# Final report

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# Status and Labelling Requirements for Bovine Derived Plasma

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# REGULATORY STATUS AND LABELLING REQUIREMENTS OF BOVINE DERIVED PLASMA IN AUSTRALIA,EUROPEAN UNION, UNITED STATES OF AMERICA AND NORTH ASIA

## INTRODUCTION

This report addresses the Regulatory status and labelling requirements of bovine derived plasma in Australia the European Union , United States of America and North Asia*.The use of bovine plasma extends from unrefined dried products ( agricultural use) to the isolation of individual components for pharmaceutical and analytical applications. An important and growing use is in the area of food additives utilising such attributes as the ability to form stable foams etc.

### Background

The use of Bovine Plasma as a prime source for pharmaceutical and medical purposes has been well established. The use of **Bovine Plasma or derivatives for** non-medical/pharmaceutical purposes is less well known but increasingly since the mid-eighties it has found application as an additive in food formulation. For example prior to 1997 bovine blood was used for fining French wines. Specifically derivatives, for example bovine globulin as a refined component i.e. the removal of fibrin and albumin proteins, resulting in desirable properties such as thickening and protein binding which can be used in food formulations such as stocks and broths.

This use of bovine plasma as a food additive therefore, is not new. This is readily apparent from the manner in which plasma based products have been utilised in food formulations as thickening agents etc. This has necessitated changes in regulations in the various instrumentalities notably the European Union and the United States (FDA) which have a global influence in such matters. This means that cases for the inclusion of products developed from bovine plasma made under these jurisdictions already have precedents on which to build individual applications. This does not preclude a thorough examination of the steps necessary for products to be registered but it does provide confidence in the process.

## PACKAGING & LABELLING

The European Union and the United States Food and Drugs Administration have similar guidelines and requirements which must be considered in the provision of product information are as follows.

### Common data requirements USA and European Union

**Name** – Must also inform the customer the nature of the product. It may also be necessary to attach a description to the product name. However, there are certain generic names which must be only used for their conventional uses, for example: Muesli, Coffee, prawns.

**Ingredients-** Ingredients have to be listed in order of weight with the heaviest first. Generally this applies to all quantities of 2% or more by weight. In some cases e.g. preservatives, a specific name is required, or in the case of the European Union a

Registration Number (E-NUMBER) can be cited. If there a number of sub-components then these too must be cited. If any of the components have allergenic associations then EU requirements must be identified.

**Nutritional information-**If any nutritional claims are made then these are subject to strict regulations

**'Use By' or 'Best Before' dates-'**Use by' is a specific date for usage. 'Best Before' indicates that the product is likely to degrade slowly with for example a loss of potency or activity (e.g. gelling).

- Best before + Day for foods with a shelf life of up to 3 months
- Best before end + Month for foods with more than a 3 month shelf life
- Best before end + Year for food with more than an 18 month shelf life

**Storage Conditions-**guidance with respect to storage conditions e.g. temperature are important.

**Business Name & Address-**essential to cite the manufacturer and /or packager if independent to the main business and the seller established within the European Union.

**Place of origin**

**Instructions for use**

## European Union

Pre-packaged foodstuffs must comply with the rules on labelling, presentation and advertising of foodstuffs. The rules are contained in the Directive 2000/13/EC (following pages) which detail the general principles which operate through the Economic Union with respect to labelling, presentation etc. Each state however may well have additional national legislation which may well add additional requirements to be observed. Local regulations can involve using **legal names** which are prescribed by law such jam or marmalade. The quantities of certain ingredients are ruled by the so-called QUID rules (Quantitative Ingredient Declarations) whereby the quantities of principal or main ingredients for food products in the EU ????.If the ingredients are in small amounts then it may not be necessary to identify the quantity. In terms of enforcement in the United Kingdom local authorities are empowered to enforce both national and international requirements.

Other factors which come into play relate to claims e.g." good for you" which require approved evidence.

In terms of pack design the format and placing of information is a key requirement. Wording must be clear and easy to read easily understood and unambiguous. The design of the pack is critical and the arrangement of information must ensure visibility and clarity.

**RUSSIA**

*Russia has a balanced consumer-friendly but relatively strict labeling requirements. Generally speaking, any industrially produced products must also be industrially labelled in Russian.*

*Russian Civil Code (article 495) mandates that the seller and manufacturer provide consumer with adequate information through labeling and if there is a need also through accompanying documentation. There are several separate laws and regulations covering mandatory labeling requirements. Russian labeling law is actually in compliance with existing EU directives and does not deviate from established European practice.*

It states:

*Must have the following label in Russian language.*

*Name of the product*
*Description*
*Standards and industrial norms with which the product is in compliance (hence besides mandatory Rosstandard the product label must state whether other norms are met, such as ISO)*
*Harmonized schedule number*
*Customs code*




*The nature of mandatory labeling[1] varies and depends on the product.*
*You should consult d'Artes[2] for more information. We will gladly explain what particular label is required for your product, whether or not it needs any additional accompanying documentation (as is*

*the case of food additives or dietary supplements, and of course absolutely all medical preparations), and how it should be structured. For a fee we will design required label for your product or product line.*

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1Russian spelling 2digital art

**IMPORTATION OF PRODUCTS**

Importation into the EU, USA or any foreign jurisdiction normally requires recognition of those countries legal requirements with respect to labelling. This can be achieved for example (Australia) by an additional label affixed to the principal container holding the product.

A typical example within the European Union is the requirements by the United Kingdom –see Appendix.

**OTHER FACTORS**

Aside from the retail pack it is important that the outer pack should be carefully considered not only with identification of the contents, but particularly with reference to the immediate environmental requirements e.g temperature of storage. Once these requirements have been established and the market requirements identified then the development of the packaging ( primary, secondary and tertiary can be formulated).

## BOVINE PLASMA DERIVATIVES

In addressing the issues of regulatory status and labelling the first essential requirement is the location of bovine derived plasma from a definition aspect. In other words under which categories or existing definitions would the term bovine derived plasma be located?

**Codex 08.1.1 Fresh meat, poultry and game, whole pieces or cuts**

**Untreated raw meat, poultry and game carcasses and cuts. Examples include: beef, hog and pork carcasses; *fresh beef blood*; fresh whole chickens and chicken parts; fresh beef cuts (e.g., steaks); beef organs (e.g. heart, kidney); fresh tripe; and pork chops.**

Under **EU REGULATIONS**

**REGULATION (EC) No 853/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 20U4 laying down specific hygiene rules for food of animal origin**

cites

**DEFINITIONS**

**For the purpose of this Regulation:**

1. **MEAT**
   **'Meat' means edible parts of the animals referred to in points 1.2 to 1.8, including blood.**

**1.11 'Offal' means fresh meat other than that of the carcase, including viscera and blood.**

In the developmental stages it is important to maintain a watching brief on those legislative changes which could impact on development.

**REGULATORY STATUS**

As a consequence of the existence of current suppliers of bovine blood derivatives as food adjuncts the issue of regulatory status and the associated labelling requirements is clearer. The first issue is what claims are to be made for the end product, namely

1. What is its prime functionality or intended use?
2. Does it have, or is any claim to be made for its nutrient value?
3. Composition data.

**Functionality**

What is the intended role of the product, is it a processing component i.e. aiding or facilitating foam stability for example? Is it an emulsifying agent?

**Nutrient Value**

Will it have any nutrient value? At what level will it be used in a food product and what claims are likely to be made for the product?

**Compositional Data**

Information on composition is an essential requirement for general information but also in labelling.

**GRAS–(GENERALLY RECOGNISED AS SAFE)**

One important factor with respect to new products relates to their safety and efficacy in particular the incorporation of specific substances which have not previously been registered

A major factor has been the opportunity to seek recognition by the Food and Drugs Administration of some components categorising them as GRAS (Generally Recognised As Safe) for use in food.

The FDA states:

"a GRAS substance is distinguished from a food additive on the basis of the common knowledge about safety of the substance for its intended use, rather than on the basis of what the substance is or the types of data and information that are necessary to establish its safety" (62 FR 18938 at 18940; April 17, 1997). "To establish [general] recognition, the proponent must show that there is a consensus of expert opinion regarding the safety of the use of the substance" (62 FR at 18939).'

Similarly the European Union has addressed the same usage (Regulation (EC) No 1333/2008). This approach to harmonisation between the two jurisdictions has been an ongoing and progressive step. This is also reflected in the *Codex General Standard for Food Additives* (CAC/STAN 192-1995).

With respect to the following press release, this is a unique example of a bovine derivative receiving GRAS status and copies of the documents identifying its progress to this status are given in the Appendices.

**ANKENY, IA (February 27, 2009)** - Proliant Health and Biologicals is pleased to announce self-affirmed GRAS (Generally Recognized as Safe) status for the company's proprietary, trademarked ingredient ImmunoLin® (bovine globulin concentrate). ImmunoLin is the first immunoglobulin concentrate ingredient available to the nutrition industry with GRAS status.

The FDA issues a no-objection statement as confirmation of self-affirmed GRAS status when qualified experts agree that a substance has been adequately shown to be safe under the conditions of its intended use. "The market for food and nutrition products that support gut health and immunity are expanding rapidly. The formal approval allows the use of ImmunoLin in products requiring GRAS such as functional foods and beverages, meal replacement, and medical foods" commented Eric Weaver, Chief Scientific Officer. Mel Vandenberg, VP, Regulatory QualityAssurance, notes the significance of the self-affirmation "Achieving GRAS status for the use of ImmunoLin in foods supports our commitment to meeting the highest standards for ingredient safety.

The United States Food and Drug Administration have recently issued (April 2012) the following draft guidance for discussion:

**Draft Guidance for Industry: Assessing the Effects of Significant {Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredient that are Color Additives.**

This is indicative of a more enlightened approach and willingness to look at new developments in new food adjuncts as well as food processes and new technologies e.g.nanotechnology.

A copy is included in the Appendices

Thus the pathway to the introduction of new materials and in particular the sensitive area of additives should be a little clearer.

## Agency Response Letter GRAS Notice No. GRN 000255

### CFSAN/Office of Food Additive Safety

December 24, 2008

John B. Dubeck
Keller & Heckman LLP
1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001

Re: GRAS Notice No. GRN 000255

Dear Mr. Dubeck:

The Food and Drug Administration (FDA) is responding to the notice, dated April 18, 2008, that you submitted on behalf of Proliant Health Ingredients, Inc. (Proliant), in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on April 22, 2008, filed it on June 9, 2008, and designated it as GRAS Notice No. GRN 000255.

The subject of the notice is bovine globulin. The notice informs FDA of the view of Proliant that bovine globulin is GRAS, through scientific procedures, for use as an ingredient in dairy foods, fruit juices, vegetable juices, snack foods, beverages, and meal replacement products at a maximum use level not exceeding 50 grams per kilogram (g/kg) (5 percent) in the finished food. However, Proliant expects more typical use levels to be 2 - 20 grams per kilogram (g/kg) (0.2 percent-2 percent) in the finished food.

21 CFR 101.4 states that all ingredients must be declared by their common or usual name. In addition, 21 CFR 102.5 outlines general principles to use when establishing common or usual names for nonstandardized foods. Our use of "bovine globulin" in this letter should not be considered an endorsement or recommendation of that term as an appropriate common or usual name for the purpose of declaring the substance in the ingredient statement of foods that contain that ingredient. Issues associated with labeling and the appropriate common or usual name of a food are the responsibility of the Office of Nutrition, Labeling and Dietary Supplements in the Center for Food Safety and Applied Nutrition.

Proliant describes the identity, method of manufacture, and provides specifications, for bovine globulin. Bovine globulin is a cream colored powder, soluble in water, with a neutral flavor and odor. The notifier states that the manufacture of bovine globulin involves two stages, namely, plasma collection and globulin production. The plasma collection is performed at the animal processing plant after a post-mortem inspection by the United States Department of Agriculture/Food Safety and Inspection Service. The plasma from centrifuged blood is cooled to 45° F, and then transported to Proliant's manufacturing facility where it is further processed to produce bovine globulin. The notifier describes bovine globulin as a purified immunoglobulin protein isolate obtained by removal of fibrin and albumin proteins from bovine plasma by chemical and mechanical processes in accordance with current good manufacturing practices (cGMP). The finished product is a spray-dried concentrate. Specifications include protein content (≥ 85 percent) of which ≥ 45 percent is immunoglobulin G, fat (≤ 1.5 percent), moisture (≤ 8 percent), ash (≤ 3 percent) and limits for microbiological counts.

Proliant calculates an estimated daily intake of bovine globulin to be 30 grams per person per day (g/p/d) based on a typical use level of 2 percent of all solid foods consumed by an average adult male.[1] Proliant considers that this estimation exaggerates the expected amount of bovine globulin to be added to the diet. Proliant states that a more reasonable estimate is 2.5 to 25 g/p/d, depending on the level of consumption and the variety of food types consumed. Proliant mentions that bovine globulin has a self-limiting use level in food with levels greater than 5 percent leading to adverse, undesirable flavor profiles.

Proliant summarizes published safety studies supporting the safe use of bovine globulin in foods. Specifically, the notifier reports the results of studies conducted in weanling pigs and calves on the safety and nutritional performance of spray-dried animal plasma containing 10-25 percent of immunoglobulins. Proliant concludes that these studies show no adverse effects. Further, the notifier includes studies regarding the oral ingestion of bovine plasma and immunoglobulin in infants and children demonstrating that oral consumption is well tolerated in humans.

Proliant discusses other safety concerns traditionally associated with protein concentrates. These concerns include: 1) the possible formation of unique amino acids during processing; 2) the potential concentration of toxic impurities when evaporations or extractions are involved in the processing; and, 3) the potential for allergenicity. The notifier states that the manufacturing process for bovine globulin yields no unique amino acids. Proliant states that their process ensures that no potential impurities will be concentrated in bovine globulin. Proliant tested representative lots to demonstrate that pesticide residues, heavy metal contaminants and antibiotic residues were below levels of concern. Proliant also states that no bovine spongiform encephalopathy (BSE)-related contaminants will be present in the product due to the effectiveness of measures taken by USDA to prevent BSE. Proliant concludes that allergenicity is of no concern because bovine globulin is highly digestible[2] and bovine plasma has a history of safe use in human foods such as surimi, sausage, and processed meats.[3] Proliant notes that, under The Food Allergen Labeling and Consumer Protection Act of 2004, bovine globulin does not fall under the definition of a "major food allergen" as one of eight foods or food groups (i.e., milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans) or a food ingredient that contains protein derived from one of those foods.

### Potential Labeling Issues

Under section 403(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA), a food is misbranded if its labeling is false or misleading in any particular. Section 403(r) of the FFDCA lays out the statutory framework for the use of labeling claims that characterize the level of a nutrient in a food or that characterize the relationship of a nutrient to a disease or health-related condition. In describing the intended use of bovine globulin and in describing the information that Proliant relies on to conclude that bovine globulin is GRAS under the conditions of its intended use, Proliant raises a potential issue under these labeling provisions of the FFDCA. This issue consists of Proliant's intended use of bovine globulin as a protein supplement. If products that contain bovine globulin bear any claims on the label or in labeling, such claims are the purview of the Office of Nutrition, Labeling and Dietary Supplements (ONLDS) in the Center for Food Safety and Applied Nutrition (CFSAN). The Office of Food Additive Safety (OFAS) neither consulted with ONLDS on this labeling issue nor evaluated the information in your notice to determine whether it would support any claims made about bovine globulin on the label or in labeling.

### Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (FFDCA)

The Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amends the FFDCA to, among other things, add section 301(ll). Section 301(ll) of the FFDCA prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FFDCA, a biological product licensed under section 351 of the Public Health Service Act,

or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In its review of Proliant's notice that bovine globulin is GRAS for use as an ingredient in various foods, FDA did not consider whether section 301(ll) or any of its exemptions apply to foods containing bovine globulin. Accordingly, this response should not be construed to be a statement that foods that contain bovine globulin, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

## Conclusions

Based on the information provided by Proliant, as well as other information available to FDA, the agency has no questions at this time regarding Proliant's conclusion that bovine globulin is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of bovine globulin. As always, it is the continuing responsibility of Proliant to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter responding to GRN 000255, as well as a copy of the information in this notice that conforms to the information in the GRAS exemption claim (proposed 21 CFR 170.36(c)(1)), is available for public review and copying via the FDA home page at http://www.fda.gov. To view or obtain an electronic copy of the text of the letter, follow the hyperlinks from the "Food" topic to the "Food Ingredients and Packaging" section to the "Generally Recognized as Safe (GRAS)" page where the GRAS Inventory is listed.

Sincerely,

Laura M. Tarantino, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition

[1]Based on FDA's default values for food consumption, a person consumes 3000 g (or 3 kg) of food per day, of which 1500 g is from solid food.

[2]Though bovine globulin is highly digestible, Proliant recognizes that under certain conditions, there is a low level of immunological activity in the colon. However, animal studies showed that spray-dried animal plasma does not elicit an allergic response.

[3]FDA is aware of publications documenting the use of bovine globulin and plasma as an ingredient in food.

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U.S. Food & Drug Administration

## GRAS Notice Inventory

- [1]

FDA Home[3] [2] GRAS Notice Inventory[4] GRAS Notice Inventory GRAS Detail

### GRN No. 255

**Proliant Health Ingredients, Inc.**
**2425 Oak Tree Court, Ankeny, Iowa 50021**

Return to Listing[5]

| | |
|---|---|
| **Substance:** | Bovine globulin |
| **Intended Use:** | Ingredient in dairy foods, fruit juices, vegetable juices, snack foods, beverages, and meal replacement products at a maximum use level not exceeding 50 grams per kilogram (5 percent) in the finished food |
| **Basis:** | Scientific procedures |
| **Date of filing:** | 09-JUN-08 |
| **Date of closure (select to view letter):** | 24-DEC-08[6] |
| **GRAS Notice (disclosable information):** | GRN 255[7] |

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4. http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/default.htm
5. /scripts/fcn/fcnNavigation.cfm?rpt=grasListing
6. http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm154991.htm
7. gras_notices/808167A.PDF

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## GRAS Notice Inventory

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FDA Home[3] [2] GRAS Notice Inventory[4] GRAS Notice Inventory GRAS Detail

### GRN No. 234

**Proliant Health Ingredients Inc.**
**2425 Oak Tree Court, Ankeny, Iowa 50021**

Return to Listing[5]

| | |
|---|---|
| **Substance:** | Bovine globulin |
| **Intended Use:** | Ingredient in dairy foods, juices, snack foods, beverages and meal replacements at maximum levels of 5 per cent of the finished product |
| **Basis:** | Scientific procedures |
| **Date of filing:** | 17-SEP-07 |
| **Date of closure (select to view letter):** | 14-FEB-08[6] |
| **Additional information:** | Resubmitted as GRN No. 255 |
| **GRAS Notice (disclosable information):** | GRN 234 [7] |

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4. http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/default.htm
5. /scripts/fcn/fcnNavigation.cfm?rpt=grasListing&displayAll=true#234
6. http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm153909.htm
7. gras_notices/710670A.PDF

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## GRN No. 169

**Proliant, Inc.**
**Southeast Oak Tree Court, Ankeny, IA 50021**

Return to Listing[5]

| | |
|---|---|
| **Substance:** | Bovine globulin |
| **Intended Use:** | Ingredient in dairy products, juices/beverages, nutritional bars, snack foods and sports nutrition protein supplements |
| **Basis:** | Scientific procedures |
| **Date of filing:** | 24-MAY-05 |
| **Date of closure (select to view letter):** | 19-JUL-05[6] |
| **Additional information:** | Resubmitted as GRN No. 234 |
| **GRAS Notice (disclosable information):** | GRN 169[7] |

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5. /scripts/fcn/fcnNavigation.cfm?rpt=grasListing&displayAll=true#169
6. http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/ucm154582.htm
7. gras_notices/GRN000169.pdf

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# Labelling, presentation and advertising of foodstuffs

Pre-packaged foodstuffs must comply with the rules on labelling, presentation and advertising of foodstuffs. These rules are harmonised at European Union (EU) level to enable European consumers to make informed choices and to remove obstacles to the free circulation of foodstuffs and unequal conditions of competition.

## ACT

**Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs** [See amending act(s)].

## SUMMARY

The Directive applies to pre-packaged foodstuffs to be delivered to the final consumer or to restaurants, hospitals, canteens and other similar mass caterers. It does not apply to products intended for export outside the European Union (EU).

The labelling, presentation and advertising of foodstuffs must not:

- mislead the consumer as to the foodstuff's characteristics or effects;
- attribute to a foodstuff (except for natural mineral waters and foodstuffs intended for special diets, which are covered by specific Community provisions) properties for the prevention, treatment or cure of a human illness.

### COMPULSORY LABELLING PARTICULARS

The labelling of foodstuffs must include compulsory information. The particulars indicated on products must be easy to understand, visible, legible and indelible. Some of them must appear in the same field of vision.

The compulsory particulars include:

- **Name under which the product is sold**;
- **List of ingredients**, which are listed in descending order of weight and designated by their specific name, subject to the derogations provided in Annexes I, II, III and III a). Ingredients which belong to more than one category are indicated according to their principal function. Under certain conditions, the listing of ingredients is not required for:
  - fresh fruit and vegetables,
  - carbonated water,
  - fermentation vinegars,
  - cheese, butter, fermented milk and cream,
  - products comprising a single ingredient, where the trade name is identical with the ingredient name, or the trade name enables the nature of the ingredient to be clearly identified.

  Certain additives and enzymes are not considered as ingredients; this relates to those which are used as processing aids or those contained in an ingredient, which serve no technological function in the finished product;
- **Quantity of ingredients or categories of ingredients** expressed as a percentage
  This requirement applies when an ingredient or a category of ingredients:

    - appears in the name under which the foodstuff is sold or is usually associated with that name by the consumer,
    - is emphasised on the labelling in words, pictures or graphics, or
    - is essential to characterise an indicated foodstuff (but certain exceptions may be provided);
- **Net quantity** expressed in units of volume in the case of liquids and units of mass in the case of other products. However, there are specific provisions for foodstuffs sold by number and solid foodstuffs presented in a liquid medium;
- **Date of minimum durability** This date consists of the day, month and year, except in the case of foodstuffs that will not keep for more than three months (the day and month are sufficient), foodstuffs which will not keep for more than 18 months (the month and year are sufficient), and foodstuffs which will keep for more than 18 months (year is sufficient).
  The date shall be preceded by the words: 'Best before ...' when the date includes an indication of the day or 'Best before end ...' in other cases.
  The date of durability is not required for the following products:
    - untreated fresh fruits and vegetables,
    - wines and beverages containing 10 % or more by volume of alcohol,
    - non-alcoholic soft drinks,
    - fruit juices and alcoholic beverages in individual containers of more than five litres, intended for supply to mass caterers,
    - bakers' or pastry cooks' wares which 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.

  In the case of foodstuffs which are highly perishable, the date of minimum durability shall be replaced by the 'use by' date;
- any **special storage conditions or conditions of use**;
- the **name or business name** and **address of the manufacturer or packager, or of a seller** established within the Community. However, Member States shall be authorised, in respect of butter produced in their territory, to require only an indication of the manufacturer, packager or seller;
- the **place of origin or provenance** where failure to give such particulars might mislead the consumer;
- **instructions for use** should be included to enable appropriate use of the foodstuff;
- indication of the **acquired alcoholic strength** of beverages containing more than 1.2 % by volume of alcohol.

## DEROGATIONS AND SPECIAL PROVISIONS

The **European provisions applicable to specific foodstuffs** may authorise making particulars such as the list of ingredients and date of minimum durability optional. These provisions may provide for other compulsory particulars, provided this does not result in the purchaser being inadequately informed.

Special provisions apply to:

- **reusable glass bottles** and **small packaging items or containers**;
- **pre-packaged foodstuffs.** Where pre-packaged foodstuffs are marketed at a stage prior to sale to the final consumer or are supplied to mass caterers for processing, the particulars need appear only on the commercial documents, provided that the name under which the product is sold, the date of minimum durability and the details of the manufacturer or packager appear on the outer packaging of the foodstuff;
- **foodstuffs offered for sale without pre-packaging and foodstuffs packaged on the sales premises** at the consumer's request.

## SAFEGUARD CLAUSE

The marketing of foodstuffs which comply with the Directive may be prohibited only in the case of non-harmonised national provisions that are justified on particular grounds, such as the protection of public health, prevention of fraud or the protection of industrial or commercial property.

**COMMITTEE AND BACKGROUND**

The implementation of the Directive is the responsibility of the European Commission, assisted by the Standing Committee on Foodstuffs (authorisation of national rules relating to certain foodstuffs and making provision for the listing of ingredients in addition to the name under which the product is sold, derogations in respect of compulsory particulars, description of an additive as an ingredient, changes to the annexes, adoption of transitional measures, etc.).

Directive 2000/13/EC replaces Council Directive 79/112/EEC on the labelling, presentation and advertising of foodstuffs.

REFERENCES

| Act | Entry into force | Deadline for transposition in the Member States | Official Journal |
|---|---|---|---|
| Directive 2000/13/EC | 26.5.2000 | - | OJ L 109 of 6.5.2000 |

| Amending act(s) | Entry into force | Deadline for transposition in the Member States | Official Journal |
|---|---|---|---|
| Directive 2001/101/EC | 18.12.2001 | 31.12.2002 | OJ L 310 of 28.11.2001 |
| Directive 2002/67/EC | 8.8.2002 | 30.6.2003 | OJ L 191 of 19.7.2002 |
| Acts of Accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia to the EU. | 1.5.2004 | No later than 2007 | OJ L 236 of 23.9.2003 |
| Directive 2003/89/EC | 25.11.2003 | 25.11.2004 | OJ L 308 25.11.2003 |
| Directive 2006/107/EC | 1.1.2007 | 1.1.2007 | OJ L 363 of 20.12.2006 |
| Directive 2006/142/EC | 12.1.2007 | 23.12.2007 | OJ L 368 of 23.12.2006 |
| Regulation (EC) No 1332/2008 | 20.1.2009 | - | OJ L 354 of 31.12.2008 |
| Regulation (EC) No 596/2009 | 7.8.2009 | - | OJ L 188 of 18.7.2009 |

**The successive amendments and corrections to Directive 2000/13/EC have been incorporated in the original text. This consolidated version is of documentary value only.**

RELATED ACTS

**Proposal for a Regulation of the European Parliament and of the Council of 30 January 2008 on the provision of food information to consumers [COM(2008) 40 - Not published in the Official Journal].**
This Proposal for a Regular amalgamates Directives 2000/13/EC and 90/496/EEC on nutritional labelling, in order to improve levels of information and protection for European consumers.
The Proposal introduces new requirements in labelling. Mandatory information should include in particular the identity of goods, their composition and nutritional characteristics, their origin and conditions for safe use (durability, incidence and likelihood of danger to health). This information must be supplied in an honest way and should be easy for the consumer to read and understand. The minimum print size should be 3mm.
Nutritional labelling should include compulsory information such as:

- energy value;
- the quantity of some nutrients in the ingredients, lipids, saturated fatty acids, carbohydrates, as well as specific information on sugar and salt.

Moreover, consumers should be able to access adequate information, in particular when purchasing foodstuffs by Internet or other means of distance selling. The same goes for the presence of allergenic substances in foodstuffs, including for foodstuffs sold without packaging and meals served in restaurants.
The Member States may also adopt additional mandatory information requirements for specific categories of foodstuffs, in order to protect public health and safety and industrial and commercial property. The information envisaged must be notified as a proposal to the Commission, who may give a negative opinion.
**Codecision procedure (2008/0028/COD)**

**USE OF LANGUAGES IN LABELLING**

**On 10 November 1993 the Commission adopted an interpretative communication concerning the use of languages in the marketing of foodstuffs in the light of the Court of Justice's judgment in the Peeters case [COM(93) 532 final – Official Journal C 345 of 23.12.1993].**
In this communication the Commission points out that the labelling of foodstuffs for sale to the final consumer must be in an easily understood language, which generally means the official language(s) of the country of marketing. However, foreign terms or expressions easily understood by the purchaser must be allowed.

Last updated: 16.11.2010

See also

› Product labelling and packaging

# Food additives

This Regulation replaces previous directives and decisions concerning food additives permitted for use in foods. Its aim is to harmonise the use of food additives in foods, or in other additives or food enzymes, at Community level. The new Regulation simplifies the approval procedure for food additives and is an opportunity for the Commission to update and supplement the European food additives list.

ACT

**Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.**

SUMMARY

The Regulation brings together in a single legislative act all types of food additives [1], including colours and sweeteners. Food enzymes are covered by Regulation (EC) No 1332/2008.

The Regulation lays down rules on food additives used in foods with a view to ensuring the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests and fair practices in the food trade.

A food additive may only be approved if it does not pose a safety concern to the health of consumers, if there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means and if its use does not mislead the consumer.

This Regulation shall not apply to the following substances unless they are also used as food additives: processing aids, substances used for the protection of plants and plant products, nutrients added to food, substances used for the treatment of water, flavourings and enzymes.

**Community lists of food additives**

Annex I defines the different functional classes of food additives: sweeteners, colours, preservatives, antioxidants, carriers, acids, acidity regulators, anti-caking agents, anti-foaming agents, bulking agents, etc.

Additives are included in a list of additives which are authorised at Community level giving details of their conditions of use (Annex II).

Moreover, this Regulation creates a list of food additives for use in other additives and in food enzymes, as well as their conditions of use (Annex III).

Before incorporating all food additives in the lists in Annexes II and III of this Regulation, the Commission must examine all existing authorisations with regard to criteria such as quantities absorbed, technological need and the potential to mislead the consumer. Whilst these lists are being drawn up, the Annexes of Directives 94/35/EC, 94/36/EC and 95/2/EC will be regularly updated and remain in force.

If the production methods or raw materials used in a food additive already included in a Community list are altered considerably, the additive produced in this way shall be considered as a different additive. Before being placed on the market, this new additive shall be submitted to the European Food Safety Authority (EFSA) for an assessment of health risks.

### Labelling

Labelling of food additives must comply with the general labelling conditions defined in Directive 2000/13/EC. It must include, in particular, the information necessary for their identification (name, batch, manufacturer, etc.).

### Common authorisation procedure and risk assessment

11.Risk assessment and the authorisation of food additives are integrated into a common authorisation procedure for food additives, enzymes and flavourings, established by Regulation (EC) No 1331/2008.

### Reassessment

The Commission will re-examine all additives that have already been authorised with the assistance of the Standing Committee on the Food Chain and Animal Health.

At the same time, all food additives which were permitted before 20 January 2009 shall be subject to a new assessment carried out by the EFSA. After consulting the Authority, the Commission will prepare an assessment programme by 20 January 2010 with a view to defining the needs and order of priorities for risk assessment.

### Transitional period

This Regulation shall apply from 20 January 2010.

Nevertheless, the reassessments of the Community food additives list (Annex II) and the list of food additives for use in food additives and enzymes (Annex III) should be completed by 1 January 2011.

### Context

This Regulation is part of extensive reforms launched by the European Commission on 18 July 2006 to modernise existing legislation concerning food additives, flavourings and enzymes. These reforms have led to the development of new legislation based on:

- Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, enzymes and flavourings;
- Regulation (EC) No 1332/2008 on food enzymes;
- Regulation (EC) No 1333/2008 on food additives (this Regulation);
- Regulation (EC) No 1334/2008 on food flavourings.

### Key terms of the Act

- Food additive: any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods.

### REFERENCES

| Act | Entry into force | Deadline for transposition in the Member States | Official Journal |
|---|---|---|---|
| Regulation (EC) No 1333/2008 | 20.1.2009 | - | OJ L 354 of 31.12.2008 |

**The successive amendments and corrections to Regulation (C) No 1333/2008 have been incorporated in the original text. This consolidated version is of documentary value only.**

RELATED ACTS

**Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives [Official Journal L 80 of 26.3.2010].**

**Commission Directive 2008/60/EC of 17 June 2008 laying down specific purity criteria concerning sweeteners for use in foodstuffs [Official Journal L 158 of 18.6.2008].**
**See consolidated version**

**Commission Directive 2008/128/EC of 22 December 2008 laying down specific purity criteria concerning colours for use in foodstuffs [Official Journal L 6 of 10.1.2009].**

**Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners [Official Journal L 253 of 20.9.2008].**
**See consolidated version**

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EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
**C2 - Management of scientific committee; scientific co-operation and networks**

**Scientific Committee on Food**

**SCF/CS/ADD/GEN/26 Final**
**12 July 2001**

# GUIDANCE ON SUBMISSIONS FOR FOOD ADDITIVE EVALUATIONS BY THE SCIENTIFIC COMMITTEE ON FOOD

(opinion expressed on 11 July 2001)

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**ANNEX**

## INTRODUCTORY REMARKS

The purpose of this document is to give guidance to petitioners and other interested parties wishing to introduce new additives into the EU market, or seeking to revise existing provisions regulating individual additives already authorised within the EU, or seeking confirmation that an already approved additive made from a new source or by a new method of production is acceptable. It gives guidance on the administrative and technical data required, on the range of toxicological tests generally required for new food additives, and on the format for formal submissions on additives (hereafter referred to as "dossiers") to the European Commission. The information submitted is needed either for the European Commission and/or for the Scientific Committee on Food.

In the European Union (EU), substances proposed as food additives may only be authorised for use if a reasonable case of technological need can be demonstrated, if they present no hazard to the health of consumers at the level of use proposed, and provided they do not mislead the consumer.[1] The European Commission is required to consult the Scientific Committee on Food (SCF) prior to submission of any proposals for legislation on food additives where these may have an effect on health. Although evaluation of the safety of proposed and permitted food additives is carried out by the SCF, the Committee generally plays no role in assessing aspects such as technological need, benefit to the consumer, or whether the use of an additive would mislead consumers. The mandate of the SCF is to advise the Commission on "scientific and technical questions concerning consumer health and food safety associated with the consumption of food products and in particular questions relating to toxicology and hygiene in the entire food production chain, nutrition, and applications of agrifood technologies, as well as those relating to materials coming into contact with foodstuffs, such as packaging".[2]

Petitioners wishing to make a food additive submission to the European Commission are advised to consult both this main Guidance Document and the accompanying Annex.

Petitioners should note that competent authorities in Member States may request copies of any dossier submitted to the Commission and should ensure that this can be supplied without delay upon request.

Member States should also be mindful of the guidance in this document when making a submission to the EU on any additive admitted provisionally for marketing and use within national territories under Directive 89/107/EEC (Article 5). Member States should ensure they submit a full dossier together with a written evaluation carried out in their country on the safety in use of the additive.

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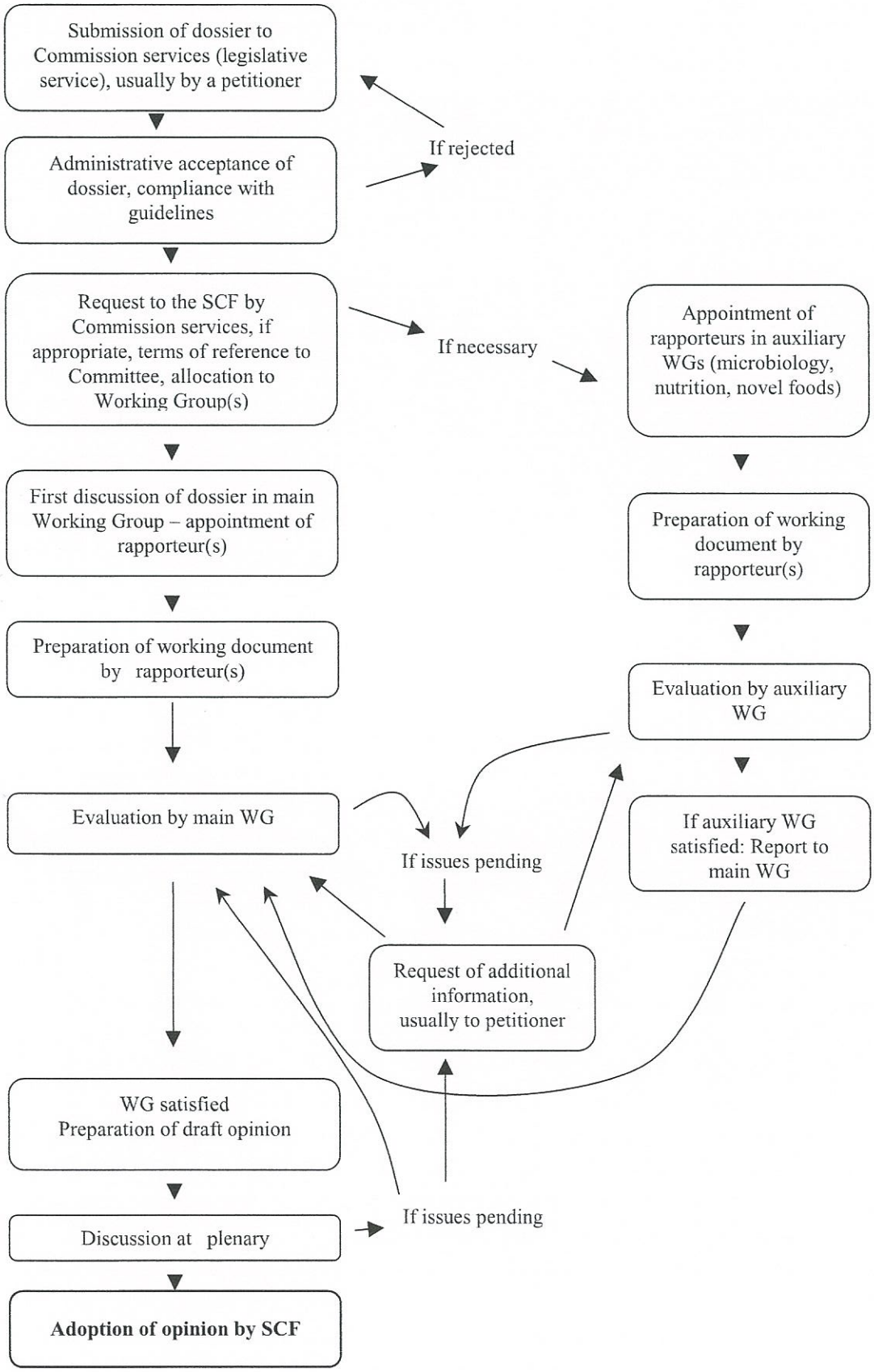
1 Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption. Official Journal of the European Communities L 40, 11.02.1989 p. 27 – 33. (Article 1.2 includes definition of a food additive)

2 Commission Decision 97/579/EC of 23 July 1997 setting up Scientific Committees in the field of consumer health and food safety. Official Journal of the European Communities L 237, 28.08.1997, p. 18.

## APPENDIX I: FLOWCHART OF THE PROCESS OF EVALUATION BY THE SCF OF A DOSSIER ON A FOOD ADDITIVE



## APPENDIX II: GENERAL CRITERIA FOR THE USE OF FOOD ADDITIVES

Note: The information below is quoted *verbatim* from Annex II of Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption. Official Journal of the European Communities, L 40, 11.2.89, p.27.

1. Food additives can be approved only provided that

   - there can be demonstrated a reasonable technological need and the purpose cannot be achieved by other means which are economically and technologically practicable,

   - they present no hazard to health of the consumer at the level of use proposed, so far as can be judged on the scientific evidence available,

   - they do not mislead the consumer.

2. The use of food additives may be considered only where there is evidence that the proposed use of the additive would have demonstrable advantages of benefit to the consumer, in other words it is necessary to establish the case for what is commonly referred to as 'need'. The use of food additives should serve one or more of the purposes set out from points (a) to (d) and only where these purposes cannot be achieved by other means which are economically and technologically practicable and do not present a hazard to the health of the consumer:

   a) to preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified only where the food does not constitute a significant item in a normal diet or where the additive is necessary for the production of foods for groups of consumers having special dietary needs;

   b) to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;

   c) to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not so change the nature, substance or quality of the food as to deceive the consumer;

   d) to provide aids in manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials of undesirable (including unhygienic) practices or techniques, during the course of any of these activities.

3. To assess the possible harmful effects of a food additive or derivatives thereof, it must be subjected to appropriate toxicological testing and evaluation. The evaluation should also take into account, for example, any cumulative, synergistic or potentiating

effect of its use and the phenomenon of human intolerance to substances foreign to the body.

4. All food additives must be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information.

5. Food additives must at all times comply with the approved criteria of purity.

6. Approval for food additives must:

   a) specify the foodstuffs to which these additives may be added and the conditions under which they may be added;

   b) be limited to the lowest level of use necessary to achieve the desired effect;

   c) take into account any acceptable daily intake, or equivalent assessment, established for the food additive and the probable daily intake of it from all sources. Where the food additive is to be used in foods eaten by special groups of consumers, account should be taken of the possible daily intake of the food additive by consumers in those groups.