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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the provision of food information to consumers

(presented by the Commission)

{SEC(2008) 92}

{SEC(2008) 93}

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{SEC(2008) 95}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Grounds for and objectives of the proposal**

The draft proposal consolidates and updates two areas of labelling legislation, the general food and nutrition labelling respectively covered by Directives 2000/13/EC and 90/496/EEC. Directive 2000/13/EC has been amended several times and the evolution of both the food market and consumers' expectations renders its update and modernisation necessary.

Directive 90/496/EEC requires the Commission to report to the European Parliament and the Council on the application of the Directive. The interinstitutional procedures have changed and in certain cases the Commission must submit an impact assessment with proposals for new legislation. The revision of the nutrition labelling legislation is accompanied by an impact assessment giving an overview of the application of Directive 90/496/EEC. Therefore, a separate report on the implementation of the Directive has not been prepared.

- **General context**

General labelling - The main political will that motivated the first "horizontal" legislative instrument on food labelling (Directive 79/112/EEC) was to provide rules for the labelling of foods as a tool for the free circulation of foods in the Community. Over time the protection of consumers' rights emerged as a specific objective of the European Community.

In 2003 DG SANCO in close co-operation with stakeholders, launched an evaluation of the food labelling legislation in order to reassess its effectiveness and legal basis, and to identify the needs and expectations of today's consumers for food information, taking into account the technical and logistical constraints. The conclusions, published in 2004, identified the focus for a future proposal.

Nutrition labelling - The recent White Paper on a Strategy for Europe on Nutrition, Overweight and Obesity related health issues stressed the need for consumers to have access to clear, consistent and evidence-based information. Nutrition labelling is an established way for providing information to consumers to support health conscious food choices. There is wide agreement that the effectiveness of nutrition labelling can be strengthened as a means to support consumers' ability to choose a balanced diet.

There have been initiatives by stakeholders to encourage the inclusion of nutrition information on the front of packs. There is divergence in the labelling schemes being used which can create barriers to trade.

- **Existing provisions in the area of the proposal**

The proposal merges and amends the following legislation::

- Directive 2000/13/EC of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.

This Directive lays down common labelling requirements applicable to all foods to be delivered to the final consumer, and to foods supplied to mass caterers. It establishes the mandatory labelling information.

The proposal introduces certain general principles regarding the provision of food information and develops a governance mechanism to take account of developments that would enable consumers to make informed food choices. The mandatory requirements remain broadly the same with the option for the Commission to propose new requirements for specific issues.

- Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs.

The proposal introduces mandatory labelling of key nutritional elements in the principal field of vision.

In addition to the merging of Directives 2000/13/EC and 90/496/EEC the following texts are recast in the text:

- Commission Directive 87/250/EEC of 15 April 1987 on the indication of alcoholic strength by volume in the labelling of alcoholic beverages for sale to the ultimate consumer
- Commission Directive 94/54/EC of 18 November 1994 concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Council Directive 79/112/EEC
- Commission Directive 1999/10/EC of 8 March 1999 providing for derogations from the provisions of Article 7 of Council Directive 79/112/EEC as regards the labelling of foodstuffs
- Commission Directive 2002/67/EC of 18 July 2002 on the labelling of foodstuffs containing quinine, and of foodstuffs containing caffeine
- Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters
- Commission Directive 2004/77/EC of 29 April 2004 amending Directive 94/54/EC as regards the labelling of certain foods containing glycyrrhizinic acid and its ammonium salt.

- **Consistency with the other policies and objectives of the Union**

The proposal is in line with the Commission's Better Regulation Policy, the Lisbon Strategy and the EU's Sustainable Development strategy. The emphasis is on simplifying the regulatory process, thus reducing the administrative burden and improving the competitiveness of the European food industry, while ensuring the safety of food, maintaining high level of public health protection and taking global aspects into consideration. There is an ongoing exercise on the measurement of administrative costs from the horizontal labelling provisions, the outcome of which could provide relevant information.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

- **Consultation of interested parties**

Consultation methods, main sectors targeted and general profile of respondents

There were broad surveys of all interested parties seeking their views on the provisions and application of existing legislation and the needs for change. The respondents were from governmental and NGOs, industry and individuals. Certain consultations were targeted at Member States, industry or consumers.

Summary of responses and how they have been taken into account

Consumers demand more and "better" information on labels and are interested in clear, simple, comprehensive, standardised and authoritative information. Industry considers there are too many labelling requirements which involve implementation of detailed, technical rules. The volume and dispersal of texts undermines the clarity and coherence of the rules. The cost of changes is a concern to industry. Member States wish to balance the needs of consumers and industry, taking into account, any issues that are specific to their country.

Specific aspects highlighted in the consultation on the general labelling were:

- consumers find it difficult to read and understand labels;
- there are a number of foods from which information on allergens is missing;
- origin labelling is a problematic area;
- there is a legal limbo concerning ingredient listing of alcoholic beverages.

For nutrition labelling it is believed that the inclusion of nutrition information is an important source of information for the consumer. There is dissatisfaction among stakeholders on the legislation but views diverge on how to improve it.

- Some consumers require or prefer a comprehensive overview of the nutrient content, while others have concerns regarding only a fraction of

this. Consumers and public health NGOs want mandatory full nutrition labelling that is easy to understand.

- Industry is concerned by the prescriptive nature of the legislation and the effect on the design of packaging. They want a more flexible voluntary approach.
- Member States are aware of the need to reduce barriers to the internal market which is facilitated by a harmonised approach. However, there is increasing pressure from some for increased flexibility at national level, in particular, where innovative nutrition labelling systems are being used.

An open consultation was conducted over the internet from 13 March 2006 to 16 June 2006. The Commission received 175 response(s). The results are available on

http://ec.europa.eu/food/food/labellingnutrition/betterregulation/index_en.htm.

- **Collection and use of expertise**

There was no need for external expertise.

- **Impact assessment**

Certain basic alternative approaches were considered:

No intervention - This would maintain the current situation with scattered legislation with the following negative effects:

- piecemeal and confusing rules undermining the effective implementation;
- unjustified burdens on food business because of outdated, redundant or unclear requirements;
- inconsistent consumer use of labels;
- ineffectiveness of labelling as a communication tool;
- failure of the legislation to adapt to changing markets and consumers' legitimate demands.

Intervention was considered in the context of deregulation, national legislation, non-statutory approach or updating Community legislation.

Deregulation - This would entail the abolition of the basic policy instruments on horizontal food labelling rules with a direct impact on vertical labelling rules.

Although food manufacturers would continue to apply the current rules for a short period of time, they would progressively remove information they consider as a burden. Non-harmonised rules would impair the internal market, lead to poor information and reduce the level of consumer protection. Existing rules have proven their merits in allowing free circulation of goods and consumers' protection. Dismantling them would meet resistance from most Member States and consumers given that they have been used to the current requirements and any change could be seen as an abandonment of a valuable "acquis". Therefore, deregulation was not considered a viable approach.

National legislation - The repeal of the harmonised rules would result in creation of national rules with the following consequences:

- different national rules would impede the internal market;
- distortion of fair competition;
- increased administrative burden for industry;
- inconsistent approach in content and availability of information creating confusion for consumers;
- different level of protection for EU citizens.

Alternative non-statutory approach (self-regulation, co-regulation, guidance) - The different features of consumer information and current trends towards the development of a "new legislative culture" called for the assessment of an approach that could strike the balance between flexibility and prescription and between action at the national and action at EU level. A multi-level bottom-up governance (local/national/community) based on the principle of commitment to formal, measurable best practice could be a viable alternative.

Moving the already harmonised detailed requirements to such an approach would have no added value given that this would unnecessarily complicate current understanding among stakeholders and could be perceived as a deregulation. Although, as far as any new policy issues are concerned, the introduction of a more elaborate and sustainable approach to consumer information emerging from best practices and from a constant dialogue with stakeholders has the potential to achieve beneficial results both for industry and consumers.

The impacts of the main options for the revision of the general and nutrition labelling provisions were examined in relation to taking no action, voluntary action or prescriptive Community requirements were examined in the impact assessment.

The Commission carried out an impact assessment listed in the Work Programme, whose report is accessible on the Commission website. The Commission completed the impact assessment reports on the options for the revision of Directive 2000/13/EC and Directive 90/496/EEC which are presented in parallel with this proposal as Commission Staff Working Papers.

The impact assessment indicated that the impact on manufacturers can be attenuated by providing transition periods that allow for labelling changes to be made during the normal cycle for label changes that are in operation within a business.

3. LEGAL ELEMENTS OF THE PROPOSAL

• Summary of the proposed action

Adoption of a Regulation of the European Parliament and of the Council on the provision of food information to consumers. The proposal modernises, simplifies and clarifies the current food labelling scene. In particular:

- Recasting of the different horizontal labelling provisions. The merging of those texts (directives) into a single piece of legislation (regulation) will maximise synergies and increase the clarity and consistency of Community rules. This is a powerful simplification method that should provide economic operators and enforcement authorities with a clearer and more streamlined regulatory framework;
- To ensure coherence between horizontal and vertical rules;
- Rationalisation (update, clarification) of the compulsory information required by Article 3(1) of Directive 2000/13/EC;
- Setting-up of a flexible bottom-up mechanism (through national schemes) that would enable industry to innovate, and allow for some aspects of the labelling rules to be adapted to different and continuously changing markets and consumer demands.

In addition, it introduces clear principles to draw a clearer borderline between mandatory and voluntary information. The main changes with respect to general labelling issues are:

- The clarification of the responsibilities regarding food labelling for the different food business operators along the supply chain;
- To improve the legibility of the information provided on the labelling a minimum print size for the mandatory information is introduced;
- The introduction of a requirement that information on allergenic ingredients should be available for non-prepacked foods sold through retail and catering outlets;

- Given the specificities of wine, spirits and beer, the proposal provides for the Commission to report on the application of current rules on ingredient listing and mandatory nutrition labelling on these products with the possibility of specific measures to be adopted.
- With respect to the labelling of the country of origin or place of provenance of a food, the basic requirement in the legislation remains the same. Therefore, such labelling is voluntary, but if the failure to give such information might mislead the consumer, the labelling becomes mandatory. Both the mandatory or the voluntary indication of the country of origin or place of provenance of a food as a marketing tool, should not deceive the consumer and should be based on harmonised criteria. The country of origin should be determined in accordance with the provisions on non-preferential origin following the Community Custom Code. The place of provenance would refer to any place that is not the country of origin as determined by the Community Customs Code. Rules for determining the place of provenance will be adopted following Comitology procedure. In addition, criteria are introduced for the declaration of country of origin or place of provenance of multi-ingredient products and the country of origin or place of provenance of meat, other than beef and veal. These criteria would equally apply to the voluntary declaration of "EC" origin labelling;
- The proposal clarifies the conditions under which Member States may adopt national rules on origin labelling.

The rules on nutrition labelling are recast with the horizontal food labelling provisions. The proposal makes nutrition labelling mandatory in the principal field of vision of a food label. Allows for the development of best practice in the presentation of nutrition information, including alternative forms of expression of the nutrition information in relation to overall daily nutrient requirements or graphical forms of presentation.

The main new aspects of the proposal on nutrition labelling are:

- The mandatory declaration is for energy, fat, saturates, carbohydrates with specific reference to sugars and salt expressed as amounts per 100g or per 100 ml or per portion in the principal field of vision (front of pack) whilst nutrients from a defined list may be declared voluntarily. In selecting the mandatory elements account has been taken of: research indicating that consumers can feel overwhelmed by excessive information; the scientific advice about the most important nutrients bearing a relationship to the risk of development of obesity and non-communicable diseases; while avoiding excessive burden on food businesses, in particular small and medium size enterprises;
- In the case of alcoholic drinks, derogations are provided for wine, spirits and beer, and will be subject to a future Commission report;

- The mandatory elements must also be declared in relation to reference intakes whilst other presentation formats may be developed through voluntary national schemes.

In order to address the problems resulting from the piecemeal legislation, the new proposal will amend, recast and replace provisions already in place under the current horizontal food labelling legislation leading to the repeal of the following legislation:

Directives 2000/13/EC, 90/496/EEC, 87/250/EEC, 94/54/EC, 1999/10/EC, 2002/67/EC, 2004/77/EC and Regulation (EC) No 608/2004.

- **Legal basis**

Article 95

- **Subsidiarity principle**

The subsidiarity principle applies insofar as the proposal does not fall under the exclusive competence of the Community.

The objectives of the proposal cannot be sufficiently achieved by the Member States for the following reason(s).

Food labelling protects consumers and informs their decision making. It is considered that action at the EU level would deliver better results than a series of individual actions by Member States because:

- (i) a harmonised approach may simplify administrative burden on food companies operating either trans-nationally or Community wide, and
- (ii) uniform action ensures Community wide minimum standards reducing inequity for citizens across the EU. Different labelling requirements could undermine the current single market opportunities for the food chain with a major impact on trade given the high volume of intra-Community trade which in 2003 accounted for over 75% of all trade with flows of around € 120 billion. One survey of the food industry indicates that 65% of companies exported their products to other Member States and in this survey over 60% of the respondents favoured harmonisation of general food labelling through European legislation.

The core of the Community action is setting the conditions for the labelling of food within the EU which cannot be appropriately addressed by Member States alone if the common internal market is to function smoothly. As to the details of the Regulation applicable, a more participative and flexible way of designing and enforcing it will be offered by the governance model for the development of national schemes.

Community action will better achieve the objectives of the proposal for the following reason(s).

Experience shows that Member States cannot achieve a harmonised common market satisfactorily and that the EU can do better and more efficiently for the provision of information to consumers. The new proposal provides also space for softer intervention mechanism at national and EU level.

Community competence is used taking full account of the principles of subsidiarity and proportionality acknowledging that, with respect to certain aspects, total uniformity of labels throughout the EU is not necessarily the only and desired way to reach the objectives sought. It would, on the contrary, dismantle the potential for rapid adjustment to changing needs and circumstances of the applicable rules.

Harmonisation is provided for prepacked foods that would potentially be part of intracommunity trade. Member States may introduce rules when the products are not subject to intracommunity trade, such as non-prepacked foods and foods provided by mass caterers.

The proposal therefore complies with the subsidiarity principle.

- **Proportionality principle**

The proposal complies with the proportionality principle for the following reason(s).

The proposal harmonises the regulatory framework for the horizontal provisions regarding food labelling and thus contributes to consumer protection by ensuring that consumers receive appropriate information to enable them to make informed, safe, healthy and sustainable choices. The proposed measures are sufficient in terms of reaching the objectives of ensuring consumers are enabled to make informed choices and to securing the smooth functioning of the internal market. At the same time they do not impose an excessive or unjustified burden.

The absence of harmonisation would result in a proliferation of national rules resulting in increased burden for the industry and lack of clarity for the consumers. The financial burden is minimised as most of the provisions currently exist whilst sufficient time is allowed for any new requirements to be part of the regular modification of labels by manufacturers.

- **Choice of instruments**

Proposed instruments: regulation, co-regulation.

Other means would not be adequate for the following reason(s).

The existing rules are, in general, prescriptive with little flexibility for Member States in how they should be applied. A Directive would have led to an inconsistent approach in the Community leading to uncertainty for both consumers and the industry. A Regulation provides a consistent approach for industry to follow and reduces the administrative burden as they do not need to familiarise themselves with the individual Regulations in the Member States. Guidelines, self-regulatory or voluntary approaches would have led to inconsistency and a potential reduction in the amount of information provided to consumers, which would not be acceptable. However, there are aspects of the legislation for which a more flexible approach was considered appropriate and for those aspects an alternative form of governance based on soft law and voluntary commitments is developed in the draft proposal.

4. BUDGETARY IMPLICATION

None.

5. ADDITIONAL INFORMATION

- **Simulation, pilot phase and transitory period**

There will be a transitory period for the proposal.

- **Simplification**

The proposal provides for simplification of legislation.

The use of a Regulation as the legal instrument supports the objective of simplification because it guarantees that all actors have to follow at the same time the same rules.

The combination of the Directive 2000/13/EC with Directive 90/496/EEC on nutrition labelling into one instrument simplifies the regulatory framework. In addition, the proposal simplifies the structure of the 2000/13/EC legislation, by recasting and replacing provisions already in place under the current horizontal food labelling legislation. By addressing certain specific policy issues the proposal will contribute significantly to easier compliance and greater clarity for stakeholders.

The proposal is included in the Commission's rolling programme for update and simplification of the *acquis communautaire* and its Work and Legislative Programme under the reference 2006/SANCO/001.

- **Repeal of existing legislation**

The adoption of the proposal will lead to the repeal of existing legislation.

- **Recasting**

The proposal involves recasting

- **European Economic Area**

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

- **Detailed explanation of the proposal**

The Regulation provides the basis for the assurance of a high level of consumer protection in relation to food in establishing general principles and requirements of food information law (Chapters II and III).

Chapter IV (mandatory information) simplifies the existing legislation while maintaining the core mandatory labelling particulars. In taking the definitions and detailed or specific rules into annexes, the text is easier to follow and amend.

The rules for the labelling of particulars of the place of origin are clarified.

Section 3 of Chapter IV specifies the nutrition information for energy value and the amounts of fat, saturates, carbohydrates with specific reference sugars and salt is made mandatory, and requires its presentation in the principal field of vision of the label.

In Chapter VII a food information governance system for national schemes is created to encourage the establishment at Member State level an interactive and sustained process of information exchange in order to allow national non binding schemes to be developed drawing on best practices. At Community level the Commission shall encourage and organise the exchange of information between the Member States and with itself on activities related to the development of national schemes.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the provision of food information to consumers

(Text with EEA relevance)

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 Commission¹,

Having regard to the opinion of the European Economic and Social Committee²,

Acting in accordance with the procedure laid down in Article 251 of the Treaty³,

Whereas:

- (1) Article 153 of the Treaty provides that the Community is to contribute to the attainment of a high level of consumer protection by the measures it adopts pursuant to Article 95 thereof.
- (2) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.
- (3) In order to achieve a high level of health protection for consumers and to guarantee their right to information, it should be ensured that consumers are appropriately informed as regards food they consume. Consumers choices can be influenced by, *inter alia*, health, economic, environmental, social and ethical considerations.
- (4) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁴ provides that it is a general principle of food law to provide a basis for consumers to make informed choices in relation to food they consume and to prevent any practices that may mislead the consumer.

¹ OJ C xxx, xx.xx.xxxx. p. xx.

² OJ C xxx, xx.xx.xxxx. p. xx.

³ Opinion of the European Parliament of, Council Common Position of

⁴ OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).

- (5) Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market⁵ covers certain aspects of the provision of information to consumers specifically to prevent misleading actions and omissions of information. The general principles on unfair commercial practices should be complemented by specific rules concerning the provision of food information to consumers.
- (6) Community rules on food labelling applicable to all foods are laid down 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 foodstuffs⁶. The majority of the provisions laid down in that Directive date back to 1978 and should therefore be updated.
- (7) Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs⁷ lays down rules on the content and presentation of nutrition information on prepacked foods. The inclusion of nutrition information is voluntary unless a nutrition related claim is made concerning the food. The majority of the provisions laid down in that Directive date back to 1990 and should therefore be updated.
- (8) The general labelling requirements are complemented by a number of provisions applicable to all foods in particular circumstances or to certain categories of foods. In addition, there are a number of specific rules which are applicable to specific foods.
- (9) While the original objectives and the core components of the current labelling legislation are still valid, it is necessary to streamline it in order to ensure easier compliance and greater clarity for stakeholders and to modernise it in order to take account of new developments in the field of food information.
- (10) There is public interest in the relationship between diet and health and in the choice of an appropriate diet to suit individual needs. The Commission White Paper on a Strategy for Europe on Nutrition, Overweight and Obesity related health issues⁸ noted that nutrition labelling is an important tool to inform consumers about the composition of the foods and help them make an informed choice. The EU consumer policy strategy 2007 - 2013 underlined that allowing consumers to make informed choice is essential both to effective competition and consumer welfare. Knowledge of the basic principles of nutrition and appropriate nutrition information on foods would contribute significantly towards enabling the consumer to make such an informed choice.
- (11) In order to enhance legal certainty and ensure rationality and consistency of enforcement, it is appropriate to repeal Directives 90/496/EEC and 2000/13/EC and to replace them by a single Regulation which ensures certainty for both consumers and the industry and reduces the administrative burden.

⁵ OJ L 149, 11.6.2005, p. 22.

⁶ OJ L 109, 6.5.2000, p. 29. Directive as last amended by Commission Directive 2006/142/EC (OJ L 368, 23.12.2006, p. 110).

⁷ OJ L 276, 6.10.1990, p. 40. Directive as last amended by Commission Directive 2003/120/EC (OJ L 333, 20.12.2003, p. 51.)

⁸ COM(2007) 279.

- (12) For the sake of clarity, it is appropriate to repeal and include in this Regulation other horizontal acts, namely Commission Directive 87/250/EEC of 15 April 1987 on the indication of alcoholic strength by volume in the labelling of alcoholic beverages for sale to the ultimate consumer⁹, Commission Directive 94/54/EC of 18 November 1994 concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Council Directive 79/112/EEC¹⁰, Commission Directive 1999/10/EC of 8 March 1999 providing for derogations from the provisions of Article 7 of Council Directive 79/112/EEC as regards the labelling of foodstuffs¹¹, Commission Directive 2002/67/EC of 18 July 2002 on the labelling of foodstuffs containing quinine, and of foodstuffs containing caffeine¹², Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters¹³ and Commission Directive 2004/77/EC of 29 April 2004 amending Directive 94/54/EC as regards the labelling of certain foods containing glycyrrhizinic acid and its ammonium salt¹⁴.
- (13) It is necessary to set common definitions, principles, requirements and procedures so as to form a clear framework and a common basis for Community and national measures governing food information.
- (14) In order to follow a comprehensive and evolutionary approach to the information provided to consumers relating to food they consume, there should be a broad definition of food information law covering rules of a general and specific nature as well as a broad definition of food information covering information provided also by other means than the label.
- (15) Community rules should apply only to undertakings, the concept of which implies a certain continuity of activities and a certain degree of organisation. Operations such as the occasional handling, serving and selling of food by private persons at events such as charities, or local community fairs and meetings are not covered by the scope of this regulation.
- (16) Food information law should provide sufficient flexibility to be able to keep up to date with new information requirements from consumers and ensure a balance between the protection of the internal market and the differences in the perception of consumers in the Member States.
- (17) The prime consideration for requiring mandatory food information should be to enable consumers to identify and make appropriate use of a food and to make choices that suit their individual dietary needs.
- (18) In order to enable food information law to adapt to changing consumers' needs for information, any considerations about the need for mandatory food information should

⁹ OJ L 113, 30.4.1987, p. 57.

¹⁰ OJ L 300, 23.11.1994, p. 14. Directive as last amended by Directive 2004/77/EC (OJ L 162, 30.4.2004, p. 76).

¹¹ OJ L 69, 16.3.1999, p. 22.

¹² OJ L 191, 19.7.2002, p. 20.

¹³ OJ L 97, 1.4.2004, p. 44.

¹⁴ OJ L 162, 30.4.2004, p. 76.

also take account of the widely demonstrated interest from the majority of consumers in the disclosure of certain information.

- (19) New mandatory food information requirements should however only be established if and where necessary, in accordance with the principles of subsidiarity, proportionality and sustainability.
- (20) The rules on food information should prohibit the use of information that would mislead the consumer or attribute medicinal properties to foods. To be effective, this prohibition should also apply to the advertising and presentation of foods.
- (21) In order to prevent a fragmentation of the rules concerning the responsibility of food business operators with respect to food information it is appropriate to clarify the responsibilities of food business operators in this area.
- (22) A list should be drawn up of all mandatory information which should in principle be provided for all foods intended for the final consumer and the mass caterers. That list should maintain the information that is already required under existing legislation given that it is generally considered as a valuable *acquis* for consumer information.
- (23) In order to take account of changes and developments in the field of food information, provisions should be made to empower the Commission to amend the list of mandatory information by adding or removing particulars and for enabling the availability of certain particulars through alternative means. Consultation with stakeholders should facilitate timely and well targeted changes of food information requirements.
- (24) When used in the production of foods and still present, certain ingredients or other substances are the cause of allergies or intolerances in consumers, and some of those allergies or intolerances constitute a danger to the health of those concerned. It is important that information on the presence of food additives, processing aids and other substances with allergenic effect should be given to enable consumers suffering from a food allergy or intolerance to make informed and safe choices.
- (25) Food labels should be clear and understandable to assist consumers wanting to make better-informed food and dietary choices. Studies show that legibility is an important element in maximising the possibility that labelled information can influence its audience and that the small print size is one of the main causes of consumer dissatisfaction with food labels.
- (26) In order to ensure the provision of food information, it is necessary to consider all ways of supplying food to consumers, including selling food by means of distance communication. Although it is clear that any food supplied through distant selling should meet the same information requirements as food sold in shops, it is necessary to clarify that in such cases the relevant mandatory food information should also be available before the purchase is concluded.
- (27) With a view to provide consumers with food information that is necessary to make an informed choice, alcoholic mixed beverages should also provide information on their ingredients.

- (28) It is also important to provide consumers with information on the other alcoholic beverages. Specific Community rules already exist on the labelling of wine. Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine¹⁵ provides an exhaustive set of technical standards which fully cover all oenological practices, manufacturing methods and means of presentation and labelling of wines, thus ensuring that all stages in the chain are covered and that consumers are protected and properly informed. In particular, this legislation describes in a precise and exhaustive manner the substances likely to be used in the production process, together with the conditions for their use via a positive list of oenological practices and treatments; any practice not included in this list is prohibited. Therefore, it is appropriate to exempt wine at this stage from the obligation to list the ingredients and to provide for a nutrition declaration. As regards beer and spirits as defined in Article 2(1) of Regulation (EC) No. [...] of [...] of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89¹⁶, and in order to ensure a consistent approach and coherence with the conditions established for wine, the same kind of exemptions shall apply. However, the Commission will produce a report after five years of the entry into force of this Regulation and may propose, if necessary, specific requirements in the context of this Regulation.
- (29) The indication of the country of origin or of the place of provenance of a food should be provided whenever its absence is likely to mislead consumers as to the true country of origin or place of provenance of that product. In other cases, the provision of the indication of country of origin or place of provenance is left to the appreciation of food business operators. In all cases, the indication of country of origin or place of provenance should be provided in a manner which does not deceive the consumer and on the basis of clearly defined criteria which ensure a level playing field for the industry and improve consumers' understanding of the information related to the country of origin or place of provenance of a food. Such criteria should not apply to indications related to the name or address of the food business operator.
- (30) In some cases, food business operators may want to indicate that the origin of a food is the European Community to draw the consumers' attention to the qualities of their product and to the European Union's production standards. Such indications should also comply with harmonised criteria.
- (31) The European Community's non-preferential rules of origin are laid down in Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code¹⁷ and its implementing provisions in Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code¹⁸.

¹⁵ OJ L 179, 14.7.1999, p. 1.

¹⁶ OJ L [...], [...], p.[...].

¹⁷ OJ L 302, 19.10.1993, p. 1. Regulation as last amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

¹⁸ OJ L 253, 11.10.1993, p. 1. Regulation as last amended by Commission Regulation (EC) No 883/2005 (OJ L 148, 11.6.2005, p. 5).

Determination of the country of origin of foods will be based on these rules, which are well known to trade operators and administrations and should ease its implementation.

- (32) The nutrition declaration on a food concerns information on the presence of energy and certain nutrients in foods. The mandatory provision of nutrition information should assist action in the area of nutrition education for the public and support informed food choice.
- (33) The Commission White Paper on a Strategy for Europe on Nutrition, Overweight and Obesity related health issues highlighted certain nutritional elements of importance to public health. Therefore, it is appropriate that the requirements on the mandatory provision of nutrition information should take into account such elements.
- (34) In general, consumers are not aware of the potential contribution of alcoholic beverages to their overall diet. Therefore, it is appropriate to ensure that information on the nutrient content of in particular mixed alcoholic beverages is provided.
- (35) In the interest of consistency and coherence of Community legislation the voluntary inclusion of nutrition or health claims on food labels should be in accordance with the Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods¹⁹.
- (36) To avoid unnecessary burdens on the industry, it is appropriate to exempt certain categories of foods that are unprocessed or for which nutrition information is not a determining factor for consumer choice from the mandatory inclusion of nutrition declaration, unless the obligation to provide such information is provided under other Community legislation.
- (37) To appeal to the average consumer and to serve the informative purpose for which it is introduced, and given the current level of knowledge on the subject of nutrition, the information provided should be simple and easily understood. Research has indicated that consumers find the information in the principal field of view or 'front of pack' is useful when making purchasing decisions. Therefore, to ensure that consumers can readily see the essential nutrition information when purchasing foods such information should be in the principal field of view of the label.
- (38) Recent developments in the expression of the nutrition declaration, other than per 100g/100ml/portion, by some Member States and organisations in the food sector suggest that consumers like such schemes as they can help them make informed choices quickly. However, there is not evidence across all the Community on how the average consumer understands and uses the alternative expression of the information. Therefore, it is appropriate to allow for different schemes to be developed and to allow research on consumer understanding in different Member States to continue so that, if appropriate, harmonised schemes may be introduced.
- (39) The declaration in the principal field of view of the amounts of nutritional elements and comparative indicators in an easily recognisable form to enable an assessment of

¹⁹ OJ L 404, 30.12.2006, p. 9. Regulation as amended by ...

the nutritional properties of a food should be considered in its entirety as part of the nutrition declaration and not be treated as a group of individual claims.

- (40) Experience shows that in many cases voluntary food information is provided to the detriment of the clarity of the mandatory food information. Therefore, criteria should be provided to help food business operators and enforcement authorities to strike a balance between the provision of mandatory and voluntary food information.
- (41) Member States should retain the right, depending on local practical conditions and circumstances, to lay down rules in respect of the provision of information concerning non-prepacked foods. Although in such cases the consumer demand for other information is limited, information on potential allergens is considered very important. Evidence suggests that most food allergy incidents can be traced back to non-prepacked food. Therefore such information should always be provided to the consumer.
- (42) Member States should not be able to adopt provisions other than those laid down in this Regulation in the field it harmonises, unless specifically indicated in it.
- (43) Food information rules should be able to adapt to a rapidly changing social, economic and technological environment.
- (44) In respect of certain aspects of food information that give rise to the development of innovative and modern commercial practices, it is necessary to allow sufficient experiments and consumer research and to provide solid evidence about the best systems. Therefore, in such cases Community food information law should restrict itself to setting out the mandatory essential requirements determining the level of consumer protection and information and leave flexibility for the fulfilment of such requirements, in a manner that is compatible with the internal market provisions.
- (45) In order to ensure that more detailed food information requirements are designed and established in a dialectic manner and emerge from best practices, there should be flexible mechanisms at Community and national level based on open and transparent public consultation and sustained interaction between a wide range of representative stakeholders. Such mechanism may result in the development of national non-binding schemes on the basis of solid consumer research and wide stakeholder consultation. There should be mechanisms for consumers to be able to identify foods labelled in compliance with the national scheme such as through an identification number or symbol.
- (46) In order to ensure a level of consistency in the results achieved in the different Member States, it is necessary to promote the constant exchange and sharing of best practices and experience between Member States and with the Commission and promote the participation of stakeholders to such exchanges.
- (47) Member States should carry out official controls in order to enforce compliance with this Regulation in accordance with Regulation (EC) No 882/2004.
- (48) References to Directive 90/496/EEC in Regulation (EC) No 1924/2006 and in 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 foods²⁰ should be updated to take this Regulation into account. Regulations (EC) No 1924/2006 and (EC) No 1925/2006 should therefore be amended accordingly.

- (49) In order to enable interested parties, especially small and medium-sized enterprises, to provide nutrition information on their products, the application of the measures to make nutrition information mandatory should be introduced gradually through extended transition periods with an additional transition period provided for micro-businesses.
- (50) Since the objectives of the actions to be taken cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (51) With the aim of simplifying and accelerating the procedure, the Commission should be entrusted with the task of adopting implementing measures of a technical nature.
- (52) The measures necessary for the implementing of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission²¹.
- (53) Power should be conferred on the Commission in particular to amend and update the Annexes to this Regulation. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, and to supplement this Regulation by the addition of new non-essential elements, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (54) On grounds of urgency it is necessary to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of amendments to Annexes II and III of this Regulation,

²⁰ OJ L 404, 30.12.2006, p. 26.

²¹ OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Regulation provides the basis for the assurance of a high level of consumer protection in relation to food information, taking into account the differences in the perception of consumers and their information needs whilst ensuring the smooth functioning of the internal market.
2. This Regulation establishes the general principles, requirements and responsibilities governing food information, and in particular food labelling. It lays down the means to guarantee the right of consumers to information and procedures for the provision of food information, taking into account the need to provide sufficient flexibility to respond to future developments and new information requirements.
3. This Regulation applies to all stages of the food chain, where the activities of food businesses concern the provision of food information to consumers.

It shall apply to all foods intended for the final consumer, including foods delivered by mass caterers and foods intended for supply to mass caterers.

4. This Regulation shall apply without prejudice to labelling requirements provided in specific Community legislation applicable to particular foods.

Article 2

Definitions

1. For the purposes of this Regulation the following definitions shall apply:
 - (a) the definitions of ‘food’, ‘food law’, ‘food business’, ‘food business operator’, ‘retail’, ‘placing on the market’ and ‘final consumer’ in Article 2 and in Article 3(1), (2), (3), (7), (8) and (18) of Regulation (EC) No 178/2002;
 - (b) the definition of ‘processing’, ‘unprocessed products’ and ‘processed products’ in Article 2(1) (m), (n) and (o) of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs²²;
 - (c) the definitions of ‘food additives’ and ‘processing aids’ in Article 1(2) and in footnote 1 of Council Directive 89/107/EEC of 21 December 1988 on the

²² OJ L 139, 30.4.2004, p. 1.

approximation of the laws of the Member States concerning food additives authorised for use in foods intended for human consumption²³;

- (d) the definition of ‘flavouring’ in Article 1(2)(a) of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production²⁴;
- (e) the definitions of ‘meat’ and ‘mechanically separated meat’ in points 1.1 and 1.14 of Annex I to Regulation (EC) No 853/2004;
- (f) the definitions of ‘claim’, ‘nutrient’, ‘other substance’, ‘nutrition claim’ and ‘health claim’ in Article 2(2) (1) to (5) of Regulation (EC) No 1924/2006.

²³ OJ L 40, 11.2.1989, p. 27.

²⁴ OJ L 184, 15.7.1988, p. 61.

2. The following definitions shall also apply:

- (a) 'food information' means information concerning a food and made available to the final consumer by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication. It does not cover commercial communications as defined by Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market²⁵;
- (b) 'food information law' means the Community provisions governing the food information, and in particular labelling, including rules of a general nature applicable to all foods or to specified foods and rules which apply only to specific foods;
- (c) 'mandatory food information' means the particulars that are required to be provided to the final consumer by Community legislation;
- (d) 'mass caterers' means any establishment (including a vehicle or a fixed or mobile stall), such as restaurants, canteens, schools and hospitals, where, in the course of a business, food is prepared for delivery to the final consumer and is ready for consumption without further preparation;
- (e) 'prepacked food' means any single item for presentation as such to the final consumer and to mass caterers, consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, but in any case in such a way that the contents cannot be altered without opening or changing the packaging;
- (f) 'ingredient' means any substance, including food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as ingredients;
- (g) 'place of provenance' means any place where a food is indicated to come from, and that is not the 'country of origin' as determined in accordance with Articles 23 to 26 of Council Regulation (EEC) No 2913/92;
- (h) 'compound ingredient' is an ingredient that is itself the product of more than one ingredient;
- (i) 'label' means any tag, brand, mark, pictorial or other descriptive matter written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of food;
- (j) 'labelling' means any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food;

²⁵ OJ L 178, 17.7.2000, p. 1.

- (k) ‘field of vision’ means all the surfaces of a package that can be read from a single viewing point, permitting rapid and easy access to labelling information by allowing consumers to read this information without needing to turn the package back and forth;
 - (l) ‘legal name’ means the name of a food prescribed in the Community provisions applicable to it or, in the absence of such Community provisions, the name provided for in the laws, regulations and administrative provisions applicable in the Member State in which the food is sold to the final consumer or to mass caterers;
 - (m) ‘customary name’ means a name which is accepted as the name of the food without it needing further explanation by consumers in the Member State in which it is sold;
 - (n) ‘descriptive name’ means a name providing a description of the food, and if necessary of its use, which is sufficiently clear to enable the consumers to know its true nature and distinguish it from other products with which it might be confused;
 - (o) ‘primary ingredient(s)’ means the significant and/or characterising ingredients of a food;
 - (p) ‘significant ingredient(s)’ means the ingredient of a food that represents more than 50% of this food;
 - (q) ‘characterising ingredient(s)’ means any ingredient of a food which is usually associated with the name of the food by the consumer and for which in most cases a quantitative indication is required;
 - (r) ‘essential requirements’ means the requirements whereby the level of consumer protection and food information is determined with respect to a given issue and which are laid down in a Community act which allows for the development of national schemes referred to in Article 44;
 - (s) ‘date of minimum durability of a food’ means the date until which the food retains its specific properties when properly stored;
 - (t) ‘best practices’ means standards, schemes, initiatives, or any other activities endorsed by competent authorities that have been shown through experience and research to be the most effective for the majority of consumers and are considered as models for others to follow.
3. For the purposes of this Regulation the country of origin of a food shall refer to the origin of a food as determined in accordance with Articles 23 to 26 of Council Regulation (EEC) No 2913/92.
4. The specific definitions set out in Annex I shall also apply.

CHAPTER II

GENERAL PRINCIPLES ON FOOD INFORMATION

Article 3

General objectives

1. The provision of food information shall pursue a high level of protection of consumers' health and interests by providing a basis for final consumers to make informed choices and to make safe use of food, with particular regard to health, economic, environmental, social and ethical considerations.
2. Food information law shall aim to achieve in the Community the free movement of food legally produced and marketed, taking into account, where appropriate, the need to protect the legitimate interests of producers and to promote the production of quality products.
3. When food information law establishes new requirements, consideration shall be given to the need for a transitory period after the entry into force of the new requirements, during which foods bearing labels not complying with the new requirements can be placed on the market and for stocks of such foods that have been placed on the market before the end of the transitory period to continue to be sold until exhausted.

Article 4

Principles governing mandatory food information

1. Where mandatory food information is required by food information law, it shall concern information that falls, in particular, into one of the following categories:
 - (a) information on the identity and composition, properties or other characteristics of the food;
 - (b) information on the protection of consumers' health and the safe use of a food. In particular, it shall concern information on:
 - (i) compositional attributes that may be harmful to the health of certain groups of consumers;
 - (ii) durability, storage and safe use;
 - (iii) the health impact, including the risks and consequences related to harmful and hazardous consumption of a food;
 - (c) information on nutritional characteristics so as to enable consumers, including those with special dietary requirements, to make informed choices.

2. When considering the need for mandatory food information, account shall be taken of a widespread need on the part of the majority of consumers for certain information to which they attach significant value or of any generally accepted benefits to the consumer to enable them to make informed choices.

Article 5
Consultation of the Authority

Any food information law measures likely to have an effect on public health shall be adopted after consultation of the European Food Safety Authority.

CHAPTER III

GENERAL FOOD INFORMATION REQUIREMENTS AND RESPONSIBILITIES OF FOOD BUSINESS OPERATORS

Article 6
Basic requirement

Any food intended for supply to the final consumer or to mass caterers shall be accompanied by food information in accordance with this Regulation.

Article 7
Fair information practices

1. Food information shall not be misleading to a material degree, particularly:
 - (a) as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production;
 - (b) by attributing to the food effects or properties which it does not possess;
 - (c) by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics.
2. Food information shall be accurate, clear, and easy to understand for the consumer.
3. Subject to derogations provided for by Community legislation applicable to natural mineral waters and foods for particular nutritional uses, food information shall not attribute to any food the property of preventing, treating or curing a human disease, nor refer to such properties.
4. The prohibition referred to in paragraph 3 shall also apply to:
 - (a) advertising;

- (b) the presentation of foods in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed.

Article 8
Responsibilities

1. Without prejudice to paragraphs 3 and 4, food business operators, within the businesses under their control, shall ensure compliance with the requirements of food information law which are relevant to their activities and shall verify that such requirements are met.
2. Food business operators, within the business under their control, shall not modify the information accompanying a food if such modification would mislead the final consumer or otherwise reduce the level of consumer protection, particularly with regard to health.
3. Food business operators placing on the market for the first time a food intended for supply to the final consumer or mass caterer shall ensure the presence and accuracy of the food information in accordance with the applicable food information law.
4. Food business operators responsible for retail or distribution activities which do not affect food information shall act with due care to ensure, within the limits of their respective activities, the presence of the applicable food information requirements, in particular by not supplying foods which they know or presume to be non compliant, on the basis of the information in their possession as professionals.
5. Food business operators within the business under their control shall ensure that information relating to non-prepacked food shall be transmitted to the operator receiving the food in order to enable, where appropriate, the provision of the mandatory food information specified in Article 9(1) points (a) to (c) and (f) to the final consumer.
6. In the following cases, food business operators, within the businesses under their control shall ensure that the mandatory particulars required under Article 9 shall appear on the external packaging in which the food is presented for marketing, or on the commercial documents referring to the foods where it can be guaranteed that such documents either accompany the food to which they refer or were sent before or at the same time as delivery:
 - (a) where prepacked food is intended for the final consumer but marketed at a stage prior to sale to the final consumer and where sale to a mass caterer is not involved at that stage;
 - (b) where prepacked food is intended for supply to mass caterers for preparation, processing, splitting or cutting up.

Notwithstanding subparagraph 1, food business operators shall ensure that the particulars referred to in Article 9(1) (a), (f) and (h) also appear on the external packaging in which the food is presented for marketing.

CHAPTER IV

MANDATORY FOOD INFORMATION

SECTION 1

CONTENT AND PRESENTATION

Article 9

List of mandatory particulars

1. In accordance with Articles 10 to 34 and subject to the exceptions contained in this Chapter, indication of the following particulars shall be mandatory.
 - (a) the name of the food;
 - (b) the list of ingredients;
 - (c) any ingredient listed in Annex II causing allergies or intolerances, and any substance derived therefrom;
 - (d) the quantity of certain ingredients or categories of ingredients;
 - (e) the net quantity of the food;
 - (f) the date of minimum durability or the 'use by' date;
 - (g) any special storage conditions or conditions of use;
 - (h) the name or business name and address of the manufacturer or packager, or of a seller established within the Community;
 - (i) the country of origin or place of provenance where failure to indicate this might mislead the consumer to a material degree as to the true country of origin or place of provenance of the food, in particular if the information accompanying the food or the label as a whole would otherwise imply that the food has a different country of origin or place of provenance; in such cases the indication shall be in accordance with the rules laid down in Article 35(3) and (4) and those established in accordance with Article 35(5);
 - (j) instructions for use when it would be impossible to make appropriate use of the food in the absence of such instructions;
 - (k) with respect to beverages containing more than 1,2 % by volume of alcohol, the actual alcoholic strength by volume;
 - (l) a nutrition declaration.

2. The particulars referred to in paragraph 1 shall be indicated with words and numbers unless the consumers are informed, as regards one or more particulars, by other forms of expression established by implementing measures adopted by the Commission. Those measures 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 49(3).
3. The Commission may amend the list of mandatory particulars laid down in paragraph 1. Those measures 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 49(3).

Article 10

Additional mandatory particulars for specific types or categories of food

1. In addition to the particulars listed in Article 9(1) additional mandatory particulars for specific types or categories of food are laid down in Annex III.
2. The Commission may amend Annex III. Those measures 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 49(4).

Article 11

Derogations from the requirement for mandatory particulars

For specific types or categories of foods, the Commission may provide for derogations, in exceptional cases, from the requirements laid down in Article 9(1) (b) and (f), provided that such derogations do not result in the final consumer and mass caterers being inadequately informed. Those measures designed to amend the non-essential elements of this Regulation by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 49(3).

Article 12

Weights and measures

Article 9 shall be without prejudice to more specific Community provisions regarding weights and measures.

Article 13

Availability and placement of mandatory food information

1. Mandatory food information shall be available and shall be easily accessible, in accordance with this Regulation for all foods.
2. In the case of prepacked food, mandatory food information shall appear on the package or on a label attached thereto.

3. The availability of certain mandatory particulars by means other than on the package or on the label may be established by the Commission provided the general principles and requirements laid down in Chapter II of this Regulation are met. Those measures 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 49(3).
4. In the case of non-prepacked food, the provisions of Article 41 shall apply.

Article 14
Presentation of mandatory particulars

1. Without prejudice to specific Community legislation applicable to particular foods as regards to the requirements referred to in Article 9(1)(a) to (k), when appearing on the package or on the label attached thereto, the mandatory particulars listed in Article 9(1) shall be printed on the package or on the label in characters of a font size of at least 3mm and shall be presented in a way so as to ensure a significant contrast between the print and background.
2. The particulars listed in Article 9(1) (a), (e) and (k) shall appear in the same field of vision.
3. Detailed rules concerning the presentation of mandatory particulars and the extension of the requirements referred to in paragraph 2 to the additional mandatory particulars for specific categories or types of food referred to in Articles 10 and 38 may be adopted by the Commission. Those measures 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 49(3).
4. The minimum font size referred to in paragraph 1 shall not apply in case of packaging or containers the largest surface of which has an area of less than 10 cm².
5. Paragraph 2 shall not apply in the case of foods specified in Article 17(1) and (2).
6. Mandatory food information shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and, where appropriate, indelible. It shall not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material.

Article 15
Distance selling

Without prejudice to the information requirements laid down in Article 9, in the case of foods offered for sale by means of distance communication as defined in Article 2 of Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts²⁶:

²⁶ OJ L 144, 4.6.1997, p. 19.

- (a) mandatory food information shall be available before the purchase is concluded and shall appear on the material supporting the distance selling or be provided through other appropriate means;
- (b) the particulars provided in Article 9(1) points (d), (f), (g), (h) and (k) shall be mandatory only at the moment of delivery.

Article 16
Language requirements

- 1. Without prejudice to Article 9(2), mandatory food information shall appear in a language easily understood by the consumers of the Member States where a food is marketed.
- 2. Within their own territory, the Member States in which a food is marketed may stipulate that the particulars shall be given in one or more languages from among the official languages of the Community.
- 3. Paragraphs 1 and 2 shall not preclude the particulars from being indicated in several languages.

Article 17
Omission of certain mandatory particulars

- 1. In the case of glass bottles intended for reuse which are indelibly marked and which therefore bear no label, ring or collar only the particulars listed in Article 9(1) (a), (c), (e), (f) and (l) shall be mandatory.
- 2. In the case of packaging or containers the largest surface of which has an area of less than 10 cm² only the particulars listed in Article 9(1) (a), (c), (e) and (f) shall be mandatory on the package or on the label. The particulars referred to in Article 9(1)(b) shall be provided through other means or shall be available at the request of the consumer.
- 3. Without prejudice to other Community legislation requiring mandatory nutrition declaration, the declaration referred to in Article 9(1)(l) shall not be mandatory for the foods listed in Annex IV.

SECTION 2

DETAILED PROVISIONS ON MANDATORY PARTICULARS

Article 18

Name of the food

1. The name of the food shall be its legal name. In the absence of such name, the name of the food shall be its customary name, or, if there is no customary name or the customary name is not used, a descriptive name of the food shall be provided.
2. Specific provisions on the use of the name of the food and particulars that shall accompany it are laid down in Annex V.

Article 19

List of ingredients

1. The list of ingredients shall be headed or preceded by a suitable heading which consists of or includes the word 'ingredients'. It shall include all the ingredients of the food, in descending order of weight, as recorded at the time of their use in the manufacture of the food.
2. Ingredients shall be designated by their specific name, where applicable, in accordance with the rules laid down in Article 18 and in Annex V.
3. Technical rules for applying paragraphs 1 and 2 are laid down in Annex VI.

Article 20

Omission of the list of ingredients

The following foods shall not be required to bear a list of ingredients:

- (a) fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated;
- (b) carbonated water, the description of which indicates that it has been carbonated;
- (c) fermentation vinegars derived exclusively from a single basic product, provided that no other ingredient has been added;
- (d) cheese, butter, fermented milk and cream, to which no ingredient has been added other than lactic products, enzymes and micro-organism cultures essential to manufacture, or in the case of cheese other than fresh cheese and processed cheese the salt needed for its manufacture;
- (e) wine as defined in Council Regulation (EC) No 1493/1999, beer, and spirits as defined in Article 2(1) of Regulation (EC) No. [...] of [...] of the European

Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89. The Commission shall produce a report after [*five years of the entry into force of this Regulation*] concerning the application of Article 19 on these products and may accompany this report by specific measures determining the rules for labelling ingredients. Those measures 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 49(3);

- (f) foods consisting of a single ingredient, where:
 - (i) the name of the food is identical with the ingredient name; or
 - (ii) the name of the food enables the nature of the ingredient to be clearly identified.

Article 21

Omission of constituents of food from the list of ingredients

The following constituents of a food shall not be required to be included in the list of ingredients:

- (a) the constituents of an ingredient which have been temporarily separated during the manufacturing process and later reintroduced but not in excess of their original proportions;
- (b) food additives and enzymes:
 - (i) whose presence in a given food is solely due to the fact that they were contained in one or more ingredients of that food, provided that they serve no technological function in the finished product; or
 - (ii) which are used as processing aids;
- (c) substances used in the quantities strictly necessary as solvents or media for nutritional substances, food additives or flavouring;
- (d) substances which are not food additives but are used in the same way and with the same purpose as processing aids and are still present in the finished product, even if in an altered form;
- (e) water:
 - (i) where the water is used during the manufacturing process solely for the reconstitution of an ingredient used in concentrated or dehydrated form; or
 - (ii) in the case of a liquid medium which is not normally consumed.

Article 22
Labelling of certain substances causing allergies or intolerances

1. Any ingredient listed in Annex II or any substance originating from an ingredient listed in that Annex, subject to the exceptions thereof provided for in that Annex, shall be indicated on the label with a precise reference to the name of the ingredient.

That indication shall not be required in cases where:

- (a) the name of the food clearly refers to the ingredient concerned; or
 - (b) the ingredient listed in Annex II from which a substance originates is already included in the list of ingredients.
2. The list in Annex II shall be systematically re-examined and, where necessary, updated by the Commission on the basis of the most recent scientific and technical knowledge.

Those measures 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 49(4).

3. Where necessary, technical guidelines may be issued for the interpretation of the list in Annex II, in accordance with the procedure referred to in Article 49(2).

Article 23
Quantitative indication of ingredients

1. The indication of the quantity of an ingredient or category of ingredients used in the manufacture or preparation of a food shall be required where:
 - (a) the ingredient or category of ingredients concerned appears in the name of the food or is usually associated with that name by the consumer; or
 - (b) the ingredient or category of ingredients concerned is emphasised on the labelling in words, pictures or graphics; or
 - (c) the ingredient or category of ingredients concerned is essential to characterise a food and to distinguish it from products with which it might be confused because of its name or appearance.
2. The Commission may amend paragraph 1 by adding other cases. Those measures 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 49(3).
3. Technical rules for applying paragraph 1, including specific cases where the quantitative indication shall not be required in respect of certain ingredients, are laid down in Annex VII.

Article 24
Net Quantity

1. The net quantity of a food shall be expressed, using litres, centilitres, millilitres, kilograms or grams, as appropriate:
 - (a) in units of liquid in the case of liquids;
 - (b) in units of mass in the case of other products.
2. The expression of the net quantity for certain specified foods in a different manner than the one described in paragraph 1 may be established by the Commission. Those measures designed to amend the non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 49(3).
3. Technical rules for applying paragraph 1, including specific cases where the indication of the net quantity shall not be required, are laid down in Annex VIII.

Article 25
Minimum durability date and ‘use by’ date

1. In the case of foods which, from a microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability shall be replaced by the ‘use by’ date.
2. The appropriate date shall be expressed in accordance with Annex IX.
3. The manner of indicating the date of minimum durability referred to in point 1(c) of Annex IX may be specified in accordance with the procedure referred to in Article 49(2).

Article 26
Instructions for use

1. The instructions for use of a food shall be indicated in such a way as to enable appropriate use to be made thereof.
2. The Commission may lay down rules as regards the way in which those instructions shall be indicated in the case of certain foods. Those measures 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 49(3).

Article 27
Alcoholic strength

1. The rules concerning indication of the alcoholic strength by volume shall, in the case of products classified under the Common Customs Tariff headings 22.04 and 22.05, be those laid down in the specific Community provisions applicable to such products.
2. The actual alcoholic strength by volume of beverages containing more than 1,2 % by volume of alcohol other than those referred to in paragraph 1 shall be indicated in accordance with Annex X.

SECTION 3

NUTRITION DECLARATION

Article 28
Relation with other legislation

1. The provisions of this Section shall not apply to foods within the scope of the following legislation:
 - (a) 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 supplements²⁷;
 - (b) Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters²⁸.
2. The provisions of this Section apply without prejudice to 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 uses²⁹ and specific Directives as referred to in Article 4(1) of that Directive.

Article 29
Content

1. The nutrition declaration shall include the following (hereinafter referred to as "mandatory nutrition declaration"):
 - (a) energy value;
 - (b) the amounts of fat, saturates, carbohydrates with specific reference to sugars, and salt.

²⁷ OJ L 183, 12.7.2002, p. 51.

²⁸ OJ L 229, 30.8.1980, p. 1.

²⁹ OJ L 186, 30.6.1989, p. 27.

This paragraph shall not apply to wine as defined in Council Regulation (EC) No 1493/1999, beer, and spirits as defined in Article 2(1) of Regulation (EC) No. [...] of [...] of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89. The Commission shall produce a report after [*five years of the entry into force of this Regulation*] concerning the application of this paragraph on these products and may accompany this report by specific measures determining the rules for a mandatory nutrition declaration for these products. Those measures 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 49(3).

2. The nutrition declaration may also include the amounts of one or more of the following:
 - (a) trans fats;
 - (b) mono-unsaturates;
 - (c) polyunsaturates;
 - (d) polyols;
 - (e) starch;
 - (f) fibre;
 - (g) protein;
 - (h) any of the minerals or vitamins listed in point 1 of Part A of Annex XI, and present in significant amounts as defined in point 2 of Part A of Annex XI.
3. The declaration of the amount of substances which belong to or are components of one of the categories of nutrients referred to in paragraph 2 shall be required where a nutrition and/or health claim is made.
4. The lists in paragraphs 1 and 2 may be amended by the Commission. Those measures 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 49(3).

Article 30 **Calculation**

1. The amount of energy shall be calculated using the conversion factors in Annex XII.
2. Conversion factors for the vitamins and minerals mentioned in point 1 of Part A of Annex XI, in order to calculate more precisely their content in foods, may be set and included in Annex XII by the Commission. Those measures 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 49(3).

3. The amounts of energy and nutrients referred to in Article 29(1) and (2) shall be those of the food as sold.

Where appropriate, the information may relate to the food after preparation, provided that sufficiently detailed preparation instructions are given and the information relates to the food as prepared for consumption.

4. The declared values shall, according to the individual case, be average values based on:
 - (a) the manufacturer's analysis of the food; or
 - (b) a calculation from the known or actual average values of the ingredients used; or
 - (c) a calculation from generally established and accepted data.

The rules for implementing the declaration of energy and nutrients with regard to the precision of the declared values such as the differences between the declared values and those established in the course of official checks may be decided upon in accordance with the procedure laid down in Article 49(2).

Article 31

Forms of expression

1. The amount of energy and nutrients or their components referred to in Article 29(1) and (2) shall be expressed using the measurement units listed in Part A of Annex XIII.
2. The amount of energy and nutrients referred to in paragraph 1 shall be expressed per 100 g or per 100 ml or, subject to Article 32(2) and (3), per portion.
3. The mandatory nutrition declaration shall be expressed, as appropriate, as a percentage of the reference intakes set out in Part B of Annex XI in relation to per 100 g or per 100 ml or per portion. When provided, the declaration on vitamins and minerals shall also be expressed as a percentage of the reference intakes set out in point 1 of Part A of Annex XI.
4. The declaration of polyols and/or starch and the declaration of type of fatty acids, other than the mandatory declaration of saturates referred to in Article 29(1)(b), shall be presented in accordance with Annex XIII Part B.

Article 32

Expression on a per portion basis

1. In addition to the nutrition declaration per 100g or per 100ml referred to in Article 31(2), the information may be expressed per portion as quantified on the label, provided that the number of portions contained in the package is stated.

2. The nutrition declaration may be expressed on a per portion basis alone if the food is prepacked as an individual portion.
3. The expression on a per portion basis alone for foods presented in packages containing multiple portions of the food, that have not been prepacked as individual portions, shall be established by the Commission. Those measures 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 49(3).

Article 33
Additional forms of expression

1. In addition to the forms of expression referred to in Article 31(2) and (3), the nutrition declaration may be given by other forms of expression provided that the following essential requirements are met:
 - (a) the form of expression aims to facilitate consumer understanding of the contribution or importance of the food to the energy and nutrient content of a diet; and
 - (b) it is based either on harmonised reference intakes, or in their absence, on generally accepted scientific advice on intakes for energy or nutrients; and
 - (c) it is supported by evidence of understanding of and use of the presentation of the information by the average consumer.
2. Such additional forms of expression referred to in paragraph 1 shall be identified under a national scheme referred to in Article 44.

Article 34
Presentation

1. The particulars referred to Article 31(2) related to the mandatory nutrition declaration shall be included in the principal field of vision. They shall be presented, where appropriate, together in a clear format in the following order: energy, fat, saturates, carbohydrates with specific reference to sugars, and salt.
2. The nutrition declaration in relation to the nutrients referred to in Article 29(2) shall appear together in one place and, as appropriate, in the order of presentation provided in Part C of Annex XIII.

When this nutrition declaration does not appear in the principal field of vision, it shall be presented in tabular form, with the numbers aligned if space permits. Where space does not permit, the declaration shall appear in linear form.

3. If the mandatory nutrition declaration appears together with the declaration on nutrients referred to in Article 29(2), the order of presentation of the energy and nutrients included in the declaration shall be, as appropriate, in the order provided in Part C of Annex XIII.

4. In cases where the amount of energy or nutrient(s) in a product is negligible, the nutrition declaration on those elements may be replaced by a statement such as ‘Contains negligible amounts of ...’ in close proximity to the nutrition declaration when present.
5. Graphical forms or symbols for the presentation of the nutrition declaration may be used under a national scheme referred to in Article 44 provided the following essential requirements are met:
 - (a) such forms of presentation shall not mislead the consumer; and
 - (b) there shall be evidence of understanding of such forms of presentation by the average consumer.
6. Rules relating to other aspects of presentation of nutrition declaration, other than those referred to in paragraph 5, may be established by the Commission. Those measures 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 49(3).

CHAPTER V

VOLUNTARY FOOD INFORMATION

Article 35

Applicable requirements

1. Where food information covered by this Regulation is provided on a voluntary basis, such information shall comply with the relevant specific requirements laid down in this Regulation.
2. Without prejudice to labelling in accordance with specific Community legislation, paragraphs 3 and 4 shall apply where the country of origin or the place of provenance of a food is voluntarily indicated to inform consumers that a food originates or comes from the European Community or a given country or place.
3. Where the country of origin or the place of provenance of the food is not the same as the one of its primary ingredient(s), the country of origin or place of provenance of those ingredient(s) shall also be given.
4. For meat, other than beef and veal, the indication on the country of origin or place of provenance may be given as a single place only where animals have been born, reared and slaughtered in the same country or place. In other cases information on each of the different places of birth, rearing and slaughter shall be given.
5. Implementing rules concerning the application of paragraph 3 shall be established by the Commission. Those measures 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 49(3).

6. Implementing rules concerning the conditions and criteria of use of particulars voluntarily provided may be established by the Commission. Those measures 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 49(3).

Article 36
Presentation

Voluntary information shall not be displayed to the detriment of the space available for mandatory information.

CHAPTER VI

NATIONAL PROVISIONS

Article 37
Principle

Member States may only adopt provisions in the field of food information where this is provided for by this Regulation.

Article 38
National provisions on additional mandatory particulars

1. In addition to the mandatory particulars referred to in Article 9(1) and in Article 10, Member States may, in accordance with the procedure laid down in Article 42, require additional mandatory particulars for specific types or categories of foods, justified on grounds of:
 - (a) the protection of public health;
 - (b) the protection of consumers;
 - (c) the prevention of fraud;
 - (d) the protection of industrial and commercial property rights, indications of provenance, registered designations of origin and the prevention of unfair competition.
2. By means of paragraph 1, Member States may introduce measures concerning the mandatory indication of the country of origin or place of provenance of foods only where there is a proven link between certain qualities of the food and its origin or provenance. When notifying such measures to the Commission, Member States shall

provide evidence that the majority of consumers attach significant value to the provision of this information.

Article 39
Milk and milk products

Member States may adopt measures derogating from Article 9(1) and Article 10(2) in the case of milk and milk products presented in glass bottles intended for reuse.

They shall communicate to the Commission the text of those measures without delay.

Article 40
Alcoholic beverages

Member States may, pending the adoption of the Community provisions referred to in Article 20(e), maintain national rules as regard the listing of ingredients in the case of beverages containing more than 1,2 % by volume of alcohol.

Article 41
National measures for non-prepacked food

1. Where foods are offered for sale to the final consumer or to mass caterers without prepackaging, or where foods are packed on the sales premises at the consumer's request or prepacked for direct sale, the Member States may adopt detailed rules concerning the manner in which the particulars specified in Articles 9 and 10 are to be shown.
2. Member States may decide not to require the provision of some of the particulars referred to in paragraph 1, other than those referred to in Article 9(1) (c), provided that the consumer or mass caterer still receives sufficient information.
3. Member States shall communicate to the Commission the text of the measures referred to in paragraphs 1 and 2 without delay.

Article 42
Notification procedure

1. When reference is made to this Article, the Member State which deems it necessary to adopt new food information legislation, shall notify in advance the Commission and the other Member States of the measures envisaged and give the reasons justifying them.
2. The Commission shall consult the Standing Committee on the Food Chain and Animal Health set up by Article 58(1) of Regulation (EC) No 178/2002 if it considers such consultation to be useful or if a Member State so requests.

3. The Member State concerned may take the envisaged measures only three months after the notification referred to in paragraph 1, provided that it has not received a negative opinion from the Commission.
4. If the Commission's opinion is negative, it shall initiate the procedure referred to in Article 49(2) before the expiry of that three-month period in order to determine whether the envisaged measures may be implemented. The Commission may require certain amendments to be made to the envisaged measures. The Member State concerned may take the envisaged measures only after the Commission has adopted its final decision.
5. 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 regulations³⁰ shall not apply to the measures falling within the notification procedure specified in paragraphs 1 to 4.

Article 43
Detailed rules

Detailed rules for the application of this Chapter may be adopted by the Commission. Those measures designed to amend non-essential elements of this Regulation by supplementing it shall be adopted in accordance with the procedure referred to in Article 49(2).

CHAPTER VII

DEVELOPMENT OF NATIONAL SCHEMES

Article 44
National Schemes

1. Member States may adopt, recommend or otherwise endorse national schemes consisting of exclusively non-binding rules, such as recommendations, guidance, standards or any other non binding rules, (hereinafter referred to as the 'national schemes') aimed at ensuring the application of the following provisions and in compliance with the essential requirements set out therein:
 - (a) Article 33(2), relating to additional forms of expression of the nutritional declaration;
 - (b) Article 34(5), relating to the presentation of the nutrition declaration.
2. The implementation by national schemes of other provisions of food information law, in addition to those listed in paragraph 1, and the relevant essential requirements may be established by the Commission. Those measures 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 49(3).

³⁰ OJ L 204, 21.7.1998, p. 37.

3. National schemes may be developed by Member States on their own initiative or at the request of stakeholders in compliance with the general principles and requirements laid down in Chapter II and III of this Regulation, and:
 - (a) as a result of sound consumer research; and
 - (b) following extensive consultation with a wide range of stakeholders drawing on best practices.
4. National schemes shall include appropriate mechanisms to allow consumers to identify foods that are labelled in compliance with national schemes, to monitor the level of compliance with the scheme and to assess its impact.
5. Member States shall provide the Commission with the details of the national schemes referred to in paragraph 1, including an identifier for foods that are labelled in compliance with that national scheme. The Commission shall make those details available to the public, in particular through a dedicated page on the Internet.
6. The Commission shall encourage and organise the exchange of information between Member States and with itself on matters relating to the adoption and implementation of the national schemes. It shall encourage the participation of stakeholders to such exchange, in particular through the Advisory Group on the Food Chain Animal and Plant Health set up by Commission Decision 2004/613/EC of 6 August 2004 concerning the creation of an advisory group on the food chain and animal and plant health³¹.
7. The Commission, after consulting with Member States, may adopt Guidelines concerning the application of this Article.

Article 45

Presumption of conformity

1. Any food information provided in conformity with a national scheme shall be presumed to comply with the essential requirements referred to in Article 44(1) and (2).
2. The application of national schemes shall not give rise to obstacles to the free movement of products.

Article 46

Community measures

1. If the Commission considers that a national scheme is not in compliance with the provisions of this Regulation, it may adopt a decision, after having informed the Committee referred to in Article 49(1), requesting a Member State to repeal or amend that national scheme.

³¹ OJ L 275, 25.8.2004, p. 17.

2. The Commission may adopt implementing measures relating to the provisions referred to in Article 44(1) and (2). Those measures 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 49(3).

Article 47
Implementing rules

Detailed rules for the application of this Chapter may be adopted by the Commission. Those measures designed to amend non-essential elements of this Regulation by supplementing it shall be adopted in accordance with the procedure referred to in Article 49(2).

CHAPTER VIII

IMPLEMENTING, AMENDING AND FINAL PROVISIONS

Article 48
Technical adaptations

Subject to the provisions relating to the amendments to Annexes II and III referred to in Article 10(2) and Article 22(2), the Annexes may be amended by the Commission. Those measures 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 49(3).

Article 49
Committee

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.
3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 50
Amendments to Regulation (EC) No 1924/2006

In Article 7 of Regulation (EC) No 1924/2006, the first and second paragraphs are replaced by the following:

“The obligation and the modalities for providing information pursuant to [Chapter IV, Section 3 of Regulation (EC) No. ...of the European Parliament and of the Council]* where a nutrition and/or health claim is made shall apply *mutatis mutandis*, with the exception of generic advertising.

In addition, and as the case may be, the amount(s) of the substance(s) to which a nutrition or health claim relates that does not appear in the nutrition labelling shall also be stated in the same field of vision as the nutrition declaration and be expressed in accordance with Articles 30 to 32 of [Regulation (EC) No ...].

* OJ L ...,dd/mm/yyyy, p.”.

Article 51
Amendments to Regulation (EC) No 1925/2006

1. In Article 6 of Regulation (EC) 1925/2006 paragraph 6 is replaced by the following:

“6. The addition of a vitamin or a mineral to a food shall result in the presence of that vitamin or mineral in the food in at least a significant amount where this is defined according to [point 2 of Part A of Annex XI of Regulation (EC) No ...]*. The minimum amounts, including any lower amounts, by derogation from the significant amounts mentioned above, for specific foods or categories of foods shall be adopted in accordance with the procedure referred to in Article 14(2).

* OJ L ...,dd/mm/yyyy, p.”.

2. In Article 7 of Regulation (EC) 1925/2006 paragraph 3 is replaced by the following:

“3. Nutrition labelling of products to which vitamins and minerals have been added and which are covered by this Regulation shall be compulsory. The information to be provided shall consist of that specified in Article 29(1) of [Regulation (EC) No ...] and of the total amounts present of the vitamins and minerals when added to the food.”.

Article 52
Repeal

1. Directives 2000/13/EC, 87/250/EC, 94/54/EC, 1999/10/EC, 2002/67/EC, 2004/77/EC and Regulation (EC) No 608/2004 are repealed with effect from the date of the entry into force of this Regulation.

2. Directive 90/496/EEC is repealed from [5 years after the entry into force].
3. References to the repealed acts shall be construed as references to this Regulation.

Article 53
Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 14(1) shall apply from [*the first day of the month 3 years after the entry into force*].

Articles 29 to 34 shall apply from [*the first day of the month 3 years after the entry into force*] except in the case of foods labelled by food business operators with, on the date of entry into force, less than 10 employees and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million where they shall apply [*the first day of the month 5 years after the entry into force*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

SPECIFIC DEFINITIONS As referred to in Article 2(4)

1. 'nutrition declaration' or 'nutrition labelling' means information consisting of:
 - (a) energy value; or
 - (b) energy value and one or more of the following nutrients:
 - fat,
 - carbohydrate,
 - fibre,
 - protein,
 - salt,
 - vitamins and minerals listed in Annex XI, Part A; point 1 and present in significant amounts as defined in Annex XI, Part A; point 2.
2. 'fat' means total lipids, and includes phospholipids;
3. 'saturates' means fatty acids without double bond;
4. 'trans fat' means fatty acids with at least one non-conjugated (namely interrupted by at least one methylene group) carbon-carbon double bond in the trans configuration;
5. 'mono-unsaturates' means fatty acids with one cis double bond;
6. 'polyunsaturates' means fatty acids with cis, cis-methylene interrupted double bonds;
7. 'carbohydrate' means any carbohydrate which is metabolized in man, and includes polyols;
8. 'sugars' means all monosaccharides and disaccharides present in food, but excludes polyols;
9. 'polyols' means alcohols containing more than two hydroxyl groups;
10. 'protein' means the protein content calculated using the formula: protein = total Kjeldahl nitrogen \times 6,25;
11. 'salt' means the salt content calculated using the formula: salt = sodium \times 2,5;
12. 'average value' means the value which best represents the amount of the nutrient which a given food contains, and reflects allowances for seasonal variability, patterns of consumption and other factors which may cause the actual value to vary;
13. 'principal field of vision' means the field of vision that is most likely to be displayed or visible under normal or customary conditions of sale or use.

ANNEX II

INGREDIENTS CAUSING ALLERGIES OR INTOLERANCES

1. Cereals containing gluten (namely wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof, except:
 - (a) wheat based glucose syrups including dextrose³²;
 - (b) wheat based maltodextrins¹;
 - (c) glucose syrups based on barley;
 - (d) cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other beverages containing more than 1,2 % by volume of alcohol.
2. Crustaceans and products thereof.
3. Eggs and products thereof.
4. Fish and products thereof, except:
 - (a) fish gelatine used as carrier for vitamin or carotenoid preparations;
 - (b) fish gelatine or Isinglass used as fining agent in beer and wine.
5. Peanuts and products thereof.
6. Soybeans and products thereof, except:
 - (a) fully refined soybean oil and fat¹;
 - (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources;
 - (c) vegetable oils derived phytosterols and phytosterol esters from soybean sources;
 - (d) plant stanol ester produced from vegetable oil sterols from soybean sources.
7. Milk and products thereof (including lactose), except:
 - (a) whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other beverages containing more than 1,2 % by volume of alcohol;
 - (b) lactitol.

³² And the products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the Authority for the relevant product from which they originated.

8. Nuts, namely almonds (*Amygdalus communis L.*), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis (Wangenh.) K. Koch*), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia nuts and Queensland nuts (*Macadamia ternifolia*), and products thereof, except:
 - (a) nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other beverages containing more than 1,2 % by volume of alcohol.
9. Celery and products thereof.
10. Mustard and products thereof.
11. Sesame seeds and products thereof.
12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂.
13. Lupin and products thereof.
14. Molluscs and products thereof.

ANNEX III

FOODS FOR WHICH THE LABELLING MUST INCLUDE ONE OR MORE ADDITIONAL PARTICULARS

TYPE OR CATEGORY OF FOOD	PARTICULARS
1. FOODS PACKAGED IN CERTAIN GASES	
1.1 Foods whose durability has been extended by means of packaging gases authorised pursuant to Council Directive 89/107/EEC ³³	‘Packaged in a protective atmosphere’
2. FOODS CONTAINING SWEETENERS	
2.1 Foods containing a sweetener or sweeteners authorised pursuant to Directive 89/107/EEC	‘with sweetener(s)’ this statement shall accompany the name of the food.
2.2 Foods containing both an added sugar or sugars and a sweetener or sweeteners authorised pursuant to Directive 89/107/EEC	‘with sugar(s) and sweetener(s)’ this statement shall accompany the name of the food.
2.3 Foods containing aspartame authorised pursuant to Directive 89/107/EEC	‘contains a source of phenylalanine’
2.4 Foods containing more than 10 % added polyols authorised pursuant to Directive 89/107/EEC	‘excessive consumption may produce laxative effects’
3. FOODS CONTAINING GLYCYRRHIZINIC ACID OR ITS AMMONIUM SALT	
3.1 Confectionery or beverages containing glycyrrhizinic acid or its ammonium salt due to the addition of the substance(s) as such or the liquorice plant <i>Glycyrrhiza glabra</i> , at concentration of 100 mg/kg or 10 mg/l or above.	‘contains liquorice’ shall be added immediately after the list of ingredients, unless the term “liquorice” is already included in the list of ingredients or in the name of the food. In absence of a list of ingredients, the statement shall accompany the name of the food.
3.2 Confectionery containing glycyrrhizinic acid or its ammonium salt due to the addition of the substance(s) as such or the liquorice plant <i>Glycyrrhiza glabra</i> at concentrations of 4 g/kg or above.	‘contains liquorice - people suffering from hypertension should avoid excessive consumption’ shall be added immediately after the list of ingredients. In absence of list of ingredients, the statement shall accompany the name of the food.

³³ OJ L 40, 11.2.1989, p. 27.

<p>3.3 Beverages containing glycyrrhizinic acid or its ammonium salt due to the addition of the substance(s) as such or the liquorice plant <i>Glycyrrhiza glabra</i> at concentrations of 50 mg/l or above, or of 300 mg/l or above in the case of beverages containing more than 1,2 % by volume of alcohol³⁴.</p>	<p>‘contains liquorice - people suffering from hypertension should avoid excessive consumption’ shall be added immediately after the list of ingredients. In absence of list of ingredients, the statement shall accompany the name of the food.</p>
<p>4. BEVERAGES WITH HIGH CAFFEINE CONTENT</p>	
<p>4.1 Beverages, with the exception of those based on coffee, tea or coffee or tea extract where the name of the food includes the term “coffee” or “tea”, which:</p> <ul style="list-style-type: none"> – are intended for consumption without modification and contain caffeine, from whatever source, in a proportion in excess of 150 mg/l, or – are in concentrated or dried form and after reconstitution contain caffeine, from whatever source, in a proportion in excess of 150 mg/l 	<p>‘High caffeine content’ in the same field of vision as the name of the beverage, followed by a reference in brackets and in accordance with Article 14(5) of this Regulation to the caffeine content expressed in mg/100 ml.</p>

³⁴ The level shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.

5. FOODS WITH ADDED PHYTOSTEROLS, PHYTOSTEROL ESTERS, PHYTOSTANOLS OR PHYTOSTANOL ESTERS

<p>5.1 Foods or food ingredients with added phytosterols, phytosterol esters, phytostanols or phytostanol esters</p>	<ol style="list-style-type: none">(1) 'with added plant sterols' or 'with added plant stanols' in the same field of vision as the name of the food;(2) the amount of added phytosterols, phytosterol esters, phytostanols or phytostanol esters content (expressed in % or as g of free plant sterols/plant stanols per 100 g or 100 ml of the food) shall be stated in the list of ingredients;(3) a statement that the food is intended exclusively for people who want to lower their blood cholesterol level;(4) a statement that patients on cholesterol lowering medication should only consume the product under medical supervision;(5) an easily visible statement that the food may not be nutritionally appropriate for pregnant or breastfeeding women and children under the age of five years;(6) advice that the food is to be used as part of a balanced and varied diet, including regular consumption of fruit and vegetables to help maintain carotenoid levels;(7) in the same field of vision as the statement required under point 3) above, a statement that the consumption of more than 3 g/day of added plant sterols/plant stanols should be avoided;(8) a definition of a portion of the food or food ingredient concerned (preferably in g or ml) with the amount of the plant sterol/plant stanol that each portion contains.
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ANNEX IV

FOODS WHICH ARE EXEMPTED FROM THE REQUIREMENT FOR THE MANDATORY NUTRITION DECLARATION

- unprocessed products that comprise a single ingredient or category of ingredients;
- processed products which the only processing they have been subjected to is smoking or maturing and that comprise a single ingredient or category of ingredients;
- waters intended for human consumption, including those where the only added ingredients are carbon dioxide and/or flavourings;
- a herb, a spice or mixtures thereof;
- salt and salt substitutes;
- products covered by Directive 1999/4/EC of the European Parliament and of the Council of 22 February 1999 relating to coffee extracts and chicory extracts³⁵, whole or milled coffee beans and whole or milled decaffeinated coffee beans;
- herbal infusion, tea, decaffeinated tea, instant or soluble tea or tea extract, decaffeinated instant or soluble tea or tea extract, which do not contain added ingredients;
- fermented vinegars and substitutes for vinegar, including those where the only added ingredients are flavourings;
- flavourings;
- food additives;
- processing aids;
- food enzymes;
- gelatine;
- jam setting compounds;
- yeast;
- food in packaging or containers the largest surface of which has an area of less than 25 cm²;
- food sold by private persons in the context of occasional activities, and not as part of an undertaking that would imply a certain continuity of activities and a certain degree of organisation;

³⁵ OJ L 66, 13.3.1999, p. 26.

- food directly supplied by the manufacturer of small quantities of products to the final consumer or to local retail establishments directly supplying the final consumer;
- food in inner package not designed for sale without the outer package (nutrition information shall be provided on the outer package unless it belongs to the categories of foods that are exempted under this Annex).

ANNEX V

NAME OF THE FOOD AND SPECIFIC ACCOMPANYING PARTICULARS

PART A – NAME OF THE FOOD

1. The use in the Member State of marketing of the name of the food under which the product is legally manufactured and marketed in the Member State of production shall be allowed.

However, where the application of the other provisions of this Regulation, in particular those set out in Article 9, would not enable consumers in the Member State of marketing to know the true nature of the food and to distinguish it from foods with which they could confuse it, the name of the food shall be accompanied by other descriptive information which shall appear in proximity to the name of the food.

2. In exceptional cases, the name of the food of the Member State of production shall not be used in the Member State of marketing when the food which it designates is so different, as regards its composition or manufacture, from the food known under that name that the provisions of point 1 are not sufficient to ensure, in the Member State of marketing, correct information for purchaser.
3. No name protected as intellectual property, brand name or fancy name may be substituted for the name of the food.

PART B – MANDATORY PARTICULARS ACCOMPANYING THE NAME OF THE FOOD

1. The name of the food shall include or be accompanied by particulars as to the physical condition of the food or the specific treatment which it has undergone (for example, powdered, freeze-dried, deep-frozen, quick-frozen, concentrated, smoked) in all cases where omission of such information could mislead the purchaser.
2. Foods treated with ionising radiation shall bear one of the following indications:
'irradiated' or 'treated with ionising radiation'.

PART C – SPECIFIC REQUIREMENTS CONCERNING THE DESIGNATION OF ‘MINCED MEAT’

1. Composition criteria checked on the basis of a daily average:

	Fat content	Connective tissue: meat protein ratio
— lean minced meat	$\leq 7 \%$	≤ 12
— minced pure beef	$\leq 20 \%$	≤ 15
— minced meat containing pigmeat	$\leq 30 \%$	≤ 18
— minced meat of other species	$\leq 25 \%$	≤ 15

2. By way of derogation from the requirements laid down in Chapter IV of Section V of Annex III to Regulation (EC) No 853/2004, the following words shall appear on the labelling:

- ‘percentage of fat under...’,
- ‘connective tissue: meat protein ratio under...’.

3. The Member States may allow the placing on their national market of minced meat which does not comply with the criteria laid down in point 1 of this Part under a national mark that cannot be confused with the marks provided for in Article 5(1) of Regulation (EC) No 853/2004.

ANNEX VI

INDICATION AND DESIGNATION OF INGREDIENTS

PART A – SPECIFIC PROVISIONS CONCERNING THE INDICATION OF INGREDIENTS BY DESCENDING ORDER OF WEIGHT

Category of ingredient	Provision concerning indication by weight
1. Added water and volatile products	Shall be listed in order of their weight in the finished product. The amount of water added as an ingredient in a food shall be calculated by deducting from the total amount of the finished product the total amount of the other ingredients used. This amount shall not be required to be taken into consideration if it does not exceed 5 % by weight of the finished product.
2. Ingredients used in concentrated or dehydrated form and reconstituted at the time of manufacture	May be listed in order of weight as recorded before their concentration or dehydration.
3. Ingredients used in concentrated or dehydrated foods, which are intended to be reconstituted by the addition of water	May be listed in order of proportion in the reconstituted product provided that the list of ingredients is accompanied by an expression, such as ‘ingredients of the reconstituted product’, or ‘ingredients of the ready-to-use product’.
4. Fruit, vegetables or mushrooms, none of which significantly predominates in terms of weight and which are used in proportions that are likely to vary, used in a mixture as ingredients of a food	May be grouped together in the list of ingredients under the designation ‘fruit’, ‘vegetables’ or ‘mushrooms’ followed by the phrase ‘in varying proportions’, immediately followed by a list of the fruit, vegetables or mushrooms present. In such cases, the mixture shall be included in the list of ingredients in accordance with Article 19 (1), on the basis of the total weight of the fruit, vegetables or mushrooms present.
5. Mixtures of spices or herbs, where none significantly predominates in proportion by weight	May be listed in another order provided that that list of ingredients is accompanied by an expression such as ‘in variable proportion’.
6. Ingredients constituting less than 2 % of the finished product	May be listed in a different order after the other ingredients.

Category of ingredient	Provision concerning indication by weight
7. Ingredients which are similar or mutually substitutable, likely to be used in the manufacture or preparation of a food without altering its composition, its nature or its perceived value, and in so far as they constitute less than 2 % of the finished product	May be referred to in the list of ingredients by means of the phrase ‘contains ... and/or ...’, where at least one of no more than two ingredients is present in the finished product. This provision shall not apply to food additives or to ingredients listed in Part C of this Annex.

PART B – DESIGNATION OF CERTAIN INGREDIENTS BY THE NAME OF A CATEGORY RATHER THAN A SPECIFIC NAME

Ingredients which belong to one of the categories of foods listed below and are constituents of another food shall only be required to be named by the designation of that category.

Definition of category of food	Designation
1. Refined oils other than olive oil	<p>‘Oil’, together with</p> <ul style="list-style-type: none"> – either the adjective ‘vegetable’ or ‘animal’, as appropriate, or – an indication of their specific vegetable or animal origin <p>The adjective ‘hydrogenated’ must accompany the indication of a hydrogenated oil unless the amount of saturates and trans fats are included in the nutrition declaration</p>

Definition of category of food	Designation
2. Refined fats	<p>‘Fat’, together with</p> <ul style="list-style-type: none"> – either the adjective ‘vegetable’ or ‘animal’, as appropriate, or – an indication of their specific vegetable or animal origin <p>The adjective ‘hydrogenated’ must accompany the indication of a hydrogenated fat unless the amount of saturates and trans fats are included in the nutrition declaration</p>
3. Mixtures of flour obtained from two or more cereal species	‘Flour’, followed by a list of the cereals from which it has been obtained, in descending order by weight
4. Starches, and starches modified by physical means or by enzymes	‘Starch’
5. All species of fish where the fish constitutes an ingredient of another food and provided that the name and presentation of such food does not refer to a specific species of fish	‘Fish’
6. All types of cheese where the cheese or mixture of cheeses constitutes an ingredient of another food and provided that the name and presentation of such food does not refer to a specific type of cheese	‘Cheese’
7. All spices not exceeding 2 % by weight of the food	‘Spice(s)’ or ‘mixed spices’
8. All herbs or parts of herbs not exceeding 2 % by weight of the food	‘Herb(s)’ or ‘mixed herbs’
9. All types of gum preparations used in the manufacture of gum base for chewing gum	‘Gum base’
10. All types of crumbed baked cereal products	‘Crumbs’ or ‘rusks’ as appropriate

Definition of category of food	Designation												
11. All types of sucrose	‘Sugar’												
12. Anhydrous dextrose or dextrose monohydrate	‘Dextrose’												
13. Glucose syrup and anhydrous glucose syrup	‘Glucose syrup’												
14. All types of milk protein (caseins, caseinates and whey proteins) and mixtures thereof	‘Milk proteins’												
15. Press, expeller or refined cocoa butter	‘Cocoa butter’												
16. All types of wine as defined in Council Regulation (EC) No 1493/1999	‘Wine’												
<p>17. Skeletal muscles³⁶ of mammalian and bird species recognised as fit for human consumption with naturally included or adherent tissue, where the total fat and connective tissue content does not exceed the values indicated below and where the meat constitutes an ingredient of another food. The products covered by the definition of ‘mechanically separated meat’ are excluded from this definition.</p> <p>Maximum fat and connective tissue contents for ingredients designated by the term ‘... meat’</p> <table border="1" data-bbox="183 1187 925 1597"> <thead> <tr> <th data-bbox="183 1187 574 1288"><i>Species</i></th> <th data-bbox="574 1187 750 1288"><i>Fat (%)</i></th> <th data-bbox="750 1187 925 1288"><i>Connective tissue³⁸ (%)</i></th> </tr> </thead> <tbody> <tr> <td data-bbox="183 1310 574 1467">Mammals (other than rabbits and porcines) and mixtures of species with mammals predominating</td> <td data-bbox="574 1310 750 1467">25</td> <td data-bbox="750 1310 925 1467">25</td> </tr> <tr> <td data-bbox="183 1489 574 1534">Porcines</td> <td data-bbox="574 1489 750 1534">30</td> <td data-bbox="750 1489 925 1534">25</td> </tr> <tr> <td data-bbox="183 1556 574 1597">Birds and rabbits</td> <td data-bbox="574 1556 750 1597">15</td> <td data-bbox="750 1556 925 1597">10</td> </tr> </tbody> </table>	<i>Species</i>	<i>Fat (%)</i>	<i>Connective tissue³⁸ (%)</i>	Mammals (other than rabbits and porcines) and mixtures of species with mammals predominating	25	25	Porcines	30	25	Birds and rabbits	15	10	<p>‘... meat’ and the name(s)³⁷ of the animal species from which it comes</p>
<i>Species</i>	<i>Fat (%)</i>	<i>Connective tissue³⁸ (%)</i>											
Mammals (other than rabbits and porcines) and mixtures of species with mammals predominating	25	25											
Porcines	30	25											
Birds and rabbits	15	10											

³⁶ The diaphragm and the masseters are part of the skeletal muscles, while the heart, tongue, the muscles of the head (other than the masseters), the muscles of the carpus, the tarsus and the tail are excluded.

³⁷ For labelling in English, this designation may be replaced by the generic name of the ingredient for the animal species concerned.

³⁸ The connective tissue content is calculated on the basis of the ratio between collagen content and meat protein content. The collagen content means the hydroxyproline content multiplied by a factor of 8.

Definition of category of food	Designation
If these maximum limits are exceeded, but all other criteria for the definition of 'meat' are satisfied, the '... meat' content must be adjusted downwards accordingly and the list of ingredients must mention, in addition to the term '... meat', the presence of fat and/or connective tissue.	
18. All types of products covered by the definition of 'mechanically separated meat'.	'mechanically separated meat' and the name(s) ⁽³⁾ of the animal species from which it comes

PART C – DESIGNATION OF CERTAIN INGREDIENTS BY THE NAME OF THEIR CATEGORY FOLLOWED BY THEIR SPECIFIC NAME OR EC NUMBER

Food additives and enzymes other than those specified in Article 21(b) belonging to one of the categories listed in this Part must be designated by the name of that category, followed by their specific name or, if appropriate, EC number. If an ingredient belongs to more than one of the categories, the category appropriate to the principal function in the case of the food in question shall be indicated. However, the designation 'modified starch' must always be accompanied by the indication of its specific vegetable origin, when that ingredient may contain gluten.

- Acid
- Acidity regulator
- Anti-caking agent
- Anti-foaming agent
- Antioxidant
- Bulking agent
- Colour
- Emulsifier
- Emulsifying salts³⁹
- Firming agent
- Flavour enhancer
- Flour treatment agent
- Gelling agent
- Glazing agent
- Humectant
- Modified starch⁴⁰

³⁹ Only for processed cheeses and products based on processed cheeses.

Preservative
Propellent gas
Raising agent
Stabiliser
Sweetener
Thickener

PART D – DESIGNATION OF FLAVOURINGS IN THE LIST OF INGREDIENTS

1. Flavourings shall be designated either by the word ‘flavouring(s)’ or by a more specific name or description of the flavouring.
2. Quinine and/or caffeine used as a flavouring in the production or preparation of a food shall be mentioned by name in the list of ingredients immediately after the term ‘flavouring(s)’.
3. The word ‘natural’ or any other word having substantially the same meaning may be used only for flavourings in which the flavouring component contains exclusively flavouring substances as defined in Article 1(2)(b)(i) of Directive 88/388/EEC and/or flavouring preparations as defined in Article 1(2)(c) of that Directive.
4. If the name of the flavouring contains a reference to the vegetable or animal nature or origin of the incorporated substances, the word ‘natural’ or any other word having substantially the same meaning may not be used unless the flavouring component has been isolated by appropriate physical processes, enzymatic or microbiological processes or traditional food-preparation processes solely or almost solely from the food or the flavouring source concerned.

PART E – DESIGNATION OF COMPOUND INGREDIENTS

1. A compound ingredient may be included in the list of ingredients, under its own designation in so far as this is laid down by law or established by custom, in terms of its overall weight, and immediately followed by a list of its ingredients.
2. The list of ingredients for compound ingredients shall not be compulsory:
 - (a) where the composition of the compound ingredient is defined in current Community legislation, and in so far as the compound ingredient constitutes less than 2 % of the finished product; however, this provision shall not apply to food additives, subject to the provisions of Article 21 (a) to (d); or
 - (b) for compound ingredients consisting of mixtures of spices and/or herbs that constitute less than 2 % of the finished product, with the exception of food additives, subject to the provisions of Article 21 (a) to (d); or
 - (c) where the compound ingredient is a food for which a list of ingredients is not required under Community legislation.

⁴⁰ The specific name or EC number shall not be required to be indicated.

ANNEX VII

QUANTITATIVE INDICATION OF INGREDIENTS

1. The quantitative indication shall not be required:
 - (a) in respect of an ingredient or category of ingredients:
 - (i) the drained net weight of which is indicated in accordance with point 5 of Annex VIII; or
 - (ii) the quantities of which are already mandatory on the labelling under Community provisions; or
 - (iii) which is used in small quantities for the purposes of flavouring; or
 - (iv) which, while appearing in the name of the food, is not such as to govern the choice of the consumer in the country of marketing because the variation in quantity is not essential to characterise the food or does not distinguish it from similar foods; or
 - (b) where specific Community provisions stipulate precisely the quantity of an ingredient or of a category of ingredients without providing for the indication thereof on the labelling; or
 - (c) in the cases referred to in points 4 and 5 of Part A of Annex VI.
2. Article 23(1) (a) and (b) shall not apply in the case of:
 - (a) any ingredient or category of ingredients covered by the indication ‘with sweetener(s)’ or ‘with sugar(s) and sweetener(s)’ if that indication accompanies the name of the food, pursuant Annex III; or
 - (b) any added vitamin and mineral if that substance is subject to a nutrition declaration .
3. The indication of quantity of an ingredient or category of ingredients shall:
 - (a) be expressed as a percentage, which shall correspond to the quantity of the ingredient or ingredients at the time of its/their use; and
 - (b) appear either in or immediately next to the name of the food or in the list of ingredients in connection with the ingredient or category of ingredients in question.

4. By way of derogation from point 3,
- (a) where foods have lost moisture following heat treatment or other treatment, the quantity shall be expressed as a percentage which shall correspond to the quantity of the ingredient(s) used, related to the finished product, unless that quantity or the total quantity of all the ingredients indicated on the labelling exceeds 100 %, in which case the quantity shall be indicated on the basis of the weight of the ingredient(s) used to prepare 100 g of finished product;
 - (b) the quantity of volatile ingredients shall be indicated on the basis of their proportion by weight in the finished product;
 - (c) the quantity of ingredients used in concentrated or dehydrated form and reconstituted during manufacture may be indicated on the basis of their proportion by weight as recorded before their concentration or dehydration;
 - (d) in the case of concentrated or dehydrated foods which are intended to be reconstituted by the addition of water, the quantity of the ingredients may be indicated on the basis of their proportion by weight in the reconstituted product.

ANNEX VIII

NET QUANTITY DECLARATION

1. The net quantity shall not be mandatory in the case of foods:
 - (a) which are subject to considerable losses in their volume or mass and which are sold by number or weighed in the presence of the purchaser; or
 - (b) the net quantity of which is less than 5 g or 5 ml; however, this provision shall not apply to spices and herbs.
2. Where the indication of a certain type of quantity (such as the nominal quantity, minimum quantity, average quantity) is required by Community provisions or, where there are none, by national provisions, this quantity shall be regarded as the net quantity for the purposes of this Regulation.
3. Where a prepacked item consists of two or more individual prepacked items containing the same quantity of the same product, the net quantity shall be indicated by mentioning the net quantity contained in each individual package and the total number of such packages. The indication of those particulars shall not, however, be mandatory where the total number of individual packages can be clearly seen and easily counted from the outside and where at least one indication of the net quantity contained in each individual package can be clearly seen from the outside.
4. Where a prepacked item consists of two or more individual packages which are not regarded as units of sale, the net quantity shall be given by indicating the total net quantity and the total number of individual packages.
5. Where a solid food is presented in a liquid medium, the drained net weight of the food shall also be indicated.

For the purposes of this point, 'liquid medium' shall mean the following products, possibly in mixtures and also where frozen or quick-frozen, provided that the liquid is merely an adjunct to the essential elements of that preparation and is thus not a decisive factor for the purchase: water, aqueous solutions of salts, brine, aqueous solutions of food acids, vinegar, aqueous solutions of sugars, aqueous solutions of other sweetening substances, fruit or vegetable juices in the case of fruit or vegetables.

ANNEX IX

DATE OF MINIMUM DURABILITY

1. The date of minimum durability shall be indicated as follows:

- (a) The date shall be preceded by the words:
 - ‘Best before ...’ when the date includes an indication of the day,
 - ‘Best before end ...’ in other cases.
- (b) The words referred to in point (a) shall be accompanied by:
 - either the date itself, or
 - a reference to where the date is given on the labelling.

If need be, these particulars shall be followed by a description of the storage conditions which must be observed if the product is to keep for the specified period.

- (c) The date shall consist of the day, month and year in uncoded chronological form.

However, in the case of foods:

- which will not keep for more than three months, an indication of the day and the month shall be sufficient,
 - which will keep for more than three months but not more than 18 months, an indication of the month and year shall be sufficient,
 - which will keep for more than 18 months, an indication of the year shall be sufficient.
- (d) Subject to Community provisions imposing other types of date indication, an indication of the date of minimum durability shall not be required for:
 - fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated; this derogation shall not apply to sprouting seeds and similar products such as legume sprouts,
 - wines, liqueur wines, sparkling wines, aromatised wines and similar products obtained from fruits other than grapes, and beverages falling within CN codes 22060091, 22060093 and 22060099 and manufactured from grapes or grape musts,
 - beverages containing 10 % or more by volume of alcohol,

- soft drinks, fruit juices, fruit nectars and alcoholic beverages containing more than 1,2 % by volume of alcohol in individual containers of more than five litres, intended for supply to mass caterers,
- bakers' or pastry cooks' wares which, given the nature of their content, are normally consumed within 24 hours of their manufacture,
- vinegar,
- cooking salt,
- solid sugar,
- confectionery products consisting almost solely of flavoured and/or coloured sugars,
- chewing gums and similar chewing products,
- individual portions of ice-cream.

2. The 'use by' date shall be indicated as follows:

- (a) It shall be preceded by the words 'use by ...';
- (b) The words in point (a) shall be accompanied by:
 - either the date itself, or
 - a reference to where the date is given on the labelling.

Those particulars shall be followed by a description of the storage conditions which must be observed.

- (c) The date shall consist of the day, the month and, possibly, the year, in that order and in uncoded form.

ANNEX X

ALCOHOLIC STRENGTH

The actual alcoholic strength by volume of beverages containing more than 1,2 % by volume of alcohol shall be indicated by a figure to not more than one decimal place. It shall be followed by the symbol ‘% vol.’ and may be preceded by the word ‘alcohol’ or the abbreviation ‘alc’.

The alcoholic strength shall be determined at 20°C.

Positive and negative allowed tolerances in respect of the indication of the alcoholic strength by volume and expressed in absolute values shall be as listed in the following table. They shall apply without prejudice to the tolerances deriving from the method of analysis used for determining the alcoholic strength.

Description of beverage	Positive or negative tolerance
1. Beers having an alcoholic strength not exceeding 5,5 % vol.; beverages classified under subheading 22.07 B II of the Common Customs Tariff and made from grapes	0,5 % vol.
2. Beers having an alcoholic strength exceeding 5,5 % vol.; beverages classified under subheading 22.07 B I of the Common Customs Tariff and made from grapes; ciders, perries, fruit wines and the like, obtained from fruits other than grapes, whether or not semi-sparkling or sparkling; beverages based on fermented honey	1 % vol.
3. Beverages containing macerated fruit or parts of plants	1,5 % vol.
4. Any other beverages containing more than 1,2 % by volume of alcohol	0,3 % vol.

ANNEX XI

REFERENCE INTAKES

PART A – REFERENCE INTAKES FOR VITAMINS AND MINERALS (ADULTS)

1. Vitamins and minerals which may be declared and their recommended daily allowances (RDAs)

Vitamin A (µg)	800	Vitamin B12 (µg)	1
Vitamin D (µg)	5	Biotin (mg)	0,15
Vitamin E (mg)	10	Pantothenic acid (mg)	6
Vitamin C (mg)	60	Calcium (mg)	800
Thiamin (mg)	1,4	Phosphorus (mg)	800
Riboflavin (mg)	1,6	Iron (mg)	14
Niacin (mg)	18	Magnesium (mg)	300
Vitamin B6 (mg)	2	Zinc (mg)	15
Folacin (µg)	200	Iodine (µg)	150

2. Significant amount of vitamins and minerals

As a rule, 15 % of the recommended allowance specified in point 1 supplied by 100 g or 100 ml or per package if the package contains only a single portion should be taken into consideration in deciding what constitutes a significant amount.

PART B – REFERENCE INTAKES FOR ENERGY AND SELECTED NUTRIENTS OTHER THAN VITAMINS AND MINERALS (ADULTS)

Energy or nutrient	Reference Intake
Energy	8400 kJ (2000 kcal)
Total fat	70 g
Saturates	20 g
Carbohydrate	230 g
Sugars	90 g
Salt	6 g

ANNEX XII

CONVERSION FACTORS

CONVERSION FACTORS FOR THE CALCULATION OF ENERGY

The energy value to be declared shall be calculated using the following conversion factors:

— carbohydrate (except polyols)	4 kcal/g —17 kJ/g
— polyols	2,4 kcal/g —10 kJ/g
— protein	4 kcal/g —17 kJ/g
— fat	9 kcal/g —37 kJ/g
— salatrims	6 kcal/g — 25 kJ/g
— alcohol (ethanol)	7 kcal/g —29 kJ/g
— organic acid	3 kcal/g — 13 kJ/g

ANNEX XIII

EXPRESSION AND PRESENTATION OF NUTRITION DECLARATION

PART A – EXPRESSION OF THE NUTRITION DECLARATION

The units to be used in the nutrition declaration shall be the following:

— energy	kJ and kcal
— fat	grams (g)
— carbohydrate	
— fibre	
— protein	
— salt	
— vitamins and minerals	the units specified in point 1 of Part A of Annex XI
— other substances	units as appropriate for the individual substances concerned

PART B – ORDER OF PRESENTATION OF NUTRITION DECLARATION ON COMPONENTS OF CARBOHYDRATE AND FAT

1. Where polyols and/or starch are declared, this declaration shall be included in the following order:

carbohydrate	g
of which:	
— sugars	g
— polyols	g
— starch	g

2. Where the amount and/or type of fatty acid is declared, this declaration shall be included in the following order:

fat	g
of which:	
— saturates	g
— trans fats	g
— mono-unsaturates	g
— polyunsaturates	g

PART C – ORDER OF PRESENTATION OF ENERGY AND NUTRIENTS APPEARING IN A NUTRITION DECLARATION

The order of presentation of the information on the energy and nutrients, as appropriate, shall be the following:

energy	kJ and kcal
fat	g
of which	
— saturates	g
— trans fats	g
— mono-unsaturates	g
— polyunsaturates	g
carbohydrate	g
of which	
— sugars	g
— polyols	g
— starch	g
fibre	g
protein	g
salt	g
vitamins and minerals	the units specified in point 1 of Part A of Annex XI

LEGISLATIVE FINANCIAL STATEMENT

1. NAME OF THE PROPOSAL:

Proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers

2. ABM / ABB FRAMEWORK

Policy Area(s) concerned and associated Activity/Activities: Health and Consumer Protection - Food Safety, Animal health, Animal Welfare and Plant Health

3. BUDGET LINES

3.1. Budget lines (operational lines and related technical and administrative assistance lines (ex- B..A lines)) including headings:

No financial implications.

3.2. Duration of the action and of the financial impact:

Open ended

3.3. Budgetary characteristics:

Budget line	Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective

4. SUMMARY OF RESOURCES

4.1. Financial Resources

4.1.1. Summary of commitment appropriations (CA) and payment appropriations (PA)

EUR million (to 3 decimal places)

Expenditure type	Section no.		Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later	Total
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Operational expenditure⁴¹

Commitment Appropriations (CA)	8.1.	a							
Payment Appropriations (PA)		b							

Administrative expenditure within reference amount⁴²

Technical & administrative assistance (NDA)	8.2.4.	c							
---	--------	---	--	--	--	--	--	--	--

TOTAL REFERENCE AMOUNT

Commitment Appropriations		a+c							
Payment Appropriations		b+c							

Administrative expenditure not included in reference amount⁴³

Human resources and associated expenditure (NDA)	8.2.5.	d							
Administrative costs, other than human resources and associated costs, not included in reference amount (NDA)	8.2.6.	e							

⁴¹ Expenditure that does not fall under Chapter xx 01 of the Title xx concerned.

⁴² Expenditure within article xx 01 04 of Title xx.

⁴³ Expenditure within chapter xx 01 other than articles xx 01 04 or xx 01 05.

Total indicative financial cost of intervention

TOTAL CA including cost of Human Resources		a+c +d +e							
TOTAL PA including cost of Human Resources		b+c +d +e							

Co-financing details

If the proposal involves co-financing by Member States, or other bodies (please specify which), an estimate of the level of this co-financing should be indicated in the table below (additional lines may be added if different bodies are foreseen for the provision of the co-financing):

EUR million (to 3 decimal places)

Co-financing body		Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later	Total
.....	f							
TOTAL CA including co-financing	a+c +d +e +f							

4.1.2. *Compatibility with Financial Programming*

- Proposal is compatible with existing financial programming.
- Proposal will entail reprogramming of the relevant heading in the financial perspective.
- Proposal may require application of the provisions of the Interinstitutional Agreement⁴⁴ (i.e. flexibility instrument or revision of the financial perspective).

⁴⁴ See points 19 and 24 of the Interinstitutional agreement.

4.1.3. Financial impact on Revenue

Proposal has no financial implications on revenue

Proposal has financial impact – the effect on revenue is as follows:

EUR million (to one decimal place)

		Prior to action [Year n-1]	Situation following action					
Budget line	Revenue		[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5] ⁴⁵
	(a) Revenue in absolute terms							
	(b) Change in revenue	Δ						

4.2. Human Resources FTE (including officials, temporary and external staff) – see detail under point 8.2.1.

Annual requirements	Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later
Total number of human resources						

5. CHARACTERISTICS AND OBJECTIVES

Details of the context of the proposal are required in the Explanatory Memorandum. This section of the Legislative Financial Statement should include the following specific complementary information:

5.1. Need to be met in the short or long term

The proposed Regulation on the provision of food information to consumers recasts and updates the present rules on food labelling that are applicable to foods in general. It establishes a flexible bottom-up mechanism that would enable stakeholders to innovate on food labelling, and the labelling rules to adapt to different and continuously changing markets and consumer demands.

⁴⁵ Additional columns should be added if necessary i.e. if the duration of the action exceeds 6 years.

The rules on nutrition labelling are recast with the general food labelling provisions. The proposal makes nutrition labelling mandatory in the principal field of vision of the food label and allows for the development of best practice in the presentation of nutrition information.

There is a transition period of 3 years for the application of the new rules.

5.2. Value-added of Community involvement and coherence of the proposal with other financial instruments and possible synergy

5.3. Objectives, expected results and related indicators of the proposal in the context of the ABM framework

The main objectives of the legislation are to:

- enable consumers to make informed, safe, healthy and sustainable choices;
- provide consumers with relevant, useful and legitimately expected information;
- ensure the smooth functioning of the internal market;
- foster a pro-competitive market environment.

Taking these objectives into account, the broad scope of the revision reflects the following specific objectives:

- ensure consistency and clarity in the provision of information;
- protect consumers' health and address specific consumer demands for information;
- avoid misleading labelling;
- enable industry innovation allowing them to make use of labelling to promote their products.

The following indicators will be monitored: the notification by Member States of national schemes related to the provision of food information to consumers.

5.4. Method of Implementation (indicative)

Show below the method(s)⁴⁶ chosen for the implementation of the action.

X Centralised Management

X directly by the Commission

⁴⁶ If more than one method is indicated please provide additional details in the "Relevant comments" section of this point.

- indirectly by delegation to:
 - executive Agencies
 - bodies set up by the Communities as referred to in art. 185 of the Financial Regulation
 - national public-sector bodies/bodies with public-service mission
- Shared or decentralised management
 - with Member states
 - with Third countries
- Joint management with international organisations (please specify)

Relevant comments:

6. MONITORING AND EVALUATION

6.1. Monitoring system

The general monitoring of the legislation on labelling is included in the Regulation (EC) No 882/2004 on official controls of food and feed. This Regulation foresees that the Member States implement efficiently the requirements of the food legislation. The Commission (Food and Veterinary Office) controls the correct enforcement of the Member States.

The monitoring would be done by the Commission and Member States for example through reports from Member States, NGOs and self monitoring activities of the industry.

6.2. Evaluation

6.2.1. Ex-ante evaluation

6.2.2. Measures taken following an intermediate/ex-post evaluation (lessons learned from similar experiences in the past)

6.2.3. Terms and frequency of future evaluation

The Commission should carry out an evaluation of the new legislation as from 5 to 7 years after the full application of the legislation in order to assess its relevance to stakeholders' needs. In particular, such evaluation should focus on the uptake and efficiency of the national schemes in view of assessing the need for Community rules on aspects for which national non-binding schemes have been adopted.

7. ANTI-FRAUD MEASURES

8. DETAILS OF RESOURCES

8.1. Objectives of the proposal in terms of their financial cost

Commitment appropriations in EUR million (to 3 decimal places)

(Headings of Objectives, actions and outputs should be provided)	Type of output	Av. cost	Year n		Year n+1		Year n+2		Year n+3		Year n+4		Year n+5 and later		TOTAL	
			No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost
OPERATIONAL OBJECTIVE No.1 ⁴⁷																
TOTAL COST																

⁴⁷ As described under Section 5.3.

8.2. Administrative Expenditure

8.2.1. Number and type of human resources

Types of post		Staff to be assigned to management of the action using existing and/or additional resources (number of posts/FTEs)					
		Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5
Officials or temporary staff ⁴⁸ (XX 01 01)	A*/AD	3,5	3,5	3,5	3,5	3,5	3,5
	B*, C*/AST	1/0.2	1/0.2	1/0.2	1/0.2	1/0.2	1/0.2
Staff financed ⁴⁹ by art. XX 01 02							
Other staff ⁵⁰ financed by art. XX 01 04/05							
TOTAL		4,7	4,7	4,7	4,7	4,7	4,7

8.2.2. Description of tasks deriving from the action

Implementing the Regulation, e.g. adoption of guidelines and implementing measures, management of the notification of national measures in consultation with the Standing Committee on the Food Chain and Animal Health. The Commission shall also facilitate the exchange of information between Member States and itself on national schemes and make available to the public the details of the national schemes and monitor their development and application.

⁴⁸ Cost of which is NOT covered by the reference amount.

⁴⁹ Cost of which is NOT covered by the reference amount.

⁵⁰ Cost of which is included within the reference amount.

8.2.3. Sources of human resources (statutory)

When more than one source is stated, please indicate the number of posts originating from each of the sources

- Posts currently allocated to the management of the programme to be replaced or extended
- Posts pre-allocated within the APS/PDB exercise for year n
- Posts to be requested in the next APS/PDB procedure
- Posts to be redeployed using existing resources within the managing service (internal redeployment)
- Posts required for year n although not foreseen in the APS/PDB exercise of the year in question

~~8.2.4. Other Administrative expenditure included in reference amount (XX 01 04/05 – Expenditure on administrative management)~~

EUR million (to 3 decimal places)

Budget line (number and heading)	Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5 and later	TOTA L
1. Technical and administrative assistance (including related staff costs)							
Executive agencies ⁵¹							
Other technical and administrative assistance							
- intra muros							
- extra muros							
Total Technical and administrative assistance							

⁵¹ Reference should be made to the specific legislative financial statement for the Executive Agency(ies) concerned.

8.2.5. *Financial cost of human resources and associated costs not included in the reference amount*

EUR million (to 3 decimal places)

Type of human resources	Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5 and later
Officials and temporary staff (XX 01 01)						
Staff financed by Art XX 01 02 (auxiliary, END, contract staff, etc.) (specify budget line)						
Total cost of Human Resources and associated costs (NOT in reference amount)						

Calculation– Officials and Temporary agents

Reference should be made to Point 8.2.1, if applicable

Calculation– Staff financed under art. XX 01 02

Reference should be made to Point 8.2.1, if applicable

8.2.6. *Other administrative expenditure not included in reference amount*

EUR million (to 3 decimal places)

	Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5 and later	TOTAL
XX 01 02 11 01 – Missions							
XX 01 02 11 02 – Meetings & Conferences							
XX 01 02 11 03 – Committees ⁵²							
XX 01 02 11 04 – Studies & consultations							
XX 01 02 11 05 - Information systems							
2. Total Other Management Expenditure (XX 01 02 11)							
3. Other expenditure of an administrative nature (specify including reference to budget line)							
Total Administrative expenditure, other than human resources and associated costs (NOT included in reference amount)							

Calculation - Other administrative expenditure not included in reference amount

⁵² Specify the type of committee and the group to which it belongs.