the scope of this Regulation.

However, a trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of food may be used without undergoing the authorisation procedures on condition that it is accompanied by a related nutrition or health claim in its labelling and advertising.

The use of nutrition and health claims are not allowed to be:

- false, ambiguous or misleading;
- give rise to doubt about the safety and/or the nutritional adequacy of other foods;
- encourage or condone excess consumption of a food;
- state, suggest or imply that a balanced and varied diet can not provide appropriate quantities of nutrients in general; or
- refer to changes in bodily functions which could give rise to or exploit fear in the consumer.

Indeed, the use of nutrition and health claims may only be used on condition that:

- the presence, absence or reduced content in a food or category of food is established by generally accepted scientific data;
- the nutrient or other substance is contained in significant enough quantities to produce the nutritional effect claimed as established by generally scientific data; and
- the nutrient is in a form that is available for use by the body.

The Commission will be responsible for preparing, by 19 January 2009, a specific nutrient profile and the conditions (including exemptions), which need to be respected vis-à-vis the use of nutrition and health claims on foods and/or categories of foods.

As far as nutrition claims are concerned, the Regulation specifies that they may only be used if they are listed in the Annex to this Regulation. As far as health claims are concerned, on the other hand, they are to be prohibited unless they comply with the general requirement of this Regulation. Further they may only be made if the labelling contains a statement indicating the importance of a varied and balanced diet and a healthy lifestyle; the quantity of the food and pattern of consumption has a beneficial effect; a statement noting who should avoid using the food; and a warning for products that are likely to present a health risk if consumed to excess. Claims relating to weight loss and/or negative messages to consumers should they not buy the food are prohibited.

The Commission will establish and maintain a Community Register on nutrition and health claims made on food. Procedures have been put in place regarding: applications for authorisation; a Community authorisation; and the modification, suspension and revocation of authorisations.

On a final point transitional measures are foreseen. They state:

- Foods placed on the market or labelled prior to the date of application of this Regulation, which do not comply with this Regulation, can be marketed until their expiry date ? but no later than 31 July 2009.
- Products bearing trade marks or brand names existing before 1 January 2005 and which do not comply with this Regulation, may continue to be marketed until 19 January 2022, after which time the provisions of this Regulation must apply.
- Nutrition claims which have been made before 1 January 2005 in compliance with national provisions and which are not included in the Annex may continue to be used until 19 January 2010.

ENTRY INTO FORCE: 19 January 2007.

APPLICATION: 1 July 2007.