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105 CMR 520.000: LABELING

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520.001: General

Notwithstanding any contrary provision of 105 CMR 520.000, items required to be labeled under 105 CMR 520.000 may be offered for sale without complying with 105 CMR 520.000, *provided, that*, such items were manufactured prior to said effective dates.

If any provision of 105 CMR 520.000 is declared void or the applicability thereof to any person or circumstance is held invalid, the validity of the remainder of the provisions promulgated hereunder and the applicability thereof to other persons and circumstances shall not be affected thereby.

105 CMR 520.000 shall be effective for all products introduced into commerce after January 1, 1978.

#### 520.003: Labeling; Label; Definitions

(A) Labeling means all labels and other written, printed or graphic matter upon any article or any of its containers or wrappers or accompanying such article.

(B) Label means any display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity.

#### 520.020: Packages: Definition; Presence of Mandatory Label Information

The term package means any container or wrapping in which any food, drug, device, or cosmetic is enclosed for use in the delivery or display of such commodities to retail purchasers, but does not include:

(A) Shipping containers or wrappings used solely for the transportation of any such commodity in bulk or in quantity to manufacturers, packers, processors, or wholesale or retail distributors;

(B) Shipping containers or outer wrappings used by retailers to ship or deliver any such commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity;

(C) Containers subject to the provisions of the Act of August 3, 1912 (37 Stat. 250, as amended; 15 U.S.C. 231-233) or the Act of March 4, 1915 (38 Stat. 1186, as amended; 15 U.S.C. 234-236).

(D) Containers used for tray pack displays in retail establishments.

(E) Transparent wrappers or containers which do not bear written, printed, or graphic matter obscuring the label information required by 105 CMR 520.001 through 520.100.

A requirement contained in 105 CMR 520.000 that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or information also appears on the outer container or wrapper of the retail package of the article, or as stated in 105 CMR 520.020(E), such information is easily legible by virtue of the transparency of the outer wrapper or

container. Where a consumer commodity is marketed in a multi-unit retail package bearing the mandatory label information as required by 105 CMR 520.001 through 520.100 and the unit containers are not intended to be sold separately, the net weight placement requirement of 105 CMR 520.205(F) applicable to such unit containers is waived if the units are in compliance with all the other requirements of 105 CMR 520.001 through 520.100.

### 520.023: Definitions

Butter shall be understood to mean the food product usually known as butter, and which is made exclusively from milk and cream, with or without common salt, and with or without additional coloring matter, and containing not less than 80% by weight of milk fat, all tolerances having been allowed for.

CFR is the abbreviation for the Code of Federal Regulations which is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government.

Commissioner the Commissioner of Public Health of the Commonwealth of Massachusetts.

Cosmetic includes articles packaged for retail sale intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance and articles packaged for retail sale intended for use as a component of any such articles, except that such term shall not include soap.

Device means instruments, apparatus, surgical implants, sutures and contrivances, including their components, parts and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals or to affect the structure or any function of the body of man or other animals, packaged for sale at retail and saleable without prescription.

Department means the Massachusetts Department of Public Health.

Director means the Director of Food and Drugs of the Massachusetts Department of Public Health.

Division the Division of Food and Drugs of the Massachusetts Department of Public Health, its inspectors and agents.

Drug includes all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, any substance or mixture of substances intended to be used for the cure, mitigation or prevention of disease of man or animal and packaged for sale at retail and saleable without prescription.

Food includes all articles, whether simple, mixed, or compound, used for food or drink, confectionery or condiment, by man, and packaged for sale at retail, but does

not include alcoholic beverages as defined in M.G.L. c. 138, § 1, nor does it include meat food products and poultry products as defined in M.G.L. c. 94, § 118 if packaged in any establishment under official inspection by the United States Department of Agriculture.

Food additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include:

- (1) A pesticide chemical in or on a raw agricultural commodity; or
- (2) A pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or
- (3) A color additive; or
- (4) Any substance used in accordance with a sanction or approval granted prior to June 25, 1939, or the enactment of the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following); or
- (5) A new animal drug.

#### 520.024: Exemptions from Required Label Statements

The following exemptions are granted from label statements required by 105 CMR 520.001 through 520.100:

(A) Foods.

- (1) While held for sale, a food shall be exempt from the required declaration of net quantity of contents specified in 105 CMR 520.001 through 520.100 if said food is received in bulk containers at a retail establishment and is accurately weighed, measured, or counted either within the view of the purchaser or in compliance with the purchaser's order.
- (2) Random food packages, as defined in 105 CMR 520.205(J), bearing labels declaring net weight, price per pound or per specified number of pounds, and total price shall be exempt from the type size, dual declaration and placement requirements of 105 CMR 520.205 if the accurate statement of net weight is presented conspicuously on the principal display panel of the package. In the case of food packed in random packages at one place for subsequent shipment and sale at another, the price sections of the label may be left blank provided they are filled in by the seller prior to retail sale. This exemption shall also apply to uniform weight packages of cheese and cheese products labeled in the same manner and by the same type of equipment as random food packages exempted by 105 CMR 520.024(A)(2), except that the labels shall bear a declaration of price per pound and not price per specified number of pounds.

(3) Individual serving-size packages of foods containing less than ½ ounce or less than ½ fluid ounce for use in restaurants, institutions, and passenger carriers, and not intended for sale at retail, shall be exempt from the required declaration of net quantity of contents specified in 105 CMR 520.001 through 520.100.

(4) Individually wrapped pieces of "penny candy" and other confectionery of less than ½ ounce net weight per individual piece shall be exempt from the labeling requirements of 105 CMR 520.001 through 520.100 when the container in which such confectionery is shipped is in conformance with the labeling requirements of 105 CMR 520.001 through 520.100. Similarly, when such confectionery items are sold in bags or boxes, such items shall be exempt from the labeling requirements of 105 CMR 520.001 through 520.100, including the required declaration of net quantity of contents specified in 105 CMR 520.001 through 520.100, if the confectionery items are sold in bags or boxes, which meet the requirements of 105 CMR 520.001 through 520.100

(5) (a) Soft drinks packaged in bottles shall be exempt from the placement requirements

for the statement of identity prescribed by 105 CMR 520.103(A) and 520.103(D) if such statement appears conspicuously on the bottle closure. When such soft drinks are marketed in a multi-unit retail package, the multi-unit retail package shall be exempt from the statement of identity declaration requirements prescribed by 105 CMR 520.103 if the statement of identity on the unit container is not obscured by the multi-unit retail package.

(b) A multi-unit retail package for soft drinks shall be exempt from the declaration regarding name and place of business required by 105 CMR 520.105 if the package does not obscure the declaration on unit containers or if it bears a statement that the declaration can be found on the unit containers and the declaration on the unit containers complies with 105 CMR 520.105. The declaration required by 105 CMR 520.105 may appear on the top or side of the closure of bottled soft drinks if the statement is conspicuous and easily legible.

(c) Soft drinks packaged in bottles which display other required label information only on the closure shall be exempt from the placement requirements for the declaration of contents prescribed by 105 CMR 520.205(F) if the required content declaration is blown, formed, or molded into the surface of the bottle in close proximity to the closure.

(d) Where a trademark on a soft drink package also serves as, or is, a statement of identity, the use of such trademark on the package in lines not parallel to the base on which the package rests shall be exempted from the requirement of 105 CMR 520.103(D) that the statement be in lines parallel to the base so long as there is also at least one statement of identity in lines generally parallel to the base.

(6) (a) Ice cream, french ice cream, ice milk, fruit sherbets, water ices, quiescently frozen confections (with or without dairy ingredients), special dietary frozen desserts, and products made in semblance of the foregoing, when measured by and packaged in ½ liquid pint and ½ gallon measure-containers, as defined in the *Measure Container Code of National Bureau of Standards Handbook 44*, are exempt from the requirements of 105 CMR 520.205(B)(2) to the extent that net contents of eight-fluid ounces and 64-fluid ounces (or two quarts) may be expressed as ½ pint and ½ gallon respectively.

(b) The foods named in 105 CMR 520.024(A)(6)(a) when measured and packaged in 1-liquid pint, 1-liquid quart, and ½ gallon measure-containers, as defined in the *Measure Container Code of National Bureau of Standards Handbook 44*, (Sec. 202 CMR 4.00) are exempt from the dual net-contents declaration requirement of 105 CMR 520.205(J).

(c) The foods named in 105 CMR 520.024(A)(6)(a), when measured by and packaged in ½ liquid pint, 1-liquid pint, 1-liquid quart, ½ gallon, and 1-gallon measure-containers, as defined in the *Measure Container Code of National Bureau of Standards Handbook 44*, are exempt from the requirement of 105 CMR 520.205(F) that the declaration of net contents be located within the bottom 30% of the principal display panel.

(7) (a) Milk, cream, light cream, coffee or table cream, whipping cream, sour or cultured

sour cream, half-and-half, sour or cultured half-and-half, reconstituted or recombined milk and milk products, concentrated milk and milk products, skim or skimmed milk, vitamin D milk and milk products, fortified milk and milk products, homogenized milk, flavored milk and milk products, buttermilk, cultured buttermilk, cultured milk or cultured whole buttermilk, low-fat milk (0.5 to 2.0% butterfat), and acidified milk and milk products, when packaged in containers of eight- and 64-fluid ounce capacity, are exempt from the requirements of 105 CMR 520.205(B)(2) to the extent that net contents of eight fluid ounces and 64 fluid ounces (or two quarts) may be expressed as ½ pint and ½ gallon, respectively.

(b) The products listed in 105 CMR 520.024(A)(7)(a), when packaged in glass or plastic containers of ½ pint, one-pint, one-quart, ½ gallon, and one-gallon capacities are exempt from the placement requirement of 105 CMR 520.205(F) that the declaration of net contents be located within the bottom 30% of the principal display panel, provided that other required label information is conspicuously displayed on the cap or outside closure and the required net quantity of contents declaration is conspicuously blown, formed, or molded into or permanently applied to that part of the glass or plastic container that is at or above the shoulder of the container.

(c) The products listed in 105 CMR 520.024(A)(6)(a) when packaged in containers of one-pint, one-quart, and ½ gallon capacities are exempt from the dual net-contents declaration requirement of 105 CMR 520.205(J).

(8) Wheat flour products, as defined by 21 CFR sections 137.105, 137.155, 137.160, 137.165, 137.170, 137.175, 137.180, 137.185, 137.200 and 137.205, packaged:

(a) In conventional 2-, 5-, 10-, 25-, 50-, and 100-pound packages are exempt from the placement requirement of 105 CMR 520.205(F) that the declaration of net contents be located within the bottom 30% of the area of the principal display panel of the label; and

(b) In conventional two-pound packages are exempt from the dual net-contents declaration requirement of 105 CMR 520.205(J) provided the quantity of contents is expressed in pounds.

(9) 12 shell eggs packaged in a carton designed to hold one dozen eggs and designed

to permit the division of such carton by the retail customer at the place of purchase into two portions of ½ dozen eggs each are exempt from the

labeling requirements of 105 CMR 520.001 through 520.100 with respect to each portion of such divided carton if the carton, when undivided, is in conformance with the labeling requirements of 105 CMR 520.001 through 520.100.

(10) Butter (excluding whipped butter):

(a) In eight-ounce and in one-pound packages is exempt from the requirements of 105 CMR 520.205(F) that the net contents declaration be placed within the bottom 30% of the area of the principal display panel;

(b) In one-pound packages is exempt from the requirements of 105 CMR 520.205(J)(1) that such declaration be in terms of ounces and pounds, to permit declaration of "1 pound" or "one pound"; and

(c) In four-ounce, eight-ounce, and one-pound packages with continuous label copy wrapping is exempt from the requirements of 105 CMR 520.103(D) and 520.205(F) that the statement of identity and net contents declaration appear in lines generally parallel to the base on which the package rests as it is designed to be displayed, provided that such statement and declaration are not so positioned on the label as to be misleading or difficult to read as the package is customarily displayed at retail.

(11) Margarine and imitations thereof in one-pound rectangular packages, except for packages containing whipped or soft margarine or packages that contain more than four sticks, are exempt from the requirement of 105 CMR 520.205(F) that the declaration of the net quantity of contents appear within the bottom 30% of the principal display panel and from the requirement of 105 CMR 520.205(J)(1) that such declaration be expressed both in ounces and in pounds to permit declaration of "1 pound" or "one pound", provided an accurate statement of net weight appears conspicuously on the principal display panel of the package.

(12) Corn flour and related products, as they are defined in 21 C.F.R 137.211, 137.215, and 137.230 through 137.290, packaged in conventional five-, ten-, 25-, 50-, and 100-pound bags are exempt from the placement requirement of 105 CMR 520.205(F) that the declaration of net contents be located within the bottom 30% of the area of the principal display panel of the label.

(13) (a) Single strength and less than single strength fruit juice beverages, imitations

thereof, and drinking water when packaged in glass or plastic containers of ½-pint, one-pint, one-quart, ½-gallon, and one-gallon capacities are exempt from the placement requirement of 105 CMR 520.205(F) that the declaration of net contents be located within the bottom 30% of the principal display panel: *provided that*, other required label information is conspicuously displayed on the cap or outside closure and the required net quantity of contents declaration is conspicuously displayed on the cap or outside closure and the required net quantity of contents declaration is conspicuously blown, formed, or molded into or permanently applied to that part of the glass or plastic container that is at or above the shoulder of the container.

(b) Single strength and less than single strength fruit juice beverages, imitations thereof, and drinking water when packaged in glass, plastic, or paper (fluid milk type) containers of one-pint, one-quart, and ½ gallon capacities are exempt from the dual net-contents declaration requirement of 105 CMR 520.205(J).

- (c) Single strength and less than single strength fruit juice beverages, imitations thereof, and drinking water when packaged in glass, plastic, or paper (fluid milk type) containers of eight- and 64-fluid-ounce capacity, are exempt from the requirements of 105 CMR 520.205(R)(2) to the extent that net contents of eight fluid ounces and 64 fluid ounces (or two quarts) may be expressed as ½ pint (or half pint) and ½ gallon (or half gallon), respectively.
- (14) The unit containers in a multi-unit or multi-component retail food package shall be exempt from compliance with the requirements of M.G.L. c. 94, § 187, as it pertains to food, subparagraph (2) of the ninth paragraph, subparagraph (2) of the eleventh paragraph, and the thirteenth paragraph with respect to the requirements for label declaration of ingredients when
- (a) the multi-unit or multi-component retail food package labeling meets all the requirements of 105 CMR 520.001 through 520.100;
  - (b) the unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale; and
  - (c) each unit container is labeled with the statement "This Unit Not Labeled For Retail Sale" in type size not less than 1/16 inch in height, and each multi-unit or multi-component package principal display panel is labeled with the statement "Inner Units Not Labeled For Retail Sale" in type size not smaller than the minimum type size required for the declaration of net quantity of contents by 105 CMR 520.205.

#### 520.032: Package Size Savings

Any food, drug, cosmetic, or device that bears on the label or labeling a representation that the consumer commodity is being offered at a lower price per unit of weight, measure, or count because of economy resulting from the size of the container or quantity of its contents is subject to the following conditions:

- (A) The container may bear a representation of economy by virtue of its size (for example, "economy size," "economy pack," "big value," "thrifty pack," "bargain size," "budget pack," etc.) only if:
- (1) The sponsor of the economy size promotion at the same time offers the same brand of that commodity in at least one other packaged size or labeled form.
  - (2) Only one packaged or labeled form of that brand of commodity is labeled with an "economy size" representation.
  - (3) The sponsor of the economy size promotion and all subsequent levels of commerce sell the commodity labeled with an "economy size" representation at a price per unit of weight, volume, measure, or count which is substantially reduced (*i.e.*, at least 5%) from the actual price of all other packaged or labeled units of the same brand of that commodity offered simultaneously.
- (B) The sponsor of the economy size promotion and all subsequent levels of commerce such as wholesalers and jobbers shall maintain for at least one year invoices or other records showing that the wholesale price per unit of weight, measure, volume or count on the economy size package is such that the retailers can sell the economy size container at a significantly lower price per unit.

#### 520.035: "Cents-off", or Other Savings Representations



Any food, drug, cosmetic, or device that bears on the label or labeling a representation that the consumer commodity is being offered for retail at a reduction in retail price is subject to the following conditions: *provided, however*, that such conditions do not apply to any such savings representations initiated by persons who do not manufacture, package, or import such commodities and who do not prescribe or specify by any means the manner in which such commodities are packaged, or labeled by a manufacturer, packager, or importer:

(A) A "cents-off" or other savings representation that states or implies a reduction in the ordinary and customary retail price may be used by a manufacturer, packer, distributor, or retailer, hereinafter known as the sponsor, initiating such promotion only if:

- (1) An ordinary and customary selling price of such consumer commodity has been established at the retail level.
- (2) The sponsor's selling price and the selling price at all subsequent levels of commerce such as wholesalers and jobbers has been reduced by at least the savings differential represented on the package or labeling, and
- (3) The sponsor and all subsequent levels of commerce keep and maintain invoices or other records for each promotion and for all successive promotions which occur within a 12-month period for at least one year subsequent to the end of the year (calendar, fiscal, or market) in which the promotion occurs in order to show that the invoice cost to the retailer has been reduced in an amount sufficient to enable the retailer to pass the savings on to the purchaser.

(B) (1) Each "cents-off" price reduction representation imprinted on the package or label

shall be limited to a phrase which reflects that the price marked by the retailer represents the savings in the amount of the "cents-off" the retailer's regular price, *e.g.*, "Price Marked Is ...Cents Off the Regular Price," "Price Marked Is...Cents-Off the Regular Price of This Package:" *Provided*, the package or label may in addition bear in the usual pricing spot a form reflecting a space for the regular price, the represented "cents-off, and a space for the price to be paid by the consumer. The sponsor who sells the commodity at retail shall display the regular price, clearly and conspicuously designated as "regular price," on the package or label of the commodity or on a sign, placard, or shelf-marker placed in a position contiguous to the retail display of the "cents-off" marked commodity. The sponsor who does not sell at retail shall provide the retailer with a sign, placard, shelf-marker, or other device for the purpose of clearly and conspicuously displaying the retailer's regular price, designated as "regular price," in a position contiguous to the "cents-off" marked commodity.

(2) Other savings representations which appear on the label or labeling of a package, *e.g.*, "bonus offer," "two-for-one sales," "one-cent sales," etc., are subject to the provisions of this section. Due to the infinite variety and scope of such promotions, the label format of such representations may differ from that set forth in 105 CMR 520.035(B)(1) for "cents-off" promotions; however, such representations shall include all material facts relative to the offer and shall in no way be misleading.

(3) For the purposes of 105 CMR 520.001 through 520.100, "ordinary and

customary" and "regular" when used with the term "price" mean the price at which a consumer commodity has been openly and actively sold in the most recent and regular course of business in a particular retail outlet or a trade area for a reasonably substantial period of time (at least 30 days). For consumer commodities that fluctuate in price, the ordinary and customary price shall be the lowest price at which any substantial sales were made during said 30 days.

(C) Shipments of consumer commodities bearing "cents-off" or other savings representations to a given geographic trade area made by the sponsor initiating such promotion shall be in no greater volume than 50% of the total units of that identical consumer commodity distributed in the same geographic trade area during any period of 12 consecutive months comprising a calendar, fiscal, or market year.

(D) The "cents-off" or other savings promotion may not be employed by a sponsor on consumer commodities for distribution to a specific geographic trade area until after one month has elapsed since their last distribution of that identical consumer commodity bearing a savings representation to the same geographic trade area. The number of such promotions for that identical consumer commodity that may occur within a 12 month period comprising a calendar, fiscal, or market year shall not exceed a total of six with no more than three of any one type or kind (*e.g.*, "cents-off," "bonus offer," "two-for-one sale," "1-cent sale," etc.), and the total period of time for all such promotions shall not exceed 6 months within that 12-month period.

(E) A newly developed consumer commodity, one which has been changed in a functionally significant respect, or one which is newly introduced into a given geographic trade area may be the subject of an "introductory offer" type promotion. Such offers are not considered subject to the provisions of 105 CMR 520.035(A) through 105 CMR 520.035(D), provided:

- (1) Each such labeled offer is clearly and conspicuously qualified with the phrase "Introductory Offer" and
- (2) If the introductory offer promotion is in the form of a "cents-off" representation, each such labeled offer shall include clearly and conspicuously in immediate conjunction therewith the phrase "...Cents Off the After-Introductory-Offer Price": and
- (3) Labeled representations do not exceed a period of six months duration.

Any subsequent price reduction promotion of the consumer commodity is subject to the provisions of 105 CMR 520.035(A) through 520.035(D), and shall be preceded by the 30-day period required for a determination of the ordinary and customary selling price in that retail establishment. At the time of making the introductory offer promotion, the sponsor must intend in good faith to offer the commodity alone, immediately following the introductory offer promotion, for a reasonably substantial period of time (at least 30 days) at the anticipated after-introductory-offer price. The sponsor of the introductory offer promotion and all subsequent levels of commerce shall sell the commodity at a reduction from their anticipated after-introductory-offer price which reduction shall be at least equal to the savings differential represented on the package or labeling. The sponsor and all subsequent levels of commerce shall maintain invoices and records for at least one year subsequent to the end of the year (calendar, fiscal, or market) in which such

introductory offer occurs.

#### 520.101: Food in Package Form; Principal Display Panel

The term "principal display panel" as it applies to food in package form and as used in 105 CMR 520.000, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by 105 CMR 520.000 with clarity and conspicuousness and without obscuring design, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term "area of the principal display panel" means the area of the side or surface that bears the principal display panel, which area shall be:

(A) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(B) In the case of a cylindrical or nearly cylindrical container, 40% of the product of the height of the container times the circumference;

(C) In the case of any otherwise shaped container, 40% of the total surface of the container: *provided, however*, that where such container presents an obvious "principal display panel" such as the top of a triangular or circular package of cheese, the area shall consist of the entire top surface. In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by 105 CMR 520.000 to appear on the principal display panel shall appear within that 40% of the circumference which is most likely to be displayed, presented shown, or examined under customary conditions of display for retail sale.

#### 520.102: Food Labeling; Information Panel

(A) The term "information panel" as it applies to packaged food means that part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel with the following exceptions:

(1) If the part of the label immediately contiguous and to the right of the principal display panel is too small to accommodate the necessary information or is otherwise unusable label space, *e.g.*, folded flaps or can ends, the panel immediately contiguous and to the right of this part of the label may be used.

(2) If the package has one or more alternate principal display panels, the information panel is immediately contiguous and to the right of any principal display panel.

(3) If the top of the container is the principal display panel and the package has

no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(B) All information required to appear on the label of any package of food pursuant to 105 CMR 520.105, 520.108, 520.104, 520.109, shall appear either on the principal display panel or on the information panel, unless otherwise specified by regulation.

(C) All information appearing on the principal display panel or the information panel pursuant to 105 CMR 520.102 shall appear prominently and conspicuously, but in no case may the letters and/or numbers be less than 1/16 inch in height unless an exemption pursuant to 105 CMR 520.102(F) is established. The requirements for conspicuousness and legibility shall include the specifications of 105 CMR 520.205(H)(1) and 520.205(H)(2) and 520.115.

(1) Packaged foods are exempt from the type size requirements of 105 CMR 520.102(C): *Provided, that:*

(a) The package is designed such that it has a surface area that can bear an information panel and/or an alternate principal display panel.

(b) The area of surface available for labeling on the principal display panel of the package as this term is defined in 105 CMR 520.101 is less than ten square inches.

(c) The label information includes nutrition information and a full list of ingredients in accordance with regulations in 105 CMR 520.001 through 520.100.

(d) The information required by 105 CMR 520.102(B) appears on the principal display panel or information panel label in accordance with the provisions of 105 CMR 520.102(C) except that the type size is not less than 3/64 inch in height.

(2) Packaged foods are exempt from the type size requirements of 105 CMR 520.102(C): *Provided, that:*

(a) The package is designed such that it has a single "obvious principal display panel" as this term is defined in 105 CMR 520.101 and has no other available surface area for an information panel or alternate principal display panel.

(b) The area of surface available for labeling on the principal display panel of the package as this term is defined in 105 CMR 510.101 is less than 12 square inches and bears all labeling appearing on the package.

(c) The label information includes nutrition information and a full list of ingredients in accordance with regulations in 105 CMR 520.001 through 520.100.

(d) The information required by 105 CMR 520.102(B) appears on the single, obvious principal display panel in accordance with the provisions of 105 CMR 520.102(C) except that the type size is not less than 1/32 inch in height.

(3) Packaged foods are exempt from the type size requirements of 105 CMR 520.102(C): *Provided, that:*

(a) The package is designed such that it has a total surface area available to bear labeling of less than 12 square inches.

(b) The label information includes nutrition information and a full list of ingredients in accordance with regulations in 105 CMR 520.001 through

520.100.

(c) The information required by 105 CMR 520.102(B) appears on the principal display panel or information panel label in accordance with the provisions of 105 CMR 520.102(C) except that the type size is not less than 1/32 inch in height.

(4) (a) Soft drinks packaged in bottles manufactured before October 31, 1975, shall be

exempt from the requirements prescribed by 105 CMR 520.102, to the extent that information which is blown, lithographed, or formed onto the surface of the bottle is exempt from the size and placement requirements of 105 CMR 520.102.

(b) Soft drinks packaged in bottles shall be exempt from the size and placement requirements prescribed by 105 CMR 520.102 if all of the following conditions are met:

1. If the soft drink is packaged in a bottle bearing a paper, plastic foam jacket or foil label, or is packaged in a non-reusable bottle bearing a label lithographed onto the surface of the bottle, the product shall not be exempt from any requirement of 105 CMR 520.102 other than the exemption created by 105 CMR 520.024(A)(5)(b) and the label shall bear all required information in the specified minimum type size, except the label will not be required to bear the information required by 105 CMR 320.105 if this information appears on the bottle closure in a type size not less than 1/16 inch in height.

2. If the soft drink is packaged in a bottle which does not bear a paper, plastic foam jacket or foil label, or is packaged in a re-usable bottle bearing a label lithographed onto the surface of the bottle:

Neither the bottle nor the closure is required to bear nutrition labeling in compliance with 105 CMR 520.109, except that any multi-unit retail package in which it is contained shall bear nutrition labeling if required by 105 CMR 520.109; and any vending machine in which it is contained shall bear nutrition labeling if nutrition labeling is not present on the bottle or closure, if required by 105 CMR 520.109.

All other information pursuant to this section shall appear on the top of the bottle closure prominently and conspicuously in letters and/or numbers no less than 1/32 inch in height, except that if the information required by 105 CMR 520.105 is placed on the side of the closure in accordance with 105 CMR 520.029(A)(5)(6) such information shall appear in letters and/or numbers no less than 1/16 inch in height.

Upon the petition of any interested person demonstrating that the bottle closure is too small to accommodate this information, the Department may by regulation establish an alternative method of disseminating such information. Information appearing on the closure shall appear in the following priority:

The warning required by 21 CFR 100.130.

The statement of ingredients.

The name and address of the manufacturer, packer, or distributor.

The statement of identity.

(D) All information required to appear on the principal display panel or on the

information panel pursuant to 105 CMR 520.102 shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, any vignettes, design, and other non-mandatory label information shall not be considered. If there is insufficient space for all of this information to appear on a single panel, it may be divided between these two panels except that the information required pursuant to any given section or part shall all appear on the same panel. A food whose label is required to bear the ingredient statement on the principal display panel may bear all other information specified in 105 CMR 520.102(B) on the information panel.

(E) All information appearing on the information panel pursuant to 105 CMR 520.102 shall appear in one place without other intervening material.

(F) If the label of any package of food is too small to accommodate all of the information required by 105 CMR 520.105, 520.108, 520.104, and 520.109, the Commissioner may establish an acceptable alternative method of disseminating such information to the public, *e.g.*, a type size smaller than 1/16 inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such an alternative shall be submitted to the Director.

520.103: Food in Package Form, Labeling, Identity

(A) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity.

(B) Such statement of identity shall be in terms of:

- (1) The name now or hereafter specified in or required by any applicable Massachusetts law or regulation; or, in the absence thereof,
- (2) The common or usual name of the food; or, in the absence thereof,
- (3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

(C) Where a food is marketed in various optional forms (whole, slices, diced, etc.), the particular form shall be considered to be a necessary part of the statement of identity and shall be declared in letters of a type size bearing a reasonable relation to the size of the letters forming the other components of the statement of identity; except that if the optional form is visible through the container or is depicted by an appropriate vignette, the particular form need not be included in the statement. This specification does not affect the required declarations of identity under definitions and standards for foods promulgated pursuant to M.G.L. c. 94, § 192 and pursuant to section 341 of the Food and Drug Act, 21 USC 301 *et seq.*

(D) This statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

(E) Under the provisions of the third paragraph, under food, of M.G.L. c. 94, § 187, a food shall be deemed to be mis-branded if it is an imitation of another food unless

its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

- (1) A food shall be deemed to be an imitation and thus subject to the requirements of the third paragraph under food, of M.G.L. c. 94, § 187 if it is a substitute for and resembles another food but is nutritionally inferior to that food.
- (2) A food that is a substitute for and resembles another food shall not be deemed to be an imitation provided it meets each of the following requirements:
  - (a) It is not nutritionally inferior to the food for which it substitutes and which it resembles.
  - (b) Its label bears a common or usual name that complies with the provisions of 21 CFR 102.5 and that is not false or misleading, or in the absence of an existing common or usual name, an appropriately descriptive term that is not false or misleading. The label may, in addition, bear a fanciful name which is not false or misleading.
- (3) A food for which a common or usual name is established by regulation or statute and which complies with all of the applicable requirements of such regulation or statute, shall not be deemed to be an imitation.
- (4) Nutritional inferiority includes:
  - (a) Any reduction in the content of an essential nutrient that is present in a measurable amount but does not include a reduction in the caloric or fat content provided the food is labeled pursuant to the provisions of 105 CMR 520.109 and provided the labeling with respect to any reduction in caloric content complies with the provisions applicable to caloric content in 21 CFR 105.
  - (b) For the purpose of 105 CMR 520.103, a measurable amount of an essential nutrient in a food shall be considered to be 2% or more of the U.S. RDA of protein or any vitamin or mineral listed under 21 CFR 105.3(b) per average or usual serving, or where the food is customarily not consumed directly, per average or usual portion, as established in 105 CMR 520.109.
  - (c) If the Director concludes that a food is a substitute for and resembles another food but is inferior to the food imitated for reasons other than those set forth in 105 CMR 520.103(E), he may propose appropriate revisions to 105 CMR 520.000 or he may propose a separate regulation governing the particular food.

(F) A label may be required to bear the percentage(s) of a characterizing ingredient(s) or information concerning the presence or absence of an ingredient(s) or the need to add an ingredient(s) as part of the common or usual name of the food pursuant to 105 CMR 520.300 through 520.399.

#### 520.104: Food Labeling; Designation of Ingredients

(A) Ingredients required by M.G.L. c. 94, § 187, paragraph 11 under food, to be declared on the label of a food, except those exempted by 105 CMR 520.200 shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of 105 CMR 520.102.

(B) The name of an ingredient shall be a specific name and not a collective (generic) name, except that:

- (1) Spices, flavorings, colorings and chemical preservatives shall be declared according to the provisions of 105 CMR 520.122;
- (2) An ingredient which itself contains two or more ingredients and which has an established common or usual name, conforms to a standard established pursuant to the Meat Inspection or Poultry Products Inspection Acts by the U.S. Department of Agriculture, or conforms to a definition and standard of identity established pursuant to section 401 of the Federal Food, Drug, and Cosmetic Act, shall be designated in the statement of ingredients on the label of such food by either of the following alternatives:
  - (a) By declaring the established common or usual name of the ingredient followed by a parenthetical listing of all ingredients contained therein in descending order of predominance; or
  - (b) By incorporating into the statement of ingredients in descending order or predominance in the finished food, the common or usual name of every component of the ingredient without listing the ingredient itself.
- (3) Skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk may be declared as "skim milk" or "nonfat milk".
- (4) Milk, concentrated milk, reconstituted milk, and dry whole milk may be declared as "milk".
- (5) Bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, *e.g.*, "made from cultured skim milk or cultured buttermilk".
- (6) Sweet cream buttermilk, concentrated sweetcream buttermilk, reconstituted sweetcream buttermilk, and dried sweetcream buttermilk may be declared as "buttermilk".
- (7) Whey, concentrated whey, reconstituted whey and dried whey may be declared as "whey".
- (8) Cream, reconstituted cream, dried cream, and plastic cream (sometimes known as concentrated milk fat) may be declared as "cream".
- (9) Butter-oil and anhydrous butter-fat may be declared as "butterfat".
- (10) Dried whole eggs, frozen whole eggs, and liquid whole eggs may be declared as "eggs".
- (11) Dried egg whites, frozen egg whites, and liquid egg whites may be declared as "egg whites".
- (12) Dried egg yolks, frozen egg yolks, and liquid egg yolks may be declared as "egg yolks".
- (13) Reserved.
- (14) Each individual fat and/or oil ingredient shall be declared by its specific common or usual name (*e.g.*, "beef fat", "cottonseed oil") in its order of predominance in the food except that blends of fats and/or oils may be designated in their order of predominance in the food as ". . . shortening" or "blend of . . . oils", the blank to be filled in with the word "vegetable", "animal", "marine", with or without the terms "fat" or "oils", or combination of these, whichever is applicable if, immediately following the term, the common or usual name of each individual vegetable, animal, or marine fat or oil is given in parentheses, *e.g.*, "vegetable oil shortening (soybean and cottonseed oil)". For products that are blends of fats and/or oils and for foods in which fats and/or oils



constitute the predominant ingredient, *i.e.*, in which the combined weight of all fat and/or oil ingredients equals or exceeds the weight of the most predominant ingredient that is not a fat or oil, the listing of the common or usual names of such fats and/or oils in parentheses shall be in descending order of predominance. In all other foods in which a blend of fats and/or oils is used as an ingredient, the listing of the common or usual names in parentheses need not be in descending order of predominance if the manufacturer, because of the use of varying mixtures, is unable to adhere to a constant pattern of fats and/or oils in the product. If the fat or oil is completely hydrogenated, the name shall include the term "saturated", or if partially hydrogenated, the name shall include the term "partially saturated". Fat and/or oil ingredients not present in the product may be listed if they may sometimes be used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", "contains one or more of the following:", *e.g.*, "vegetable oil shortening (contains one or more of the following: cottonseed oil, palm oil, soybean oil)". No fat or oil ingredient shall be listed unless actually present if the fats and/or oils constitute the predominant ingredient of the product, as defined in 105 CMR 520.104(B)(14). (15) When all the ingredients of a wheat flour are declared in an ingredient statement, the principal ingredient of the flour shall be declared by the name(s) specified in 21 CFR 137.105, 137.220, 137.200 and 137.225 *i.e.*, the first ingredient designated in the ingredient list of flour, or bromated flour, or enriched flour, or self-rising flour is "flour", "white flour", "wheat flour", or "plain flour"; the first ingredient designated in the ingredient list of durum flour is "durum flour"; the first ingredient designated in the ingredient list of whole wheat flour, or bromated whole wheat flour is "whole wheat flour", "graham flour", or "entire wheat flour"; and the first ingredient designated in the ingredient list of whole durum wheat flour is "whole durum wheat flour".

(C) When water is added to reconstitute, completely or partially, an ingredient permitted by 105 CMR 520.104(B) to be declared by a class name, the position of the ingredient class name in the ingredient statement shall be determined by the weight of the unreconstituted ingredient plus the weight of the quantity of water added to reconstitute that ingredient, up to the amount of water needed to reconstitute the ingredient to single strength. Any water added in excess of the amount of water needed to reconstitute the ingredient to single strength shall be declared as "water" in the ingredient statement.

520.105: Food Labeling; Name and Place of Business of Manufacturer, Packer, or Distributor

(A) The label of a food in packaged form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.

(B) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name, which may be preceded or followed by the name of the particular division of the corporation. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

(C) Where the food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person

has with such food; such as "Manufactured for . . .," "Distributed by . . .," or any other wording that expresses the facts.

(D) The statement of the place of business shall include the street address, city, state, and ZIP code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP code shall apply only to consumer commodity labels developed or revised after the effective date of 105 CMR 520.105. In the case of non-consumer packages, the ZIP code shall appear either on the label or the labeling (including invoice).

(E) If a person manufactures, packs, or distributes a food at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where such food was manufactured or packed or is to be distributed, unless such statement would be misleading.

#### 520.108: Food Labeling; Number of Servings

(A) The label of any package of a food which bears a representation as to the number of servings contained in such package shall bear in immediate conjunction with such statement, and in the same size type as is used for such statement, a statement of the net quantity (in terms of weight, measure, or numerical count) of each such serving; however, such statement may be expressed in terms that differ from the terms used in the required statement of net quantity of contents (for example, cupfuls, tablespoonfuls, etc.) when such differing term is common to cookery and describes a constant quantity. Such statement may not be misleading in any particular. A statement of the number of units in a package is not in itself a statement of the number of servings.

(B) If there exists a voluntary product standard promulgated pursuant to the procedures found in Part 10, Title 15, Code of Federal Regulations, by the Department of Commerce, quantitatively defining the meaning of the term "serving" with respect to a particular food, then any label representation as to the number of servings in such packaged food shall correspond with such quantitative definition. (Copies of published standards are available upon request from the National Bureau of Standards, Department of Commerce, Washington, D.C. 20234.

#### 520.109: Food; Nutrition Labeling

(A) Nutrition information relating to food may be included on the label and in the labeling of a product: *Provided, that* it conforms to the requirements of 105 CMR 520.109. Except as provided in 105 CMR 520.109(H), inclusion of any added vitamin, mineral, or protein in a product or of any nutrition claim or information, other than sodium content, on a label or in advertising for a food subjects the label to the requirements of 105 CMR 520.109, and in labeling for a food subjects the label and that labeling to the requirement of 105 CMR 520.109.

(1) Solicitation of requests for nutrition information by a statement "For nutrition information write to -----" on the label or in the labeling or advertising for a food, or providing such information in a direct written reply to a solicited or unsolicited request, does not subject the label or the

labeling to the requirements of 105 CMR 520.109 if no other nutrition claim is made on the label or in other labeling or advertising, if the reply to the request conforms to the requirements of 105 CMR 520.109, and if no vitamin, mineral, or protein is added to the food.

(2) If any vitamin and/or mineral is added to a food so that a single serving provides 50% or more of the U.S. Recommended Daily Allowance (U.S. RDA) for adults and children four years or more of age, as specified in 21 CFR 105.3 of any one of the added vitamins and/or minerals, unless such addition is permitted or required in other regulations, *e.g.*, a standard of identity or nutritional quality guideline, or is otherwise exempted by the Director or by the Commissioner of the Federal Food and Drug Administration the food shall conform to the standard of identity set forth in 21 CFR 105.85, and shall also conform to the labeling established in 21 CFR 105.85, except that the labeling established in 105 CMR 520.109(c) including the order for listing vitamins and minerals established in 105 CMR 520.109(C)(7)(d), shall be used in lieu of the labeling established in 21 CFR 105.85(i) (1).

(B) All nutrient quantities (including vitamins, minerals, calories, protein, carbohydrate, and fat) shall be declared in relation to the average or usual serving or, where the food is customarily not consumed directly, in relation to the average or usual portion. Another column of figures may be used to declare the nutrient quantities in relation to the average or usual amount consumed on a daily basis, in the same format required in 105 CMR 520.109(c) for the serving (portion), where reliable data have established that the food is customarily consumed more than once during the day and the average or usual amount so consumed.

(1) The term "serving" means that reasonable quantity of food suited for or practicable of consumption as part of a meal by an adult male engaged in light physical activity, or by an infant or child under four years of age when the article purports or is represented to be for consumption by an infant or child under four years of age. The term "portion" means the amount of food customarily used only as an ingredient in the preparation of a meal component (*e.g.*, ½ cup flour, ½ tablespoon cooking oil or ¼ cup tomato paste). A label statement regarding a serving (portion) shall be in terms of a convenient unit of such food or a convenient unit of measure that can be easily identified as an average or usual serving (portion) and can be readily understood by purchasers of such food (*e.g.*, a serving (portion) may be expressed in slices, cookies, or wafers; or in terms of ounces, fluid ounces, teaspoonfuls, tablespoonfuls, or cupfuls).

(2) A teaspoonful shall be considered to mean five milliliters (approximately 1/6 fluid oz.) in volume; a tablespoon shall be considered to mean 15 milliliters (approximately ½ fluid oz.) in volume; and a cupful shall be considered to mean 240 milliliters (approximately eight fluid oz.) in volume. The weight of the serving (portion) may also be expressed in grams.

(3) The declaration of nutrient quantities shall be on the basis of the food as packaged. Another column of figures may be used to declare the nutrient quantities on the basis of the food as consumed after cooking or other preparation, in the same format required in 105 CMR 520.109(c) for the food alone: Provided, that the specific method of cooking or other preparation shall be disclosed in a prominent statement immediately following the information required by 105 CMR 520.109(c).

(C) The declaration of nutrition information on the label and in labeling shall contain the following information in the following order, using the headings specified, under the overall heading of "Nutrition Information Per Serving (Portion)." The terms "Per Serving (Portion)" are optional and may follow or be placed directly below the terms "Nutrition Information."

(1) "Serving (portion) size": A statement of the serving (portion) size.

(2) "Servings (portions) per container": The number of servings (portions) per container.

(3) "Caloric content" or "Calories": A statement of the caloric content per serving (portion), expressed to the nearest two-calorie increment up to and including 20 calories, five-calorie increment above 20 calories and up to and including 50 calories, and 10-calorie increment above 50 calories.

Caloric content shall be determined by the Atwater method as described in A. L. Merrill and B. K. Watt, "Energy Value of Foods-Basis and Derivation," USDA Handbook 74 (1955) . Caloric content may be calculated on the basis of four, four, and nine calories per gram for protein, carbohydrate, and fat respectively unless the use of these values gives a caloric value more than 20% greater than the caloric value obtained when using the more accurate values determined by use of the Atwater method as found in USDA Handbook 74 (1955).

(4) "Protein content" or "Protein": A statement of the number of grams of protein in a serving (portion), expressed to the nearest gram. Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis of the Association of Official Analytical Chemists, 11th edition, 1970, except when the official procedure for a specific food requires another factor.

(5) "Carbohydrate content" or "Carbohydrate": A statement of the number of grams of carbohydrate in a serving (portion) expressed to the nearest gram.

(6) "Fat content" or "Fat": A statement of the number of grams of fat in a serving (portion) expressed to the nearest gram. Fatty acid composition, cholesterol content, and sodium content may also be declared in compliance with 21 CFR 101.25 and 21 CFR 105.69.

(a) When fatty acid composition is declared, the information on fatty acids required by 21 CFR 101.25(c) shall be placed on the label immediately following the statement of fat content. The declaratory information statement required by 21 CFR 101.25(d) shall be placed either immediately following the statement on fat and fatty acids or shall be appropriately referenced by symbol and placed immediately following the completed nutrition information statement.

(b) When cholesterol content is declared, the information on cholesterol required by 21 CFR 101.25(b) shall immediately follow the statement on fat content (and fatty acids, if stated). The declaratory information statement required by 21 CFR 101.25(d) shall be placed either immediately following the statement on cholesterol or shall be appropriately referenced by symbol and placed immediately following the completed nutrition information statement.

(c) When both fatty acid and cholesterol information are provided, the declaratory information statement may be combined as permitted by 21 CFR 101.25(d).

(d) When sodium is declared, the information on sodium required by 21 CFR 105.69 shall be placed on the label immediately following the statement on fat content (and fatty acid and/or cholesterol, if stated).

\* Copies may be obtained from: Division of Nutrition (HFF-260), Bureau of Foods, Food and Drug Administration, 200 C Street S. W., Washington, DC 20204.

(7) "Percentage of U.S. Recommended Daily Allowances (U.S. RDA)": A statement of the amount per serving (portion) of the protein, vitamins, and minerals, as described in this subparagraph, expressed in percentage of the U.S. Recommended Daily Allowance (U.S. RDA).

(a) The percentages shall be expressed in 2% increments up to and including the 10% level, 5% increments above 10% and up to and including the 50% level, and 10% increments above the 50% level. Nutrients present in amounts less than 2% of the U.S. RDA may be indicated by a zero, or by an asterisk referring to another asterisk placed at the bottom of the table and followed by the statement "contains less than 2% of the U.S. RDA of this (these) nutrient (nutrients)." However, when a product contains less than 2% of the U.S. RDA for each of five or more of the eight nutrients specified in 105 CMR 520.109(C)(7)(c), the manufacturer or distributor may choose to declare no more than three of those nutrients and none of the remainder listed in 105 CMR 520.109(C)(7)(d). The statement "contains less than 2% of the U.S. RDA of . . . . .," listing whichever of the eight nutrients are present at less than 2% of the U.S. RDA and have not been declared, shall directly follow the declared nutrient in the same type size. Any nutrient declared shall always appear in the order established in 105 CMR 520.109(C)(7)(d).

(b) The declaration of protein, which shall come first, shall be a statement of the amount per serving (portion) of protein, expressed as a percentage of the U.S. RDA.

1. The U.S. RDA of the protein in a food product is 45 grams if the protein efficiency ration (PER) of the total protein in the product is equal to or greater than that of casein, and 65 grams if the PER of the total protein in the product is less than that of casein. The percentage of the U.S. RDA shall be declared as described in 105 CMR 520.109(C)(7)(a).

2. Total protein with a PER less than 20 of the PER of casein may not be stated on the label in terms of percentage U.S. RDA, and the statement of protein content in grams per serving (portion) under 105 CMR 520.109(C)(4) shall be modified by the statement "not a significant source of protein" immediately adjacent to the protein content statement regardless of the actual amount of protein present.

(c) The declaration of vitamins and minerals as a percent of the U.S. RDA which shall follow the protein declaration, shall include vitamin A, vitamin C, thiamine, riboflavin, niacin, calcium, and iron, in that order, and shall include any of the other vitamins and minerals listed in 105 CMR 520.109(C)(7)(f), when they are added and may list any of the other vitamins and minerals listed in 105 CMR 520.109(C)(7)(d), when they are naturally occurring in the order listed therein.

(d) The following U.S. Recommended Daily Allowances (U.S. RDA) and nomenclature are established for these vitamins and minerals, essential in

human nutrition:

Vitamin A, 5,000 International Units.  
Vitamin C, 60 milligrams\* .  
Thiamine, 1.5 milligrams .  
Riboflavin, 1.7 milligrams.  
Niacin 20 milligrams.  
Calcium, 1.0 gram.  
Iron, 18 milligrams.  
Vitamin D, 400 International Units.  
Vitamin E, 30 International Units.  
Vitamin B<sub>6</sub>, 2.0 milligrams.  
Folic acid, 0.4 milligram\* .  
Vitamin B<sub>12</sub>, 6 micrograms.  
Phosphorus, 1.0 gram.  
Iodine, 150 micrograms.  
Magnesium, 400 milligrams.  
Zinc, 15 milligrams.  
Copper, 2 milligrams.  
Biotin, 0.3 milligram.

Pantothenic acid, 10 milligrams.

These nutrients and levels have been derived by the U.S. Food and Drug Administration from the "Recommended Dietary Allowances," published by the Food and Nutrition Board, National Academy of Sciences-National Research Council, and are subject to amendment from time to time as more information on human nutrition becomes available.

(e) No claim may be made that a food is a significant source of a nutrient unless that nutrient is present in the food at a level equal to or in excess of 10% of the U.S. RDA in a serving (portion). No claim may be made that a food is nutritionally superior to another food unless it contains at least 10% more of the U.S. RDA of the claimed nutrient per serving (portion).

(D) Products with separately packaged ingredients or to which other ingredients are added by the user may be labeled as follows:

(1) If a product is comprised of two or more separately packaged ingredients enclosed in an outer container, nutrition labeling of the total product shall be located on the outer container to provide information for the consumer at the point of purchase. However, when two or more food products are simply combined together in such a manner that no outer container is used, or no outer label is available, each product shall have its own nutrition information, *e.g.*, two boxes taped together or two cans combined in a clear plastic overwrap.

(2) If a food is commonly combined with another ingredient(s) before eating and directions for such combination are provided, another column of figures may be used to provide a list of the nutrient contents for the final combination in the same format required in 105 CMR 520.109(C), for the food alone (*e.g.*, a dry ready-to-eat cereal may be described with one set of percentage U.S. RDA values for the cereal as sold (per ounce) , and another set for the cereal and milk as suggested in the label (per ounce of cereal and ½ cup of vitamin D fortified whole milk); and a cake mix may be labeled with one set of percentage U.S.

RDA values for the dry mix (per serving), and another set for a serving of the final cake when prepared). The type and quantity of the other ingredient(s) to be added by the user to the product shall be specified.

(E) Compliance with 105 CMR 520.109 shall be determined as follows:

(1) A collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, or in the absence of any common container code or marking a day's production, constitutes a "lot".

(2) The sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken one from each of 12 different randomly chosen shipping cases, to be representative of a lot. Composites shall be analyzed by Association of Official Analytical Chemists (AOAC) methods where available or, if no AOAC method is available, by reliable and appropriate analytical procedures.

(3) Two classes of nutrients are defined for purposes of compliance:

Class I. Added nutrients in fortified or fabricated foods.

Class II. Naturally occurring (indigenous) nutrients.

\* The following synonyms may be added in parentheses immediately following the Biotin, 0.3 milligram:

Vitamin C .....	Ascorbic acid
Folic acid .....	Folacin
Riboflavin .....	Vitamin B <sub>2</sub>
Thiamine .....	Vitamin B <sub>1</sub>

If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food the total amount of such nutrient in the final food product is subject to Class II requirements unless the same nutrient is also added.

(4) A food with a label declaration of a vitamin, mineral, or protein shall be deemed to be mis-branded under the first phrase under food of M.G.L. c. 94, § 187 unless it meets the following requirements:

(a) Class I vitamin, mineral, or protein. The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(b) Class II vitamin, mineral, or protein. The nutrient content of the composite is at least equal to 80% of the value for that nutrient declared on the label.

*Provided*, that no regulatory action will be based on a determination of a nutrient value which falls below this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(5) A food with a label declaration of calories, carbohydrates or fat shall be deemed to be mis-branded under the first phrase under food of M.G.L. c. 94, § 187 unless the nutrient content of the composite is no greater than 20% in excess of the value for that nutrient declared on the label.

(6) Reasonable excesses of a vitamin, mineral, or protein over labeled amounts are acceptable within good manufacturing practices. Reasonable deficiencies of calories or fat under labeled amounts are acceptable within good manufacturing practices.

(F) Nutrition information provided by a manufacturer or distributor directly to professionals (*e.g.*, physicians, dietitians, educators) may vary from the requirements of 105 CMR 520.109 but shall also contain or have attached to it the nutrition information exactly as required by 105 CMR 520.109

(G) The location of nutrition information on a label shall be in compliance with 105 CMR 520.102.

(H) The following foods are exempt from 105 CMR 520.109, or are subject to special labeling requirements:

(1) (a) Except where expressly covered by 21 CFR 105.65, infant, baby, and junior-type

food promoted for infants and children under four years of age shall include nutrition information on the label and in labeling in compliance with 105 CMR 520.109, except that the U.S. Recommended Daily Allowance (U.S. RDA) levels for infants from birth to 12 months of age or for children under four years of age contained in 21 CFR 105.3(b) shall be used in lieu of the U.S. RDA levels contained in 105 CMR 520.109(C)(7)(d).

(b) Both the U.S. RDA levels for infants from birth to 12 months of age and the U.S. RDA values for children under four years of age may be declared for foods represented or intended for use by both infants and children under four years of age. If such dual declaration is used on any label, it shall also be included in all labeling, and equal prominence shall be given to both values in all promotional material.

(c) For the purposes of labeling these foods with a percent of the U.S. RDA for protein for infants, a value of 18 grams of protein shall be the U.S. RDA value for protein with a protein efficiency ratio (PER) equal to or greater than casein, and 25 grams if the PER of the protein is less than the PER of casein but greater than 40% of casein. For purposes of labeling foods for children under four years of age with a percent of the U.S. RDA for protein, a value of 20 grams of protein shall be the U.S. RDA value for protein with a PER equal to or greater than casein, and 28 grams if the PER of the protein is less than the PER of casein but greater than 20% of casein.

(d) Total protein with a PER less than 40% of the PER of casein may not be stated on the label in terms of percentage U.S. RDA for infants, and the statement of protein content in grams per serving under 105 CMR 520.109(C)(4) shall be modified by the statement "not a significant source of protein for infants" immediately adjacent to the protein content statement regardless of the actual amount of protein present.

(2) Dietary supplements, the nutrients of which consist solely of vitamins and/or minerals, shall be labeled in compliance with 21 CFR 105.85 and 21 CFR 105.77, except that the labeling of a dietary supplement in food form, *e.g.*, a breakfast cereal, shall conform to the labeling established in 105 CMR 520.109(C), including the order for listing vitamins and minerals established in 105 CMR 520.109(C)(7)(d) in lieu of the labeling established in 21 CFR 105.85(i)(1).

(3) Any food represented for use as the sole item of the diet shall be labeled in compliance with 21 CFR Part 105.

(4) Food represented for use solely under medical supervision to meet



nutritional requirements in specific medical conditions shall be labeled in compliance with 21 CFR Part 105.

(5) Iodized salt shall be labeled in compliance with 21 CFR 100.155 and when used in a food does not subject that food to labeling under 105 CMR 520.109 if it is declared in the ingredient statement by its name (iodized salt) and neither iodine nor iodized salt is otherwise referred to on the label or in labeling or in advertising.

(6) A nutrient(s) included in food solely for technological purposes may be declared solely in the ingredient statement, without complying with 105 CMR 520.109, if the nutrient(s) is otherwise not referred to on the label or in labeling or in advertising.

(7) A standardized food containing an added nutrient(s) *e.g.*, enriched flour, and included in another food as a component may be declared in the ingredient statement by its standardized name, without compliance with 105 CMR 520.109, if neither the nutrient(s) nor the component is otherwise referred to on the label or in labeling or in advertising.

(8) Food products shipped in bulk form for use solely in the manufacture of other foods and not for distribution to consumers in such bulk form or container.

(9) Food products containing an added vitamin, mineral, or protein, or for which a nutritional claim is made on the label or in labeling or in advertising, which are supplied for institutional food service use only: *Provided, that* the manufacturer or distributor provides the nutrition information required by 105 CMR 520.109 directly to those institutions on a current basis.

(10) Fresh fruits and fresh vegetables, pending promulgation of specific labeling requirements for these products.

(I) A food labeled under the provisions of 105 CMR 520.109, shall be deemed to be mis-branded under M.G.L. c. 94, § 187 if its labeling represents, suggests, or implies:

(1) That the food because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom.

(2) That a balanced diet of ordinary foods cannot supply adequate amount of nutrients.

(3) That the lack of optimum nutritive quality of a food, by reason of the soil on which that food was grown, is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(4) That the storage, transportation, processing, or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(5) That the food has dietary properties when such properties are of no significant value or need in human nutrition. Ingredients or products such as rutin, other bioflavonoids, para-amino-benzoic acid, inositol, and similar substances which have in the past been represented as having nutritional properties but which have not been shown to be essential in human nutrition may not be combined with vitamins and/or minerals, added to food label in accordance with 105 CMR 520.109, or otherwise used or represented in any way which states or implies nutritional benefit. Ingredients or products of this type may be marketed as individual products or mixtures thereof: *Provided, that* the possibility of nutritional, dietary, or therapeutic value is not stated or implied

(e.g., their labeling does not state that their usefulness in human nutrition has not been established and does not otherwise disclaim nutritional, dietary, or therapeutic value).

(6) That a natural vitamin in a food is superior to an added or synthetic vitamin, or to differentiate in any way between vitamins naturally present from those added.

520.115: Food; Labeling; Prominence of Required Statements

(A) A word, statement, or other information required by or under authority of M.G.L. c. 94 to appear on the label may lack that prominence and conspicuousness required by M.G.L. c. 94, § 187 paragraph 7, under food, by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part of panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of M.G.L. c. 94 to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(B) No exemption depending on insufficiency of label space, as prescribed by M.G.L. c. 94, § 187 paragraphs 6 and 11 under food or regulations promulgated pursuant thereto, shall apply if such insufficiency is caused by:

(1) The use of label space for any word, statement, design, or device which is not required by or under authority of M.G.L. c. 94 to appear on the label;

(2) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by M.G.L. c. 94, § 187, 7th paragraph under food of: or

(3) The use of label space for any representation in a foreign language.

(C) (1) All words, statements, and other information required by or under authority of

M.G.L. c. 94 to appear on the label or labeling shall appear thereon in the English language: *provided, however, that* in the case of articles distributed

solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of M.G.L. c. 94 to appear on the label shall appear thereon in the foreign language: *provided, however, that* individual serving-size packages of foods containing no more than 1½ *avoirdupois* ounces or no more than 1½ fluid ounces served with meals in restaurants, institutions, and passenger carriers and not intended for sale at retail are exempt from the requirements of 105 CMR 520.115(C)(2), if the only representation in the foreign language(s) is the name of the food.

(3) If any article of labeling (other than a label) contains any representation in a foreign language, all words, statements, and other information required by or under authority of M.G.L. c. 94 to appear on the label or labeling shall appear on such article of labeling.

#### 520.116: Food; Natural and Organic Labeling

(A) For the purposes of 105 CMR 520.116, the following words shall have the following meanings:

(1) Distribution or sale, includes traffic, trade, transportation, display for sale, offer for sale, deliver for sale, intent to sell, or sell.

(2) "Natural food" means food which in its processing has not been treated with preservatives, antibiotics, synthetic additives, artificial flavoring, artificial coloring, or has been processed in such a manner so that it become significantly less nutritive. Natural foods may only be processed by extracting, purifying, heating, fermenting, concentrating, dehydrating, cooling, or freezing.

(3) "Organically grown food", means natural food which has not been subjected to pesticides or artificial fertilizers, hormones, or antibiotics.

(B) Every person whose business predominantly consists of the retail sale of food products which are represented on the label, or in labeling, or in advertising as being "organic," "organically grown," or "natural," or similarly represented, shall register with the Director, his name, address, and the addresses of all establishments operated or owned by him which also predominantly sell or offer for retail sale such products. Registration shall expire one year from the date of issuance. Each registration shall be accompanied by sufficient evidence and information to assure the Director that such food distributed or sold by that person complies with the above definitions.

(C) (1) No person may advertise, distribute or sell a food or food supplement as "organic,"

"organically grown," "natural," or with words of similar meaning, unless such food complies with the above definitions.

(2) The advertisement, distribution or sale of a food as "organic," "organically grown," "natural," or with words of similar meaning in violation of 105 CMR 520.116, or by a person required to register under 105 CMR 520.116(B) who has not so registered, is prohibited. All foods advertised, distributed or sold not in conformance with 105 CMR 520.116 shall be deemed to be mis-branded under

M.G.L. c. 94, § 187.

- (D) The following foods are exempt from 105 CMR 520.116:  
Cheese.

520.118: Food Labeling; Misbranding

(A) Among representations in the labeling of a food which render such food mis-branded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.

(B) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(C) Among representations in the labeling of a food which render such food mis-branded is any representation that expresses or implies a geographical origin of the food or any ingredient of the food except when such representation is either:

- (1) A truthful representation of geographical origin.
- (2) A trademark or trade name provided that as applied to the article in question its use is not deceptively mis-descriptive. A trademark or trade name comprised in whole or in part of geographical words shall not be considered deceptively mis-descriptive if it:
  - (a) Has been so long and exclusively used by a manufacturer or distributor that it is generally understood by the consumer to mean the product of a particular manufacturer or distributor; or
  - (b) Is so arbitrary or fanciful that it is not generally understood by the consumer to suggest geographic origin.
- (3) A part of the name required by applicable law or regulation.
- (4) A name whose market significance is generally understood by the consumer to connote a particular class, kind, type, or style of food rather than to indicate geographical origin.

520.119: Food, Open Date Labeling

(A) Purpose. The purpose of 105 CMR 520.101 through 520.205 is to cause certain food products offered for sale in the Commonwealth of Massachusetts to be identified relative to physical sensory qualities for the information of consumers, distributors, and retailers.

(B) Scope. 105 CMR 520.101 through 520.205 prescribe the method of posting an identification date, date determination, required records, responsible persons and foods subject to 105 CMR 520.119, In addition, 105 CMR 520.101 through 520.205 provide for exemption of certain foods and for sale of foods, under stipulated conditions, after the expiration of an identifying open date.

(C) Definitions. For purposes of 105 CMR 520.101 through 520.205, the following

definitions shall be applicable:

Best If Used by Date: A date no later than the expiration of the estimated shelf life of a food product.

Frozen Food: A food product which has been packaged and preserved by freezing.

Long Shelf-Life Food: A food product having an estimated shelf life of 90 days or more, including foods preserved by dehydration or packaged in a hermetically sealed container, but excluding frozen foods.

Perishable Food: A food product having an estimated shelf life of 60 days or less.

Person: An individual, partnership, association, or corporation.

Prepackaged: Packaged prior to being displayed or offered for sale at retail.

Sell by Date: A recommended last date of retail sale of a food product which provides for a reasonable subsequent period of home shelf life.

Semi-Perishable Food: A food product having an estimated shelf life greater than 60 days but less than 90 days.

Shelf Life: A period of time after the date of packaging during which a food product has no significant risk of spoilage, loss of value, or loss of palatability, given compliance with recommended conditions of storage and handling as disclosed on the label of such product.

(D) Open Dating of Perishable and Semi-Perishable Food Products. No person shall sell, offer for sale, or have in his possession with intent to sell, prepackaged perishable or semi-perishable food products unless they are identified with a "sell-by-date" or a "best if used by date" determined by the manufacturer, processor, packer, repacker, retailer, or other person who had packaged such food products and displayed in the form specified in 105 CMR 520.119(G).

(E) Open Dating of Frozen and Long Shelf Life Food Products. A manufacturer, processor, packer, repacker, retailer, or other person who prepackages frozen or long shelf life food products may mark the individual retail packages of such products with a "sell by date" or "best if used by date," but shall be subject to the requirements as to form outlined in 105 CMR 520.119(G).

(F) Sale of Past Date Food Products. No person shall offer for sale in the Commonwealth any food product after the expiration of a "sell by date" or a "best if used by date" unless:

- (1) It is wholesome and its sensory physical qualities have not significantly diminished; and,
- (2) It is segregated from food products which are not "past date"; and,
- (3) It is clearly and conspicuously marked either on the package or through the use of shelf markers or place cards, as being offered for sale after the recommended last date of sale or best use.

(G) (1) Placement of the Date. A date shall be displayed with the term "sell by" or "best if used by" in reasonable proximity to the designated date.

- (2) Such a date shall consist of the common abbreviation for the calendar month and numerals for the day and year, *e.g.*, Feb. 10, 1980; or numerals for the month, day and year, *e.g.*, 2/10/80, except that:

(a) Perishable food products need not have the year identification included in the date, and frozen and long shelf life foods need not have the day identification included in the date.

(b) Fresh bakery products may be dated with only the day designation, e.g., Monday, or an abbreviation thereof, e.g., Mon.

(3) A date shall be accompanied by disclosure of recommended product storage conditions, if such conditions significantly affect the validity of such a date.

(4) A date and any recommended storage conditions shall be printed, stamped, embossed, perforated, or otherwise shown on the retail package, a label on such package, or a tag attached to such package in a manner that is easily readable and separate from other information, graphics, or lettering so as to be clearly visible to a prospective purchaser.

(5) If a date and recommended storage conditions do not appear on the principal display panel, the information panel, or on another conspicuous portion of the individual retail package, a statement must appear on the principal display or information panel indicating where such information can be found elsewhere on the package.

(6) An individual prepackaged food product which is not labeled in accordance with the provisions of 105 CMR 520.119 shall be deemed "mis-branded" pursuant to M.G.L. c. 94, § 187.

(H) Product Rotation, Storage and Handling Information. Any person who prepackages a food product for sale in the Commonwealth shall disclose to the retailer of such product;

(1) Whether or not such product is open dated.

(2) Any required or recommended storage and handling conditions.

(3) Information to facilitate the sequential rotation of product inventory.

Information shall be conveyed in a readily understandable form.

(I) (1) Factors for Shelf-Life Determination. A person who is responsible for placing a "sell by date" or a "best if used by date" on a food product as required or permitted by these regulations, shall estimate the shelf life of such a product, taking into consideration the quality, characteristics, formulation, processing impact, packaging or container and other protective wrapping or coating, typical transportation and storage and display conditions of such a food product.

(2) Considerations should also include those of the retail store and consumer; and for purposes of estimating shelf life, home storage conditions shall be considered similar to the usual retail store, except that refrigerated food may be calculated using a home temperature storage standard of 40¼°F or 4.4¼°C.

(3) Such factors shall be measured or otherwise determined utilizing testing and sampling procedures customarily utilized by the food industry for such purposes.

(J) (1) Required Records. A person responsible for estimating the shelf life of a food product shall keep a record of the method used for the determination of such shelf life and the corresponding "sell by date" or "best if used by date." A record revision is necessary whenever a factor affecting such date determination is altered. Such record shall be retained for not less than six months after the most recent "last date of sale" or "best if used by date" and be available upon written request by the Department.

(2) If, after conducting an investigation, the Department determines that the date selected is not supported by such records, it may direct the responsible person to change the date in accordance with such findings. Any person aggrieved by such an order shall be afforded the opportunity for hearing; but the order shall not be overturned unless the appellant establishes by clear and convincing evidence that the date originally selected is, in fact, justifiable. The order shall be considered final unless reversed upon such review; and pending review, the affected product may not be offered for sale, unless the date is modified in accordance with the order of the Department.

- (K) (1) Exemptions. 105 CMR 520.101 through 520.205 do not apply to:
- (a) Fresh meat, fresh poultry, fresh fish, fresh fruits, and fresh vegetables offered for sale unpackaged or in a container permitting sensory examination.
  - (b) Salt and crystallized refined sugar.
  - (c) Food products shipped in bulk form for use solely in the manufacture of other foods and not for distribution to the consumer in such bulk form or container.
  - (d) Individually packaged food products which are prepackaged as components of a larger food item, if the larger food item is identified with a date no later than the corresponding date for any such components.
  - (e) Food products prepackaged for retail sale with a net weight of less than 1½ ounces.
  - (f) Food products manufactured for sale outside the Commonwealth, processed for sale outside the Commonwealth, or stored for sale outside the Commonwealth.
- (2) Any person may apply to the Department for an exemption from the provisions of 105 CMR 520.000, which exemption shall be granted if the product for which the exemption is sought:
- (a) Is open dated in accordance with the regulations of another agency; and, compliance with the regulations of the other agency will result in the disclosure of substantially the same information as is required by 105 CMR 520.000; or,
  - (b) Has been voluntarily open dated prior to the promulgation of 105 CMR 520.000 in a manner which will result in the disclosure of substantially the same information as is required by 105 CMR 520.000.

- (L) Effective Dates. Notwithstanding any other effective dates set forth in 520.119(L) shall take effect in accordance with the following schedule:
- (1) For perishable foods, 105 CMR 520.119(C), the effective date shall be the date on which 105 CMR 520.000 are published March 12, 1981.
  - (2) For semi-perishable foods, 105 CMR 520.119(C), effective date shall be May 1, 1982.
  - (3) For frozen foods, 105 CMR 520.119(C), the effective date shall be December 1, 1981.
  - (4) For long shelf life foods, 105 CMR 520.119(C), the effective date shall be May 1, 1982.

(A) (1) The term artificial flavor or artificial flavoring means any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof. Artificial flavor includes the substances listed in 21 CFR 182.60 and 21 CFR 172.515(b) except where these are derived from natural sources.

(2) The term spice means any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, such as onions, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in 21 CFR 182.10, 182.20, 182.30, 182.40, 182.50, such as the following;

Allspice

Anise

Basil

Bay

Caraway Seed

Cardamom

Celery Seed

Chervil

Cinnamon

Cloves

Coriander

Cumin Seed

Dill seed

Fennel seed

Fenugreek

Ginger

Horseradish

Mace

Marjoram

Mustard flour

Nutmeg

Oregano

Paprika

Parsley

Pepper, red

Pepper, black

Pepper, white

Rosemary

Saffron

Sage

Savory

Star aniseed

Tarragon



Thyme

Turmeric

Paprika, turmeric, and saffron are also colors which shall be declared as "spice and coloring" unless declared by their common or usual name.

(3) The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit, or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in 21 CFR 182.10, 182.20, 182.30, 182.40, 132.50, and the substances listed in 21 CFR 172.510.

(4) The term artificial color or artificial coloring means any "color additive" as defined in 21 CFR 70.3(f).

(5) The term chemical preservative means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties.

(B) A food which is subject to the requirements of M.G.L. c. 94, § 187 paragraph 13 under food, shall bear labeling, even though such food is not in package form.

(C) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food, or on its container or wrapper, or on any two or all of these, as may be necessary to render such statement likely to be read by the ordinary individual under customary conditions of purchase and use of such food.

(D) A food shall be exempt from compliance with the requirements of M.G.L. c. 94, § 187 paragraph 13 under food if it is not in package form and the units thereof are so small that a statement of artificial flavoring, artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

(E) A food shall be exempt while held for sale from the requirements of M.G.L. c. 94, § 187 paragraph 13 under food (requiring label statement of any artificial flavoring, artificial coloring, or chemical preservatives) if said food, having been received in bulk containers at a retail establishment, is displayed to the purchaser with either

- (1) the labeling of the bulk container plainly in view or
- (2) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to M.G.L. c. 94, § 187 paragraph 13.

(F) A fruit or vegetable shall be exempt from compliance with the requirements of M.G.L. c. 94, § 187 paragraph 13 under food with respect of a chemical preservative applied to the fruit or vegetable as a pesticide chemical prior to harvest.

(G) A flavor shall be labeled in the following way when shipped to a food manufacturer or processor (but not a consumer) for use in the manufacture of a fabricated food, unless it is a flavor for which a standard of identity has been promulgated, in which case it shall be labeled as provided in the standard:

(1) If the flavor consists of one ingredient, it shall be declared by its common or usual name.

(2) If the flavor consists of two or more ingredients the label either may declare each ingredient by its common or usual name or may state "All flavor ingredients contained in this product are approved for use in a regulation of the Food and Drug Administration." Any flavor ingredient not contained in one of 105 CMR 520.000, and any non-flavor ingredient, shall be separately listed on the label.

(3) In cases where the flavor contains a solely natural flavor(s), the flavor shall be so labeled, *e.g.*, "strawberry flavor," "banana flavor," or "natural strawberry flavor." In cases where the flavor contains both a natural flavor and an artificial flavor, the flavor shall be so labeled, *e.g.*, "natural and artificial strawberry flavor." In cases where the flavor contains a solely artificial flavor(s), the flavor shall be so labeled, *e.g.*, "artificial strawberry flavor."

(H) The label of a food to which flavor is added shall declare the flavor in the statement of ingredients in the following way;

(1) Spice, natural flavor, and artificial flavor may be declared as "spice," "natural flavor," or "artificial flavor," or any combination thereof, as the case may be.

(2) An incidental additive in a food, originating in a spice or flavor used in the manufacture of the food, need not be declared in the statement of ingredients if it meets the requirements of 105 CMR 520.200(A)(3).

(3) Substances obtained by cutting, grinding, drying, pulping, or similar processing of tissues derived from fruit, vegetable, meat, fish, or poultry, *e.g.*, powdered or granulated onions, garlic powder, and celery powder, are commonly understood by consumers to be food rather than flavor and shall be declared by their common or usual name.

(4) Any salt (sodium chloride) used as an ingredient in food shall be declared by its common or usual name "salt."

(5) Any monosodium glutamate used as an ingredient in food shall be declared by its common or usual name "monosodium glutamate."

(6) Any pyroligneous acid or other artificial smoke flavors used as an ingredient in a food may be declared as artificial flavor or artificial smoke flavor. No representation may be made, either directly or implied, that a food flavored with pyroligneous acid or other artificial smoke flavor has been smoked or has a true smoked flavor, or that a seasoning sauce or similar product containing pyroligneous acid or other artificial smoke flavor and used to season or flavor other foods will result in a smoked product or one having a true smoked flavor.

(I) If the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, vignette, *e.g.*, depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than

through the statement of ingredients, such flavor shall be considered the characterizing flavor and shall be declared in the following way:

(1) If the food contains no artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, *e.g.*, "vanilla", in letters not less than ½ the height of the letters used in the name of the food, except that:

(a) If the food is one that is commonly expected to contain a characterizing food ingredient, *e.g.*, strawberries in "strawberry shortcake", and the food contains natural flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food, or the food contains no such ingredient, the name of the characterizing flavor may be immediately preceded by the word "natural" and shall be immediately followed by the word "flavored" in letters not less than ½ the height of the letters in the name of the characterizing flavor, *e.g.*, "natural strawberry flavored shortcake," or "strawberry flavored shortcake".

(b) If none of the natural flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as "artificially flavored."

(c) If the food contains both a characterizing flavor from the product whose flavor is simulated and other natural flavor which simulates, resembles or reinforces the characterizing flavor, the food shall be labeled in accordance with the provisions of 105 CMR 520.122(I)(1)(a) and the name of the food shall be immediately followed by the words "with other natural flavor" in letters not less than ½ the height of the letters used in the name of the characterizing flavor.

(2) If the food contains any artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name(s) of the characterizing flavor, in letters not less than ½ the height of the letters used in the name of the food and the name of the characterizing flavor shall be accompanied by the word(s) "artificial" or "artificially flavored," in letters not less than ½ the height of the letters in the name of the characterizing flavor, *e.g.*, "artificial vanilla," "artificially flavored strawberry", or "grape artificially flavored".

(3) Wherever the name of the characterizing flavor appears on the label (other than in the statement of ingredients) so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by 105 CMR 520.122(I) shall immediately and conspicuously precede or follow such name, without any intervening written, printed, or graphic matter, except:

(a) Where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor; and

(b) If the finished product contains more than one flavor subject to the requirements of 105 CMR 520.122(I), the statements required by 105 CMR 520.122(I) need appear only once in each statement of characterizing flavors

present in such food, *e.g.*, "artificially flavored vanilla and strawberry."

(c) If the finished product contains three or more distinguishable characterizing flavors, or a blend of flavors with no primary recognizable flavor, the flavor may be declared by an appropriately descriptive generic term in lieu of naming each flavor, *e.g.*, "artificially flavored fruit punch."

(J) A food to which a chemical preservative(s) is added shall, except when exempt pursuant to 105 CMR 520.200 bear a label declaration stating both the common or usual name of the ingredient(s) and a separate description of its function, *e.g.*, "preservative," "to retard spoilage," "a mold inhibitor," "to help protect flavor" or "to promote color retention."

#### 520.200: Food Labeling; Exemptions from Labeling Requirements

(A) The following foods are exempt from compliance with the requirements of M.G.L. c. 94, § 187 paragraph 11, phrase 2 under food (requiring a declaration on the label of the common or usual name of each ingredient when the food is fabricated from two or more ingredients).

(1) An assortment of different items of food, when variations in the items that make up different packages packed from such assortment normally occur in good packing practice and when such variations result in variations in the ingredients in different packages, with respect to any ingredient that is not common to all packages. Such exemption, however, shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement (in terms that are as informative as practicable and that are not misleading) indicating by name other ingredients which may be present.

(2) A food having been received in bulk containers at a retail establishment, if displayed to the purchaser with either

(a) the labeling of the bulk container plainly in view or

(b) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to M.G.L. c. 94, § 187 paragraph II, phrase 2 under food.

(3) Incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. For the purposes of 105 CMR 520.200(A)(3), incidental additives are:

(a) Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.

(b) Processing aids, which are as follows:

1. Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.

2. Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food.

3. Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at

insignificant levels and do not have any technical or functional effect in that food.

(c) Substances migrating to food from equipment or packaging or otherwise affecting food that are not food additives or if they are food additives, they are used in conformity with regulations established pursuant to section 409 of the Federal Food, Drug and Cosmetic Act.

(B) A food repackaged in a retail establishment is exempt from the following provisions of the act, if the conditions specified are met.

(1) M.G.L. c. 94, § 187, sixth paragraph, phrase 1 under food (requiring a statement on the label of the name and place of business of the manufacturer, packer, or distributor).

(2) Reserved.

(3) M.G.L. c. 94, § 187, eleventh paragraph, phrase 1 under food, in (requiring the label to bear the common or usual name of the food), if the food is displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the common or usual name of the food, or if the common or usual name of the food is clearly revealed by its appearance.

(C) An open container (a container of rigid or semi-rigid construction, which is not closed by lid, wrapper, or otherwise other than by an uncolored transparent wrapper which does not obscure the contents) of a fresh fruit or fresh vegetable, the quantity of contents of which is not more than one dry quart, shall be exempt from the labeling requirements of M.G.L. c. 94, § 187, sixth paragraph under food of and M.G.L. c. 94, § 187, eleventh paragraph, phrase 1 under food of ; but such exemption shall be on the condition that if two or more such containers are enclosed in a crate or other shipping package, such crate or package shall bear labeling showing the number of such containers enclosed therein and the quantity of the contents of each.

(D) Except as provided by 105 CMR 520.200(E) and 520.200(F), a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of M.G.L. c. 94, § 187, paragraphs 3, 6, 8, 9, 10, 11, 12, and 13 under food if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such food is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such food in such establishment as will insure, if such specifications are followed, that such food will not be adulterated or mis-branded within the meaning of M.G.L. c. 94 upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such

agreement until two years after the final shipment or delivery of such food from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Division who requests them.

(3) The article is an egg product subject to a standard of identity promulgated in 21 CFR 160, is to be shipped under the conditions specified in 105 CMR 520.200(D)(1) and 520.200(D)(2) and for the purpose of pasteurization or other treatment as required in such standard, and each container of such egg product bears a conspicuous tag or label reading "Caution -- This egg product has not been pasteurized or otherwise treated to destroy viable Salmonella micro-organisms." In addition to safe and suitable bactericidal processes designed specifically for Salmonella destruction in egg products, the term "other treatment" in the first sentence of 105 CMR 520.200(D)(3) shall include use in acidic dressings in the processing of which the pH is not above 4.1 and the acidity of the aqueous phase, expressed as acetic acid, is not less than 1.4%, subject also to the conditions that:

(a) The agreement required in 105 CMR 520.200(D)(2) shall also state that the operator agrees to utilize such unpasteurized egg products in the processing of acidic dressings according to the specifications of pH and acidity set forth in 105 CMR 520.200(D), agrees not to deliver the acidic dressing to a user until at least 72 hours after such egg product is incorporated in such acidic dressing, and agrees to maintain for inspection adequate records covering such processing for two years after such processing.

(b) In addition to the caution statement referred to above, the container of such egg product shall also bear the statement "Unpasteurized - - - for use in acidic dressings only," the blank being filled in with the applicable name of the eggs or egg product.

(E) Conditions affecting expiration of exemptions.

(1) An exemption of a shipment or other delivery of a food under 105 CMR 520.200(D)(1) or 520.200(D)(3) shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment become void *ab initio* if the food comprising such shipment, delivery, or part is adulterated or mis-branded within the meaning of M.G.L. c. 94 when so removed.

(2) An exemption of a shipment or other delivery of a food under 105 CMR 520.200(D)(2) or 520.200(D)(3) shall become void *ab initio* with respect to the person who introduced such shipment or delivery into commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by 105 CMR 520.220(D)(2) or 520.200(D)(3).

(3) An exemption of a shipment or other delivery of a food under 105 CMR 520.200(D)(2) or 520.200(D)(3) shall expire:

(a) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the food comprising such shipment, delivery, or part is adulterated or mis-branded within the meaning of M.G.L. c. 94 when so removed; or

(b) Upon refusal by the operator of the establishment where such food is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such paragraph.

(F) The word "processed" as used in 105 CMR 520.200(F) shall include the holding of cheese in a suitable warehouse at a temperature of not less than 35°F. for the purpose of aging or curing to bring the cheese into compliance with requirements of an applicable definition and standard of identity. The exemptions provided for in 105 CMR 520.200(D) shall apply to cheese which is, in accordance with the practice of the trade, shipped to a warehouse for aging or curing, on condition that the cheese is identified in the manner set forth in one of the applicable following paragraphs, and in such case the provisions of 105 CMR 520.200(E) shall also apply:

(1) In the case of varieties of cheese for which definitions and standards of identity require a period of aging whether or not they are made from pasteurized milk, each such cheese shall bear on the cheese a legible mark showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each cheese, on its wrapper or immediate container, shall be affixed a removable tag bearing the statement "Uncured - - - cheese for completion of curing and proper labeling," the blank being filled in with the applicable name of the variety of cheese. In the case of swiss cheese, the date at which the preliminary manufacturing process had been completed and at which date curing commences is the date on which the shaped curd is removed from immersion in saturated salt solution as provided in the definition and standard of identity for swiss cheese, and such cheese shall bear a removable tag reading, "To be cured and labeled as 'swiss cheese,' but if eyes do not form to be labeled as 'swiss cheese for manufacturing.' "

(2) In the case of varieties of cheeses which when made from unpasteurized milk are required to be aged for not less than 60 days, each such cheese shall bear a legible mark on the cheese showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each such cheese or its wrapper or immediate container shall be affixed a removable tag reading, " - - - cheese made from unpasteurized milk. For completion of curing and proper labeling," the blank being filled in with the applicable name of the variety of cheese.

(3) In the case of cheddar cheese, washed curd cheese, colby cheese, granular cheese, and brick cheese made from unpasteurized milk, each such cheese shall bear a legible mark on the cheese showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each such cheese or its wrapper or immediate container shall be affixed a removable tag reading " - - - cheese made from unpasteurized milk. For completion of curing and proper labeling, or for labeling as - - - cheese for manufacturing," the blank being filled in with the applicable name of the variety of cheese.

(G) The label declaration of a harmless marker used to identify a particular manufacturer's product may result in unfair competition through revealing a trade secret. Exemption from the label declaration of such a marker is granted, therefore, provided that the following conditions are met:

(1) The person desiring to use the marker without label declaration of its presence has submitted to the Director full information concerning the proposed usage and the reasons why he believes label declaration of the marker should be subject to this exemption; and

(2) The person requesting the exemption has received from the Director a finding that the marker is harmless and that the exemption has been granted.

(H) Wrapped fish fillets of non-uniform weight intended to be unpacked and marked with the correct weight at or before the point of retail sale in an establishment other than that where originally packed shall be exempt from the requirement of M.G.L. c. 94, § 187 paragraph 6, clause 2, under food during introduction and movement in commerce and while held for sale prior to weighing and marking:

(1) Provided, that:

(a) The outside container bears a label declaration of the total net weight; and

(b) The individual packages bear a conspicuous statement "To be weighed at or before time of sale" and a correct statement setting forth the weight of the wrapper; *and*

(2) Provided further, that it is the practice of the retail establishment to weigh and mark the individual packages with a correct net-weight statement prior to or at the point of retail sale. A statement of the weight of the wrapper shall be set forth so as to be readily read and understood, using such term as "wrapper tare - - - ounce," the blank being filled in with the correct average weight of the wrapper used.

(3) The act of delivering the wrapped fish fillets during the retail sale without the correct net-weight statement shall be deemed an act which results in the product's being mis-branded while held for sale. Nothing in 105 CMR 520.200(H) shall be construed as requiring net-weight statements for wrapped fish fillets delivered into institutional trade provided the outside container bears the required information.

(I) Wrapped clusters (consumer units) of bananas of non-uniform weight intended to be unpacked from a master carton or container and weighed at or before the point of retail sale in an establishment other than that where originally packed shall be exempt from the requirements of M.G.L. c. 94, § 187, sixth paragraph, clause 2, under food during introduction and movement in commerce and while held for sale prior to weighing:

(1) *Provided*, that:

(a) The master carton or container bears a label declaration of the total net weight; and

(b) The individual packages bear a conspicuous statement "To be weighed at or before the time of sale" and a correct statement setting forth the weight of the wrapper; using such term as "wrapper tare - - - ounce," the blank being filled in with the correct average weight of the wrapper used;

(2) *And provided, further*, that it is the practice of the retail establishment to weigh the individual packages either prior to or at the time of retail sale.

(3) The act of delivering the wrapped clusters (consumer units) during the retail sale without an accurate net weight statement or alternatively without weighing at the time of sale shall be deemed an act which results in the product's being mis-branded while held for sale. Nothing in 105 CMR 520.200(I) shall be construed as requiring net-weight statements for clusters (consumer units) delivered into institutional trade, provided that the master container or carton



bears the required information.

520.205: Food Labeling; Declaration of Net Quantity of Contents; When Exempt

(A) The principal display panel of a food in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The statement shall be in terms of fluid measure if the food is liquid, or in terms of weight if the food is solid, semi-solid, or viscous, or a mixture of solid and liquid; except that such statement may be in terms of dry measure if the food is a fresh fruit, fresh vegetable, or other dry commodity that is customarily sold by dry measure. If there is a firmly established general consumer usage and trade custom of declaring the contents of a liquid by weight, or a solid, semi-solid, or viscous product by fluid measure, it may be used. Whenever the Director determines that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination on the case of a specific packaged food does not facilitate value comparisons by consumers and offers opportunity for consumer confusion, he will by regulation designate the appropriate term or terms to be used for such commodity.

- (B) (1) Statements of weight shall be in terms of avoirdupois pound and ounce.  
(2) Statements of fluid measure shall be in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof, and shall:
- (a) In the case of frozen food that is sold and consumed in a frozen state, express the volume at the frozen temperature.
  - (b) In the case of refrigerated food that is sold in the refrigerated state, express the volume at 40°F. (4°C.).
  - (c) In the case of other foods, express the volume at 68°F. (20°C.).
- (3) Statements of dry measure shall be in terms of the U.S. bushel of 2,150.42 cubic inches and peck, dry quart, and dry pint subdivisions thereof.

(C) When the declaration of quantity of contents by numerical count does not give adequate information as to the quantity of food in the package, it shall be combined with such statement of weight, measure, or size of the individual units of the foods as will provide such information.

(D) The declaration may contain common or decimal fractions. A common fraction shall be in terms of halves, quarters, eighths, sixteenths, or thirty-seconds; except that if there exists a firmly established general consumer usage and trade custom of employing different common fractions in the net quantity declaration of a particular commodity, they may be employed. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places. A statement that includes small fractions of an ounce shall be deemed to permit smaller variations than one which does not include such fractions.

(E) The declaration shall be located on the principal display panel of the label, and with respect to packages bearing alternate principal panels it shall be duplicated on each principal display panel.

(F) The declaration shall appear as a distinct item on the principal display panel, shall be separated (by at least a space equal to the height of the lettering used in the declaration) from other printed label information appearing above or below the declaration and (by at least a space equal to twice the width of the letter "N" of the style of type used in the quantity of contents statement) from other printed label information appearing to the left or right of the declaration. It shall not include any term qualifying a unit of weight, measure, or count (such as "jumbo quart" and "full gallon") that tends to exaggerate the amount of the food in the container. It shall be placed on the principal display panel within the bottom 30 percent of the area the label panel in lines generally parallel to the base on which the package rests as it is designed to be displayed: *provided*, that on packages having a principal display panel of five square inches or less, the requirement for placement within the bottom 30% of the area of the label panel shall not apply when the declaration of net quantity of contents meets the other requirements of 105 CMR 520.200 through 520.299.

(G) The declaration shall accurately reveal the quantity of food in the package exclusive of wrappers and other material packed therewith; provided that in the case of foods packed in containers designed to deliver the food under pressure, the declaration shall state the net quantity of the contents that will be expelled when the instructions for use as shown on the container are followed. The propellant is included in the net quantity declaration.

(H) The declaration shall appear in conspicuous and easily legible boldface print or type in distinct contrast (by typography, layout, color, embossing, or molding) to other matter on the package; except that a declaration of net quantity blown, embossed, or molded on a glass or plastic surface is permissible when all label information is so formed on the surface. Requirements of conspicuousness and legibility shall include the specifications that:

- (1) The ratio of height to width (of the letter) shall not exceed a differential of three units to one unit (no more than three times as high as it is wide).
- (2) Letter heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter "o" or its equivalent that shall meet the minimum standards.
- (3) When fractions are used, each component numeral shall meet  $\frac{1}{2}$  the minimum height standards.

(I) The declaration shall be in letters and numerals in a type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type specifications:

- (1) Not less than  $\frac{1}{16}$  inch in height on packages the principal display panel of which has an area of five square inches or less.
- (2) Not less than  $\frac{1}{8}$  inch in height on packages the principal display panel of which has an area of more than five but not more than 25 square inches.
- (3) Not less than  $\frac{3}{16}$  inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches.
- (4) Not less than  $\frac{1}{4}$  inch in height on packages the principle display panel of which has an area of more than 100 square inches, except not less than inch in

height if the area is more than 400 square inches.

Where the declaration is blown, embossed, or molded on a glass or plastic surface rather than by printing, typing, or coloring, the lettering sizes specified in 105 CMR 520.205(I)(1) through 520.205 (I)(4) shall be increased by 1/16 of an inch.

(J) On packages containing less than four pounds or one gallon and labeled in terms of weight or fluid measure:

(1) The declaration shall be expressed both in ounces, with identification by weight or by liquid measure and, if applicable (one pound or one pint or more) followed in parentheses by a declaration in pounds for weight units, with any remainder in terms of ounces or common or decimal fractions of the pound (see examples set forth in 105 CMR 520.205(L)(1) and 520.205(L)(2)), or in the case of liquid measure, in the largest whole units (quarts, quarts and pints, or pints, as appropriate) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (see examples in 105 CMR 520.205(L)(3) and 520.205(L)(4)).

(2) If the net quantity of contents declaration appears on a random package, that is a package which is one of a lot, shipment, or delivery of packages of the same consumer commodity with varying weights and with no fixed weight pattern it may, when the net weight exceeds one pound, be expressed in terms of pounds and decimal fractions of the pound carried out to not more than two decimal places. When the net weight does not exceed one pound, the declaration on the random package may be in decimal fractions of the pound in lieu of ounces (see example in 105 CMR 520.205(L)(5)).

(3) The declaration may appear in more than one line. The term "net weight" shall be used when stating the net quantity of contents in terms of weight. Use of the terms "net" or "net contents" in terms of fluid measure or numerical count is optional. It is sufficient to distinguish *avoirdupois* ounce from fluid ounce through association of terms; for example, "Net wt. 6 oz." or "6 oz. Net wt." and "6 fl. oz." or "Net contents 6 fl. oz.".

(K) On packages containing four pounds or one gallon or more and labeled in terms of weight or fluid measure, the declaration shall be expressed in pounds or weight units with any remainder in terms of ounces or common or decimal fraction of the pound, or in the case of fluid measure, it shall be expressed in the largest whole unit (gallons followed by common or decimal fraction of a gallon or by the next smaller whole unit or units (quarts, or quarts and pints)) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (see 105 CMR 520.205(L)(6)).

(L) Examples:

(1) A declaration of 1½ pounds weight shall be expressed as "Net Wt. 24 oz. (1 lb 8 oz.)," "Net Wt. 24 oz. (1½ lb.)," or "Net Wt. 24 oz. (1.5 lb.)."

(2) A declaration of ¾ pound *avoirdupois* weight shall be expressed as "Net Wt. 12 oz."

(3) A declaration of 1 quart liquid measure shall be expressed as "Net 32 fl. oz. (1 qt.)."

(4) A declaration of 1¾ quarts liquid measure shall be expressed as "Net contents

56 fluid ounces (1 quart 1 pints)" or as "Net 56 fluid oz. (1 qt. 1 pt. 8 oz.)," but not in terms of quart and ounce such as "Net 56 fluid oz. (1 quart 24 ounces)".

(5) On a random package, declaration of  $\frac{3}{4}$  pound avoirdupois may be expressed as "Net Wt.. 75 lb."

(6) A declaration of  $2\frac{1}{2}$  gallons liquid measure shall be expressed as "Net contents  $2\frac{1}{2}$  gallons," "Net contents 2.5 gallons," or "Net contents 2 gallons 2 quarts" and not as "2 gallons 4 pints".

(M) For quantities, the following abbreviations and none other may be employed (periods and plural forms are optional):

weight	wt.	pint	pt.
ounce	oz.	quart	qt.
pound	lb.	fluid	fl.
gallon	gal.		

(N) Nothing in 105 CMR 520.205 shall prohibit supplemental statements at locations other than the principal display panel(s) describing in non-deceptive terms the net quantity of contents; provided, that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the food contained in the package; for example, "jumbo quart" and "full gallon". Dual or combination declarations of net quantity of contents as provided for in 105 CMR 520.205(A), 520.205(C) and 520.205(J) (for example, a combination of net weight plus numerical count, net contents plus dilution directions of a concentrate, etc.) are not regarded as supplemental net quantity statements and may be located on the principal display panel.

(O) A separate statement of the net quantity of contents in terms of the metric system is not regarded as a supplemental statement and an accurate statement of the net quantity of contents in terms of the metric system of weight or measure may also appear on the principal display panel or on other panels.

(P) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large.

(Q) The declaration of net quantity of contents on pickles and pickle products, including relishes but excluding one or two whole pickles in clear plastic bags which may be declared by count, shall be expressed in terms of the U.S. gallon on 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof.

(R) On a multi-unit retail package, a statement of the quantity of contents shall appear on the outside of the package and shall include the number of individual units, the quantity of each individual unit, and, in parentheses, the total quantity of contents of the multi-unit package in terms of avoirdupois or fluid ounces, except that such declaration of total quantity need not be followed by an additional

parenthetical declaration in terms of the largest whole units and subdivisions thereof, as required by 105 CMR 520.205(J)(1). A multi-unit retail package may thus be properly labeled: "6-16 oz. bottles -(96 fl. oz.)" or "3-16 oz. cans - (net wt. 48 oz.)." For the purposes of 105 CMR 520.205, "multi-unit retail package" means a package containing two or more individually packaged units of the identical commodity and in the same quantity, intended to be sold as part of the multi-unit retail package but capable of being individually sold in full compliance with all requirements of the regulations in 105 CMR 520.200 through 520.299. Open multi-unit retail packages that do not obscure the number of units nor prevent examination of the labeling on each of the individual units are not subject to 105 CMR 520.205(R) if the labeling of each individual unit complies with the requirements of 105 CMR 520.205(F) and 520.205(I). The provisions of 105 CMR 520.205 do not apply to that butter or margarine covered by the exemptions in 105 CMR 520.205(A)(10) and 520.205(A)(11).

(S) Where the declaration of net quantity of contents is in terms of net weight and/or drained weight or volume and does not accurately reflect the actual quantity of the contents or the product falls below the applicable standard of fill of container because of equipment malfunction or otherwise unintentional product variation, and the label conforms in all other respects to the requirements of applicable federal and state laws and regulations, the mis-labeled food product may be sold by the manufacturer or processor directly to institutions operated by Federal, State or local governments (schools, prisons, hospitals, etc.): *provided, that:*

(1) The purchaser shall sign a statement at the time of sale stating that he is aware that the product is mis-labeled to include acknowledgment of the nature and extent of the mis-labeling, e.g., "Actual net weight may be as low as ...% below labeled quantity") and that any subsequent distribution by him of said product except for his own institutional use is unlawful. This statement shall be kept on file at the principal place of business of the manufacturer or processor for two years subsequent to the date of shipment of the product and shall be available to the Division of Food and Drugs upon request.

(2) The product shall be labeled on the outside of its shipping container with the statement(s):

(a) When the variation concerns net weight and/or drained weight or volume -- "Product Mis-labeled. Actual net weight (drained weight or volume where appropriate) may be as low as ....% below labeled quantity. This Product Not for Retail Distribution", the blank to be filled in with the maximum percentage variance between the labeled and actual weight or volume of contents of the individual packages in the shipping container, and  
(b) When the variation is in regard to a fill of container standard -- "Product Mis-labeled. Actual fill may be as low as...% below standard of fill. This Product Not for Retail Distribution."

(3) The statements required by 105 CMR 520.205(S)(2)(a) and 520.205(S)(2)(b), which may be consolidated where appropriate, shall appear prominently and conspicuously as compared to other printed matter on the shipping container and in boldface print or type on a clear, contrasting background in order to render them likely to be read and understood by the purchaser under ordinary conditions of purchase.

## 520.305: General Principles

(A) The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or sub-class of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.

(B) The common or usual name of a food shall include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case. The following requirements shall apply unless modified by a specific regulation in 105 CMR 520.326 through 520.357.

(1) The percentage of a characterizing ingredient or component shall be declared on the basis of its quantity in the finished product (*i.e.*, weight/weight in the case of solids, or volume/volume in the case of liquids).

(2) The percentage of a characterizing ingredient or component shall be declared by the words "containing (or contains) --- percent (or %) ---" or "--- percent (or %) ---" with the first blank filled in with the percentage expressed as a whole number not greater than the actual percentage of the ingredient or component named and the second blank filled in with the common or usual name of the ingredient or component. The word "containing" (or "contains"), when used, shall appear on a line immediately below the part of the common or usual name of the food required by 105 CMR 520.305(A). For each characterizing ingredient or component, the words "--- percent (or %) ---" shall appear following or directly below the word "containing" (or "contains"), or directly below the part of the common or usual name of the food required by 105 CMR 520.305(A) when the word "containing" (or "contains") is not used, in easily legible bold-face print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(a) Not less than 1/16 inch in height on packages having a principal display panel with an area of five square inches or less and not less than 1/8 inch in height if the area of the principal display panel is greater than five square inches; or

(b) Not less than 1/2 the height of the largest type appearing in the part of the common or usual name of the food required by 105 CMR 520.305(A).

(C) The common or usual name of a food shall include a statement of the presence or absence of any characterizing ingredient(s) or component(s) and/or the need for the user to add any characterizing ingredient(s) or component(s) when the presence or absence of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food

may otherwise create an erroneous impression that such ingredient(s) or component(s) is present when it is not, and consumers may otherwise be misled about the presence or absence of the ingredient(s) or component(s) in the food. The following requirements shall apply unless modified by a specific regulation in 105 CMR 520.326 through 520.357.

(1) The presence or absence of a characterizing ingredient or component shall be declared by the words "containing (or contains) ---" or "containing (or contains) no ---" or "no---" or does not contain ---," with the blank being filled in with the common or usual name of the ingredient or component.

(2) The need for the user of a food to add any characterizing ingredient(s) or component(s) shall be declared by an appropriate informative statement.

(3) The statement(s) required under 105 CMR 520.305(C)(1) and/ or 520.305(C)(2) shall appear following or directly below the part of the common or usual name of the food required by 105 CMR 520.305(A) and 520.305(B), in easily legible bold face print or type in distinct contrast to other printed or graphic matter and in a height not less than the larger of the alternatives established under 105 CMR 520.305(B)(2)(a) and 520.305(B)(2)(b).

(D) A common or usual name of a food may be established by common usage or by establishment of a regulation in 105 CMR 520.326 through 520.357 in a standard of identity, or in other regulations.

#### 520.319: Petitions

(A) The Director, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish or amend, under 105 CMR 520.326 through 520.357 a regulation prescribing a common or usual name for a food. Any such petition shall include an adequate factual basis to support the petition and will be published for comment if it contains reasonable grounds for the proposed regulation.

(B) If the principal display panel of a food for which a common or usual name regulation is established is too small to accommodate all mandatory requirements, the Commissioner may establish by regulation an acceptable alternative (*e.g.*, a smaller type size). A petition requesting such a regulation, which would amend the applicable regulation, shall be submitted to the Director.

#### 520.326: Frozen "Heat and Serve" Dinner

(A) A frozen "heat and serve" dinner:

(1) Shall contain at least three components, one of which shall be a significant source of protein and each of which shall consist of one or more of the following: meat, poultry, fish, cheese, eggs, vegetables, fruit, potatoes, rice, or other cereal based products (other than bread or rolls).

(2) May also contain other servings of food (*e.g.*, soup, bread or rolls, beverage, dessert).

(B) The common or usual name of the food consists of all of the following:

(1) The phrase "frozen 'heat and serve' dinner," except that the name of the

predominant characterizing ingredient or other appropriately descriptive term may immediately precede the word "dinner" (e.g., "frozen chicken dinner" or "frozen heat and serve a dinner"). The words "heat and serve" are optional. The word "frozen" is also optional, provided that the words "Keep Frozen" or the equivalent are prominently and conspicuously placed on the principal display panel in type size not less than that specified in 105 CMR 520.305(B)(2)(a).

(2) The phrase "containing (or contains) - - -" the blank to be filled in with an accurate description of each of the three or more dish components listed in 105 CMR 520.326(A)(1) in their order of descending predominance by weight (e.g. ham, mashed potatoes, and peas), followed by any of the other servings specified in 105 CMR 520.326(A)(2) contained in the package (e.g., onion soup, enriched white bread, and artificially flavored vanilla pudding) in their order of descending predominance by weight. This part of the name shall be placed immediately following or directly below the part specified in 105 CMR 520.326(B)(1) in the manner set forth in 105 CMR 520.305(C)(3). The words "contains" or "containing" are optional.

(3) If the labeling implies that the package contains other foods and these foods are not present in the package, e.g., if a vignette on the package depicts a "serving suggestion" which includes any foods not present in the package, the principal display panel shall bear a statement that such foods are not present, in type size not less than that specified in 105 CMR 520.305(B)(2)(a).

#### 520.328: Foods Packaged for Use in the Preparation of "Main Dishes" or "Dinners"

(A) The common or usual name of a packaged food which is represented on the principal display panel by work or vignette to be used in the preparation of a "main dish" or "dinner" or other such food serving, and to which some other important characterizing ingredient(s) or component(s) not present in the package must be added, consists of all of the following:

- (1) The common or usual name of each important ingredient or component in the package, in descending order of predominance by weight (e.g., "noodles and tomato sauce").
- (2) An appropriate informative statement identifying the food to be prepared by use of the package contents (e.g., "for preparation of chicken casserole").
- (3) An appropriate informative statement that additional characterizing ingredient(s) or component(s) must be added and which names the additional characterizing ingredient(s) or component(s) (e.g., "you must add - - - to complete the recipe," the blank to be filled in with the name(s) of the important characterizing ingredient(s) or component(s) that must be added).

(B) The labeling required by 105 CMR 520.328(A) shall appear on the principal display panel.

(1) No word in the statement required by 105 CMR 520.328(A)(2) may appear on the principal display panel more conspicuously or in larger type than the smallest and least conspicuous type employed on the panel for any word, phrase or statement within the scope of 105 CMR 520.328(A)(1).

(2) Every work in the statement required by 105 CMR 520.328(A)(3) shall appear on the principal display panel in easily legible bold-face print or type in



distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

- (a) Not less than 1/16 inch in height on packages having a principal display panel with an area of five square inches or less and not less than 1/8 inch in height if the area of the principal display panel is greater than five square inches; or
- (b) Not less than 1/2 the height of the largest type appearing in the part of the common or usual name of the food required by 105 CMR 520.328(A)(1) and 520.328(A)(2).

(C) Any vignette which shows any food or characterizing ingredient(s) or component(s) not included in the package shall be accompanied either by the statement required by 105 CMR 520.328(A)(3) or by a separate statement specifying the food or characterizing ingredient(s) or component(s) shown in the vignette but not included in the package.

(D) If the statement specified in 105 CMR 520.328(A)(2) is used on any panel in addition to the principal display panel as a product identification statement, the complete common or usual name shall appear on such panel in the manner specified in 105 CMR 520.328(B).

(E) When a brand name or other prominent product designation contains a word or words that includes or suggests an important characterizing ingredient(s) or component(s) that must be added, or otherwise states or implies that the package contains a complete main dish, dinner, or other food serving, the part of the common or usual name of the food required by 105 CMR 520.328(A)(3) shall appear in direct conjunction with such brand name or other designation and in type size not less than 1/2 the height of the largest type appearing in such brand name or other designation.

#### 520.330: Non-Carbonated Beverage Products Containing No Fruit or Vegetable Juice

The common or usual name of non-carbonated beverage products (including a concentrated, dehydrated, powdered, or other counterpart) containing no fruit or vegetable juice shall include the following:

(A) A descriptive name for the product meeting the requirements of 105 CMR 520.305(A);

(B) When the labeling or the color and flavor of the beverage represents, suggests, or implies that any fruit or vegetable juice may be present (e.g., the product label bears the name or a variation of the name or any pictorial representation of any fruit or vegetable, or the product contains color and flavor which gives the beverage the appearance and taste of containing a fruit or vegetable juice) the statement "Containing (or contains) no - - - juice", or "no - - - juice", or "does not contain - - - juice", the blank to be filled in with the name of the fruit(s) or vegetable(s) represented, suggested, or implied, in the manner set forth in 105 CMR 520.305(C). If a non-specific fruit or vegetable juice content is represented, suggested, or implied, the blank shall be filled in with the word "fruit" or "vegetable" as applicable.

520.332: Diluted Orange Juice Beverages

(A) The common or usual name of a non-carbonated beverage containing less than 100% and more than 0% orange juice shall be as follows:

(1) A descriptive name for the product meeting the requirements of 105 CMR 520.305(A) (e.g.; diluted orange juice beverage or another descriptive phrase) and

(2) A statement of the percent of orange juice contained in the product in the manner set forth in 105 CMR 520.305(B)(2). The percent of orange juice shall be declared in 5% increments, expressed as a multiple of five not greater than the actual percentage of orange juice in the product, except that the percent of orange juice in products containing more than 0% but less than 5% orange juice shall be declared in the statement as "less than 5"%.

(B) The percent of orange juice in the product shall be determined on the basis of the orange juice having an equivalent single strength of 11.8% orange juice soluble solids.

520.337: Mixtures of Edible Fat or Oil and Olive Oil

The common or usual name of a mixture of edible fats and oils containing less than 100% and more than 0% olive oil shall be as follows:

(A) A descriptive name for the product meeting the requirements of 105 CMR 520.305(A), e.g. "cottonseed oil and olive oil" or another descriptive phrase, and

(B) When the label bears any representation, other than in the ingredient listing, of the presence of olive oil in the mixture, the descriptive name shall be followed by a statement of the percentage of olive oil contained in the product in the manner set forth in 105 CMR 520.305(B)(2).

520.347: Bonito

"Bonito" or "bonito fish" is the common or usual name of the food fish *Sardi chilensis* and *Sardi velox*.

520.350: Crabmeat

The common or usual name of crabmeat derived from each of the following designated species of crabs shall be as follows:

<u>Scientific Name of Crab</u>	<u>Common or Usual Name of Crabmeat</u>
<i>Paralithodes camtschatica</i> and <i>Paralithodes platypus</i>	King crabmeat.
<i>Paralithodes brevipes</i>	King crabmeat or Hanasaki crabmeat.
<i>Erimacrus isenbeckii</i>	Korean variety crabmeat or Kegani crabmeat.
<i>Chionoecetes oplio</i> , <i>Chionoecetes tanneri</i> ,	

*Chionoecetes bairdii*,  
and *Chionoecetes angulatus*                      Snow crabmeat.

520.354: Seafood Cocktails

The common or usual name of a seafood cocktail in package form fabricated with one or more seafood ingredients shall be:

(A) When the cocktail contains only one seafood ingredient, the name of the seafood ingredient followed by the word "cocktail" (e.g., shrimp cocktail, crabmeat cocktail) and a statement of the percentage by weight of that seafood ingredient in the product in the manner set forth in 105 CMR 520.305(B).

(B) When the cocktail contains more than one seafood ingredient, the term "seafood cocktail" and a statement of the percentage by weight of each seafood ingredient in the product in the manner set forth in 105 CMR 520.305(B).

520.357: Greenland Turbot (*Reinhardtius hippoglossoides*)

"Greenland turbot" is the common or usual name of the food fish *Reinhardtius hippoglossoides*, a species of *Pleuronectidae* right-eye flounders. The term "halibut" may be associated only with Atlantic halibut (*Hippoglossus hippoglossus*) or Pacific halibut (*Hippoglossus stenolepis*).

Note: 105 CMR 520.357 as to "halibut" is a reiteration of M.G.L. c. 94, § 194B effective January 1, 1969.

REGULATORY AUTHORITY

105 CMR 520.000: M.G.L. c. 94, §§ 192, 126, 10I, 65S through 65U, 73A, 91, 119,  
125;  
M.G.L. c. 111, § 6.